US 20160278809A1

(19) **United States**

(12) **Patent Application Publication**

SATO

(10) **Pub. No.: US 2016/0278809 A1**

(43) **Pub. Date: Sep. 29, 2016**

(54) **PUNCTURE NEEDLE FOR ULTRASOUND ENDOSCOPE**

(71) Applicant: **OLYMPUS CORPORATION**, Tokyo (JP)

(72) Inventor: **Masatoshi SATO**, Tokyo (JP)

(73) Assignee: **OLYMPUS CORPORATION**, Tokyo (JP)

(21) Appl. No.: **15/175,566**

(22) Filed: **Jun. 7, 2016**

Related U.S. Application Data

(63) Continuation of application No. PCT/JP2014/082671, filed on Dec. 10, 2014.

(30) **Foreign Application Priority Data**

Dec. 12, 2013 (JP) 2013-257469

Publication Classification

(51) **Int. Cl.**

A61B 17/34	(2006.01)
A61B 1/018	(2006.01)
A61B 1/06	(2006.01)
A61B 8/12	(2006.01)
A61B 8/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/3478*** (2013.01); ***A61B 8/12*** (2013.01); ***A61B 8/445*** (2013.01); ***A61B 1/06*** (2013.01); ***A61B 1/018*** (2013.01)

(57) **ABSTRACT**

A puncture needle for an ultrasound endoscope is provided in which: a needle tube has a side hole configured in such a manner that, among a tube wall of the needle tube at a side more distal than a curved shape part, a part of a tube wall is cut off, the tube wall crossing a plane including a central line of the curved shape part, the tube wall being positioned on the inside of a curve of the curved shape part, and a wire being capable of being delivered from the side hole; and at least a part of the wire is positioned at the curved shape part in a state that the wire is stretched and loaded into the needle tube.

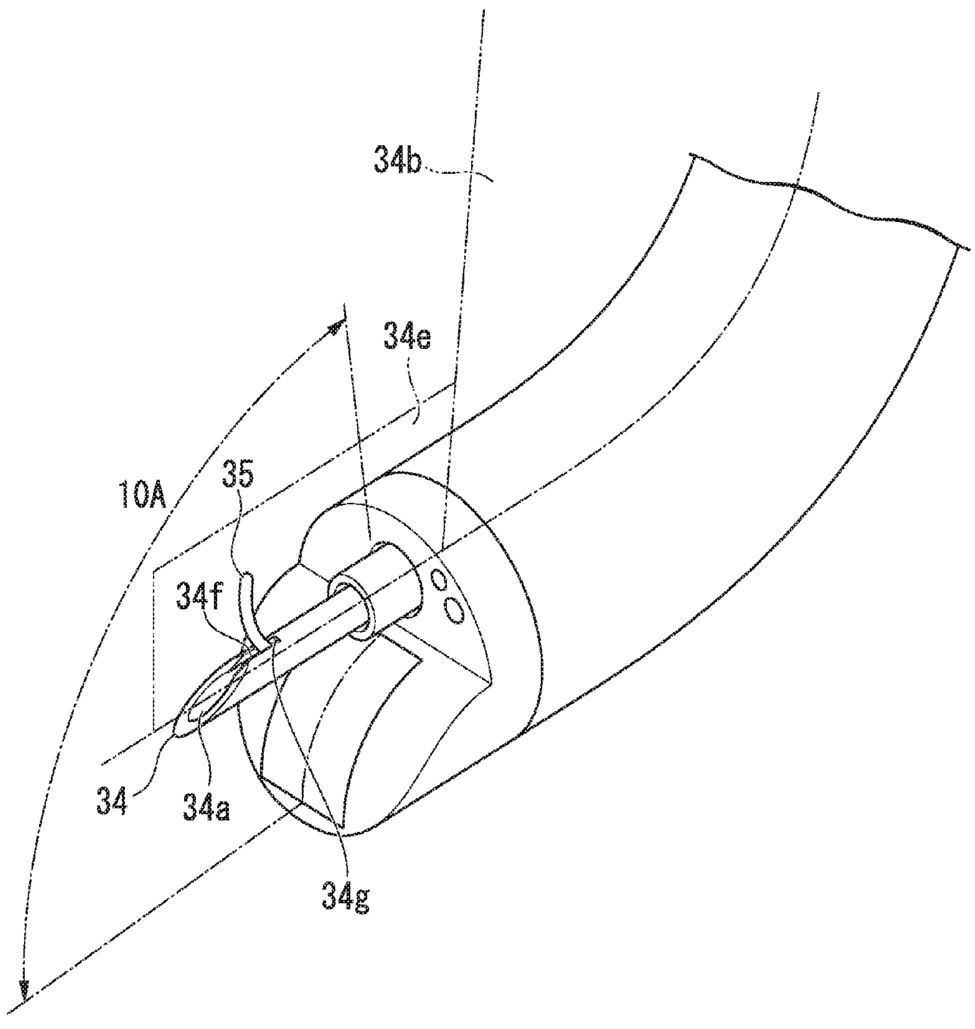


FIG. 1

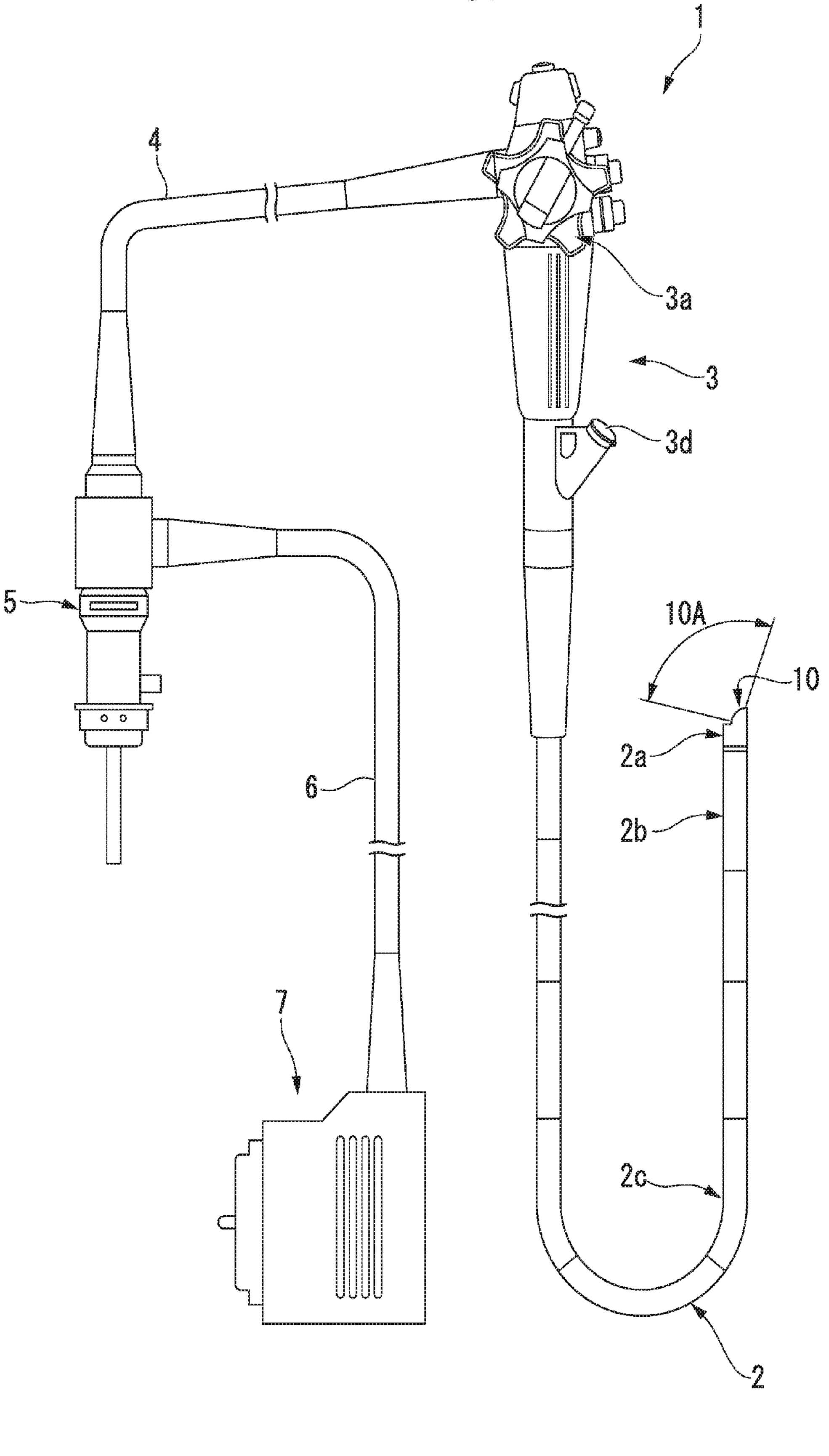


FIG. 2

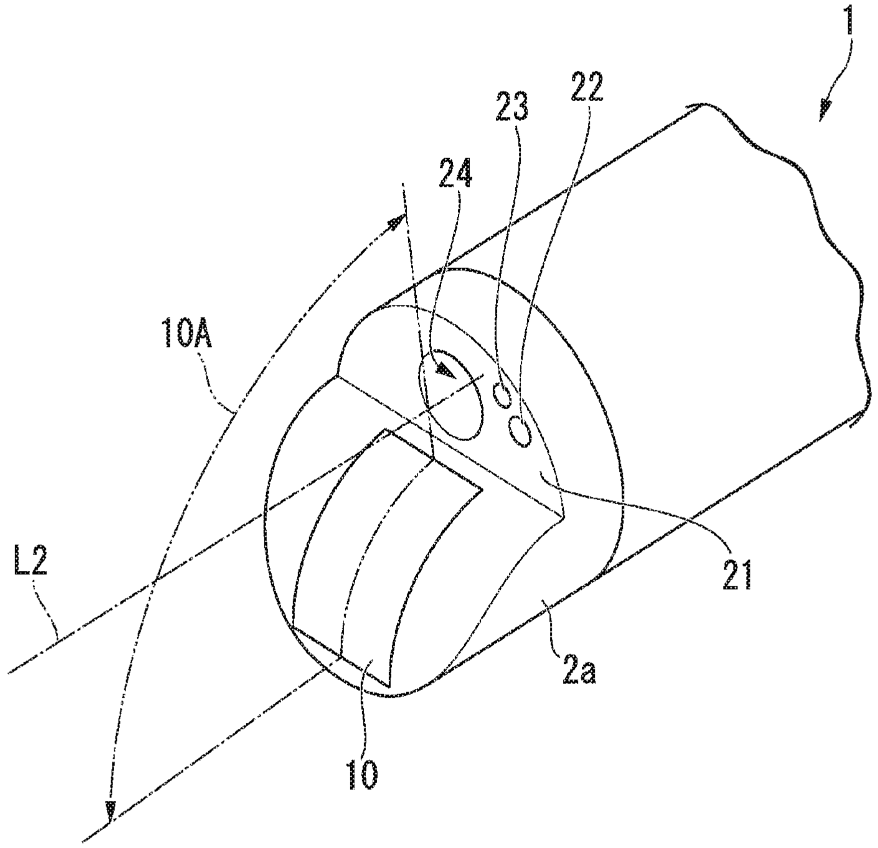


FIG. 3

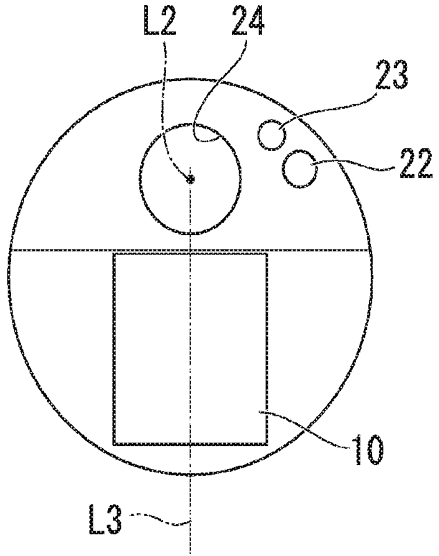


FIG. 4

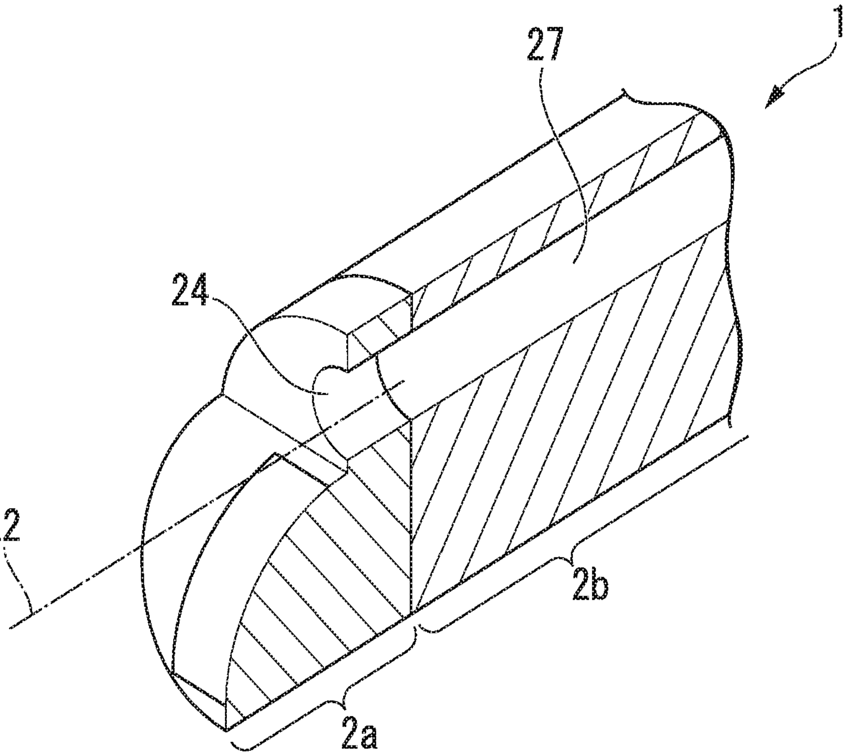


FIG. 5

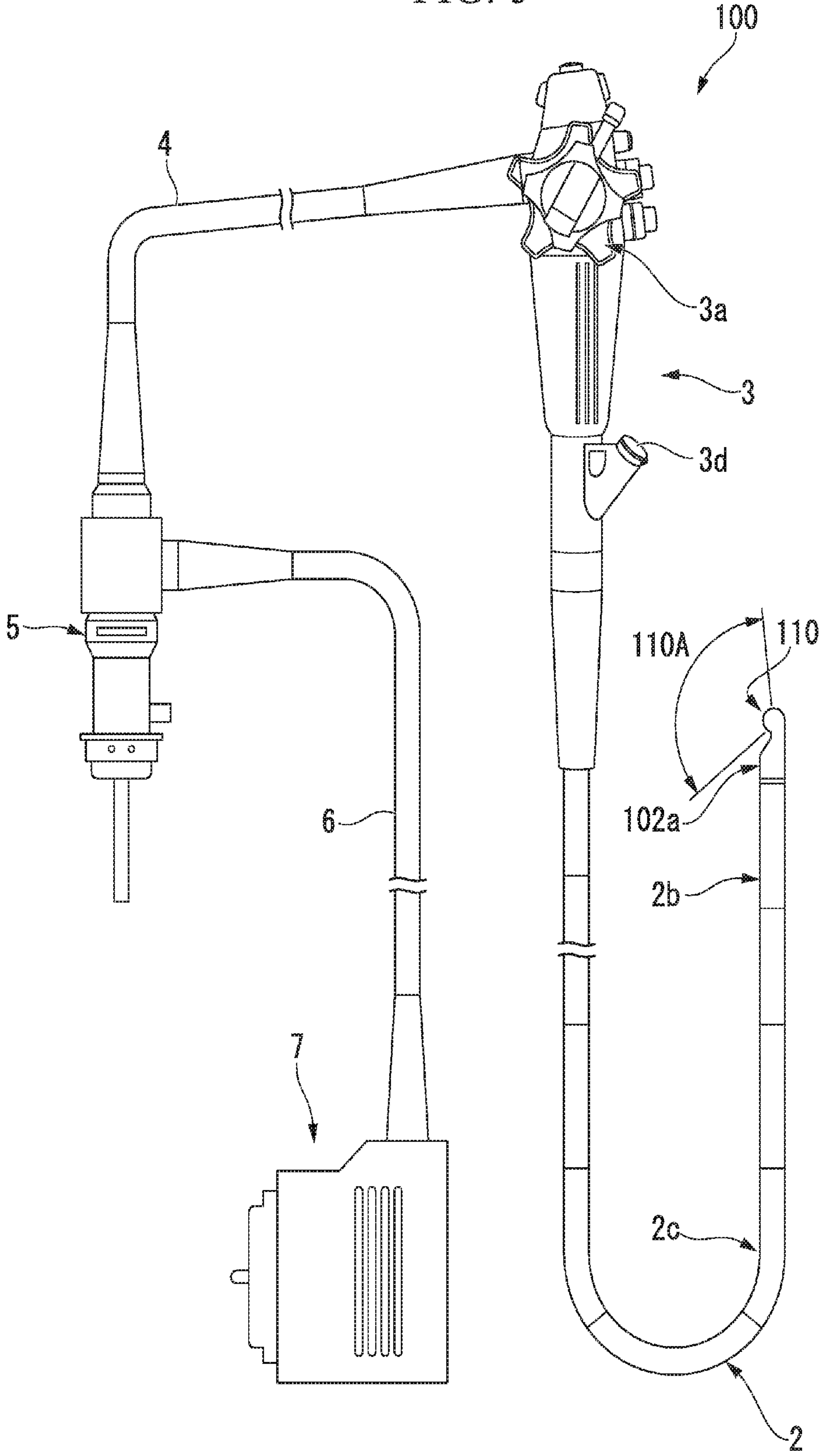


FIG. 6

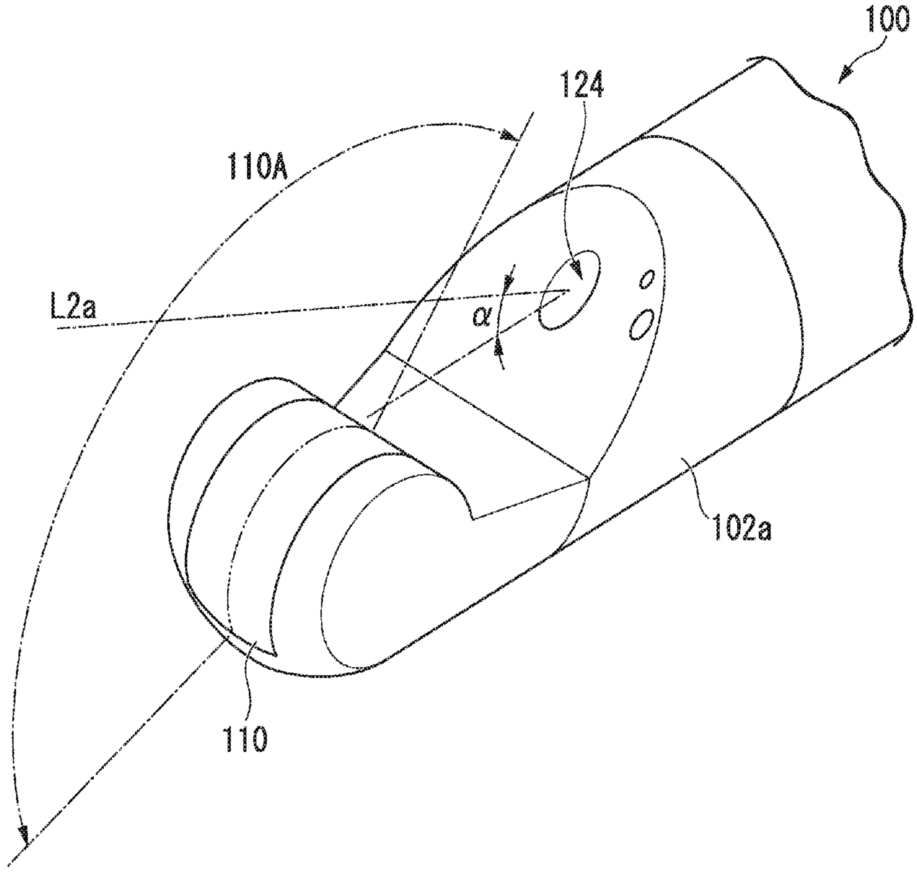


FIG. 7

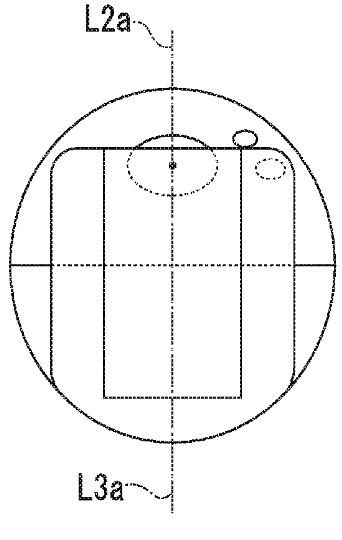


FIG. 8

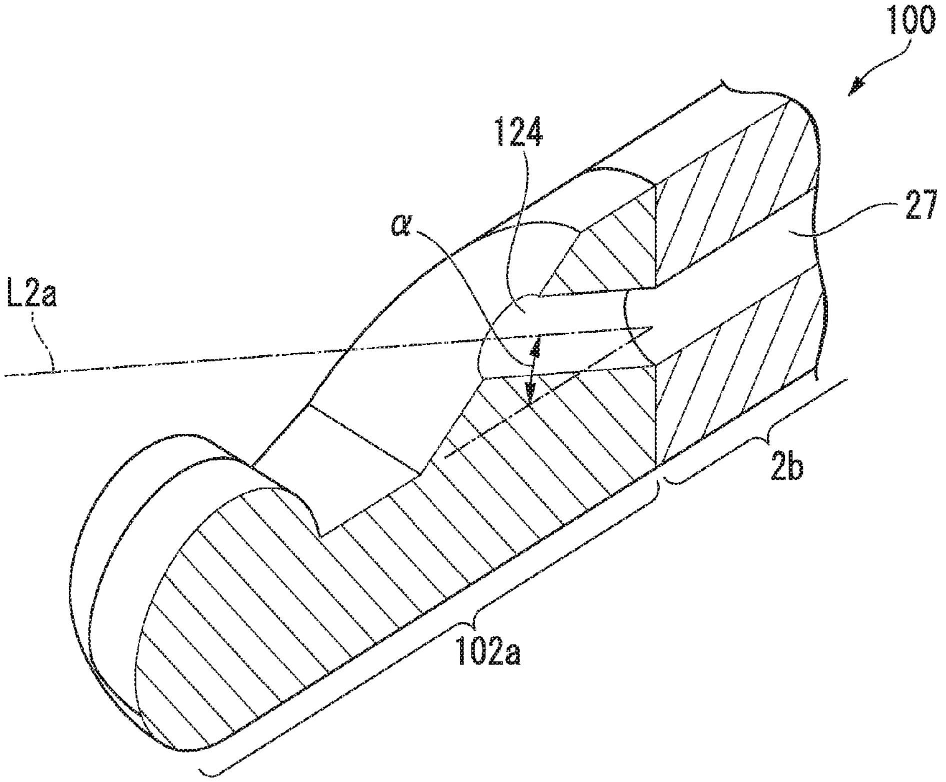


FIG. 9

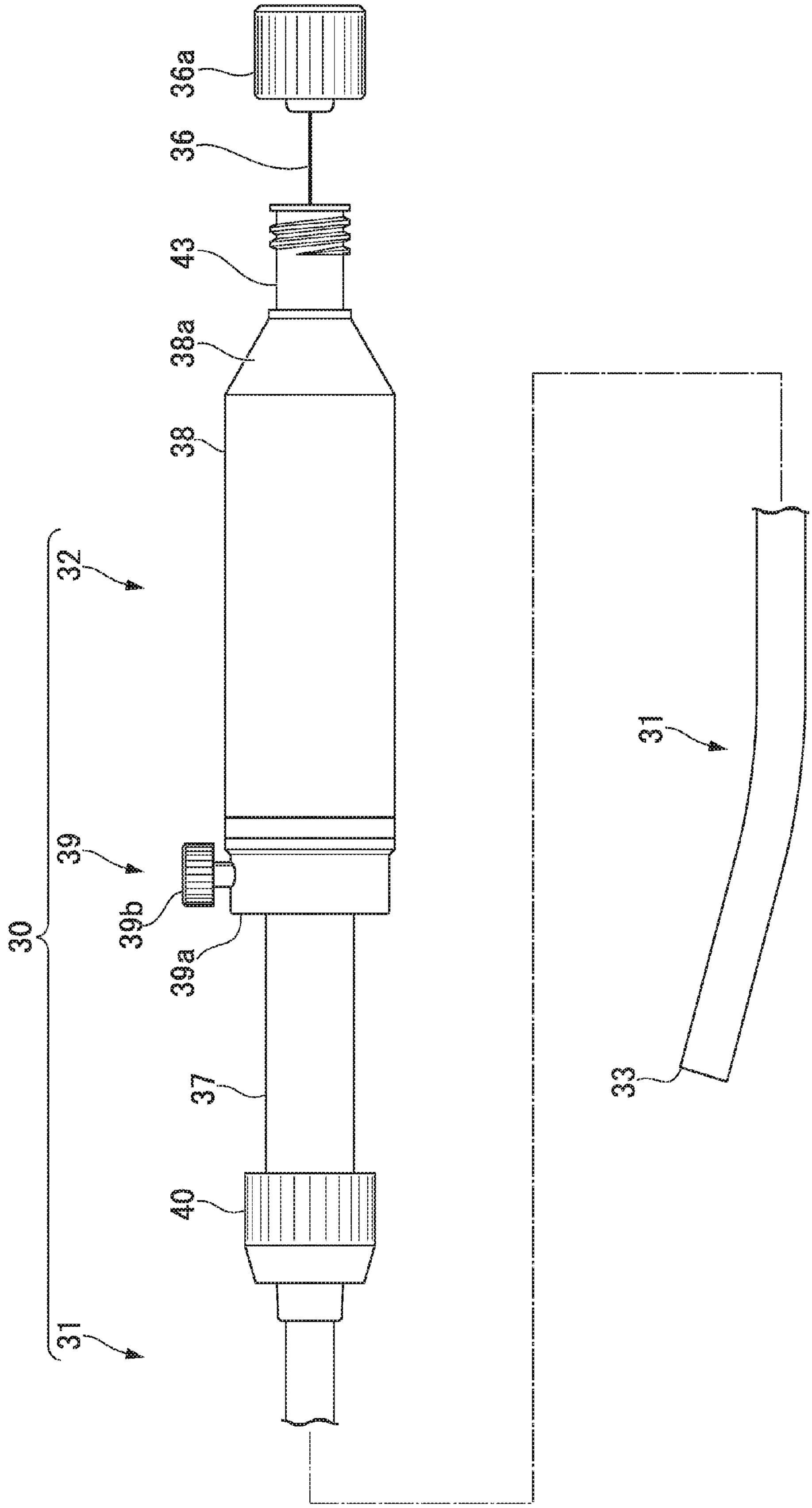


FIG. 10

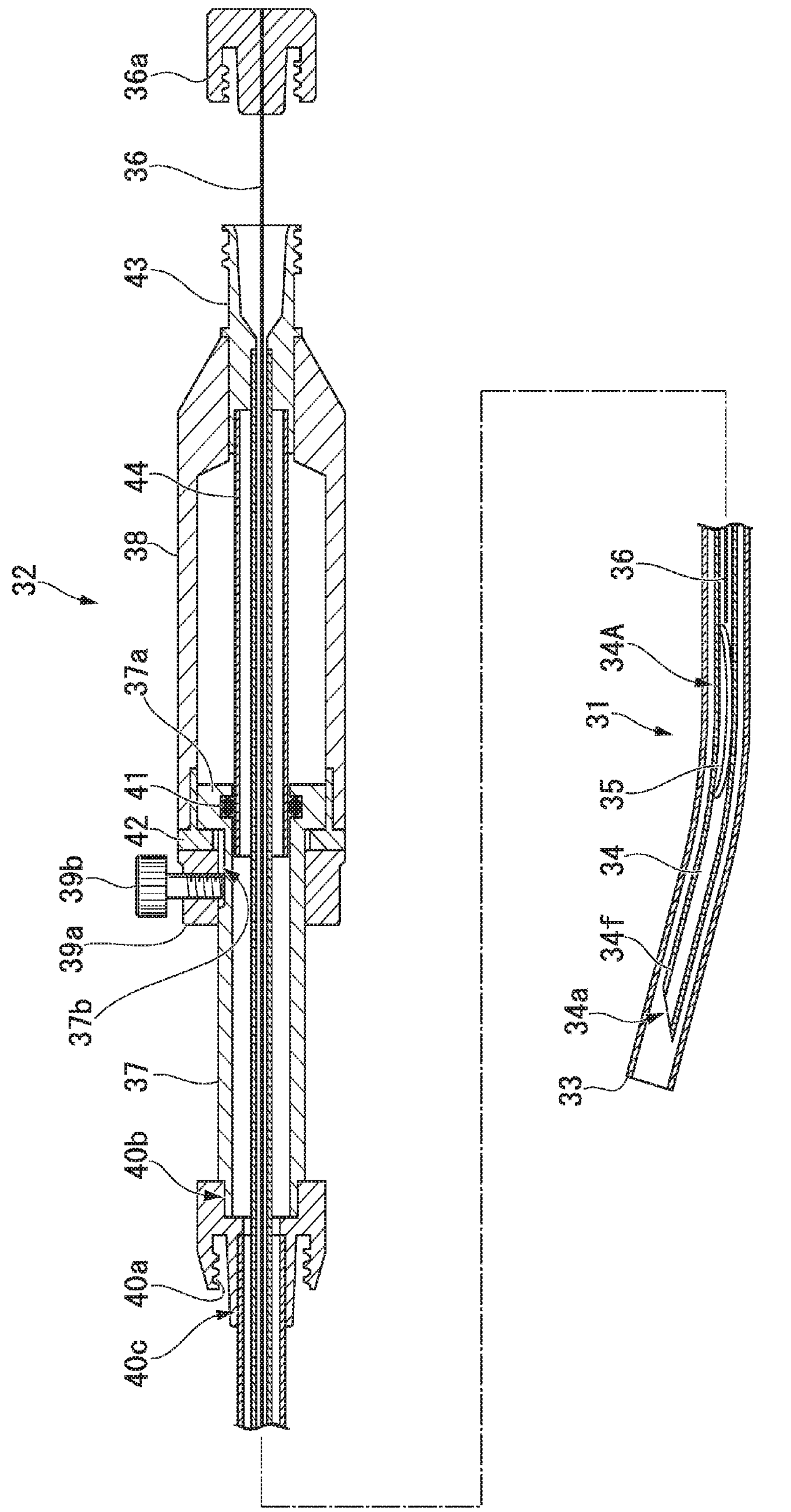

36a
36
43
44
38
32
37a
41
42
39b
39a
37b
37
40b
40a
40c
36
34A
31
35
34
34f
34a
33

FIG. 11

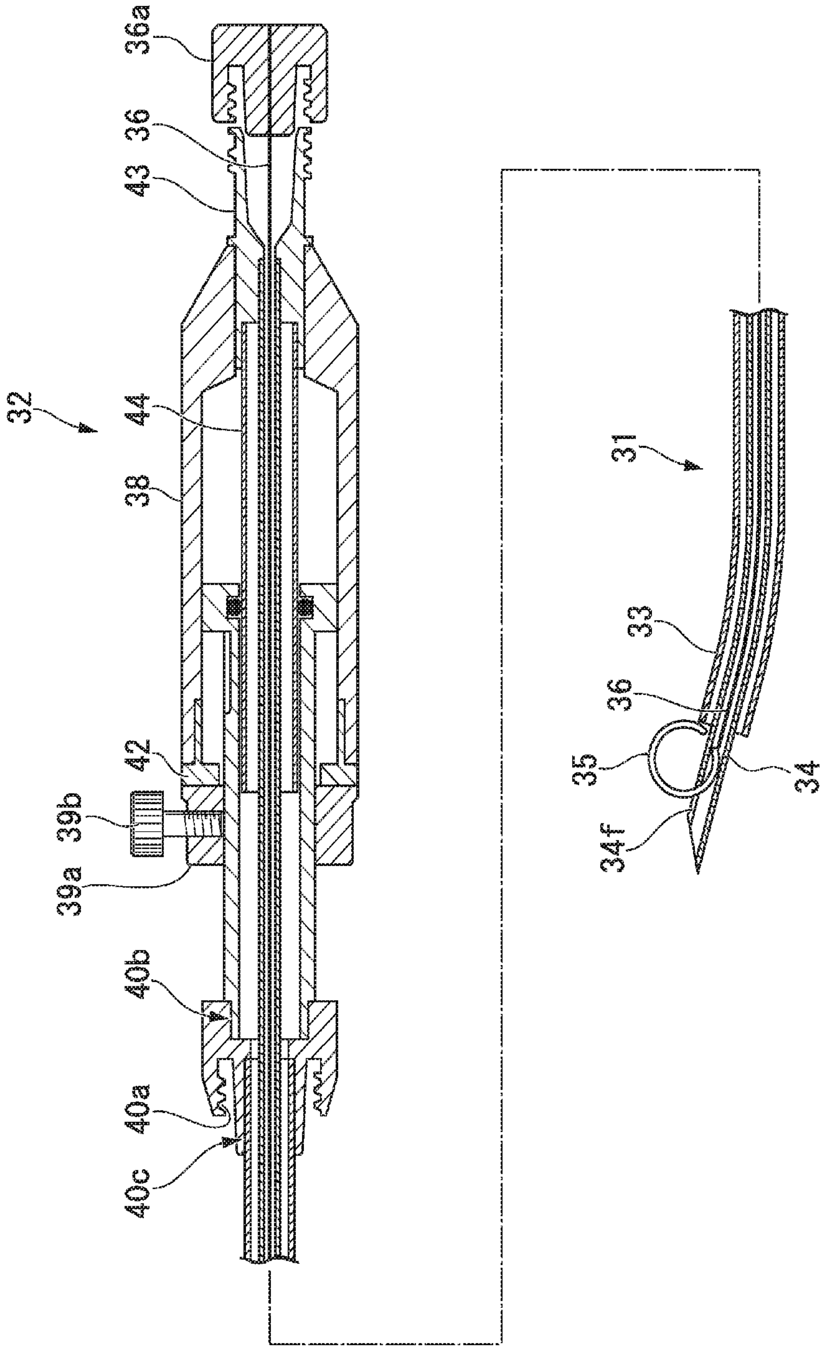


FIG. 12A

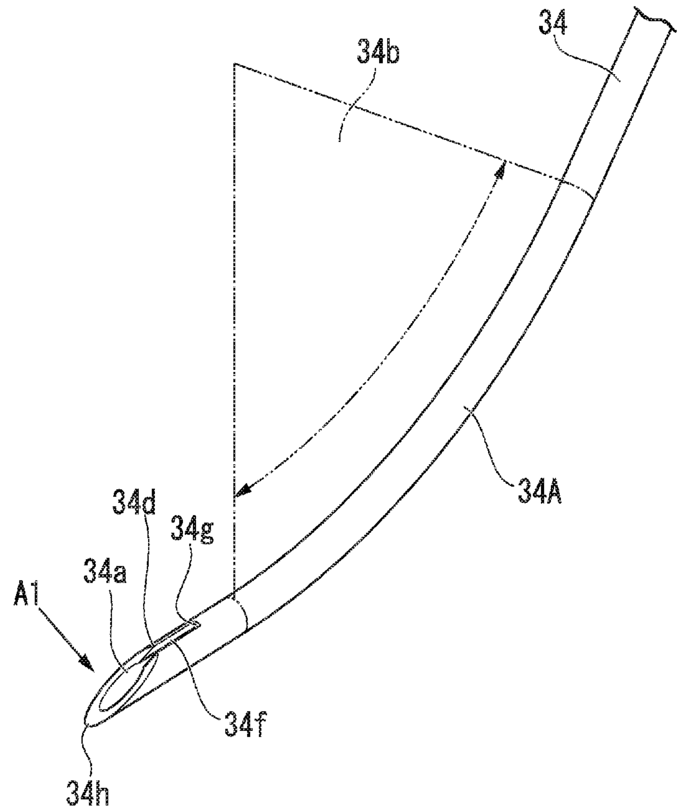


FIG. 12B

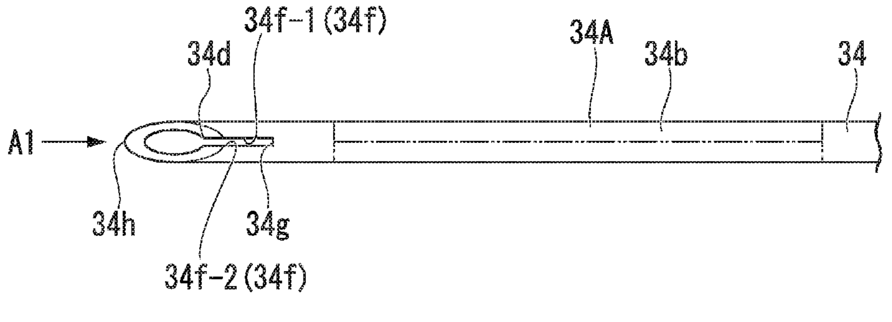


FIG. 13A

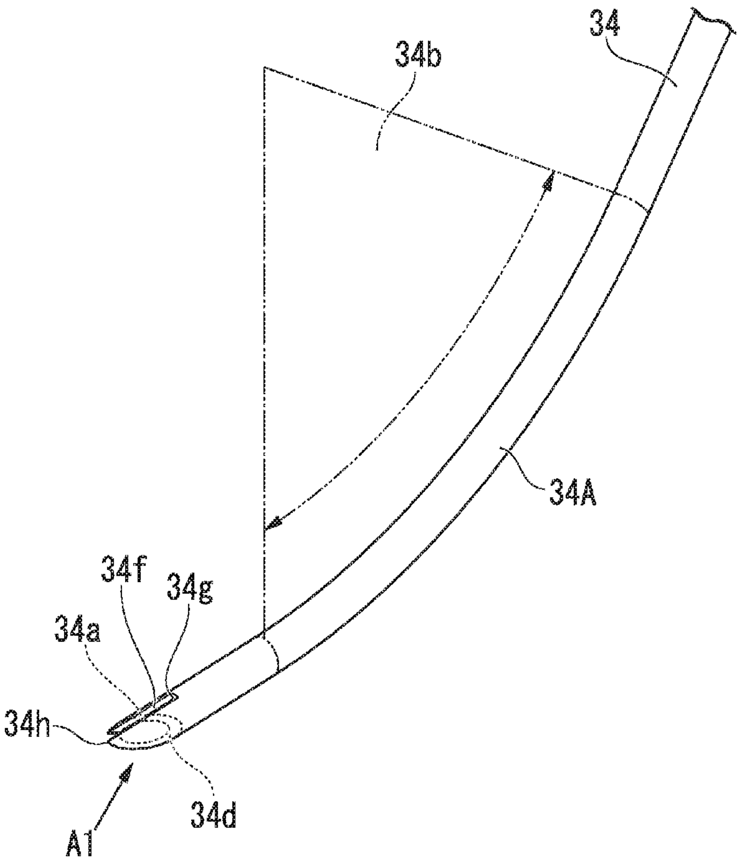


FIG. 13B

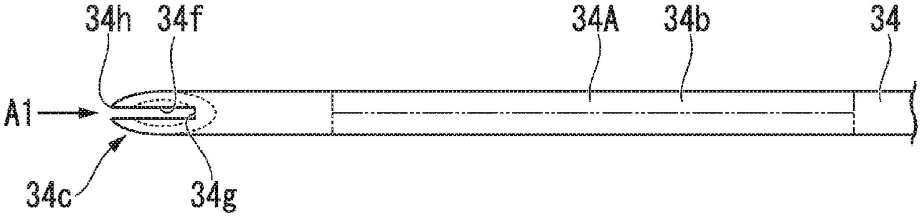


FIG. 14A

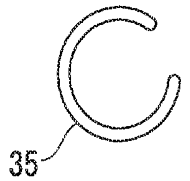


FIG. 14B

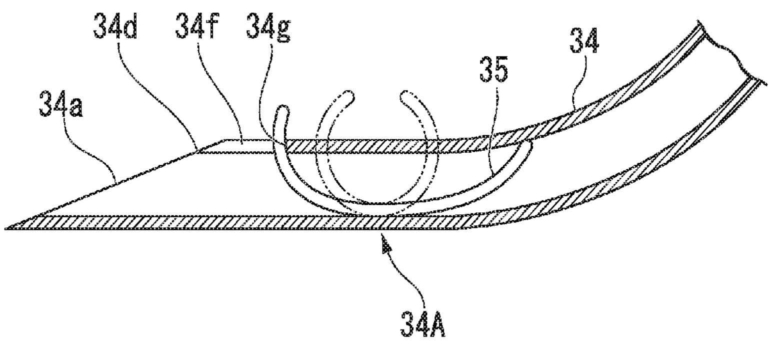


FIG. 15

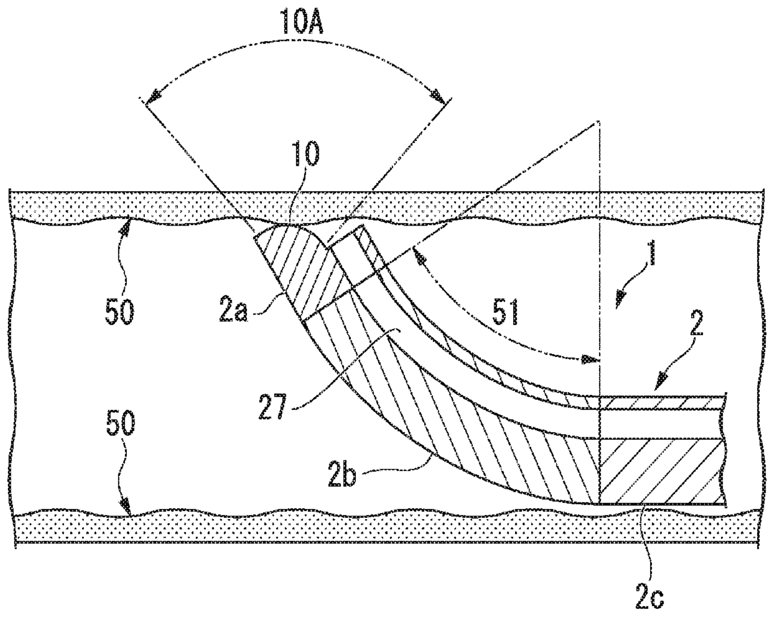


FIG. 16A

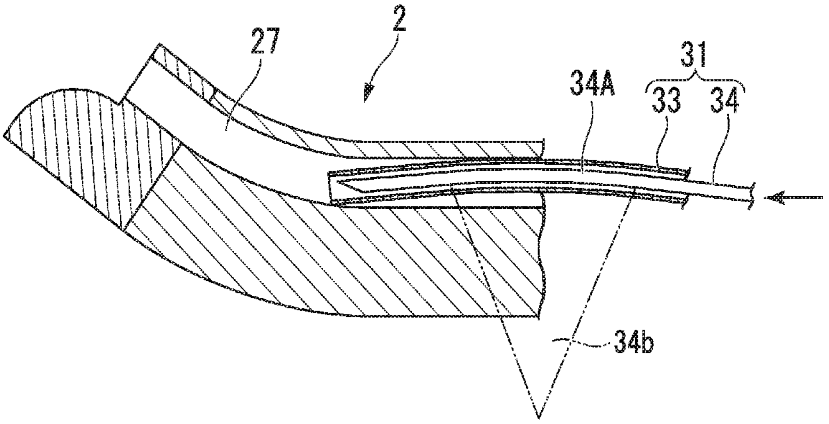


FIG. 16B

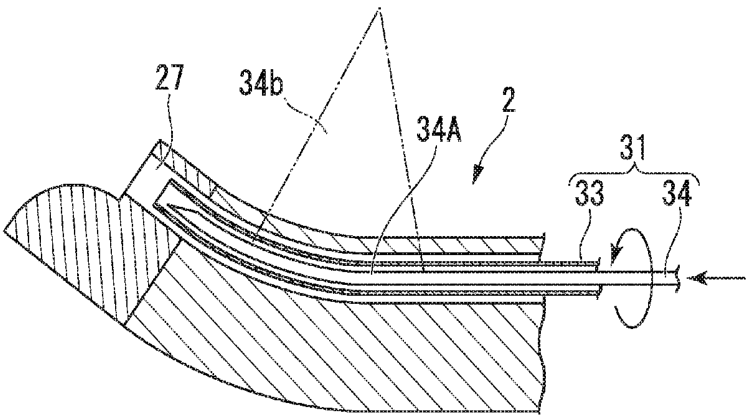


FIG. 16C

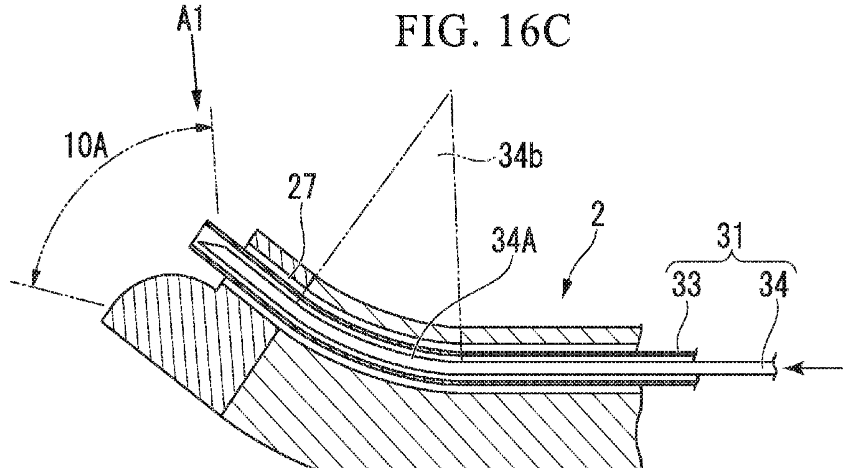


FIG. 17

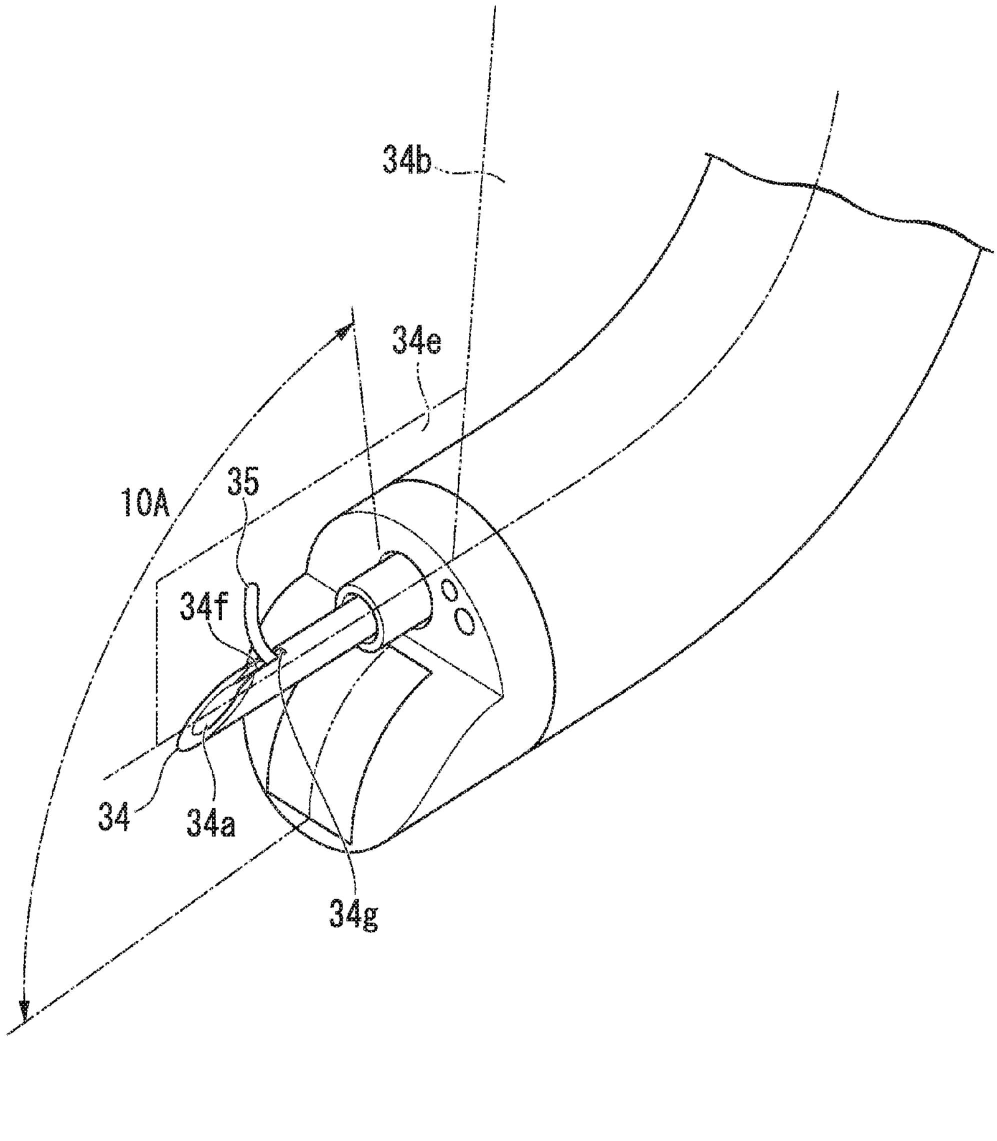


FIG. 18

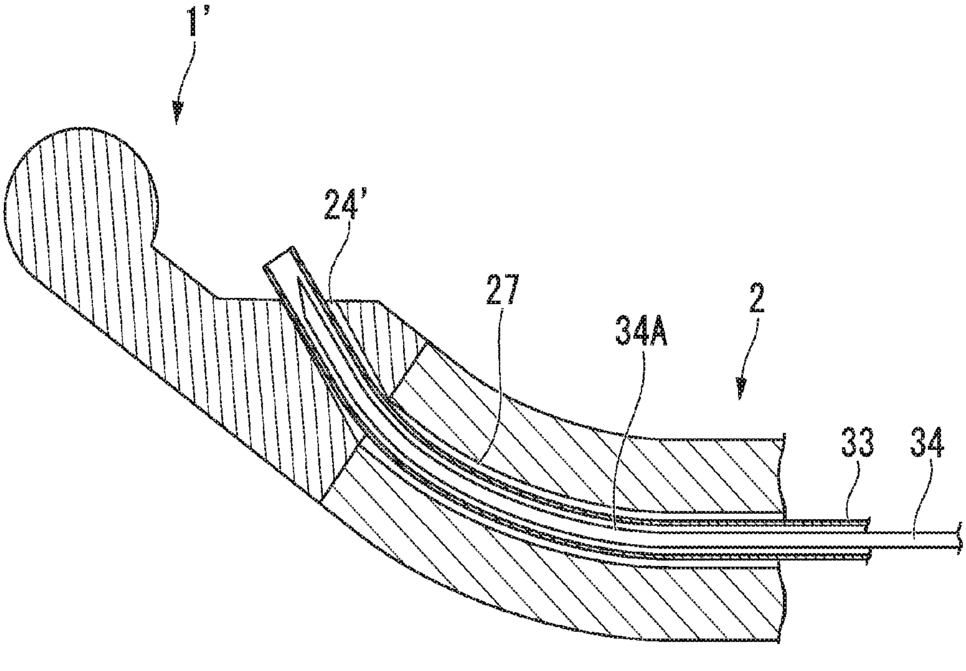


FIG. 19

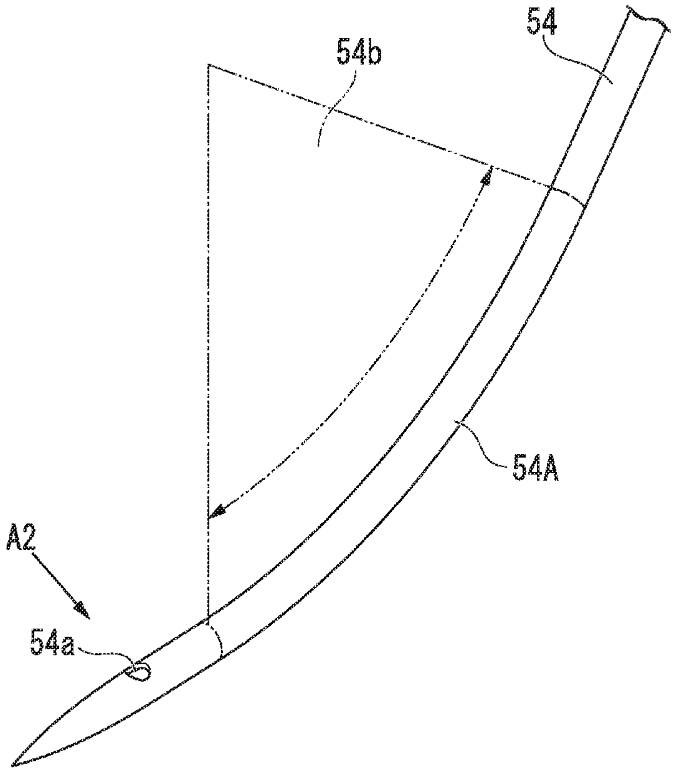


FIG. 20

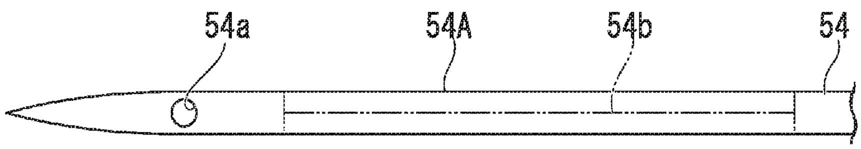


FIG. 21

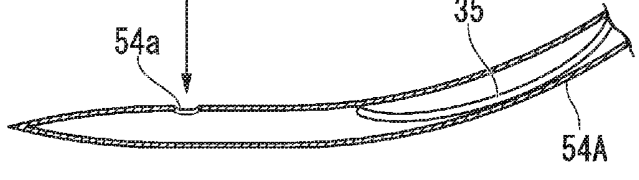


FIG. 22

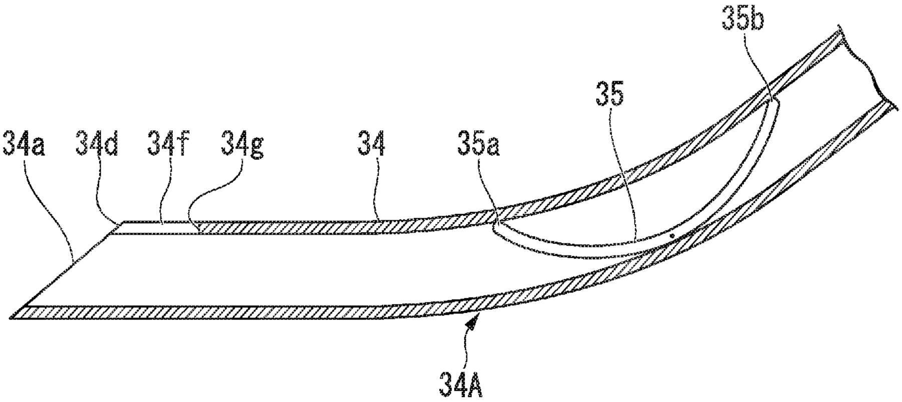


FIG. 23

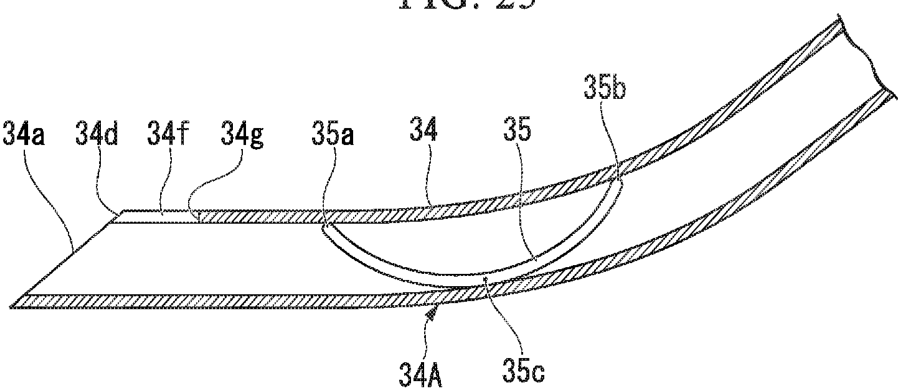
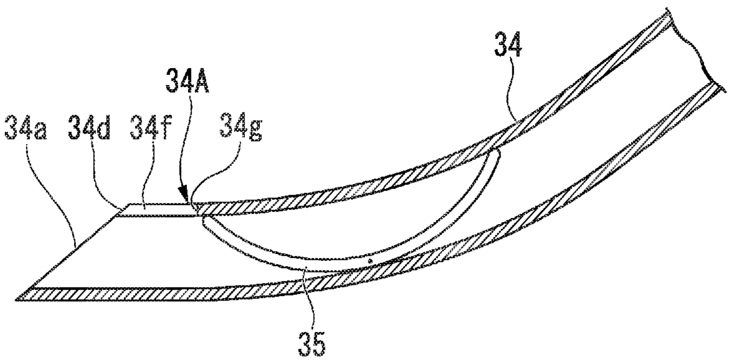


FIG. 24



PUNCTURE NEEDLE FOR ULTRASOUND ENDOSCOPE

[0001] This application is a continuation application based on PCT Patent Application No. PCT/JP2014/082671, filed Dec. 10, 2014, whose priority is claimed on Japanese Patent Application No. 2013-257469, filed Dec. 12, 2013. The contents of both the PCT Patent Application and the Japanese Patent Application are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to a puncture needle for an ultrasound endoscope which is inserted into a body cavity and used for delivering a medicine or a treatment device into a body.

[0004] 2. Description of Related Art

[0005] Conventionally, a surgical technique for aspirating and collecting a tissue in a body cavity or a body fluid has been performed for examining or diagnosing an affected area in the body cavity. The surgical technique is performed by, while observing the inside of the body cavity by means of an ultrasound endoscope, piercing a digestive tract wall or the like of a stomach or a duodenum using a puncture needle, and puncturing, with the puncture needle, a target site of an underlying organ such as a pancreas, a liver, and a kidney. The surgical technique is called an endoscopic ultrasound-guided fine needle aspiration (EUS-FNA).

[0006] In recent years, as an advanced application of the EUS-FNA surgical technique, a surgical technique for treatment has been studied which delivers a substance such as a medicine, a marker, and a radiation source directly to an interest site from a puncture needle, instead of aspirating a tissue or a body fluid. By using this surgical technique for treatment, a treatment effect is expected to be improved and a side effect is expected to be reduced since a substance is accurately delivered to an interest site. Therefore, it is preferable to perform the surgical technique while observing, through an ultrasound endoscope, a substance that is actually being delivered.

[0007] In addition, an apparatus that places a tool in a living tissue is known (for example, refer to Published Japanese Translation No. 2000-515054 of the PCT International Publication and Published Japanese Translation No. 2008-504943 of the PCT International Publication). Specifically, a tool such as a clip and a fastener to be placed in a living tissue is loaded into a distal end of a puncture needle, and placed by the apparatus.

SUMMARY OF THE INVENTION

[0008] According to a first aspect of the present invention, a puncture needle used with an ultrasound endoscope, which has a bendable part capable of being operated to be bent and is configured such that a central axis extending from an outlet of an insertion channel substantially coincides with an ultrasound observation plane, includes: a sheath configured to be freely advanced or retracted in the insertion channel, the sheath being configured to be capable of being inserted into the insertion channel; a needle tube having an outer surface and an inner surface that forms an internal space extending along a longitudinal axis of the needle tube, the needle tube being capable of being inserted into the sheath; a wire having a proximal end and a distal end, the wire having elasticity such that the wire is restored to a wind shape in an absence of external force, the wire being stretched and loaded into the internal space of the needle tube against restoration to the wind shape such that the wire is supported by portions of the inner surface of the needle tube which are spaced apart from one another in the longitudinal axis direction of the needle tube; a side hole formed to open from the inner surface to the outer surface of the needle tube, the side hole having a pair of wall surfaces which are spaced apart from one another, the side hole having an opening width larger than an external diameter of the wire; and a stylet configured to push the proximal end of the wire loaded within the needle tube. In a state that the needle tube projects from the insertion channel and the distal end of the wire is pushed from the side hole by the stylet, the pair of wall surfaces support the wire such that the wire is sandwiched between the pair of wall surfaces, and a section of the inner surface facing the side hole supports the wire within the needle tube, such that the distal end of the wire is restored to the wind shape in the ultrasound observation plane.

[0009] According to a second aspect of the present invention, in the puncture needle according to the first aspect, each of the portions of the inner surface of the needle tube supporting the wire may be positioned on a prescribed plane.

[0010] According to a third aspect of the present invention, the puncture needle according to the second aspect may further include a needle tube curved shape part formed at a distal side of the needle tube, the needle tube curved shape part having elasticity such that the needle tube curved shape part is restored to a curved shape along the prescribed plane in an absence of external force.

[0011] According to a fourth aspect of the present invention, the puncture needle according to the second aspect may further include a needle tube distal part having a needle tip formed to be sharpened to puncture a tissue within a body cavity, the needle tube distal part being formed at a side more distal than the needle tube curved shape part. The side hole may be formed at the needle tube distal part and opens toward an inside of the curved shape of the needle tube curved shape part. In a state that the distal end of the wire is arranged inside the needle tube curved shape part positioned in the insertion channel, as the insertion channel is bent by the bendable part, the needle tube curved shape part may follow a curve of the insertion channel, and the wire may receive a force from the inner surface of the needle tube in the needle tube curved shape part, so that the wire may rotate such that the wind shape of the wire follows the curved shape of the needle tube curved shape part, and the distal end of the wire may be positioned on the ultrasound observation plane.

[0012] According to a fifth aspect of the present invention, in the puncture needle according to the first aspect, in a state that the wire is supported by the portions of the inner surface of the needle tube which are spaced apart from one another in the longitudinal axis direction of the needle tube, the portions supporting the wire may be positioned on a plane which includes the side hole and which is along a central axis of the needle tube, and the portions may hold the wire between a proximal end of the side hole and the stylet.

[0013] According to a sixth aspect of the present invention, in the puncture needle according to the first aspect, the wire may be positioned within a range of the opening width of the side hole in a circumferential direction of the needle tube.

[0014] According to a seventh aspect of the present invention, in the puncture needle according to the second aspect, in a state that the distal end of the wire is restored to the wind shape in the ultrasound observation plane and the pair of wall surfaces support the wire such that the wire is sandwiched between the pair of wall surfaces, the proximal end of the wire and a central part between the distal end and the proximal end of the wire may be positioned on the prescribed plane.

[0015] According to an eighth aspect of the present invention, in the puncture needle according to the second aspect, the distal end, the proximal end, and a central part between the distal end and the proximal end of the wire may be positioned on the prescribed plane.

[0016] According to a ninth aspect of the present invention, in the puncture needle according to the first aspect, a distal end opening which is in communication with the internal space may be opened at a distal end of the needle tube. The distal end opening may be in communication with a distal end of the side hole.

[0017] According to a tenth aspect of the present invention, in the puncture needle according to the third aspect, the distal end of the wire positioned at a distal side of the needle tube may be positioned at the needle tube curved shape part in a state that the wire is stretched and loaded into the needle tube.

[0018] According to an eleventh aspect of the present invention, in the puncture needle according to the third aspect, a central part of the wire may be positioned at the needle tube curved shape part in a state that the wire is stretched and loaded into the needle tube.

[0019] According to a twelfth aspect of the present invention, in the puncture needle according to the third aspect, a proximal end of the side hole may be positioned at the needle tube curved shape part.

[0020] According to a thirteenth aspect of the present invention, in the puncture needle according to the first aspect, the wire may have an arc shape.

[0021] According to a fourteenth aspect of the present invention, in the puncture needle according to the thirteenth aspect, the arc shape may be a C-shape.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] FIG. **1** is an overall view showing an ultrasound endoscope which is used in combination with a puncture needle for an ultrasound endoscope according to a first embodiment of the present invention.

[0023] FIG. **2** is a perspective view showing a distal end part of the ultrasound endoscope.

[0024] FIG. **3** is a front view of the distal end part of the ultrasound endoscope.

[0025] FIG. **4** is a perspective cross-sectional view of the distal end part of the ultrasound endoscope.

[0026] FIG. **5** is an overall view showing another ultrasound endoscope which is used in combination with the puncture needle for an ultrasound endoscope according to the first embodiment of the present invention.

[0027] FIG. **6** is a perspective view showing a distal end part of another ultrasound endoscope according to the first embodiment of the present invention.

[0028] FIG. **7** is a front view showing the distal end part of the other ultrasound endoscope.

[0029] FIG. **8** is a perspective cross-sectional view of the distal end part of the other ultrasound endoscope.

[0030] FIG. **9** is an overall external view of the puncture needle for an ultrasound endoscope according to the first embodiment of the present invention.

[0031] FIG. **10** is an overall cross-sectional view of the puncture needle for an ultrasound endoscope according to the first embodiment of the present invention.

[0032] FIG. **11** is an overall cross-sectional view of the puncture needle for an ultrasound endoscope according to the first embodiment of the present invention.

[0033] FIG. **12**A is a view showing a distal end side of a needle tube of the puncture needle for an ultrasound endoscope according to the first embodiment of the present invention.

[0034] FIG. **12**B is a view showing the distal end side of the needle tube of the puncture needle for an ultrasound endoscope according to the first embodiment of the present invention.

[0035] FIG. **13**A is a view showing a distal end side of another exemplary needle tube according to the first embodiment of the present invention.

[0036] FIG. **13**B is a view showing a distal end side of another exemplary needle tube according to the first embodiment of the present invention.

[0037] FIG. **14**A is a view of an implant to be housed within the needle tube according to the first embodiment and a second embodiment of the present invention.

[0038] FIG. **14**B is a view showing the implant to be housed within the needle tube according to the first embodiment of the present invention, housed in the needle tube according to the first embodiment.

[0039] FIG. **15** is a view showing operation of the ultrasound endoscope during the use of the puncture needle for an ultrasound endoscope according to the first embodiment of the present invention.

[0040] FIG. **16**A is a view showing operation of the puncture needle for an ultrasound endoscope according to the first embodiment within the bent ultrasound endoscope.

[0041] FIG. **16**B is a view showing the operation of the puncture needle for an ultrasound endoscope according to the first embodiment within the bent ultrasound endoscope.

[0042] FIG. **16**C is a view showing the operation of the puncture needle for an ultrasound endoscope according to the first embodiment within the bent ultrasound endoscope.

[0043] FIG. **17** is a view showing the implant discharged from the puncture needle for an ultrasound endoscope according to the first embodiment.

[0044] FIG. **18** is a view showing the puncture needle for an ultrasound endoscope according to the first embodiment inserted into the other ultrasound endoscope.

[0045] FIG. **19** is a view showing a distal end side of a needle tube of a puncture needle for an ultrasound endoscope according to a second embodiment of the present invention.

[0046] FIG. **20** is a view showing the distal end side of the needle tube of the puncture needle for an ultrasound endoscope according to the second embodiment of the present invention.

[0047] FIG. **21** is a view showing the distal end side of the needle tube of the puncture needle for an ultrasound endoscope according to the second embodiment of the present invention.

[0048] FIG. **22** is a partial cross-sectional view showing an exemplary design change for the above-mentioned embodiments.

[0049] FIG. **23** is a partial cross-sectional view showing another exemplary design change for the above-mentioned embodiments.

[0050] FIG. **24** is a partial cross-sectional view showing still another exemplary design change for the above-mentioned embodiments.

DETAILED DESCRIPTION OF THE INVENTION

[0051] Hereinafter, embodiments of the present invention will be described with reference to the drawings.

First Embodiment

[0052] A puncture needle for an ultrasound endoscope according to the present embodiment is used in combination with an ultrasound endoscope.

[0053] The ultrasound endoscope according to the present embodiment will be described using FIGS. **1** to **4**. FIG. **1** is a view showing a configuration of the ultrasound endoscope. FIG. **2** is a perspective view showing a distal end part of the ultrasound endoscope. FIG. **3** is a front view of the distal end part shown in FIG. **2** viewed from the front. FIG. **4** is a perspective cross-sectional view of the distal end part of the ultrasound endoscope.

[0054] The ultrasound endoscope **1** includes a thin elongated insertion part **2** inserted into a body cavity, an operation part **3** provided at a proximal end of the insertion part **2**, and a universal cord **4** extending from a side part of the operation part **3**.

[0055] A proximal end part of the universal cord **4** is provided with an endoscope connector **5**. An ultrasound cable **6** extends from a side part of the endoscope connector **5**. A proximal end part of the ultrasound cable **6** is provided with an ultrasound connector **7**.

[0056] In order from a distal end side of the ultrasound endoscope **1**, the insertion part **2** includes a hard part **2***a* formed of a hard member, a bendable part **2***b* configured to be bent, and a flexible tube part **2***c* which is long and extends from a proximal end of the bendable part **2***b* to a distal end of the operation part **3** and has flexibility, wherein the hard part **2***a*, the bendable part **2***b*, and the flexible tube part **2***c* are connected to one another.

[0057] An ultrasound transducer part **10** forms an ultrasound observation plane **10**A that scans a forward direction with respect to an insertion axis direction. In other words, the ultrasound transducer part **10** has the ultrasound observation plane **10**A that scans the forward direction. A signal cable (not shown) is connected to the ultrasound transducer part **10**. The signal cable passes through the insertion part **2**, the operation part **3**, the universal cord **4**, the endoscope connector **5**, and the ultrasound cable **6** and extends to the ultrasound connector **7**.

[0058] The ultrasound connector **7** is connected to an ultrasound observation apparatus (not shown). The ultrasound observation apparatus exchanges a signal with an ultrasound transducer through the signal cable, and converts a signal received from the ultrasound transducer to an ultrasound image to display the ultrasound image on a monitor (not shown).

[0059] The operation part **3** is provided with an angle knob **3***a* for performing a curving operation. When an operator appropriately operates the angle knob **3***a*, a curve wire (not shown) operated in accordance with the operation is pulled and loosened, whereby the bendable part **2***b* is operated to be bent.

[0060] As shown in FIG. **2**, the ultrasound transducer part **10** is configured to project from a distal end surface **21** of the hard part **2***a*. Furthermore, the distal end surface **21** of the hard part **2***a* is provided with an observing window **22**, an illumination window **23**, and an insertion channel outlet **24**. The observing window **22** constitutes the farthest distal end side of an observing optical system (not shown). The illumination window **23** constitutes the farthest distal end side of an illumination optical system (not shown). The insertion channel outlet **24** is an opening of a treatment tool insertion channel from which a treatment tool such as a puncture needle is guided. The insertion channel outlet **24** is provided substantially in parallel with a longitudinal axis direction of the hard part **2***a*, and connected to the treatment tool insertion channel (hereinafter abbreviated as "insertion channel") **27** arranged within the insertion part **2** (refer to FIG. **4**).

[0061] The observing optical system and the illumination optical system (not shown) extend through the insertion part **2**, the operation part **3**, and the universal cord **4** to the endoscope connector **5**. The endoscope connector **5** is connected to an endoscope observation apparatus (not shown). The endoscope observation apparatus transmits illumination light through the illumination optical system to the illumination window **23**. The illumination light illuminates the front of the hard part **2***a*. The endoscope observation apparatus converts, to an observing image, a signal delivered from the observing window **22** through the observing optical system, and displays the observing image on a monitor (not shown). Therefore, an observing image illuminated with illumination light is displayed on the monitor.

[0062] A proximal end side of the insertion channel **27** is in communication with a treatment tool insertion port **3***d* provided in the operation part **3**. A proximal end part of the treatment tool insertion port **3***d* is formed in a luer-lock shape capable of connecting a syringe. A treatment tool inserted through the treatment tool insertion port **3***d* is guided from the insertion channel outlet **24**.

[0063] A central axis L**2** of the insertion channel outlet **24** is substantially in parallel with the longitudinal axis direction of the hard part **2***a*. A surface defined by the central axis L**2** and a central line L**3** in a vertical direction of the ultrasound transducer part **10** is configured to substantially coincide with the ultrasound observation plane **10**A. Since the treatment tool guided from the insertion channel outlet **24** is guided onto the ultrasound observation plane **10**A, the treatment tool is displayed visibly on an ultrasound image.

[0064] Another ultrasound endoscope which can be used in the present embodiment will be described using FIGS. **5** to **8**.

[0065] FIG. **5** is a view showing a configuration of the ultrasound endoscope **100**. FIG. **6** is a perspective view showing a distal end part of the ultrasound endoscope **100**. FIG. **7** is a front view of the distal end part shown in FIG. **5** viewed from the front. FIG. **8** is a perspective cross-sectional view of the distal end part of the ultrasound endoscope **100**.

[0066] In the ultrasound endoscope **100**, components having the same configurations as those of the ultrasound endoscope **1** which has already been described are denoted by the same reference signs in FIGS. **5** to **8**. A difference from the ultrasound endoscope **1** is that an ultrasound transducer part **110** at the distal end is larger than the ultrasound transducer part **10** according to the first embodiment. As a result, an ultrasound observation plane **110**A that scans a forward direction with respect to an insertion axis direction is formed at a wider angle.

[0067] Furthermore, as shown in FIG. **6**, an insertion channel outlet **124** of the ultrasound endoscope **100** is provided so as to be inclined by an angle a with respect to a longitudinal axis direction of a hard part **102***a* such that a treatment tool guided from the insertion channel outlet does not come into contact with the ultrasound transducer part **110** formed in a large size.

[0068] However, a surface configured by a central axis L2*a* in a longitudinal direction of the insertion channel outlet **124** and a central line L3*a* in a vertical direction of the ultrasound transducer part **110** is configured to substantially coincide with the ultrasound observation plane **110**A. This configuration is the same as that of the ultrasound endoscope **1**. Therefore, the treatment tool guided from the insertion channel outlet **124** is guided onto the ultrasound observation plane **110**A, and displayed visibly on an ultrasound image.

[0069] Next, the puncture needle for an ultrasound endoscope according to the present embodiment will be described using FIGS. **9** to **14**B. FIG. **9** is an overall external view of the puncture needle for an ultrasound endoscope. FIGS. **10** and **11** are overall cross-sectional views. FIGS. **12**A, **12**B, **13**A, and **13**B are explanatory views of a shape of a needle tube. FIGS. **14**A and **14**B are explanatory views of an implant.

[0070] The puncture needle **30** for an ultrasound endoscope according to the present embodiment includes an insertion part **31** and an operation part **32**. The insertion part **31** is a part to be inserted into the insertion channel **27** of the ultrasound endoscope **1**. The operation part **32** is arranged at a proximal end part of the insertion part **31**, and fixed to the treatment tool insertion port **3***d* of the ultrasound endoscope **1**.

[0071] Parts of the insertion part **31** will be described.

[0072] A sheath **33** is a tube having flexibility, and positioned at the farthest distal end side of the insertion part **31**. As a material for the sheath **33**, for example, resin such as polyether ether ketone, polyether sulfone, and Teflon (registered trademark) is suitable. Alternatively, as a material for the sheath **33**, a metal wire generally called a flexible shaft, and in particular, a metal obtained by winding a stainless steel wire into a coiled spring shape are suitable. The needle tube **34** is inserted into an inner cavity of the sheath **33**. This structure can prevent the needle tube **34** from coming into direct contact with an inner surface of the insertion channel **27** to damage the needle tube **34** and the insertion channel **27**.

[0073] The needle tube **34** is formed of a shape memory alloy which can be restored to a predetermined shape, a thin stainless steel pipe, or the like. A distal end part of the needle tube **34** is formed in a sharp shape. The needle tube **34** is inserted and arranged in the sheath **33** so as to advance and retract.

[0074] The vicinity of the distal end of the needle tube **34** is shown in detail in FIGS. **12**A to **13**B. In a natural state, at least a portion in the vicinity of the distal end of the needle tube **34** is worked into a smooth arc shape. Specifically, the needle tube **34** is provided with a curved shape part **34**A that is formed in an arc shape in the absence of external force, deformed by the external force, and restored to the original arc shape when the external force is released. In FIGS. **12**A and **12**B, the farthest distal end part of the needle tube **34** is not worked into the arc shape. However, the farthest distal end part may be included in a range to be worked into the arc shape.

[0075] The distal end of the needle tube **34** is formed in such a shape that the distal end is shaved off at an angle in the same way as a general syringe needle. An inner cavity is opened in a surface shaved off at an angle. This distal end opening **34***a* is formed in such a manner that a direction vertical to a distal end surface, that is, a direction in which the distal end opening **34***a* is viewed to be a maximum area (represented by an arrow **A1** in FIG. **12**A) is substantially in parallel with a plane **34***b* including a longitudinal central axis of the needle tube **34**. A point **34***d* at the farthest proximal end side of the distal end opening **34***a* is on the same plane as the plane **34***b*.

[0076] A slit part (side hole) **34***f* is configured in such a manner that, among a tube wall of the needle tube **34** at a side more distal than the curved shape part **34**A, a part of a tube wall is cut off, the tube wall crossing a plane including a central line of the curved shape part **34**A, the tube wall being on the inside of a curve of the curved shape part **34**A (side facing a curve center of the needle tube **34** in a curved state). The implant **35** can be delivered from the slit part **34***f*. Specifically, the slit part **34***f* extends, to the further proximal side, from the point **34***d* at the farthest proximal end side of the distal end opening **34***a* at the distal end of the needle tube **34**. The slit part **34***f* is formed, in a longitudinal central axis direction of the needle tube **34**, in an elongated hole shape larger than a diameter of the implant **35** which will be described later. In the present embodiment, a point **34***g* at the farthest proximal end side of the slit part **34***f* is on the same plane as the plane **34***b*. The slit part **34***f* may extend until the point **34***g* at the farthest proximal end side is positioned at the curved shape part **34**A.

[0077] The opening width of the slit part **34***f* is set based on an external dimension of the implant **35**. Specifically, the opening width of the slit part **34***f* has such a clearance that the implant **35** can advance and retract, and is larger than an external dimension of a wire constituting the implant **35**.

[0078] In the example shown in FIGS. **13**A and **13**B, the distal end of the needle tube **34** is shaved off in the reverse direction of the example shown in FIGS. **12**A and **12**B. In this case, the slit part **34***f* is formed in such a shape that the tube wall of the needle tube **34** is cut off, from a point **34***h* at the farthest distal end side of the distal end opening **34***a*, in an elongated hole shape in the longitudinal central axis direction of the needle tube **34**. In this case as well, the point **34***g* at the farthest proximal end side of the slit part **34***f* is on the same plane as the plane **34***b*, and positioned at the curved shape part **34**A.

[0079] Any of the configuration shown in FIGS. **12**A and **12**B and the configuration shown in FIGS. **13**A and **13**B may be selected depending on the purpose.

[0080] The implant **35** is a piece of metal containing a substance that generates very weak radiation for treatment. The implant **35** is shown in detail in FIGS. **14**A and **14**B. The implant **35** has such a shape that a wire thinner than the inner cavity of the needle tube **34** is bent. The implant **35** is a rod spring having elasticity or an elastic wire having a coil shape. In a straight state, therefore, the implant **35** has restoring force to restore the implant **35** to a wind shape. Since the implant **35** loaded into the inner cavity of the needle tube **34** at a position near a distal end of the inner cavity has elasticity, the implant **35** always pushes an inner wall of the needle tube **34** with the force to return to the original shape. Therefore, the implant **35** is not easily removed from the needle tube **34** to the outside.

[0081] A stylet **36** is a thin elongated wire. A material for the stylet **36** is, for example, stainless steel or nickel titanium. The stylet **36** is arranged at a proximal end side of the inner cavity of the needle tube **34** so as to be inserted into and removed from the needle tube **34**. The stylet **36** is a releasing mechanism that pushes the implant **35** out of the needle tube **34**.

[0082] Components of the operation part **32** will be described.

[0083] An operation part main body **37** is formed of a resin material.

[0084] A slider **38** is provided so as to slide against the operation part main body **37**. The slider **38** is formed of a resin material.

[0085] A stopper **39** is a member capable of setting a sliding distance of the slider **38** against the operation part main body **37** to a desired value depending on a measurement result, and configured as follows. A stopper member **39***a* is arranged so as to slide against the operation part main body **37**. A material for the stopper member **39***a* is formed of, for example, resin. A fixing screw (stopper screw) **39***b* is arranged to be screwed with the stopper member **39***a*, and fixes the stopper member **39***a* to a desired position. A material for the fixing screw **39***b* is made of metal or a hard resin.

[0086] The operation part main body **37** is formed in a thin elongated pipe shape, a proximal end part of which is provided with a flange part **37***a*. A connection part **40** made of resin is stuck and fixed to a distal end part of the operation part main body **37**. A proximal end part of the sheath **33** is fixedly provided on the connection part **40**. A screw **40***a* connected and fixed to the treatment tool insertion port **3***d* of the ultrasound endoscope **1** is formed at a distal end side of the connection part **40**. A recessed part **40***b* in which the distal end part of the operation part main body **37** is arranged is formed at a proximal end part of the connection part **40**. The sheath **33** is fixed to a distal end connection part **40***c* formed at the connection part **40**.

[0087] A recessed part is formed in an inner peripheral surface of the flange part **37***a*. An O ring **41** holding a guide pipe which will be described later is arranged in the recessed part of the flange part **37***a*. A notch stepped portion **37***b* that has a plane part on which a distal end surface of the fixing screw **39***b* abuts is formed at a predetermined position on an outer peripheral surface at an end side more distal than the flange part **37***a*.

[0088] When the puncture needle **30** for an ultrasound endoscope is manufactured and shipped, the distal end surface of the fixing screw **39***b* abuts on the plane part of the notch stepped portion **37***b* with predetermined torque. This allows the slider **38** to be arranged at the proximal end side of the operation part main body **37**.

[0089] In this arrangement state, distal end parts of the needle tube **34** and the stylet **36** are arranged within the sheath **33**. If the slider **38** is affected by some external force and moved to a distal end side, a side part of the fixing screw **39***b* abuts on a raised part of the notch stepped portion **37***b* to stop the movement of the slider **38** to the distal end side. Needless to say, the distal end parts of the needle tube **34** and the stylet **36** do not project from a distal end of the sheath **33** in this abutting state.

[0090] When the stopper screw **39***b* is loosened, the stopper member **39***a* is allowed to slide and move on the operation part main body **37** in a longitudinal direction. The stopper member **39***a* is caused to slide and move to an arbitrary position, and the fixing screw **39***b* is screwed into the stopper member **39***a* to fix the stopper member **39***a*, whereby a maximum movable distance of the slider is set.

[0091] The slider **38** is formed in a pipe shape, a proximal end part of which is provided with a small diameter part **38***a*. A sliding arrangement member **42** for arranging the slider **38** such that the slider **38** can slide against the operation part main body **37** is stuck and fixed to the distal end part of the slider **38**.

[0092] In addition, a ferrule member **43** made of resin is arranged at an opening part at the proximal end part of the slider **38**. A proximal end part of the needle tube **34** and a proximal end part of the guide pipe **44**, a distal end part of which is held by the O ring **41**, are fixed to a distal end part of the ferrule member **43**. A proximal end part of the ferrule member **43** is formed in a luer-lock shape capable of connecting a syringe or the like.

[0093] The stylet **36** is inserted from the ferrule member **43** of the slider **38**. A lug **36***a* made of resin is integrally provided at a proximal end part of the stylet **36**.

[0094] After the components are assembled, the puncture needle **30** for an ultrasound endoscope configured in the above-mentioned manner is housed in a sterilization bag (not shown) and disinfected.

[0095] Operation of the disposable puncture needle **30** for an ultrasound endoscope configured in the above-mentioned manner will be described. First, a combination of the ultrasound endoscope **1** shown in FIGS. **1** to **4** and the needle tube **34** shown in FIGS. **12**A and **12**B will be described. Next, it will be described that the ultrasound endoscope **100** shown in FIGS. **5** to **8** and the needle tube **34** shown in FIGS. **13**A and **13**B can be used to achieve exactly the same function.

[0096] First, the puncture needle **30** for an ultrasound endoscope housed in a sterilization bag (not shown) is taken out of the sterilization bag. The implant **35** is loaded in advance into the needle tube **34** of the puncture needle **30** for an ultrasound endoscope. In the straight state, the implant **35** is inserted from the distal end opening **34***a* of the needle tube **34** into the needle tube **34**. Alternatively, the implant **35** may be inserted from the proximal end of the needle tube **34** and delivered to the distal end by the stylet **36**.

[0097] While loading the implant **35** into the needle tube **34**, it is not easy to direct an orientation of the implant **35** in a circumferential direction of the needle tube **34** to a specific orientation and simultaneously insert the implant **35** into the needle tube **34**. In addition, the wire constituting the implant **35** might be somewhat twisted during the process of inserting the implant **35** into the needle tube **34**. In the present embodiment, regardless of the orientation of the implant **35** in the circumferential direction while being inserted into the needle tube **34**, when the implant **35** is arranged such that a distal end of the implant **35** is positioned at the curved shape part **34**A of the needle tube **34**, the implant **35** rotates within the needle tube **34** such that a wind direction of the implant **35** follows a curved direction of the curved shape part **34**A. Therefore, after the rotation of the implant **35**, the distal end of the implant **35** is positioned within the plane **34***b* including the longitudinal central axis of the needle tube **34**. Specifically, the implant **35** is arranged with respect to the needle tube **34** such that the distal end of the implant **35** can reach the point **34***g* at the farthest proximal end side of the slit part **34***f* when the implant **35** is pushed by the stylet **36** within the needle tube **34**.

[0098] When a part of the implant **35** is positioned at the curved shape part **34**A, the implant **35** receives, from the inner surface of the needle tube **34**, force to rotate to follow the curved direction of the curved shape part **34**A. In addition, when the distal end of the implant **35** is positioned at the curved shape part **34**A, the position of the distal end of the implant **35** that enters the slit part **34***f* first is easily moved to a suitable position.

[0099] Next, the sheath **33** is inserted from the treatment tool insertion port **3***d* of the ultrasound endoscope **1** into the insertion channel **27**. The screw **40***a* provided at the connection part **40** of the operation part **32** is screwed with the treatment tool insertion port **3***d* to fix the puncture needle **30** for an ultrasound endoscope to the ultrasound endoscope **1**.

[0100] An ultrasound image of the distal end part of the sheath **33** is clearly drawn on an ultrasound observing image on which a target site is displayed. In this case, a positional relation between the distal end of the sheath **33** and the target site is set. After that, the distance between the distal end of the sheath **33** and the target site is measured.

[0101] Next, the fixing screw **39***b* is loosened, and the stopper member **39***a* is caused to slide and move on the operation part main body **37** so as to correspond to the above-mentioned distance. When the stopper member **39***a* is moved to a predetermined position, the fixing screw **39***b* is fastened.

[0102] After that, an operator grips the slider **38** and quickly moves the slider **38** toward the stopper **39**. As a result, the distal end of the needle tube **34** infallibly punctures the target site.

[0103] When the needle tube **34** is confirmed to have reached the target site, the lug **36***a* of the stylet **36** is pushed into a distal end side. This allows the stylet **36** to move to the distal end side, and the implant **35** is discharged from the distal end opening **34***a* at the distal end of the needle tube **34** to be placed within a body.

[0104] In order to place the implant **35** accurately at the target site, the implant **35** needs to be discharged while being monitored on an ultrasound observing image. In the embodiment of the present invention, therefore, an angular position around an axis of the needle tube **34** is controlled to cause a direction in which the implant **35** is discharged to correspond to the ultrasound observation plane. Hereinafter, a method for causing the direction in which the implant **35** is discharged to correspond to the ultrasound observation plane will be described.

[0105] Since ultrasound is significantly attenuated in the air, the ultrasound transducer part **10** arranged at the distal end of the ultrasound endoscope **1** needs to be brought into close contact with a tissue within a body during the observing of an ultrasound image. In FIG. **15**, since the ultrasound endoscope **1** is inserted into a body lumen tissue **50**, the bendable part **2***b* of the insertion part **2** of the endoscope needs to be bent in a direction generally called an up direction to be directed to the body lumen tissue **50** in order to bring the ultrasound transducer part **10** into contact with the tissue. Since the bendable part **2***b* is bent and results in a substantially arc shape, the insertion channel **27** arranged within the bendable part **2***b* is also inevitably formed in a substantially arc shape. At this time, a plane **51** including a longitudinal central axis of the insertion channel **27** is substantially the same plane as the ultrasound observation plane **10**A.

[0106] In FIGS. **16**A to **16**C, the insertion part **31** of the puncture needle **30** for an ultrasound endoscope, which includes the needle tube **34**, a portion in the vicinity of the distal end of which is curved in the smooth arc shape as mentioned above, passing through the bent insertion channel **27** is shown in time series order of operation. In FIG. **16**A, the distal end of the insertion part **31** is pushed to advance to the edge of the bendable part of the insertion channel **27** of the ultrasound endoscope **1**. When the insertion part **31** is pushed to advance to the further distal end side, the arc shape of the needle tube **34** reaches the bent shape of the insertion part **2** as shown in FIG. **16**B. Since the needle tube **34** receives the force from the inner wall of the insertion channel **27** due to the insertion, the needle tube **34** is rotated around a longitudinal axis such that the arc shape of the insertion channel **27** and the arc shape of the needle tube **34** are positioned on the same plane (including substantially the same plane). As a result, the plane **34***b* including the longitudinal central axis of the needle tube **34** (i.e. plane including an axial line that coincides with an orientation of the distal end opening of the needle tube **34**) becomes substantially the same as the plane **51** including the longitudinal central axis of the insertion channel **27**. Therefore, the plane **34***b* becomes substantially the same plane as the ultrasound observation plane **10**A.

[0107] Even in a case where the wind direction of the implant **35** does not follow the curved direction of the curved shape part **34**A of the needle tube **34** before the needle tube **34** is inserted into the insertion channel **27**, once the curved shape part **34**A is arranged within the bent insertion channel **27**, the implant **35** rotates within the needle tube **34** such that the wind shape of the implant **35** follows the curved shape of the needle tube **34** by means of the restoring force to restore the implant **35** to the coil shape. Specifically, the curved shape part **34**A of the needle tube **34** rotationally moves until the curved shape part **34**A of the needle tube **34** follows the arc shape of the insertion channel **27**, and the implant **35** rotationally moves until the wind shape of the implant **35** follows the curved shape part **34**A of the needle tube **34**.

[0108] In FIG. **16**C, the insertion part **31** that has reached a predetermined position is shown. Although the angular position around the axis of the needle tube **34** does not change from that of FIG. **16**B, the angular position around the axis of the needle tube **34** becomes more stable since an overlapping length of the arc shape of the needle tube **34** and the bent shape of the insertion part **2** is increased. Since the direction Al in which the distal end opening **34***a* is viewed to be the maximum area is substantially in parallel with the plane **34***b*, the direction Al is substantially in parallel with the ultrasound observation plane **10**A. In other words, the axial line that coincides with the orientation of the distal end opening of the needle tube **34** in the direction Al is substantially in parallel with the ultrasound observation plane **10**A.

[0109] It has already been stated that the implant **35** has elasticity and is in the straight state when housed in the needle tube **34**. As shown in FIG. **17**, when the implant **35** is discharged from the distal end opening **34***a* of the needle tube **34**, the distal end of the implant **35** is delivered from the point **34***g* at the farthest proximal side of the slit part **34***f* to the outside of the needle tube **34**. Therefore, an outer surface of the implant **35** is delivered along the plane **34***b* including the longitudinal central axis of the needle tube **34** while being supported by the slit part **34***f*. Specifically, in the present embodiment, the implant **35** is always within the plane **34***b* including the longitudinal central axis of the needle tube **34** without operation to project in a direction crossing the plane **34***b* including the longitudinal central axis of the needle tube **34**.

[0110] The implant **35** is supported so as to be sandwiched between a pair of wall surfaces **34***f*-**1**, **34***f*-**2** (refer to FIG. **12**B) facing each other at the slit part **34***f*. The implant **35** is further supported by an inner peripheral surface of the needle tube **34** which is a surface located at a position facing the slit part **34***f* when the needle tube **34** is viewed in a longitudinal central axis direction of the needle tube **34**. Therefore, when the implant **35** is delivered through the slit part **34***f* of the needle tube **34**, the implant **35** is delivered along a plane **34***e* and hardly moves in a direction crossing the plane **34***e*.

[0111] The implant **35** is discharged on the plane **34***e*. In this case, the plane **34***e* is substantially the same as the plane **34***b* and includes the proximal end point **34***d*. Since the plane **34***b* is substantially the same as the ultrasound observation plane **10**A, the implant **35** can be suitably monitored on an ultrasound image.

[0112] Next, use of the ultrasound endoscope **100** shown in FIGS. **5** to **8** and the needle tube **34** shown in FIGS. **13**A and **13**B will be described.

[0113] FIG. **18** shows a state where the insertion part **31** of the puncture needle **30** for an ultrasound endoscope, which includes the needle tube **34**, a portion in the vicinity of the distal end of which is curved in the smooth arc shape in a natural state, has passed through the bent insertion channel **27** and reached a predetermined position.

[0114] As shown in FIG. **6**, the insertion channel outlet **124** is provided so as to be inclined by the angle a with respect to the longitudinal axis direction of the hard part **102***a* such that the guided treatment tool does not come into contact with the large ultrasound transducer part **110**. As shown in FIG. **15**, when a surgical technique is practiced, the bendable part **2***b* of the endoscope insertion part **2** is bent in the direction generally called the up direction. At this time, it can be understood that a lumen formed by the insertion channel outlet **124** and the insertion channel **27** can let the needle tube **34** curved in the arc shape smoothly pass therethrough. The implant **35** enters the slit part **34***f* from a proximal end of the slit part **34***f* extending to a proximal side from the point **34***h* at the farthest distal end side of the distal end opening **34***a* of the needle tube **34**. The implant **35** is then ejected from the needle tube **34** to the outside while keeping a positional relation that allows the implant **35** to be monitored on an ultrasound image.

[0115] Therefore, when the implant **35** is discharged from the distal end opening **34***a* of the needle tube **34**, the implant **35** can be suitably monitored on an ultrasound image.

[0116] As a matter of course, use of the ultrasound endoscope **1** shown in FIGS. **1** to **4** in combination with the needle tube shown in FIGS. **13**A and **13**B and use of the ultrasound endoscope **100** shown in FIGS. **5** to **8** in combination with the needle tube shown in FIGS. **12**A and **12**B also achieve the same function. When the release of the implant **35** into a body is finished, the puncture needle **30** for an ultrasound endoscope is removed from the ultrasound endoscope and discarded. A series of surgical techniques is thus finished.

[0117] As mentioned above, according to the puncture needle **30** for an ultrasound endoscope according to the present embodiment, a position of the implant **35** released from the needle tube **34** can always be recognized by the ultrasound endoscope **1** from the first time the implant **35** is delivered from the needle tube **34**. By using the puncture needle **30** for an ultrasound endoscope according to the present embodiment, therefore, it is possible to proceed with the surgical technique while recognizing a position of the distal end of the implant **35**. Thus, the possibility that the distal end of the implant **35** comes into contact with a living tissue outside a field of view of the ultrasound endoscope **1** can be suppressed to a low level.

Second Embodiment

[0118] A second embodiment is different from the first embodiment in a configuration of a distal end shape of a needle tube.

[0119] As shown in FIGS. **19** to **21**, a distal end of a needle tube **54** is sharp, a side surface of which is provided with an opening **54***a*. This opening **54***a* is formed in such a manner that a direction in which the opening **54***a* is viewed from the front, that is, a direction in which the opening **54***a* is viewed to be a maximum area (represented by an arrow A**2** in FIGS. **19** and **21**) is substantially in parallel with a plane **54***b* including a longitudinal central axis of the needle tube **54**. Only a single opening **54***a* is provided in the present embodiment. The opening **54***a* is a path for ejecting the implant **35** from the inside of the needle tube **54** to the outside, and corresponds to the slit part **34***f* described in the above-mentioned first embodiment. In the present embodiment, a curved shape part **54**A formed in a curved shape same as the first embodiment is provided at a distal part of the needle tube **54**.

[0120] Even in this configuration, the implant **35** is pushed out of the opening **54***a* by the stylet **36**, whereby the implant **35** can be observed through the ultrasound endoscope **1**.

[0121] The embodiments of the present invention have been described in detail so far with reference to the drawings. However, the specific configuration is not limited to the embodiments, and design changes or the like within a range not departing from the scope of the present invention are also included.

[0122] FIGS. **22** to **24** are partial cross-sectional views showing exemplary design changes for the above-mentioned embodiments.

[0123] For example, as shown in FIG. **22**, when the implant **35** made of a wire is stretched and loaded into the needle tube **34**, a distal end **35***a* of the wire constituting the implant **35** may be positioned at the curved shape part **34**A.

[0124] As shown in FIG. **23**, when the implant **35** made of a wire is stretched and loaded into the needle tube **34**, a central part **35***c* of the implant **35** in a straight state may be positioned at the curved shape part **34**A.

[0125] As shown in FIG. **24**, the point **34***g* at the proximal end of the slit part **34***f* may be positioned at the curved shape part **34**A.

[0126] While preferred embodiments of the present invention have been described above, the present invention is not limited to these embodiments and their modifications. Configurations can be added, omitted, replaced, and otherwise changed within a range not departing from the spirit and scope of the present invention.

[0127] The present invention is not limited by the aforementioned description, and is only limited by the scope of appended claims.

What is claimed is:

1. A puncture needle used with an ultrasound endoscope having a bendable part capable of being operated to be bent, the ultrasound endoscope being configured such that a central axis extending from an outlet of an insertion channel substantially coincides with an ultrasound observation plane, the puncture needle comprising:

a sheath configured to be freely advanced or retracted in the insertion channel, the sheath being configured to be capable of being inserted into the insertion channel;

a needle tube having an outer surface and an inner surface that forms an internal space extending along a longitudinal axis of the needle tube, the needle tube being capable of being inserted into the sheath;

a wire having a proximal end and a distal end, the wire having elasticity such that the wire is restored to a wind shape in an absence of external force, the wire being stretched and loaded into the internal space of the needle tube against restoration to the wind shape such that the wire is supported by portions of the inner surface of the needle tube which are spaced apart from one another in the longitudinal axis direction of the needle tube;

a side hole formed to open from the inner surface to the outer surface of the needle tube, the side hole having a pair of wall surfaces which are spaced apart from one another, the side hole having an opening width larger than an external diameter of the wire; and

a stylet configured to push the proximal end of the wire loaded within the needle tube, wherein

in a state that the needle tube projects from the insertion channel and the distal end of the wire is pushed from the side hole by the stylet, the pair of wall surfaces support the wire such that the wire is sandwiched between the pair of wall surfaces, and a section of the inner surface facing the side hole supports the wire within the needle tube, such that the distal end of the wire is restored to the wind shape in the ultrasound observation plane.

2. The puncture needle according to claim **1**, wherein

each of the portions of the inner surface of the needle tube supporting the wire is positioned on a prescribed plane.

3. The puncture needle according to claim **2**, further comprising

a needle tube curved shape part formed at a distal side of the needle tube, the needle tube curved shape part having elasticity such that the needle tube curved shape part is restored to a curved shape along the prescribed plane in an absence of external force.

4. The puncture needle according to claim **3**, further comprising

a needle tube distal part having a needle tip formed to be sharpened to puncture a tissue within a body cavity, the needle tube distal part being formed at a side more distal than the needle tube curved shape part, wherein

the side hole is formed at the needle tube distal part and opens toward an inside of the curved shape of the needle tube curved shape part, and

in a state that the distal end of the wire is arranged inside the needle tube curved shape part positioned in the insertion channel, as the insertion channel is bent by the bendable part, the needle tube curved shape part follows a curve of the insertion channel, and the wire receives a force from the inner surface of the needle tube in the needle tube curved shape part, so that the wire rotates such that the wind shape of the wire follows the curved shape of the needle tube curved shape part, and the distal end of the wire is positioned on the ultrasound observation plane.

5. The puncture needle according to claim **1**, wherein

in a state that the wire is supported by the portions of the inner surface of the needle tube which are spaced apart from one another in the longitudinal axis direction of the needle tube, the portions supporting the wire is positioned on a plane which includes the side hole and which is along a central axis of the needle tube, and the portions holds the wire between a proximal end of the side hole and the stylet.

6. The puncture needle according to claim **1**, wherein

the wire is positioned within a range of the opening width of the side hole in a circumferential direction of the needle tube.

7. The puncture needle according to claim **2**, wherein

in a state that the distal end of the wire is restored to the wind shape in the ultrasound observation plane and the pair of wall surfaces support the wire such that the wire is sandwiched between the pair of wall surfaces, the proximal end of the wire and a central part between the distal end and the proximal end of the wire are positioned on the prescribed plane.

8. The puncture needle according to claim **2**, wherein

the distal end, the proximal end, and a central part between the distal end and the proximal end of the wire are positioned on the prescribed plane.

9. The puncture needle according to claim **1**, wherein

a distal end opening which is in communication with the internal space is opened at a distal end of the needle tube, and

the distal end opening is in communication with a distal end of the side hole.

10. The puncture needle according to claim **3**, wherein

the distal end of the wire positioned at a distal side of the needle tube is positioned at the needle tube curved shape part in a state that the wire is stretched and loaded into the needle tube.

11. The puncture needle according to claim **3**, wherein

a central part of the wire is positioned at the needle tube curved shape part in a state that the wire is stretched and loaded into the needle tube.

12. The puncture needle according to claim **3**, wherein

a proximal end of the side hole is positioned at the needle tube curved shape part.

13. The puncture needle according to claim **1**, wherein

the wire has an arc shape.

14. The puncture needle according to claim **13**, wherein

the arc shape is a C-shape.

* * * * *

专利名称(译)	超声内窥镜穿刺针
公开(公告)号	US20160278809A1
公开(公告)日	2016-09-29
申请号	US15/175566
申请日	2016-06-07
[标]申请(专利权)人(译)	奥林巴斯株式会社
申请(专利权)人(译)	OLYMPUS CORPORATION
当前申请(专利权)人(译)	OLYMPUS CORPORATION
[标]发明人	SATO MASATOSHI
发明人	SATO, MASATOSHI
IPC分类号	A61B17/34 A61B1/018 A61B1/06 A61B8/12 A61B8/00
CPC分类号	A61B17/3478 A61B8/12 A61B1/018 A61B1/06 A61B8/445 A61B1/00098 A61B1/00179 A61B8/0841 A61B8/4444 A61B17/3468 A61B2010/045 A61B2017/00331 A61B2017/0034 A61B2090/3908 A61B2090/3987 A61M25/0108 A61M2025/009 A61N2005/1025
优先权	2013257469 2013-12-12 JP
外部链接	Espacenet USPTO

摘要(译)

本发明提供一种超声波内窥镜用穿刺针，其特征在于，针管具有侧孔，该侧孔构成为在针管的比弯曲形状部分更远侧的管壁之间的一部分管壁被切断，管壁穿过包括弯曲形状部分的中心线的平面，管壁位于弯曲形状部分的弯曲的内侧，并且导线能够从侧孔输送;并且，在线被拉伸并装入针管的状态下，线的至少一部分位于弯曲形状部分。