(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 June 2019 (27.06.2019)

WIPO | PCT

(10) International Publication Number
WO 2019/121987 A1

(51) International Patent Classification:
A61B 17/34 (2006.01) *A61B 17/00* (2006.01)

(21) International Application Number:
PCT/EP2018/085950

(22) International Filing Date:
19 December 2018 (19.12.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
1721596.3 21 December 2017 (21.12.2017) GB

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*

(54) Title: CANNULA

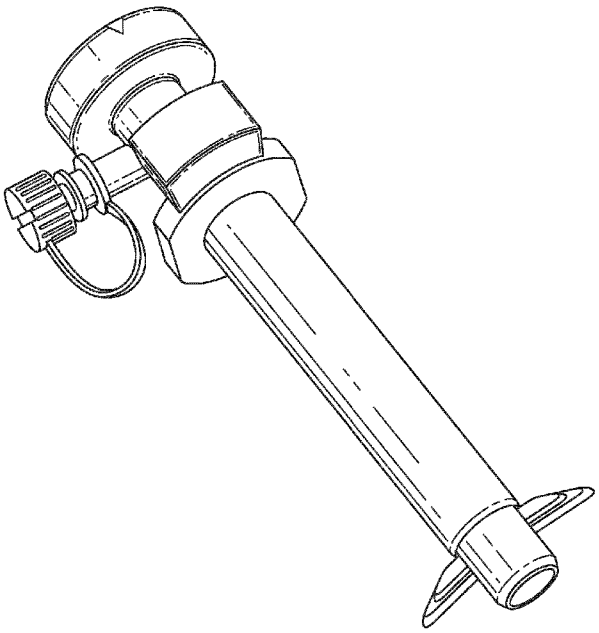


FIG. 1A

(57) Abstract: The present invention provides a cannula including an elongate hollow tubular body, the body having a first end and an opposing second end, and an inflatable chamber at the second end. The inflatable chamber is adapted to be inflatable by fluid so as to be expanded circumferentially about the elongate hollow tubular body at the second end, whereby the expanded inflatable chamber has a surface which is coplanar with the exit of the central elongate passage at the second end of the elongate hollow tubular body. The cannula further comprises a transverse wall which extends outwardly in a transverse direction from the elongate hollow tubular body at the first end, and an inflation port for permitting injection of fluid into the chamber for inflating the chamber. The transverse wall provides an entrance to the central elongate passage, and an exit to the central elongate passage is provided at the second end. Optionally the inflatable chamber of the cannula is divided into two or more sub-chambers. Methods of using such a cannula are also disclosed. The cannula of the invention may be inserted through a minimally invasive portal, and its position may be stably maintained once inserted and inflated.

WO 2019/121987 A1

CANNULA

Field of the Invention

The present invention relates to a cannula, a method of inserting a cannula into human or animal tissue, and a method of inflating a cannula.

Background of the Invention

A cannula is a hollow tube that can be inserted into a vein, an artery, or another body cavity. Cannulas are used widely in medicine in order to gain access to blood vessels to administer drugs or to take blood samples. In endoscopic surgical procedures, cannulas provide a convenient passageway through which cameras, instruments, tissue grafts, fixation materials (e.g. mesh), and sutures/suture anchors may be passed.

In order to insert cannulas into a body space such as a joint space, abdominal cavity (peritoneal cavity), pelvic space and harder structures such as the skull, a portal or channel (opening) is made in the skin, and it is then extended through to the deeper structures to gain access to the body space. Typically, a smooth-tipped rod or a switching stick is first inserted through the portal into the body space. The cannula is then forced or passed over the rod or switching stick. In other methods, cannulas are provided with an inner trocar which most commonly has a smooth tip. The trocar helps to guide the cannula into the body through the portal. Once the cannula is in place, the trocar is removed.

Once inserted into the desired position in the body, it is necessary to secure the cannula in place. Current techniques for securing include physically tying the cannula to the skin with a holding stitch or employing cannulas with a screw thread which can be physically screwed into place. Other existing cannulas such as the Expanula™ (Arthrex, Inc.) have stabilizing flap-like structures which are deployed/opened once the cannulas have been inserted into the body (Figure 1A).

The PassPort Button™ Cannula (Arthrex, Inc.) which is described in US 8, 038, 652 B2, has a deformable inner portion for securing its position in the body. This cannula is essentially in the shape of a dumbbell; it comprises a thick outer portion that has some rigidity and that provides an entry point for surgical instruments, a central tubular portion, and a thin, deformable inner portion (Figure 1B).

During insertion into a body space, typically the inner portion is folded and grasped with a curved hemostat, a metal clip is attached to the inner portion to maintain its folded configuration, and the cannula is passed through the portal. After insertion, the metal clip is removed in order to release the folded inner portion such that is unfolds and sits appropriately against the internal tissue. The removal of the metal clip has the potential to cause tissue damage as well as damage to the cannula itself. Alternatively, the cannula may be advanced into the body over a switching stick, again keeping the inner portion in a folded or condensed state during insertion. At the end of the surgery, the cannula may be pulled out easily as the inner portion is deformable.

The problem with existing cannulas is that the portal must be of a relatively large diameter into order to insert the cannulas. To make the portal, the skin is first incised with a scalpel. Often, the scalpel is passed or "stabbed" all the way through to the deeper tissues and into the body space. In some instances, it is preferable to make an initial "stab" incision in the skin, and then use a blunt-nosed metal instrument such as a hemostat to make a passageway through the soft tissues and into the body space that is being targeted. The portal is then dilated in order to be able to accept the cannula. Dilation can be achieved either by opening the hemostat or by using a clip dilator.

The incision, stabbing and clip dilation is minimised as much as possible. However, usually the resulting wound is quite large in order to get adequate access. The insertion of existing cannulas through the portal may also take as long as ten to fifteen minutes. It is also difficult to pass existing cannulas through a non-linear path (for example, into a hip joint space).

Furthermore, once inserted, existing cannulas, particularly those with a deformable inner portion as described above, are prone to movement in the body space and may even fall out, with the consequent requirement that they be re-inserted during the surgical procedure.

To maintain stability once inserted into a body cavity, other existing cannulas are known to have an inflatable non-latex balloon which extends around a rigid elongate portion of the cannula. The inflatable balloon is positioned away from the tip of the cannula (i.e. the exit point for surgical instruments and other materials that are passed through the cannula) to avoid puncturing of the balloon by surgical instruments that are passed through.

However, cannulas of this type pose problems when performing surgery in small cavities (for example, small joint spaces). When the cannula is inserted into a small joint space, the tip of the cannula does not sit flush with the joint capsule, and may, in some cases, contact the joint

surface. This significantly limits the amount of available working space within the joint cavity, making surgery difficult.

Additionally, with existing cannulas such as those defined above, there is often a space between the outer portion of the cannula (which does not enter the body) and the surface of the skin. This allows unwanted movement of the cannula as instruments are passed in and out of the cannula. For example, a cannula may inadvertently be removed as instruments are passed out of the cannula, or the cannula may move too far into the body space restricting the surgeon's visibility of the body space.

Moreover, since existing cannulas are not "press fit", there is also usually a gap between the main body of the cannula which is embedded in body tissue, and the tissue itself. This allows fluid to escape from the body cavity causing a swelling or dilation of soft tissues. The swelling/dilation can be painful for the patient after surgery and can make the surgery more difficult. This is especially true of shoulder surgery

The present invention aims at least partially to solve these problems. In particular, there is a need in the art for cannulas which can easily be inserted into a body space with minimal invasion, and which, once inserted, are held securely in place.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides a cannula for insertion through a portal into human or animal tissue, the cannula comprising:

an elongate hollow tubular body the body having a first end and an opposing second end,

wherein the elongate hollow tubular body provides a central elongate passage which extends from the first end to the second end,

a transverse wall at the first end,

wherein the transverse wall provides an entrance to the central elongate passage and wherein the transverse wall extends outwardly in a transverse direction from the elongate hollow tubular body;

wherein an exit to the central elongate passage is provided at the second end;

an inflatable chamber which is adapted to be inflatable by fluid so as to be expanded circumferentially about the elongate hollow tubular body, whereby the expanded inflatable chamber has a surface which is coplanar with the exit of the central elongate passage at the second end of the elongate hollow tubular body;

and an inflation port which is in fluid communication with the inflatable chamber for permitting injection of fluid into the inflatable chamber,
optionally wherein the inflatable chamber is divided into two or more sub-chambers.

The cannula of the present invention is suitable for insertion into human or animal tissue, and more particularly, into a joint space or body compartment such as the abdominal or peritoneal cavity.

The elongate hollow tubular body of the cannula may be rigid, semi-rigid or flexible. In preferred embodiments, the elongate hollow tubular body is semi-rigid or flexible which enables it to be easily inserted and navigated through a small portal into human or animal tissue, particularly through a non-linear or curved path.

The inflatable chamber is easily deformable which enables it to be readily inserted in a compacted or condensed state through a small portal into human or animal tissue. Thus advantageously, it is not necessary to make large incisions to insert the cannula of the present invention into the tissue, nor is it necessary to use any metal clips during insertion.

After insertion of the cannula into the body, a fluid such as air or carbon dioxide, or an aqueous liquid such as saline solution, is introduced into the inflation chamber through the inflation port.

In some embodiments, an inflation channel, typically an elongate inflation channel, connects the inflation port to the inflatable chamber, such that when fluid is injected through the inflation port, it passes through the inflation channel and into the inflatable chamber at the second end.

On introduction of fluid through the inflation port, the inflatable chamber at the second end (which, in use, is in the innermost position of the body) expands circumferentially about the elongate hollow tubular body at the second end. Preferably, the inflatable chamber expands outwardly in a transverse direction with respect to the elongate tubular body such that its diameter is increased. In preferred embodiments, the inflatable chamber expands circumferentially or outwardly in a transverse direction such that it is in the form of an annulus extending around the elongate tubular body. In preferred embodiments, the inflatable chamber at the second end also expands longitudinally in an upwards direction (i.e. towards the first end). The inflatable chamber, once expanded, prevents the cannula from moving upwards through the portal, and allows the cannula to be securely positioned in the tissue.

The inflatable chamber in an inflated or expanded state, has a surface which is coplanar with the exit of the central elongate passage at the second end. Thus, in embodiments where the inflatable chamber expands to form an annulus, the surface of the annulus that is most distal to the first end of the cannula is coplanar with the exit to the central elongate passage. In the context of the present invention, the plane of the exit is normal to the longitudinal axis of the cannula. The coplanar arrangement of the surface of the inflatable chamber and the exit to the cannula maximises work space in the body cavity compared to other existing cannulas. This is particularly useful in small joints where it is desirable for a cannula to be flush with the joint capsule.

The extension of the transverse wall in an outwardly direction with respect to the elongate tubular body further prevents the cannula from moving through the portal and becoming "over-inserted".

Thus, the cannula of the present invention provides multiple fixation points for secure and stable positioning in the body, rendering it resistant to unwanted movement during surgery.

In a second aspect, the present invention provides a method of inflating the cannula as defined above, wherein the method comprises administering fluid through the inflation port.

In a third aspect, the present invention provides a method of inserting the cannula as defined above through a portal into human or animal tissue, wherein the method comprises:

a) inserting a rod into the central elongate passage of the cannula,
b) moving the rod through the portal into the human or animal tissue to guide the cannula to a desired position,
c) inflating the inflatable chamber by introducing fluid through the inflation in order to secure the cannula in the desired position, and
d) removing the rod from the central elongate passage of the cannula after inflation.

A trocar or other elongate inserter may be used in place of a rod.

Preferred features of all aspects of the present invention are defined in the dependent claims.

Brief Description of the Figures

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

Figure 1A illustrates a cannula with a deployable inner portion (Arthrex, Inc.)

Figure 1B illustrates a PassPort Button™ Cannula (Arthrex, Inc.)

Figure 2 illustrates a cannula according to the first aspect of the present invention, prior to inflation.

Figure 3 illustrates the second end of the cannula of the invention

Figure 4 is a top view of the cannula of Figure 2.

Figure 5 illustrates the internal structure of the cannula of Figure 2.

Figure 6 illustrates a partially inflated cannula of Figure 2 when it has been inserted through a portal into a body cavity.

Figure 7 illustrates a fully inflated cannula of Figure 2 when it has been inserted through a portal into a body cavity.

Detailed Description of the Invention

The present invention relates to a cannula with an inflatable portion which is suitable for insertion into human or animal tissue, into a large joint space (for example, shoulder, elbow, wrist, knee, ankle, hip, shoulder or tempero-mandibular joint), and more particularly, into a small joint space (for example, the first Metatarso-phalangeal joint (joint of the big toe) or temporomandibular joint), or into a body space (for example, abdominal cavity, peritoneal cavity, intracranial space, or spinal cavity.)

Figure 2 shows a cannula 2 of the present invention. The cannula includes an elongate hollow tubular body 3. By "tubular", it is meant that the body is long in proportion to its diameter. The tubular body 3 may be cylindrical or substantially cylindrical. In other embodiments, the tubular body 3 may have an oval cross-section or a substantially oval cross-section. The elongate hollow tubular body 3 has a longitudinal axis extending from the first end 4 to the second end 5.

The elongate hollow tubular body 3 provides a central elongate passage 9 which extends from the first end to the second end. This passage permits the passing of surgical instruments and

surgical materials such as cameras, tissue grafts, fixation materials and sutures/suture anchors. the passing of surgical instruments and any other materials needed for surgery. The exit to the central elongate passage 9 is at the second end.

The cannula of the present invention comprises an inflatable chamber 8 at the second end. Inflatable chamber 8 is capable of inflation by fluid so as to be expanded circumferentially about the elongate hollow tubular body 3. The circumferential expansion provides an outward expansion in the transverse direction such that the diameter of inflatable chamber 8 increases. In preferred embodiments, on expansion, inflatable chamber 8 is in the form of an annulus which extends all the way around the circumference of the elongate hollow tubular body 3. In some embodiments, inflatable chamber 8 extends only partially around the circumference of the elongate hollow tubular body 3.

With reference to Figure 3, on inflation with fluid, the inflatable chamber 8 has a surface 8a that is coplanar with the exit of central elongate passage 9. In embodiments where inflatable chamber 8 has an annular structure, the major surface of the annulus which is distal to the first end 4 of the cannula is coplanar with the exit of the central elongate passage 9. In the context of the present invention, the plane of the exit of central elongate passage 9 is normal to the long axis of the cannula. By providing the coplanar arrangement of the inflatable chamber 8 and the exit to the central elongate passage 8, in use, work space is maximised. In particular, when the cannula is inserted into a small joint space, the inflatable chamber 8 enables the cannula to be stably maintained flush to the joint capsule.

Preferably, the inflatable chamber 8 is composed of a flexible film. By “flexible film”, it is meant that the film can be deformed or bent without the film breaking, at ambient temperatures such as room temperature or body temperature. This enables the second end of the cannula to be readily deformed and inserted into a portal in human or animal tissue without the need for a large incision or the use of metal clips.

The inflatable chamber 8 may be disposed on the outer surface of the elongate hollow tubular body 3 or it may be integral with the elongate hollow tubular body 3. In some embodiments, the tubular body 3 is formed from an outer tubular wall 6 and an inner tubular wall 7, as illustrated in Figure 2, both of which extend from the first end 4 to the second end 5. In these embodiments, the inner tubular wall 7 defines a central elongate passage 9 extending from the first end 4 to the second end 5. In these embodiments, at second end 5, the outer tubular wall 6 and inner tubular wall 7 may enclose a space therebetween which forms inflatable chamber 8.

The portion of the outer tubular wall 6, and optionally, the portion of the inner tubular wall 7, which in combination define the inflatable chamber 8, are preferably composed of a flexible film as defined above.

In some embodiments, the portion of the outer tubular wall 6, and optionally, the portion of the inner tubular wall 7, which in combination define the inflatable chamber 8, are composed of a flexible film as described above, whilst the remaining portion of the outer tubular wall 6 and inner tubular wall 7 (which do not define the inflatable chamber) are composed of a more rigid material. In these embodiments, the cannula is easily deformable at the second end whilst the elongate tubular portion of the cannula is semi-rigid or rigid and less deformable.

In some embodiments, particularly wherein the inflatable chamber 8 is formed from outer tubular wall 6 and an inner tubular wall 7, the inflatable chamber 8 may extend from the first end 4 to the second end 5 of the cannula. In these embodiments, the elongate hollow tubular body 3 may be easily deformable along its entire length facilitating insertion of the cannula into tissue. Preferably, the inflation chamber 8 expands to have the greatest diameter at the second end to form an annular structure. As the inflatable elongate tubular chamber expands with the introduction of fluid, the cannula becomes rigid and has a “press fit”, enabling the cannula to be held securely and stably within the tissue without moving or falling out. The press fit of the cannula within the body advantageously prevents loss of fluid from the body space and associated swelling of adjacent tissues. The central passage 9 consequently also expands facilitating the passage of surgical instruments.

Referring to Figure 4, a transverse wall 10 provides an entrance to the central elongate passage 9 at the second end and extends outwardly in a transverse direction with respect to the central elongate passage 9. Transverse wall 10 may preferably also be capable of expansion on administration of fluid. During expansion, transverse wall 10 may expand in a transverse direction and/or a longitudinal direction. Expansion in the longitudinal direction ensures that the cannula is securely positioned against the skin surface.

An exit to central elongate passage 9 is provided at the second end 5. The exit may be formed by the outer tubular wall 6 and/or inner tubular wall 7. Alternatively, in embodiments where inflatable chamber 8 is closed by a further wall which is not integral with the outer tubular wall 6 or inner tubular wall 7, the exit may be formed by the further wall.

Referring to Figures 4 and 5, in some embodiments, transverse wall 10 provides an inflation port 11 which is in fluid connection with inflatable chamber 8. In preferred embodiments, an

inflation channel 19 extends from the inflation port 11 to the inflatable chamber 8. Transverse wall 10 may also comprise a valve 12 at the entrance to central elongate passage 9 to allow entry of surgical instruments into the passage and to prevent backflow of fluid from the body cavity. Inflation port 11 may be present at a site other than the transverse wall 10, for example, in the outer tubular wall 6 of the elongate hollow tubular body 3.

Fluid which may be a gas such as air or carbon dioxide, or a liquid, typically an aqueous liquid such as a saline solution, is introduced through the inflation port 11. Fluid is preferably introduced once the cannula has been inserted into a body space or compartment, and is in the desired position. When fluid is introduced through inflation port 11, fluid passes through inflation channel 19 and into inflatable chamber 8 such that it becomes filled with the fluid. The fluid exerts an outward force causing inflatable chamber 8 to expand at the second end. Consequently, the second end of the cannula becomes rigid, and increases in width and/or length.

In some embodiments, as described above, inflatable chamber 8 is an elongate tubular chamber that extends from the first end 4 to the second end 5. In these embodiments, inflation port 11 is directly connected to the inflatable chamber without a further inflation channel. In these embodiments, on inflation, the central passage 9 also expands between the first end 4 and second end 5 facilitating the insertion of surgical instruments through the cannula. The expansion of the cannula along its length and ensuing rigidity imparts a “press fit”, and enables the position of the cannula to be maintained stably within the body space or compartment by making tighter contact with the adjacent tissue. Additionally, the press fit minimises escape of fluid from the body cavity which has been insufflated with such.

Inflatable chamber 8 is preferably composed of a flexible film. In some embodiments, where the inflatable chamber 8 is an elongate chamber extending from the first end 4 to the second end 5, the entire outer tubular wall 6 and optionally inner tubular wall 7 may be composed of a flexible film. The film material of the cannula of the present invention is not particularly limited and may be any material which enables the cannula, particularly, the inflatable chamber 8, to be deformable. When the inflatable chamber 8 is deformed or condensed, it can be inserted into a body space through a portal of relatively small diameter, typically guided by an inserter 16 which may be a rod or switching stick. The film material should also be capable of expanding on inflation without rupturing, and capable of supporting the passage of surgical instruments. Preferred film materials are elastomeric and tissue-compatible, such as silicone or

fluoroelastomer polymers. Other materials include Polyethylene Tetrafluoride, urethane or nylon. In some embodiments, all components of the cannula are formed from the same material, preferably silicone. In some embodiments where inflatable chamber 8 is a non-elongate chamber at the second end 5, the inflatable chamber 8 is composed of a flexible film as defined above, whilst the remaining portion of the cannula is composed of a more rigid material. In some embodiments, the transverse wall 10 and/or the inner tubular wall 7 may be composed of a material that is more rigid than the material of the remaining components of the cannula, such as reinforced silicone, to support the entry and passage of surgical instruments. Since transverse wall 10 remains on the outside of the body and does not enter the portal, it is not necessarily deformable.

In some embodiments, the inflatable chamber 8 may be divided into a series of sub-chambers 8a. In particular, the inflatable chamber 8 may be divided into two or more sub-chambers 8a. For example, if the inflatable chamber 8 is formed by outer tubular wall 6 and inner tubular wall 7, the outer tubular wall 6 may be connected to the inner tubular wall 7 at one or more points, thereby defining one or more sub-chambers 8a within the inflatable chamber 8. This is illustrated in Figure 6. In any embodiment, the sub-chambers 8a may be arranged in chamber 8 a longitudinal and/or transverse fashion. One or more of these sub-chambers 8a are in fluid communication with inflation port 11 and any further inflation ports which may be present on the cannula. In preferred embodiments, each of the sub-chambers 8a is in fluid communication with inflation port 11 and optionally, any further inflation ports which may be present on the cannula. In preferred embodiments, adjacent sub-chambers 8a may be separated from each other by a transverse dividing wall 15. In exemplary embodiments, the transverse dividing wall 15 is composed of the same material as wall of the inflatable chamber, and is thus deformable. In some embodiments the cannula comprises more than one inflation port, and each inflation port is in fluid communication with a different sub-chamber or different group of sub-chambers. The sub-chamber arrangement allows control over the degree of inflation and thus rigidity and size of the cannula. Thus the inflation of some, but not all, the sub-chambers 8a will result in chamber 8 which has a smaller width and length as compared to a cannula in which all the sub-chambers 8a are inflated. The sub-chamber arrangement may further allow the structure of the cannula to be maintained should there be a puncture in one or more of the sub-chambers 8a, particularly when different sub-chambers or different groups of sub-chambers are in communication with different inflation ports. In some embodiments, self-sealing valves 18, which may open and close in response to changes in pressure, are provided

between sub-chambers 8a. In these embodiments, the valves may be open when the cannula is being inflated to allow fluid to pass from one sub-chamber to the next. When the cannula is inflated, the valves may close thus enabling fluid to be retained in each sub-chamber independently of adjacent sub-chambers in the event of a puncture.

Fluid may be introduced through the inflation port 11 provided in transverse wall 10 or another location in the elongate tubular body 3 in different ways. The inflation port 11 may have an opening and closing means to allow or prevent fluid access, respectively, to inflatable chamber 8. In preferred embodiments, inflation port 11 is adapted to be connected to a syringe 17 by means of an adapter or adapting portion. The adapter or adapting portion which enables connection to a syringe is in some embodiments integral to inflation port 11. In other embodiments, the adapter or adapting portion is detachable from the inflation port. The adapter or adapting portion may vary in size according to the syringe that is to be connected. In some embodiments, the adapter or adapting portion is a Luer lock which provides a leak-free seal for syringes. Figure 6 illustrates the introduction of fluid using a syringe.

In other embodiments, fluid may be introduced through inflation port by means of a pumping device or fluid line connected to the port. The adapter or adapting portion may be modified to allow introduction of fluid by a pumping device or fluid line, or any other means for introducing fluid.

As described above, the cannula of the present invention may comprise at least one additional inflation port 11 as defined herein which is in fluid communication with the inflatable chamber 8 or sub-chambers 8a. In preferred embodiments, the cannula comprises two, three, four, or a plurality of additional inflation ports 11. The location of the at least one further inflation port is not particularly restricted. In a preferred embodiment, the at least one additional inflation port is located within the outer tubular wall 6 at the first end of the elongate tubular body 3. The at least one additional inflation port may also be provided within the transverse wall 10. The at least one further additional port may allow the user to introduce fluid into the cannula at a faster rate than would be achieved if only a single inflation port were present. The at least one additional inflation port, particularly if provided within the outer tubular wall 6, may also be useful if further inflation is required during a surgical procedure, and access to the first inflation port 11 is hindered by instruments that are being passed through the cannula.

In some embodiments where multiple inflation ports are present, each inflation port 11 may be in fluid communication with, and therefore may enable the inflation of, a different portion of

the chamber. For example, a first inflation port may be in fluid communication with the inflatable chamber 8 and a second inflation port may be in fluid communication with transverse wall 10. The arrangement of multiple inflation ports provides increased control over inflation and consequent rigidity of individual parts of the cannula.

Referring to Figure 6, at the second end 5, the material of cannula is typically pre-formed to enable inflatable chamber 8 to expand circumferentially around the elongate tubular body or expand outwardly in a transverse direction with respect to the longitudinal axis of the tubular body 3. When the cannula is inserted using an inserter 16 through a portal into a body space or compartment, the pre-formed inflatable chamber is in a deformed or condensed state, and therefore can pass easily through the portal. Referring to Figure 6 and 7, once the cannula is inflated by fluid, the inflatable chamber 8 expands circumferentially or outwardly in the transverse direction at the second end to form expanded portion 13. In these embodiments, chamber 8 at the second end 5 is in the form of an enlarged annulus which has a greater outer transverse dimension than the central portion of the tubular body 3. The width or diameter (measured in the transverse direction) of expanded portion 13 is larger than the width or diameter of the central portion of the elongate tubular body 3. In exemplary embodiments, the central portion of elongate tubular body 3 has a width or diameter of from about 0.2 cm to about 1.5 cm (as measured from one outer surface of outer wall 6 to the outer surface of the opposing outer tubular wall 6) and expanded portion 13 has a width or diameter of from about 1 cm to about 2.5 cm. The expanded portion 13 ensures that the cannula is maintained in position once inserted into the body, and prevents the cannula from passing back out through the portal.

In other embodiments, the inflatable chamber 8 is not pre-formed to expand circumferentially or outwardly as described above. Rather, the chamber 8 expands at the second end as a result of fluid pressure. The material used to manufacture the inflatable chamber 8 at the second end may be different to the the elongate tubular body and selected to facilitate expansion to form expanded portion 13.

In preferred embodiments, the inflatable chamber 8 at the second end 5 does not expand longitudinally to allow maximum space for surgery to take place. In other embodiments, the inflatable chamber 8 at the second 5 expands circumferentially or outwardly as described above, and longitudinally. It is preferred that the longitudinal expansion is towards the first end to enable the expanded portion 13 to be positioned flush against the tissue and minimise

movement of the cannula. Therefore, in some embodiments, the inflatable chamber 8 at second end 5 expands circumferentially about the elongate tubular body or outwardly in a transverse direction, and in a longitudinal direction towards first end 4, with limited or no expansion in the opposing longitudinal direction. The longitudinal expansion may again be achieved by pre-forming the inflatable chamber. Alternatively or additionally, the material of the inflatable chamber may be selected so as to enable expansion in a longitudinal direction towards first end 4 but to resist expansion in the opposing longitudinal direction.

In the cannula of the present invention, transverse wall 10 has a width or diameter in the transverse direction that is greater than the width or diameter in the transverse direction of the elongate tubular body 3. Thus, the transverse wall 10 extends outwardly in a transverse direction with respect to the elongate tubular body 3. In exemplary embodiments, prior to inflation, transverse wall 10 has a width or diameter of from 1.5 cm to 2.5 cm. Paediatric cannulas may have significantly smaller dimensions. The greater width or diameter of transverse wall 10 prevents the transverse wall 10 from passing through a portal and consequent "over-insertion" of the cannula. In an exemplary embodiment, the width or diameter in the transverse direction of transverse wall 10 is at least three times the width or diameter in the transverse direction of elongate tubular body 3.

The transverse wall 10 may be circular or oval in cross-section. In preferred embodiments, the transverse wall 10 is more rigid than the remaining portions of the cannula. A rigid transverse wall 10 is advantageous since it supports the entry of surgical instruments through central passage 9 and further hinders deformation of the wall and consequent "over-insertion" of the cannula into the portal.

As illustrated in Figures 6 and 7, in preferred embodiments, the transverse wall 10 is expandable on inflation by fluid pressure. Introduction of fluid through inflation port 11 causes the transverse wall 10 to expand outwardly in a transverse direction and/or outwardly in a longitudinal direction.

Expansion of the transverse wall 10 in the transverse direction provides further stability to the cannula and facilitates the entry of instruments through central passage 9. By expanding in a longitudinal direction, the transverse wall 10 comes into contact with the surface of the skin enabling it to be held more securely in the desired position and preventing "over-insertion" of the cannula into the body. The degree of inflation and therefore, the degree of transverse and/or longitudinal expansion can be controlled to suit the size of the body space.

Transverse wall 10 may expand in the transverse direction to a width or diameter that is up to 50%, 100%, 150% or 200% greater than the width of the central portion of the elongate tube. In exemplary embodiments, transverse wall 10 may expand in the transverse direction to have a width or diameter of from about 2 cm to about 5 cm. Transverse wall 10 may expand in the longitudinal direction to have a longitudinal length of from about 0.5 cm to 3cm. The dimensions are not particularly limited and may vary according to the patient. Thus, paediatric cannulas will naturally have smaller dimensions than adult cannulas.

Referring further to Figure 6 the central elongate passage 9 is a continuous passage allowing the passage of instruments, surgical materials, and/or fluids from the outside into the body. In some embodiments, the central elongate passage 9 contains a one-way valve 12. This may be positioned at any point in the passage but in preferred embodiments it is positioned at the entrance to the passage. The valve 12 may be integral with the transverse wall 10, or it may be integral with the inner tubular wall 7 defining central elongate passage 9. In colorectal surgery and abdominal surgery, air is often introduced through a cannula into a body space or compartment to improve visibility. In orthopaedic surgery, fluid such as saline solution is often introduced through a cannula into flush out joint spaces. A one-way valve is particularly useful in these circumstances to prevent the back flow of air or liquid through the cannula. In some embodiments, particularly where the cannula is used for the passage of surgical instruments, the central passage 9 is devoid of any valves, with the exception of a valve 12 that may be present at its entrance, as described above.

In some embodiments, the outer surface of the elongate tubular body 3 is smooth. A smooth outer surface facilitates insertion of the cannula into the body tissue. In other embodiments of the invention, the outer surface of the elongate tubular body 3, or at least a portion thereof, is non-uniform or profiled. The non-uniformity or profiling increases the resistance of the cannula to moving or slipping in the body once inserted. Non-uniformity or profiling may be achieved in different ways. For example, the outer surface may be embossed with a pattern, or alternatively, the outer surface may be ribbed. Preferably the outer surface comprises a plurality of ribs 14. The ribs 14 may be mutually spaced between the first end 4 and second end 5. The cross-section of the ribs is not particularly limited. In preferred embodiments, the ribs have a substantially semi-circular cross-section. The ribs may be arranged circumferentially around the outer surface, or only partially around the outer surface. In alternative embodiments, the ribs may be arranged in a helical fashion around the tubular body 3, similar to a screw thread. The height of the ribs above the outer surface may range from 0.5 mm to 3 mm depending on

the size of the cannula. In exemplary embodiments, the ribs themselves are inflatable and therefore become visible only on inflation. This ensures that the cannula can be inserted with minimal resistance.

Whilst exemplary sizes of the cannula of the present invention have been provided herein, neither the width or diameter, nor length of the cannula, is particularly limited. Advantageously, the dimensions of the cannula may be adjusted according to the degree of inflation. The degree of inflation, and consequently the width or diameter and length of the cannula, can be selected to suit the clinical or surgical application for which the cannula is used. Smaller cannulas are useful for surgery involving the small bones in the face, jaw and ear or for foetal or paediatric surgery. Larger cannulas are useful for abdominal surgeries, for surgeries involving large joints or for surgery involving large animals. The length of the cannula in the longitudinal direction may vary from about 0.2 cm to about 15 cm. For example, in the inflated state, the length of the cannula in the longitudinal direction is desirably from about 0.2 cm to about 3 cm for a paediatric cannula for use in the knee joint, or from about 2 cm to about 5 cm for an adult cannula for use in the knee joint. The width or diameter of the central portion of elongate tubular body 3 in the transverse direction may vary from about 0.2 cm to about 1.5 cm. For example, in the inflated state, the width or diameter of the central portion of elongate tubular body 3 in the transverse direction is desirably from about 0.2 cm to about 0.5 cm for a paediatric cannula for use in the knee joint, or from about 2 cm to about 4 cm for an adult cannula for use in the knee joint.

Method of Use

Referring to Figure 2, insertion of the cannula through a portal into a body space or compartment is achieved using an inserter 16 which is preferably in the form of a rod or trocar. The rod or trocar may be metal or plastic and is preferably smooth-tipped. The inserter 16 is inserted into the central elongate passage 9 of the cannula and the cannula is then guided through the portal and into the desired position. Preferably, the inserter 16 is flexible to allow efficient navigation through tissues and particularly, through curved passageways.

A syringe 17 is connected to inflation port 11 and a fluid which may be a gas such as air or carbon dioxide, or a liquid, typically an aqueous liquid such as a saline solution, is injected through the port. As fluid enters the cannula, the inflatable chamber 8 at the second end of the cannula expands circumferentially around the elongate tubular body 3, or outwardly in a transverse direction, to form expanded portion 13: this is seen in Figures 6 and 7. Expanded

portion 13 rests within the body compartment or tissue into which the cannula has been inserted, and prevents movement of the cannula up through the portal. For increased stability, inflatable chamber 8 preferably also expands longitudinally towards the first end 4 to allow expanded portion 13 to be flush against the tissue. Furthermore, the transverse wall 10 expands in both in a transverse and longitudinal direction, as illustrated in Figure 7. This enables the cannula to be positioned securely against the surface of the skin. Thus, in preferred embodiments, the cannula of the present invention provides multiple points of fixation for secure positioning. If additional inflation ports are present then fluid may also be introduced through these ports. The amount of fluid introduced into the cannula is selected to achieve the desired width and/or length.

Surgical instruments and/or fluid may be introduced into the body space through central elongate passage 9. A one-way valve may be provided in central elongate passage 9 to prevent the back-flow of fluid.

Once inflated, the inserter 16 is removed from the central elongate passage 9 of the cannula, allowing access for surgical instruments or other surgical materials. Inflation port 11 is closed to prevent loss of fluid. After surgery is complete, the cannula may be deflated by withdrawing the previously introduced fluid. A syringe or suction device may be used to withdraw the fluid. Once deflated, the cannula may be pulled out of the portal.

Method of manufacture

The cannula of the present invention may be made according to standard methods of moulding, including injection moulding.

Claims

1. A cannula for insertion through a portal into human or animal tissue, the cannula comprising:

an elongate hollow tubular body the body having a first end and an opposing second end,

wherein the elongate hollow tubular body provides a central elongate passage which extends from the first end to the second end,

a transverse wall at the first end, wherein the transverse wall provides an entrance to the central elongate passage and wherein the transverse wall extends outwardly in a transverse direction from the outer tubular wall;

wherein an exit to the central elongate passage is provided at the second end;

an inflatable chamber which is adapted to be inflatable by fluid so as to be expanded circumferentially about the elongate hollow tubular body at the second end,

whereby the expanded inflatable chamber has a surface which is coplanar with the exit of the central elongate passage at the second end of the elongate hollow tubular body;

and an inflation port which is in fluid communication with the inflatable chamber for permitting injection of fluid into the inflatable chamber,

optionally wherein the inflatable chamber is divided into two or more sub-chambers.

2. The cannula of claim 1, wherein the elongate hollow tubular body comprises an outer tubular wall and an inner tubular wall, the inner tubular wall surrounding the central elongate passage extending from the first end to the second end; and
wherein the outer tubular wall and inner tubular wall define the inflatable chamber.

3. The cannula of claim 1 or claim 2, wherein the cannula comprises an inflation channel extending from the inflation port to the inflatable chamber for delivering fluid from the inflation port to the inflatable chamber.

4. The cannula of any of claims 1 to 3, wherein the inflatable chamber extends between the first end and second end of the elongate hollow tubular body.

5. The cannula of any of claims 1 to 3, wherein the elongate hollow tubular body has an outer surface, and the outer surface is profiled.

6. The cannula of claim 5, wherein the outer surface is ribbed.

7. The cannula of claim 6, wherein the outer surface comprises a plurality of ribs.

8. The cannula of claim 7, wherein the plurality of ribs are mutually spaced between the first and second ends.

9. The cannula of any of claims 6 to 8, wherein the ribs have a substantially semi-circular cross-section.

10. The cannula of any of claims 6 to 9, wherein the ribs are arranged circumferentially around the outer surface.

11. The cannula of any of claims 1 to 4, wherein the elongate hollow tubular body has an outer surface has an outer surface, and the outer surface is smooth.

12. The cannula of any preceding claim, wherein the inflation port is provided in the transverse wall.

13. The cannula of any preceding claim, wherein the inflation port is adapted to connect to a syringe.

14. The cannula of any preceding claim, wherein a one-way valve is provided within the central elongate passage to prevent flow of fluid through the central elongate passage in a direction from the second end to the first end.

15. The cannula of any preceding claim, wherein the transverse wall comprises a one-way valve at the entrance to the central elongate passage.

16. The cannula of any one of claims 1 to 13, wherein the central elongate passage is a valveless continuous passage.

17. The cannula of any preceding claim, wherein the transverse wall at the first end is expandable.

18. The cannula of claim 17, wherein the transverse wall is expandable by fluid pressure so as to be expanded outwardly in a transverse direction and/or so as to be expanded outwardly in a longitudinal direction.

19. The cannula of any preceding claim, wherein diameter of the transverse wall at the first end is larger than the external diameter of the elongate tubular body.

20. The cannula of any preceding claim, wherein the diameter of the elongate tubular body, in the transverse direction, is from about 0.2cm to about 1.5cm.

21. The cannula of claim 20, wherein the elongate hollow tubular body is substantially cylindrical, and the diameter of the elongate hollow tubular body is the same as the width in the transverse direction.

22. The cannula of any preceding claim, wherein the length of the cannula, in the longitudinal direction, is from about 0.5cm to about 15cm.

23. The cannula of any preceding claim, comprising at least one further inflation port located within the outer tubular wall and/or within the transverse wall.

24. The cannula of claim 23, wherein the at least one further port is adapted to connect to a syringe.

25. The cannula of any preceding claim, wherein at the second end, the outer tubular wall is preformed to expand outwardly in a transverse direction on inflation.

26. The cannula of any preceding claim, wherein at the second end, the outer tubular wall is preformed to expand longitudinally towards the first end.

27. The cannula of any preceding claim, wherein the inflatable chamber is expandable by fluid to form an enlarged annulus at the second end which has a greater diameter than the external diameter of the elongate tubular body.

28. The cannula of any preceding claim, wherein the cannula is adapted for insertion into one or more human or animal tissues selected from: the tempero-mandibular joint, abdominal cavity, peritoneal cavity, spinal cavity and intracranial space.

29. A cannula of any preceding claim, wherein the inflatable chamber being divided into two or more sub-chambers allows the degree of inflation to be controlled and/or the structure of the expanded inflatable chamber to be maintained should there be a puncture in a sub-chamber.

30. A cannula of any preceding claim, which comprises at least one further inflation port located within the outer tubular wall and/or within the transverse wall, and wherein one or more of the two or more sub-chambers are in fluid communication with the at least one further inflation port, such that different sub-chambers of the inflatable chamber are in fluid communication with different inflation ports.

31. A cannula of any preceding claim, wherein self-sealing valves are provided between sub-chambers.

32. A method of inflating the cannula of any preceding claim, wherein the method comprises introducing fluid through the inflation port.

33. The method of claim 32, wherein the fluid is introduced using a syringe.

34. The method of claim 32 or claim 33, wherein the fluid is air, carbon dioxide or an aqueous liquid.

35. A method of inserting the cannula of any of claims 1 to 31 through a portal into human or animal tissue, wherein the method comprises:

a) inserting a rod into the central elongate passage of the cannula,

b) moving the rod through the portal into the human or animal tissue to guide the cannula to a desired position,

c) inflating the inflatable chamber at the second end by introducing fluid through the inflation port in order to secure the cannula in the desired position, and

d) removing the rod from the central elongate passage of the cannula after inflation.

36. The method of claim 35, wherein the fluid is introduced using a syringe.

37. The method of claim 35 or 36, wherein the fluid is air, carbon dioxide or an aqueous liquid.

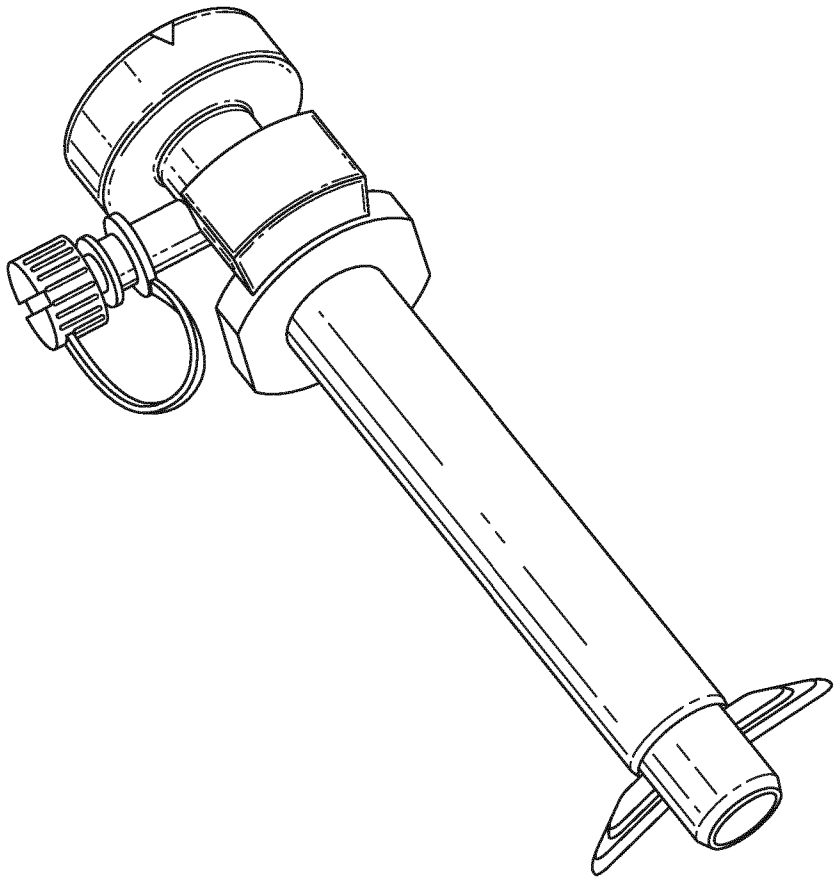


FIG. 1A

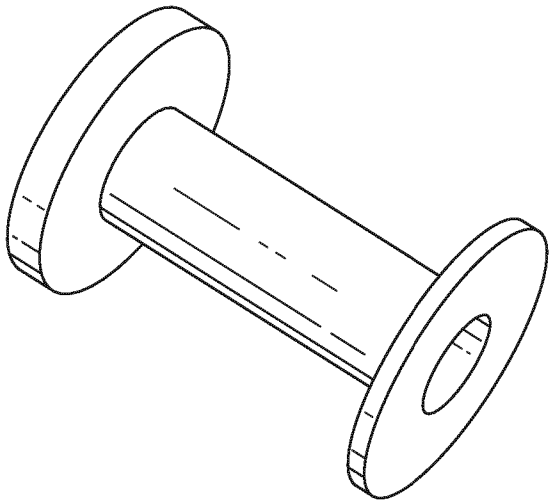


FIG. 1B

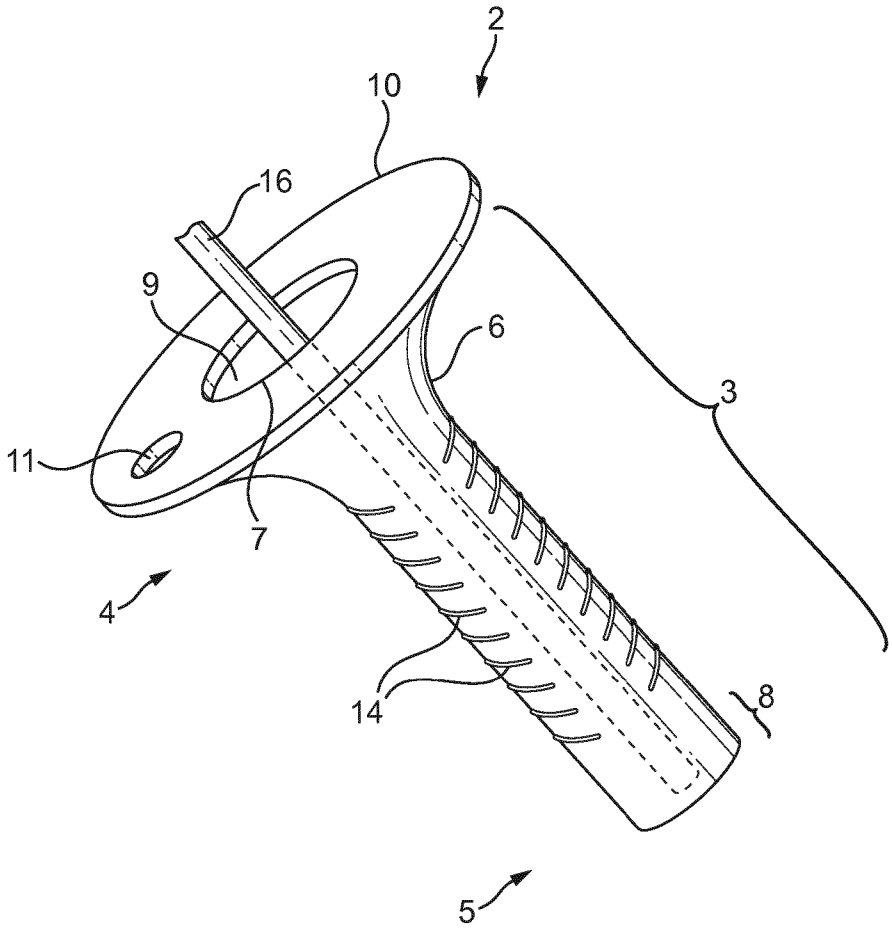


FIG. 2

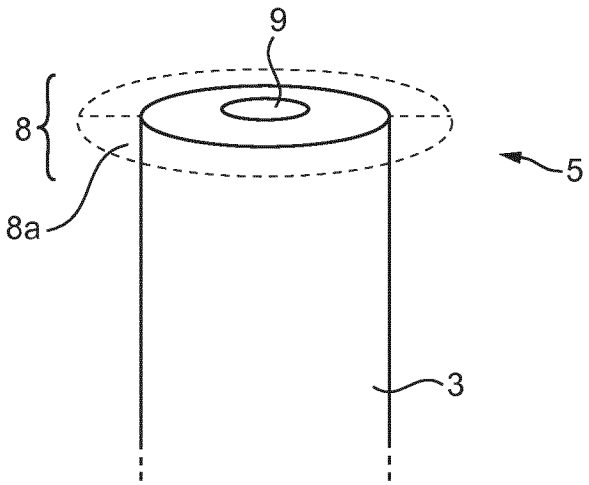


FIG. 3

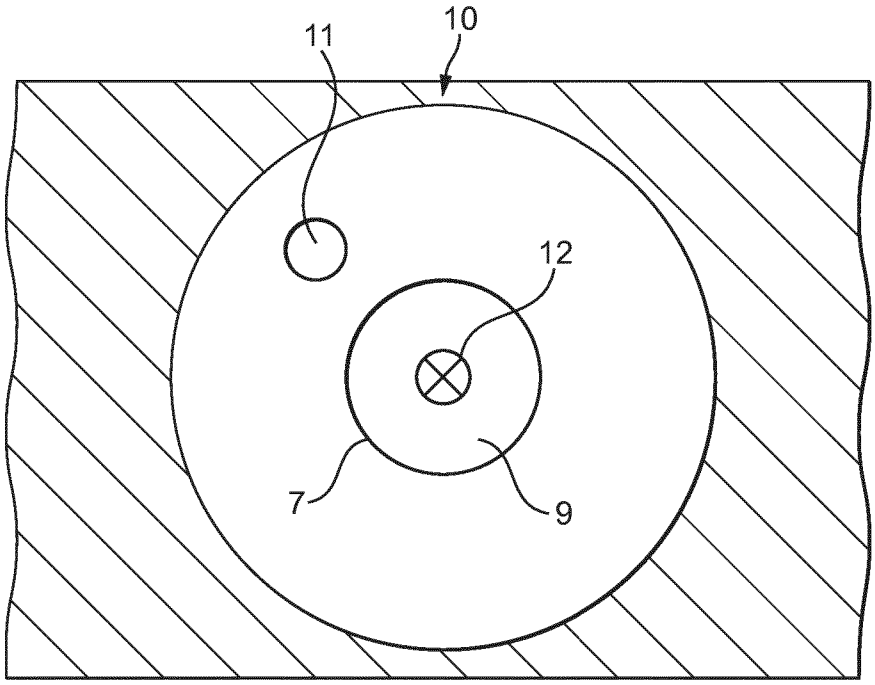


FIG. 4

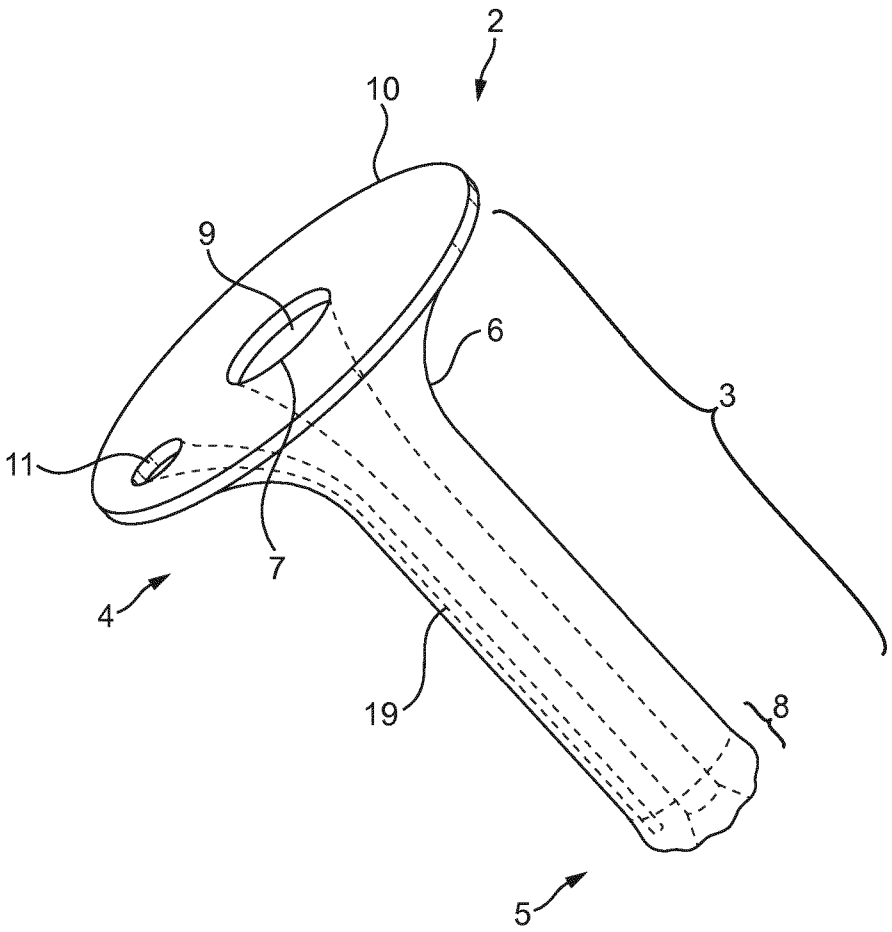


FIG. 5

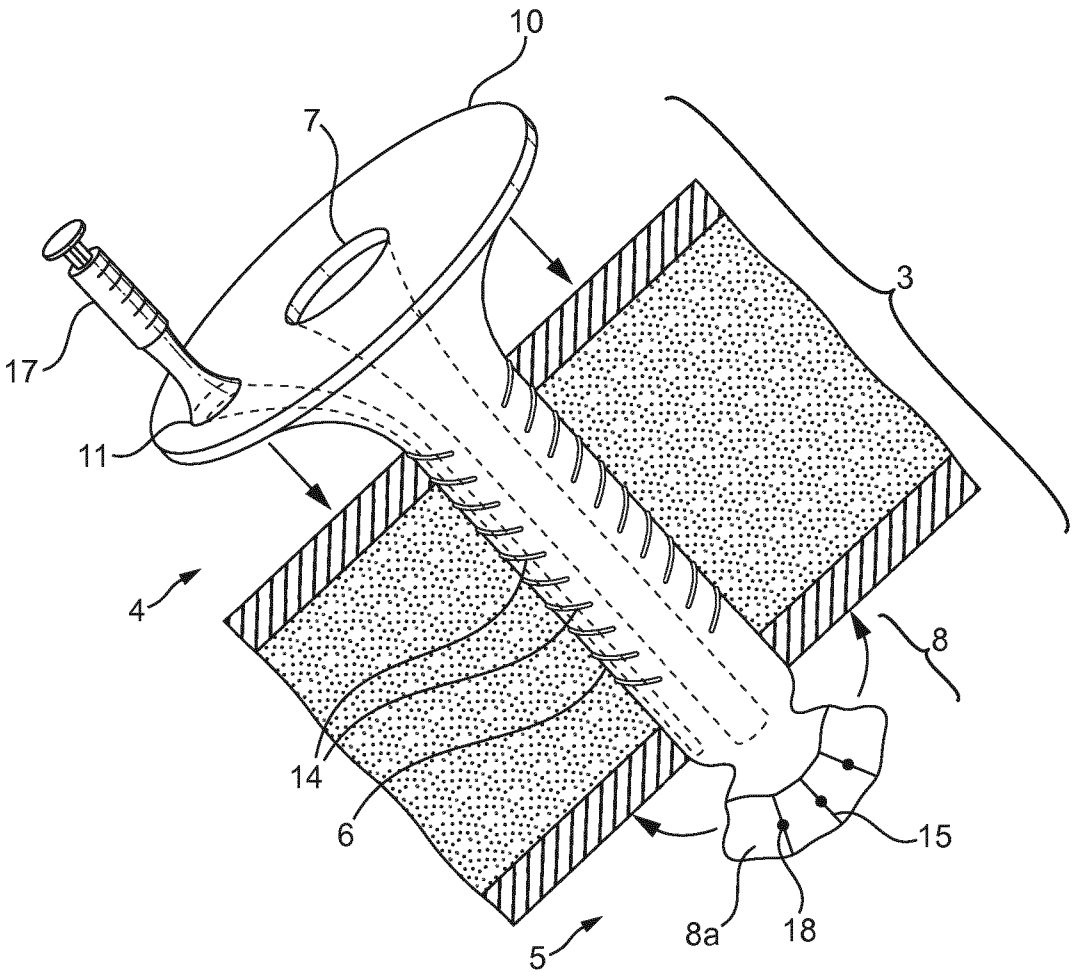


FIG. 6

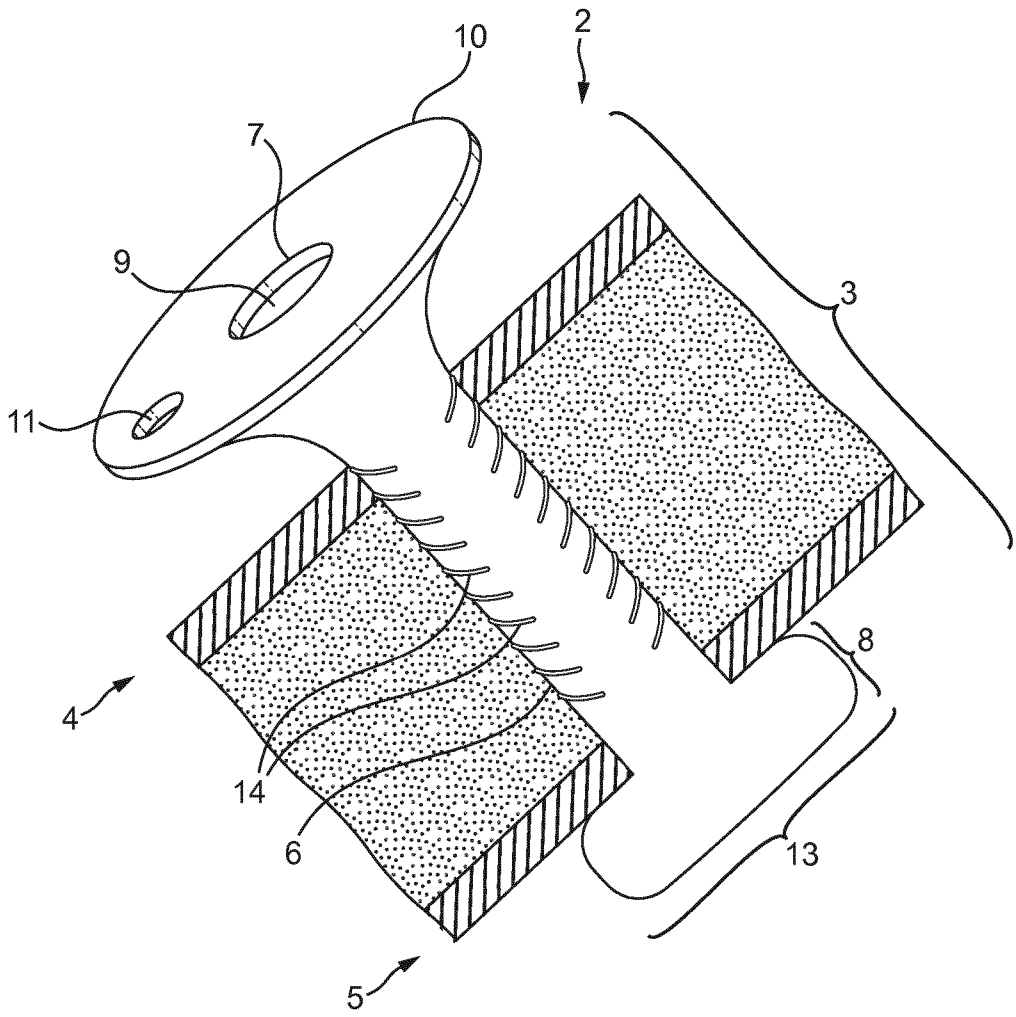


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/085950

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/34 A61B17/00
ADD.

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 2 499 979 A2 (TYCO HEALTHCARE [US]) 19 September 2012 (2012-09-19) paragraphs [0004], [0021]; figures 1-3 -----	1-28 29-31
Y	EP 2 457 526 A2 (TYCO HEALTHCARE [US]) 30 May 2012 (2012-05-30) paragraphs [0029], [0033]; figures 1,5 -----	29-31
A	WO 2007/109700 A2 (APPLIED MED RESOURCES [US]; HART CHARLES C [US]; AU GIGI [US]; PRAVONG) 27 September 2007 (2007-09-27) page 13, line 21 - page 16, line 2; figures 21-26 -----	1-31

☐ 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	Date of mailing of the international search report
28 February 2019	13/03/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Lee, Ronan

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2018/085950

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. [X] Claims Nos.: 32-37
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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

Information on patent family members

International application No
PCT/EP2018/085950

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 2499979 A2	19-09-2012	AU 2012201524 A1	04-10-2012
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		EP 2891463 A1	08-07-2015
		US 2007225650 A1	27-09-2007
		WO 2007109700 A2	27-09-2007

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 32-37

The subject-matter of claims 31-37 appears to constitute a surgical procedure on the human body, and therefore under Rule 39.1(iv) PCT (Method for treatment of the human or animal body by surgery), these claims have not been searched. For the same reason, the claims do not require preliminary examination, Rule 67.1 (iv) PCT.