

DIRECTIONAL BALLOON TRANSSEPTAL INSERTION DEVICE FOR MEDICAL PROCEDURES

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the priority of U.S. Provisional Application Serial No. 62/821,062, filed on March 20, 2019, which is hereby incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

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

BACKGROUND

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

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

Some medical procedures may require catheterization into the left atrium of the heart. For this purpose, to avoid having to place a catheter in the aorta, access to the left atrium is generally achieved by accessing the right atrium, puncturing the interatrial septum between the left and right atria of the heart, and threading the catheter through the septum and into the left atrium. Transseptal 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 and other advantages may be provided by, for example, 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 balloons, one or more ultrasound transceivers, and a dilator. The sheath has a distal end that
17 is closest to the cardiac interatrial septum of a patient when the transseptal insertion device is in
18 use and a proximal end that is external to the patient. The one or more balloons are connected to
19 the distal end of the sheath and are contained in the sheath. The balloons, when inflated and the
20 transseptal insertion device is in use, overhangs and extends past the distal end of the sheath,
21 preventing accidental puncturing of the cardiac interatrial septum and stabilizing the transseptal
22 insertion device against fossa ovalis of the cardiac interatrial septum. The one or more ultrasound
23 transceivers emit and receive ultrasound waves, and convert the ultrasound waves to electrical
24 signals. The dilator is positioned within the at least one lumen. The dilator has a distal end and is
25 designed to and is capable of precisely puncturing the cardiac interatrial septum.

26 The transseptal insertion device may further include one or more hypotubes connected to
27 the one or more balloons. The one or more balloons are inflated by gas or fluid flowing through
28 the one or more hypotubes. The transseptal insertion device may further include at least one lumen
29 shaft contained in the sheath. The at least one lumen shaft defines the at least one lumen and the
30 dilator is positioned in said at least one lumen shaft. The one or more hypotubes may be contained

1 in the sheath outside said at least one lumen shaft. The one or more ultrasound transceivers may
2 be located on surfaces of the one or more balloons. The one or more ultrasound transceivers may
3 be located between the balloons. The one or more ultrasound transceivers may be oriented towards
4 the cardiac interatrial septum when the one or more balloons are inflated and the distal end of the
5 sheath is oriented towards the cardiac interatrial septum. The one or more ultrasound transceivers
6 may be oriented perpendicular to the sheath when the balloons are deflated. The one or more
7 ultrasound transceivers may be configured in the shape of a disc. The one or more ultrasound
8 transceivers may be connected to an external imaging device wirelessly or through a wire that runs
9 via the sheath, and may transmit the electrical signals to the external imaging device to produce
10 images of the cardiac interatrial septum from the received electrical signals. The dilator may
11 include cap or crown with radio frequency (RF) energy capability or capable of delivering RF
12 energy.

13 These and other advantages may be provided by, for example, 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, at least
16 one balloon, one or more ultrasound transceivers, and a dilator. The sheath has a distal end that is
17 closest to the cardiac interatrial septum of a patient when the transseptal insertion device is in use
18 and a proximal end that is external to the patient. The at least one balloon is connected to the distal
19 end of the sheath. The balloon, when inflated and the transseptal insertion device is in use,
20 overhangs and extends past the distal end of the sheath, preventing accidental puncturing of the
21 cardiac interatrial septum and stabilizing the transseptal insertion device against fossa ovalis of the
22 cardiac interatrial septum. The one or more ultrasound transceivers emit and receive ultrasound
23 waves, and convert the ultrasound waves to electrical signals. The dilator is positioned within the
24 at least one lumen. The dilator has a distal end and is designed to and is capable of precisely
25 puncturing the cardiac interatrial septum.

26 The transseptal insertion device may further include at least one hypotube connected to the
27 at least one balloon. The at least one balloon is inflated by gas or fluid flowing through the at least
28 one hypotube. The transseptal insertion device may further include at least one lumen shaft
29 contained in the sheath. The lumen shaft may define the at least one lumen and the dilator may be
30 positioned in said at least one lumen shaft. The hypotube may be contained in the sheath outside
31 the at least one lumen shaft. The one or more ultrasound transceivers may be located on a surface

of the at least one balloon. The one or more ultrasound transceivers may be oriented towards the distal end of the sheath when the at least one balloon is inflated and the distal end of the sheath is oriented towards the cardiac interatrial septum. The one or more ultrasound transceivers may be oriented perpendicular to the sheath when the at least one balloon is deflated. The one or more ultrasound transceivers may be connected to an external imaging device wirelessly or through a wire that runs via the sheath, and transmit the electrical signals to the external imaging device to produce images of the cardiac interatrial septum from the received electrical signals. The dilator may include cap or crown with radio frequency (RF) energy capability or capable of delivering RF energy.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features of embodiments disclosed herein are described below in connection with the accompanying drawings. The preferred embodiments described herein and illustrated by the drawings hereinafter be to illustrate and not to limit the invention, where like designations denote like elements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 **DETAILED DESCRIPTION**

4 The following detailed description is merely exemplary in nature and is not intended to
5 limit the described embodiments or the application and uses of the described embodiments. As
6 used herein, the word “exemplary” or “illustrative” means “serving as an example, instance, or
7 illustration.” Any implementation described herein as “exemplary or “illustrative” is not
8 necessarily to be construed as preferred or advantageous over other implementations. All of the
9 implementations described below are exemplary implementations provided to enable persons
10 skilled in the art to make or use the embodiments of the disclosure and are not intended to limit
11 the scope of the disclosure, which is defined by the claims. Furthermore, there is no intention to
12 be bound by any expressed or implied theory presented in the preceding technical field,
13 background, brief summary or the following detailed description. It is also to be understood that
14 the specific devices and processes illustrated in the attached drawings, and described in the
15 following specification, are simply exemplary embodiments of the inventive concepts defined in
16 the appended claims. Hence, specific dimensions and other physical characteristics relating to the
17 embodiments disclosed herein are not to be considered as limiting, unless the claims expressly
18 state otherwise.

19 With reference to FIGS. **1A-1C**, shown is an embodiment of transseptal insertion device
20 or catheter **10**. Shown is the distal end of transseptal insertion device **10**, *i.e.*, the end of transseptal
21 insertion device **10** with opening through which dilator, catheter, and needle may extend, *e.g.*, to
22 puncture interatrial cardiac septum. As shown in FIG. **1A**, transseptal insertion device **10** includes
23 outer sheath or balloon shaft **12** and one or more balloons **14** located at distal tip **13** of transseptal
24 insertion device **10**. Sheath **12** may contain and define a center lumen **15**. Sheath **12** may be
25 fabricated from various materials, including, *e.g.*, polymers, including thermoplastics elastomers
26 (TPEs) such as PEBA (*e.g.*, Pebax®), nylons, thermoplastic polyurethanes (TPUs) such as
27 Pellathane®, similar materials and combinations thereof. Sheath **12** may be referred to as catheter
28 shaft and used in cardiac catheterizations. After puncture, sheath **12** may be inserted through
29 septum into left atrium. Alternatively, sheath **12** may contain a separate catheter that is inserted
30 through septum post puncture. Transseptal insertion device **10** also includes dilator **16**, positioned

1 in center lumen **15**, as shown in FIG. **1B**. The one or more balloons **14** are preferably sealed, air-
2 tight and water-tight, on both its ends to sheath **12**.

3 With continuing reference to FIG. **1A**, in view shown, overhanging one or more balloons
4 **14** are uninflated. Although cross-section of balloons **14** shown on top and bottom of distal tip **13**,
5 balloons **14** preferably extend around circumference of distal tip or end **13** of transseptal insertion
6 device **10**. Overhanging one or more balloons **14** are of form such that balloons **14** overhang or
7 extend from distal tip **13** of sheath **12** when inflated.

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

16 With reference now to FIG. **1C**, dilator **16** is shown positioned within center lumen **15** of
17 sheath **12**. Tip of dilator **16** is positioned within distal tip **13** of transseptal insertion device **10** sub-
18 planar to end of transseptal insertion device **10**. The position shown is position dilator **16** may be
19 in immediately prior to inflation of one or more balloons **14**. It is noted that the relative sizes of
20 catheter/sheath **12** and dilator **16** shown are for illustrative purposes as the diameter of dilator **16**
21 may be relatively larger or smaller than shown in relation to the diameter of sheath **12**. Ordinarily,
22 dilator **16** has smaller diameter or gauge than catheter/sheath **12**, although fit of dilator **16** in
23 catheter/sheath **12** is preferably snug enough so that dilator **16** does not move (laterally or axially)
24 relative to position or “wobble” within transseptal insertion device **10**. Dilator **16** necessarily has
25 a smaller diameter than sheath **12**. In embodiments, sheath **12** material may be sufficiently
26 malleable to enable larger diameter dilators **16**, and other larger diameter devices, to be passed
27 through sheath **12**. In such embodiments, sheath **12** will stretch to accommodate the larger
28 diameter dilator **16** or other device.

29 With reference to FIG. **2A**, shown is a side perspective view of an embodiment of
30 transseptal insertion device or catheter **200**. With reference to FIG. **2B**, shown is the distal end of
31 transseptal insertion device **200**, *i.e.*, the end of transseptal insertion device **200** with opening

1 through which dilator, catheter, and needle may extend, *e.g.*, to puncture interatrial cardiac septum.
2 As shown in FIG. 2A, transseptal insertion device 200 includes outer sheath or catheter shaft 212
3 and one or more balloons 214 located at distal tip 213 of transseptal insertion device 200. Sheath
4 212 may contain lumen shaft 211 that defines center lumen 215. Sheath 212 may be fabricated
5 from various materials, including, *e.g.*, polymers, including thermoplastics elastomers (TPEs) such
6 as PEBA (*e.g.*, Pebax®), nylons, thermoplastic polyurethanes (TPUs) such as Pellathane®, similar
7 materials and combinations thereof. Sheath 212 may be referred to as catheter shaft and used in
8 cardiac catheterizations. After puncture, sheath 212 may be inserted through septum into left
9 atrium. Alternatively, sheath 212 may contain multiple lumen shafts that define multiple lumens
10 separately. Transseptal insertion device 200 also includes dilator 216, positioned in center lumen
11 215. The one or more balloons 214 are preferably sealed, air-tight and water-tight, on both their
12 ends to sheath 212. Transseptal insertion device 200 includes hypotube 217 for inflation or
13 deflation of one or more balloons 214. Hypotube 217 may be contained in sheath or catheter shaft
14 212. Transseptal insertion device 200 may further include a port (not shown) connected to
15 hypotube 217 to supply gas or fluid to inflate one or more balloons 214, or to remove gas or fluid
16 from one or more balloons 214 to deflate balloons 214. Balloons 214 may be fully inflated or
17 deflated, or may be inflated or deflated as much as desired. With reference to FIG. 2B, shown is a
18 front, cross-sectional view of distal end 213 of the embodiment of transseptal insertion device 200
19 that shows cross-sectional views of sheath 212, center lumen 215, and hypotube 217.

20 In the embodiment shown in FIGS. 2A and 2B, transseptal insertion device 200 may
21 include ultrasound chips or transducers 26 for ultrasound imaging or visualizing (see FIGS. 2C
22 and 2D). The transseptal sheath 212 or balloon 214 may house (inside or on) an ultrasound chip
23 or transducer which may be used to guide the insertion procedure. Ultrasound chip or transducer
24 emits and receives ultrasound energy, that may be detected by known ultrasound visualization
25 devices, to create an image of the cardiac chambers (*e.g.*, the right atrium, fossa, interatrial septum,
26 left atrium, atrial appendage, mitral valve, ventricle, etc.). Ultrasound chips and transducers are
27 transducers that convert ultrasound waves to electrical signals and/or vice versa. Those that both
28 transmit and receive may also be called ultrasound transceivers; many ultrasound sensors besides
29 being sensors are indeed transceivers because they can both sense and transmit. Such imaging will
30 allow the operator(s) of transseptal insertion device 200 to visualize the cardiac chambers and the
31 determine the location of the distal end or tip 213 of transseptal insertion device 200, enabling

1 more precise operation of transseptal insertion device **200**. Such a ultrasound chips or transducers
2 used may be similar to ultrasound chip or transducer described in US Patent Application
3 Publication No. 2003/019546, which is herein incorporated by reference, or any other ultrasound
4 transducer known to those of ordinary skill in the art that may be fabricated on scale small enough
5 to be deployed on or in sheath **212** or balloon **214**.

6 With reference to FIGS. **2C** and **2D**, shown are embodiments of transseptal insertion device
7 **200** with ultrasound imaging or visualizing capability. Balloon **14** shown includes one or more
8 ultrasound chips or transducers **26** deployed in or on balloon **14**. Ultrasounds chips or transducers
9 **26** may be ultrasound transceivers that both emit and receive waves, convert the ultrasound waves
10 to electrical signals, transmit the electrical signals, *e.g.*, through a wire that runs via sheath **12**.
11 Ultrasounds chips or transducers **26** may be connected via WiFi or other wireless connection, to
12 an external imaging device that produces images from the received signals (both still and video
13 images).

14 Ultrasound chips or transducers **26** may be affixed to interior or exterior surface of balloon
15 **14**. Ultrasound chips or transducers **26** may be arranged in a line, disc, or cross-shape. Ultrasound
16 chips or transducers **26** may be arranged to be forward facing (*e.g.*, on distal end of balloon facing
17 towards interatrial septum), as shown in FIG. **2C**, or in a different direction/orientation, such as
18 sideways and forward facing (*e.g.*, facing towards interatrial septum and facing perpendicular to
19 the distal or front end), as shown in FIG. **2D**. Indeed, orientation of ultrasound chips or transducers
20 **26** may depend on whether balloon **14** is inflated or not. When balloon **14** is fully inflated, as
21 shown in FIGS. **2C** and **2D**, ultrasound transducer **26** may be forward facing as shown in FIG. **2C**
22 or forward and perpendicularly facing as shown in FIG. **2D**. However, when balloon **14** is deflated,
23 ultrasound transducer **26** may be folded flat and positioned on side of distal tip **13** of sheath **12**.
24 Hence, when balloon **14** is deflated, ultrasound chip or transducer **26** may be side-facing
25 (perpendicular to an axis of the sheath). During inflation ultrasound transducer **26** orientation will
26 change as balloon **14** inflates (moving from side-facing orientation to forward facing orientation
27 with the ultrasound transducer **26** shown in FIG. **2C**). Accordingly, operator(s) of transseptal
28 insertion device **200** may vary the inflation of balloon **14** to achieve different orientations of
29 ultrasound transducer **26** for different imaging views.

30 Ultrasound chip or transducers **26** may emit and/or receive/detect ultrasound waves that
31 may be reflect off of surfaces and structures, *e.g.*, within atrium, and then read by imaging system

1 (not shown), *e.g.*, connected to ultrasound chips or transducers **26** via wire or cable extending
2 through, *e.g.*, lumen **15** in sheath **12**. In this manner, ultrasound chips or transducers **26** may enable
3 visualization of the interatrial septum and the left atrial structures.

4 It is also noted that ultrasound chips or transducers **26** may be deployed on distal tip **13** of
5 sheath **12** (or elsewhere on or in sheath **12**). Ultrasound chips or transducers **26** may be installed
6 or configured to be forward facing (facing towards distal end of sheath **12**). Alternatively,
7 ultrasound chips or transducers **26** may be flipped to be rear facing (facing towards proximal end
8 of sheath **12**). Varying orientations of ultrasound chips or transducers **26** may be implemented.

9 With reference to FIGS. **3A** and **3B**, shown is transseptal insertion device **300** including
10 multiple balloons **314**, which surround center lumen shaft **311** that defines center lumen **315**, and
11 sheath or catheter shaft **312** that includes center lumen shaft **311** and hypotubes **317** connected to
12 multiple balloons **314**. FIG. **3A** is a side view of sheath or catheter shaft **312**, and FIG. **3B** is a
13 front cross-sectional view of sheath or catheter shaft **312**. Balloons **314** are in various shapes such
14 as round, cylindrical, spherical, tear drop shaped or pear shaped, and are in various lengths.
15 Balloons **314** may be with or without overhang over shaft. Balloons **314** are positioned around
16 distal tip or end **313**, and may extend around circumference of distal tip or end **313**. Multiple
17 balloons **314** are connected to one or more hypotubes **317**, and inflated or deflated via hypotubes
18 **317** that are contained in sheath or catheter shaft **312**. Each of balloons **314** may be connected to
19 corresponding hypotube **317** to independently control the inflation and deflation of balloons **314**.
20 Alternatively, balloons **314** may share one or more hypotubes **317**. Inflation fluid or gas may flow
21 through hypotubes **317** to inflate or deflate balloons **314**. Outer covering **319** may cover the
22 multiple balloons **314**.

23 In between balloons **314**, there are one or more ultrasound chips or transducers **326** that
24 provide ultrasound imaging or visualizing capability. For illustrative purposes, FIG. **3B** shows
25 ultrasound chips or transducers **326** disposed between balloons **314**, but ultrasound chips or
26 transducers **326** may be deployed in or on balloons **314**. Ultrasound chips or transducers **326** may
27 be affixed to interior or exterior surface of balloon **314**. Ultrasounds chips or transducers **326** may
28 be ultrasound transceivers that both emit and receive waves, convert the ultrasound waves to
29 electrical signals, transmit the electrical signals, *e.g.*, through wire **320** that runs inside sheath or
30 catheter shaft **312**. However, ultrasound chips or transducers **326** may be connected wirelessly via

1 WiFi or other wireless connection, to an external imaging device that produces images from the
2 received signals (both still and video images).

3 Ultrasound chips or transducers **326** may be designed based on the shape of the balloons
4 **314**. The balloons **314** may be round, cylindrical, spherical, tear drop shaped or pear shaped with
5 overhang or without overhang. Ultrasound chips or transducers **326** may have shapes
6 corresponding to the shapes of balloons **314**. Alternatively, one or more ultrasound chips or
7 transducers **326** may be deployed in a shape corresponding to the shapes of balloons **314**.
8 Depending on the shapes of balloons **314**, ultrasound chips or transducers **326** may be side facing,
9 front facing or back facing. Ultrasound chips or transducers **326** may be arranged in a line, disc,
10 or cross-shape. Ultrasound chips or transducers **326** may be arranged to be forward facing (*e.g.*,
11 on distal end of balloon facing towards interatrial septum), or in a different direction/orientation,
12 such as sideways and forward facing (*e.g.*, facing towards interatrial septum and facing
13 perpendicular to the distal or front end).

14 Orientations of ultrasound chips or transducers **326** may depend on whether balloons **314**
15 are inflated or not. When balloons **314** are fully inflated, ultrasound chips or transducers **326** may
16 be forward facing. However, when balloons **314** are deflated, ultrasound chips or transducer **326**
17 may be folded flat and positioned on side of distal tip **313** of center lumen **315**. Hence, when
18 balloons **314** are deflated, ultrasound chips or transducer **326** may be side-facing. During inflation,
19 orientation of ultrasound chips or transducers **326** may change as balloons **314** inflate (moving
20 from side-facing orientation to forward facing orientation). Accordingly, operator(s) of transseptal
21 insertion device **300** may vary the inflation of balloons **314** to achieve different orientations of
22 ultrasound chips or transducers **326** for different imaging views.

23 With reference now to FIG. 4, shown is an embodiment of transseptal insertion device **10**
24 with radiofrequency (RF) energy capability. Transseptal insertion device **10** shown includes sheath
25 **12**, overhanging one or more balloons **14**, and dilator **16**. Dilator **16** may include cap or crown **22**,
26 on distal end as shown, with RF energy capability or capable of delivering RF energy.
27 Alternatively, cap or crown may include or be an RF electrode. Dilator **16** may be connected, *e.g.*,
28 on proximate end (not shown) to a radiofrequency energy source (not shown) at, *e.g.*, external hub,
29 that provides RF energy to cap or crown **22**. The RF energy may be delivered through dilator **16**.
30 So equipped with cap or crown **22**, dilator **16** may tent interaxial septum and create puncture of
31 interaxial septum through delivery of RF energy. In this embodiment, the use of a sharp needle

1 may be avoided. The dilator with cap or crown on distal end with RF energy capability or capable
2 of delivering RF energy may be used for transseptal insertion devices **200** and **300** shown in FIGS.
3 **2A-2B** and **3A-3B**.

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

10 With reference now to FIG. **6**, shown is distal end of an embodiment of transseptal insertion
11 device **10** in which overhanging balloons **14** is inflated by supplying gas or fluid into balloon **14**
12 through hypotube (not shown). Dilator **16** is shown positioned within center lumen **15** of sheath
13 **12** with tip of dilator **16** positioned at distal tip **13** of transseptal insertion device **10** and sub-planar
14 to overhanging balloon **14**. The plane that is referred to here is the plane perpendicular to the axis
15 of transseptal insertion device **10** and dilator **16**, formed by the end of overhanging balloon **14**.
16 Hence, dilator **16** remains sub-planar to overhanging balloon **14** until operator intends balloon **14**
17 to be deflated and dilator **16** to tent and puncture interatrial septum **100**. As noted above, balloon
18 **14** preferably extends completely around circumference of tip **13** of transseptal insertion device
19 **10**. Accordingly, FIG. **7** only illustrates cross-section of inflated balloon **14**.

20 With reference now to FIG. **7**, shown is a front, cross-sectional view of distal end an
21 embodiment of transseptal insertion device **10** in which overhanging balloon **14** is inflated. As
22 shown, inflated overhanging balloon **14** preferably extends around entire circumference of sheath
23 **12** (and, therefore, device **10**). Shown situated within lumen **15** of sheath **12** is tip of dilator **16**.
24 Tip of dilator **16** is positioned within tip **13** of transseptal insertion device **10**, as it would be prior
25 to being extended past tip **13** and puncturing an interatrial cardiac septum.

26 With reference now to FIG. **8**, shown is distal end of an embodiment of transseptal insertion
27 device **10** with dilator **16** advanced forward in order to tent the interatrial septum **100**. Dilator **16**
28 is shown extending through center lumen **15** of sheath **12** and past overhanging balloon **14**. At this
29 stage, balloon **14** may be deflated by removing gas or fluid in balloon **14** through hypotube.
30 Extended as such, and pressed against interatrial septum **100**, dilator **16** tents the interatrial septum
31 **100** away from transseptal insertion device **10**.

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

7 Wire rail **20** may act as a guide for devices to enter the left atrium through the puncture in
8 the septal wall made by transseptal insertion device **10**. For example, wire rail **20** may guide
9 transseptal insertion device **10** or other catheters in the left atrium. In this manner, catheters may
10 be advanced safely into the left atrium over or guided by wire rail **20**. In an embodiment, wire rail
11 **20** may be energized (*e.g.*, to ablate or puncture the septum with energy delivered from source at
12 proximal end of transseptal insertion device **10**).

13 With continued reference to FIG. 9, dilator **16** preferably defines and includes an opening
14 or lumen **19** extending through its tip and through which transseptal wire **20** extends. With dilator
15 **16** extended as shown and tenting interatrial septum, septum may be punctured by energy delivered
16 through cap or electrode at tip of dilator **16** and transseptal wire rail **20** extended through opening
17 in tip of dilator **16** and through puncture made in interatrial septum by dilator **16** cap.

18 With reference to FIGS. **10A-10C**, shown are different views of an embodiment of
19 transseptal insertion device **10** with a flexible sheath **12** flexed or angulated at different angles.
20 Transseptal insertion device **10** may be flexed or angulated depending on the anatomy of the atria
21 using fixed angled dilators **16** that are inserted into lumen shaft of sheath **12**, causing sheath **12** to
22 flex. Such fixed angled dilators **16** may be, *e.g.*, any angle from 0-270°. Alternatively, sheath **12**,
23 lumen shaft and dilator **16** may be all flexible (preferably, hypotubes, needle and catheter inserted
24 through such flexible sheath **12** are flexible or malleable, at least in part) and transseptal insertion
25 device **10** may be flexed or angulated, thereby flexing or angulating sheath **12** and dilator **16**, using,
26 *e.g.*, a handle or wire (not shown) connected to tip **13** of device **10**. Handle and/or wire may also
27 be used to turn or flex or move tip **13** of transseptal insertion device **10**, *e.g.*, moving tip **13** of
28 sheath “up” or “down” or “left” or “right” or angulating tip **13** relative to axis of sheath **12** as
29 shown.

30 With reference now to FIG. **11**, shown is distal end of an embodiment of transseptal
31 insertion device **10** with inflated overhanging balloon **14**. Balloon **14** shown is an embodiment

1 with one or more markers **24**. Marker **24** may be, *e.g.*, a radiopaque and/or echogenic marker **24**.
2 As a radiopaque or echogenic marker, marker **24** will be visible on scanners used by those
3 performing cardiac catheterizations. The markers **24** may be in the form of letters, such as an E or
4 a C. Marker **24** enables the appropriate positioning of balloon **14** and sheath **12** in the 3-
5 dimensional space (*e.g.*, of the atrium) using imaging to view the marker **24** and, therefore, the
6 position of balloon **14**. Specifically, in operation, the less posterior distal tip **13** is positioned, the
7 more of the E (or C) will be shown. As operator of transseptal insertion device **10** turns or rotates
8 distal tip **13** toward posterior of patient, less of the arms of the E will be seen. In a preferred
9 embodiment, when only the vertical portion of the E is visible (*i.e.*, appearing as an I) distal tip **13**
10 will be rotated to its maximum posterior position.

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

16 With reference now to FIG. **12**, shown is another embodiment of overhanging balloon **14**
17 which may be deployed in embodiments of transseptal insertion device **10**. Overhanging balloon
18 **14** may include ring or band **28** around a portion of balloon **14**. Ring or band **28** may serve as a
19 marker, similar to markers **24** shown in FIG. **11**. Hence, ring **28** may be radiopaque or echogenic
20 and may be view by scanning devices used for visualization in cardiac catheterizations (*e.g.*,
21 fluoroscopic imaging devices). Similar to the letter E or C, the view of the ring **28** changes as the
22 distal tip **13** of transseptal insertion device **10** moves more posterior. When in a least posterior
23 position, ring **28** may appear as just a line or band positioned across axis of transseptal insertion
24 device **10**. When device **10** is rotated so that distal tip **13** is significantly closer to the posterior,
25 ring **28** may appear as a full “flat” circle or ring. In FIG. **12**, distal tip **13** is partially rotated so that
26 ring **28** is partially visible.

27 With reference to both FIGS. **11** and **12**, the marker **24** and ring **28** are described and shown
28 as located on balloon **14**. In embodiments, marker **24** and/or ring **28** may also be located on sheath
29 **12** and/or dilator **16**. So located, marker **24** and/or ring **28** would operate in effectively the same
30 manner as described above (*i.e.*, the arms of the E would disappear as the distal end was moved

1 more to the posterior and the ring would become more visible). Markers **24** and/or rings **28** may
2 be placed on all of balloon **14**, sheath **12**, and dilator **16**, or a combination thereof.

3 With reference now to FIG. **13**, shown is distal end of an embodiment of transseptal
4 insertion device **10** that includes dilator **16** with electrode tip. Shaft of dilator **16** defines and
5 contains a center lumen **50**. Lumen **50** may be defined in the range of, but not limited to, 0.020 to
6 0.040 inches. Dilator **16** may be made from a polymer material (*e.g.*, HDPE, LDPE, PTFE, or
7 combination thereof). Dilator shaft **16** shown includes a distal electrode tip **52**. Electrode tip **52**
8 may be comprise a metallic alloy (*e.g.*, PtIr, Au, or combination thereof). In preferred
9 embodiments, the size and shape of electrode tip **52** is selected to be sufficient to generate a plasma
10 for in vivo ablation of tissue in an applied power range of, but not limited to, 20-30W. Electrical
11 conductor **54** extends from electrode tip **52** to the proximal end (not shown) of the dilator **16**.
12 Electrical conductor **54** may run axially through an additional lumen **56** defined by and contained
13 in dilator shaft **16**. Electrical conductor **54** may contain a coil feature **58** to accommodate
14 lengthening during bending or flexing of dilator **16**.

15 Attached to distal end of sheath **12** is contains overhanging balloon **14** that is connected to
16 hypotube **17**. Overhanging balloon **14** may be made from a polymer material (*e.g.*, PET, Nylon,
17 Polyurethane, Polyamide, or combination thereof). Overhanging balloon **14** may be in the range
18 of, but not limited to, 5-20 mm in diameter and 20-30 mm in length. Overhanging balloon **14** may
19 be inflated via injection of gas or fluid through hypotube **17** connected to balloon **14**. Overhanging
20 balloon **14** may be deflated by removing gas or fluid in balloon **14** through hypotube **17** connected
21 to balloon **14**. During the proper functioning or operation of transseptal insertion device **10** for
22 puncturing the interatrial septum, balloon **14** may be deflated when dilator **16** moves out of lumen
23 **15** by removing gas or fluid from balloon **14**. Overhanging balloon **14** is of form such balloon **14**
24 overhangs or extends from distal end **13** of sheath **12**. Overhang or extension **60** may be in the
25 range of, but not limited to, 0.0 mm-5.0 mm. The end of the overhang or extension **60** is the plane
26 to which dilator **16** remains sub-planar until moving to tent and puncture the interatrial septum.

27 With reference now to FIG. **14**, shown is an embodiment of transseptal insertion device **10**
28 that includes a mechanical deflection mechanism. Mechanical deflection mechanism may enable
29 distal end of sheath **12** to be deflected or angulated to various angles with respect to axis of
30 transseptal insertion device **10**. Mechanical deflection mechanism may include a pull wire anchor
31 **40** affixed to distal end of sheath **12** and pull wire actuator **42** connected to pull wire anchor **40**

1 with pull wire (not shown). Rotation of pull wire actuator **42**, as shown, may exert force on pull
2 wire anchor **40** that deflects or angulates distal end of sheath **12**. Pull wire actuator **42** may be
3 rotated by handle connected thereto (not shown). Deflection or angulation of distal end of sheath
4 **12** may enable better intersection (*e.g.*, more perpendicular, flush) with interaxial septum and,
5 therefore, better puncture and insertion by transseptal insertion device **10**.

6 With reference now to FIG. **15**, shown are three (3) embodiments of curved dilators **16**,
7 each with a different curve profile (*i.e.*, different angle of deflection or curve). Curved dilators **16**
8 may be used in embodiments of transseptal insertion device **10** with flexible or malleable sheath
9 **12**. Such a flexible or malleable sheath **12** may be referred to as a steerable sheath **12** as it is
10 “steered” by curved dilator **16** inserted in sheath **12**.

11 With reference now to FIG. **16**, shown is an embodiment of transseptal insertion device **10**
12 with an external stabilizer **80**. Stabilizer **80** keeps proximal end of transseptal insertion device **10**
13 stable while allowing movement of transseptal insertion device **10** towards the distal and proximal
14 ends of device **10**, rotational/torqueing movement of proximal end of device **10**, and manipulation
15 of dials or other controls of device **10**. In effect, stabilizer **80** substantially prevents unwanted
16 movement of the transseptal insertion device **10** and, importantly, distal end of sheath **12**, balloon
17 **14**, and dilator **16**.

18 Stabilizer **80** includes connecting rods or arms **82** that connect stabilizer **80** to handle **70** at
19 proximal end of transseptal insertion device **10**. Connecting arms **82** are attached to stabilizer
20 platform **84**. Connecting arms **82** preferably hold the handle **70** securely and tightly, while
21 permitting desired rotational movements and control manipulation. Stabilizer platform **84** is
22 moveably attached to stabilizer base **86** so that stabilizer platform **84**, and hence handle **70** and
23 transseptal insertion device **10**, may be slid forwards and backwards along axis of transseptal
24 insertion device **10** towards and away from insertion point in patient (typically femoral vein at the
25 groin of patient). Stabilizer base **86** is typically secured to a flat, stable surface, such as a table, or
26 the leg of the patient. Configured as such, stabilizer **80** prevents unwanted vertical, rotational, or
27 other movement of transseptal insertion device **10** and its handle **70**, keeping transseptal insertion
28 device **10** and its handle **70** stable while permitting precise manipulation of handle **70** and its
29 controls.

30 With continuing reference to FIG. **16**, as shown, proximal end of transseptal insertion
31 device **10** may include a handle **70** for control and manipulation of transseptal insertion device **10**

1 and, particularly, dilator **16** and distal end of dilator **16**. Handle **70** may include a first dial **72** that
2 may be used to turn or deflect distal end of dilator **16**, effectively moving the distal end of dilator
3 **16** up or down in relation to axis of transseptal insertion device **10** (as indicated by arrows in FIG.
4 **16**). Handle **70** may also include a second dial **74** for extruding/extending distal end of dilator **16**
5 out of sheath **12** and retracting dilator **16** back into sheath **12**, effectively moving dilator **16** along
6 axis of transseptal insertion device **10** (as indicated by arrows in FIG. **16**). Handle **70** may also be
7 rotated, as indicated by rotational arrow in FIG. **16**, in order to deflect or turn distal end of
8 transseptal insertion device to left or right in relation to axis of transseptal insertion device **10**,
9 increasing or decreasing dilator **16** angle of deflection in that direction. If dial **72** moves distal end
10 of dilator **16** along Y axis, and transseptal insertion device **10** axis is considered the Z axis, so that
11 dial **74** moves dilator **16** along Z axis rotating handle **70** moves distal end of transseptal insertion
12 device **10** (and hence distal end of dilator **16**) along X axis. Handle **70** includes a port through
13 which dilator **16** and other devices inserted into transseptal insertion device **10** may be inserted.
14 Handle **70** may also include one or more tubes or other ports permitting connection to external
15 hubs and external energy sources, inflation liquids or gas.

16 In embodiments shown herein, balloon **14** and dilator **16** may be used as energy sources in
17 the left atrium and may be used to deliver energy to the pulmonary veins, left atrial appendage,
18 mitral valve and the left ventricle present in the left atrium. Such embodiments may include
19 external energy sources connected to balloon **14** and/or dilator **16** through wires or other
20 conductors extending lumen in sheath **12**. Delivery of energy via balloon **14** or dilator **16** may be
21 thermal/Cryo or radiofrequency, laser or electrical. The delivery of such energy could be through
22 a metallic platform such as a Nitinol cage inside or outside balloon **14**. Transseptal insertion device
23 **10** may also include an energy source external to the proximal end of the sheath and operatively
24 connected to balloon **14** to deliver energy to balloon **14**.

25 With reference now to FIGS. **17A** and **17B** shown is an embodiment of transseptal insertion
26 device **10** enabling differential expansion of balloon **14**. Differential expansion of balloon **14**
27 enables balloon **14** inflation to be adjusted based on the needs of the device operator and the
28 conditions present in the patient's heart. For example, the size of the fossa ovalis portion of the
29 interatrial septum may dictate the desired size of the inflated balloon **14** needed at the puncture
30 site (interatrial septum is often punctured through the fossa ovalis). Fossae can vary greatly in size.
31 The larger the fossa, the harder it will be to tent the interatrial septum with balloon **14**. Large fossa

1 tend to be saggy and more difficult to manipulate. Hence, with a large fossa, a larger distal end of
2 balloon **14** will make proper tenting of the interatrial septum easier. Indeed, it may be ideal to have
3 balloon **14** inflated uniformly until intersecting or passing through fossa and then differentially
4 expanding distal end **142** of balloon **14** to move fossa out of the way. In FIG. **17A**, distal end or
5 portion **142** of balloon **14** is smaller (less expanded) than proximal end **144** of balloon **14**.

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

13 This differential expansion of balloon **14** may be achieved, *e.g.*, by using different materials
14 for different portions of balloon **14** (*e.g.*, a more expandable material for distal end **142** than
15 proximal end or portion **144**, or vice versa). In general, balloon **14** may be made of either compliant
16 or non-compliant material, or a combination thereof. Compliant material will continue expanding
17 as more inflating liquid or gas is added to balloon **14** (at least until failure). Non-compliant material
18 will only inflate up to a set expansion or designated inflation level. Combinations of compliant
19 and non-compliant material may be used to provide a differentially expanding balloon **14**. For
20 example, distal end **142** may be formed from compliant material and proximal end **144** from non-
21 compliant material to enable a larger distal end **142**. Oppositely, proximal end **144** may be formed
22 from compliant material and distal end **142** from non-compliant material to enable a larger
23 proximal end **144**. Other means for providing differential expansion of balloon **14** may be used,
24 such as applying energy to different portions of balloon **14** to increase or decrease the compliance,
25 and expandability, of that portion.

26 Balloon **14** may also be used to direct other equipment into these anatomical locations or
27 be used as an angiographic or hemodynamic monitoring balloon. Differential expansion of balloon
28 **14** may be utilized for proper orientation or direction of such equipment.

29 With reference now to FIG. **18**, shown is an embodiment of a malleable transseptal needle
30 **90** that may be used with transseptal insertion device **10** with a flexible sheath or otherwise capable
31 of multiple angulations. In embodiments, malleable transseptal needle **90** may be of a variety of

1 diameters and lengths. For example, embodiments may include an eighteen (18) gauge transseptal
2 needle and that is available in 71 cm, 89 cm, and 98 cm lengths. In embodiments, the malleable
3 transseptal needle **90** has different stiffness in a proximal segment **92**, distal segment **94**, and in a
4 middle segment **96** between. For example, malleable transseptal needle **90** may be stiffer in the
5 proximal segment **92** and distal segment **94** and more flexible (less stiff) in a middle segment or
6 mid-section **96**. The mid-section may be the section where transseptal insertion device **10** and
7 dilator **16** angulate. In an embodiment, malleable transseptal needle **90** is used and a control handle
8 provided that enables three-dimensional movements. Malleable transseptal needle **90** shown is,
9 preferably, malleable or flexible at least in part. Proximal end **92** of malleable transseptal needle
10 **90** may be stiff (*e.g.*, made from a stiff material, such as a metal). Mid-section or middle **96** of
11 malleable transseptal needle **90** may be malleable or flexible (*e.g.*, made from a flexible, malleable
12 material, such as rubber). Accordingly, mid-section may flex or bend, enabling malleable
13 transseptal needle **90** to pass through angulated or flexed sheath **12**.

14 Distal end **94** of malleable transseptal needle **90** (*i.e.*, end that punctures interatrial cardiac
15 septum) may be stiff with a cap or electrode at its tip for delivering energy to interatrial septum to
16 puncture interatrial septum. In embodiments, transseptal needle is able to transmit radiofrequency
17 energy to create a controlled septal puncture. Such a transseptal needle may or may not be
18 malleable, but is able deliver RF energy through a cap or crown (*e.g.*, an electrode) at its distal end
19 tip. The needle **90** may be connected, *e.g.*, on proximate end (not shown) to a radiofrequency (RF)
20 energy source (not shown) at, *e.g.*, external hub, that provides RF energy through needle to its
21 distal end tip. In such an embodiment, dilator **16** may tent interaxial septum and RF energy capable
22 transseptal needle may create puncture of interaxial septum through delivery of RF energy.

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

29 In embodiments, energy, typically electrical energy, may directed through transseptal
30 insertion device **10** may be used to increase or decrease the French size of sheath **12**. In such
31 embodiments, sheath **12** is fabricated from materials that are known to increase in malleability and

1 or expand when certain energies are applied. In this manner, the French size of sheath **12** may be
2 adjusted to a size deemed necessary during a given procedure. Such energy may be applied through
3 wires or conductive material, connected to energy source external to proximal end of transseptal
4 insertion device **10**, attached to or fabricated within sheath **12** or other components of transseptal
5 insertion device **10**. Likewise, parts or portions of transseptal insertion device **10** may be
6 selectively made more rigid or more malleable/soft with the application of energy. Therefore, with
7 the application of differential energy to different parts of transseptal insertion device **10** at different
8 times, transseptal insertion device **10** size may be adjusted to enable various devices that are
9 ordinarily larger and bulkier than the catheter to traverse through the catheter. In embodiments,
10 transseptal insertion device **10** may accommodate devices up to 36 Fr (French size).

11 In an embodiment of transseptal insertion device **10**, visualization of an intrathoracic region
12 of interest using MRI techniques may be provided. Embodiments may, for example, provide a
13 needle system comprising a hollow needle having a distal portion and a proximal portion, said
14 distal portion having a distal-most end sharpened for penetrating a myocardial wall. The needle
15 may include a first conductor, an insulator/dielectric applied to cover the first conductor over the
16 proximal portion of said needle and a second conductor applied to cover the insulator/dielectric.
17 The method may further direct the needle system into proximity to a myocardial wall, track
18 progress of the needle system using active MRI tracking, penetrate the myocardial wall to approach
19 the intrathoracic region of interest, and, use the needle system as an MRI antenna to receive
20 magnetic resonance signals from the intrathoracic region of interest.

21 In related embodiments, MRI antenna may be installed on distal tip **13** of sheath **12**, dilator
22 **16** or on balloon **14**, similar to ultrasound chips or transducers **226** or **326** described above. Wires
23 connecting such MRI antenna or other MRI components may pass through lumen in dilator **16** or
24 sheath **12** and connect with appropriate magnetic resonance energy source on exterior of distal end
25 of transseptal insertion device **10**.

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

1 **WHAT IS CLAIMED IS:**

2 1. A transseptal insertion device which is suitable for facilitating precise and safe transseptal
3 puncture of a cardiac interatrial septum, comprising:

4 a sheath that defines at least one lumen therein and has a distal end that is closest to the
5 cardiac interatrial septum of a patient when the transseptal insertion device is in use and a proximal
6 end that is external to the patient;

7 one or more balloons that are connected to the distal end of the sheath and are contained in
8 the sheath, wherein the balloons, when inflated and the transseptal insertion device is in use,
9 overhangs and extends past the distal end of the sheath, preventing accidental puncturing of the
10 cardiac interatrial septum and stabilizing the transseptal insertion device against fossa ovalis of the
11 cardiac interatrial septum;

12 one or more ultrasound transceivers that emit and receive ultrasound waves, and convert
13 the ultrasound waves to electrical signals; and

14 a dilator that is positioned within the at least one lumen, wherein the dilator has a distal
15 end and is designed to and is capable of precisely puncturing the cardiac interatrial septum.

16 2. The transseptal insertion device of claim 1 further comprising one or more hypotubes
17 connected to the one or more balloons, wherein the one or more balloons are inflated by gas or
18 fluid flowing through the one or more hypotubes.

19 3. The transseptal insertion device of claim 2 further comprising at least one lumen shaft
20 contained in the sheath, wherein said at least one lumen shaft defines the at least one lumen and
21 the dilator is positioned in said at least one lumen shaft.

22 4. The transseptal insertion device of claim 3 wherein the one or more hypotubes are
23 contained in the sheath outside said at least one lumen shaft.

24 5. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers
25 are located on surfaces of the one or more balloons.

26 6. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers
27 are located between the balloons.

28 7. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers
29 are oriented towards the cardiac interatrial septum when the one or more balloons are inflated and
30 the distal end of the sheath is oriented towards the cardiac interatrial septum.

1 8. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers
2 are oriented perpendicular to the sheath when the balloons are deflated.

3 9. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers
4 are configured in the shape of a disc.

5 10. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers
6 are connected to an external imaging device wirelessly or through a wire that runs via the sheath,
7 and transmit the electrical signals to the external imaging device to produce images of the cardiac
8 interatrial septum from the received electrical signals.

9 11. The transseptal insertion device of claim 1 wherein the dilator includes cap or crown with
10 radio frequency (RF) energy capability or capable of delivering RF energy.

11 12. A transseptal insertion device which is suitable for facilitating precise and safe transseptal
12 puncture of a cardiac interatrial septum, comprising:

13 a sheath that defines at least one lumen therein and has a distal end that is closest to the
14 cardiac interatrial septum of a patient when the transseptal insertion device is in use and a proximal
15 end that is external to the patient;

16 at least one balloon that is connected to the distal end of the sheath, wherein the balloon,
17 when inflated and the transseptal insertion device is in use, overhangs and extends past the distal
18 end of the sheath, preventing accidental puncturing of the cardiac interatrial septum and stabilizing
19 the transseptal insertion device against fossa ovalis of the cardiac interatrial septum;

20 one or more ultrasound transceivers that emit and receive ultrasound waves, and convert
21 the ultrasound waves to electrical signals; and

22 a dilator that is positioned within the at least one lumen, wherein the dilator has a distal
23 end and is designed to and is capable of precisely puncturing the cardiac interatrial septum.

24 13. The transseptal insertion device of claim 12 further comprising at least one hypotube
25 connected to the at least one balloon, wherein the at least one balloon is inflated by gas or fluid
26 flowing through the at least one hypotube.

27 14. The transseptal insertion device of claim 13 further comprising at least one lumen shaft
28 contained in the sheath, wherein said at least one lumen shaft defines the at least one lumen and
29 the dilator is positioned in said at least one lumen shaft.

30 15. The transseptal insertion device of claim 14 wherein the at least one hypotube is contained
31 in the sheath outside the at least one lumen shaft.

- 1 16. The transseptal insertion device of claim 15 wherein the one or more ultrasound
2 transceivers are located on a surface of the at least one balloon.
- 3 17. The transseptal insertion device of claim 12 wherein the one or more ultrasound
4 transceivers are oriented towards the distal end of the sheath when the at least one balloon is
5 inflated and the distal end of the sheath is oriented towards the cardiac interatrial septum.
- 6 18. The transseptal insertion device of claim 12 wherein the one or more ultrasound
7 transceivers are oriented perpendicular to the sheath when the at least one balloon is deflated.
- 8 19. The transseptal insertion device of claim 12 wherein the one or more ultrasound
9 transceivers are connected to an external imaging device wirelessly or through a wire that runs via
10 the sheath, and transmit the electrical signals to the external imaging device to produce images of
11 the cardiac interatrial septum from the received electrical signals.
- 12 20. The transseptal insertion device of claim 12 wherein the dilator includes cap or crown with
13 radio frequency (RF) energy capability or capable of delivering RF energy.