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(54) **INTRODUCER SHEATH ASSEMBLY HAVING A LOCKING DILATOR**

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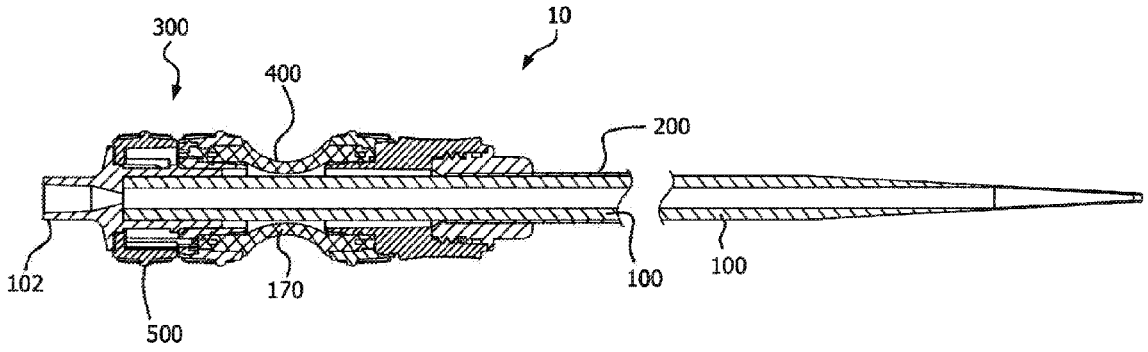
(57) **ABSTRACT**

An introducer assembly includes a valve having a first end and an opposite second end; a sheath fixedly secured to and extending axially from one of the first and second ends of the valve; a dilator extending through the valve and sheath; and a lock knob rotatable between locked and unlocked positions to releasably axially lock the tool relative to the sheath without causing corresponding rotation of the tool therewith.



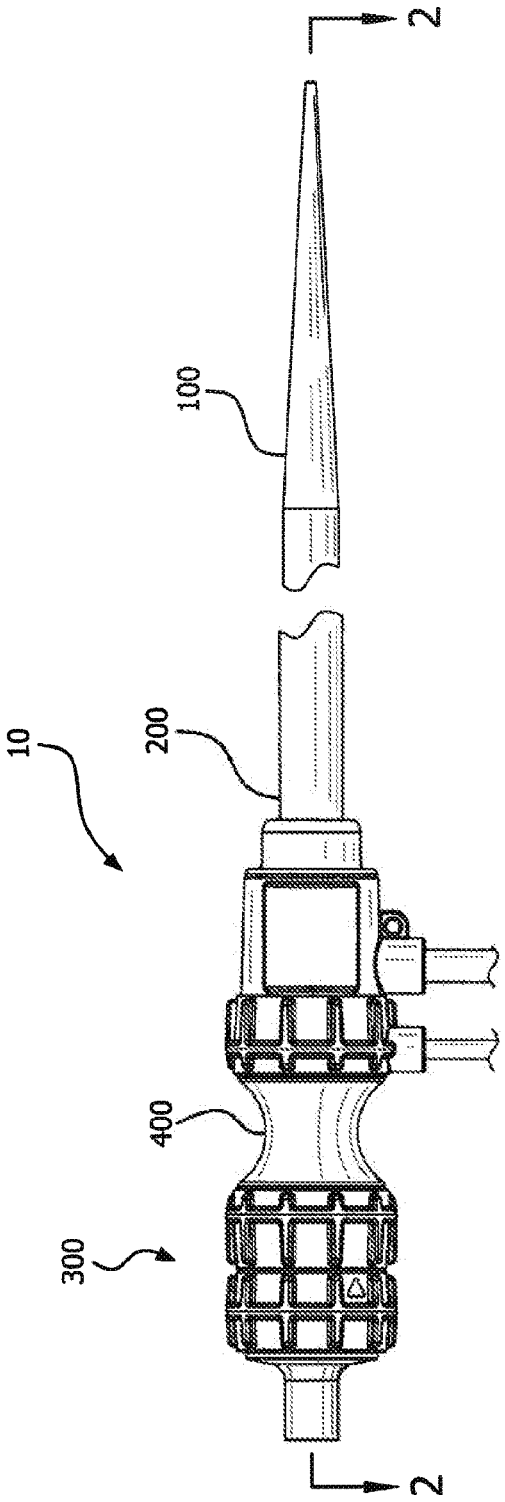


FIG. 1

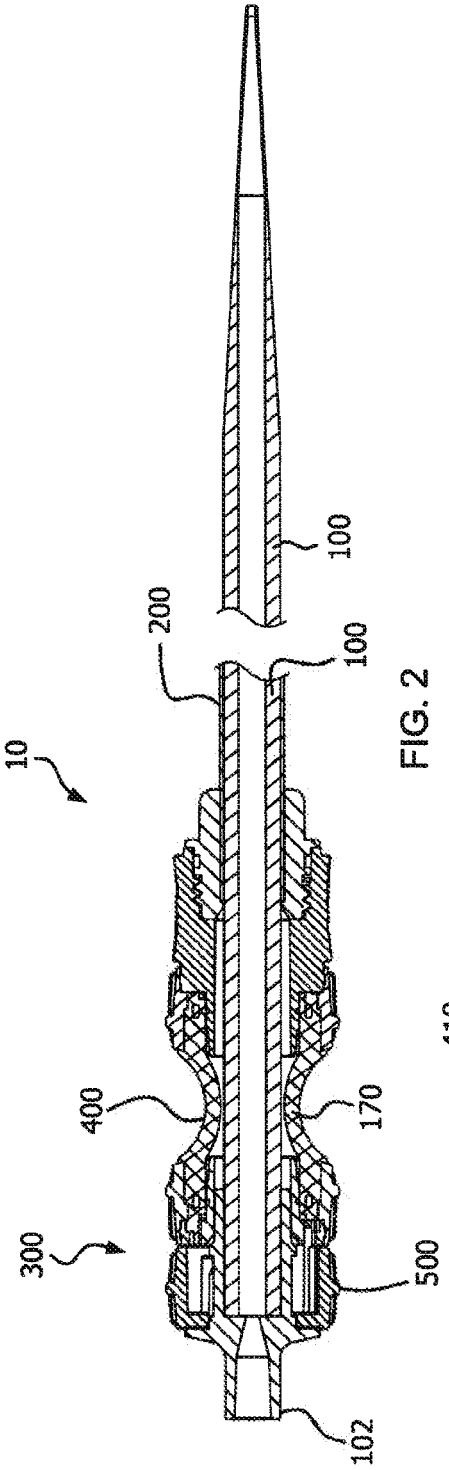

10
100
200
100
400
170
300
500
102

FIG. 2

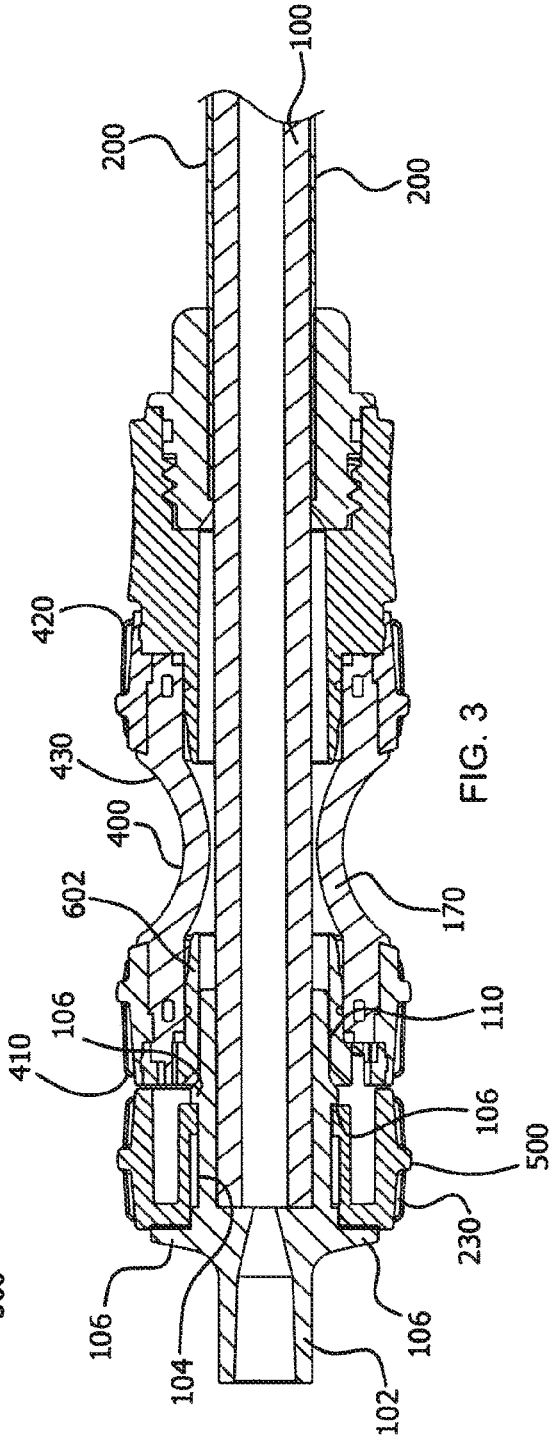

100
200
200
420
430
400
602
170
106
110
410
106
500
230
106
106
104
102

FIG. 3

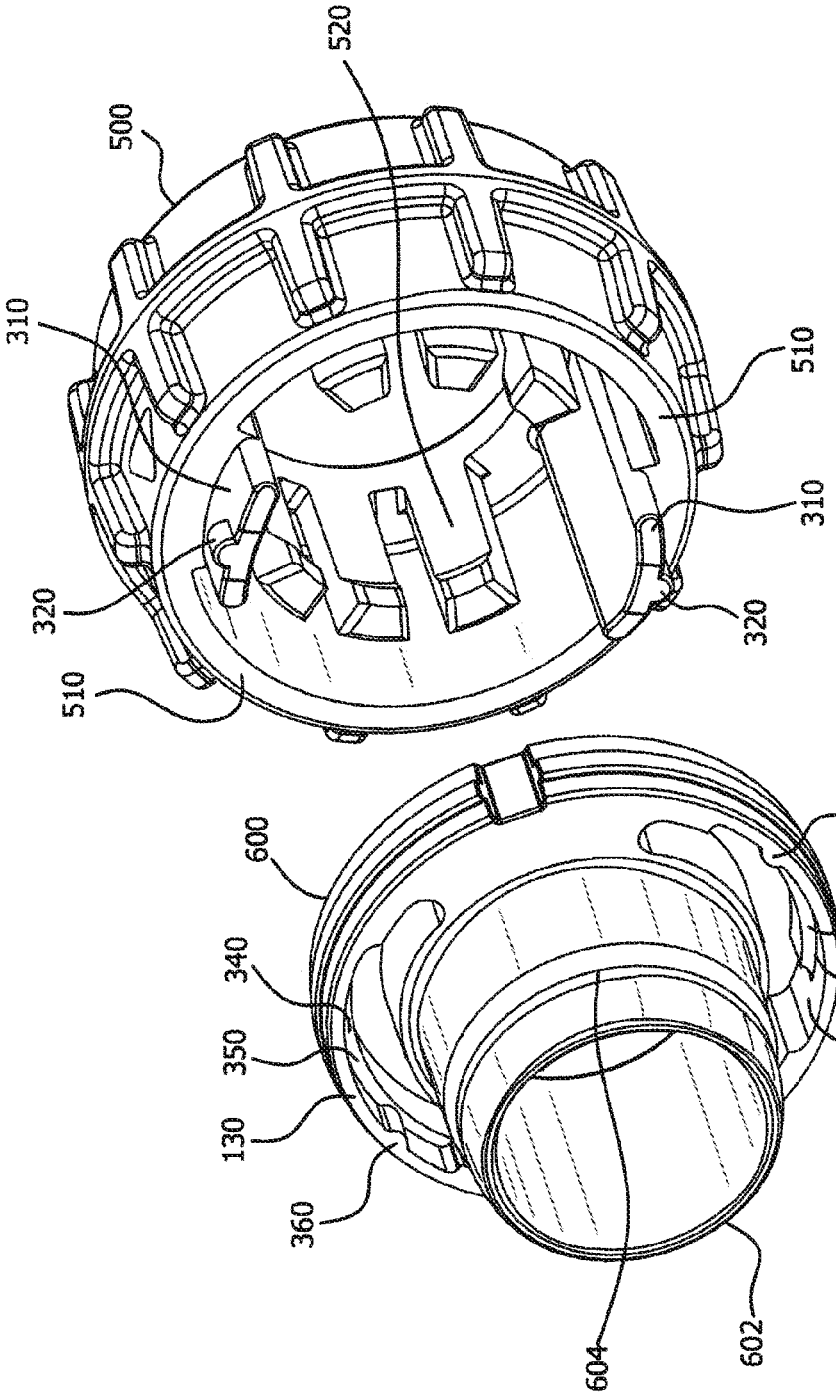

520
500
310
510
310
320
320
510
600
360
340
350
350
340
130
330
360
604
602

FIG. 4

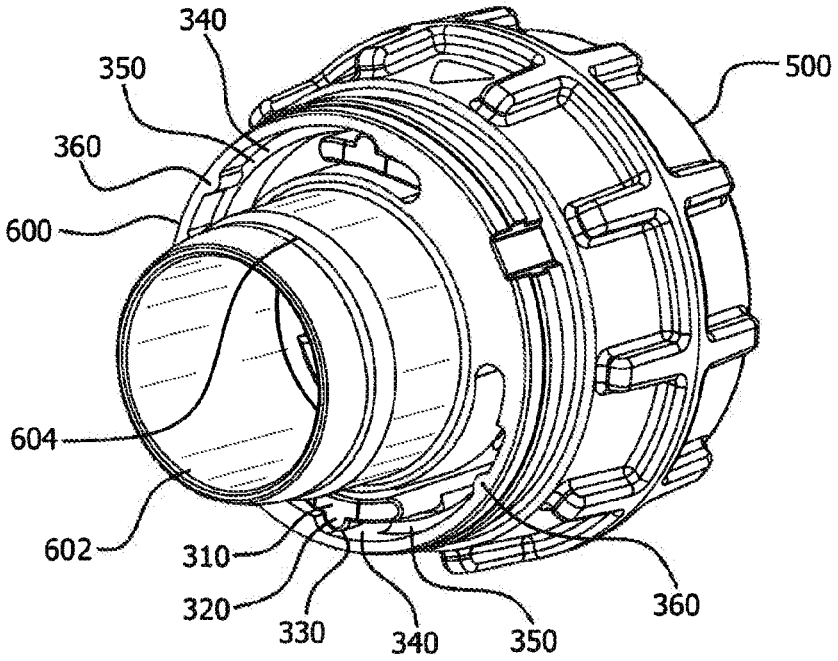

340
350
360
600
604
602
310
320
330
340
350
360
500

FIG. 5

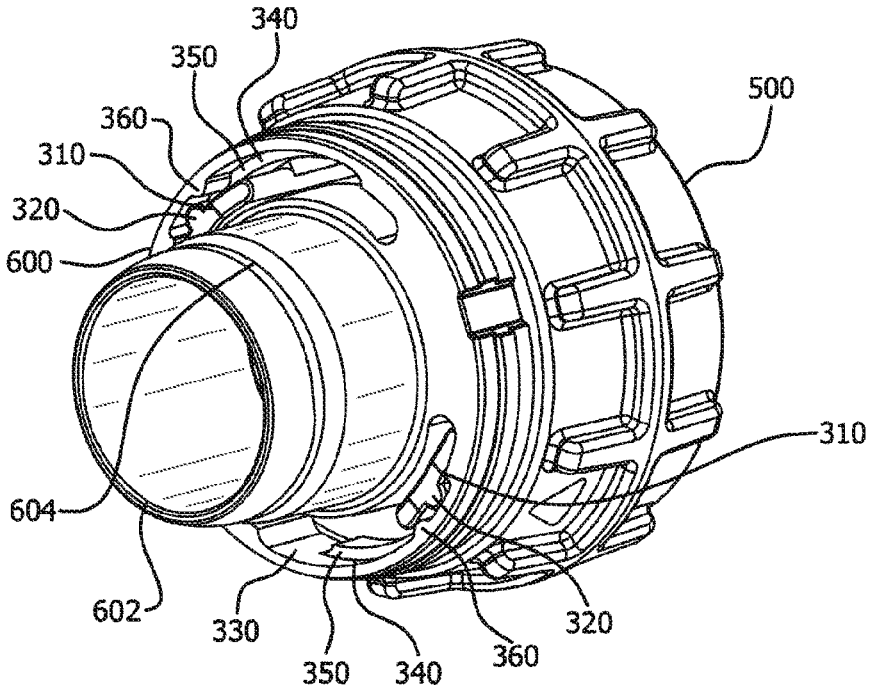

340
350
360
310
320
600
604
602
330
350
340
360
320
310
500

FIG. 6

INTRODUCER SHEATH ASSEMBLY HAVING A LOCKING DILATOR

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Ser. No. 61/560,638, which was filed on Nov. 16, 2011 and is hereby incorporated by reference in its entirety.

BACKGROUND

[0002] 1. Field

[0003] The invention relates to an introducer sheath assembly for medical procedures and, more particularly, a locking mechanism for releasably axially locking an introducer sheath and a surgical implement inserted through the introducer sheath.

[0004] 2. Discussion

[0005] Introducer sheath assemblies are used in a wide variety of minimally invasive and conventional surgical procedures, such as endoluminal delivery of surgical implements. Introducer sheath assemblies typically include an introducer sheath and valve for controlling leakage while accessing the introducer sheath with surgical implements, such as endoprosthetic devices, dilators, guidewires and the like. Introducer sheath valves generally rely on contact between a resilient elastomeric sealing body and a surgical implement inserted through the introducer sheath valve to form a desired fluid tight seal. It remains desirable to provide a mechanism for locking an introducer sheath and surgical implement without disrupting the seal between the introducer sheath valve and surgical implement.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] The accompanying drawings are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification, illustrate embodiments of the invention, and together with the description serve to explain the principles of the invention.

[0007] FIG. **1** is a side elevational view of an introducer sheath assembly in accordance with various embodiments;

[0008] FIG. **2** is a cross sectional view of an introducer sheath assembly in accordance with various embodiments;

[0009] FIG. **3** is an enlarged cross sectional view of an introducer sheath assembly in accordance with various embodiments;

[0010] FIG. **4** is an exploded perspective view of a locking mechanism in accordance with various embodiments;

[0011] FIG. **5** is a perspective view of a locking mechanism in accordance with various embodiments shown in an unlocked position; and

[0012] FIG. **6** is a perspective view of a locking mechanism in accordance with various embodiments shown in a locked position.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

[0013] An introducer sheath assembly, in accordance with various embodiments, is disclosed herein, which includes a locking mechanism for releasably axially locking the introducer sheath and a surgical implement or tool inserted through the introducer sheath assembly, such as dilators, endoprosthetics, endoscopes and the like. The introducer sheath assembly can include a sheath, and a valve for preventing leakage during insertion of a tool through the sheath. Examples and detailed descriptions of an introducer sheath assembly and valve are disclosed in co-pending U.S. Patent Application Publication 2009/0306598, the content of which is incorporated herein by reference in its entirety.

[0014] Referring to FIG. **1**, an introducer sheath assembly in accordance with various embodiments is shown and generally indicated at **10**. The introducer sheath assembly **10** includes a tubular sheath **200** adapted to receive an elongated tool therethrough. In the figures, a tool **100** is shown illustratively as a dilator, though it should be readily appreciated that the tool can be any tool or device deliverable through the sheath, such as an endoscope or a stent graft. The introducer sheath assembly **10** can include a valve **400** to prevent leakage while inserting the tool **100** through the sheath **200**. More specifically, the sheath **200** can be fixedly secured at one end **410** of the valve **400**. The sheath **200** and a resilient inner tube **430** of the valve **400** can be generally coaxially aligned to receive the tool **100** therethrough. In various embodiments, described further in detail below, the introducer sheath assembly **10** includes a locking mechanism **300** that allows selective locking of the tool **100** to the sheath **200** and valve **400**.

[0015] Referring to FIGS. **2** and **3**, a locking mechanism **300** is disposed on an end **420** of the valve **400** opposite the sheath **200**. The locking mechanism **300** is actuatable between locked and unlocked positions to allow selective locking of the tool **100** to the sheath **200** and valve **400**. In various embodiments, the locking mechanism **300** includes a lock knob **500** rotatable between locked and unlocked positions to releasably axially lock the tool **100** to the sheath **200** or, more specifically, to the valve **400** without causing corresponding rotation of the tool **100** relative to the valve **400**. In various embodiments, the tool **100** includes a hub **102**. The hub **102** includes an annular bearing surface **104**. The hub **102** includes radially outwardly extending locating surfaces **106** that are axially spaced apart on the bearing surface **104**. The hub **102** also includes an annular portion **110** adjacent axially to the bearing surface **104**. The annular portion **110** protrudes axially to facilitate alignment of the tool **100** as the tool **100** is inserted through the valve **400** and sheath **200**. In other embodiments, the lock knob may be moveable in other directions, such as axially, relative to the hub

[0016] The lock knob **500** includes at least one radially extending rib **520** that engages the annular bearing surface **104** of the hub **102**, thereby generally radially locating the lock knob **500** relative to the hub **102**. The rib **520** also axially engages the axially spaced apart locating surfaces **106**, thereby axially locating and constraining the lock knob **500** relative to the hub **102**. The lock knob **500** and hub **102** are, therefore, generally axially constrained relative to each other, but are also free to rotate relative to each other. Thus, as described below, the clinician can selectively rotate the lock knob **500** relative to the hub **102** to lock or unlock the locking mechanism **300** and not cause undesired rotation of the tool **100** relative to the sheath **200**, valve **400** and/or vasculature.

[0017] The introducer sheath assembly **10** includes a trailing fitting **600** fixedly secured to the end **410** of the valve **400** opposite the sheath **200**. More specifically, the trailing fitting includes an annular tapered portion **602**. A resilient lip or ring (not shown) can be positioned along a slot **604** that extends around the annular portion **602**. The ring can be formed from silicon or other suitable resilient sealing material. In assembly with the valve arrangement, the tapered portion **602** of the

trailing fitting **600** extends into the inner tube **430** of the valve **400**. Insertion of the tapered portion **602** into the inner tube **430** during assembly causes the ring to engage and elastically radially displace or deform the inner tube **430** thereby forming a fluid seal therewith. The trailing fitting can also include a locking feature, such as a tab or barb extending through an aperture or recess, to secure its orientation relative to the valve once installed within.

[0018] The locking mechanism **300** includes a locking tab **310** extending generally axially from an end surface **510** of the lock knob **500**. A protrusion **320** extends generally radially from an end of the locking tab **310** and is axially spaced apart from the end surface **510** of the lock knob **500**. Alternatively, the locking mechanism can include more than one locking tab. In FIG. **4**, for example, a pair of locking tabs **310** extends from generally opposite sides of the end surface **510** of the lock knob **500**.

[0019] The locking mechanism **300** includes an axially extending groove **330** formed on the trailing fitting **600** to accommodate passing of each locking tab **310** therethrough as the lock knob **500** and trailing fitting **600** are positioned toward each other axially. The locking mechanism **300** includes an annular recess or slot **340** formed in the trailing fitting **600** that intersects with and extends rotationally from the groove **330** to accommodate the protrusion **320** as the lock knob **500** is rotated relative to the trailing fitting **600**, for example, by an assembler during manufacture of the assembly or by a clinician when actuating the locking mechanism **300** to lock or release the tool **100** from the sheath **200** during an operating procedure. The locking mechanism **300** includes an annular edge **350** adjacent the annular slot **340** that axially can engage the protrusion **320** to axially interlock the lock knob **500** and the trailing fitting **600**. The lock knob **500** is, therefore, selectively movable between an unlocked position (FIG. **5**), wherein the protrusion **320** on the tab **310** of the lock knob **500** is aligned and movable along the axially extending groove **330** of the trailing fitting **600** to allow axial movement of the lock knob **500** relative to the trailing fitting **600**, and a locked position (FIG. **6**), wherein the protrusion **320** on the tab **310** of the lock knob **500** is aligned with and movable along the annular slot **340** such that the protrusion **320** can contact the annular edge **350** to axially interlock the lock knob **500** and the trailing fitting **600**. As best shown in FIG. **6**, a bump **360** formed on the trailing fitting **600** along the annular slot **340** can engage the protrusion **320** to hold the lock knob **500** rotatably toward the locked position.

[0020] An introducer assembly, in accordance with a number of embodiments, can utilize any tool or device deliverable through the sheath. Exemplary use of the introducer assembly is described below in connection with a dilator. It should, however, be readily appreciated that other surgical implements may be utilized with the introducer assembly, such as stent grafts, endoprosthetics, endoscopes, or other surgical implements. A guide wire is inserted endoluminally into a patient and toward an intended vascular treatment site. A flexible, elongated dilator is provided with a hub and lock knob for engaging the trailing fitting. The dilator is inserted through the valve and sheath. The annular portion of the hub radially aligns the dilator relative to the valve and sheath. The introducer sheath assembly, with the sheath, valve and dilator axially locked via the locking engagement of the lock and trailing fitting, as discussed above, is inserted into the patient along the guidewire. More specifically, the dilator is loaded onto the guidewire and inserted with the sheath into the patient along the guidewire. After dilating the intended endovascular delivery path, the dilator can be removed while the sheath remains in place. To remove the dilator, the lock is rotated so that the protrusion on the tab translates along the annular recess toward the axially extending groove until the protrusion is aligned with the groove. The protrusion translates through the groove as the lock and dilator are generally axially separated from the trailing fitting and valve arrangement.

[0021] As discussed, the lock knob freely rotates with respect to the hub and dilator. Thus, unlocking the lock knob from the trailing fitting does not cause undesired rotation of the dilator while still in the patient and further does not disturb fluid sealing engagement between the dilator and valve arrangement. Additionally, axial separation of the lock knob from the trailing fitting causes corresponding axial displacement of the dilator from the vasculature and sheath, as a result of the rib or ribs extending from the lock knob and engaging the locating surfaces of the hub. The dilator can be completely removed by continued axial separation of the lock knob relative to the trailing fitting. Thus, the locking mechanism allows selective locking and unlocking of the lock knob relative to the trailing fitting without causing rotation of the dilator and hub relative to the sheath and valve, while the tool remains in the vasculature of the patient and further without compromising fluid sealing engagement between the tool and the valve arrangement.

[0022] Although the valve arrangement has been discussed illustratively as an introducer sheath valve, various embodiments encompass other applications such as bariatric port access, medical injection port, vascular access port, valve for insertion sites such as feeding tubes or dialysis access port, etc.

[0023] It will be apparent to those skilled in the art that various modifications and variations can be made in the present invention without departing from the spirit or scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents.

What is claimed is:

1. An introducer assembly comprising:
- a sheath that is generally tubular;
- a tool that is slidable through the sheath; and
- a lock operatively coupling the sheath and the tool for selectively locking the tool and the sheath, the lock being actuatable between locked and unlocked positions to releasably axially lock the tool and the sheath without causing movement of the tool relative to the sheath.

2. An introducer assembly as set forth in claim **1**, wherein the locking mechanism includes a lock knob rotatable between locked and unlocked positions without causing rotation of the tool relative to the sheath.

3. An introducer assembly as set forth in claim **2**, wherein the locking mechanism includes a hub coupled to the tool, the hub having an annular bearing surface slidably engaged with the lock knob to allow rotation of the lock knob between the locked and unlocked positions.

4. An introducer assembly as set forth in claim **3**, wherein the locking mechanism includes a locating surface extending from the annular bearing surface that engages the lock knob to axially constrain the lock knob relative to the tool.

5. An introducer assembly as set forth in claim **4**, wherein the lock knob includes at least one radially extending rib that

engages the annular bearing surface for rotation of the lock knob relative to the tool and engages the locating surface to axially constrain the lock knob relative to the tool.

6. An introducer assembly as set forth in claim **5** including a trailing fitting coupled to an end of the valve opposite the sheath.

7. An introducer assembly as set forth in claim **6**, wherein the locking mechanism includes a locking tab that extends axially from an end of the lock knob and engages the trailing fitting while in the locked position to axially lock the tool relative to the sheath.

8. An introducer assembly as set forth in claim **7**, wherein the locking mechanism includes an annular slot formed in the trailing fitting that receives the locking tab therealong to accommodate rotation of the lock knob between the locked and unlocked positions.

9. An introducer assembly as set forth in claim **8**, wherein the locking mechanism includes a groove that extends axially and intersects with the annular slot to receive the locking tab as the lock knob is positioned axially toward the trailing fitting.

10. An introducer assembly as set forth in claim **9**, wherein the locking mechanism includes a protrusion that extends generally radially from the locking tab so as to slidably engage the annular slot during movement of the lock knob between the locked and unlocked positions.

11. An introducer assembly as set forth in claim **10**, wherein the locking mechanism includes an annular edge formed on the trailing fitting adjacent the annular slot, the annular edge axially engaging the protrusion during movement of the lock knob between the unlocked and locked positions to axially constrain the tool relative to the sheath.

12. An introducer assembly as set forth in claim **1**, wherein the valve includes an inner tube comprising a porous substrate, the inner tube sealingly engageable with a tool inserted through the valve.

13. An introducer assembly as set forth in claim **3**, wherein the valve includes an outer tube, and a pressurizable space formed between the inner surface of the outer tube and an outer surface of the inner tube.

14. An introducer assembly as set forth in claim **13**, wherein the locking mechanism includes a lock knob rotatable between locked and unlocked positions without causing rotation of the tool relative to the sheath.

15. An introducer assembly as set forth in claim **14**, wherein the locking mechanism includes a hub coupled to the tool, the hub having an annular bearing surface slidably engaged with the lock knob to allow rotation of the lock knob between the locked and unlocked positions.

16. An introducer assembly as set forth in claim **15**, wherein the locking mechanism includes a locating surface extending from the annular bearing surface that engages the lock knob to axially constrain the lock knob relative to the tool.

17. An introducer assembly as set forth in claim **16**, wherein the lock knob includes at least one radially extending rib that engages the annular bearing surface for rotation of the lock knob relative to the tool and engages the locating surface to axially constrain the lock knob relative to the tool.

18. An introducer assembly as set forth in claim **13**, wherein the tool includes a dilator.

19. An introducer assembly as set forth in claim **13**, wherein the tool includes a catheter and an endoprosthetic device disposed on an end of the catheter.

20. An introducer assembly as set forth in claim **19**, wherein the endoprosthetic device is a stent graft

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