

1 **WHAT IS CLAIMED IS:**

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

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

7 one or more positioning balloons that are connected to the distal end of the sheath, wherein
8 the one or more positioning balloons, when inflated and the transseptal insertion device is in use,
9 overhang and extend past the distal end of the sheath, wherein the sheath includes one or more
10 hypotubes respectively connected to the one or more positioning balloons to inflate and deflate the
11 one or more positioning balloons;

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

16 a puncture member balloon located on the distal end of the puncture member, wherein the
17 puncture member includes at least one puncture member tube connected to the puncture member
18 balloon to inflate and deflate the puncture member balloon.

19 2. The transseptal insertion device of claim 1 wherein the one or more positioning balloons
20 are inflated by gas or fluid supplied through the one or more hypotubes, and the one or more
21 positioning balloons and the puncture member balloon are inflated and deflated independently of
22 each other.

23 3. The transseptal insertion device of claim 1 wherein the one or more hypotubes comprises
24 one or more inflation hypotubes to inflate the one or more positioning balloons, and one or more
25 deflation hypotubes to deflate the one or more positioning balloons.

26 4. The transseptal insertion device of claim 1 wherein the one or more positioning balloons,
27 when inflated, delivers energy in the form of heat or is used for cryoablation with fluid that is
28 circulated through the one or more positioning balloons.

29 5. The transseptal insertion device of claim 1 wherein the puncture member balloon, when
30 inflated, is positioned at a predetermined distance from a tip of the distal end of the puncture
31 member to prevent the puncture member from being pushed beyond the predetermined distance

1 while the puncture member is tenting the cardiac interatrial septum and the puncture member
2 balloon is pressing against the cardiac interatrial septum.

3 6. The transseptal insertion device of claim 1 wherein the puncture member includes a
4 radiofrequency (RF) tip at the distal end of the puncture member, wherein the RF tip is capable of
5 delivering RF energy.

6 7. The transseptal insertion device of claim 1 further comprising a wire member movably
7 positioned in a center lumen formed in the puncture member, wherein the wire member advances
8 beyond a tip of the distal end of the puncture member when in use.

9 8. The transseptal insertion device of claim 7 wherein the wire member is one selected from
10 a group consisting of a Brockenbrough needle, a radiofrequency tip needle, a radiofrequency wire,
11 a pigtail catheter that delivers fluid or pharmaceuticals in the left atrial appendage, and a transseptal
12 wire designed to and is capable of precisely puncturing the cardiac interatrial septum.

13 9. The transseptal insertion device of claim 7 wherein the sheath includes a side port proximal
14 to the positioning balloons, wherein an additional catheter or wire advances into the cardiac
15 interatrial septum through the side port and the additional catheter or wire is capable of capturing
16 the wire member.

17 10. A method for suitably facilitating precise and safe transseptal puncture of a cardiac
18 interatrial septum with a transseptal insertion device, comprising:

19 inflating one or more positioning balloons connected to a distal end of a sheath of the
20 transseptal insertion device, wherein the one or more positioning balloons, when inflated and the
21 transseptal insertion device is in use, overhang and extend past the distal end of the sheath, and the
22 sheath includes one or more hypotubes respectively connected to the one or more positioning
23 balloons to inflate and deflate the one or more positioning balloons;

24 advancing a puncture member while the positioning balloons are inflated, wherein the
25 puncture member is movably positioned within at least one lumen of the sheath, and wherein a
26 puncture member balloon is located on a distal end of the puncture member and the puncture
27 member includes at least one puncture member tube connected to the puncture member balloon to
28 inflate and deflate the puncture member balloon;

29 positioning the puncture member against the cardiac interatrial septum;

30 deflating the one or more positioning balloons;

31 further advancing the puncture member to puncture the cardiac interatrial septum; and

1 advancing the transseptal insertion device crossing the cardiac interatrial septum.

2 11. The method of claim 10 wherein the one or more positioning balloons are inflated by gas
3 or fluid supplied through the one or more hypotubes, and the one or more positioning balloons and
4 the puncture member balloon are inflated and deflated independently of each other.

5 12. The method of claim 10 wherein the one or more hypotubes comprises one or more
6 inflation hypotubes to inflate the one or more positioning balloons, and one or more deflation
7 hypotubes to deflate the one or more positioning balloons.

8 13. The method of claim 10 further comprising:

9 inflating the puncture member balloon once the puncture member advances beyond the
10 distal end of the sheath and is tenting the cardiac interatrial septum, wherein the puncture member
11 balloon is pressing against the cardiac interatrial septum while the puncture member is tenting the
12 cardiac interatrial septum; and

13 deflating the puncture member balloon before said further advancing the puncture member
14 to puncture the cardiac interatrial septum.

15 14. The method of claim 13 wherein the puncture member balloon, when inflated, is positioned
16 at a predetermined distance from a tip of the distal end of the puncture member to prevent the
17 puncture member from being pushed beyond the predetermined distance while the puncture
18 member balloon is pressing against the cardiac interatrial septum.

19 15. The method of claim 10 further comprising re-inflating the one or more positioning
20 balloons to navigate in an atraumatic fashion to different parts of the left atrium after the distal end
21 of the transseptal insertion device crosses the cardiac interatrial septum.

22 16. The method of claim 10 further comprising re-inflating the puncture member balloon to
23 anchor the transseptal insertion device against the cardiac interatrial septum after the distal end of
24 the transseptal insertion device crosses the cardiac interatrial septum.

25 17. The method of claim 10 further comprising delivering, via the one or more positioning
26 balloons, energy in the form of heat or using the one or more positioning balloons for cryoablation
27 with fluid that is circulated through the one or more positioning balloons.

28 18. The method of claim 10 further comprising advancing a wire member beyond a tip of the
29 distal end of the puncture member after the distal end of the transseptal insertion device crosses
30 the cardiac interatrial septum, wherein the wire member movably positioned in a center lumen
31 formed in the puncture member.

- 1 19. The method of claim 18 further comprising advancing an additional catheter or wire into
2 the cardiac interatrial septum, wherein the sheath includes a side port proximal to the positioning
3 balloons, and the additional catheter or wire advances through the side port; and
4 capturing the wire member with the additional catheter or wire forming a loop with the
5 captured wire member.
- 6 20. The method of claim 18 wherein the wire member is one selected from a group consisting
7 of a Brockenbrough needle, a radiofrequency tip needle, a radiofrequency wire, a pigtail catheter
8 that delivers fluid or pharmaceuticals in the left atrial appendage, and a transseptal wire designed
9 to and is capable of precisely puncturing the cardiac interatrial septum.