

CLAIMS

What is claimed is:

1. A sheath locking system comprising:
an introducer locking hub comprising a hub body having a proximal end and a distal end and defining a central lumen extending longitudinally between the proximal end and the distal end, and a locking channel disposed on the hub body; and
a sheath locking sleeve removably coupled to the introducer locking hub, the sheath locking sleeve comprising a sleeve body having a proximal end and a distal end and defining a central lumen extending longitudinally between the proximal end and the distal end, a guide disposed on an outer surface of the sleeve body,
wherein the guide is movable within the locking channel between an unlocked position where the sheath locking sleeve is rotationally and axially movable with respect to the introducer locking hub, and a locked position where the sheath locking sleeve is axially fixed with respect to the introducer locking hub.
2. The system of claims 1, wherein the guide protrudes from the outer surface of the locking sleeve and extends at least partially around a circumference of the sheath locking sleeve.
3. The system of any one of claims 1-2, wherein the central lumen of the sheath locking sleeve is aligned with the central lumen of the introducer locking hub.
4. The system of any one of claims 1-3, wherein the locking channel includes a guide portion and a locking portion,
wherein the guide portion is configured to direct the guide in an axial direction along a side wall of the guide portion towards the locking portion upon rotation of at least one of the introducer locking hub and the sheath locking sleeve wherein the locking portion of the locking channel is configured to securely engage the guide fixing an axial position of the introducer locking hub with respect to the sheath locking sleeve.
5. The system of any one of claims 1-4, wherein the locking portion includes a catch, securing the guide within the locking portion of the locking channel.
6. The system of any one of claims 1-5, wherein the guide is configured to bias the locking sleeve in a distal axial direction toward the distal end of the introducer locking hub when the sheath locking sleeve is rotated in a second axial direction such that the guide advances away from the locking portion of the locking channel, to the unlocked position,

wherein rotation in the second causes the guide to bias against the catch and overcome the oppositional forces of the catch retaining the guide within the locking portion of the locking channel.

7. The system of any one of claims 1-6, wherein the sheath locking sleeve is securely couplable to a sheath hub, the sheath hub having an elongated body portion with a central lumen extending therethrough and an expandable sheath coupled to a distal end of the body portion, where a central lumen of the expandable sheath is aligned with the central lumens of the sheath hub, the sheath locking sleeve, and the introducer locking hub.

8. The system any of claims 1-7, wherein a portion of the locking sleeve overlaps axially with the locking hub when the locking channel engages the guide.

9. The system of any one of claims 1-8, further including:
an elongated sheath member coupled to the sheath locking sleeve the sheath member extending beyond the distal end of the hub body, the sheath member having a central lumen extending therethrough, the central lumen of the sheath member aligned with the central lumen of the sheath locking sleeve; and

an elongated introducer member coupled to the introducer locking hub, the introducer member extending beyond the distal end of the hub body and through the central lumen of the sheath locking sleeve, the introducer member having a central lumen extending therethrough, the central lumen of the introducer member aligned with the central lumen of the introducer locking hub,

wherein the locking sleeve forms a continuous inner lumen with the lumen of the sheath, wherein the introducer member is disposed within the central lumen of the sheath member.

~~10. —A method of securing a delivery sheath to an introducer in a device for prosthetic heart valve delivery device, the method comprising:~~

~~providing an introducer locking hub having an elongated introducer coupled to a hub body of the locking hub, the introducer locking hub including a locking channel disposed in the hub body;~~

~~advancing a sheath locking sleeve to a position adjacent a distal end of the introducer locking hub such that a guide projecting from an outer surface of the sheath locking sleeve is received within a locking channel opening on the introducer locking hub, the sheath locking~~

~~sleeve coupled to an expandable delivery sheath, where advancing the sheath locking sleeve to a position adjacent the distal end of the introducer locking hub includes advancing the introducer axially within the central lumen of the expandable delivery sheath;~~

~~rotating the introducer locking hub in a first direction with respect to the locking sleeve to move the guide along the locking channel into a locked position;~~

~~rotating the introducer locking hub in a second direction with respect to the locking sleeve to move the guide along the locking channel into an unlocked position.~~

~~11. —The method of claim 10, wherein movement of the guide along the locking channel into a locked position includes:~~

~~movement of the guide along a guide portion of the locking channel toward a locking portion of the locking channel, where the guide portion of the locking channel extends from the distal end of the introducer locking hub axially towards the proximal end of the introducer locking hub and circumferentially around the introducer locking hub;~~

~~wherein further rotation of the introducer locking hub directs the guide into the locking portion of the locking channel, the locking portion configured to securely engage the guide and fix the axial position of the introducer locking hub with respect to the sheath locking sleeve.~~

12.10. An expandable introducer sheath for deploying a medical device, comprising:

a first layer including a central lumen extending axially therethrough;

a resilient elastic layer radially outward of the first layer, the elastic layer being configured to apply radial force to the first layer; and

wherein when a medical device is passed through the sheath, the diameter of the sheath expands from an initial diameter to an expanded diameter around the medical device,

wherein the sheath resiliently returns to the initial diameter by radial force applied by the elastic layer upon passage of the medical device,

wherein a distal tip of the sheath is configured to bend in a direction away from a longitudinal axis of the sheath.

13.11. The expandable sheath of claim 12.10, wherein the distal tip of the sheath is more flexible than a remaining portion of the sheath.

14.12. The expandable sheath of any one of claims 12-13.10-11 further including:

a pull wire lumen extending from the distal tip of the sheath and a proximal end of the sheath;

a pull wire fixedly coupled to the distal tip of the sheath and passing through the pull wire lumen;

wherein a force applied to the pull wire causes the distal tip of the sheath to approximate a curved shape.

15.13. The expandable sheath of any one of claims ~~12-14~~10-12, further including:

a curved stylet movable within the central lumen of the first layer, wherein a distal end of the stylet includes a curved portion that, when received within the central lumen of the first layer, effects a corresponding curvature of the sheath.

16.14. The expandable sheath of claim ~~15~~13, wherein the stylet is movable within the sheath to a final position such that the curved portion of the stylet is proximate the distal tip of the sheath and the stylet effects a corresponding curvature of the distal tip.

17.15. The expandable sheath of claim ~~16-14~~ further comprising:

a braided layer radially outward of the first polymeric layer, the braided layer comprising a plurality of filaments braided together;

the resilient elastic layer radially outward of the braided layer;

a second polymeric layer radially outward of the elastic layer and bonded to the first polymeric layer such that the braided layer and the elastic layer are encapsulated between the first and second polymeric layers;

wherein the resilient elastic layer is radially outward of the braided layer, the elastic layer being configured to apply radial force to the braided layer and the first polymeric layer.

18.16. The expandable sheath of claim ~~17~~15, wherein when the diameter of the sheath expands from the initial diameter to the expanded diameter, the first and second polymeric layers resist axial elongation of the sheath such that a length of the sheath remains substantially constant.

19.17. The expandable sheath of any one of claims ~~17-18~~15-16, the first and second polymeric layers comprise a plurality of longitudinally-extending folds when the sheath is at the first diameter.

20.18. The expandable sheath of claim ~~19~~17, wherein the longitudinally extending folds create a plurality of circumferentially spaced ridges and a plurality of circumferentially spaced valleys.

21.19. The expandable sheath of any one of claims ~~17-20~~15-18, wherein the filaments of the braided layer are movable between the first and second polymeric layers such that the braided layer is configured to radially expand as a medical device is passed through the sheath while the length of the sheath remains substantially constant.

22.20. The expandable sheath of any one of claims ~~17-21~~15-19, wherein the filaments of the braided layer are resiliently buckled when the sheath is at the first diameter, and the first and second polymeric layers are attached to each other at a plurality of open spaces between the filaments of the braided layer.

23.21. The expandable sheath of claim ~~22~~20, wherein the first layer includes a thick wall portion integrally connected to a thin wall portion, wherein the thick wall portion has a C-shaped cross section with a first longitudinally extending end and a second longitudinally extending end and wherein the thin wall portion extends between the first and second longitudinally extending ends so as to define an expanded central lumen extending axially through the first layer, the expanded central lumen defined by the expanded diameter.