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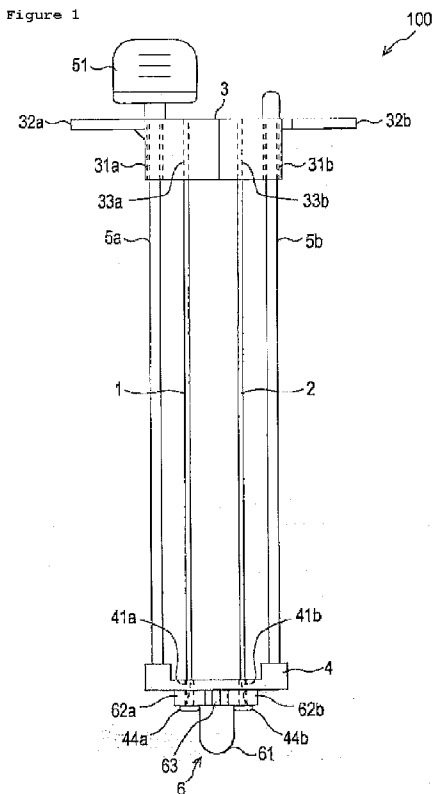
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[Continued on next page]

(54) Title: PUNCTURE DEVICE



(57) Abstract: A puncture device comprises: a suture thread introduction needle 1; a loop introduction needle 2 which is provided a prescribed distance apart from the suture thread introduction needle 1 and substantially parallel thereto; a tip-end support part 4 for supporting the suture thread introduction needle 1 and the loop introduction needle 2 in such a way that said needles can slide axially; and a cylindrical protrusion 6 for creating a depression in the abdominal wall, the cylindrical protrusion 6 being provided between the positions where the suture thread introduction needle 1 and the loop introduction needle 2 pass through the tip-end support part 4, in such a way that said cylindrical protrusion 6 projects further towards the tip end side than the suture thread introduction needle 1 and the loop introduction needle 2 when the suture thread introduction needle 1 and the loop introduction needle 2 are moved as far as possible towards the base end.

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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 in order to suture the abdominal wall and the wall of an internal organ such as the stomach or bladder.

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

A medical tool used for suturing an internal organ wall  
20 and the abdominal wall typically has a suture thread-insertion puncture needle; a suture thread-gripping puncture needle which is provided a prescribed distance apart from said suture thread-insertion puncture needle and substantially parallel thereto; a stylet which is  
25 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 needle and the suture thread-gripping puncture needle, wherein the stylet has an annular member at the tip end  
30 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-insertion puncture  
35 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 example).

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## Summary of the Invention

When a medical tool is employed, it may involve making  
5 a puncture with the needle at a position where the  
stomach wall and abdominal wall can be fixed, but there  
are occasions when the needle has pierced the abdominal  
wall from the surface of the body without piercing the  
10 stomach wall because the stomach wall and abdominal  
wall are separated. The practitioner therefore usually  
performs a procedure for confirming the puncture site  
prior to making a puncture with the needle.  
Specifically, the puncture site is confirmed by  
15 pressing the surface of the body using the fingers  
while an endoscope is inserted inside the stomach, and  
then confirming the position where the stomach wall has  
been depressed by the finger pressure using the  
endoscope images (finger push test).

20 A medical tool can be then set up and a puncture is  
made using the needle at the position/direction  
confirmed as the puncture location in the finger push  
test.

25 However, if the medical tool is set up with the fingers  
having been temporarily moved away from the puncture  
site after the site has been confirmed by the finger  
push test, there is a risk that the confirmed puncture  
site and the actual puncture site will be misaligned,  
30 and the puncture will not be made at the intended  
position. Furthermore, if the practitioner uses the  
medical tool to make the puncture while still marking  
the puncture site with his or her fingers, the tool is  
difficult to use and there is also a danger of  
35 inadvertent puncturing of the practitioner's fingers.  
The present invention has been devised in order to  
resolve issues such as those outlined above by

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providing a puncture device which allows a puncture position to be easily confirmed.

5 The puncture device according to the present invention can comprise a suture thread introduction needle; a loop introduction needle which is provided a prescribed distance apart from the suture thread introduction needle and substantially parallel thereto; a tip-end support part for supporting the suture thread  
10 introduction needle and the loop introduction needle in such a way that said needles can slide axially; and a pressing part for creating a depression in the abdominal wall, the pressing part being provided between the positions where the suture thread  
15 introduction needle and the loop introduction needle pass through the tip-end support part, in such a way that said pressing part projects further towards the tip end side than the suture thread introduction needle and the loop introduction needle when the suture thread  
20 introduction needle and the loop introduction needle are moved as far as possible towards the base end.

The pressing part in the puncture device according to the present invention is detachable from the tip-end  
25 support part.

With the puncture device according to the present invention, the surface of the body is pressed by the pressing part provided on the tip-end support part  
30 before punctures are made by the suture thread introduction needle and the loop introduction needle, so it is possible to realize an equivalent function to that of the finger push test which a practitioner performs with the fingers. The puncture site can  
35 therefore be easily confirmed. Furthermore, after the practitioner has confirmed the puncture site by pressing the surface of the body using the pressing

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part, punctures can be made using the suture thread introduction needle and the loop introduction needle while this state is maintained, so the device is easy to use. Furthermore, the practitioner's fingers will  
5 not be inadvertently pierced because there is no need for the practitioner to perform the finger push test with the fingers.

With the puncture device according to the present invention, the pressing part is provided in such a way as to be detachable from the tip-end support part and therefore the pressing part can be detached if there is no need to confirm the puncture site using pressure. This means that there is no loss of operability because  
10 the pressing part does not impede the practitioner's operation.  
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#### Brief Description of the Figures

20 Figure 1 is an external view of a suturing tool according to Mode of Embodiment 1;  
Figure 2 is an external view of the suturing tool according to Mode of Embodiment 1 when the puncture needles thereof are projecting;  
25 Figure 3 is an enlargement of the main parts of the suturing tool according to Mode of Embodiment 1, illustrating the situation when the cylindrical protrusion has been detached;  
Figure 4 illustrates the cylindrical protrusion of the  
30 suturing tool according to Mode of Embodiment 1;  
Figure 5 illustrates the suture thread retrieval loop according to Mode of Embodiment 1;  
Figure 6 illustrates the situation when the suturing tool according to Mode of Embodiment 1 is being used;  
35 Figure 7 illustrates the cylindrical protrusion of the suturing tool according to Mode of Embodiment 2;

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Figure 8 is an enlargement of the main parts of the suturing tool according to Mode of Embodiment 2, illustrating the situation when the cylindrical protrusion has been detached; and

5 Figure 9 illustrates the attachment/detachment structure of the cylindrical protrusion of the suturing tool according to Mode of Embodiment 2.

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

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#### Suturing Tool

Figure 1 is an external view of a suturing tool 100 according to Mode of Embodiment 1. Figure 2 is an  
20 external view of the suturing tool according to Mode of Embodiment 1 when the puncture needles thereof are projecting.

As shown in Figure 1, the suturing tool 100 comprises:  
25 a suture thread introduction needle 1; a loop introduction needle 2; a base-end support part 3; a tip-end support part 4; and guide rods 5a, 5b (which may be referred to collectively below as "guide rods 5").

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The suture thread introduction needle 1 is a needle having a lumen, and a suture thread 11 (see Figure 6) is housed inside this lumen in such a way as to be able to move axially. The suture thread introduction needle  
35 1 is formed from a metal such as stainless steel, for example. The suture thread introduction needle 1 has a cutting face at the tip end thereof for puncturing the

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skin. The cutting face is 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  
5 needle 1 is preferably attached to the base-end support part 3 in such a way that the tip end opening thereof is oriented in the direction of the loop introduction needle 2.

10 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  
15 needle of outer diameter around 21 - 17 G (preferably 20 - 18 G) and length around 50 mm - 120 mm (preferably 70 - 90 mm) should be used as the suture thread introduced needle 1.

The loop introduction needle 2 is typically a needle  
20 having a lumen, and a suture thread retrieval loop 12 (described below in relation to Figure 5) is typically 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,  
25 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 typically formed as a surface which obliquely intersects the axial centre of the loop introduction needle 2. The  
30 loop introduction needle 2 is preferably attached to the base-end support part 3 in such a way that the tip end opening thereof is oriented in the direction of the suture thread introduction needle 1.

35 The base-end support part 3 has the function of fixedly supporting the base ends of the suture thread introduction needle 1 and the loop introduction thread

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2, while also supporting the guide rods 5 in such a way that they can slide axially. The base-end support part 3 typically has a substantially cuboid outer shape formed with guide rod through-holes 31a, 31b into which the guide rods 5 are typically slidably inserted, and is typically provided with a pair of lateral manipulating plates 32a, 32b. The manipulating plates 32a, 32b are typically flat plate-like members which extend laterally from the base-end support part 3, and the planar shape thereof (not depicted) typically has a size and shape which can be pressed by the practitioner's fingers. It should be noted that in this mode of embodiment, a description is given of a tool in which the base ends of the suture thread introduction needle 1 and the loop introduction needle 2 are fixedly supported by the base-end support part 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 part 3, for example.

Furthermore, the base-end support part 3 is typically provided with a communicating hole 33a which communicates with the lumen of the suture thread introduction needle 1, and 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 part 3, and the suture thread 11 and suture thread retrieval loop 12 are typically inserted through these openings into the communicating holes 33a, 33b. The suture thread 11 and suture thread retrieval loop 12 typically are 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

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suture thread introduction needle 1 and loop introduction needle 2 are inserted into the communicating holes 33a, 33b.

5 The tip-end support part 4 typically has the function of 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-  
10 end support part 4 typically has a substantially flat plate-like shape and is formed with a needle through-hole 41a into which the suture thread introduction needle 1 is slidably inserted, and a needle through-hole 41b into which the loop introduction needle 2 is  
15 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  
20 surfaces of the 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  
25 is no impediment to practitioner operations. Furthermore, the tip-end support part 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  
30 thereof is guided, and the needle through-holes 41a, 41b into which the two needles are slidably inserted do not necessarily have to be provided. For example, grooves running in the puncture direction of the suture thread introduction needle 1 and the loop introduction  
35 needle 2 may be provided on the side surfaces of the tip-end support part 4 instead of the needle through-holes 41a, 41b. Furthermore, in this mode of

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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 part 4, but it is feasible for the guide rods 5a, 5b to be detachably supported by the base-end support part 3, for example.

The base ends of the suture thread introduction needle 1 and the loop introduction needle 2 typically are fixed to the base-end support part 3, while the tip ends thereof are typically slidably supported by the tip-end support part 4. The suture thread introduction needle 1 and the loop introduction needle 2 are typically held a prescribed distance apart and substantially parallel by means of the base-end support part 3 and the tip-end support part 4. Furthermore, the tip ends and base ends of said needles are typically held by the base-end support part 3 and the tip-end support part 4, whereby flexing of the suture thread introduction needle 1 and the loop introduction needle 2 is restricted.

A grip part 51 is typically 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 provided as a flat plate-shaped member which can be gripped using two fingers. It should be noted that there are no particular restrictions as to the shape of the grip part 51, and it is possible to omit the grip part 51.

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, the suture thread introduction needle 1 and the loop introduction needle 2 which are fixed to the base-end support part 3

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typically move axially towards the tip end side and project from the tip-end support part 4.

Furthermore, as shown in Figure 1, when the  
5 manipulating plate 32 is typically 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 part 4 and typically do not project from  
10 the tip-end support part 4.

A cylindrical protrusion 6 is typically provided on the tip-end support part 4. The cylindrical protrusion 6 is a pressing part for creating a depression in the  
15 patient's abdominal wall and internal organ wall when the abdominal wall and internal organ wall have been pressed from the surface of the body. The cylindrical protrusion 6 is typically provided in such a way as to project from the tip-end support part 4 in the same  
20 direction as the direction of projection of the suture thread introduction needle 1 and the loop introduction needle 2.

As shown in Figure 1, when the manipulating plate 32  
25 has been drawn to the furthest extent towards the base end side so that the needle tips of the suture thread introduction needle 1 and the loop introduction needle 2 are housed inside the tip-end support part 4, the tip end of the cylindrical protrusion 6 projects further  
30 towards the tip end side than the needle tips of the suture thread introduction needle 1 and the loop introduction needle 2.

Furthermore, as shown in Figure 2 when the needle tips  
35 of the suture thread introduction needle 1 and the loop introduction needle 2 are projecting a prescribed distance from the tip-end support part 4, the needle

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tips of the suture thread introduction needle 1 and the loop introduction needle 2 can be positioned further towards the tip end side than the tip end of the cylindrical protrusion 6.

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Figure 3 is an enlargement of the main parts of the suturing tool according to Mode of Embodiment 1, illustrating the situation when the cylindrical protrusion has been detached. Furthermore, Figure 4 illustrates the cylindrical protrusion of the suturing tool according to Mode of Embodiment 1. It should be noted that Figure 4(A) is a front view of the cylindrical protrusion, Figure 4(B) is a plan view of the cylindrical protrusion, and Figure 4(C) is an oblique view of the cylindrical protrusion.

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As shown in Figure 3, the tip-end support part 4 has a protrusion attachment part 42 for detachably attaching the cylindrical protrusion 6. In Mode of Embodiment 1, the protrusion attachment part 42 comprises: two shaft parts 43a, 43b; and flange-shaped enlarged-diameter parts 44a, 44b where the tip-end diameters of the shaft parts 43a, 43b are enlarged. Furthermore, needle through-holes 41a, 41b are formed inside the shaft parts 43a, 43b and enlarged-diameter parts 44a, 44b.

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As shown in Figure 4, the cylindrical protrusion 6 can comprise a protruding part 61; a pair of fitting parts 62a, 62b; and a holding part 63.

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The protruding part 61 is typically a cylindrical member with a bottom, formed with a hemispherical tip end. There are no particular restrictions as to the size and shape of the protruding part 61, but it is preferably designed so as not to readily cause the patient pain when the body surface such as the abdominal wall of the patient is pressed by the

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protruding part 61, and so as to be sufficiently hard that the depression in the internal organ wall produced by pressure from the protruding part 61 can be confirmed by an endoscope inserted into the internal organ. The protruding part 61 is preferably made of a rigid or semi-rigid plastic, for example polypropylene, ABS or polyurethane, or the like. Furthermore, the tip end of the protruding part 61 may consist of a soft member in order to improve the feeling on the skin.

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The fitting parts 62a, 62b are preferably substantially C-shaped members which are partly open annular members when seen in plan view. The fitting parts 62a, 62b are typically made of elastic synthetic resin or similar, and the openings in the fitting parts 62a, 62b elastically deform radially to enable detachment from the shaft parts 43a, 43b.

The holding part 63 is preferably a manipulating part which is used when the cylindrical protrusion 6 is attached to or detached from the protrusion attachment part 42, and said holding part 63 has a size and shape which allows it to be gripped by the practitioner. In Mode of Embodiment 1, the holding part 63 is formed as rod shape extending in the same direction as the attachment/detachment direction of the fitting parts 62a, 62b.

When the cylindrical protrusion 6 is attached to the protrusion attachment part 42, the practitioner typically grips the holding part 63 and presses the openings in the fitting parts 62a, 62b against the shaft parts 43a, 43b. When this is done, the fitting parts 62a, 62b elastically deform and the openings widen so that the shaft parts 43a, 43b fit together with the fitting parts 62a, 62b. The fitting parts 62a, 62b can be prevented from dropping downwards by means

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of the enlarged diameter parts 44a, 44b provided at the tip ends of the shaft parts 43a, 43b.

5 When the cylindrical protrusion 6 is detached from the protrusion attachment part 42, the practitioner typically grips the holding part 63 and pulls it towards himself or herself. When this is done, the fitting parts 62a, 62b typically elastically deform and the openings widen so that the shaft parts 43a, 43b are  
10 withdrawn from the fitting parts 62a, 62b.

When the holding part 63 is held in this way and pressed or pulled, the cylindrical protrusion 6 can be readily attached to or detached from the protrusion  
15 attachment part 42.

The suture thread retrieval loop 12 will be described next. Figure 5 illustrates the suture thread retrieval loop according to Mode of Embodiment 1.  
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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 can comprise a narrow-diameter shaft part 121 which can move inside the lumen of the loop  
25 introduction needle 2; an annular loop 122 provided at the tip end of the shaft part 121; and a manipulating part 123 provided at the base end of the shaft part 121. The loop 122 preferably has a substantially circular planar shape. The loop 122 is typically made of a flexible material and is typically housed inside the lumen of the loop introduction needle 2 by deforming to a substantially linear shape when inserted  
30 into 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).  
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The suture thread 11 in use is inserted into the loop 122, as shown in Figure 6(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 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 tip end of the suture thread introduction needle 1 is more reliably inserted into the loop 122 if the loop 122 is formed with a size such that the centre of the loop 122 lies on the line of extension of the suture thread introduction needle 1. As a further 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 part 3 in the state shown in Figure 6(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 can be provided on the base-end support part 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,

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tin, aluminium or potassium etc. therewith), nickel-aluminium alloy etc.).

The shaft part 121 may be constructed using, among  
5 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  
10 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.

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The suture thread 11 will be described next. It should  
be noted that although the suture thread 11 is  
typically not part of the suturing tool 100 it will be  
briefly described here as it functions as an organopexy  
20 tool. The suture thread 11 can consist 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  
25 suture thread 11 is typically 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  
30 suture thread 11 is preferably 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  
35 from the base end of the suture thread introduction  
needle 1.

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### Usage of the Suturing Tool

Usage of the suturing tool 100 according to Mode of  
5 Embodiment 1 will be described next. Figure 6  
illustrates the situation when the suturing tool  
according to Mode of Embodiment 1 is being used, where  
Figures 6(A) - (E) successively show the suturing  
procedure carried out using the suture thread 11. A  
10 description will be given here of an exemplary case in  
which a patient's abdominal wall 102 and stomach wall  
101 are sutured using the suturing tool 100.

The practitioner first of all inserts an endoscope  
15 orally or nasally into the patient's stomach. The  
practitioner then expands the internal organ by filling  
the internal organ with 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  
20 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 is then confirmed by the light emitted from the  
endoscope, and a local anaesthetic is applied at this  
25 site.

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

30 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, the suture thread  
35 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.

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Furthermore, the suturing tool 100 is in a state in which the base-end support part 3 is pulled up and separated from the tip-end support part 4 (the state shown in Figure 1), so that the tip ends of the suture thread introduction needle 1 and the loop introduction needle 2 are not projecting from the tip-end support part 4. Furthermore, the cylindrical protrusion 6 is attached to the protrusion attachment part 42 of the tip-end support part 4.

10

As shown in Figure 6(A), the practitioner first of all presses the protruding part 61 of the cylindrical protrusion 6 against the patient's skin 103, and then, holding the grip part 51, pushes the suturing tool 100 towards the patient with a suitable amount of force. By doing so, the force applied to the grip part 51 is transferred to the guide rod 5a and the tip-end support part 4 fixed to the guide rod 5a, and also to the cylindrical protrusion 6 attached to the tip-end support part 4. As a result, the protruding part 61 of the cylindrical protrusion 6 pushes the abdominal wall 102 and stomach wall 101 to create a depression, and the bulge formed by the pressure of the protruding part 61 can be confirmed using the endoscope which has been inserted into the stomach. This allows the practitioner to confirm the puncture site for the suture thread introduction needle 1 and the loop introduction needle 2.

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As shown in Figure 6(B), the practitioner having confirmed the puncture site then pushes the base-end support part 3 downwards while the protruding part 61 is still pressed against the patient's skin 103 to confirm the puncture site. By doing so, the suture thread introduction needle 1 and the loop introduction needle 2 which are attached to the base-end support part 3 are pushed downwards and pierce the patient's

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abdominal wall 102 and stomach wall 101. The practitioner pushes the base-end support part 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.

As shown in Figure 6(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.

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

As shown in Figure 6(D), the practitioner having confirmed 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 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.

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As shown in Figure 6(E), the practitioner pulls the suture 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.

At the point shown in Figure 6(E), the practitioner withdraws the suture thread introduction needle 1 and the loop introduction needle 2 from the patient's body. By doing so, 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 (not shown in the figures). The practitioner then ties the two ends of the exposed suture thread 11 together in order to complete the suturing process.

As described above, the suturing tool 100 according to Mode of Embodiment 1 is provided with the cylindrical protrusion 6, so it is possible to determine the puncture site using an endoscope which has been inserted into an internal organ, and it is also possible to make the punctures with the suture thread introduction needle 1 and the loop introduction needle 2 while the puncture site can still be confirmed. This makes it possible to more reliably pierce the target site, so the success rate for organopexy can be improved.

Furthermore, the cylindrical protrusion 6 is provided between the two puncture needles (the suture thread introduction needle 1 and the loop introduction needle 2). This means that the puncture site of both needles can be confirmed using a single cylindrical protrusion 6.

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Furthermore, with the suturing tool 100 according to Mode of Embodiment 1, the cylindrical protrusion 6 is detachably provided and therefore the cylindrical protrusion 6 can be detached if there is no need to confirm the puncture site using the cylindrical protrusion 6. This means that there is no loss of operability because the cylindrical protrusion 6 does not impede the procedure when it is not required. Furthermore, the fitting structure of the fitting parts 62a, 62b and shaft parts 43a, 43b and the holding part 63 enable the practitioner to attach or detach the cylindrical protrusion 6 by a simple procedure which involves gripping the holding part 63 and pushing or pulling the same. The direction of attachment/detachment employing the holding part 63 is orthogonal to the direction of pressing by the cylindrical protrusion 6, and the two directions do not match. It is therefore possible to suppress inadvertent removal of the cylindrical protrusion 6 when the patient's abdomen is pressed by the cylindrical protrusion 6 using the suturing tool 100.

It should be noted that a structure equivalent to that of the shaft parts 43a, 43b and enlarged-diameter parts 44a, 44b in Mode of Embodiment 1 may be provided on the cylindrical protrusion 6; and a structure corresponding to the fitting parts 62a, 62b may be provided on the tip-end support part 4.

Furthermore, Figure 4 shows an example in which the protruding part 61 has a hollow structure, but the protruding part 61 may equally have a filled solid structure.

Furthermore, in Mode of Embodiment 1 a description has been given of an example in which the grip part 51 is

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provided only on the guide rod 5a, but a similar grip part 51 may also be provided on the guide rod 5b.

5 Furthermore, in Mode of Embodiment 1 a description has been given of an example in which the two guide rods 5a, 5b are provided, but it is equally possible to adopt a structure in which a single guide rod 5a is provided between the suture thread introduction needle 1 and the loop introduction needle 2.

10

Another example of the cylindrical protrusion attachment/detachment structure will be described in Mode of Embodiment 2. 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 15 which are the same as in Mode of Embodiment 1 bear the same reference symbols and will not be described again.

20 Figure 7 illustrates the cylindrical protrusion of the suturing tool according to Mode of Embodiment 2, where Figure 7(A) is a front view of the cylindrical protrusion and Figure 7(B) is a plan view of the cylindrical protrusion.

25 As shown in Figure 7, a cylindrical protrusion 7 according to Mode of Embodiment 2 comprises: a protruding part 71; an edge part 72; and engaging parts 73.

30 The protruding part 71 is a cylindrical member with a bottom, formed with a hemispherical tip end. There are no particular restrictions as to the size and shape of the protruding part 61, but it is designed so as not to readily cause the patient pain when the body surface 35 such as the abdominal wall of the patient is pressed by the protruding part 61, and so as to enable the depression in the internal organ wall produced by

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pressure from the protruding part 61 to be confirmed using an endoscope inserted into the internal organ. Furthermore, the tip end of the protruding part 61 may consist of a soft member in order to improve the  
5 feeling on the skin.

The edge part 72 is a flange-shaped part which projects radially outwards from the upper end of the protruding part 71. A plurality of (three in Mode of Embodiment 2)  
10 engaging parts 73 which project radially outwards are provided on the outer periphery of the edge part 72.

Figure 8 is an enlargement of the main parts of the suturing tool according to Mode of Embodiment 2, illustrating the situation when the cylindrical protrusion has been detached, where Figure 8(A) is a front view in the region of the base-end support part and Figure 8(B) is a plan view of the base-end support  
15 part.

20 As shown in Figure 8, the tip-end support part 4 has a protrusion attachment part 46 for detachably attaching the cylindrical protrusion 7. In Mode of Embodiment 2, the protrusion attachment part 46 comprises an  
25 insertion hole 47 which is formed in the tip-end support part 4, and a plurality of (three in Mode of Embodiment 2) latching hooks 48 which are provided on the opening edge of the insertion hole 47. The  
30 insertion hole 47 has a diameter which allows the insertion of the protruding part 71. The edge part 72 and engaging parts 73 of the cylindrical protrusion 7 are latched between the latching hooks 48 and the edge section of the insertion hole 47.

35 Figure 9 illustrates the cylindrical protrusion of the suturing tool according to Mode of Embodiment 2, and the attachment/detachment structure of the cylindrical

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protrusion. As shown in Figure 9(A), the cylindrical protrusion 7 can be inserted into the insertion hole 47 from the upper side of the tip-end support part 4. When the cylindrical protrusion 7 is attached, the protruding part 71 of the cylindrical protrusion 7 is inserted into the insertion hole 47, and the cylindrical protrusion 7 and the tip-end support part 4 are turned relative to each other in the circumferential direction of the cylindrical protrusion 7, and the engaging parts 73 are latched by the latching hooks 48. When this is done, the cylindrical protrusion 7 is attached to the tip-end support part 4, as shown in Figure 9(B). Figure 9(C) is a top view of the situation when the cylindrical protrusion 7 is attached to the tip-end support part 4, with the latching hooks 48 being shaded for illustrative purposes. As shown in Figure 9(C), when seen from above, the latching hooks 48 latch the engaging parts 73 from above and restrict the vertical movement of the cylindrical protrusion 7.

The cylindrical protrusion 7 is used for pressing the patient's abdominal wall, in the same way as the cylindrical protrusion 6 described in Mode of Embodiment 1. When the abdominal wall is pressed by the cylindrical protrusion 7, an upward force is applied to the cylindrical protrusion 7 from the abdominal wall, but the engaging parts 73 of the cylindrical protrusion 7 are latched with the latching hooks 48 so the cylindrical protrusion 7 does not become detached.

When the cylindrical protrusion 7 is detached, the cylindrical protrusion 7 and the base-end support part are turned relative to each other in the circumferential direction of the cylindrical protrusion 7, and the latching of the engaging parts 73 by the latching hooks 48 is released. The cylindrical

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protrusion 7 can be detached from the tip-end support part 4 by withdrawing the cylindrical protrusion 7 upwards, as shown in Figure 9(A).

5 As described above, the same advantages as in Mode of Embodiment 1 can also be achieved when the attachment/detachment structure for the cylindrical protrusion according to Mode of Embodiment 2 is adopted.

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It should be noted that the number of latching hooks 48 and engaging parts 73 is not limited to three of each, as shown in Mode of Embodiment 2, but a plurality of each is preferred from the point of view of increasing the engagement strength.

15

Furthermore, the above description relates to an exemplary case in which the stomach wall and the abdominal wall are fixed, but the puncture device according to the present invention can equally be applied as a suturing tool which is used when another organ such as the bladder is fixed to the abdominal wall.

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## Claims

1. A puncture device comprising:
  - a suture thread introduction needle;
  - 5 a loop introduction needle which is provided a prescribed distance apart from the suture thread introduction needle and substantially parallel thereto;
  - a tip-end support part for supporting the suture thread introduction needle and the loop introduction
  - 10 needle in such a way that said needles can slide axially; and
  - a pressing part for creating a depression in the abdominal wall,
  - the pressing part being provided between the
  - 15 positions where the suture thread introduction needle and the loop introduction needle pass through the tip-end support part, in such a way that said pressing part projects further towards the tip end side than the suture thread introduction needle and the loop
  - 20 introduction needle when the suture thread introduction needle and the loop introduction needle are moved as far as possible towards the base end.
2. The puncture device according to Claim 1,
- 25 characterized in that the pressing part is detachable from the tip-end support part.
3. The puncture device according to Claim 1,
- characterized in that it comprises a base-end support
- 30 part for holding the base end of the suture thread introduction needle and the loop introduction needle; and guide rods which extend in the same direction as the suture thread introduction needle and the loop
- introduction needle, whereof the tip ends are held by
- 35 the tip-end support part while the base ends pass through the base-end support part in such a way as to be able to slide axially.

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4. The puncture device according to Claim 2, characterized in that a shaft member is provided on either the tip-end support part or the pressing part, and a fitting member which detachably fits together with the shaft member is provided on the other, whereby the pressing part can be attached to or detached from the tip-end support part.

5. The puncture device according to Claim 2, characterized in that flange-shaped engaging parts are provided on the outer periphery at the base end of the pressing part, while latching hooks which latch onto the engaging parts are provided on the tip-end support part, and the pressing part and the tip-end support part are turned relative to each other in the circumferential direction of the pressing part, whereby the pressing part can be attached to or detached from the tip-end support part.

6. The puncture device according to Claim 2, characterized in that it comprises a base-end support part for holding the base end of the suture thread introduction needle and the loop introduction needle; and guide rods which extend in the same direction as the suture thread introduction needle and the loop introduction needle, whereof the tip ends are held by the tip-end support part while the base ends pass through the base-end support part in such a way as to be able to slide axially.

7. The puncture device according to Claim 3, characterized in that a shaft member is provided on either the tip-end support part or the pressing part, and a fitting member which detachably fits together with the shaft member is provided on the other, whereby

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the pressing part can be attached to or detached from the tip-end support part.

8. The puncture device according to Claim 3,  
5 characterized in that flange-shaped engaging parts are provided on the outer periphery at the base end of the pressing part, while latching hooks which latch onto the engaging parts are provided on the tip-end support  
10 part, and the pressing part and the tip-end support part are turned relative to each other in the circumferential direction of the pressing part, whereby the pressing part can be attached to or detached from the tip-end support part.

Figure 1

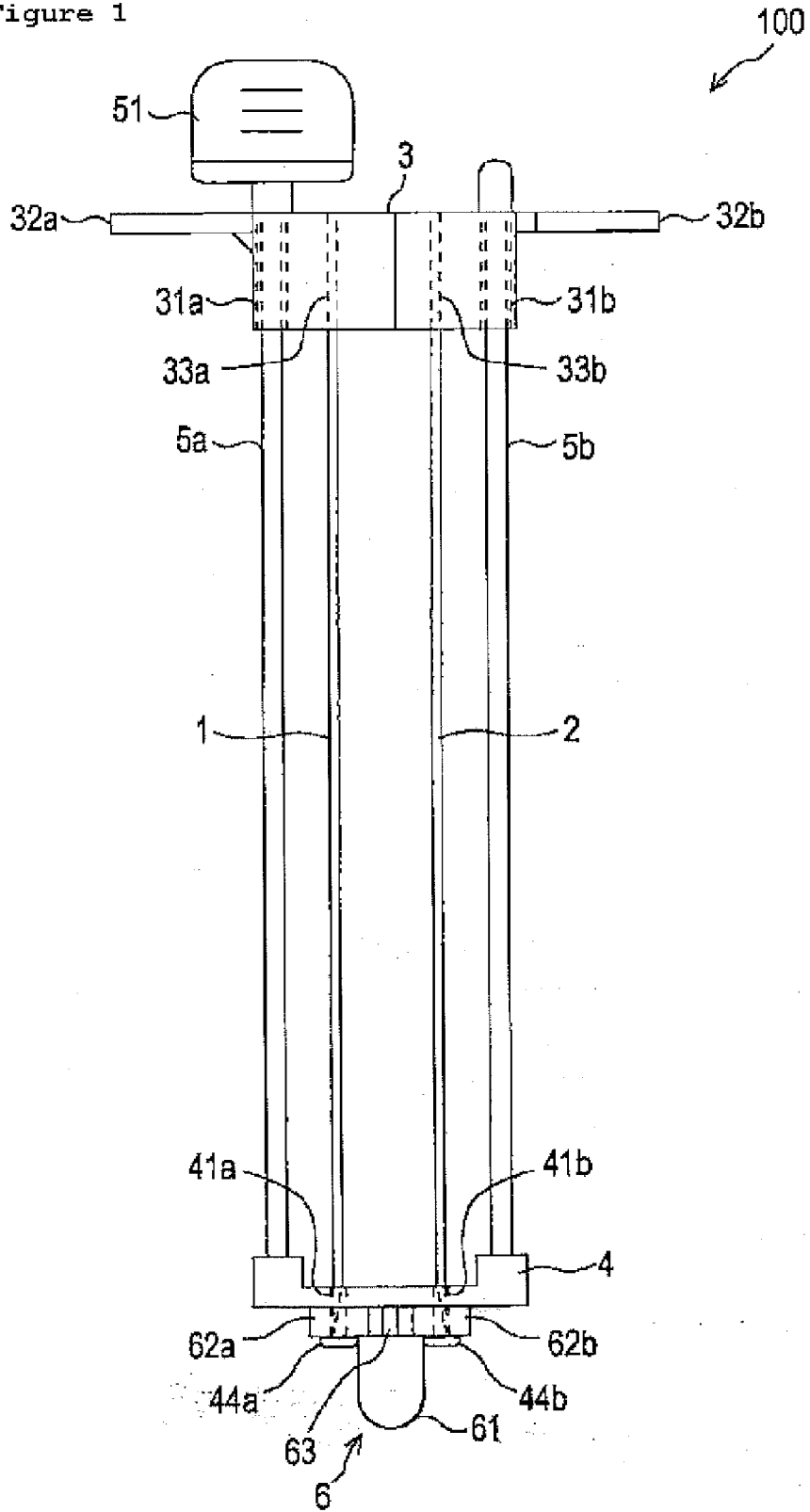


Figure 2

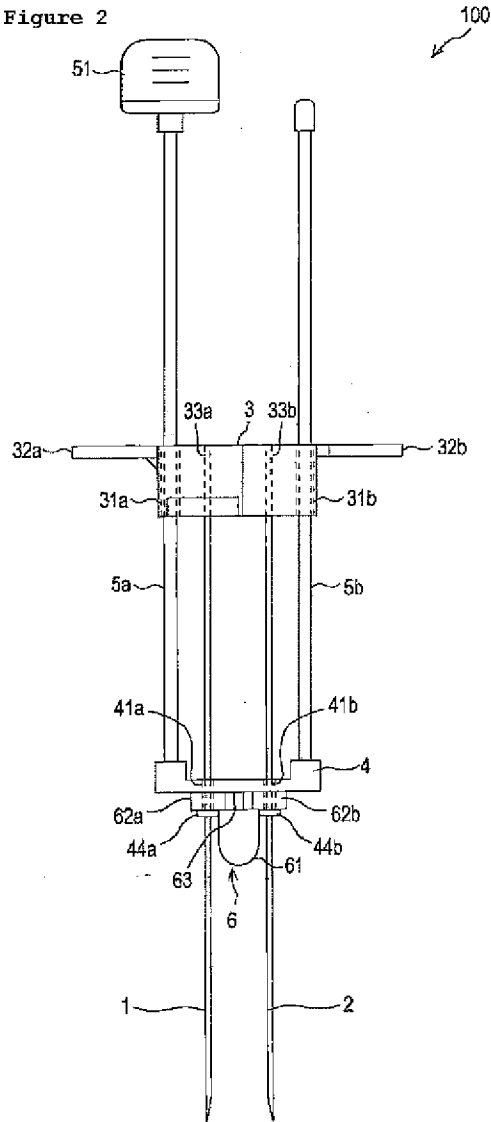


Figure 3

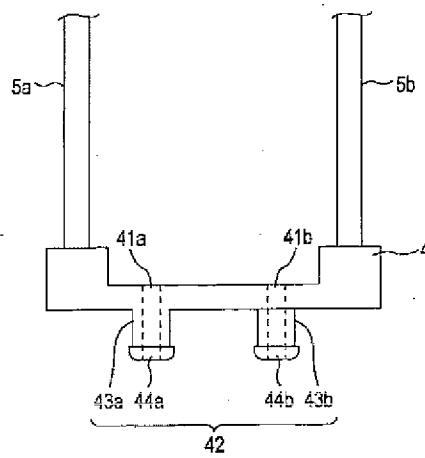


Figure 4

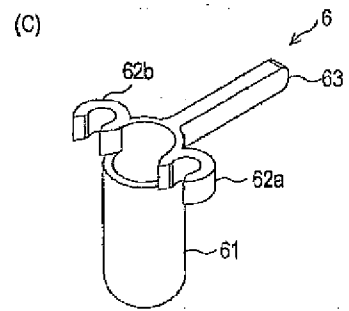
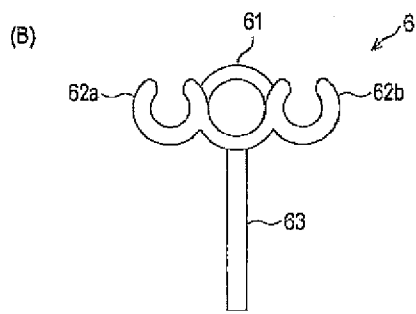
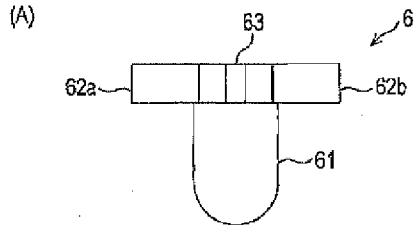


Figure 5

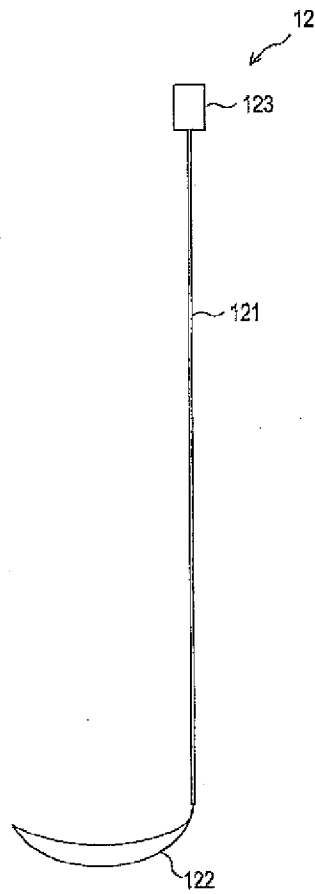


Figure 6

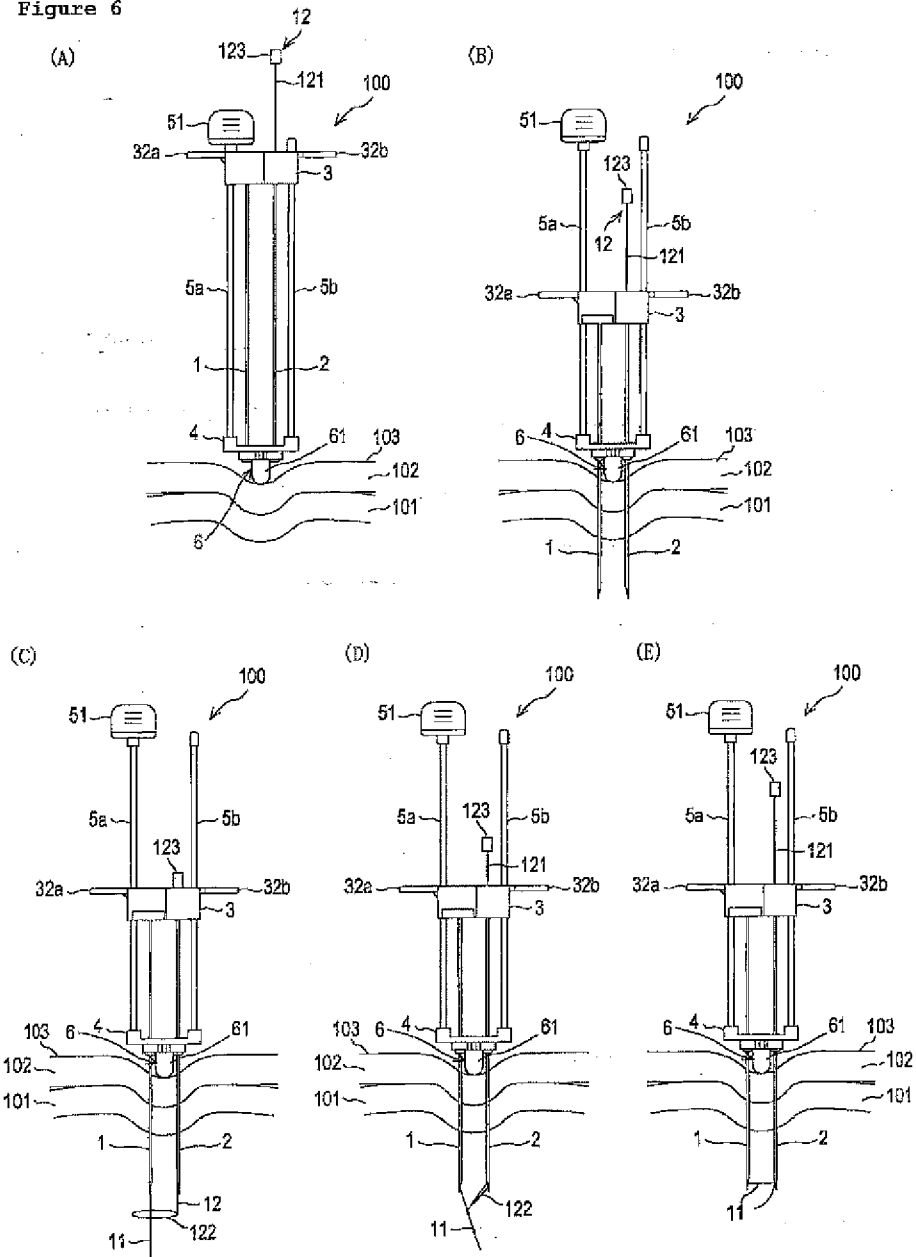
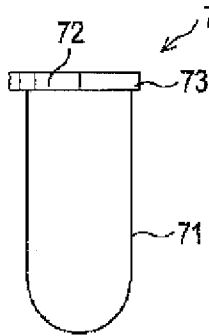


Figure 7

(A)

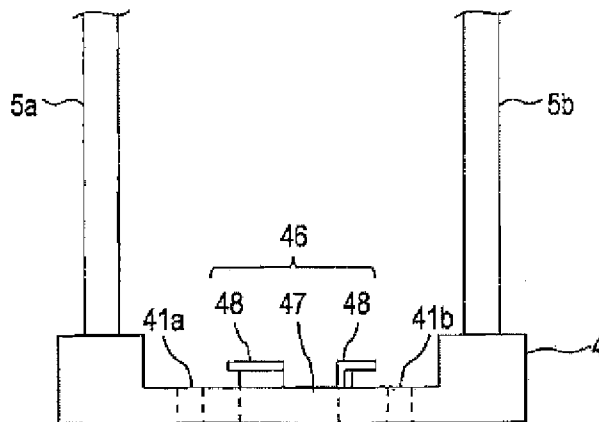


(B)



Figure 8

(A)



(B)

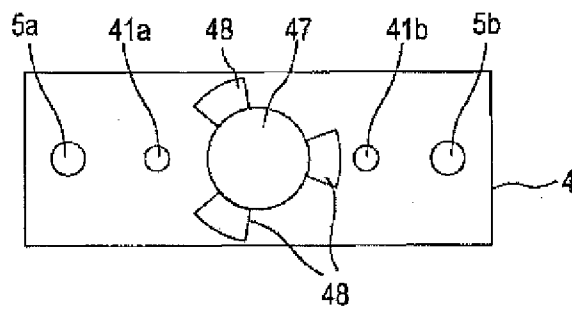
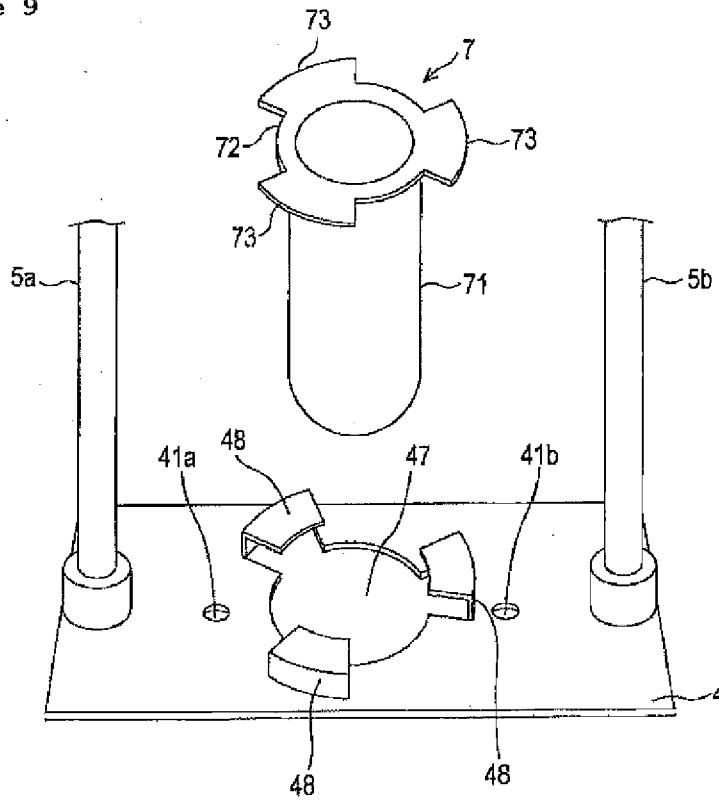
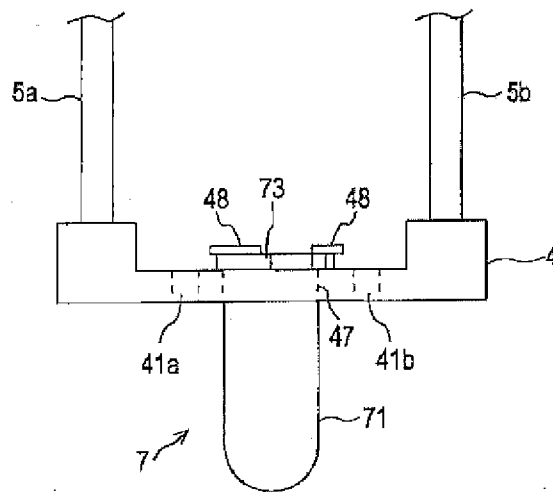


Figure 9

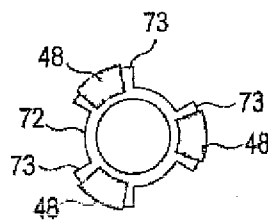
(A)



(B)



(C)



# INTERNATIONAL SEARCH REPORT

International application No <b>PCT/US2012/035801</b>
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<b>A. CLASSIFICATION OF SUBJECT MATTER</b> INV. A61B17/04 ADD.				
According to International Patent Classification (IPC) or to both national classification and IPC				
<b>B. FIELDS SEARCHED</b>				
Minimum documentation searched (classification system followed by classification symbols) <b>A61B</b>				
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) <b>EPO-Internal, WPI Data</b>				
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X	US 2005/043746 A1 (POLLAK STANLEY B [US] ET AL) 24 February 2005 (2005-02-24) paragraph [0032] - paragraph [0041]; figures -----	1,3		
A	US 2010/137888 A1 (WULC ALLAN E [US] ET AL) 3 June 2010 (2010-06-03) paragraph [0034] - paragraph [0067]; figures -----	1		
A	EP 1 598 017 A1 (SUMITOMO BAKELITE CO [JP]; SUZUKI YUTAKA [JP]) 23 November 2005 (2005-11-23) paragraph [0047] - paragraph [0190]; figures ----- -/--	1		
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C.</td> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> See patent family annex.</td> </tr> </table>			<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C.	<input checked="" type="checkbox"/> See patent family annex.
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C.	<input checked="" type="checkbox"/> See patent family annex.			
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"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family			
Date of the actual completion of the international search	Date of mailing of the international search report			
10 July 2012	17/07/2012			
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer  <b>Nistor, Loredana</b>			

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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