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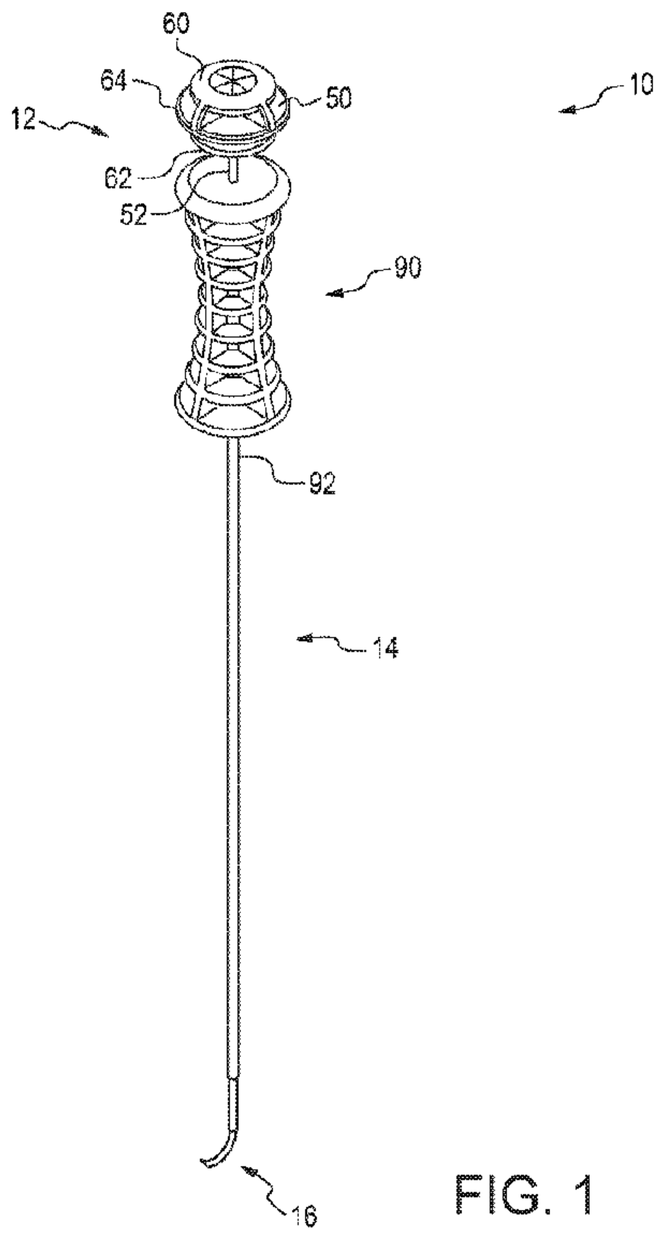

FIG. 1

(57) Abrégé/Abstract:
A suturing device includes a curved needle, a suture, an elongate body, an actuator and a curved needle holder. The suture connects with the curved needle. The actuator interacts with the elongate body and is operable between a first operating position and a second operating position. The curved needle holder extends away from a distal end portion or is provided as part of the distal end portion of the elongate body. The curved needle holder includes a distal end section having a distal-most tip. The curved needle holder includes an inner surface defining a needle passage for holding the needle and a distal opening. The curved needle has a curved needle radius and the curved needle passage has a curved needle passage radius that is different than the curved needle radius and the curved needle frictionally engages the inner surface when the needle is in a retracted position.

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Abstract

A suturing device includes a curved needle, a suture, an elongate body, an actuator and a curved needle holder. The suture connects with the curved needle. The actuator interacts with the elongate body and is operable between a first operating position and a second operating position. The curved needle holder extends away from a distal end portion or is provided as part of the distal end portion of the elongate body. The curved needle holder includes a distal end section having a distal-most tip. The curved needle holder includes an inner surface defining a needle passage for holding the needle and a distal opening. The curved needle has a curved needle radius and the curved needle passage has a curved needle passage radius that is different than the curved needle radius and the curved needle frictionally engages the inner surface when the needle is in a retracted position.

DEVICES AND METHODS FOR SUTURE PLACEMENT

[0001] This application claims priority to U.S. Provisional Application Serial No. 62/291,602 filed on February 5, 2016, the entirety of which is expressly incorporated by reference.

BACKGROUND

[0002] The present disclosure relates generally to surgery and the placement of sutures, and more particularly, to devices and methods for the suture repair of tissue, for example, tears of the dura mater that occur during spinal surgery.

[0003] Tears of the dura mater (durotomy) are a relatively common occurrence during spinal surgery. Incidences of durotomy can vary by procedure and can be an additional challenge during surgical repairs such as, for example, lumbar surgeries or the like. Moreover, it is desirable to form a substantially watertight closure of the dura mater to inhibit or preclude, for example, cerebrospinal fluid (CSF) leaks that can otherwise lead to patient complications.

[0004] Surgical closure techniques using sutures is one approach to dural repair. In some instances, however, these techniques can be difficult to execute due to anatomic constraints, obstruction of visualization by CSF or blood, and the proximity to nerve rootlets. In some instances, these challenges can be further complicated when using minimally invasive techniques such as, for example, a tubular retractor. In some such instances, surgeons may choose not repair the durotomy or they may attempt to repair the durotomy using traditional suturing tools. Such tools and devices can be limited and, in some instances, lack maneuverability to avoid obstructions and/or to enable adequate passage of the needle and suture through the tissue. As a result, surgical repairs of the dura mater are often time consuming and expensive.

SUMMARY

[0005] In view of the foregoing, a suturing device includes a curved needle, a suture, an elongate body, an actuator and a curved needle holder. The curved needle includes first end, which is pointed, and a second end. The suture connects with the curved needle. The elongate body includes a proximal end portion and a distal end portion. The actuator interacts with the elongate body and is operable between a first operating position and a second operating position. The curved needle holder extends away from the distal end portion or is provided as part of the distal end portion of the elongate body. The curved needle holder includes a distal end section having a distal-most tip. The curved needle holder includes an inner surface defining a curved needle passage for holding the needle and a distal opening. The curved needle has a curved needle radius and the curved needle passage has a curved needle passage radius that is different than the curved needle radius and the curved needle frictionally engages the inner surface when the needle is in a retracted position.

[0006] In view of the foregoing, a method of assembling a suturing device includes inserting a curved needle having a suture attached thereto through a distal opening into a curved needle passage of a curved needle holder connected with or configured to be connected with an elongate body of a suturing device. The method further includes frictionally engaging an inner surface of the curved needle holder with the curved needle to retain a pointed end of the curved needle offset inwardly from the distal opening or offset below a distal-most tip of the suturing device.

[0007] Another example of a suturing device includes a needle, a suture, an elongate body, an actuator and a curved needle holder. The needle includes first end, which is pointed, and a second end. The suture connects with the needle. The elongate body includes a proximal end portion and a distal end portion. The actuator interacts with the elongate body and is operable between a first operating position and a second operating position. The curved needle holder extends away from the distal end portion or is provided as part of the distal end portion of the elongate body. The curved needle holder includes a distal end section having a distal-most tip. The curved needle holder includes an inner surface defining a curved needle passage for holding the needle and a distal opening. The needle frictionally engages the inner surface when the needle is in a retracted position and the actuator is in the first operating position.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. 1 is a perspective view of a suturing device.

[0009] FIG. 2 is a cross – sectional view of a lower portion of the suturing device of FIG. 1 and a schematic depiction of a tissue tear.

[0010] FIG. 3 is another cross – sectional view of the lower portion of the suturing device of FIG. 1, and FIG. 3A is an enlarged view of the circled portion in FIG. 3.

[0011] FIG. 4 is a perspective view of a suturing kit including two suturing devices, a suture holding structure and a knot pusher.

[0012] FIGS. 5 – 7 are perspective views of variations of a lower portion of an actuator of the suturing device of FIG. 1.

[0013] FIG. 8 is a cross – sectional view of an upper portion of the suturing device of FIG. 1, and FIG. 8A is an enlarged view of the circled portion in FIG. 8.

[0014] FIG. 9 is a side view of the suturing device of FIG. 1 next to a tubular retractor shown in cross section.

[0015] FIG. 10 is another cross – sectional view of the lower portion of the suturing device of FIG. 1.

[0016] FIG. 11 is a perspective view of the lower portion of the suturing device of FIG. 1 showing a needle holder disconnected from an elongate body of the suturing device.

[0017] FIG. 12 is a schematic cross – sectional view of the lower portion of a variation of the needle holder of the suturing device of FIG. 1.

[0018] FIG. 13 is a cross – sectional view of the lower portion of another variation of the needle holder of the suturing device of FIG. 1.

[0019] FIG. 14 is a perspective view of a lower portion of the suturing device showing the variation of FIG. 13, and FIG. 14A is an enlarged view of the circled portion in FIG. 14.

[0020] FIG. 15 is a side view showing a variation of the elongate body and a variation of the needle holder of the suturing device.

[0021] FIG. 16 is a cross – sectional view of the lower portion of the variation of the needle holder shown in FIG. 15.

[0022] FIG. 17 is an alternative embodiment of a suturing device, and FIG. 17A is an enlarged view of the circled portion in FIG. 17.

DETAILED DESCRIPTION

[0023] FIG. 1 depicts an example of a suturing device 10 that is useful to suture tears in dura mater, which may occur during spinal surgery procedures; however, the suturing device 10 can be used in other types of surgical procedures. The suturing device 10 generally includes an actuator 12, an elongate body 14, and a needle holder 16. The suturing device 10 is particularly useful during a minimally invasive surgical procedure that is performed through a tubular retractor or other small surgical portal to accurately locate a needle 20 and a suture 22, which are shown in FIG. 2, with respect to target tissue 24 to be sutured. The target tissue 24 shown in FIG. 2 is part of a dural sac having a tear. Again, the suturing device 10 may be useful in other surgical procedures.

[0024] With reference to FIG. 2, the needle 20 in the illustrated embodiment is a curved needle having a first end 30, which is pointed, and a second end 32, which is opposite to the first end 30. The needle 20 can be similar to commercially available curved needles made from known materials. The needle 20 can be formed having a curved needle radius 34. The needle 20 could also be formed from a malleable, or flexible, material such that the needle 20 could follow a curve when positioned within the needle holder 16, which is curved in FIG. 2, and then later straighten after exiting the needle holder 16. The needle 20 can take other configurations, such as straight. Also, the needle 20 could be formed as part of the suture 22, e.g., the needle 20 could be a rigid end of the suture 22 that is configured so as to be suitable to pass through animal tissue. Actuation of the actuator 12 moves the needle 20 in an advance direction 36 (FIG. 3) with respect to the needle holder 16. The needle 20 moves from a retracted position, which is shown in FIG. 3, to a released condition, which is shown in FIG. 2, in which the needle 20 is released from the needle holder 16. When in the released condition, the surgeon can grasp the needle 20, for example with forceps, and pull the needle 20 and the suture 22.

[0025] With reference back to FIG. 2, the suture 22 connects with the needle 20 and extends from the second end 32 of the needle 20. The suture 22 can be swaged to the second end 32 of the needle 20. The suture 22 can also connect with the needle 20 in other conventional manners. The suture 22 can be acquired from known suture manufacturers. The average diameter of the suture 22 can be very close to the outer diameter of the second end 32 of the needle 20, for example, the average diameter of the suture 22 can be between 90% and 110% of the outer diameter of the second end 32 of the needle 20.

[0026] The actuator 12 is operable between a first operating position and a second operating position. As seen when comparing FIG. 1 to FIG. 4, the actuator 12 in the illustrated embodiment is moveable between a first operating position, which is shown in FIG. 1, and a second operating position, which is shown in FIG. 4. Movement of the actuator 12 from the first operating position toward the second operating position moves the needle 20 in the advance direction 36 (FIG. 3) with respect to the needle holder 16 thus moving the needle 20 toward the released condition, which is shown in FIG. 2, in which the needle 20 is released from the needle holder 16.

[0027] With reference back to FIG. 1, in the illustrated embodiment the actuator 12 includes a button 50, a tube 52, which could also be a rod, and a wire 54 (FIG. 2). In the illustrated embodiment, the button 50 connects with the tube 52, which is connected with the wire 54. Alternatively, the button 50 could connect with the wire 54 without the tube 52. Also, the button 50 could connect with a rod having no elongate passage, and the rod can connect with the wire 54. In the illustrated embodiment, the actuator 12 includes a flexible section, which in the illustrated embodiment is made up of the wire 54, which can

be made from nitinol. The flexible section is configured to bend within the needle holder 16 when the actuator 12 is moved from the first operating position toward the second operating position.

[0028] The tube 52 (or rod) is received within the elongate body 14 and moves with respect to the elongate body 14 when the actuator 12 moves between the first operating position and the second operating position. In the illustrated embodiment, the tube 52 moves along a longitudinal axis 56 (FIG. 2). The longitudinal axis 56 in the illustrated embodiment is a straight line; however, the longitudinal axis could be a curved line, for example if the elongate body 14 is curved. The tube 52 includes an elongate passage 58, which receives the wire 54 in the illustrated embodiment. Alternatively, the wire 54 could extend from a distal end of a rod, which would connect with the button 50, in lieu of providing the tube 52. The tube 52 is made from a rigid material, such as a rigid plastic or metal, and is more rigid than the wire 54.

[0029] With reference back to FIG. 1, the button 50 includes an operator contact surface 60 that is configured to be depressed by a surgeon's finger or thumb to move the actuator 12 from the first operating position toward the second operating position. The button 50 also includes a handle contact surface 62 spaced from the operator contact surface 60 along the longitudinal axis 56. The button 50 also includes an outer surface 64, which follows a surface of revolution about the longitudinal axis 56 and spans between the operator contact surface 60 and the handle contact surface 62, which allows for the surgeon to easily manipulate the suturing device 10 and rotate the suturing device 10 about the longitudinal axis 56. The button 50 connects with the tube 52 (or the rod) and the wire 54 such that movement of the button 50 along the longitudinal axis 56 results in movement of the tube 52 (or rod) and the wire 54 along the longitudinal axis 56.

[0030] With reference to FIG. 2, a distal end 70 of the actuator 12, which in the illustrated embodiment is located at a distal end of the wire 54, contacts the second end 32 of the needle 20 as the actuator 12 is moved from the first operating position (shown in FIGS. 1 and 3) toward the second operating position (shown in FIGS. 2 and 4) to move the needle 20 in the advance direction 36. With reference to FIG. 5, which shows a lower portion of the actuator 12, the actuator 12 could include a distal tube 72, which could be made from plastic, at a distal portion. As illustrated, the distal tube 72 connects with the wire 54. An outer diameter of the distal tube 72 could be nearly equal to an inner diameter of the elongate body 14 and/or the needle holder 16, while being small enough so that the distal tube 72 is freely moveable within the elongate body 14 and the needle holder 16. An alternative arrangement is shown in FIG. 6, which also shows a distal portion of the actuator 12 where the actuator 12 includes a spherical distal tip 74. As illustrated, the spherical distal tip 74 can be provided on the wire 54. The outer diameter of the spherical distal tip 74 can be nearly equal to the inner diameter of the elongate body 14 and/or the needle holder 16. FIG. 7 also depicts a distal portion of the actuator 12 where the actuator 12 includes a pocket 76 at a distal end. The pocket 76 is configured to receive the second end 32 of the needle 20. The pocket 76 can also be configured to receive the suture 22. The pocket 76 could be formed from a resilient material that clamps onto the second end 32 of the needle 20 while the needle 20 is being advanced through the needle holder 16 in the advance direction 36.

[0031] Other types of actuators can be employed to move the needle 20 in the advance direction 36. For example, air pressure through a pneumatic mechanism could be used to move the needle 20 from the retracted position shown in FIG. 3 to the released condition shown in FIG. 2. Other types of mechanical actuators could also be used to move the needle 20. For example, rollers that contact the

compared to the handle 90 described above and is generally T-shaped. The elongate bore 442 extends from a proximal end surface 444 to a distal end surface 446 and is aligned with a longitudinal axis 448 that is parallel with a longest dimension of each elongate body 414, 414a.

[0069] Each actuator 412, 412a operates similarly to the actuator 12 described above. The first actuator 412 includes a button 450, a tube 452, which could also be a rod, and a wire, which is not visible in FIG. 17 but is similar to the wire 54 described above. Similarly, the second actuator 412a includes a button 450a, a tube 452a, which could also be a rod, and a wire, which is not visible in FIG. 17 but is similar to the wire 54 described above.

[0070] The first actuator 412 is identical to the second actuator 412a. Accordingly, the first actuator 412 will be described in detail with respect to the first elongate body 414 and the first needle holder 416 with the understanding that the second actuator 412a cooperates with the second elongate body 414a and the second needle holder 416a in the same manner. The first tube 452 (or rod) and the first wire (not visible) of the first actuator 412 is received within the first elongate body 414 and moves with respect to the first elongate body 414 between the first operating position and the second operating position, similar to the actuator 12 described above. The first tube 452 moves in a direction parallel with the longitudinal axis 448. The wire (not visible) contacts the second end 32 (see FIG. 2) of the first needle 20 to advance the needle 20 from the retracted position toward the released condition. The buttons 450, 450a differ from the button 50 described above, however, the actuators 412, 412a can operate in the same manner as the actuator 12 described above. Therefore, the operation of the actuators 412, 412a will not be described in further detail.

[0071] Both FIGS. 4 and 13 disclose suturing kits including a double-armed suture, at least one suturing device and a suture holding structure. In both embodiments, the at least one suturing device includes a portion configured to be inserted into a patient.

[0072] In the embodiment depicted in FIG. 4, the first needle holder 16 and the first elongate body 14 are part of a first suturing device 10, which is a physically separate device from the second suturing device 10a. The second suturing device 10a is, however, loaded with the second needle 20a and the suture 22 in a similar manner to that shown in FIG. 2 so that a double-armed suture is connected with both suturing devices 10, 10a. Instead of providing the second suturing device 10a shown in FIG. 4, the suturing kit could include the actuator 12, the elongate body 14 and at least two needle holders 16 where the needle holders are disconnected from the elongate body 14, similar to what is shown in FIG. 11. Alternatively, one of the needle holders 16 could be connected with the elongate body 14 and additional needle holders 16, which can be loaded with a respective needle 20 and suture 22, can also be provided with the kit. In the embodiment depicted in FIG. 17, the first needle holder 416, the first elongate body 414, the second needle holder 416a, the second elongate body 414a are all part of the same suturing device 410.

[0073] In each of the aforementioned embodiments, the suture holding structure 210 holds at least a portion of the suture 22 between the first end and the second end of the suture 22. In both embodiments, the suture holding structure 210 is separate from the at least one suturing device, e.g. the suturing devices 10, 10a or the suturing device 410, so as not to be inserted into the patient during the surgical procedure. In other words, the suture holding structure 210, and thus much of the suture, remains outside of the patient during the surgical procedure. Both the kit 200 shown in FIG. 4, the kit having another needle holder disconnected from the elongate body 14, and the kit 400 shown in FIG. 17 can be

provided with a sealed package 460 (only schematically depicted in FIG. 17), which contains the suture 22, the at least one suturing device, e.g. the first suturing device 10 and the second suturing device 10a in FIG. 4 or the suturing device 410 in FIG. 17, and the suture holding structure 210.

[0074] A method of operating a suturing device to repair a tissue tear will be described with reference to the suturing devices 10, 10a and 410 described above; however, the method may be practiced using differently configured suturing devices and/or the variations shown in FIGS. 12-16, and these variations may be referred to below where relevant. The physician can insert the suturing device 10 into a tubular retractor, such as the tubular retractor TR depicted in FIG. 9, or into another small surgical portal. With reference to FIG. 2, the physician can position the distal-most tip 142 of the suturing device 10 under the internal side 26 of the target tissue 24 on a first (left per the orientation of FIG. 2) side of a tear through the target tissue 24. The target tissue 24 depicted in FIG. 2 is a dural sac, which is a sheath of dura mater that surrounds the spinal cord, which is not shown in FIG. 2 for purposes of clarity. With the distal-most tip 142 under the internal side 26 of the target tissue 24, the physician then actuates the actuator 12 on the suturing device 10 to advance the first end 30 of the needle 20 through the target tissue 24 from the internal side 26 toward the outer side 28 until the second end 32 of the needle 20 and the suture 22 are released from the suturing device 10. The physician can then remove the suturing device 10 from inside the patient (and inside the dural sac) and grasp the needle 20 and pull the suture 22 through the hole that was formed in the target tissue 24 with the needle 20. The physician can then take another suturing device, for example, the second suturing device 10a shown in FIG. 4, which has the second needle 20a loaded in it and the opposite end of the suture 22 attached to the second needle 20a and insert the second suturing device 10a into the tubular retractor TR (FIG. 9) or other small surgical portal. The physician can position the distal-most tip of the second suturing device 10a, which is the same as the distal-most tip 142 depicted in FIG. 2, under the internal side 26 of the target tissue 24 on a second (right per the orientation of FIG. 2) side of the tear through the target tissue 24. With the distal-most tip of the second suturing device 10a under the internal side 26 of the target tissue 24, the physician then actuates the actuator 12a (FIG. 4) on the second suturing device 10a to advance the first (pointed) end of the second needle 20a through the target tissue 24 from the internal side 26 toward the outer side 28 until the second end of the second needle 20a and the suture 22 are released from the second suturing device 10a. The physician can then remove the second suturing device 10a from inside the patient (and inside the dural sac) and grasp the second needle 20a and pull the suture 22 through the hole that was formed in the target tissue 24 with the second needle 20a. The physician can then tie a knot in the suture 22 in a conventional manner to close the tear, and this process can be repeated until the tear has been adequately closed.

[0075] Instead of using two different suturing device 10 and 10a, the physician may use only the first suturing device 10. In this example, the second needle 20a would still be connected to an opposite end of the suture 22 as the first needle 20; however, the second needle 20a would not be pre-loaded into a suturing device. Instead, the second needle 20a would be free from a suturing device, and the second needle 20a would be loaded into the first suturing device 10 after the first needle had been deployed from the first suturing device 10. So, the physician would deploy the first needle 20 from the suturing device 10 in the same manner as described above and remove the suturing device 10 from the patient. The physician would then pull the actuator 12 back to the first operating position from the second operating position. The second needle 20a having the suture 22 attached thereto would then be inserted through

the distal opening 146 and into the needle passage 144 until the second needle 20a is in the retracted position, which is shown for the first needle 20 in FIG. 3. In an alternative arrangement, the actuator 12 can remain in the second operating position while the needle 20 is being loaded into the needle holder 16. For example, the actuator 12 could facilitate drawing the needle 20 into the retracted position. As one example, the pocket 76 (see FIG. 7) could grasp the second end 32 of the needle 20, and movement of the actuator 12 from the second operating position toward the first operating position could draw the needle 20 toward the retracted position. With reference back to the illustrated embodiment and like that shown in FIG. 3, a portion of the suture 22 would be maintained extending out of the distal opening 146 and outside of the suturing device 10. The physician would then operate the suturing device 10 with the second needle 20a loaded therein in a similar manner how the physician operated the second suturing device 10a above.

[0076] The physician could also use the suturing device 410 in a similar manner. The physician can position the distal-most tip, which is not particularly called out in FIG. 17 but could have a similar configuration to the distal-most tip 142 in FIG. 11, on the first needle holder 416 of the suturing device 410 under the internal side of the target tissue on a first (e.g., left) side of a tear through the target tissue. With the distal-most tip on the first needle holder 416 of the suturing device 410 under the internal side of the target tissue, the physician then actuates the first actuator 412 on the suturing device 410 to advance the first end of the first needle (not visible in FIG. 17 because it is loaded within the first needle holder 416) through the target tissue from the internal side toward the outer side until the second end of the first needle and the suture 22 are released from the suturing device 410. The physician can then rotate the suturing device 410 about the longitudinal axis 448 and position the distal-most tip on the second needle holder 416a of the suturing device 410 under the internal side of the target tissue on a second (e.g., right) side of the tear. With the distal-most tip on the second needle holder 416a of the suturing device 410 under the internal side of the target tissue, the physician then actuates the second actuator 412a on the suturing device 410 to advance the first end of the second needle 20a through the target tissue from the internal side toward the outer side until the second end of the second needle 20a and the suture 22 are released from the suturing device 410. The physician can then remove the suturing device 410 from inside the patient (and inside the dural sac) and grasp the needles 20, 20a and pull the suture 22 through the holes that were formed in the target tissue with the needles 20, 20a. The physician can then tie a knot in the suture 22 in a conventional manner to close the tear, and this process can be repeated until the tear has been adequately closed.

[0077] Because of the configuration of the suturing devices 10, 310, 410, the physician is able to repair tears in the dural sac and avoid the many nerves that are located within the dural sac. The suturing devices 10, 310, 410 have a desirable J-hook configuration that allows the physician to grasp the target tissue 24 just underneath the internal side 26, and the shape of the distal-most tip 142 allows the physician to indent the target tissue 24 prior to actuation to provide a visual indication of where the needle 20 or 20a will pass through the target tissue. Because of the J-hook configuration of the suturing devices 10, 310, 410, when the physician is positioning the distal-most tip 142 under the internal side 26 of the target tissue 24, the elongate body 14, 314 or 414, 414a can be maintained in an orientation closer to vertical as compared to horizontal. For example with reference to FIGS. 9 and 15, at least the distal end portion 322 of the elongate body 314 can be maintained in an orientation closer to parallel with a central axis CA of the tubular retractor TR as compared to perpendicular with the central axis CA while

positioning the distal-most tip 142. This is particularly useful because during spinal surgery the patient is typically lying on his stomach and the physician is working from above the patient. Because of the J-hook configuration of the suturing devices 10 and 410, when the physician is advancing the needle 20 or 20a through the target tissue 24, the needle 20 or 20a is advanced toward the physician, which allows the physician to see the needle. When using either of the suturing devices 10 and 410, at least a portion of the suture 22 remains outside of the patient. Since only a small portion of the suture 22 is received inside the suturing devices 10 or 410, the suturing devices 10 or 410 can be made much smaller as compared to other known suturing device, which makes the suturing devices 10, 410 very useful for repairing tears in a dural sac.

[0078] Even though the method of operating the suturing devices was described as passing the needle 20 from inside the dural sac to the outside, the suturing devices 10, 310 and 410 can be used to pass the needle 20 through tissue in other manners, e.g., from outside to inside. Also, the suturing devices 10, 310 and 410 can also be used to suture tissue other than the dural sac.

[0079] A method of assembling a suturing device will be described with reference to the suturing device 10 described above; however, the method may be practiced using differently configured suturing devices and/or the variations shown in FIGS. 12-17. The method includes inserting the needle 20 having the suture 22 attached thereto through the distal opening 146 into the needle passage 144 of the needle holder 16 connected with or configured to be connected with the elongate body 14 of the suturing device 10. When assembling the suturing device, the needle 20 is inserted into the needle passage 144 in an insertion direction, which is opposite to the advance direction 36 (see FIG. 3). The method also includes frictionally engaging the inner surface 162 of the needle holder 16 with the needle 20 to retain the first (pointed) end 30 of the needle 20 offset inwardly from the distal opening 146 or offset below the distal-most tip 142 of the suturing device 10. Inserting the needle 20 can further include inserting the second end 32 of the needle 20 and folding the suture 22 such that a portion of the suture 22 extends along the needle passage 144 between the needle 20 and the inner surface 162 (see FIG. 3). The method can further include placing the needle holder 16 with the needle 20 inserted therein and the suture 22 extending out of the distal opening 146 in a package (a sealed package 460 is schematically depicted in FIG. 17), and sealing the package. The method can further include removing the needle holder 16 from a sealed package prior to inserting the needle 20 into the needle passage 144. Accordingly, the needle 20 can be inserted into the needle passage 144 in the operating room or surgical facility instead of at the manufacturing facility, if desired. Frictionally engaging the inner surface 162 of the needle holder 16 can further include contacting the inner surface 162 of the needle holder 16 in at least three different locations along the needle 20 when the needle 20 is in a retracted position (see FIGS. 3 and 16). When in the retracted position, the needle 20 can contact the inner surface 162 of the needle holder 16 at the first location 164, the second location 166 and the third location 168 shown in FIG. 16.

[0080] The method of assembling the suturing device 10 can also include inserting the needle 20 having the suture 22 attached thereto through the distal opening 146 into the needle passage 144 of a suturing device 10. The method also includes maintaining a portion of the suture 22 extending out of the distal opening 146 and outside of the suturing device 10. As mentioned above, inserting the needle 20 can further include inserting the second end 32 of the needle 20 and folding the suture 22 such that a portion of the suture 22 extends along the needle passage 144 between the needle 20 and the inner surface 162 (see FIG. 3). FIG. 12 shows the variant including the keyway 220. The method can further

include inserting the suture 22 into the keyway 220 while inserting the needle 20 through the distal opening 146 into the needle passage 144 of the suturing device 10. Inserting the needle 20 having the suture 22 attached thereto can further include pushing the needle 20 into the needle passage 144 until the needle 20 frictionally engages the inner surface 162 of the suturing device 10 defining the needle passage 144. Inserting the needle 20 having the suture 22 attached thereto can also include inserting the second end 32 of the needle 20 and folding the suture 22 such that a portion of the suture 22 extends along the needle passage 144 between the needle 20 and the inner surface 162 (see FIG. 3) of the suturing device 10 defining the needle passage 144.

[0081] It will be appreciated that various of the above-disclosed embodiments and variations and other features and functions, or alternatives or varieties thereof, may be desirably combined into many other different devices or applications. Also, components from one embodiment can be used in other embodiments described above. Also, various presently unforeseen or unanticipated alternatives, modifications, variations or improvements therein may be subsequently made by those skilled in the art which are also intended to be encompassed by the following claims.

CLAIMS:

1. A suturing device comprising:

a curved needle having first end, which is pointed, and a second end;

a suture connected with the curved needle;

an elongate body including a proximal end portion and a distal end portion;

an actuator interacting with the elongate body and operable between a first operating position and a second operating position; and

a curved needle holder extending away from the distal end portion or provided as part of the distal end portion of the elongate body, the curved needle holder including a distal end section having a distal-most tip, the curved needle holder including an inner surface defining a curved needle passage for holding the needle and a distal opening,

wherein the curved needle has a curved needle radius and the curved needle passage has a curved needle passage radius that is different than the curved needle radius and the curved needle frictionally engages the inner surface when the needle is in a retracted position.

2. The suturing device of claim 1, wherein at least a portion of the suture extends through the distal opening when the curved needle is received in the curved needle passage and the actuator is in the first operating position.

3. The suturing device of claim 2, wherein at least a portion of the suture extends along the curved needle passage from the second end of the curved needle toward the distal opening between the curved needle and the inner surface of the curved needle holder when the curved needle is received in the curved needle passage and the actuator is in the first operating position.

4. The suturing device of claim 1, wherein the distal opening is non-circular.

5. The suturing device of claim 1, wherein the curved needle is moveable from the retracted position, in which the curved needle is received in the curved needle passage with the first end of the curved needle recessed inwardly from the distal-most tip in the curved needle passage, toward a released condition in an advance direction, wherein the curved needle contacts the inner surface of the curved needle holder along a portion of its travel path in the needle holder as the curved needle moves from the retracted position toward the released condition.

6. The suturing device of claim 1, wherein the curved needle is moveable from the retracted position, in which the curved needle is received in the curved needle passage with the first end of the curved needle recessed inwardly from the distal-most tip in the curved needle passage, toward a released condition in an advance direction, wherein the curved needle contacts the inner surface of the curved needle holder at least along a majority of its travel path in the needle holder as the curved needle moves from the retracted position toward the released condition.

7. The suturing device of claim 1, wherein the curved needle contacts the inner surface of the curved needle holder in at least three different locations along the needle when the curved needle is in the retracted position.

8. The suturing device of claim 7, wherein the curved needle contacts the inner surface of the curved needle holder at a first location, a second location and a third location along the curved needle, wherein the first location is located beneath and adjacent to the distal-most tip, wherein the second location is located near a middle of an arc length of the curved needle, and wherein the third location is located adjacent a location where the curved needle holder begins to curve away from a longitudinal axis of the suturing device.

9. The suturing device of claim 1, wherein the inner surface of the curved needle holder is electropolished.

10. The suturing device of claim 1, wherein a distal end of the actuator is recessed inwardly from the distal-most tip when the actuator is in the second operating position.

11. The suturing device of claim 1, wherein movement of the actuator from the first operating position toward the second operating position results in a distal end of the actuator contacting the second end of the curved needle and pushing the curved needle in an advance direction.

12. The suturing device of claim 1, wherein a maximum outer diameter of the curved needle holder is about equal to or less than a maximum outer diameter of the elongate body.

13. The suturing device of claim 1, wherein the distal end section is configured such that a portion of the distal end section adjacent the distal-most tip extends towards the proximal end portion of the elongate body.

14. The suturing device of claim 1, wherein the curved needle and at least a portion of the suture are received within the curved needle holder in the curved needle passage with the first end of the curved needle recessed inwardly from the distal-most tip when the actuator is in the first operating position.

15. The suturing device of claim 1, wherein the distal opening is offset from an axis along which at least a majority of the actuator travels when moving from the first operating position toward the second operating position.

16. The suturing device of claim 1, further comprising an additional curved needle connected with the suture.

17. The suturing device of claim 1, wherein the curved needle holder is releasably connected with the distal end portion.

18. The suturing device of claim 1, further comprising an open cell foam needle retainer covering the distal opening.

19. The suturing device of claim 1, wherein the arc length of the curved needle holder is between 5 – 25 % longer than the arc length of the curved needle.

20. The suturing device of claim 1, wherein the curved needle has a maximum outer diameter that is at least 40% of an inner diameter of the curved needle passage, and the maximum outer diameter is not greater than 90% of the inner diameter of the curved needle passage.

21. The suturing device of claim 1, wherein the curved needle passage radius follows an arc length less than about 140 degrees between a location where the curved needle holder begins to curve away from a longitudinal axis of the suturing device and the distal-most tip.

22. The suturing device of claim 1, wherein the curved needle passage radius follows an arc length less than about 110 degrees between a location where the curved needle holder begins to curve away from a longitudinal axis of the suturing device and the distal-most tip.

23. A method of assembling a suturing device, comprising:

inserting a curved needle having a suture attached thereto through a distal opening into a curved needle passage of a curved needle holder connected with or configured to be connected with an elongate body of a suturing device; and

frictionally engaging an inner surface of the curved needle holder with the curved needle to retain a pointed end of the curved needle offset inwardly from the distal opening or offset below a distal-most tip of the suturing device.

24. The method of claim 23, wherein the needle includes a first end, which is the pointed end, and a second end, which is opposite the first end, wherein inserting the curved needle further includes inserting the second end of the curved needle and folding the suture such that a portion of the suture extends along the needle passage between the curved needle and the inner surface.

25. The method of claim 23, further comprising:

placing the curved needle holder with the needle inserted therein and the suture extending out of the distal opening in a package; and

sealing the package.

26. The method of claim 23, further comprising:

removing the curved needle holder from a sealed package prior to inserting the needle into the needle passage.

27. The method of claim 23, wherein frictionally engaging the inner surface of the curved needle holder further includes contacting the inner surface of the curved needle holder in at least three different locations along the needle when the curved needle is in a retracted position.

28. The method of claim 27, wherein the curved needle contacts the inner surface of the curved needle holder at a first location, a second location and a third location along the curved needle, wherein the first location is located beneath and adjacent to the distal-most tip, wherein the second location is located near a middle of an arc length of the curved needle, and wherein the third location is located adjacent a location where the curved needle holder begins to curve away from a longitudinal axis of the suturing device.

29. A suturing device comprising:

a needle having first end, which is pointed, and a second end;

a suture connected with the needle;

an elongate body including a proximal end portion and a distal end portion;

an actuator interacting with the elongate body and operable between a first operating position and a second operating position; and

a curved needle holder extending away from the distal end portion or provided as part of the distal end portion of the elongate body, the curved needle holder including a distal end section having a distal-most tip, the curved needle holder including an inner surface defining a curved needle passage for holding the needle and a distal opening,

wherein the needle frictionally engages the inner surface when the needle is in a retracted position and the actuator is in the first operating position.

30. The suturing device of claim 29, wherein the needle is a curved needle, and the curved needle has a curved needle radius and the curved needle passage has a curved needle passage radius that is different than the curved needle radius and the curved needle frictionally engages the inner surface when the needle is in the retracted position.

31. The suturing device of claim 29, wherein at least a portion of the suture extends through the distal opening when the needle is received in the curved needle passage and the actuator is in the first operating position.

32. The suturing device of claim 31, wherein at least a portion of the suture extends along the curved needle passage from the second end of the needle toward the distal opening between the needle and the inner surface of the curved needle holder when the needle is received in the curved needle passage and the actuator is in the first operating position.

33. The suturing device of claim 29, wherein the distal opening is non-circular.

34. The suturing device of claim 29, wherein the curved needle contacts the inner surface of the curved needle holder in at least three different locations along the length of the needle when the curved needle is in the retracted position.

35. The suturing device of claim 29, wherein movement of the actuator from the first operating position toward the second operating position results in a distal end of the actuator contacting the second end of the curved needle and pushing the curved needle in an advance direction.

36. The suturing device of claim 29, wherein the distal end section is configured such that a portion of the distal end section adjacent the distal-most tip extends towards the proximal end portion of the elongate body.

38. The suturing device of claim 29, wherein the needle is a curved needle, and wherein the arc length of the curved needle holder is between 5 – 25 % longer than the arc length of the curved needle.

39. The suturing device of claim 29, wherein the needle has a maximum outer diameter that is at least 40% of an inner diameter of the curved needle passage, and the maximum outer diameter is not greater than 90% of the inner diameter of the curved needle passage.

40. The suturing device of claim 29, wherein the curved needle passage has a curved needle passage radius that follows an arc length less than about 140 degrees between a location where the curved needle holder begins to curve away from a longitudinal axis of the suturing device and the distal-most tip.

41. The suturing device of claim 29, wherein the curved needle passage has a curved needle passage radius that follows an arc length less than about 110 degrees between a location where the curved needle holder begins to curve away from a longitudinal axis of the suturing device and the distal-most tip.

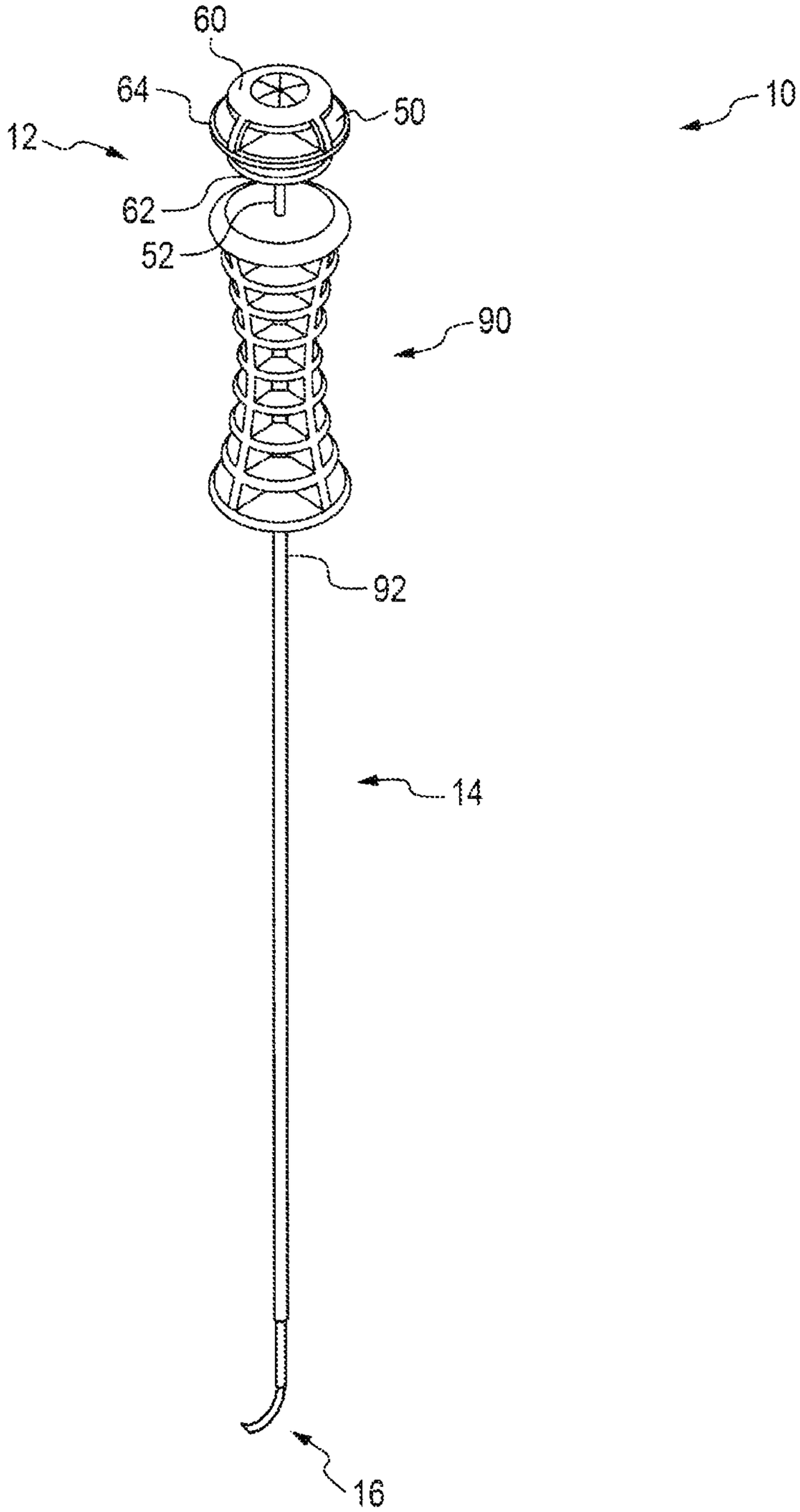

FIG. 1

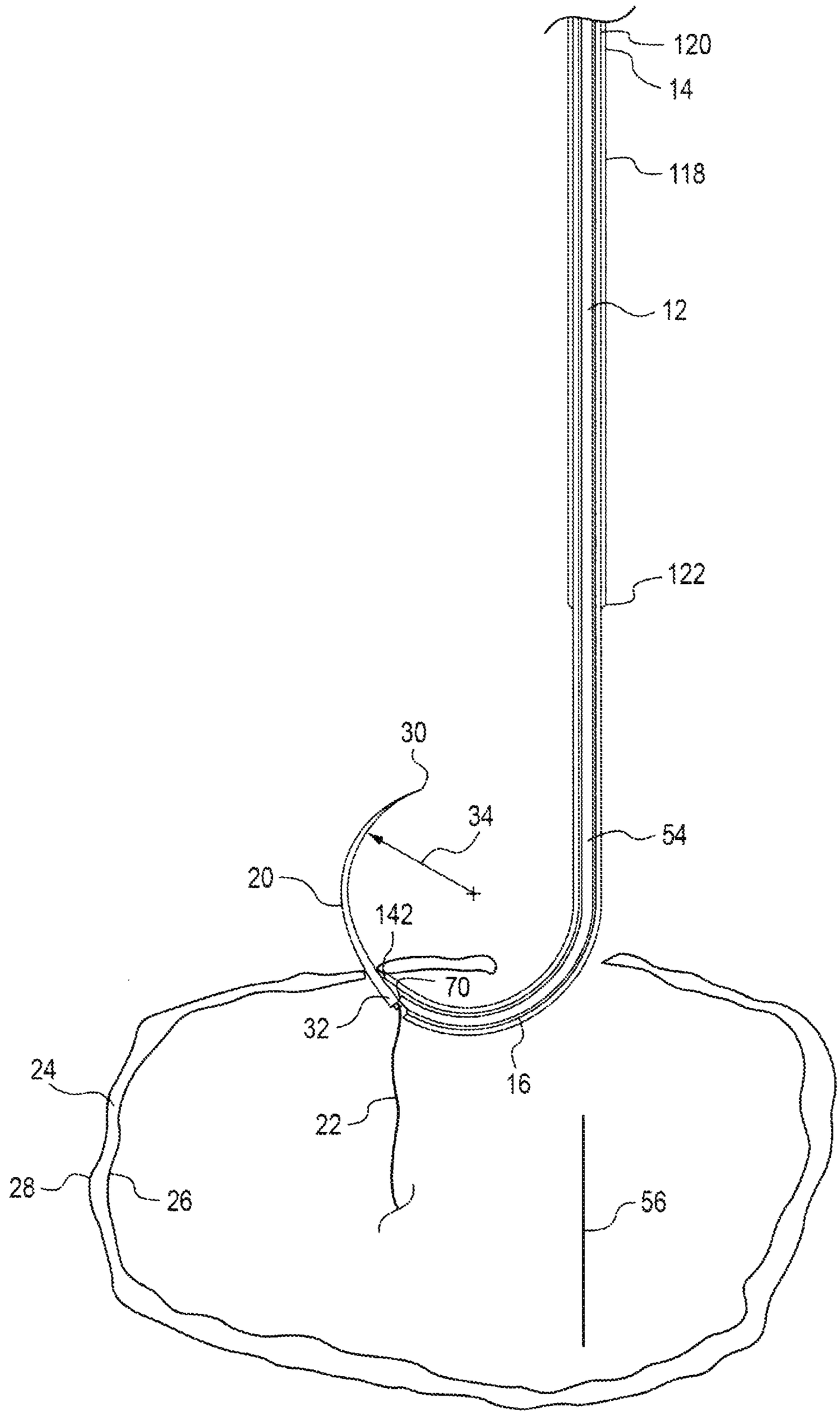

FIG. 2

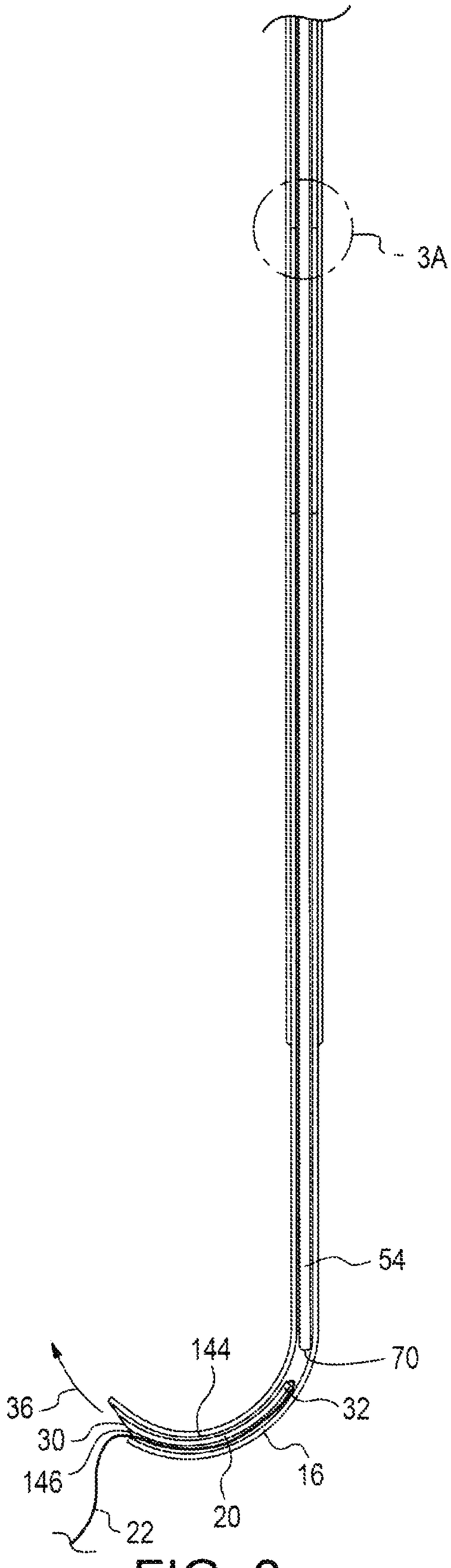

FIG. 3

FIG. 3A

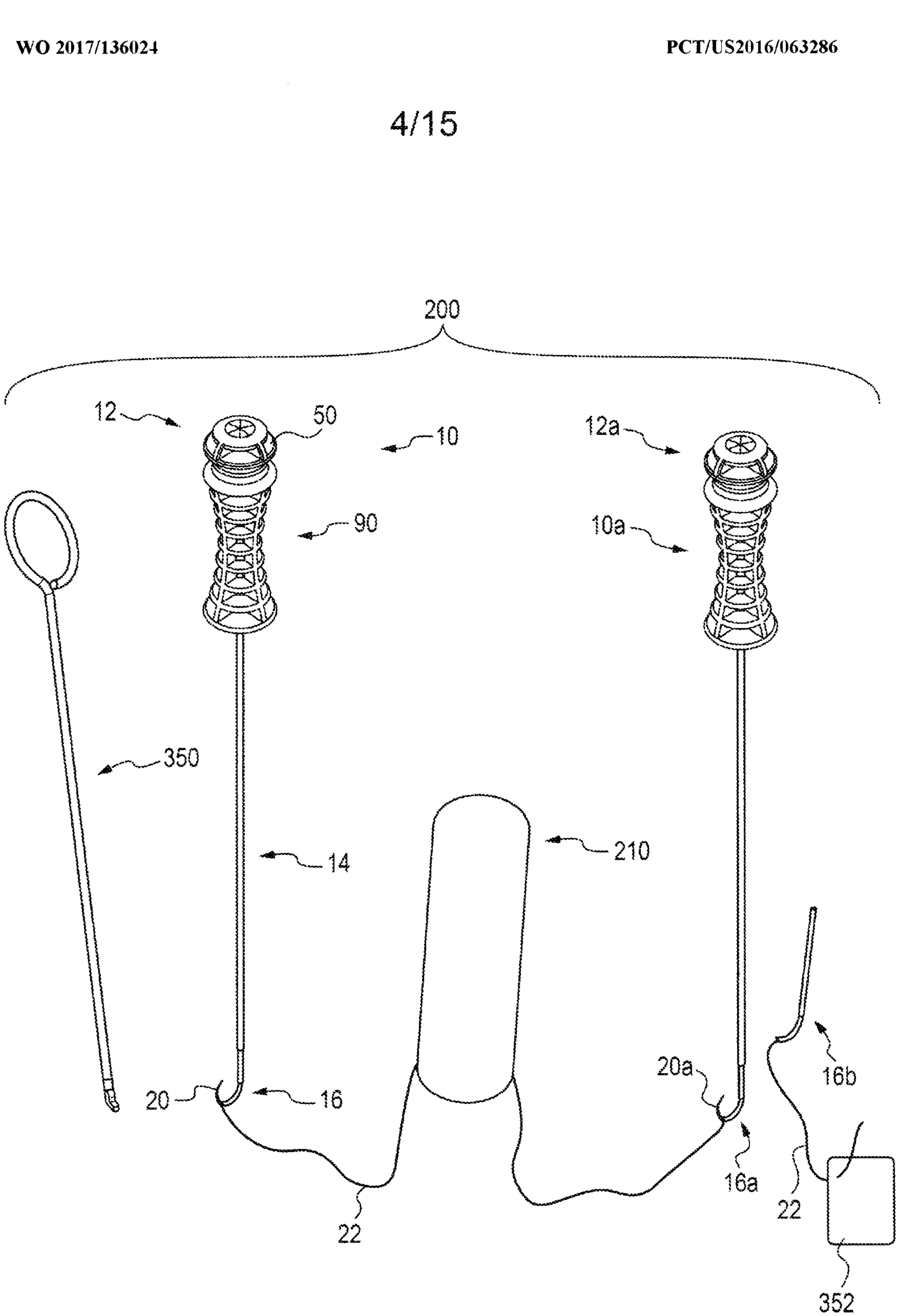

FIG. 4

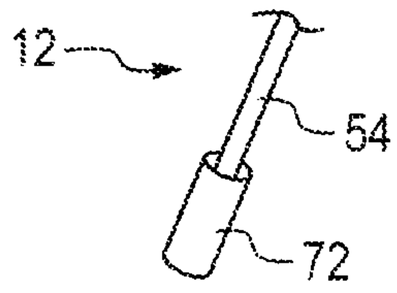

FIG. 5

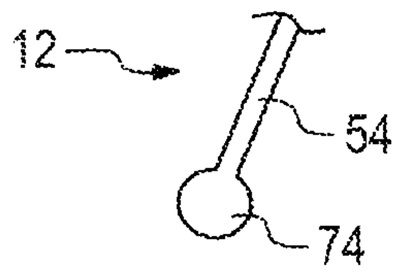

FIG. 6

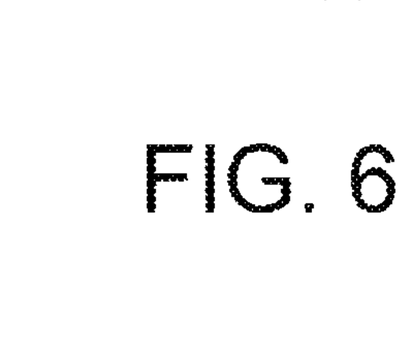

FIG. 7

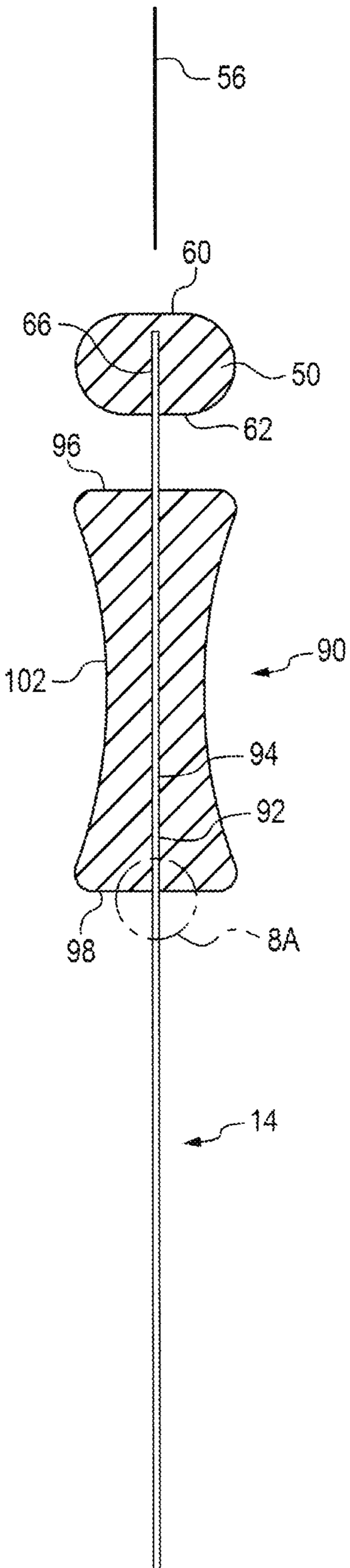

FIG. 8

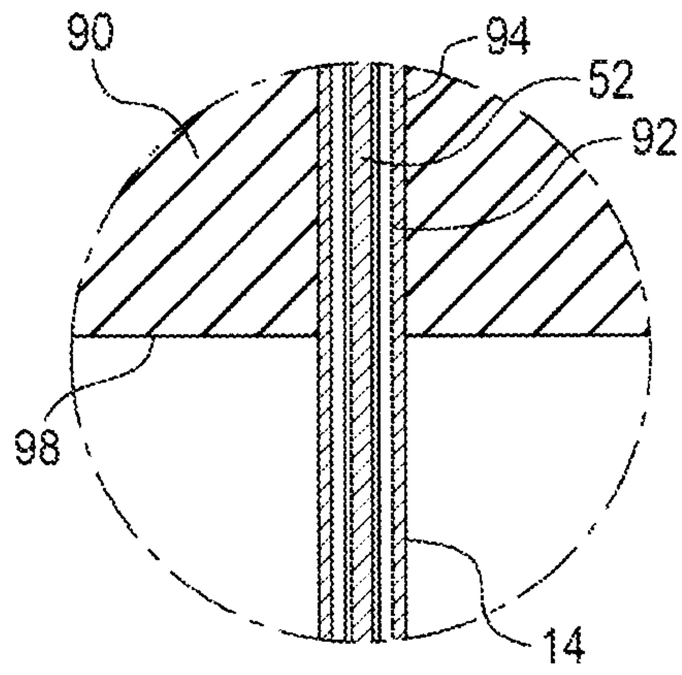

FIG. 8A

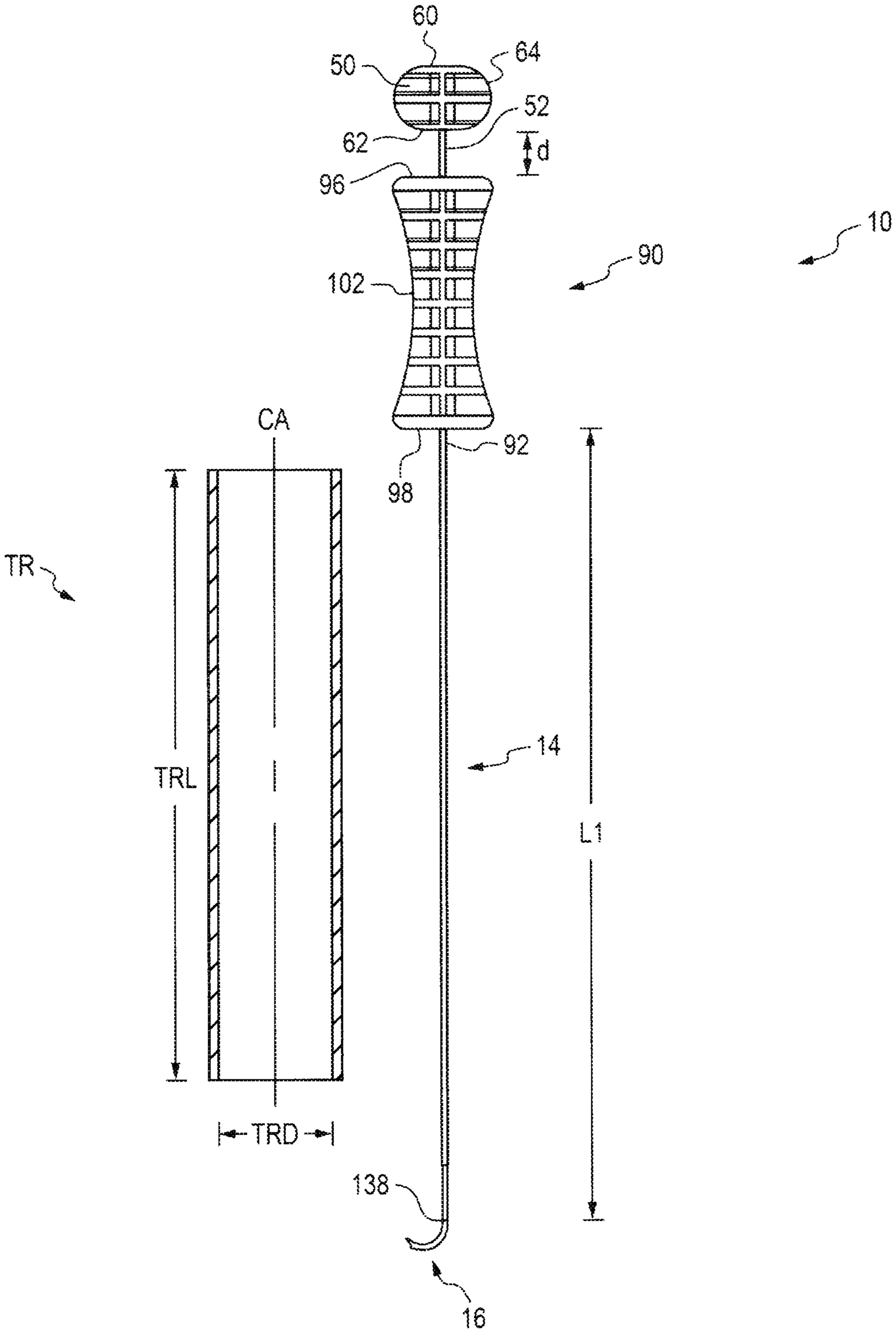

FIG. 9

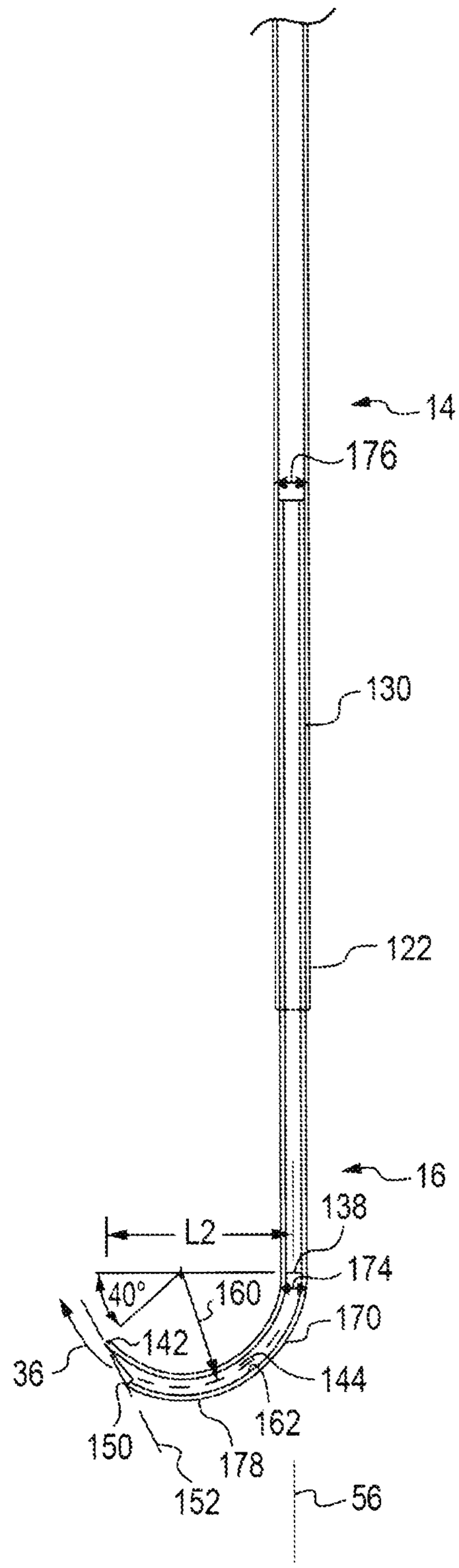
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FIG. 10

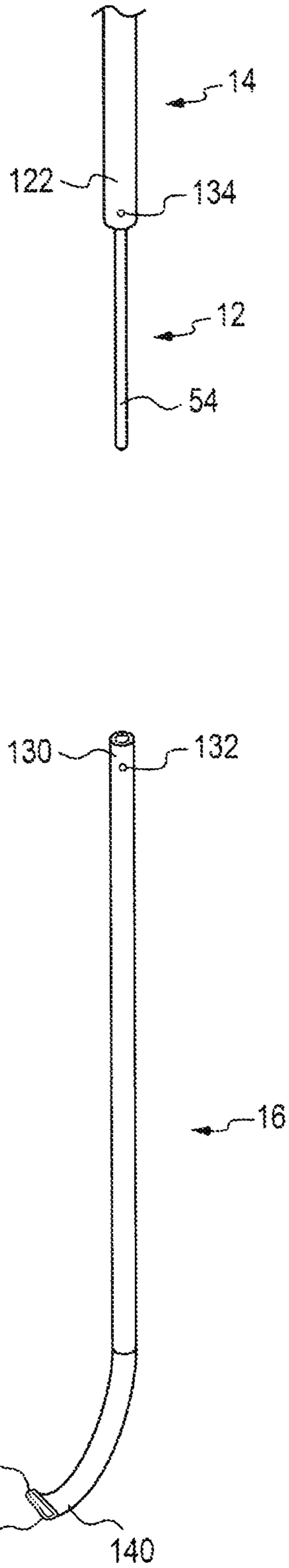

FIG. 11

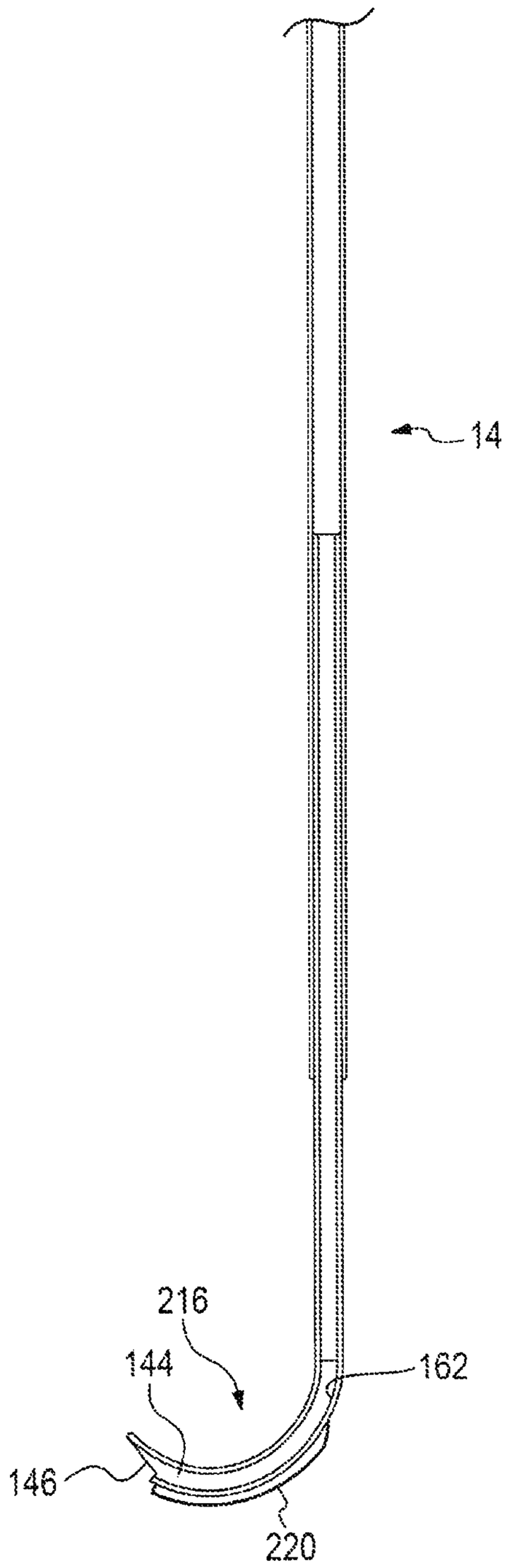

FIG. 12

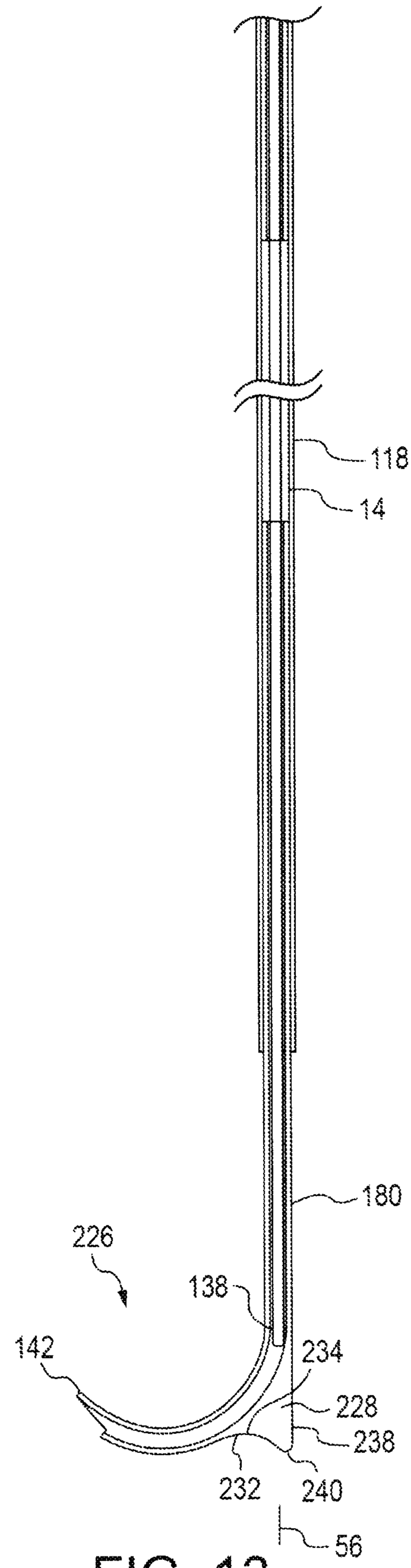

FIG. 13

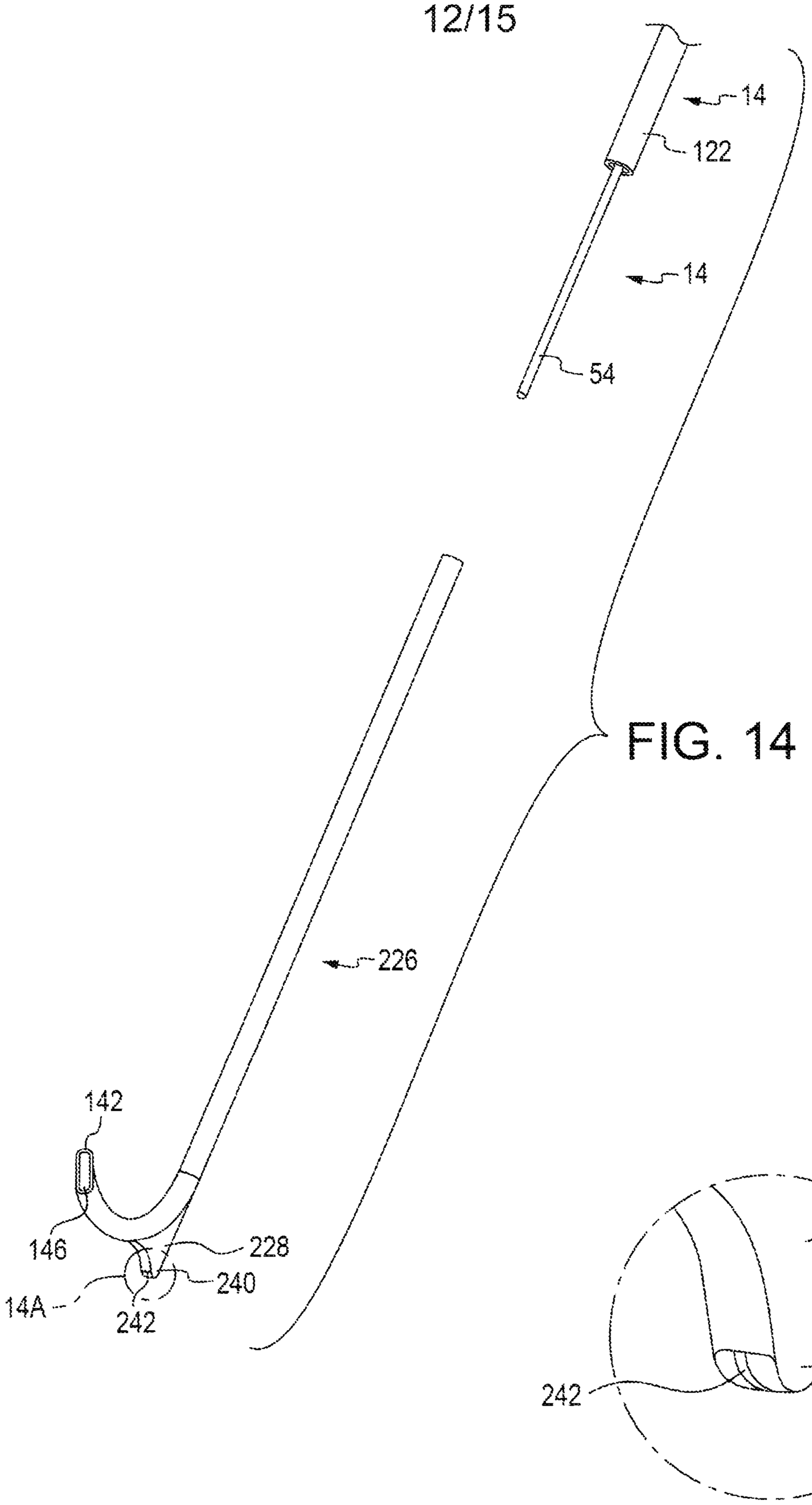

FIG. 14

FIG. 14A

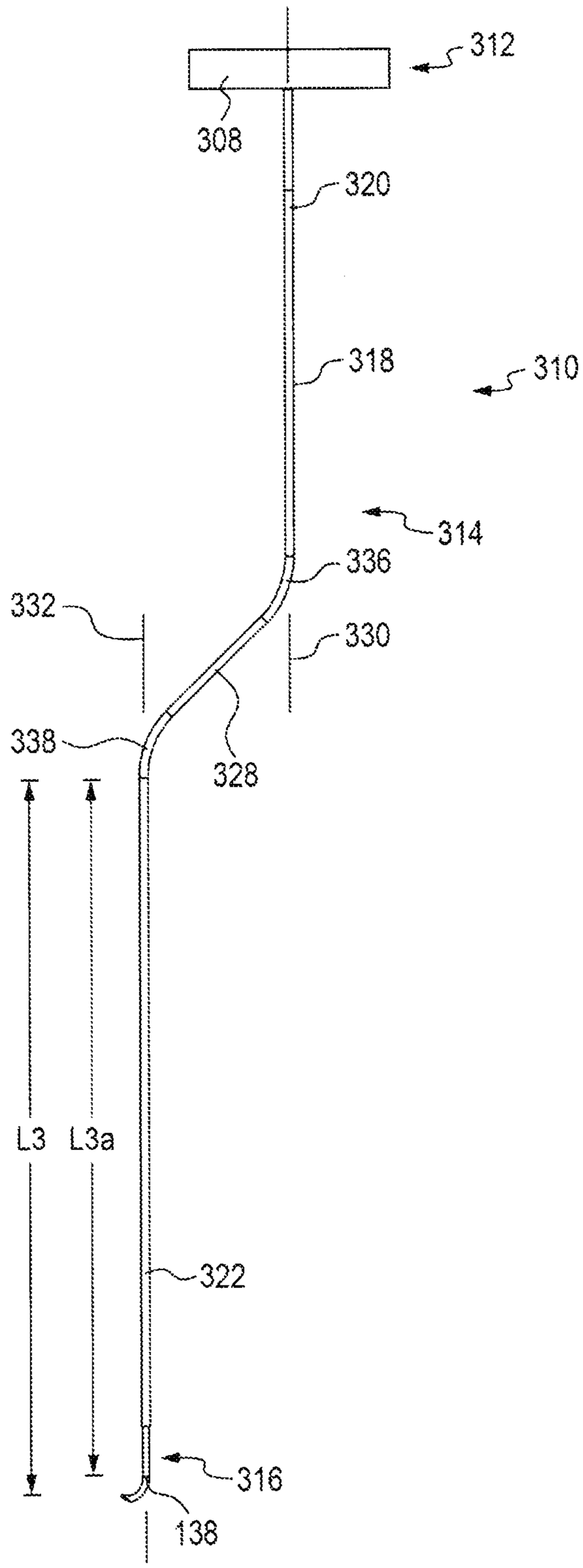

FIG. 15

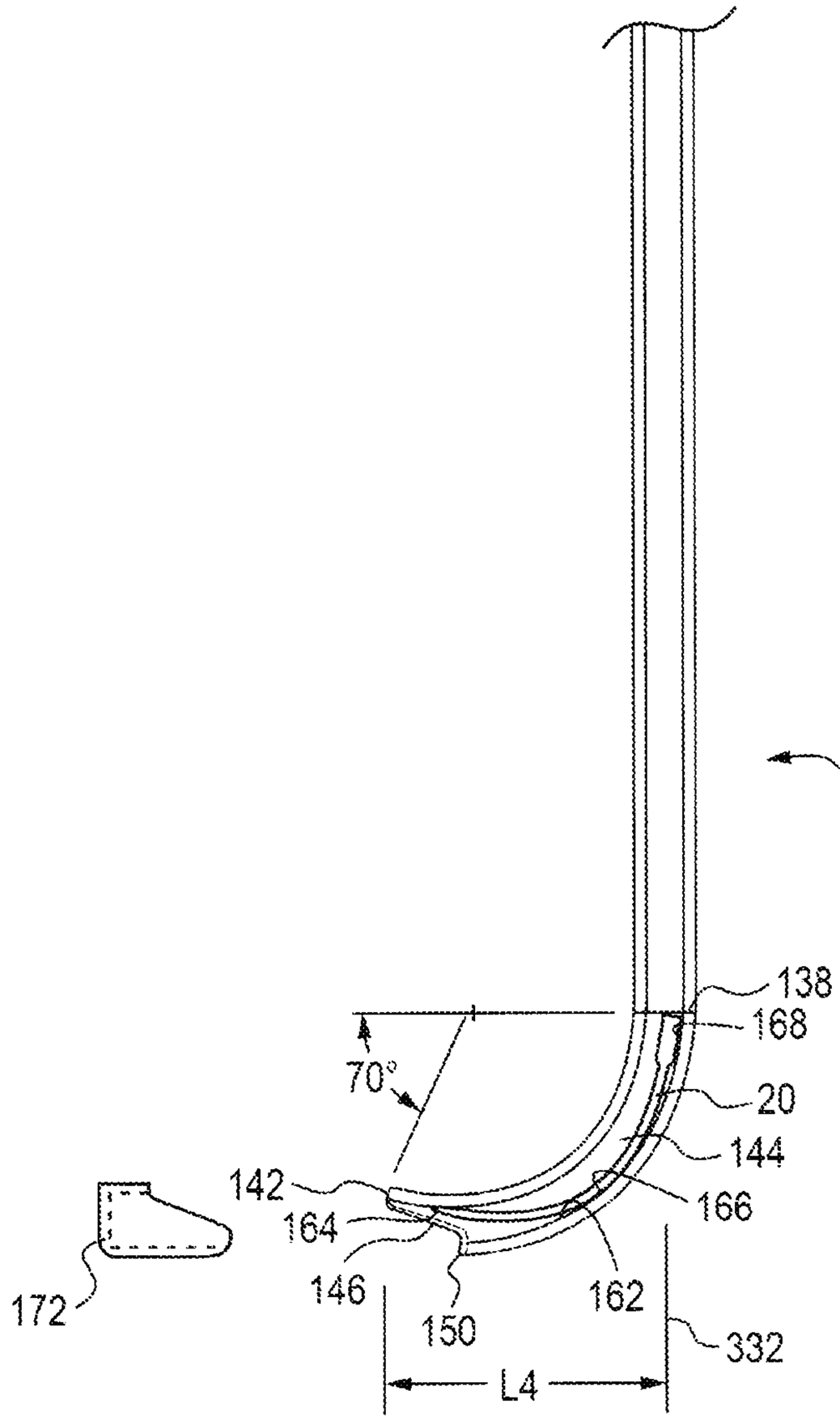

FIG. 16

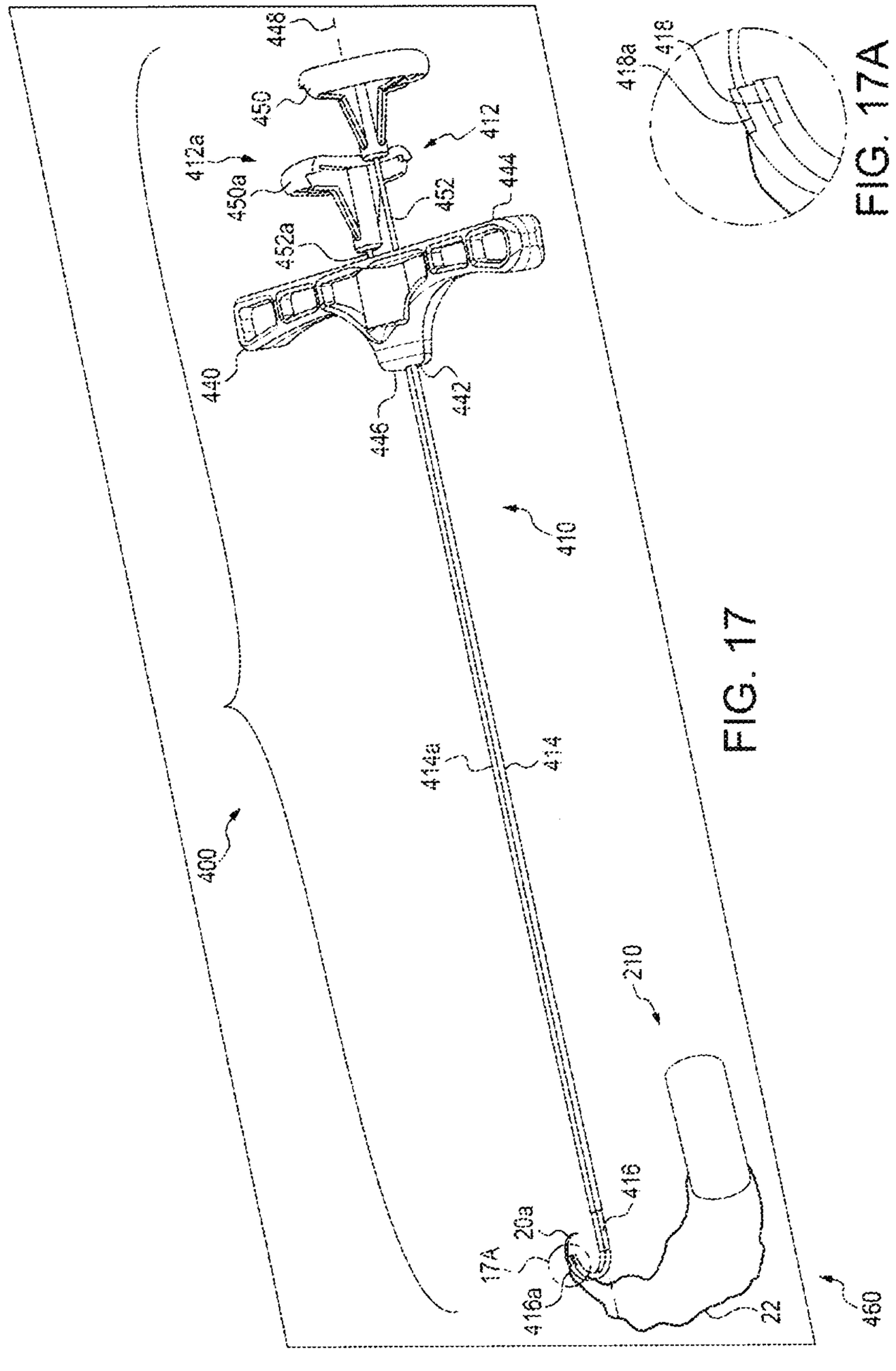
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FIG. 17A

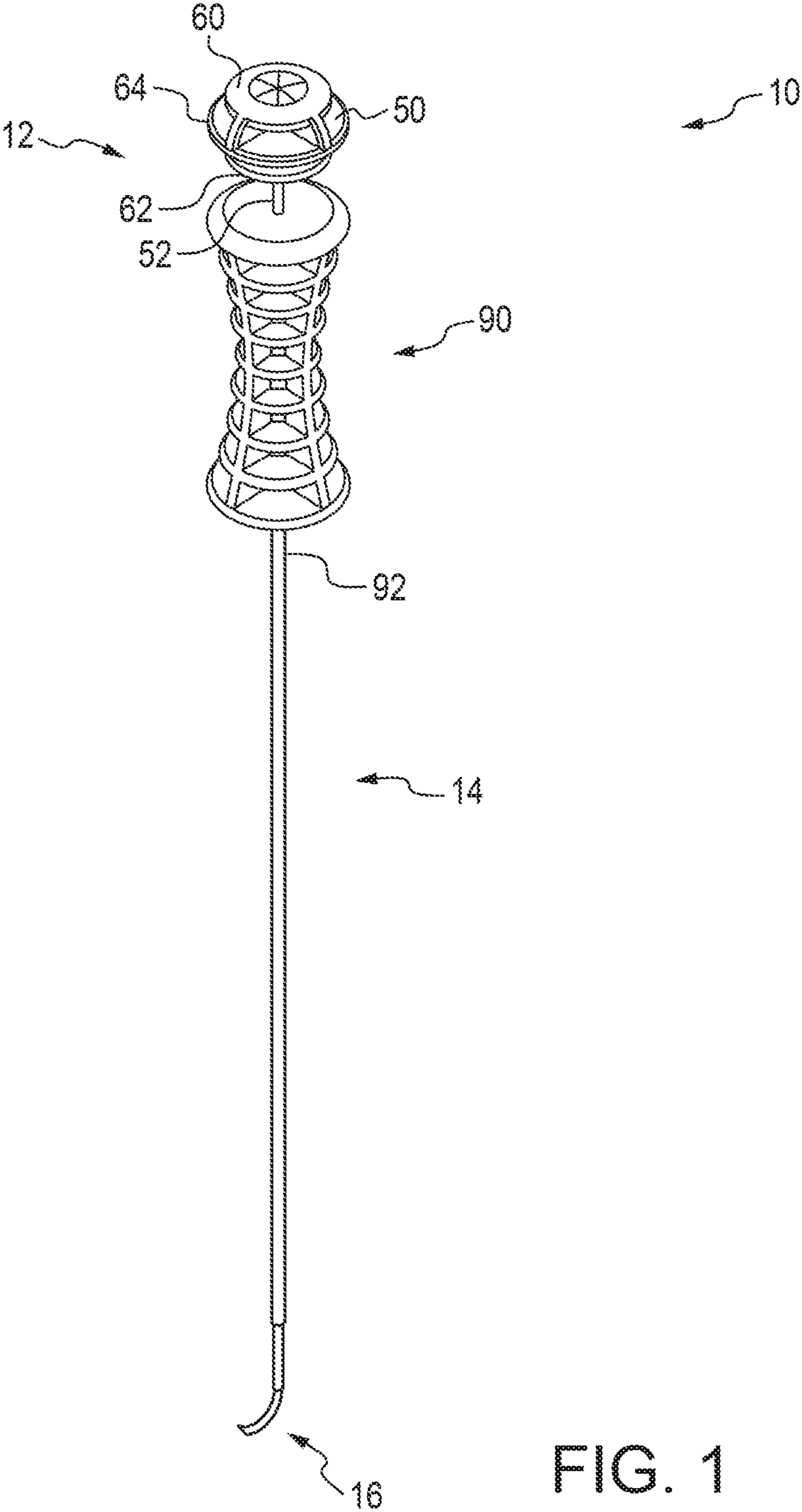

FIG. 1