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(71) Applicant: **MERIT MEDICAL SYSTEMS, INC.** [US/US]; 1600 West Merit Parkway, South Jordan, Utah 84095 (US).

(72) Inventors: **LAMPROPOULOS, Justin**; 4708 North Eagle Nest Lane, Lehi, Utah 84043 (US). **STEVENS, Brian**; 1560 West 1800 North, Grove, Utah 84062 (US). **JENKINS, Richard**; 2221 Mountainside Drive, Bluffdale, Utah 84065 (US). **MCARTHUR, Gregory R.**; 8990 Shady Meadow Drive, Sandy, Utah 84093 (US).

(74) Agent: **MCCAMMON, Jason B.**; Stoel Rives LLP, 201 So. Main Street, Suite 1100, One Utah Center, Salt Lake City, Utah 84111 (US).

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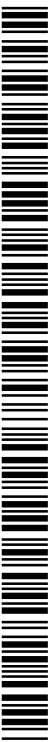
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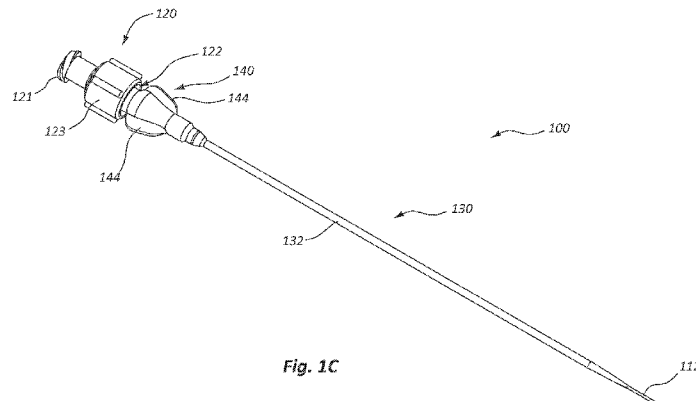
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(54) Title: QUICK-RELEASE HUBS FOR MEDICAL DEVICES



(57) Abstract: Hub assemblies that include a first hub and a second hub can be used to selectively couple and uncouple medical device components to and from each other without rotating the first hub relative to the second hub. Some hub assemblies can include a dilator that includes a dilator hub and an introducer sheath that includes an introducer sheath hub.

QUICK-RELEASE HUBS FOR MEDICAL DEVICES

RELATED APPLICATIONS

[0001] This application claims priority to United States Provisional Application No. 62/162,302 filed on May 15, 2015 and titled, "Quick-Release Hubs for Medical Devices," which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The present disclosure relates generally to the field of medical devices. More specifically, the present disclosure relates to hubs and hub assemblies that can be used to couple components of a medical device or assembly to one another. Related methods are also disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] The written disclosure herein describes illustrative embodiments that are non-limiting and non-exhaustive. Reference is made to certain of such illustrative embodiments that are depicted in the figures, in which:

[0004] FIG. 1A is a side view of a dilator.

[0005] FIG. 1B is a side view of an introducer sheath.

[0006] FIG. 1C is a perspective view of an introducer sheath assembly that includes the dilator of FIG. 1A and the introducer sheath of FIG. 1B.

[0007] FIG. 2A is a perspective view of an unassembled introducer sheath hub assembly according to another embodiment.

[0008] FIG. 2B is a cross-sectional side view of the unassembled introducer sheath hub assembly of FIG. 2A.

[0009] FIG. 2C is a perspective view of the introducer sheath hub assembly of FIGS. 2A and 2B in an assembled configuration.

[0010] FIG. 2D is another perspective view of the introducer sheath hub assembly of FIGS. 2A–2C in an assembled configuration.

[0011] FIG. 3A is a perspective view of an unassembled introducer sheath hub assembly according to another embodiment.

[0012] FIG. 3B is a side view of the introducer sheath hub assembly of FIG. 3A in another unassembled configuration.

[0013] FIG. 3C is a side view of the introducer sheath hub assembly of FIGS. 3A and 3B in an assembled configuration.

[0014] FIG. 3D is a close-up perspective view of a portion of the introducer sheath hub assembly of FIGS. 3A and 3B in an assembled configuration.

[0015] FIG. 4A is a perspective view of an unassembled introducer sheath hub assembly according to another embodiment.

[0016] FIG. 4B is an alternative perspective view of the introducer sheath hub assembly of FIG. 4A.

[0017] FIG. 4C is a perspective view of the introducer sheath hub assembly of FIG. 4A in an assembled configuration.

[0018] FIG. 4D is a cross-sectional view of the assembled introducer sheath hub assembly of FIG. 4A.

[0019] FIG. 4E is another cross-sectional view of the assembled introducer sheath hub assembly of FIG. 4A.

[0020] FIG. 4F is another cross-sectional view of the assembled introducer sheath hub assembly of FIG. 4A with a cylindrical member in an unconstrained configuration.

[0021] FIG. 4G is another cross-sectional view of the assembled introducer sheath hub assembly of FIG. 4A with a cylindrical member in a constrained configuration.

DETAILED DESCRIPTION

[0022] This disclosure broadly relates to hubs, hub assemblies, and introducer sheath assemblies for medical devices, along with related methods. Certain embodiments relate, more particularly, to introducer sheath assemblies that allow a practitioner to selectively couple and/or uncouple a dilator hub to and/or from an introducer sheath hub.

[0023] The components of the embodiments as generally described and illustrated in the figures herein can be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description of various embodiments, as represented in the figures, is not intended to limit the scope of the present disclosure, but is merely representative of various embodiments. While various aspects of the embodiments are presented in drawings, the drawings are not necessarily drawn to scale unless specifically indicated.

[0024] The directional terms “proximal” and “distal” are generally given their ordinary meanings in the art. That is, the distal end of a device or component is the end of the component that is furthest from the practitioner during ordinary use. The

proximal end refers to the opposite end, or the end nearest the practitioner during ordinary use.

[0025] Introducer sheath assemblies may be used to facilitate the introduction of a medical device, such as a guidewire or catheter, into the vasculature or other body cavity of a patient. In an exemplary procedure, a needle (e.g., a small gauge needle) may be used to create an initial access puncture into the patient's vasculature. A guidewire (e.g., a small diameter guidewire) may then be threaded through the needle. Once the guidewire has been properly placed, the needle used to access the patient's vasculature may then be withdrawn from the patient. An introducer sheath assembly is then threaded over the guidewire and inserted into the patient. The introducer sheath assembly can include an introducer sheath and a dilator that is positioned inside the introducer sheath. The dilator may impart increased stiffness to the introducer sheath, thereby facilitating insertion of the introducer sheath into the patient. Stated differently, the pliant nature of the introducer sheath may make it difficult to introduce the introducer sheath into the vasculature of the patient without a stiffening dilator. Once the introducer sheath is properly positioned within the patient, the dilator may be uncoupled from the introducer sheath and withdrawn from the patient. Other medical devices may then be inserted into the patient through the introducer sheath. The introducer sheath assemblies described herein may also be used in connection with other medical procedures, such as biopsy procedures, etc.

[0026] FIGS. 1A–1C depict an introducer sheath assembly 100, or components thereof. In particular, FIG. 1A provides a side view of a dilator 110. FIG. 1B provides a side view of an introducer sheath 130. And FIG. 1C provides a perspective view of an introducer sheath assembly 100 in which the dilator 110 of FIG. 1A is coupled to the introducer sheath 130 of FIG. 1B.

[0027] With reference to FIG. 1A, the dilator 110 may include an elongate shaft 112 and a dilator hub 120 that is coupled to the elongate shaft 112 adjacent a proximal end of the elongate shaft 112. In the depicted embodiment, the dilator hub 120 includes a female luer lock fitting 121 adjacent the proximal end of the dilator hub 120, and a male luer lock fitting 122 that is disposed distal of the female luer lock fitting 121. The male luer lock fitting 122 includes a sleeve 123 having a plurality of threads (not shown) on its inner surface and a protuberance 124 that is at least partially disposed within the sleeve 123. The elongate shaft 112 may extend distally from the protuberance 124. The length of the elongate shaft 112 may approximate

the length of an introducer sheath 130 to be used with the dilator 110. In some embodiments, the elongate shaft 112 partially defines a lumen (not shown) that extends through the dilator 110. Stated differently, in some embodiments, the elongate shaft 112 is a tube having a hollow interior.

[0028] With reference to FIG. 1B, the introducer sheath 130 may include an elongate tubular member 132 and an introducer sheath hub 140. In the depicted embodiment, the tubular member 132 is coupled to and extends distally from the introducer sheath hub 140. The tubular member 132 may partially define a lumen (not shown) that extends through the introducer sheath 130.

[0029] With reference to the embodiment depicted in FIGS. 1A–1C, the introducer sheath hub 140 may comprise a female luer lock fitting 142 and wings 144. In the depicted embodiment, the female luer lock fitting 142 is configured to facilitate coupling of the introducer sheath hub 140 to the dilator hub 120. Stated differently, the female luer lock fitting 142 is configured to threadably engage with the male luer lock fitting 122 of the dilator hub 120. Each of the wings 144 extends radially away from a longitudinal axis of the of the introducer sheath hub 140 and is configured to facilitate manipulation of the introducer sheath 130 by providing a gripping point for the practitioner.

[0030] The dilator 110 may be inserted within and coupled to the introducer sheath 130 to stiffen the introducer sheath 130 and/or ensure that the dilator 110 and the introducer sheath 130 travel as a single unit when advanced within a patient. For example, the elongate shaft 112 may be inserted through an opening adjacent the proximal end of the introducer sheath 130 and advanced within the introducer sheath 130 until the dilator hub 120 is adjacent to the introducer sheath hub 140. The dilator hub 120 may then be coupled to the introducer sheath hub 140 by rotating the dilator hub 120 relative to the introducer sheath hub 140, thereby securing the dilator hub 120 to the introducer sheath hub 140 via a luer lock engagement. Stated differently, when the dilator hub 120 is rotated relative to the introducer sheath hub 140, the threads of the female luer lock fitting 142 for the introducer sheath hub 140 may engage with threads on the sleeve 123 of the male luer lock fitting 122 of the dilator 110, thereby securing the dilator hub 120 to the introducer sheath hub 140. In some embodiments, an introducer sheath assembly 100 is packaged and/or delivered to the practitioner in an assembled configuration in which the dilator 110 is coupled to

the introducer sheath 130. In other embodiments, the practitioner couples the dilator 110 to the introducer sheath 130.

[0031] Once the dilator 110 is coupled to the introducer sheath 130, a distal portion of the introducer sheath assembly 100 may be percutaneously inserted into and advanced within the patient. Once the introducer sheath 130 is properly placed within the patient, the dilator 110 may be uncoupled from the introducer sheath 130 by rotating the dilator 110 relative to the introducer sheath 130, thereby disconnecting the luer lock connection between the dilator 110 and the introducer sheath 130. Rotation of the dilator 110 relative to the introducer sheath 130 to uncouple the dilator 110 from the introducer sheath 130 generally requires two hands: one hand to grasp and rotate the dilator hub 120 and a second hand to grasp the introducer sheath hub 140 to prevent rotation of the introducer sheath 130 while the dilator hub 120 is rotated. The rotational force that is applied to uncouple the dilator 110 from the introducer sheath 130 may affect the positioning of the introducer sheath 130 within the patient. For example, in some instances, the distal end of the introducer sheath 130 may be inadvertently displaced as the practitioner attempts to rotate the dilator hub 120 relative to the introducer sheath hub 140.

[0032] FIGS. 2A–2D depict an embodiment of an introducer sheath assembly 200 that resembles the introducer sheath assembly 100 described above in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to “2.” For example, the embodiment depicted in FIGS. 2A–2D includes a dilator 210 that may, in some respects, resemble the dilator 110 of FIGS. 1A–1C. Relevant disclosure set forth above regarding similarly identified features thus may not be repeated hereafter. Moreover, specific features of introducer sheath assemblies and related components shown in FIGS. 1A–1C may not be shown or identified by a reference numeral in the drawings or specifically discussed in the written description that follows. However, such features may clearly be the same, or substantially the same, as features depicted in other embodiments and/or described with respect to such embodiments. Accordingly, the relevant descriptions of such features apply equally to the features of the introducer sheath assembly 200 and related components depicted in FIGS. 2A–2D. Any suitable combination of the features, and variations of the same, described with respect to the introducer sheath assembly 100 and related components illustrated in FIGS. 1A–1C can be employed with the introducer sheath assembly 200 and related

components of FIG. 2A–2D, and vice versa. This pattern of disclosure applies equally to further embodiments depicted in subsequent figures and described hereafter, wherein the leading digits may be further incremented.

[0033] FIGS. 2A–2D provide various views of an introducer sheath assembly 200 and related components. More particularly, FIG. 2A provides a perspective view of the introducer sheath assembly 200 in an unassembled configuration. FIG. 2B provides a cross-sectional side view of the unassembled introducer sheath assembly 200. And FIGS. 2C and 2D provide alternative perspective views of the introducer sheath assembly 200 in an assembled configuration. In the depicted embodiment, the introducer sheath assembly 200 is substantially symmetrical across two planes: (1) the plane used to define the cross-section depicted in FIG. 2B, and (2) the plane going into the page of FIG. 2B that bisects the introducer sheath assembly 200 along the longitudinal axis of the introducer sheath assembly 200.

[0034] With reference to FIGS. 2A–2D, the introducer sheath assembly 200 may include a dilator 210 and an introducer sheath 230. The dilator 210 may include an elongate shaft 212 and a dilator hub 220. The elongate shaft 212 may comprise a tubular member that defines, in part, a lumen 214 that extends through the dilator 210. The lumen 214 may be sized to accommodate a guidewire (not shown). In the depicted embodiment, the dilator hub 220 includes a female luer lock fitting 221, a protuberance 224, a cylindrical member 225, finger input portions 262, and catches 250.

[0035] In the depicted embodiment, the protuberance 224 is at least partially disposed within the cylindrical member 225. In some embodiments, the protuberance 244 is configured to contact an inner surface 248 of the introducer sheath hub 240 when the dilator 210 is coupled to the introducer sheath 230. The elongate shaft 212 may extend distally from the protuberance 224. In the depicted embodiment, the elongate shaft 212 is a hollow tube. Stated differently, the elongate shaft 212 may include a tubular member that at least partially defines a lumen 214 that extends through the elongate shaft 212.

[0036] In the depicted embodiment, cylindrical member 225 includes two finger input portions 262 and two slits 264. The two finger input portions 262 are positioned on opposite sides of the dilator hub 220. The two slits 264 are also positioned on opposite sides of the dilator hub 220 and are radially offset from the finger input portions 262 relative to a longitudinal axis of the dilator hub 220. As described in

further detail below, the finger input portions 262 are configured to facilitate uncoupling of the dilator hub 220 from the introducer sheath hub 240 when pressed toward one another.

[0037] In the depicted embodiment, the catches 250 extend distally from a proximal portion of the dilator hub 220. Each catch 250 may include a tail 251 and a barb 252. As depicted in FIGS. 2A–2D, the barb 252 may include a leading angled surface 254 and a trailing surface 256. The catches 250 may be radially offset from the finger input portions 262.

[0038] The introducer sheath 230 may include a tubular member 232 and an introducer sheath hub 240. The tubular member 232 may partially define a lumen (not shown) that extends through the introducer sheath 230. The introducer sheath hub 240 may include a female luer lock fitting 242, wings 244, and two or more semi-annular ridges 246. In contrast with the embodiment depicted in FIGS. 1A and 1C, the female luer lock fitting 242 does not threadably engage with the dilator hub 220, as the dilator hub 220 does not include threads for mating with the female luer lock fitting 242.

[0039] The wings 244 may include a first wing and a second wing that each extend radially away from the longitudinal axis of the introducer sheath hub 240. Stated differently, the wings 244 may each extend radially away from a longitudinal axis of the introducer sheath hub 240.

[0040] The two or more semi-annular ridges 246 may protrude radially away from a longitudinal axis of the introducer sheath hub 240. In the depicted embodiments, each semi-annular ridge 246 extends less than halfway around the circumference of the introducer sheath hub 240. The semi-annular ridges 246 may be spaced from one another to provide for openings between the semi-annular ridges 246. As described in further detail below, these ridges 246 may be configured to interact with the catches 250 to couple the dilator hub 220 to the introducer sheath hub 240.

[0041] The dilator 210 may be inserted within and coupled to introducer sheath 230. For example, the distal end of the dilator 210 may be inserted through a proximal opening of the introducer sheath 230 and advanced within the introducer sheath 230. As the dilator 210 is advanced within the introducer sheath 230, each catch 250 may approach a semi-annular ridge 246. More particularly, as the dilator 210 is advanced within the introducer sheath 230, the leading angled surface 254 of each barb 252 may interact with a ridge 246, thereby causing displacement and/or

deflection of the catch 250. Such displacement and/or deflection may narrow the width of a distal portion of the slit 264. As the catches 250 are displaced and/or deflected, each catch 250 may at least partially pass through an opening between the ridges 246. Stated differently, displacement and/or deflection of the catches 250 may allow the barbs 252 to extend past the ridges 246. Once the barbs 252 of the catches 250 have passed through the openings, the catches 250 may engage with the ridges 246 to couple the dilator hub 220 to the introducer sheath hub 240. Stated differently, when the dilator hub 220 is coupled to the introducer sheath hub 240, the barbs 252 may be disposed distal of the ridges 246 and impede withdrawal of the dilator 210 from the introducer sheath 230 due to the impediment provided by the trailing surfaces 256 of the barbs 252.

[0042] As the introducer sheath assembly 200 transitions from a configuration in which the dilator hub 220 is uncoupled from the introducer sheath hub 240 to a configuration in which the dilator hub 220 is coupled to the introducer sheath hub 240, the catches 250 may snap in place, thereby providing audible and/or tactile feedback to the practitioner. Once the dilator hub 220 is coupled to the introducer sheath hub 240, the practitioner may visually inspect the coupling and confirm that the catches 250 are properly engaged with the ridges 246. Stated differently, the introducer sheath assembly 200 may include a positive stop that is visually observable when the dilator hub 220 is coupled to the introducer sheath hub 240.

[0043] In some embodiments, the process of inserting the dilator 210 into the introducer sheath 230 and coupling the dilator 210 to the introducer sheath 230 may be accomplished (1) without rotating the dilator hub 220 relative to the introducer sheath hub 240, (2) without applying an external force directly to the finger input portions 262 (e.g., without squeezing or pressing the finger input portions 262 toward one another), and/or (3) by a mechanism that does not involve an interaction between threads on the dilator hub 220 and threads on the introducer sheath hub 240.

[0044] Once the dilator 210 has been coupled to the introducer sheath 230, a portion of the introducer sheath assembly 200 may be percutaneously inserted into a patient to facilitate the introduction of a medical device into the vasculature of a patient. For example, in an illustrative procedure, a needle may be used to create an initial access puncture into the patient's vasculature. A guidewire may then be threaded through the needle. Once the guidewire has been properly placed, the

needle used to access the patient's vasculature may be withdrawn from the patient. The introducer sheath assembly 200 may then be threaded over the guidewire that has been placed within the patient. More specifically, the proximal end of the guidewire may be inserted into the distal end of the lumen 214 while the dilator 210 is coupled to the introducer sheath 230. The guidewire may be threaded through the lumen 214 until the proximal end of the guidewire emerges from the proximal end of the dilator 210. The introducer sheath assembly 200 may then be advanced over the guidewire to insert a distal region of the introducer sheath assembly 200 into the patient. Stated differently, the introducer sheath 230 and dilator 210 may be inserted into and advanced within the patient while the dilator 210 is disposed within the introducer sheath 230. The dilator 210 may impart increased stiffness to the introducer sheath 230, thereby facilitating insertion of the introducer sheath assembly 200 into the patient.

[0045] Once the introducer sheath 230 has been properly positioned within the patient, the dilator 210 may be uncoupled from the introducer sheath 230 and withdrawn from the introducer sheath 230. For example, the dilator hub 220 may be uncoupled from the introducer sheath hub 240 by first pressing the finger input portions 262 toward one another (i.e., squeezing the finger input portions 262). Pressing the finger input portions 262 toward one another may cause each catch 250 to deflect away from a semi-annular ridge 246, thereby narrowing the width of a distal portion of the slit 264. Once the catches 250 have been deflected away from the semi-annular ridges 246, the dilator 210 may be withdrawn from the introducer sheath 230. Stated differently, when the finger input portions 262 are pressed toward one another and thereby displace the catches 250, the barb 252 of each catch 250 may be displaced, thereby allowing each barb 252 to be retracted through an opening between the ridges 246.

[0046] In some embodiments, the process of uncoupling the dilator hub 220 from the introducer sheath hub 240 may be accomplished without rotating the dilator hub 220 relative to the introducer sheath hub 240. In other or further embodiments, the process of uncoupling the dilator hub 220 from the introducer sheath hub 240 may be accomplished using only a single hand. Additionally or alternatively, the dilator hub 220 may be uncoupled from the introducer sheath hub 240 via a mechanism that does not involve an interaction between threads on the dilator hub 220 and threads on the introducer sheath hub 240.

[0047] FIGS. 3A–3D depict an introducer sheath assembly 300 according to another embodiment. More particularly, FIG. 3A provides a perspective view of the introducer sheath assembly 300 in an unassembled state. FIG. 3B provides a side view of the introducer sheath assembly 300 in another unassembled state. FIG. 3C provides a side view of the introducer sheath assembly 300 in an assembled state. And FIG. 3D provides a perspective view of the introducer sheath assembly 300 in an assembled state. In the depicted embodiment, the introducer sheath assembly 300 is substantially symmetrical across two planes: (1) the “vertical” plane that both bisects the wings 344 and extends through the finger input portions 362 and (2) the “horizontal” plane that bisects the slits 364.

[0048] With reference to FIGS. 3A–3D, the introducer sheath assembly 300 may include a dilator 310 and an introducer sheath 330. The dilator 310 may include an elongate shaft 312 and a dilator hub 320. The elongate shaft 312 may include a tubular member that defines, in part, a lumen (not shown) that extends through the dilator 310. In the depicted embodiment, the dilator hub 320 includes a female luer lock fitting 321, a protuberance 324, a cylindrical member 325, finger input portions 362, and coupling regions 370 that are each radially aligned with a finger input portion 362. The female luer lock fitting 321, the protuberance 324, the cylindrical member 325, and finger input portions 362 are generally analogous to similar features identified in connection with the introducer sheath assembly 200.

[0049] In the embodiment depicted in FIGS. 3A–3D, the coupling region 370 of the dilator hub 320 extends distally from a proximal region of the dilator hub 320. The coupling region 370 may include two hooks 372 that form a gap 374 disposed between the two hooks 372. The gap 374 may include a distal portion 376 and a proximal portion 378. In some embodiments, the distal portion 376 of the gap 374 is narrower than the proximal portion 378 of the gap 374.

[0050] The introducer sheath 330 may include a tubular member 332 and an introducer sheath hub 340. The tubular member 332 may partially define a lumen (not shown) that extends through the introducer sheath 330. The introducer sheath hub 340 may include a female luer lock fitting 342, wings 344, and protrusions 345. In the depicted embodiment, the female luer lock fitting 342 does not threadably engage with the dilator hub 320, as the dilator hub 320 does not include threads for mating with the female luer lock fitting 342.

[0051] The wings 344 may include a first wing and a second wing that each extend radially away from the longitudinal axis of the introducer sheath hub 340. In the depicted embodiment, each wing 344 includes two protrusions 345 that extend in opposite directions from the wing 344. Stated differently, for each wing 344, a first protrusion 345 may extend from a first side of the wing 344 and a second protrusion 345 may extend from a second side of the wing 344.

[0052] The protrusions 345 may be shaped in any suitable manner. For example, in the embodiment depicted in FIGS. 3A–3D, the protrusions 345 are shaped as triangular prisms. In the depicted embodiment, each protrusion 345 includes an angled surface 347 and a distal surface 349. The angled surface 347 may extend distally toward the longitudinal axis of the introducer sheath hub 340. Stated differently, the angled surface 347 may be slanted such that a distal portion of the angled surface 347 is disposed closer to the longitudinal axis of the introducer sheath hub 340 than a proximal portion of the angled surface 347. In contrast with the introducer sheath hub 240 described above in connection with FIGS. 2A–2D, the introducer sheath hub 340 does not include semi-annular ridges that are configured for coupling to a barbed catch. The omission of such semi-annular ridges may allow the introducer sheath hub 340 to have a lower profile than the introducer sheath hub 240.

[0053] The dilator 310 may be inserted within and coupled to introducer sheath 330. For example, the distal end of the dilator 310 may be inserted through a proximal opening of the introducer sheath 330 and advanced within the introducer sheath 330. As the dilator 310 is advanced within the introducer sheath 330, the coupling regions 370 may approach the protrusions 345 as shown in FIG. 3B. More particularly, as the dilator 310 is advanced within the introducer sheath 330, the distal ends of the hooks 372 may interact with the angled surfaces 347 of the protrusions 345, thereby causing displacement and/or deflection of the coupling regions 370 toward the longitudinal axis of the dilator 310. Such displacement and/or deflection may narrow the width of a distal portion of the slits 364 that extend along a portion of the dilator hub 320 and are radially offset from the finger input portions 262. As the coupling regions 370 are displaced and/or deflected, the hooks 372 may be forced toward the longitudinal axis of the dilator 310 due to interaction with the angled surfaces 347, thereby allowing a distal portion of each hook 372 to extend past the protrusion 345. Once the distal portion of the hook 372 is disposed distal of

the protrusion 345, the distal portion of the hook 372 may engage with the distal surface 349 of the protrusion 345 to couple the dilator hub 320 to the introducer sheath hub 240. Stated differently, when the dilator hub 320 is coupled to the introducer sheath hub 340, a distal portion of the coupling region 370 (e.g., distal portions of the hooks 372) may be disposed distal of the protrusions 345 and impede withdrawal of the dilator 310 from the introducer sheath 330 due to the interaction between the hooks 372 and the distal surfaces 349 of the protrusions 345.

[0054] In some instances, as the introducer sheath assembly 300 transitions from a configuration in which the dilator hub 320 is uncoupled from the introducer sheath hub 340 to a configuration in which the dilator hub 320 is coupled to the introducer sheath hub 340, the coupling regions 370 may snap in place once the distal ends of the hooks 372 have cleared the protrusions 345, thereby providing audible and tactile feedback to the practitioner (or to anyone else who couples the dilator 310 to the introducer sheath 330). Once dilator hub 320 is coupled to the introducer sheath hub 340, the practitioner may visually inspect the coupling and confirm that the coupling hooks 372 are properly engaged with the protrusions 345. Stated differently, the introducer sheath assembly 300 may include a positive stop that is visually observable when the dilator hub 320 is coupled to the introducer sheath hub 340.

[0055] In some embodiments, the process of inserting the dilator 310 into the introducer sheath 330 and coupling the dilator 310 to the introducer sheath 330 may be accomplished (1) without rotating the dilator hub 320 relative to the introducer sheath hub 340, (2) without applying an external force directly to the finger input portions 362 (e.g., without squeezing or pressing the finger input portions 362 toward one another), and/or (3) by a mechanism that does not involve an interaction between threads on the dilator hub 320 and threads on the introducer sheath hub 340.

[0056] Once the dilator 310 has been coupled to the introducer sheath 330, a portion of the introducer sheath assembly 300 may be percutaneously inserted into a patient in a manner analogous to that described above in connection with the introducer sheath assembly 200.

[0057] Once the introducer sheath 330 of the introducer sheath assembly 300 has been properly positioned within the patient, the dilator 310 may be uncoupled from the introducer sheath 330 and withdrawn from the introducer sheath 330. For

example, the dilator hub 320 may be uncoupled from the introducer sheath hub 340 by first pressing the finger input portions 362 toward one another (i.e., squeezing the finger input portions 362). When the finger input portions are pressed toward one another, each coupling region 370 (including hooks 372) may be deflected toward the longitudinal axis of the dilator 310, thereby narrowing the width of a distal portion of the slit 364. Once the distal portions of the hooks 372 have been deflected toward the longitudinal axis of the dilator 310, the dilator 310 may be withdrawn from the introducer sheath 330.

[0058] In this manner, the dilator hub 320 may be single-handedly uncoupled from introducer sheath hub 340 without rotating the dilator hub 320 relative to the introducer sheath hub 340. Further, the dilator hub 320 and the introducer sheath hub 340 may be coupled and uncoupled from one another by a process that does not involve threads.

[0059] FIGS. 4A–4G depict an introducer sheath assembly 400 according to another embodiment. More particularly, FIGS. 4A and 4B provide alternative perspective views of the introducer sheath assembly 400 in an unassembled configuration. FIG. 4C provides a perspective view of the introducer sheath assembly 400 in an assembled configuration. FIGS. 4D and 4E provide alternative cross-sectional side views of the assembled introducer sheath assembly 400. And FIGS. 4F and 4G provide cross-sectional front views of the introducer sheath assembly 400 in an unconstrained (FIG. 4F) and constrained (FIG. 4G) configuration.

[0060] With reference to FIGS. 4A–4G, the introducer sheath assembly 400 may include a dilator 410 and an introducer sheath 430. The dilator 410 may include an elongate shaft 412 and a dilator hub 420. The elongate shaft 412 may include a tubular member that defines, in part, a lumen 414 that extends through the dilator 410. In the depicted embodiment, the dilator hub 420 includes a female luer lock fitting 421, a protuberance 424, a cylindrical member 425, and finger input portions 462. The female luer lock fitting 421, the protuberance 424, and the finger input portions 462 are generally analogous to similar features identified in connection with other introducer sheath assemblies described herein.

[0061] In the depicted embodiment, the base of the cylindrical member 425, when unconstrained, is oblong in shape. For example, in some embodiments the base of the cylindrical member 425, when unconstrained, is oval or elliptical in shape. Stated

differently, a plane that is perpendicular to the longitudinal axis of the cylindrical member 425 may intersect the cylindrical member 425 to form an oblong shape when the cylindrical member 425 is in an unconstrained configuration.

[0062] In the depicted embodiment, the cylindrical member 425 includes one or more protrusions 480. In some embodiments, the one or more protrusions 480 are radially offset from the finger input portions 462. The one or more protrusions 480 may be disposed on and/or extend radially inward from an inner surface of the cylindrical member 425. The cylindrical member 425 may be made from resilient material, such as a resilient polyethylene, polypropylene, polyurethane, or another type of resilient material.

[0063] The introducer sheath 430 is generally analogous to the introducer sheath 130 depicted in FIG. 1B. As depicted in FIGS. 4A–4E, the introducer sheath 430 includes a tubular member 432 and an introducer sheath hub 440 that is coupled to and disposed generally proximal of the tubular member 432. The introducer sheath hub 440 may include wings 444 that extend radially away from a longitudinal axis of the introducer sheath hub 440 and a female luer lock fitting 442 adjacent the proximal end of the introducer sheath hub 440. In the depicted embodiment, the female luer lock fitting 442 does not threadably engage with the dilator hub 420, as the dilator hub 420 does not include threads for mating with the female luer lock fitting 442.

[0064] The dilator 410 may be inserted within and coupled to the introducer sheath 430 as shown in FIG. 4C. For example, the distal end of the dilator 410 may be inserted through a proximal opening of the introducer sheath 430 and advanced within the introducer sheath 430. As the dilator 410 is advanced within the introducer sheath 430, the finger input portions 462 may be pressed toward one another, thereby causing the cylindrical member 425 to transition from an unconstrained configuration (e.g., FIG. 4F) to a constrained configuration (e.g., FIG. 4G).

[0065] As the cylindrical member 425 transitions from an unconstrained to a constrained configuration, the shape of the cylindrical member 425 may be altered. For example, constraining the cylindrical member 425 may cause a cross-section of the cylindrical member 425, such as that shown in FIGS. 4F and 4G, to become less oblong. Stated differently, when the cylindrical member 425 is in a constrained configuration (see, e.g., FIG. 4G), a plane that is perpendicular to the longitudinal axis of the cylindrical member 425 may intersect the cylindrical member 425 to form

a shape that is less oblong than the shape formed by the intersection of the same plane with the cylindrical member 425 when the cylindrical member 425 is in an unconstrained configuration (see, e.g., FIG. 4F). For example, in some embodiments, a cross-section of the cylindrical member 425 may become more circular in shape as the finger input portions 462 are pressed toward one another.

[0066] Due to the changing shape of the cylindrical member 425 and the radial offset of the finger input portions 462 from the one or more protrusions 480, pressing the finger input portions 462 toward one another may cause the one or more protrusions 480 to be displaced radially outward from a longitudinal axis of the dilator 410 (compare FIGS. 4F and 4G). Such radial displacement of the one or more protrusions 480 may allow a proximal portion of the introducer sheath hub 440 (e.g., the female luer lock fitting 442) to extend past at least one protrusion 480. Once the female luer lock fitting 442 is positioned within the cylindrical member 425 such that the protuberance 424 is in contact with an inner surface of the introducer sheath hub 440, the practitioner may cease to provide input to the finger input portions 462, thereby allowing the finger input portions 462 to revert to an unconstrained configuration in which the one or more protrusions 480 engage the female luer lock fitting 442, thereby coupling the dilator hub 420 to the introducer sheath hub 440. In an analogous manner, the dilator hub 420 can more generally couple to other connectors that include an annular ridge or circular portion at or adjacent to one end.

[0067] In some embodiments, the process of inserting the dilator 410 into the introducer sheath 430 and coupling the dilator 410 to the introducer sheath 430 may be accomplished (1) without rotating the dilator hub 420 relative to the introducer sheath hub 440, and/or (2) by a mechanism that does not involve an interaction between threads on the dilator hub 320 and threads on the introducer sheath hub 340.

[0068] Once the dilator 410 has been coupled to the introducer sheath 430, a portion of the introducer sheath assembly 400 may be percutaneously inserted into a patient in a manner analogous to that described above in connection with other introducer sheath assemblies.

[0069] Once the introducer sheath 430 of the introducer sheath assembly 400 has been properly positioned within the patient, the dilator 410 may be uncoupled from the introducer sheath 430 and withdrawn from the introducer sheath 430. In some instances, such a process essentially reverses the steps described above for

inserting the dilator 410 into the introducer sheath 430 and coupling the dilator 410 to the introducer sheath 430. For example, a practitioner may press the finger input portions 462 toward one another, thereby causing the one or more protrusions 480 of the cylindrical member 425 to be radially displaced. Once the one or more protrusions 480 have been radially displaced, the practitioner may withdraw the dilator 410 from the introducer sheath 430. In this manner, the dilator hub 420 may be single-handedly uncoupled from the introducer sheath hub 440 without rotating the dilator hub 420 relative to the introducer sheath hub 440. Further, the dilator hub 420 and the introducer sheath hub 440 may be coupled and uncoupled from one another by a process that does not involve threads.

[0070] While the hubs and hub assemblies disclosed herein are described above with reference to introducer sheath assemblies that include a dilator and an introducer sheath, the hubs disclosed herein—such as hubs 210, 230, 310, 330, 410, and 430—may be used in many other medical contexts. For example, hubs disclosed herein may be used to couple any suitable medical device or medical device component to another medical device or medical device component. More particularly, the hubs 210, 230, 310, 330, 410, and/or 430 may be used, for example, to couple a medical tube, a catheter, a needle, a trocar, etc. to any other medical device or medical device component. For example, the hubs 210, 230, 310, 330, 410, and/or 430 may facilitate coupling of a first medical tube to a second medical tube. In many instances, the hubs disclosed herein may be used in lieu of standard luer fittings.

[0071] Any methods disclosed herein include one or more steps or actions for performing the described method. The method steps and/or actions may be interchanged with one another. In other words, unless a specific order of steps or actions is required for proper operation of the embodiment, the order and/or use of specific steps and/or actions may be modified. Moreover, sub-routines or only a portion of a method described herein may be a separate method within the scope of this disclosure. Stated otherwise, some methods may include only a portion of the steps described in a more detailed method.

[0072] Reference throughout this specification to “an embodiment” or “the embodiment” means that a particular feature, structure, or characteristic described in connection with that embodiment is included in at least one embodiment. Thus, the

quoted phrases, or variations thereof, as recited throughout this specification are not necessarily all referring to the same embodiment.

[0073] Similarly, it should be appreciated by one of skill in the art with the benefit of this disclosure that in the above description of embodiments, various features are sometimes grouped together in a single embodiment, figure, or description thereof for the purpose of streamlining the disclosure. This method of disclosure, however, is not to be interpreted as reflecting an intention that any claim requires more features than those expressly recited in that claim. Rather, as the following claims reflect, inventive aspects lie in a combination of fewer than all features of any single foregoing disclosed embodiment. Thus, the claims following this Detailed Description are hereby expressly incorporated into this Detailed Description, with each claim standing on its own as a separate embodiment. This disclosure includes all permutations of the independent claims with their dependent claims.

[0074] Recitation in the claims of the term “first” with respect to a feature or element does not necessarily imply the existence of a second or additional such feature or element. It will be apparent to those having skill in the art that changes may be made to the details of the above-described embodiments without departing from the underlying principles of the present disclosure.

CLAIMS

1. An introducer sheath assembly comprising:
an introducer sheath comprising:
a first tubular member configured to be at least partially inserted into a patient, the first tubular member at least partially defining a lumen that extends therethrough; and
an introducer sheath hub coupled to the first tubular member and disposed adjacent a proximal end of the first tubular member; and
a dilator comprising:
an elongate shaft that is configured to be at least partially disposed within the lumen that extends through the first tubular member; and
a dilator hub coupled to the elongate shaft and disposed adjacent a proximal end of the elongate shaft, wherein the dilator hub is configured to selectively couple to the introducer sheath hub without rotating the dilator hub relative to the introducer sheath hub.
2. The introducer sheath assembly of claim 1, wherein the dilator hub is configured to couple to the introducer sheath hub via a snap-fit connection.
3. The introducer sheath assembly of any one of claims 1–2, wherein the dilator hub is configured to facilitate single-handed uncoupling of the dilator hub from the introducer sheath hub.
4. The introducer sheath assembly of any of claims 1–3, wherein the dilator hub is configured to couple and uncouple from the introducer sheath hub via a mechanism that does not involve an interaction between threads on the dilator hub and threads on the introducer sheath hub.
5. The introducer sheath assembly of any of claims 1–4, wherein the introducer sheath assembly provides audible feedback when the introducer sheath assembly transitions from a configuration in which the dilator hub is uncoupled from the introducer sheath hub to a configuration in which the dilator hub is coupled to the introducer sheath hub.

6. The introducer sheath assembly of any of claims 1–5, wherein the introducer sheath assembly comprises a positive stop that is visually observable when the dilator hub is coupled to the introducer sheath hub.
7. The introducer sheath assembly of any of claims 1–6, wherein the introducer sheath assembly is configured for use in vascular procedures.
8. The introducer sheath assembly of any of claims 1–7, wherein the elongate shaft of the dilator comprises a second tubular member that at least partially defines a second lumen that extends through the second tubular member.
9. The introducer sheath assembly of any one of claims 1–8, wherein the introducer sheath hub comprises a female luer lock fitting.
10. The introducer sheath assembly of any one of claims 1–9, wherein the introducer sheath hub comprises a first wing and a second wing that each extend radially away from a longitudinal axis of the introducer sheath hub.
11. The introducer sheath assembly of any of claims 1–10, wherein the dilator hub comprises two finger input portions that are on opposite sides of the dilator hub, wherein the finger input portions are configured to facilitate uncoupling of the dilator hub from the introducer sheath hub when pressed toward one another.
12. The introducer sheath assembly of claim 11, wherein the dilator is configured to be inserted into the introducer sheath such that the dilator hub couples to the introducer sheath hub without applying an external force directly to the two finger input portions.
13. The introducer sheath assembly of any of claims 1–12, wherein:
 - the introducer sheath hub comprises two or more semi-annular ridges;
 - the dilator hub comprises a plurality of catches that extend distally from a proximal portion of the dilator hub; and

each catch of the plurality of catches is configured to at least partially pass through an opening between the two or more semi-annular ridges and engage with at least one of the two or more semi-annular ridges to couple the dilator hub to the introducer sheath hub.

14. The introducer sheath assembly of claim 13, further comprising two finger input portions, wherein each catch of the plurality of catches is radially offset from the two finger input portions.

15. The introducer sheath assembly of any of claims 13–14, wherein each catch of the plurality of catches comprises a barb.

16. The introducer sheath assembly of claim 15, wherein the barb comprises a leading angled surface and a trailing surface.

17. The introducer sheath assembly of claim 15 or 16, wherein the introducer sheath assembly is configured such that insertion of the dilator into the introducer sheath causes the barb of each catch to interact with a ridge of the two or more semi-annular ridges, thereby deflecting each catch and allowing the barb of each catch to extend past the ridge.

18. The introducer sheath assembly of any one of claims 1–9 and 11–12, wherein:

the introducer sheath hub comprises a first wing and a second wing, wherein the first wing and the second wing each comprise two protrusions that extend in opposite directions the wing;

wherein the dilator hub comprises a coupling region that extends distally from a proximal region of the dilator hub; and

wherein the coupling region is configured to engage with a protrusion of the two protrusions to couple the dilator hub to the introducer sheath hub.

19. The introducer sheath assembly of claim 18, wherein each protrusion presents an angled surface that is configured for interaction with the coupling region

of the dilator hub as the dilator is inserted into the introducer sheath, wherein the angled surface extends distally toward a longitudinal axis of the introducer sheath hub.

20. The introducer sheath assembly of any one of claims 18–19, wherein the protrusion comprises a distal surface, wherein the distal surface is configured to engage with the coupling region to secure the dilator hub to the introducer sheath hub when the dilator hub and the introducer sheath hub are coupled to one another.

21. The introducer sheath assembly of any one of claims 18–20, wherein the coupling region comprises two hooks that form a gap disposed between the two hooks.

22. The introducer sheath assembly of claim 21, wherein the gap comprises a distal portion and a proximal portion, wherein the distal portion is narrower than the proximal portion.

23. The introducer sheath assembly of any one of claims 21–22, wherein the gap is sized to deflect the two hooks of the coupling region toward a longitudinal axis of the introducer sheath as the dilator is advanced within the introducer sheath.

24. The introducer sheath assembly of any one of claims 22–23, wherein the proximal portion of the gap is wide enough to extend around both the first and second protrusions of either the first wing or the second wing when the dilator hub is coupled to the introducer sheath hub.

25. The introducer sheath assembly of any one of claims 18–24, wherein:

the dilator hub comprises two finger input portions that are on opposite sides of the dilator hub, wherein the finger input portions are configured to facilitate uncoupling of the dilator hub from the introducer sheath hub when pressed toward one another; and

the coupling region is radially aligned with a finger input portion of the two finger input portions.

26. The introducer sheath assembly of any of claims 1–12, wherein the dilator hub comprises a cylindrical member that is configured to transition between unconstrained and constrained configurations to facilitate coupling and uncoupling of the dilator hub to the introducer sheath hub.

27. The introducer sheath assembly of claim 26, wherein the cylindrical member, when unconstrained, is shaped such that a plane that is perpendicular to a longitudinal axis of the cylindrical member intersects the cylindrical member to form an oblong shape.

28. The introducer sheath assembly of claim 27, wherein:

the cylindrical member comprises two finger input portions that, when pressed toward one another, transition the cylindrical member from an unconstrained configuration to a constrained configuration; and

the cylindrical member, when in a constrained configuration, is shaped such that the plane that is perpendicular to the longitudinal axis of the cylindrical member intersects the cylindrical member to form a shape that is less oblong than the shape formed by the intersection of the plane with the cylindrical member when the cylindrical member is in an unconstrained configuration.

29. The introducer sheath assembly of any of claims 26–28, wherein the cylindrical member comprises one or more protrusions that are disposed on or extend radially inward from an inner surface of the cylindrical member, wherein the one or more protrusions are configured to engage with a proximal region of the introducer sheath hub.

30. The introducer sheath assembly of claim 19, wherein the proximal region of the introducer sheath hub comprises a female luer lock fitting.

31. A hub assembly for selectively coupling components of a medical device, the hub assembly comprising:

a first medical device component comprising a first hub, wherein the first hub comprises two finger input portions that are disposed on opposite sides of the first hub; and

a second medical device component comprising a second hub that is configured to selectively couple to the first hub;

wherein the first hub is configured to selectively couple to the second hub without rotating the first hub relative to the second hub; and

wherein the two finger input portions are configured to be pressed toward one another to uncouple the first hub from the second hub.

32. The hub assembly of claim 31, wherein the first hub is configured for single-handed uncoupling of the first hub from the second hub.

33. The hub assembly of any one of claims 31–32, wherein the second hub comprises a first wing and a second wing.

34. The hub assembly of any one of claims 31–33, wherein:

the first hub comprises a plurality of catches that extend distally from a proximal portion of the first hub;

the second hub comprises two or more ridges; and

each catch of the plurality of catches is configured to at least partially pass through an opening between the two or more ridges and engage with a ridge of the two or more ridges to couple the first hub to the second hub.

35. The hub assembly of claim 34, wherein each catch comprises a barb, wherein an angled surface of the barb is configured to interact with the ridge of the two or more ridges as the first hub is coupled to the second hub, thereby deflecting each catch and allowing the barb to extend past the ridge.

36. The hub assembly of claim 33, wherein the first wing and second wing each comprise two protrusions that extend in opposite directions from the wing.

37. The hub assembly of claim 36, wherein the protrusions each comprise an angled surface that extends distally toward a longitudinal axis of the second hub.

38. The hub assembly of any one of claims 36–37, wherein the first hub comprises a coupling region, wherein the coupling region comprises a plurality of hooks that form a gap disposed between the hooks.
39. The hub assembly of claim 38, wherein the gap comprises a distal portion and a proximal portion, wherein the distal portion of the gap is narrower than the proximal portion of the gap.
40. The hub assembly of any one of claims 31–33, wherein the first hub comprises a cylindrical member that is configured to transition from an unconstrained configuration to a constrained configuration to uncouple the first hub from the second hub.
41. The hub assembly of claim 40, wherein the first hub is configured to transition from the unconstrained configuration to the constrained configuration by pressing finger input portions toward one another.
42. The hub assembly of any one of claims 40–41, wherein the cylindrical member, when unconstrained, is shaped such that a plane that is perpendicular to a longitudinal axis of the cylindrical member intersects the cylindrical member to form an oblong shape.
43. A method of accessing body fluid via an introducer sheath, the method comprising:
percutaneously inserting at least a portion of a tubular member of an introducer sheath into a patient; and
uncoupling a hub of a dilator from a hub of the introducer sheath while the dilator is disposed within the introducer sheath without rotating the dilator hub relative to the introducer sheath hub.
44. The method of claim 43, further comprising inserting at least a portion of a needle and a guidewire into the patient prior to percutaneously inserting at least a portion of the tubular member of the introducer sheath into the patient.

45. The method of claim 44, further comprising removing the needle from the patient prior to percutaneously inserting at least a portion of the tubular member of the introducer sheath into the patient.
46. The method of any one of claims 43–45, further comprising advancing the introducer sheath and dilator within the patient while the dilator is disposed within the introducer sheath.
47. The method of any one of claims 43–46, further comprising withdrawing the dilator from the tubular member of the introducer sheath.
48. The method of claim 47, wherein uncoupling the hub of the dilator from the hub of the introducer sheath comprises squeezing finger input portions of the dilator hub.
49. The method of any of claims 47–48, wherein uncoupling the hub of the dilator from the hub of the introducer sheath comprises narrowing a width of a distal portion of a slit, wherein the slit extends along a portion of the dilator hub.
50. The method of any of claims 47–49, wherein uncoupling the hub of the dilator from the hub of the introducer sheath comprises deflecting a catch away from a semi-annular ridge.
51. The method of any of claims 43–48, wherein uncoupling the hub of the dilator from the hub of the introducer sheath comprises displacing a coupling region toward a longitudinal axis of the dilator.
52. The method of claim 51, wherein:
the coupling region comprises a plurality of hooks that form a gap disposed between the hooks;
the gap comprises a distal portion and a proximal portion; and
the distal portion of the gap is narrower than the proximal portion of the gap.

53. The method of any one of claims 47–48, wherein uncoupling the hub of the dilator from the hub of the introducer sheath comprises transitioning a cylindrical member of the dilator from an unconstrained configuration to a constrained configuration.

54. The method of claim 53, wherein a cross-section of the dilator hub is more oblong when the cylindrical member is in an unconstrained configuration than when the cylindrical member is in a constrained configuration.

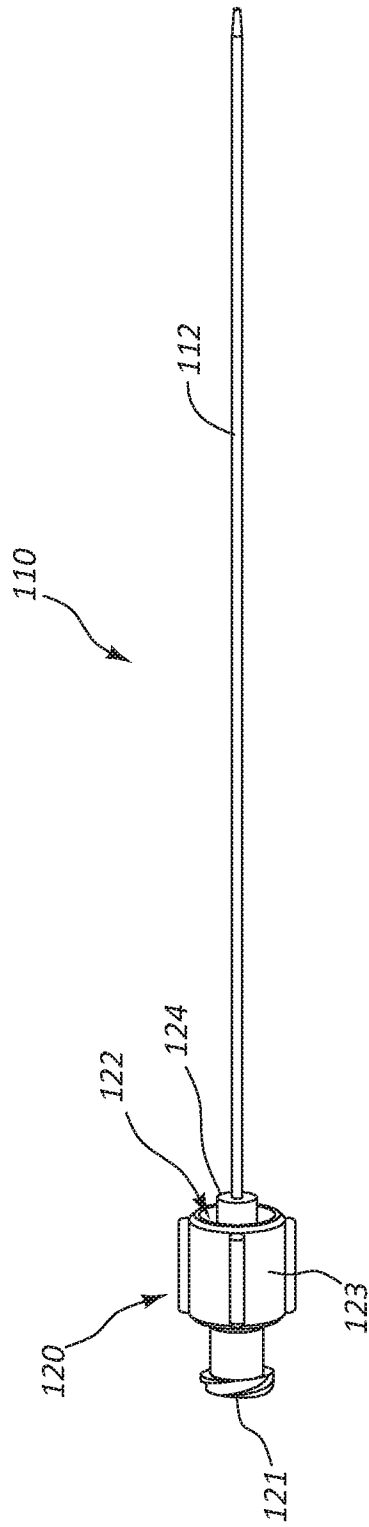


Fig. 1A

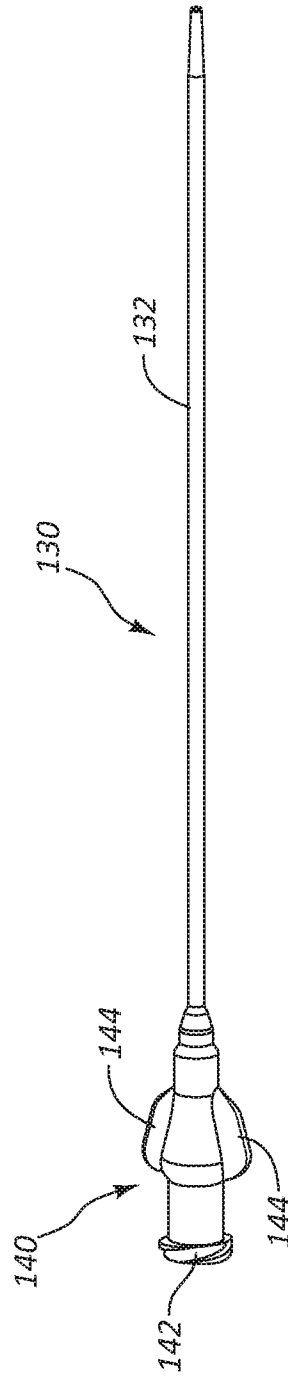


Fig. 1B

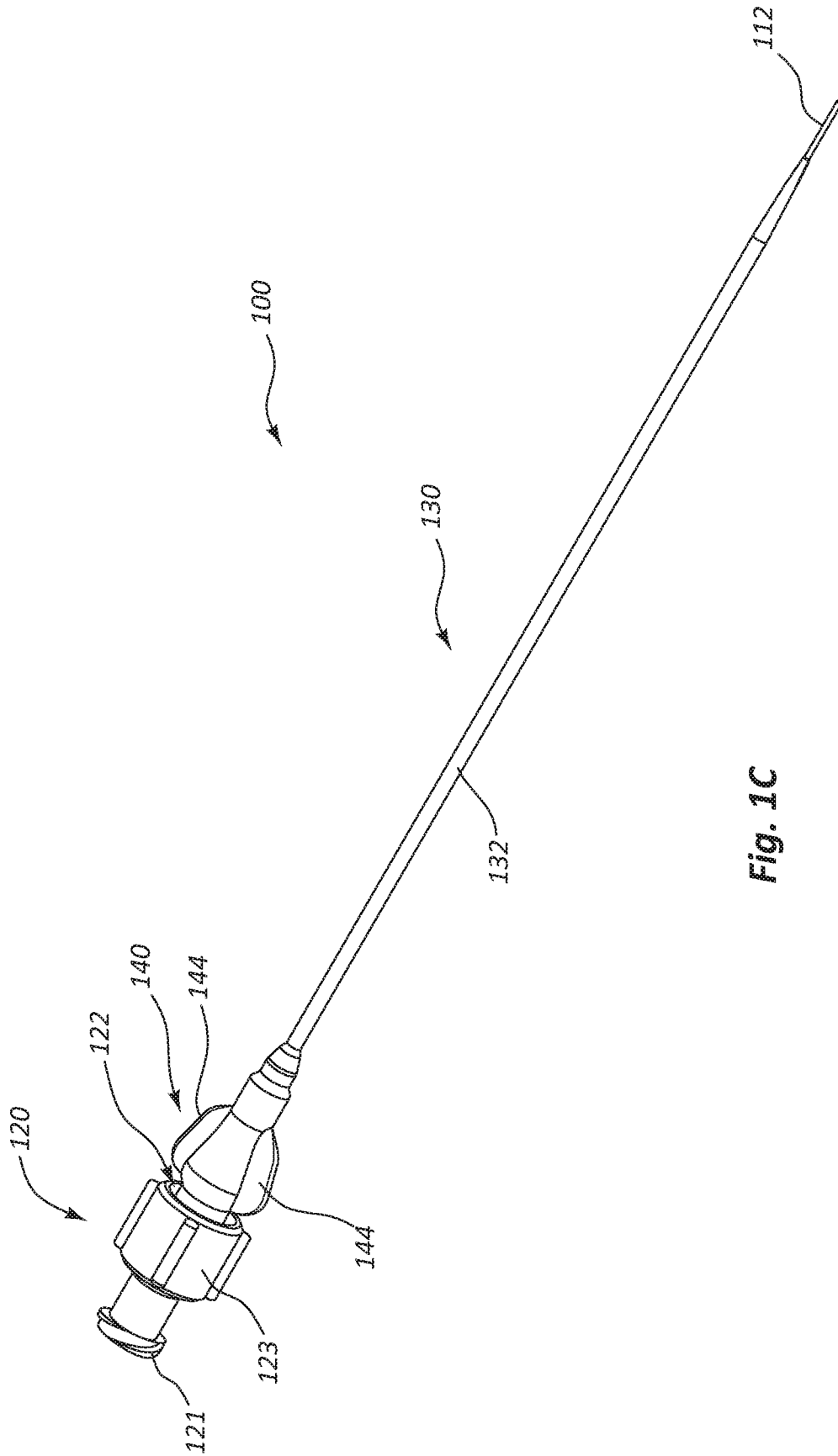


Fig. 1C

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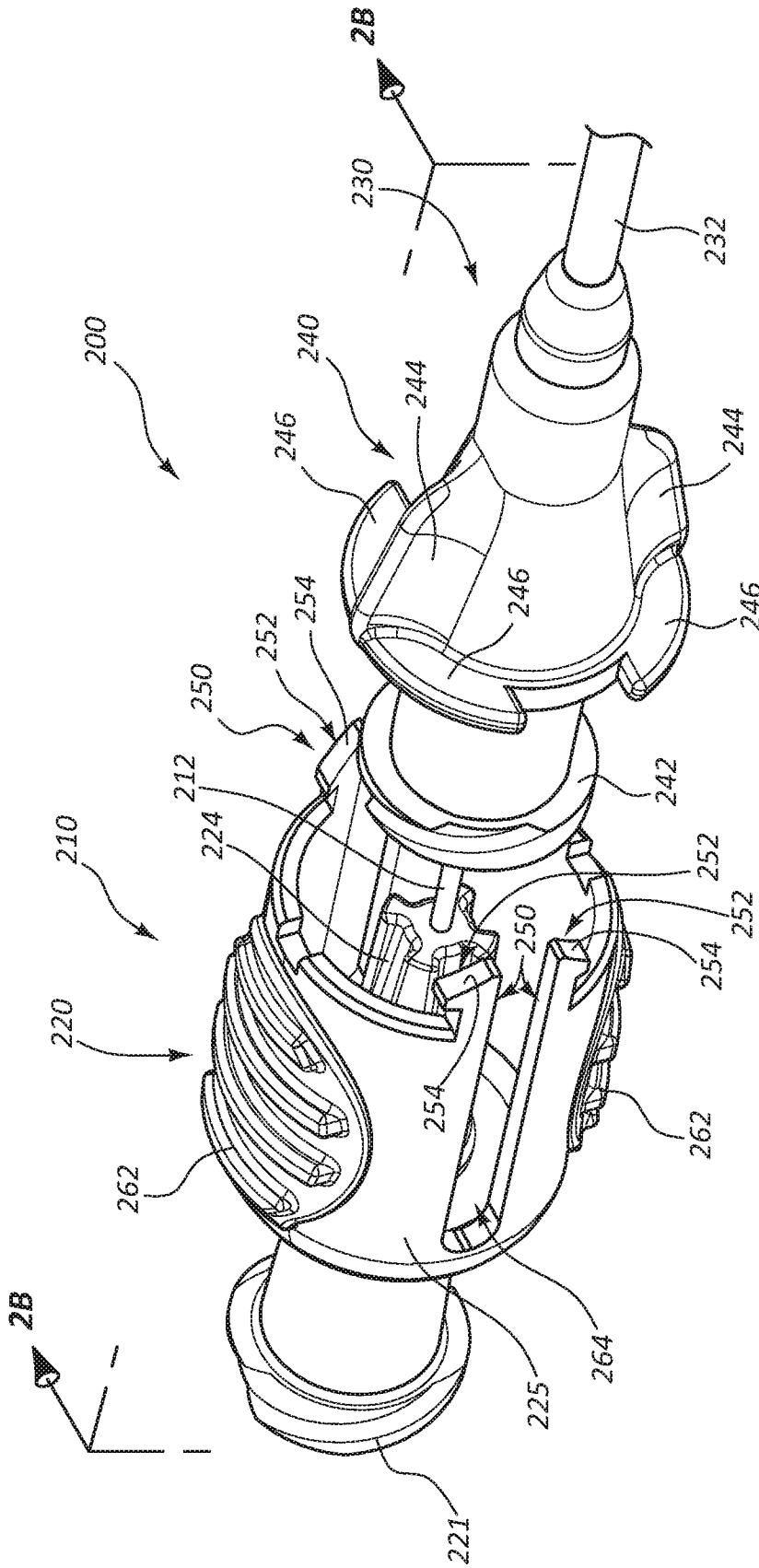


Fig. 2A

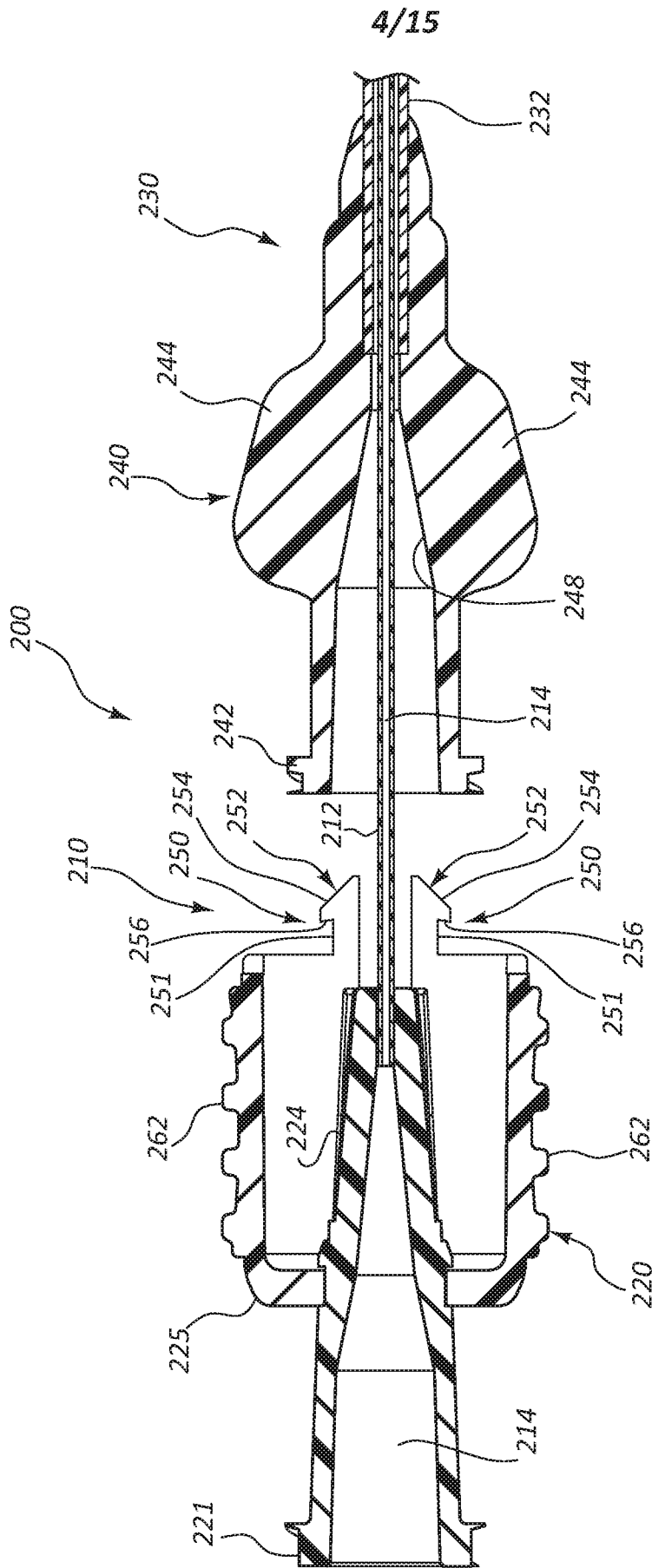


Fig. 2B

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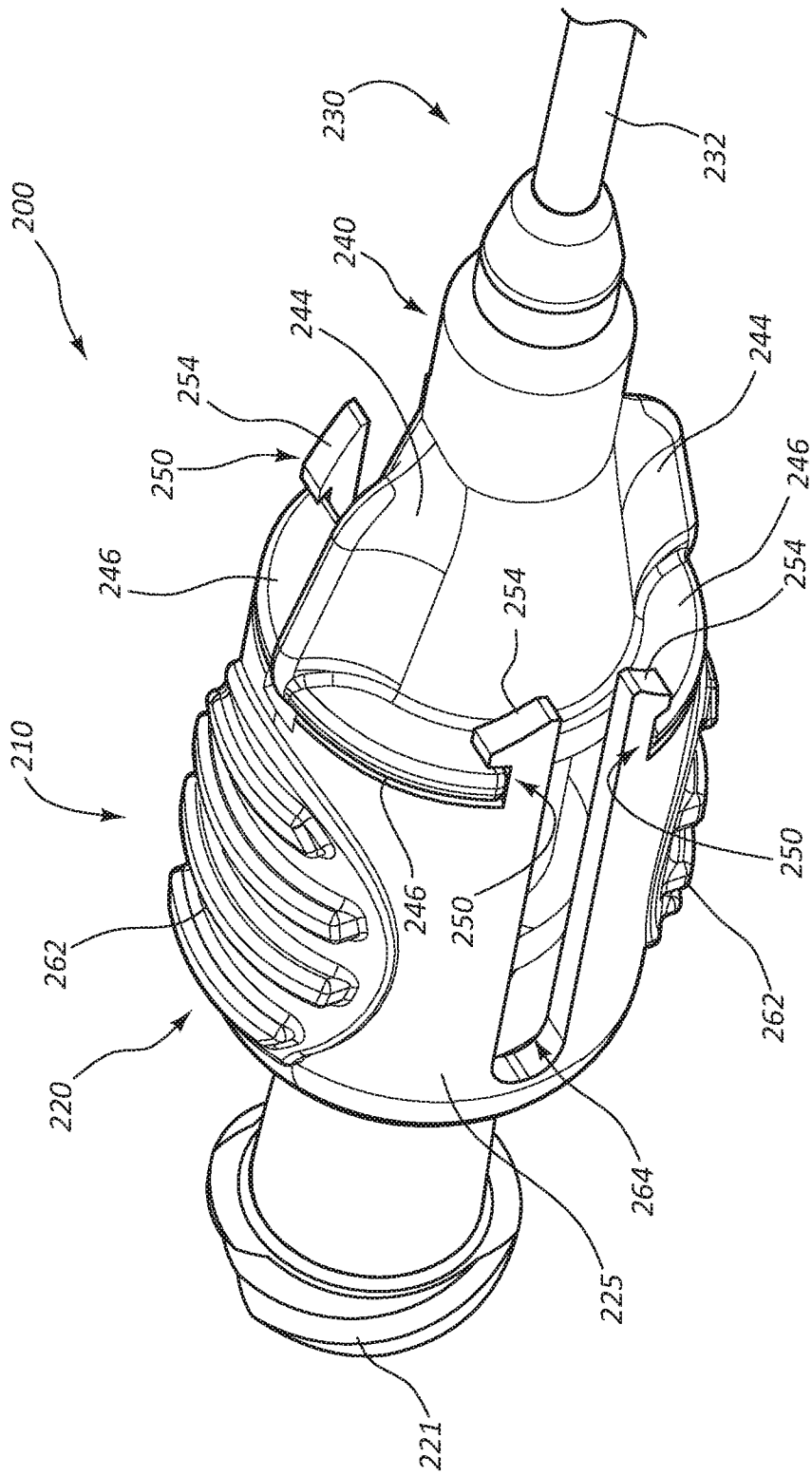


Fig. 2C

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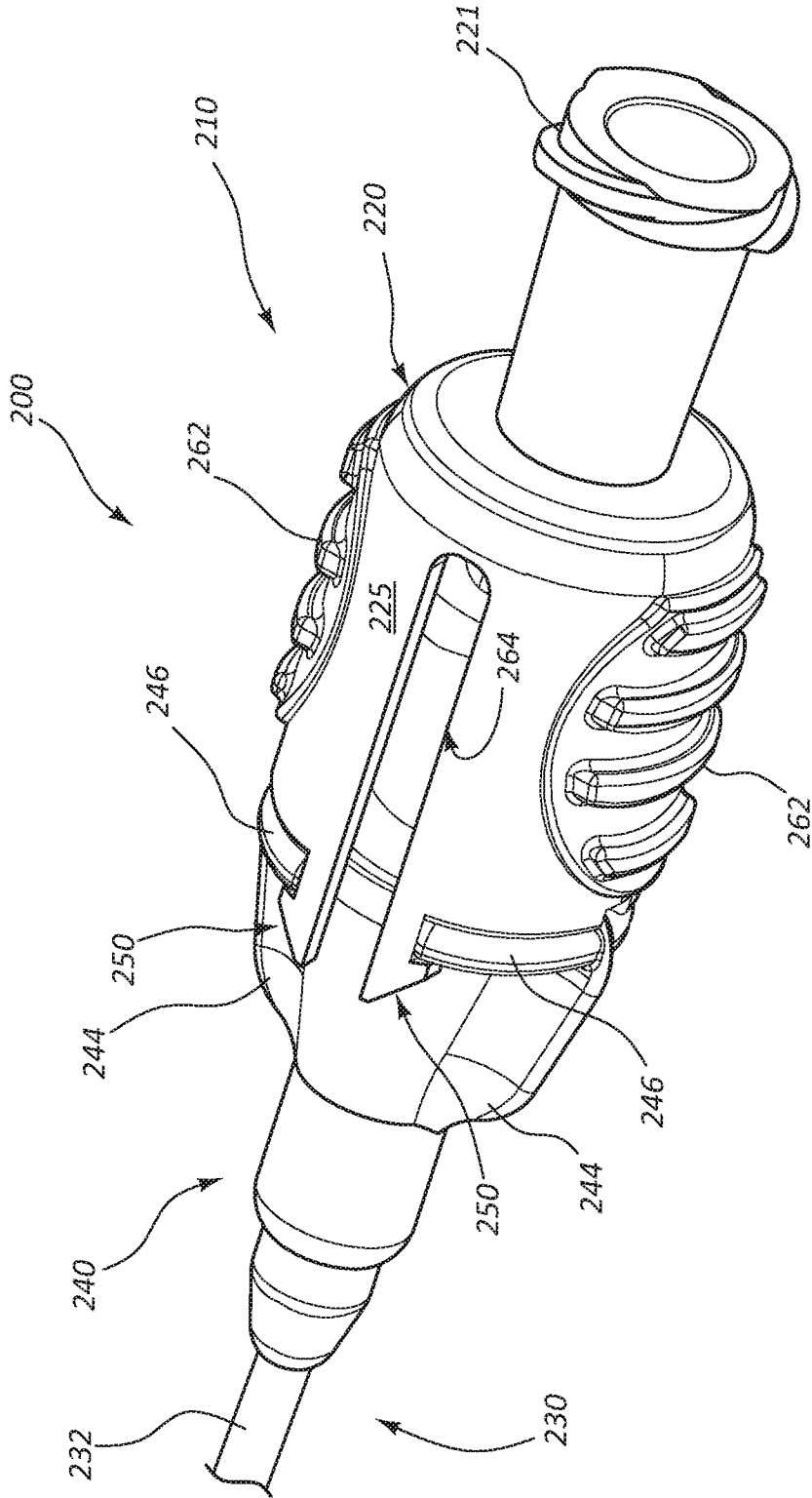


Fig. 2D

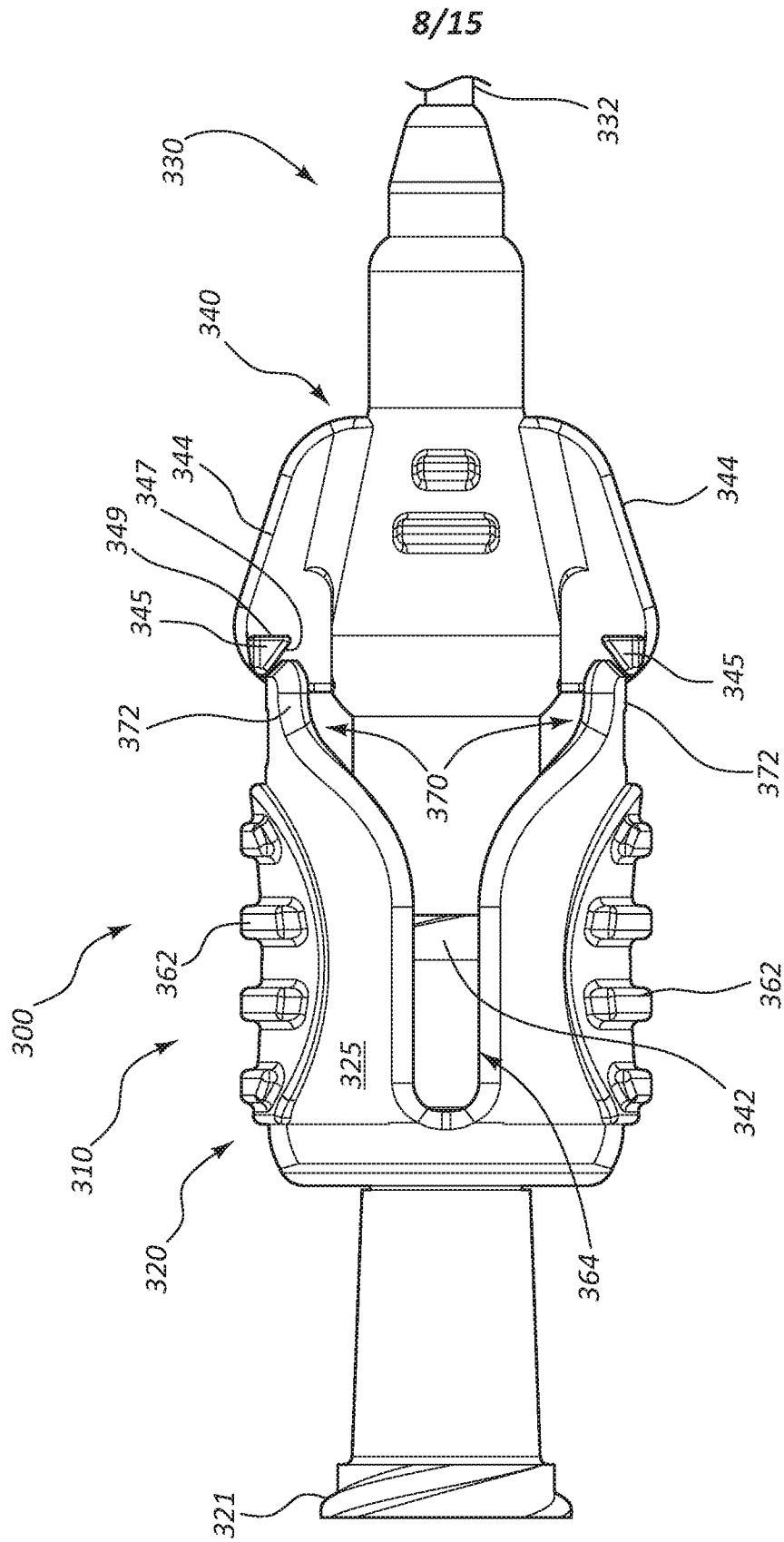


Fig. 3B

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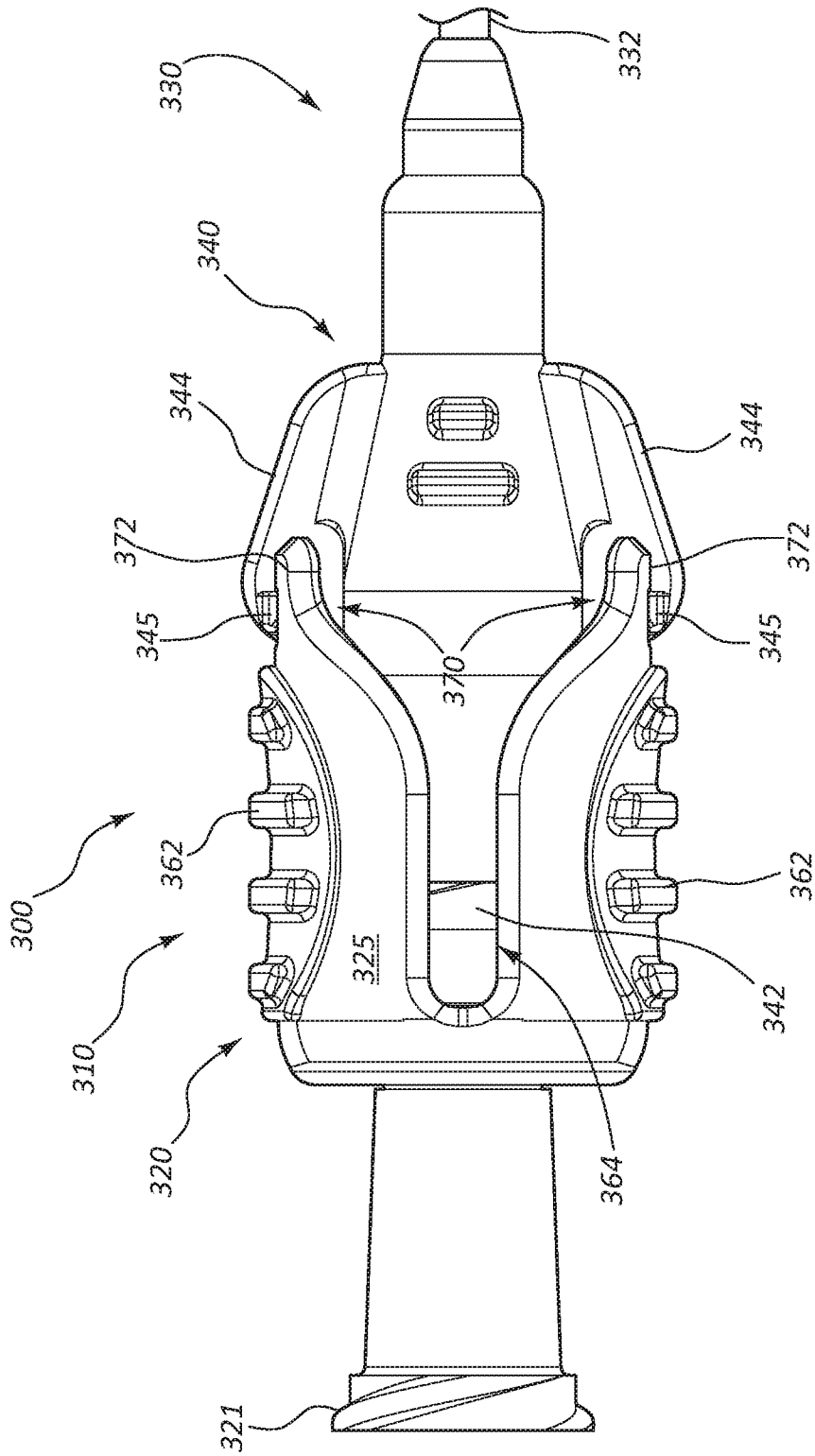


Fig. 3C

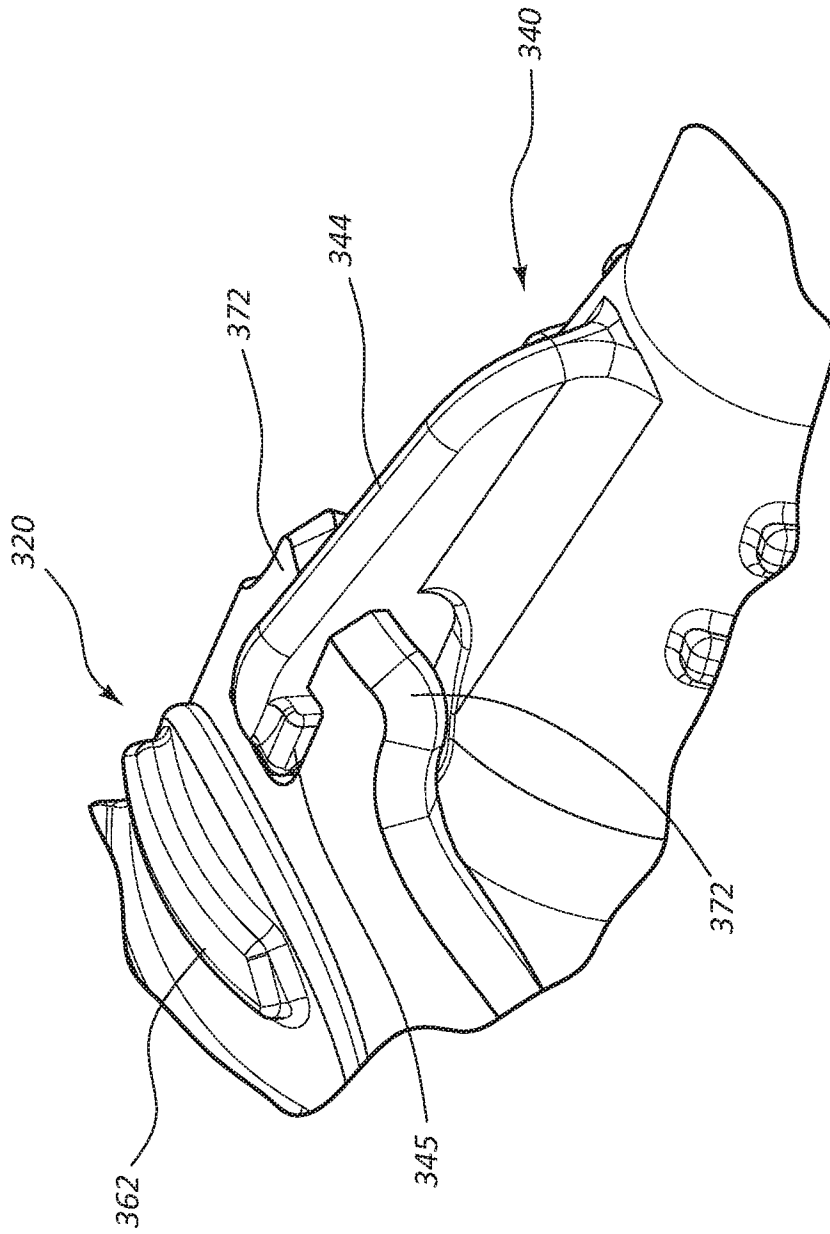


Fig. 3D

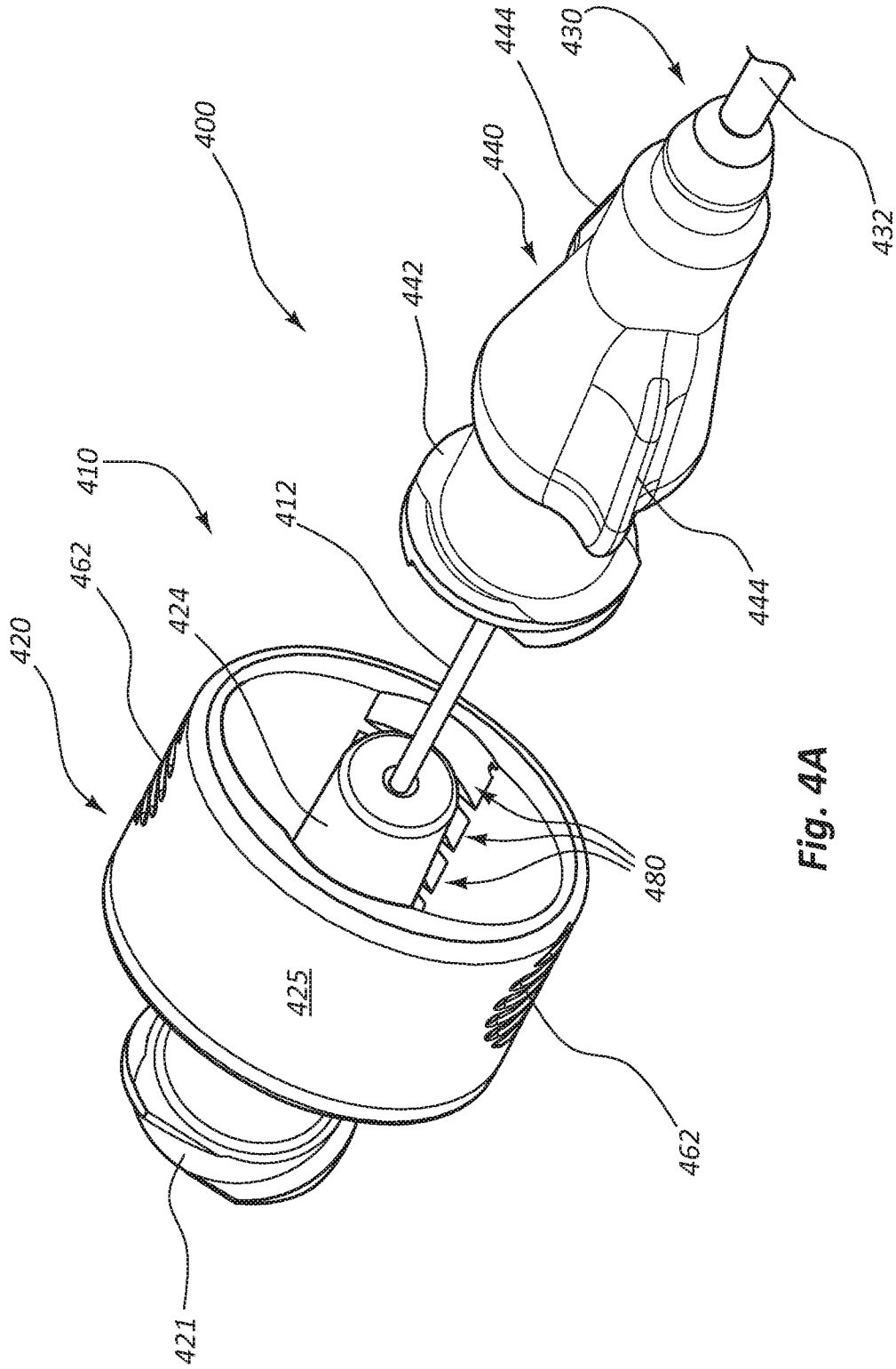


Fig. 4A

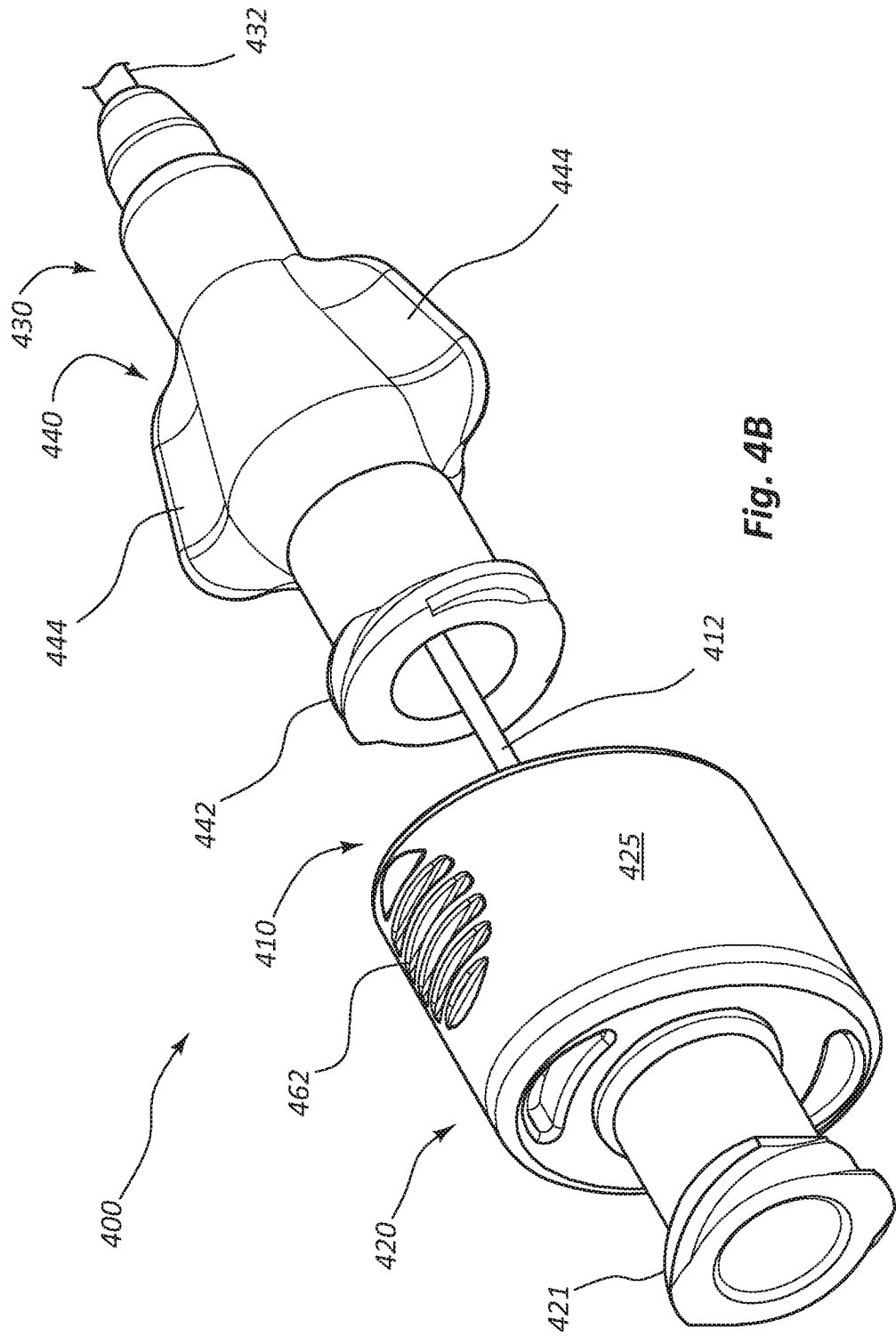


Fig. 4B

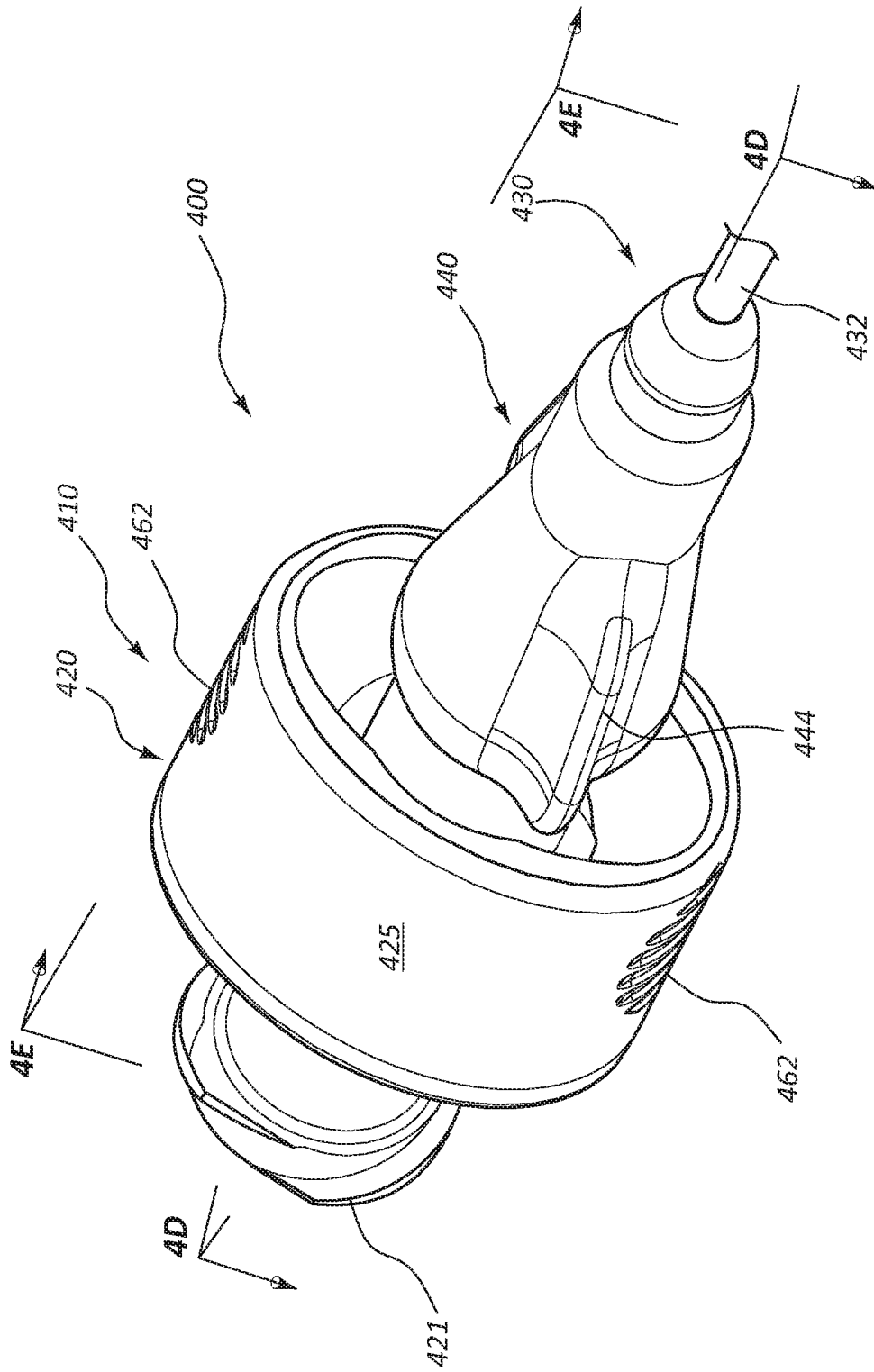


Fig. 4C

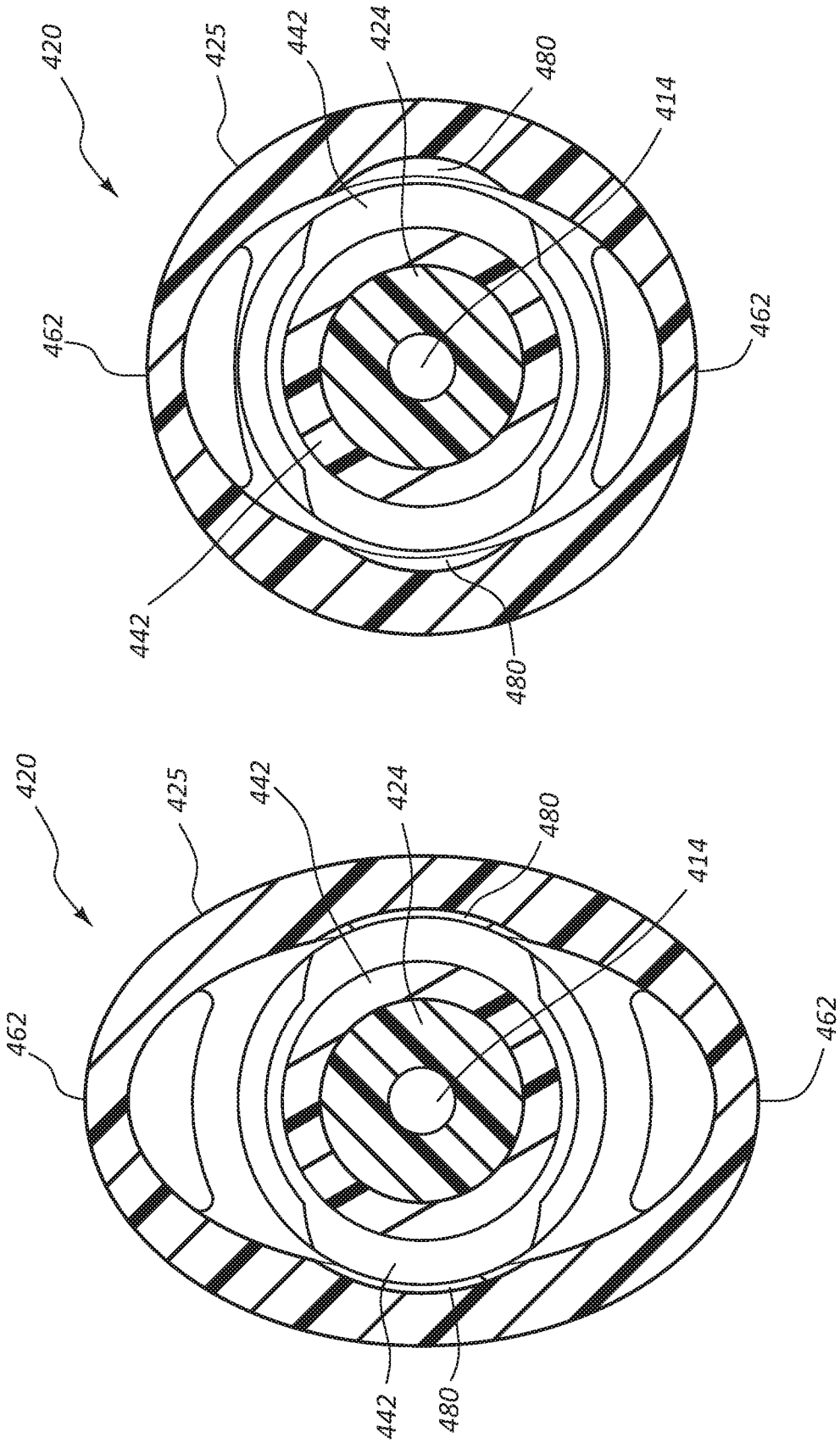


Fig. 4G

Fig. 4F

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/032010**A. CLASSIFICATION OF SUBJECT MATTER****A61M 25/00(2006.01)I, A61M 39/10(2006.01)I, A61M 29/00(2006.01)I**

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M 25/00; A61M 25/01; A61M 5/00; A61B 17/34; A61M 5/178; A61B 1/32; A61M 39/10; A61M 29/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & keywords: introducer, dilator, hub, interlocking, snap-fit

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 7922696 B2 (TAL, MICHAEL et al.) 12 April 2011 See abstract; column 7, lines 2-15; claims 1-23; and figures 1A-5.	1-3,31-33
A		36-39
Y	US 2003-0050611 A1 (CINDRICH, CHRISTOPHER NOEL) 13 March 2003 See abstract; paragraphs [0030]-[0040]; claims 1-13; and figures 1-3, 5	1-3,31-33
A	WO 2008-131289 A2 (ACCESS SCIENTIFIC, INC.) 30 October 2008 See the whole document	1-3,31-33,36-39
A	US 2009-0048485 A1 (HEISLER, GARY R.) 19 February 2009 See the whole document.	1-3,31-33,36-39
A	US 2013-0150793 A1 (BEISSEL, JASON RYAN et al.) 13 June 2013 See the whole document.	1-3,31-33,36-39

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

12 August 2016 (12.08.2016)

Date of mailing of the international search report

01 September 2016 (01.09.2016)

Name and mailing address of the ISA/KR

International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea

Facsimile No. +82-42-481-8578

Authorized officer

Han, Inho

Telephone No. +82-42-481-3362



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/032010

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

- 1. Claims Nos.: 43-54
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 43-54 pertain to methods for treatment of the human body and thus relate to a subject-matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.

- 2. Claims Nos.: 12,14,16,19,22,27-28,30,35,41,48,52,54
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claims 12,14,16,19,22,27-28,30,35,41,48,52, and 54 directly or indirectly refer to one of the unsearchable claims which do not comply with PCT Rule 6.4(a).

- 3. Claims Nos.: 4-11,13,15,17-18,20-21,23-26,29,34,40,42,47,49-51,53
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

- 1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

- 2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

- 3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

- 4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

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