

**DIRECTIONAL BALLOON TRANSSEPTAL INSERTION DEVICE FOR MEDICAL
PROCEDURES WITH IMPROVED TRANSSEPTAL PUNCTURE SYSTEM WITH
PUNCTURE MEMBER BALLOON SEAL**

1 CROSS REFERENCE TO RELATED APPLICATIONS

2 This application claims the priority of U.S. Provisional Application Serial No. 62/903,261,
3 filed on September 20, 2019, which is hereby incorporated herein by reference in its entirety.

4 FIELD

5 The present invention relates generally to cardiac catheters, and more particularly, to a
6 transseptal insertion device which is suitable for facilitating quick and safe transseptal puncture
7 and insertion of a catheter through a cardiac septum to provide access to the left atrium in
8 implementation of a left atrial intervention.

9 BACKGROUND

10 Cardiac catheterization is a medical procedure in which a long thin tube or catheter is
11 inserted through an artery or vein into specific areas of the heart for diagnostic or therapeutic
12 purposes. More specifically, cardiac chambers, vessels and valves may be catheterized.

13 Cardiac catheterization may be used in procedures such as coronary angiography and left
14 ventricular angiography. Coronary angiography facilitates visualization of the coronary vessels
15 and finding of potential blockages by taking X-ray images of a patient who has received a dye
16 (contrast material) injection into a catheter previously injected in an artery. Left ventricular
17 angiography enables examination of the left-sided heart chambers and the function of the left sided
18 valves of the heart, and may be combined with coronary angiography. Cardiac catheterization can
19 also be used to measure pressures throughout the four chambers of the heart and evaluate pressure
20 differences across the major heart valves. In further applications, cardiac catheterization can be
21 used to estimate the cardiac output, or volume of blood pumped by the heart per minute.

22 Some medical procedures may require catheterization into the left atrium of the heart. For
23 this purpose, to avoid having to place a catheter in the aorta, access to the left atrium is generally
24 achieved by accessing the right atrium, puncturing the interatrial septum between the left and right
25 atria of the heart, and threading the catheter through the septum and into the left atrium. Transseptal
26 puncture must be carried out with extreme precision, as accidental puncturing of surrounding tissue

1 may cause very serious damage to the heart. In addition, transseptal puncture may require
2 complicated instruments which are not helpful in guaranteeing the precision of the puncture.

3 The use of devices available today present many challenges for doctors attempting to
4 puncture the interatrial septum and perform cardiac catheterization. Locating the interatrial septum,
5 properly placing the distal end of the puncturing device at the desired location of the septum, safely
6 puncturing the interatrial septum, avoiding accidental punctures, and tracking and maneuvering
7 the catheter post-puncture, are among the many challenges facing those performing cardiac
8 catheterization today.

9 SUMMARY

10 Accordingly, there is an established need for a device that is suitable for facilitating quick
11 and safe transseptal puncturing to provide access to the left atrium in implementation of a left atrial
12 intervention.

13 These advantages and others are achieved, for example, by a transseptal insertion device
14 which is suitable for facilitating precise and safe transseptal puncture of a cardiac interatrial septum.
15 The transseptal insertion device includes a sheath that defines at least one lumen therein, one or
16 more positioning balloons that are connected to the distal end of the sheath, a puncture member
17 movably positioned within the at least one lumen, and a puncture member balloon located on the
18 distal end of the puncture member. The sheath has a distal end that is positioned toward the cardiac
19 interatrial septum of a patient when the transseptal insertion device is in use and a proximal end
20 that is external to the patient. The one or more positioning balloons, when inflated and the
21 transseptal insertion device is in use, overhang and extend past the distal end of the sheath. The
22 sheath includes one or more hypotubes respectively connected to the one or more positioning
23 balloons to inflate and deflate the one or more positioning balloons. The puncture member has a
24 distal end that is positioned toward the cardiac interatrial septum of the patient. The puncture
25 member has a distal end and is designed to and is capable of precisely puncturing the cardiac
26 interatrial septum. The puncture member includes at least one puncture member tube connected to
27 the puncture member balloon to inflate and deflate the puncture member balloon.

28 The one or more positioning balloons may be inflated by gas or fluid supplied through the
29 one or more hypotubes, and the one or more positioning balloons and the puncture member balloon
30 may be inflated and deflated independently of each other. The one or more hypotubes may include
31 one or more inflation hypotubes to inflate the one or more positioning balloons, and one or more

1 deflation hypotubes to deflate the one or more positioning balloons. The one or more positioning
2 balloons, when inflated, may deliver energy in the form of heat or is used for cryoablation with
3 fluid that is circulated through the one or more positioning balloons. The puncture member balloon,
4 when inflated, may be positioned at a predetermined distance from a tip of the distal end of the
5 puncture member to prevent the puncture member from being pushed beyond the predetermined
6 distance while the puncture member is tenting the cardiac interatrial septum and the puncture
7 member balloon is pressing against the cardiac interatrial septum.

8 The transseptal insertion device may further include a wire member movably positioned in
9 a center lumen formed in the puncture member. The wire member advances beyond a tip of the
10 distal end of the puncture member when in use. The wire member may be a Brockenbrough needle,
11 a radiofrequency tip needle, a radiofrequency wire, a pigtail catheter that delivers fluid or
12 pharmaceuticals in the left atrial appendage, or a transseptal wire designed to and is capable of
13 precisely puncturing the cardiac interatrial septum. The sheath may include a side port proximal
14 to the positioning balloons. An additional catheter or wire advances into the cardiac interatrial
15 septum through the side port and the additional catheter or wire is capable of capturing the wire
16 member.

17 These advantages and others are also achieved, for example, by a method for suitably
18 facilitating precise and safe transseptal puncture of a cardiac interatrial septum with a transseptal
19 insertion device. The method includes steps of inflating one or more positioning balloons
20 connected to a distal end of a sheath of the transseptal insertion device, advancing a puncture
21 member while the positioning balloons are inflated, positioning the puncture member against the
22 cardiac interatrial septum, deflating the one or more positioning balloons, further advancing the
23 puncture member to puncture the cardiac interatrial septum, and advancing the transseptal insertion
24 device crossing the cardiac interatrial septum. The one or more positioning balloons, when inflated
25 and the transseptal insertion device is in use, overhang and extend past the distal end of the sheath.
26 The sheath includes one or more hypotubes respectively connected to the one or more positioning
27 balloons to inflate and deflate the one or more positioning balloons. The puncture member is
28 movably positioned within at least one lumen of the sheath. A puncture member balloon is located
29 on a distal end of the puncture member and the puncture member includes at least one puncture
30 member tube connected to the puncture member balloon to inflate and deflate the puncture member
31 balloon.

1 The method may further include steps of inflating the puncture member balloon once the
2 puncture member advances beyond the distal end of the sheath and is tenting the cardiac interatrial
3 septum, and deflating the puncture member balloon before said further advancing the puncture
4 member to puncture the cardiac interatrial septum. The puncture member balloon may be pressing
5 against the cardiac interatrial septum while the puncture member is tenting the cardiac interatrial
6 septum. The method may further include one or more of steps of re-inflating the one or more
7 positioning balloons to navigate in an atraumatic fashion to different parts of the left atrium after
8 the distal end of the transseptal insertion device crosses the cardiac interatrial septum, re-inflating
9 the puncture member balloon to anchor the transseptal insertion device against the cardiac
10 interatrial septum after the distal end of the transseptal insertion device crosses the cardiac
11 interatrial septum, delivering, via the one or more positioning balloons, energy in the form of heat
12 or using the one or more positioning balloons for cryoablation with fluid that is circulated through
13 the one or more positioning balloons, advancing a wire member beyond a tip of the distal end of
14 the puncture member after the distal end of the transseptal insertion device crosses the cardiac
15 interatrial septum where the wire member movably positioned in a center lumen formed in the
16 puncture member, advancing an additional catheter or wire into the cardiac interatrial septum
17 where the sheath includes a side port proximal to the positioning balloons, and the additional
18 catheter or wire advances through the side port, and capturing the wire member with the additional
19 catheter or wire forming a loop with the captured wire member.

20 **BRIEF DESCRIPTION OF THE DRAWINGS**

21 The preferred embodiments described herein and illustrated by the drawings hereinafter be
22 to illustrate and not to limit the invention, where like designations denote like elements.

23 FIG. 1A is a side perspective, cross-sectional view of an embodiment of a transseptal
24 insertion device.

25 FIG. 1B is a side perspective, cross-sectional view of an embodiment of a transseptal
26 insertion device showing a dilator extending partially through and extending out from device.

27 FIG. 1C is a side perspective, cross-sectional view of an embodiment of a transseptal
28 insertion device showing a dilator extending partially through the device.

29 FIG. 2A is a is a perspective view of an embodiment of a transseptal insertion device with
30 hypotube connected to one or more balloons.

1 FIG. 2B is a front view of an embodiment of a transseptal insertion device with
2 hypotube connected to one or more balloons.

3 FIGS. 2C-2D are side views of embodiments of transseptal insertion device with ultrasound
4 imaging or visualizing capability.

5 FIG. 3A is a perspective view of an embodiment of a transseptal insertion device with
6 multiple balloons and hypotubes connected to the multiple balloons.

7 FIG. 3B is a front view of an embodiment of a transseptal insertion device with multiple
8 balloons and hypotubes connected to the multiple balloons.

9 FIG. 4 is a perspective, cross-sectional view of an embodiment of a transseptal insertion
10 device with radiofrequency energy capability.

11 FIG. 5 is a perspective view of an embodiment of a transseptal insertion device with a
12 drive assembly coupled to dilator, and knob coupled to the drive assembly.

13 FIG. 6 is a perspective, cross-sectional view of an embodiment of a transseptal insertion
14 device showing inflated overhanging balloon and dilator positioned within device and subplanar
15 to overhanging balloon.

16 FIG. 7 is a cross-sectional, end view of an embodiment of a transseptal insertion device
17 and dilator shown prior to puncturing an interatrial cardiac septum with inflated overhanging
18 balloon.

19 FIG. 8 is a perspective, cross-sectional view of an embodiment of a transseptal insertion
20 device with dilator advanced forward in order to tent an interatrial septum.

21 FIG. 9 is a perspective, cross-sectional view of an embodiment of a transseptal insertion
22 device with a transseptal wire advanced post-puncture through interatrial septum.

23 FIGS. 10A-10C are perspective, cross-sectional views of an embodiment of a flexible
24 transseptal insertion device with different angulations.

25 FIG. 11 is a side view of an embodiment of transseptal insertion device with an
26 overhanging balloon with marking.

27 FIG. 12 is a side view of an embodiment of transseptal insertion device with an
28 overhanging balloon with a marker band.

29 FIG. 13 is a cross-sectional side view of an embodiment of a transseptal insertion device
30 that includes a dilator with an electrode tip.

1 FIG. 14 is a side view of an embodiment of a transseptal insertion device with mechanical
2 deflection capability.

3 FIG. 15 is side views of embodiments of curved dilators that may be used in embodiments
4 of a transseptal insertion device.

5 FIG. 16 is a perspective side view of a proximal end of an embodiment of a transseptal
6 insertion device showing a handle and a stabilizer.

7 FIGS. 17A-17B are side views of an embodiment of a transseptal insertion device with
8 balloons capable of differential inflation.

9 FIG. 18 is a side view of a malleable or flexible transseptal needle that may be used in
10 embodiments of a flexible transseptal insertion device with multiple angulations.

11 FIGS. 19A-19C are a side view, a close side view, and a cross-sectional end view of a
12 puncture tip of an embodiment of an improved transseptal puncture system with puncture member
13 balloon seal with a deflated puncture member balloon.

14 FIGS. 20A-20C are a side view, a close side view, and a cross-sectional end view of a
15 puncture tip of an embodiment of an improved transseptal puncture system with puncture member
16 balloon seal with an inflated puncture member balloon.

17 FIGS. 21A-21B are cross-sectional side view and a close, cross-sectional side view of a
18 puncture tip of an embodiment of an improved transseptal puncture system with puncture member
19 balloon seal with an inflated positioning balloon.

20 FIGS. 22A-22B are cross-sectional side view and a close, cross-sectional side view of a
21 puncture tip of an embodiment of an improved transseptal puncture system with puncture member
22 balloon seal with a deflated positioning balloon.

23 FIGS. 23A-23C show an embodiment of an improved transseptal puncture member balloon
24 that is inflated through the inflation port once the puncture member is outside the shaft and is
25 tenting the septum, guidewire that is advanced into the left atrium, and the puncture member
26 balloon that is deflated.

27 FIGS. 24A-24B show an embodiment of an improved positioning balloon on the shaft that
28 has a separate hypotube for inflation and deflation.

29 FIGS. 25A-25C show side views of the distal end portion of the puncture member multi-
30 lumen extension, and a cross-sectional view of the distal end portion of the puncture member multi-
31 lumen extension of the transseptal puncture system.

1 FIG. 26 illustrates an embodiment of a method of using the improved transseptal puncture
2 system.

3 FIG. 27 shows an embodiment of a method of using the improved transseptal puncture
4 system for left atrial appendage thrombectomy.

5 FIG. 28 shows an embodiment of a method of using the improved transseptal puncture
6 system for MitraClip or other mitral repair prosthesis device removal.

7 FIG. 29 shows an embodiment of a method of using the improved transseptal puncture
8 system for laceration of a bioprosthetic valve leaflet.

9 FIG. 30 shows an embodiment of a method of using the improved transseptal puncture
10 system wherein the system anchors in the pulmonary veins, performs pulmonary venous
11 angioplasty, and deliver either radiofrequency heat energy or cryo-energy.

12 FIGS. 31A-31B and 32A-32B show an embodiment of a method of using the improved
13 transseptal puncture system in which the positioning balloon anchors in the patent foramen ovale
14 and identify multiple small atrial septal defects in a cribriform atrial septal defect.

15 FIG. 33 is a workflow diagram for a method for suitably facilitating precise and safe
16 transseptal puncture of a cardiac interatrial septum with a transseptal insertion device.

17 **DETAILED DESCRIPTION**

18 The following detailed description is merely exemplary in nature and is not intended to
19 limit the described embodiments or the application and uses of the described embodiments. As
20 used herein, the word “exemplary” or “illustrative” means “serving as an example, instance, or
21 illustration.” Any implementation described herein as “exemplary or “illustrative” is not
22 necessarily to be construed as preferred or advantageous over other implementations. All of the
23 implementations described below are exemplary implementations provided to enable persons
24 skilled in the art to make or use the embodiments of the disclosure and are not intended to limit
25 the scope of the disclosure, which is defined by the claims. Furthermore, there is no intention to
26 be bound by any expressed or implied theory presented in the preceding technical field,
27 background, brief summary or the following detailed description. It is also to be understood that
28 the specific devices and processes illustrated in the attached drawings, and described in the
29 following specification, are simply exemplary embodiments of the inventive concepts defined in
30 the appended claims. Hence, specific dimensions and other physical characteristics relating to the

1 embodiments disclosed herein are not to be considered as limiting, unless the claims expressly
2 state otherwise.

3 With reference to FIGS. **1A-1C**, shown is an embodiment of transseptal insertion device
4 or catheter **10**. Shown is the distal end of transseptal insertion device **10**, *i.e.*, the end of transseptal
5 insertion device **10** with opening through which dilator, catheter, and needle may extend, *e.g.*, to
6 puncture interatrial cardiac septum. As shown in FIG. **1A**, transseptal insertion device **10** includes
7 outer sheath or balloon shaft **12** and one or more balloons **14** located at distal tip **13** of transseptal
8 insertion device **10**. Sheath **12** may contain and define a center lumen **15**. Sheath **12** may be
9 fabricated from various materials, including, *e.g.*, polymers, including thermoplastics elastomers
10 (TPEs) such as PEBA (*e.g.*, Pebax®), nylons, thermoplastic polyurethanes (TPUs) such as
11 Pellathane®, similar materials and combinations thereof. Sheath **12** may be referred to as catheter
12 shaft and used in cardiac catheterizations. After puncture, sheath **12** may be inserted through
13 septum into left atrium. Alternatively, sheath **12** may contain a separate catheter that is inserted
14 through septum post puncture. Transseptal insertion device **10** also includes dilator **16**, positioned
15 in center lumen **15**, as shown in FIG. **1B**. The one or more balloons **14** are preferably sealed, air-
16 tight and water-tight, on both its ends to sheath **12**.

17 With continuing reference to FIG. **1A**, in view shown, overhanging one or more balloons
18 **14** are uninflated. Although cross-section of balloons **14** shown on top and bottom of distal tip **13**,
19 balloons **14** preferably extend around circumference of distal tip or end **13** of transseptal insertion
20 device **10**. Overhanging one or more balloons **14** are of form such that balloons **14** overhang or
21 extend from distal tip **13** of sheath **12** when inflated.

22 In FIG. **1B**, dilator **16** is shown positioned within and partially extending out of sheath **12**,
23 past distal tip **13** of device **10**. Overhanging one or more balloons **14** are uninflated and dilator **16**
24 extends past balloons **14**. It is noted that the relative sizes of sheath **12** and dilator **16** shown are
25 for illustrative purposes as the diameter of dilator **16** may be relatively larger or smaller than shown
26 in relation to the diameter of sheath **12**, although dilator **16** necessarily has a smaller diameter than
27 sheath **12**. Although dilator **16** is shown to have a pointed end, dilator **16** may have a rounded or
28 relatively flat end. Embodiments, as described herein, are designed and intended to puncture
29 septum without use of a needle or other sharp instrument.

30 With reference now to FIG. **1C**, dilator **16** is shown positioned within center lumen **15** of
31 sheath **12**. Tip of dilator **16** is positioned within distal tip **13** of transseptal insertion device **10** sub-

1 planar to end of transseptal insertion device **10**. The position shown is position dilator **16** may be
2 in immediately prior to inflation of one or more balloons **14**. It is noted that the relative sizes of
3 catheter/sheath **12** and dilator **16** shown are for illustrative purposes as the diameter of dilator **16**
4 may be relatively larger or smaller than shown in relation to the diameter of sheath **12**. Ordinarily,
5 dilator **16** has smaller diameter or gauge than catheter/sheath **12**, although fit of dilator **16** in
6 catheter/sheath **12** is preferably snug enough so that dilator **16** does not move (laterally or axially)
7 relative to position or “wobble” within transseptal insertion device **10**. Dilator **16** necessarily has
8 a smaller diameter than sheath **12**. In embodiments, sheath **12** material may be sufficiently
9 malleable to enable larger diameter dilators **16**, and other larger diameter devices, to be passed
10 through sheath **12**. In such embodiments, sheath **12** will stretch to accommodate the larger
11 diameter dilator **16** or other device.

12 With reference to FIG. **2A**, shown is a side perspective view of an embodiment of
13 transseptal insertion device or catheter **200**. Shown is the distal end of transseptal insertion device
14 **200**, *i.e.*, the end of transseptal insertion device **200** with opening through which dilator, catheter,
15 and needle may extend, *e.g.*, to puncture interatrial cardiac septum. As shown in FIG. **2A**,
16 transseptal insertion device **200** includes outer sheath or catheter shaft **212** and one or more
17 balloons **214** located at distal tip **213** of transseptal insertion device **200**. Sheath **212** may contain
18 lumen shaft **211** that defines center lumen **215**. Sheath **212** may be fabricated from various
19 materials, including, *e.g.*, polymers, including thermoplastics elastomers (TPEs) such as PEBA
20 (*e.g.*, Pebax®), nylons, thermoplastic polyurethanes (TPUs) such as Pellathane®, similar materials
21 and combinations thereof. Sheath **212** may be referred to as catheter shaft and used in cardiac
22 catheterizations. After puncture, sheath **212** may be inserted through septum into left atrium.
23 Alternatively, sheath **212** may contain multiple lumen shafts that define multiple lumens separately.
24 Transseptal insertion device **200** also includes dilator **216**, positioned in center lumen **215**. The
25 one or more balloons **214** are preferably sealed, air-tight and water-tight, on both their ends to
26 sheath **212**. Transseptal insertion device **200** includes hypotube **217** for inflation or deflation of
27 one or more balloons **214**. Hypotube **217** may be contained in sheath or catheter shaft **212**.
28 Transseptal insertion device **200** may further include a port (not shown) connected to hypotube
29 **217** to supply gas or fluid to inflate one or more balloons **214**, or to remove gas or fluid from one
30 or more balloons **214** to deflate balloons **214**. Balloons **214** may be fully inflated or deflated, or
31 may be inflated or deflated as much as desired. With reference to FIG. **2B**, shown is a front, cross-

1 sectional view of distal end **213** of the embodiment of transseptal insertion device **200** that shows
2 cross-sectional views of sheath **212**, center lumen **215**, and hypotube **217**.

3 In the embodiment shown in FIGS. **2A-2B**, transseptal insertion device **200** may include
4 ultrasound chips or transducers **26** for ultrasound imaging or visualizing (see FIGS. **2C-2D**). The
5 transseptal sheath **212** or balloon **214** may house (inside or on) an ultrasound chip or transducer
6 which may be used to guide the insertion procedure. Ultrasound chip or transducer emits and
7 receives ultrasound energy, that may be detected by known ultrasound visualization devices, to
8 create an image of the cardiac chambers (*e.g.*, the right atrium, fossa, interatrial septum, left atrium,
9 atrial appendage, mitral valve, ventricle, etc.). Ultrasound chips and transducers are transducers
10 that convert ultrasound waves to electrical signals and/or vice versa. Those that both transmit and
11 receive may also be called ultrasound transceivers; many ultrasound sensors besides being sensors
12 are indeed transceivers because they can both sense and transmit. Such imaging will allow the
13 operator(s) of transseptal insertion device **200** to visualize the cardiac chambers and the determine
14 the location of the distal end or tip **213** of transseptal insertion device **200**, enabling more precise
15 operation of transseptal insertion device **200**. Such a ultrasound chips or transducers used may be
16 similar to ultrasound chip or transducer described in US Pat. App. Pub. 2003/019546, which is
17 herein incorporated by reference, or any other ultrasound transducer known to those of ordinary
18 skill in the art that may be fabricated on scale small enough to be deployed on or in sheath **212** or
19 balloon **214**.

20 With reference to FIGS. **2C-2D**, shown are embodiments of transseptal insertion device
21 **200** with ultrasound imaging or visualizing capability. Balloon **14** shown includes one or more
22 ultrasound chips or transducers **26** deployed in or on balloon **14**. Ultrasounds chips or transducers
23 **26** may be ultrasound transceivers that both emit and receive waves, convert the ultrasound waves
24 to electrical signals, transmit the electrical signals, *e.g.*, through a wire that runs via sheath **12**.
25 Ultrasounds chips or transducers **26** may be connected via WiFi or other wireless connection, to
26 an external imaging device that produces images from the received signals (both still and video
27 images).

28 Ultrasound chips or transducers **26** may be affixed to interior or exterior surface of balloon
29 **14**. Ultrasound chips or transducers **26** may be arranged in a line, disc, or cross-shape. Ultrasound
30 chips or transducers **26** may be arranged to be forward facing (*e.g.*, on distal end of balloon facing
31 towards interatrial septum), as shown in FIG. **2C**, or in a different direction/orientation, such as

1 sideways and forward facing (*e.g.*, facing towards interatrial septum and facing perpendicular to
2 the distal or front end), as shown in FIG. 2D. Indeed, orientation of ultrasound chips or transducers
3 26 may depend on whether balloon 14 is inflated or not. When balloon 14 is fully inflated, as
4 shown in FIG. 2C, ultrasound transducer 26 may be forward facing (or forward and
5 perpendicularly facing as shown in FIG. 2D). However, when balloon 14 is deflated, ultrasound
6 transducer 26 may be folded flat and positioned on side of distal tip 13 of sheath 12. Hence, when
7 balloon 14 is deflated, ultrasound chip or transducer 26 may be side-facing. During inflation
8 ultrasound transducer 26 orientation will change as balloon 14 inflates (moving from side-facing
9 orientation to forward facing orientation with the ultrasound transducer 26 shown in FIG. 2C).
10 Accordingly, operator(s) of transseptal insertion device 200 may vary the inflation of balloon 14
11 to achieve different orientations of ultrasound transducer 26 for different imaging views.

12 Ultrasound chip or transducers 26 may emit and/or receive/detect ultrasound waves that
13 may be reflect off of surfaces and structures, *e.g.*, within atrium, and then read by imaging system
14 (not shown), *e.g.*, connected to ultrasound chips or transducers 26 via wire or cable extending
15 through, *e.g.*, lumen 15 in sheath 12. In this manner, ultrasound chips or transducers 26 may enable
16 visualization of the interatrial septum and the left atrial structures.

17 It is also noted that ultrasound chips or transducers 26 may be deployed on distal tip 13 of
18 sheath 12 (or elsewhere on or in sheath 12). Ultrasound chips or transducers 26 may be installed
19 or configured to be forward facing (facing towards distal end of sheath 12). Alternatively,
20 ultrasound chips or transducers 26 may be flipped to be rear facing (facing towards proximal end
21 of sheath 12). Varying orientations of ultrasound chips or transducers 26 may be implemented.

22 With reference to FIGS. 3A-3B, shown is transseptal insertion device 300 including
23 multiple balloons 314, which surround center lumen shaft 311 that defines center lumen 315, and
24 sheath or catheter shaft 312 that includes center lumen shaft 311 and hypotubes 317 connected to
25 multiple balloons 314. FIG. 3A is a side view of sheath or catheter shaft 312, and FIG. 3B is a
26 front cross-sectional view of sheath or catheter shaft 312. Balloons 314 are in various shapes such
27 as round, cylindrical, spherical, tear drop shaped or pear shaped, and are in various lengths.
28 Balloons 314 may be with or without overhang over shaft. Balloons 314 are positioned around
29 distal tip or end 313, and may extend around circumference of distal tip or end 313. Multiple
30 balloons 314 are connected to one or more hypotubes 317, and inflated or deflated via hypotubes
31 317 that are contained in sheath or catheter shaft 312. Each of balloons 314 may be connected to

1 corresponding hypotube **317** to independently control the inflation and deflation of balloons **314**.
2 Alternatively, balloons **314** may share one or more hypotubes **317**. Inflation fluid or gas may flow
3 through hypotubes **314** to inflate or deflate balloons **314**. Outer covering **319** may cover the
4 multiple balloons **314**.

5 In between balloons **314**, there are one or more ultrasound chips or transducers **326** that
6 provide ultrasound imaging or visualizing capability. For illustrative purposes, FIG. **3B** shows
7 ultrasound chips or transducers **326** disposed between balloons **314**, but ultrasound chips or
8 transducers **326** may be deployed in or on balloons **314**. Ultrasound chips or transducers **326** may
9 be affixed to interior or exterior surface of balloon **314**. Ultrasounds chips or transducers **326** may
10 be ultrasound transceivers that both emit and receive waves, convert the ultrasound waves to
11 electrical signals, transmit the electrical signals, *e.g.*, through wire **320** that runs inside sheath or
12 catheter shaft **312**. However, ultrasound chips or transducers **326** may be connected wirelessly via
13 WiFi or other wireless connection, to an external imaging device that produces images from the
14 received signals (both still and video images).

15 Ultrasound chips or transducers **326** may be designed in the shape of the balloons **314**. The
16 balloons **314** may be round, cylindrical, spherical, tear drop shaped or pear shaped with overhang
17 or without overhang. Ultrasound chips or transducers **326** may have shapes corresponding to the
18 shapes of balloons **314**. Alternatively, one or more ultrasound chips or transducers **326** may be
19 deployed in a shape corresponding to the shapes of balloons **314**. Depending on the shapes of
20 balloons **314**, ultrasound chips or transducers **326** may be side facing, front facing or back facing.
21 Ultrasound chips or transducers **326** may be arranged in a line, disc, or cross-shape. Ultrasound
22 chips or transducers **326** may be arranged to be forward facing (*e.g.*, on distal end of balloon facing
23 towards interatrial septum), or in a different direction/orientation, such as sideways and forward
24 facing (*e.g.*, facing towards interatrial septum and facing perpendicular to the distal or front end).

25 Orientations of ultrasound chips or transducers **326** may depend on whether balloons **314**
26 are inflated or not. When balloons **314** are fully inflated, ultrasound chips or transducers **326** may
27 be forward facing. However, when balloons **314** are deflated, ultrasound chips or transducer **326**
28 may be folded flat and positioned on side of distal tip **313** of center lumen **315**. Hence, when
29 balloons **314** are deflated, ultrasound chips or transducer **326** may be side-facing. During inflation,
30 orientation of ultrasound chips or transducers **326** may change as balloons **314** inflate (moving
31 from side-facing orientation to forward facing orientation). Accordingly, operator(s) of transseptal

1 insertion device **300** may vary the inflation of balloons **314** to achieve different orientations of
2 ultrasound chips or transducers **326** for different imaging views.

3 With reference now to FIG. **4**, shown is an embodiment of transseptal insertion device **10**
4 with radiofrequency (RF) energy capability. Transseptal insertion device **10** shown includes sheath
5 **12**, overhanging one or more balloons **14**, and dilator **16**. Dilator **16** may include cap or crown **22**,
6 on distal end as shown, with RF energy capability or capable of delivering RF energy.
7 Alternatively, cap or crown may include or be an RF electrode. Dilator **16** may be connected, *e.g.*,
8 on proximate end (not shown) to a radiofrequency energy source (not shown) at, *e.g.*, external hub,
9 that provides RF energy to cap or crown **22**. The RF energy may be delivered through dilator **16**.
10 So equipped with cap or crown **22**, dilator **16** may tent interaxial septum and create puncture of
11 interaxial septum through delivery of RF energy. In this embodiment, the use of a sharp needle
12 may be avoided. The dilator with cap or crown on distal end with RF energy capability or capable
13 of delivering RF energy may be used for transseptal insertion devices **200** and **300** shown in FIGS.
14 **2A-2B** and **3A-3B**.

15 With reference to FIG. **5**, shown is transseptal insertion device **400** including drive
16 assembly **421**, which is coupled to dilator **416**, and knob **422** coupled to drive assembly **421** to
17 cause dilator **416** to traverse along an axial direction of sheath or catheter shaft **412**. Dilator **416**
18 may move backwards or forwards along the axial direction of sheath **412** while knob **422** is rotated.
19 The drive assembly **421** may include nut assembly to drive the dilator **416**. Dilator **416** may be
20 with or without RF energy capability.

21 With reference now to FIG. **6**, shown is distal end of an embodiment of transseptal insertion
22 device **10** in which overhanging balloons **14** is inflated by supplying gas or fluid into balloon **14**
23 through hypotube (not shown). Dilator **16** is shown positioned within center lumen **15** of sheath
24 **12** with tip of dilator **16** positioned at distal tip **13** of transseptal insertion device **10** and sub-planar
25 to overhanging balloon **14**. The plane that is referred to here is the plane perpendicular to the axis
26 of transseptal insertion device **10** and dilator **16**, formed by the end of overhanging balloon **14**.
27 Hence, dilator **16** remains sub-planar to overhanging balloon **14** until operator intends balloon **14**
28 to be deflated and dilator **16** to tent and puncture interatrial septum **100**. As noted above, balloon
29 **14** preferably extends completely around circumference of tip **13** of transseptal insertion device
30 **10**. Accordingly, FIG. **7** only illustrates cross-section of inflated balloon **14**.

1 With reference now to FIG. 7, shown is a front, cross-sectional view of distal end an
2 embodiment of transseptal insertion device **10** in which overhanging balloon **14** is inflated. As
3 shown, inflated overhanging balloon **14** preferably extends around entire circumference of sheath
4 **12** (and, therefore, device **10**). Shown situated within lumen **15** of sheath **12** is tip of dilator **16**.
5 Tip of dilator **16** is positioned within tip **13** of transseptal insertion device **10**, as it would be prior
6 to being extended past tip **13** and puncturing an interatrial cardiac septum.

7 With reference now to FIG. 8, shown is distal end of an embodiment of transseptal insertion
8 device **10** with dilator **16** advanced forward in order to tent the interatrial septum **100**. Dilator **16**
9 is shown extending through center lumen **15** of sheath **12** and past overhanging balloon **14**. At this
10 stage, balloon **14** may be deflated by removing gas or fluid in balloon **14** through hypotube.
11 Extended as such, and pressed against interatrial septum **100**, dilator **16** tents the interatrial septum
12 **100** away from transseptal insertion device **10**.

13 With reference now to FIG. 9, shown is shown is distal end of an embodiment of transseptal
14 insertion device **10** with dilator **16** advanced forward through interatrial septum **100**, after
15 puncturing septal wall (*e.g.*, through application of energy through dilator **16** as described herein)
16 and transseptal wire or wire rail **20** extending through dilator **16** and into left atrium chamber **110**.
17 Wire rail **20** may sit in a lumen **19** of dilator **16**. Dilator **16** may be used as a conduit to advance
18 the wire rail **20** into the left atrium.

19 Wire rail **20** may act as a guide for devices to enter the left atrium through the puncture in
20 the septal wall made by transseptal insertion device **10**. For example, wire rail **20** may guide
21 transseptal insertion device **10** or other catheters in the left atrium. In this manner, catheters may
22 be advanced safely into the left atrium over or guided by wire rail **20**. In an embodiment, wire rail
23 **20** may be energized (*e.g.*, to ablate or puncture the septum with energy delivered from source at
24 proximal end of transseptal insertion device **10**).

25 With continued reference to FIG. 9, dilator **16** preferably defines and includes an opening
26 or lumen **19** extending through its tip and through which transseptal wire **20** extends. With dilator
27 **16** extended as shown and tenting interatrial septum, septum may be punctured by energy delivered
28 through cap or electrode at tip of dilator **16** and transseptal wire rail **20** extended through opening
29 in tip of dilator **16** and through puncture made in interatrial septum by dilator **16** cap.

30 With reference to FIGS. **10A-10C**, shown are different views of an embodiment of
31 transseptal insertion device **10** with a flexible sheath **12** flexed or angulated at different angles.

1 Transseptal insertion device **10** may be flexed or angulated depending on the anatomy of the atria
2 using fixed angled dilators **16** that are inserted into lumen shaft of sheath **12**, causing sheath **12** to
3 flex. Such fixed angled dilators **16** may be, *e.g.*, any angle from 0-270°. Alternatively, sheath **12**,
4 lumen shaft and dilator **16** may be all flexible (preferably, hypotubes, needle and catheter inserted
5 through such flexible sheath **12** are flexible or malleable, at least in part) and transseptal insertion
6 device **10** may be flexed or angulated, thereby flexing or angulating sheath **12** and dilator **16**, using,
7 *e.g.*, a handle or wire (not shown) connected to tip **13** of device **10**. Handle and/or wire may also
8 be used to turn or flex or move tip **13** of transseptal insertion device **10**, *e.g.*, moving tip **13** of
9 sheath “up” or “down” or “left” or “right” or angulating tip **13** relative to axis of sheath **12** as
10 shown.

11 With reference now to FIG. **11**, shown is distal end of an embodiment of transseptal
12 insertion device **10** with inflated overhanging balloon **14**. Balloon **14** shown is an embodiment
13 with one or more markers **24**. Marker **24** may be, *e.g.*, a radiopaque and/or echogenic marker **24**.
14 As a radiopaque or echogenic marker, marker **24** will be visible on scanners used by those
15 performing cardiac catheterizations. The markers **24** may be in the form of letters, such as an E or
16 a C. Marker **24** enables the appropriate positioning of balloon **14** and sheath **12** in the 3-
17 dimensional space (*e.g.*, of the atrium) using imaging to view the marker **24** and, therefore, the
18 position of balloon **14**.

19 Specifically, in operation, the less posterior distal tip **13** is positioned, the more of the E
20 (or C) will be shown. As operator of transseptal insertion device **10** turns or rotates distal tip **13**
21 toward posterior of patient, less of the arms of the E will be seen. In a preferred embodiment, when
22 only the vertical portion of the E is visible (*i.e.*, appearing as an I) distal tip **13** will be rotated to
23 its maximum posterior position.

24 With continuing reference to FIG. **11**, balloon **14** is shown as inflated. However, distal end
25 of dilator **16** is shown extruding or extending distally from balloon **14**, past plane formed by distal
26 end of inflated balloon **14**. According, dilator **16** has been moved into the tenting and puncturing
27 position, adjacent to interaxial septum. At this stage, balloon **14** may be deflated or will soon be
28 deflated, and puncture of the interaxial septum is imminent.

29 With reference now to FIG. **12**, shown is another embodiment of overhanging balloon **14**
30 which may be deployed in embodiments of transseptal insertion device **10**. Overhanging balloon
31 **14** may include ring or band **28** around a portion of balloon **14**. Ring or band **28** may serve as a

1 marker, similar to markers **24** shown in FIG. 11. Hence, ring **28** may be radiopaque or echogenic
2 and may be view by scanning devices used for visualization in cardiac catheterizations (*e.g.*,
3 fluoroscopic imaging devices). Similar to the letter E or C, the view of the ring **28** changes as the
4 distal tip **13** of transseptal insertion device **10** moves more posterior. When in a least posterior
5 position, ring **28** may appear as just a line or band positioned across axis of transseptal insertion
6 device **10**. When device **10** is rotated so that distal tip **13** is significantly closer to the posterior,
7 ring **28** may appear as a full “flat” circle or ring. In FIG. 12, distal tip **13** is partially rotated so that
8 ring **28** is partially visible.

9 With reference to both FIGS. 11 and 12, the marker **24** and ring **28** are described and shown
10 as located on balloon **14**. In embodiments, marker **24** and/or ring **28** may also be located on sheath
11 **12** and/or dilator **16**. So located, marker **24** and/or ring **28** would operate in effectively the same
12 manner as described above (*i.e.*, the arms of the E would disappear as the distal end was moved
13 more to the posterior and the ring would become more visible). Markers **24** and/or rings **28** may
14 be placed on all of balloon **14**, sheath **12**, and dilator **16**, or a combination thereof.

15 With reference now to FIG. 13, shown is distal end of an embodiment of transseptal
16 insertion device **10** that includes dilator **16** with electrode tip. Shaft of dilator **16** defines and
17 contains a center lumen **50**. Lumen **50** may be defined in the range of, but not limited to, 0.020 to
18 0.040 inches. Dilator **16** may be made from a polymer material (*e.g.*, HDPE, LDPE, PTFE, or
19 combination thereof). Dilator shaft **16** shown includes a distal electrode tip **52**. Electrode tip **52**
20 may be comprise a metallic alloy (*e.g.*, PtIr, Au, or combination thereof). In preferred
21 embodiments, the size and shape of electrode tip **52** is selected to be sufficient to generate a plasma
22 for in vivo ablation of tissue in an applied power range of, but not limited to, 20-30W. Electrical
23 conductor **54** extends from electrode tip **52** to the proximal end (not shown) of the dilator **16**.
24 Electrical conductor **54** may run axially through an additional lumen **56** defined by and contained
25 in dilator shaft **16**. Electrical conductor **54** may contain a coil feature **58** to accommodate
26 lengthening during bending or flexing of dilator **16**.

27 Attached to distal end of sheath **12** is contains overhanging balloon **14** that is connected to
28 hypotube **17**. Overhanging balloon **14** may be made from a polymer material (*e.g.*, PET, Nylon,
29 Polyurethane, Polyamide, or combination thereof). Overhanging balloon **14** may be in the range
30 of, but not limited to, 5-20 mm in diameter and 20-30 mm in length. Overhanging balloon **14** may
31 be inflated via injection of gas or fluid through hypotube **17** connected to balloon **14**. Overhanging

balloon **14** may be deflated by removing gas or fluid in balloon **14** through hypotube **17** connected to balloon **14**. During the proper functioning or operation of transseptal insertion device **10** for puncturing the interatrial septum, balloon **14** may be deflated when dilator **16** moves out of lumen **15** by removing gas or fluid from balloon **14**. Overhanging balloon **14** is of form such balloon **14** overhangs or extends from distal end **13** of sheath **12**. Overhang or extension **60** may be in the range of, but not limited to, 0.0 mm-5.0 mm. The end of the overhang or extension **60** is the plane to which dilator **16** remains sub-planar until moving to tent and puncture the interatrial septum.

With reference now to FIG. **14**, shown is an embodiment of transseptal insertion device **10** that includes a mechanical deflection mechanism. Mechanical deflection mechanism may enable distal end of sheath **12** to be deflected or angulated to various angles with respect to axis of transseptal insertion device **10**. Mechanical deflection mechanism may include a pull wire anchor **40** affixed to distal end of sheath **12** and pull wire actuator **42** connected to pull wire anchor **40** with pull wire (not shown). Rotation of pull wire actuator **42**, as shown, may exert force on pull wire anchor **40** that deflects or angulates distal end of sheath **12**. Pull wire actuator **42** may be rotated by handle connected thereto (not shown). Deflection or angulation of distal end of sheath **12** may enable better intersection (*e.g.*, more perpendicular, flush) with interaxial septum and, therefore, better puncture and insertion by transseptal insertion device **10**.

With reference now to FIG. **15**, shown are three (3) embodiments of curved dilators **16**, each with a different curve profile (*i.e.*, different angle of deflection or curve). Curved dilators **16** may be used in embodiments of transseptal insertion device **10** with flexible or malleable sheath **12**. Such a flexible or malleable sheath **12** may be referred to as a steerable sheath **12** as it is “steered” by curved dilator **16** inserted in sheath **12**.

With reference now to FIG. **16**, shown is an embodiment of transseptal insertion device **10** with an external stabilizer **80**. Stabilizer **80** keeps proximal end of transseptal insertion device **10** stable while allowing movement of transseptal insertion device **10** towards the distal and proximal ends of device **10**, rotational/torqueing movement of proximal end of device **10**, and manipulation of dials or other controls of device **10**. In effect, stabilizer **80** substantially prevents unwanted movement of the transseptal insertion device **10** and, importantly, distal end of sheath **12**, balloon **14**, and dilator **16**.

Stabilizer **80** includes connecting rods or arms **82** that connect stabilizer **80** to handle **70** at proximal end of transseptal insertion device **10**. Connecting arms **82** are attached to stabilizer

1 platform **84**. Connecting arms **82** preferably hold the handle **70** securely and tightly, while
2 permitting desired rotational movements and control manipulation. Stabilizer platform **84** is
3 moveably attached to stabilizer base **86** so that stabilizer platform **84**, and hence handle **70** and
4 transseptal insertion device **10**, may be slid forwards and backwards along axis of transseptal
5 insertion device **10** towards and away from insertion point in patient (typically femoral vein at the
6 groin of patient). Stabilizer base **86** is typically secured to a flat, stable surface, such as a table, or
7 the leg of the patient. Configured as such, stabilizer **80** prevents unwanted vertical, rotational, or
8 other movement of transseptal insertion device **10** and its handle **70**, keeping transseptal insertion
9 device **10** and its handle **70** stable while permitting precise manipulation of handle **70** and its
10 controls.

11 With continuing reference to FIG. **16**, as shown, proximal end of transseptal insertion
12 device **10** may include a handle **70** for control and manipulation of transseptal insertion device **10**
13 and, particularly, dilator **16** and distal end of dilator **16**. Handle **70** may include a dial **72** that may
14 be used to turn or deflect distal end of dilator **16**, effectively moving the distal end of dilator **16** up
15 or down in relation to axis of transseptal insertion device **10** (as indicated by arrows in FIG. **16**).
16 Handle **70** may also include dial **74** for extruding/extending distal end of dilator **16** out of sheath
17 **12** and retracting dilator **16** back into sheath **12**, effectively moving dilator **16** along axis of
18 transseptal insertion device **10** (as indicated by arrows in FIG. **16**). Handle **70** may also be rotated,
19 as indicated by rotational arrow in FIG. **16**, in order to deflect or turn distal end of transseptal
20 insertion device to left or right in relation to axis of transseptal insertion device **10**, increasing or
21 decreasing dilator **16** angle of deflection in that direction. If dial **72** moves distal end of dilator **16**
22 along Y axis, and transseptal insertion device **10** axis is considered the Z axis, so that dial **74** moves
23 dilator **16** along Z axis rotating handle **70** moves distal end of transseptal insertion device **10** (and
24 hence distal end of dilator **16**) along X axis. Handle **70** includes a port through which dilator **16**
25 and other devices inserted into transseptal insertion device **10** may be inserted. Handle **70** may
26 also include one or more tubes or other ports permitting connection to external hubs and external
27 energy sources, inflation liquids or gas.

28 In embodiments shown herein, balloon **14** and dilator **16** may be used as energy sources in
29 the left atrium and may be used to deliver energy to the pulmonary veins, left atrial appendage,
30 mitral valve and the left ventricle present in the left atrium. Such embodiments may include
31 external energy sources connected to balloon **14** and/or dilator **16** through wires or other

1 conductors extending lumen in sheath **12**. Delivery of energy via balloon **14** or dilator **16** may be
2 thermal/Cryo or radiofrequency, laser or electrical. The delivery of such energy could be through
3 a metallic platform such as a Nitinol cage inside or outside balloon **14**. Transseptal insertion device
4 **10** may also include an energy source external to the proximal end of the sheath and operatively
5 connected to balloon **14** to deliver energy to balloon **14**.

6 With reference now to FIGS. **17A-17B** shown is an embodiment of transseptal insertion
7 device **10** enabling differential expansion of balloon **14**. Differential expansion of balloon **14**
8 enables balloon **14** inflation to be adjusted based on the needs of the device operator and the
9 conditions present in the patient's heart. For example, the size of the fossa ovalis portion of the
10 interatrial septum may dictate the desired size of the inflated balloon **14** needed at the puncture
11 site (interatrial septum is often punctured through the fossa ovalis). Fossae can vary greatly in size.
12 The larger the fossa, the harder it will be to tent the interatrial septum with balloon **14**. Large fossa
13 tend to be saggy and more difficult to manipulate. Hence, with a large fossa, a larger distal end of
14 balloon **14** will make proper tenting of the interatrial septum easier. Indeed, it may be ideal to have
15 balloon **14** inflated uniformly until intersecting or passing through fossa and then differentially
16 expanding distal end **142** of balloon **14** to move fossa out of the way. In FIG. **17A**, distal end or
17 portion **142** of balloon **14** is smaller (less expanded) than proximal end **144** of balloon **14**.

18 Oppositely, the smaller the fossa, the easier it will be to tent the interatrial septum but, there
19 will be less room to maneuver balloon **14** near interatrial septum. Consequently, a smaller distal
20 end of balloon **14** is desired. It also may be beneficial to expand the proximal portion **144** more in
21 order to help fix or secure balloon **14** in place. In FIG. **17B**, distal end or portion of balloon **14** is
22 larger (more expanded) than proximal end or portion of balloon **14**. In both FIGS. **17A** and **17B**,
23 dilator **16** has extruded from sheath **12** and past distal end of balloon **14**, tenting interatrial septum
24 **100**, and puncture is imminent.

25 This differential expansion of balloon **14** may be achieved, *e.g.*, by using different materials
26 for different portions of balloon **14** (*e.g.*, a more expandable material for distal end **142** than
27 proximal end or portion **144**, or vice versa). In general, balloon **14** may be made of either compliant
28 or non-compliant material, or a combination thereof. Compliant material will continue expanding
29 as more inflating liquid or gas is added to balloon **14** (at least until failure). Non-compliant material
30 will only inflate up to a set expansion or designated inflation level. Combinations of compliant
31 and non-compliant material may be used to provide a differentially expanding balloon **14**. For

1 example, distal end **142** may be formed from compliant material and proximal end **144** from non-
2 compliant material to enable a larger distal end **142**. Oppositely, proximal end **144** may be formed
3 from compliant material and distal end **142** from non-compliant material to enable a larger
4 proximal end **144**. Other means for providing differential expansion of balloon **14** may be used,
5 such as applying energy to different portions of balloon **14** to increase or decrease the compliance,
6 and expandability, of that portion.

7 Balloon **14** may also be used to direct other equipment into these anatomical locations or
8 be used as an angiographic or hemodynamic monitoring balloon. Differential expansion of balloon
9 **14** may be utilized for proper orientation or direction of such equipment.

10 With reference now to FIG. **18**, shown is an embodiment of a malleable transseptal needle
11 **90** that may be used with transseptal insertion device **10** with a flexible sheath or otherwise capable
12 of multiple angulations. In embodiments, malleable transseptal needle **90** may be of a variety of
13 diameters and lengths. For example, embodiments include an 18 gauge transseptal needle and that
14 is available in 71 cm, 89 cm, and 98 cm lengths. In embodiments, the malleable transseptal needle
15 **90** has different stiffness in a proximal segment **92**, distal segment **94**, and in a middle segment **96**
16 between. For example, malleable transseptal needle **90** may be stiffer in the proximal segment **92**
17 and distal segment **94** and more flexible (less stiff) in a middle segment or mid-section **96**. The
18 mid-section may be the section where transseptal insertion device **10** and dilator **16** angulate. In
19 an embodiment, malleable transseptal needle **90** is used and a control handle provided that enables
20 three-dimensional movements. Malleable transseptal needle **90** shown is, preferably, malleable or
21 flexible at least in part. Proximal end **92** of malleable transseptal needle **90** may be stiff (*e.g.*, made
22 from a stiff material, such as a metal). Mid-section or middle **96** of malleable transseptal needle
23 **90** may be malleable or flexible (*e.g.*, made from a flexible, malleable material, such as rubber).
24 Accordingly, mid-section may flex or bend, enabling malleable transseptal needle **90** to pass
25 through angulated or flexed sheath **12**.

26 Distal end **94** of malleable transseptal needle **90** (*i.e.*, end that punctures interatrial cardiac
27 septum) may be stiff with a cap or electrode at its tip for delivering energy to interatrial septum to
28 puncture interatrial septum. In embodiments, transseptal needle is able to transmit radiofrequency
29 energy to create a controlled septal puncture. Such a transseptal needle may or may not be
30 malleable, but is able deliver RF energy through a cap or crown (*e.g.*, an electrode) at its distal end
31 tip. The needle **90** may be connected, *e.g.*, on proximate end (not shown) to a radiofrequency (RF)

1 energy source (not shown) at, *e.g.*, external hub, that provides RF energy through needle to its
2 distal end tip. In such an embodiment, dilator **16** may tent interaxial septum and RF energy capable
3 transseptal needle may create puncture of interaxial septum through delivery of RF energy.

4 Embodiments may include an additional dilator which would be able to dilate the distal
5 end of sheath **12**, or the entire sheath length, thereby significantly increasing the French size of the
6 sheath **12**. For example, balloons deployed within sheath **12** may be inflated to expand sheath **12**.
7 In such embodiments, transseptal insertion device **10** may, therefore, be used to accommodate and
8 deliver larger devices or be able to retrieve devices once they have been extruded from sheath **12**
9 and have embolized. Such balloons may be inflated through one or more hypotubes.

10 In embodiments, energy, typically electrical energy, may directed through transseptal
11 insertion device **10** may be used to increase or decrease the French size of sheath **12**. In such
12 embodiments, sheath **12** is fabricated from materials that are known to increase in malleability and
13 or expand when certain energies are applied. In this manner, the French size of sheath **12** may be
14 adjusted to a size deemed necessary during a given procedure. Such energy may be applied through
15 wires or conductive material, connected to energy source external to proximal end of transseptal
16 insertion device **10**, attached to or fabricated within sheath **12** or other components of transseptal
17 insertion device **10**. Likewise, parts or portions of transseptal insertion device **10** may be
18 selectively made more rigid or more malleable/soft with the application of energy. Therefore, with
19 the application of differential energy to different parts of transseptal insertion device **10** at different
20 times, transseptal insertion device **10** size may be adjusted to enable various devices that are
21 ordinarily larger and bulkier than the catheter to traverse through the catheter. In embodiments,
22 transseptal insertion device **10** may accommodate devices up to 36 Fr.

23 In an embodiment of transseptal insertion device **10**, visualization of an intrathoracic region
24 of interest using MRI techniques may be provided. Embodiments may, for example, provide a
25 needle system comprising a hollow needle having a distal portion and a proximal portion, said
26 distal portion having a distal-most end sharpened for penetrating a myocardial wall. The needle
27 may include a first conductor, an insulator/dielectric applied to cover the first conductor over the
28 proximal portion of said needle and a second conductor applied to cover the insulator/dielectric.
29 The method may further direct the needle system into proximity to a myocardial wall, track
30 progress of the needle system using active MRI tracking, penetrate the myocardial wall to approach

1 the intrathoracic region of interest, and, use the needle system as an MRI antenna to receive
2 magnetic resonance signals from the intrathoracic region of interest.

3 In related embodiments, MRI antenna may be installed on distal tip **13** of sheath **12**, dilator
4 **16** or on balloon **14**, similar to ultrasound chips or transducers **226** or **326** described above. Wires
5 connecting such MRI antenna or other MRI components may pass through lumen in dilator **16** or
6 sheath **12** and connect with appropriate magnetic resonance energy source on exterior of distal end
7 of transseptal insertion device **10**.

8 With reference now to FIGS. **19A-22B**, shown are an embodiment of an improved
9 transseptal puncture system **500** with puncture member balloon seal. With reference to FIGS. **19A-**
10 **19C**, shown are a side view, a close-in side view of the section C, and a cross-sectional view of
11 the section D-D of the transseptal puncture device **500**, respectively, when the puncture member
12 balloon **504** is deflated. With reference now to FIGS. **20A-20C**, shown are a side view, a close-in
13 side view of the section E, and a cross-sectional view of the section F-F of the transseptal puncture
14 device **500**, respectively, when the puncture member balloon **504** is inflated.

15 Referring to FIGS. **19A-20C**, the transseptal puncture device **500** includes a radio-
16 frequency (RF) generator plug **501**, Y-connector **502**, and puncture member multi-lumen extension
17 **503** that includes sheath **514** and puncture member **515** (see FIG. **21B**). The RF generator plug
18 **501** is connected to the puncture member multi-lumen extension **503** through a Y-connector **502**,
19 and provides power for a RF generator (not shown) that may be positioned in the puncture member
20 **515** located in the multi-lumen extension **503**. The puncture member **515** is located inside the
21 sheath **514**, and has a distal end (puncture tip) **506** that is positioned toward the cardiac interatrial
22 septum of the patient when the device **500** is in use. The puncture member balloon **504** is mounted
23 on the puncture member **515** and is located near the distal end **506** of the puncture member **515**.
24 The close-in side view FIG. **19B** and the cross-sectional view FIG. **19C** show deflated puncture
25 member balloon **504**, while the close-in side view FIG. **20B** and the cross-sectional view FIG. **20C**
26 show inflated puncture member balloon **504**.

27 The puncture member **515** includes an puncture member tube **507** for inflating or deflating
28 the puncture member balloon **504**, and a lumen **508** which is connected to the puncture member
29 tube **507** that supplies gas or fluid to the puncture member tube **507** to inflate the puncture member
30 balloon **504**. The puncture member **515** also includes at least one RF tip **505** at the distal end **506**
31 of the puncture member **515**. The RF tip **505** is capable of delivering RF energy. The RF generator

(not shown) produces RF energy, and the RF energy is supplied to the RF tip 505. The puncture member 515 includes a lumen 509 for wires that delivers RF energy to the RF tip 505.

With reference to FIGS. 21A-21B, shown are a side view and a close-in side view of the section D of the transseptal puncture device 500, respectively, when the positioning balloon 510 is inflated. The puncture member multi-lumen extension 503 includes the sheath 514 and the puncture member 515. The sheath 514 may have the sheath marker band 513, and the puncture member balloon 504, which is mounted on the puncture member 515, may be aligned with the sheath marker band 513. The sheath 514 includes one or more positioning balloons 510, one or more inflation ports 512 connected to the positioning balloons 510, and at least one tube 516 that delivers gas or fluid to the inflation port 512 to inflate the positioning balloons 510. The tube 516 may be the hypotube 17 (see FIG. 13). The sheath 514 also includes one or more deflation ports 511 that is connected to the positioning balloons 510. When the puncture member balloon 504 is inflated, the inflated puncture member balloon 504 seals the one or more deflation ports 511 in the sheath 514, preventing leak from the positioning balloons 510 and permitting inflation of the positioning balloons 510. The position balloons 510 are then inflated through the inflation port 512 of the sheath 514. The non-compliant or semi-compliant puncture member balloon 504 seals off the deflation ports 511 of the sheath 514, allowing the positioning balloons 510 to inflate and position the distal end 506 of the puncture member 515 to the fossa ovalis (see FIG. 6 for example).

With reference to FIGS. 22A-22B, shown are a side view and a close-in side view of the section B of transseptal puncture device 500, respectively, when the puncture member 515 advances toward fossa ovalis. Once precisely positioned, the puncture member 515 is then pushed distally towards the fossa ovalis. The inflated puncture member balloon 504 moves away from the deflation ports 511, exposing the deflation ports 511. The positioning balloons 510 deflate through the deflation ports 511. However, the positioning balloons 510 may be deflated through both inflation ports 512 and the deflation ports 511.

Additional embodiments, implementations, applications and methods of use of the above improved transseptal puncture system are possible. With reference now to FIGS. 23A-23C, shown are a close-in side view of the section E with inflated balloon, a close-in side view of section C with deflated balloon, and a cross-sectional view of the section D-D of the transseptal puncture device 500, respectively. With reference now to FIGS. 24A-24B, shown are a side view of a puncture member that is advanced beyond a shaft and a side view of a puncture member with

1 inflated balloon **510** of the transseptal puncture device **500**, respectively. With reference to FIGS.
2 **25A-25C**, shown are side views of the distal end portion of the puncture member multi-lumen
3 extension **503** and a cross-sectional view of the distal end portion of the puncture member multi-
4 lumen extension **503** of the transseptal puncture device **500** of the additional embodiment,
5 respectively.

6 In these embodiments, a method of using the improved transseptal puncture system may
7 use the puncture member balloon **504** for visibility, anchoring against the septum and preventing
8 inadvertent advancement into the left atrium. In such an embodiment, the transseptal puncture
9 member balloon **504** is inflated (see FIG. **23A**) through the puncture member tube **507**, once the
10 puncture member is outside the shaft and is tenting the septum (*i.e.*, the puncture member balloon
11 is pressing against the septum, tenting the septum away from shaft end). The puncture member
12 balloon **504** is 5 to 8 mm (distance L in FIG. **25B**) proximal to the tip of the puncture member and
13 prevents the puncture member from being pushed beyond the 5 to 8 mm into the left atrium. After
14 successful puncture of the interatrial septum, a 035 (0.035") guidewire in the guide wire access
15 lumen (or center lumen) **518** (See FIG. **23C**) is advanced into the left atrium and the puncture
16 member balloon **504** is deflated (see FIG. **23B**) and the puncture member withdrawn back into the
17 shaft.

18 In the embodiments, the positioning balloon **510** on the sheath or shaft **514** may have
19 separate hypotubes for inflation and deflation. For example, the sheath **514** may have inflation
20 hypotube **516a** and a deflation hypotube **516b** to inflate and deflate the positioning balloon **510**,
21 respectively. However, the embodiment is not limited to this configuration. The positioning
22 balloons **510** may be inflated and deflated through the same hypotube (for example, see FIG. **3A**).
23 The puncture member **515** has a puncture member tube **507** to inflate and deflate the puncture
24 member balloon **504**. The puncture member has a radiofrequency tip **505** at a distal end of the
25 puncture member **506**. For the small, medium and large curl shafts, the puncture member length
26 is small, medium and large. The curl shaft chosen depends on the size of the atrium. For example,
27 a small curl shaft is used for small atrium. When advanced beyond the shaft **514**, the puncture
28 member **515** can only be advanced to a max of 5 to 8 mm coming to a hard stop (see FIG. **24A**).
29 In another embodiment, the positioning balloon **510** may be inflated through a separate hypotube,
30 overhangs the shaft by 3 mm, and has variable dimension based on the amount of fluid or air
31 infused or insufflated into the balloon (see FIG. **24B**). For small, medium and large curl shafts, the

1 puncture member **515** has a conical tip with no radiofrequency or another energy source. The
2 puncture member may have an 0352 lumen (0.0352”) to 040 (0.040”) lumen **518**. Through this
3 lumen, a wire which may or may not have radiofrequency energy capability may be advanced
4 across the septum. Through this lumen a Brockenbrough needle or a radiofrequency tip needle
5 could be advanced and used to cross the septum. In FIGS. **25A-25B**, the wiring member **519** may
6 be the wire, Brockenbrough needle, or a radiofrequency tip needle. The transseptal insertion device
7 **500** includes a sheath **514** that defines at least one lumen **517** therein, one or more positioning
8 balloons **510** that are connected to the distal end **506** of the sheath **514**, a puncture member **515**
9 movably positioned within the at least one lumen **517**, and a puncture member balloon **504**
10 mounted on the puncture member **515**. The puncture member **515** defines a center lumen **518**
11 therein, and a wire member **519**, for example, is positioned inside the center lumen **518**.

12 Embodiments may also include a method of performing a septostomy using the improved
13 transseptal puncture system **500**. In such a method, once the shaft has crossed the septum, the
14 positioning balloon **510** may be used to perform a septostomy. The positioning balloon **510** could
15 be configured in multiple shapes and forms; for example, the positioning balloon may be shaped
16 in a spherical, conical, reverse conical, teardrop shaped, pear-shaped, double-balloon shape with a
17 double balloon being of varying sizes proximally or distally. Embodiments of the improved
18 transseptal puncture system **500** may include two or more positioning balloons **510** adjacent to one
19 another with separate micro-ports connected to the hypotube for external inflation or deflation.

20 Embodiments may also include methods using the improved transseptal puncture system
21 **500** for atraumatic navigation in the left atrium. Once the shaft **514** of the improved transseptal
22 puncture system **500** has crossed over into the left atrium, the positioning balloon **510** may be re-
23 inflated for navigation in an atraumatic fashion to different parts of the left atrium including
24 navigating to the left atrial appendage, to the pulmonary veins, to the mitral valve and in the left
25 ventricle.

26 Embodiments may also include methods of using the improved transseptal puncture system
27 **500** wherein the puncture member balloon **504** is used for anchoring the improved transseptal
28 puncture system **500** against the septum. In the embodiments of the method, once the transseptal
29 puncture system **500** is passed into the left atrium, the puncture member balloon **504** is re-inflated
30 and then the system is pulled back. When pulled back, the puncture member balloon **504** act as an
31 anchor against the septum.

1 Embodiments may also include methods of using the improved transseptal puncture system
2 **500** wherein the shaft **514** of the system is used as a delivery guiding catheter to deliver devices.
3 The shaft may be used as a delivery guiding catheter for delivering various devices including left
4 atrial appendage occluder devices.

5 With reference now to FIG. **26**, shown is an embodiment of a method of using the improved
6 transseptal puncture system **500** where the positioning balloon **510a** is used as an occlusion balloon.
7 In embodiments, the positioning balloon **510a** may be used as an occlusion balloon in the left atrial
8 appendage and pulmonary veins in case of trauma, perforation and bleeding to either the left atrial
9 appendage or pulmonary veins. The catheter **515** may be used in the left atrial appendage with the
10 positioning balloon **510a** being inflated such as to occlude the left atrial appendage especially in
11 the eventuality of a perforation. The shaft positioning balloon may be inflated in the left atrial
12 appendage such as to occlude the left atrial appendage.

13 With reference now to FIG. **27**, shown is an embodiment of a method of using the improved
14 transseptal puncture system **500** for left atrial appendage thrombectomy. In the embodiment shown,
15 the improved transseptal puncture system **500** includes a pigtail catheter **519a** that is located within
16 the shaft of the guiding catheter. As shown, through the shaft of the guiding catheter a pigtail
17 catheter is advanced into the distal left atrial appendage. Lavage of the left atrial appendage may
18 be performed while injecting fluid, using the pigtail catheter **519a**, into the left atrial appendage
19 and aspirating it through the shaft of the guiding catheter. The pigtail catheter **519a** may also be
20 used to infuse other pharmaceuticals including thrombolytics in the left atrial appendage.

21 Embodiments may also include methods using the improved transseptal puncture system
22 **500** for identifying and positioning over a paravalvular leak. The positioning balloon **510** may be
23 used for visualization and anchoring against a prosthetic valves sewing ring annulus and stabilize
24 the guiding catheter such that a paravalvular leak may be traversed with the guiding wire more
25 easily.

26 Embodiment may also include a method of using the improved transseptal puncture system
27 **500** for laceration of the anterior mitral leaflet. Using the positioning balloon **510**, which would be
28 advanced to the anterior mitral leaflet, radiofrequency puncture member **515** or a radiofrequency
29 wire is advanced through the anterior mitral leaflet and advanced into the left ventricle.
30 Embodiments include a side port **509a** (see FIG. **25C**) in the shaft of the guiding catheter just
31 proximal to the positioning balloon through which a small 4 French Gauge catheter may be passed

1 over a wire into the left ventricle over this catheter or wire. A snare may be passed into the left
2 ventricle. The snare may be used to capture the wire which was placed in the left ventricle through
3 the positioning balloon guide and retracted back into the left atrium. Using this radiofrequency
4 wire which has now formed a loop traversing through the anterior mitral leaflet into the left
5 ventricle and returning back into the left atrium and the anterior mitral leaflet could therefore be
6 lacerated.

7 With reference now to FIG. 28, shown is an embodiment of a method of using the improved
8 transseptal puncture system 500 for MitraClip or other mitral repair prosthesis device removal.
9 Embodiments of this method may use a technique similar to placing the positioning balloon against
10 the mitral valve. Here, the positioning balloon 510 may be placed against a prosthesis like the
11 MitraClip which is now forming double orifices of the mitral valve with the radiofrequency wire
12 519b being advanced via one of the orifices into the left ventricle. The wire snared via a side port
13 catheter or wire 519c which is advanced into the left ventricle via the adjacent orifice thereby
14 forms a reel from the left atrium into the left ventricle and back into the left atrium such as to snare
15 the MitraClip or other percutaneous mitral repair devices. Using radiofrequency wire, the anterior
16 mitral leaflet is then lacerated right next to the repair device such as to cause an iatrogenic single
17 leaflet detachment. The method described herein could be repeated with the posterior aspect and
18 including the posterior mitral leaflet.

19 The MitraClip device or a similar mitral repair device would be held in place with a snare
20 or other holding devices such as an alligator clip which may be mechanical or may have magnetic
21 properties so as to prevent embolization of the MitraClip or other repair device. Once the repair
22 device is free, the clip may be retrieved back into the positioning balloon guiding catheter and
23 removed from the body.

24 With reference now to FIG. 29, shown is an embodiment of a method of using the improved
25 transseptal puncture system 500 for laceration of a bioprosthetic valve leaflet. The positioning
26 balloon 510 is placed into the base of the bioprosthetic valve leaflet using a radiofrequency
27 puncture member 515 and a radiofrequency capable wire or a radiofrequency wire which is
28 advanced through the bioprosthetic valve leaflet. A snare catheter over wire is then advanced via
29 the guiding catheter to a separate hole through the orifice of the bioprosthetic valve into the
30 adjacent chamber. The radiofrequency wire which was advanced through the bioprosthetic valve

1 leaflet is then snared by the snare catheter wire, thereby forming a loop or radial with the snared
2 radiofrequency wire. Using radiofrequency energy, the bioprosthetic leaflet is then lacerated.

3 With reference now to FIG. 30, shown is an embodiment of a method of using the improved
4 transseptal puncture system 500 wherein the system anchors in the pulmonary veins, performs
5 pulmonary venous angioplasty, and deliver either radiofrequency heat energy or cryo-energy. In
6 embodiments, the positioning balloon 510 is used to navigate into the pulmonary veins for
7 anchoring purposes as well as to deliver other therapeutic catheters into the pulmonary veins, such
8 as ablation catheters. The positioning balloon 510 may also be used for balloon angioplasty of the
9 pulmonary veins. The positioning balloon 510 may also be used itself to deliver energy in the form
10 of heat or used for cryoablation with the use of products such as liquid nitrogen which could be
11 circulated through the balloon via hypotubes from the outside.

12 With reference now to FIGS. 31A-32B, shown is an embodiment of a method of using the
13 improved transseptal puncture system 500 in which the positioning balloon 510 anchors in the
14 patent foramen ovale and identify multiple small atrial septal defects in a cribriform atrial septal
15 defect. The positioning balloon 510 may be positioned against the fossa from the right atrium and
16 navigated to a patent foramen ovale or identify multiple small atrial septal defects in a cribriform
17 atrial septal defect such that a patent foramen ovale or small atrial septal defects in a cribriform
18 atrial septal defect could be easily be traversed with a wire with a stable catheter.

19 Other embodiments include methods of using the improved transseptal puncture system
20 500 to deliver occluder devices. The positioning balloon shaft may also be used as a delivery
21 guiding catheter for delivering closure devices 519d including atrial septal defect occluder devices,
22 patent foramen ovale closure devices, patent ductus arteriosus, paravalvular leak closure devices
23 etc.

24 With reference to FIG. 33, shown is a workflow diagram for a method 600 for suitably
25 facilitating precise and safe transseptal puncture of a cardiac interatrial septum with a transseptal
26 insertion device 500. One or more positioning balloons 510, which are connected to a distal end
27 of a sheath 514 of the transseptal insertion device, are inflated, block 610. The puncture member
28 515 while the positioning balloons are inflated is advanced toward cardiac interatrial septum, block
29 611. The puncture member balloon 504 is inflated, once the puncture member 515 advances
30 beyond the distal end of the sheath 514 and is tenting the cardiac interatrial septum, block 612.
31 The puncture member 515 is positioned against the cardiac interatrial septum, block 613. The

1 puncture member balloon **504** is pressing against the cardiac interatrial septum while the puncture
2 member **515** is tenting the cardiac interatrial septum. The puncture member balloon **504** is deflated,
3 block **614**, and the one or more positioning balloons **510** are deflated, block **615**, before the
4 puncture member further advances to puncture the cardiac interatrial septum. Then, the puncture
5 member **515** advances to puncture the cardiac interatrial septum, block **616**. The transseptal
6 insertion device **500** advances crossing the cardiac interatrial septum, block **617**.

7 Since many modifications, variations, and changes in detail can be made to the described
8 preferred embodiments of the invention, it is intended that all matters in the foregoing description
9 and shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense.
10 Consequently, the scope of the invention should be determined by the appended claims and their
11 legal equivalents.