Trans-Septal Puncture Procedures and Devices

Problem statement

Trans-septal punctures are generally used to access the left side of the heart without having to place catheters in the aorta, by puncturing the septum that separates the left and right atria. Access to the left atrium is commonly required for atrial fibrillation ablation and treatment of structural heart disease. Devices used must be able to both locate the fossa ovalis reliably, and safely puncture the septum.

Description of procedure

The catheter being used enters the right atrium via either the inferior or superior vena cava, after being inserted into either a femoral or brachiocephalic vein, respectively. The catheter is pressed up against the fossa ovalis, and a hole through the septum is created. Location of the fossa is usually determined through the use of fluoroscopy or intra-cardiac echo (ICE).

Figure 1: Anatomy of the atria. From US patent application 2005/0055089.
Figure 2: Typical TS puncture. Catheter entering RA through the IVC. 502 points to location of actual puncture (fossa ovalis).
From patent application 2006/0135962.

Current Products

Current products include many variations on needles for puncture and a method of using RF energy to create the perforation.

NRG RF Transseptal needle (Baylis Inc)

- Predictably crosses all types of septa
- Can cross an aneurismal septum in a controlled manner
- Can effectively cross a fibrotic septum
- Removes the danger of skiving and scraping
- Compatible with standard sheaths / dilators

- Proximal Gauge: 18 Ga
- Distal Gauge: 21 Ga
• The curves of the NRG™ RF Transseptal Needles mimic those of conventional needles
• Inner lumen for fluid injection and pressure waveforms
• Electrically insulated

Figure 3: Baylis RF needle (http://www.baylismedical.com/Cardionrg.html)

BRK Transseptal needles

BRK Transseptal Needles are designed for cardiology procedures that require a transseptal puncture. They are available in a variety of sizes and curves and are designed to be used with Fast-Cath™ transseptal, venous transseptal and St. Jude Medical guiding introducers.

Figure 4: BRK transseptal needles (http://www.sjmprofessional.com/Products/US/EP-Access-Tools/BRK-Transseptal-Needles.aspx)
SafeSept Transseptal guidewire

SafeSept is a 135cm long, 0.014 inch diameter nitinol guidewire specifically designed for transseptal puncture. After the transseptal dilator has “tented” the fossa ovalis, effortless advancement of the SafeSept tip perforates the membranous fossa. Unsupported by the needle and dilator, the tip of the wire assumes a ‘J’ shape, rendering it incapable of further tissue penetration.
Emerging Applications for Transseptal Left Heart Catheterization

Old Techniques for New Procedures

Vasilis C. Babaliaros, MD, Jacob T. Green, MD, Stamatios Lerakis, MD, FACC, Michael Lloyd, MD, Peter C. Block, MD, FACC

Atlanta, Georgia

Transseptal (TS) catheterization was introduced in 1959 as a strategy to directly measure left atrial (LA) pressure. Despite acceptable feasibility and safety, TS catheterization has been replaced by indirect measurements of LA pressure using the Swan-Ganz catheter. Today, TS puncture is rarely performed for diagnostic purposes but continues to be performed for procedures such as balloon mitral valvoplasty, antegrade balloon aortic valvuloplasty, and ablation of arrhythmias in the LA. Thus, the “art” of TS puncture has been lost, except in centers that perform these procedures with regularity. Recently, there has been a renewed interest in the TS technique because of emerging therapeutic procedures for structural heart disease and atrial fibrillation ablation. Invasive cardiologists will have to refamiliarize themselves with the TS technique, newer TS devices, and advanced ultrasound imaging for guidance of the procedure. (J Am Coll Cardiol 2008;51:2116–22) © 2008 by the American College of Cardiology Foundation

Measurement of left atrial (LA) pressure is important in the evaluation of heart disease. Various direct methods, such as transbronchial, supraclavicular (1), and transseptal (TS) puncture (2–4), were developed in the 1950s to measure LA pressure. Despite acceptable feasibility and safety (1,2,5), these methods were replaced by indirect measurements of LA pressure with a Swan-Ganz catheter. Right heart catheterization with a balloon wedge catheter replaced TS left heart catheterization not only because of ease and safety, but because many hemodynamic parameters could be measured with a single catheter. Today, TS catheterization is rarely performed for diagnostic purposes unless the wedge pressure reading is in question or retrograde access to the left ventricle is not possible. Thus, the “art” of TS puncture has been lost by invasive cardiologists, except in centers that perform balloon mitral valvoplasty and LA arrhythmia ablation with regularity.

With the introduction of new procedures for percutaneous structural heart disease therapy (6–8) and atrial fibrillation ablation (9) in the last 5 years, TS catheterization is increasingly necessary. This review focuses on the current state of TS catheterization, with emphasis on updated techniques and emerging indications.

**TS Technique**

Current TS technique has changed very little since the initial reports in 1959 (3,4). In brief, a needle is inserted into a catheter that is in contact with the right atrial (RA) septum at the level of the fossa ovalis. The needle is then advanced, puncturing the atrial septum and allowing access to the LA. The key to a successful procedure is a thorough understanding of the anatomy of the fossa ovalis and the surrounding landmarks.

**Anatomy of the Fossa Ovalis and Surrounding Structures**

The intact atrial septum is formed from fusion of the septum primum and the septum secundum. Both septae extend from the roof of the atria toward the endocardial cushions. The septum primum, which is the LA septum, is absorbed superiorly, leaving the septum secundum, or the RA septum, to cover this superior defect (ostium secundum) and separate the atria. The area of fusion of the muscular, septum secundum and the thin portion of the septum primum is known as the limbus (10). The limbus is most pronounced superiorly and laterally, and forms the raised margin around the fossa ovalis (Fig. 1). Thus, the fossa ovalis appears as a depression in the interatrial septum when viewed from the RA (Fig. 1) and is composed primarily of

---

From the Andreas Gruentzig Cardiovascular Center, Emory University Hospital, Atlanta, Georgia. Dr. Babaliaros is a consultant for Medtronic. Dr. Block is an E-Valve consultant and stock holder, Direct Flow stock holder, Medtronic consultant, and Ample Medical consultant. Dr. Lloyd is a Medtronic research grant recipient.

Manuscript received December 7, 2007; revised manuscript received January 15, 2008, accepted January 24, 2008.
Localization of the Fossa Ovalis

Localization of the fossa ovalis for TS puncture has traditionally been done by fluoroscopic imaging. A pigtail catheter is placed retrograde into the aortic root so that its tip marks the location of the aortic valve. The cardiac silhouette identifies the posterior and lateral borders of the atria (12). Several different angiographic projections are used to puncture the septum safely. In the anteroposterior projection, the fossa lies below the pigtail catheter in the mid RA silhouette (Fig. 2A). In the lateral projection, the fossa is usually halfway along the imaginary line from the pigtail catheter tip to the posterior border of the heart (Fig. 2B). In the right anterior oblique projection (40° to 50°), the outline of the atrial septum is en face. The fossa is posterior and 1 to 3 cm inferior to the pigtail catheter tip, but anterior to the RA silhouette (Fig. 2B). In difficult cases, an RA angiogram with delayed LA angiography can help visualize the septum (overlap area). “Tattooing” of the septum with a 1-ml contrast injection through the TS puncture needle can also help visualize the septum.

Echocardiographic visualization of the atrial septum has aided in the safety of TS catheterization (13). Transthoracic echocardiography (TTE) has limited utility, but transesophageal echocardiography (TEE) is more useful, particularly when visualizing a specific area of the fossa ovalis to be punctured. Superior/inferior localization is seen best in the bicaval view (90°), and anterior/posterior localization is seen best in the 4-chamber view (0°). Tenting (Fig. 3A) of the fossa ovalis (the thin septum) by the TS catheter tip indicates correct positioning, even if the needle or catheter cannot be visualized. Newer imaging modalities such as intracardiac echocardiography (AcuNav ICE, Siemens Medical Systems, Mountain View, California) (12,14,15) have also been used with success. The role of 3-dimensional TEE has yet to be fully evaluated, although initial experience is positive (Fig. 3B). CardioOptics (Boulder, Colorado) manufactures a catheter that emits infrared light and can image through flowing blood in real time. This catheter may be useful in TS catheterization, allowing direct visualization of the fossa ovalis. Animal testing has been completed, and Phase I human trials are pending.

Puncture of the Fossa Ovalis

Puncture of the fossa ovalis begins with insertion of the needle delivery catheter and dilator to the level of the superior vena cava from the right common femoral vein. The catheter has a 270° curve at the end that is straightened by the dilator, and is most commonly a Mullins TS introducer (Medtronic, Minneapolis, Minnesota). The radius of the end of the catheter is available in different sizes, allowing variable reach within the RA. The needle is then inserted into the dilator, and allowed to freely rotate as it is advanced. Passage of the needle is easier if the sheath and dilator is introduced from the right rather than left femoral vein because of tortuosity. Fluoroscopy is used to visualize the needle as it is advanced up to the tip of the dilator so as to avoid inadvertent passage out of the dilator and sheath.

The needle most commonly used is a Brockenbrough needle (Medtronic). This needle is an 18-gauge hollow tube that tapers distally to 21 gauge. The proximal end has a flange with an arrow that points to the position of the needle tip. With the needle tip just within the dilator, the entire assembly is rotated such that the needle points to a 4 o’clock orientation (ceiling of the room is 12 o’clock orientation, floor is 6 o’clock orientation) and withdrawn into the mid RA. Using the fluoroscopic projections as previously described, the dilator is then advanced to catch the limbus of the fossa ovalis. In the minority of patients in whom the limbus is not prominent, echocardiographic guidance is helpful. The sheath, dilator, and needle assem-

Figure 1 Gross Examination of the FO From the Right Atrium

Right atrial view of the atrial septum with limbus ledge seen superiorly (below dotted line) and depressed fossa ovalis (FO) inferiorly. SVC = superior vena cava.
bly are advanced as a unit, tenting the fossa. The needle is then rotated to 3 o’clock to prevent posterior puncture and is fully advanced. Puncture into the LA can be confirmed by pressure transduction through the needle (Fig. 4), aspiration of oxygenated blood, and injection of contrast.

In 20% to 25% of adult patients, the fossa ovalis is probe patent (patent foramen ovale [PFO]) and may not require needle puncture (10,11). In approximately two-thirds of patients, the fossa is paper thin, and the catheter can be passed into the LA with gentle pressure and rotation of the dilator (10). Puncture is associated with a tactile feeling of the septum giving way. The dilator and sheath are then advanced over the needle (without advancing the needle) to avoid injury to the posterior LA wall. Some operators introduce a 0.014-inch angioplasty wire through the needle into the LA and pulmonary vein to prevent inadvertent puncture of the LA free wall by the needle or dilator (16). Fortunately, serious morbidity or mortality after needle puncture of the LA free wall or aorta is uncommon if the sheath and dilator are not advanced. Overall, serious complications from TS catheterization are ≤1% (1,17,18). After successful puncture of the atrial septum, the patient should be immediately anticoagulated (heparin or direct thrombin antagonist) to minimize the risk of thromboembolism.

**Newer Methods for Atrial Septal Puncture**

In an attempt to improve the TS technique, a new system that uses radiofrequency (RF) energy to puncture the septum (Radiofrequency Transseptal System, Baylis Medi-
cal, Montreal, Canada) has been developed (19). Instead of a needle, an RF catheter is introduced into the dilator/sheath assembly (Fig. 5A). This catheter delivers 5 W energy for 2 to 5 s and can perforate the atrial septum after 1 to 4 pulses. It has been used in 5 patients undergoing balloon mitral valvuloplasty and was successful in 4. This technology may have an advantage in thick, scarred, calcified, or patched atrial septa, where excess force could result in unsuccessful puncture or in perforation of the LA free wall secondary to catheter momentum.

Another new technology that also may improve the safety of TS puncture is the excimer laser catheter (0.9-mm Clirpath X-80, Spectranetics, Colorado Springs, Colorado) (20–22). The laser catheter is inserted via a modified Mullins sheath and dilator (inner lumen compatible with a 0.038-inch wire) and can puncture the septum after a brief (2 to 5 s) application of laser energy. The laser catheter requires less force (<10-fold) to cross the septum compared with the Brockenbrough needle, and can then be used as a rail over which the Mullins sheath and dilator can be advanced. Currently, only data from animal studies are available, although the technology seems promising and can be used “off the shelf” with existing deflectable guiding catheters (Morph catheter, Biocardia, San Francisco, California, and Naviport catheter, Cardima, Fremont, California).

In cases in which TS catheterization cannot be performed from the femoral vein, a new system has been developed for safe puncture of the LA from the internal jugular vein. The LA-Crosse system (St. Jude Medical, St. Paul, Minnesota) is composed of 3 parts: a stabilizer sheath, a guide catheter, and a flexible puncture screw (Fig. 5B). The stabilizer sheath is placed from the right internal jugular vein such...
that the distal end lies in the inferior vena cava and the side opening faces the mid RA. A guide catheter is advanced through the stabilizer sheath and out the side opening until its distal end is in contact with the fossa ovalis. The flexible puncture screw is then advanced through the guide catheter to its tip. When it contacts the atrial septum, the puncture screw is rotated and penetrates the atrial septum. Once LA pressure is measured through the end hole of the puncture screw, an Inoue guidewire is advanced into the LA. This system has been 100% successful in animal models guided by fluoroscopy, and can be used to perform multiple punctures in selective portions of the atrial septum. Additionally, introduction of catheters from the internal jugular vein through the superior vena cava and across the atrial septum may offer a more favorable trajectory than the femoral approach for transcatheter interventions on the mitral valve. Human evaluation is pending.

**Emerging Indications for TS Puncture**

**TS catheterization in electrophysiology (EP).** The cardiac subspecialty of EP accounts for the single most common context in which TS punctures are performed in the U.S. Interest in the refinement and perfection of the TS technique has paralleled the dramatic increase in the number of ablative procedures performed for atrial fibrillation in the last 5 years (9,23). In addition to RF ablation for atrial fibrillation, TS puncture is routine for ablation of accessory pathways located along the mitral annular region, LA tachycardias and flutters, and less commonly for variants of atrioventricular nodal reentrant tachycardia. The TS route also provides a useful alternative to the retroaortic approach for ablation within the left ventricle and left ventricular outflow tract.

In most centers, TS puncture is performed under fluoroscopic biplanar guidance using methods described above. Additionally, a diagnostic catheter in the coronary sinus aids in the localization of the fossa ovalis. Often, EP procedures require 2 or more sheaths across the fossa ovalis. This can be accomplished by 2 separate TS punctures or a single pass with the Brockenbrough needle. In the latter case, the initial sheath, which is already across the atrial septum, can be withdrawn into the RA over a guidewire in the LA. A second sheath or ablation catheter can then pass through the previously created rent in the septum. The initial sheath is then reinserted over the guidewire. On occasion, patients require repeat TS procedures for atrial fibrillation ablation (24). If previous punctures have been performed, the fossa ovalis can become thickened and fibrotic. This can obscure the physical landmarks, prevent the characteristic leftward movement of the TS needle into the fossa, and require significant forward pressure for puncture with the needle. In this situation and in the case of prior aortic root surgery adjuncts to fluoroscopic visualization, such as intracardiac or TEE, are most useful.

**PFO and atrial septal defect (ASD) repair.** The second most common use for TS catheterization is percutaneous repair of ASD and PFO. Percutaneous ASD repair is a validated alternative to surgical repair (25), and is used primarily to prevent or reverse the untoward consequences of left-to-right shunting across the atrial septum (pulmonary hypertension, right ventricular failure). Alternatively, percutaneous PFO closure has been used to prevent the problems of right-to-left shunting, specifically secondary stroke prevention. Ongoing trials are also evaluating the role of PFO closure in migraine reduction.

In the majority of cases, the ASD and PFO can be crossed with the use of a multipurpose catheter and a J-wire without the need for TS puncture. In rare occasions, atrial septal aneurysms may “pocket” the catheter tip and wire, preventing the camulation of a small ASD or PFO. In this situation and in the long-tunnel variant PFO, TS puncture has been used to place a catheter in the LA, and deploy a closure device to seal the defect (26,27). This technique requires echocardiographic guidance to puncture the septum as close to the defect as possible.

**Percutaneous mitral valve repair.** Percutaneous mitral valve repair strategies include leaflet repair, coronary sinus annuloplasty, and noncoronary sinus annuloplasty with or without myocardial reduction (6,7,28,29). The largest experience with repair strategies has been with percutaneous leaflet clipping in the treatment of primary mitral regurgitation. The MitraClip device (Evalve Inc., Menlo Park, California), requires the introduction of a 22-F device via TS puncture (8). The TS puncture should be performed under ultrasound guidance in order to pierce the septum superiorly and posteriorly. This high TS puncture allows adequate distance above the mitral valve plane for manipulation of the guiding and delivery catheter and to properly place the mitral valve clip.

The Ample PS3 System (Ample Medical, Foster City, California) also involves TS puncture. A T-bar implant is delivered to the posterior annulus via the coronary sinus. A TS puncture is performed to tether the T-bar to an Amplatzer (AGA Medical, Minneapolis, Minnesota) device anchored in the atrial septum.

**LA appendage closure.** The LA appendage is positioned in the anterior–superior portion of the LA, above the mitral valve. The Watchman device (Atritech Company, Plymouth, Minnesota) is a nitinol cage with a polyethylene membrane that can be implanted into the LA appendage of patients with atrial fibrillation to prevent stroke (30). For placement of this device, TS puncture is performed in the superior fossa ovalis so that the delivery sheath is coaxial with the LA appendage, and device deployment is facilitated.

**Percutaneous left ventricular assist device.** The TandemHeart Device (CardiacAssist, Pittsburgh, Pennsylvania) is a circulatory assist device (31–33) that retrogradely perfuses the aorta with oxygenated blood from the LA. After TS puncture, a 21-F cannula is advanced across the atrial septum from the femoral vein, the proximal end of the
venous cannula (inflow) is connected to a 15- to 18-F cannula in the iliac artery (outflow) via a rotary pump. The flow can be as high as 4.0 l/min and requires appropriate placement of the distal end of the LA cannula in the mid-posterior LA. Ultrasound guidance for placement of the LA catheter is recommended.

**Paravalvular leak (PVL) closure.** Paravalvular leak of mitral prostheses can be repaired percutaneously from a TS approach (34), particularly if the leak is along the lateral aspect of the LA. The TS puncture should be in the middle or inferior fossa ovalis to direct a right Judkins catheter to the lateral wall of the atrium at the level of the mitral valve. A PVL along the medial aspect of mitral prostheses is technically more difficult to repair because the acute angle needed to access the PVL. Such leaks might be approached from a TS puncture performed from the right internal jugular in the future. A TS puncture has also been performed to snare a wire from the left ventricle or LA when closing an aortic or mitral PVL.

**Other procedures.** The TS technique has been used in a variety of other procedures, including pulmonary vein stenosis intervention, antegrade VSD closure, stent implantation in the right internal carotid artery (35), and atrial septostomy. Indications for TS catheterization will increase as more interventions are performed for treatment of structural heart disease.

**Conclusions**

Although once popular, TS catheterization has been shelved by all except electrophysiologists and a few interventionalists until recently. Today’s invasive cardiologists will have to refamiliarize themselves with the technique as well as become involved with the newer TS devices and more advanced imaging. Training will remain an issue because of the number of cases and the lack of recent experience. Therefore, simulators and echocardiographic imaging should prove helpful. In the current era of catheter therapies for structural heart disease and EP, we will certainly see new and a resurgence of old techniques to aid in the success of forthcoming procedures.

**REFERENCES**


TRANSSEPTAL PUNCTURE APPARATUS

Inventors: Andrzej J. Chanduszko, Weymouth, MA (US); Carol A. Devellian, Topsfield, MA (US)

Assignee: NMT Medical, Inc., Boston, MA (US)

Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

Appl. No.: 10/841,695
Filed: May 7, 2004

Prior Publication Data
US 2005/0101984 A1 May 12, 2005

Related U.S. Application Data
Provisional application No. 60/517,983, filed on Nov. 6, 2003.

Int. Cl.
A61B 17/34 (2006.01)

U.S. Cl. 606/185; 128/898

Field of Classification Search 606/185,
606/213, 151, 41; 600/411; 604/96.01;
128/898

See application file for complete search history.

References Cited
U.S. PATENT DOCUMENTS

3,103,666 A 9/1963 Bone
3,470,834 A 10/1969 Bone
3,874,388 A 4/1975 King et al. 128/334 R
3,875,648 A 4/1975 Bone
3,990,619 A 11/1976 Russell
4,007,743 A 2/1977 Blake 128/334 R
4,039,078 A 8/1977 Bone

FOREIGN PATENT DOCUMENTS

EP 0553259 8/1993

OTHER PUBLICATIONS


Primary Examiner—Anhtuan T Nguyen
Assistant Examiner—Tuan V Nguyen

ABSTRACT

Devices and methods for performing a transeptal puncture procedure are described. In certain embodiments, the device includes a blunt outer needle, and a second inner needle disposed longitudinally through the lumen of the outer needle, wherein the inner needle is flexible, e.g., has a flexible portion and/or a bend or other non-traumatic conformation at its tip.

5 Claims, 16 Drawing Sheets


* cited by examiner
TRANSEPTAL PUNCTURE APPARATUS

RELATED APPLICATIONS

This application claims priority to and the benefit of U.S. Ser. No. 60/517,983, filed Nov. 6, 2003, the contents of which are incorporated by reference herein.

FIELD OF THE INVENTION

The invention generally relates to a device for performing an intracardiac transseptal puncture procedure. More specifically, the device relates to transseptal puncture of the atrial septum for the treatment of intracardiac defects such as patent foramen ovale (PFO) and other therapeutic applications for diseases associated with the heart.

BACKGROUND OF THE INVENTION

Septal puncture is utilized in patients in which a communication is present between the two atria of the heart, for example, a patient with a patent foramen ovale (PFO). A PFO consists of two layers of overlapping but unfused tissues, the septum primum and the septum secundum, forming a tunnel-like "hole" between the two tissues that can put the patient at a high risk of embolic stroke. Due to the tunnel-like nature of many PFOs, an occlusion device that is used to repair the PFO often does not sit flat on the septal wall when it is implanted, such that a portion of the occluder is positioned in the PFO tunnel. For this reason a second hole in the septum primum part of the atrial septum near the PFO is introduced by septal puncture through which the occlusion device is then positioned (rather than through the PFO tunnel).

Septal puncture through an intact atrial septum from the right atrium to the left atrium is also often necessary. This is traditionally performed using rigid, long needles, such as Brockenbrough or Ross needles. In all types of septal puncture, the needle that is used to puncture the atrial septum poses a high risk of inadvertent puncture through tissue other than the septum primum, for example, the atrial free wall, posing a significant risk to the patient. For PFO closure, this risk is potentially even higher, due to the fact that the septal tissue is defective and often thinning, and may stretch an even greater amount during the puncture procedure, bringing the tip of the needle dangerously close to the atrial free wall or the left atrial appendage.

A device and method that permits the surgeon to safely puncture both an intact atrial septum and an atrial septum having a PFO is therefore needed.

SUMMARY OF THE INVENTION

The invention relates generally to devices and methods for performing a transseptal puncture procedure that are safe alternatives to those currently being performed.

In one aspect, the invention relates to a device for puncturing the atrial septum of a patient. In one embodiment of the invention, the device includes a first, outer needle with a blunt distal end and a lumen longitudinally disposed therethrough and a second, inner needle axially disposed in the lumen of the outer needle. In an embodiment, the inner needle has a proximal portion, an intermediate portion, and a distal portion, wherein the intermediate portion is more flexible than either the proximal portion or the distal portion of the inner needle.

In another embodiment, the intermediate portion is a segment that is approximately 20 mm from the distal end of the inner needle. The intermediate portion may be, for example, 3 mm in length. In another embodiment, the intermediate portion has a waist. The waist of the intermediate portion is, for example, about 0.2 mm in diameter. In a particular embodiment, the intermediate portion of the inner needle may be made of a polymer.

In another embodiment, the inner needle has a distal portion and a proximal portion, wherein the distal portion is more flexible than the proximal portion. In another embodiment, the inner needle is flexible in both the distal portion and the proximal portion (e.g., has homogeneous flexibility).

As another feature, the distal portion of the inner needle has a distal portion that deviates from the linear path of the inner needle such as, for example, a taper, a bend, a curve, a cork screw or a hook. In a particular embodiment, the tip of the inner needle is turned inward during the delivery procedure to avoid the risk of inadvertent puncture of tissue. In another embodiment, the inner needle contains a portion that has a different thickness or diameter than the rest of the inner needle such as, for example, a tapered portion, whereby the inner needle is tapered from one thickness to another.

In an embodiment, the distal portion of the outer needle is more flexible than the proximal portion of the outer needle.

In still another embodiment, the device includes a outer needle with a blunt distal end and a lumen axially disposed therethrough and a pump for introducing a high pressure jet spray through the lumen of the outer needle.

In a further embodiment of the invention, the device has a outer needle with a blunt distal end and an insulating material for insulating the length of the proximal and intermediate portion, leaving the distal tip of the outer needle uninsulated. As an additional feature, the device may include unipolar electrodes or, alternatively, the device may include bipolar electrodes.

In another aspect, the invention provides a method for puncturing the atrial septum of a patient's heart by accessing the right atrium via a vessel. The method includes introducing into the right atrium a transseptal puncture device that includes a first outer needle with a blunt distal end and a lumen longitudinally disposed therethrough and a second inner needle axially disposed in the lumen of the outer needle, the inner needle having a proximal portion, a distal portion, and an intermediate portion that is more flexible than the proximal portion or the distal portion. The outer needle is contacted with the atrial septum and the inner needle is pushed through the septum in advance of the outer needle. A delivery sheath is then positioned using a standard catheterization laboratory technique in the left atrium and the transseptal puncture device is withdrawn from the patient's body.

In another aspect, the invention provides a method for puncturing the atrial septum of a patient's heart by accessing the right atrium via a vessel. The method includes introducing into the right atrium a transseptal puncture device that includes a first, outer needle with a blunt distal end and a lumen longitudinally disposed therethrough and a second, inner needle axially disposed in the lumen of the outer needle, the inner needle having a proximal portion and a distal portion, wherein the distal portion is more flexible than the proximal portion. The outer needle is first contacted with the atrial septum. The inner needle is then pushed through the septum in advance of the outer needle. A delivery sheath is positioned.
in the left atrium and the transseptal puncture device is withdrawn from the patient’s body.

**BRIEF DESCRIPTION OF THE DRAWINGS**

In the drawings, like reference numbers generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

FIG. 1 is a plan view of a transseptal puncture device according to an illustrative embodiment of the invention.

FIG. 2 is a longitudinal plan view of the distal end of a transseptal puncture device according to an illustrative embodiment of the invention.

FIG. 3 is a cross-sectional view of the distal end of a transseptal puncture device taken along lines 3-3 in FIG. 2.

FIG. 4A is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to an illustrative embodiment of the invention in which the intermediate portion contains a shaft.

FIG. 4B is an exploded view of the intermediate portion of FIG. 4A.

FIG. 5 is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to another illustrative embodiment of the invention in which the inner needle has a tapered intermediate portion.

FIG. 6 is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to another illustrative embodiment of the invention, in which the inner needle has an intermediate portion.

FIG. 7 is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to another illustrative embodiment of the invention in which the distal tip of the inner needle is bent.

FIG. 8 is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to another illustrative embodiment of the invention in which the distal end of the inner needle has a hook.

FIGS. 9A-9G depicts the steps in an illustrative method for puncturing an atrial septum with an illustrative transseptal puncture device according to the invention.

FIG. 10 is a fragmented illustration of a septal puncture apparatus according to an illustrative embodiment of the invention.

FIG. 11 is a schematic side view of a portion of a septal puncture apparatus including a set of flexible members according to an illustrative embodiment of the invention.

FIG. 12A is a schematic side view of a portion of an embodiment of a septal puncture apparatus including a set of flexible members partially extended from an elongate member.

FIG. 12B is a schematic side view of the flexible members of FIG. 12A fully extended from the opening in the elongate member.

FIG. 13 is a schematic side view of another embodiment of a set of flexible members according to the invention.

FIG. 14A is a schematic side view of an embodiment of a flexible member according to the invention.

FIG. 14B is a schematic end-on view of the flexible member of FIG. 14A.

FIG. 15A is a schematic side view of an embodiment of a flexible member according to the invention.

FIG. 15B is a schematic end-on view of the flexible member of FIG. 15A.

**FIG. 16A** is a schematic side view of an embodiment of a set of flexible members, a cutting member, and an elongate member of a portion of a septal puncture apparatus according to the invention.

FIG. 16B is an illustration of the set of flexible members and the cutting member extended out of the elongate member of FIG. 16A.

FIG. 17 is a partially broken-away view of a heart depicting a portion of a septal puncture apparatus, according to the invention, on a second side of the septal wall.

FIG. 18A is a cross-sectional view of a septal wall of a heart depicting a set of flexible members located outside an opening in an end of an elongate member, according to an illustrative embodiment of the invention.

FIG. 18B is a cross-sectional view of the flexible members of FIG. 19A in which a portion of the flexible members is located in contact with a first side of a septal wall and another portion of the flexible members is located in proximity to a second side of the septal wall.

FIG. 18C is a cross-sectional view of the flexible members of FIGS. 19A and 19B in which a cutting member is extended from a lumen in the delivery member creating a hole through the septal wall.

FIG. 19 is a schematic side view of a flexible member, a cutting member, and an elongate member according to an illustrative embodiment of the invention.

**DETAILED DESCRIPTION OF THE INVENTION**

The invention described herein relates to devices and methods for puncturating the atrial septum via the percutaneous route for the treatment of intracardiac defects such as, for example, patent foramen ovale, intracardiac sources of emboli that may cause embolic stroke, and defects related to cardiac disease.

In one aspect, the invention relates to a percutaneous device for making a transseptal puncture in the atrial septum of the heart. FIG. 1 is a plan view of the transseptal puncture device according to an illustrative embodiment of the invention. The illustrative percutaneous device 10 includes a first, outer needle 12 including a lumen 13 axially disposed along the long axis of the outer needle 12 and including a blunt distal end 17 having an opening 18. A second, inner needle 14 is axially disposed within the lumen of the outer needle 12. The outer needle 12 provides structural support for the inner needle 14 and also functions as a dilator of the hole created in the atrial wall by the inner needle 14. The device 10 may further feature a transcatheter intravascular sheath 22 through which the device 10 passes from outside the patient’s body through a vessel, for example, the femoral vein, through the inferior vena cava to the right atrium, and a control handle 26 at the distal end 27 of the sheath 22. The sheath and/or other components of the delivery system may be steerable by actuators (not shown) on the control handle 26 to aid in delivering the device along the tortuous vascular path leading to the patient’s right atrium. In certain embodiments, the distal end 17 of the outer needle 12 is tapered toward the inner needle 14, and the distal end 27 of the sheath 22 is tapered toward the outer needle 12.

In an embodiment, the outer needle 12 is similar in size to a Brockenbrough needle, e.g., with tip diameter of about 0.8 mm. The percutaneous device 10 also features a septal perforator, for example, a second, inner needle 14. Alternatively, the septal perforator is a radio frequency electrode (not shown) that is coupled to the outer needle 12, or is a high pressure jet spray (not shown) that is emitted from the opening 18 of the outer needle 12.
In an embodiment depicted in FIGS. 2 and 3, the inner needle 14 includes a sharp tip 25 at a distal end 15 of the inner needle 14. The inner needle 14 is axially disposed within the lumen 13 of the outer needle 12. The inner needle 14 is reciprocally and axially moveable in the lumen 13 of the outer needle 12. The inner needle 14 can be rotated as well. The distal end 15 of the inner needle 14 is extendable through the opening 18 at the distal end 17 of the outer needle 12. The inner diameter of the lumen 13 of the outer needle 12 typically approximates the outer diameter of the inner needle 14.

The outer needle 12 and the inner needle 14 are made from various metals such as, for example, nitinol, steel, or titanium, or alloys thereof or polymers such as polyimide, PEBAX®, polyethylene, polytetrafluoroethylene (PTFE), fluorinated-ethylenepropylene (FEP), and polyurethane. In one embodiment, the inner needle 14 is solid to increase its sharpness. Alternatively the inner needle 14 is hollow. The use of the outer needle 12 for introducing the inner needle 14 into the patient’s cardiac tissue is preferred. In another embodiment, a dilator that is made from material that provides sufficient support during the transapental puncture procedure is used and the outer needle 12 may not be needed.

FIGS. 4A and 4B are a longitudinal view and an exploded view, respectively, of the distal end of an inner needle of a transapental puncture device according to another illustrative embodiment of the invention. The illustrative inner needle 14 includes a waist 30 near the distal end 15 of the inner needle 14. The waist 30 is positioned on an intermediate portion 16 of the inner needle 14 that is narrower in diameter than the portion of the inner needle 14 that is proximal to the intermediate portion 16 and the portion of the inner needle 14 that is distal to the intermediate portion 16. The waist 30 is thereby more flexible or bendable than the portions of the inner needle 14 that are proximal or distal to the waist 30. In one embodiment, the distal portion 15 is more flexible than the proximal portion 11 of the inner needle 14. The intermediate portion 16 having waist 30 is positioned about 5 mm to about 30 mm, preferably about 20 mm proximal to the distal end 15 of the inner needle 14. In an embodiment, the diameter of the waist 30 ranges from about 0.1 mm to about 0.5 mm, e.g., if the waist is composed of a metal, while the diameter of the inner needle 14 proximal to the waist 30 ranges from about 0.5 mm to about 1.5 mm and the diameter of the inner needle 14 distal to the waist 30 ranges from about 0.2 mm to about 1 mm.

In another embodiment, the diameter of the waist 30 ranges from about 0.1 to about 1 mm, e.g., if the waist is composed of a non-metal, such as, for example, a polymer, such as (PEBAX) or polyurethane, a plastic, rubber, or any other polymer deemed suitable to those skilled in the art. In that case, the diameter of the inner needle 14 proximal to the waist 30 ranges from about 0.5 mm to about 3.0 mm and the diameter of the inner needle 14 distal to the waist 30 ranges from about 0.2 mm to about 3.0 mm. For example, the diameter of the waist 30 is about 0.2 mm, the diameter of the inner needle 14 proximal to the waist 30 is about 1 mm and the diameter of the inner needle 14 distal to the waist 30 is about 0.4 mm.

FIG. 5 is a longitudinal view of the distal end of an inner needle of a transapental puncture device according to another illustrative embodiment of the invention. In one embodiment, the inner needle 14 diameter is larger (e.g., 1 mm larger) at the proximal end of the inner needle 14 than the distal end 17. Alternatively, the inner needle 14 diameter is larger throughout the length of the inner needle 14 except for the most distal about 20 mm of the distal end 15. In one embodiment, the inner needle 14 contains a portion 31 at the distal end 15 that is tapered or the diameter of the inner needle 14 is gradually stepped down, for example, to a diameter of about 0.1 to about 0.25 mm, preferably about 0.2 mm, at a point “A” about 10 mm to about 20 mm proximal to the tip 25 of the inner needle 14. In an embodiment, the diameter of the inner needle 14 from the tip 25 to the point “A” is uniform. In a particular embodiment, the distal about 10 mm of the inner needle 14 adjacent to the tip 25 has a diameter of about 0.2 mm. According to this embodiment of the invention, the distal end 15 of the inner needle 14 is thinner and therefore is more flexible than the proximal portion 11 of the inner needle 14. In another embodiment the tapered or step-down portion 31 can extend to the tip 25 of the inner needle 14 and can be about 5 mm to about 30 mm long.

FIG. 6 is a longitudinal view of the distal end of an inner needle of a transapental puncture device according to another illustrative embodiment of the invention. At a position about 5 mm to about 30 mm, preferably about 20 mm from the distal end 15, the inner needle 14 includes an intermediate portion 16 manufactured from, or coated with, a material or treated such that the intermediate portion 16 is more likely to bend than the portions of the inner needle 14 that are proximal 11 and distal 15 to the intermediate portion 16. For example, if the inner needle 14 is composed of nitinol, the intermediate portion 16 may be annealed at 500 degrees Centigrade for 10 minutes to relieve stress in otherwise superelastic nitinol wire in an as drawn condition. Alternatively, the intermediate portion 16 may be made from a softer material than the proximal portion 11 and distal portion 15 of the inner needle 14. For example, the material of the intermediate portion 16 may be a polymer while the proximal portion 11 and distal portion 15 on the inner needle 14 are made from, for example, a rigid metal or, alternatively, a nickel titanium alloy such as nitinol. The intermediate portion 16 may be welded to, crimped or attached by adhesives to the proximal portion 11 and distal portion 15 of the inner needle 14. In one embodiment, the intermediate portion 16 is about 0.5 mm to about 30 mm, preferably about 2 mm in length. Alternatively, geometric modification may make the intermediate portion 16 more flexible, for example, by the introduction of slits, grooves, cut-aways, notches, dimples, or other modification that thins portions of the wall of the intermediate portion 16.

In another embodiment (not shown), the distal, the proximal, and/or the intermediate portion (if present) of the inner needle 14 is flexible.

FIG. 7 is a longitudinal view of the distal end of an inner needle of a transapental puncture device according to another illustrative embodiment of the invention. The distal end 15 of the illustrative inner needle 14 may be straight (e.g., 0 degrees) or is bent at an angle ranging from about 0 degrees to about 270 degrees, preferably about 180 degrees relative to the long axis of the inner needle 14. Alternatively, referring to FIG. 8, when the distal end 15 of the inner needle 14 is not constrained within the lumen 13 of the outer needle 12, the distal end 15 has an essentially non-traumatic configuration, such as a helical, curved, cork screw, or hook shape. For example, the diameter “B” of the loop that forms the hook 32 can be between about 5 mm and about 30 mm, preferably about 10 mm. When the distal end 15 is enclosed within the lumen 13 of the outer needle 12, the entire length of the inner needle 14 is substantially straight and parallels the long axis of the outer needle 12.

In an alternative embodiment of the transapental puncture device, the inner needle is replaced by a pulsating high pressure saline jet (or other suitable fluid) (not shown) generated by a pump. The jet spray is directed to the atrial septum from the distal end of the blunt, outer needle according to the invention and incises the tissue. The outer needle is then gradually advanced through the incision. Because the inci-
sion is made gradually and slowly, the method is safer than the currently used methods, for example, because there is a reduced risk of trauma and/or bleeding.

In yet another embodiment of the transseptal puncture device, the blunt, outer needle is replaced by a radio frequency (RF) apparatus (not shown). The outer needle according to the invention is insulated except for the outer needle tip. The alternating current travels down the outer needle. Preferably, unipolar electrodes can be used for the outer needle with grounding pads typically placed on the patient's thighs. Alternatively, a bipolar electrode system can be employed as well. The application of RF to the outer needle increases the tissue temperature around the outer needle tip to over 100 degrees C. Mechanical cohesion in the tissue is diminished and allows the outer needle to be advanced as pressure is applied to the tissue by the outer needle tip. Any other method producing heat (e.g., such as electrical resistance, laser, or ultrasound) can be potentially used instead of RF. As with the saline jet described above, the incision is created slowly therefore the risk of accidental puncture of tissue that is not targeted for incision is minimal.

In another aspect, the invention provides a method using a percutaneous approach for puncturing the atrial septum of a patient to treat, for example, patent foramen ovale or to gain access to the left atrium to ablate the left atrial appendage. FIGS. 9A-9E depict the steps of a illustrative method for puncturing an atrial septum with the transseptal puncture device according to the invention. The illustrative method includes the step of introducing an intravascular sheath 22 in a vessel to access the lumen of the right atrium 24. In an embodiment, the sheath 22 is tapered to enhance advancement of the sheath 22 through the atrial septum 26. Referring to FIG. 9A, after the sheath 22 is properly positioned in the right atrium 24, the outer needle 10 of the transseptal device 10 is advanced distally toward the atrial septum 26 and positioned against septum primum 26a at the puncture site. The blunt distal end 17 of the outer needle 12 is then pushed against septum primum 26a until some tenting of the atrial septum 26 is visible. The tenting should be sufficient to correctly identify the puncture site in the septum primum 26a. Alternatively, visualization techniques such as, three-dimensional echocardiogram or magnetic resonance imaging can be used that may work without tenting. Some amount of tenting also assists with the puncture itself.

Referring to FIG. 9B, once the outer needle 12 is positioned, the inner needle 14 is advanced relative to the outer needle 12 through the septum 26. At its most distal position, about 10 mm of the inner needle 14 should extend from the distal end 17 of the outer needle 12. Alternatively, the most distal position could be about 30 mm, if the distal portion 15 of the inner needle 14 had a hook shape, as is shown in FIG. 8. In an embodiment, the transition from the hook portion to the straight portion of the inner needle 14 is exposed. The outer needle 12 follows the path of the inner needle 14 through the septum 26. Because of the fine diameter, extreme sharpness, and the added stiffness provided by the outer needle 12, the inner needle 14 can be initially advanced into the septum 26. The motion of the inner needle 14 may be forward, vibrating, reciprocating, linear, or rotational, for example. In one embodiment, movement of the inner needle 14 is accomplished manually. Alternatively, movement of the inner needle 14 may be automated and therefore require additional controls such as a spring-loaded needle to be attached to the delivery system components such as the sheath 22. Such devices of the invention are easier for the doctor to manipulate and safer for the patient.

Referring now to FIG. 9C, once the distal end 15 of the inner needle 14 is positioned within the septum 26, the tissue provides support to the exposed part of the inner needle 14 until the whole tip of the inner needle 14 is delivered into the left atrium 28. Referring to FIG. 9D, the outer needle 12 is advanced and positioned in the left atrium 28. Referring to FIG. 9E, standard catheterization laboratory procedures are utilized to place the sheath 22 within the left atrium 28. Once the sheath 22 is in the left atrium 28, the other components of the device, for example, the inner needle 14 and the outer needle 12, can be completely removed from the sheath 22 and the sheath 22 can be used to deliver implants, for example, such as an atrial occluder for the treatment of a patent foramen ovale, suture, or other intracardiac therapeutic devices. For example, referring to FIG. 9F, one half of an occluder 30 is released from the sheath 22 and positioned in the left atrium 28. Referring to FIG. 9G, the sheath 22 is then withdrawn into the right atrium 24 and the other half of the occluder 30 is released and positioned in the right atrium 24. In an embodiment, the inner needle 14 is left behind, traversing the puncture site, and acts to maintain the puncture site as well as to act as a guidewire (e.g., and the other outer needle 12 is withdrawn). In another embodiment, the inner needle 14 is withdrawn, e.g., into the outer needle 12.

The method for transseptal puncture using the transseptal device described herein is advantageous over conventional methods. For example, when using the devices and methods of the invention inadvertent contact of the inner needle 14 with the left atrial free wall (not shown) immediately after the septum 26 is punctured does not result in damage to or perforation of the left atrial free wall because the distal end 15 of the inner needle 14 is very flexible, as illustrated, for example, in FIG. 4 and corresponding text, or has an alternative tip 25, as illustrated, for example, in FIG. 8 and corresponding text, when fully extended from the distal opening 18 of the outer needle 12. When the distal end 15 of the inner needle 14 contacts the left atrial free wall, the distal end 15 of the inner needle 14 harmlessly bends rather than perforates the left atrial free wall. In one embodiment, the distal end 15 of the inner needle 14 bends because of the enhanced flexibility of the inner needle 14 at the intermediate portion 16, as described above in connection with FIGS. 4-8, between the proximal portion 11 and distal portion 15 of the inner needle 14. In an embodiment, perforation of the left atrial wall is avoided by modifying the shape of the inner needle 14 to form, for example, a hook or a bend.

Another advantage of the transseptal puncture devices described herein is the ability of the device to puncture through thick septum such as septum secundum. The transseptal puncture devices according to the invention can be used for remote suturing of a PFO or other defects that may be accessed percutaneously.

The transseptal puncture device according to the invention can also be used with various atrial septal defect locators such as those described in U.S. Ser. No. 10/660,444. For example, the locator may stabilize (e.g., constrain) the motion of the septum during insertion of the inner needle. Generally, a locator system includes a plurality of flexible members, at least one flexible member positionable on a side of the tissue opposite to another flexible member.

FIG. 10 illustrates a septal puncture apparatus 100 including three flexible members 142a, 142b, and 142c (generally 142) coupled to a delivery member 120 for applying, e.g., a pressure or force to a region in a body by pushing, pulling, or restraining the tissue, thereby stabilizing the tissue. The flexible members 142a, 142b, and 142c may be hexagonal in shape and coupled to a distal end 124 of the delivery member.
120, thereby forming, generally, a planar array 150. The delivery member 120 is sidable receivable within a lumen 110 of the elongate member 104. Instruments, e.g., the delivery member 120 and a cutting member 300 (e.g., a member that perforate the tissue, which can comprise, referring to FIG. 1, an inner needle 14 and/or an outer needle 12, for example), are sidably receivable in the lumen 110 of the elongate member 104. In this embodiment, the cutting member 300 is sidably receivable in a lumen 308 of the delivery member 120 and extends distally or withdraws proximally from an opening 312 at the distal end 124 of the delivery member 120.

FIG. 10 also illustrates an exemplary interface 130 that permits controllers, for example, a set of apparatus controllers 134 and 138 to communicate with the elongate member 104 and the delivery member 120, respectively. The exemplary controllers 134 and 138 extend, retract, or otherwise manipulate, e.g., the elongate member 104 and the delivery member 120, respectively. A single controller, could, alternatively, control all functions and operations of the tissue puncture apparatus 100 and the instruments disposed therein.

By way of example, the elongate member 104 and the delivery member 120 are flexible tubes fabricated from a biocompatible material, e.g., polyethylene, polyether-amide block co-polymer (PEBAX™), polyurethane, or fluorinated ethylene propylene. By way of example, the flexible members 142 are manufactured using nickel-titanium material, such as Nitinol™ (Nitinol Devices and Components, Fremont, Calif.), or other shape memory alloy materials. The nickel-titanium wire, when properly manufactured, exhibits elastic properties for the wire to be manipulated (e.g., bent) by an operator and then returned to, substantially, the same shape the wire possessed prior to it being manipulated.

Alternatively, FIG. 11 illustrates a portion of a septal puncture apparatus 100 including exemplary flexible members 142a and 142b, which each include a leg such as a wire having a first end 202a and 202b, respectively, joined to the distal end 124 of the delivery member 120. Each of the flexible members 142a and 142b also have a second distal end 202a and 202b, respectively, that is free, i.e., not joined to any other structure of the septal puncture apparatus 100. The longitudinal axis of the flexible members 142a and 142b are oriented substantially parallel to the elongate member 104 when the flexible members 142a and 142b are located within the lumen 110 of the elongate member 104. The flexible members 142a and 142b have a first portion 272a and 272b, respectively, and a second portion 270a and 270b, respectively. The flexible members 142a and 142b are disposed within the lumen 110 in a contacted position such that the second ends 202a and 202b are directed distally towards the opening 112 in the distal end 106 of the elongate member 104. The flexible members 142a and 142b are freed from the confines of the lumen 110 by moving the flexible members 142a and 142b between the contracted position illustrated, for example, in FIG. 11 and an extended position, such as the extended position depicted in FIG. 12A. After insertion into the lumen 110 of the elongate member 104, the flexible members 142a and 142b apply a force to an inner surface 210 of the elongate member 104 in a first location 230a and 230b, respectively, on the inner surface 210 of the lumen 110 that the flexible members 142a and 142b contact.

Referring now to FIG. 12A, as the delivery member 120 is extended out of the opening 112 of the elongate member 104, the second ends 202a and 202b of the flexible members 142a and 142b, respectively, undergo an articulation and point, generally, in a proximal direction toward the handle (not shown). Referring now to FIG. 12B, the elongated delivery member 120 is further extended distally along the lengthwise dimension (in the positive direction along the X-axis) of the lumen 110 until the distal end 124 of the delivery member 120 emerges from the opening 112 of the elongate member 104. The second ends 202a and 202b of the exemplary pre-shaped flexible members 142a and 142b, respectively, undergo an additional articulation and as a result point, generally, towards one another. In this extended position, each of the flexible members 142a and 142b is substantially planar in shape.

Alternatively, the second ends, for example, the second ends 202a and 202b, may have a different diameter than other locations along the length of the flexible elastic members 142a and 142b. By way of example, an operator may select an apparatus having flexible members that have second ends 202a and 202b having a larger diameter, for example, to reduce trauma to the tissue ends 202a and 202b during contact with, e.g., the tissue ends 202a and 202b may have a ball shaped tip. FIG. 13 depicts exemplary flexible members 142a and 142b that include a first wire loop section 220a and a second loop section 220b, respectively. The tip 406a and 406b of the loop sections 220a and 220b, respectively, point, generally, towards one another and towards the elongate member 120. Loop sections 220a and 220b may, alternatively, be oriented in a variety of directions (e.g., away from the delivery member 120 or at a 45 degree angle away from the delivery member 120).

Referring now to FIGS. 14A and 14B, a septal puncture apparatus 100 includes a single flexible member 142a that has a middle section 540 located, generally, intermediate the first end 206 and the second end 208 of the flexible member 142a. The flexible member 142a thereby forms a closed loop.

In this embodiment, the flexible member 142a is configured so the middle section 540 is located, generally, in the center of a plane defined by the flexible member 142a as illustrated by the end-on view of FIG. 14B. In this configuration, the middle section 540 of the flexible member 142a aids in stiffening the flexible member 142a, which minimizes bending when, for example, the flexible member 142a is used by an operator to apply forces to a tissue, e.g., the atrial septum. In this configuration, the flexible member 142a forms a closed loop that is sized and shaped, for example, to contact a first and second side of a tissue.

Referring now to FIGS. 15A and 15B, the flexible elastic member 142a is a coil and has a spiral shape. By way of example, in use, a portion 1410 of the flexible member 142a can be located on a first side of a tissue and a portion 1420 of the flexible member 142a can be located on a second side of the tissue. For example, the flexible member 142a can be screwed through a tunnel or a hole, such as a defect in the atrial septum. Alternatively, the distal end 124 of the delivery member 120 may be located axially through, for example, a hole in a tissue such that the flexible member 142a may be withdrawn partially through the hole by a rotational (screw-like) motion of the delivery member 120 thereby locating the portion 1410 of the flexible member 142a on a first side of the tissue and the portion 1420 of the flexible member 142a on a second side of a tissue.

Referring to FIG. 16A, the delivery member 120 is translated axially along the lengthwise dimension of the lumen 110 until the distal end 124 of the delivery member 120 emerges from an opening 112 in the elongate member 104 and the flexible members 142a, 142b, and 142c transition from the contracted first position 330 shown in FIG. 16A to a second extended position 340 shown in FIG. 16B.
ply flexible members 142a, 142b, and 142c: expand to assume, for example, substantially hexagonal shapes upon emerging from the opening 112 in the elongate member 104 and expanding. The extended flexible members 142a, 142b, and 142c: are substantially planar. The plane defines a plurality of axes that lie in the plane and the plurality of axes are non-parallel to (i.e., biased relative to) the elongate member 104. An angle 344 defined by at least one of the plurality of axes of the plane of the flexible members 142a, 142b, and 142c: and the longitudinal axis of the elongate member 104 is typically specified (e.g., by an operator) such that the flexible members 142a, 142b, and 142c: are flush with tissue surface and are capable of applying a force across a large tissue area. For example, the angle 344 might be chosen to ensure the flexible members 142a, 142b, and 142c: conform to the shape of a tissue surface abutting the flexible members 142a, 142b, and 142c: if the force is applied, e.g., across a large tissue area the movement of the tissue in any location across the tissue area will be minimized. The flexible members 142a, 142b, and 142c: could, alternatively, be of any shape (e.g., polygonal, circular, or ellipsoidal) or of any quantity (e.g., one, two, or five) where the shape and/or quantity of the flexible members 142a, 142b, and 142c: are typically selected to distribute as much force as possible while still being able to fit within the lumen 110 of the elongate member 104 and emerge from or retract into the lumen 110.

When the flexible members 142a, 142b, 142c: are extended in the second expanded position 340 upon emerging from the opening 112, the exemplary cutting member 300 extends axially in the lumen 308 of the delivery member 120 until a cutting tip 304 of the cutting member 300 emerges from the opening 312 in the distal end 124 of the delivery member 120. The tip 304 of the cutting member 300 cuts the tissue in close proximity to the opening 312 of the delivery member 120.

Referring now to FIG. 17, an operator introduces an elongate member 104 into the right atrium 748 of a heart 742 through the descending vena cava 750. The elongate member 104 is advanced distally until the distal end 106 of the elongate member 104 passes through a defect 620 (for example, a patent foramen ovale) in the septum 740. The distal end 106 of the elongate member 104 is shown at an angle 770 of about 45 degrees relative to the longitudinal axis of the elongate member 104 due to a bend 760 in the distal end 106 of the elongate member 104. The bend 760 in the elongate member 104 may be mechanically pre-formed or pre-bent at the angle 770 between about 0 degrees and about 180 degrees prior to insertion of the elongate member into the body. The bend 760 could, alternatively, be accomplished by heating a nickel-titanium material or other shape memory alloy located within the distal end 106 of the elongate member 104.

The septal puncture apparatus shown in FIGS. 18A, 18B, and 18C includes two flexible members 142a and 142b coupled to the distal end 124 of the delivery member 120. The flexible members 142a and 142b are initially located within the lumen 110 of the elongate member 104. An operator initially guides the distal end 106 of the elongate member 104 through the defect (hole) 620 such that the distal end 106 is located on a second side 820 (in the left atria of the heart) of the septum secundum 600 and septum primum 610. Now referring to FIG. 18A, the operator then extends the flexible members 142a and 142b as described herein with respect to, for example, FIGS. 12A and 12B.

With continued reference to FIG. 18A, the elongate member 104 is retracted proximally until the distal end 106 of the elongate member 104 passes back through the defect 620 and is positioned on the first side 810 of the septum 740.

The delivery member 120 is then retracted proximally so that the second portions 270a and 270b of the flexible members 142a and 142b and the distal end 124 of the delivery member 120 are in close proximity to the defect 620, the septum primum 610, and the septum secundum 600 on the second side 820 of the septum 740.

Now referring to FIG. 18B, as the delivery member 120 is further retracted proximally such that the distal end 124 of the delivery member 120 is withdrawn through the defect 620 until it is in contact with or in close proximity to the first surface 880 of the septum primum 610 on the first side 810 of the septum primum 610. The second portions 270a and 270b of the flexible members 142a and 142b are positioned, generally non-parallel to the longitudinal axis of the elongate member 104 and are in physical contact with at least the second surface 870 of the septum primum 610 on the second side 820 of the septum primum 610 and also partially located within the defect 620 in the septum 740. The first portions 272a and 272b of the flexible members 142a and 142b are located on the first side 810 of the septum 740. Accordingly, the flexible members 142a and 142b are sized and shaped for contact with the first side 810 and the second side 820 of the septum 740. The flexible members 142a and 142b are thus capable of limiting movement of the septum primum 610. Now referring to FIG. 18C, the cutting member 300 is extended from the opening 312 in the distal end 124 of the delivery member 120. The cutting tip 304 of the cutting member 300 introduces a hole 1005 (tissue opening) through the septum primum 610.

Referring now to FIG. 19, an exemplary flexible member 142 is attached to the distal end 124 of the delivery member 120, which extends from the opening 112 in the distal end 106 of the elongate member 104. The delivery member 120 and the elongate member 124 are located on the first side 810 of the septum secundum 600. The distal end 124 of the delivery member 120 is located in close proximity to the tissue surface of the septum secundum 600 on the first side 810 of the septum secundum 600. The flexible member 142 extends through the hole 620 between the septum primum 610 and the septum secundum 600 from the first side 810 to the second side 820. The first side 810 of the septum primum 610 opposes the second side 820 of the septum primum 610. The flexible member 142 is positioned so that the second end 202 and second portion 270 of the flexible member 142 are located on the second side 820 of the septum secundum 600 and the first portion 272 of the flexible member 142 is located on the first side 810 of the septum secundum 600. In this configuration, the flexible member 142 is thus capable of limiting movement of the septum secundum 600. In this embodiment only the septum secundum 600 is secured to limit movement. In alternative embodiments, however, the septum secundum 600 and/or the septum primum 610 may be secured to limit movement.

Additionally, it should be noted that Applicants intend any operable embodiments existing between the devices, methods and applications thereof disclosed in the illustrative embodiments described above to be considered within the scope of the inventions disclosed herein and, as such, claimable subject matter.

Equivalents

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The foregoing embodiments are therefore to be considered in all respects illustrative rather than limiting on the invention described herein. Scope of the invention is thus
indicated by the appended claims rather than by the foregoing description, and all changes that come within the meaning and range of equivalency of the claims are intended to be embraced therein.

Incorporation by Reference

All publications and patent documents cited in this application are incorporated by reference in their entirety for all purposes to the same extent as if the contents of each individual publication or patent document was incorporated herein.

What is claimed is:
1. A method for treating a patent foramen ovale of a patient’s heart, comprising:
   accessing the right atrium via a vessel;
   introducing into the right atrium via said vessel a transseptal puncture device comprising:
   a sheath including a distal end and a longitudinally lumen disposed within;
   an outer needle comprising a blunt distal end and a lumen longitudinally disposed substantially thereof; and
   a solid inner needle axially disposed in the lumen of the outer needle and moveable beyond the distal end of the outer needle, the solid inner needle comprised substantially of a single material and comprising a proximal portion, an intermediate portion, and a distal portion, wherein the intermediate portion is more flexible than the distal portion and the distal portion is more flexible than the proximal portion, and wherein the distal portion includes a sharp tip configured to pierce the atrial septum;
   contacting the outer needle with the atrial septum adjacent a patent foramen ovale;
   while maintaining contact of the outer needle against the atrial septum, advancing the sharp tip of the solid inner needle through the atrial septum and into the left atrium; advancing at least part of the solid inner needle into the left atrium, such that at least one of the intermediate and distal portions of the solid inner needle will deflect upon contact with a wall of the left atrium to prevent puncture of the left atrial wall;
   advancing the distal end of the outer needle through the atrial septum and into the left atrium;
   advancing the distal end of the sheath through the atrial septum and into the left atrium;
   withdrawing at least one of the needles from the left atrium;
   and
   introducing a flexible member via the lumen of the sheath to at least partially occlude the patent foramen ovale.

2. The method of claim 1, further comprising the step of using a locator device to stabilize the atrial septum prior to advancing the sharp tip of the inner needle through the septum.

3. The method of claim 1, further comprising the step of withdrawing the sheath from the left atrium.

4. The method of claim 1, wherein the flexible member is configured to reside within a lumen in a compressed state and configured to reside in an expanded state when outside the lumen, the method further including expanding the flexible member from a compressed state to an expanded state.

5. The method of claim 4, further including the step of guiding the flexible member through the patent foramen ovale.

* * * * *
METHOD OF SURGICAL PERFORATION VIA THE DELIVERY OF ENERGY

Inventors: Gareth Davies, Toronto (CA); Amanda April Hartley, Brampton (CA); Naheed Visram, Wimbledon (GB); Krishan Shah, Mississauga (CA); Frank Baylis, Toronto (CA)

Correspondence Address:
OGILVY RENAUTLL LLP
1981 MCGILL COLLEGE AVENUE
SUITE 1600
MONTREAL, QC H3A2Y3 (CA)

Assignee: Baylis Medical Company Inc., Montreal (CA)

Appl. No.: 11/265,304
Filed: Nov. 3, 2005

Continuation-in-part of application No. 10/760,479, filed on Jan. 21, 2004.
Continuation-in-part of application No. 10/666,288, filed on Sep. 19, 2003, which is a continuation-in-part of application No. 10/347,366, filed on Jan. 21, 2003.

Provisional application No. 60/522,753, filed on Nov. 3, 2004.

Publication Classification

Int. Cl. A61B 18/18 (2006.01)
U.S. Cl. ........................................................................... 606/45

ABSTRACT

A method of surgical perforation via the delivery of electrical, radiant or thermal energy comprising the steps of: introducing an apparatus comprising an energy delivery device into a patient's heart via the patient's superior vena cava; positioning the energy delivery device at a first location adjacent material to be perforated; and perforating the material by delivering energy via the energy delivery device; wherein the energy is selected from the group consisting of electrical energy, radiant energy and thermal energy.
FIG. 14B
Figure 16A

1600

1601 Insert apparatus, dilator and sheath into the heart via the Superior Vena Cava

1602 Deliver dilator tip against upper atrial septum

1604 Advance device until tip region is proximate to dilator tip

1606 Record ECG while dragging device along atrial septum

1608 Position device against fossa ovallis and stain

1610 Monitor pressure at tip region

1612 Confirm position using radiopaque markers

1614 Position Confirmed?

1616 YES Deliver energy to create perforation

1618 YES Advance device through to second location

1620 Evaluate pressure contours to confirm position

1622 Confirm desirable position by measuring ECG

1624 Position Confirmed?

1626 NO Retract device to re-position

A
Figure 16B

1628 Fully advance device into left atrium

1630 Fix device and advance dilator and sheath together

1632 With tip of dilator in place, advance sheath over dilator into left atrium

1634 Confirm position of device, dilator and sheath

1636 Position Confirmed? NO

1638 Withdraw device and dilator
METHOD OF SURGICAL PERFORATION VIA THE DELIVERY OF ENERGY

CROSS-REFERENCES TO RELATED APPLICATIONS


TECHNICAL FIELD

[0002] The invention relates to a method, and device therefore, for creating a perforation in a patient material via energy delivery.

BACKGROUND OF THE ART

[0003] Trans-septal catheterization procedures typically involve insertion of a needle, such as the trans-septal needle of Cook Incorporated (Bloomington, Ind., USA) into a patient’s heart. The needle comprises a stiff metal cannula with a sharpened distal tip. The needle is generally introduced through a dilator and guiding sheath set in the femoral vein and advanced through the vasculature into the right atrium. From there the needle tip is positioned at the fossa ovalis, the preferred location on the septum for creating a puncture. Using a needle trans-septal puncture is complicated by the necessity of accessing the heart through the femoral vein and inferior vena cava. Occasionally, due to abnormalities of the venous system such as azygous continuation of the inferior vena cava or thrombosis or obliteration of the iliofemoral veins it may not be possible to gain access to the right atrium using a femoral approach. In addition, the standard femoral transvenous approach to the atrial septum for trans-septal access, as described earlier, may be difficult in situation where the cardiac anatomy is grossly distorted such as in patients with longstanding and marked elevation of left atrial and pulmonary artery pressures, or patients who have previously undergone cardiac surgery. Gaining trans-septal access from the femoral approach may also be difficult in patients with dextrocardia, a condition in which the heart is located on the right side of the chest rather than the left and in whom there is significant variation in the orientation of the atrial septum.

[0004] A trans-jugular approach, using a needle to gain trans-septal access, is described by Joseph et. al. (1997). Joseph states that trans-jugular septal puncture may find application in cardiac electrophysiology because it offers a more direct approach to the mitral annulus, left ventricle, and inferior aspect of the left atrium. In another publication by Joseph et. al. (2000), the author states that in transvenous mitral valveplasty, the jugular approach simplifies septal puncture and mitral valve crossing in patients with a huge left atrium and distorted anatomy, besides making the procedure feasible in the presence of obstruction of the inferior vena cava. However, needle trans-septal punctures from the jugular approach are more difficult to perform and require significant practice. Cheng (2003), commenting on the aforementioned articles, states that the transjugular approach for trans-septal needle puncture is more difficult to perform than the transfemoral approach and that only with larger studies and more experience will we be able to tell whether the innovative tranjugular approach is as versatile, efficacious, and safe as the conventional transfemoral approach.

[0005] U.S. Pat. No. 6,565,562 to Shah et al., entitled “Method for the radio frequency perforation and the enlargement of a body tissue” issued May 20, 2003, describes a method of perforating tissue using a radiofrequency (RF) perforating device. A functional tip on the RF perforating device is placed against target tissue and as RF current is applied a perforation is created. This method allows the RF perforating device to easily pass through the tissue without applying significant force that could cause the tissue to tear. However, Shah et al. do not describe employing such a device using a non-femoral approach to perforate bodily tissue, which would require a means of positioning the perforation device appropriately to allow for perforation and/or dilation.

[0006] The SafeSheath® CSG Worley, described in the publication entitled “Using the Pressure Products SafeSheath CSG Worley with Radio Opaque Soft-Tipped Braided Core” is a surgical sheath designed to be introduced into a patient’s heart through the Superior Vena Cava (SVC) and on through the coronary sinus. The SafeSheath® device is not intended or structured to allow for perforation of patient material nor is it structured to allow for positioning within a patient’s heart for perforation and/or dilation.

[0007] Thus, patients requiring trans-septal punctures would benefit from a device that utilizes a non-femoral, i.e. superior, approach and which is more reliable and user-friendly than the trans-septal needle. In particular, the patient population discussed above would benefit from a device and technique for trans-septal perforation that allows for a multiplicity of uncomplicated intravascular approaches as well as providing a more controlled method of perforation.

SUMMARY OF THE INVENTION

[0008] A broad object of the present invention is to overcome the disadvantages and limitations of the prior art in a novel and non-obvious manner by providing a method for creating a surgical perforation via the delivery of electrical, thermal or radiant energy. This is accomplished by describing a method, and device therefore, for introducing an apparatus into a patient’s heart, positioning at least a portion of the apparatus at an appropriate location and delivering energy to create a perforation at the location. Advantageously, the apparatus may be introduced via the superior vena cava, which may be useful in instances where a femoral approach is contra-indicated. The apparatus may include an energy delivery device which may be operable to deliver energy such as electrical, radiant or thermal energy. The method may further comprise a step of advancing the energy delivery device through the perforation and optionally dilating the perforation to allow, for example, for the insertion of further devices and/or treatment compositions across the perforation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] In order that the invention may be readily understood, embodiments of the invention are illustrated by way of examples in the accompanying drawings, in which:
[0010] FIG. 1 illustrates a schematic view of an electro-

surgical system including an electrosurgical device in ac-
cordance with an embodiment of the invention;

[0011] FIG. 2 illustrates a side cross-sectional view of the
device of FIG. 1;

[0012] FIG. 3 illustrates a cross-sectional view of an alter-
nate embodiment of the device;

[0013] FIG. 4 illustrates an active electrode of the device of
FIG. 1;

[0014] FIG. 5 illustrates the distal region of a device in
accordance with an alternate embodiment of the invention;

[0015] FIG. 6 illustrates a side cross-sectional view of an
alternate embodiment of the device;

[0016] FIG. 7 illustrates a side cross-sectional view of an
alternate embodiment of the device;

[0017] FIGS. 8A and 8B illustrate two possible embodi-
ments of a guiding sheath;

[0018] FIG. 9 illustrates one embodiment of a dilator;

[0019] FIGS. 10A, 10B and 10C illustrate alternate embodi-
ments of a dilator;

[0020] FIG. 11 illustrates a first position of one embodi-
ment of the present invention within a patient’s heart;

[0021] FIG. 12 illustrates a second position of one embodi-
ment of the present invention within a patient’s heart;

[0022] FIGS. 13A and 13B illustrate first positions of
alternate embodiments of the present invention within a
patient’s heart;

[0023] FIGS. 14A and 14B illustrate second positions of
alternate embodiments of the present invention within a
patient’s heart;

[0024] FIG. 15 illustrates a position of one embodiment of
a guiding sheath of the present invention within a patient’s
heart; and

[0025] FIGS. 16A and 16B illustrate a flow chart of a
trans-septal perforation method in accordance with an
embodiment of this invention.

[0026] It will be noted that throughout the appended
drawings, like features are identified by like reference
numerals.

**DETAILED DESCRIPTION OF THE INVENTION**

**Definition**

**RF Ablation vs. RF Perforation**

[0027] Benson et. al. (2002) discuss the fundamental dif-
fferences between RF ablation and RF perforation. In an RF
perforation procedure, energy is applied to rapidly increase
tissue temperature to the extent that the intracellular fluid
becomes converted to steam, inducing cell lysis as a result
of elevated pressure within the cell. Upon the occurrence of
cell lysis and rupture, a void is created, allowing the tip of
the catheter to penetrate the tissue. In order to achieve this
effect, RF perforation devices must apply a high voltage to
the tissue region over a short period of time. Also, the tip of
the device being used should be relatively small, in order to
increase the impedance of the device. This is in contrast to
RF ablation, whereby a larger-tipped device is utilized to
deliver a low impedance and high power signal to the region
involved. Furthermore, as opposed to RF perforation, which
creates a void in the tissue through which the device may be
advanced, the objective of RF ablation is to create a large,
non-penetrating lesion in the tissue, in order to disrupt
electrical conduction. Thus, for the purposes of the present
invention, perforation is defined as the creation of a void
within a material.

[0028] With specific reference now to the drawings in
detail, it is stressed that the particulars shown are by way of
example and for purposes of illustrative discussion of
embodiments of the present invention only, and are pre-

tented in the cause of providing what is believed to be the
most useful and readily understood description of the prin-
ciples and conceptual aspects of the invention. In this regard,
no attempt is made to show structural details of the invention
in more detail than is necessary for a fundamental under-
standing of the invention, the description taken with the
drawings making apparent to those skilled in the art how the
several forms of the invention may be embodied in practice.

[0029] Before explaining at least one embodiment of the
invention in detail, it is to be understood that the invention
is not limited in its application to the details of construction
and the arrangement of the components set forth in the
following description or illustrated in the drawings. The
invention is capable of other embodiments or of being
practiced or carried out in various ways. Also, it is to be
understood that the phraseology and terminology employed
herein is for the purpose of description and should not be
regarded as limiting.

**Electrosurgical Device**

[0030] FIG. 1 illustrates an embodiment of an apparatus
102 in a system 100. Apparatus 102 comprises an elongate
member 104 having a distal region 106, and a proximal
region 108. Distal region 106 is adapted to be inserted within
and along a lumen of a body of a patient, such as a patient’s
vasculature, and maneuverable therethrough to a desired
location proximate material, such as tissue, to be perforated.

[0031] In some embodiments, the elongate member 104
may be tubular in configuration, having at least one lumen
extending from proximal region 108 to distal region 106
such as lumen 200 shown in FIG. 2. Elongate member 104
may be constructed of a biocompatible polymer material that
provides column strength to apparatus 102. The elongate
member 104 is sufficiently stiff to permit a dilator 910 and
a guiding sheath 800 (See FIG. 8) to be easily advanced over
apparatus 102 and through a perforation. Examples of suit-
able materials for the tubular portion of elongate member
104 are polyetheretherketone (PEEK), and polyimide. In the
illustrated embodiment, the outer diameter along the tubular
portion of elongate member 104 tapers down to distal region
106. In alternate embodiments, the outer diameter along
elongate member 104 remains substantially constant from
proximal region 108 to distal region 106.

[0032] Distal region 106 is constructed of a softer polymer
material so that it is pliable and atraumatic when advanced
through vasculature. In some embodiments, the material is
also formable, so that its shape can be changed during
manufacturing, typically by exposing it to heat while it is fixed in a desired shape. In an alternate embodiment, the shape of distal region is modifiable by the operator during use. An example of a suitable plastic is Pebax (a registered trademark of Atofina Chemicals, Inc.). In the present embodiment, the distal region 106 comprises a curve portion 115. Referring to FIG. 12, as the distal region 106 is advanced out of a guiding sheath, it curls away from the general axis of the sheath which helps ensure that energy delivery device 112 is not in a position to inadvertently injure unwanted areas within a patient's heart after trans-septal perforation. Curve length may be about 4 cm (about 1.57") to about 6 cm (about 2.36") and the curve may traverse about 225 to about 315 degrees of the circumference of a circle. For example, the curve may be about 5 cm in length and may traverse about 270 degrees of the circumference of a circle. Such an embodiment may be useful to avoid unwanted damage to cardiac structures.

[0033] In some embodiments, curve portion 115 begins about 0.5 cm to about 1.5 cm proximal to energy delivery device 112, leaving an approximately 1 cm (about 0.39") straight portion in the distal region 106 of apparatus 102. This ensures that this initial portion of apparatus 102 will exit dilator 910 (see FIG. 9 below) without curving, enabling the operator to easily position the apparatus 102, for example, against a septum as described further below. This feature further ensures that the distal region 106 of apparatus 102 will not begin curving within the atrial septum.

[0034] Distal region 106 may have a smaller outer diameter compared to the remainder of elongate member 104 so that dilation of a perforation is limited while the distal region 106 is advanced through the perforation. Limiting dilation ensures that the perforation will not cause hemodynamic instability once apparatus 102 is removed. In some embodiments, the outer diameter of distal region 106 may be no larger than about 0.8 mm to about 1.0 mm. For example, the outer diameter of distal region 106 may be about 0.9 mm (about 0.035"). This is comparable to the distal outer diameter of the trans-septal needle that is traditionally used for creating a perforation in the atrial septum. Similarly, in some embodiments, the outer diameter of elongate member 104 may be no larger than about 0.040" to about 0.060". For example, the outer diameter of elongate member 104 may be about 0.050" (1.282 mm), which is also comparable to the trans-septal needle dimensions.

[0035] Distal region 106 terminates at functional tip region 110, which comprises a device that functions as an energy delivery device as well as an ECG measuring device. Functional tip region 110 comprises at least one energy delivery device 112 made of a conductive and radiopaque material, such as stainless steel, tungsten, platinum, or another metal. One or more radiopaque markings (not shown) may be affixed to elongate member 104 to highlight the location of the transition from distal region 106 to the remainder of elongate member 104, or other important landmarks on apparatus 102. Alternatively, the entire distal region 106 of apparatus 102 may be radiopaque. This can be achieved by filling the polymer material, for example Pebax, used to construct distal region 106 with a radiopaque filler. An example of suitable radiopaque filler is Bismuth. Distal region 106 may contain at least one opening 109 which is in fluid communication with main lumen 200 (FIG. 2) as described further below.

[0036] In the illustrated embodiment, proximal region 108 comprises a hub 114, to which are attached a catheter connector cable 116, and connector 118. Tubing 117 and adapter 119 are attached to hub 114 as well. Proximal region 108 may also have one or more depth markings 113 to indicate distances from functional tip region 110, or other important landmarks on apparatus 102. Hub 114 comprises a curve direction or orientation indicator 111 that is located on the same side of apparatus 102 as the curve 115 in order to indicate the direction of curve 115. Orientation indicator 111 may comprise inks, etching, or other materials that enhance visualization or tactile sensation. One or more curve direction indicators may be used and they may be of any suitable shape and size and a location thereof may be varied about the proximal region 108.

[0037] In the illustrated embodiment, adapter 119 is configured to releaseably couple apparatus 102 to an external pressure transducer 121 via external tubing 123. External pressure transducer 121 is coupled to a monitoring system 125 that converts a pressure signal from external pressure transducer 121 and displays pressure as a function of time. Catheter connector cable 116 connects to Electro-cardiogram (ECG) interface unit 120 via connector 118. ECG connector cable 122 connects ECG interface unit 120 to ECG recorder 126, which displays and captures ECG signals as a function of time. Generator connector cable 124 connects ECG interface unit 120 to an energy source such as generator 128. In this embodiment, ECG interface unit 120 functions as a splitter, permitting connection of electrosurgical apparatus 102 to both ECG recorder 126 and generator 128 simultaneously. ECG signals can be continuously monitored and recorded and the filtering circuit within ECG interface unit 120 may permit energy, for example RF energy, to be delivered from generator 128 through electrosurgical apparatus 102 without compromising ECG recorder 126.

[0038] In another embodiment (not shown) of apparatus 102, there may be a control mechanism associated with the distal region 106 of apparatus 102 and an operating mechanism to operate said control mechanism associated with the proximal region 108 of apparatus 102. The control mechanism may be used to steer or otherwise actuate at least a portion of distal region 106.

[0039] Generator 128 may be a radiofrequency (RF) electrical generator that is designed to work in a high impedance range. Because of the small size of energy delivery device 112 the impedance encountered during RF energy application is very high. General electrosurgical generators are typically not designed to deliver energy in these impedance ranges, so only certain RF generators can be used with this device. In one embodiment, the energy is delivered as a continuous wave at a frequency between about 400 kHz and about 550 kHz, a voltage of between 100 to 200 V RMS and a duration of up to 99 seconds. An appropriate generator for this application is the BMC RF Perforation Generator (model number RFP-100, Baylis Medical Company, Montreal, Canada). This generator delivers continuous RF energy at about 460 kHz. A grounding pad 130 is coupled to generator 128 for attaching to a patient to provide a return
path for the RF energy when generator 128 is operated in a monopolar mode. Other embodiments could use pulsed or non-continuous RF energy. In still other embodiments of apparatus 102, different energy sources may be used, such as radiant (e.g., laser), ultrasound, thermal or other frequencies of electrical energy (e.g., microwave), with appropriate energy sources, coupling devices and delivery devices.

[0040] Referring to FIG. 2 a cross-section of apparatus 102 is illustrated in accordance with the embodiment of FIG. 1. Functional tip region 110 comprises an energy delivery device 112 that is coupled to an insulated conducting wire 202. Conducting wire 202 may be attached to distal region 106 using an adhesive. Alternatively, distal region 106 may be melted onto insulation 204 on conducting wire 202 to form a bond.

[0041] Conducting wire 202 carries electrical energy from generator 128 to the energy delivery device 112. Conducting wire 202 also carries action potentials or voltage measured by energy delivery device 112 to ECG recorder 126. Action potentials or voltage measured by energy delivery device 112 is with reference to a zero potential or ground electrode (not shown) within ECG recorder 126 or with reference to a ground electrode (not shown) attached to the patient (not shown). Conducting wire 202 is covered with electrical insulation 204 made of a biocompatible material that is able to withstand high temperatures such as polytetrafluoroethylene (PTFE), or other insulating material. Conducting wire 202 may extend through a main lumen 200 of apparatus 102, which lumen may extend from proximal region 108 to distal region 106.

[0042] In an alternate embodiment shown in cross section view in FIG. 3, an elongate member 300 comprises main lumen 302 and a separate lumen 304. The separate lumen 304 contains a conducting wire 306 covered with electrical insulation 308 and main lumen 302 can be used for aspiration of blood and injection of contrast (e.g., for staining) and other media. This embodiment of elongate member 300 allows a dedicated lumen for each function of apparatus 102. In yet further embodiments, apparatus 102 may not comprise a lumen and the present invention is not limited in this regard.

[0043] In the embodiment of FIG. 2, main lumen 200 extends from proximal region 108 along elongate member 104 and through distal region 106 of apparatus 102. At least one opening 109 at the distal region 106 provides a pathway between main lumen 200 and the environment surrounding distal region 106, such as a desired location within a patient’s body. Openings 109 may be sufficiently dimensioned to easily aspirate blood to and through main lumen 200 and to inject radiopaque contrast; however, openings 109 may be limited in number and dimension so that they do not compromise the structural integrity of distal region 106. In order to facilitate even distribution of contrast agent and to prevent pooling in main lumen 200 at distal region 106, openings 109 may be dimensioned such that distally located openings are larger than proximally located openings. The location of openings 109 is as close to energy delivery device 112 as possible so that only a small portion of apparatus 102 is required to extend from dilator 910 and sheath 800 in order to measure pressure. In this embodiment, adapter 119 is configured for releasably coupling to an external pressure transducer 121 or to a standard syringe.

For example, adapter 119 comprises a female Luer lock connection. Adapter 119 is coupled to main lumen 200 via tubing 117 to provide a pathway from main lumen 200 to external pressure transducer 121 so that blood pressure can be measured. In embodiments that don’t comprise a lumen, apparatus 102 may or may not comprise openings 109.

[0044] In the illustrated embodiment, insulated conducting wire 202 exits elongate member 104 through an exit point 210. Exit point 210 may be sealed with an adhesive or a polymeric material. Conducting wire 202 extends along elongate member 104 from distal region 106 to proximal region 108 and is electrically coupled to catheter connector cable 116 within hub 114 by an electrical joint 206. Soldering or another wire joining method can be used to make joint 206. Catheter connector cable 116 terminates with a connector 118 that can mate with either the ECG interface unit 120, or a separate extension connector cable (not shown). Catheter connector cable 116 and connector 118 may be made of materials suitable for sterilization, and may insulate the user from energy traveling through the conductor.

[0045] In the illustrated embodiment, elongate member 104 is coupled to tubing 117 at proximal end 212 of elongate member 104. Tubing 117 may be made of a polymeric material that is more flexible than elongate member 104. A suitable material for tubing 117 is polyvinylchloride (PVC), or another flexible polymer. Tubing 117 is coupled to adapter 119. This configuration provides a flexible region for the user to handle when releaseably coupling external pressure transducer 121, or other devices to adapter 119. Couplings between elongate member 104 and tubing 117, and between tubing 117 and adapter 119 may be made with an adhesive such as a UV curable adhesive, an epoxy, or another type of bonding agent.

[0046] A hub 114 surrounds electrical joint 206 and proximal end 212 of elongate member 104 in order to conceal the aforementioned connections. The hub 114 may be made of a polymeric material, and may be filled with a filling agent 208 such as an epoxy, or another polymeric material, in order to hold catheter connector cable 116 and tubing 117 in place.

[0047] Referring now to FIG. 4, there is illustrated a side cross-sectional view of an embodiment of functional tip region 110. In one embodiment, functional tip region 110 comprises one energy delivery device 112 configured as an active electrode in a bullet shape. Energy delivery device 112 may be about 0.10 cm to about 0.20 cm in length and may have an outer diameter of 0.02 cm to about 0.06 cm. For example, energy delivery device 112 may have a length of about 0.15 cm (about 0.05”) and may have an outer diameter of about 0.04 cm (about 0.016”). Energy delivery device 112 is coupled to an end of conducting wire 202, which may also be made out of a conductive and radiopaque material. Energy may be delivered through energy delivery device 112 to tissue, and may travel through the patient to grounding pad 130, which is connected to generator 128. Additionally, action potentials or voltage measured from tissue through energy delivery device 112 travel through conducting wire 202 to ECG recorder 126. Alternate embodiments of energy delivery device 112 may be configured in shapes other than a bullet. These shapes include a spherical shape, a rounded shape, a ring shape, a semi-annular shape, an ellipsoid shape, an arrowhead shape, a spring shape and a cylindrical shape, among others.
Referring now to FIG. 5, there is illustrated an alternate embodiment of a functional tip region 500. Functional tip region 500 comprises one energy delivery device 502 in a ring configuration. Conducting wire 504 covered with electrical insulation 506 is coupled to the energy delivery device 502, and energy delivery device 502 is positioned around the perimeter of a single opening 508 that provides a pathway between main lumen 510 and a patient's body. Another similar embodiment to functional tip region 500 comprises an active electrode in a partially annular shape (not shown).

In further embodiments, a functional tip may comprise multiple electrodes. Such electrodes may operate in a monopolar mode as with the embodiments detailed in FIGS. 2 and 5.

In order to measure pressure at the distal region 106 of the apparatus 102, an external pressure transducer 121 may be coupled to apparatus 102. For example, adapter 119 may be releasably coupled to external tubing 123 that is coupled to external pressure transducer 121. In use, external tubing 123 may be flushed with saline to remove air bubbles. When apparatus 102 is positioned in a blood vessel in a body, pressure of fluid at distal region 106 exerts pressure through openings 109 on fluid within main lumen 200, which exerts pressure on saline in external tubing 123, which exerts pressure on external pressure transducer 121. The at least one opening 109 and lumen 200 provide a pressure sensing mechanism in the form of a pressure transmitting lumen for coupling to pressure transducer 121. External pressure transducer 121 produces a signal that varies as a function of the pressure it senses. External pressure transducer 121 may also be releasably electrically coupled to a pressure monitoring system 125 that converts the transducer's signal and displays a pressure contour as a function of time. Thus, pressure may be optionally measured and/or recorded and, in accordance with one embodiment of a method aspect as described further herein below, used to determine a position of the distal region 106 in a patient's body. In those embodiments of apparatus 102 that do not comprise any lumens, a pressure transducer may be mounted at or proximate to distal region 106 and coupled to pressure monitoring system 125 via an electrical connection.

Referring now to FIG. 6, there is illustrated a side cross-sectional view of an alternate embodiment of apparatus 600 which operates in a bipolar mode. Apparatus 600 comprises an elongate member 602 having a distal region 604, and a proximal region 606. Elongate member 602 has at least one lumen 608 extending from proximal region 606 to distal region 604. In some embodiments, the outer diameter of elongate member 602 tapers down to distal region 604. In alternate embodiments the outer diameter of elongate member 602 remains substantially constant along its length.

Distal region 604 terminates at functional tip region 610. Functional tip region 610 comprises one energy delivery device 612 and one reference electrode 614. In an alternate embodiment comprising a kit including apparatus 600 and at least one of a sheath, such as sheath 800, and a dilator, such as dilator 910, a reference electrode may be located at the distal tip 912 of dilator 910 or at the distal tip 802 of sheath 800. Both the energy delivery device 612 and reference electrode 614 can be configured in various shapes. These shapes include a spherical shape, a rounded shape, a ring shape, a semi-annular shape, an ellipsoid shape, an arrowhead shape, a spring shape and a cylindrical shape, among others. One or more radiopaque markings may be affixed to elongate member 602 to highlight the location of the transition from distal region 604 to the remainder of elongate member 602, or other important landmarks on apparatus 600. Alternatively, the entire distal region 604 of apparatus 600 may be radiopaque. Distal region 604 may define at least one opening 613 in fluid communication with lumen 608.

In an alternate embodiment, the distal region 604 comprises a curve portion. Curve length may be about 4 cm (about 1.57") to about 6 cm (about 2.35") and the curve may traverse about 225 to about 315 degrees of the circumference of a circle. For example, the curve may be about 5 cm in length and may traverse about 270 degrees of the circumference of a circle. Such an embodiment may be useful to avoid unwanted damage to cardiac structures.

In some embodiments, the curve portion begins about 0.5 cm to about 1.5 cm proximal to energy delivery device 612, leaving an approximately 1 cm (about 0.39") straight portion in the distal region 604 of apparatus 600. This ensures that this initial portion of apparatus 600 will exit dilator 910 (see FIG. 9 below) without curving, enabling the operator to easily position the apparatus 600, for example, against a septum as described further below. This feature further ensures that the distal region 604 of apparatus 600 will not begin curving within the atrial septum.

Lumen 608 extends from proximal region 606 along elongate member 602 and through distal region 604 of apparatus 600. At least one opening 613 at the distal region 604 provides a pathway between lumen 608 and the environment surrounding distal region 604, such as a desired location within a patient's body. Openings 613 may be sufficiently dimensioned to easily aspirate blood to and through lumen 608 and to inject radiopaque contrast; however, openings 613 may be limited in number and dimension so that they do not compromise the structural integrity of distal region 604. In order to facilitate even distribution of contrast agent and to prevent pooling in lumen 608 at distal region 604, openings 613 may be dimensioned such that distally located openings are larger than proximally located openings. The location of openings 613 is as close to energy delivery device 612 as possible so that only a small portion of apparatus 600 is required to extend from dilator 910 and sheath 800 in order to measure pressure.

Proximal region 606 comprises a hub 616, an active connector cable 618, a reference connector cable 620, tubing 626 and an adapter 628. Hub 616 may comprise a curve direction or orientation indicator that is located on the same side of apparatus 600 as the curve in order to indicate the direction of the curve. Proximal region 606 may also have one or more depth markings 630 to indicate distances from energy delivery device 612, or other important landmarks on apparatus 600. Adapter 628 is configured to releasably couple apparatus 600 to an external pressure transducer. Both active connector cable 618 and reference connector cable 620 may connect to an ECG interface unit.

Energy delivery device 612 may be coupled to an insulated conducting wire 622. Conducting wire 622 carries
electrical energy from a generator to the energy delivery device 612. Conductor wire 622 also carries action potentials or voltage measured by energy delivery device 612 to an ECG recorder. Conducting wire 622 extends through main lumen 608 of apparatus 600. Conducting wire 622 extends along elongate member 602 from distal region 604 to proximal region 606 and is electrically coupled to active connector cable 618 within hub 616.

[0058] Reference electrode 614 may be coupled to an insulated conducting wire 624. Conducting wire 624 carries electrical energy from a patient to a generator. Conducting wire 624 also carries action potentials or voltage measured by reference electrode 614 to an ECG recorder. Conducting wire 624 extends through main lumen 608 of apparatus 600. Conducting wire 624 extends along elongate member 602 from distal region 604 to proximal region 606 and is electrically coupled to reference connector cable 620 within hub 616.

[0059] In the bipolar mode, RF energy is delivered through energy delivery device 612 (i.e. active electrode 612), and returns to the generator through reference electrode 614. The use of an active and a reference electrode attached to apparatus 600 eliminates the need for a grounding pad to be attached to the patient. With an active-return electrode arrangement at functional tip region 610, action potentials or voltage measured by the energy delivery device 612 are with reference to the ground or reference electrode 614 located at the functional tip region 610. The ECG recorder assigns a zero potential value to the reference electrode 614. A zero potential or ground electrode within the ECG recorder or placement of a ground electrode on the patient is not required and a higher fidelity recording may be facilitated.

[0060] Referring now to FIG. 7, there is illustrated a side cross-sectional view of proximal 706 and distal 704 regions of an alternate embodiment of an apparatus 700 that does not require an external pressure transducer. In this embodiment the pressure sensing mechanism comprises an on-board pressure transducer 708 coupled by an adhesive to elongate member 702 at distal region 704. The pressure transducer 708 is configured at distal region 704 such that pressure close to energy delivery device 710 can be transduced. The on-board pressure transducer 708 is electrically coupled to a pressure communicating cable 712 to provide power to transducer 708 and to carry a pressure signal to proximal region 706 of the apparatus 700. Pressure communicating cable 712 terminates in a monitoring system connector 714 that is configured to be releasely coupled to a pressure monitoring system. The pressure monitoring system converts the pressure signal and displays pressure as a function of time. In the embodiment of FIG. 7, a main lumen such as the main lumen 200 of FIG. 2 is not required for fluid communication with an external pressure transducer 121 (shown in FIG. 1). In addition, this embodiment does not require openings, such as openings 109 shown in FIG. 1, at distal region 704 for fluid communication with a main lumen. However, a lumen with openings may be provided for injecting or aspirating fluids, if desired.

[0061] Optionally, to measure and record ECG at the distal region of the apparatus 102, ECG recorder 126 is connected to apparatus 102 through the ECG interface unit 120. Hub 114 is coupled to catheter connector cable 116 that is coupled to connector 118 as shown in FIG. 1. Connector 118 is attached to ECG interface unit 120. When apparatus 102 is maneuvered in a patient's body, particularly in a heart, electrical action potentials or voltage detected by energy delivery device 112 are transmitted along conducting wire 202 and catheter connector cable 116, through ECG interface unit 120 and are captured and displayed on ECG recorder 126. Different locations in a heart are at different electric potentials and thus the voltage measured varies as the position of energy delivery device 112 is varied. A conversion circuit within ECG recorder 126 may be used to convert the measured voltage or potential into a picture or waveform recording that varies as a function of time.

Sheaths and Dilators

[0062] In order to create a perforation in the heart, apparatus 102 is delivered to the heart using a guiding sheath and dilator known to those of ordinary skill in the art. FIGS. 8A and 8B show alternate embodiments 800 and 810 of a guiding sheath. Guiding sheaths 800 and 810 both comprise distal tips (802 and 812, respectively) and proximal hubs 804. Distal tip 802 is configured and shaped for approaching the heart via the inferior vena cava (IVC) while distal tip 812 is configured and shaped for approaching the heart via the superior vena cava (SVC). Distal tip 812 may comprise a curve of about 45 degrees to about 90 degrees with a relatively short radius such that, when sheath 812 is advanced into the left atrium, the entire curve may sit within the left atrium. Then, through rotating the sheath shaft, the orientation of distal tip 812 may be rotated about its lateral axis. One purpose of the sheath is to provide a conduit for any catheters or other devices that may be introduced therethrough into a patient's heart and to orient the devices such that it facilitates their use. Thus, various curves would be useful depending on the final desired position of the sheath within the patient's heart. The curve of distal tip 812 shown in FIG. 8B may be particularly useful for mitral valve access for balloon valvuloplasty and/or RF ablation of the left side of the heart. Sheaths 800 and 810 may both define a lumen through which a dilator or other device may be delivered. In addition, sheaths 800 and 810 may comprise one or more radiopaque markers or reference electrodes.

[0063] FIG. 9 illustrates a dilator 910 comprising a tip 912 at the distal end thereof and a proximal hub 914. Dilator 910 may be useful when approaching the heart via the IVC due to the shape thereof. Dilator 910 may have one or more radiopaque markers or reference electrodes. In addition, dilator 910 may define a lumen sized to allow for passage of said dilator over a guidewire or for delivery of Apparatus 102 through said dilator.

[0064] FIGS. 10A, 10B and 10C show alternate embodiments of dilator shapes that may be useful when approaching the heart via the SVC. As illustrated in FIGS. 13A, 13B, 14A and 14B below, and as will be discussed in greater detail, performing a trans-septal perforation utilizing a sheath and dilator typically involves several steps, including positioning the energy delivery device against the septum and advancing the dilator and/or sheath across the septum. Each of these steps may require the dilator to be configured in a specific manner in order to perform the desired function. For example, in order to position the energy delivery device against the septum for perforation, it may be desirable to position the energy delivery device at an angle of about 80°.
to about 100 degrees relative to the surface of the septum. In some embodiments, the energy delivery device should be positioned substantially perpendicularly to the septum prior to perforation. In order to achieve this results, a dilator as shown in FIG. 10A (1010) or 103 (1020) may be employed. Both of these dilators comprise distal tips (1012 and 1022, respectively) that are shaped so as to position the energy delivery device appropriately against the septum when the heart is approached via the SVC.

[0065] Once the perforation is created, the dilator and/or sheath may be advanced across the perforation into the left atrium. In order to achieve this most efficiently, it may be advantageous to employ a dilator that can transmit a longitudinal force applied at a proximal end thereof into a force directed at the perforation in order to dilate the perforation sufficiently. In some embodiments, a dilator 1030, as illustrated in FIG. 10C, may be used. Dilator 1030 comprises a distal tip 1032 with a relatively gentle curve (less than 90 degrees) that lends itself to transmitting mechanical force applied at a proximal end of the dilator to advance the dilator through the perforation. In this configuration, the apparatus comprising the energy delivery device may serve to act as a rail to prevent dilator 1030 from slipping down the septum. Alternatively, dilator 1010 may be used to advance the dilator and/or sheath through the perforation. In such an embodiment, as a longitudinal force is applied at a proximal end of the dilator, the dilator and/or sheath may flex and push against the free wall of the right atrium, thereby providing back support and directing force towards the septum. The specific curve used in this embodiment may depend on the specific geometry of the right atrium of the patient. Any of dilators 1010, 1020 and 1030 may comprise hubs 914 as well as radiopaque markers and/or reference electrodes. In alternate embodiments, one or more of the sheath and dilator may be steerable and/or articulating, whereby a shape of the sheath or dilator may be adjusted during the course of the procedure. This may allow for a user to define the precise curve required for each step of the trans-septal perforation.

[0066] Referring now to FIGS. 11 and 12 there is illustrated Apparatus 102 inserted through dilator 910 and sheath 800 within a heart 1600 of a patient. In these figures, the heart has been approached via the inferior vena cava. FIGS. 13 and 14 provide illustrations of apparatus 102 inserted into the heart via the superior vena cava. FIGS. 13A and 14A show apparatus 102 inserted through dilator 1010 while FIGS. 13B and 14B show apparatus 102 inserted through dilators 1020 and 1030, respectively. In all of FIGS. 13 and 14 the dilators are inserted within sheath 810.

Method

[0067] Broadly speaking, embodiments of the present invention provide a method of surgical perforation via the delivery of electrical, radiant or thermal energy. They method may typically involved at least the following steps: introducing an apparatus comprising an energy delivery device into a patient’s heart via the patient’s superior vena cava; positioning the energy delivery device at a first location adjacent the material to be perforated; and perforating the material by delivering energy via the energy delivery device; wherein the energy is selected from the group consisting of electrical energy, radiant energy and thermal energy.

[0068] As one specific example of this method, operational steps 1600 for a method of creating a trans-septal perforation in accordance with an embodiment of the invention are outlined in flowchart form in FIGS. 16A and 16B. In accordance with a method aspect of the invention for creating a trans-septal perforation, the apparatus, dilator and sheath may be introduced into the heart via the SVC (step 1601). Alternatively, the heart may be accessed via the IVC, as shown in FIGS. 11 and 12. In order to deliver the tip of the dilator against the upper region of the atrial septum 1102 (step 1602) a guiding sheath and dilator with a lumen sufficient to accommodate the outer diameter of the Apparatus 102 may be introduced into a patient’s vasculature. In alternate embodiments of the present invention, the procedure may be performed without a sheath and/or dilator. In either case, the method comprises steps of introducing one or more devices and/or apparatuses into the patient’s vasculature and advancing the devices/apparatuses through the vasculature into the patient’s heart. Access to the vasculature may be achieved through a variety of veins large enough to accommodate the guiding sheath and dilator and the present invention is not limited in this regard. The guiding sheath and dilator may be advanced together through the vasculature. In one embodiment, illustrated in FIGS. 11 and 12, they approach the heart from the inferior Vena Cava (IVC) 1106 and proceed into the Superior Vena Cava (SVC) 1108 of the heart 1100. In accordance with this embodiment, access to the vasculature may be gained via the femoral vein. The sheath and dilator may then be withdrawn from the SVC 1108, into the right atrium 1110. In another embodiment, illustrated in FIGS. 13-14, the guiding sheath and dilator approach the heart via the SVC and proceed directly into the right atrium. In accordance with this alternate embodiment, access to the vasculature may be gained via one or more of the subclavian vein, the brachial vein, the axillary vein and the jugular vein.

[0069] Contrast agent may be delivered through the dilator while positioning the dilator and sheath along the atrial septum 1102. The sheath and dilator are now positioned within the right atrium 1110 of heart 1100 so that the tip of the dilator is located against the upper region of the atrial septum 1102 (step 1602).

[0070] Once the tip of the dilator is in position against the upper region of the atrial septum 1102, apparatus 102 can be advanced through the dilator until functional tip region 110 is located distally to the tip of the dilator (step 1604). Distal region 106 of apparatus 102 is pliable so that the curve 115 straightens out within the dilator and takes on the shape of the dilator as it is advanced to the atrial septum 1102. Apparatus 102 is coupled to the ECG recorder 126 and an ECG tracing monitored through energy delivery device 112, known to those of ordinary skill in the art, may be shown on ECG recorder 126. The technique for obtaining an ECG tracing was previously described. In some embodiments, apparatus 102, the dilator and the sheath are now dragged along the atrial septum 1102 while monitoring the ECG tracing on the ECG recorder 126 (step 1606). Confirmation of the position of energy delivery device 112 of apparatus 102 against the fossa ovalis 1104 is made once a distinctive change in the ECG tracing on ECG recorder 126 is observed. This is due to energy delivery device 112 advancing over the region of the fossa ovalis 1104 which is membranous in comparison with the muscular atrial septum 1102.
[0071] H. Bidoglia et al. (1991) who performed experiments on the usefulness of the intracavitary ECG (recorded using a trans-septal needle) in the localization of the fossa ovalis states that when the tip of the needle was laid against the fossa ovalis floor, the endocardial electrocardiogram registered a slight or no injury curve, even when the pressure was sufficient to perforate the septum. On the contrary, pressure on any other areas of the muscular septum or atrial walls elicited a bizarre monophasic injury curve. This shows that the ECG signal recorded by a surgical device while on the membranous fossa ovalis will be damped in comparison with the ECG signal recorded on the muscular areas of the atrial septum or atrial walls. This difference in ECG signal may be useful in locating the region of the fossa ovalis as a surgical device is positioned within a heart. ECG may be displayed on a screen and/or printed on a chart, for example. The distinctive change may be signaled for observation as well using an alarm such as an audible or visual signal.

[0072] The position of apparatus 102 may also be confirmed by monitoring pressure at the functional tip region 110 (step 1610). Apparatus 102 is coupled to external pressure transducer 121 and a right atrial pressure contour, known to those of ordinary skill in the art, may be displayed on monitoring system 125. The technique for obtaining a pressure contour was previously described.

[0073] The position of functional tip region 110 and energy delivery device 112 may be additionally confirmed using an imaging modality such as fluoroscopy. Under fluoroscopy, radiopaque markings associated with distal region 106 of apparatus 102 may be aligned with a radiopaque marker located distally on the dilator such that functional tip region 110 of apparatus 102 is located at the fossa ovalis 1104. Alternately, radiopaque markings associated with distal region 106 of apparatus 102 may be aligned with a radiopaque marker located distally on the sheath such that functional tip region 110 of apparatus 102 is located at the fossa ovalis 1104 (step 1612).

[0074] In some embodiments, radiopaque contrast agent or dye delivered through apparatus 102 will be directed through the openings 109 in functional tip region 110 into the tissue of the fossa ovalis 1104 in order to stain the tissue and make it more visible under radiographic imaging (step 1608). Using fluoroscopy, the stained region of the fossa ovalis 1104 can be seen as a dark patch in contrast to the atrial septum 1102, which appears as a lighter color. Functional tip region 110 may now be easily directed towards the fossa ovalis 1104. In embodiments whereby the heart is approached via the SVC (for example, FIGS. 13A and 13B), one or more of the dilator, sheath and apparatus may be shaped and or configured such that, upon positioning the apparatus within the right atrium 1110, functional tip region 110 may be positioned at an angle of about 80 degrees to about 100 degrees relative to the fossa ovalis 1104. In further embodiments, functional tip region 110 may be positioned substantially perpendicularly relative to the fossa ovalis 1104. Such a position may be achieved, for example, by using dilators 1010 or 1020, as shown in FIGS. 13A and 13B.

[0075] The position of functional tip region 110 of apparatus 102 is evaluated and if the desired position is not confirmed (step 1614, No branch), step 1606 may be repeated. If confirmed (step 1614, Yes branch), energy may be delivered to create the perforation. For example, generator 128 may be activated and RF energy may be delivered through apparatus 102 to make a perforation (step 1616). As mentioned above, the perforation may alternatively be created using radiant (e.g. laser) or thermal energy.

[0076] Referring to FIGS. 12 and 14, functional tip region 110 of apparatus 102 is thereafter advanced through the perforation and into a second location (step 1618). Advancement may be monitored under fluoroscopy using radiopaque markings on the distal region 106 of apparatus 102. In some embodiments, the second location is the left atrium 1112 of the heart. The distal region 106 of apparatus 102 is advanced incrementally into the left atrium 1112 through the dilator, for example, in about 1 cm (about 0.39") increments. After the first 1 cm of distal region 106 of apparatus 102 has been advanced out of the dilator across the atrial septum 1102, into left atrium 1112, the curve portion 115 of distal region 106 of apparatus 102 establishes its curved shape within the left atrium 1112. In other words, the distal tip of apparatus 102 may be directing in a desired direction, for example away from cardiac structures, following perforation of the septum. An orientation indicator located on apparatus 102 may be monitored in order to determine the direction of the distal tip of apparatus 102. The position of depth markings 113 of apparatus 102 relative to the proximal hub of the dilator can be used as a guide. Additionally, advancement of perforating apparatus 102 can be controlled by monitoring radiopaque markings on the distal region 106 of apparatus 102 under fluoroscopy. When the openings 109 on distal region 106 of apparatus 102 are located in the left atrium 1112, the evaluation of pressure contours from the left atrium via pressure transducer 121 (step 1620) can be performed. Apparatus 102 may remain coupled to external pressure transducer 121 so that a pressure contour at the second location can be measured and/or monitored confirming the desired location of the distal region following the perforation.

[0077] Additionally, when the distal region 106 of apparatus 102 is located in the left atrium 1112, the evaluation of the ECG tracing (step 1622) can be performed. Apparatus 202 remains coupled to ECG recorder 126 so that an ECG tracing at the second location can be monitored. After successful perforation, a left atrial pressure contour known to those of ordinary skill in the art, will be shown on monitoring system 125. In addition, a left atrial ECG tracing, known to those of ordinary skill in the art, will be shown on the ECG recorder 126. In the event that at least one of the imaging, pressure contours and ECG tracings show that the perforation has been made in an undesirable location (step 1624, No branch), apparatus 102 may be retracted into the right atrium 1110 (step 1626) and may be repositioned for another perforation attempt (step 1606). If the perforation is successfully made in the correct location (step 1624, Yes branch), distal region 106 of apparatus 102 may be further advanced through the perforation. In some embodiments, when apparatus 102 is fully inserted into the dilator, hub 114 of the apparatus 102 will be flush against the proximal hub of the dilator, and no depth markings 113 of apparatus 102 will be visible (step 1628, FIG. 16B). When fully inserted, apparatus 102 provides sufficient support to permit the dilator to be advanced over it through the perforation.

[0078] The dilator may be advanced through the perforation by applying a longitudinal force to the proximal end of
the dilator. If the heart has been approached via the IVC, this longitudinal force may directly advance the dilator through the perforation. However, in some embodiments whereby the heart has been approached via the SVC, applying a longitudinal force may push the dilator down along the septum rather than through the perforation. In such embodiments, the dilator may be designed in such a way so that application of a longitudinal force onto a proximal end of the dilator may advance the distal end of the dilator through the perforation. For example, in FIG. 14A, dilator 1010 is shaped such that application of a longitudinal, downward force onto a proximal end of the dilator will cause a portion (1016 in FIG. 10A) of dilator 1010 to push against the free atrial wall. This in turn will transmit the longitudinal force in a lateral direction, thus forcing the distal end of dilator 1010 through the perforation. Alternatively, as shown in FIG. 14B, dilator 1030 may comprise a gentle curve which lends itself to transmitting mechanical force, such that the longitudinal force applied at a proximal end of the dilator will advance the distal end through the perforation. In such an embodiment, apparatus 102 may serve as a rail to support dilator 1030 and to ensure that dilator 1030 does not slip down the septal wall.

In order to advance the sheath and dilator, hub 114 of apparatus 102 may be fixed in place spatially, and both the proximal hub 914 of the dilator and proximal hub 804 of the sheath may be incrementally advanced forward, together, thus sliding the dilator and sheath over apparatus 102 (step 1630). The distal tip of the dilator and the distal tip of the sheath may be monitored under fluoroscopy as they are advanced over apparatus 102 and, once the tip of the dilator has traversed the perforation and has advanced into the left atrium 1112, the tip of the sheath may then be advanced over the dilator, across the perforation and into the left atrium 1112 as well (step 1632). In an alternate method of advancing the sheath and dilator into the left atrium, once distal region 106 is fully advanced through the perforation and into the left atrium 1112, and hub 114 of apparatus 102 is flush against proximal hub 914 of the dilator, hub 114 of apparatus 102, proximal hub 914 of the dilator and proximal hub 804 of the sheath may all be advanced forward together, for example under fluoroscopy. Forward momentum will cause the distal tip of the dilator to traverse the perforation, advancing into the left atrium 1112. The distal tip of the sheath will follow over the dilator, across the perforation and into the left atrium 1112. Alternatively, apparatus 102, the dilator and the sheath may each be advanced independently through the perforation. For example, the sheath may be advanced prior to the dilator.

At step 1634, the positions of distal region 106 of apparatus 102, the distal tip of the dilator and the distal tip of the sheath may be confirmed, for example, under fluoroscopy, to be in the left atrium 1112. If not in the desired location (step 1636), step 1630 may be repeated. If the positions are confirmed (step 1636), apparatus 102 and the dilator may now be respectively withdrawn outside the body, for example under fluoroscopic guidance (step 1638). While maintaining the position of the distal tip of the dilator and the distal tip of the sheath in the left atrium 1112, apparatus 102 may be withdrawn. The dilator may then be withdrawn outside the body under fluoroscopic guidance, while maintaining the position of the distal tip of the sheath in the left atrium 1112. In some embodiments (see, for example, FIG. 15), the sheath may assume its original shape once the dilator is withdrawn. In other words, while the dilator is located within the sheath lumen, the sheath may conform to the shape of the dilator. However, once the dilator is removed, the sheath may revert to its original shape, i.e. the shape it had prior to receiving the dilator within the sheath. Optionally, a contrast agent may now be injected through the sheath into the left atrium 1112, blood may be aspirated through the sheath from the left atrium 1112, or other devices (for example treatment devices or diagnostic devices) or treatment compositions may be introduced into the left atrium 1112 through the perforation (for example, through the sheath).

As has been mentioned above, it may be advantageous, particularly in embodiments wherein the heart is approached via the SVC, to employ one or more dilators of various configurations throughout the procedure. For example, a dilator having a first shape may be used to facilitate positioning of apparatus 102 adjacent the fossa ovalis or other material to be perforated. Subsequently, a dilator having a second shape may be used to facilitate advancement of the dilator across the perforation. These two dilator shapes may be achieved in a number of ways. For example, two separate dilators may be used. One embodiment may comprise two dilators which may be exchanged during the course of the procedure. In other words, one dilator may be used to position the apparatus for perforation and, after perforation has been completed, the dilator may be exchanged for a second dilator configured to facilitate advancement of the dilator across the perforation. Alternatively, another embodiment may comprise a first, more flexible dilator configured to facilitate advancement of the dilator through the perforation. A second, stiffer dilator may be located within a lumen defined by the more flexible dilator. The stiffer dilator may be configured to facilitate positioning of the apparatus for perforation. Thus, in use, the stiffer dilator may be inserted within the more flexible dilator in order to position the apparatus for perforation. Once perforation has been completed, the stiffer dilator may be retracted, thus allowing the more flexible dilator to assume its natural shape, configured to allow for advancement of the dilator through the perforation. In a further embodiment, the dilator may be configured such that a user can modify the shape of the dilator during the course of the procedure. In other embodiments, the dilator may have a single configuration throughout the procedure, as illustrated, for example, in FIGS. 13A and 14A.

The present invention in various embodiments thus provides a device and method that is capable of creating a perforation while determining a position of the device in response to action potentials or measured voltage at a location in the heart as well as determining a position of the device in response to pressure at a location in the body. In some embodiments, the present invention decreases the risk of inadvertent and unwanted cardiac injury associated with creating the perforation. One means for decreasing the risk of unwanted injury comprises a curve at the distal end of the device. In further embodiments, the present invention also provides a method for staining the area to be perforated in order to make it easier to locate during the perforation. In addition, embodiments of the present invention provide a method for delivering a dilator and sheath over the device after the perforation. Various embodiments of dilators and sheaths are described in the specification. The perforation may be created by the application of energy produced by a
generator and delivered to an active tip on the device. The energy may be selected from the group consisting of electrical energy (various frequencies), radiant energy (e.g., laser) and thermal energy, amongst others. A means for determining the position of the device may comprise an ECG measuring device for monitoring action potentials or measured voltage through an active electrode in a unipolar or bipolar manner and displaying the ECG tracings on an ECG recorder. In this embodiment there is at least one active electrode at the functional tip region for monitoring action potentials which are captured and displayed as ECG tracings on an ECG recorder. A means for determining the position of the device may also comprise a pressure transmitting lumen that may be releasably coupled to an external pressure transducer. In this embodiment, there is at least one opening near the distal region of the device for blood or other fluid to enter and fill the lumen and exert a measurable pressure on a coupled external transducer. The lumen and opening may also be useful for injecting radiopaque contrast or other agents through the device. In an alternate embodiment, the means for determining the position of the device in response to pressure comprises a transducer located on the device proximal to the functional tip.

[0083] The device of the invention may be used as a substitute for a traditional trans-septal needle to create a trans-septal perforation. Some embodiments of the device of the present invention may have a soft and curved distal region with a functional tip that uses RF energy to create a perforation across a septum, making the procedure more easily controlled and less operator dependent than a trans-septal needle procedure. The soft distal region of the device may reduce incidents of vascular trauma as the device is advanced through the vasculature. The application of RF energy may be controlled via an electric generator, eliminating the need for the operator to subjectively manage the amount of force necessary to cross the septum with a traditional needle. Thus, the present invention may reduce the danger of applying too much mechanical force and injuring the posterior wall of the heart.

[0084] The present invention also provides a method for the creation of a perforation in, for example, an atrial septum. ECG as well as pressure monitoring may be advantageous in this procedure, as there is the possibility of inadvertently perforating the aorta due to its proximity to the atrial septum. Electrical action potential or voltage measurements displayed as ECG tracings allow the operator to position the device accurately at the fossa ovalis on the septum as well as confirm that the distal end of the device has entered the left atrium, and not the aorta or another undesirable location in the heart. As well, pressure measurements allow the operator to confirm that the distal end of the device has entered the left atrium, and not the aorta, or another undesirable location in the heart. Staining the atrial septum may also be advantageous in this procedure, as it easily identifies the region of the atrial septum (fossa ovalis) to be perforated. The device may also be visible using standard imaging techniques; however the ability to monitor both ECG and pressure provides the operator with a level of safety and confidence that would not exist using only these techniques. It should be noted, however, that a method of the present invention may be practiced without any or all of pressure monitoring, ECG monitoring and staining and is thus intended to comprise, in a basic form, a method of creating a perforation in a tissue utilizing any intravascular approach.

[0085] In some embodiments of the present invention, the heart is approached via the inferior vena cava (IVC) (an ‘inferior’ approach). In such embodiments, the device may be introduced into the patient’s vasculature via the femoral vein. In alternate embodiments, the heart may be approached via the superior vena cava (SVC) (a “superior” approach). Such embodiments may be useful in instances where introduction via the IVC is contra-indicated, as has been discussed. In such embodiments, access to the patient’s vasculature may be achieved through one or more of a brachial vein, an axillary vein, a subclavian vein and a jugular vein.

[0086] In order to create the perforation, it may be desirable to position the device at a specific orientation relative to the material to be perforated. For example, the device may be oriented at an angle of between about 80 to about 100 degrees relative to the fossa ovalis. Achieving such an orientation using a superior approach may require the use of dilators and/or sheaths having appropriate shapes, as has been described herein above.

[0087] The present invention also provides a method for delivering the dilator and sheath over the device into the left atrium once a successful perforation has been created. Once again, in order to successfully advance the dilator and/or sheath through the perforation when using a superior approach, it may be advantageous to employ devices with appropriate shapes and configurations, as has been described.

[0088] One of the motivations for creating a trans-septal perforation is to gain access to the left side of the heart for delivery of catheters or devices to treat left-sided heart arrhythmias or defects. An application of a method aspect of the present invention may involve the implantation of a device, such as an implantable pressure monitor or other sensor into the left atrium of a patient’s heart. Using an embodiment of a method aspect of the present invention, a perforation may be created between the right and left atria of a patient’s heart utilizing a superior intravascular approach, for example through a subclavian vein. Following the creation of the perforation, an implantable device may be inserted through to the left atrium and implanted at a desired location. In one embodiment, the implantable device may be initially mounted on one of an electrosurgical device, a dilator, a sheath or a guidewire, thus obviating the need for an additional device to insert the implantable device. In additional embodiments, a pressure sensor or other device may be inserted into the left atrium after the creation of a perforation in order to monitor pressure or some other physiological parameter without being permanently implanted. In other words, the device may be used to monitor some parameter and may then be removed, in the same procedure, without being permanently implanted into the patient. All of these applications are intended to be exemplary only and are not intended to limit the scope of the present invention in any way.

[0089] While the surgical device thus described is capable of perforating living tissue, it will be understood by persons of ordinary skill in the art that an appropriate device in accordance with the invention will be capable of perforating or removing material such as plaque or thrombotic occu-
sions from diseased vessels as well. Furthermore, any of the hubs referred to throughout this specification (e.g. hub 114, hub 804 and hub 914) may be removable in order to facilitate exchange or removal of any devices or components during the course of a procedure.

[0090] Persons of ordinary skill in the art will appreciate that one or more features of the device and method aspects of the present invention are optional. For example, a device may be made within the scope of the invention without a curve portion of the distal region. Further, a pressure sensing mechanism for positioning the device is optional and, in other instances, the ECG monitoring feature is optional.

[0091] The embodiments of the invention described above are intended to be exemplary only. The scope of the invention is therefore intended to be limited solely by the scope of the appended claims.

[0092] It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

[0093] Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are hereby incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in any application shall not be construed as an admission that such reference is available as prior art to the present invention.

What is claimed is:

1. A method of surgical perforation via the delivery of electrical, radiant or thermal energy comprising the steps of:
   (i) introducing an apparatus comprising an energy delivery device into a patient’s heart via said patient’s superior vena cava;
   (ii) positioning said energy delivery device at a first location adjacent material to be perforated; and
   (iii) perforating said material by delivering energy via said energy delivery device;
   wherein said energy is selected from the group consisting of electrical energy, radiant energy and thermal energy.

2. The method as claimed in claim 1, wherein step (ii) comprises positioning said energy delivery device at an angle of about 80 degrees to about 100 degrees relative to said material to be perforated.

3. The method as claimed in claim 2, wherein step (ii) comprises positioning said energy delivery device substantially perpendicularly relative to said material to be perforated.

4. The method as claimed in claim 1 further comprising a step of:
   (iv) advancing said energy delivery device to a second location through the perforation.

5. The method as claimed in claim 4, wherein said apparatus further comprises a distal region capable of adopting a curved shape and wherein step (iv) further comprises directing a distal tip of said apparatus in a desired direction.

6. The method as claimed in claim 5, wherein said distal tip is directed away from cardiac structures in order to decrease risk of unwanted injury.

7. The method as claimed in claim 5 wherein said apparatus further comprises a repositioning indicator for determining a direction of said distal tip and wherein said method comprises monitoring said orientation indicator.

8. The method as claimed in claim 1 wherein step (ii) comprises staining at least a portion of said first location with a radiopaque dye.

9. The method as claimed in claim 1 wherein the step of introducing an apparatus comprises the steps of:
   (a) introducing said apparatus into said patient’s vasculature; and
   (b) advancing said apparatus through said patient’s vasculature into said patient’s heart.

10. The method as claimed in claim 9 wherein step (a) comprises inserting said apparatus into a vein selected from the group consisting of a jugular vein, a subclavian vein, a brachial vein and an axillary vein.

11. The method as claimed in claim 1, wherein step (i) further comprises inserting a dilator and a sheath into said patient’s heart.

12. The method as claimed in claim 11, wherein step (ii) comprises positioning said dilator such that a distal end of said dilator is oriented at an angle of about 80 degrees to about 100 degrees relative to said material to be perforated.

13. The method as claimed in claim 12, wherein step (ii) comprises positioning said dilator such that a distal end of said dilator is oriented substantially perpendicularly relative to said material to be perforated.

14. The method as claimed in claim 11, further comprising advancing said energy delivery device, said dilator and said sheath to a second location through the perforation.

15. The method as claimed in claim 14, wherein said dilator is shaped such that a distal end of said dilator will be advanced through said perforation upon an application of a longitudinal force onto a proximal end of said dilator.

16. The method as claimed in claim 1 wherein said material to be cut is tissue of an atrial septum of said patient’s heart.

17. The method as claimed in claim 16, wherein said material comprises a fossa ovalis of said patient’s heart.

18. The method as claimed in claim 4 wherein said second location is a left atrium of said patient’s heart.

19. The method as claimed in claim 18 wherein said apparatus further comprises at least one pressure sensing mechanism selected from the group consisting of a pressure-transmitting lumen and a pressure transducer and wherein said method further comprises a step of measuring pressure at said second location.

20. The method as claimed in claim 1, further comprising a step of monitoring ECG in said patient’s heart using said apparatus.
21. The method as claimed in claim 20, wherein step (ii) comprises dragging said energy delivery device about a surface of said patient’s heart while monitoring ECG in order to determine said first location.

22. The method as claimed in claim 21, wherein said ECG at said first location comprises a damped signal in comparison with ECG monitored otherwise on said surface of said patient’s heart.

23. The method as claimed in claim 1, further comprising a step of delivering one or more of a treatment device, a diagnostic device and a treatment composition through said perforation.

24. A method of surgical perforation comprising the steps of:

(i) introducing an apparatus into a patient’s heart via said patient’s superior vena cava, said apparatus comprising an energy delivery device and a means for determining the position of said energy delivery device; and

(ii) positioning said energy delivery device adjacent material to be perforated in response to the means for determining position.

25. The method as claimed in claim 24 further comprising the step of:

(iii) perforating said material by delivering energy via said energy delivery device.

26. The method as claimed in claim 25, wherein said energy comprises radiant energy.

27. The method as claimed in claim 25, wherein said energy comprises electrical energy.

28. The method as claimed in claim 25, wherein said energy comprises thermal energy.

29. The method as claimed in claim 24 wherein said means for determining position comprises at least one pressure sensing mechanism selected from the group consisting of a pressure transmitting lumen and a pressure transducer.

30. The method as claimed in claim 24 wherein said means for determining position comprises an ECG measuring device.

31. The method as claimed in claim 24 wherein said means for determining position comprises at least one marker selected from the group consisting of a radiopaque marker and a depth marker.

* * * * *
Abstract

Systems and methods for penetrating a tissue membrane to gain access to a target site are disclosed. In some examples, systems and methods for accessing the left atrium from the right atrium of a patient's heart are carried out by puncturing the intra-atrial septal wall. One embodiment provides a system for transseptal cardiac access that includes a stabilizer sheath having a side port, a shaped guiding catheter configured to exit the side port and a tissue penetration member disposed within and extendable from the distal end of the guide catheter. The tissue penetration member may be configured to penetrate tissue upon rotation and may be coupled to a distal portion of a torqueable shaft. In some embodiments, the stabilizer sheath and shaped guiding catheter may be moved relative to the patient's body structure and relative to each other so that a desired approach angle may be obtained for the tissue penetration member with respect to the target tissue.
TRANSMEMBRANE ACCESS SYSTEMS AND METHODS

BACKGROUND

[0001] Access to the left side of the heart plays an important role in the diagnosis and treatment of cardiovascular disease. Invasive cardiologists commonly perform a left heart catheterization for angiographic evaluation or transcatheter intervention of cardiac or coronary artery disease. In a left heart catheterization, the operator achieves vascular access through a femoral artery and passes a catheter in a retrograde direction until the catheter tip reaches the coronary artery ostia or crosses the aortic valve and into the left ventricle. From a catheter positioned in the left ventricle, an operator can measure left ventricular systolic and end-diastolic pressures and evaluate aortic valve disease. Ventriculography, where contrast is injected into the left ventricle, may be performed to evaluate left ventricular function. Alternative insertion sites, such as the brachial or radial artery, are used sometimes when femoral artery access is contraindicated due to iliomesenteric atherosclerosis, but manipulation of the catheter can be more difficult from these other insertion sites.

[0002] Although left heart catheterization can be a fast and relatively safe procedure for access to the coronary arteries and the left ventricle, its usefulness for accessing structures beyond the left ventricle, namely the left atrium and the pulmonary veins, is limited by the tortuous path required to access these structures from the left ventricle via the mitral valve. For example, electrophysiologic procedures requiring access to the left atrium or pulmonary veins, performance of balloon mitral valve commissurotomy, and left ventricular access across an aortic prosthetic disc valve can be difficult, and sometimes unfeasible, through traditional left heart catheterization techniques.

[0003] Transseptal cardiac catheterization is another commonly employed percutaneous procedure for gaining access to the left side of the heart from the right side of the heart. Access occurs by transaxing across the fibro-muscular tissue of the intra-atrial septum from the right atrium and into the left atrium. From the left atrium, other adjoining structures may also be accessed, including the left atrial appendage, the mitral valve, left ventricle and the pulmonary veins.

[0004] Transseptal cardiac catheterization has been performed in tens of thousands of patients around the world, and is used for both diagnostic and therapeutic purposes. Diagnostically, operators utilize transseptal catheterization to carry out electrophysiologic procedures requiring access to the pulmonary veins and also to do left heart catheterizations where a diseased aortic valve or an aortic disc prosthetic valve prohibits retrograde left ventricular catheterization across the valve. Therapeutically, operators employ transseptal cardiac catheterization to perform a host of therapeutic procedures, including balloon dilatation for mitral or aortic valve valvuloplasty and radiofrequency ablation of arrhythmias originating from the left side of the heart. Transseptal cardiac catheterization is also used to implant newer medical devices, including occlusion devices in the left atrial appendage for stroke prevention and heart monitoring devices for the treatment of cardiovascular disease.

[0005] The vast majority of transseptal procedures is performed via a femoral vein access site, using special set of devices, called a Brockenbrough needle and catheter/dilator, designed for this approach. In this standard approach the Brockenbrough catheter/dilator, with the hollow Brockenbrough needle within, is advanced from a femoral vein, through the inferior vena cava, through the right atrium and into the superior vena cava. The distal end is then pulled back to the right atrium and rotated until it points at the foramen ovale of the atrial septum. The Brockenbrough needle has a gentle bend that facilitates guiding the system from the vena cava into and through the right atrium, to the intra-atrial septum. The right atrial surface of the septum faces slightly downward, toward the inferior vena cava, so that the natural path of the Brockenbrough needle/catheter brings it to the atrial surface at nearly a right angle of incidence. After verifying the location of the catheter tip at the septal surface by fluoroscopy and/or ultrasound imaging, the operator can firmly but gradually advance the needle within the catheter until its tip penetrates the septum. Contrast material is then injected through the lumen of the Brockenbrough needle and observed fluoroscopically to verify placement of the tip in the left atrium. Once this placement is verified, the catheter/dilator may be advanced through the septum into the left atrium. The Brockenbrough needle is removed and a guide wire can be placed into the left atrium through the dilator lumen. At this point, access to the left atrium has been established and the Brockenbrough needle can be removed, allowing introduction of other devices either over the guide wire or through a Mullins sheath placed over the dilator, or both, as is well known to those skilled in the art.

[0006] Transseptal cardiac catheterization using the standard technique described above is generally successful and safe when performed by skilled individuals such as invasive cardiologists, interventional cardiologists, and electrophysiologists with appropriate training and experience. Lack of success may be attributable to anatomic variations, especially with respect to the size, location and orientation of the pertinent cardiovascular structures and imaging-related anatomic landmarks. Another reason for failure may be the relatively fixed dimensions and curvatures of currently available transseptal catheterization equipment. One major risk of existing transseptal catheterization techniques lies in the inadvertent puncture of atrial structures, such as the atrial free wall or the coronary sinus, or entry into the aortic root or pulmonary artery. In some cases, these punctures or perforations can lead to bleeding around the heart resulting in impaired cardiac function known as cardiac tamponade, which if not promptly recognized and treated, may be fatal. As such, surgical repair of such a cardiac perforation is sometimes required.

[0007] One problem with the standard transseptal needle/catheter system is that once an inadvertent puncture has occurred, it may be difficult to realize what structure has been compromised because contrast injection through the needle is limited by the small bore lumen thereof. Thus visualization of the structure entered may be inadequate and non-diagnostic. Also, the tip of the catheter dilator of existing devices may cross the puncture site which has the effect of further enlarging the puncture hole.

[0008] Other than minor refinements in technique and equipment, the standard transseptal catheterization procedure has remained relatively constant for years. Even so, the technique has several recognized limitations that diminish
the efficacy and safety of this well-established procedure. Thus, there remains a need for an alternative system that effectively and safely provides access to the left atrium, or other desired site in the body.

[0009] As noted above, standard transseptal cardiac catheterization is performed via the inferior vena cava approach from an access site in a femoral vein. In some situations it is clinically desirable to perform transseptal cardiac catheterization via the superior vena cava from an access site in a vein in the neck or shoulder area, such as a jugular or subclavian vein. The superior vena cava approach is more problematic than the standard inferior vena cava approach because of the downward anatomical orientation of the intra-atrial septum, mentioned above: the Brockenbrough needle must make more than a 90° bend to engage the atrial septum at a right angle of incidence, which makes it difficult to exert a sufficient force along the axis of the needle to penetrate the septum. In fact, it is in general problematic to exert an axial force around a bend in a flexible wire, rod, needle, or other elongated member, because the axial force tends to bend or flex the device rather than simply translate it axially. Thus, there is a need for improved apparatus and methods for performing procedures requiring an axial force, such as punctures, when a bend in the flexible member transmitting the force is unavoidable. Another problem not infrequently encountered with conventional transseptal catheterization is that advancement of a Brockenbrough needle against the septum can cause substantial displacement or tenting of the septum from right to left prior to puncture. Sudden penetration can result in the needle injuring other structures in the left atrium. Two approaches to these needs are addressed in this invention: reduction or elimination of the force required to perform the procedure, such as a transseptal puncture; and provision of a stabilizing apparatus for transmitting an axial force around a bend.

SUMMARY

[0010] One embodiment is directed to a transmembrane access system having a stabilizer sheath with a tubular configuration and an inner lumen extending therein and having a side port disposed on a distal section of the sheath and in communication with the inner lumen. A tubular guide catheter having a shaped distal section that has a curved configuration in a relaxed state and an outer surface which is configured to move axially within a portion of the inner lumen of the stabilizer sheath that extends from the proximal end of the stabilizer sheath to the side port. A tissue penetration member is disposed within a distal end of the guiding catheter and is axially extendable from the distal end of the guiding catheter for membrane penetration. In one particular embodiment, the tissue penetration member is configured to penetrate tissue upon rotation and the system further includes an elongate torqueable shaft coupled to the tissue penetration member.

[0011] Another embodiment of a transmembrane access system includes a tubular guide catheter having a shaped distal section that has a curved configuration in a relaxed state. A tissue penetration member configured to penetrate tissue on rotation includes a helical tissue penetration member. The tissue penetration member is configured to move axially within an inner lumen of the tubular guide catheter and is axially extendable from the guide catheter for membrane penetration. An activation modulator is coupled to the tissue penetration member by a torqueable shaft and is configured to axially advance and rotate the torqueable shaft upon activation of the activation modulator.

[0012] One embodiment of a method of use of a transmembrane access system includes a method of accessing the left atrium of a patient's heart from the right atrium of the patient's heart wherein a transmembrane access system is provided. The transmembrane access system includes a stabilizer sheath having a tubular configuration with an inner lumen extending therein and a side port disposed on a distal section of the sheath in communication with the inner lumen. The system also includes a tubular guide catheter having a shaped distal section that has a curved configuration in a relaxed state and an outer surface which is configured to move axially within a portion of the inner lumen of the stabilizer sheath that extends from the proximal end of the stabilizer sheath to the side port. A tissue penetration member is disposed within a distal end of the guiding catheter and is axially extendable from the distal end of the guiding catheter for membrane penetration.

[0013] Once the transmembrane access system has been provided, the stabilizer sheath is advanced over a guidewire from the vascular access site in a subclavian or jugular vein through superior vena cava of the patient and positioned with the distal end of the stabilizer sheath within the inferior vena cava with the side port of the stabilizer sheath within the right atrium facing the intra-atrial septum of the patient's heart. The guidewire is removed and the distal end of the guide catheter is advanced through the inner lumen of the stabilizer sheath until the distal end of the guide catheter exits the side port of the stabilizer sheath and is positioned adjacent target tissue of a desired site of the septum of the patient's heart. The tissue penetration member is advanced from the distal end of the guide catheter and activated so as to penetrate the target tissue. For some embodiments, the tissue penetration member is activated by rotation of the tissue penetration member. The tissue penetration member is then advanced distally through the septum.

[0014] Another embodiment of using a transmembrane access system includes a method of accessing a second side of a tissue membrane from a first side of a tissue membrane wherein a transmembrane access system is provided. The transmembrane access system includes a guide catheter with a shaped distal section that has a curved configuration in a relaxed state. The system also includes a tissue penetration member which is disposed within a distal end of the guide catheter and which is axially extendable from the distal end of the guide catheter for membrane penetration. The tissue penetration member is configured to penetrate tissue upon rotation and has a guidewire lumen disposed therein. The distal end of the guide catheter is positioned until the distal end of the guide catheter is adjacent to a desired site on the first side of the tissue membrane.

[0015] The tissue penetration member is advanced distally from the guide catheter until the distal end of the tissue penetration member is in contact with the tissue membrane. The tissue penetration member is then rotated and advanced distally through the tissue membrane. Contrast material may be injected through the guidewire lumen of the penetrating member while observing fluoroscopically to verify that the tissue penetration member has entered the desired distal chamber. Alternatively, pressure can be monitored through
the guidewire lumen to verify that the tissue penetration member has entered the desired distal chamber, as is well known to those skilled in the art. It is also well known to both inject contrast under fluoroscopic observation and to monitor pressure through the same lumen to verify positioning of the tissue penetration member. Finally, a guidewire is advanced through the guidewire lumen of the tissue penetration member until a distal end of the guidewire is disposed on the second side of the tissue membrane.

[0016] These and other advantages of embodiments will become more apparent from the following detailed description when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1 is an elevational view of an embodiment of a transmembrane access system.

[0018] FIG. 2 is an enlarged view in partial section of the side port portion of the transmembrane access system of FIG. 1 indicated by the encircled portion 2.2 of FIG. 1 and showing a distal portion of the guidewire and tissue penetration member secured to a distal end of the torquable shaft to form the elongate tissue penetration device.

[0019] FIG. 2A is an enlarged view of the tissue penetration member secured to the torquable shaft, indicated by the encircled portion 2A-2A in FIG. 2.

[0020] FIG. 3 is an enlarged view in longitudinal section of the tissue penetration member and attachment of the tissue penetration member to the torquable shaft.

[0021] FIG. 3A is a transverse cross sectional view of the joint between the tissue penetration member and torquable shaft indicated by lines 3A-3A in FIG. 3.

[0022] FIG. 3B is an elevational view of the tissue penetration member and torquable shaft of the entire elongate tissue penetration device.

[0023] FIGS. 3C and 3D illustrate transverse cross sectional views of the elongate tissue penetration device taken along lines 3C-3C and 3D-3D of FIG. 3B, respectively.

[0024] FIG. 4 is an enlarged view in longitudinal section of the proximal adapters of the proximal portion of the transmembrane access system of FIG. 1.

[0025] FIG. 5 is an elevational view of the stabilizer sheath of the transmembrane access system of FIG. 1 with the curved distal portion of the sheath lying in a plane which is orthogonal to the page.

[0026] FIG. 6 is an elevational view of the stabilizer sheath of FIG. 5 shown with the curved distal section lying in the plane of the page and with the proximal adapter not shown attached to the luer connector fitting.

[0027] FIG. 7 is an enlarged transverse cross sectional view of the stabilizer sheath taken at the side port along lines 7-7 of FIG. 6.

[0028] FIG. 7A is a transverse cross sectional view of the stabilizer sheath taken along lines 7A-7A of FIG. 7.

[0029] FIG. 8 is an enlarged view in longitudinal section of the side port of the stabilizer sheath indicated by the encircled portion 8-8 in FIG. 6.

[0030] FIG. 8A is a perspective view of the reinforcement member of the side port section of the stabilizer sheath of FIG. 8.

[0031] FIG. 8B illustrates the side port section of an embodiment of the stabilizer sheath having an inflatable abutment.

[0032] FIG. 9 is an enlarged view in longitudinal section of distal portion of the stabilizer sheath immediately distal of the side port indicated by the encircled portion 9-9 in FIG. 6 and illustrating the tapered characteristic of the distal portion of the stabilizer sheath.

[0033] FIG. 10 is an enlarged view in longitudinal section of the distal most portion of the stabilizer sheath indicated by the encircled portion 10-10 in FIG. 6 an illustrating the curled curvature or "pig tail" of the distal most portion of the stabilizer sheath.

[0034] FIG. 11 is an enlarged view in longitudinal section of the proximal end portion of the stabilizer sheath indicated by the encircled portion 11-11 in FIG. 6 and illustrating the inner lumen of the stabilizer sheath and the luer connector secured to the proximal end of the stabilizer sheath.

[0035] FIG. 12 illustrates the guide catheter of FIG. 1 showing the curved distal section of the guide catheter lying in the plane of the page with the guide catheter in a relaxed state.

[0036] FIG. 13 illustrates the guide catheter of FIG. 1 showing the curved distal section of the guide catheter lying in a plane that is orthogonal to the page with the guide catheter in a relaxed state.

[0037] FIG. 12A illustrates a transverse cross sectional view of the guide catheter taken along lines 12A-12A of FIG. 12 and showing the braided layer of the guide catheter.

[0038] FIG. 14 illustrates an embodiment of an obturator sheath configured to be disposed within the inner lumen of the stabilizer sheath and block the side port of the stabilizer sheath to prevent damage to tissue adjacent the stabilizer sheath during insertion thereof.

[0039] FIG. 15 illustrates an enlarged view in longitudinal section of the obturator disposed within the side port of the stabilizer sheath and having a guidewire disposed within the inner lumen of the obturator sheath.

[0040] FIG. 16 is a transverse cross sectional view of the stabilizer sheath, obturator sheath and guidewire taken along lines 16-16 of FIG. 15.

[0041] FIG. 17 is an elevational view in longitudinal section of the distal end of the obturator sheath illustrating the tapered configuration of the distal end of the obturator sheath and showing the guidewire disposed within and extending from the inner lumen of the obturator sheath.

[0042] FIG. 17A illustrates an enlarged view in section of an alternative embodiment of a side port configuration of an embodiment of a stabilizer sheath wherein the guidewire extending through the inner lumen of the stabilizer sheath embodiment is maintained in a concentric arrangement with the longitudinal axis of the stabilizer sheath by a sleeve portion that is also shaped within the side port to act as a deflective surface.
Fig. 18 shows a diagramatic view of the stabilizer sheath of the transmembrane access system of Fig. 1 being advanced into position over a guidewire with the distal end of the stabilizer sheath, which is being maintained in a straightened configuration by the guidewire, disposed within the inferior vena cava and the side port facing the right atrium of the patient. The obturator sheath is shown disposed within the inner lumen of the stabilizer sheath and is blocking the side port. The guidewire is also disposed within the inner lumen of the obturator sheath.

Fig. 19 shows an enlarged elevational view of the side port section of the stabilizer sheath after removal of the obturator sheath with the distal end of the guide catheter and the distal end of the tissue penetration device, disposed within the distal end of the guidewire, being advanced distally through the inner lumen of the stabilizer sheath to the side port.

Fig. 20 shows the transmembrane system with the elongate tissue penetration device disposed within and extending from the guide catheter which is disposed within the inner lumen of the stabilizer sheath. The guide catheter proximal end is extending radially from the side port of the stabilizer sheath and is positioned adjacent a desired area of the septum for access.

Figs. 20A-20C illustrate a tissue penetration sequence by the tissue penetration member through the septum of the patient.

Fig. 21 illustrates the tissue penetration member having been activated by rotation of the torqueable shaft from a proximal portion of the torqueable shaft and having penetrated the septal wall of the patient’s heart with the guidewire having been extended into the left atrium of the patient’s heart.

Fig. 22 is an enlarged view of the heart portion of Fig. 21.

Fig. 23 shows the guidewire in position across the septal wall with the distal end of the guidewire in position in the left atrium after the stabilizer sheath, guide catheter and elongate tissue penetration device have been withdrawn proximally over the guidewire.

Figs. 24A-24C illustrate how the orientation of the distal end of the guide catheter can be controlled by advancing and retracting the guide catheter within the side port of the stabilizer sheath, and axial movement of the stabilizer sheath relative to the right atrium.

Figs. 25 and 26 illustrate a method of transmembrane access across a patient’s septal wall by using an embodiment of a guide catheter and elongate tissue penetration device having a tissue penetration member activated by rotation without the use of a stabilizer sheath.

Fig. 27 is an elevational view of an alternative embodiment of a transmembrane access system that includes a proximal activation modulator.

Fig. 28 is an enlarged view in partial section of the side port portion of the transmembrane access system of Fig. 27 indicated by the encircled portion 28-28 of Fig. 27.

Fig. 29 is an enlarged view of the tissue penetration member secured to the torqueable shaft, indicated by the encircled portion 29-29 in Fig. 27.

Fig. 29A is an enlarged view of an alternative embodiment of a tissue penetration member having two helical tissue penetration members.

Fig. 30 is a perspective view of an embodiment of an activation modulator for applying controlled axial movement to the tissue penetration member and limiting the rotational movement of the tissue penetration member.

Fig. 31 is an exploded view of the activation modulator and proximal section of the torqueable shaft of the transmembrane access system of Fig. 27.

Fig. 32 is an enlarged view of a distal portion of the threaded inner barrel of the activation modulator.

Fig. 33 is an elevational view of the activation modulator of Fig. 30.

Fig. 34 is an elevational view in longitudinal section of the activation modulator of Fig. 33 taken along lines 34-34 of Fig. 33 showing the threaded inner barrel disposed at a proximal limit of axial movement.

Fig. 35 is an enlarged view of the rotation seal disposed about the threaded inner barrel of the activation modulator indicated by the encircled portion 35-35 of Fig. 34.

Fig. 36 is an elevational view in longitudinal section of the activation modulator of Fig. 34 with the threaded inner barrel disposed at a distal limit of axial movement.

Fig. 37 is an elevational view, partially broken away, of an alternative embodiment of a tissue penetration device.

Fig. 38 is an enlarged view in longitudinal section of the tissue penetration device of Fig. 37 indicated by the encircled portion 38-38 in Fig. 37.

Fig. 39 is an enlarged view in longitudinal section of the tissue penetration device of Fig. 37 indicated by the encircled portion 39-39 in Fig. 37.

Fig. 40 is an elevational view, partially broken away, of yet another alternative embodiment of a tissue penetration device.

Fig. 41 illustrates a distal portion of a tubular needle of the tissue penetration device of Fig. 40 which has a series of alternating partial transverse cuts in the tubular member to enhance the flexibility of the distal portion of the tubular needle.

Fig. 42 is an enlarged view in longitudinal section of the tissue penetration device of Fig. 37 indicated by the encircled portion 42-42 in Fig. 40.

Detailed Description

Embodiments are directed to systems and methods for accessing a second side of a tissue membrane from a first side of a tissue membrane. In more specific embodiments, devices and methods for accessing the left atrium of a patient’s heart from the right atrium of a patient’s heart are disclosed. Indications for such access devices and methods can include the placement of cardiac monitoring devices, transponders or leads for measuring intracardiac pressures, temperatures, electrical conduction patterns and voltages...
and the like. The deployment of cardiac pacemaker leads can also be facilitated with such access devices and methods. Such access can also be useful in order to facilitate the placement of mitral valve repair devices and prosthetics.

[0070] FIG. 1 illustrates an embodiment of a transmembrane access system 10. The system 10 shown in FIG. 1 includes a stabilizer sheath 12, a guide catheter 14, an elongate tissue penetration device 16 and a guidewire 18 disposed within an inner lumen of the elongate tissue penetration device 16. The stabilizer sheath 12 has a tubular configuration with an inner lumen 13 extending from a proximal end 20 of the stabilizer sheath 12 to a side port 22 disposed in the sheath 12. In one embodiment, the inner lumen 13 extends to the distal port 70 of the stabilizer sheath 12, and is open to one or more side ports 22 at one or more locations between the proximal and distal ends. The guide catheter 14 has a tubular configuration and is configured with an outer surface profile which allows the guide catheter 14 to be moved axially within the inner lumen of the stabilizer sheath 12. The guide catheter 14 has a shaped distal section 24 with a curved configuration in a relaxed state which can be straightened and advanced through the inner lumen of the stabilizer sheath 12 until it exits the side port 22 of the stabilizer sheath 12 as shown in more detail in FIG. 2.

[0071] The elongate tissue penetration device 16 includes a tubular flexible, torqueable shaft 26 having a proximal end 28, shown in FIG. 1, and a distal end 30. The distal end 30 of the torqueable shaft 26 is secured to a tissue penetration member 32, shown in FIG. 2A, which is configured to penetrate tissue upon activation by rotation of the tissue penetration member 32. The tissue penetration member 32 has a tubular needle 34 with a proximal end 36, a sharpened distal end 38 and an inner lumen 40 that extends longitudinally through the tubular needle 34. A helical tissue penetration member 42 has a proximal end 44 and a sharpened distal end 46 and is disposed about the tubular needle 34. The helical tissue penetration member 42 has an inner diameter which is larger than an outer diameter of the tubular needle 34 so as to leave a gap between the tubular needle 34 and the helical tissue penetration member 42 for the portion of the helical tissue penetration 42 that extends distally from the distal end 30 of the torqueable shaft 26. Referring to FIG. 3, a proximal portion 48 of a coil of the helical tissue penetration member 42 is secured to a distal portion 50 of the inner lumen of the tubular torqueable shaft 26 and a proximal portion 52 of the tubular needle 34 is secured to the proximal portion 48 of the coil of the helical tissue penetration member 42. A conical ramp 54 may be disposed at the proximal end 56 of the tubular needle 34 in order to form a smooth transition from the inner lumen 58 of the tubular torqueable shaft 26 to the inner lumen 40 of the tubular needle 34 which facilitates guidewire movement therethrough. The proximal end 56 of the tubular needle 34 may also have a tapered section 55 formed or machined into the inner surface of the tubular needle 34.

[0072] Referring to FIG. 2, an abutment 60 having a radially deflective surface 62 is disposed within the inner lumen 13 of the stabilizer sheath 12 opposite the side port 22 of the sheath 12. In the embodiment shown, the apex 63 of the abutment 60 is disposed towards the distal end of the side port 22 which disposes the deflective surface 62 in a position which is longitudinally centered in the side port 22. This configuration allows for reliable egress of the distal end 66 of the guide catheter 14 from the side port 22 after lateral deflection of the guide catheter 14 by the deflective surface 62. The deflective surface 62 of the abutment 60 serves to deflect the distal end 66 of the guide catheter 14 from a nominal axial path and out of the side port 22 during advancement of the guide catheter 14 through the inner lumen 13 of the stabilizer sheath 12. The abutment 60 may be a fixed mass of material or may be adjustable in size and configuration. In one embodiment the abutment 60 is inflatable and has an inflation lumen extending proximally through the stabilizer sheath 12 from the inflatable abutment to the proximal end 20 of the stabilizer sheath 12. An optional guidewire exit port 68 may be disposed in the wall of the stabilizer sheath 12 distal of the side port 22 that is in fluid communication with a distal guidewire port 70 of the stabilizer sheath 12. Such a configuration allows the stabilizer sheath 12 to be advanced into position over a guidewire (not shown) with the guide catheter 14 and elongate tissue penetration device 16 disposed in the inner lumen 13 of the stabilizer sheath 12. A standard guidewire may also be disposed in the distal guidewire port 70 of the stabilizer sheath 12 and extend proximally in the inner lumen 13 of the stabilizer sheath 12 to the proximal end 20 of the sheath 12. Guidewire 18 that may be used in conjunction with the tissue penetration device 16 may be an Inoue wire, manufactured by TORAY Company, of JAPAN. This type of guidewire 18, such as the Inoue CMS-1 guidewire, may have a length of about 140 cm to about 260 cm, more specifically, about 160 cm to about 200 cm. The guidewire 18 may have a nominal transverse outer dimension of about 0.6 mm to about 0.8 mm. The distal section 19 of this guidewire 18 embodiment may be configured to be self-coiling which produces an anchoring structure.

[0073] The elongate tissue penetration device 16, as shown in more detail in FIGS. 3-3D, includes the tubular torqueable shaft 26 secured to the tissue penetration member 32 at a distal end of the tubular torqueable shaft 26 and a Luer fitting 57 at the proximal end 28 of the shaft 26. FIGS. 3 and 3A illustrate an enlarged view in section of the junction between the tissue penetration member 32 and the tubular torqueable shaft 26. As shown, the proximal portion 48 of the coil of the helical tissue penetration member 42 is secured to the distal portion 50 of the inner lumen 58 of the tubular torqueable shaft 26 by an adhesive. Adhesives such as epoxy, UV epoxy or polyurethane may be used. Other suitable methods of joining the helical tissue penetration member 42 to the tubular torqueable shaft 26 may include soldering, welding or the like. The proximal portion 52 of the tubular needle 34 is secured to the proximal portion 48 of the helical tissue penetration member 42 in a substantially concentric arrangement also by an adhesive that may be the same as or similar to those discussed above. The conical ramp 54 is disposed at the proximal end 56 of the tubular needle 34 in order to form a smooth transition from the inner lumen 58 of the tubular torqueable shaft 26 to the inner lumen 40 of the tubular needle 34 and may be formed of a polymer or epoxy material. The distal end 46 of the helical tissue penetration member 42 has a sharpened tip 38 in order to facilitate tissue penetration upon rotation and advancement of the tissue penetration member 32.

[0074] The outer transverse dimension or diameter of the helical tissue penetration member 42 may be the same as or similar to an outer transverse dimension or diameter of the
tubular torqueable shaft 26. Alternatively, the outer transverse dimension or diameter of the helical tissue penetration member 42 may also be greater than the nominal outer transverse dimension of the tubular torqueable shaft 26. The outer transverse dimension of an embodiment of the helical tissue penetration member 42 may also taper distally to a larger or smaller transverse dimension.

[0075] The helical tissue penetration member 42 can have an exposed length distally beyond the distal end 30 of the torqueable shaft 26 of about 4 mm to about 15 mm. The inner transverse diameter of the coil structure of the helical tissue penetration member 42 can be from about 0.5 mm to about 2.5 mm. The pitch of the coil structure may be from about 0.3 mm to about 1.5 mm of separation between axially adjacent coil elements of the helical tissue penetration member 42. In addition, helical tissue penetration member embodiments may include coil structures having multiple elongate wire coil elements 72 that can be wound together. The elongate wire element 72 may have an outer transverse dimension or diameter of about 0.02 mm to about 0.4 mm. The helical tissue penetration member can be made of a high strength material such as stainless steel, nickel titanium alloy, MP35N, Elgiloy or the like. The elongate coiled element 72 may also be formed of a composite of two or more materials or alloys. For example, one embodiment of the elongate coiled element 72 is constructed of drawn filled tubing that has about 70 percent to about 80 percent stainless steel on an outer tubular portion and the remainder a tantalum alloy in the inner portion of the element. Such a composition provides high strength for the helical tissue penetration member 42 is compatible for welding or soldering as the outer layer of material may be the same or similar to the material of the braid of the torqueable shaft 26 or the tubular needle 34. Such a drawn filled configuration also provides enhanced radiopacity for imaging during use of the tissue penetration device 16.

[0076] The tubular needle 34 of the tissue penetration member 34 may be made from tubular metallic material, such as stainless steel hypodermic needle material. The outer transverse dimension of an embodiment of the tubular needle 34 may vary from about 0.25 mm to about 1.5 mm and the inner transverse dimension or diameter of the inner lumen 40 of the tubular needle 34 may be from about 0.2 mm to about 1.2 mm. The wall thickness of the tubular needle 34 may be from about 0.05 mm to about 0.3 mm. The tubular needle 34 may be made from other high strength materials such as stainless steel, nickel titanium alloy, MP35N, monel or the like.

[0077] The tubular torqueable shaft 26 has a distal section 74 and a proximal section 76 as shown in FIG. 3B. The proximal section 76 of the shaft 26 has a tubular polymer layer 78 disposed about a high strength tubular member 80. The tubular polymer layer 78 may be made from materials such as Pebax, polyurethane, or the like. The material of the tubular polymer layer 78 may have a hardness of about 25 D shore hardness to about 75 D shore hardness. The high strength tubular member 80 may be made from materials such as stainless steel, nickel titanium alloy, MP35N, monel or the like. The distal section 74 of the tubular torqueable shaft 26 may be constructed from a tubular polymer 82 similar to that of the proximal section 76 which is reinforced by a braid 84 of high strength material that provides torque-

[0078] FIG. 4 is an enlarged view in longitudinal section of the proximal adapters 130, 132 and 134 of the proximal portion of the transmembrane access system 10 shown in FIG. 1. The guidewire 18 is not shown for clarity of illustration. Proximal adapter 134, having inner lumen 135, is secured to the Luer fitting 57 on the proximal end 28 of the tubular torqueable shaft 26 of the elongate tissue penetration device 16. The elongate tissue penetration device 16 passes through an inner lumen 136 of proximal adapter 132 which is secured to a Luer fitting 138 secured to a proximal end 140 of the guide catheter 14. The guide catheter 14 and elongate tissue penetration device 16 are disposed within an inner lumen 142 of proximal adapter 130 which is secured to a Luer fitting 144 secured to the proximal end 20 of the stabilizer sheath 12. The proximal adapters 130, 132 and 134 all have inner lumens 135, 136 and 142 which allow for passage of appropriately sized devices while maintaining a seal between the devices and the inner lumens 135, 136 and 142. Each proximal adapter includes a resilient annular seal 146 that may be compressed by a threaded compression cap 148 so as to constrict the seal and form a seal around an outside surface of a catheter or other device disposed within an inner lumen of the seals 146. Each proximal adapter 130, 132 and 134 is also configured with a side port 150 in fluid communication with the respective inner lumens 135, 136 and 142 of the proximal adapters to allow for aspiration and flushing of the inner lumen, injection of contrast material, measurement of fluid pressure and the like. A proximal adapter embodiment suitable for use with embodiments 130, 132 and 134 of the system 10 can include the Toughy Borst made by Martek Company or commercially available hemostasis valves, including rotating hemostasis valves.

[0079] FIGS. 5-11 illustrate the stabilizer sheath 12 in more detail. The stabilizer sheath 12 has a substantially tubular configuration with a distal section 152 that tapers to a reduced transverse dimension or diameter and includes a pigtail or curled section 154 at the distal end 156 of the sheath 12 to avoid undesirable entry into small vessels and reduce vascular trauma. The side port 22, detailed in FIGS. 7 and 8, includes the abutment 60 having the radially deflective surface 62 disposed within the inner lumen 13 of the stabilizer sheath 12 opposite the side port 22 of the sheath 12. The deflective surface 62 forms an approximate angle 158 with the nominal longitudinal axis 160 of the side port section 162 of the stabilizer sheath 12 and extends radially inward from the nominal surface 164 of the inner lumen 13 of the stabilizer sheath 12. The deflective surface 62 of the abutment 60 serves to deflect the distal end 66 of the guide catheter 14 out of the side port 22 during advancement of the guide catheter 14 through the inner lumen 13 of the stabilizer sheath 12. The optional guidewire exit port 68
may be disposed in the wall of the stabilizer sheath 12 distal of the side port 22 that is in fluid communication with a distal guidewire port 70 of the stabilizer sheath 12.

[0080] The side port 22 is configured to allow egress of the distal section 24 of the guide catheter 14 and elongate tissue penetration device 16. The side port 22 may have an axial or longitudinal length of about 10 mm to about 20 mm. The side port 22 may a width of about 1.5 mm to about 4 mm. The side port section 162 of the stabilizer sheath 12 may also include a reinforcement member 166 that strengthens the side port section 162 of the sheath 12 where material of the sheath 12 has been removed in order to create the side port 22. The reinforcement member 166 as well as the stabilizer sheath 12 optionally includes a peel away tear line 167 shown in FIGS. 7 and 7A that extends from the side port 22 of the stabilizer sheath 12 proximally to the proximal Luer fitting 144. The tear line 167 provides a fluid tight but weakened fault line that allows the stabilizer sheath to be removed from the patient's body without removal of the tissue penetration device 16 disposed within the inner lumen of the stabilizer sheath 12 when the tissue penetration device is positioned within the patient's body. The proximal adapter 130 and proximal Luer fitting 144 may also include a peel away tear line (not shown) in order to facilitate peel away removal of the stabilizer sheath 12.

[0081] The reinforcement member 166 may have a feature integrated within to collapse a portion of the inner lumen of the stabilizer sheath 12 and create the abutment or ramp 60 or alternatively a component, such as a dowel pin section or the like, can be trapped between the inner wall of the reinforcement member 166 and the outer wall of the stabilizer sheath 12 or an adhesive can be placed on the inner wall of the stabilizer sheath 12. The reinforcement member 166 shown in FIGS. 8 and 8A includes a deflected section 167 that replaces the stabilizer sheath wall to create the abutment 60. The reinforcement member 166 may be made from a section of high strength tubular material bonded or secured to the outer surface of the stabilizer sheath 12 that is cut to an outline that matches the side port 22 of the sheath 12. The reinforcement member 166 may have a length of about 15 mm to about 30 mm. The reinforcement member 166 may have a wall thickness of about 0.05 mm to about 0.2 mm. The reinforcement member 166 may be made from any suitable high strength material such as stainless steel, nickel titanium alloy, MP35N, Eligloy, composites such as carbon fiber composites, or the like.

[0082] The abutment 60 may be a fixed mass of material or may be adjustable in size and configuration. In one embodiment, the abutment 60 is inflatable and has an inflation lumen extending proximally through the stabilizer sheath 12 from the inflatable abutment 60 to the proximal end 20 of the stabilizer sheath 12. FIG. 8A illustrates the side port section 162 of an embodiment of the stabilizer sheath 12 having an inflatable abutment 60A that may be inflated for varying sizes by injection of an inflation fluid, gas or the like through an inflation lumen 61. The inflatable abutment 60A may be made from a compliant or non-compliant material. For inflatable abutment embodiments made from compliant materials, such as elastomers, the size of the abutment 60A may be adjusted by the amount of expansion or distortion of the abutment 60A which could be controlled by the pressure level of the inflation substance. The side port section 162A includes a reinforcement member 166A that does not include a deflected section 167 as shown on the reinforcement member 166 discussed above.

[0083] FIG. 9 illustrates the tapered characteristic a distal section 168 of the stabilizer sheath 12 immediately distal of the side port 22. The outer transverse dimension or diameter of the stabilizer sheath 12 may taper continuously from the side port 22 to the distal end 156 of the sheath 12. The inclusive taper angle of the sheath 12 over this distal section may be from about 0.1 degrees to about 5.0 degrees. The nominal outer transverse dimension or diameter of the stabilizer sheath 12 may be from about 2.5 mm to about 6.0 mm, specifically, from about 3 mm to about 4 mm. The inner transverse dimension or diameter of the inner lumen 13 of the stabilizer sheath between the side port 22 and the Luer fitting 144, which is sized to accept the outer dimension of the guide catheter 14, may be from about 2.0 mm to about 5.0 mm. The Luer fitting 144 is secured to the proximal end 20 of the sheath by any suitable bonding method such as adhesive bonding, welding or the like. The Luer fitting 144 and joint between the Luer fitting 144 and proximal end 20 of the sheath 12 is shown in FIG. 11.

[0084] The distal end 156 of the stabilizer sheath 12 can include the curled section 154 having curvature or a “pig tail” arrangement which produces an atrumatic distal end 156 of the stabilizer sheath 12 while positioned within a patient’s anatomy. The curled section 154 may have a radius of curvature of about 3 mm to about 12 mm and may have an angle of curvature 170 between a discharge axis 172 of the distal end 156 of the stabilizer sheath 12 and the nominal longitudinal axis 174 of the stabilizer sheath 12 of about 200 degrees to about 350 degrees. The inner transverse dimension of the inner lumen 13 of the sheath 12 at the distal end 156 of the sheath 12 may be from about 0.5 mm to about 1.6 mm. The overall length of the stabilizer sheath 12 may be from about 40 cm to about 100 cm. The distance from the side port 22 to the distal end 156 of the sheath 12 may be from about 30 cm to about 65 cm. The stabilizer sheath 12 may be made from any suitable flexible material which is biocompatible, such as PEBAX, polyurethane, polyethylene, and the like.

[0085] FIGS. 12-13 illustrate the embodiment of the guide catheter 14 of FIG. 1 showing the curved distal section 24 of the guide catheter 14 while the guide catheter 14 is in a relaxed state. The guide catheter 14 has a Luer fitting 138 secured to the proximal end 140 of the guide catheter 14. The curved distal section 24 may have an inner radius of curvature 181 of about 1 cm to about 4 cm. The discharge axis 180 of the guide catheter 14 may form an angle 182 with the nominal longitudinal axis 184 of the guide catheter 14 of about 90 degrees to about 270 degrees. Although many commercially available guide catheters 14 have a soft pliable distal tip for atrumatic advancement into a patient’s vasculature, this may not be desirable in some instances for use with embodiments of the access systems discussed herein. More specifically, for some procedures, it may be necessary for the distal end of the guide catheter to have sufficient structural rigidity to maintain the round transverse cross section at the distal tip of the guide catheter so that the wall of the guide catheter at the distal tip does not collapse when pressed against target tissue. Such wall collapse or deformation could cause the tissue penetration device 16 to impinge on the wall of the guide catheter which may impede progress or the procedure generally. It may be desirable for
the guide catheter to have a distal tip or distal section that has a wall structure with a nominal flexibility or shore hardness that is substantially similar to or the same as the nominal flexibility or shore hardness of the shaft proximal to the distal tip or section.

[0086] The guide catheter 14 may be made from a standard guide catheter construction that includes a plurality of polymer layers 186 and 188 reinforced by a braid 190. The nominal outer transverse dimension or diameter of the guide catheter 14 may be from about 0.04 inches to about 0.10 inches. The overall length of the guide catheter 14 should be sufficiently longer than the overall length of the stabilizer sheath 12 from its proximal end to the side port 22 including the length of its proximal adapter 130 and may be from about 40 cm to about 80 cm. The inner transverse dimension of the inner lumen 192 of the guide catheter 14 may be from about 0.03 inches to about 0.09 inches. I may desire to select the flexibility of embodiments of the guide catheter 14, and particularly the curved distal section 24 of the guide catheter 14, and the flexibility of the tissue penetration member 32 such that the tissue penetration member 32 does not substantially straighten the curved distal section 24 of the guide catheter 14 when the tissue penetration device 16 is being advanced through the guide catheter 14. Otherwise, the maneuverability of the stabilizer sheath 12 and guide catheter 14 combination could be compromised for some procedures.

[0087] Suitable commercially available guide catheters 14 with distal curves such as a “hockey stick”, Amplatz type, XB type, RC type, as well as others, may be useful for procedures involving transseptal access from the right atrium of a patient’s heart and the left atrium of the patient’s heart. Guide catheters 14 have a “torqueable” shaft that permits rotation of the shaft. Once the distal tip of the guide catheter has exited the stabilizer sheath side port and extended more or less radially away from the stabilizer sheath, rotation of the guide catheter shaft causes its distal end to swing in an arc around the axis of the stabilizer sheath, providing for lateral adjustment of the guide catheter distal tip for precise positioning with respect to the septum. The variety of distal curve shapes described above and illustrated in FIGS. 12 and 13 are curves lying in a single plane. More complex distal curve shapes involving three dimensional space may also be useful. One such example commonly used in coronary angioplasty is the XB-LAD shape where the most distal portion of the curve is bent in another plane.

[0088] FIG. 14 illustrates an embodiment of an obturator sheath 196 configured to be disposed within the inner lumen 13 of the stabilizer sheath 12 and block the side port 22 of the stabilizer sheath 12 to prevent damage to tissue adjacent the stabilizer sheath 12 and stop blood flow into the stabilizer sheath 12 during insertion of the stabilizer sheath 12 in a patient’s anatomy. The obturator sheath 196 has a substantially tubular configuration with proximal end 198, a distal end 200 and an inner lumen 202 extending through the obturator sheath 196 that is configured to accept the guidewire 18. The outer transverse dimension or cross sectional area of the obturator sheath 196 is configured to fill the gap between the side port 22 and the inner surface 164 of the inner lumen 13 of the stabilizer sheath 12 opposite the side port 22. Filling of the side port 22 by the obturator sheath 196 is illustrated in FIGS. 15 and 16 where the obturator sheath 196 is shown within the inner lumen 13 of the stabilizer sheath 12 passing over the abutment 60 of the side port 22 which forces a portion of it out of the side port 22 and extending distally within the inner lumen 13 of the stabilizer sheath 12 towards the distal end 156 of the stabilizer sheath 12. Guidewire 203 is shown disposed within the inner lumen 202 of the obturator sheath 196. FIG. 17 shows the distal end 200 of the obturator sheath 196 having a tapered configuration and showing the guidewire 203 disposed within and extending from the inner lumen 202 of the obturator sheath 196. Guidewire 203 may be a standard floppy tip guidewire used for interventional procedures. One embodiment of guidewire 203 is a floppy tip guidewire having a nominal outer diameter of about 0.036 inches to about 0.04 inches and a length of about 150 cm to about 200 cm. In another embodiment, guidewire 203 may be an exchange length guidewire having a length of about 250 cm to about 350 cm.

[0089] FIG. 17A illustrates an enlarged view in section of an alternative embodiment of a side port configuration of an embodiment of a stabilizer sheath 204. The guidewire 203 extending through the inner lumen 206 of the stabilizer sheath embodiment is maintained in a concentric arrangement with the longitudinal axis of the stabilizer sheath 204 by a sleeve portion 208 that is also shaped within the side port 210 to act as a deflective surface 212.

[0090] Referring to FIG. 18, embodiments of the transmembrane access system 10 may be used for a transseptal access procedure from the right atrium 220 of a patient’s heart to the left atrium 222. In one embodiment, this procedure begins by placing a guidewire 203 into the patient’s superior vena cava 224 through a needle inserted at a vascular access point such as a subclavian vein near the shoulder or a jugular vein on the neck, similar to a standard technique for placing pacemaker leads which is well known to skilled artisans. Thereafter, the distal port 70 of the stabilizer sheath 12 is then fed over the proximal end of the guidewire 203 which extends from the patient’s body. The guidewire 203 is then advanced proximally through the inner lumen of the stabilizer sheath 12 until the proximal end of the guidewire 203 extends from the proximal end of the stabilizer sheath 12 or exits the optional guidewire port 68. The distal end of the obturator sheath 196 is then tracked over the proximal end of the guidewire 203 into the stabilizer sheath 12 until the obturator sheath 196 seats and comes to a stop. The distal end of pigtail portion 154 of the stabilizer sheath 12, which is maintained in a substantially straightened configuration by the stiffness of the guidewire 203, is tapered and thinned, as shown in FIG. 10, so that it is serves as a dilator during insertion through the skin and into the vein. The stabilizer sheath 12 and obturator sheath 196 are then advanced distally together over the guidewire 18 into the superior vena cava of the patient. The stabilizer sheath 12 is advanced distally until the distal end 156 of the stabilizer sheath 12 is disposed within the inferior vena cava 226 and the side port 22 is within the right atrium 220 of the patient. Thereafter, the guidewire 203 and obturator sheath 196 are withdrawn from the inner lumen 13 of the stabilizer sheath 12, allowing the distal portion 154 of the stabilizer sheath 12 to assume its relaxed pigtail configuration, and allowing the guide catheter 14 and elongate tissue penetration device 16 to be advanced through the proximal adapter 130 of the stabilizer sheath 12 and through the inner lumen 13 of the stabilizer sheath 12 towards the side port 22.
[0091] This procedure may also be initiated from an access point from the patient's inferior vena cava 226 beginning by placing a guidewire into the patient's inferior vena cava through a needle inserted at a vascular access point such as a femoral vein near the groin, well known to skilled artisans. In the same manner described above for the superior vena cava approach, the proximal end of the guidewire 203 is backloaded into the stabilizer sheath 12, the obturator sheath 196 is advanced over the guide wire 203 into the stabilizer sheath until its distal end seats at the side port. The stabilizer sheath 12 and obturator sheath 196 are then inserted together over the guidewire 18 through the skin and into the vein, and then advanced distally together over the guidewire 18 through the inferior vena cava 226 of the patient until the distal end 156 of the stabilizer sheath 12 is disposed within the superior vena cava 224 and the side port 22 is disposed within the right atrium 220 of the patient.

[0092] FIG. 18 illustrates the stabilizer sheath 12 positioned through a chamber in the form of the right atrium 220 with the side port 22 of the stabilizer sheath 12 positioned in the chamber 220. The side port section 162 of the stabilizer sheath 12 spans the chamber 220 between a first orifice which is the opening of the superior vena cava 224 into the right atrium 220 and a second orifice which is the opening of the inferior vena cava 226 into the right atrium 220. The superior vena cava 224 and inferior vena cava 226 form two tubular structures extending from opposite sides of the chamber 220 which provide lateral support to the side port section 162 of the stabilizer sheath 12. The lateral support of the tubular structures 224 and 226 and respective orifices adjacent the side port section 162 of the stabilizer sheath 12 provides a stable platform from which the guide catheter 14 may be extended for performing procedures within the chamber 220. The lateral stability of the side port section provides back up support for the guide catheter 14 to be pushed or extended distally from the side port 22 and exert distal force against structures within the chamber 220 while maintaining positional control over the distal end of the guide catheter 14. This configuration provides the necessary stability and support for performing procedures within the chamber and beyond regardless of the size and shape of the chamber 220 which can vary greatly due to dilation or distortion caused by disease or other factors. This configuration contemplates lateral stabilization of the side port section 162 as a result of confinement of the stabilizer sheath portions adjacent the side port section 162 in respective tubular structures. However, a similar result could be achieved with a stabilizer sheath embodiment similar to stabilizer sheath 12 having a short distal section or no distal section extending distally from the side port section 22. For such an embodiment, stabilization of the side port section could be achieved by lateral or transverse confinement of a section of the stabilizer sheath proximal of the side port section in a tubular structure and lateral confinement of a guidewire extending distally from the inner lumen of the stabilizer sheath in a similar tubular structure.

[0093] Although the embodiment of the method illustrated in FIG. 18 is directed to a transseptal cardiac procedure, the stabilizer sheath 12 and guide catheter 14 arrangement could also be used for a variety of other indications depending on the shape of the guide or access catheter 14 used in conjunction with the stabilizer sheath 12. If the optional peel away tear line 167 is incorporated into the stabilizer sheath 12 and reinforcement member 166, applicable procedures could include deployment of pacing leads, e.g., into the coronary sinus for cardiac resynchronization therapy or biventricular pacing, placement of a prosthesis for mitral valve repair annulus repair as well as others. It will also be clear to the skilled artisan that the usefulness of the present invention is not limited to the venous circulation: many other anatomical areas, that may be accessed by catheter are advantageously accessed by making use of the added support and control provided by the side port stabilizer sheath and shaped guide catheter of this invention. A few additional examples include, but are not limited to: the coronary arteries via a stabilizer sheath with its side port very near its distal end as described above, or with a distal section designed with a “pig-tail” designed to pass through the aortic valve and into the left ventricle; retrograde access to the mitral valve and left atrium via the left ventricle using a stabilizer sheath with a short pigtail distal segment as described for the coronary arteries, but with its side port located more distally so that it may be placed in the mid left ventricle; and other areas, such as the renal arteries, where acute angles limit the control provided by conventional catheters.

[0094] Once in place, the stabilizer sheath 12 can be rotated within the chamber 220 to direct the side port 22 to any lateral direction within the chamber 220. The rotational freedom of the stabilizer sheath 12 within the chamber 220 can be combined with axial translation of the stabilizer sheath 12, in either a distal direction or proximal direction, to allow the stabilizer sheath 12 to be directed to most any portion of the chamber 220. When these features of the stabilizer sheath 12 are combined with a guide catheter 14 having a curved distal section extending from the side port 22, a subselective catheter configuration results whereby rotation, axial translation or both can be applied to the stabilizer sheath 12 and guide catheter 14 in order to access any portion of the interior of the chamber 220 from a variety of approach angles. The selectivity of the configuration is also discussed below with regard to FIGS. 24A-24C.

[0095] During insertion of the guide catheter 14 and elongate tissue penetration device 16, the tissue penetration member 32 of the elongate tissue penetration device 16 is disposed within the inner lumen of the distal portion 24 of the guide catheter 14 to prevent contact of the tissue penetration member 32 with the inner lumen 13 of the stabilizer sheath 12 during advancement. FIG. 19 shows an enlarged elevational view of the side port section 162 of the stabilizer sheath 12 with the distal end 66 of the guide catheter 14 and the distal end 38 of the tissue penetration device 32, disposed within the distal end 66 of the guide catheter, being advanced distally through the inner lumen 13 of the stabilizer sheath 12. As the guide catheter 14 and elongate tissue penetration device 16 continue to be advanced distally, the distal end 66 of the guide catheter 14 impinges on the deflective surface 62 of the abutment 60 opposite the side port 22. The distal section 24 of the guide catheter 14 then emerges from the side port 22 and begins to assume the pre-shaped configuration of the guide catheter 14. The pre-shaped configuration of the distal section 24 curves the distal end 66 of the guide catheter 14 away from the longitudinal axis 160 of the side port section 162 of the stabilizer sheath 12 and extends the distal end 66 of the guide catheter 14 radially from the side port 22 and against the septal wall 230 as shown in FIG. 20.
The distal end of the guide catheter 66 is advanced until it is positioned adjacent a desired area of the patient’s septum 230 for transeptal access. In this arrangement, the orientation and angle of penetration or approach of the distal end 66 of the guide catheter 14 and elongate tissue penetration device 16 can be manipulated by axially advancing and retracting the stabilizer sheath 12 in combination with advancing and retracting the guide catheter 14 from the side port 22 of the stabilizer sheath 12. This procedure allows for access to a substantial portion of the patient’s right atrial surface and allows for transmembrane procedures in areas other than the septum 230, and more specifically, the fossa ovalis of the septum 230. FIGS. 20A-20C illustrate a tissue penetration sequence by the tissue penetration member 32 through the septum of the patient. FIG. 20A shows an enlarged view of the distal end 66 of the guide catheter 14 disposed adjacent target tissue of the septal wall 230 with the tissue penetration member 32 withdrawn into the distal portion 24 of the guide catheter 14. FIG. 20B shows the tissue penetration member 32 during activation with the rotation of the tissue penetration member 32 causing the sharpened tip 38 of the tubular needle 34 to cut into and penetrate the septal wall 230 and allow advancement of the tubular needle 34. The sharpened distal end 46 of the helical tissue penetration member 42 penetrates tissue helically due to the rotational motive force of the tissue penetration member 32. The helical tissue penetration member 42 may also help pull the tubular needle 34 into the target tissue 230 as it advances. FIG. 20C shows the distal tip 38 of the tubular needle 34 having penetrated the septal wall 230 and in communication with the left atrium 222.

Once the distal end 66 of the guide catheter 14 is disposed adjacent a desired area of target tissue, the tissue penetration member 32 of the elongate tissue penetration device 16 is advanced distally until contact is made between the sharpened tip 38 of the tubular needle 34 and the target tissue. The tissue penetration member 32 is then activated by rotation, axial movement or both, of the torqueable shaft 26 of the elongate tissue penetration device 16. As the tissue penetration member 32 is rotated, the sharpened tip 38 of the tubular needle 34 begins to cut into the target tissue 230 and the sharpened distal end 46 of the helical tissue penetration member 42 begins to penetrate into target tissue in a helical motion. As the sharpened tip 38 of the tubular needle 34 penetrates the target tissue, the tubular needle 34 provides lateral stabilization to the tissue penetration member 32 and particularly the helical tissue penetration member 42 during penetration. The rotation continues until the distal tip 38 of the tubular needle 34 perforates the septal membrane 230 and gains access to the left atrium 222 as shown in FIG. 21 and in an enlarged view in FIG. 22. Confirmation of access to the left atrium 222 can be achieved visually by injection of contrast media under fluoroscopy through the inner lumen 58 of the elongate tissue penetration device 16 from the side port 150 of the proximal adapter 134 of the elongate tissue penetration device 16. Confirmation can also be carried out by monitoring the internal pressure within the inner lumen of the elongate tissue penetration device 16 at the side port 150 of the proximal adapter 134 of the elongate tissue penetration device 16 during the rotation of the tissue penetration member 32.

Once the tubular needle 34 has perforated the septal wall 230 and gained access to the left atrium 222, the guidewire 18 can then be advanced through the inner lumen 58 of the elongate tissue penetration device 16 and into the left atrium 222 opposite the membrane of the septum 230 of the right atrium 220. An embodiment of a guidewire 18 that may be useful for this type of transeptal procedure may be an Inoue wire, manufactured by TORAY Company, of JAPAN. This type of guidewire 18 may have a length of about 140 cm to about 180 cm, and a nominal transverse outer dimension of about 0.6 mm to about 0.8 mm. The distal section 19 of the guidewire 18 embodiment may be configured to be self-coiling which produces an anchoring structure in the left atrium 222 after emerging from the distal port 40 of the tubular needle 34. The anchoring structure helps prevent inadvertent withdrawal of the guidewire 18 during removal of the guide catheter 14 and elongate tissue penetration device 16 once access across the tissue membrane 230 has been achieved. The guidewire 18 is shown in position across the septal wall 230 in FIGS. 22 and 23 with the distal end 232 of the guidewire 18 in position in the left atrium 222 after the stabilizer sheath 12, guide catheter 14 and elongate tissue penetration device 16 have been withdrawn proximally over the guidewire 18.

FIGS. 24A-24C illustrate how the orientation of the distal section 24 of the guide catheter 14 can be controlled by advancing and retracting the guide catheter 14 within the side port of the stabilizer sheath 12, and axial movement of the stabilizer sheath 12 relative to the right atrium 220. This arrangement and orientation technique can also be adapted to accessing other portions of the patient’s anatomy. The tip angle and radius of curvature of the guide catheter 14 can be also be manipulated by pushing it against the surrounding anatomy.

FIGS. 25 and 26 illustrate a method of transmembrane access across a patient’s septal wall 230 by using an embodiment of a guide catheter 14 and elongate tissue penetration device 16 having a tissue penetration member 32 activated by rotation without the use of a stabilizer sheath 12. In this embodiment of use, the guide catheter 14 is advanced distally through the superior vena cava 224 of a patient and into the right atrium 220 over a guidewire 18. The guide catheter 14 is maneuvered until the distal end 66 of the guide catheter 14 is oriented towards a target area of the septum 230. The elongate tissue penetration device is then advanced distally from the distal end of the guide catheter until the sharpened distal tip 38 of the tissue penetration member 32 is in contact with the target tissue. The tissue penetration member 32 is then activated with rotational movement which causes the sharpened distal tip 38 of the tubular needle 34 and sharpened tip 46 of the helical tissue penetration member 42 of the tissue penetration member 32 to advance into the target tissue. Once the distal end 38 of the tubular needle 34 has penetrated the septum 230, as confirmed by either of the methods discussed above, the guidewire 18 is advanced distally through the inner lumen of the elongate tissue penetration device 16 and out of the distal end 40 of the tubular needle 34 and into the left atrial space 222. Thereafter, the elongate tissue penetration device 16 may be withdrawn proximally leaving the guidewire 18 in place across the septum 230 as shown in FIG. 26.

FIG. 27 is an elevational view of an alternative embodiment of a transmembrane access system 310 that includes a proximal activation modulator 312 secured to a proximal end 314 of the guide catheter 14. Embodiments of
the proximal activation modulator 312 may be configured to apply axial force while simultaneously advancing the device at an appropriate rate on the torqueable shaft, limit the number of rotations of the proximal end of the torqueable shaft 26 which controls the axial penetration of the tissue penetration member 32, or both of these functions as well as others. The system 310 shown in FIG. 27 includes a stabilizer sheath 12, a guide catheter 14, an elongate tissue penetration device 16 and a guidewire 18 disposed within an inner lumen of the elongate tissue penetration device 16. The stabilizer sheath 12 has a tubular configuration with an inner lumen 13 extending from a proximal end 20 of the stabilizer sheath 12 to a side port 22 disposed in the sheath 12. In one embodiment, the inner lumen 13 extends to the distal port 70 of the stabilizer sheath 12, and is open to one or more side ports 22 at one or more locations between the proximal end and distal end of the stabilizer sheath 12. The guide catheter 14 has a tubular configuration and is configured with an outer surface profile which allows the guide catheter 14 to be moved axially within the inner lumen of the stabilizer sheath 12. The guide catheter 14 has a shaped distal section 24 with a curved configuration in a relaxed state which can be straightened and advanced through the inner lumen of the stabilizer sheath 12 until it exits the side port 22 of the stabilizer sheath 12 as shown in more detail in FIG. 28.

[0102] The elongate tissue penetration device 16 includes a tubular flexible, torqueable shaft 26 having a proximal end 28, shown in FIG. 27, and a distal end 30. The distal end 30 of the torqueable shaft 26 is secured to a tissue penetration member 32, shown in more detail in FIG. 29, which is configured to penetrate tissue upon activation by rotation of the tissue penetration member 32. The tissue penetration member 32 has a tubular needle 34 with a proximal end 36, a sharpened distal end 38 and an inner lumen 40 that extends longitudinally through the tubular needle 34. A helical tissue penetration member 42 has a proximal end 44 and a sharpened distal end 46 and is disposed about the tubular needle 34. The helical tissue penetration member 42 has an inner diameter which is larger than an outer diameter of the tubular needle 34 so as to leave a gap between the tubular needle 34 and the helical tissue penetration member 42 for the portion of the helical tissue penetration 42 that extends distally from the distal end 30 of the torqueable shaft 26.

[0103] Referring to FIG. 28, an abutment 316 having a radially deflective surface 62 is disposed within the inner lumen 13 of the stabilizer sheath 12 opposite the side port 22 of the sheath 12. In the embodiment shown, the apex 63 of the abutment 316 is disposed towards the distal end of the side port 22 which disposes the deflective surface 62 in a position which is longitudinally centered, or substantially longitudinally centered, in the side port 22. This configuration allows for reliable egress of the distal end 66 of the guide catheter 14 from the side port 22 after lateral deflection of the guide catheter 14 by the deflective surface 62. The deflective surface 62 of the abutment 316 serves to deflect the distal end 66 of the guide catheter 14 from a nominal axial path and out of the side port 22 during advancement of the guide catheter 14 through the inner lumen 13 of the stabilizer sheath 12. The abutment 316 is formed from a section of solid dowel pin 318 disposed between an inner surface of the tubular reinforcement member 166 and an outer surface of the stabilizer sheath 12. The solid dowel pin 318 is secured in place by epoxy potting material 320, but may be secured in place by a variety of other methods including mechanical capture or solvent bonding.

[0104] FIG. 29A is an enlarged view of an alternative embodiment of a tissue penetration member 322 having two helical tissue penetration members. The tissue penetration member has a tubular needle 34 secured to a distal end 30 of the torqueable shaft 26. A first helical tissue penetration member 324 has a proximal end 326 secured to the tubular needle 34 and distal end 30 of the torqueable shaft 26. A second helical tissue penetration member 328 has a proximal end 330 secured to the tubular needle 34 and distal end 30 of the torqueable shaft 26. The first helical tissue penetration member 324 has a sharpened distal tip 332 configured to penetrate tissue upon rotation of the tissue penetration member 322. The second helical tissue penetration member 328 has a sharpened distal tip 334 configured to penetrate tissue upon rotation of the tissue penetration member 322. The first and second helical tissue penetration members 324 and 328 provide opposing forces which cancel each other to a certain extent and minimize the lateral deflection of the tissue penetration member 322 during rotation and tissue penetration member 322. Sharpened distal tips 332 and 334 of the helical tissue penetration members 324 and 328 are disposed opposite the tubular needle 34 180 degrees apart and oriented such that the sharpened tips 332 and 334 are disposed about 90 degrees from the distal extremity of the sharpened tip 38 of the tubular needle 34.

[0105] FIGS. 30-36 illustrate the activation modulator 312 for applying controlled axial movement and rotation to the tissue penetration member 32 and limiting the rotational movement of the tissue penetration member 32. The activation modulator 312 has a fixed member in the form of an outer barrel 334 which has a threaded portion 336 shown if FIG. 34. A rotating member in the form of an inner barrel 338 has a threaded portion 340 that is engaged with the threaded portion 336 of the outer barrel 334. The inner barrel 338 has a distal surface 342 and annular flange 344 which are axially captured within a cavity 346 of the outer barrel 334 shown in FIG. 34. FIG. 34 shows the threaded inner barrel 338 disposed at a proximal limit of axial movement wherein a proximal surface of the annular flange 344 is engaged with a distal surface of an annular flange 340 of the outer barrel 334. FIG. 36 shows the threaded inner barrel 338 disposed at a distal limit of axial movement with the distal surface 342 engaged with a distal cavity surface 350 of the outer barrel 334. The distance from distal surface 342 to distal cavity surface 350 controls or limits the depth of penetration of the tissue penetration member 32.

[0106] FIG. 35 is an enlarged view of the rotation seal 352 of the inner barrel 338 disposed within an annular groove 354 of the threaded inner barrel. The rotation seal 352 may be an annular seal such as an o-ring type seal that is secured within the annular groove 354 and is sized to seal against an inner surface 356 of the proximal portion of the cavity 346 of the outer barrel 334. The rotation seal 352 provides a fluid seal between the outer surface of the inner barrel 338 and the cavity 346 while allowing relative rotational movement between the inner barrel 338 and outer barrel 334.

[0107] The outer barrel 334 has a substantially tubular configuration with a Luer type fitting 358 at the distal end 360 of the outer barrel 334. The Luer fitting 358 can be used to secure the activation modulator 312 in a fluid tight
arrangement to a standard guide catheter 14 having a mating Luer connector arrangement on a distal end thereof. The outer barrel 334 also has a side port 360 which is in fluid communication with an inner lumen 362 disposed within the distal end of the outer barrel 334. The side port 360 can be used to access the space between the outer surface of the torqueable shaft 26 and inner surface of the guide catheter lumen for injection of contrast media and the like. The outer barrel 334 has a series of longitudinal slots 364 that allow the annular flange 348 portion of the outer barrel 334 to expand radially for assembly of the inner barrel 338 into the cavity 346 of the outer barrel 334.

[0108] The inner barrel 338 has a knurled ring 366 that may be useful for gripping by a user in order to manually apply torque to the inner barrel 338 relative to the outer barrel 334. A threaded portion 370 is configured to engage a threaded portion 372 of the inner barrel 338, as shown in FIG. 34. The compression cap 368 has an inner lumen to accept the torqueable shaft 26 of the tissue penetration device. A sealing gland 374 having a substantially tubular configuration and an inner lumen configured to accept the torqueable shaft 26 is disposed within a proximal cavity 376 of the inner barrel 338 and can be compressed by the compression cap 368 within the proximal cavity 376 such that the sealing gland 374 forms a seal between an inner surface of the proximal cavity 376 and an outer surface of the torqueable shaft 26. The compressed sealing gland 374 also provides mechanical coupling between the inner barrel 338 and the torqueable shaft 26 so as to prevent relative axial movement between the torqueable shaft 26 and the inner barrel 338. The sealing gland may be made from any suitable elastomeric material that is sufficiently deformable to provide a seal between the proximal cavity 376 and the torqueable shaft 26. A distal inner lumen 380 of the inner barrel 338 is keyed with a hexagonal shape for the transverse cross section of the inner lumen 380 which mates with a hexagonal member 382 secured to the outer surface of a proximal portion of the torqueable shaft 26 so as to allow relative axial movement between the hexagonal member 382 and the inner lumen 380 but preventing relative rotational movement. This arrangement prevents rotational and axial slippage between the inner barrel 338 and the torqueable shaft 26 during rotational activation of the activation modulator 312.

[0109] Axial movement or force on the tissue penetration member is generated by the activation modulator 312 upon relative rotation of the inner barrel 338 relative to the outer barrel 334. The axial movement and force is then transferred to the tissue penetration member 32 by the torqueable shaft 26. The pitch of the threaded portions may be matched to the pitch of the helical tissue penetration member 42 so that the tissue penetration member 32 is forced distally at a rate or velocity consistent with the rotational velocity and pitch of the helical tissue penetration member 42.

[0110] For use of the transmembrane access system 310, the distal end of the guide catheter 14 is positioned adjacent a desired target tissue site in a manner similar to or the same as discussed above with regard to the transmembrane access system 10. The tissue penetration member 32 of the tissue penetration device is then advanced until the distal tip 38 of the tissue penetration member 32 is disposed adjacent target tissue. The torqueable shaft 26 is then secured to the inner barrel 338 of the activation modulator 312 by the sealing gland 374 with the inner barrel disposed at a proximal position within the cavity 346 of the outer barrel 334. The user then grasps the knurled ring 366 and rotates the ring 366 relative to the outer barrel 334 which both rotates and advances both the inner barrel 338 relative to the outer barrel 334. This activation also rotates and distally advances the torqueable shaft 26 and tissue penetration member 32 relative to the guide catheter 14. The rotational activation of the activation modulator can be continued until the distal surface 342 of the inner barrel 338 comes into contact with the surface 350 of the outer barrel 334. The axial length of the cavity 346 can be selected to provide the desired number of maximum rotations and axial advancement of the torqueable shaft 26 and tissue penetration member 32. In one embodiment, the maximum number of rotations of the inner barrel 338 relative to the outer barrel 334 can be from about 4 rotations to about 10 rotations.

[0111] The tissue penetration device 16 discussed above may have a variety of configurations and constructions. FIGS. 37-39 illustrate an alternative embodiment of a tissue penetration device 410. The tissue penetration device 410 has a construction and configuration that is similar in some ways to the tissue penetration device 16 discussed above. The tissue penetration device 410 has a tissue penetration member 412 secured to a distal end of a torqueable shaft 414. A keyed hexagonal member 382 is secured to a proximal portion of the torqueable shaft 414 for coupling with the activation modulator 312 discussed above. The distal portion 416 of the tissue penetration device 410 has a flexible construction that includes a helical coil member 418 disposed within a braided tubular member 420, both of which are covered by a polymer sheath 422 that provides a fluid tight lumen to contain fluids passing therethrough. The proximal portion of the torqueable shaft 414 is made from a tubular member 424 of high strength material, such as a hypodermic tubing of stainless steel. The distal end 426 of the tubular member is secured to the proximal ends of the helical coil member 416 and braided tubular member 420 by any suitable method such as soldering, brazing, welding, adhesive bonding or the like.

[0112] A tubular needle 34 forms the center of the tissue penetration member 412 along with the distal portion 428 of the helical coil member 418 which is configured as a helical tissue penetration member disposed about the tubular needle 34. The proximal end 430 of the tubular needle 34 is secured to the helical coil member 418 and braided tubular member 420 by any suitable method such as soldering, brazing, welding, adhesive bonding or the like. The polymer sheath 422 may be bonded to the outer surface of the braided tubular member 420 or mechanically secured to the braided tubular member by methods such as heat shrinking the polymer sheath material over the braided tubular member 420. The flexible distal section 416 can have any suitable length. In one embodiment, the flexible distal section has a length of about 15 cm to about 40 cm. The configuration, dimensions and materials of the tissue penetration member 412 can be the same as or similar to the configuration, dimensions and materials of the tissue penetration members 32 and 322 discussed above.

[0113] FIGS. 40-42 illustrate yet another alternative embodiment of a tissue penetration device 430 having a construction similar to that of the tissue penetration device 410 except that the tubular member 432 of the torqueable
shaft 434 extends continuously from the proximal end 436 of the device 430 to the distal end 438 and the helical coil member 418 of the tissue penetration device 410 has been replaced with a flexible section 438 of the tubular member 432. The flexible section 438 is made by producing a series of adjacent alternating partial transverse cuts into the tubular member 432 so as to allow improved longitudinal flexibility of the tubular member 432 in the flexible section 438 while maintaining the radial strength of the tubular member 432. The flexible section 438 is covered by a braided tubular member 440 and a polymer sheath 442. The braided tubular member 440 may be secured at its proximal end and distal end 444 by soldering, brazing, welding, adhesive bonding or the like. The polymer sheath 442 may be secured by adhesive bonding, thermal shrinking or the like. The tissue penetration member 446 includes a helical tissue penetration member 448 secured at its proximal end to the tubular member 432 which terminates distally with a sharpened tip 448 in a configuration similar to the tissue penetration members discussed above. The configuration, dimensions and materials of the tissue penetration member 446 can be the same as or similar to the configuration, dimensions and materials of the tissue penetration members 32 and 322 discussed above.

[0114] With regard to the above detailed description, like reference numerals used therein refer to like elements that may have the same or similar dimensions, materials and configurations. While particular forms of embodiments have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited by the foregoing detailed description.

We claim:

1. A transmembrane access system, comprising:
   a stabilizer sheath having a tubular configuration with an inner lumen extending therein and having a side port disposed on a distal section of the sheath and in communication with the inner lumen;
   a tubular guide catheter having a shaped distal section that has a curved configuration in a relaxed state and an outer surface which is configured to move axially within a portion of the inner lumen of the stabilizer sheath that extends from the proximal end of the stabilizer sheath to the side port; and
   a tissue penetration member which is configured to move axially within an inner lumen of the tubular guide catheter and which is axially extendable from the guide catheter for membrane penetration.

2. The system of claim 1 wherein the tissue penetration member is configured to penetrate tissue upon rotation and the system further comprises an elongate torqueable shaft coupled to the tissue penetration member.

3. The system of claim 1 wherein the stabilizer sheath further comprises a radially deflective surface disposed within the inner lumen of the stabilizer sheath opposite the side port.

4. The system of claim 1 further comprising an obturator sheath comprising an elongate tubular member having an inner lumen configured to accommodate axial movement of a guidewire therein and having an outer surface profile that is configured to occupy the inner lumen and side port of the stabilizer sheath during initial deployment of the stabilizer sheath in a patient’s body.

5. The system of claim 2 wherein the tissue penetration member comprises a tubular needle with a sharpened distal end and an inner lumen, a helical tissue penetration member disposed about the hypodermic needle and a torqueable shaft having a distal end secured to a proximal portion of the hypodermic needle and a proximal portion of the helical tissue penetration member.

6. The system of claim 5 wherein the torqueable shaft comprises a tubular member having an inner lumen disposed therein and configured to allow passage of a guidewire and wherein the inner lumen of the torqueable shaft is in fluid communication with the inner lumen of the tubular needle.

7. A stabilizer sheath system, comprising
   an elongate tubular shaft having an inner lumen;
   a side port disposed in a distal section of the elongate tubular shaft in fluid communication with the inner lumen;
   a mechanical reinforcement member disposed at the side port; and
   a deflecting surface disposed in the inner lumen opposite the side port.

8. The stabilizer sheath system of claim 7 wherein a distal portion of the distal section comprises a curled section wherein the discharge axis of the distal end of the elongate tubular shaft is greater than 180 degrees from the longitudinal axis of the elongate tubular shaft proximal of the curled section.

9. The stabilizer sheath system of claim 7 further comprising an obturator sheath comprising an elongate tubular member having an inner lumen configured to accommodate axial movement of a guidewire therein and having an outer surface profile that is configured to occupy the inner lumen and side port of the stabilizer sheath during initial deployment of the stabilizer sheath in a patient’s body.

10. A tissue penetration member comprising a tubular hypodermic needle with a sharpened distal end and an inner lumen, a helical tissue penetration member disposed about the hypodermic needle and a tubular torqueable shaft having an inner lumen and a distal end secured to a proximal portion of the hypodermic needle and helical tissue penetration member.

11. A tissue penetration member comprising a helical tissue penetration member with a proximal end and a distal end and a modular base having an annular shape and a quick release coupling mechanism secured to a proximal end of the helical tissue penetration member.

12. A method of accessing the left atrium of a patient’s heart from the right atrium of the patient’s heart, comprising providing a transmembrane access system, including:
   a stabilizer sheath having a tubular configuration with an inner lumen extending therein and having a side port disposed on a distal section of the sheath and in communication with the inner lumen;
   a tubular guide catheter having a shaped distal section that has a curved configuration in a relaxed state and an outer surface which is configured to move axially within a portion of the inner lumen of the stabilizer sheath that extends from the proximal end of the stabilizer sheath to the side port; and
a tissue penetration member which is configured to move axially within an inner lumen of the tubular guide catheter and which is axially extendable from the distal end of the guiding catheter for membrane penetration.
advancing the stabilizer sheath through a superior vena cava of the patient and positioning the stabilizer sheath with the distal end of the sheath within the inferior vena cava with the side port of the stabilizer sheath facing the right atrium of the patient’s heart;
advancing the distal end of the guide catheter through the inner lumen of the stabilizer sheath until the distal end of the guide catheter is positioned adjacent a desired site of the septum of the patient’s heart;
advancing the tissue penetration member from the distal end of the guide catheter; and
activating the tissue penetration actuator and advancing the tissue penetration member distally through the septum.

13. The method of claim 12 wherein the tissue penetration member further comprises a guidewire lumen and wherein after the tissue penetration member has penetrated the septum, a guidewire is advanced through the guidewire lumen of the tissue penetration member until a distal end of the guidewire is disposed within the left atrium of the patient’s heart.

14. The method of claim 12 wherein the system further comprises an obturator sheath having an elongate tubular member having an inner lumen configured to accommodate axial movement of a guidewire therein and having an outer surface profile that is configured to occupy the inner lumen and side port of the stabilizer sheath during initial deployment and removal of the stabilizer sheath in a patient’s body and wherein the stabilizer sheath is advanced into position with the obturator disposed within the inner lumen of the stabilizer sheath and a guidewire within the inner lumen of the obturator.

15. The method of claim 13 further comprising removing the guide catheter and tissue penetration member from the patient’s body while maintaining the guidewire in place with a distal portion of the guidewire located in the left atrium.

16. The method of claim 12 wherein the tissue penetration member is configured to penetrate tissue upon rotation and wherein the activation of the tissue penetration member comprises rotating the tissue penetration member.

17. The method of claim 16 wherein the tissue penetration member is coupled to an elongate torqueable shaft and rotation of the tissue penetration member is carried out by rotation of the torqueable shaft.

18. A method of accessing a second side of a tissue membrane from a first side of a tissue membrane, comprising
providing a transmembrane access system, having
a guide catheter with a shaped distal section that has a curved configuration in a relaxed state, and
a tissue penetration member which is disposed within a distal end of the guide catheter and which is axially extendable from the distal end of the guide catheter for membrane penetration and which is configured to penetrate tissue upon rotation and which has a guidewire lumen disposed therein;
positioning the distal end of the guide catheter until the distal end of the guide catheter is adjacent a desired site on the first side of the tissue membrane;
adverting the tissue penetration member distally from the guide catheter until the distal end of the tissue penetration member is in contact with the tissue membrane;
rotating the tissue penetration member and advancing the tissue penetration member distally through the tissue membrane; and
advancing a guidewire through the guidewire lumen of the tissue penetration member until a distal end of the guidewire is disposed on the second side of the tissue membrane.

19. The method of claim 18 further comprising removing the guide catheter and tissue penetration member from the patient’s body while maintaining the guidewire in place with a distal portion of the guidewire located in place on the second side of the tissue membrane.

20. A transmembrane access system, comprising:
a tubular guide catheter having a shaped distal section that has a curved configuration in a relaxed state;
a tissue penetration member configured to penetrate tissue on rotation which includes a helical tissue penetration member and which is configured to move axially within an inner lumen of the tubular guide catheter and which is axially extendable from the guide catheter for membrane penetration; and
an activation modulator coupled to the tissue penetration member by a torqueable shaft and configured to axially advance the torqueable shaft upon activation of the activation modulator.

21. The transmembrane access system of claim 20 wherein the activation modulator is configured to limit the number of turns of the torqueable shaft.

22. The transmembrane access system of claim 21 wherein the activation modulator is configured to limit the number of turns of the torqueable shaft from about 4 turns to about 10 turns.

23. The transmembrane access system of claim 20 further comprising a stabilizer sheath having a tubular configuration with an inner lumen extending therein and having a side port disposed on a distal section of the sheath and in communication with the inner lumen and wherein the tissue penetration member is disposed within the inner lumen of the stabilizer sheath.

24. The system of claim 20 wherein the stabilizer sheath further comprises a radially deflective surface disposed within the inner lumen of the stabilizer sheath opposite the side port.

25. The system of claim 20 further comprising an obturator sheath comprising an elongate tubular member having an inner lumen configured to accommodate axial movement of a guidewire therein and having an outer surface profile that is configured to occupy the inner lumen and side port of the stabilizer sheath during initial deployment of the stabilizer sheath in a patient’s body.

26. The system of claim 21 wherein the tissue penetration member comprises a tubular needle with a sharpened distal end and an inner lumen with the helical tissue penetration member disposed about the hypodermic needle and with the torqueable shaft having a distal end secured to a proximal portion of the hypodermic needle.
27. The system of claim 24 wherein the torqueable shaft comprises a tubular member having an inner lumen disposed therein and configured to allow passage of a guidewire and wherein the inner lumen of the torqueable shaft is in fluid communication with the inner lumen of the tubular needle.

28. The transmembrane access system of claim 20 wherein the activation modulator comprises a fixed member secured to a proximal portion of the guide catheter and a rotating member having a threaded portion engaged with a threaded portion of the fixed member and having a gripping mechanism configured to apply torque to the torqueable shaft relative to the fixed member.

29. The transmembrane access system of claim 20 wherein the fixed member of the activation modulator comprises a outer barrel secured to a proximal portion of the guide catheter and the rotating member of the activation modulator comprises an inner barrel which is axially captured within a cavity of the outer barrel, which has a threaded portion engaged with a threaded portion of the outer barrel and which has a gripping mechanism configured to apply torque to the torqueable shaft relative to the outer barrel.

30. A method of positioning an access catheter within a chamber of a patient's body, comprising:

   providing an access system, including:

   a stabilizer sheath having a tubular configuration with an inner lumen extending therein and having a side port disposed on a distal section of the sheath and in communication with the inner lumen; and

   a tubular access catheter having a shaped distal section that has a curved configuration in a relaxed state and an outer surface which is configured to move axially within a portion of the inner lumen of the stabilizer sheath that extends from the proximal end of the stabilizer sheath to the side port;

   advancing the stabilizer sheath through a first tubular structure of the patient which is in fluid communication with the chamber and positioning the stabilizer sheath with the side port of the stabilizer sheath within the chamber of the patient's body and with a portion of the stabilizer sheath distal of the side port into a second tubular structure which is also in fluid communication with the chamber;

   advancing the distal end of the access catheter through the inner lumen of the stabilizer sheath until the distal end of the access catheter exits the side port of the stabilizer sheath; and

   rotating the stabilizer sheath and axially translating the access catheter until the distal end of the access catheter is positioned adjacent a desired site of the chamber.

31. The method of claim 30 wherein the access system further comprises an obturator sheath having an elongate tubular member having an inner lumen configured to accommodate axial movement of a guidewire therein and having an outer surface profile that is configured to occupy the inner lumen and side port of the stabilizer sheath during initial deployment of the stabilizer sheath into the patient's body and wherein the stabilizer sheath is advanced into position in the chamber with the obturator disposed within the inner lumen of the stabilizer sheath and a guidewire within the inner lumen of the obturator.

33. A method of accessing the left atrium of a patient's heart from the right atrium of the patient's heart, comprising providing a transmembrane access system, including:

   a stabilizer sheath having a tubular configuration with an inner lumen extending therein and having a side port disposed on a distal section of the sheath and in communication with the inner lumen;

   a tubular guide catheter having a shaped distal section that has a curved configuration in a relaxed state and an outer surface which is configured to move axially within a portion of the inner lumen of the stabilizer sheath that extends from the proximal end of the stabilizer sheath to the side port; and

   a tissue penetration member which is configured to move axially within an inner lumen of the tubular guide catheter and which is axially extendable from the distal end of the guiding catheter for membrane penetration.

   advancing the stabilizer sheath through an inferior vena cava of the patient and positioning the stabilizer sheath with the distal end of the sheath within the superior vena cava with the side port of the stabilizer sheath facing the right atrium of the patient's heart;

   advancing the distal end of the guide catheter through the inner lumen of the stabilizer sheath until the distal end of the guide catheter is positioned adjacent a desired site of the septum of the patient's heart;

   advancing the tissue penetration member from the distal end of the guide catheter; and

   activating the tissue penetration actuator and advancing the tissue penetration member distally through the septum.

34. The method of claim 33 wherein the tissue penetration member further comprises a guidewire lumen and wherein after the tissue penetration member has penetrated the septum, a guidewire is advanced through the guidewire lumen of the tissue penetration member until a distal end of the guidewire is disposed within the left atrium of the patient's heart.

35. The method of claim 33 wherein the system further comprises an obturator sheath having an elongate tubular member having an inner lumen configured to accommodate axial movement of a guidewire therein and having an outer surface profile that is configured to occupy the inner lumen and side port of the stabilizer sheath during initial deployment and removal of the stabilizer sheath in a patient's body and wherein the stabilizer sheath is advanced into position with the obturator disposed within the inner lumen of the stabilizer sheath and a guidewire within the inner lumen of the obturator.

36. The method of claim 33 further comprising removing the guide catheter and tissue penetration member from the patient's body while maintaining the guidewire in place with a distal portion of the guidewire located in the left atrium.

37. The method of claim 33 wherein the tissue penetration member is configured to penetrate tissue upon rotation and wherein the activation of the tissue penetration member comprises rotating the tissue penetration member.

38. The method of claim 37 wherein the tissue penetration member is coupled to an elongate torqueable shaft and rotation of the tissue penetration member is carried out by rotation of the torqueable shaft.

* * * * *