

BRIEF SUMMARY

[0004] The packaging systems disclosed herein provide a platform for the compact storage and transportation of a replacement heart valve and its associated delivery system. The packaging systems also provide for the handling, preparation and assembly of the replacement heart valve and its associated delivery system in the operating room. The packaging system described herein provides a combination of features that facilitate this process in an efficient manner by reducing the number of steps and operating room personnel required to prepare and assemble the replacement heart valve onto its delivery system and also by ensuring that the steps are performed in the required sequence. The features of the packaging system also advantageously permit the prosthetic valve and associated delivery system to be secured in a compact configuration that allows for reduced overall dimensions of the packaging system.

[0005] It is understood that the packaging systems disclosed herein are not only suitable for the prosthetic valves and delivery systems specifically disclosed herein but also for other prosthetic valves and delivery systems, such as those disclosed in U.S. Pub. No. 2010/0049313, published Feb. 25, 2010; U.S. Pub, No. 2012/0239142, published Sep. 20, 2012, and U.S. Pub. No. 2014/0343670, published Nov 20, 2014, the entire contents of each of which are incorporated herein by reference in its entirety.

[0006] A packaging system for storing a prosthetic valve and an elongated delivery system in a non-fluid environment is provided. The packaging system can comprise an elongated delivery system comprising a main catheter and a shaft extending coaxially through the main catheter, wherein the shaft comprises a nose cone secured to a distal end of the shaft, and the main catheter comprises a delivery sheath coupled to a distal end of the main catheter so as to be axially moveable in a direction towards or away from the nose cone, a prosthetic valve mounted around a portion of the shaft adjacent the nose cone, and a tray that can secure both the prosthetic valve and the elongated delivery system. The packaging system also comprise a valve cover coupled to the elongated delivery system so as to store the prosthetic valve in a compressed

state within the valve cover .

[0007] The tray can include a cavity having an open end, a floor, and a peripheral side wall defining a depth of the cavity. The cavity can be sized and shaped to house the valve cover and the prosthetic valve. The tray can also comprise an engaging surface peripherally of the cavity and elevated above the cavity floor.

CLAIMS:

1. A packaging system for storing a prosthetic valve and an elongated delivery system in a non-fluid environment, the packaging system comprising:
 - an elongated delivery system comprising a main catheter and a shaft extending coaxially through the main catheter, wherein the shaft comprises a nose cone secured to a distal end of the shaft, and the main catheter comprises a delivery sheath coupled to a distal end of the main catheter so as to be axially moveable in a direction towards or away from the nose cone;
 - a prosthetic valve mounted around a portion of the shaft adjacent the nose cone;
 - a tray for securing both the prosthetic valve and the elongated delivery system;
 - a valve cover coupled to the elongated delivery system so as to store the prosthetic valve in a compressed state within the valve cover;
 - the tray including
 - a cavity comprising an open end, a floor, and a peripheral side wall defining a depth of the cavity, the cavity sized and shaped to house the valve cover and the prosthetic valve;
 - a mounting surface to removably couple the valve cover to the cavity floor;
 - an engaging surface peripherally of the cavity and elevated above the cavity floor; and
 - a ramp extending downwardly from the engaging surface and into the cavity through an opening defined in the peripheral side wall and adjacent the floor of the cavity;
 - wherein the engaging surface and the ramp are configured to secure at least a portion of the elongated delivery system externally of the cavity.

2. The packaging system of claim 1, wherein the prosthetic valve comprises a stent and a plurality of leaflets coupled to the stent, the plurality of leaflets comprising a biological tissue.

3. The packaging system of any one of the preceding claims, wherein the engaging surface comprises a channel formed in the tray and shaped to accommodate the elongated delivery system and wherein the channel comprises tabs to resiliently engage the elongated delivery system within the channel.

4. The packaging system of any one of the preceding claims, wherein the ramp is angled downwardly from the engaging surface to the floor of the cavity.
5. The packaging system of claim 4, wherein the ramp is provided at an angle of about 4 degrees to about 10 degrees relative to a horizontal plane bisecting the tray.
6. The packaging system of any one of the preceding claims, further comprising a lock configured to be removably coupled to one or both of the valve cover and the distal portion of the elongated delivery system.
7. The packaging system of claim 6, further comprising:
a lid removably coupled to the tray and partially enclosing the open end of the cavity, the lid defining an opening to the cavity.
8. The packaging system of claim 7, wherein the lock comprises a first end and a second end, wherein the first end is removably coupled to one or both of the valve cover and the distal portion of the elongated delivery system.
9. The packaging system of claim 8, wherein the second end is configured to protrude externally of the cavity through an aperture disposed on the lid, the second end being sized or shaped to prevent it from being passed through the aperture.
10. The packaging system of claim 8, wherein second end is fixed to or integrated with the lid.
11. The packaging system of any one of claims 9-10, wherein removing the lid also removes the first end of the lock from the one or both of the valve cover and the elongated delivery system.
12. The packaging system of any one of the preceding claims, wherein the valve cover comprises an internal cavity to house a nose piece, the prosthetic valve and part of the distal portion of the elongated delivery system.

19. The packaging system of any one of claims 1-5 and 12, wherein the mounting surface resiliently engages at least a portion of the external surface of the valve cover.

20. The packaging system of claim 19, wherein the valve cover comprises a flared open end, an opposing securing end, and a lock ring mounted slidably around the securing end between a locked position and an unlocked position.

21. The packaging system of claim 20, wherein in the locked position, the lock ring exerts a radially inward force around the securing end of the valve cover to secure the valve cover onto the delivery system and wherein in the unlocked position, the radially inward force exerted by the lock ring is released to permit removal of the delivery device from the valve cover.

22. The packaging system of claim 21, wherein the lock ring is housed within a spaced area of the mounting surface to permit the lock ring to slide between the locked and the unlocked positions.

23. The packaging system of any one of the preceding claims, further comprising a lid removably coupled to the tray, and wherein the lid completely encloses the upper surface of the tray.

24. The packaging system of any one of the preceding claims, further comprising a handle attached to the delivery system and packaged within the tray.

25. The packaging system of any one of the preceding claims, further comprising a reservoir in fluid communication with the cavity.