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(54) Title: MEDICAL TUBING ASSEMBLY TO FACILITATE TUBE FIXATION

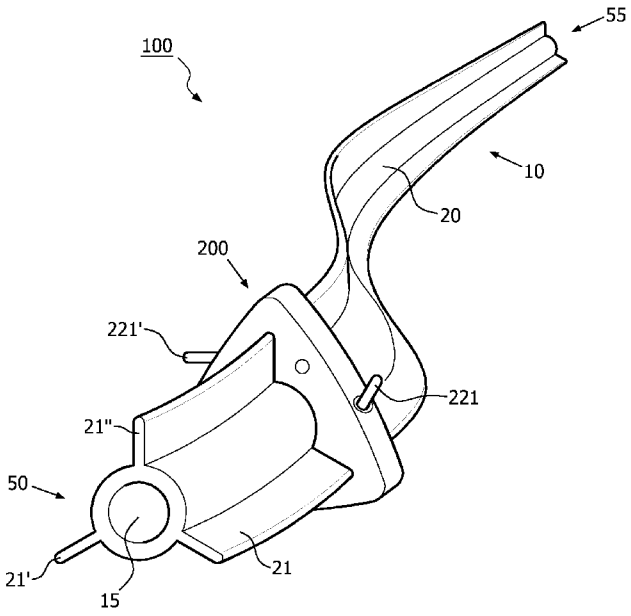

FIG. 1

(57) Abstract: The invention concerns a medical tubing assembly (100) comprising: finned medical tubing (10) formed from an elongate tubular member (20) disposed with one or more longitudinal fins (21, 21', 21"), a collar (200), slidably mountable on the finned tubing (10), equipped with a locking means and optionally one or more suture eyelets (250, 250'), said locking means configured to provide a locking force against one or more of the longitudinal fins (21, 21', 21"). The invention allows securing of a medical tubing in situ that prevents slippage or damage to the tubing wall.

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MEDICAL TUBING ASSEMBLY TO FACILITATE TUBE FIXATION

FIELD OF THE INVENTION

The invention concerns a medical tubing assembly that facilitates the secure fixation of tubing such as a brachytherapy catheter, or other type of access catheter such as for light based therapy, or drainage tube to the tissue of a subject which fixation prevents undesirable movement by the tubing.

BACKGROUND OF THE INVENTION

Medical tubing such as a catheter is employed in the art to deliver treatment to the tissue of a subject from outside the body. Medical tubing often needs to be in held in place for a long period of time *e.g.* days to weeks. For example, a drainage tube is commonly employed after an operation to remove a tumour, which tube prevents fluid build up from the section site. The implanted tube exits the body and is secured at the exit point by a stitch that wraps around the tubing and which hooks the adjoining skin. Another example of a medical tube is a catheter tube implanted in a subject that provides passage for a brachytherapy source wire (*i.e.* for example an elongated wire disposed with a radioactive tip for high dose rate or pulsed dose rate brachytherapy). The catheter needs to be held accurately in place for up to a number of weeks, so that the radiologist can provide through the tubing, brachytherapy sessions across several intervals, and to the same site of treatment. In an alternative configuration, the radiation oncologist may load the catheter tube after positioning at the described location with radioactive wires or seeds (Palladium 103, Iodine 125) both of which will remain in place for several days or weeks. Another example of a medical tube is a catheter tube implanted in a subject that provides passage for a wave guide allowing to treat an organ interstitially with light and photosensitizing agents (photodynamic therapy) or with laser light (interstitial hyperthermia with infrared light). The surgeon will typically suture the proximal end of the medical tubing as it exits the body to the surrounding skin, using a stitch that is wrapped one or more times around the tubing which hooks the adjoining skin.

Because the tubing is typically made from or coated with a friction resistive material to enable passage through the body, the stitch does not adequately grip the tubing. Since the tubing cannot be punctured by the needle, the stitch may only wrap around the exterior wall, which attachment loosens with time. As a consequence movements by the tubing in the longitudinal direction are common during wearing by the subject *i.e.* the tubing moves further out from or further into the body. Critically, for brachytherapy or light

based applications, the position of the tubing can change over time; as a result, the precise location for delivery of brachytherapy or light can no longer be ascertained with confidence.

The prior art, therefore, demands a way to securely prohibit the medical tubing from moving in and out of the body and possibly attach medical tubing to body tissue using a suture, which allows the physician to place the stitch at one or more points along the tubing without damaging the integrity of the tubing lumen.

SUMMARY OF THE INVENTION

One embodiment of the invention is a medical tubing assembly (100) comprising:

- finned medical tubing (10) formed from an elongate tubular member (20) disposed with one or more longitudinal fins (21, 21', 21"),
- a collar (200), slidably mountable on the finned tubing (10), equipped with a locking means and one or more suture eyelets (250, 250'), which one or more suture eyelets (250, 250') may be optionally provided,
- said locking means configured to provide a locking force against one or more of the longitudinal fins (21, 21', 21").

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein the locking means comprises one or more pins (221, 221', 221"), configured to frictionally engage or penetrate the surface of a fin (21, 21', 21").

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein the locking means comprises one or more screws, configured to frictionally engage or penetrate the surface of a fin (21, 21', 21").

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein the locking means comprises a clamp mechanism, configured to engage frictionally a surface of a fin (21, 21', 21") with at least part of an aperture (210) in the collar (200) adapted to receive slidably the finned medical tubing (10).

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein the number of fins (21, 21', 21") is one, two, three or four.

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein number of pins (221, 221', 221") or screws is equal to the number of fins, each pin (221, 221', 221") or screw configured to frictionally engage or penetrate the surface of a single fin (21, 21', 21").

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein at least one fin (21, 21', 21") projects radially from the outside surface of the elongate tubular member (20).

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein at least one pin (221, 221', 221") or screw comprises:
a pointed end (226) configured to frictionally engage or penetrate the surface of a fin (21, 21', 21"), and
head end (224) configured to receive in the case of a pin a pushing force, or in the case of a screw a rotational force, which force advances the pointed end towards a fin (21, 21', 21") to frictionally engage or penetrate its surface .

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein at least one fin (21, 21', 21") projects radially from the outside surface of the tubing increasing the maximum width of the tubing by no more than 50%.

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein the locking means is disengagable.

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein at least one longitudinal fin (21, 21', 21") extends continuously along the entire length of the elongate tubular member (20).

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein at least one fin is at least partly castellated.

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein the castellation comprises a tandem arrangement of alternating tabs (60, 60', 60", 60"') and notches (65, 65', 65", 65'"), and the tabs are adapted to facilitate entry of the tubing (10) into the subject and/or hinder withdrawal of the tubing (10) from the subject.

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein the longitudinal fins (21, 21', 21") have a continuous straight path along the length of the elongate tubular member (20).

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein the longitudinal fins (21, 21', 21") have a continuous spiral path along the length of the elongate tubular member (20).

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein the collar (20) comprises a coupling means (251).

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein said coupling means (251) is adapted to couple to an afterloader.

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein said coupling means (251) is adapted to couple to a laser emitting device.

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein said coupling means (251) comprises a Luer fitting.

Another embodiment of the invention is a medical tubing assembly (100) as described above, wherein said coupling means (251) comprises a male or female screw fitting.

Another embodiment of the invention is a catheter (300) incorporating an assembly (100) as defined above.

FIGURE LEGENDS

FIG. 1: Three dimensional view of the tubing assembly according to the invention.

FIG. 2: Transverse cross-section through the finned tubing of the invention, with dimensions indicated.

FIG. 3: Transverse cross-section through a collar of the invention.

FIG. 4: Transverse cross-section through a pin of the invention.

FIG. 5: Transverse cross-section through a pin of the invention disposed with a head formed from a cylindrical member.

FIG. 6: Transverse cross-section through the assembly of the invention, showing a set of locking pins in an unengaged position.

FIG. 7: Transverse cross-section through the assembly of the invention, showing a set of locking pins in an engaged position.

FIG. 8: Transverse cross-section through the assembly of the invention, showing a set of locking pins in an non-engaged position.

FIG. 9: Transverse cross-section through the assembly of the invention, showing a set of locking pins in an engaged position.

FIG 10: Longitudinal cross-section through the assembly of the invention, showing a locking pin of the invention disposed with a protrusion, in a non-engaged position.

FIG. 11: Plan view of a split collar of the invention.

FIG. 12: Plan view of a split collar of the invention in an open (unclamped) position, disposed with finned medical tubing in the aperture.

FIG. 13: Plan view of a split collar of the invention in a closed (clamped), disposed with finned medical tubing in the aperture.

FIG. 14: Transverse cross-section through part of the assembly of the invention, showing a locking clip in a pre-engaged position.

FIG. 15: Transverse cross-section through part of the assembly of the invention, showing a locking clip in an engaged position.

FIG. 16: Three dimensional view of a collar of the invention, provided with a coupling means.

FIG. 17: Three dimensional view of a collar of the invention, provided with a coupling means disposed with locating slots.

FIG. 18: Three dimensional view of a collar of the invention, provided with a coupling means disposed with a screw thread.

FIG. 15: Three dimensional view of a collar of the invention, provided with a coupling comprising a Luer fitting.

FIGs. 20A to 22: Three dimensional views of a pigtail catheter disposed with finned tubing of the invention, where the distal end is in a curled (FIGs. 20A & B), intermediate (FIG. 21) or straight (FIG. 22) configuration concurrent with the advancement of a stiffening stylet.

FIG. 23: Three dimensional view of a section of finned tubing, provided with rectangular castellations on one fin.

FIG. 24: Three dimensional view of a section of finned tubing, provided with sloping castellations on one fin.

FIG. 25: Three dimensional view of a section of finned tubing, provided with rounded castellations on one fin.

FIG. 26: View of a fin, with dimensions indicated.

DETAILED DESCRIPTION OF THE INVENTION

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as is commonly understood by one of skill in the art. All publications referenced herein are incorporated by reference thereto. The articles "a" and "an" are used herein to refer to one or to more than one, *i.e.* to at least one of the grammatical object of the article. By way of example, "an eyelet" means one eyelet or more than one eyelet. The recitation of numerical ranges by endpoints includes all integer numbers and, where appropriate, fractions subsumed within that range (*e.g.* 1 to 5 can include 1, 2, 3, 4 when referring to, for example, a number of articles, and can also include 1.5, 2, 2.75 and 3.80, when referring to, for example, measurements). The recitation of end points also includes the end point values themselves (*e.g.* from 1.0 to 5.0 includes both 1.0 and 5.0).

With reference to **FIG. 1**, present invention concerns a medical tubing assembly **100** comprising:

- finned medical tubing **10** formed from an elongate tubular member **20** disposed with one or more longitudinal fins **21**, **21'**, **21"**,
- a collar **200**, slidably mountable on the finned tubing **10**, equipped with a locking means and optionally one or more suture eyelets **250**, **250'**,
- said locking means configured to provide a locking force against the one or more longitudinal fins **21**, **21'**, **21"**.

The slidable collar may be mounted on and placed at any position along the length of the finned tubing **10**, and subsequently be locked in place by the surgeon. The locking means applies a force against a fin **21**, **21'**, **21"**, rather than against the tubing wall **20**, as a consequence the tubing lumen **15** does not suffer from distortion or collapse which might otherwise affect the passage of fluid or of brachytherapy tubes or waveguides for light therapy. The assembly **100** does not require any special equipment to operate; it is self-contained, and requires only activation of the locking meaning, which is generally a push pin or a screw. The collar **200** provides also one or more suture eyelets **250**, **250'** through which medical twine can be threaded and secured to the tissue of the subject such as to the exterior skin, or to interior tissue, using a stitch. The finned tubing **10** may be disposed with one collar, either for suturing the tubing externally or internally. Alternatively, the finned tubing may be disposed with more than one collar for suturing the tube at two or more positions internally, or at one position externally and at one or more positions

internally. The collar **200** secures the finned tube **10** preventing its movement further into the entry puncture or incision. The collar **200** and stitch secure the finned tube **10** to prevent its movement further out from the puncture or incision. This can be critical when the medical tubing has been accurately placed, for example, in brachytherapy or for interstitial light based therapy, and needs to remain *in situ* for a number of days or weeks between treatments and without movement. Because the collar is adjustable, the assembly is suitable for any level of penetration by the tubing.

The finned medical tubing **10** is formed from an elongate tubular member **20** disposed with one or more longitudinal fins **21**, **21'**, **21"**. It is disposed with a lumen **15** that extends from the proximal **50** to the distal **55** end. The finned medical tubing **10** is flexible and suitable for introduction into the subject. It is usually formed from a single, continuous length of tubing. However, it may be attached at the distal **55** and/or proximal **50** ends to other tubing of the same or different material joined end to end by heating, crimping or friction. Typically, the finned tubing **10** is formed from polyurethane, polyurethane compounds, polyimide, or other biocompatible flexible polymeric material. The tubing **10** may be coated at least on the exterior surface with an anti-microbial agent such as silver or its derivatives, chlorhexidine derivatives, heparin derivatives or any suitable anti-microbial agent that reduces the risk of infection through the point of exit from the skin.

The terms "distal" and "proximal" are used through the specification, and are terms generally understood in the field to mean towards (proximal) or away (distal) from the physician side of the apparatus. Thus, "proximal" means towards the physician side and, therefore, away from the patient side. Conversely, "distal" means towards the patient side and, therefore, away from the physician side.

With reference to **FIG. 2**, the total width, **TW**, or total diametric width, **TDW**, of the finned tubing is sufficiently narrow to exit through the appropriate opening with a minimum incision or skin puncture. The finned tubing is flexible. It may be flexible enough not to damage when kinked. The design of the finned tubing advantageously facilitates insertion, withdrawal and wearing, while being minimally intrusive. In wearing, the proximal end of the medical tubing protrudes from the skin, and is held in place for example, using a suture that passes through the eyelet provided on the collar. For medical applications, the total width **DTW** of the finned tubing will typically be 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm or 20 mm.

The elongate tubular member **20** (devoid of fins) is preferably cylindrical. As general guidance, the maximum external width of the elongate tubular member **20**, or its external diameter **OW**, may be equal to or greater than 1 mm, 1.2 mm, 1.4 mm, 1.6 mm, 1.8 mm, 2.0 mm, 2.2 mm, 2.4 mm, 2.6 mm, 2.8 mm, 3.0 mm, 3.2 mm, 3.4 mm, 3.6 mm, 3.8mm, 3.9 mm, 4.00 mm, 4.2 mm, 4.4 mm, 4.6 mm, 4.8mm, 4.9 mm, 5.00 mm, 5.2 mm, 5.4 mm, 5.6 mm, 5.8mm, 5.9 mm, 6.00 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, or 19 mm, or a value in the range between any two of the aforementioned values, preferably between 1.6 mm and 7 mm.

The diameter of the lumen **15** of the tubing will depend on the application. For fluid delivery, it will be sufficiently wide to allow passage of fluid to the distal end, without the need to apply undue pressure at the proximal end. For the passage of wires or waveguides, as seen for example in brachytherapy or light based therapy respectively, the diameter is sufficiently larger than the diameter of the radiation source or catheter of wave guide to allow the radiation source or catheter or the wave guide to be advanced and removed from the source wire lumen without hindrance. Generally the diameter, **IW**, of the lumen **15** will be 1 %, 2 %, 3 %, 4 %, 5 %, 6 %, 7 %, 8 %, 9 %, 10 %, 11 %, 12 %, 13 %, 14 %, 15 %, 16 %, 17 %, 18 %, 19 %, 20 %, 25 %, 30 %, 35 %, 40 %, 45 %, or 50% greater than the diameter of the radiation source wire.

According to one aspect of the invention, the wall of elongate tubular member **20** has a thickness **WT** of 0.05 mm, 0.1 mm, 0.2 mm, 0.3 mm, 0.4 mm, 0.5 mm, 0.6 mm, 0.7 mm, 0.8 mm, 0.9 mm, 1.0 mm or a value between any two of the aforementioned values, preferably between 0.05 mm and 0.4 mm.

The tubing is preferably supplied as a length to be cut to size by the skilled practitioner before use, which length will depend on the application and location of use. For instance, in prostate cancer, the length inside the body is typically between 10 and 14 cm; for breast cancer, the length inside the body is typically between 8 and 20 cm from the tip to the collar; the tubing would be trimmed according. The tubing may be supplied as a length **LC** of 10 cm, 11 cm, 15 cm, 20 cm, 25 cm, 30 cm, 35 cm, 40 cm, 45 cm, 50 cm, 55 cm, 60 cm, 65 cm, 70 cm, 75 cm, 80 cm, 85 cm, 90 cm, or a value in the range between any two of the aforementioned values. Preferably, it is between 15 cm and 30 cm in length. The tubing may be supplied as a kit of two or more precut lengths of different sizes.

A fin **21**, **21'**, **21"** projects from the outside surface of the elongated tubular member **20**, providing a structure for the locking means to engage with, and to prevent free lateral and free rotational movement by the locked collar. The medical tubing is disposed with one or more longitudinal fins. The number of fins may be 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10, or a value in the range between any two of the aforementioned values, preferably between 1 and 4, most preferably 3. A fin may project radially from the outside surface of the tubing *i.e.* at a 90 degree tangent to the surface, however, other angles are envisaged within the scope of the invention, for example, at ±30, ±40, ±50, ±60, ±70, ±80 deg to the surface or at an angle in the range between any two of the aforementioned angles, preferably between 30 to 150 deg, most preferably 90 deg.

A fin **21**, **21'**, **21"** typically extends longitudinally along the entire length of the medical tubing *i.e.* from the tip of proximal end **50** to the tip of the distal end **55**. However, at least part of the distal or proximal half may be devoid of fins and not affect functioning of the assembly. The fin **21**, **21'**, **21"** preferably extends along the length of the tubing in straight line, however, the path may deviate therefrom, for example, adopting a spiral path that causes the collar or tubing to rotate as the collar is linearly advanced. Alternatively, it may undulate, causing the collar or tubing to oscillate as the collar is linearly advanced.

A fin **21, 21', 21"** that projects from the outside surface of the elongate tubular member **20** increases the total width **TW** of the finned tubing **10** compared with the width **OW** of the elongate tubular member **20** by no more than 10 %, 20 %, 30 %, 40 %, 50 %, 60 % or 70 %, or by a value in the range between any two of the aforementioned values, preferably between 20 and 50 %, most preferably by no more than 40%. The total width **TW** of the finned tubing refers to the maximum distance between the outer tips of two **21**, **21'**, **21"** fins.

A fin **21, 21', 21"** that projects from the outside surface of the elongate tubular member **20** increases the total diametric width **DTW** of the finned tubing **10** compared with the width **OW** of the elongate tubular member **20** by no more than 10 %, 20 %, 30 %, 40 %, or 50 %, or by a value in the range between any two of the aforementioned values, preferably between 10 and 30 %, most preferably by no more than 20%. The diametric width **DTW** of the finned tubing **10** refers to the diameter of a fictive circle **30**, centred at the midpoint of a transverse cross section of the finned tubing **10** that touches the outer tips of the fins **21**, **21'**, **21"**.

With reference to **FIG. 2**, the height of a fin, **FL**, may be 0.2 mm, 0.5 mm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm or 20 mm, or a value in the range between any two of the aforementioned values, preferably between 0.2 and 2 mm. Any two fins may be of equal height. Alternatively, all the fins may be of equal height. Alternatively, the majority of fins may be of equal height.

With reference to **FIG. 2**, the maximum width of a fin, **FW**, may be 0.05 mm, 0.1 mm, 0.3 mm, 0.5 mm, 0.7 mm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, or a value in the range between any two of the aforementioned values, preferably between 0.05 mm and 2 mm.

As a general rule, the fin is made from the same material as the wall of the medical tubing. It is typically is manufactured during extrusion of the tubing and forms part of the outside wall. One embodiment of the invention relates to a method of manufacture of the assembly or tubing of the invention, comprising the step of extruding a length of finned tubing to the desired diameter.

According to one aspect of the invention, a fin **21, 21', 21"** has an essentially uniform height (FL) along its longitudinal length. According to another aspect, the height (**FL**) of at least part of a fin **21, 21', 21"** varies as a function its longitudinal length. For example, a fin **21, 21', 21"** may be at least partly castellated along its longitudinal length. Thus, one embodiment of the invention is finned medical tubing **10** formed from an elongate tubular member **20** disposed with one or more longitudinal fins **21**, **21'**, **21"**, as described herein, wherein at least part of a fin is castellated.

A castellated region **62** of a fin **21, 21', 21"** comprises a tandem or side-by-side arrangement of alternating tabs **60**, **60'**, **60"**, **60"'** and notches **65**, **65'**, **65"**, **65"'** as indicated in **FIG. 23**. Each and every fin **21, 21', 21"** may contain a castellated region **62**, alternatively, one or more (*e.g.* 2, 3, 4) fins may contain a castellated region **62**; in **FIG. 23**, one fin **21"** comprises a castellated region **62**. The castellated region **62** may be located anywhere on a fin, for example, towards the proximal **50,** distal end **55**, in a mid portion. It is preferably not located at the distal **55** terminal end to prevent trauma to the region of treatment, and also it is preferably not located at the proximal **50** distal terminal end to facilitate ease of movement by the collar **200**. The height (**TH**) of a tab **60**, **60'**, **60"**, **60"'** is greater that than (**NH**) of a notch **65**, **65'**, **65"**, **65"'**.

The shape of a tab **60**, **60'**, **60"**, **60"'** may be rectangular as shown in **FIG. 23**, however, other shapes are envisaged. For example, the tabs may be adapted to facilitate entry of the tubing into the subject and/or hinder withdrawal of the tubing from the subject. Preferably the distal **55** edge of a tab **60**, **60'**, **60"**, **60"'** is adapted to facilitate entry of the tubing into the subject, while the proximal **50** edge of a tab **60**, **60'**, **60"**, **60"'** is adapted to hinder withdrawal of the tubing. According to one aspect of the invention, a tab **60**, **60'**, **60"**, **60"'** is rounded on its distal edge **55** as shown in **FIG. 25**. According to another aspect of the invention, the distal **55** edge of a tab **60**, **60'**, **60"**, **60"'** is angled (leans) towards the proximal end **50** of the tubing as shown in **FIG. 24**. Both aspects facilitate atraumatic entry of the tubing.

According to one aspect of the invention, the proximal **50** edge of a tab **60**, **60'**, **60"**, **60"'** is angled (leans) towards the proximal end **50** of the tubing as shown in **FIG. 24**. This aspect prevents withdrawal of the tubing without the application of force. With a castellated region of 10 cm, and tabs of 3 to 4 mm in length, a force of 3Kg may be required to remove the assembly.

A castellated region **62** of a fin **21, 21', 21"** can be defined by several parameters including the notch length, tab length, number of tabs, and the length of the region **62**. Parameters of a castellated region, as indicated in **FIG. 26** include the length **CL** of the castellated region, width **TW** of a tab **60"**, height **TH** of a tab **60"**, width **NW** of a notch **65"'**, height **NH** of a notch **65"'**. As a general guidance, the following dimension may apply. The length **CL** of a castellated region may be equal to or greater than 2 cm, 3 cm, 5 cm, 6 cm, 8 cm, 10 cm, 12 cm or more or a value in the range between any two of the aforementioned values, preferably between 3 and 8 cm. The width **TW** of a tab**60"**, measured along its base, may be equal to or greater than 1 mm, 2 mm, 3 mm, 4 mm, 5 mm or a value in the range between any two of the aforementioned values, preferably between 2 and 4 mm. The width **NW** of a notch **65"'**, measured along its base, may be equal to or greater than 1 mm, 2 mm, 3 mm, 4 mm, 5 mm or a value in the range between any two of the aforementioned values, preferably between 2 and 4 mm. The height **TH** of a tab **60"**, measured radially from the base to the tip of the tab, may be 0.2 mm, 0.5 mm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm or 20 mm, or a value in the range between any two of the aforementioned values, preferably between 0.2 and 2 mm. The height **NH** of a notch **65"'**, measured radially from the base to the tip of the notch, may be 0 mm, 0.1 mm, 0.2 mm, 0.3 mm, 0.4 mm, 0.5 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8

mm, 9 mm, 10 mm or a value in the range between any two of the aforementioned values, preferably between 0 and 1 mm.

An at least partially castellated fin has been found to further lock the position of the medical tubing assembly *in situ i.e.* longitudinal withdrawal movement by the tubing is restricted. When combined with the collar **200** which prevents insertion, both unwarranted withdrawal and insertion are reduced.

A collar **200** of the invention is slidably mountable on the finned tubing **10**, allowing it to move in a longitudinal direction over said tubing from the proximal **50** to distal end **55** or *vice versa* when the locking means is not engaged. The collar **200** has a body **25**, with a generally flattened form, and an aperture **210** running between the flattened surfaces that receives the finned tubing **10**. The collar **200** is equipped with an engagable locking means that in the engaged position prevents longitudinal movement of the collar relative to the finned tubing **10** and in the non-engaged position permits longitudinal movement of the collar relative to the finned tubing **10**. The body **25** of the collar **200** is preferably adapted to prevent movement by the collar **200** past the incision typically by having a flattened shape that extends at least partly over the opening of the incision when the collar is for suturing to the skin. Being so configured, the collar may not be taken into the incision. When the collar is for suturing internally, it is not necessarily a requirement that it should be adapted to prevent movement by the collar **200** past the incision. The collar **200** may be made from any bio-compatible material that has the requisite properties *i.e.* has a low coefficient of friction and has sufficient strength to support a suture. Suitable materials include PEEK, polypropylene, polyoxypropylene (Delrin 500P™) and others.

The aperture **210** may have a profile (transverse cross section) that matches the profile (transverse cross section) of the finned tubing, and is slightly larger than finned tubing profile to allow movement by the collar **200** without substantial hindrance. The profile of the collar aperture **210** may be larger than that of the finned tubing by 1 %, 5 %, 10 %, 15 %, 20 %, 25 %, 30 %, 35 %, or a value in the range between any two of the aforementioned values, said values representing a difference in area.

With reference to **FIG. 3**, which depicts a transverse cross-section of a collar **200**, the aperture **210** comprises a circular component **210""** that reciprocates the circumference of elongate tubing member **20**, and three slot components **210'**, **210"**, **210"'** that reciprocate each of the fins **21**, **21'**, **21"**. The circular component **210""** may have a diameter **AW** that

is equal to or no more than 1 %, 2 %, 3 %, 4 %, 5 %, 6 %, 7 %, 8 %, 9 %, 10 %, 15 %, or 20 % larger than the diameter **OW** of the tubular member **20**, or a value in the range between any two of the aforementioned values, preferably between 1 and 10 % larger. A slot component **210', 210", 210"'** may have a width **FAW** that is equal to or no more than 1 %, 2 %, 3 %, 4 %, 5 %, 6 %, 7 %, 8 %, 9 %, 10 %, 15 %, or 20 % larger than the width **FW** of a fin of the tubular member **20**, or a value in the range between any two of the aforementioned values, preferably between 1 and 10 % larger. A slot component **210', 210", 210"'** may have a length **AL** that is equal to or no more than 1 %, 2 %, 3 %, 4 %, 5 %, 6 %, 7 %, 8 %, 9 %, 10 %, 15 %, or 20 % larger than the length **FL** of a fin of the tubular member **20**, or a value in the range between any two of the aforementioned values, preferably between 1 and 10 % larger.

The locking means (mechanism) provides a locking force against a fin, meaning that it provides force against the fin **21**, either frictional, penetrative or otherwise that prevents the collar **200** from moving longitudinally. In the locked position, the locking means is engaged, and the collar **200** may not move longitudinally along the finned tubing **10**; in the non-locked position, the locking means is not engaged, and the collar **200** may move slidably longitudinally along the finned tubing **10**. The locking means may be any, for example, a pin, screw or clamp as elaborated below.

The locking means most preferably takes the form of a pushable pin **221**, **221'**, **221"** or rotatable screw, configured for advancement to and for frictional or penetrative contact with a single tubing fin **21**, **21'**, **21"**. Where the locking means comprises a pin, (**FIGs. 4** and **5**), the pin **221**, **221'**, **221"** typically comprises a shaft **228** that is an elongated member, preferably cylindrical, disposed with a head **224** at one end and a tip **226** at the other end. While the present invention has been illustrated principally with a pin locking mechanism (*e.g.* **FIG. 1**), it must be understood the invention is not limited thereto, and the locking mechanism may be any, which includes those described below.

The head **224** presents a surface for the application of force in the longitudinal direction of the pin, for example using a finger, thumb, set of pliers, screwdriver or other suitable object, to move the pin towards the aperture, and into the locked position. The head **224** may be formed from the terminal end of the shaft **228** as shown in **FIG 4**. Alternatively, the head **224** may be formed from a member **225** attached to the shaft **228**, which member provides a greater surface area for the application of force. As shown in **FIG 5**. the

member **225** may comprise an essentially cylindrical form, having a diameter greater than that of the pin shaft **228**.

The tip **226** is most preferably pointed, though other shapes are envisaged including rounded, rivet shaped, or flat. The non-pointed tip may be provided with a friction-enhancing coating such an abrasive diamond coating. The pin or screw is dimensioned to sit in a passage **260'**, **260"**, **260"'** in the body **25** of the collar **200** .

The body **25** of the collar **200** preferably comprises a linear passage **260'**, **260"**, **260"'** (**FIG. 3**) that runs from the peripheral surface **230** of the collar toward the aperture **210**, particularly towards the slot component **210'**, **210"**, **210"'**. The number of passages may be equal to the number of fins **21**, **21'**, **21"**. The passage **260'**, **260"**, **260"'** is configured to retain the pin or screw, and to prevent movement thereof without the application of external force. The passage **260'**, **260"**, **260"'** is also configured to guide pin or screw in a straight line towards the aperture **210**, particularly the slot component **210'**, **210"**, **210"'**. The passage **260'**, **260"**, **260"'** preferably lies such that its central axis is normal to the fin **21**, **21'**, **21"** or slot component **210'**, **210"**, **210"'**. The passage preferably has an essentially cylindrical shape. It may adopt the profile (longitudinal cross section) of the pin **221** or screw. The passage **260'**, **260"**, **260"'** may extend from the peripheral surface **230** of the collar **200**, past the slot component **210'**, **210"**, **210"'** and into the inner body of the collar **200** where it forms a well **269** (see **FIG. 10**) that can accommodate the tip **226** of the pin **221** or screw in cases when it spears the fin **21**, **21'**, **21"** in the locked position.

Various configurations of pin **221** are within the scope of the invention. For instance, with reference to **FIGs. 8** and **9**, the shaft of the pin **221"** may be disposed with a circumferential groove **264** configured to engage with a complementary protrusion **262** in the passage **260"'** when the pin **221"** is advanced to the locked position (**FIG. 9**). Linear movement of the protrusion **262** into the groove **264** provides feedback (*e.g.* sound or vibration) indicating the pin **221"** has advanced sufficiently. While **FIGs. 8** and **9** depict a pin **221** disposed with a groove and the protrusion disposed in the passage **260"'**, the inverse configuration (not shown) is within the scope of the invention, *i.e.* the groove may be disposed in the passage and the protrusion disposed on the pin.

In an alternative configuration depicted in **FIG 10**, the head **224** of the pin **221** is formed from a cylindrical member **225** that is disposed with a protrusion **267**, and the passage **260** is disposed with a first groove **266**, which accommodates said protrusion **267** when

the pin **221** is housed in the passage **260**. The protrusion **267** is preferably an annular or partly annular ring. The groove **266** may be annular or partly annular, and is preferably a notch in the wall passage **260**. The first groove **266** and protrusion **267** are configured such that they disengagably support the pin **221** in the non-locked position, the tip **226** of the pin **221** not contacting the fin **21**, **21'**, **21"** when the protrusion **267** is engaged in the first groove **266**. Applying a force to the head **224** of the pin **221** disengages the protrusion **267** from the first groove **266** allowing the tip **226** of the pin **221** to advance towards the slot component **210** and to contact the fin **21**, **21'**, **21"** in the locked position. The passage **260** may be disposed with a limit stop **265** that restricts the linear distance by which the pin **221** may advance; as shown in **FIG. 10**, the limit stop **265** contacts the cylindrical member **225** that forms the head of the pin **221** when the pin **221** is in the locked position. A second groove **268** in the passage **260** may abut the limit stop **265**, which second groove **268** is configured to engage the protrusion **267** of the pin **221** when the pin is in the locked position. The second groove **268** prevents the pin **221** from retreating out from the passage **260**.

FIG. 6 depicts a transverse cross-section of a collar **200** mounted on a finned tubing **10** of the invention. The locking means is shown as is a set of slidably mounted pins **221**, **221'**, **221"** each within a passage **260'**, **260"**, **260"'** in the body **25** of the collar **200**. In the non-locked position, there is no or insufficient frictional or penetrative contact between the pins **221**, **221'**, **221"** the fins **21, 21', 21"** of the tubing **10** to prevent linear advancement of the tubing **10** through the collar **200**. **FIG. 7** also depicts a transverse cross-section of a collar **200** mounted on a finned tubing **10** of the invention where the pins **221**, **221'**, **221"** are in the locked position *i.e.* after the pins **221**, **221'**, **221"** have been advanced towards the fins **21, 21', 21"** of the tubing **10**. Each pin **221**, **221'**, **221"** penetrates and pierces each fin **21, 21', 21"** of the tubing **10** thereby fixing the position of the collar **200** relative to the finned tubing **10**. The lumen **15** of the finned tubing **10** remains unbreeched.

The pin **221**, **221'**, **221"** , may be made from single material or combination of materials that have the requisite compression strength *i.e.* does not deform upon the application of force in the longitudinal direction, for example, stainless steel, titanium, nitenol, PEEK, bakelite or polycarbonate. The member **225**, where present, that forms pin head **224**, may be made from any material that has the requisite compression strength *i.e.* does not deform upon the application of force in the longitudinal direction, for example, stainless steel, titanium, nitenol, PEEK, bakelite or polycarbonate.

In an alternative embodiment, the locking means is a screw (not illustrated) configured to advance linearly towards the single tubing fin **21**, **21'**, **21"** by the application of rotational force. The screw comprises a threaded shaft, disposed with a head at one end and a tip at the other end. The shaft may be tapered or non-tapered. The diameter of the head may be larger than that of the tip. The head is configured (*e.g.* slotted, Philips, Pozidriv, Hex (Allen), Double hex) for coupling with a tool for the application of rotational force that drives the screw in the longitudinal direction towards the aperture, preferably the slotted component. The screw tip is most preferably pointed, though other shapes are envisaged included rounded, rivet shaped, or flat. The non-pointed tip may be provided with a friction-enhancing coating such an abrasive diamond coating. The screw is dimensioned to sit in a passage **260'**, **260"**, **260"'** in the body **25** of the collar **200**, which passage may be at least partially reciprocally threaded to engage with the screw thread. The screw may be made from any material that has the requisite compression strength *i.e.* does not deform upon the application of rotational force, for example, stainless steel, titanium, nitinol or polycarbonate.

In an alternative embodiment, the locking means comprises a clamp mechanism configured to engage frictionally at least part of the aperture **210** in the collar **200** with a surface of a fin **21**, **21'**, **21"**, preferably the side walls. More in particular, the clamp mechanism is configured to frictionally engage a slot component **210', 210", 210"'** of an aperture **210**, with a surface of a fin **21**, **21'**, **21"**. By doing so, the side walls of a fin **21**, **21'**, **21"** are clamped against the collar **200**. The fin is clamped by the application of pressure either side of the fin, applied through the walls of a slot component **210', 210", 210"'**. When the walls of a slot component **210', 210", 210"'** are compressed towards the fin, the collar is clamped and slidably locked. When the walls are released, the collar is also released and is slidable again relative to the tubing **10**.

FIG. 11 shows a particular embodiment of a collar **200** disposed with a clamp mechanism. In this embodiment the collar **200** is split by virtue of a closable gap **212** extending outwards from one of the slots component **210', 210", 210"'** towards the periphery of the collar **200**. When the gap **212** is open and tubing **10** present in the aperture as shown in **FIG. 12**, no pressure is applied *via* the slot component **210"** to the corresponding fin **21"**; the tubing can slide relative to the collar **200**. When the gap **212** is closed as shown in **FIG. 13**, pressure is applied *via* the walls of the slot component **210"** to the side walls of the corresponding fin **21"**; the tubing is clamped, and its position slidably locked relative to the collar **200**. A slidable clip **240** may be employed to control the opening and closure of

the gap **212** which clip flanks the gap **212**; when the clip **240** is in an upper (pre-engaged) position (**FIG. 14**) the gap **212** is open and the tubing can slide relative to the collar **200**. When the clip **240** is in a lower (engaged) position, *i.e.* pushed into the collar (**FIG. 15**) the gap **212** is closed, the slot component **210"** presses against the fin **21"**, and the tubing **10** is clamped relative to the collar **200**.

The clip **240** preferably has a U-shaped profile, *i.e.* has two legs connected by a cross-piece. Each of the two legs is disposed with an inward pointing rounded protrusion **241**, **241'** positioned towards the open ends of the legs, each protrusion configured to releasably engage with a reciprocating upper recess **246**, **246'** in the collar **200**, each recess present in a pair of slots **242**, **242'** that flanks the gap **212**. When the clip **240** protrusions **241**, **241'** are seated in the upper recess **246**, **246'**, the clip is in a pre-engaged position (**FIG. 14**) and the gap **212** is open. Each slot **242**, **242'** is further equipped with a lower reciprocating recess **246**, **246'** which lower recesses are adapted to received the protrusions **241**, **241'** when the clip **240** is advanced further into the slots **242**, **242'**. The lower reciprocating recess **244**, **244'** are positioned at a greater distance from the gap **212** compared with the upper recess **246**, **246'**, with the result that the movement by the clip into the lower recess **244**, **244'** (**FIG. 15**) forces narrowing of the gap **212**, and there is a concomitant clamping of the fin **21"** to the slot component **210"**. To facilitate movement by the clip **240**, the path **248**, **248'** between the upper recess **246**, **246'** and the lower recess **244**, **244'**, may be gradual.

The clip **240**, may be made from single material or combination of materials that have the requisite compression and tensile strength *i.e.* does not deform upon the downward application and when seated in the lower recess, for example, stainless steel, titanium, nitenol or polycarbonate.

The collar **200** is optionally provided with one or more suture eyelets **250**, **250'**. A suture eyelet **250**, **250'** has an opening suitable for the passage of a needle and thread. It has the requisite strength to support the collar while sutured to the tissue. Typically it will be provided towards the periphery of the collar.

The number of collars **200** mounted on the finned tubing **10** may be 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or more, or a number in the range between any two of the aforementioned numbers. When the finned tubing **10** is disposed with one collar **200**, it may be used for suturing the tubing externally *i.e.* to the skin, or internally *i.e.* to internal tissue such as adipose,

muscle, connective tissue. When the finned tubing **10** is disposed with more than one collar **200**, the collars **200** may be used to suture the tube at two or more positions internally, or at two or more positions externally, or at one position externally and at one or more positions internally. Advantageously, internal and external sutured collars provide improved anchoring, and prevent, for instance, movement of the external collar into the body due to a sudden pulling motion.

Besides optionally providing a structure to immobilize and/or to suture medical tubing to the skin, the collar **200**, suitably adapted, may further provide a coupling means **251** for attachment of another element such as another tubing or a device. After the implanted medical tubing **10** has been shortened above the collar, it leaves the proximal end **50** of the tubing terminating with an open end. By virtue of a coupling means **251** that extends from the collar, the open end can be directly attached to, for example, an extension tubing to assist with drainage or aspiration of an internal cavity. This coupling means **251** may alternatively be used to introduce a brachytherapy catheter connected to an afterloader for the delivery of brachytherapy or a wave guide connected to a laser emitting instrument. One embodiment of the invention is an assembly **100** as described herein, wherein the collar **200** is further provided with a coupling means **251**. The coupling means **251** preferably extends from the proximal end **50** of the collar **200**. The coupling means preferably provides a water impermeable connection to a reciprocating coupling means. According to one embodiment of the invention, the coupling means **251** comprises a circular flange as shown, for instance, in **FIG. 16**. According to one embodiment of the invention, the coupling means **251** comprises a circular flange disposed with a pair of radial locating notches **252'**, **252"** as shown, for instance, in **FIG. 17**. According to one embodiment of the invention, the coupling means **251** comprises screw thread, as shown, for instance, in **FIG. 18**. While **FIG. 18** shows a male type thread on the exterior circumferential edge of the flange, it may, alternatively by a female thread extending into the circular component **210""** of the aperture. According to another embodiment of the invention, the coupling means **251** comprises a Luer fitting, disposed on the proximal **50** side. The Luer fitting can be any *e.g.* male or female, threaded or non-threaded. Illustrated in **FIG. 19** is a Luer fitting configured to engage a male non-threaded syringe-type fitting with its internal conical passage **253**, or a female threaded Luer connection with its outer threaded rim **254**. The Luer fitting facilitates connection to standard equipment, such as to medical tubing, a valve or a drainage cap.

One embodiment of the invention is an inline fitting having at one end a self-tapping threaded male connector adapted for rotational insertion into the lumen **15** of the finned tubing **10**, and at the other end, a connector for external tubing. When screwed into position, the fitting sealably connects the proximal end of the lumen **15** of the finned tubing **10** with the lumen of an external tubing. The fitting may be straight or angled (*e.g.* 90 deg). The fitting is particularly suited for connection to the proximal **50** end of finned tubing **10**, when it has been truncated flush with the proximal side of the collar **200**.

The finned medical tubing **10** may be incorporated into a catheter of the art. That is to say, the outer shaft of a lumened catheter of the art may be at least partially disposed with fins along its longitudinal length. Commonly there is a need to maintain a catheter position *in situ*, for example, during the course of treatment which lasts several days, which the present tubing provides. Examples of catheters incorporating the finned medical tubing **10** of the invention include a drainage catheter and a brachytherapy catheter. The finned medical tubing **10** may be provided towards the proximal **50** end, in a central region, or towards the distal **55** end of the catheter, or may be disposed essentially along the entire longitudinal length of the catheter, depending on the application. The finned medical tubing **10** may be incorporated using any technique including extrusion, heating, crimping, gluing or friction. The catheter may further be provided with the collar **200** of the invention, preferably mounted.

One embodiment of the invention is a pigtail drainage catheter incorporating a finned medical tubing **10** of the invention. A pigtail drainage catheter is known in the art, and is characterised by a perforated curled distal end, adapted to straighten or linearise by the advancement of a stiffening stylet through a drainage lumen connecting the perforations with the port on the proximal end. An example of a pigtail catheter **300** is given in **FIGs. 20A, 20B, 21** and **22**. **FIGs. 20A and B** show the pigtail drainage catheter **300** in its native state, comprising a curled distal **55** end region **302** disposed with perforations **304** for the passage of fluid; it also has a distal terminal port **305**. The proximal **50** end of the catheter **300** contains a handle region **306** that terminates in a male screw connector **308** surrounding an open proximal port (not shown). A drainage lumen (not shown) connects the proximal port with the distal terminal port **305** and perforations **304**. The proximal port is adapted to receive a stiffening stylet **310** having a distal end **55** tip for advancement into the drainage lumen, and a proximal **50** end handle region **312**. The handle region **312** of the stylet **310** is provided at the proximal **50** end with a Luer connection, and at the distal **55** end with a female threaded opening (not shown) adapted to engage with the male

thread of the catheter handle region **306**. In **FIG. 20A**, the pigtail catheter incorporates a finned medical tubing of the invention in a region **318** disposed towards a central portion of the catheter longitudinal shaft. In **FIG. 20B**, the pigtail catheter incorporates a finned medical tubing of the invention in a region **318** towards the distal end **55** of the catheter. One of the three fins **21** is labelled in **FIGs. 20A** to **22**. **FIGs. 21** and **22** illustrate a sequential uncurling of the catheter shown in **FIG 20B**. When the stiffening stylet **310** is partially advanced into the drainage lumen, the curled distal **55** end region **302** is partially straightened (**FIG. 21**). When fully advanced, the curled distal **55** end region **302** isfully straightened (**FIG. 22**); the male screw connector **308** of the catheter handle region **306** may engage with the reciprocating female threaded opening at the distal end of the handle region **312** of the stylet.While the finned region **318** is shown towards the distal end **55** (**FIGs. 20B** to **22**), or central part (**FIG. 20A**), it may equally be disposed towards the proximal end **50** of the pigtail catheter (not shown). Although not shown, the pigtail catheter may further be provided with the collar **200** of the invention, preferably mounted over the finned region **318**.

The present invention also includes the assembly defined here for use as a catheter. In particular, it includes the catheter for use as a drainage catheter, as a brachytherapy catheter, or as a wave guide catheter. The present invention also includes the use of an assembly as defined herein as a catheter, in particular as a drainage catheter, as a brachytherapy catheter, or as a wave guide catheter. The present invention also includes the assembly as defined herein for use in medical treatment, in particular for use in the treatment of a tumour by brachytherapy.

CLAIMS

1. A medical tubing assembly (100) comprising:

- finned medical tubing (10) formed from an elongate tubular member (20) disposed with one or more longitudinal fins (21, 21', 21"),

- a collar (200), slidably mountable on the finned tubing (10), equipped with a locking means and optionally one or more suture eyelets (250, 250'),

- said locking means configured to provide a locking force against one or more of the longitudinal fins (21, 21', 21").

2. Assembly according to claim 1, wherein the number of fins (21, 21', 21") is one, two, three or four.

3. Assembly according to claim 1 or 2, wherein at least one fin (21, 21', 21") projects radially from the outside surface of the elongate tubular member (20).

4. Assembly according to any of claims 1 to 3, wherein the locking means comprises one or more pins (221, 221', 221"), configured to frictionally engage or penetrate the surface of a fin (21, 21', 21").

5. Assembly according to any of claims 1 to 4, wherein the locking means comprises one or more screws, configured to frictionally engage or penetrate the surface of a fin (21, 21', 21").

6. Assembly according to claim 4 or 5, wherein number of pins (221, 221', 221") or screws is equal to the number of fins, each pin (221, 221', 221") or screw configured to frictionally engage or penetrate the surface of a single fin (21, 21', 21").

7. Assembly according to any of claims 4 to 6, wherein at least one pin (221, 221', 221") or screw comprises:

- a pointed end (226) configured to frictionally engage or penetrate the surface of a fin (21, 21', 21"), and

- head end (224) configured to receive in the case of a pin a pushing force, or in the case of a screw a rotational force, which force advances the pointed end towards a fin (21, 21', 21") to frictionally engage or penetrate its surface.

8. Assembly according to claims 1 to 3, wherein the locking means comprises a clamp mechanism, configured to engage frictionally a surface of a fin (21, 21', 21") with at least part of an aperture (210) in the collar (200) adapted to receive slidably the finned medical tubing (10).

9. Assembly according to any of claims 1 to 8, wherein at least one fin (21, 21', 21") projects radially from the outside surface of the tubing increasing the maximum width of the tubing by no more than 50%.

10. Assembly according to any of claims 1 to 9, wherein the locking means is disengagable.

11. Assembly according to any of claims 1 to 10, wherein at least one longitudinal fin (21, 21', 21") extends continuously along the entire length of the elongate tubular member (20).

12. Assembly according to any of claims 1 to 11, wherein at least one fin is at least partly castellated.

13. Assembly according to claim 12, wherein the castellation comprises a tandem arrangement of alternating tabs (60, 60', 60", 60"') and notches (65, 65', 65", 65'"), and the tabs are adapted to facilitate entry of the tubing (10) into the subject and/or hinder withdrawal of the tubing (10) from the subject.

14. Assembly according to any of claims 1 to 13, wherein the collar (20) comprises a coupling means (251).

15. Assembly according to claim 14, wherein said coupling means (251) is adapted to couple to an afterloader.

16. Assembly according to claim 14, wherein said coupling means (251) is adapted to couple to a laser emitting device.

17. Assembly according to claim 14, wherein said coupling means (251) comprises a Luer fitting.

18. Assembly according to claim 14, wherein said coupling means (251) comprises a male or female screw fitting.

19. A catheter (300) incorporating an assembly (100) as defined in any of claims 1 to 18.

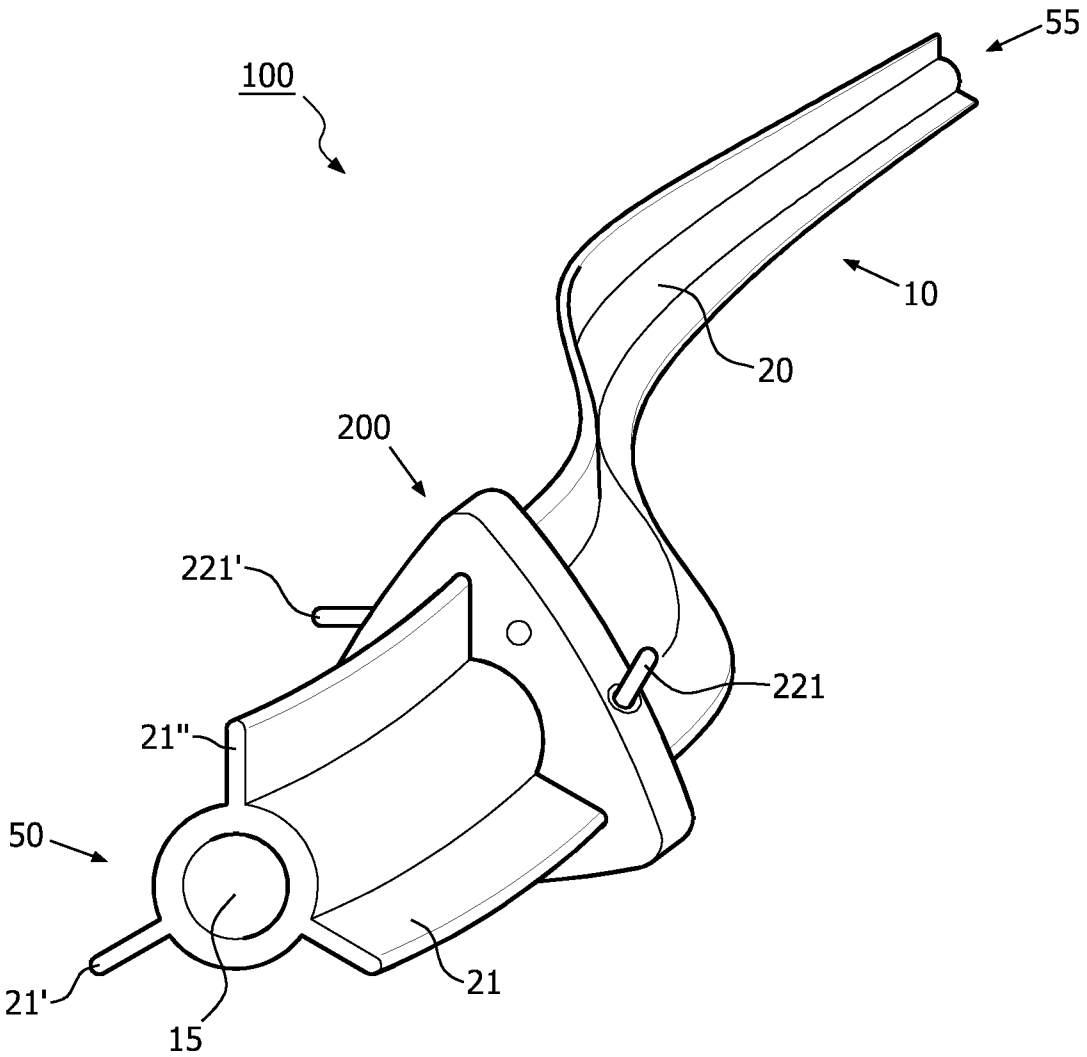

FIG. 1

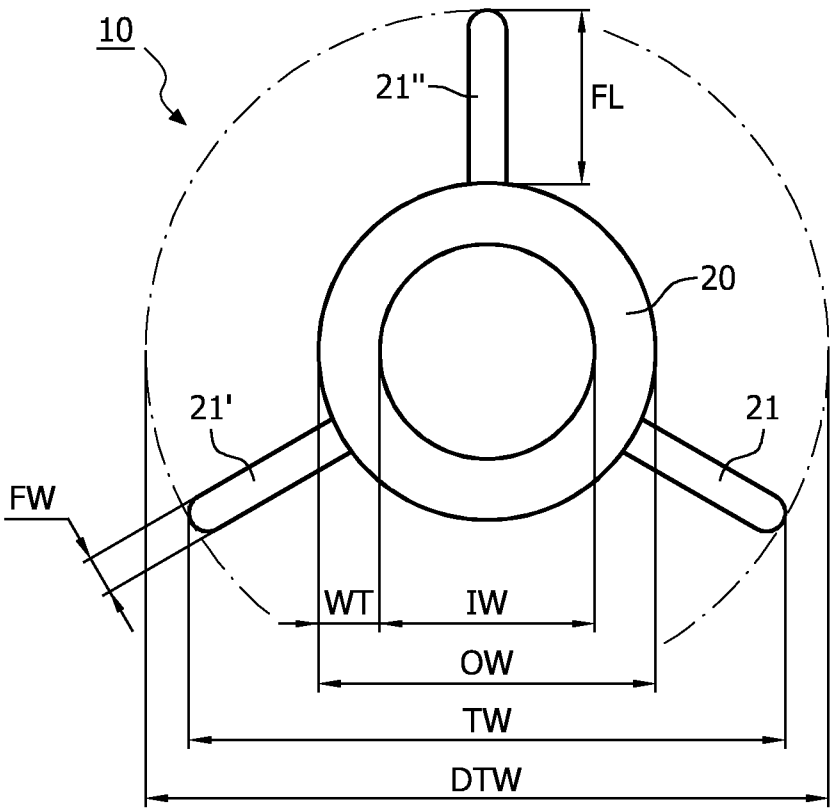

FIG. 2

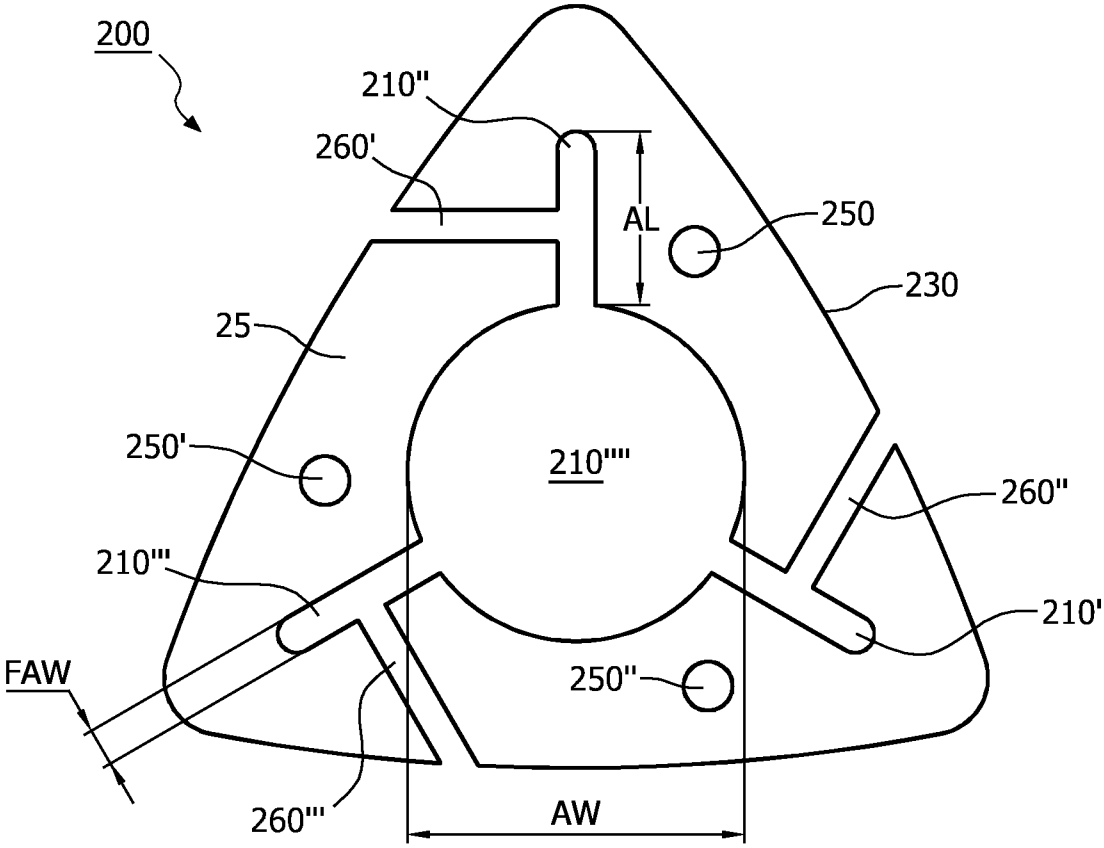

FIG. 3

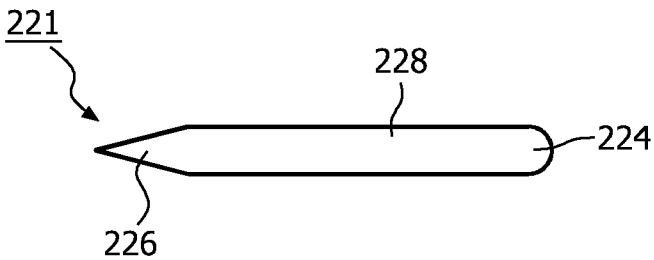

FIG. 4

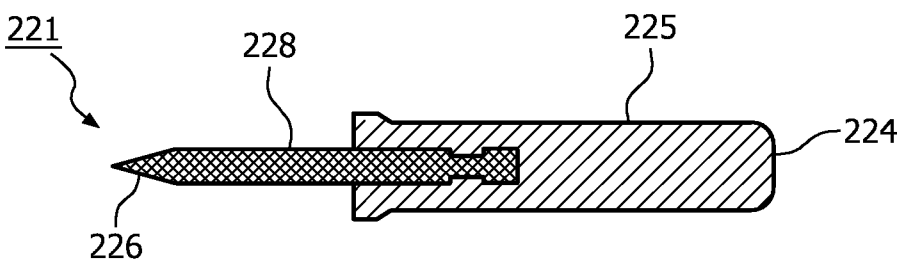

FIG. 5

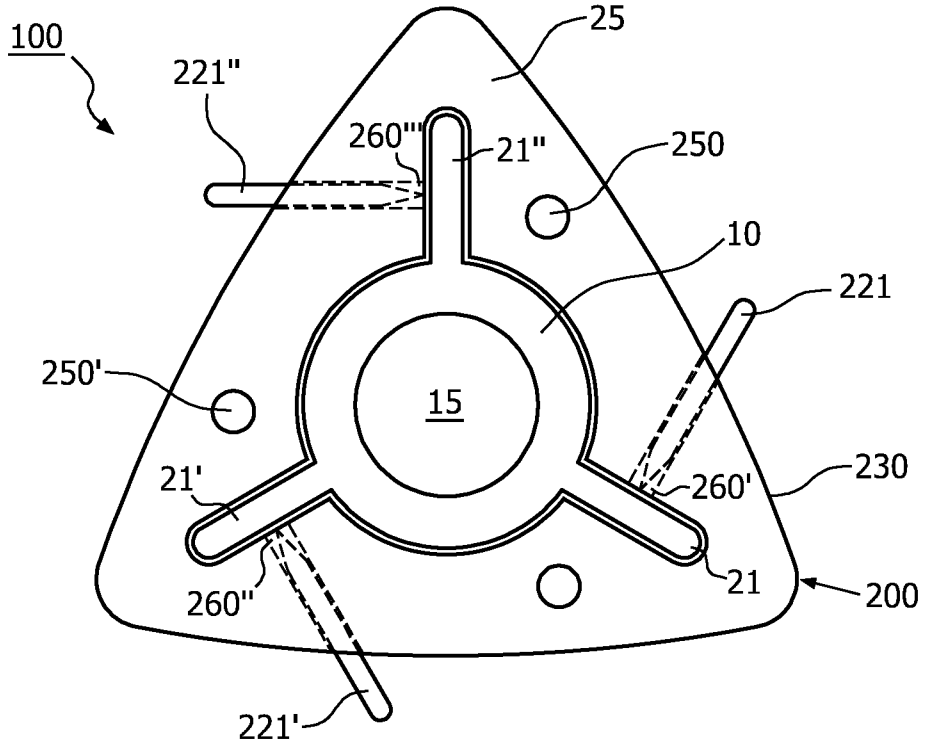
100
221"
25
260'''
21"
250
10
221
250'
15
21'
230
260'
260"
21
200
221'

FIG. 6

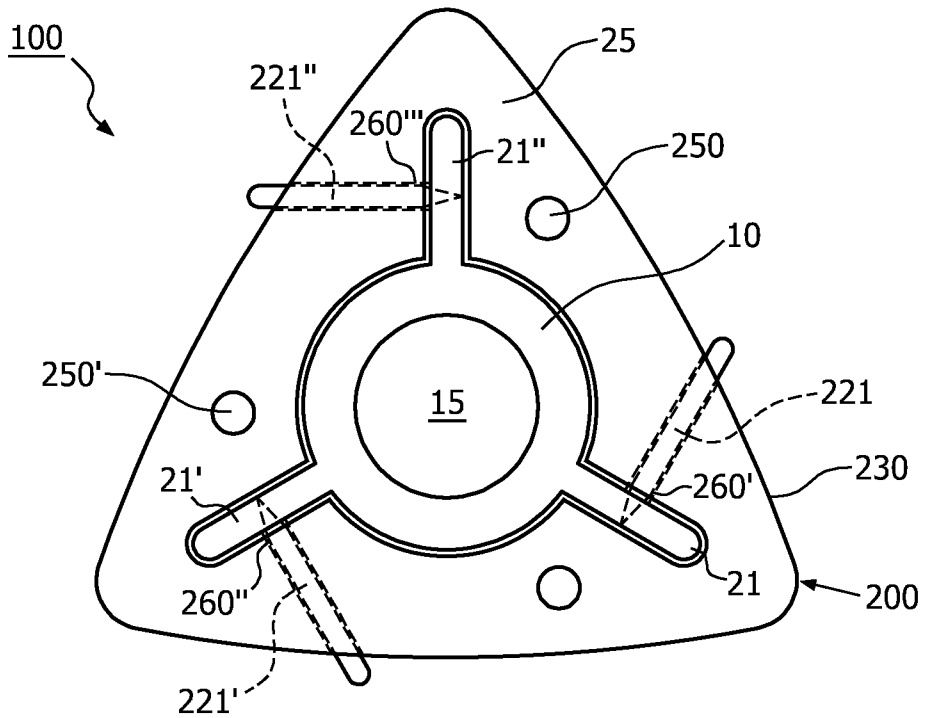
100
221"
25
260'''
21"
250
10
250'
15
221
21'
230
260'
260"
21
200
221'

FIG. 7

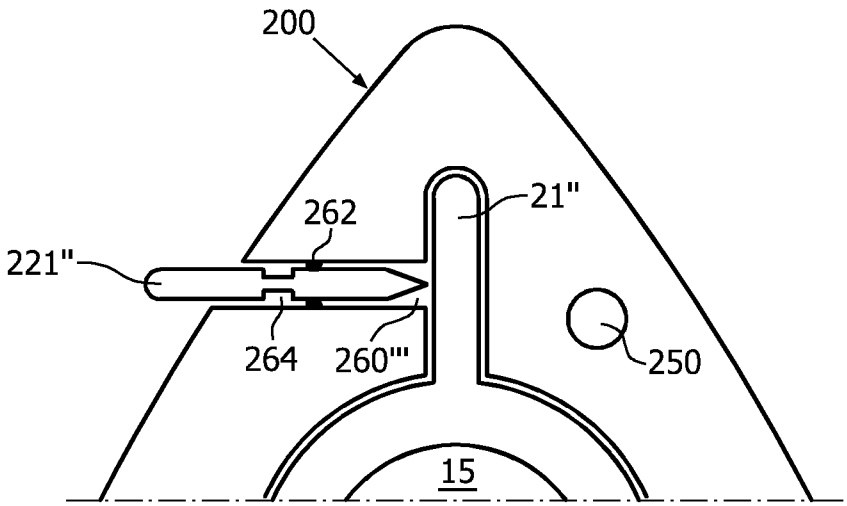

FIG. 8

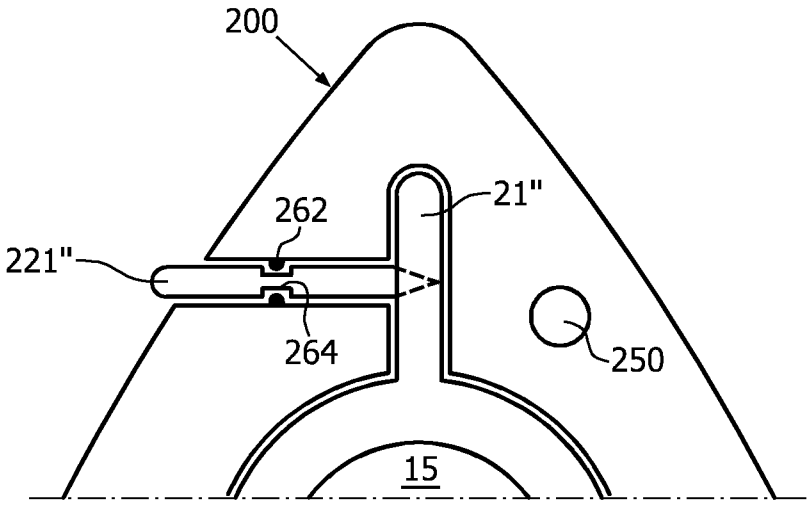

FIG. 9

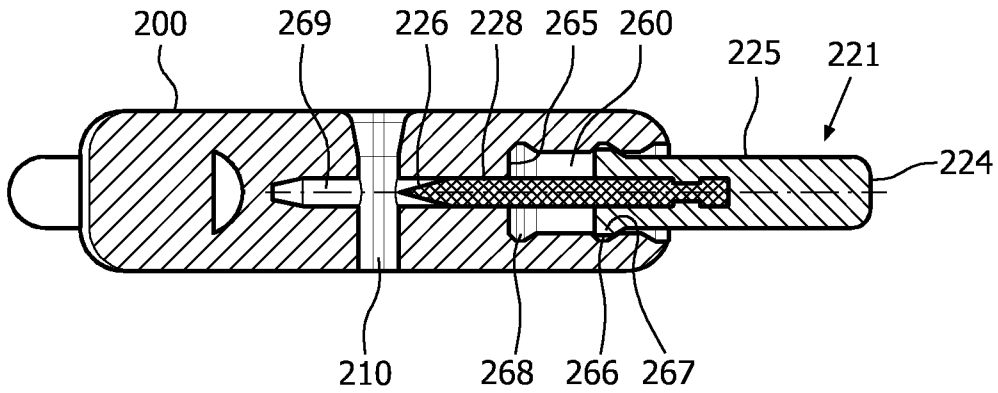
200
269
226
228
265
260
225
221
224
210
268
266
267

FIG. 10

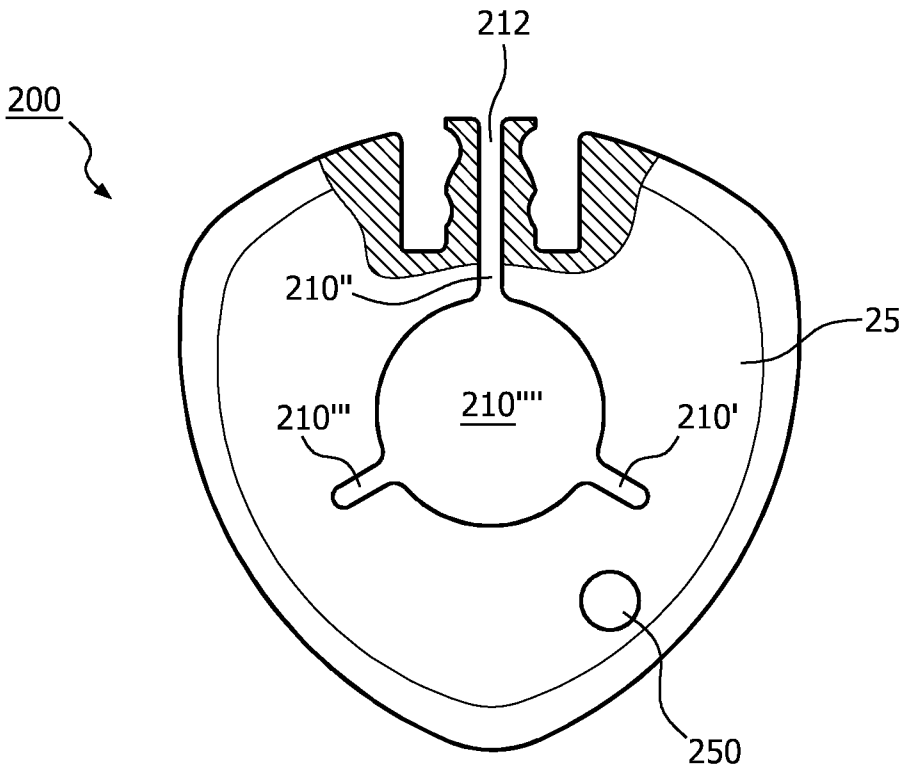
212
200
210"
25
210'''
210''''
210'
250

FIG. 11

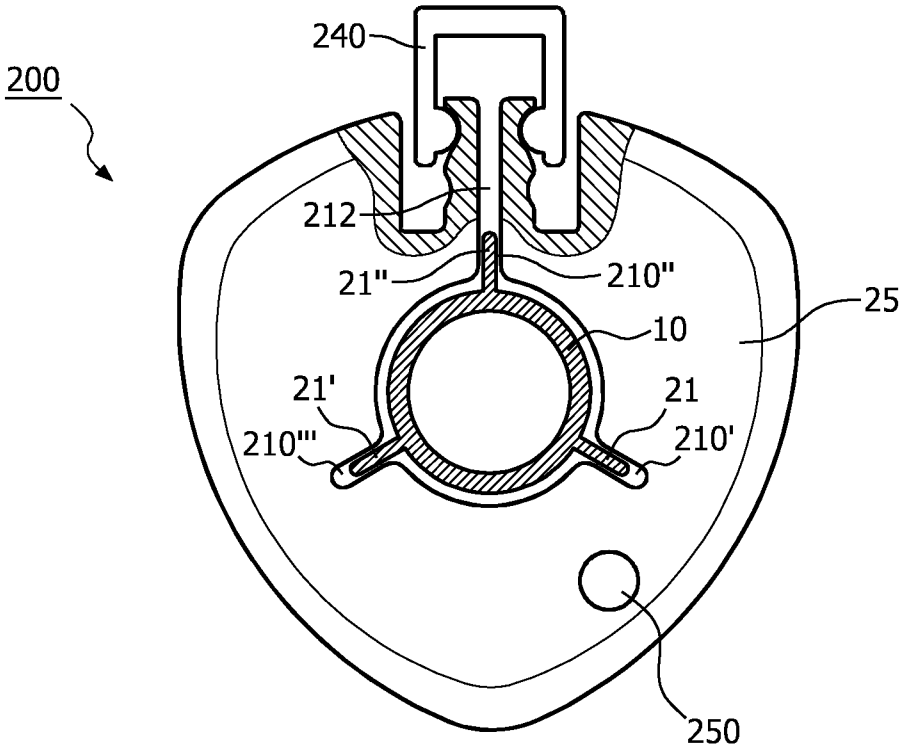
200
240
212
21"
210"
25
10
21'
21
210'''
210'
250

FIG. 12

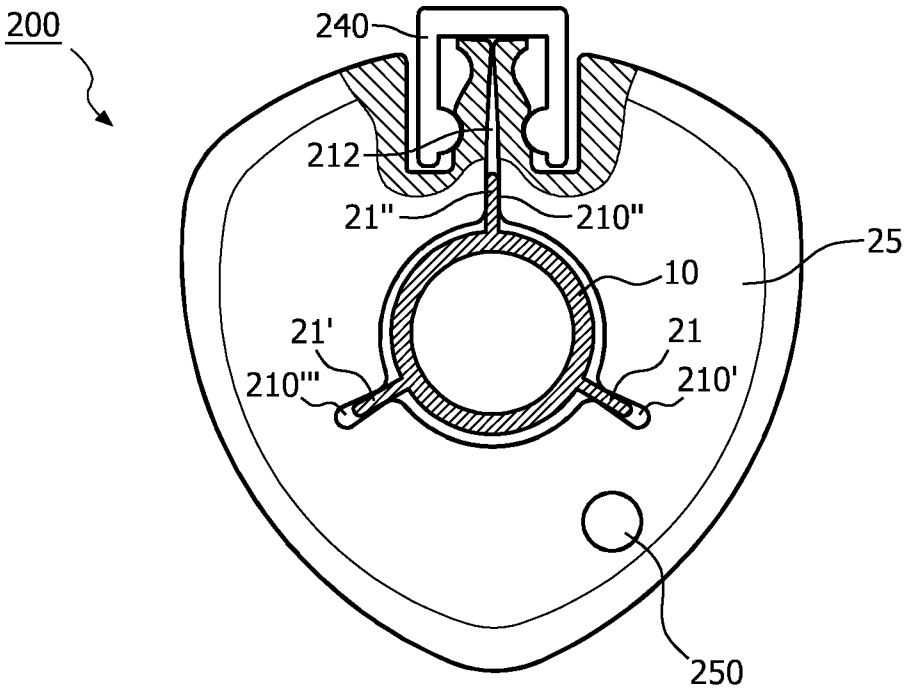
200
240
212
21"
210"
25
10
21'
21
210'''
210'
250

FIG. 13

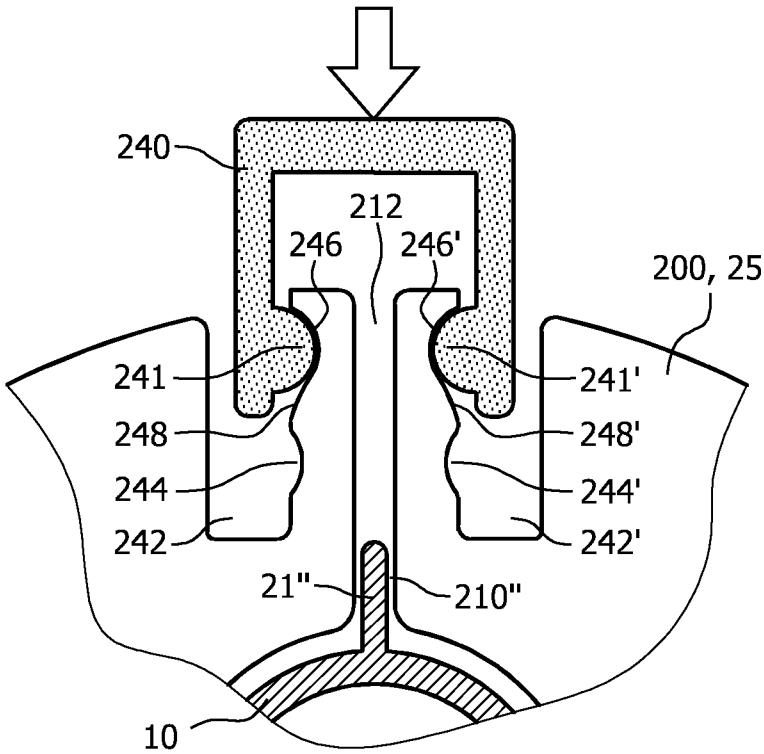
240
212
246
246'
200, 25
241
241'
248
248'
244
244'
242
242'
21"
210"
10

FIG. 14

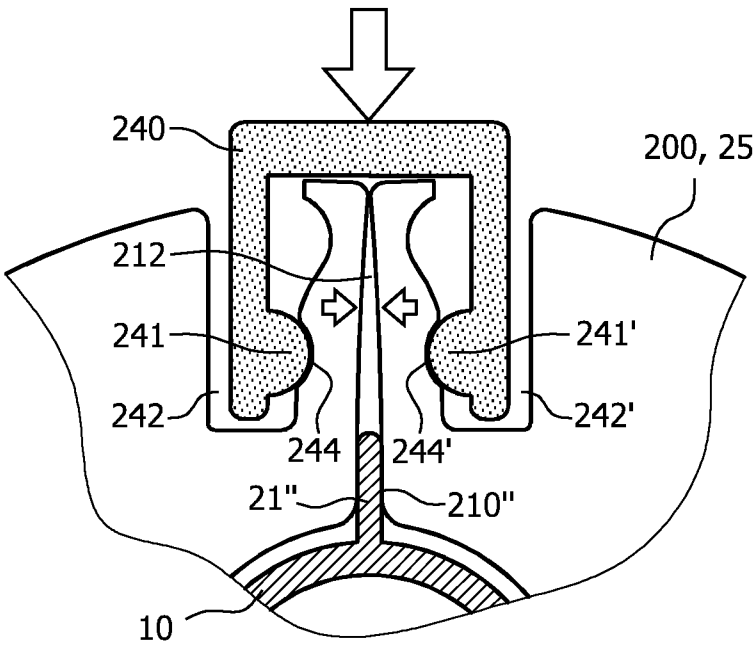
240
200, 25
212
241
241'
242
242'
244
244'
21"
210"
10

FIG. 15

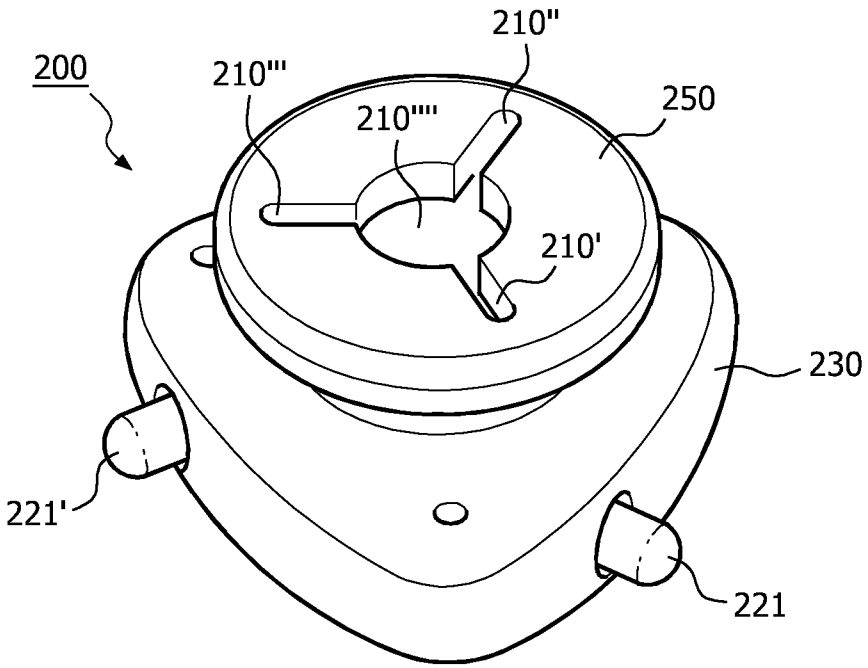
200
210'''
210''''
210''
250
210'
230
221'
221

FIG. 16

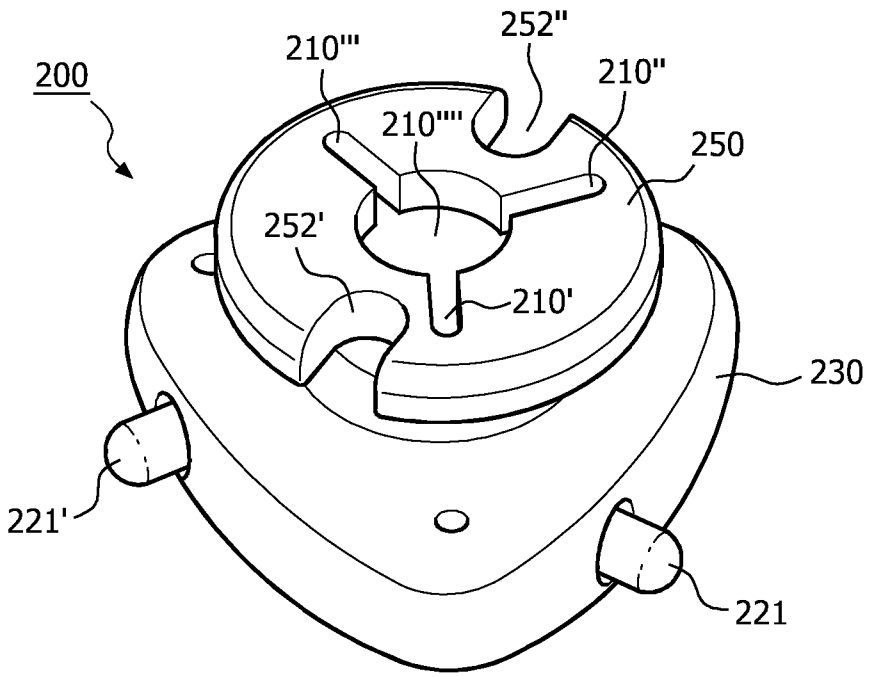
200
210'''
252''
210''
210''''
250
252'
210'
230
221'
221

FIG. 17

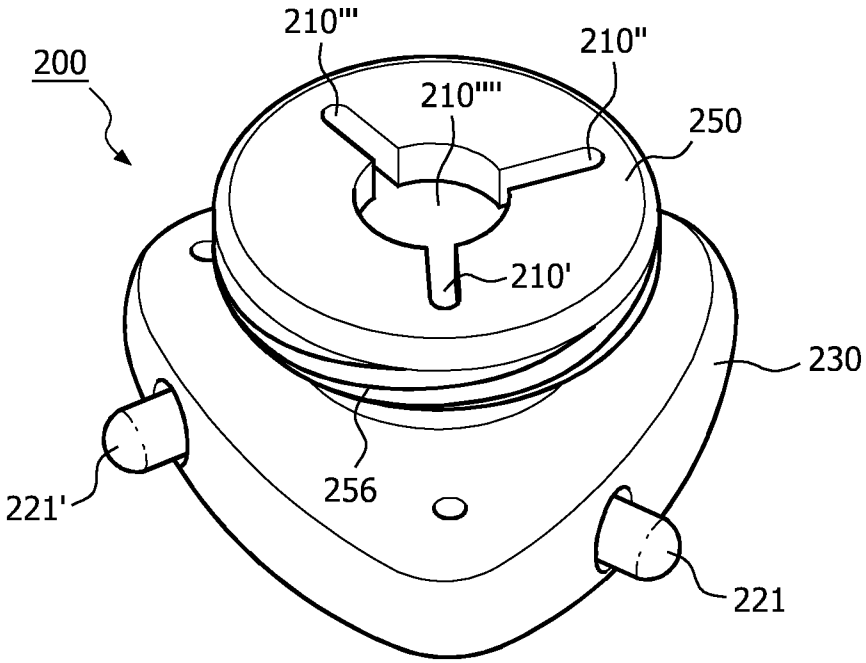
200
210'''
210''
210''''
250
210'
230
256
221'
221

FIG. 18

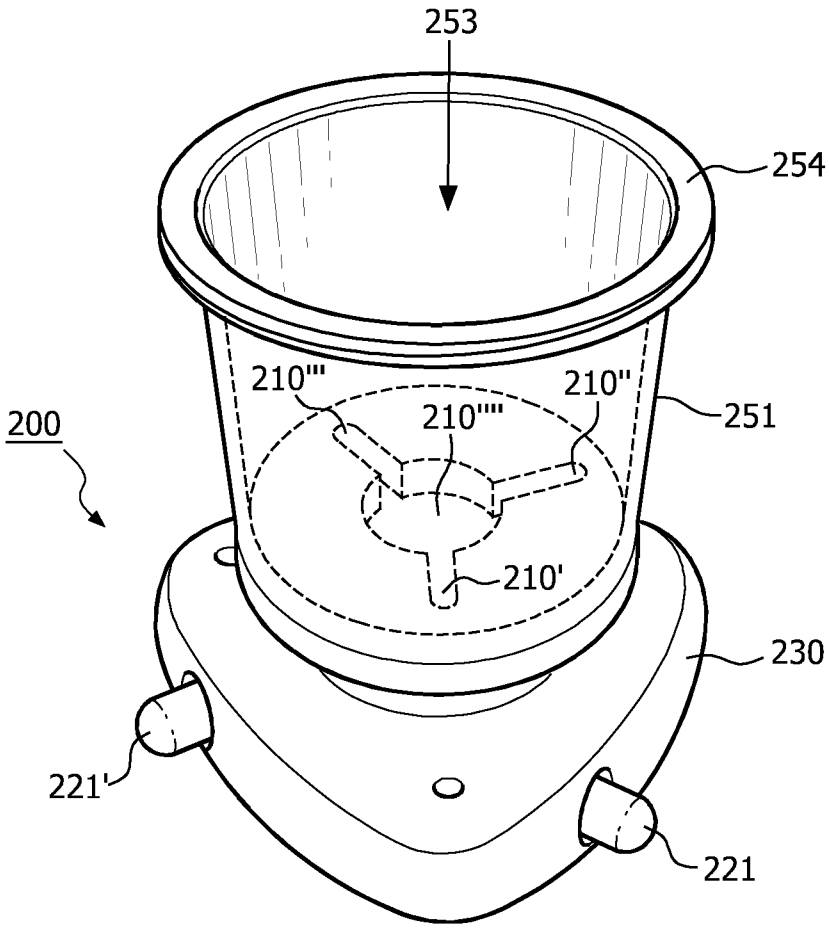
253
254
210'''
210''
210''''
251
200
210'
230
221'
221

FIG. 19

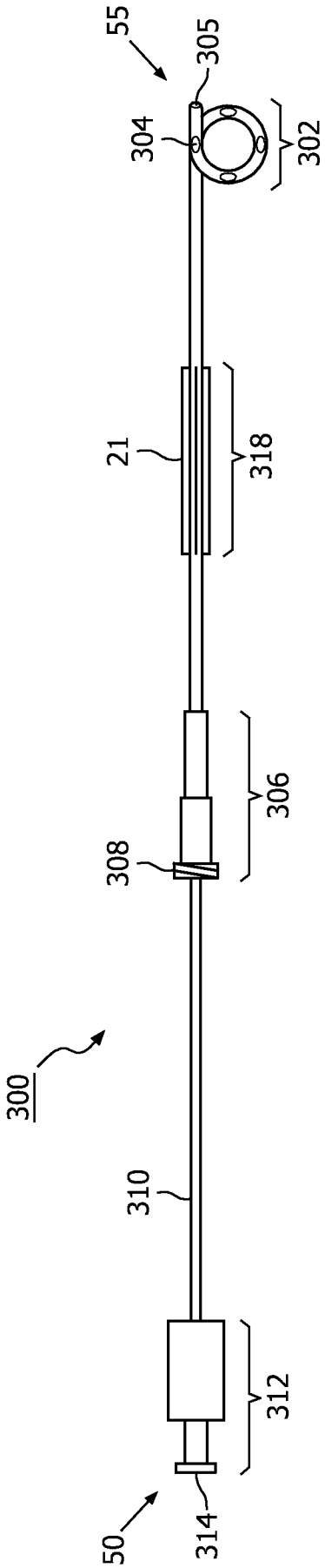

FIG. 20A

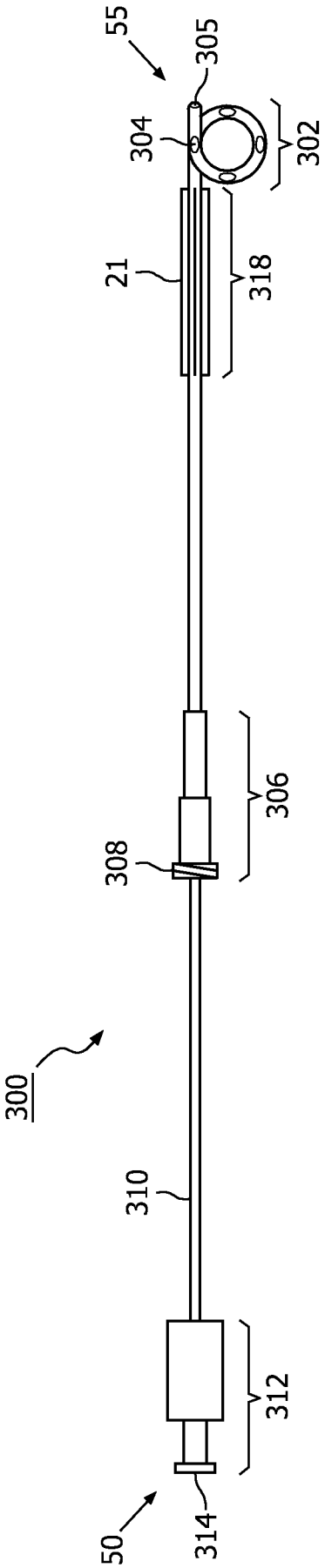

FIG. 20B

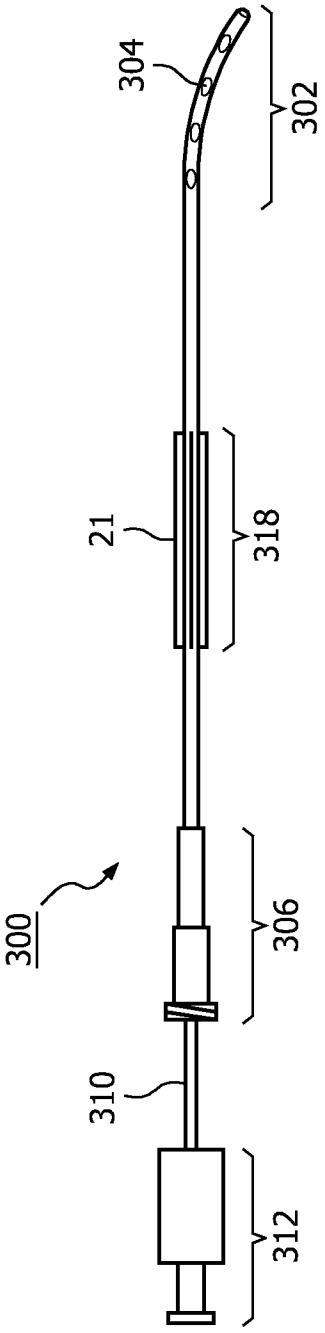

FIG. 21

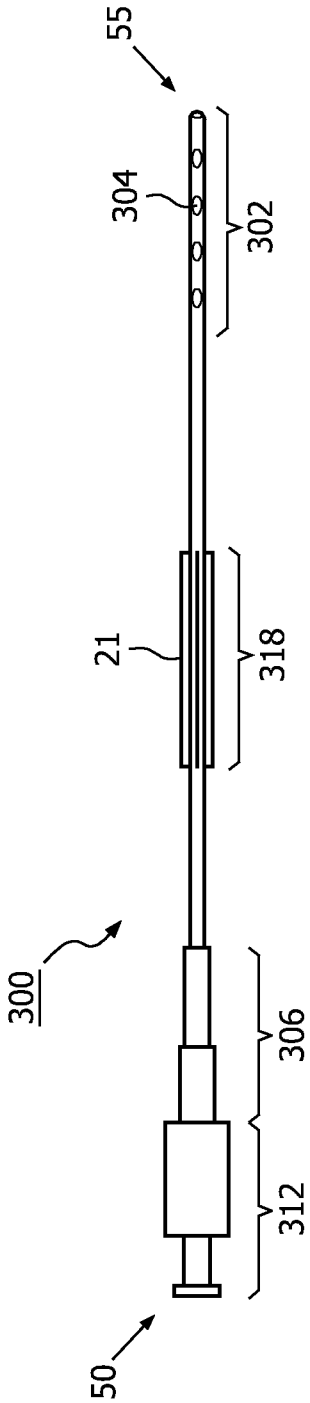

FIG. 22

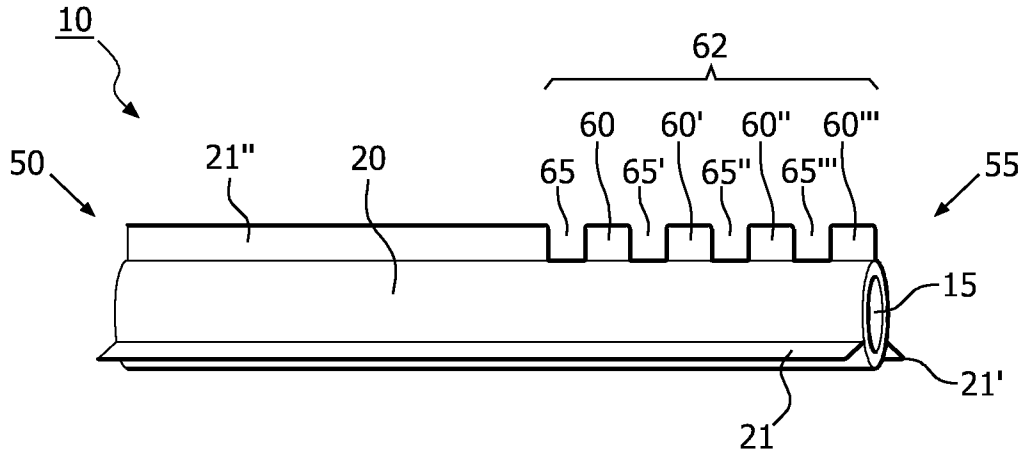

FIG. 23

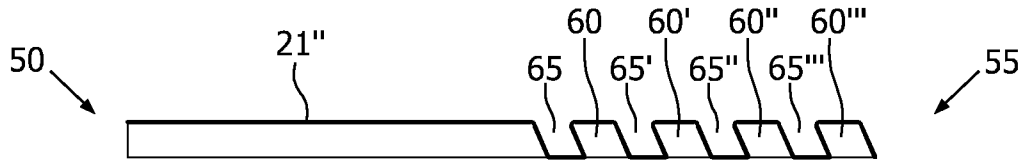

FIG. 24

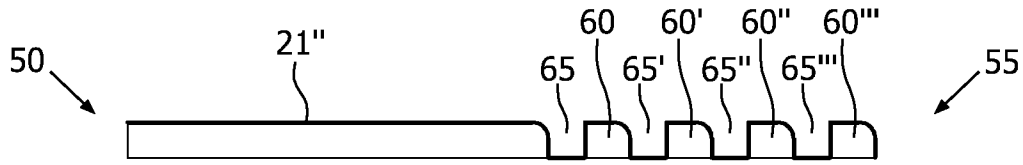

FIG. 25

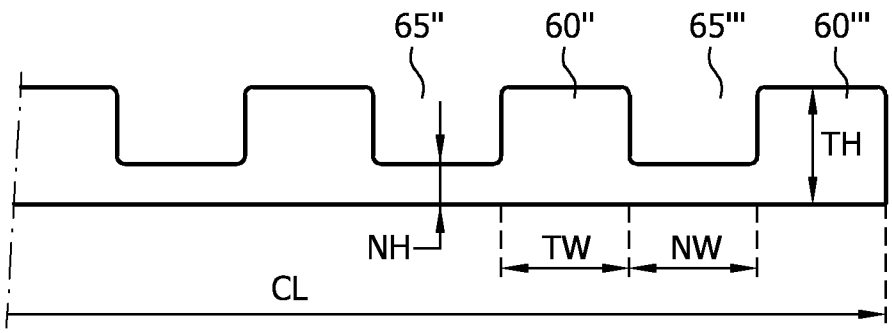

FIG. 26

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2009/063111

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00 A61M25/02

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

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 practical, 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.
A	US 5 105 807 A (KAHN MARK J [US] ET AL) 21 April 1992 (1992-04-21) abstract figures 1-4g	1-15
A	US 6 558 349 B1 (KIRKMAN THOMAS R [US]) 6 May 2003 (2003-05-06) abstract figures 1-4	1-15
A	EP 1 731 190 A (BIOENGINEERING LAB S P A [IT]) 13 December 2006 (2006-12-13) abstract figures 1-40	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 February 2010	03/03/2010

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	Manschot, Jan

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2009/063111

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5105807 A	21-04-1992	NONE	
US 6558349 B1	06-05-2003	NONE	
EP 1731190 A	13-12-2006	NONE	