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(51) INT CL:
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A61M 25/01 (2006.01)

(56) Documents Cited:
WO 2010/076555 A1 **WO 1991/009563 A1**
US 3750651 A **US 3565061 A**

(58) Field of Search:
INT CL **A61B, A61M**
Other: **ONLINE: EPODOC, WPIAP**

(54) Title of the Invention: **Access tool**
Abstract Title: **Blood vessel access device**

(57) An access tool such as a speculum comprising an elongate arm 2, and a foot 3 for insertion into a blood vessel, the foot 3 being located at one end of the elongate arm 2. The foot 3 comprises a first footplate 31 and second footplate 32 slideably movable relative to one another in the direction of the longitudinal axis of the elongate arm 2 to control a variable separation between the footplates 31, 32 such that, when the foot 3 is inserted into the blood vessel, a separation defined between the two footplates 31, 32 forms a pathway into the vessel. The footplates may be biased into their separated positions by a spring mechanism 4. There may be a guide portion, pivotally attached to the elongate arm 2. The separation may be effected by means of a screw mechanism.

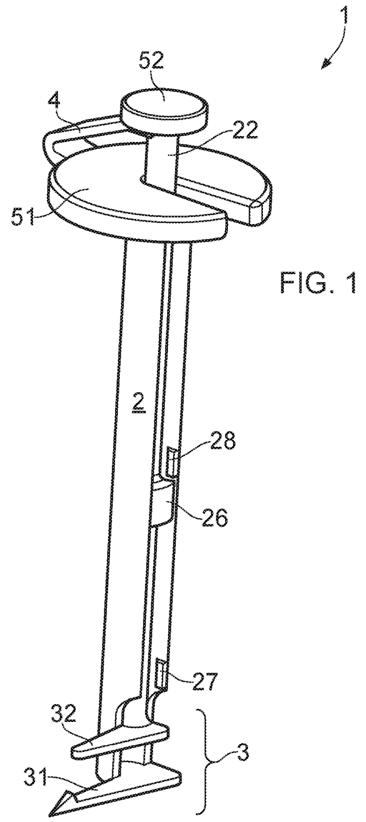

FIG. 1

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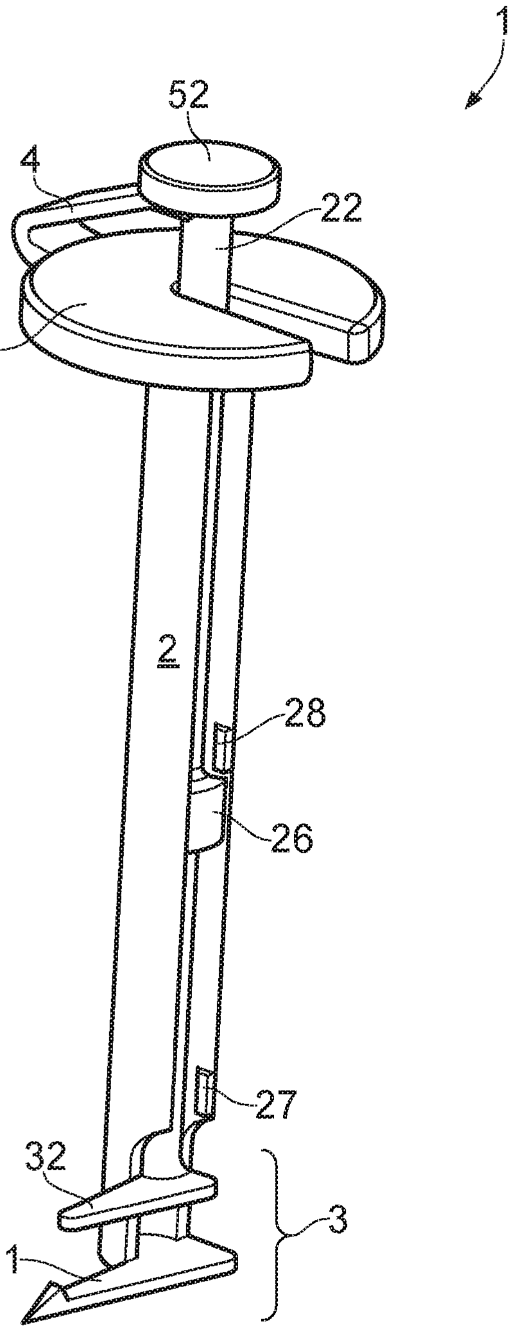

FIG. 1

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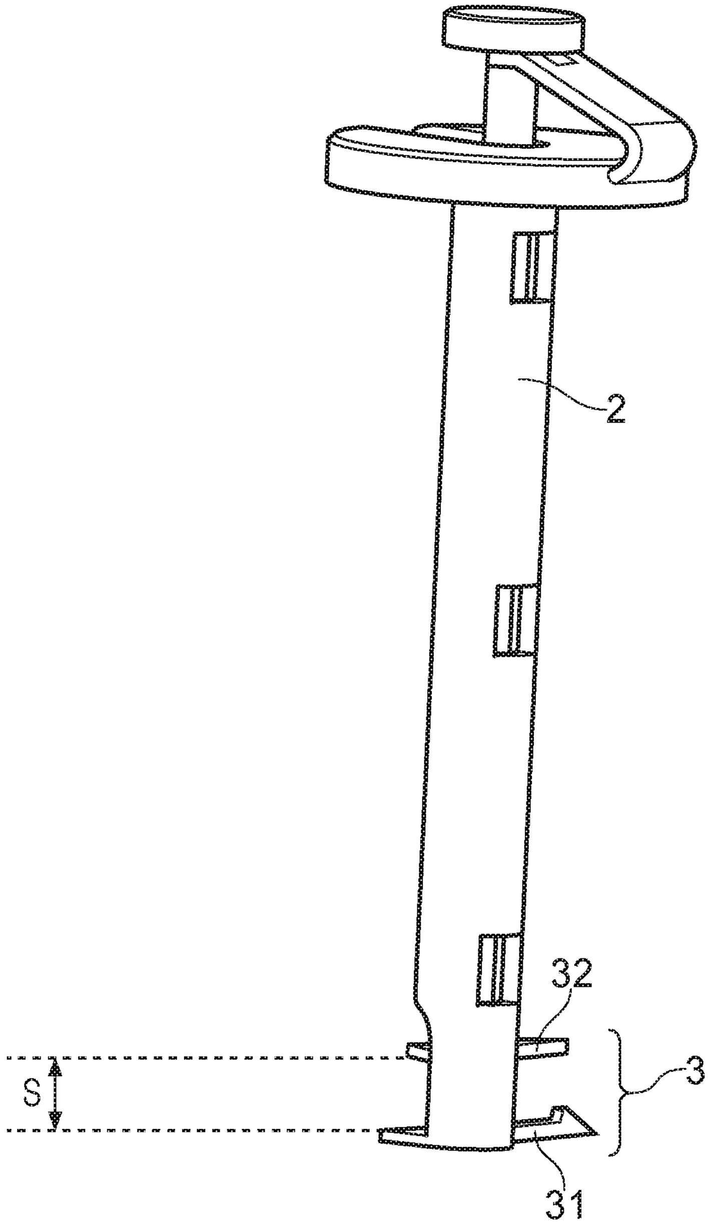

FIG. 2

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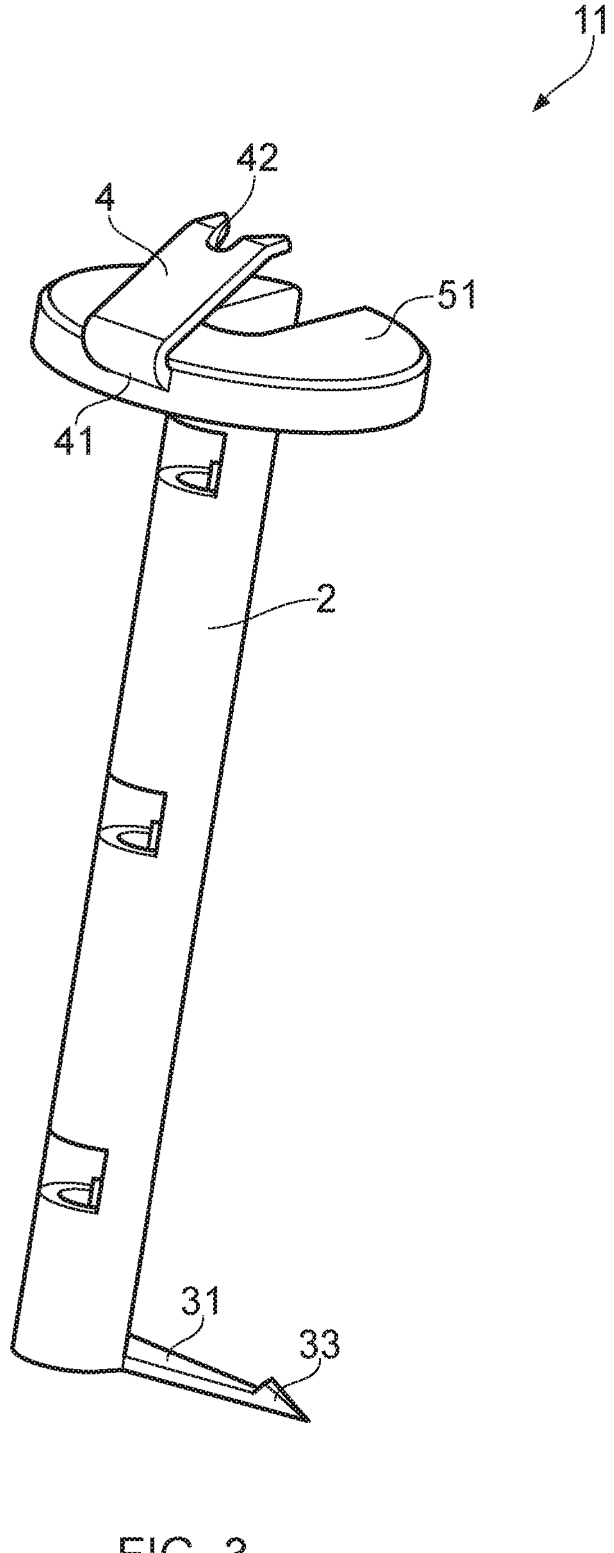

FIG. 3

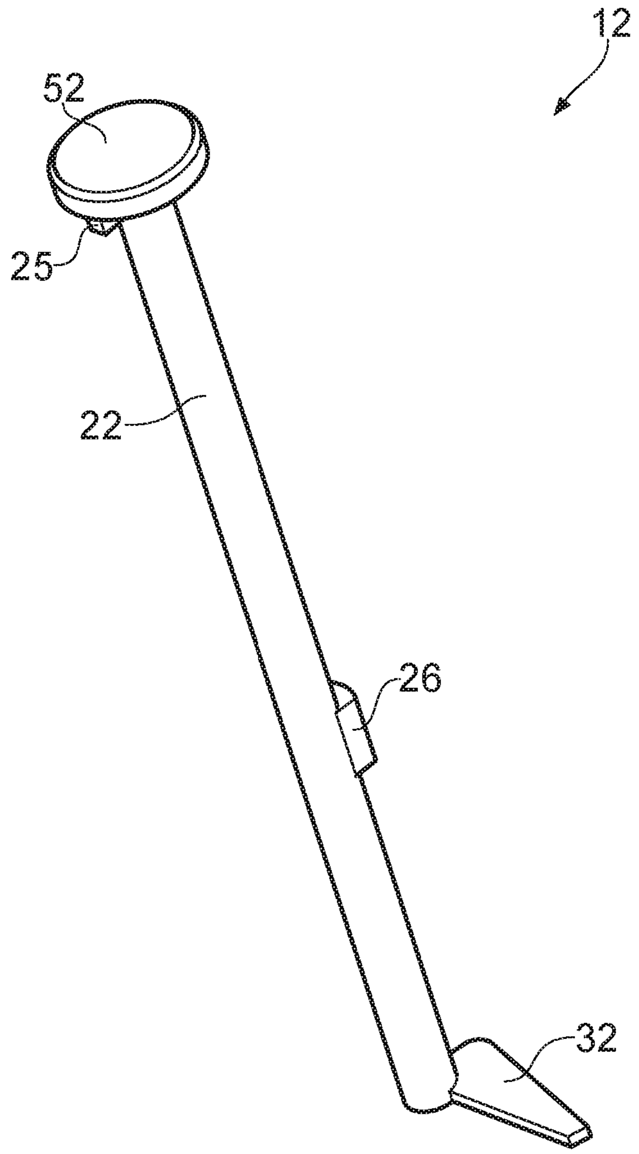

FIG. 4

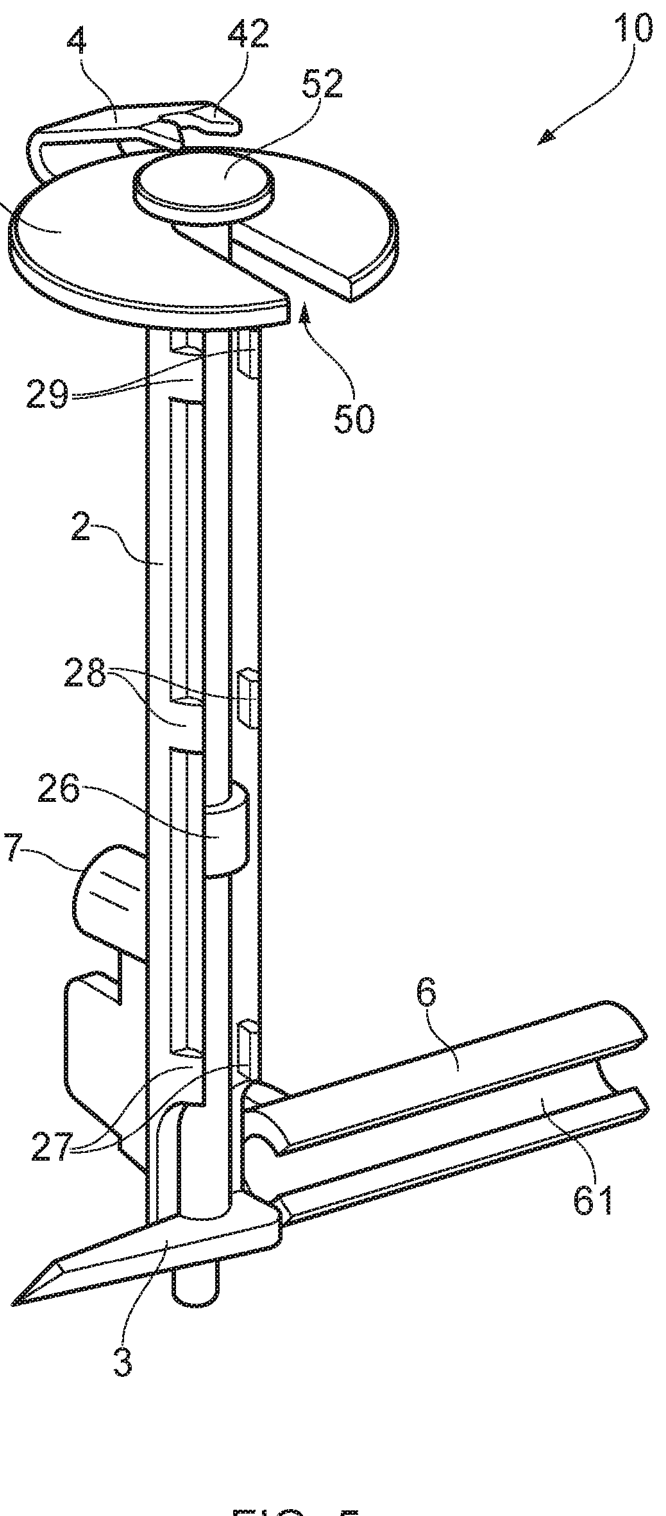

FIG. 5

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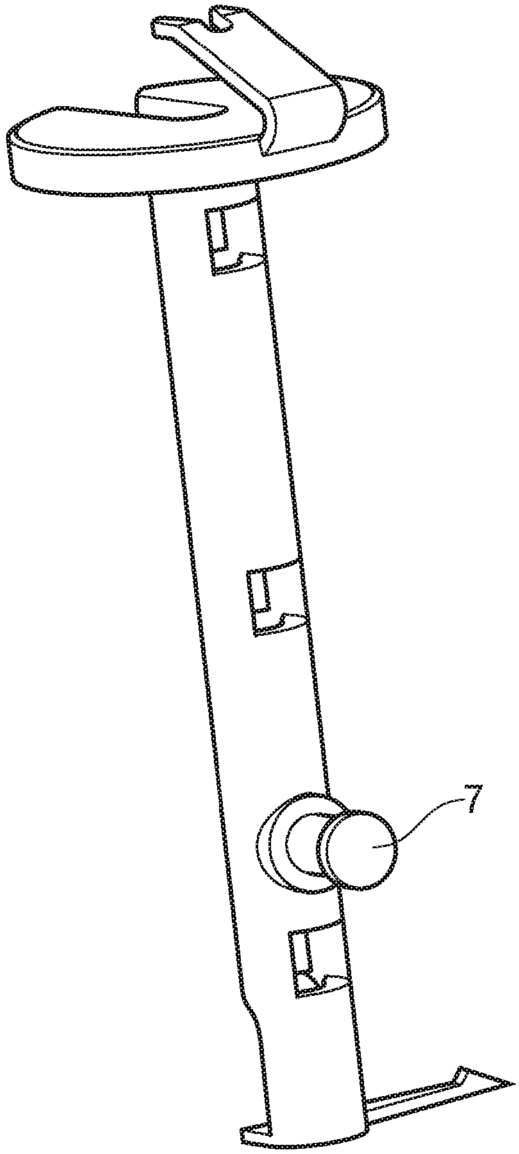

FIG. 6

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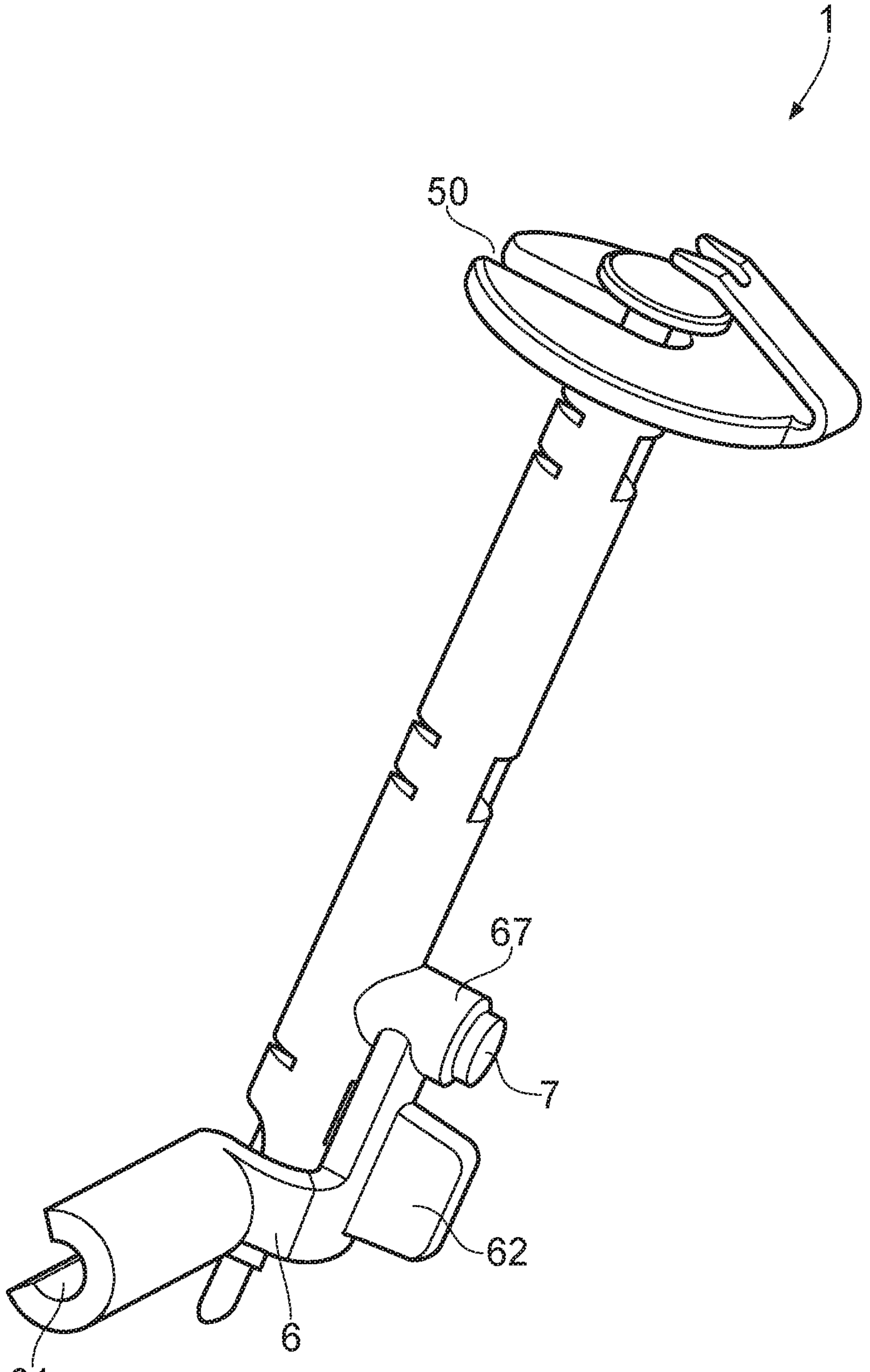

FIG. 7

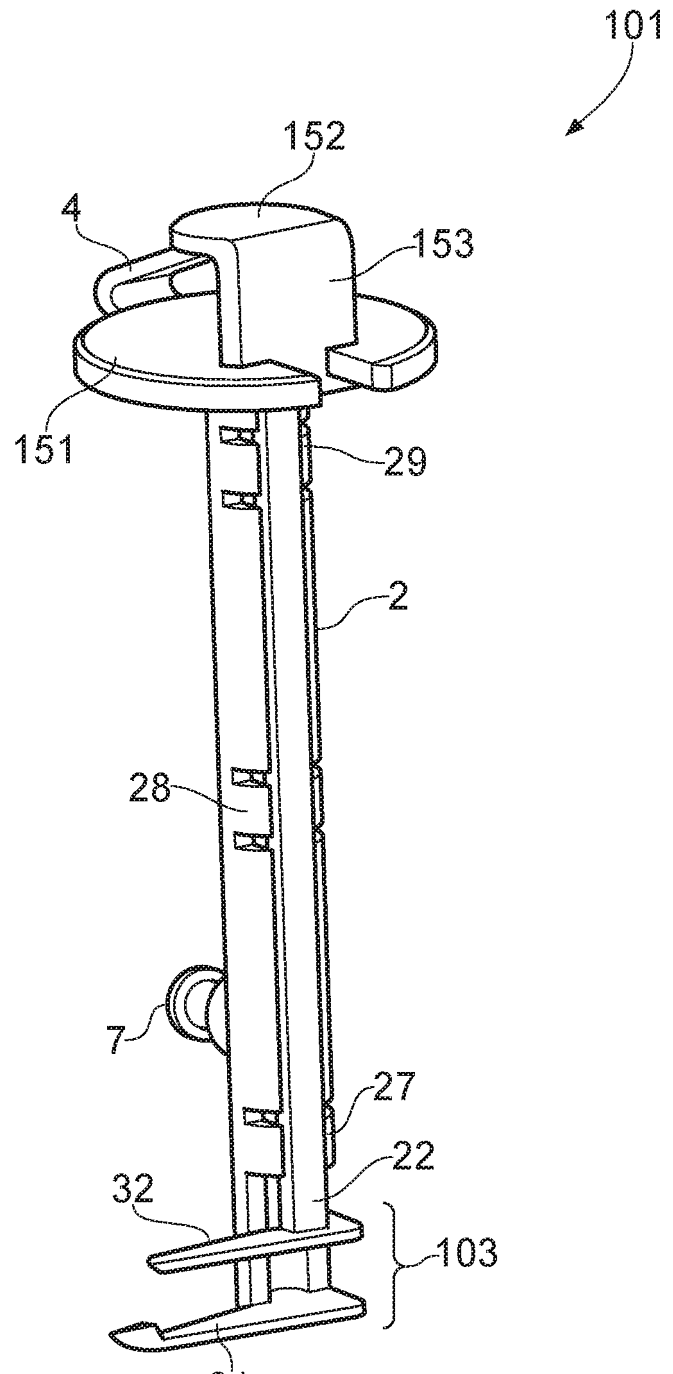

FIG. 8

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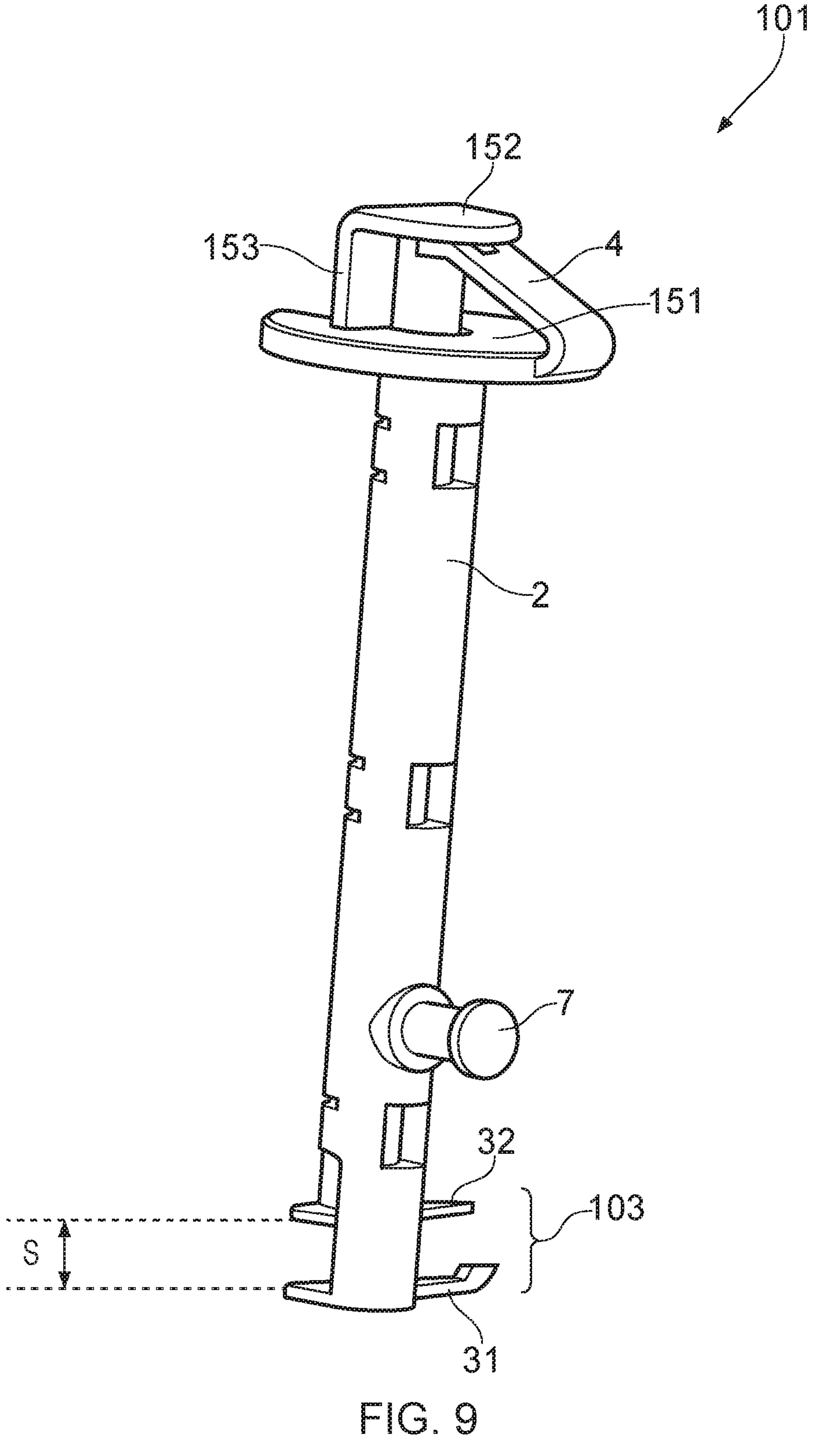

FIG. 9

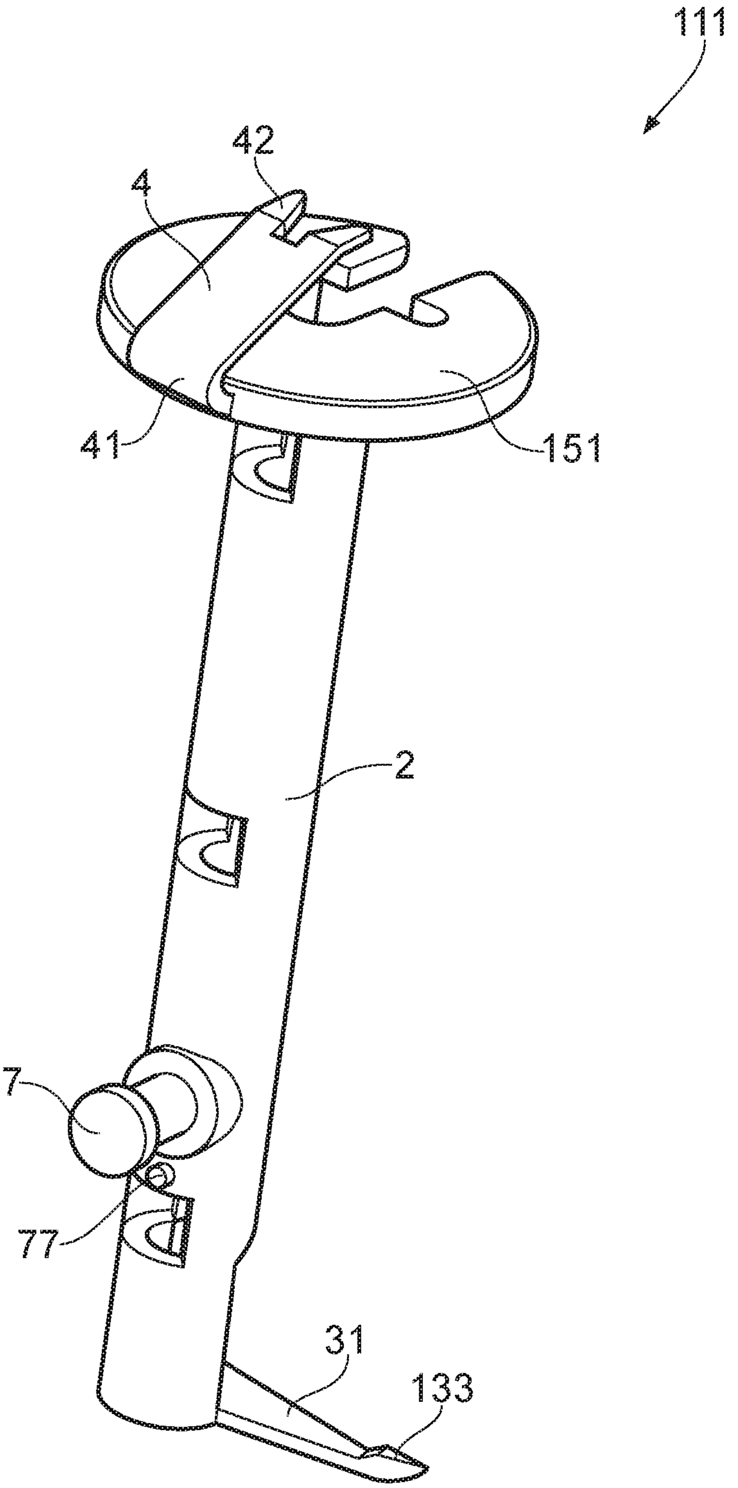

FIG. 10

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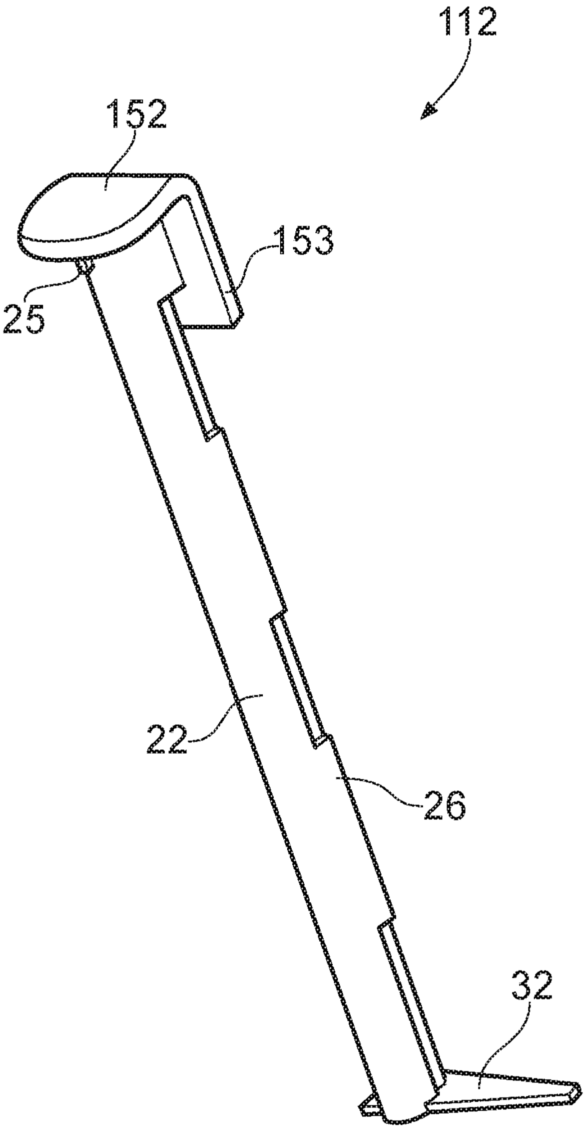

FIG. 11

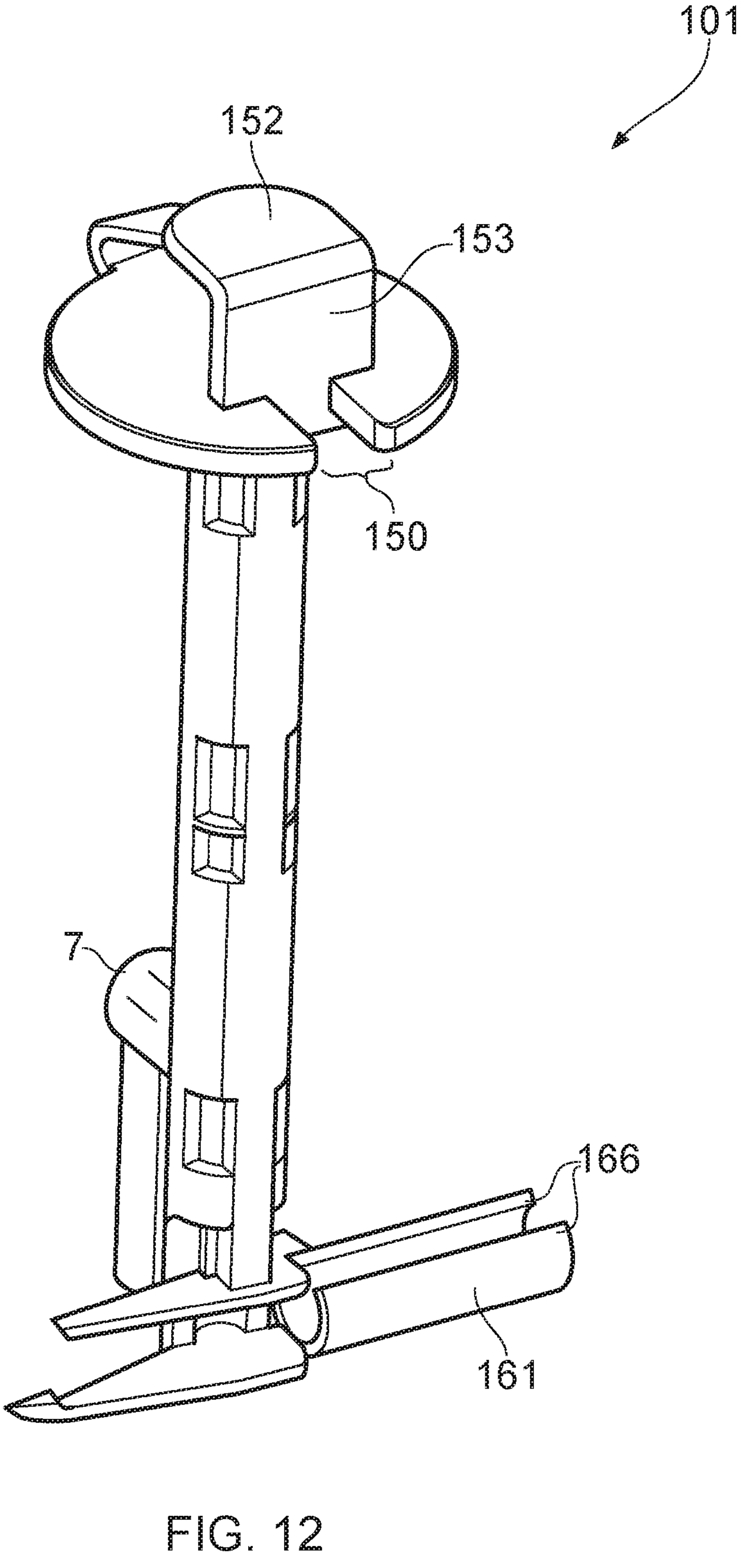

FIG. 12

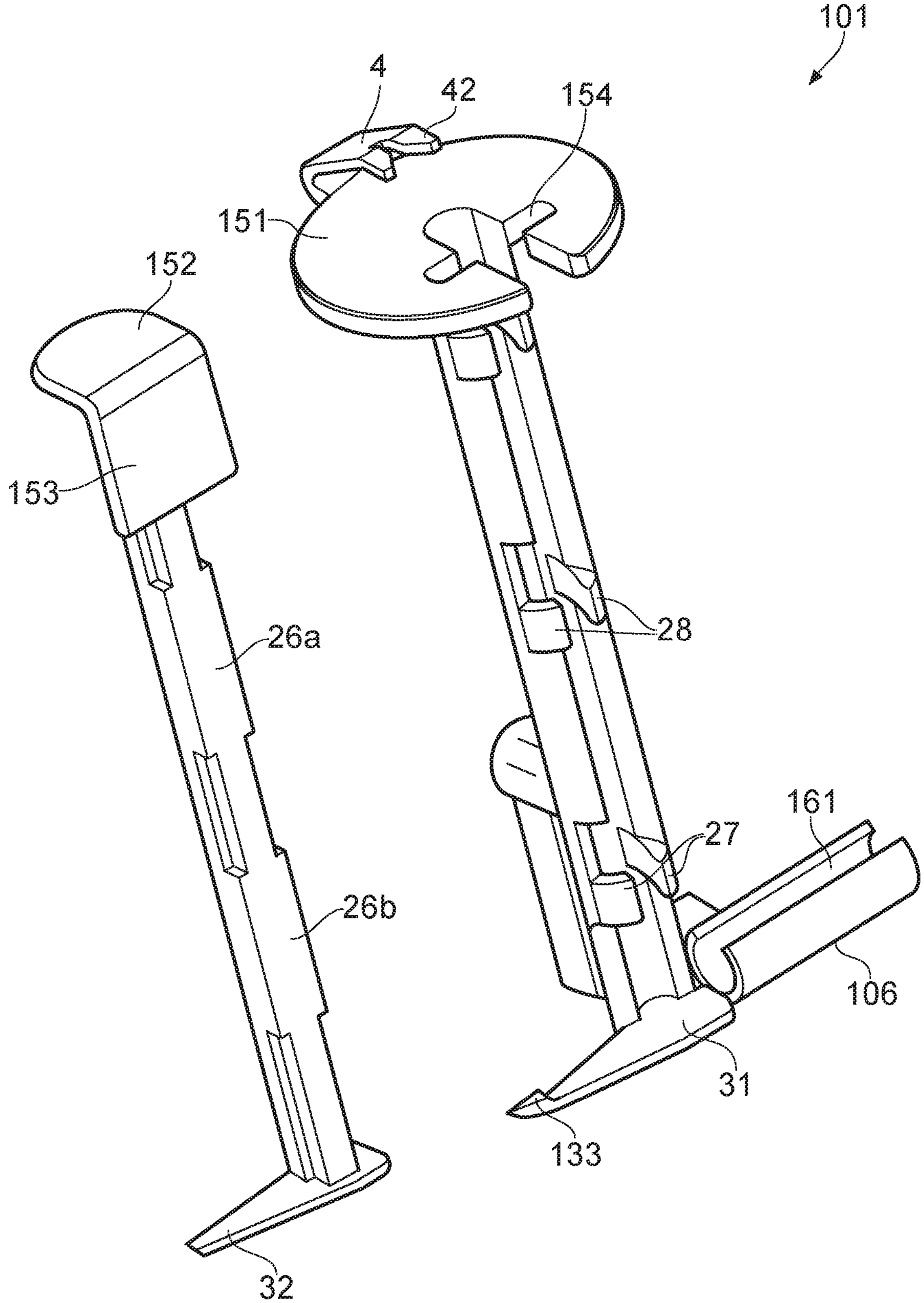

FIG. 13

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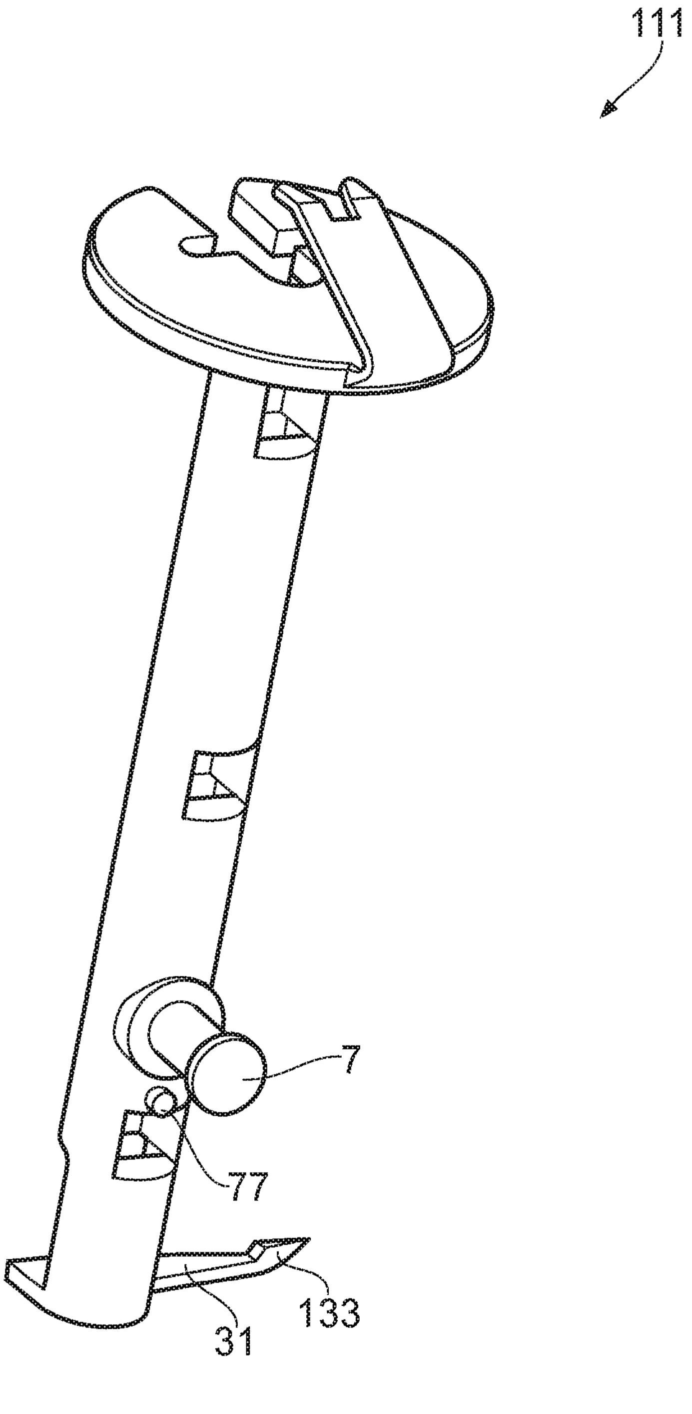

FIG. 14

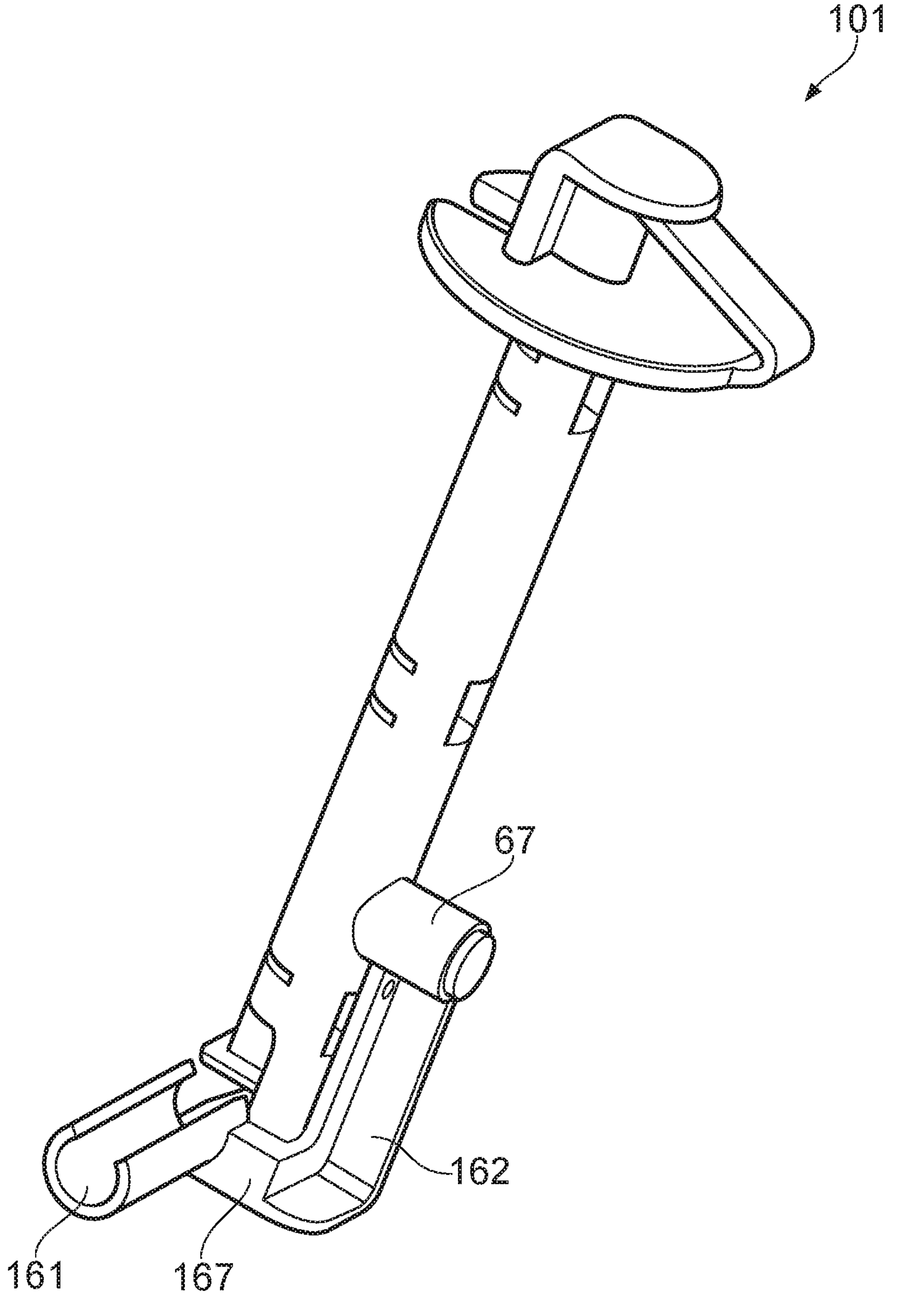

FIG. 15

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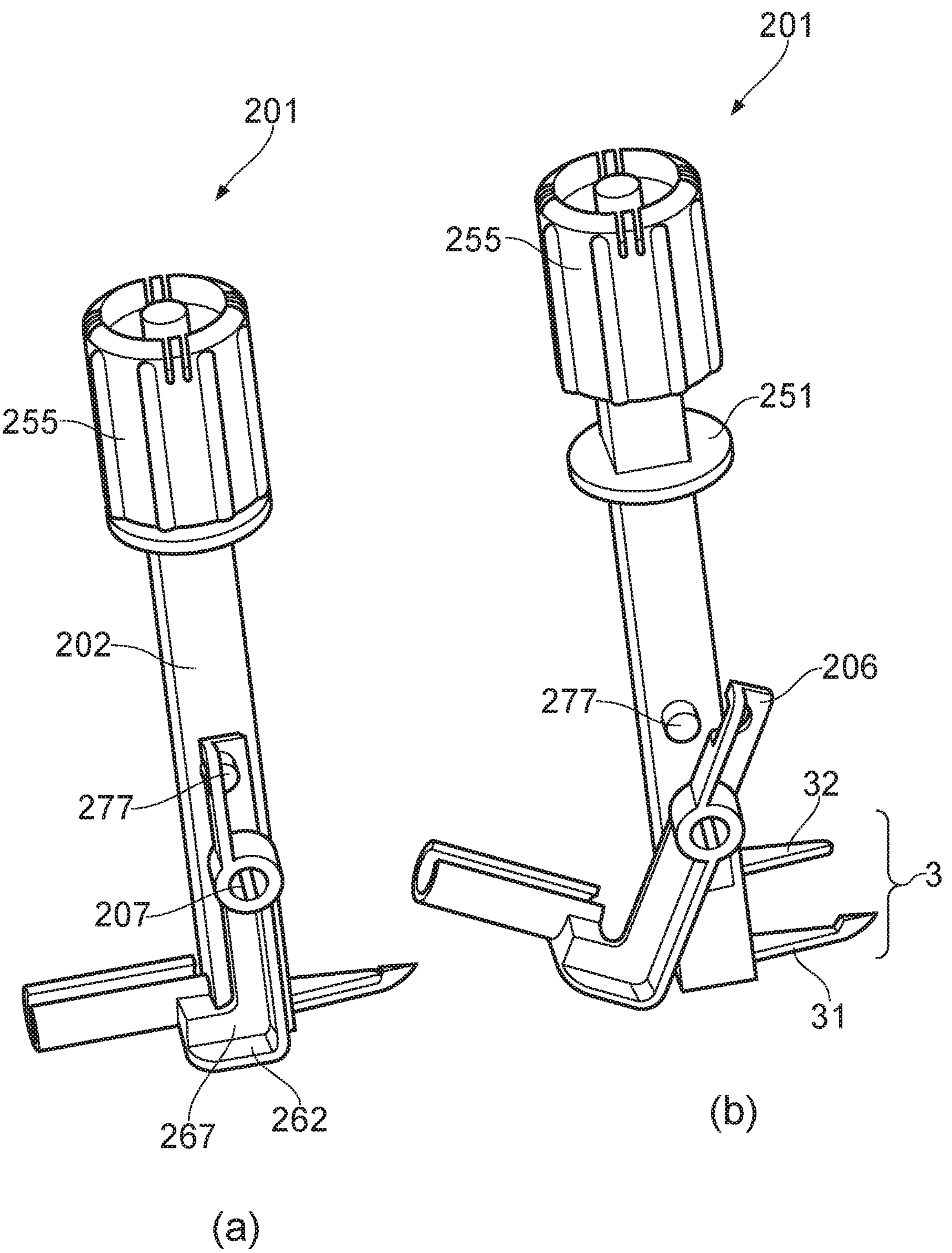

FIG. 16

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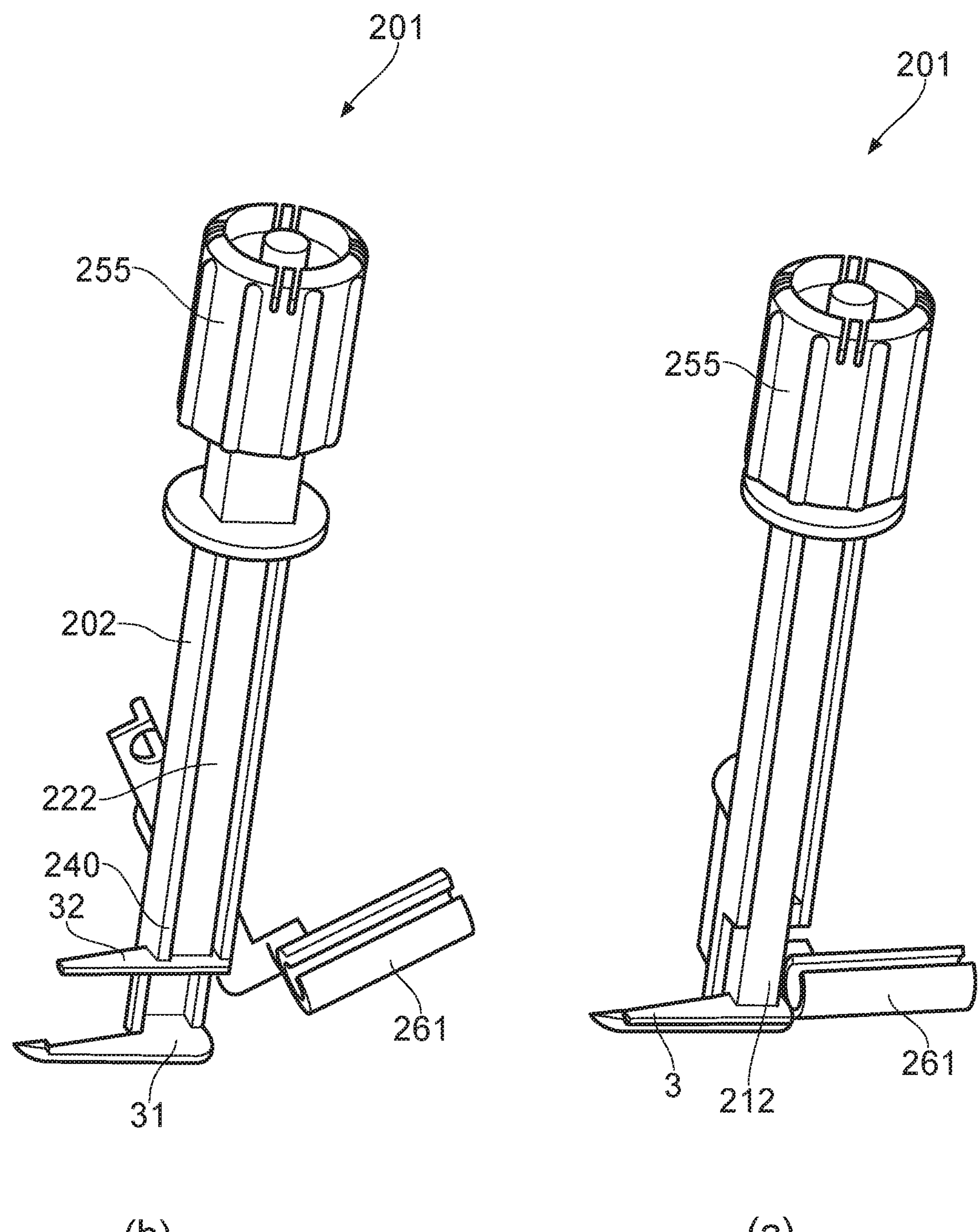

FIG. 17

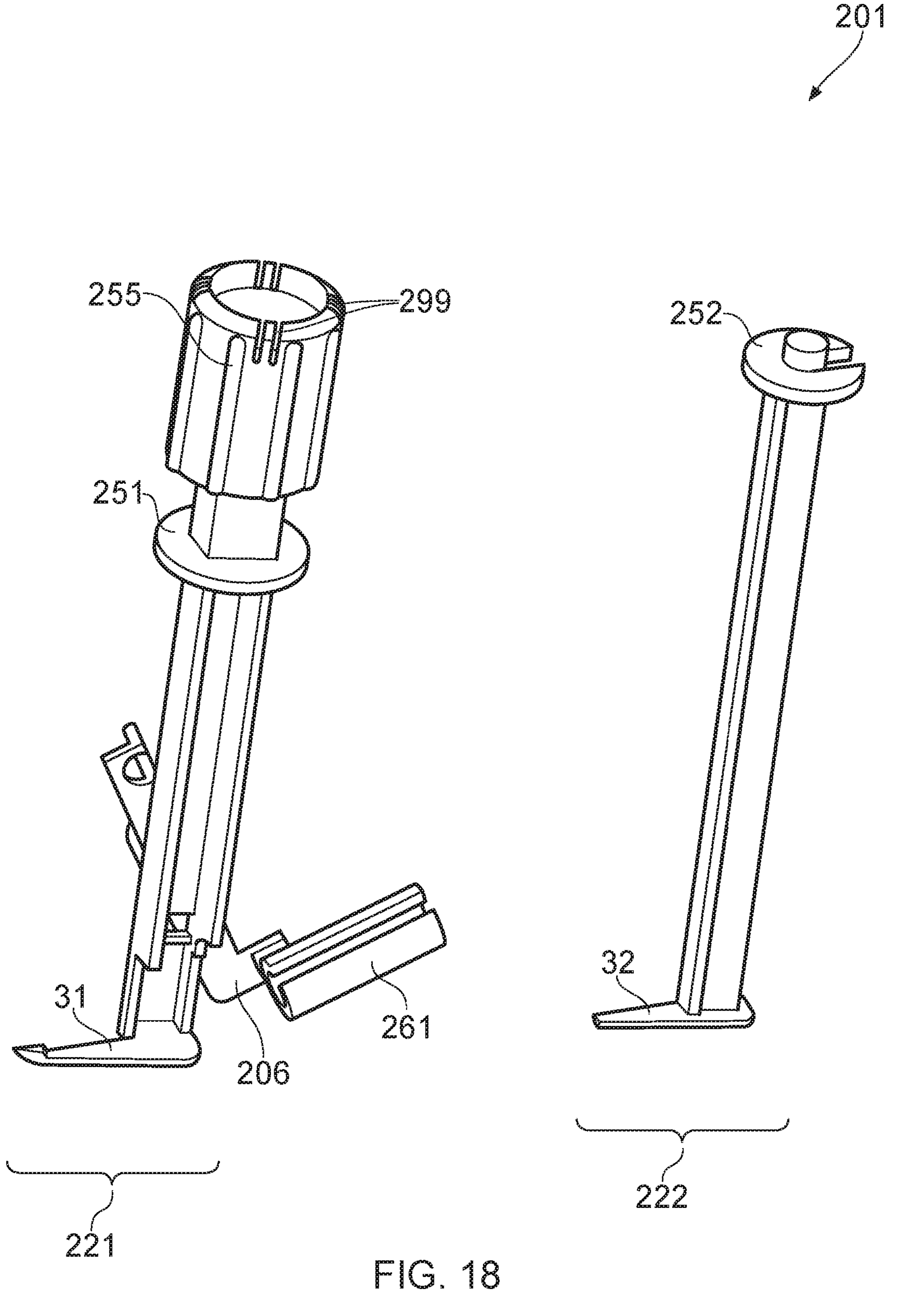

FIG. 18

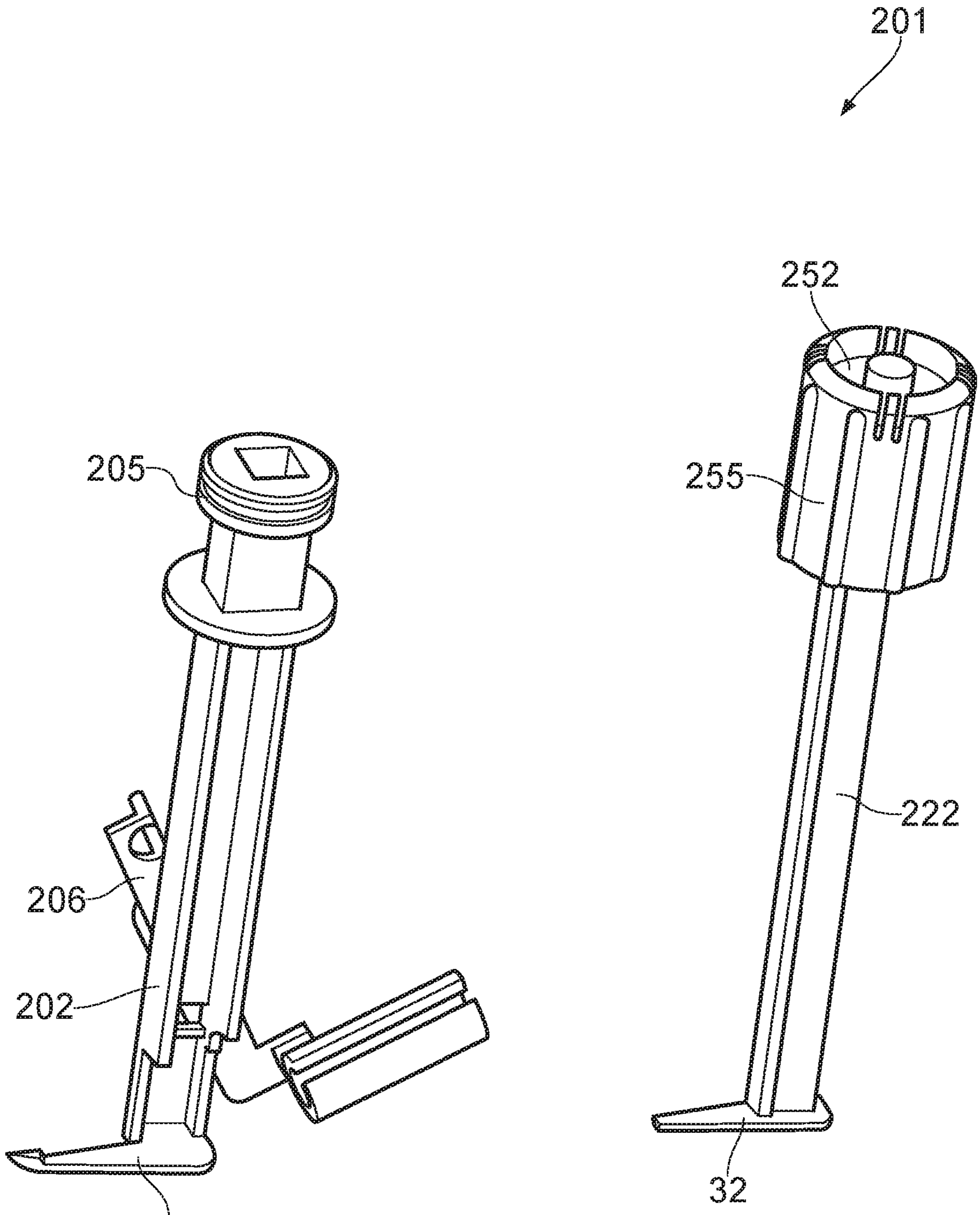

FIG. 19

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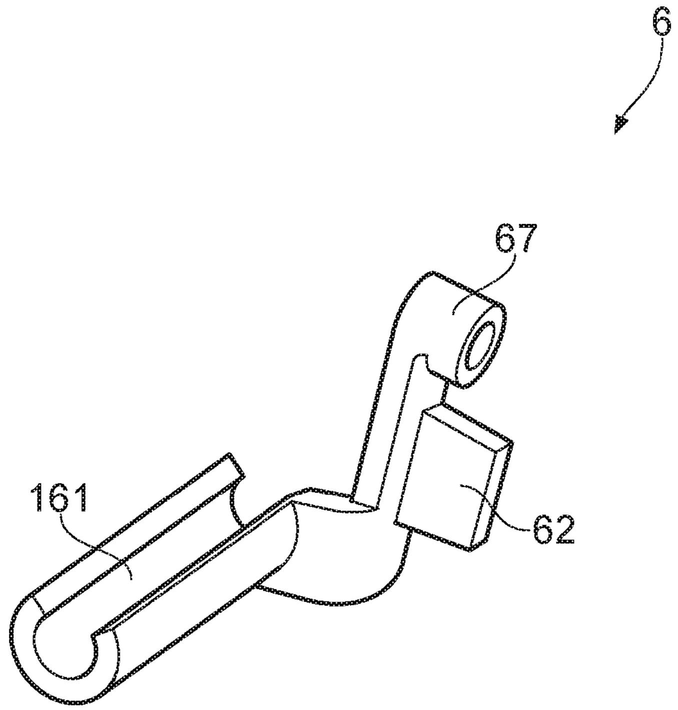

FIG. 20

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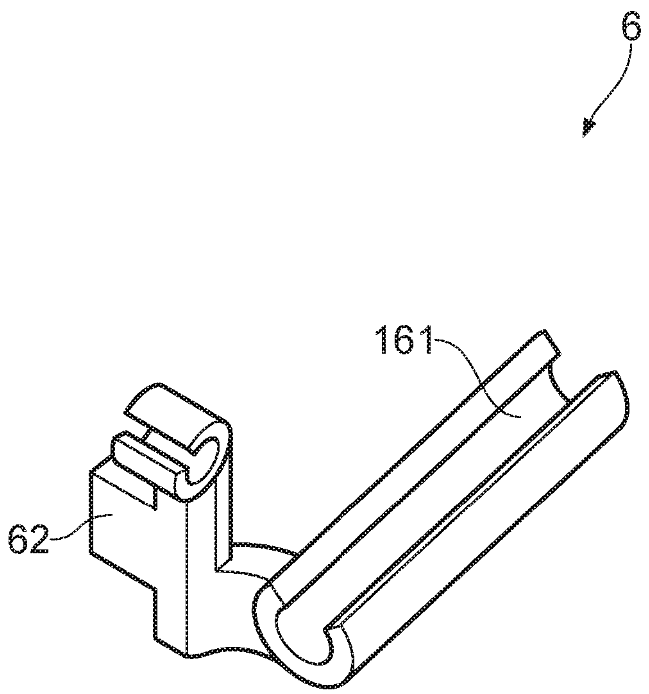

FIG. 21

ACCESS TOOL

Field of the Invention

The present invention relates to an access tool for providing access into a vessel of a human or animal body, in particular to an access tool having separable footplates for defining a pathway into the vessel.

Background of the Invention

There are many instances during open surgical procedures in which a blood vessel would need to be used either as an access to deeper vessel or to a deeper organ into which catheters, or wires or leads would need introducing. The introduction of a catheter, lead or a wire into a vessel such as a vein can be problematic and the difficulty of the procedure increases with decreasing size of the vessel.

Standard techniques include the use of a disposable guide instrument sometimes known as a “guide pick” such as that disclosed in “Disposable guide for introducing catheters into small vessels” Am, Hear J. May 1967. The guide pick instrument includes an arm and a tapered plate at right angles to the arm. An incision is made in the vessel of interest and the tapered plate inserted into the incision and lifted so that the catheter or a guide wire can be slid underneath the guide portion.

When such a “guide pick” instrument is used, there is always a risk that the instrument may slip out of the vessel while the operator (the medical practitioner/surgeon) is trying to feed the catheter or guide wire into the vessel. The skill of using the guide can be a difficult one for the medical practitioner to master; particularly the combination of holding the vessel open with one hand whilst inserting the guide wire or catheter into the vessel using the other hand. Moreover, once the “guide pick” instrument is lifted whilst the plate is within the vessel, blood which oozes from the vessel can obscure the operator’s view of the area underneath the guide portion. This may result in increased levels of difficulty and increased time delay as well as an increased blood loss.

There is therefore a need for an improved tool/instrument for guiding the insertion of objects such as guide wires, leads such as pacing leads and catheters into vessels such as veins. Such a tool could be used in different scenarios. For example as a guide instrument for use with: cephalic vein access during pacemaker insertion; umbilical vein access in neonatal patients; saphenous vein surgery; vascular surgery; other venous surgeries such as stripping; veterinary surgery; and animal research studies including access to aorta, femoral arteries, and veins, particularly in small animals.

Summary of the Invention

The present invention aims to solve the above problems by way of an access tool for providing access into a vessel of a human or animal body, the access tool comprising: an elongate arm; and a foot for insertion into the vessel, the foot being located at one end of the elongate arm; wherein the foot comprises a first footplate and second footplate slideably movable relative to one another in the direction of the longitudinal axis of the elongate arm to control a variable separation between the footplates; such that, when the foot is inserted into the vessel, a separation defined between the two footplates forms a pathway into the vessel.

In this way, the first footplate and second footplate are configured to be inserted into the vessel together as a single foot (the single foot having two pieces; the first foot piece being the first footplate and the second piece being the second footplate). Once the foot has been inserted into the vessel, the footplates can be separated along a direction parallel to the direction of the longitudinal axis of the elongate arm. When separated, the two footplates define therebetween a pathway into the vessel through which a wire and/or catheter can pass to gain access to the vessel. The presence of the two footplates which are separable relative to one another therefore facilitates access to the vessel.

The footplates are preferably capable of being separated to a point at which the outer surfaces of the footplates contact the inner wall of the vessel at opposite sides across its diameter. In this way, the access tool can be used to hold the vessel open during insertion of an object such as a catheter or wire.

Optional features of the invention will now be set out. These are applicable singly or in any combination with any aspect of the invention.

Preferably, the access tool further comprises a biasing means and the biasing means preferably resiliently biases the second foot away from contact with the first foot.

The self-retracting ability of the access tool makes it easier to open the aperture of the vessel to which access is required. In addition, unlike the prior art tools mentioned above, the access tool with biasing means will itself hold open the entrance opening to the vessel which means that the surgeon can let go of the access tool and have both hands free to insert the wire/catheter that is being inserted into the vessel. Not only does this make the process of guiding an object into the vessel of the body easier for the surgeon but it also results in a safer procedure with less risk of damage to the vessel.

Optionally, the biasing means is a spring.

The spring may be a manual spring such as that used in a ball point pen (for example an external spring puller mechanism).

The biasing means may also include a rubber band.

The biasing means may include a manual retraction mechanism for use by the operator. This manual retraction mechanism may, for example, be a screw thread retraction mechanism.

The biasing means may include a reusable ratchet mechanism.

The biasing means is chosen such that the tool is stiff enough to hold itself (i.e. the two footplates) open even when the two footplates abut opposite sides of the vessel, but not too stiff such that damage is not caused to the vessel.

Given that different veins will have different tensile strengths, the spring constant of the biasing means may be chosen to provide an optimal resistance for a given vessel or range of vessels.

Preferably, the spring constant is chosen to have a value of no more than one quarter of the force needed to rupture the walls of the relevant vessel.

Optionally the maximum possible separation of the first footplate and second footplate may be 4mm. That is to say, the variable separation may only be increased up to a value of no more than 4mm. A device with such a maximum separation would be suitable for use as a Cephalic vein tool.

However, the maximum separation of the device will vary depending on the type of vessel and the diameter of the vessel for which the tool is to be used. For a smaller vessel such as an umbilical vein, the maximum possible separation of the first footplate and the second footplate may be no more than 2mm. For a larger vein such as a saphenous vein, the tool may have a maximum separation of no more than 8mm or may have a maximum separation of more than 8mm.

For an access tool designed to access the Cephalic vein, the spring constant of the biasing means is preferably no more than 100N/m.

For a Cephalic vein of tensile strength 190gram-load, this value of 100N/m corresponds to less than one quarter of the force required to rupture the vein. (The tensile strength of the Cephalic vein is given as 190 N/m in "Comparative study of the tensile strength of autogenous systemic veins and preserved venous homografts", Journal of surgical research, 12, 99-104 (1972). The spring constant k is thereofere given by the equation k=F/x. By converting the force of 190 gram-load into SI units and dividing by 4mm, the spring constant at rupture of the Cephalic vein is given as 466 N/m).

Regardless of whether or not the access tool includes a biasing means, the variable separation of the two footplates may be controlled by a screw mechanism.

Optionally, the access tool comprises: a first guide portion comprising the elongate arm (the first elongate arm) and the first footplate; and a second guide portion comprising a second elongate arm and the second footplate, the second footplate being located at one end of the second elongate arm; wherein the second guide portion is slideably movable along the longitudinal axis of the first elongate arm to control the relative separation of the first footplate and the second footplate.

In this configuration, and when a biasing means is present, the biasing means is preferably configured to apply the relative biasing force between the first foot and second foot via the first arm and the second arm respectively.

Optionally, the second guide portion is configured to nest within the first guide portion.

Optionally, the first arm (the "elongate arm") defines a tubular shell inside of which the second arm is locatable. In this way, the first guide portion forms an outer guide portion and the second guide portion forms an inner guide portion which can be slideably located within the first guide portion. The tubular shell may have a circular cross section or any other suitable cross section e.g. square, rectangular, and polygonal.

The second elongate arm may include a thumb rest at the opposite end of the arm to the second footplate. In this way, the second elongate arm of the tool can operate as a plunger and the user can apply a force to the thumb rest to reduce the separation distance between the two footplates.

Preferably, the first footplate contains a receiving portion for location of the second footplate when the two footplates are in contact with one another.

In this way, the second footplate sits on top of a portion of the first footplate when the two footplates are superimposed. This facilitates insertion of the foot into the incision of a vessel before the two footplates are separated relative to one another.

The second footplate is preferably smaller than the first footplate to enable it to sit within the first footplate in that its outer dimensions do not extend beyond the outer dimensions of the first footplate.

Preferably, the first footplate has a heel, a toe, and two opposite sides extending from the heel to the toe; and the elongate arm is connected to the first footplate at one side of the footplate.

In this way, when the first foot and second foot are separated, a clear pathway is defined between the two footplates from their heels to their toes such that a wire or catheter can follow this pathway from the heel end of the footplates towards the toe end without being obstructed by the arm.

Preferably, the second foot also has a heel, a toe, and two opposite sides extending from the heel to the toe; wherein the second arm is connected to the second foot at a side of the second footplate.

The side of the first footplate at which the first arm (the "elongate arm") is attached to the first footplate is preferably the same side as that of the second footplate at which the second arm is attached. In this way, when the second guide portion is nested within the first guide portion, the second arm will be aligned with the first arm.

Preferably, one or both of the first footplate and second footplate are tapered from a wider heel to a narrower toe.

Preferably, the toe part of the footplate terminates in a point thereby enabling the footplate to slide into the cut vessel.

Preferably the access tool further comprises a guide configured to form a pathway into the separation between the two footplates when the first footplate and second footplate are separated from one another.

Optionally the guide is linear. However, the guide could alternatively be curved. A linear guide minimises resistance as the catheter, lead or wire is being passed along it.

The guide is preferably a trough along which the catheter, lead or wire is passed, the trough having an open access slit which is preferably located so that it faces upwards (i.e. towards the proximal end of the tool) when the tool is in use.

Optionally the guide is pivotally mounted to the elongate arm. In this way it can be stowed out of the way when the foot of the tool are being inserted into the vessel and when the footplates are being separated from one another, but it can then be moved into alignment with the footplates once they are in the open position at the incision.

The pivot connection between the elongate arm and the guide is preferably positioned so that when the guide is pivoted towards the footplates, the end of the trough which contacts foot end of the device will be aligned with the first footplate (i.e. the distal footplate).

Preferably, the first and second footplates lie within a first and a second plane, each of which is a plane transverse to the longitudinal axis of the elongate arm.

Preferably, the access tool is disposable.

The access tool may be manufactured from any suitable material which is safe for medical use. For example, the tool may be formed from any medically safe nylon synthetic material.

Optionally, the access tool may be manufactured from Delrin. As well as being suitable for medical use, Delrin provides advantageous strength and flexibility from a single material. Further optional features of the invention are set out below.

The access tool is preferably a handheld device, and its size may be chosen to optimise ease of use and performance depending on the size and/or location of vessel for which it is intended to access. For example, where the access tool is suitable for accessing the cephalic vein, the overall height of the tool may optionally lie within the range of 4 cm to 15 cm. Optionally, the overall height of the tool may be no more than 4.5 cm, no more than 7 cm or no more than 10 cm.

Optionally, the heights of the first guide portion and the second guide portion may differ by as much as 0.5 cm, where the first guide portion has a greater height than the second guide portion. For embodiments which include a biasing means in the form of a spring, this extra height of the first guide portion may correspond to the height of the spring (along the axis parallel to the longitudinal axis of the first guide portion). The height of the first guide portion with a spring (i.e. the height from the uppermost part of the spring to the lowermost part of the footplate) may be no more than 4.5 cm. Optionally, the diameter of the tool (its breadth and/or its thickness) may be no more than 0.5 cm.

The footplates may be no more than 1.5 cm in length and may be no more than 0.5 cm wide. Preferably, for a cephalic vein tool, the footplates may be no more than 0.4 cm wide.

Where the footplate of a second guide portion is smaller than the footplate of the first guide portion, the footplate of the first guide portion may have a length of no more than 1.5 cm, and the footplate of the second guide portion may have a length of no more than 1.3 cm.

Brief Description of the Drawings

Embodiments of the invention will now be described by way of example with reference to the accompanying drawings in which:

Figure 1 shows a perspective view of an access tool according to a first embodiment of the present invention;

Figure 2 shows an alternative perspective view of the access tool of Figure 1;

Figure 3 shows a perspective view of a first portion of the access tool of Figures 1 and 2;

Figure 4 shows a perspective view of a second portion of the access tool of Figures 1 and 2 which also corresponds to a portion of the access tool of Figure 5;

Figure 5 shows a perspective view of an access tool according to a second embodiment of the present invention;

Figure 6 shows a perspective view of a first portion of the access tool of Figure 5;

Figure 7 shows an alternative perspective view of the access tool of Figure 5;

Figure 8 shows a perspective view of an access tool according to a third embodiment of the present invention;

Figure 9 shows an alternative perspective view of the access tool of Figure 8;

Figure 10 shows a perspective view of a first portion of the access tool of the third embodiment;

Figure 11 shows a perspective view of a second portion of the access tool of the third embodiment;

Figure 12 shows a further perspective view of the access tool of the third embodiment including a guide;

Figure 13 shows an exploded view of the first and second portions of the access tool shown in Figure 12;

Figure 14 shows a further perspective view of the first guide portion of the third embodiment;

Figure 15 shows a further perspective view of the third embodiment including a guide;

Figure 16 shows a perspective view of a fourth embodiment of the present invention (a) in a closed configuration, and (b) in an open configuration;

Figure 17 shows a perspective view of the fourth embodiment (a) in a closed configuration and (b) in an open configuration;

Figure 18 shows an exploded view of the fourth embodiment;

Figure 19 shows an alternative exploded view of the fourth embodiment;

Figure 20 shows a perspective view of a guide suitable for use with an access tool according to the present invention; and

Figure 21 shows an alternative perspective view of the guide shown in Figure 20.

Detailed Description and Further Optional Features of the Invention

An access tool 1 according to a first embodiment of the invention is described with reference to Figures 1 to 4. The access tool 1 is suitable for providing access into a vessel of a human or animal body. The tool includes an elongate arm 2 and a foot 3 for insertion into the vessel, the foot 3 being located at one end of the elongate arm 2, at the distal end of the tool.

The foot is made up of a first footplate 31 and a second footplate 32 which are slideably movable relative to one another along a direction corresponding to and/or parallel to that of the longitudinal axis of the elongate arm 2. The two footplates are slidable between a closed position where the second footplate 32 is superimposed upon the first footplate 31; and an open position which creates a separation S between the two footplates. The separation can be varied by sliding one footplate relative to the other along the elongate axis of the arm.

A biasing means 4 in the form of a spring is configured to exert a biasing force between the first and second footplates 31, 32 to urge them away from contact with one another into an open position. In Figures 1 and 2, the access tool is shown in such an open configuration with the first footplate and second footplate defining a variable separation S between the lower surface of the second footplate 32 and the upper surface of the first footplate 31.

In the embodiment shown in Figures 1 and 2, the access tool is made up of two parts; a first guide portion 11 and a second guide portion 12. The first guide portion, which is shown individually in Figure 3, is made up of the elongate arm 2 and the first footplate 31. The second guide portion, which is shown individually in Figure 4, is made up of a second elongate arm 22 and the second footplate 32. Both of the footplates are located at the distal end of their respective elongate arm. In this way, when one guide portion is slideably moved relative to the other guide portion, the footplates will move relative to one another to vary the separation therebetween.

Each footplate is a planar object having a heel and a toe. The sides of the footplate which connect the heel to the toe taper inwards from the heel to the toe to form a triangular shaped plate. The first footplate 31 includes a lip 33 at the toe which extends upwards out of the plane of the first footplate. The second footplate 32 has a frusto-triangular shape with a sawn off tip so that it fits behind the lip of the first footplate. In this way, when the second footplate is in contact with the first footplate (i.e. when there is no separation), the lip extends upwards in front of the toe of the second footplate.

The lip feature 33 therefore reduces the risk of separation of the footplates during insertion of the foot into the vessel. In addition, the lip itself is tapered to a point at the toe end so that it has a wedge shape. The tapered point further facilitates the insertion of the foot into an incision.

As shown in Figures 1 and 2, the second guide portion 12 is configured to nest within the first guide portion 11. The elongate arm 2 which forms a part of the first guide portion 11 is a tubular shell inside of which the elongate arm 12 of the second guide can be located.

The tubular shell defines a clearance at the distal end which ensures that the shell does not impede the movement of the second footplate relative to the first footplate. In addition, the tubular shell includes a slit which extends along its length to provide access into the inside of the shell.

Each of the first and second guide portions 11, 12 includes a plate 51, 52 at its proximal end (i.e. at the opposite end of the elongate arms to the footplates). The plates shown in Figures 1 to 4 lie transverse to the longitudinal axis of the elongate arms and therefore each lie in a plane which is parallel with the planes of the footplates. The plate 52 at the proximal end of the second elongate arm 22 acts as a thumb or finger rest so that the second guide portion can act as a plunger enabling a user to apply a downwards force in order to reduce the separation distance between the two footplates. The plate 51 of the first guide portion includes an access slit 50

In the embodiment shown in Figures 1-4, when the second guide portion is located within the first guide portion, the two guide portions are connected by the spring 4. The spring takes the form of a single resilient folded strip which is attached at one end of the strip 41 to the first guide portion at the proximal plate; and which includes a connection 42 at the other end of the strip for attachment to the second guide portion. The connection 42 has a forked end into which the elongate arm of the second guide portion can be clipped.

A rotation prevention mechanism in the form of protrusion 25 extends from the second guide portion 12 and is positioned at the proximal end of the second elongate arm 22, such that when the second guide portion 12 is located within the first guide portion 11, the protrusion mates with the forked connection 42 to hold the second guide portion in its nested position and to prevent relative rotation of the first footplate and the second footplate.

The second guide portion 12 includes a further rotation prevention mechanism in the form of a further protrusion 26 located at the opposite side of the elongate arm to the upper rotation prevention mechanism 25 and at a distance between the distal and the proximal ends. This further protrusion 26 fits within a groove or slit in an inner wall of the first guide portion such that when the second guide portion is located inside the first guide portion in use, the second guide portion is prevented from rotating by the protrusion 26 which would abut against the walls of the groove or slit if a relative rotational force were to be applied. Corresponding pairs of protrusions 27, 28, 29 (29 not visible in Figure 1) are located on the first elongate arm and protrude outwards from the surface of the tubular shell 2. These protrusions act as stops to stop unwanted movement along the direction of the elongate arms and thereby preventing the second guide portion from falling out of the first guide portion in use.

When in use, the surgeon will push down on the plunger to bring the two footplates into a closed configuration so that the second footplate 32 is superimposed upon the first footplate 31. The superimposed foot will then be inserted into an incision in the vessel into which access is sought. Once the foot is located at least partially within the vessel, the surgeon will release the pressure applied to the plunger and the resilient force applied by the biasing means will cause the two guide portions (and therefore the two footplates) to move relative to one another thereby creating a separation S which forms a pathway into the vessel. A catheter, wire, lead or other object can easily be inserted into the vessel via this pathway.

The biasing of the footplates into an open configuration means that once the footplates are inside the vessel, the surgeon can let go of the access tool leaving both of his hands free. The access tool will hold itself in place as the upper (i.e. proximal) surface of the first footplate and the lower (i.e. distal) surface of the second footplate will rest against the inner walls of the vessel.

A second embodiment of an access tool is described in relation to Figures 5 to 7 where like reference numerals are used to label features described above in relation to the first embodiment.

The access tool of the second embodiment differs from that of the first embodiment in that it includes a further feature of a guide 6.

The guide comprises: a main body including a channel 61 which can be brought into alignment with the footplates 31, 32 of the foot 3 to provide a pathway into the separation between the first footplate and the second footplate when they are in an open configuration.

The channel is a straight channel and includes a channel opening located at the side of the channel when the tool is in use, the opening extending along the entire length of the channel

61 of the guide. An alternative guide is shown in Figures 20 and 21 wherein the opening is located at the top of the channel when the tool is in use.

The main body of the guide 6 is connected to the elongate arm 2 of the first guide portion 11 via a guide arm which includes a connection means 67 and a tab 62. The connection means 67 is pivotally connectable to a corresponding connection means 7 on the outer shell of the first elongate arm which takes the form of a cylindrical protrusion which extends outwardly from the outer surface of the elongate arm 2. The connection means 7 is located at the opposite side of the elongate arm 2 to the slit which extends along the length of the elongate arm to provide access for the second elongate arm.

The resulting pivot connection is oriented such that the guide pivots about an axis transverse to the longitudinal axis of the elongate arm 2. It enables the guide to be pivoted away from the footplates to provide a better visibility while the footplates are being inserted into the vessel but then to be brought into position behind the heels of the footplates once they are in place.

The tab 62 facilitates the movement of the guide relative to the elongate arm of the access tool by the surgeon.

A third embodiment of an access tool is now described in relation to Figures 8 to 15 where like reference numerals are used to label features described above in relation to the first and second embodiments.

Firstly, the third embodiment differs from the first and second embodiment in that it includes extra features 151, 152, 153, 154 for prevention of rotation during use of the plunger mechanism.

Secondly, the access tool 101 of the third embodiment differs from access tools 1, 10 of the first and second embodiments in that it includes an improved footplate design 103.

Thirdly, access tool 101 of the third embodiment differs from the first and second embodiment 10 in that it includes an improved guide 106.

Each of the three differences described above could be applied separately to one or both of the access tools of the first or second embodiments in order to adapt the first and/or second embodiment to achieve the isolated advantage associated with that particular difference.

Taking first of all the improvements in relation to rotation prevention, each of the first and second guide portions 2, 22 include a plate 151, 152 at their respective proximal ends (i.e. at the opposite end of the elongate arms to the footplates). The plates shown in Figures 8 to 15 lie transverse to the longitudinal axis of the elongate arms and therefore each lie in a plane which is parallel with the planes of the footplates. The plate 152 at the proximal end of the second elongate arm 22 acts as a thumb or finger rest so that the second guide portion can act as a plunger enabling a user to apply a downwards force in order to reduce the separation distance between the two footplates.

The plates of the third embodiment 151, 152 differ from those of the first and second embodiment in that they include alignment means which retain the first and second guide portions in alignment to prevent relative rotational movement between the two guide portions during use. The alignment means take the form of a slot 154 in the plate of the first guide portion 151 and a protrusion 153 extending from the plate of the second guide portion, the protrusion extending in a direction parallel to the longitudinal axis of the second elongate arm.

The protrusion 153 takes the form of a planar structure capable of fitting within the slot 154 so that it is slidably located within the slot when the tool is in use. The planar structure 153 is formed from a portion of the plate 152 of the second elongate arm which has been folded downwards. The alignment slot 154 lies perpendicular to an access slit 150 which provides access through the plate of the first guide portion for the elongate arm of the second guide portion.

Secondly, with regards to the improved footplate design, the footplate 103 of the third embodiment differs from the footplates of the first and second embodiments in that the first footplate includes a curved lip 133 at the toe of the first footplate which curves upwards away from the base of the first footplate to the upper surface of the first footplate. The curved shape further facilitates insertion of the tool into the vessel.

As with previous embodiments, the lip 133 of the first footplate extends upwards out of the plane of the first footplate. The second footplate has a frusto-triangular planar shape with a sawn off tip so that it fits behind the curved lip of the first footplate. In this way, when the second footplate is in contact with the first footplate (i.e. when there is no separation), the curved lip extends upwards in front of the toe of the second footplate. The lip 133 therefore also reduces the risk of separation of the footplates during insertion of the foot into the vessel in addition to facilitating the actual insertion.

Thirdly, the access tool 101 of the third embodiment differs from the access tool of the second embodiment in that it includes an improved guide 106.

The improved guide comprises a main body with a channel 161 which can be brought into alignment with the footplates 31, 32 of the foot 103 to provide a pathway into the separation S between the first footplate and the second footplate when they are in an open configuration.

The pathway defined by the improved guide 106 of the access tool is a linear channel 161 for guiding a wire, lead etc. along a straight line into position behind the footplates. Access to the channel 161 is improved in that the channel includes an opening at the top of the channel (i.e. upwards when in use). The opening extends along the entire length of the channel.

The straight channel of the main body 106 is connected to the elongate arm 2 of the first guide portion 111 via a guide arm which includes a connection means 167. The connection means 167 is pivotally connectable to a corresponding connection means 7 on the outer shell of the first elongate arm which takes the form of a cylindrical protrusion which extends outwardly from the outer surface of the elongate arm 2.

The resulting pivot connection is oriented such that the guide pivots about an axis transverse to the longitudinal axis of the elongate arm 2. It enables the guide to be pivoted away from the footplates to provide a better visibility while the footplates are being inserted into the vessel but then to be brought into position behind the heels of the footplates once they are in place.

A tab 162 facilitates the pivotal movement of the guide relative to the elongate arm of the access tool by the surgeon.

A protrusion 77 which protrudes outwards from the outer surface of the second elongate arm 2 is located next to the connection means 7, between the connection means and the footplates. This protrusion can engage the guide when the guide is in position behind the footplates to prevent unwanted pivoting.

A fourth embodiment of an access tool 201 is described below in relation to Figures 16 to 19, where like reference numerals are used to label features described above in relation to the first to third embodiments.

The fourth embodiment of the access tool differs from the previous embodiments described in that the variable separation between the first footplate 31 and the second footplate 32 is controlled by a screw mechanism.

The screw mechanism comprises a screw cap 255, a cut washer 252 (otherwise known as a "split washer") and a screw thread 205. The screw thread 205 is shown in Figure 19.

In the embodiment shown in Figures 16 to 19, the screw thread 205 is located on an outer surface of the first guide portion. The inner surface of the screw cap 255 includes a corresponding screw thread configured to mate with the screw thread on the first guide portion.

The access tool 201 itself is therefore made up of four components: a first guide portion 221 (The "mother" guide portion); a second guide portion 222 (the "child" guide portion); a screw cap 255; and a cut washer 252.

As with previous embodiments, each guide portion 221, 222 includes an elongate arm 202, 212 and a footplate at one end of the elongate arm. The elongate arm of the first guide portion defines a tubular shell inside of which the second arm (i.e. the elongate arm of the second guide portion) is locatable.

As shown in figures 16 to 19, the tubular shell of the first elongate member defines a tubular cavity at least a portion of which has a square cross section. The elongate arm 212 of the second guide portion 222 has a corresponding square cross section so that it fits within the tubular cavity and can be slidably moved along the elongate axis of the first guide portion. The upper portion (i.e. the most proximal portion) is closed but an opening extends along the side of the rest of the first elongate portion.

The four components of the access tool 201 are assembled in the following way:

1. The second guide portion is pushed into the cavity defined by the tubular shell of the first guide portion. This may require flexing of the elongate arm of the second guide portion so a flexible material must be chosen for at least the second guide portion. The second guide

portion will extend through the closed portion of the first guide portion. Locators 240 ‘snap’ the second guide portion into position within the cavity.

2. The screw cap 255 is fitted onto the outside of the first guide portion so that it is at its lowest setting (so that the footplates are in a closed configuration and the screw cap is at the most distal position possible i.e. towards the direction of the footplates).

3. The cut washer 252 is pushed onto the proximal end of the elongate arm of the second guide portion.

4. A connection mechanism such as a ‘snap fit’ mechanism is located at an inside wall of the screw cap and is configured to be connectable to cut washer 252 on the second elongate member 222 to lock the second elongate member into attachment with the screw cap.

Thus, when the screw cap 255 of the assembled access tool is rotated around the screw thread of the first elongate member, the cut washer will be lifted by the screw cap and will bring with it the second guide portion including the second footplate. The second footplate will therefore be lifted away from the first footplate so that the separation between the two footplates is increased.

The fourth embodiment includes a guide 206 comprising a main body with a channel 261 which can be brought into alignment with the footplates 31, 32 of the foot 3 to provide a pathway into the separation between the first footplate and the second footplate when they are in an open configuration.

The pathway defined by the guide 206 is a linear channel 261 for guiding a wire, lead etc. along a straight line into position behind the footplates. The channel 261 includes an opening at the top of the channel (i.e. facing in an upwards direction when the tool is in use). The opening extends along the entire length of the channel 261.

The straight channel of the main body 206 is connected to the elongate arm 202 of the first guide portion 221 via a guide arm which includes a connection means 267. The connection means 267 is pivotally connectable to a corresponding connection means 207 on the outer shell of the first elongate arm which takes the form of a protrusion which extends outwardly from the outer surface of the elongate arm 202.

The resulting pivot connection is oriented such that the guide pivots about an axis transverse to the longitudinal axis of the elongate arm 202. It enables the guide to be pivoted away from the footplates to provide a better visibility while the footplates are being inserted into the vessel but then to be brought into position behind the heels of the footplates once they are in place. A tab 262 facilitates the movement of the guide relative to the elongate arm of the access tool by the surgeon.

A protrusion 277 which protrudes outwards from the outer surface of the second elongate arm 2 is located next to the connection means 7, between the connection means and the screw cap 255. The main body 206 of the guide abuts the protrusion when the channel of the guide reaches the desired position behind the footplates to prevent unwanted pivoting.

The access tool of any of the embodiments described above may be constructed by injection moulding. As shown in the Figures, the body of the access tool may include holes which arise due to restrictions imposed by the injection moulding process.

The shape of the first guide portion, 2 is designed to be moulded in an open and shut tool and the holes allow the undercut of the first guide portion (the clip that holds the second guide portion in place) to be moulded without more complex retractable side movement in the mould tool. This detail is called a shut off.

Where the first guide portion totally encloses the second guide portion, a retractable tool is required during the manufacture process to form the tube which can disadvantageously add cost to the manufacture process.

While the invention has been described in conjunction with the exemplary embodiments described above, many equivalent modifications and variations will be apparent to those skilled in the art when given this disclosure. Accordingly, the exemplary embodiments of the invention set forth above are considered to be illustrative and not limiting. Various changes to the described embodiments may be made without departing from the spirit and scope of the invention.

All references referred to above are hereby incorporated by reference.

CLAIMS

1. An access tool for providing access into a vessel of a human or animal body, the access tool comprising:

an elongate arm; and

a foot for insertion into the vessel, the foot being located at one end of the elongate arm;

wherein the foot comprises a first footplate and second footplate slideably movable relative to one another in the direction of the longitudinal axis of the elongate arm to control a variable separation between the footplates;

such that, when the foot is inserted into the vessel, a separation defined between the two footplates forms a pathway into the vessel.

2. The access tool of claim 1, further comprising a biasing means which resiliently biases the second foot away from contact with the first foot.

3. The access tool of claim 2, wherein the biasing means is a spring.

4. The access tool of any one of claims 1 to 3, comprising:

a first guide portion comprising the elongate arm and the first footplate; and

a second guide portion comprising a second elongate arm and the second footplate, the second footplate being located at one end of the second elongate arm;

wherein the second guide portion is slideably movable along the longitudinal axis of the first elongate arm to control the relative separation of the first footplate and the second footplate.

5. The access tool of claim 4, wherein the second guide portion is configured to nest within the first guide portion.

6. The access tool of claim 5, wherein the first elongate arm defines a tubular shell inside of which the second arm is locatable.

7. The access tool of any one of the preceding claims, wherein the first footplate contains a receiving portion for location of the second footplate when the two footplates are in contact with one another.

8. The access tool of any one of the preceding claims, wherein the first footplate has a heel, a toe, and two opposite sides extending from the heel to the toe; and wherein the elongate arm is connected to the first footplate at one side of the footplate.

9. The access tool of claim 8, wherein the second foot also has a heel, a toe, and two opposite sides extending from the heel to the toe; wherein the second arm is connected to the second foot at one side of the foot.

10. The access tool of any one of the preceding claims, wherein one or both of the first footplate and second footplate are tapered from a wider heel to a narrower toe.

11. The access tool of any one of the preceding claims, further comprising a guide configured to form a pathway into the separation between the two footplates when the first footplate and second footplate are separated from one another.

12. The access tool of claim 11, wherein the guide is linear.

13. The access tool of claim 11 or claim 12, wherein the guide trough is pivotally mounted to the elongate arm.

14. The access tool of any one of the preceding claim, wherein the first and second footplates lie within a first and a second plane each of which is a plane transverse to the longitudinal axis of the elongate arm.

15. The access tool of any one of the preceding claims, further comprising a screw mechanism to control the variable separation between the footplates.

16. The access tool substantially as described herein with reference to the figures.

Intellectual Property Office

Application No:	GB1407808.3	**Examiner:**	Dr Joanna Manning
Claims searched:	1-16	**Date of search:**	15 January 2015

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
Y	1, 4-10, 14	US 3750651 A (PANTHER PLAST AS) Whole document relevant, see especially Figures
Y	1, 4-10, 14	US 3565061 A (VERNE) Whole document relevant, see especially Figures
Y	1, 4-10, 14	WO 91/09563 A1 (ADVANCED MEDICAL DEVICES INC) Whole document relevant, see especially Figures
Y	1, 4-10, 14	WO 2010/076555 A1 (UNIV HOSPITALS COVENTRY & WARW) Whole document relevant, see especially page 1, paragraph 4

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Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

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A61B; A61M

The following online and other databases have been used in the preparation of this search report

EPODOC, WPIAP

International Classification:

Subclass	Subgroup	Valid From
A61B	0017/34	01/01/2006
A61B	0001/32	01/01/2006
A61M	0025/01	01/01/2006