

**DIRECTIONAL BALLOON TRANSSEPTAL INSERTION DEVICE FOR MEDICAL
PROCEDURES WITH IMPROVED HANDLE**

1 CROSS REFERENCE TO RELATED APPLICATIONS

2 This application claims the priority of U.S. Provisional Application Serial No. 62/910,977,
3 filed on October 4, 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 transseptal insertion device or shaft that is
9 suitable for facilitating quick and safe transseptal puncturing to provide access to the left atrium in
10 implementation of a left atrial intervention, and a handle that efficiently controls the movements
11 of the transseptal insertion device.

12 These advantages and others are achieved, for example, by a transseptal puncture system
13 which is suitable for facilitating precise and safe transseptal puncture of a cardiac interatrial septum
14 of a patient. The transseptal puncture system includes a handle and a transseptal insertion shaft
15 coupled to the handle. The handle includes two twister thread half shells having internal threads,
16 a twister bolt inner placed inside and locked into the two twister thread half shells, a nut inner
17 placed inside the two twister thread half shells, a nut outer placed inside the two twister thread half
18 shells, a first pull wire coupled to the nut inner and a second pull wire coupled to the nut outer, a
19 grip overmold over-molded onto the two twister thread half shells. The nut inner engages with the
20 twister bolt inner. The internal threads of the twister thread half shells engage with the nut outer.
21 The nut inner and nut outer rotate in opposite directions to each other when the two twister thread
22 half shells are turned in a direction. The transseptal insertion shaft includes a sheath that defines
23 one or more lumens therein and has a distal end that is positioned toward the patient when the
24 transseptal insertion shaft is in use, and at least one positioning balloon connected to the distal end
25 of the sheath. Said at least one positioning balloon, when inflated and the transseptal insertion shaft
26 is in use, overhangs and extends past the distal end of the sheath. The sheath includes one or more
27 hypotubes connected to the at least one positioning balloon to inflate the positioning balloon. A
28 proximal end of the transseptal insertion shaft is coupled to the handle. A distal end of the first
29 pull wire is attached to a first side of the transseptal insertion shaft and a distal end of the second
30 pull wire is attached to a second side of the transseptal insertion shaft.

1 The nut inner pulls the first pull wire when the two twister thread half shells are rotated in
2 a first direction, and the distal end of the transseptal insertion shaft bends toward the first side of
3 the transseptal insertion shaft while the first pull wire is pulled. The nut outer pulls the second pull
4 wire when the two twister thread half shells are rotated in a second direction, and the distal end of
5 the transseptal insertion shaft bends toward the second side of the transseptal insertion shaft while
6 the second pull wire is pulled. The handle further includes a clamp assembly for clamping the first
7 and second pull wires, and a coupler that couples the first pull wire to the nut inner and the second
8 pull wire to the nut outer. The handle may further include a handle inner that is slid onto ends of
9 the nut inner and nut outer. The twister bolt inner and the handle inner may have cavities in which
10 the transseptal insertion shaft is placed. The handle may further include an introducer assembly
11 formed at a proximal end of the handle and one or more tubes connected to the introducer assembly
12 to supply inflation gas to the one or more hypotubes of the sheath to inflate the positioning balloon.
13 The introducer assembly may include a shaft connector that holds the proximal end of the
14 transseptal insertion shaft, and an introducer assembly connector that adheres to the shaft
15 connector, the transseptal insertion shaft and the handle inner. The one or more tubes may include
16 an additional tube that is connected to the one or more hypotubes to remove gas from the
17 positioning balloon to deflate the positioning balloon.

18 The introducer assembly may include at least one flush port connected to the one or more
19 lumens of the sheath to flush fluid or materials taken from the distal end of the sheath. The at least
20 one flush port may be connected to a flush tube through which suction is applied to flush the fluid
21 or materials.

22 The transseptal insertion shaft may further include a puncture member movably positioned
23 within the one or more lumens and a puncture member balloon located on the distal end of the
24 puncture member. The puncture member has a distal end that is positioned toward the cardiac
25 interatrial septum of the patient. The distal end of the puncture member is capable of precisely
26 puncturing the cardiac interatrial septum. The puncture member may include at least one puncture
27 member tube connected to the puncture member balloon to inflate and deflate the puncture member
28 balloon. The one or more tubes may include an additional tube connected to the introducer
29 assembly to supply gas to the puncture member tube to inflate the puncture member balloon.

30 These advantages and others are achieved, for example, by a handle for controlling
31 movements of a transseptal insertion shaft which is suitable for facilitating precise and safe

1 transseptal puncture of a cardiac interatrial septum of a patient. The handle includes two twister
2 thread half shells having internal threads, a twister bolt inner placed inside and locked into the two
3 twister thread half shells, a nut inner placed inside the two twister thread half shells, a nut outer
4 placed inside the two twister thread half shells, a first pull wire connected to a first side of the
5 transseptal insertion shaft and coupled to the nut inner, a second pull wire connected to a second
6 side of the transseptal insertion shaft and coupled to the nut outer, and a grip overmold over-
7 molded onto the two twister thread half shells. The nut inner engages with the twister bolt inner.
8 The internal threads of the twister thread half shells engage with the nut outer. The nut inner and
9 nut outer rotate in opposite directions to each other when the two twister thread half shells are
10 turned in a direction. A proximal end of the transseptal insertion shaft is coupled to the handle.

11 **BRIEF DESCRIPTION OF THE DRAWINGS**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 FIGS. 19A-19C are a side view, a close side view, and a cross-sectional end view of a
2 puncture tip of an embodiment of an transseptal insertion device with puncture member balloon
3 seal with a deflated puncture member balloon.

4 FIGS. 20A-20C are a side view, a close side view, and a cross-sectional end view of a
5 puncture tip of an embodiment of an transseptal insertion device with puncture member balloon
6 seal with an inflated puncture member balloon.

7 FIGS. 21A-21B are cross-sectional side view and a close, cross-sectional side view of a
8 puncture tip of an embodiment of an transseptal insertion device with puncture member balloon
9 seal with an inflated positioning balloon.

10 FIGS. 22A-22B are cross-sectional side view and a close, cross-sectional side view of a
11 puncture tip of an embodiment of an improved transseptal insertion device with puncture member
12 balloon seal with a deflated positioning balloon.

13 FIGS. 23A-23C show side views and cross-sectional side view of a puncture tip of an
14 embodiment of an transseptal insertion device in which puncture member balloon is inflated and
15 deflated through the inflation port.

16 FIGS. 24A-24C show side views of the distal end portion of the transseptal insertion device,
17 and a cross-sectional view of the distal end portion of the transseptal insertion device.

18 FIG. 25A-25B show a side view and a cross-sectional view of the distal tip portion of
19 another embodiment of the transseptal insertion device which include one or more lumens for
20 infusion and flushing of fluid.

21 FIG. 26 is a perspective view of a transseptal puncture system including transseptal
22 insertion device and a handle to control movements of the transseptal insertion device.

23 FIGS. 27A-27B are side and cross-sectional side views of an embodiment of the handle for
24 the transseptal puncture system.

25 FIG. 28 is partial cross-sectional, perspective view of the embodiment of the handle for the
26 transseptal puncture system.

27 FIG. 29 is a perspective view of the embodiment of the handle for the transseptal puncture
28 system showing the transseptal insertion device coupled to the handle.

29 FIG. 30 is a cross-sectional view of a proximal end of the handle for the transseptal
30 puncture system.

1 FIG. 31 is a cross-sectional view of components of the handle for the transseptal puncture
2 system.

3 FIG. 32 is a cross-sectional view of components of the handle for the transseptal puncture
4 system.

5 FIGS. 33A-33D are perspective, cross-sectional views of an embodiment of the handle,
6 with a flush port, for the transseptal puncture system.

7 DETAILED DESCRIPTION

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

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

1 shaft and used in cardiac catheterizations. After puncture, sheath **12** may be inserted through
2 septum into left atrium. Alternatively, sheath **12** may contain a separate catheter that is inserted
3 through septum post puncture. Transseptal insertion device **10** also includes dilator **16**, positioned
4 in center lumen **15**, as shown in FIG. 1B. The one or more balloons **14** are preferably sealed, air-
5 tight and water-tight, on both its ends to sheath **12**.

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

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

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

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

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

1 being sensors are indeed transceivers because they can both sense and transmit. Such imaging will
2 allow the operator(s) of transseptal insertion device **200** to visualize the cardiac chambers and the
3 determine the location of the distal end or tip **213** of transseptal insertion device **200**, enabling
4 more precise operation of transseptal insertion device **200**. Such a ultrasound chips or transducers
5 used may be similar to ultrasound chip or transducer described in US Pat. App. Pub. 2003/019546,
6 which is herein incorporated by reference, or any other ultrasound transducer known to those of
7 ordinary skill in the art that may be fabricated on scale small enough to be deployed on or in sheath
8 **212** or balloon **214**.

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

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

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

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

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

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

1 catheter shaft **312**. However, ultrasound chips or transducers **326** may be connected wirelessly via
2 WiFi or other wireless connection, to an external imaging device that produces images from the
3 received signals (both still and video images).

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

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

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

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

28 With reference to both FIGS. **11** and **12**, the marker **24** and ring **28** are described and shown
29 as located on balloon **14**. In embodiments, marker **24** and/or ring **28** may also be located on sheath
30 **12** and/or dilator **16**. So located, marker **24** and/or ring **28** would operate in effectively the same
31 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 dial **72** that may
2 be used to turn or deflect distal end of dilator **16**, effectively moving the distal end of dilator **16** up
3 or down in relation to axis of transseptal insertion device **10** (as indicated by arrows in FIG. 16).
4 Handle **70** may also include dial **74** for extruding/extending distal end of dilator **16** out of sheath
5 **12** and retracting dilator **16** back into sheath **12**, effectively moving dilator **16** along axis of
6 transseptal insertion device **10** (as indicated by arrows in FIG. 16). Handle **70** may also be rotated,
7 as indicated by rotational arrow in FIG. 16, in order to deflect or turn distal end of transseptal
8 insertion device to left or right in relation to axis of transseptal insertion device **10**, increasing or
9 decreasing dilator **16** angle of deflection in that direction. If dial **72** moves distal end of dilator **16**
10 along Y axis, and transseptal insertion device **10** axis is considered the Z axis, so that dial **74** moves
11 dilator **16** along Z axis rotating handle **70** moves distal end of transseptal insertion device **10** (and
12 hence distal end of dilator **16**) along X axis. Handle **70** includes a port through which dilator **16**
13 and other devices inserted into transseptal insertion device **10** may be inserted. Handle **70** may
14 also include one or more tubes or other ports permitting connection to external hubs and external
15 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 include an 18 gauge transseptal needle and that
2 is available in 71 cm, 89 cm, and 98 cm lengths. In embodiments, the malleable transseptal needle
3 **90** has different stiffness in a proximal segment **92**, distal segment **94**, and in a middle segment **96**
4 between. For example, malleable transseptal needle **90** may be stiffer in the proximal segment **92**
5 and distal segment **94** and more flexible (less stiff) in a middle segment or mid-section **96**. The
6 mid-section may be the section where transseptal insertion device **10** and dilator **16** angulate. In
7 an embodiment, malleable transseptal needle **90** is used and a control handle provided that enables
8 three-dimensional movements. Malleable transseptal needle **90** shown is, preferably, malleable or
9 flexible at least in part. Proximal end **92** of malleable transseptal needle **90** may be stiff (*e.g.*, made
10 from a stiff material, such as a metal). Mid-section or middle **96** of malleable transseptal needle
11 **90** may be malleable or flexible (*e.g.*, made from a flexible, malleable material, such as rubber).
12 Accordingly, mid-section may flex or bend, enabling malleable transseptal needle **90** to pass
13 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.

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 With reference now to FIGS. **19A-22B**, shown are an embodiment of transseptal insertion
27 device **500** with puncture member balloon seal. With reference to FIGS. **19A-19C**, shown are a
28 side view, a close-in side view of the section C, and a cross-sectional view of the section D-D of
29 the transseptal insertion device **500**, respectively, when the puncture member balloon **504** is
30 deflated. With reference now to FIGS. **20A-20C**, shown are a side view, a close-in side view of

1 the section E, and a cross-sectional view of the section F-F of the transseptal insertion device **500**,
2 respectively, when the puncture member balloon **504** is inflated.

3 Referring to FIGS. **19A-20C**, the transseptal insertion device **500** includes a radio-
4 frequency (RF) generator plug **501**, Y-connector **502**, and puncture member multi-lumen extension
5 **503** that includes sheath **514** and puncture member **515** (see FIG. **21B**). The RF generator plug
6 **501** is connected to the puncture member multi-lumen extension **503** through a Y-connector **502**,
7 and provides power for a RF generator (not shown) that may be positioned in the puncture member
8 **515** located in the multi-lumen extension **503**. The puncture member **515** is located inside the
9 sheath **514**, and has a distal end (puncture tip) **506** that is positioned toward the cardiac interatrial
10 septum of the patient when the device **500** is in use. The puncture member balloon **504** is mounted
11 on the puncture member **515** and is located near the distal end **506** of the puncture member **515**.
12 The close-in side view FIG. **19B** and the cross-sectional view FIG. **19C** show deflated puncture
13 member balloon **504**, while the close-in side view FIG. **20B** and the cross-sectional view FIG. **20C**
14 show inflated puncture member balloon **504**.

15 The puncture member **515** includes an puncture member port **507** for inflating or deflating
16 the puncture member balloon **504**, and a lumen **508** which is connected to the puncture member
17 port **507** that supplies gas or fluid to the puncture member port **507** to inflate the puncture member
18 balloon **504**. The puncture member **515** may include at least one RF tip **505** at the distal end **506**
19 of the puncture member **515**. The RF tip **505** is capable of delivering RF energy. The RF generator
20 (not shown) produces RF energy, and the RF energy is supplied to the RF tip **505**. The puncture
21 member **515** includes a lumen **509** for wires that delivers RF energy to the RF tip **505**.

22 With reference to FIGS. **21A-21B**, shown are a side view and a close-in side view of the
23 section D of the transseptal insertion device **500**, respectively, when the positioning balloon **510**
24 is inflated. The sheath **514** may have the sheath marker band **513**, and the puncture member balloon
25 **504** may be aligned with the sheath marker band **513**. The sheath **514** includes one or more
26 inflation ports **512** connected to the positioning balloons **510**, and at least one tube **516** that delivers
27 gas or fluid to the inflation port **512** to inflate the positioning balloons **510**. The tube **516** may be
28 the hypotube **17** (see FIG. **13**). The sheath **514** also includes one or more deflation ports **511** that
29 is connected to the positioning balloons **510**. When the puncture member balloon **504** is inflated,
30 the inflated puncture member balloon **504** seals the one or more deflation ports **511** in the sheath
31 **514**, preventing leak from the positioning balloons **510** and permitting inflation of the positioning

1 balloons **510**. The position balloons **510** are then inflated through the inflation port **512** of the
2 sheath **514**. The non-compliant or semi-compliant puncture member balloon **504** seals off the
3 deflation ports **511** of the sheath **514**, allowing the positioning balloons **510** to inflate and position
4 the distal end **506** of the puncture member **515** to the fossa ovalis (see FIG. 6 for example).

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

12 With reference to FIGS. **23A-23C**, shown are a close-in side view of the section E with
13 inflated balloon, a close-in side view of section C with deflated balloon, and a cross-sectional view
14 of the section D-D of an embodiment of transseptal insertion device **600**, respectively. With
15 reference to FIGS. **24A-24C**, shown are side views of the distal end portion of the puncture
16 member multi-lumen extension **503** and a cross-sectional view of the section A-A of the distal end
17 portion of the puncture member multi-lumen extension **503** of the transseptal insertion device **600**
18 of the additional embodiment, respectively.

19 In these embodiments, the improved transseptal insertion device may utilize the puncture
20 member balloon **504** for visibility, anchoring against the septum and preventing inadvertent
21 advancement into the left atrium. In such an embodiment, the transseptal puncture member balloon
22 **504** is inflated (see FIG. **23A**) through the puncture member port **507**, once the puncture member
23 is outside the shaft and is tenting the septum (*i.e.*, the puncture member balloon is pressing against
24 the septum, tenting the septum away from shaft end). The puncture member balloon **504** is 5 to 8
25 mm (distance L in FIG. **24B**) proximal to the tip of the puncture member and prevents the puncture
26 member from being pushed beyond the 5 to 8 mm into the left atrium. After successful puncture
27 of the interatrial septum, a 035 (0.035") guidewire in the guide wire access lumen (or center lumen)
28 **518** (See FIG. **23C**) is advanced into the left atrium and the puncture member balloon **504** is
29 deflated (see FIG. **23B**) and the puncture member withdrawn back into the shaft.

30 In the embodiments, the positioning balloon **510** on the sheath or shaft **514** may have
31 separate hypotubes for inflation and deflation. For example, the sheath **514** may have inflation

1 hypotube **516a** and a deflation hypotube **516b** to inflate and deflate the positioning balloon **510**,
2 respectively. However, the embodiment is not limited to this configuration. The positioning
3 balloons **510** may be inflated and deflated through the same hypotube (for example, see FIG. **3A**).
4 The puncture member **515** has a puncture member port **507** to inflate and deflate the puncture
5 member balloon **504**. The puncture member may have a radiofrequency tip **505** at a distal end of
6 the puncture member **506**. For the small, medium and large curl shafts, the puncture member length
7 is small, medium and large. The curl shaft chosen depends on the size of the atrium. For example,
8 a small curl shaft is used for small atrium. When advanced beyond the shaft **514**, the puncture
9 member **515** can only be advanced to a max of 5 to 8 mm coming to a hard stop.

10 In the embodiment, the positioning balloon **510** may be inflated through a separate
11 hypotube, overhangs the shaft by 3 mm, and has variable dimension based on the amount of fluid
12 or air infused or insufflated into the balloon. For small, medium and large curl shafts, the puncture
13 member **515** has a conical tip with no radiofrequency or another energy source. The puncture
14 member may have an 0352 lumen (0.0352") to 040 (0.040") lumen **518**. Through this lumen, a
15 wire which may or may not have radiofrequency energy capability may be advanced across the
16 septum. Through this lumen a Brockenbrough needle or a radiofrequency tip needle could be
17 advanced and used to cross the septum. In FIGS. **24A-24B**, the wiring member **519** may be the
18 wire, Brockenbrough needle, or a radiofrequency tip needle. The transseptal insertion device **600**
19 includes a sheath **514** that defines at least one lumen **517** therein, one or more positioning balloons
20 **510** that are connected to the distal end **506** of the sheath **514**, a puncture member **515** movably
21 positioned within the at least one lumen **517**, and a puncture member balloon **504** mounted on the
22 puncture member **515**. The puncture member **515** defines a center lumen **518** therein, and a wire
23 member **519**, for example, is positioned inside the center lumen **518**.

24 With reference to FIG. **25A-25B**, shown are a side view of the distal tip **13** portion and a
25 cross-sectional view of the section B-B of the distal tip **13** portion of the transseptal insertion
26 device **700** of the disclosed invention, respectively. In the embodiments, the balloon **14** on the
27 sheath **12** may have separate hypotubes for inflation and deflation. For example, the sheath **12** may
28 have inflation hypotube **516a** and a deflation hypotube **516b** to inflate and deflate the balloon **14**,
29 respectively. However, the embodiment is not limited to this configuration. The balloon **14** may
30 be inflated and deflated through the same hypotube (for example, see FIGS. **2A** and **3A**). The
31 balloon **14** of pulmonary artery and venous balloon tipped transseptal insertion device **10** may be

1 used to completely occlude the respective vessels they are introduced into. The transseptal
2 insertion device **10** has a center lumen **15** in which a wire member or dilator **16** is movably
3 disposed. The dilator **16** may be a wire, Brockenbrough needle, radiofrequency tip needle, pigtail
4 catheter, or transseptal wire.

5 In an embodiment, the transseptal insertion device **10** may have additional lumens **15a**,
6 **15b** for flushing and aspirating with presence of proximal and distal ports forming a loop of fluid
7 circulation for aspiration either mechanically or using the venturi effect. However, the disclosed
8 invention is not limited to this configuration. The catheter insertion device **10** may be configured
9 to perform flushing and/or aspirating through the lumen **15**, or may have more than one lumen for
10 dilator, flushing and aspirating. When the catheter insertion device **10** has a multiple lumens, one
11 lumen **15a**, for example, may be used for an aspiration port which may be attached to a mechanical
12 aspiration system or an automated closed loop system capable of applying varying degrees of
13 aspiration force, and the other lumen **15b** may be used for an infusion port for infusing fluids and
14 pharmaceutical agents either mechanically or using an infusion system with varying levels of
15 infusion pressures. The pulmonary artery balloon tipped transseptal insertion device **10** may be
16 used to infuse fluids and pharmaceutical agents through the one or more lumens. The pulmonary
17 artery and venous transseptal insertion device **10** may be connected in a closed loop system
18 whereby the optimal pressure for retrograde perfusion/flushing of the pulmonary vasculature may
19 be performed.

20 In an embodiment, various types of wire members or dilators **516** may be separately
21 disposed on one or more lumens. For example, one of the wire members **516** may be a pigtail
22 catheter, and the pigtail catheter may be present as well either via a separate lumen **15a** or **15b** or
23 in the main lumen **15**. The pigtail catheter may be a straight catheter with multiple pores for
24 pharmaceutical infusion.

25 With reference now to FIG. **26**, shown is an embodiment of transseptal puncture system
26 **2000** including an improved handle **2300** assembled with and connect to transseptal insertion
27 device **2350**. The transseptal insertion device **2350** may be any transseptal insertion devices
28 disclosed in this specification. The transseptal insertion device **2350** may be referred to as
29 transseptal puncture system shaft or transseptal insertion shaft. As is shown in FIG. **26**, distal end
30 **2358** of the transseptal insertion shaft **2350** is at opposite end of improved transseptal puncture
31 system **2000** from handle **2300**. Distal end **2358** bends or flexes as handle overmold of the handle

1 **2300** is rotated. Handle **2300** may also be moved towards or away from distal end **2358** of the
2 transseptal puncture system shaft **2350** in order to insert or retract improved transseptal puncture
3 system **2000**.

4 With reference to FIGS. **27A-27B**, shown are side and cross-sectional views of an
5 embodiment of an improved handle **2300** for an improved transseptal puncture system **2000**. The
6 handle **2300** may be used to control movements of the transseptal insertion shaft **2350**, for example
7 by extending the transseptal insertion shaft **2350** shown in FIG. **26**, turning/flexing the distal end
8 **2958** of the transseptal insertion shaft **2350** of the transseptal puncture system **2000**, inflating
9 puncture member balloon and positioning balloons, etc. The handle **2300** includes two twister
10 thread half shells **2302**, a grip overmold **2304**, a handle outer sleeve **2306**, a stop cock **2308** for
11 controlling flow of inflation gas for inflating puncture member and positioning balloons, tubing
12 **2310** through which inflation gas flows, and introducer assembly **2312**. Transseptal insertion shaft
13 **2350** extends out of the distal end of the handle **2300** on which the grip overmold **2304** is located
14 (left side of the handle in FIG. **27A**). Introducer assembly **2312** includes silicon seal to tubing **2310**
15 which seals a connection between the transseptal insertion shaft **2350**, and the tubing **2310**. Grip
16 overmold **2304** provides grip for handle **2300** and is used to turn or rotate twister half shells **2302**
17 and otherwise operate handle **2300**. Handle outer sleeve **2306** encases proximal end (right side of
18 the handle in FIG. **27A**). The tubing **2310** may include one or more supply tubes that may supply
19 gas to inflate one or more positioning balloons and to inflate the puncture member balloon. The
20 tubing **2310** may have additional tube to remove gas from the positioning balloon, deflating the
21 one or more positioning balloons.

22 With reference to FIG. **27B**, shown is a cross-section (on line A-A shown in FIG. **27A**) of
23 the embodiment of the handle **2300** for the transseptal puncture system **2000**. FIG. **27B** shows
24 cross-section of two twister thread half shells **2302**. Also shown is grip overmold **2304** and cross-
25 section of introducer assembly **2312** through which tubing **2310** introduces inflation gas. As shown,
26 handle **2300** also includes twister bolt inner **2314**, a nut inner **2316**, a nut outer **2318**, a handle
27 inner **2320**, a coupler **2322**, a wire clamp assembly **2324**, and a handle inner cover **2326**. Nut inner
28 **2316** and nut outer **2318** are each connected to one of two pull wires **2352** and **2354** (see FIG. **32**)
29 that extend through shaft **2350** of the transseptal puncture system **2000** and attached to different
30 sides of distal end of the shaft **2350**. Nut inner **2316** and nut outer **2318** are rotated in different,
31 opposite directions by turning of twister thread half shells **2302**. Twister thread half shells **2302**

1 have internal threads that engage with nut outer **2318**. Nut outer **2318** has an alignment key that
2 engages the nut inner **2316** and allows nut inner **2316** to move linearly, sliding against the nut
3 outer **2318**. The internal thread of the nut inner **2316** engages with the twister bolt inner **2314**. The
4 twister bolt inner **2314** is locked into the twister half shell **2302**. Both twister half shells **2302** and
5 the twister bolt inner **2314** turn together then simultaneously engaging the outer nut **2318** and inner
6 nut **2316** moving in opposite directions. When twister thread half shells **2302** are rotated in a first
7 direction, nut inner **2316** rotates and pulls the pull wire, to which the nut inner **2316** is coupled by
8 wire clamp assembly **2324**, towards the proximal end of handle **2300** (right side of handle **2300** in
9 FIG. **27B**). This movement causes the side of the distal end of shaft **2350**, to which nut inner **2316**
10 pull wire is attached, to bend or flex towards proximal end of the transseptal puncture system **2000**.
11 Rotating twister thread half shells **2302** in a second direction causes the nut outer **2318** to rotate
12 and pull the pull wire, to which the nut outer **2318** is coupled by wire clamp assembly **2324**,
13 towards the proximal end of handle **2300** (right side of handle **2300** in FIG. **27B**). This movement
14 causes the side of the distal end of shaft **2350**, to which nut outer **2318** pull wire is attached, to
15 bend or flex towards proximal end of the transseptal puncture system **2000**. Embodiments provide
16 up to 180 degrees of flex or turn for distal end of shaft. When nut inner **2316** and nut outer **2318**
17 so rotate, the nut inner **2316** and the nut outer **2318** each slides in the opposite direct along their
18 smooth adjoining surfaces.

19 The puncture system shaft **2350** of the transseptal puncture system **2000** extends through
20 cavity defined by and at center of twister bolt inner **2314** and handle inner **2320** through to
21 proximal end (right side of FIG. **27B**) of handle and introducer assembly **2312**. The proximal end
22 of the transseptal insertion shaft **2350** is coupled to the introducer assembly **2312**. Twister bolt
23 inner **2314** has external thread that engages with the nut inner **2316**. The twister thread half shells
24 **2302**, nut inner **2316**, and nut outer **2318** rotate about the twister bolt inner **2314**. Twister bolt
25 inner **2314** is also clamped between twister thread half shells **2302**. Twister bolt inner **2314** turns
26 or rotates together with grip overmold **2304**, engaging nut inner **2316**. Coupler **2322** couples nut
27 inner **2316** and nut outer **2318** to wire clamp assembly **2324**. Grip overmold **2304** is over-molded
28 onto twister half shells **2302**.

29 With reference now to FIG. **28**, shown is a partial cross-sectional perspective side view of
30 an embodiment of the handle **2300** for the transseptal puncture system **2000**. Shown are twister
31 thread half shells **2302**, grip overmold **2304**, handle outer sleeve **2306**, twister bolt inner **2314**, nut

1 inner **2316**, nut outer **2318**, and handle inner **2320**. FIG. **28** more clearly shows threads of twister
2 thread half shells **2302** and twister bolt inner **2314**, and their interaction with nut inner **2316** and
3 nut outer **2318**.

4 With reference now to FIG. **29**, shown is perspective view of an embodiment of the handle
5 **2300** for the transseptal puncture system **2000**. Shown are grip overmold **2304**, handle outer sleeve
6 **2306**, stop cock **2308**, tubing **2310**, and introducer assembly **2312**. Also shown is transseptal
7 insertion shaft **2350** of the transseptal puncture system **2000** attached to handle **2300** and extending
8 out of distal end of handle **2300**.

9 With reference now to FIG. **30**, shown is a cross-section perspective view of proximal end
10 of an embodiment of the handle **2300** for the transseptal puncture system **2000**. Shown is
11 introducer assembly **2312** in greater detail. Tubing **2310** is coupled to introducer assembly **2312**
12 with silicon seal. Proximal end of the transseptal insertion shaft **2350** of the transseptal puncture
13 system **2000** extends through proximal end of the handle **2300** to introducer assembly **2312**. As
14 shown, introducer assembly **2312** defines an opening or port **2347** allowing communication to the
15 interior of shaft **2350** (e.g., through which drugs, etc. can be introduced into improved transseptal
16 puncture system). For example, drugs may be delivered through the center lumen **15** or additional
17 lumen **15a** or **15b** (see FIGS. **25A-25B**) from the opening defined in the introducer assembly **2312**.
18 Introducer assembly **2312** includes introducer assembly connector **2342**, shaft connector **2344**, and
19 assembly cover **2346**. The shaft connector **2344** hold the proximal end of the shaft **2350**. Also
20 shown are handle outer sleeve **2306**, handle inner **2320** and a handle inner cover **2326**. The
21 introducer assembly **2312** may have a gas supply port **2347** that connects the tubing **2310** to an
22 interior of the shaft **2350** such that gas supplied from the tubing **2310** is supplied to one of the
23 hypotubes **516a** and **516b** of the sheath **12** of the shaft **2350**. The tubing **2310** may include
24 additional tube that is configured to remove gas from the positioning balloon **14** through one of
25 the hypotubes **516a** and **516b** of the sheath **12** of the shaft **2350**.

26 One of the many advantages of embodiments of the improved handle **2300** for the
27 transseptal puncture system **2000** is the minimal amount of adhesive that is used to assembly
28 handle **2300**. In embodiments, introducer assembly connector **2342** adheres to handle inner **2320**,
29 shaft **2350**, and shaft connector **2344**. Shaft connector **2344** adheres to shaft and assembly cover
30 **2346**, and assembly cover **2346** adheres to tubing **2310**. Substantially all of the remaining parts of
31 embodiments of the improved handle **2300** are connected without adhesive.

1 With reference now to FIG. 31, shown is a cross-sectional view of various components of
2 an embodiment of the handle 2300 for the transseptal puncture system 2000. Shown are a twister
3 thread half shell 2302, twister bolt inner 2314, nut inner 2316, nut outer 2318, and handle inner
4 2320. These components snap in place when assembled. For example, twister bolt inner 2314 snaps
5 into twister thread half shells 2302, and nut inner 2316 and nut outer 2318 are assembled onto
6 twister bolt inner 2314. Handle inner 2320 is slid onto proximal ends of nut inner 2316 and nut
7 outer 2318.

8 With reference now to FIG. 32, shown is a cross-sectional view of various components of
9 an embodiment of the handle 2300 for the transseptal puncture system 2000. Shown are twister
10 thread half shells 2302, handle overmold 2304, twister bolt inner 2314, nut inner 2316, nut outer
11 2318, handle inner 2320, coupler 2322, clamp assembly 2324, and shaft 2350. Also shown are pull
12 wires 2352 and 2354, which are clamped and coupled to nut inner 2316 and nut outer 2318 with
13 clamp assembly 2324 and coupler 2322. As shown, guide wires 2352 and 2354 extend into shaft
14 2350 through lumen (not shown) in outer sheath of shaft 2350.

15 With reference now to FIGS. 33A-33D, shown is an embodiment of improved handle 2400,
16 with at least one flush port 2382 formed in the introducer assembly 2312, for an improved
17 transseptal puncture system 2000. As shown, handle 2400 further includes at least one flush port
18 2382 which may be used to flush fluid and material retrieved by the improved transseptal puncture
19 system 2000. Such fluid or material may be taken from the distal end of the system (e.g., by the
20 distal tip of the shaft) from inside the atrium. The flush port 2382 may be in communication with
21 at least one flush tube 2384 to which a gentle suction may be applied to flush the fluid or material
22 out of the atrium (i.e., by sucking such fluid or material through the shaft of the improved
23 transseptal puncture system) to the flush port 2382 and out the flush tube 2384. The flush port
24 2382 is in communication with interior of the puncture system shaft 2350, and may be connected
25 to a center lumen 15 or additional lumen 15a or 15b (see FIGS. 25A-25B). The flush port 2382
26 may be used as an opening through which drugs, etc. can be introduced into the transseptal
27 puncture system shaft 2350. For example, drugs may be delivered through the center lumen 15 or
28 additional lumen 15a or 15b (see FIGS. 25A-25B) from the flush port 2382. In another
29 embodiment, the introducer assembly 2312 may include multiple ports 2382, to which multiple
30 tubes 2384 are connected, for infusing fluids and pharmaceutical agents and for flushing and
31 aspirating of materials. FIGS. 33A-33D also show tubing 2310 through which inflation gas flows.

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