

1 **WHAT IS CLAIMED IS:**

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

4 a handle comprising:

5 two twister thread half shells having internal threads;

6 a twister bolt inner placed inside and locked into the two twister thread half shells;

7 a nut inner placed inside the two twister thread half shells, wherein the nut inner
8 engages with the twister bolt inner;

9 a nut outer placed inside the two twister thread half shells, wherein the internal
10 threads of the twister thread half shells engage with the nut outer, and wherein the nut inner
11 and nut outer rotate in opposite directions to each other when the two twister thread half
12 shells are turned in a direction;

13 a first pull wire coupled to the nut inner and a second pull wire coupled to the nut
14 outer; and

15 a grip overmold over-molded onto the two twister thread half shells; and

16 a transseptal insertion shaft comprising:

17 a sheath that defines one or more lumens therein and has a distal end that is
18 positioned toward the patient when the transseptal insertion shaft is in use; and

19 at least one positioning balloon connected to the distal end of the sheath, wherein
20 the at least one positioning balloon, when inflated and the transseptal insertion shaft is in
21 use, overhangs and extends past the distal end of the sheath, and wherein the sheath
22 includes one or more hypotubes connected to the at least one positioning balloon to inflate
23 the positioning balloon,

24 wherein a proximal end of the transseptal insertion shaft is coupled to the handle,
25 and a distal end of the first pull wire is attached to a first side of the transseptal insertion
26 shaft and a distal end of the second pull wire is attached to a second side of the transseptal
27 insertion shaft.

28 2. The transseptal puncture system of claim 1 wherein the nut inner pulls the first pull wire
29 when the two twister thread half shells are rotated in a first direction, and the distal end of the
30 transseptal insertion shaft bends toward the first side of the transseptal insertion shaft while the
31 first pull wire is pulled.

1 3. The transseptal puncture system of claim 1 wherein the nut outer pulls the second pull wire
2 when the two twister thread half shells are rotated in a second direction, and the distal end of the
3 transseptal insertion shaft bends toward the second side of the transseptal insertion shaft while the
4 second pull wire is pulled.

5 4. The transseptal puncture system of claim 1 wherein the handle further comprises:
6 a clamp assembly for clamping the first and second pull wires; and
7 a coupler that couples the first pull wire to the nut inner and the second pull wire to the nut
8 outer.

9 5. The transseptal puncture system of claim 1 wherein the handle further comprises a handle
10 inner that is slid onto ends of the nut inner and nut outer, wherein the twister bolt inner and the
11 handle inner have cavities in which the transseptal insertion shaft is placed.

12 6. The transseptal puncture system of claim 5 wherein the handle further comprises:
13 an introducer assembly formed at a proximal end of the handle, wherein the introducer
14 assembly comprises:

15 a shaft connector that holds the proximal end of the transseptal insertion shaft; and
16 an introducer assembly connector that adheres to the shaft connector, the transseptal
17 insertion shaft and the handle inner; and
18 one or more tubes connected to the introducer assembly to supply inflation gas to the one
19 or more hypotubes of the sheath to inflate the positioning balloon.

20 7. The transseptal puncture system of claim 6 wherein the one or more tubes include an
21 additional tube that is connected to the one or more hypotubes to remove gas from the positioning
22 balloon to deflate the positioning balloon.

23 8. The transseptal puncture system of claim 6 wherein the transseptal insertion shaft further
24 comprises:

25 a puncture member movably positioned within the one or more lumens, wherein the
26 puncture member has a distal end that is positioned toward the cardiac interatrial septum of the
27 patient, wherein the distal end of the puncture member is capable of precisely puncturing the
28 cardiac interatrial septum; and

29 a puncture member balloon located on the distal end of the puncture member, wherein the
30 puncture member includes at least one puncture member tube connected to the puncture member
31 balloon to inflate and deflate the puncture member balloon,

1 wherein the one or more tubes include an additional tube connected to the introducer
2 assembly to supply gas to the puncture member tube to inflate the puncture member balloon.

3 9. The transseptal puncture system of claim 6 wherein the introducer assembly includes at
4 least one flush port connected to the one or more lumens of the sheath to flush fluid or materials
5 taken from the distal end of the sheath.

6 10. The transseptal puncture system of claim 9 wherein the at least one flush port is connected
7 to a flush tube through which suction is applied to flush the fluid or materials.

8 11. A handle for controlling movements of a transseptal insertion shaft which is suitable for
9 facilitating precise and safe transseptal puncture of a cardiac interatrial septum of a patient,
10 comprising:

11 two twister thread half shells having internal threads;

12 a twister bolt inner placed inside and locked into the two twister thread half shells;

13 a nut inner placed inside the two twister thread half shells, wherein the nut inner engages
14 with the twister bolt inner;

15 a nut outer placed inside the two twister thread half shells, wherein the internal threads of
16 the twister thread half shells engage with the nut outer, and wherein the nut inner and nut outer
17 rotate in opposite directions to each other when the two twister thread half shells are turned in a
18 direction;

19 a first pull wire connected to a first side of the transseptal insertion shaft and coupled to
20 the nut inner, wherein a proximal end of the transseptal insertion shaft is coupled to the handle;

21 a second pull wire connected to a second side of the transseptal insertion shaft and coupled
22 to the nut outer; and

23 a grip overmold over-molded onto the two twister thread half shells.

24 12. The handle of claim 11 wherein the nut inner pulls the first pull wire when the two twister
25 thread half shells are rotated in a first direction, and a distal end of the transseptal insertion shaft
26 bends toward the first side of the transseptal insertion shaft while the first pull wire is pulled.

27 13. The handle of claim 11 wherein the nut outer pulls the second pull wire when the two
28 twister thread half shells are rotated in a second direction, and a distal end of the transseptal
29 insertion shaft bends toward the second side of the transseptal insertion shaft while the second pull
30 wire is pulled.

31 14. The handle of claim 11 further comprising:

- 1 a clamp assembly for clamping the first and second pull wires; and
2 a coupler that couples the first pull wire to the nut inner and the second pull wire to the nut
3 outer.
- 4 15. The handle of claim 11 further comprising a handle inner that is slid onto ends of the nut
5 inner and nut outer, wherein the twister bolt inner and the handle inner have cavities in which the
6 transseptal insertion shaft is placed.
- 7 16. The handle of claim 15 further comprising:
8 an introducer assembly formed at a proximal end of the handle, wherein the introducer
9 assembly comprises:
10 a shaft connector that holds the proximal end of the transseptal insertion shaft; and
11 an introducer assembly connector that adheres to the shaft connector, the transseptal
12 insertion shaft and the handle inner; and
13 one or more tubes connected to the introducer assembly to supply inflation gas to one or
14 more hypotubes of the transseptal insertion shaft to inflate at least one positioning balloon formed
15 at a distal end of the transseptal insertion shaft.
- 16 17. The handle of claim 16 wherein the one or more tubes include an additional tube that is
17 connected to the introducer assembly to deflate the positioning balloon through the one or more
18 hypotubes of the transseptal insertion shaft.
- 19 18. The handle of claim 16 wherein the one or more tubes include an additional tube connected
20 to the introducer assembly to supply gas to a puncture member tube of the transseptal insertion
21 shaft to inflate a puncture member balloon located on a distal end of a puncture member, wherein
22 the puncture member is movably positioned within one or more lumens of the transseptal insertion
23 shaft and has a distal end that is positioned toward the cardiac interatrial septum of the patient,
24 wherein the distal end of the puncture member is capable of precisely puncturing the cardiac
25 interatrial septum.
- 26 19. The handle of claim 16 wherein the introducer assembly includes at least one flush port
27 connected to one or more lumens of the transseptal insertion shaft to flush fluid or materials taken
28 from a distal end of the transseptal insertion shaft.
- 29 20. The handle of claim 19 wherein the at least one flush port is connected to a flush tube
30 through which suction is applied to flush the fluid or materials.