



US 20200016387A1

(19) **United States**(12) **Patent Application Publication**
FUSEYA et al.(10) **Pub. No.: US 2020/0016387 A1**(43) **Pub. Date: Jan. 16, 2020**(54) **DILATOR****Publication Classification**(71) Applicant: **ASAHI INTECC CO., LTD.**, Seto-shi (JP)(51) **Int. Cl.****A61M 29/00** (2006.01)**A61M 25/06** (2006.01)(72) Inventors: **Yukihiro FUSEYA**, Seto-shi (JP);
Hideaki MAKI, Seto-shi (JP); **Daiki TAKAHASHI**, Seto-shi (JP); **Akira SAWAI**, Seto-shi (JP); **Marina KITAI**, Seto-shi (JP)(52) **U.S. Cl.****CPC** **A61M 29/00** (2013.01); **A61M 25/005** (2013.01); **A61M 25/0662** (2013.01)(73) Assignee: **ASAHI INTECC CO., LTD.**, Seto-shi (JP)

(57)

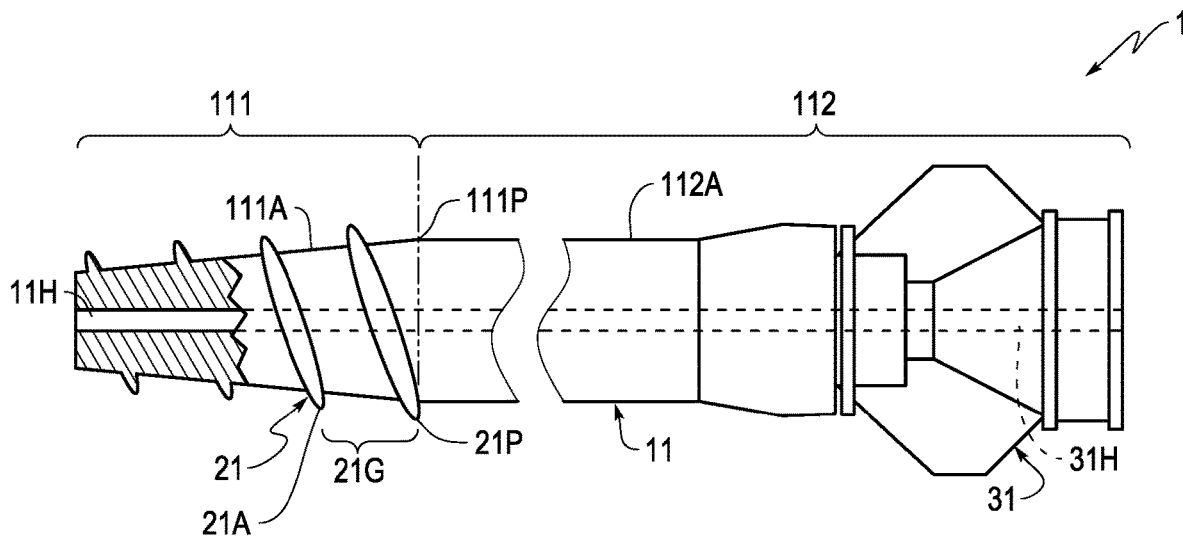
ABSTRACT(21) Appl. No.: **16/580,437**(22) Filed: **Sep. 24, 2019****Related U.S. Application Data**

(63) Continuation of application No. PCT/JP2018/011671, filed on Mar. 23, 2018.

(30) **Foreign Application Priority Data**

Mar. 24, 2017 (JP) PCT/JP2017/012024

A dilator includes a hollow shaft having a tapered portion and a body portion having a distal end located at a proximal end of the tapered portion. The tapered portion has an outer diameter that is smaller at a distal end than at a proximal end, and the body portion extends toward a proximal end side in an axis direction of the shaft. A spirally-arranged protruding portion is provided on an outer peripheral surface of the tapered portion, and the spirally-arranged protruding portion has gaps between adjacent portions of the spirally-arranged protruding portion along an axis direction of the shaft. A proximal end of the spirally-arranged protruding portion is located at the proximal end of the tapered portion.



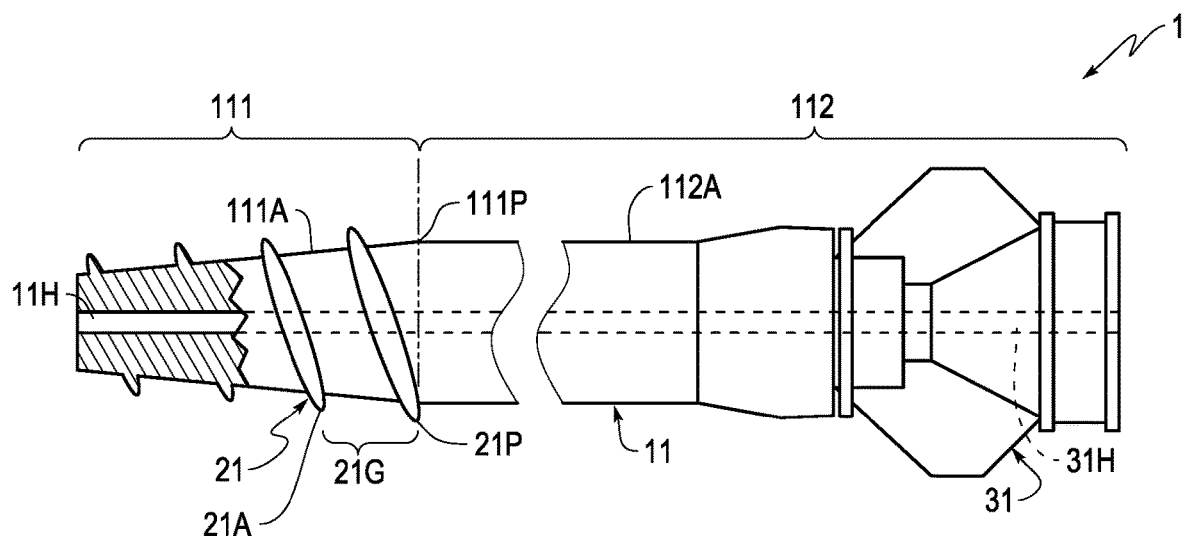


FIG. 1

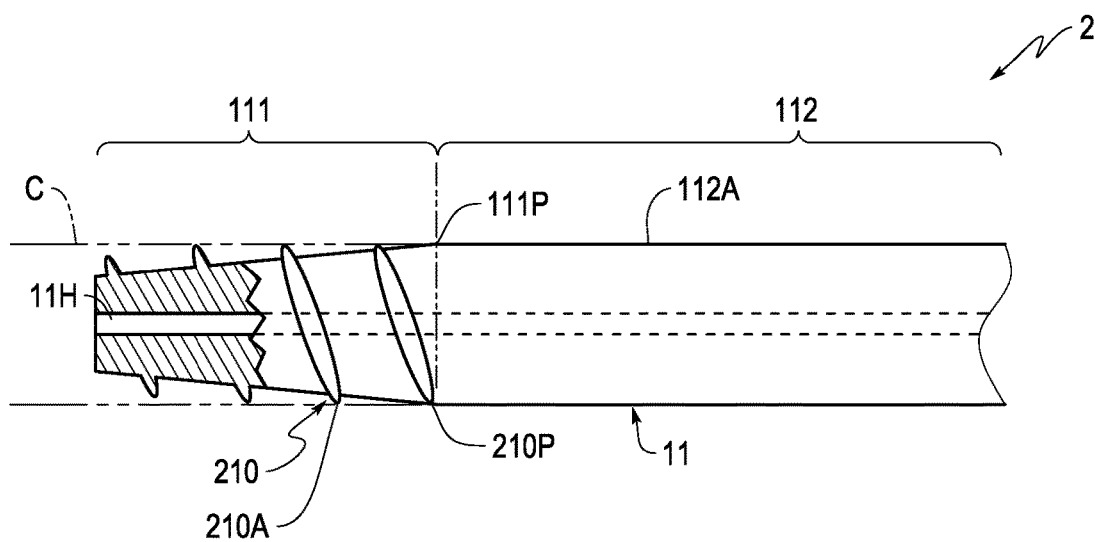


FIG. 2

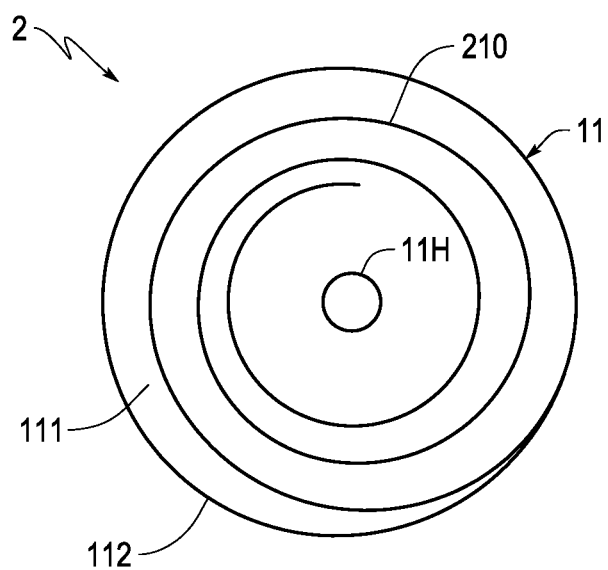


FIG. 3

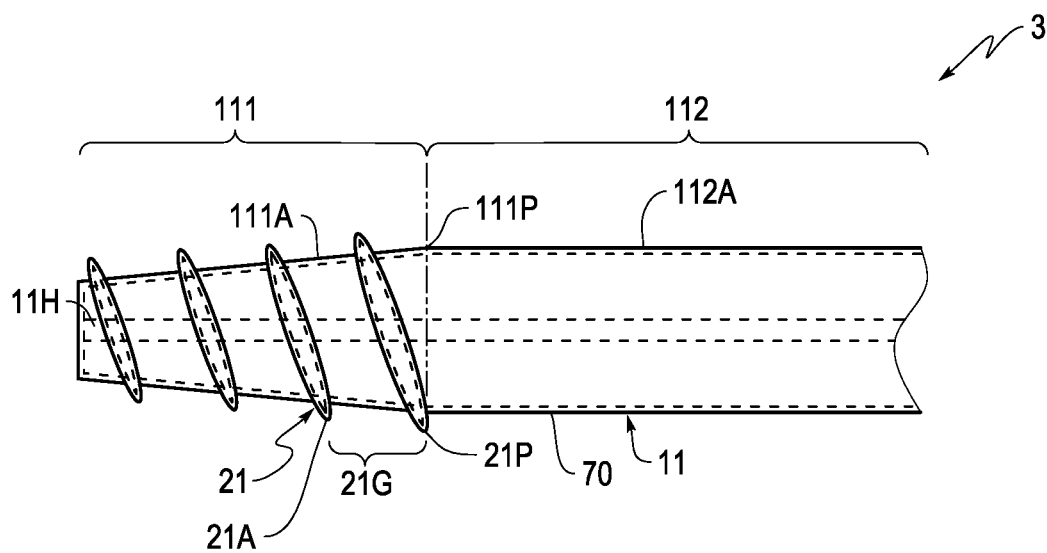


FIG. 4

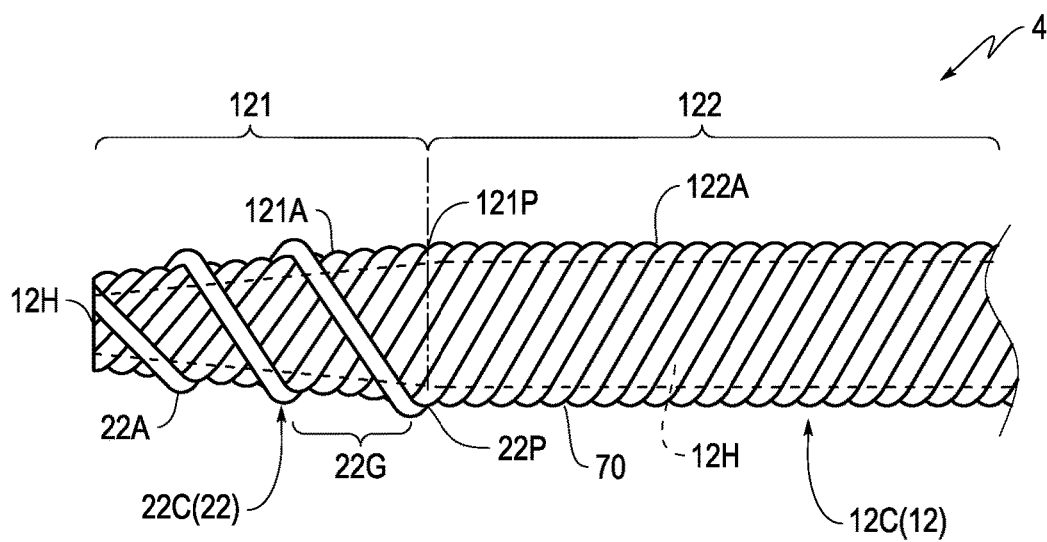


FIG. 5

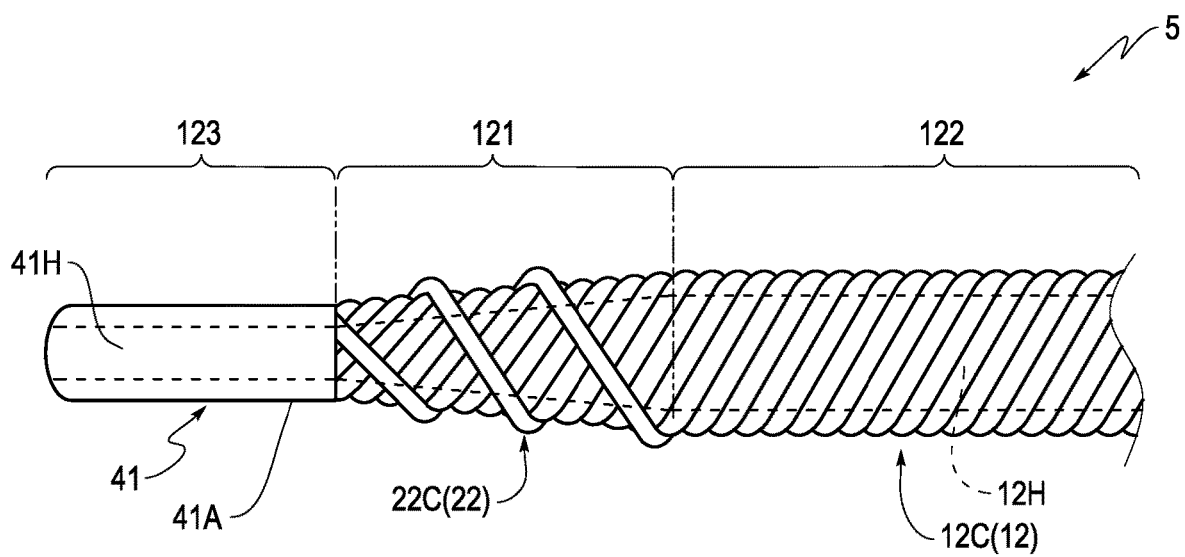


FIG. 6

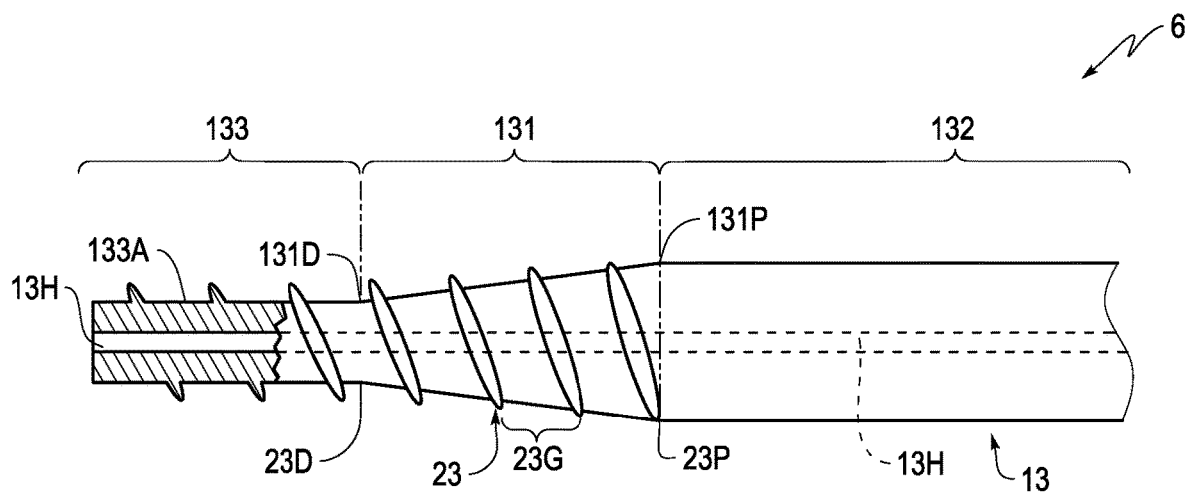


FIG. 7

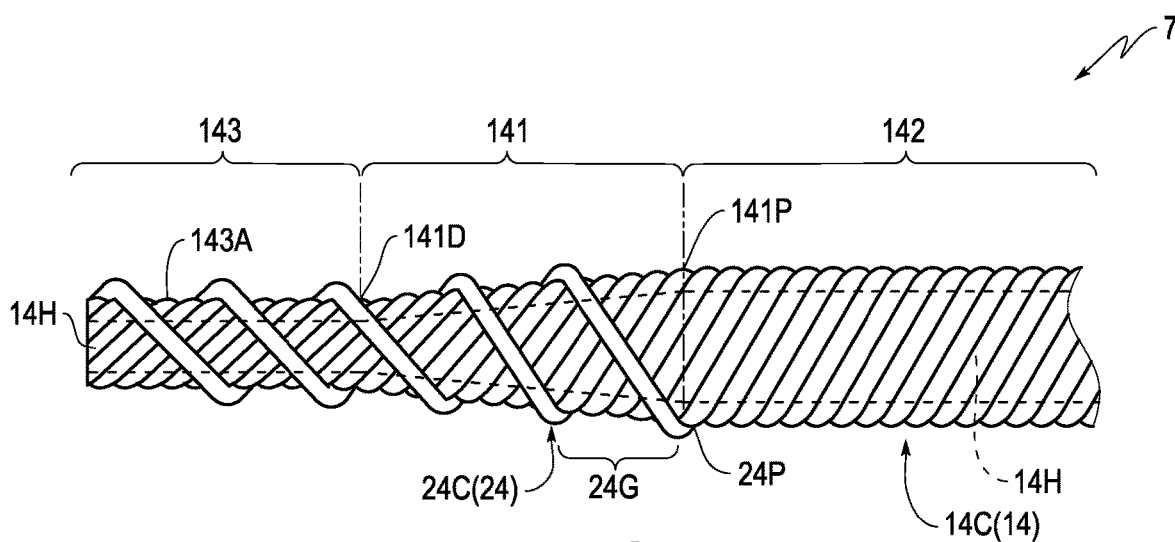


FIG. 8

DILATOR

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation application of International Application No. PCT/JP2018/011671, filed Mar. 23, 2018, which claims priority to International Application No. PCT/JP2017/012024, filed Mar. 24, 2017. The contents of these applications are incorporated herein by reference in their entirety.

BACKGROUND

[0002] The disclosed embodiments relate to a dilator.

[0003] A dilator is known, for example, as a device for expanding a hole opened on the wall of an organ such as stomach and liver, a narrowed segment in a body cavity such as bile duct and pancreatic duct, and the like.

[0004] Such a dilator usually includes a shaft having a tapered portion for expanding a pre-opened hole, the tapered portion having an outer diameter gradually increasing from the distal end toward the proximal end. Here, during the procedure, the distal end of an endoscope is first positioned in the vicinity of a site where a hole is to be opened, and a needle is allowed to advance through the distal end of the endoscope to open a hole on the wall of an organ and the like. Then a guide wire is inserted into the hole through a through-hole of the needle, and then the needle is withdrawn. Subsequently, the dilator is delivered to the hole along the guide wire, and pushed into the hole to expand the hole by the aforementioned tapered portion.

[0005] In view of the above circumstances, for example, a dilator including a contrast maker disposed in the vicinity of a hole-expanding tapered portion is disclosed as a technology for determining the position of a dilator inside the body, according to JP 2017-51328.

[0006] According to the above technology, the position of a contrast maker can be perceived under X-ray imaging, enabling the position of the tapered portion inside the body to be approximately detected during the procedure.

SUMMARY

[0007] Nonetheless, the completion of hole expansion with the tapered portion is difficult to be accurately detected in the conventional dilator as described above although the position of the tapered portion during the procedure can be approximately detected. This may result in insufficient insertion of the dilator and thus insufficient expansion of a hole, or may result in excessive pushing-in of the dilator.

[0008] The disclosed embodiments have been devised in view of the above circumstances. An object of the disclosed embodiments is to provide a dilator allowing accurate detection of the completion of hole expansion in a target object.

[0009] To achieve the above object, a dilator according to the disclosed embodiments includes: a hollow shaft having a tapered portion that is smaller at a distal end than at a proximal end; and a body portion having a distal end located at a proximal end of the tapered portion, and extending toward a proximal end side in an axis direction of the shaft. A spirally-arranged protruding portion is provided on an outer peripheral surface of the tapered portion and has gaps between adjacent portions of the spirally-arranged protruding portion along the axis direction of the shaft. A proximal

end of the spirally-arranged protruding portion is located at the proximal end of the tapered portion.

[0010] It is noted that the term “distal end side” as used herein refers to a direction along the axis direction of the shaft in which the tapered portion is located with respect to the body portion. Further, the term “proximal end side” refers to a direction along the axis direction of the shaft which is opposite to the distal end side. Moreover, the term “distal end” refers to an end of any member or part at the distal end side, while the term “proximal end” refers to an end of any member or part at the proximal end side.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 is a schematic partial cutaway side view of the entirety of a dilator of the disclosed embodiments;

[0012] FIG. 2 is an enlarged schematic partial cutaway side view of a portion of a dilator of the disclosed embodiments;

[0013] FIG. 3 is a schematic distal view of FIG. 2;

[0014] FIG. 4 is an enlarged schematic side view of a portion of a dilator of the disclosed embodiments;

[0015] FIG. 5 is an enlarged schematic side view of a portion of a dilator of the disclosed embodiments;

[0016] FIG. 6 is an enlarged schematic side view of a portion of a dilator of the disclosed embodiments;

[0017] FIG. 7 is a schematic partial cutaway side view of a portion of a dilator of the disclosed embodiments; and

[0018] FIG. 8 is an enlarged schematic side view of a portion of a dilator of the disclosed embodiments.

DETAILED DESCRIPTION OF EMBODIMENTS

[0019] Provided is a dilator including a hollow shaft having a tapered portion and a body portion. An outer diameter of the tapered portion is smaller at a distal end of the shaft than at a proximal end of the shaft. A distal end of the body portion is located at a proximal end of the tapered portion, and the body portion extends toward a proximal end side in an axis direction of the shaft (along a longitudinal axis of the shaft). A spirally-arranged protruding portion is provided on an outer peripheral surface of the tapered portion, and has gaps between adjacent portions of the spirally-arranged protruding portion along the axis direction of the shaft. A proximal end of the spirally-arranged protruding portion is located at the proximal end of the tapered portion.

[0020] Below, embodiments of the present invention will be described with reference to the figures, but the present invention shall not only be limited to the embodiments shown in the accompanying figures. It is noted that the dimensions of dilators shown in the figures are provided to merely facilitate understanding of the embodiments, but do not necessarily correspond to the actual dimensions.

[0021] FIG. 1 shows a schematic partial cutaway side view of the entirety of a dilator of the disclosed embodiments. As shown in FIG. 1, a dilator 1 generally includes a shaft 11, a spirally-arranged protruding portion 21, and a connector (proximal portion) 31.

[0022] The shaft 11 is a hollow member having a through-hole 11H. A guide wire (not shown) and the like, for example, can be inserted through the through-hole 11H. In order to allow them to be inserted freely, the through-hole extends continuously from a distal end of the shaft to a

proximal end of the shaft 11. The shaft 11 has a tapered portion 111 and a body portion 112.

[0023] The tapered portion 111 is a part having an outer diameter that is smaller at a distal end than at a proximal end. Specifically, the tapered portion 111 is connected to a distal end of the body portion 112 described below, and extends from that distal end toward the distal end side, and has a shape that is tapered toward the distal end side.

[0024] The body portion 112 is a part having a distal end located at a proximal end 111P of the tapered portion 111, and it extends toward the proximal end side in the axis direction of the shaft 11 (along a longitudinal axis of the shaft 11). Specifically, the body portion 112 is connected at its distal end to the proximal end 111P of the aforementioned tapered portion 111, and is also connected at its proximal end to the connector 31 described below. The body portion 112 has a substantially constant outer diameter from the distal end thereof through the proximal end. It is noted that the body portion 112 may be integrally formed with the tapered portion 111, or may be formed as a separate body. The body portion 112 may be integrally formed with the tapered portion 111 by casting or the like.

[0025] Materials for the tapered portion 111 and the body portion 112 as described above preferably have antithrombogenicity, flexibility, and biocompatibility because they are to be inserted into a body cavity. Examples of the materials include resin materials such as polyamide resin, polyolefin resin, polyester resin, polyurethane resin, silicone resin, and fluororesin; metal materials such as stainless steel and superelastic alloys (nickel-titanium alloys); and the like. It is noted that the tapered portion 111 and the body portion 112 may have various types of coating in their surface side portions. Examples of the coating include a protective film(s) (representative example: a plating film(s)) located at the surfaces of the tapered portion 111 and the body portion 112; an underlying film for improving adhesiveness of the tapered portion 111 and the body portion 112 with the spirally-arranged protruding portion 21; and the like.

[0026] The spirally-arranged protruding portion 21 is disposed on an outer peripheral surface 111A of the tapered portion 111, and has gaps 21G between adjacent portions of the spirally-arranged protruding portion 21 along the axis direction of the shaft 11. Specifically, the above spirally-arranged protruding portion 21 can be formed, for example, as a single-thread or multi-thread protruded portion protruded radially and outwardly from the outer peripheral surface 111A of the tapered portion 111 (the outermost surface, outermost portion of the dilator 1), the single-thread or multi-thread protruded portion being continuous or discontinuous in the axis direction. Further, the spirally-arranged protruding portion 21 is arranged so that adjacent portions of the spirally-arranged protruding portion 21 are spaced apart in the axis direction. This enables the tapered portion 111 to be moved forward due to the screw action of the spirally-arranged protruding portion 21 by a rotational operation of the shaft 11, leading to smooth expansion of a hole with the tapered portion 111. It is noted that the spirally-arranged protruding portion 21 may be integrally formed with the shaft 11, or may be formed as a separate body. The spirally-arranged protruding portion 21 may be integrally formed with the tapered portion 111 of the shaft 11 by casting or the like.

[0027] Here, a proximal end 21P of the spirally-arranged protruding portion 21 is located at the proximal end 111P of

the tapered portion 111. That is, the spirally-arranged protruding portion 21 is disposed on the outer peripheral surface 111A of the tapered portion 111.

[0028] It is noted that the spirally-arranged protruding portion 21 preferably does not serve as a blade (it does not have a shape where a living body tissue may be cut). That is, the spirally-arranged protruding portion 21 preferably does not have a sharp edge at an end portion on a radially outer side of the shaft in a cross-section (for example, in a cross-section perpendicular to the spiral direction of the spirally-arranged protruding portion). Such end portions can include, for example, a part having a shape including an obtuse edge or a curve (for example, a curve constituting a part of a circle or an ellipse), and the like. This enables the dilator 1 to expand a hole pre-formed in a target object (for example, the wall of the digestive tract such as the patient's stomach) without damaging living body tissues at the inner surface of the hole.

[0029] There is no particular limitation for a material of the spirally-arranged protruding portion 21 as long as the effects of the disclosed embodiments are not impaired. The following materials can be used: for example, metal materials such as stainless steel and superelastic alloys (nickel-titanium alloys), biocompatible resin materials such as polyamide resin and fluororesin, or the like. A radiopaque material can preferably be included. Such radiopaque materials include, for example, gold, platinum, tungsten, or alloys including these elements (for example, platinum-nickel alloys and the like), and the like. Further, a radiopaque material may be combined with a material other than the radiopaque material such as a radiopaque material to be coated on a non-radiopaque material.

[0030] When a material of the spirally-arranged protruding portion 21 contains a radiopaque material as described above, the position of the spirally-arranged protruding portion 21 can be perceived under radiographic imaging. This enables the completion of hole expansion to be detected more accurately.

[0031] The connector 31 as shown in FIG. 1 is a part with which an operator pushes the dilator 1 into the body, and/or performs a rotation operation. The above connector 31 has a distal end connected to the proximal end of the body portion 112 and a through-hole 31H in communication with the through-hole 11H of the shaft 11. During a procedure, a guide wire or the like can be inserted through the through-hole 31H of the connector 31.

[0032] The length of each portion of the dilator 1 in the axis direction is usually as follows: 1,600 mm to 2,500 mm for the entire shaft 11, and 5 mm to 100 mm for the tapered portion 111. The outer diameter of each portion of the shaft 11 is usually as follows: 0.6 mm to 2.3 mm for the distal end of the tapered portion 111, and 1.2 mm to 4.0 mm for the proximal end 111P of the tapered portion 111 and for the body portion 112. The inner diameter of the through-hole 11H of the shaft 11 is usually 0.4 mm to 1.0 mm.

[0033] For example, the length of each portion of the dilator 1 can be as follows: 2,000 mm for the entire shaft 11, and 30 mm for the tapered portion 111. The outer diameter of each portion of the shaft 11 can be as follows: 1.1 mm for the distal end of the tapered portion 111, and 1.9 mm for the proximal end 111P of the tapered portion 111 and for the body portion 112. The inner diameter of the through-hole 11H of the shaft 11 can be 0.7 mm.

[0034] Next, an example of operating modes of the above dilator 1 will be described.

[0035] First, a target object is punctured with an introducer needle to open a hole. Subsequently, a guide wire (not shown) is inserted into a through-hole of the introducer needle, and then the introducer needle is withdrawn.

[0036] Next, the proximal end of the guide wire is inserted into the through-hole 11H, 31H of the dilator 1, and the dilator 1 is then inserted. Subsequently, the dilator 1 is pushed in while rotating the shaft 11 to expand the hole at a punctured portion. During this, the tapered portion 111 can be moved forward to the distal end side due to the screw action and the like of the spirally-arranged protruding portion 21 by a rotation operation of the shaft 11, leading to smooth hole expansion with the tapered portion 111. It is noted that the screwing-in resistance of the shaft 11 suddenly decreases when the proximal end 111P of the tapered portion 111 passes through a punctured portion and hole expansion in a target object is completed (when the hole expansion at the punctured portion is completed) because the spirally-arranged protruding portion 21 is not disposed on the outer peripheral surface 112A of the body portion 112. This can allow an operator to accurately detect when the hole expansion is completed.

[0037] As described above, the dilator 1 having the aforementioned configuration can reduce the screwing-in resistance of the shaft 11 when expansion of a hole in a target object is completed, allowing an operator to accurately detect when the hole expansion is completed by means of a sensuous communication received by the operator.

[0038] Modifications of the dilator 1 are possible. For example, as shown in FIGS. 2 and 3, a dilator 2 of the disclosed embodiments can include a spirally-arranged protruding portion 210 having an outer shape (outer profile) that falls within the outer shape (outer profile) of the body portion 112 when viewed in the axis direction of the shaft 11 in a state where the tapered portion 111 and the body portion 112 extend in a substantially linear fashion. That is, the shape (the outer shape) of an outer peripheral surface 210A of a spirally-arranged protruding portion 210 viewed from the distal end side along the axis of the shaft 11 preferably falls in a region within a virtual cylinder C. The virtual cylinder C is defined by virtual lines extending from the outer peripheral surface 112A (the outer shape) of the body portion 112 toward the distal end side.

[0039] The outer shape of the spirally-arranged protruding portion 210 formed as described above can reduce the screwing-in resistance of the shaft 11 more noticeably (and thus can allow an operator to reliably perceive it) when expansion of a hole in a target object is completed. Therefore, the completion of hole expansion can be more accurately detected.

[0040] Also, the outer periphery or peripheries of the shaft and/or the spirally-arranged protruding portion 21 described above may have a coating 70 as shown in FIG. 4. FIG. 4 is an enlarged schematic side view of a portion of a dilator 3 of the disclosed embodiments. Such a coating 70 may be formed for the purposes of, for example, improving slidability and preventing pinching of a living body tissue. Materials which can be used to form the coating 70 include, for example, biocompatible resin materials such as polyamide resin and fluororesin, hydrophilic coating materials, and the like. The above coating 70 may be configured to have a thickness of, for example, 0.1 μm to 300 μm . It is

noted that when the shaft 11 and/or the spirally-arranged protruding portion 21 have/has the coating 70, the outer peripheral surface (the outer surface) of the coating 70 corresponds to an outer peripheral surface of a shaft 11 (an outer peripheral surface 111A of the tapered portion 111 and an outer peripheral surface 112A of a body portion 112) or an outer peripheral surface 21A of a spirally-arranged protruding portion 21.

[0041] FIG. 5 shows an enlarged schematic side view of a portion of a dilator 4 according to the disclosed embodiments. As shown in FIG. 5, a dilator 4 generally includes a shaft 12, a spirally-arranged protruding portion 22, and the connector 31 (see FIG. 1). The dilator 4 differs from the dilator 1 in the configurations of the shaft 12 and the spirally-arranged protruding portion 22. It is noted that the configurations other than those of the shaft 12 and the spirally-arranged protruding portion 22 and the operating modes of the dilator 4 are similar to those of the dilator 1. Therefore, the same reference symbol is given to the same part, and detailed description thereof will be omitted.

[0042] The shaft 12 is a hollow member having a through-hole 12H. The shaft 12 has a tapered portion 121 and a body portion 122. The tapered portion 121 is a part where the outer diameter is smaller at the distal end than at the proximal end. The body portion 122 is a part having a distal end located at a proximal end 121P of the tapered portion 121, and it extends toward the proximal end side in the axis direction of the shaft 12.

[0043] The shaft 12 is formed by winding a wire around the axis of the above shaft 12. Specifically, the above shaft 12 is formed as a coil body 12C in which a single wire is spirally wound around (coiled) so that adjacent portions of the wire are brought into close contact with each other in the axis direction as shown in FIG. 5. The coil body 12C serves as the aforementioned tapered portion 121 and the aforementioned body portion 122, depending on the shape of the outer peripheral surface thereof. It is noted that in FIG. 5, the common inscribed lines of the coil body 12C are shown by dotted lines, and the through-hole 12H is formed in a region surrounded by the common inscribed lines.

[0044] The spirally-arranged protruding portion 22 is disposed on an outer peripheral surface 121A of the tapered portion 121, and has gaps 22G between adjacent portions of the spirally-arranged protruding portion 22 along the axis direction of the shaft 12. Further, a proximal end 22P of the spirally-arranged protruding portion 22 is located at the proximal end 121P of the tapered portion 121.

[0045] The spirally-arranged protruding portion 22 is formed by winding a wire around on the outer peripheral surface of the shaft 12 (the outer peripheral surface 121A of the tapered portion 121). Specifically, the above spirally-arranged protruding portion 22 is, for example, formed as a coil body 22C in which a single wire is spirally wound around so that adjacent portions of the wire are spaced apart from each other. The inner periphery of the coil body 22C is brought into close contact with the outer periphery of the coil body 12C, and both the coil body 22C and the coil body 12C are joined to each other, for example, by soldering or welding each end of the both, fixing each end of the both via an adhesive, or fusing each end of the both via coating.

[0046] The number of wires used for the shaft 12 and the spirally-arranged protruding portion 22 may be one or more. It is noted that the winding directions of wires of the shaft 12 and the spirally-arranged protruding portion 22 are

preferably opposite to each other as shown in FIG. 5. That is, preferably, one of the coil body 12C and the coil body 22C is S-twisted, and the other is Z-twisted. By this configuration, the direction of a force axially applied to a wire of the shaft 12 can be directed as opposed to the direction of a force axially applied to a wire of the spirally-arranged protruding portion 22, preventing decreases of torquability and pushability due to separation of adjacent portions of a wire of the shaft 12.

[0047] As materials for a wire of the aforementioned coil body 12C, for example, materials similar to those listed as materials of the tapered portion and the body portion in the dilator 1 can be exemplified. As materials for a wire of the aforementioned coil body 22C, for example, materials similar to those listed as materials of the spirally-arranged protruding portion 21 in the dilator 1 can be exemplified.

[0048] As described above, the dilator 4 includes the shaft 12 and the spirally-arranged protruding portion 22 which are formed with the coil body 12C, 22C, respectively. This configuration can improve the flexibility and torquability of the shaft 12 and the spirally-arranged protruding portion 22.

[0049] A dilator 5 of the disclosed embodiments includes a distal tip 41 having a substantially tubular and hollow shape that is attached to the distal end of the shaft 12 as shown in FIG. 6. The distal tip 41 has a surface 41A that is flatter (smoother) than the outer peripheral surface of the coil 12C (an uneven surface due to the presence of a wire), and has a through-hole 41H that is in communication with the through-hole 12H of the shaft 12. The distal tip 41 may be formed so as to have a surface that is smoothed by applying a soldering material such as silver-tin solder, gold-tin solder, or the like to a distal end portion 123 of the coil body 12C. This can improve the insertability of the shaft 12 into a hole opened with an introducer needle, enabling the procedure to be performed smoothly.

[0050] FIG. 7 shows a schematic partial cutaway side view of a portion of a dilator 6 of the disclosed embodiments. As shown in FIG. 7, a dilator 6 generally includes a shaft 13, a spirally-arranged protruding portion 23, and the connector 31 (see FIG. 1). The dilator 6 differs from the dilator 1 in the configurations of the shaft 13 and the spirally-arranged protruding portion 23. It is noted that the configurations other than those of the shaft 13 and the spirally-arranged protruding portion 23 and the operating modes of the dilator 6 are similar to those of the dilator 1. Therefore, the same reference symbol is given to the same part, and detailed description thereof will be omitted.

[0051] The shaft 13 is a hollow member having a through-hole 13H. The shaft 13 has a tapered portion 131, a body portion 132, and a distal end portion 133. It is noted that the tapered portion 131 and the body portion 132 have the same configurations as the tapered portion 111 and the body portion 112 of the dilator 1, and the descriptions thereof will be applied.

[0052] The distal end portion 133 is a part having a proximal end located at a distal end 131D of the tapered portion 131 of the shaft 13 and extending toward the distal end side in the axis direction of the shaft 13. Specifically, the distal end portion 133 has, for example, a substantially constant outer diameter from the distal end thereof through the proximal end as shown in FIG. 7. It is noted that the distal end portion 133 may be integrally formed with the tapered portion 131, or may be formed as a separate body.

In FIG. 7, the distal end portion 133 is integrally formed with the tapered portion 131 by casting or the like.

[0053] As materials for the distal end portion 133, for example, materials similar to those listed as materials for the tapered portion 111 and the body portion 112 in the dilator 1 can be exemplified.

[0054] The spirally-arranged protruding portion 23 is disposed on outer peripheral surfaces 133A and 131A of the distal end portion 133 and the tapered portion 131, and has gaps 23G along the axis direction of the shaft 13. It is noted that the spirally-arranged protruding portion 23 is formed as a continuous single thread in the dilator 6. Moreover, the spirally-arranged protruding portion 23 is integrally formed with the distal end portion 133 and the tapered portion 131 by casting or the like.

[0055] Here, the distal end of the spirally-arranged protruding portion 23 is preferably located at the distal end of the tapered portion 131 or the outer peripheral surface 133A of the distal end portion 133. In FIG. 7, the distal end of the spirally-arranged protruding portion 23 is located at the distal end of the distal end portion 133, and the proximal end is located at the proximal end 131P of the tapered portion 131. Thereby, a large driving force can be obtained from the spirally-arranged protruding portion 23 when the shaft 13 is rotated, leading to more reliable hole expansion.

[0056] As described above, the distal end portion 133 included in the dilator 6 can be pre-inserted into a hole before expanding the hole with the tapered portion 131, leading to stable and reliable hole expansion with the tapered portion 131.

[0057] FIG. 8 shows an enlarged schematic side view of a portion of a dilator 7 according to the disclosed embodiments. As shown in FIG. 8, a dilator 7 generally includes a shaft 14, a spirally-arranged protruding portion 24, and the connector 31 (see FIG. 1). The dilator 7 differs from the dilator 6 in the configurations of the shaft 14 and the spirally-arranged protruding portion 24. It is noted that the configurations other than those of the shaft 14 and the spirally-arranged protruding portion 24 and the operating modes of the dilator 7 are similar to those of the dilator 6. Therefore, the same reference symbol is given to the same part, and detailed description thereof will be omitted.

[0058] The shaft 14 is a hollow member having a through-hole 14H. The shaft 14 has a tapered portion 141, a body portion 142, and a distal end portion 143. The tapered portion 141 is a part where the outer diameter is smaller at the distal end than at the proximal end. The body portion 142 is a part having a distal end located at a proximal end 141P of the tapered portion 141 and extending toward the proximal end side in the axis direction of the shaft 14. The distal end portion 143 is a part having a proximal end located at a distal end 141D of the tapered portion 141 and extending toward the distal end side in the axis direction of the shaft 14.

[0059] The shaft 14 is formed by winding a wire around the axis of the shaft 14. Specifically, the shaft 14 is formed with a coil body 14C, and can serve as the tapered portion 141, the body portion 142, and the distal end portion 143, depending on the shape of the outer peripheral surface thereof. It is noted that in FIG. 8, the common inscribed lines of the coil body 14C are shown by dotted lines, and the through-hole 14H is formed in a region surrounded by the common inscribed lines.

[0060] The spirally-arranged protruding portion **24** is disposed on outer peripheral surfaces **143A** and **141A** of the distal end portion **143** and the tapered portion **141**, and has gaps **24G** along the axis direction of the shaft **14**. Further, a proximal end **24P** of the spirally-arranged protruding portion **24** is located at the proximal end **141P** of the tapered portion **141**.

[0061] The spirally-arranged protruding portion **24** is formed by winding a wire around on the outer peripheral surface of the shaft **14** (the outer peripheral surface **143A** of the distal end portion **143** and the outer peripheral surface **141A** of the tapered portion **141**). Specifically, the above spirally-arranged protruding portion **24** is, for example, formed as a coil body **24C** in which a single wire is spirally wound around so that adjacent portions of the wire are spaced apart from each other.

[0062] It is noted that a method of joining the coil body **24C** with the coil body **14C**, a material for a wire of each coil body, and the like are similar to those of the dilator **4**, and the descriptions thereof will be applied.

[0063] As described above, the dilator **7** includes the shaft **14** and the spirally-arranged protruding portion **24** which are formed with the coil body **14C**, **24C**, respectively. This configuration can improve the flexibility and torquability of the shaft **14** and the spirally-arranged protruding portion **24**. Further, the distal end portion **143** included in the dilator **7** can be pre-inserted into a hole before expanding the hole with the tapered portion **141**, leading to stable and reliable hole expansion with the tapered portion **141**.

[0064] It is noted that the present invention shall not be limited to the configurations of the aforementioned embodiments. All alterations made within the scope of the claims and within the meaning and range equivalent to the scope of the claims are intended to be included.

[0065] For example, the dilators **1** to **7** are described in which the distal ends of the spirally-arranged protruding portions **21** and **22** are located at the distal ends of the tapered portions **111** and **121** in the aforementioned dilators **1** to **5**, and the distal ends of the spirally-arranged protruding portions **23** and **24** are located at the distal ends of the distal end portions **133** and **143** in the dilators **6** and **7**. However, a dilator having a distal end portion may be configured such that the distal end of a spirally-arranged protruding portion is located at a part between the distal end of a distal end portion and the proximal end of a tapered portion, and a dilator without having a distal end portion may be configured such that the distal end of a spirally-arranged protruding portion is located at a part between the distal end and the proximal end of a tapered portion.

[0066] Moreover, the dilators **4**, **5** are described where the shaft **12** and the spirally-arranged protruding portion **22** are formed with the coil body **12C**, **22C**, respectively, and the dilator **7** is described where the shaft **14** and the spirally-arranged protruding portion **24** are formed with the coil body **14C**, **24C**, respectively. However, a dilator formed with a coil body may be configured such that only either one of a shaft and a spirally-arranged protruding portion is formed with a coil body.

[0067] Moreover, the dilators **4**, **5** are described where the coil body **12C** and the coil body **22C** are each formed with a continuous single thread of wire, and the dilator **7** is described where the coil body **14C** and the coil body **24C** are each formed with a continuous single thread of wire. However, a dilator may include coil bodies each including a multi-thread coil formed with a plurality of wires, or a dilator may include intermittently-wound-around coil bodies.

What is claimed is:

1. A dilator comprising:

a hollow shaft comprising:

a tapered portion having an outer diameter that is smaller at a distal end of the tapered portion than at a proximal end of the tapered portion; and

a body portion having a distal end located at a proximal end of the tapered portion, the body portion extending in a proximal direction; and

a spirally-arranged protruding portion provided on an outer peripheral surface of the tapered portion, the spirally-arranged protruding portion having gaps between adjacent portions of the spirally-arranged protruding portion along a longitudinal axis of the shaft, and having a proximal end that is located at the proximal end of the tapered portion.

2. The dilator according to claim 1, wherein:

in a distal view in a direction of the longitudinal axis of the shaft, an outer profile of the spirally-arranged protruding portion falls within an outer profile of the body portion.

3. The dilator according to claim 1, wherein a material of the spirally-arranged protruding portion includes a radiopaque material.

4. The dilator according to claim 1, wherein the shaft further comprises a distal end portion having a proximal end located at the distal end of the tapered portion and extending in a distal direction.

5. The dilator according to claim 4, wherein a distal end of the spirally-arranged protruding portion is located at the distal end of the tapered portion or at an outer peripheral surface of the distal end portion.

6. The dilator according to claim 1, wherein the shaft comprises a hollow coil formed of a wire coiled around the longitudinal axis of the shaft.

7. The dilator according to claim 1, wherein the spirally-arranged protruding portion comprises a coil formed of a wire wound around on an outer peripheral surface of the shaft.

8. The dilator according to claim 1, wherein:

the shaft comprises a first coil formed of a wire coiled around the longitudinal axis of the shaft into a hollow shape; and

the spirally-arranged protruding portion comprises a second coil formed of a wire wound around on an outer peripheral surface of the shaft; and

a winding direction of the wire of the shaft and a winding direction of the wire of the spirally-arranged protruding portion are opposite to each other.

* * * * *