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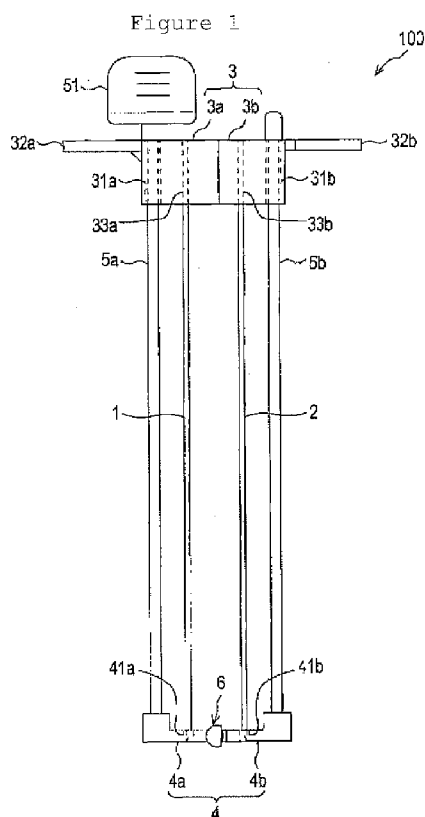
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(54) Title: PUNCTURE DEVICE



(57) Abstract: A puncture device comprises : a suture thread introduction needle 1; a loop introduction needle 2; a base-end support part 3a for holding the base end of the suture thread introduction needle 1; a base-end support part 3b, provided in such a way as to be separable from the base-end support part 3a, for holding the base end of the loop introduction needle 2; a tip-end support part 4a for supporting the suture thread introduction needle 1 in such a way as to be axially mobile; a tip-end support part 4b for supporting the loop introduction needle 2 in such a way as to be axially mobile; and a linking part 6 for linking the tip-end support part 4a and the tip-end support part 4b in such a way that the linking angle thereof is adjustable.



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Puncture device

Background

5 The present invention relates to a puncture device which is used when a plurality of puncture needles are made to pierce a patient's body.

10 When a gastric fistula is created for percutaneous endoscopic gastrostomy (PEG), it may involve forming a through-hole passing through a patient's abdominal wall and internal organ wall. Suturing techniques have been proposed for fixing the internal organ wall, which readily moves, to the abdominal wall in order to facilitate forming of the through-hole.

15 A conventional medical tool used for suturing an internal organ wall and the abdominal wall which has been proposed is: a medical tool comprising: a suture thread-insertion puncture needle; a suture thread-gripping puncture needle which is provided a prescribed distance apart from said suture thread-
20 insertion puncture needle and substantially parallel thereto; a stylet which is slidably inserted inside said suture thread-gripping puncture needle; and a fixing member to which are fixed the base ends of the suture thread-insertion puncture
25 needle and the suture thread-gripping puncture needle, wherein the stylet has an annular member at the tip end thereof which is formed from an elastic material and can be housed inside the suture thread-gripping puncture needle, said annular member extending in the direction of said suture thread-
30 insertion puncture needle in such a way that the centre axis or line of extension of the suture thread-insertion puncture needle passes through the inside of said annular member when said annular member is projecting from the tip end of the suture thread-gripping puncture needle" (see JP06-24533B, for
35 example). The medical tool is typically a tool which allows parallel punctures a fixed distance apart to be made by the suture thread-insertion puncture needle and the suture thread-gripping puncture needle.

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Technology has also been proposed in which a suture thread-insertion puncture needle and a suture thread-gripping puncture needle can be used to make punctures separately
5 through a "housing part 23" (see JP2007-82827A, for example).

Summary of the Invention

Patient internal organs (e.g. the stomach) do not have a fixed
10 position or shape, and the stomach wall sometimes stretches when pierced. For various reasons such as this, it is not always possible to insert puncture needles, namely a suture thread insertion puncture needle and a suture thread gripping puncture needle, at the required position inside an internal
15 organ.

With the technology disclosed in the prior art, it is only possible to make parallel punctures with the suture thread insertion puncture needle and the suture thread gripping
20 puncture needle and the puncture direction cannot be varied. Consequently, even if only one of the needles out of the suture thread insertion puncture needle and the suture thread gripping puncture needle has not made a successful puncture, for example, both needles have to be withdrawn and a new
25 puncture made, which is more invasive for the patient and also increases the practitioner's work. Furthermore, even if the needle punctures are corrected, the puncture direction of the two needles cannot be changed, so there is also a possibility that the puncture will once again not be made at the required
30 position, which creates an issue in terms of the puncture success rate.

Furthermore, the prior art typically relates to a system in which separate punctures are made by the suture thread
35 insertion puncture needle and the suture thread gripping puncture needle. If only one of the puncture needles has not

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made a successful puncture, for example, some of the prior art references makes it possible to withdraw one of the needles to correct the puncture. However, the latter technology is the same as that disclosed in other cases in that the needles make punctures through the housing part, and the suture thread insertion puncture needle and the suture thread gripping puncture needle can only make parallel punctures. As a result, there is also a possibility that the puncture will once again not be made at the required position even if the needle puncture is corrected, which creates an issue in terms of the puncture success rate.

Furthermore, there are also conventional techniques which are known in the art in which the suture thread insertion puncture needle and the suture thread gripping puncture needle make separate punctures. If the suture thread insertion puncture needle and the suture thread gripping puncture needle are used separately, punctures can be made in any direction by each needle, but the gap between the two needles is not fixed. Consequently, it may not be possible for the suture thread which is fed out from the tip end of the suture thread insertion puncture needle to be gripped by the gripping loop fed out from the tip end of the suture thread gripping puncture needle. If this happens, it is necessary to correct the puncture made by the needle, which increases the burden on the patient and the practitioner.

The present invention can provide a puncture device which has a high degree of freedom to enable a plurality of needles to make punctures at required positions. The present invention also can provide a puncture device which makes it possible to improve the success rate for fixing an internal organ wall and the abdominal wall when used as a suturing tool for fixing said internal organ wall and the abdominal wall.

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The puncture device according to the present invention can comprise a first puncture needle; a second puncture needle; a first base-end support part for holding the base end of the first puncture needle; a second base-end support part, provided in such a way as to be separable from the first base-end support part, for holding the base end of the second puncture needle; a first tip-end support part for supporting the first puncture needle in such a way as to be axially mobile; a second tip-end support part for supporting the second puncture needle in such a way as to be axially mobile; and a linking part for linking the first tip-end support part and the second tip-end support part in such a way that the linking angle thereof is adjustable.

The puncture device according to the present invention can comprise a connecting part for separably connecting the first base-end support part and the second base-end support part.

The puncture device according to the present invention is preferably a device in which, when the first base-end support part and the second base-end support part have been connected by through the connecting part, the first puncture needle and the second puncture needle are disposed substantially parallel to each other with a prescribed distance therebetween.

The puncture device according to the present invention is preferably a device in which the linking part makes it possible to adjust the linking angle of the first tip-end support part and the second tip-end support part at least in any direction from among the front-to-rear direction, the lateral direction and the vertical direction.

With the puncture device according to the present invention, there is a high degree of freedom in the puncture direction of the first puncture needle and the second puncture needle, and punctures can be made with the first puncture needle and the

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second puncture needle at the required positions. Consequently, if the puncture device according to the present invention is used as a suturing tool for suturing the abdominal wall and an internal organ wall, the practitioner
5 can make needle punctures in a suitable direction to suit the state of the patient's abdominal wall and internal organ wall, and the success rate for fixing the internal organ wall and the abdominal wall can be improved.

10 Brief Description of the Figures

Figure 1 is an external view of a suturing tool according to Mode of Embodiment 1;

15 Figure 2 is an external view of the suturing tool according to Mode of Embodiment 1 when the puncture needles thereof are projecting;

Figure 3 is an external view illustrating the situation when the stopper member of the suturing tool according to Mode of Embodiment 1 has been detached;

20 Figure 4 illustrates an exemplary structure of the stopper member according to Mode of Embodiment 1;

Figure 5 illustrates the linking part of the suturing tool according to Mode of Embodiment 1;

25 Figure 6 illustrates the suture thread retrieval loop according to Mode of Embodiment 1;

Figure 7 illustrates the situation when the suturing tool according to Mode of Embodiment 1 is being used;

30 Figure 8 illustrates the state of usage of the suturing tool according to Mode of Embodiment 1 when the suture thread introduction needle and the loop introduction needle make separate punctures; and

Figure 9 illustrates the linking part of the suturing tool according to Mode of Embodiment 2.

35 In Mode of Embodiment 1, a description will be given of an exemplary case in which the puncture device according to the

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present invention is applied to a suturing tool which is used when the stomach wall and the abdominal wall are fixed using suture thread (organopexy tool).

5 Suturing Tool

Figure 1 is an external view of a suturing tool 100 according to Mode of Embodiment 1. Figure 2 is an external view of the suturing tool according to Mode of Embodiment 1 when the
10 puncture needles thereof are projecting. Furthermore, Figure 3 is an external view illustrating the situation when the stopper member of the suturing tool according to Mode of Embodiment 1 has been detached.

15 As shown in Figures 1 to 3, the suturing tool 100 can comprise a suture thread introduction needle 1; a loop introduction needle 2; base-end support parts 3a, 3b (which may be referred to collectively below as "base-end support parts 3"); tip-end support parts 4a, 4b (which may be referred to collectively
20 below as "tip-end support parts 4"); and guide rods 5a, 5b (which may be referred to collectively below as "guide rods 5").

The suture thread introduction needle 1 is preferably a
25 puncture needle having a lumen, and a suture thread 11 (see Figure 7) is housed inside this lumen in such a way as to be able to move axially. The suture thread introduction needle 1 is preferably formed from a metal such as stainless steel, for example. The suture thread introduction needle 1 typically has
30 a cutting face at the tip end thereof for puncturing the skin. The cutting face is preferably formed as a surface which obliquely intersects the axial centre of the suture thread introduction needle 1. Although there are no particular restrictions, the suture thread introduction needle 1 is
35 preferably attached to the base-end support parts 3 in such a

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way that the tip end opening thereof is oriented in the direction of the loop introduction needle 2.

Moreover, there are no particular restrictions as to the shape of the suture thread introduction needle 1 provided that it is able to pierce the skin and allows the suture thread 11 to be inserted. For example, a needle of outer diameter around 21 - 17 G (preferably 20 - 18 G) and length around 50 mm - 120 mm (preferably 70 - 90 mm) may be used as the suture thread introduction needle 1.

The loop introduction needle 2 is preferably a puncture needle having a lumen, and a suture thread retrieval loop 12 (described below in relation to Figure 6) is housed inside this lumen in such a way as to be able to move axially. The loop introduction needle 2 is typically formed from a metal such as stainless steel, for example. The loop introduction needle 2 typically has a cutting face at the tip end thereof for puncturing the skin. The cutting face is formed as a surface which obliquely intersects the axial centre of the loop introduction needle 2. The loop introduction needle 2 is preferably attached to the base-end support parts 3 in such a way that the tip end opening thereof is oriented in the direction of the suture thread introduction needle 1.

The base-end support parts 3 typically have the function of fixedly supporting the base ends of the suture thread introduction needle 1 and the loop introduction thread 2, while also supporting the guide rods 5 in such a way that they can slide axially. The base-end support parts 3 preferably comprise or consist of a pair of lateral base-end support parts 3a, 3b having a substantially cuboid outer shape. As shown in Figure 3, the base-end support parts 3a, 3b are typically separable from each other. The base-end support parts 3a, 3b are typically each formed with guide rod through-holes 31a, 31b into which the guide rods 5 are typically

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slidably inserted, and can be provided with a pair of lateral manipulating plates 32a, 32b. The manipulating plates 32a, 32b are preferably flat plate-like members which extend laterally from the base-end support parts 3, and the planar shape thereof (not depicted) has a size and shape which can be pressed by the practitioner's fingers. The manipulating plate 32b in this mode of embodiment can be detached from the base-end support part 3b by way of a stopper member 7, as will be described later in relation to Figure 4. It should be noted that this mode of embodiment describes a tool in which the base ends of the suture thread introduction needle 1 and the loop introduction needle 2 are preferably fixedly supported by the base-end support parts 3, but it is equally feasible for the suture thread introduction needle 1 and the loop introduction needle 2 to be detachably supported by the base-end support parts 3, for example.

Furthermore, the base-end support part 3a is preferably provided with a communicating hole 33a which communicates with the lumen of the suture thread introduction needle 1, while the base-end support part 3b is provided with a communicating hole 33b which communicates with the lumen of the loop introduction needle 2. The communicating holes 33a, 33b typically each have an opening at the upper surface of the base-end support parts 3, and the suture thread 11 and suture thread retrieval loop 12 preferably are inserted through these openings into the communicating holes 33a, 33b. The suture thread 11 and suture thread retrieval loop 12 are preferably further inserted through the communicating holes 33a, 33b into the suture thread introduction needle 1 and the loop introduction needle 2. It should be noted that a structure may be adopted in which the base ends of the suture thread introduction needle 1 and loop introduction needle 2 are inserted into the communicating holes 33a, 33b. In addition, the base ends of the suture thread introduction needle 1 and loop introduction needle 2 may pass through the communicating

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holes 33a, 33b and extend to the top surfaces of the base-end support parts 3a, 3b.

The stopper member 7 has preferably the function of detachably linking the base-end support parts 3a, 3b. As shown in Figure 2, when the stopper member 7 has been attached, the base-end support parts 3a, 3b typically form a single piece. In this state, the suture thread introduction needle 1 and the loop introduction needle 2 are preferably held substantially parallel with a prescribed distance therebetween by the base-end support parts 3 and the tip-end support parts 4.

Furthermore, as shown in Figure 3, when the stopper member 7 has been detached, the base-end support parts 3a, 3b are separated.

Figure 4 illustrates an exemplary structure of the stopper member according to Mode of Embodiment 1, focusing on the base-end support parts 3 and the stopper member 7. As shown in Figure 4, the stopper member 7 is preferably formed as a flat plate-like member which is substantially U-shaped in plan view; the stopper member 7 is typically inserted into laterally-extending holes, which are provided in the base-end support parts 3a, 3b, respectively, in such a way that it can be inserted and withdrawn. In this mode of embodiment, the stopper member 7 preferably forms a single piece with the manipulating plate 32b, and the practitioner can grasp the manipulating part 32b in order to insert or withdraw the stopper member 7. It should be noted that the stopper member 7 and the manipulating part 32b may be separately provided, in which case the manipulating part 32b does not have to be detachable from the base-end support part 3b.

It should be noted that the structure of the stopper member 7 shown in Figure 4 only constitutes one example, and there is no restriction as to the specific structure thereof provided

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that it can separably link the base-end support parts 3a, 3b. For example, the stopper member 7 may be a rod-like member which can be inserted and withdrawn along the base-end support parts 3a, 3b. Furthermore, a protrusion may be provided on
5 either the base-end support part 3a or 3b, while a hook which can catch the protrusion may be provided on the other, and the stopper member 7 may consist of the protrusion and the hook.

The tip-end support parts 4 preferably have the function of
10 fixedly supporting the tip ends of the guide rods 5a, 5b while also supporting the suture thread introduction needle 1 and the loop introduction needle 2 in such a way that they can slide axially. The tip-end support parts 4 can comprise or consist of the pair of lateral tip-end support parts 4a, 4b
15 which have typically a substantially flat plate-like shape. The tip-end support parts 4a, 4b are preferably respectively formed with a needle through-hole 41a into which the suture thread introduction needle 1 is typically slidably inserted, and a needle through-hole 41b into which the loop introduction
20 needle 2 is typically slidably inserted. It should be noted that the inner diameters of the needle through-holes 41a, 41b do not necessarily have to have a size relationship such that the inner peripheral surfaces of the needle through-holes 41a, 41b are in contact with the outer peripheral surfaces of the
25 suture thread introduction needle 1 and the loop introduction needle 2, and this size relationship should make it possible to restrict shaking of the suture thread introduction needle 1 and the loop introduction needle 2 to the extent that there is no impediment to practitioner operations. Furthermore, the
30 tip-end support parts 4 should have a structure which enables the suture thread introduction needle 1 and the loop introduction needle 2 to be supported in such a way that the puncture direction thereof is guided, and the needle through-holes 41a, 41b into which the two needles are slidably
35 inserted do not necessarily have to be provided. For example, grooves running in the puncture direction of the suture thread

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introduction needle 1 and the loop introduction needle 2 may be provided on the side surfaces of the tip-end support parts 4 instead of the needle through-holes 41a, 41b. Furthermore, in this mode of embodiment, a description has been given of a tool in which the tip ends of the guide rods 5a, 5b are fixedly supported by the tip-end support parts 4, but it is feasible for the guide rods 5a, 5b to be detachably supported by the tip-end support parts 4, for example.

10 The tip-end support parts 4a, 4b are preferably joined by the linking part 6 in such a way as to be able to move relative to each other in three directions, namely the front-to-rear direction, lateral direction and vertical direction. Here, the front-to-rear direction refers to the depthwise direction from
15 in front of the page in Figures 1 to 3; the lateral direction refers to the lateral direction on the page in Figures 1 - 3; and the vertical direction refers to the vertical direction on the page in Figures 1 - 3.

20 Figure 5 illustrates the linking part of the suturing tool according to Mode of Embodiment 1. Figure 5(A) is a plan view of the tip-end support parts 4a, 4b; Figure 5(B) is a schematic view in cross section showing the tip-end support parts 4a, 4b when they have been separated; Figure 5(C) is a
25 schematic view in cross section showing the tip-end support parts 4a, 4b when they have been linked; Figure 5(D) is a schematic view in cross section showing the tip-end support parts 4a, 4b when they have been moved; and Figure 5(E) is a view in which the suture thread introduction needle 1 and the
30 loop introduction needle 2 have been added to Figure 5(D). It should be noted that the guide rods 5a, 5b are not shown in Figure 5 for the sake of convenience.

As shown in Figure 5, the linking part 6 can comprise or
35 consist of a spherical protrusion 61 and a receiving part 62.

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The spherical protrusion 61 is a protrusion which is provided on the side surface of the tip-end support part 4b facing the tip-end support part 4a, and the tip end thereof is substantially spherical. The receiving part 62 is a bowl-shaped member provided on the side surface of the tip-end support part 4a on the side facing the spherical protrusion 61 which slidably fits together therewith. The spherical protrusion 61 and the receiving part 62 preferably form a ball joint.

When the spherical protrusion 61 is fitted together with the receiving part 62 by means of a method such as press-fitting while the tip-end support parts 4a, 4b are in a state of separation, as shown in Figures 5(A), (B), the tip-end support parts 4a, 4b are linked, as shown in Figure 5(C). The tip-end support part 4a and the tip-end support part 4b can then rotate by way of the ball joint formed by the spherical protrusion 61 and the receiving part 62, and the linking angle between the two can be varied. If the linking angle between the tip-end support parts 4a, 4b is varied, the suture thread introduction needle 1 and the loop introduction needle 2 may assume a positional relationship other than parallel, as shown in Figure 5(E).

The guide rods 5 shown in Figures 1 - 3 preferably have the function of guiding the axial movement of the base-end support parts 3a, 3b. The guide rod 5a is slidably inserted into the base-end support part 3a, while the guide rod 5b is slidably inserted into the base-end support part 3b.

A grip part 51 is preferably provided at the base end of the guide rod 5a. The grip part 51 is typically a member which is provided in order to aid gripping of the guide rod 5a by the practitioner, and in Mode of Embodiment 1 it is preferably provided as a flat plate-shaped member which can be gripped using two fingers. It should be noted that there are no

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particular restrictions as to the shape of the grip part 51, and it is possible to omit the grip part 51.

5 The base ends of the suture thread introduction needle 1 and the loop introduction needle 2 are preferably fixed to the base-end support parts 3, while the tip ends thereof are preferably supported by the tip-end support parts 4. When the base-end support parts 3a, 3b have been linked by means of the stopper member 7, the suture thread introduction needle 1 and
10 the loop introduction needle 2 are typically held a prescribed distance apart and substantially parallel by means of the base-end support parts 3 and the tip-end support parts 4. Furthermore, the tip ends and base ends of said needles are typically held by the base-end support parts 3 and the tip-end
15 support parts 4, whereby flexing of the suture thread introduction needle 1 and the loop introduction needle 2 is restricted.

20 As shown in Figure 2, when the practitioner depresses the manipulating plate 32 while gripping the grip part 51 of the guide rod 5a with one hand once the stopper member 7 has been attached to the base-end support parts 3, the suture thread introduction needle 1 and the loop introduction needle 2 which are fixed to the base-end support parts 3 typically move
25 axially towards the tip end side and project from the tip-end support parts 4.

30 Furthermore, as shown in Figure 1, when the manipulating plate 32 is drawn to the furthest extent towards the base end side, the needle tips of the suture thread introduction needle 1 and the loop introduction needle 2 are housed inside the tip-end support parts 4 and do not project from the tip-end support parts 4.

35 Furthermore, as shown in Figure 3, when the stopper member 7 is removed, the base-end support part 3a and the base-end

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support part 3b can be operated separately, so separate punctures can be made by the suture thread introduction needle 1 and the loop introduction needle 2.

5 The suture thread retrieval loop 12 will be described next. Figure 6 illustrates the suture thread retrieval loop according to Mode of Embodiment 1.

10 The suture thread retrieval loop 12 is inserted for use into the lumen of the loop introduction needle 2 in such a way as to be axially mobile. The suture retrieval loop 12 comprises: a narrow-diameter shaft part 121 which can move inside the lumen of the loop introduction needle 2; an annular loop 122 provided at the tip end of the shaft part 121; and a
15 manipulating part 123 provided at the base end of the shaft part 121. The loop 122 has a substantially circular planar shape. The loop 122 is made of a flexible material and is housed inside the lumen of the loop introduction needle 2 by deforming to a substantially linear shape when inserted into
20 the loop introduction needle 2, but returns to its original circular shape when fed out from the tip end of the loop introduction needle 2 (when no external force is applied thereto).

25 The suture thread 11 in use is inserted into the loop 122, as shown in Figure 7(C), which will be described later. The size and extension direction of the loop 122 are therefore set in such a way that the suture thread 11 which has been fed out from the tip end of the suture thread introduction needle 1 is
30 more reliably inserted into the loop 122 which has been fed out from the tip end of the loop introduction needle 2. For example, the suture thread 11 which has been fed out from the suture thread introduction needle 1 is more reliably inserted into the loop 122 if the loop 122 is formed with a size such
35 that the centre of the loop 122 lies on the line of extension of the suture thread introduction needle 1. As a further

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example, a mark corresponding to the extension direction of the loop 122 with respect to the shaft part 121 may be provided on the manipulating part 123 so that the practitioner can ascertain the extension direction of the loop 122 from outside the body. Furthermore, a structure may be adopted in which the manipulating part 123 snap-fits together with the base-end support parts 3 in the state shown in Figure 7(C) in such a way that the practitioner can ascertain, from outside the body, that the loop 122 is definitely protruding from the tip end of the loop introduction needle 2 (for example, a protrusion is provided on the base-end support parts 3 while a groove which fits together with the protrusion is provided on the manipulating part 123).

The loop 122 does not have to be a deformable member, and, for example, it may consist of: stainless steel wire (high tensile stainless steel for springs); piano wire (nickel-plated or chromium-plated piano wire); or superelastic alloy wire (titanium-nickel alloy, copper-zinc alloy (or an alloy containing beryllium, silicon, tin, aluminium or potassium etc. therewith), nickel-aluminium alloy etc.).

The shaft part 121 may be constructed using, among other things, a metal (e.g. stainless steel) or a synthetic resin (e.g. a polyolefin such as polypropylene or polyethylene, polyamide, or a fluororesin such as PTFE or ETFE). The shaft part 121 may consist of a stylet or the like. It should be noted that when the loop 122 is made of a relatively rigid material, the shaft part 121 and the loop 122 may be made of the same material. If that is the case, the shaft part 121 and the loop 122 may be formed as a single element or as separate elements.

The suture thread 11 will be described next. It should be noted that although the suture thread 11 is not part of the suturing tool 100 it will be briefly described here as it

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functions as an organopexy tool. The suture thread 11 consists of a material which is sufficiently flexible that it can bend along body tissue when inserted into the body and has sufficient tensile strength that it can raise the internal organ (e.g. nylon yarn). Furthermore, the suture thread 11 is cut when it is attached to or removed from the patient. The suture thread 11 is therefore preferably made of a material and has a diameter size which can be cut by a tool provided in a clinical setting, such as scissors. Furthermore, the suture thread 11 is housed in the suture thread introduction needle 1 for use, in such a way that the tip end thereof is inserted as far as the tip end of the suture thread introduction needle 1, while the base end thereof projects by a prescribed length from the base end of the suture thread introduction needle 1.

It should be noted that in Mode of Embodiment 1, the suture thread introduction needle 1 corresponds to the first puncture needle according to the present invention, and the loop introduction needle 2 corresponds to the second puncture needle according to the present invention. Furthermore, the base-end support part 3a corresponds to the first base-end support part according to the present invention, and the base-end support part 3b corresponds to the second base-end support part according to the present invention. Furthermore, the tip-end support part 4a corresponds to the first tip-end support part according to the present invention, and the tip-end support part 4b corresponds to the second tip-end support part according to the present invention. Furthermore, the stopper member 7 corresponds to the connecting part according to the present invention.

Usage of the Suturing Tool

Usage of the suturing tool 100 according to Mode of Embodiment 1 will be described next. Figure 7 illustrates the situation when the suturing tool according to Mode of Embodiment 1 is

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being used, where Figures 7(A) - (F) successively show the suturing procedure carried out using the suture thread 11. A description will be given here of an exemplary case in which a patient's abdominal wall 102 and stomach wall 101 are sutured
5 using the suturing tool 100.

The practitioner first of all inserts an endoscope orally or nasally into the patient's stomach. The practitioner then expands the internal organ by filling the internal organ with
10 a gas (e.g., carbon dioxide). As a result, the stomach wall 101 is placed in close contact with the abdominal wall 102. Next, the skin 103 is sterilized, including the site to be pierced by the suture thread introduction needle 1 and the loop introduction needle 2. The position of the internal organ
15 is then confirmed by the light emitted from the endoscope, and a local anaesthetic is applied at this site. It should be noted that the puncture site may be confirmed by pressing the surface of the body with the fingers while an endoscope is inserted into the stomach, and then confirming the position
20 where the stomach wall has been depressed by the finger pressure using the endoscope images (finger push test).

The state of the suturing tool 100 prior to puncturing will be described here.

25 The suturing tool 100 is in a state in which the loop 122 of the suture thread retrieval loop 12 is housed inside the loop introduction needle 2 and the suture thread 11 is housed inside the suture thread introduction needle 1. At this point,
30 the suture thread 11 is housed inside the suture thread introduction needle 1 in such a way as not to project from the tip end of the suture thread introduction needle 1. Furthermore, the suturing tool 100 is in a state in which the base-end support parts 3 are pulled up and separated from the
35 tip-end support parts 4 (the state shown in Figure 1) so that the tip ends of the suture thread introduction needle 1 and

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the loop introduction needle 2 are not projecting from the tip-end support parts 4. Furthermore, the stopper member 7 is attached to the base-end support parts 3a, 3b, and the suture thread introduction needle 1 and the loop introduction needle 2 are substantially parallel.

As shown in Figure 7(A), the practitioner first of all places the tip-end support parts 4 in contact with the site to be punctured.

10

As shown in Figure 7(B), the practitioner having confirmed the puncture site then pushes the base-end support parts 3 downwards while the tip-end support parts 4 are still in contact with the patient's skin 103. By doing so, the suture thread introduction needle 1 and the loop introduction needle 2 which are attached to the base-end support parts 3 are pushed downwards and pierce the patient's abdominal wall 102 and stomach wall 101. The practitioner pushes the base-end support parts 3 downwards until the tip ends of the suture thread introduction needle 1 and the loop introduction needle 2 are projecting inside the stomach wall 101.

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As shown in Figure 7(C), the practitioner having confirmed with the endoscope that the tip ends of the suture thread introduction needle 1 and the loop introduction needle 2 are projecting inside the stomach wall 101 then pushes the suture thread retrieval loop 12 towards the tip end side and feeds out the loop 122 of the suture thread retrieval loop 12 from the tip end of the loop introduction needle 2. The loop 122 which has been fed out from the tip end of the loop introduction needle 2 returns to its annular shape.

25
30

The practitioner then feeds the suture thread 11 towards the tip end side in order to cause the suture thread 11 to project from the tip end of the suture thread introduction needle 1. The suture thread 11 is fed out towards the tip end side in

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- 19 -

order to insert the suture thread 11 into the circle of the loop 122 which has already been fed out into the stomach.

As shown in Figure 7(D), the practitioner having confirmed
5 that the suture thread 11 has been inserted into the loop 122 then holds the manipulating part 123 of the suture thread retrieval loop 12 and pulls it towards him- or herself. By doing so, the annular loop 122 projecting from the tip end of the loop introduction needle 2 starts to be pulled back into
10 the loop introduction needle 2, and the suture thread 11 which is inserted through the loop 122 is caught by the loop 122 and drawn in towards the loop introduction needle 2.

As shown in Figure 7(E), the practitioner pulls the suture
15 thread retrieval loop 12 further towards him- or herself. By doing so, the tip end section of the suture thread 11 enters the loop introduction needle 2 together with the loop 122 of the suture thread retrieval loop 12.

20 At the point shown in Figure 7(E), the practitioner withdraws the suture thread introduction needle 1 and the loop introduction needle 2 from the patient's body.

As shown in Figure 7(F), when the suture thread introduction
25 needle 1 and the loop introduction needle 2 are withdrawn, both ends of the suture thread 11 which has passed through the abdominal wall 102 and the stomach wall 101 are then exposed at the surface of the body. The practitioner then ties the two ends of the exposed suture thread 11 together in order to
30 complete the suturing process.

The description given above relates to usage of the suturing
tool 100 when punctures are made simultaneously by the suture
thread introduction needle 1 and the loop introduction needle
35 2.

- 20 -

The following description relates to usage of the suturing tool 100 when punctures are made separately by the suture thread introduction needle 1 and the loop introduction needle 2. When the abdominal wall 102 and the stomach wall 101 are fixed, it is not always possible to make suitable punctures in the abdominal wall 102 and the stomach wall 101 because the suture thread introduction needle 1 and the loop introduction needle 2 are inserted in parallel, as shown in Figure 7. In such a case, separate punctures are made by the suture thread introduction needle 1 and the loop introduction needle 2.

Figure 8 illustrates usage of the suturing tool according to Mode of Embodiment 1 when the suture thread introduction needle 1 and the loop introduction needle 2 are used to make separate punctures.

As shown in Figure 8(A), when the stopper member 7 has been removed in order to separate the base-end support part 3a and the base-end support part 3b, one of the base-end support parts 3 (the base-end support part 3a in the example shown in Figure 8(A)) is depressed. When this is done, the suture thread introduction needle 1 which is attached to the base-end support part 3 is pushed downwards and the patient's abdominal wall 102 and stomach wall 101 are pierced. The practitioner pushes the base-end support part 3a downwards until the tip end of the suture thread introduction needle 1 is projecting inside the stomach wall 101.

Then, holding the base-end support part 3b, the practitioner moves the tip-end support part 4b in the front-to-rear direction, the lateral direction, or the vertical direction. The tip-end support part 4a and the tip-end support part 4b are joined by means of the linking part 6 which is constructed as a ball joint, and therefore the tip-end support part 4b can be moved. The tip-end support part 4b is then aligned with the

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direction in which the puncture is to be made by the loop introduction needle 2.

As shown in Figure 8(B), the practitioner having determined
5 the puncture site for the loop introduction needle 2 then depresses the base-end support part 3b. When this is done, the loop introduction needle 2 which is attached to the base-end support part 3b is pushed downwards and the patient's abdominal wall 102 and stomach wall 101 are pierced. The
10 practitioner pushes the base-end support part 3b downwards until the tip end of the loop introduction needle 2 is projecting inside the stomach wall 101. The subsequent procedure is the same as in Figures 7(C) - (F).

15 It should be noted that the description given above relates to an example of operation for when separate punctures are to be made by the suture thread introduction needle 1 and the loop introduction needle 2 from the outset, but the suturing tool 100 can equally be used when only one of the needles, which
20 pierced at the same time, as shown in Figure 7, has not made a suitable puncture, for example.

When one of the needles has not made a suitable puncture, the stopper member 7 is removed from the base-end support parts 3
25 and only the needle which did not make a successful puncture is withdrawn from the patient. The puncture made by the needle which has been withdrawn is then corrected, as illustrated in Figures 8(A), (B). It should be noted that if it is only the puncture to the stomach wall 101 which is unsuitable, the
30 needle can be withdrawn from the stomach wall 101 while it is still piercing the abdominal wall 102, and the needle puncture of the stomach wall 101 can be corrected.

As described above, with the suturing tool 100 according to
35 Mode of Embodiment 1, the tip-end support part 4a and the tip-end support part 4b are joined in such a way that the linking

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angle between the two can be adjusted by means of the linking part 6. It is therefore possible to increase the degree of freedom in the puncture direction of the suture thread introduction needle 1 and the loop introduction needle 2, and punctures can be made by the suture thread introduction needle 1 and the loop introduction needle 2 in any direction. This means that the practitioner can make needle punctures in a suitable direction according to the state of the patient's abdominal wall and stomach wall, so the success rate for fixing an internal organ wall and the abdominal wall can be increased.

For example, if a suitable puncture has not been made by either the suture thread introduction needle 1 or the loop introduction needle 2 which pierced at the same time, it is possible to temporarily withdraw only that needle in order to make a new puncture, and the work involved in making a puncture again can be minimized. This means that the process is less invasive for the patient so the burden on the patient can be lightened, while the ease of use for the practitioner is improved, making it possible to shorten the duration of the procedure.

Furthermore, the linking part 6 is constructed as a ball joint. It is therefore possible to vary the linking angle of the tip-end support part 4a and the tip-end support part 4b in three directions, namely the front-to-rear direction, lateral direction and vertical direction. This means that it is possible to further increase the degree of freedom in the puncture direction of the suture thread introduction needle 1 and the loop introduction needle 2 which are guided in the puncture direction by the tip-end support parts 4a, 4b. For example, if another organ is forming an impediment (obstacle) and it is difficult to make two needle punctures in parallel, the suturing tool 100 enables a needle puncture to be made at

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a suitable place, so the success rate for organopexy can be improved.

Furthermore, the linking part 6 links the tip-end support parts 4a, 4b while the positional relationship of the two is variable. That is, the suture thread introduction needle 1 and the loop introduction needle 2 are not completely separated because of the linking part 6, while there is also a greater degree of freedom in the puncture direction of the two needles, and therefore the distance between the suture thread introduction needle 1 and the loop introduction needle 2 can be kept within a prescribed range. The degree of freedom in changing the positions of the tip-end support parts 4a, 4b by means of the linking part 6 is appropriately set taking account of the diameter of the loop 122 of the suture thread retrieval loop 12 and the range of movement of the tips of the suture thread introduction needle 1 and the loop introduction needle 2; as a result, it is possible to increase the likelihood of the suture thread 11 being suitably inserted into the circular part of the loop 122 compared with conventional technology in which the suture thread introduction needle and loop introduction needle are provided separately and each make a puncture. That is, the likelihood of the suture thread 11 being gripped by the suture thread retrieval loop 12 can be increased, so the success rate for organopexy can be improved.

Furthermore, the base-end support part 3a and the base-end support part 3b can be linked by means of the stopper member 7. When the base-end support part 3a and the base-end support part 3b are linked, the two needles can be axially moved at the same time. The suture thread introduction needle 1 and the loop introduction needle 2 can be made to pierce the patient's body at the same time, and therefore the device demonstrates good operability. Furthermore, when the base-end support part 3a and the base-end support part 3b are linked by means of the

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stopper member 7, the suture thread introduction needle 1 and the loop introduction needle 2 can be kept substantially parallel with a prescribed distance therebetween. Punctures can therefore be made by the suture thread introduction needle 1 and the loop introduction needle 2 in a positional relationship such that the suture thread 11 can be grasped with certainty by the suture thread retrieval loop 12, and there is no reduction in the success rate for organopexy when punctures are made simultaneously by the two needles.

It should be noted that Mode of Embodiment 1 describes an example in which the grip part 51 is provided only on the guide rod 5a, but a similar grip part 51 may also be provided on the guide rod 5b.

Mode of Embodiment 2 describes another exemplary structure of the linking part. It should be noted that the description given in Mode of Embodiment 2 will focus on the differences with Mode of Embodiment 1, and elements which are the same as in Mode of Embodiment 1 bear the same reference symbols and will not be described again.

Figure 9 illustrates the linking part of the suturing tool according to Mode of Embodiment 2. As shown in Figure 9, the linking part 6A according to Mode of Embodiment 2 consists of a helical spring 63 which is an elastic member. The spring 63 is attached at both ends to the opposing faces of the tip-end support parts 4a, 4b. The tip-end support parts 4a, 4b are joined by means of the linking part 6A comprising the spring 63, and therefore the relative positional relationship of the tip-end support parts 4a, 4b can be varied in three directions, namely the longitudinal direction, transverse direction and heightwise direction. In this way, the same advantages as in Mode of Embodiment 1 can also be achieved when the linking part 6A consists of the spring 63.

- 25 -

In addition to the linking part 6A which consists of the helical spring 63, the linking part 6A may equally consist of a plate spring. Furthermore, the linking part 6A may equally be formed by an elastic member such as rubber or silicone. In this way, any construction may be adopted for the linking part 6A, provided that it is a member having elastic properties enabling the linking angle of the tip-end support parts 4a, 4b to be varied. Furthermore, the linking part 6A preferably enables the linking angle of the tip-end support parts 4a, 4b to be varied in three directions from the point of view of further increasing the degree of freedom in the puncture direction of the suture thread introduction needle 1 and the loop introduction needle 2, but the effect of increasing the degree of freedom in the puncture direction of the suture thread introduction needle 1 and the loop introduction needle 2 is still achieved if the linking angle is varied in one or two directions.

Key to Symbols

1 suture thread introduction needle; 2 loop introduction needle; 3 base-end support parts; 3a, 3b base-end support part; 4 tip-end support parts; 4a, 4b tip-end support part; 5 guide rods; 5a, 5b guide rod; 6 linking part; 6A linking part; 7 stopper member; 11 suture thread; 12 suture thread retrieval loop; 31a, 31b guide rod through-hole; 32 manipulating plate; 32a, 32b manipulating plate; 33a, 33b communicating hole; 41a, 41b needle through-hole; 51 grip part; 61 spherical protrusion; 62 receiving part; 63 spring; 100 suturing tool; 101 stomach wall; 102 abdominal wall; 103 skin; 121 shaft part; 122 loop; 123 manipulating part.

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Claims

1. Puncture device characterized in that it comprises:

a first puncture needle;

5 a second puncture needle;

a first base-end support part for holding the base end of the first puncture needle;

10 a second base-end support part, provided in such a way as to be separable from the first base-end support part, for holding the base end of the second puncture needle;

a first tip-end support part for supporting the first puncture needle in such a way as to be axially mobile;

a second tip-end support part for supporting the second puncture needle in such a way as to be axially mobile; and

15 a linking part for linking the first tip-end support part and the second tip-end support part in such a way that the linking angle thereof is adjustable.

20 2. The puncture device according to Claim 1, characterized in that it comprises a connecting part for separably connecting the first base-end support part and the second base-end support part.

25 3. The puncture device according to Claim 2, characterized in that when the first base-end support part and the second base-end support part have been connected by means of the connecting part, the first puncture needle and the second puncture needle are disposed substantially parallel to each other with a prescribed distance therebetween.

30 4. The puncture device according to any one of Claims 1 to 3, characterized in that the linking part makes it possible to adjust the linking angle of the first tip-end support part and the second tip-end support part at least in any direction from
35 among the front-to-rear direction, the lateral direction and the vertical direction.

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5. The puncture device according to any one of Claims 1 to 4, characterized in that the linking part consists of a ball joint.

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6. The puncture device according to any one of Claims 1 to 4, characterized in that the linking part consists of an elastic member.

10 7. The puncture device according to any one of Claims 1 to 6, characterized in that the first puncture needle is a suture thread introduction needle which allows a suture thread to be inserted into the lumen thereof; and
the second puncture needle is a loop introduction needle which
15 allows a suture thread retrieval tool having an elastically deformable loop at the tip end to be inserted into the lumen thereof.

Figure 1

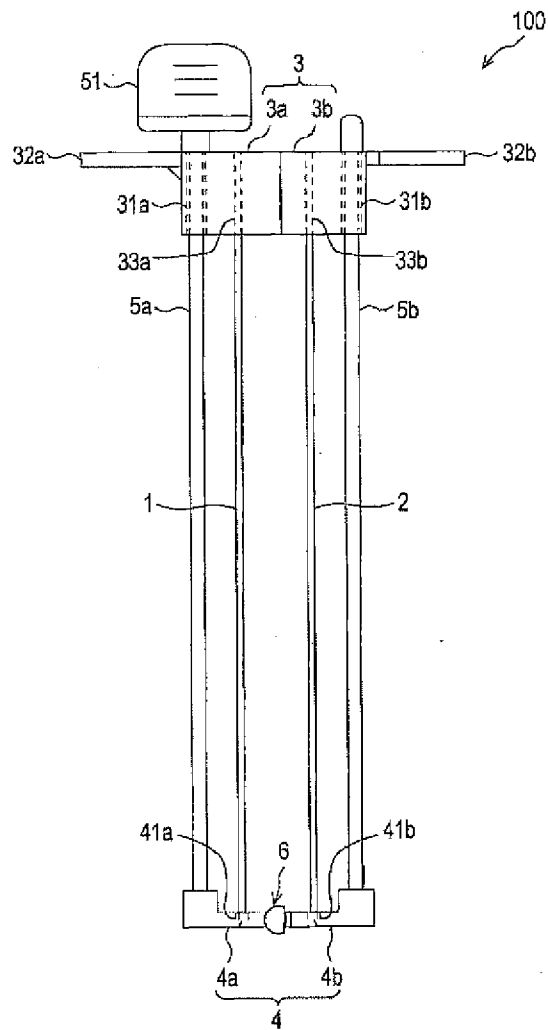


Figure 2

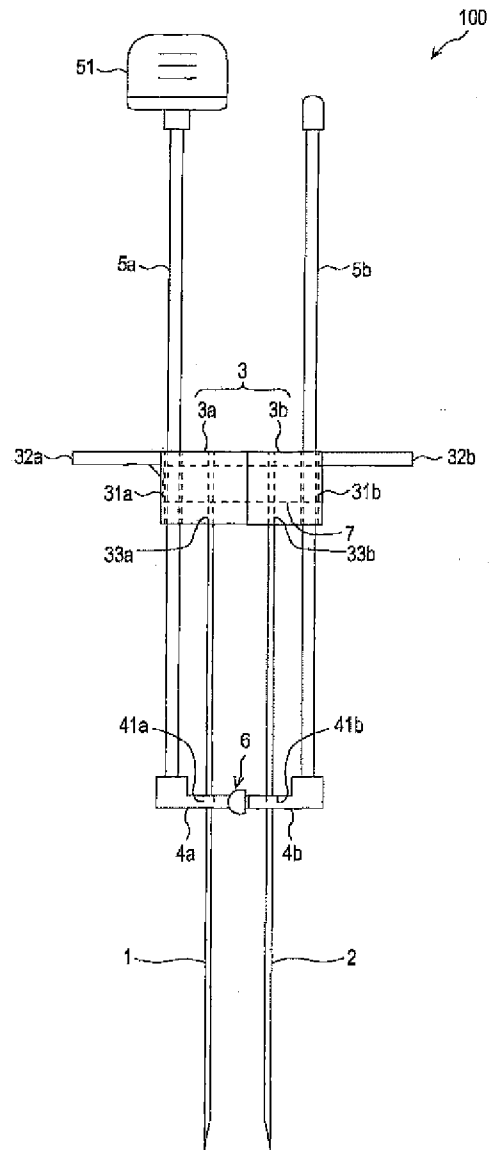


Figure 3

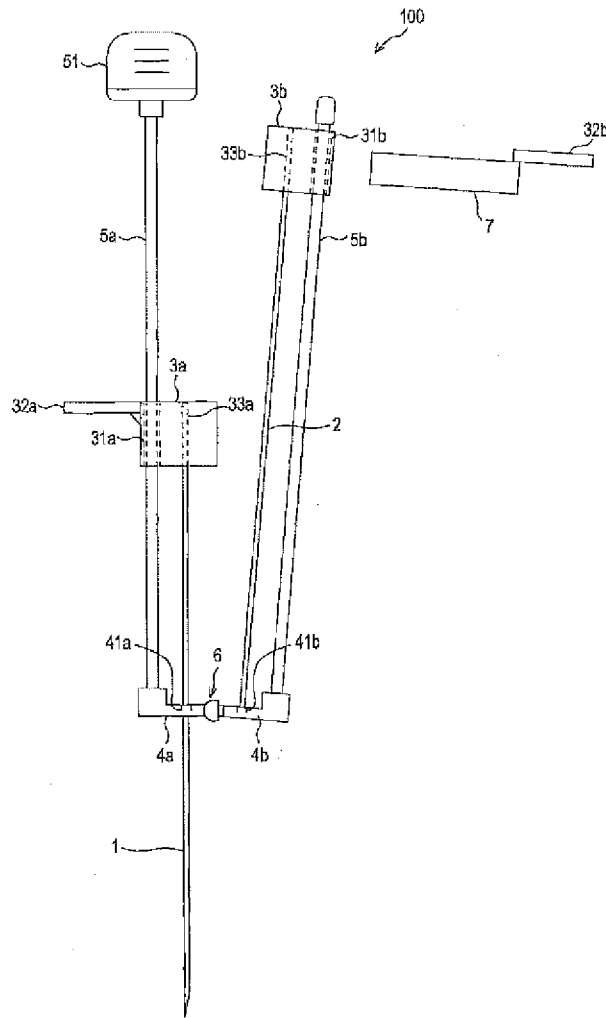


Figure 4

5

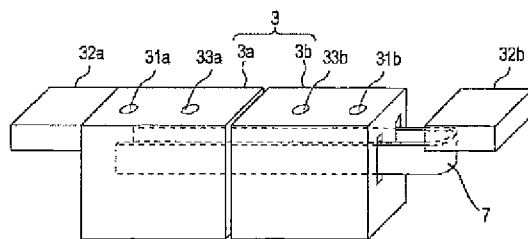
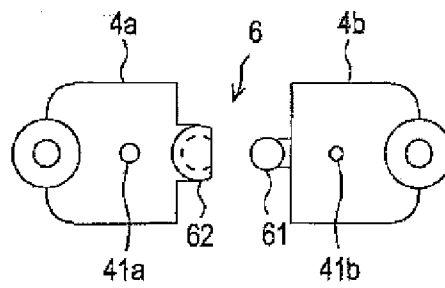
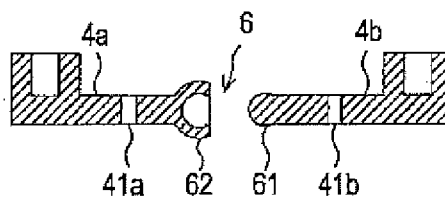


Figure 5

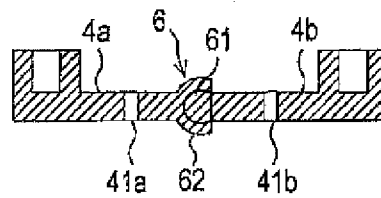
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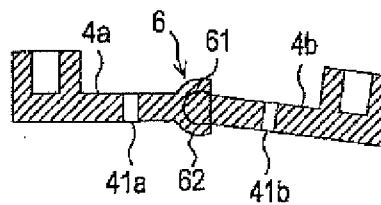
(B)



(C)



(D)



(E)

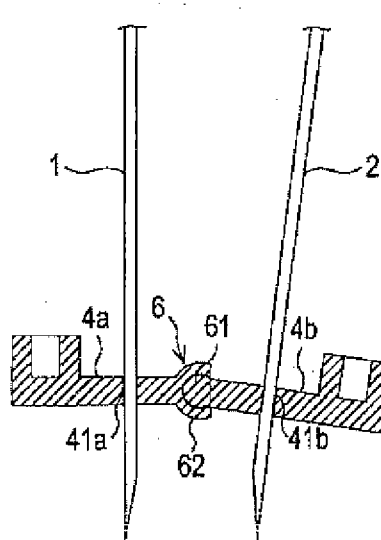


Figure 6

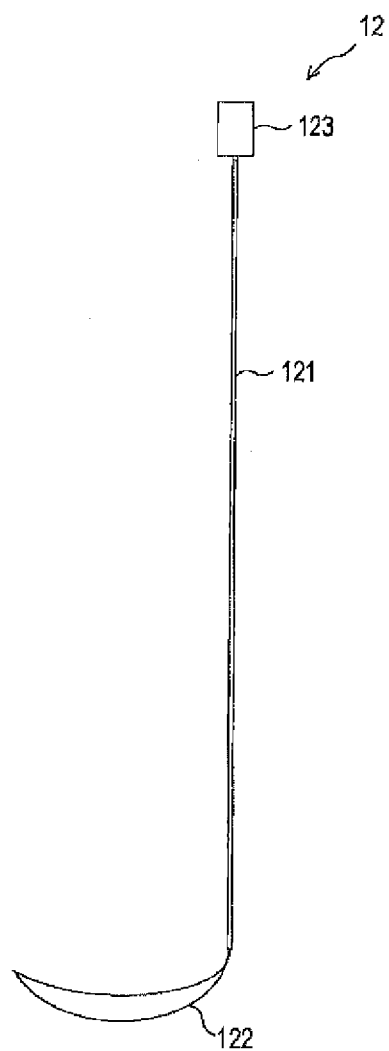


Figure 7

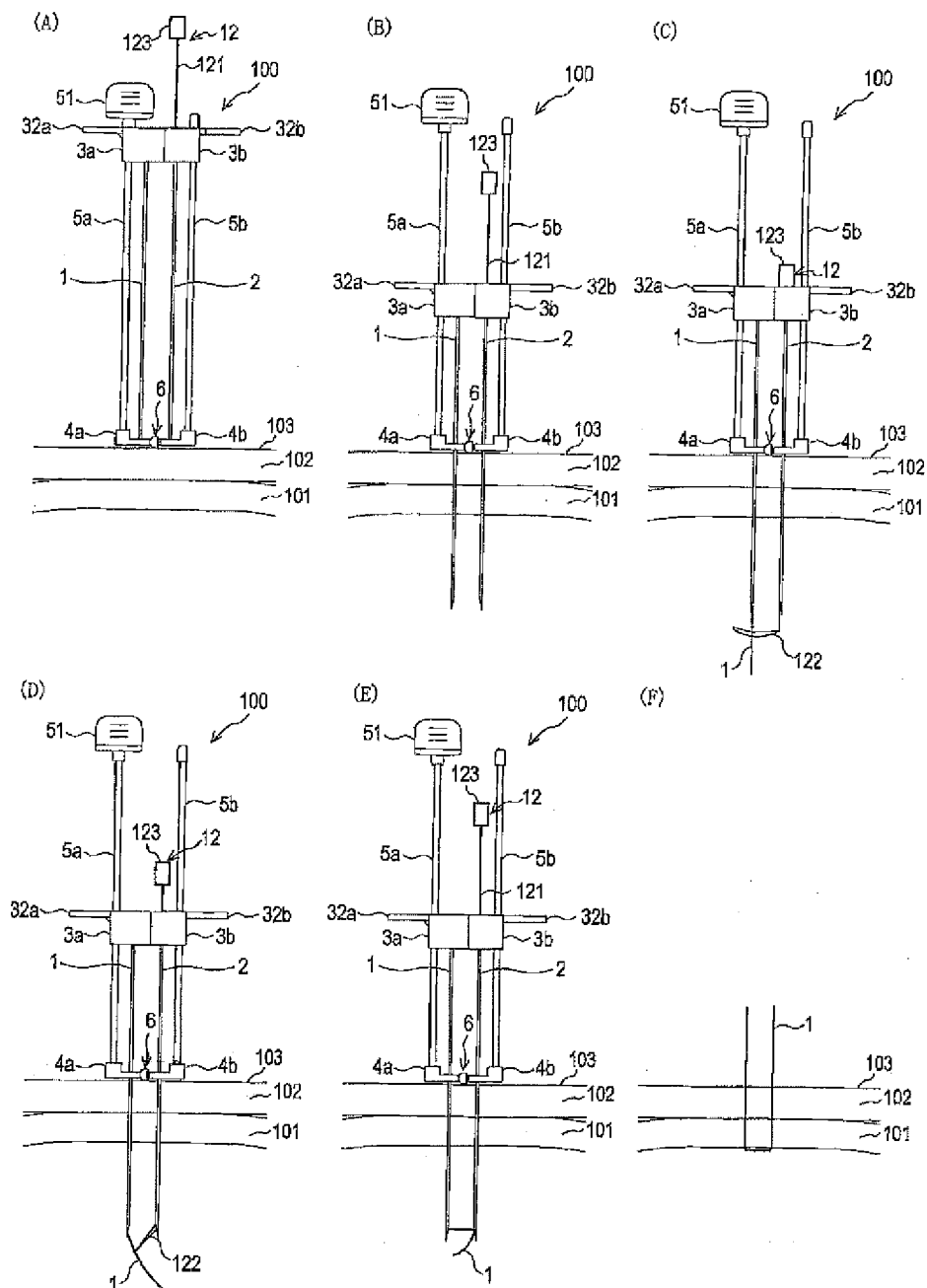
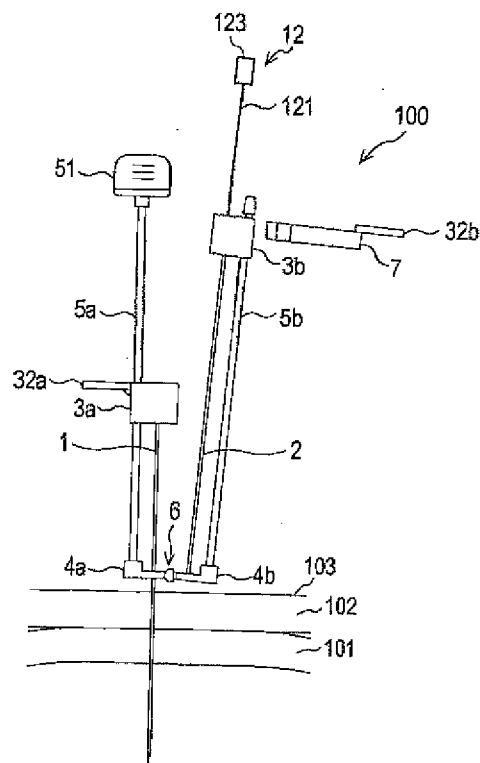
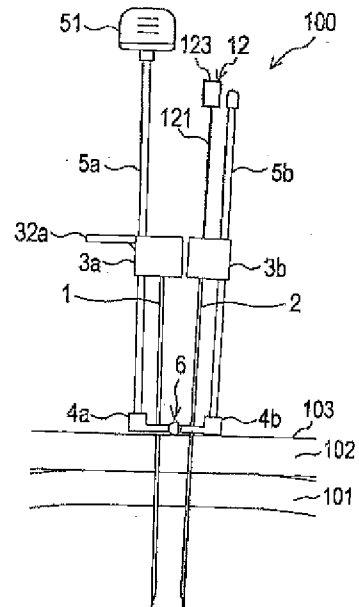


Figure 8

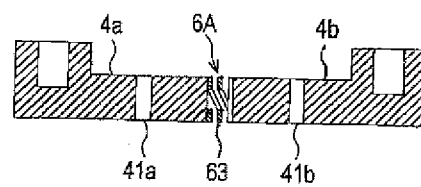
(A)



(B)



5 Figure 9



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/035804

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 2 193 750 A1 (SUMITOMO BAKELITE CO [JP]; SUZUKI YUTAKA [JP]) 9 June 2010 (2010-06-09) paragraph [0017] - paragraph [0069]; figures -----	1
A	EP 2 005 892 A2 (SUMITOMO BAKELITE CO [JP]; SUZUKI YUTAKA [JP]) 24 December 2008 (2008-12-24) paragraph [0025] - paragraph [0164]; figures -----	1
A	US 5 782 845 A (SHEWCHUK DWIGHT [US]) 21 July 1998 (1998-07-21) column 3, line 1 - column 5, line 38; figures ----- -/--	1



Further documents are listed in the continuation of Box C.



See patent family annex.

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

10 July 2012

Date of mailing of the international search report

17/07/2012

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Authorized officer

Nistor, Loredana

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2012/035804

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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			WO 2009041057 A1 02-04-2009

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