

PERCUTANEOUS RETROGRADE THERAPY FOR PULMONARY EMBOLISM**1 CROSS REFERENCE TO RELATED APPLICATIONS**

2 This application claims the priority of U.S. Provisional Application Serial No. 63/080,332,
3 filed on September 18, 2020, which is hereby incorporated herein by reference in its entirety.

4 FIELD

5 The present invention relates generally to cardiac catheter system and method with balloon
6 tipped catheter insertion devices which are suitable for facilitating precise and safe cannulation of
7 pulmonary veins or pulmonary arteries to provide treatment for pulmonary embolism.

8 BACKGROUND

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

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

21 Some medical procedures may require catheterization into the left atrium of the heart. For
22 this purpose, to avoid having to place a catheter in the aorta, access to the left atrium is generally
23 achieved by accessing the right atrium, puncturing the interatrial septum between the left and right
24 atria of the heart, and threading the catheter through the septum and into the left atrium. Transseptal
25 puncture must be carried out with extreme precision, as accidental puncturing of surrounding tissue
26 may cause very serious damage to the heart. In addition, transseptal puncture may require
27 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 Furthermore, the use of different types of catheters to treat pulmonary embolism in the
8 cardiopulmonary circulation has emerged over the past several years. The advantage of catheter
9 based systems to treat pulmonary embolism is to provide less invasive methods for clot removal.
10 As such, the development of novel catheters to effectively remove clot in the setting of pulmonary
11 embolism can be life-saving and preserve quality of life to patients. The currently available devices
12 in the space, while effective, currently have limited utility for complete clot removal in most
13 patients.

14 **SUMMARY**

15 In order to overcome the disadvantages of the conventional art, the disclosed invention
16 provides a closed loop catheter system including multiple catheter insertion devices for treating
17 pulmonary embolism. The closed loop catheter system, while in use, creates an isolated segment
18 of closed segments of the pulmonary vein, corresponding pulmonary capillaries and corresponding
19 pulmonary artery. Pulmonary embolectomy is more efficiently performed with the isolated
20 segment created by the closed loop catheter system of the disclosed invention. Further, by using
21 this closed loop system, clot in the pulmonary circulation can be effectively removed by pushing
22 it out from the pulmonary vein into a catheter placed in the corresponding pulmonary artery. To
23 access the pulmonary vein system, transseptal access will be required as described above.

24 These advantages may be achieved by a catheter system for pulmonary embolism with
25 balloon tipped catheter insertion devices. The catheter system includes a first catheter insertion
26 device configured to be suitable for facilitating precise and safe cannulation of pulmonary veins
27 and a second catheter insertion device configured to be suitable for facilitating precise and safe
28 cannulation of pulmonary arteries. The first catheter insertion device includes a sheath that defines
29 at least one lumen therein and has a distal end that is configured to be positioned at proximal
30 segment of a designated pulmonary vein and a proximal end that is external to the patient and at
31 least one balloon that is positioned at the distal end of the sheath. The at least one balloon is

1 configured to seal ostium of the designated pulmonary vein when inflated. The first catheter
2 insertion device is configured to be connected to an infuser to supply fluid to the pulmonary veins.
3 The second catheter insertion device includes a sheath that defines at least one lumen therein and
4 has a distal end that is configured to be positioned at proximal segment of a designated pulmonary
5 artery and a proximal end that is external to the patient and at least one balloon that is positioned
6 at the distal end of the sheath. The at least one balloon is configured to seal the designated
7 pulmonary artery when inflated. The second catheter insertion device is configured to be connected
8 to an aspirator to aspirate materials from the pulmonary arteries.

9 The first and second catheter insertion devices each may include a dilator movably
10 positioned in the at least one lumen. The dilator is configured to puncture septum. The first and
11 second catheter insertion devices each may include one or more additional lumens defined by the
12 sheath to deliver additional fluids into the designated pulmonary vein or for flushing or aspirating.
13 The first and second catheter insertion devices each may have a plurality of curls and flexion points
14 for multidirectional deflections. The at least one lumen of the first catheter insertion device may
15 be configured to deliver the fluid supplied by the infuser. The at least one lumen of the second
16 catheter insertion device may be configured to carry the materials to the aspirator.

17 These advantages may be also achieved by a method of using a catheter system including
18 a first catheter insertion device and a second catheter insertion device for pulmonary embolism.
19 The method includes steps of engaging a distal portion of a first catheter insertion device with an
20 ostium and proximal segment of a designated pulmonary vein, inflating at least one balloon of the
21 first catheter insertion device to seal the ostium of the designated pulmonary vein, positioning a
22 distal portion of the second catheter insertion device within a proximal segment of a corresponding
23 designated pulmonary artery, inflating at least one balloon of the second catheter insertion device
24 to seal the designated pulmonary artery, performing infusion of fluid into the designated
25 pulmonary vein through at least one lumen defined in a sheath of the first catheter insertion device
26 by using an infuser connected to the first catheter insertion device, and performing aspiration of
27 materials from the designated pulmonary artery through at least one lumen defined in a sheath of
28 the second catheter insertion device by using an aspirator connected to the second catheter insertion
29 device.

30 The engaging the distal portion of the first catheter insertion device may be performed by
31 using a fluoroscopic or echocardiographic guidance. The infusion of fluid may be performed such

1 that the fluid flows into the designated pulmonary vein, corresponding pulmonary capillaries and
2 the corresponding designated pulmonary artery. The infusion of fluid may be performed with a
3 designated rate of flow and pressure to dislodge thrombotic materials from a pulmonary arterial
4 vascular bed into the proximal segment of the corresponding designated pulmonary artery. The
5 performing aspiration of materials may include removing thrombotic materials from the designated
6 pulmonary artery. The performing infusion of fluid may include infusing pharmaceuticals into the
7 designated pulmonary vein, and the performing aspiration of materials may include aspirating the
8 pharmaceuticals and thrombotic materials through the designated pulmonary artery. The
9 performing aspiration of materials may include aspirating blood from the designated pulmonary
10 artery, and the method may further include filtering the blood, and reinfusing the filtered blood
11 into circulations using extracorporeal membrane oxygenation (ECMO) system.

12 BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 FIG. 19 shows closed loop catheter system of the disclosed invention isolating desired
4 segment of pulmonary vascular circulation.

5 FIG. 20 shows a balloon tipped pulmonary venous catheter insertion device in the proximal
6 pulmonary vein via trans septal access.

7 FIG. 21 shows a close view of the portion C1 of FIG. 20 in which balloon tipped pulmonary
8 venous catheter insertion device cannulates and isolates designated pulmonary vein after balloon
9 at distal tip of the venous catheter insertion device is fully inflated.

10 FIG. 22 shows a balloon tipped pulmonary artery catheter insertion device cannulating and
11 isolating designated pulmonary artery after distal balloon tip is fully inflated.

12 FIG. 23 shows a balloon tipped catheter insertion device cannulating the pulmonary artery
13 and isolating designated pulmonary artery after distal balloon is inflated being attached to an
14 aspiration apparatus on its proximal end (outside the body) and aspirating matter through the lumen
15 of the balloon tipped pulmonary artery catheter and a balloon tipped catheter cannulating the
16 pulmonary vein as described in FIG. 20 and FIG. 21 attached to an apparatus that can infuse fluid
17 at a designated pressure and flow rate on its proximal end (outside the body).

18 FIG. 24A-24B show a side view and a cross-sectional view of the distal tip portion of the
19 balloon tipped catheter insertion device of the disclosed invention.

20 FIG. 25 shows a flowchart diagram for a method of using the closed loop catheter system
21 that includes a first balloon tipped catheter insertion device and a second balloon tipped catheter
22 insertion device for pulmonary embolism.

23 DETAILED DESCRIPTION

24 In this section, some embodiments of the invention will be described more fully with
25 reference to the accompanying drawings, in which preferred embodiments of the invention are
26 shown. This invention, however, may be embodied in many different forms and should not be
27 construed as limited to the embodiments set forth herein. Rather, these embodiments are provided
28 so that this disclosure will be thorough and complete, and will convey the scope of the invention
29 to those skilled in the art. Like numbers refer to like elements throughout, and prime notation is
30 used to indicate similar elements in alternative embodiments. Parts that are the same or similar in
31 the drawings have the same numbers and descriptions are usually not repeated.

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

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

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

28 With reference now to FIG. **1C**, dilator **16** is shown positioned within lumen **15** of sheath
29 **12**. Tip of dilator **16** is positioned within distal tip **13** of catheter insertion device **10** sub-planar to
30 end of catheter insertion device **10**. The position of dilator **16** may be in immediately prior to
31 inflation of one or more balloons **14**. It is noted that the relative sizes of catheter/sheath **12** and

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

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

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

18 With reference to FIGS. **2C-2D**, shown are embodiments of catheter insertion device **200**
19 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-3B, shown is catheter 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 through

1 hypotubes **314** to inflate or deflate balloons **314**. Outer covering **319** may cover the multiple
2 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 catheter
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 catheter insertion device **10** with
2 radiofrequency (RF) energy capability. Catheter insertion device **10** shown includes sheath **12**,
3 overhanging one or more balloons **14**, and dilator **16**. Dilator **16** may include cap or crown **22**, on
4 distal end as shown, with RF energy capability or capable of delivering RF energy. Alternatively,
5 cap or crown may include or be an RF electrode. Dilator **16** may be connected, *e.g.*, on proximate
6 end (not shown) to a radiofrequency energy source (not shown) at, *e.g.*, external hub, that provides
7 RF energy to cap or crown **22**. The RF energy may be delivered through dilator **16**. So equipped
8 with cap or crown **22**, dilator **16** may tent interaxial septum and create puncture of interaxial
9 septum through delivery of RF energy. In this embodiment, the use of a sharp needle may be
10 avoided. The dilator with cap or crown on distal end with RF energy capability or capable of
11 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 catheter insertion device **400** including drive assembly
14 **421**, which is coupled to dilator **416**, and knob **422** coupled to drive assembly **421** to cause dilator
15 **416** to traverse along an axial direction of sheath or catheter shaft **412**. Dilator **416** may move
16 backwards or forwards along the axial direction of sheath **412** while knob **422** is rotated. The drive
17 assembly **421** may include nut assembly to drive the dilator **416**. Dilator **416** may be with or
18 without RF energy capability.

19 With reference now to FIG. 6, shown is distal end of an embodiment of catheter 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 catheter 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 catheter insertion device **10** and dilator **16**, formed by the end of overhanging balloon **14**. Hence,
25 dilator **16** remains sub-planar to overhanging balloon **14** until operator intends balloon **14** to be
26 deflated and dilator **16** to tent and puncture interatrial septum **100**. As noted above, balloon **14**
27 preferably extends completely around circumference of tip **13** of catheter insertion device **10**.
28 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 catheter insertion device **10** in which overhanging balloon **14** is inflated. As shown,
31 inflated overhanging balloon **14** preferably extends around entire circumference of sheath **12** (and,

1 therefore, device **10**). Shown situated within lumen **15** of sheath **12** is tip of dilator **16**. Tip of
2 dilator **16** is positioned within tip **13** of catheter insertion device **10**, as it would be prior to being
3 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 catheter insertion device **10**.

10 With reference now to FIG. **9**, shown is shown is distal end of an embodiment of catheter
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 catheter insertion device **10** or other catheters in the left atrium. In this manner, catheters may be
19 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 catheter 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 catheter
28 insertion device **10** with a flexible sheath **12** flexed or angulated at different angles. Catheter
29 insertion device **10** may be flexed or angulated depending on the anatomy of the atria using fixed
30 angled dilators **16** that are inserted into lumen shaft of sheath **12**, causing sheath **12** to flex. Such
31 fixed angled dilators **16** may be, *e.g.*, any angle from 0-270°. Alternatively, sheath **12**, lumen shaft

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

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

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

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

24 With reference now to FIG. **12**, shown is another embodiment of overhanging balloon **14**
25 which may be deployed in embodiments of catheter insertion device **10**. Overhanging balloon **14**
26 may include ring or band **28** around a portion of balloon **14**. Ring or band **28** may serve as a marker,
27 similar to markers **24** shown in FIG. **11**. Hence, ring **28** may be radiopaque or echogenic and may
28 be view by scanning devices used for visualization in cardiac catheterizations (*e.g.*, fluoroscopic
29 imaging devices). Similar to the letter E or C, the view of the ring **28** changes as the distal tip **13**
30 of transseptal insertion device **10** moves more posterior. When in a least posterior position, ring
31 **28** may appear as just a line or band positioned across axis of catheter insertion device **10**. When

1 device **10** is rotated so that distal tip **13** is significantly closer to the posterior, ring **28** may appear
2 as a full “flat” circle or ring. In FIG. **12**, distal tip **13** is partially rotated so that ring **28** is partially
3 visible.

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

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

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

1 range of, but not limited to, 0.0 mm-5.0 mm. The end of the overhang or extension **60** is the plane
2 to which dilator **16** remains sub-planar until moving to tent and puncture the interatrial septum.

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

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

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

25 Stabilizer **80** includes connecting rods or arms **82** that connect stabilizer **80** to handle **70** at
26 proximal end of transseptal insertion device **10**. Connecting arms **82** are attached to stabilizer
27 platform **84**. Connecting arms **82** preferably hold the handle **70** securely and tightly, while
28 permitting desired rotational movements and control manipulation. Stabilizer platform **84** is
29 moveably attached to stabilizer base **86** so that stabilizer platform **84**, and hence handle **70** and
30 catheter insertion device **10**, may be slid forwards and backwards along axis of catheter insertion
31 device **10** towards and away from insertion point in patient (typically femoral vein at the groin of

1 patient). Stabilizer base **86** is typically secured to a flat, stable surface, such as a table, or the leg
2 of the patient. Configured as such, stabilizer **80** prevents unwanted vertical, rotational, or other
3 movement of catheter insertion device **10** and its handle **70**, keeping transseptal insertion device
4 **10** and its handle **70** stable while permitting precise manipulation of handle **70** and its controls.

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

22 In embodiments shown herein, balloon **14** and dilator **16** may be used as energy sources in
23 the left atrium and may be used to deliver energy to the pulmonary veins, left atrial appendage,
24 mitral valve and the left ventricle present in the left atrium. Such embodiments may include
25 external energy sources connected to balloon **14** and/or dilator **16** through wires or other
26 conductors extending lumen in sheath **12**. Delivery of energy via balloon **14** or dilator **16** may be
27 thermal/Cryo or radiofrequency, laser or electrical. The delivery of such energy could be through
28 a metallic platform such as a Nitinol cage inside or outside balloon **14**. Transseptal insertion device
29 **10** may also include an energy source external to the proximal end of the sheath and operatively
30 connected to balloon **14** to deliver energy to balloon **14**.

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

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

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

1 such as applying energy to different portions of balloon **14** to increase or decrease the compliance,
2 and expandability, of that portion.

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

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

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

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

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

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

30 In related embodiments, MRI antenna may be installed on distal tip **13** of sheath **12**, dilator
31 **16** or on balloon **14**, similar to ultrasound chips or transducers **226** or **326** described above. Wires

1 connecting such MRI antenna or other MRI components may pass through lumen in dilator **16** or
2 sheath **12** and connect with appropriate magnetic resonance energy source on exterior of distal end
3 of catheter insertion device **10**.

4 The embodiments of the disclosed invention includes a balloon tipped catheter insertion
5 device which is suitable for facilitating precise and safe cannulation of pulmonary veins. The
6 catheter insertion device includes a sheath that defines at least one lumen therein and has a distal
7 end that is closest to the cardiac structure of a patient when the device is in use and a proximal end
8 that is external to the patient; a balloon that is connected to the distal end of the sheath, wherein
9 the balloon, when inflated and the insertion device is in use, may overhang and extend past the
10 distal end of the sheath, preventing accidental puncturing of the cardiac structures and stabilizing
11 the insertion device against the pulmonary vein; and a dilator that is positioned within the at least
12 one lumen when the insertion device is in use.

13 The embodiments of the disclosed invention also includes a balloon tipped catheter
14 insertion device which is suitable for facilitating precise and safe cannulation of pulmonary arteries.
15 The catheter insertion device includes a sheath that defines at least one lumen therein and has a
16 distal end that is closest to the cardiac structure of a patient when the device is in use and a proximal
17 end that is external to the patient; a balloon that is connected to the distal end of the sheath, wherein
18 the balloon, when inflated and the insertion device is in use, may overhang and extend past the
19 distal end of the sheath, preventing accidental puncturing of the cardiac structures and stabilizing
20 the insertion device against the pulmonary artery; and a dilator that is positioned within the at least
21 one lumen when the insertion device is in use.

22 The embodiments of the disclosed invention also includes a balloon tipped catheter
23 insertion device which is suitable for facilitating precise and safe cannulation of pulmonary arteries.
24 The catheter insertion device includes a sheath that defines at least one lumen therein and has a
25 distal end that is closest to the cardiac structure of a patient when the device is in use and a proximal
26 end that is external to the patient; a pigtail catheter is present as well either via a separate lumen
27 or in the main lumen. The pigtail catheter may be a straight catheter with multiple pores for
28 pharmaceutical infusion.

29 The embodiments of the disclosed invention also includes a balloon tipped catheter
30 insertion device which is suitable for facilitating precise and safe cannulation of pulmonary arteries.
31 The catheter insertion device includes a sheath that defines at least one lumen therein and has a

1 distal end that is closest to the cardiac structure of a patient when the device is in use and a proximal
2 end that is external to the patient; A separate two-way lumen may be present in the main lumen
3 for flushing and aspirating with presence of proximal and distal ports forming a loop of fluid
4 circulation for aspiration either mechanically or using the Venturi effect.

5 The pulmonary artery and venous balloon tipped catheter insertion devices are either
6 multidirectional or have fixed curls. The pulmonary artery and venous balloon tipped catheter
7 insertion devices may vary from 6 to 42 Fr (French size). The pulmonary artery balloon tipped
8 catheter insertion device may have an aspiration port which could be attached to a mechanical
9 aspiration system or an automated closed loop system capable of applying varying degrees of
10 aspiration force. The pulmonary venous balloon tipped catheter insertion device may have an
11 infusion port for infusing fluids and pharmaceutical agents either mechanically or using an infusion
12 system with varying levels of infusion pressures. The pulmonary artery and venous balloon tipped
13 catheter insertion devices may have balloons which may be used to completely occlude the
14 respective vessels they are introduced into. The pulmonary artery balloon tipped catheter insertion
15 device would also be used to infuse fluids and pharmaceutical agents. The pulmonary artery and
16 venous catheter insertion devices may be connected in a closed loop system whereby the optimal
17 pressure for retrograde perfusion/ flushing of the pulmonary vasculature may be performed.

18 With reference to FIG. 19, shown is closed loop catheter system 500 of the disclosed
19 invention isolating desired segment of pulmonary vascular circulation. The closed loop catheter
20 system 500 includes balloon tipped pulmonary venous catheter insertion device 10a and balloon
21 tipped pulmonary artery catheter insertion device 10b. The pulmonary venous catheter insertion
22 device 10a is configured to be suitable for facilitating precise and safe cannulation of pulmonary
23 veins, and the pulmonary artery catheter insertion device 10b is configured to be suitable for
24 facilitating precise and safe cannulation of pulmonary arteries. The pulmonary venous catheter
25 insertion device 10a and the pulmonary artery catheter insertion device 10b may have a plurality
26 of curls and flexion points for multidirectional deflections. FIG. 19 exemplarily shows the flexion
27 points 12b' formed on the pulmonary venous catheter insertion device 10a. The flexion points
28 enables the catheter insertions devices 10a, 10b to deflect multi-directionally. The deflection
29 directions may be controlled by the pull wire anchor 40 affixed to distal end of sheath 12 and pull
30 wire actuator 42 as shown in FIG. 14.

1 When the balloon **14a** of the pulmonary venous catheter insertions device **10a** is inflated
2 while the catheter insertion devices **10a** is in use, the balloon **14a** inflated around the distal tip **13a**
3 of the catheter insertion device **10a** seals ostium **601a** of the pulmonary vein **601** and becomes
4 occlusive to flow into and out of the proximal segment of the desired pulmonary vein **601**. When
5 the balloon **14b** of the pulmonary artery catheter insertions device **10b** is inflated while the catheter
6 insertion devices **10b** is in use, the distal end of the catheter insertion device **10b** is positioned in
7 a desired pulmonary artery and the balloon **14b** inflated around the distal tip **13b** of the catheter
8 insertion device **10b** becomes occlusive to flow into the segmental pulmonary artery. In this
9 configuration, the isolated segment **510** together with the catheter insertion devices **10a**, **10b** form
10 a closed loop. The isolated segment **510** includes closed segments of the pulmonary vein **601**,
11 corresponding pulmonary capillaries **602** and corresponding pulmonary arterial **603**.

12 With reference to FIG. **20**, shown is balloon tipped pulmonary venous catheter insertion
13 device **10a** in the proximal pulmonary vein **601** via trans septal access **TS** in the heart **610**. With
14 reference to FIG. **21**, shown is a close view of the portion **C1** of FIG. **20** in which balloon tipped
15 pulmonary venous catheter insertion device **10a** cannulates and isolates designated pulmonary vein
16 **601** after balloon **14a** at distal tip **13a** of the venous catheter insertion device **10a** is fully inflated.
17 FIG. **20** shows the structure of heart **610** that has right atrium **611**, left atrium **612**, right ventricle
18 **613** and left ventricle **614**. The distal portion of the pulmonary venous catheter insertion device
19 **10a** may reach the designated ostium and proximal segment of the designated pulmonary vein **601**
20 via trans septal access **TS** across the interatrial septum between the right atrium **611** and the left
21 atrium **612**. The pulmonary venous catheter insertion device **10a** is configured to cannulate the
22 designated pulmonary vein.

23 With reference to FIG. **22**, shown is balloon tipped pulmonary artery catheter insertion
24 device **10b** cannulating and isolating designated pulmonary artery after balloon **14b** at distal tip
25 **13b** is fully inflated. With reference to FIG. **23**, shown is balloon tipped pulmonary artery catheter
26 insertion device **10b** cannulating and isolating designated pulmonary artery after distal balloon
27 **14b** is inflated and attached to an aspiration apparatus **604** on its proximal end (outside the body)
28 and aspirating matter **622** through the lumen of the balloon tipped pulmonary artery catheter.

29 Creating A Closed Loop System in the Pulmonary Vasculature.

30 With reference to FIGS. **19-23**, an embodiment of the disclosed invention involves systems
31 and methods for isolating both the desired pulmonary vein and the corresponding pulmonary

1 arterial segment using closed loop catheter system **500** that includes first and second balloon tipped
2 catheter insertion devices **10a** and **10b**. Once these catheter insertion devices **10a**, **10b** are
3 cannulated and isolated percutaneously, the cannulated catheter insertion devices **10a**, **10b** will
4 create an isolated segment **510** which includes closed segments of pulmonary vein **601**,
5 corresponding pulmonary capillaries **602**, and corresponding pulmonary arterial **603**, whereby
6 fluids and/or pharmaceutical agents can be delivered in a retrograde fashion (*i.e.* from the
7 pulmonary vein into the pulmonary artery using a set rate of flow and designated infusion pressure)
8 into the closed segments of the pulmonary vein **601** then into the pulmonary capillaries **602** and
9 then into the distal and then more proximal corresponding pulmonary artery **603** that is already
10 isolated and cannulated with the pulmonary artery balloon tipped catheter insertion device **10b**.
11 The first catheter insertion device **10a** includes a sheath **12a** and at least one balloon **14a** that is
12 connected to the distal end **13a** of the sheath **12a**.

13 The second catheter insertion device **10b** includes a sheath **12b** and at least one balloon
14 **14b** that is connected to the distal end **13b** of the sheath **12b**. This closed loop catheter system **500**,
15 which includes the first and second catheter insertion devices **10a** and **10b**, will serve to create
16 isolated segment **510** as defined by the fact that no material can flow through or around the catheter
17 insertion devices **10a**, **10b** with inflated balloon tips **14a**, **14b** into the cannulated vessels
18 (pulmonary artery or pulmonary vein). Any fluid or pharmaceutical introduced into this isolated
19 segment **510** must flow from within the designated catheters. This closed loop catheter system **500**
20 can serve as a closed loop system to (1) dislodge and clear thrombotic material in the distal and
21 proximal pulmonary arterial system that can then be aspirated by the pulmonary arterial balloon
22 tipped catheter or (2) deliver concentrated thrombolytics or other pharmaceuticals using the
23 pulmonary venous balloon tipped catheter into the area affected by thrombus and then
24 removed/aspirated (both thrombotic material and remaining pharmaceutical agent) by the
25 pulmonary artery balloon tipped catheter.

26 This process occurs with cannulating (via transseptal access) the aforementioned
27 pulmonary venous balloon catheter **10a** with the appropriate size based on the pulmonary vein.
28 The distal portion of the pulmonary venous balloon tipped catheter **10a** is used to engage the
29 ostium and proximal segment of the desired pulmonary vein **601** using fluoroscopic and
30 echocardiographic guidance. Once the distal portion of the pulmonary venous catheter **10a** is in
31 the ostium and proximal segment of the desired pulmonary vein, the balloon **14a** at the distal tip

1 **13a** of the venous catheter insertion device **10a** is inflated to secure its position and create a seal
2 so as not to let anything exit or enter from the ostium of the selected pulmonary vein (see FIG. **21**).
3 Next, the balloon tipped catheter insertion device **10b** which is suitable for facilitating safe and
4 precise cannulation of the designated and corresponding pulmonary arterial segment is positioned
5 such that the distal tip **13b** is within the proximal segment of the desired pulmonary artery **603**.
6 Once this is in place, the balloon **14b** on the distal tip **13b** of the catheter insertion device **10b** is
7 inflated to isolate the pulmonary artery **603** meaning that no material can flow around or through
8 it.

9 Using a Closed Loop System in the Pulmonary Vasculature to Perform Embolectomy.

10 Utilizing the aforementioned closed loop catheter system **500** in the pulmonary vasculature,
11 embolectomy can be performed by infusion of fluid **621** (*i.e.* saline, heparinized saline, blood,
12 thrombolytics in fluid, any pharmaceutical agent in fluid, or any combination thereof) through the
13 central lumen **15** or another lumens **15a**, **15b** (see FIGS. **24A-24B**) of the pulmonary venous
14 balloon tipped catheter **10a** positioned with inflated balloon **14a** in the proximal segment of the
15 designated pulmonary vein **601**. The infusion will occur at the proximal segment of the pulmonary
16 venous catheter outside the patient's body. The infusion can occur with manual infusion using a
17 large syringe or using a pre-programmed machine that can designate a given volume of fluid at a
18 designated rate of flow and pressure. For this purpose, a proximal end of the pulmonary venous
19 balloon tipped catheter **10a** is connected to infuser **605**, located outside the patient's body, such as
20 a syringe and a machine that supplies fluid in controlled manners. This infusion will flow into the
21 pulmonary veins **601** and into the pulmonary capillaries **602** and then into the pulmonary arterial
22 vasculature **603**. This pressured infusion will then act to dislodge thrombotic material **622** from
23 the pulmonary arterial vascular bed into the more proximal pulmonary artery in question that is
24 already cannulated with a balloon tipped pulmonary arterial catheter **10b** with the balloon **14b** in
25 an inflated configuration.

26 Once the infusion is started, then aspiration will be performed through the lumen (such as
27 central lumen **15** or another lumens **15a**, **15b**) of the balloon tipped pulmonary arterial catheter
28 **10b** that is positioned with balloon inflated into the designated pulmonary artery. An aspirator or
29 apparatus **604** for aspiration (*i.e.* large syringe, mechanical aspiration device) will be attached to
30 the proximal end of the lumen of the balloon tipped catheter **10b** in the pulmonary artery. This
31 apparatus **604** will then be used to aspirate fluid and thrombotic material from the isolated

1 pulmonary vasculature, out of the body via the balloon tipped pulmonary artery catheter insertion
2 device **10b** (see FIG. **23**). Once the procedure is completed, the balloon of the catheter insertion
3 device **10a** in the pulmonary vein and the balloon of the catheter insertion device **10b** in the
4 pulmonary artery will be deflated and the respective catheter insertion devices will be disengaged
5 from the respective vessels and removed from the body via the same route they were introduced.
6 This technique may also be utilized for the treatment of chronic thromboembolic disease of the
7 pulmonary vasculature in addition to acute pulmonary embolism.

8 Using a Closed Loop System in the Pulmonary Vasculature to Deliver Pharmaceuticals
9 while Minimizing Systemic Effects of Pharmaceuticals.

10 Thrombolytics and other pharmaceuticals can be used to treat pulmonary arterial embolism.
11 However, systemic administration in higher concentrations can result in off target effects such as
12 intracranial bleeding. As such, delivering pharmaceuticals into a closed loop system can be used
13 and then the remaining can be aspirated in the closed loop system to prevent said pharmaceutical
14 from making its way into the systemic circulation to avoid off target effects. Utilizing the
15 aforementioned closed loop catheter system **500** in the pulmonary vasculature, pharmaceuticals
16 can be delivered by infusion of said drug in a carrier (*i.e.* saline, heparinized saline in fluid) through
17 the central lumen **15** of the pulmonary venous balloon tipped catheter **10a** positioned with inflated
18 balloon **14a** in the proximal segment of the designated pulmonary vein **601**. The infusion will
19 occur at the proximal segment of the pulmonary venous catheter outside the patient's body. The
20 infusion can occur with infuser **605** such as manual infusion using a large syringe or using a pre-
21 programmed machine that can designate a given volume of fluid at a designated rate of flow and
22 pressure. This infusion will flow into the pulmonary veins **601** and into the pulmonary capillaries
23 **602** and then into the pulmonary arterial vasculature **603**. This pressured infusion will then act in
24 the designated area in the isolated segment of the pulmonary arterial vascular bed and into the
25 more proximal pulmonary artery in question that is already cannulated with a balloon tipped
26 pulmonary arterial catheter **10b** with the balloon **14b** in an inflated configuration.

27 Once the infusion is started, then aspiration will be performed through the lumen **15** of the
28 balloon tipped pulmonary arterial catheter **10b** that is positioned with balloon **14b** inflated into the
29 designated pulmonary artery **603**. An aspirator or apparatus **604** for aspiration (*i.e.* large syringe,
30 mechanical aspiration device) will be attached to the proximal end of the lumen **15** of the balloon
31 tipped catheter **10b** in the pulmonary artery. This apparatus will then be used to aspirated fluid,

1 pharmaceutical and thrombotic material **622** from the isolated pulmonary vasculature, out of the
2 body via the balloon tipped pulmonary artery catheter insertion device **10b**. Once the procedure is
3 completed, the balloon tipped catheter insertion device **10a** in the pulmonary vein and the balloon
4 tipped catheter **10b** in the pulmonary artery will be deflated and the respective catheters will be
5 disengaged from the respective vessels and removed from the body via the same route they were
6 introduced.

7 The closed loop system as described above can be used to filter aspirated blood and reinfuse
8 it into the systemic circulation. The aspirated blood is removed via the pulmonary artery catheter
9 insertion device **10b** which can be connected to an apparatus which serves to aspirate blood and
10 other contents from the pulmonary artery into the container whereby it is filtered through and blood
11 products are collected into a reservoir and returned from a reservoir into the circulation using
12 extracorporeal membrane oxygenation (ECMO) system via one of two ways:

13 a) Venous system: Blood is removed from the reservoir using an ECMO system which then
14 diverts blood (with use of a pump) into a cannula placed into the central venous system either via
15 common femoral vein or internal jugular vein access.

16 b) Arterial system: Blood is removed from the reservoir using an ECMO system which
17 then diverts blood (with use of a pump) into an oxygenator which is then diverted via tubing into
18 a cannula in the femoral artery.

19 With reference to FIG. **24A-24B**, shown are a side view of the distal tip **13** portion and a
20 cross-sectional view of the section A-A' of the distal tip **13** portion of the balloon tipped catheter
21 insertion devices **10a**, **10b** which are used for the closed loop catheter system **500** of the disclosed
22 invention. In the embodiments, the balloon **14** on the sheath **12** may have separate hypotubes **517a**,
23 **517b** for inflation and deflation. For example, the sheath **12** may have inflation hypotube **517a** and
24 a deflation hypotube **517b** to inflate and deflate the balloon **14**, respectively. However, the
25 embodiment is not limited to this configuration. The balloons **14** may have a hypotube that may
26 be used for both inflation and deflation. The balloon **14** may be inflated and deflated through the
27 same hypotube. The balloon **14** of pulmonary artery and venous balloon tipped catheter insertion
28 device **10** may be used to completely occlude the respective vessels into which they are introduced.
29 The catheter insertion device **10** has a center lumen **15** in which a wire member or dilator **516** is
30 movably disposed. The dilator **516** may be a wire, Brockenbrough needle, radiofrequency tip
31 needle, pigtail catheter, or transseptal wire.

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

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

21 With reference to FIG. **25**, shown is a flowchart diagram for a method of using the closed
22 loop catheter system **500** that includes a first balloon tipped catheter insertion device **10a** and a
23 second balloon tipped catheter insertion device **10b** for pulmonary embolism. The method **700**
24 includes steps of engaging a distal portion of a first catheter insertion device with an ostium and
25 proximal segment of a designated pulmonary vein, block **S710**, inflating at least one balloon of
26 the first catheter insertion device to seal the ostium of the designated pulmonary vein, block **S720**,
27 positioning a distal portion of the second catheter insertion device is within a proximal segment of
28 a corresponding designated pulmonary artery, block **S730**, inflating at least one balloon of the
29 second catheter insertion device to seal the designated pulmonary artery, block **S740**, performing
30 infusion of fluid into the designated pulmonary vein through at least one lumen defined in a sheath
31 of the first catheter insertion device by using an infuser connected to the first catheter insertion

1 device, block **S750**, and performing aspiration of materials from the designated pulmonary artery
2 through at least one lumen defined in a sheath of the second catheter insertion device by using an
3 aspirator connected to the second catheter insertion device, block **S760**.

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

1 **WHAT IS CLAIMED IS:**

2 1. A catheter system for pulmonary embolism with balloon tipped catheter insertion devices,
3 comprising:

4 a first catheter insertion device configured to be suitable for facilitating precise and safe
5 cannulation of pulmonary veins, wherein the first catheter insertion device is configured to be
6 connected to an infuser to supply fluid to the pulmonary veins, the first catheter insertion device
7 comprising:

8 a sheath that defines at least one lumen therein and has a distal end that is configured
9 to be positioned at proximal segment of a designated pulmonary vein and a proximal end
10 that is external to the patient; and

11 at least one balloon that is positioned at the distal end of the sheath, wherein the at
12 least one balloon is configured to seal ostium of the designated pulmonary vein when
13 inflated; and

14 a second catheter insertion device configured to be suitable for facilitating precise and safe
15 cannulation of pulmonary arteries, wherein the second catheter insertion device is configured to
16 be connected to an aspirator to aspirate materials from the pulmonary arteries, the second catheter
17 insertion device comprising:

18 a sheath that defines at least one lumen therein and has a distal end that is configured
19 to be positioned at proximal segment of a designated pulmonary artery and a proximal end
20 that is external to the patient; and

21 at least one balloon that is positioned at the distal end of the sheath, wherein the at
22 least one balloon is configured to seal the designated pulmonary artery when inflated.

23 2. The catheter system of claim 1 wherein the fluid includes one or more selected from a
24 group consisting of saline, heparinized saline, blood, thrombolytics in fluid, and pharmaceutical
25 agent in fluid.

26 3. The catheter system of claim 1 wherein the at least one lumen of the first catheter insertion
27 device is configured to deliver the fluid supplied by the infuser.

28 4. The catheter system of claim 1 wherein the first catheter insertion device comprises a
29 dilator movably positioned in the at least one lumen, wherein the dilator is configured to puncture
30 septum.

1 5. The catheter system of claim 4 wherein the dilator includes a pigtail catheter having
2 multiple pores for pharmaceutical infusion.

3 6. The catheter system of claim 1 wherein the sheath of the first catheter insertion device
4 defines one or more additional lumens to deliver additional fluids into the designated pulmonary
5 vein.

6 7. The catheter system of claim 1 wherein the first catheter insertion device has a plurality of
7 curls and flexion points for multidirectional deflections.

8 8. The catheter system of claim 1 wherein the at least one lumen of the second catheter
9 insertion device is configured to carry the materials to the aspirator.

10 9. The catheter system of claim 1 wherein the second catheter insertion device comprises a
11 dilator movably positioned in the at least one lumen, wherein the dilator is configured to puncture
12 septum.

13 10. The catheter system of claim 1 wherein the sheath of the second catheter insertion device
14 defines one or more additional lumens for flushing or aspirating.

15 11. The catheter system of claim 1 wherein the second catheter insertion device has a plurality
16 of curls and flexion points for multidirectional deflections.

17 12. A method of using a catheter system including a first catheter insertion device and a second
18 catheter insertion device for pulmonary embolism, comprising:

19 engaging a distal portion of a first catheter insertion device with an ostium and proximal
20 segment of a designated pulmonary vein;

21 inflating at least one balloon of the first catheter insertion device to seal the ostium of the
22 designated pulmonary vein;

23 positioning a distal portion of the second catheter insertion device within a proximal
24 segment of a corresponding designated pulmonary artery;

25 inflating at least one balloon of the second catheter insertion device to seal the designated
26 pulmonary artery;

27 performing infusion of fluid into the designated pulmonary vein through at least one lumen
28 defined in a sheath of the first catheter insertion device by using an infuser connected to the first
29 catheter insertion device; and

1 performing aspiration of materials from the designated pulmonary artery through at least
2 one lumen defined in a sheath of the second catheter insertion device by using an aspirator
3 connected to the second catheter insertion device.

4 13. The method of claim 12 wherein the fluid includes one or more selected from a group
5 consisting of saline, heparinized saline, blood, thrombolytics in fluid, and pharmaceutical agent
6 in fluid.

7 14. The method of claim 12 wherein the engaging the distal portion of the first catheter
8 insertion device is performed by using a fluoroscopic or echocardiographic guidance.

9 15. The method of claim 12 wherein the infusion of fluid is performed such that the fluid flows
10 into the designated pulmonary vein, corresponding pulmonary capillaries and the corresponding
11 designated pulmonary artery.

12 16. The method of claim 12 wherein the infusion of fluid is performed with a designated rate
13 of flow and pressure to dislodge thrombotic materials from a pulmonary arterial vascular bed into
14 the proximal segment of the corresponding designated pulmonary artery.

15 17. The method of claim 12 wherein the performing aspiration of materials includes removing
16 thrombotic materials from the designated pulmonary artery.

17 18. The method of claim 12 wherein the performing infusion of fluid comprises infusing
18 pharmaceuticals into the designated pulmonary vein, and the performing aspiration of materials
19 comprises aspirating the pharmaceuticals and thrombotic materials through the designated
20 pulmonary artery.

21 19. The method of claim 12 wherein the performing aspiration of materials includes aspirating
22 blood from the designated pulmonary artery, and the method further comprises:

23 filtering the blood; and

24 reinfusing the filtered blood into circulations using extracorporeal membrane oxygenation
25 (ECMO) system.