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(71) Applicant: **RENISHAW PLC** [GB/GB]; New Mills,
Gloucestershire, Wotton-under-Edge Gloucestershire GL12
8JR (GB).

(72) Inventors: **GILL, Steven**; North Bristol NHS Trust, Fren-
chay Hospital, Frenchay Park Road, Bristol South
Gloucestershire BS16 1LE (GB). **ANTALFY, Attila**; 262
Columbine Road, Ely Cambridgeshire CB6 3WP (GB).

(74) Agents: **DUNN, Paul** et al.; Patent Department, New
Mills, Gloucestershire, Wotton-under-Edge Gloucester-
shire GL12 8JR (GB).

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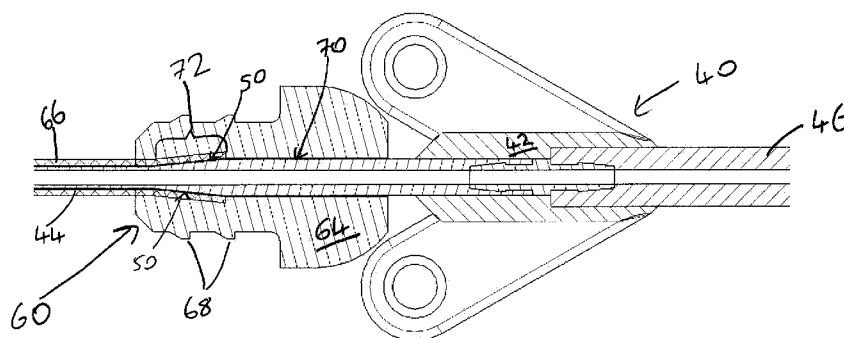


FIG. 4

(57) Abstract: Neurosurgical apparatus is described that comprises a guide device (60) and a neurosurgical instrument (40). The guide device includes a tube (66) for insertion into the brain of a subject and a head (64) attached to the proximal end of the tube (66) for affixing the guide device (60) to a hole formed in the skull. The head has a passageway (70) therethrough in communication with the bore of the tube (66) such that the bore of the tube and the passageway (70) through the head (64) define an internal channel through which a neurosurgical instrument (40) can be passed into the brain (10) of the subject. The neurosurgical instrument (40), such as a catheter, is for insertion to a desired brain target through the internal channel of the guide device (60). The apparatus comprises one or more sealing elements (50,72) for providing a substantially fluid tight seal between the internal channel of the guide device (60) and the exterior of the neurosurgical instrument (40) when inserted therein. This prevents fluid leakage from guide tube.

Neurosurgical Apparatus

The present invention relates to apparatus for neurosurgery and in particular to improved guide tube and catheter apparatus in which reflux effects are reduced.

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US6609020 describes a guide device comprising a head that can be affixed to a burr hole formed in the skull and an elongate tube attached to the head. In use, the guide device is inserted into the brain towards a desired target and the head is affixed to the burr hole formed in the skull. Neurosurgical instruments (e.g. catheters, electrodes etc) may then be inserted through the guide device to a desired target. A fine catheter for use with such a guide device is also described in WO2003/077785.

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The present inventors have found that a problem can arise when using a guide device system as described above, especially when dispensing fluid through a catheter. Fluid has been found to reflux along the internal lumen of the guide tube, (between the internal wall of the guide tube and the inserted catheter) and exit the head of the guide tube outside of the cranial cavity. This can reduce the amount of fluid delivered to the desired target and can also alter the extent or shape of fluid delivery to the brain.

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According to a first aspect of the invention, there is provided neurosurgical apparatus comprising; a guide device comprising a tube for insertion into the brain of a subject and a head attached to the proximal end of the tube for affixing the guide device to a hole formed in the skull, the head having a passageway therethrough in communication with the bore of the tube, wherein the bore of the tube and the passageway through the head define an internal channel through which a neurosurgical instrument can be passed into the brain of the subject, and a neurosurgical instrument for insertion to a desired brain target through the internal channel of the guide device, characterised in that the apparatus comprises one or more sealing elements for providing a substantially fluid tight seal between the internal channel of the guide device and the exterior of the neurosurgical instrument when inserted therein.

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The present invention thus relates to neurosurgical apparatus comprising a guide device and a neurosurgical instrument, such as a catheter. The guide device comprises an elongate tube having a head at its proximal end. In use, the elongate
5 tube is inserted into the brain towards a target via a hole formed in the skull and the head is used to securely attach the guide device to the skull. This insertion may be performed using a stereoguide or surgical robot based technique. An internal channel is provided through the head and bore of the tube. The neurosurgical instrument (e.g. a catheter) can then be passed down this channel and into the
10 brain in the vicinity of the selected target.

The apparatus of the present invention also comprises one or more sealing elements. The sealing elements allow, when the neurosurgical instrument is inserted into the guide device, a substantially fluid tight seal to be established
15 between the internal channel of the guide device and the exterior of the inserted neurosurgical instrument. The sealing elements may be provided as appropriately shaped portions or regions of the guide device and/or the neurosurgical instrument. For example, the guide tube and neurosurgical instrument may be shaped, profiled or otherwise configured to fit together in a way that provides the
20 fluid tight seal. Alternatively, one or more separate sealing elements (e.g. o-rings, washers etc) may be appropriately located between the guide device and the neurosurgical instrument.

The apparatus of the present invention thus provides a fluid tight seal between an
25 inner surface of the internal channel of the guide device and the outer surface of the inserted neurosurgical instrument. This fluid tight seal prevents fluid flow along the inside of the guide device in the gap between the internal surface of the internal channel and the outer surface of an inserted neurosurgical instrument. For example, if the inserted neurosurgical instrument is a catheter for delivering fluid
30 to a target site reflux back along the guide device is prevented. In particular, it prevents leakage of fluid from the intracranial cavity through the passageway of the head of the guide device.

As explained above, any suitable sealing element or elements may be used to provide the fluid tight seal. Advantageously, the one or more sealing elements comprise a tapered outer surface of the neurosurgical instrument that seals against the inner surface of the internal channel of the guide device when the neurosurgical instrument is inserted therein. The tapered outer surface of the neurosurgical instrument preferably comprises a tapered decrease in outer diameter when passing from the proximal to distal end of the instrument. Conveniently, the one or more sealing elements comprise a tapered inner surface of the internal channel of the guide device that seals against the neurosurgical instrument when the neurosurgical instrument is inserted into the guide device. The tapered innermost surface of the guide device preferably comprises a tapered decrease in internal diameter when passing from the proximal to distal end of the guide device. The neurosurgical instrument alone may comprise a tapered outer surface for engagement with a non-tapered guide device. Alternatively, the guide device alone may comprise a tapered innermost surface for engagement with a non-tapered neurosurgical instrument. In a preferred embodiment, the one or more sealing elements comprise a tapered outer surface of the neurosurgical instrument and a correspondingly tapered inner surface of the internal channel of the guide device. In other words, the neurosurgical instrument and guide device preferably include tapered surfaces that are dimensioned to engage and provide a fluid tight seal. Preferably, the taper comprises a smooth (e.g. non-stepped) change in diameter.

The neurosurgical instrument may, for example, comprise an electrode, needle, rod or any other suitable neurosurgical device. Advantageously, the neurosurgical instrument comprises a catheter. The neurosurgical instrument may be formed as a single component or may comprise a plurality of parts. For example, the neurosurgical instrument may comprise a plurality of concentric components (e.g. an inner tube and one or more outer tubes) that when assembled provide a catheter device.

As mentioned above, the neurosurgical instrument may comprise a catheter. The catheter conveniently comprises a hub. The hub may be connected to a length of

fine tubing for insertion into the brain. The hub may comprise a tapered outer surface that provides a sealing element. The sealing element of the catheter may be configured for engagement with a corresponding taper provided in the passageway of the head of the guide device. Advantageously, the tapered outer surface of the hub and the corresponding taper of the passageway act as a depth stop. The depth stop may control the depth of insertion of the fine tubing into the brain. In other words, the corresponding tapers may engage and prevent further insertion of the catheter into the guide device. The length of fine tubing may thus be cut to a length that ensures the distal end (tip) of the catheter reaches a desired target site within the brain.

The hub conveniently comprises a body portion. The tapered outer surface of the hub may be located between the fine tubing and the body portion. The hub may also comprise at least one protruding wing. Conveniently, a pair of protruding wings may be provided. The at least one protruding wing is preferably configured (e.g. shaped and positioned) to engage the head of the guide device on over-insertion of the catheter into the guide device, thereby acting as a safety stop. In particular, the at least one protruding wing prevents the portion of the catheter between the tapered outer surface and the at least one protruding wing from buckling, deforming or splitting if further force is applied after the tapered outer surface of the hub has engaged the corresponding taper of the passageway. The at least one protruding wing preferably also provides a visual indication that the desired depth of catheter insertion into the guide device has been achieved. For example, the at least one protruding wing may be spaced apart from the head by a small preset distance (e.g. 0.5mm) when the tapered outer surface of the hub and the corresponding taper of the passageway have engaged to stop further catheter insertion. The at least one protruding wing ensures that the maximum over-insertion equals the preset distance (e.g. 0.5mm); i.e. the at least one protruding wing engages the head if over-insertion of more than the preset distance is attempted. In this manner, the apparatus is much less likely to be incorrectly implanted or damaged during implantation.

The hub of the catheter preferably comprises a fluid passageway in

communication with the lumen or bore of the fine tubing. Advantageously, the fluid passageway of the hub links the fine tubing to the distal end of a connector tube. The proximal end of such a connector tube may be connected to the outlet of a fluid pump. The connector tube may be directly connected to the outlet of the fluid pump. The connector tube may be indirectly connected to the outlet of the fluid pump, via further tubing, ports, connectors etc.

The catheter advantageously comprises fine tubing for insertion into the brain that has an outer diameter of less than 1mm. Preferably, the outer diameter is less than 0.7mm. Preferably, the internal diameter of the fine tubing is greater than 0.2mm or more preferably greater than 0.3mm. An internal diameter of between 0.3mm and 0.5mm is preferred. The internal diameter of the fine tubing is preferably invariant through any externally tapered part of the hub.

Although a catheter arrangement is described in detail herein, it should be remembered the invention can be used for any neurosurgical instrument. The neurosurgical instrument may advantageously comprise at least one protruding wing for securing the neurosurgical instrument to the skull after insertion. The wing(s) may comprise one or more holes that allow attachment to the skull using bone screws. As mentioned above, such a wing or wings may also or alternatively be used as an over-insertion or safety stop and/or to provide a visual indication of depth of neurosurgical insertion into the guide device.

The apparatus may be formed from any suitable material. Advantageously, the apparatus is suitable for long term implantation in a subject. Preferably, at least one of the guide device and neurosurgical instrument comprises a polyurethane plastic, such as Carbothane. Carbothane has been found to be particularly resistant to blockage during long term implantation.

The one or more sealing elements may be placed at any suitable location along the length of the apparatus. Sealing elements may be placed at a plurality of locations along the length of the apparatus. For example, sealing elements may be spaced apart along the guide device. Advantageously, the one or more sealing elements

are provided in the vicinity of the head of the guide device. This is preferred because the larger size of the head (compared to the tube) permits a more robust seal to be provided. In particular, a tapered section in the vicinity of the head can be made to be less deformable than a taper formed further along the tube.

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Conveniently, one or more features are provided on the external surface of the head of the guide device for securing the guide device to a hole formed in the skull. The features may comprise ribs. The features may comprise a screw thread. The features may enable the head to be press fitted into a hole formed in the skull.

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The head of the guide device may comprise a slot. The slot allows an inserted instrument to be bent so that it exits from the head in a direction orthogonal to the longitudinal axis of the tube of the guide device (i.e. it allows an inserted device to be bent so as to lie parallel to bone). The provision of a slot with screw thread formations allows the guide device to be unscrewed from the skull.

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The apparatus may include other components. For example, it may comprise a fluid pump (e.g. a fluid pump for convection enhanced delivery), a port (e.g. a percutaneous access port) a fluid connector and/or a filter (e.g. a bubble and/or bacterial filter).

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The invention also extends to a guide device modified to provide a fluid seal with a neurosurgical instrument inserted therein. An aspect of the invention thus provides a guide device comprising; a tube for insertion into the brain of a subject and a head attached to the proximal end of the tube for affixing the guide device to a hole formed in the skull, the head having a passageway therethrough in communication with the bore of the tube, wherein the bore of the tube and the passageway through the head define an internal channel through which a neurosurgical instrument can be passed into the brain of the subject, wherein the guide device is arranged to receive an associated neurosurgical instrument for insertion to a desired brain target through the internal channel of the guide device, characterised in that the guide device comprises one or more sealing elements for providing a substantially fluid tight seal between the internal channel of the guide device and the exterior of an associated neurosurgical instrument when inserted

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therein. The guide device may have any of the other features described in more detail above.

5 The invention also extends to a neurosurgical instrument (e.g. a catheter or electrode) modified to provide a fluid seal with a guide device when it is inserted therein. An aspect of the invention thus provides a neurosurgical instrument for insertion to a desired brain target through an associated guide device that comprises a tube for insertion into the brain of a subject and a head attached to the proximal end of the tube for affixing the guide device to a hole formed in the
10 skull, the head having a passageway therethrough in communication with the bore of the tube, wherein the bore of the tube and the passageway through the head define an internal channel through which the neurosurgical instrument can be passed into the brain of the subject, characterised in that the neurosurgical instrument comprises one or more sealing elements for providing a substantially
15 fluid tight seal with the internal channel of the associated guide device. The neurosurgical instrument may have any of the other features described in more detail above.

The invention also extends to a method of surgically implanting apparatus as
20 described above. The apparatus may be implanted in a human patient or in an animal. The invention thus extends to a method of inserting a neurosurgical instrument to a target in the brain of a subject using neurosurgical apparatus as described above, the method comprising the steps of; (i) forming a hole in the skull of the subject, (ii) inserting the tube of the guide device into the brain and
25 engaging the head with the hole formed in the skull thereby securing the guide device in place, (iii) passing the neurosurgical instrument through the internal channel of the guide device until the distal end of the neurosurgical instrument is located at the desired brain target. Advantageously, suction is applied to the head of the guide device during the insertion process of step (iii) to prevent fluid (e.g.
30 air bubbles) being driven into the brain. The fluid seal established between the neurosurgical instrument and the guide device during step (iii) preferably reduces or prevents fluid reflux back through the guide device. The method may use any suitable guidance technique for inserting the guide device and neurosurgical

instrument. For example, a surgical robot or manual stereoguide may be used.

The neurosurgical instrument inserted into the guide device is preferably a catheter. The method may then comprise a step of delivering fluid to the brain
5 through the implanted catheter. The fluid may comprise any pharmaceutical composition for treating a neurological condition or a cytotoxic agent for oncology. The method may comprise delivering a growth factor, such as GDNF, or a viral vector. Delivery of fluid may be continuous or intermittent. The apparatus may be used to treat acute or chronic conditions. The apparatus, or part
10 thereof, may be explanted after delivery. Alternatively, the apparatus (e.g. the guide device) may be left implanted long-term (e.g. for the rest of the subject's life).

The invention will now be described, by way of example only, with reference to
15 the accompanying drawings in which;

Figure 1 illustrates a prior art neurosurgical catheter and guide tube arrangement,

Figure 2 shows a catheter of the present invention,
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Figure 3 shows an alternative view of the catheter of figure 2,

Figure 4 shows a catheter of the present invention inserted into a guide tube of the present invention,
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Figure 5 shows the catheter and guide tube of figure 4 after the catheter has been bent following implantation,

Figure 6 is an external view of the catheter and guide tube of the present
30 invention,

Figure 7 is an alternative view of the catheter and guide tube of the present invention,

Figure 8 is a further alternative view of the catheter and guide tube of the present invention,

5 Figure 9 is a further alternative view of the catheter and guide tube of the present invention,

Figure 10 is a further alternative view of the catheter and guide tube of the present invention, and

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Figure 11 shows the full length of the catheter and guide tube of the present invention.

Referring to figure 1, a prior art implanted fluid delivery system of the type
15 described in WO2003/077785 is illustrated.

The fluid delivery system comprises a guide device comprising an elongate tube 2 having a head 4 at its proximal end. The head 4 has an external thread 6 to allow attachment to a burr hole formed in the skull bone 8 of a subject. The guide device
20 is inserted stereotactically into the brain parenchyma 10 using a stereoguide device. In particular, the guide device can be accurately inserted in the brain along a predefined axis of insertion such that its distal end 12 is located just short (by a distance d) of a target point 15. More details concerning accurate (e.g. stereotactic) insertion of the guide tube can be found elsewhere; for example, see
25 WO2003/077784, WO2003/077785 and US6609020.

After the guide device has been implanted, a flexible catheter is inserted through the head 4 and into the tube 2. The flexible catheter comprises a length of fine tubing 16 having an outside diameter of 1mm or less. During implantation, the
30 fine tubing 16 is inserted into the guide device 2 and advanced therethrough until the distal end 18 of the fine tube 16 protrudes a distance "d" from the distal end 12 of the tube 2 and thereby reaches the target point 15. As described in WO2003/077785, the fine tube 16 is flexible and is typically reinforced by a guide

wire (not shown) during implantation to prevent the catheter significantly deviating from the required axis of insertion as it exits the distal end 12 of the elongate tube 2 and is driven towards target point 15. Once implanted, the guide wire is withdrawn from the catheter leaving the fine tube 16 in situ.

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The fine tube 16 of the catheter is connected to a hub 20 that is screwed to the outside of the skull 8. A supply or connector tube 22 is in fluid communication with the fine tube 16 via a channel formed in the hub 20. The supply tube 22 may receive fluid from a remotely located drug pump, the fluid then being routed along the fine tube 16 to the target volume 14.

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Although the prior art guide tube and catheter device has been found to perform well, the present inventor has identified a potential problem. In particular, it has been found that during fluid delivery via the catheter there can be reflux of fluid along the inside of the guide device in the gap between the catheter and the guide device. This can reduce the pressure that is established at the catheter tip (potentially altering the fluid delivery profile) and may cause unwanted reflux of fluid out of the intracranial cavity.

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Referring to figures 2 and 3, a catheter 40 of the present invention is illustrated. The catheter 40 comprises a hub 42, a fine tube 44 and a connector tube 46. The hub 42 comprises a body portion 48, a sealing element in the form of a tube having a tapered surface 50 and a pair of protruding wings 52. The wings 52 have apertures 54 formed therein for receiving bone screws.

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Referring to figures 4 and 5, a catheter 40 of the type described with reference to figures 2 and 3 is shown when inserted into a guide device 60 of the present invention. The catheter 40 comprises a bore or lumen 62 that runs through the connector tube 46, a hub 42 and a fine tube 44. The internal diameter of the lumen 62 is substantially constant through the catheter 40, although it could be varied if required. The guide device 60 comprises a head 64 and an elongate tube 66. The head 64 comprises external ridges 68 that allow it to be attached to a hole formed in the skull by a press fit action. The guide device 60 comprises a passageway 70

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through the head 64 in which the catheter 40 can be located.

The passageway 70 of the head 64 comprises an internally tapered region 72 that forms a fluid tight seal with the tapered surface 50 of the inserted catheter. This seal prevent fluids from passing along the gap between the fine tube 44 and the elongate tube 66 into the head 64. Fluid leakage and reflux is thus inhibited. However, as shown in figure 5, this seal does not obstruct the lumen 62 running through the catheter 40.

Figure 4 shows the catheter 40 after insertion in to the guide device 60, whilst Figure 5 shows the arrangement after the catheter has been bent through ninety degrees in the slot formed in the head 64. The wings 52 of the catheter are, when the tapered region 72 of the guide device 60 engages the tapered surface 50 of the catheter 40, arranged to be located very close (e.g. within 0.5mm) to the head 64 of the guide device 60. This provides a visual indication that the tapered surfaces have engaged to form the fluid seal. The wings 52 and head 64 will also engage if further insertion of the catheter is attempted, thereby acting as an insertion limiter or safety stop to prevent buckling or other damage to the catheter

Figures 6 and 7 show various external views of the catheter 40 when inserted in to the guide device 60. Figures 8, 9 and 10 show various external views of the catheter 40 when inserted in to the guide device 60 after the catheter 40 has been bent. In particular, figures 7, 8 and 10 show the slot 80 formed in the head 64 of the guide device 60.

Figure 11 is an overview of the combined catheter and guide tube system. The length of the elongate tube 66 and fine tube 44 can cut to any desired length to reach the required targets in the brain.

The skilled person would appreciate that the above is merely one example of the present invention and that variants to the above described embodiments would be possible. In particular, the catheter could be replaced with any suitable neurosurgical instrument, such as an electrode. The devices could also be made

from any suitable material, implanted using any suitable surgical technique and used to deliver a variety of therapeutic agents.

Claims

1. Neurosurgical apparatus comprising;
 a guide device comprising a tube for insertion into the brain of a
5 subject and a head attached to the proximal end of the tube for affixing the guide
 device to a hole formed in the skull, the head having a passageway therethrough in
 communication with the bore of the tube, wherein the bore of the tube and the
 passageway through the head define an internal channel through which a
 neurosurgical instrument can be passed into the brain of the subject, and
10 a neurosurgical instrument for insertion to a desired brain target
 through the internal channel of the guide device,
 characterised in that the apparatus comprises one or more sealing
 elements for providing a substantially fluid tight seal between the internal channel
 of the guide device and the exterior of the neurosurgical instrument when inserted
15 therein.
2. An apparatus according to claim 1, wherein the one or more sealing
 elements comprise a tapered outer surface of the neurosurgical instrument that
 seals against the inner surface of the internal channel of the guide device when the
20 neurosurgical instrument is inserted therein.
3. An apparatus according to any preceding claim, wherein the one or more
 sealing elements comprise a tapered inner surface of the internal channel of the
 guide device that seals against the neurosurgical instrument when the
25 neurosurgical instrument is inserted into the guide device.
4. An apparatus according to any preceding claim, wherein the neurosurgical
 instrument comprises a catheter.
- 30 5. An apparatus according to claim 4, wherein the catheter comprises a hub
 connected to a length of fine tubing for insertion into the brain, the hub
 comprising a tapered outer surface that provides a sealing element for engagement
 with a corresponding taper provided in the passageway of the head of the guide

device, wherein the tapered outer surface of the hub and the corresponding taper of the passageway act as a depth stop for controlling the depth of insertion of the fine tubing into the brain.

5 6. An apparatus according to claim 5, wherein the hub also comprises a body portion, the tapered outer surface being located between the fine tubing and the body portion, wherein the hub also comprises at least one protruding wing that is spaced apart from the head by a small preset distance when the tapered outer surface of the hub and the corresponding taper of the passageway have engaged
10 thereby providing a visual indication of engagement.

7. An apparatus according to claim 6, wherein the hub comprises a fluid passageway that links the fine tube to the distal end of a connector tube, the proximal end of the connector tube being connected to the outlet of a fluid pump.

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8. An apparatus according to any one of claims 4 to 7, wherein the catheter comprises fine tubing for insertion into the brain that has an outer diameter of less than 0.7mm.

20 9. An apparatus according to any one of claims 4 to 8, wherein the catheter comprises fine tubing for insertion into the brain that has an inner diameter of more than 0.3mm.

10. An apparatus according to any preceding claim, wherein the neurosurgical
25 instrument comprises at least one protruding wing for securing the neurosurgical instrument to the skull after insertion.

11. An apparatus according to any preceding claim, wherein at least one of the guide device and neurosurgical instrument comprises a polyurethane plastic, such
30 as Carbothane.

12. An apparatus according to any preceding claim, wherein the one or more sealing elements are provided in the vicinity of the head of the guide device.

13. An apparatus according to any preceding claim, wherein one or more features are provided on the external surface of the head of the guide device for securing the guide device to a hole formed in the skull.

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14. An apparatus according to any preceding claim, further comprising at least one of a fluid pump, a port, a fluid connector and a filter.

15. A guide device comprising;

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a tube for insertion into the brain of a subject and a head attached to the proximal end of the tube for affixing the guide device to a hole formed in the skull, the head having a passageway therethrough in communication with the bore of the tube, wherein the bore of the tube and the passageway through the head define an internal channel through which a neurosurgical instrument can be passed into the brain of the subject,

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wherein the guide device is arranged to receive an associated neurosurgical instrument for insertion to a desired brain target through the internal channel of the guide device,

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characterised in that the guide device comprises one or more sealing elements for providing a substantially fluid tight seal between the internal channel of the guide device and the exterior of an associated neurosurgical instrument when inserted therein.

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16. A neurosurgical instrument for insertion to a desired brain target through an associated guide device that comprises a tube for insertion into the brain of a subject and a head attached to the proximal end of the tube for affixing the guide device to a hole formed in the skull, the head having a passageway therethrough in communication with the bore of the tube, wherein the bore of the tube and the passageway through the head define an internal channel through which the neurosurgical instrument can be passed into the brain of the subject,

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characterised in that the neurosurgical instrument comprises one or more sealing elements for providing a substantially fluid tight seal with the internal channel of the associated guide device.

17. A method of inserting a neurosurgical instrument to a target in the brain of a subject using neurosurgical apparatus according to any preceding claim, the method comprising the steps of;

- 5 (i) forming a hole in the skull of the subject,
(ii) inserting the tube of the guide device into the brain and engaging the head with the hole formed in the skull thereby securing the guide device in place,
(iii) passing the neurosurgical instrument through the internal channel of the guide device until the distal end of the neurosurgical instrument is located at
10 the desired brain target.

18. A method according to claim 17, wherein suction is applied to the head of the guide device during the insertion process of step (iii) to prevent fluid being driven into the brain.

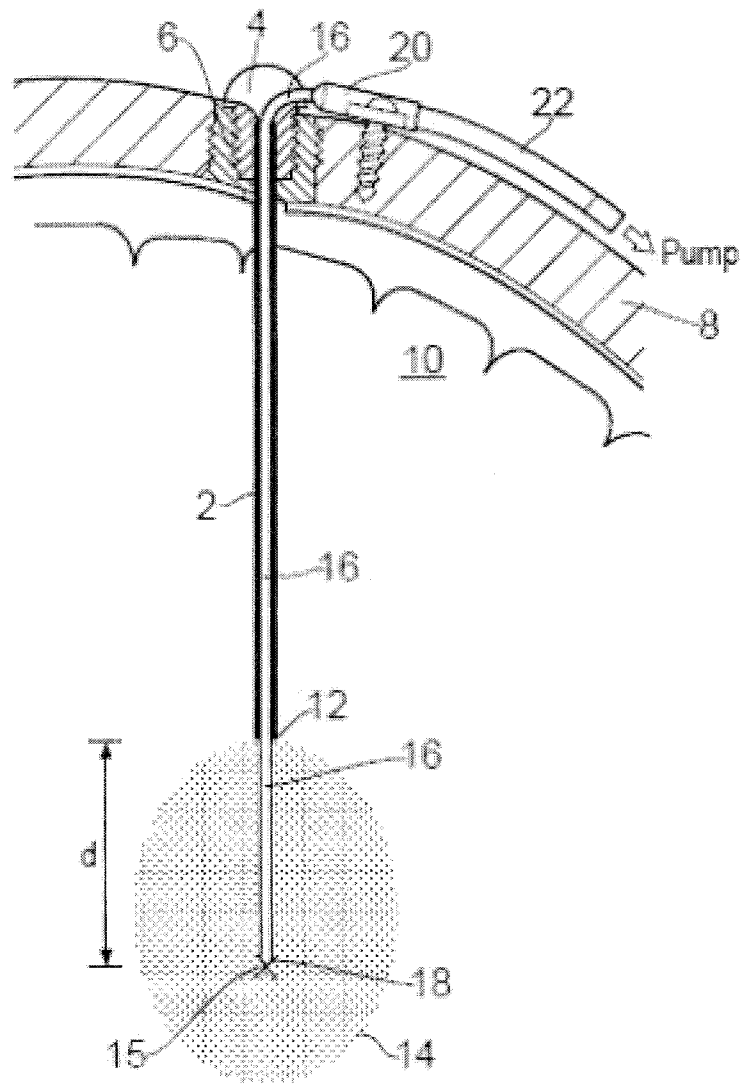


FIG. 1 (Prior Art)

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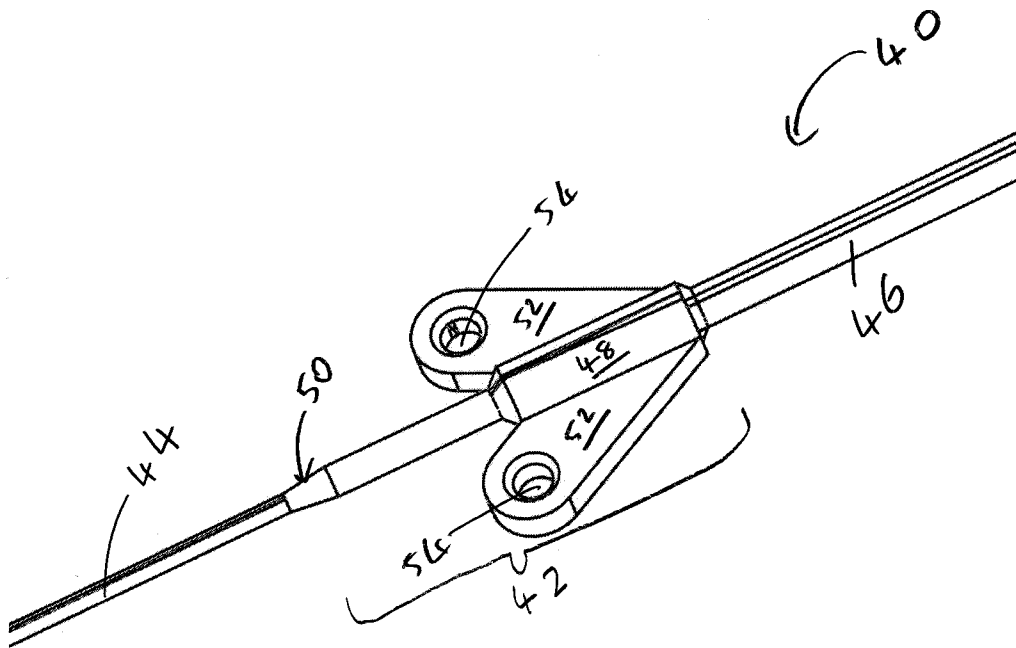


FIG. 2

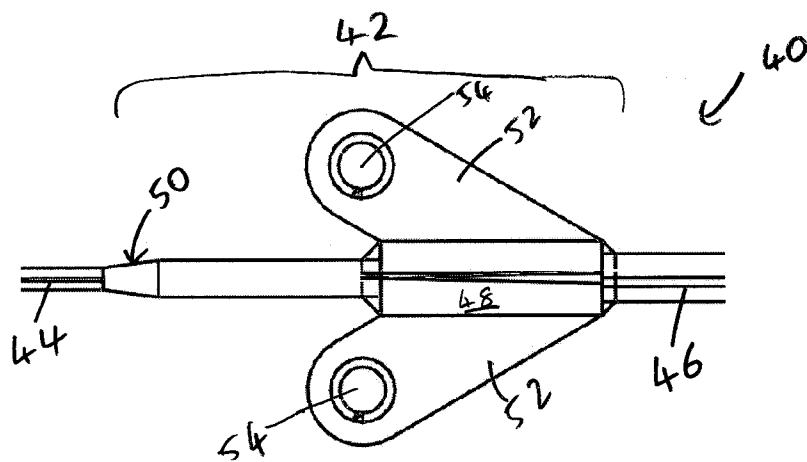


FIG. 3

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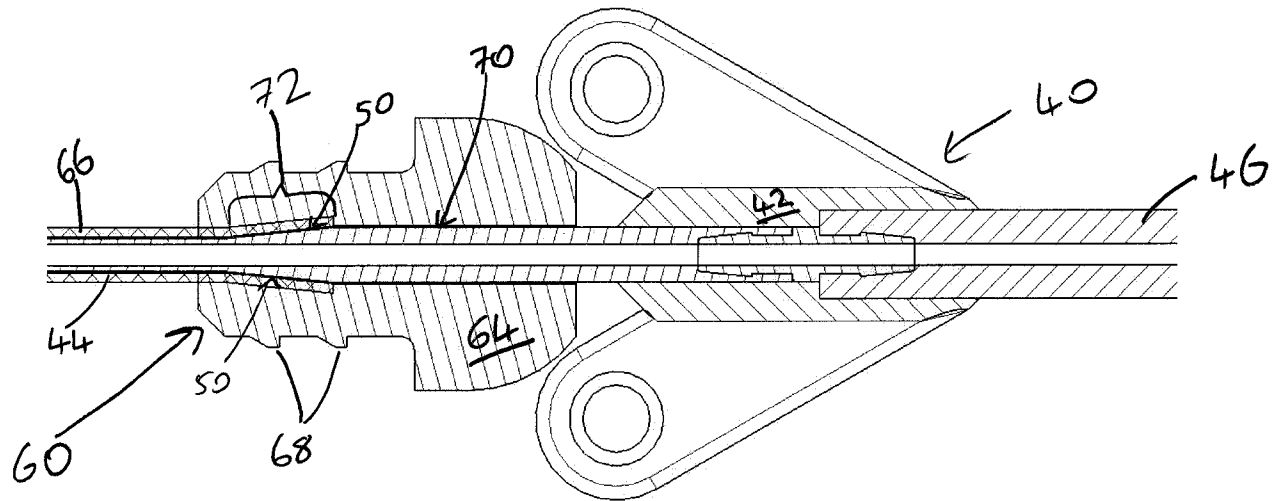


FIG. 4

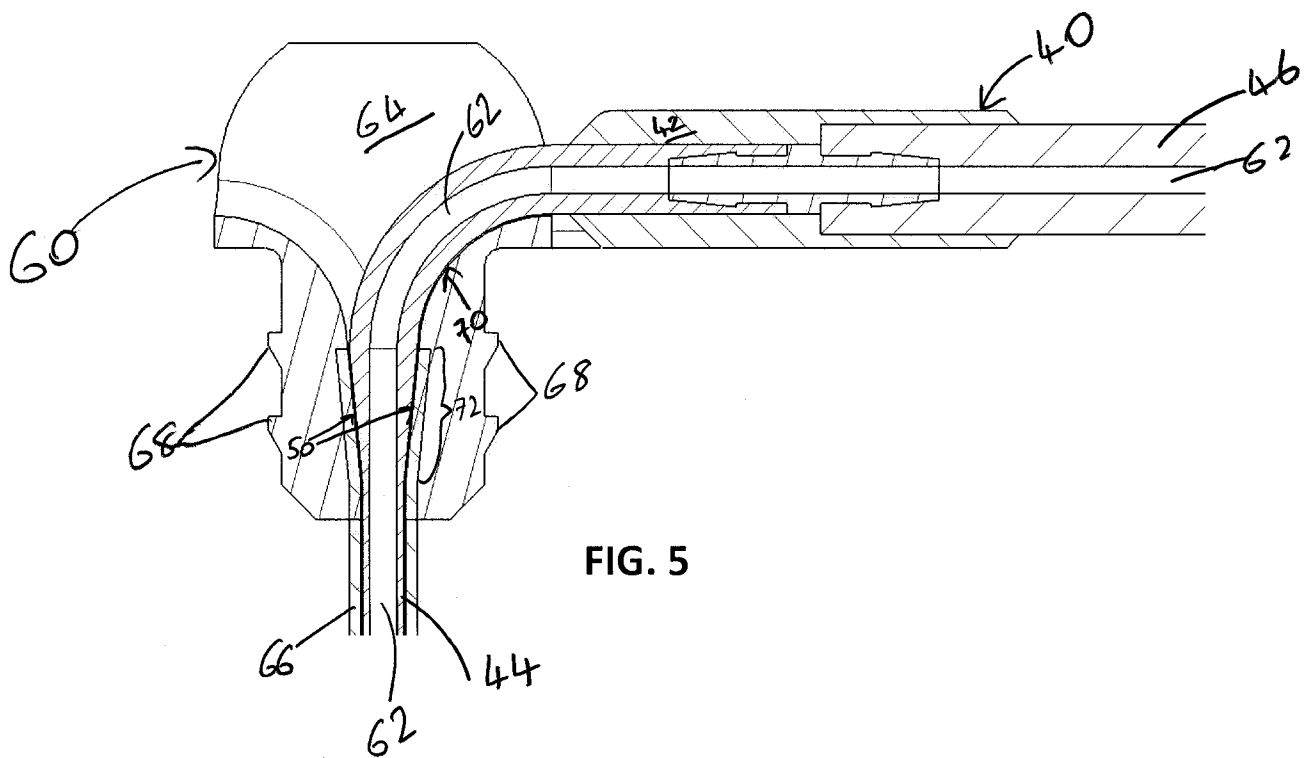


FIG. 5

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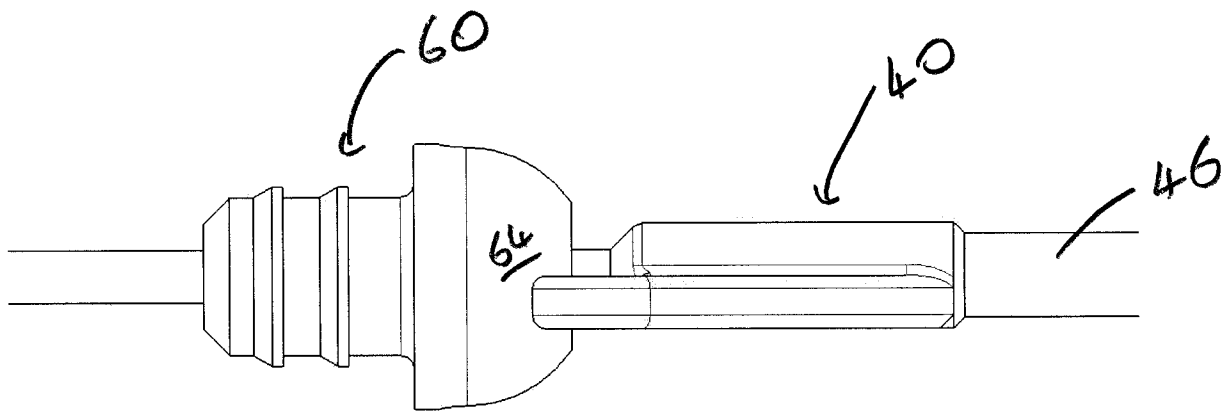


FIG. 6

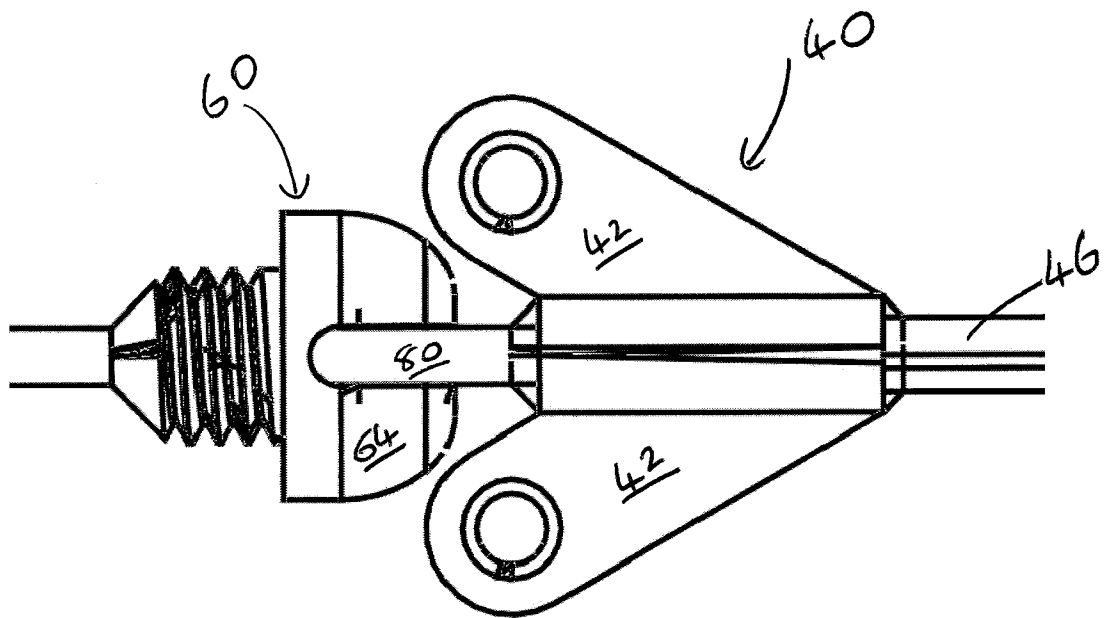


FIG. 7

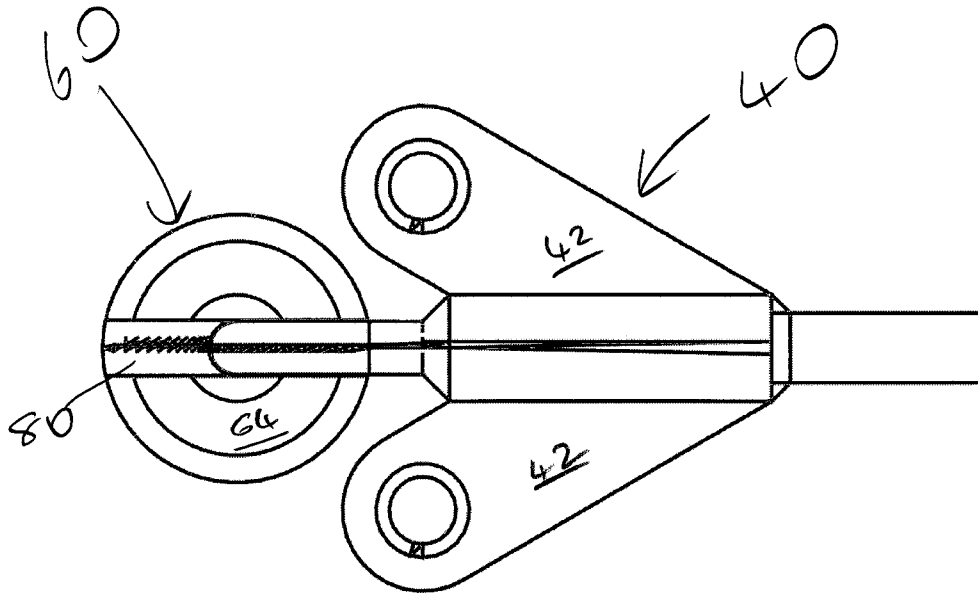


FIG. 8

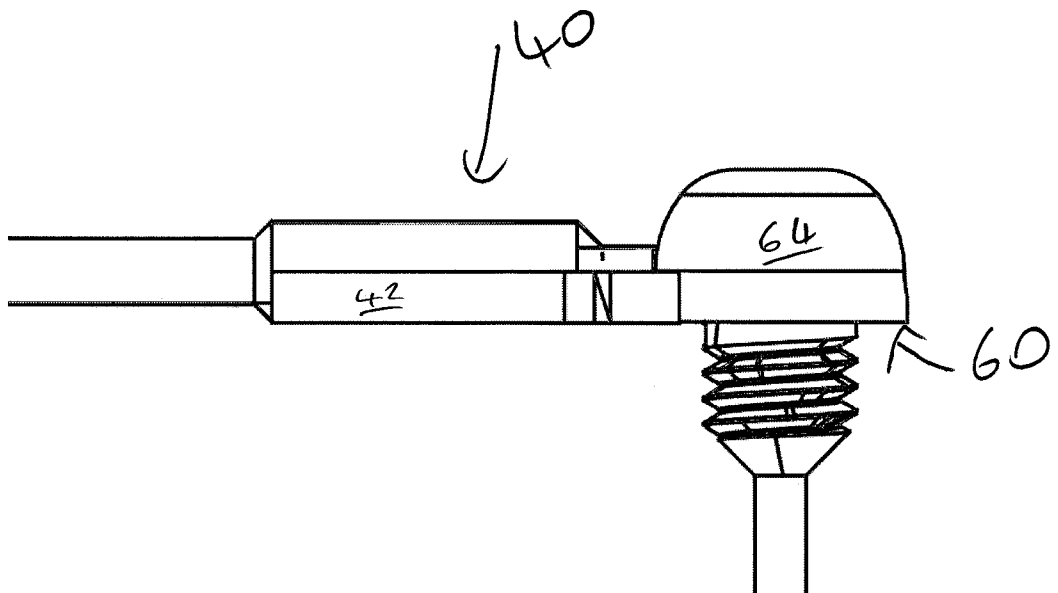


FIG. 9

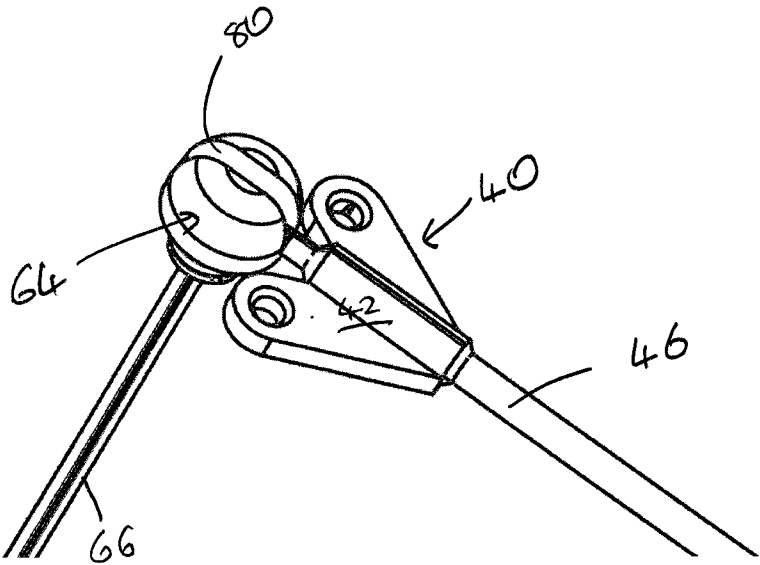


FIG. 10

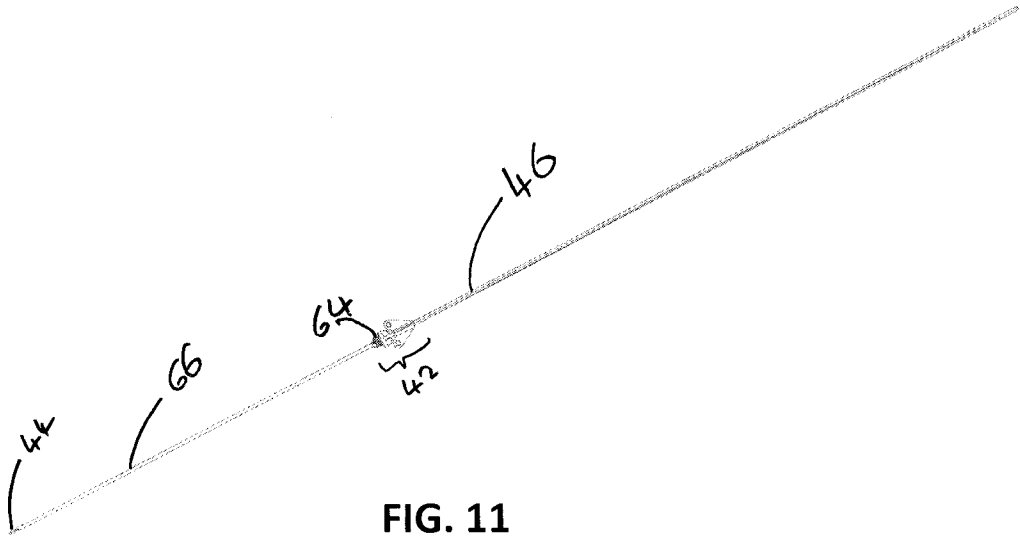


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2013/053972

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 17, 18
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/053972

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M25/02 A61B19/00 A61B17/34 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61M A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 03/077785 A1 (STREATFIELD GILL STEVEN [GB]) 25 September 2003 (2003-09-25) cited in the application abstract; figures 1-3, 10, 11 -----	1-16
Y	US 5 800 390 A (HAYAKAWA TORU [JP] ET AL) 1 September 1998 (1998-09-01) column 5, line 45 - column 6, line 5; figures 1d, 4a, 5 column 8, line 32 - line 43 -----	1-16
A	US 4 944 729 A (BUCKBERG GERALD D [US] ET AL) 31 July 1990 (1990-07-31) column 3, line 33 - column 4, line 2; figures 3-5, 7 ----- -/--	1,12,15, 16
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "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 17 May 2013		Date of mailing of the international search report 27/05/2013
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 Moers, Roelof

INTERNATIONAL SEARCH REPORT

International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 2004/158136 A1 (GOUGH EDWARD J [US] ET AL) 12 August 2004 (2004-08-12) paragraph [0081] - paragraph [0082]; figures 10-12 -----	1,15,16
A	WO 2008/020241 A2 (RENISHAW PLC [GB]; GILL STEPHEN STREATFIELD [GB]; STRATTON MATHEW DAVI) 21 February 2008 (2008-02-21) page 11, line 12 - line 30; figures 4b, 5 -----	1,15,16

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