

**DIRECTIONAL BALLOON TRANSEPTAL INSERTION DEVICE FOR MEDICAL
PROCEDURES WITH IMPROVED TRANSEPTAL 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. 62/859,943,
3 filed on June 11, 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
27 may cause very serious damage to the heart. In addition, transseptal puncture may require
28 complicated instruments which are not helpful in guaranteeing the precision of the puncture.

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

7 **SUMMARY**

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

11 These advantages and others are achieved, for example, by a transseptal insertion device
12 which is suitable for facilitating precise and safe transseptal puncture of a cardiac interatrial
13 septum. The transseptal insertion device includes a sheath that defines at least one lumen therein
14 and has a distal end that is positioned toward the cardiac interatrial septum of a patient when the
15 transseptal insertion device is in use and a proximal end that is external to the patient, one or more
16 positioning balloons that are connected to the distal end of the sheath, in which the one or more
17 positioning balloons, when inflated and the transseptal insertion device is in use, overhang and
18 extend past the distal end of the sheath, preventing accidental puncturing of the cardiac interatrial
19 septum and stabilizing the transseptal insertion device against fossa ovalis of the cardiac interatrial
20 septum, and in which the sheath includes one or more deflation ports to deflate the one or more
21 positioning balloons, a puncture member movably positioned within the at least one lumen, in
22 which the puncture member has a distal end that is positioned toward the cardiac interatrial septum
23 of the patient, and a puncture member balloon located on the puncture member, in which the
24 puncture member balloon, when inflated, is capable of sealing the one or more deflation ports of
25 the sheath, permitting the inflation of the one or more positioning balloons.

26 These advantages and others are also achieved, for example, by a method for suitably
27 facilitating precise and safe transseptal puncture of a cardiac interatrial septum with a transseptal
28 insertion device. The method includes inflating a puncture member balloon located on a puncture
29 member that has a distal end that is positioned toward the cardiac interatrial septum of the patient,
30 sealing one or more deflation ports located in a sheath with the inflated puncture member balloon,
31 inflating one or more positioning balloons connected to a distal end of the sheath, in which the

1 inflated one or more positioning balloons overhang and extend past the distal end of the sheath,
2 positioning the puncture member against fossa ovalis of the cardiac interatrial septum while the
3 positioning balloons are inflated, advancing the puncture member toward the fossa ovalis, in which
4 the distal end of the puncture member extends past the overhanging one or more positioning
5 balloons, in which the puncture member balloon moves away from the one or more deflation ports
6 while the puncture member advances, and deflating the one or more positioning balloons while
7 the distal end of the puncture member presses the fossa ovalis.

8 BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 FIGS. 23A-23D are side views of distal end portion of the puncture member multi-lumen
11 extension of the transseptal puncture device.

12 FIG. 24 is a workflow diagram for a method for suitably facilitating precise and safe
13 transseptal puncture of a cardiac interatrial septum with a transseptal insertion device.

14 **DETAILED DESCRIPTION**

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

30 With reference to FIGS. **1A-1C**, shown is an embodiment of transseptal insertion device
31 or catheter **10**. Shown is the distal end of transseptal insertion device **10**, *i.e.*, the end of transseptal

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

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

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

26 With reference now to FIG. **1C**, dilator **16** is shown positioned within center lumen **15** of
27 sheath **12**. Tip of dilator **16** is positioned within distal tip **13** of transseptal insertion device **10** sub-
28 planar to end of transseptal insertion device **10**. The position shown is position dilator **16** may be
29 in immediately prior to inflation of one or more balloons **14**. It is noted that the relative sizes of
30 catheter/sheath **12** and dilator **16** shown are for illustrative purposes as the diameter of dilator **16**
31 may be relatively larger or smaller than shown in relation to the diameter of sheath **12**. Ordinarily,

dilator **16** has smaller diameter or gauge than catheter/sheath **12**, although fit of dilator **16** in catheter/sheath **12** is preferably snug enough so that dilator **16** does not move (laterally or axially) relative to position or “wobble” within transseptal insertion device **10**. Dilator **16** necessarily has a smaller diameter than sheath **12**. In embodiments, sheath **12** material may be sufficiently malleable to enable larger diameter dilators **16**, and other larger diameter devices, to be passed through sheath **12**. In such embodiments, sheath **12** will stretch to accommodate the larger diameter dilator **16** or other device.

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

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

18 With reference to FIGS. **2C-2D**, shown are embodiments of transseptal insertion device
19 **200** with ultrasound imaging or visualizing capability. Balloon **14** shown includes one or more
20 ultrasound chips or transducers **26** deployed in or on balloon **14**. Ultrasounds chips or transducers
21 **26** may be ultrasound transceivers that both emit and receive waves, convert the ultrasound waves
22 to electrical signals, transmit the electrical signals, *e.g.*, through a wire that runs via sheath **12**.
23 Ultrasounds chips or transducers **26** may be connected via WiFi or other wireless connection, to
24 an external imaging device that produces images from the received signals (both still and video
25 images).

26 Ultrasound chips or transducers **26** may be affixed to interior or exterior surface of balloon
27 **14**. Ultrasound chips or transducers **26** may be arranged in a line, disc, or cross-shape. Ultrasound
28 chips or transducers **26** may be arranged to be forward facing (*e.g.*, on distal end of balloon facing
29 towards interatrial septum), as shown in FIG. **2C**, or in a different direction/orientation, such as
30 sideways and forward facing (*e.g.*, facing towards interatrial septum and facing perpendicular to
31 the distal or front end), as shown in FIG. **2D**. Indeed, orientation of ultrasound chips or transducers

26 may depend on whether balloon 14 is inflated or not. When balloon 14 is fully inflated, as shown in FIG. 2C, ultrasound transducer 26 may be forward facing (or forward and perpendicularly facing as shown in FIG. 2D). However, when balloon 14 is deflated, ultrasound transducer 26 may be folded flat and positioned on side of distal tip 13 of sheath 12. Hence, when balloon 14 is deflated, ultrasound chip or transducer 26 may be side-facing. During inflation ultrasound transducer 26 orientation will change as balloon 14 inflates (moving from side-facing orientation to forward facing orientation with the ultrasound transducer 26 shown in FIG. 2C). Accordingly, operator(s) of transseptal insertion device 200 may vary the inflation of balloon 14 to achieve different orientations of ultrasound transducer 26 for different imaging views.

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

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

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

1 through hypotubes **314** to inflate or deflate balloons **314**. Outer covering **319** may cover the
2 multiple balloons **314**.

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

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

23 Orientations of ultrasound chips or transducers **326** may depend on whether balloons **314**
24 are inflated or not. When balloons **314** are fully inflated, ultrasound chips or transducers **326** may
25 be forward facing. However, when balloons **314** are deflated, ultrasound chips or transducer **326**
26 may be folded flat and positioned on side of distal tip **313** of center lumen **315**. Hence, when
27 balloons **314** are deflated, ultrasound chips or transducer **326** may be side-facing. During inflation,
28 orientation of ultrasound chips or transducers **326** may change as balloons **314** inflate (moving
29 from side-facing orientation to forward facing orientation). Accordingly, operator(s) of transseptal
30 insertion device **300** may vary the inflation of balloons **314** to achieve different orientations of
31 ultrasound chips or transducers **326** for different imaging views.

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

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

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

29 With reference now to FIG. 7, shown is a front, cross-sectional view of distal end an
30 embodiment of transseptal insertion device **10** in which overhanging balloon **14** is inflated. As
31 shown, inflated overhanging balloon **14** preferably extends around entire circumference of sheath

1 **12** (and, therefore, device **10**). Shown situated within lumen **15** of sheath **12** is tip of dilator **16**.
2 Tip of dilator **16** is positioned within tip **13** of transseptal insertion device **10**, as it would be prior
3 to being extended past tip **13** and puncturing an interatrial cardiac septum.

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

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

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

22 With continued reference to FIG. **9**, dilator **16** preferably defines and includes an opening
23 or lumen **19** extending through its tip and through which transseptal wire **20** extends. With dilator
24 **16** extended as shown and tenting interatrial septum, septum may be punctured by energy delivered
25 through cap or electrode at tip of dilator **16** and transseptal wire rail **20** extended through opening
26 in tip of dilator **16** and through puncture made in interatrial septum by dilator **16** cap.

27 With reference to FIGS. **10A-10C**, shown are different views of an embodiment of
28 transseptal insertion device **10** with a flexible sheath **12** flexed or angulated at different angles.
29 Transseptal insertion device **10** may be flexed or angulated depending on the anatomy of the atria
30 using fixed angled dilators **16** that are inserted into lumen shaft of sheath **12**, causing sheath **12** to
31 flex. Such fixed angled dilators **16** may be, *e.g.*, any angle from 0-270°. Alternatively, sheath **12**,

1 lumen shaft and dilator **16** may be all flexible (preferably, hypotubes, needle and catheter inserted
2 through such flexible sheath **12** are flexible or malleable, at least in part) and transseptal insertion
3 device **10** may be flexed or angulated, thereby flexing or angulating sheath **12** and dilator **16**, using,
4 *e.g.*, a handle or wire (not shown) connected to tip **13** of device **10**. Handle and/or wire may also
5 be used to turn or flex or move tip **13** of transseptal insertion device **10**, *e.g.*, moving tip **13** of
6 sheath “up” or “down” or “left” or “right” or angulating tip **13** relative to axis of sheath **12** as
7 shown.

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

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

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

26 With reference now to FIG. **12**, shown is another embodiment of overhanging balloon **14**
27 which may be deployed in embodiments of transseptal insertion device **10**. Overhanging balloon
28 **14** may include ring or band **28** around a portion of balloon **14**. Ring or band **28** may serve as a
29 marker, similar to markers **24** shown in FIG. **11**. Hence, ring **28** may be radiopaque or echogenic
30 and may be view by scanning devices used for visualization in cardiac catheterizations (*e.g.*,
31 fluoroscopic imaging devices). Similar to the letter E or C, the view of the ring **28** changes as the

1 distal tip **13** of transseptal insertion device **10** moves more posterior. When in a least posterior
2 position, ring **28** may appear as just a line or band positioned across axis of transseptal insertion
3 device **10**. When device **10** is rotated so that distal tip **13** is significantly closer to the posterior,
4 ring **28** may appear as a full “flat” circle or ring. In FIG. **12**, distal tip **13** is partially rotated so that
5 ring **28** is partially visible.

6 With reference to both FIGS. **11** and **12**, the marker **24** and ring **28** are described and shown
7 as located on balloon **14**. In embodiments, marker **24** and/or ring **28** may also be located on sheath
8 **12** and/or dilator **16**. So located, marker **24** and/or ring **28** would operate in effectively the same
9 manner as described above (*i.e.*, the arms of the E would disappear as the distal end was moved
10 more to the posterior and the ring would become more visible). Markers **24** and/or rings **28** may
11 be placed on all of balloon **14**, sheath **12**, and dilator **16**, or a combination thereof.

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

24 Attached to distal end of sheath **12** is contains overhanging balloon **14** that is connected to
25 hypotube **17**. Overhanging balloon **14** may be made from a polymer material (*e.g.*, PET, Nylon,
26 Polyurethane, Polyamide, or combination thereof). Overhanging balloon **14** may be in the range
27 of, but not limited to, 5-20 mm in diameter and 20-30 mm in length. Overhanging balloon **14** may
28 be inflated via injection of gas or fluid through hypotube **17** connected to balloon **14**. Overhanging
29 balloon **14** may be deflated by removing gas or fluid in balloon **14** through hypotube **17** connected
30 to balloon **14**. During the proper functioning or operation of transseptal insertion device **10** for
31 puncturing the interatrial septum, balloon **14** may be deflated when dilator **16** moves out of lumen

1 **15** by removing gas or fluid from balloon **14**. Overhanging balloon **14** is of form such balloon **14**
2 overhangs or extends from distal end **13** of sheath **12**. Overhang or extension **60** may be in the
3 range of, but not limited to, 0.0 mm-5.0 mm. The end of the overhang or extension **60** is the plane
4 to which dilator **16** remains sub-planar until moving to tent and puncture the interatrial septum.

5 With reference now to FIG. **14**, shown is an embodiment of transseptal insertion device **10**
6 that includes a mechanical deflection mechanism. Mechanical deflection mechanism may enable
7 distal end of sheath **12** to be deflected or angulated to various angles with respect to axis of
8 transseptal insertion device **10**. Mechanical deflection mechanism may include a pull wire anchor
9 **40** affixed to distal end of sheath **12** and pull wire actuator **42** connected to pull wire anchor **40**
10 with pull wire (not shown). Rotation of pull wire actuator **42**, as shown, may exert force on pull
11 wire anchor **40** that deflects or angulates distal end of sheath **12**. Pull wire actuator **42** may be
12 rotated by handle connected thereto (not shown). Deflection or angulation of distal end of sheath
13 **12** may enable better intersection (*e.g.*, more perpendicular, flush) with interaxial septum and,
14 therefore, better puncture and insertion by transseptal insertion device **10**.

15 With reference now to FIG. **15**, shown are three (3) embodiments of curved dilators **16**,
16 each with a different curve profile (*i.e.*, different angle of deflection or curve). Curved dilators **16**
17 may be used in embodiments of transseptal insertion device **10** with flexible or malleable sheath
18 **12**. Such a flexible or malleable sheath **12** may be referred to as a steerable sheath **12** as it is
19 “steered” by curved dilator **16** inserted in sheath **12**.

20 With reference now to FIG. **16**, shown is an embodiment of transseptal insertion device **10**
21 with an external stabilizer **80**. Stabilizer **80** keeps proximal end of transseptal insertion device **10**
22 stable while allowing movement of transseptal insertion device **10** towards the distal and proximal
23 ends of device **10**, rotational/torqueing movement of proximal end of device **10**, and manipulation
24 of dials or other controls of device **10**. In effect, stabilizer **80** substantially prevents unwanted
25 movement of the transseptal insertion device **10** and, importantly, distal end of sheath **12**, balloon
26 **14**, and dilator **16**.

27 Stabilizer **80** includes connecting rods or arms **82** that connect stabilizer **80** to handle **70** at
28 proximal end of transseptal insertion device **10**. Connecting arms **82** are attached to stabilizer
29 platform **84**. Connecting arms **82** preferably hold the handle **70** securely and tightly, while
30 permitting desired rotational movements and control manipulation. Stabilizer platform **84** is
31 moveably attached to stabilizer base **86** so that stabilizer platform **84**, and hence handle **70** and

transseptal insertion device **10**, may be slid forwards and backwards along axis of transseptal insertion device **10** towards and away from insertion point in patient (typically femoral vein at the groin of patient). Stabilizer base **86** is typically secured to a flat, stable surface, such as a table, or the leg of the patient. Configured as such, stabilizer **80** prevents unwanted vertical, rotational, or other movement of transseptal insertion device **10** and its handle **70**, keeping transseptal insertion device **10** and its handle **70** stable while permitting precise manipulation of handle **70** and its controls.

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

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

1 **10** may also include an energy source external to the proximal end of the sheath and operatively
2 connected to balloon **14** to deliver energy to balloon **14**.

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

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

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

1 proximal end **144**. Other means for providing differential expansion of balloon **14** may be used,
2 such as applying energy to different portions of balloon **14** to increase or decrease the compliance,
3 and expandability, of that portion.

4 Balloon **14** may also be used to direct other equipment into these anatomical locations or
5 be used as an angiographic or hemodynamic monitoring balloon. Differential expansion of balloon
6 **14** may be utilized for proper orientation or direction of such equipment.

7 With reference now to FIG. **18**, shown is an embodiment of a malleable transseptal needle
8 **90** that may be used with transseptal insertion device **10** with a flexible sheath or otherwise capable
9 of multiple angulations. In embodiments, malleable transseptal needle **90** may be of a variety of
10 diameters and lengths. For example, embodiments include an 18 gauge transseptal needle and that
11 is available in 71 cm, 89 cm, and 98 cm lengths. In embodiments, the malleable transseptal needle
12 **90** has different stiffness in a proximal segment **92**, distal segment **94**, and in a middle segment **96**
13 between. For example, malleable transseptal needle **90** may be stiffer in the proximal segment **92**
14 and distal segment **94** and more flexible (less stiff) in a middle segment or mid-section **96**. The
15 mid-section may be the section where transseptal insertion device **10** and dilator **16** angulate. In
16 an embodiment, malleable transseptal needle **90** is used and a control handle provided that enables
17 three-dimensional movements. Malleable transseptal needle **90** shown is, preferably, malleable or
18 flexible at least in part. Proximal end **92** of malleable transseptal needle **90** may be stiff (*e.g.*, made
19 from a stiff material, such as a metal). Mid-section or middle **96** of malleable transseptal needle
20 **90** may be malleable or flexible (*e.g.*, made from a flexible, malleable material, such as rubber).
21 Accordingly, mid-section may flex or bend, enabling malleable transseptal needle **90** to pass
22 through angulated or flexed sheath **12**.

23 Distal end **94** of malleable transseptal needle **90** (*i.e.*, end that punctures interatrial cardiac
24 septum) may be stiff with a cap or electrode at its tip for delivering energy to interatrial septum to
25 puncture interatrial septum. In embodiments, transseptal needle is able to transmit radiofrequency
26 energy to create a controlled septal puncture. Such a transseptal needle may or may not be
27 malleable, but is able deliver RF energy through a cap or crown (*e.g.*, an electrode) at its distal end
28 tip. Embodiments of malleable transseptal needle **90** may include a stiff and sharpened end for
29 mechanically or physically piercing or puncturing the interatrial septum. The needle **90** may be
30 connected, *e.g.*, on proximate end (not shown) to a radiofrequency (RF) energy source (not shown)
31 at, *e.g.*, external hub, that provides RF energy through needle to its distal end tip. In such an

1 embodiment, dilator **16** may tent interaxial septum and RF energy capable transseptal needle may
2 create puncture of interaxial septum through delivery of RF energy.

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

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

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

1 In related embodiments, MRI antenna may be installed on distal tip **13** of sheath **12**, dilator
2 **16** or on balloon **14**, similar to ultrasound chips or transducers **226** or **326** described above. Wires
3 connecting such MRI antenna or other MRI components may pass through lumen in dilator **16** or
4 sheath **12** and connect with appropriate magnetic resonance energy source on exterior of distal end
5 of transseptal insertion device **10**.

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

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

25 The puncture member **515** includes an inflation port **507** for inflating the puncture member
26 balloon **504**, and a lumen **508** which is connected to the inflation port **507** that supplies gas or fluid
27 to the inflation port **507** to inflate the puncture member balloon **504**. The puncture member **515**
28 also includes at least one RF tip **505** at the distal end **506** of the puncture member **515**. The RF tip
29 **505** is capable of delivering RF energy. The RF generator (not shown) produces RF energy, and
30 the RF energy is supplied to the RF tip **505**. The puncture member **515** includes a lumen **509** for
31 wires that delivers RF energy to the RF tip **505**.

1 With reference to FIGS. **21A-21B**, shown are a side view and a close-in side view of the
2 section D of the transseptal puncture device **500**, respectively, when the positioning balloon **510**
3 is inflated. The puncture member multi-lumen extension **503** includes the sheath **514** and the
4 puncture member **515**. The sheath **514** may have the sheath marker band **513**, and the puncture
5 member balloon **504**, which is mounted on the puncture member **515**, may be aligned with the
6 sheath marker band **513**. The sheath **514** includes one or more positioning balloons **510**, one or
7 more inflation ports **512** connected to the positioning balloons **510**, and at least one tube **516** that
8 delivers gas or fluid to the inflation port **512** to inflate the positioning balloons **510**. The tube **516**
9 may be the hypotube **17** (see FIG. **13**). The sheath **514** also includes one or more deflation ports
10 **511** that is connected to the positioning balloons **510**. When the puncture member balloon **504** is
11 inflated, the inflated puncture member balloon **504** seals the one or more deflation ports **511** in the
12 sheath **514**, preventing leak from the positioning balloons **510** and permitting inflation of the
13 positioning balloons **510**. The position balloons **510** are then inflated through the inflation port
14 **512** of the sheath **514**. The non-compliant or semi-compliant puncture member balloon **504** seals
15 off the deflation ports **511** of the sheath **514**, allowing the positioning balloons **510** to inflate and
16 position the distal end **506** of the puncture member **515** to the fossa ovalis (see FIG. **6** for example).

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

24 With reference to FIGS. **23A-23D**, shown are side views of distal end portion of the
25 puncture member multi-lumen extension **503** of the transseptal puncture device **500** of the
26 disclosed invention. The transseptal insertion device **500** includes a sheath **514** that defines at least
27 one lumen **517** therein, one or more positioning balloons **510** that are connected to the distal end
28 **506** of the sheath **514**, a puncture member **515** movably positioned within the at least one lumen
29 **517**, and a puncture member balloon **504** mounted on the puncture member **515**. The sheath **514**
30 has one or more deflation ports **511** and one or more inflation ports **512**. The inflation ports **512**
31 are connected to at least one tube **516** that supplies gas or fluid to the positioning balloons **510**.

1 The puncture member **515** has an inflation port **507** through which gas or fluid is supplied to inflate
2 the puncture member balloon **504**. The puncture member balloon **504** may be deflated through the
3 inflation port **507**. The puncture member **515** defines a center lumen **518** therein, and a transseptal
4 wire **519** is positioned inside the center lumen **518**. The transseptal wire **519** has a distal end and
5 is designed to and is capable of precisely puncturing the cardiac interatrial septum.

6 Referring FIG. **23A**, the puncture member balloon **504** is deflated, and the deflation ports
7 **511** are open. Referring to FIG. **23B**, the puncture member balloon **504** is inflated sealing the
8 deflation ports **511**. Referring to FIG. **23C**, the positioning balloons **510** are inflated by supplying
9 gas or fluid through the inflation ports **512**. Because the deflation ports **511** are sealed by the
10 inflated puncture member balloon **504**, the positioning balloons **510** can be inflated without leak.
11 Referring to FIG. **23D**, when the puncture member **515** advances forward, the inflated puncture
12 member balloon **504** moves away from the deflation ports **511**. Consequently, the deflation ports
13 **511** is open, and the positioning balloons **510** begin to deflate through the deflation ports **511**.

14 With reference to FIG. **24**, shown is a workflow diagram for a method **600** for suitably
15 facilitating precise and safe transseptal puncture of a cardiac interatrial septum with a transseptal
16 insertion device. A puncture member balloon **504** located on a puncture member **515** is inflated,
17 block **610**. The puncture member **515** has a distal end that is positioned toward the cardiac
18 interatrial septum of the patient. One or more deflation ports **511**, which are located in a sheath
19 **514**, are sealed with the inflated puncture member balloon **504**, block **611**. One or more positioning
20 balloons **510** connected to the distal end of the sheath **514** are inflated, block **612**. The inflated
21 positioning balloons **510** overhang and extend past the distal end of the sheath. The puncture
22 member **515** is positioned against fossa ovalis of the cardiac interatrial septum while the
23 positioning balloons are inflated, block **613**. The puncture member **515** is moved toward the fossa
24 ovalis, block **614**. At this step, the distal end of the puncture member **515** extends past the
25 overhanging one or more positioning balloons **510**, and the puncture member balloon **504** moves
26 away from the one or more deflation ports **511** while the puncture member **515** is advancing. The
27 one or more positioning balloons **510** are deflated, block **615**, while the distal end of the puncture
28 member presses the fossa ovalis.

29 Since many modifications, variations, and changes in detail can be made to the described
30 preferred embodiments of the invention, it is intended that all matters in the foregoing description
31 and shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense.

- 1 Consequently, the scope of the invention should be determined by the appended claims and their
- 2 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 positioned toward
5 the cardiac interatrial septum of a patient when the transseptal insertion device is in use and a
6 proximal end that is external to the patient;

7 one or more positioning balloons that are connected to the distal end of the sheath, wherein
8 the one or more positioning balloons, when inflated and the transseptal insertion device is in use,
9 overhang and extend 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, and wherein the sheath includes one or more deflation ports to deflate
12 the one or more positioning balloons;

13 a puncture member movably positioned within the at least one lumen, wherein the puncture
14 member has a distal end that is positioned toward the cardiac interatrial septum of the patient; and

15 a puncture member balloon located on the puncture member, wherein the puncture member
16 balloon, when inflated, is capable of sealing the one or more deflation ports of the sheath,
17 permitting the inflation of the one or more positioning balloons.

18 2. The transseptal insertion device of claim 1 wherein the puncture member includes an
19 inflation port to inflate the puncture member balloon.

20 3. The transseptal insertion device of claim 1 wherein the puncture member balloon is aligned
21 with the one or more deflation ports of the sheath while the puncture member balloon stays inside
22 the sheath.

23 4. The transseptal insertion device of claim 1 wherein the puncture member balloon is
24 configured to move away from the one or more deflation ports of the sheath when the puncture
25 member moves past the distal end of the sheath.

26 5. The transseptal insertion device of claim 1 wherein the sheath includes one or more
27 inflation ports to inflate the one or more positioning balloons.

28 6. The transseptal insertion device of claim 5 further comprising one or more hypotubes
29 connected to the one or more inflation ports of the sheath, wherein the one or more positioning
30 balloons are inflated by gas or fluid supplied through the one or more hypotubes.

1 7. The transseptal insertion device of claim 5 wherein the one or more deflation ports of the
2 sheath are positioned closer to the distal end of the sheath than the one or more inflation ports of
3 the sheath.

4 8. The transseptal insertion device of claim 1 further comprising a transseptal wire positioned
5 within a center lumen formed in the puncture member, wherein the transseptal wire has a distal
6 end and is designed to and is capable of precisely puncturing the cardiac interatrial septum.

7 9. The transseptal insertion device of claim 1 wherein the puncture member includes a radio
8 frequency (RF) tip at the distal end of the puncture member, wherein the RF tip is capable of
9 delivering RF energy.

10 10. The transseptal insertion device of claim 9 wherein the puncture member includes a RF
11 generator that produces RF energy that is transmitted to the RF tip.

12 11. The transseptal insertion device of claim 1 further comprising one or more ultrasound
13 transceivers that emit and receive ultrasound waves, and convert the ultrasound waves to electrical
14 signals.

15 12. The transseptal insertion device of claim 11 wherein the one or more ultrasound
16 transceivers are located on surfaces of the one or more balloons.

17 13. The transseptal insertion device of claim 11 wherein the one or more ultrasound
18 transceivers are located between the balloons.

19 14. A method for suitably facilitating precise and safe transseptal puncture of a cardiac
20 interatrial septum with a transseptal insertion device, comprising:

21 inflating a puncture member balloon located on a puncture member that has a distal end
22 that is positioned toward the cardiac interatrial septum of the patient;

23 sealing one or more deflation ports located in a sheath with the inflated puncture member
24 balloon;

25 inflating one or more positioning balloons connected to a distal end of the sheath, wherein
26 the inflated one or more positioning balloons overhang and extend past the distal end of the sheath;

27 positioning the puncture member against fossa ovalis of the cardiac interatrial septum while
28 the positioning balloons are inflated;

29 advancing the puncture member toward the fossa ovalis, wherein the distal end of the
30 puncture member extends past the overhanging one or more positioning balloons, wherein the

1 puncture member balloon moves away from the one or more deflation ports while the puncture
2 member advances; and

3 deflating the one or more positioning balloons while the distal end of the puncture member
4 presses the fossa ovalis.

5 15. The method of claim 14 further comprising advancing a transseptal wire past the distal end
6 of the puncture member to puncture the fossa ovalis, wherein the transseptal wire is positioned in
7 a center lumen formed in the puncture member.

8 16. The method of claim 14 wherein the puncture member balloon is inflated by gas or fluid
9 supplied through an inflation port located in the puncture member.

10 17. The method of claim 14 wherein the one or more positioning balloons are inflated by gas
11 or fluid supplied through one or more inflation ports located in the sheath.

12 18. The method of claim 17 wherein the one or more deflation ports of the sheath are
13 positioned closer to the distal end of the sheath than the one or more inflation ports of the sheath.

14 19. The method of claim 14 wherein the one or more positioning balloons are deflated through
15 the one or more deflation ports of the sheath.

16 20. The method of claim 14 wherein the one or more positioning balloons are deflated through
17 both the one or more deflation ports of the sheath and the one or more inflation ports of the sheath.