

What is claimed is:

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

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

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

a dilator that is positioned within the at least one lumen when the transseptal insertion device is in use, wherein the dilator has a distal end and is designed to and is capable of precisely puncturing the cardiac interatrial septum without the use of a needle or other sharp instrument, wherein the dilator includes a dilator seal that is greater in diameter than the lumen and provides a water-tight seal of the lumen while the dilator seal remains within the lumen.

2. The transseptal insertion device of claim 1 wherein the balloon portion that overhangs and extends past the distal end of the sheath is the overhanging portion and the dilator is designed to remain sub-planar to the overhanging portion of the balloon until the dilator is extended to puncture the cardiac interatrial septum.

3. The transseptal insertion device of claim 1 wherein the sheath is made from malleable material capable of accommodating larger diameter devices within the lumen.

4. The transseptal insertion device of claim 1 wherein the sheath further comprises inflation ports communicatively coupling the lumen to the balloon so that inflation liquid may be passed through lumen into the balloon, inflating the balloon.

5. The transseptal insertion device of claim 4 wherein the dilator seal is located on the distal end of the dilator and moving the distal end of the dilator out of the lumen so that the dilator seal is external to the distal end of the sheath un-seals the lumen and causes the inflation liquid to flow out of the balloon and through the inflation ports, deflating the balloon.

6. The transseptal insertion device of claim 1 further comprising an energy source external to the proximal end of the sheath and operatively connected to the distal end of the dilator to deliver energy to the distal end of the dilator.
7. The transseptal insertion device of claim 6 wherein the dilator is designed to and is capable of precisely puncturing the cardiac interatrial septum using the energy delivered to the distal end of the dilator.
8. The transseptal insertion device of claim 7 wherein the energy source is a radio-frequency (RF) energy source and the energy delivered to the distal end of the dilator is RF energy.
9. The transseptal insertion device of claim 6 wherein the dilator comprises a cap on the distal end of the dilator capable of applying the delivered energy to the cardiac interatrial septum.
10. The transseptal insertion device of claim 1 further comprising an external stabilizer connected to the proximal end of the sheath that stabilizes the transseptal insertion device and substantially prevents unwanted movement of the transseptal insertion device.
11. The transseptal insertion device of claim 1 wherein the balloon includes one or more radiopaque or echogenic markers.
12. The transseptal insertion device of claim 11 wherein the one or more markers include a marker in the shape of an E.
13. The transseptal insertion device of claim 11 wherein the one or more markers include a ring-shaped marker.
14. A method of using a transseptal insertion device for precisely and safely transseptal puncturing a cardiac interatrial septum, comprising:
 - inserting the transseptal insertion device into a right atrium of a patient's heart, wherein the transseptal insertion device includes:
 - a sheath that defines at least one lumen therein and has a distal end that is inserted in the right atrium of the patient's heart and a proximal end that is external to the patient;
 - a balloon that is connected to the distal end of the sheath; and

a dilator that is positioned within the at least one lumen, wherein the dilator has a distal end, wherein the dilator includes a dilator seal that is greater in diameter than the lumen and provides a water-tight seal of the lumen while the dilator seal remains within the lumen;

inflating the balloon, wherein the inflated balloon overhangs and extends past the distal end of the sheath and the dilator is sub-planar to the balloon overhang, preventing accidental puncturing of the cardiac interatrial septum;

extending the distal end of the sheath so that the inflated balloon is positioned against the fossa ovalis of the cardiac interatrial septum at a desired puncture point, thereby stabilizing the transseptal insertion device against fossa ovalis;

extending the distal end of the dilator past the balloon overhang; and

puncturing the cardiac interatrial septum with the dilator without the use of a needle or other sharp instrument.

15. The method of claim 14 wherein extending the distal end of the dilator past the balloon overhang causes the balloon to deflate.

16. The method of claim 15 further comprising:

extending the distal end of the sheath past the cardiac interatrial septum; and
re-inflating the balloon.

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

a sheath that defines a lumen therein and has a distal end that is closest to the cardiac interatrial septum of a patient when the transseptal insertion device is in use and a proximal end that is external to the patient, wherein the sheath includes inflation ports near the distal end that enable inflation fluid in the lumen to exit and enter the sheath;

a balloon that is connected to the distal end of the sheath, wherein:

the balloon, when inflated and the transseptal insertion device is in use, overhangs and extends past the distal end of the sheath, preventing accidental puncturing of the cardiac interatrial septum and stabilizing the transseptal insertion device against fossa ovalis of the cardiac interatrial septum; and

the balloon is positioned over the inflation ports of the sheath so that inflation fluid may exit the sheath and enter the balloon, inflating the balloon, and exit the balloon and enter the sheath, deflating the balloon;

a dilator that is positioned within the lumen when the transseptal insertion device is in use, wherein the dilator has a distal end and includes a dilator seal at the distal end that occludes the lumen when the dilator is sub-planar to the balloon overhang so that the balloon remains inflated after inflation fluid is passed through the lumen into the balloon and automatically deflates when the distal end of the dilator is extended sufficiently past the distal end of the sheath so that the dilator seal does not occlude the lumen.

18. The transseptal insertion device of claim 17 further comprising an RF energy source external to the proximal end of the sheath and operatively connected to the distal end of the dilator to deliver RF energy to the distal end of the dilator.

19. The transseptal insertion device of claim 18 wherein the dilator comprises a cap on the distal end of the dilator capable of applying the delivered RF energy to the cardiac interatrial septum and precisely puncturing the cardiac interatrial septum using the delivered RF energy.