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(54) **Title:** A URINARY CATHETER ASSEMBLY

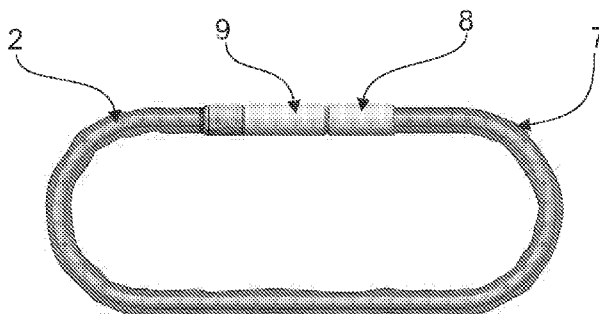


Fig. 2

(57) **Abstract:** A urinary catheter assembly having a sleeve is provided. The urinary catheter assembly comprises a urinary catheter (2) having a hydrophilic surface; the urinary catheter being provided with an insertion tip (5) in a proximal insertion end of the urinary catheter and an outlet (4) at a distal end of the urinary catheter, a handle (8) being slidably disposed on the urinary catheter, a collapsible, flexible sleeve (7) attached to the handle and being configured to cover the urinary catheter from the outlet to the tip portion in an extended configuration of the urinary catheter assembly, the sleeve being attached to a connector (9) at the outlet, the connector and handle configured to be detachably attached to each other and define a cavity provided by the sleeve, handle and connector encapsulating an entirety of the urinary catheter in a storage condition.

A Urinary Catheter Assembly

The invention relates to a urinary catheter assembly comprising a sleeve.

Summary of the Invention

The invention relates to a urinary catheter assembly comprising a urinary catheter having
5 a hydrophilic surface. The urinary catheter is provided with a tip portion in a proximal end
of the urinary catheter and an outlet at a distal end of the urinary catheter. A handle is
slidingly disposed on the urinary catheter, and a collapsible, flexible sleeve is attached to
the handle and is configured to cover the urinary catheter from the outlet to the insertion
tip in an extended configuration. The sleeve is attached to a connector at the outlet, the
10 connector and handle are configured to be attached to each other in a detachable
manner, so that in the storage condition when the connector and handle are attached to
each other, the urinary catheter is encapsulated completely inside a cavity provided by the
sleeve, handle and connector.

Brief Description of the Drawing

15 The accompanying drawings are included to provide a further understanding of
embodiments and are incorporated into and are a part of this specification. The drawings
illustrate embodiments and together with the description serve to explain principles of
embodiments. Other embodiments and many of the intended advantages of embodiments
will be readily appreciated as they become better understood by reference to the following
20 detailed description. The elements of the drawings are not necessarily to scale relative to
each other. Like reference numerals designate corresponding similar parts.

Figure 1 illustrates an embodiment of the urinary catheter assembly in a configuration,
where it is ready to be used.

Figure 2 illustrates a top view of an embodiment of the urinary catheter assembly in a
25 configuration for storing.

Figure 3 illustrates a cross-sectional view of an embodiment of the urinary catheter
assembly in a configuration for storing.

Figure 4 illustrates an embodiment of a urinary catheter assembly stored in a storage
package.

Figure 5 illustrates a side view of a detail of an embodiment of the attachment between the handle and the connector in the storage condition.

Figure 6 illustrates a cross-sectional view of a detail of an embodiment of the attachment between the handle and the connector in the attached configuration.

- 5 Figure 7 illustrates a side view of a detail of an embodiment of the handle and the connector in the un-attached configuration.

Figure 8 illustrates a cross-sectional view of a detail of an embodiment of the attachment between the handle and the connector in the un-attached configuration.

- 10 Figure 9 illustrates a cross-sectional view of a detail of an embodiment of the attachment between the handle and the connector in the un-attached configuration.

Figure 10 illustrates a side view of an embodiment of a urinary catheter assembly in a rolled-up configuration in a storage package.

Figure 11 illustrates a side view of an embodiment of a urinary catheter assembly in a rolled-up configuration.

- 15 Figure 12 illustrates a perspective view of an embodiment of a urinary catheter in a use condition.

Figure 13 and 14 illustrate cross-sectional views of details of embodiments of a drainage structure.

Detailed Description of the Invention

- 20 Urinary catheter assemblies for draining the bladder are increasingly used for intermittent as well as indwelling or permanent catheterisation. Typically, urinary catheters are used by patients suffering from urinary incontinence or by disabled individuals like paraplegics or tetraplegics, who may have no control permitting voluntary urination and for whom catheterisation may be the way of urinating.
- 25 Urinary catheters are divided into two major groups of catheters, indwelling catheters and intermittent catheters. Indwelling catheters are typically inserted into the urethra and the

bladder by medical personal (i.e. a trained professional, typically a nurse or physician) and has means for retaining the catheter inside the bladder for up to two weeks or more. Indwelling catheters are soft and flexible since they have to remain in the urethra for weeks. Indwelling catheters empty the bladder continuously.

- 5 Intermittent catheters are typically inserted by the user him- or herself and sits only in the urethra and bladder for as long as it takes to empty the bladder – e.g. for about 5-10 minutes. Intermittent catheters are used every 4-6 hours to empty the bladder corresponding roughly to the interval with which people having no urinary problems will usually go to the bathroom. Intermittent catheters are typically more rigid than indwelling
- 10 catheters since they have to be inserted by the user him-/herself and since they do not need to sit in the urethra for days or weeks. An important feature for the intermittent catheter is to ease the insertion into the urethra. This is done by providing the intermittent catheter with a low friction surface. A low friction surface may be obtained by providing the intermittent urinary catheters with a hydrophilic coating that needs to be wetted prior to
- 15 use and thereby absorbs a considerable amount of liquid. Such a hydrophilic coating will provide a very lubricious surface that has very low-friction when the catheter is to be inserted. Hydrophilic coated catheters, where the coating absorbs a considerable amount of liquid for a low friction surface (swelling degree >100%), will not be suitable for indwelling catheters, because the hydrophilic surface coating would stick inside the
- 20 mucosa of the urethra if left inside the body for a longer period of time, due to the hydrophilic coating transforming from being highly lubricious when fully wetted to being adhesive when the hydration level of the coating is reduced.

The urinary catheter as described above is configured to be used intermittently and is provided with a hydrophilic surface.

- 25 Embodiments relate to a urinary catheter assembly comprising a urinary catheter having a hydrophilic surface, the urinary catheter being provided with an insertion tip in a proximal end of the urinary catheter and an outlet at a distal end of the urinary catheter, a handle being slidably disposed on the urinary catheter, a collapsible, flexible sleeve attached to the handle and being configured to cover the urinary catheter from the outlet to the
- 30 insertion tip in an extended configuration, the sleeve being attached to a connector at the outlet, the connector and handle being configured to be attached to each other in a detachable manner, so that when the connector and handle are attached to each other,

the urinary catheter is encapsulated completely inside a cavity provided by the sleeve, handle and connector.

By being configured to cover the urinary catheter from the outlet to the insertion tip is meant that the sleeve covers a majority of the longitudinal extent of the catheter in an extended configuration. The connector and handle are typically attached to each other in a storage condition, and in that storage condition, the urinary catheter is encapsulated completely inside the cavity provided by the sleeve, handle and connector. In a use condition or extended configuration of the assembly, the connector and handle are detached from each other and, typically, the liquid will be drained out from the cavity. The storage condition may also be known as the closed configuration of the urinary catheter assembly and the use condition may be known as the open configuration of the urinary catheter assembly.

One advantage of the urinary catheter assembly is that the sleeve, connector and handle provide a complete enclosure (a cavity) for the urinary catheter, so that in the storage condition, the sterility is not compromised in any way – even as the catheter assembly is removed from an optional storage package. The user may drop the assembly on the floor or even into the toilet, without compromising the sterility of the urinary catheter itself. In particular, the insertion tip is protected from being contaminated by contact with anything unclean as long as the connector is connected to the handle. Furthermore, when the urinary catheter is to be used, the user simply detaches the connector from the handle. Following unfolding or unrolling of the urinary catheter assembly, the urinary catheter is ready to be used. The sleeve further provides the user with the possibility of gripping and holding the urinary catheter so that it is easier to use. Thereby, the catheter itself can be made of a softer and more bendable material than a catheter that is to be inserted in a straight position.

In a urinary catheter assembly as described above, the user of the assembly only has to handle one item. Users of urinary catheter assemblies may have reduced hand dexterity making it difficult for them to handle several items. Therefore, it may be an advantage that no extra items (e.g. caps or closures) need to be handled. Furthermore, when the connector and handle are separated, each of these two parts provides an intuitive location for handling the catheter, which can be done without compromising the sterility of any part of the catheter.

In the following, whenever referring to a proximal end of an element of the invention, the referral is to the end adapted for insertion. Whenever referring to the distal end of an element, the referral is to the end opposite the insertion end. In other words, the proximal end is the end closest to the user, when the catheter is to be inserted and the distal end is the opposite end – the end furthest away from the user when the catheter is to be inserted. The same definitions apply to the package and container – the proximal end is the end storing the proximal end of the catheter and the distal end is the opposite end.

The longitudinal direction is the direction from the distal to the proximal end. The transverse direction is the direction perpendicular to the longitudinal direction, which corresponds to the direction across a shaft of the catheter.

The urinary catheter comprises a main tubular part extending from the distal end to the proximal end. The tip portion is positioned at a proximal end of the catheter and comprises an eyelet part with eyelets and a proximal part proximal of the eyelet part. The proximal part may comprise a proximal rounded closed end of the tubular part. The eyelets may serve the purpose of letting urine enter into the inner lumen of the tube. The tip portion may be a Nelaton tip, where the proximal end is simply closed off providing a half-spherical closed end. The tip portion may be integrally moulded with the main tubular part – either as 1 component or 2 component moulding – or it may be provided as a separate element and then attached to the main tubular part, e.g. by welding or adhering. The tip portion may also be made by modifying the main tubular part, i.e. by punching the eyelets and rounding the proximal end to close it off.

The urinary catheter may be made of a polyurethane material (PU) or polyvinyl chloride (PVC) or poly-olefins such as a polyethylene (PE).

Usually urinary catheters for intermittent use are from size 8 FR to size 18 FR. FR (or French size or Charriere (Ch)) is a standard gauge for catheters approximately corresponding to the outer circumference in mm. More accurately, the outer diameter of the catheter in mm corresponds to FR divided by 3. Thus, 8 FR corresponds to a catheter with an outer diameter of 2.7 mm and 18 FR corresponds to a catheter with an outer diameter of 6 mm.

Urinary catheters of this invention has a hydrophilic surface imparting a low-friction insertion and may prior to use be provided with a hydrophilic coating.

The hydrophilic coating may be provided only on the insertable part of the catheter. The hydrophilic surface coating is of the kind which, when hydrated or swelled using a swelling medium, reduces the friction on the surface area of the catheter which is intended to be inserted into the urinary channel of a user corresponding to the insertable part of the catheter.

An intermittent hydrophilic catheter differs from an indwelling catheter in that the hydrophilic surface coating of such a catheter is not suitable for indwelling use, because the surface coating tends to stick inside the mucosa of the urethra if left inside the body for a period exceeding 5-20 minutes, due to the hydrophilic coating transforming from being highly lubricious when fully wetted (95% weight water) to being adhesive when the hydration level of the coating is reduced (<75% weight water).

In the storage condition, the urinary catheter assembly comprises a medium for activating the hydrophilic surface coating of the catheter. The activating medium may be a water based substance, such as sterile water, or a saline-solution.

In an embodiment, the catheter is a male catheter meaning that the catheter has an insertion length of at least 250 mm, more preferred at least 300 mm.

At its proximal end, the sleeve is connected to the handle. In the distal end, the sleeve is connected to the connector. This ensures that the entire catheter is protected from being contaminated by bacteria from the exterior.

In an embodiment, the connector and handle are provided with interlocking means.

In an embodiment, the interlocking means are in form of a threaded coupling. The thread may be short so that the user only has to turn the handle and connector about 90 degrees or even less, such as 60 degrees, to disconnect the handle and connector from each other. The threaded coupling has the advantage that it is easy to use even for users having poor hand dexterity.

In an embodiment, a kit of parts is provided with a catheter assembly as mentioned above in combination with a urine collecting bag and a tube connecting the urine collecting bag with the connector on the catheter assembly. The catheter assembly may be provided with interlocking means in the form of a threaded coupling and the tube may be provided

with a threaded coupling adapted for cooperation with the threaded coupling on the connector. Such a threaded coupling may be used to provide a secure connection between the catheter and the tube connecting a urine collecting bag to the catheter. Users may experience that a urine collecting bag coupled to a catheter may accidentally detach
5 from the connection and as a result urine leaks out onto the clothes or on the floor. This drawback may be alleviated by using a threaded coupling in the connector and provide a urine collecting bag with a corresponding threaded coupling at the connecting tube.

In an embodiment, the interlocking means are provided as first snap-fit means on the connector and second snap-fit means on the handle, the first and second snap-fit means
10 being complementary snap-fit means. This is an easy and well-functioning way of making the connector and handle detachably attached to each other. The snap-fitting means may be provided as an annular and radially inwardly extending ridge inside the connector adapted for cooperation with an annular groove on the outer surface of the handle. However, other means such as resilient vanes cooperating with grooves may be used.

15 The interlocking means between the connector and handle may, in some embodiments, allow for reclosing the urinary catheter assembly following use – as will be explained later. For example, a threaded coupling allows for opening as well as reclosing the sleeve. Likewise, a snap-fit coupling may also allow for opening as well as reclosing the sleeve. In other words, embodiments relate to a catheter assembly as described above wherein the
20 sleeve is recloseable.

A recloseable product allows for a hygienic handling of the catheter throughout the entire procedure from removing it from the storage package to disposal of the product.

In an embodiment, the connector is configured to contain and protect the tip portion of the catheter.

25 The connector may be made of a rigid material, so that the insertion tip can be protected inside the connector, when the connector is connected to the handle. Thereby, in the storage condition, the urinary catheter assembly may be in the form of a ring-shaped assembly, completely contained inside the cavity provided by the sleeve, handle and connector. A flexible insertion tip portion, meaning a tip portion that is easily bendable,
30 may be prone to permanent deformation during storage, unless it is ensured that the tip portion is prevented from being bent during storage. This is obtained by providing the

connector of a relatively rigid material so that the storage cavity provides protection against bending for the tip portion.

In an embodiment, the sleeve is liquid tight and configured to store liquid in the cavity provided by the sleeve, handle and connector. This means that the swelling medium or activating medium needed for the hydrophilic coating can be contained inside the sleeve so that the hydrophilic surface on the catheter is activated by the liquid. The material for the sleeve may, for example, be a foil-material of polyethylene, such as a soft polyethylene of LDPE. The material may also be an ethylene based elastomer. It is contemplated that materials having a flexural modulus of less than 300 MPa measured according to ISO 178 will be adequately collapsible. By adequately collapsible is meant that the sleeve provides only little resistance to being collapsed towards the distal end. Thus sleeve materials having a flexural modulus of less than 100 MPa may also be used. The sleeve provides an antimicrobial barrier.

One advantage of storing the liquid inside the cavity provided by the sleeve, handle and connector may be that the outer surface of the sleeve is dry.

Embodiments relate to a kit of parts comprising the assembly as described above and a storage package of a water vapour impermeable material. The storage package provides an enclosure for the urinary catheter assembly including the sleeve, handle, connector and urinary catheter.

By water vapour impermeable is meant that the material has such a low water vapour permeability that the urinary catheter assembly can be stored in the storage package with the coating being kept in a fully hydrated condition for a storage time of up to 3 years. As an example, the material for the storage package is a foil-package of a laminate including a thermoplastic material and aluminium, e.g. a laminate of a PETP polyester as an outer layer, aluminium in an intermediate layer and an inner layer of polyethylene. This foil-package may be provided in one sheet of material folded over and welded or adhered along the edges to provide an enclosure. It may also be provided in two sheets of material laid on top of one another and welded or adhered along the edges to provide an enclosure. As another example, the storage package is a hard-box injection moulded of Polypropylene or Poly-ethylene in a thickness of about 0.7 mm or more. This hard-box may be provided with a lid integrated with or separate from the remaining part of the hard-box and provides an enclosure inside it.

In an embodiment, a storage package of water vapour impermeable material includes a number of urinary catheter assemblies. As an example, the storage package includes 5-6 urinary catheter assemblies, so that the user has the number of catheters to be used in a day in one storage package. This is possible, because the sleeve includes the swelling
5 medium and is able to store the urinary catheter in a hydrated or swelled condition for at least 24 hours. Thus, the storage package provides the water vapour impermeability needed for long-term storage (e.g. 3 years) and the sleeve provides water vapour impermeability needed for approximately a day or two.

The storage package may be recloseable, irrespective of whether the storage package is
10 provided for storing one or more catheters. If the storage package is provided as a foil-package, it may be provided with a peelable opening and a resealable tape allowing the storage package to be resealed over the opening. In case the storage package is provided as a hard-box, it may be resealed by reclosing the lid.

In an embodiment, the tip portion is a flex tip. In this type of embodiment, the tip portion of
15 the urinary catheter comprises, from the distal end of the tip portion, an eyelet part with eyelets for letting urine into the inner lumen of the catheter, an intermediate part, where the catheter diameter is decreased with respect to the diameter of the remaining part of the catheter, and a proximal part having a bulb with a diameter close to or exceeding the diameter of the tubular part of the catheter. The bulb may also have a diameter that is
20 slightly less than the diameter of the tubular part of the catheter. The bulb may be close to spherical in shape or may be slightly elongated and shaped as an olive or droplet. This type of tip portion may be useful for male users to guide the catheter around the bend in the urethra at the prostate. The urinary catheter assembly as described above allows the tip portion to be protected inside the connector without being bend. A flexible tip portion is
25 adapted to bend easily – and because of the visco-elasticity of the material, the tip portion will have a tendency to deform permanently into a curved position if being subjected to bending for a prolonged period of time. This means that such a bend in the tip portion may be difficult, if not impossible to straighten out again, when the catheter is to be used. Thereby, the catheter will be difficult to insert during the straight part of the urethra.

30 The eyelets will influence the bending stiffness of the catheter in such a way that the eyelet part will have a reduced bending stiffness compared to the main tubular part of the catheter. The intermediate part may have a diameter that is decreased to such an extent that the bending stiffness of this part is between 60% and 80% of the bending stiffness of

the main tubular part of the catheter. This reduced diameter and resulting reduced bending stiffness assist in preventing the catheter from kinking at the eyelets, because the deflection of the catheter will be more evenly distributed, when the intermediate part of the catheter is less rigid (has a lower bending stiffness) than the eyelet part.

- 5 In an embodiment, when the urinary catheter is straightened out, the sleeve does not completely cover the insertion tip, but up to 10 mm of the tip portion projects beyond the proximal end of the handle. This has the effect that the proximal end of the tip portion is immediately visible and accessible for insertion into the urethra, whereas the eyelet part with the eyelets will still be positioned inside the handle. Having the eyelets inside the
- 10 protection of the handle is an advantage, because the catheter is more likely to kink at the eyelets than at other cross-sections along the length of the catheter. So the user can initiate insertion of the urinary catheter into the urethra and still support the eyelet part of the urinary catheter by squeezing the handle into contact with this part.

- The handle may have a soft proximal end. A soft proximal end of the handle prevents
- 15 irritation of the glans of a penis, should the handle come into contact with the glans, when catheterization is to be done. This may be done by providing the proximal end of the handle with a sealing ring, e.g. of thermoplastic elastomeric material (TPE). Another or additional way of doing this is to provide an entire outer surface of the handle with a soft material and provide an inner supporting part of Polypropylene (PP). In an embodiment,
- 20 the handle has an outer surface of TPE and an inner supporting part of PP comprising the threaded surface. The handle may then be squeezed into contact with the catheter surface so that the catheter can be easily handled through the sleeve.

- The connector may comprise an inner connector part and an outer connector part. This allows a standard inner connector to be used as an outlet, which allows connection to a
- 25 urine bag. As an example, the inner connector may be made of polyurethane. The outer connector part may be made of Polyethylene, such as HDPE. In an embodiment, where the connector and handle are adapted for being threaded together, the outer connector part supports the thread, thus it is rigid enough to support the thread. The two connector parts may be configured to be friction-fitted, press-fitted or snap-fitted together.

- 30 Embodiments relate to a urinary catheter assembly, wherein the connector forms a drainage structure providing drainage of liquid (activating medium) from the cavity in the open configuration without providing drainage in the closed configuration.

In other words, when the connector and handle are detached from each other and the urinary catheter assembly is in the use condition, the liquid may be drained out from the assembly through a drainage structure in the connector, whereas the liquid is prevented from being drained out from the assembly in the storage condition. When the catheter is to
5 be used, it is advantageous to handle and dispose of the liquid (typically around 15ml) appropriately.

The urinary catheter assembly connector is capable of forming a closed configuration and an open configuration. In the closed configuration, the connector and handle can be attached to each other such that the urinary catheter is encapsulated completely in a
10 cavity formed by the sleeve, handle, and connector. This is achieved by looping or coiling the assembly such that the connector and handle meet and can attach.

The connector forms a drainage structure which provides drainage of liquid from the cavity in the open configuration without providing drainage in the closed configuration. Typically, the drainage structure is a hole which extends through the connector and allows liquid
15 drainage from the cavity in the open configuration. The drainage structure may be located in the interlocking means of said connector.

In a particular embodiment, the connector comprises an inner connector and an outer connector, said inner and outer connectors being separated by a channel for liquid, wherein said drainage structure is present in said inner connector. In this embodiment, the
20 outer connector may comprise said interlocking means.

By means of the drainage structure, liquid in form of an activating medium can be drained from the distal end of the catheter. The activating medium may be drained into a toilet. The distal end of the catheter may be connected to a urine bag or hose for disposal, as described above.

25 Embodiments also relate to a method for preparing a urinary catheter for insertion, said method comprising the steps of:

- providing the urinary catheter assembly in said closed configuration;
- releasing the connector and handle from each other to form the open configuration;

- draining liquid from the cavity through said drainage structure.

Embodiments relate to providing a catheter assembly as described above in a rolled-up configuration. By a rolled-up configuration is meant that the catheter is rolled in at least two convolutions. Providing a catheter in a rolled-up configuration during storage has the effect that the catheter is more compact during storage.

Embodiments include a kit of parts comprising a catheter with a standard connector and a sleeve with a connector part in the distal end adapted for being fitted, as mentioned above, to the standard connector of the catheter. The sleeve includes a handle as described above. The catheter may be provided with a hydrophilic coating as described above. The cooperation between the handle and the connector may be as described above.

The catheter assembly can advantageously be delivered to the user in a rolled-up configuration with the connector attached to the handle. When a user is about to use the catheter, he may initially remove the catheter enclosed in the sleeve from the storage package, in case a storage package is provided. The connector is separated from the handle and the activating medium is drained out of the sleeve, in some embodiment through a drainage structure as described above. In some embodiments the sleeve is reclosable and the assembly can be kept in a bag or pocket for later disposal. In some embodiments, re-storing the catheter assembly in a storage package and re-sealing this is possible, as it is described above.

Detailed Description of the Drawing

Embodiments, and features of the various exemplary embodiments described in this application, may be combined with each other ("mixed and matched"), unless specifically noted otherwise.

Figure 1 illustrates a cross-sectional view of an embodiment of a urinary catheter assembly **1**, when it is ready to be used. The urinary catheter assembly **1** includes a urinary catheter **2**, extending from a proximal insertion end **3** to a distal end comprising outlet **4**. The proximal end **3** includes a tip portion **5** with eyelets **6** for letting urine enter into the catheter. The assembly **1** further includes a sleeve **7** extending between a handle **8** and a connector **9**. The sleeve **7** is collapsible as the handle **8** is slid along the catheter **2**, e.g. during insertion. The connector **9** includes a first snap-fit means **10** configured to

cooperate with a complementary second snap-fit means **11** on the handle. The second snap-fit means **11** may be in the form of a resilient flange configured for snapping behind a first snap-fit means in form of a flange **10** on the connector.

Figure 2 illustrates a top view and figure 3 illustrates a cross-sectional view of an embodiment of a urinary catheter assembly **1** in a storage condition. When stored, the connector **9** is attached to the handle **8** and the catheter **2** is thus completely enclosed or encapsulated in the cavity provided by the sleeve **7**, connector **9** and handle **8**.

Figure 4 illustrates an embodiment of a urinary catheter assembly **1** packed and stored in a storage package **20**. In this embodiment, the storage package **20** is made of foil material welded along the edges to provide an enclosure **21** in which, the urinary catheter (not visible) including the sleeve **7** is stored during storage.

Figures 5 to 8 illustrate an embodiment of a detail of the attachment between the connector **9** and the handle **8**. Figures 5 and 7 illustrate perspective views of the attachment in an attached configuration and an un-attached configuration, respectively. Figures 6 and 8 illustrate cross-sectional views of the attachment in an attached configuration and in an un-attached configuration, respectively.

Figures 5 and 6 illustrate how the handle **8** and connector **9** are attached to each other to provide a closed connection and provide a storage cavity for the tip portion **5**. Figure 5 illustrates a view of the closed connection as seen from outside and figure 6 illustrates a cross-sectional view of the closed connection. The first and second snap-fit means **10** and **11** are also illustrated in figure 6.

Figures 7 and 8 illustrate the handle **8** and the connector **9** in an un-attached configuration. In figure 7, the handle **8** and the connector **9** are illustrated in a side-view and in figure 8 a cross-section view is illustrated. The second snap-fit means **11** on the handle providing for the possibility of attaching the handle to the connector. Figure 8 also illustrates a tip portion **5** in the form of a flex-tip. The flex-tip has a proximal bulb-shaped part **12** and an intermediate part **13** immediately distal of bulb where the diameter is reduced with respect to the main tubular part **14** of the catheter.

Figure 9 illustrates another embodiment of a connection between the handle **8** and the connector **9** in an un-attached configuration. In this embodiment, the handle and the

connector are connected by a threaded coupling. The outer thread **15** is in this embodiment positioned at the connector **9** and the inner thread **16** is positioned at the handle **8**. The handle **8** may be provided with a soft proximal end **17**, for example made of a softer material. In the illustrated embodiment, the outer material **18** of the handle covers
5 the handle from the distal end to the proximal end, whereas the inner material is only present at a central part of the handle. Thus, the distal end and the proximal end of the handle are unsupported by the inner material and are thus softer and more compliant.

Figures 10 and 11 illustrate an embodiment of a urinary catheter assembly **1** in a configuration, where it is rolled up in two convolutions. In figure 10, the urinary catheter
10 assembly is illustrated in a storage package **22**. The storage package **22** provides an enclosure **23** for the urinary catheter. Figure 11 illustrates the urinary catheter assembly **1** in a rolled-up configuration without a storage package.

Figure 12 illustrates an embodiment of a urinary catheter assembly **1** when it is ready to be used with the handle **8** and connector **9** separated from each other and the catheter
15 ready for insertion. The sleeve **7** can be seen as covering the urinary catheter **2** for a majority of the entire length.

The embodiment of figure 13 incorporates a drainage structure **30**, which takes the form of one or more channels through the connector **9**. It can be seen that any liquid present within the cavity formed by the connector **9**, sleeve **7** and handle **8** can drain from the
20 assembly through the connector **9**, when the assembly is in the use condition or open configuration.

Figure 14 illustrates a particular embodiment in which the connector **9** comprises an inner connector **31** and an outer connector **32**. The inner and outer connectors (**31**, **32**) are separated by a channel for liquid **33**, wherein said drainage structure **30** is present in said
25 inner connector **31**.

Claims

1. A urinary catheter assembly comprising a urinary catheter having a hydrophilic surface, the urinary catheter being provided with an insertion tip in a proximal end of the urinary catheter and an outlet at a distal end of the urinary catheter, a handle being
5 slidingly disposed on the urinary catheter, a collapsible, flexible sleeve attached to the handle and being configured to cover the urinary catheter from the outlet to the tip portion in an extended configuration of the urinary catheter assembly, the sleeve being attached to a connector at the outlet, the connector and handle configured to be detachably attached to each other and define a cavity encapsulating an entirety of the
10 urinary catheter in a storage condition.
2. The urinary catheter assembly as in claim 1, wherein the connector and handle are provided with interlocking means
3. The urinary catheter assembly as in claim 2, wherein the interlocking means are provided as first snap-fit means on the connector and second snap-fit means on the
15 handle, the first and second snap-fit means being complementary snap-fit means.
4. The urinary catheter assembly as in claim 2, wherein the interlocking means are in the form of a threaded coupling.
5. The urinary catheter assembly as in any of the preceding claims, wherein the connector is configured to contain and protect the insertion tip of the catheter in the
20 storage condition.
6. The urinary catheter assembly as in any of the preceding claims, wherein the sleeve-material is liquid tight and configured to store liquid inside it in the storage condition of the assembly.
7. The urinary catheter assembly as in any of the preceding claims, wherein the tip
25 portion is a flex tip.
8. The urinary catheter assembly as in any of the preceding claims, wherein the handle has a soft proximal end.

9. The urinary catheter assembly as in any of the preceding claims, wherein the connector is provided with an inner connector part and outer connector part.
10. The urinary catheter assembly as in any of the preceding claims, wherein, in the storage condition, the catheter assembly is provided in a rolled-up configuration in such a way that the urinary catheter is rolled in at least two convolutions.
11. The urinary catheter assembly as in any of the preceding claims, wherein the connector forms a drainage structure providing drainage of fluid from the cavity in the use condition without providing drainage in the storage condition.
12. The urinary catheter assembly according to any one of the preceding claims, wherein said connector comprises an inner connector and an outer connector, said inner and outer connectors being separated by a channel for liquid, wherein said drainage structure is present in said inner connector.
13. A kit of parts comprising a catheter assembly as defined in any of claims 1 – 12 in combination with a urine collecting bag and a tube connecting the urine collecting bag with the connector on the catheter assembly.
14. The kit of parts as in claim 13, wherein the catheter assembly is provided with interlocking means in the form of a threaded coupling and the tube is provided with a threaded coupling adapted for cooperation with the threaded coupling on the connector.
15. A kit of parts comprising a catheter assembly as defined in any of claims 1-12 with a catheter with a standard connector and a sleeve with a connector part in the distal end adapted for being fitted, to the standard connector of the catheter.
16. A kit of parts comprising a storage package of a water vapour impermeable material and a urinary catheter assembly as in any of the preceding claims.
17. The kit of parts as in claim 16, wherein the storage package is reclosable.
18. The kit of parts as in any of claims 16-17, wherein the storage package comprises a number of urinary catheter assemblies such as 5 or 6.

19. A method for preparing a urinary catheter for insertion, said method comprising the steps of:

- providing the urinary catheter assembly according to any one of claims 1-12 in said storage condition;
- 5 - releasing the connector and handle from each other to form the use condition;
- draining fluid from the cavity.

20. The method of claim 19, wherein the draining is done through the connector forming a drainage structure providing drainage of fluid from the cavity in the use condition without providing drainage in the storage condition.

10 21. The method of claim 20, wherein said connector comprises an inner connector and an outer connector, said inner and outer connectors being separated by a channel for liquid, wherein said drainage structure is present in said inner connector.

22. A method of using a urinary catheter, said method comprising the steps of:

- providing a kit of parts as in any of claims 16 to 18;
- 15 - removing the urinary catheter assembly in a storage condition from the storage package
- releasing the connector and handle from each other to form the use condition;
- draining fluid from the cavity
- inserting the urinary catheter into the urethra for draining urine from the bladder by advancing the catheter proximally out through the proximal end of the handle by squeezing the handle into contact with the catheter surface
- 20 - removing the urinary catheter from the urethra
- retracting the sleeve over the catheter to cover a majority of the longitudinal extent of the catheter and reclosing the sleeve

25

23. The method as in claim 22 further comprising re-storing the catheter assembly in a storage package and re-sealing the storage package.

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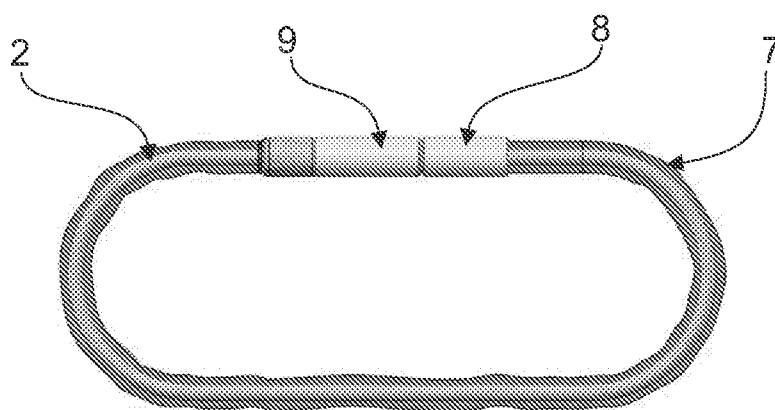
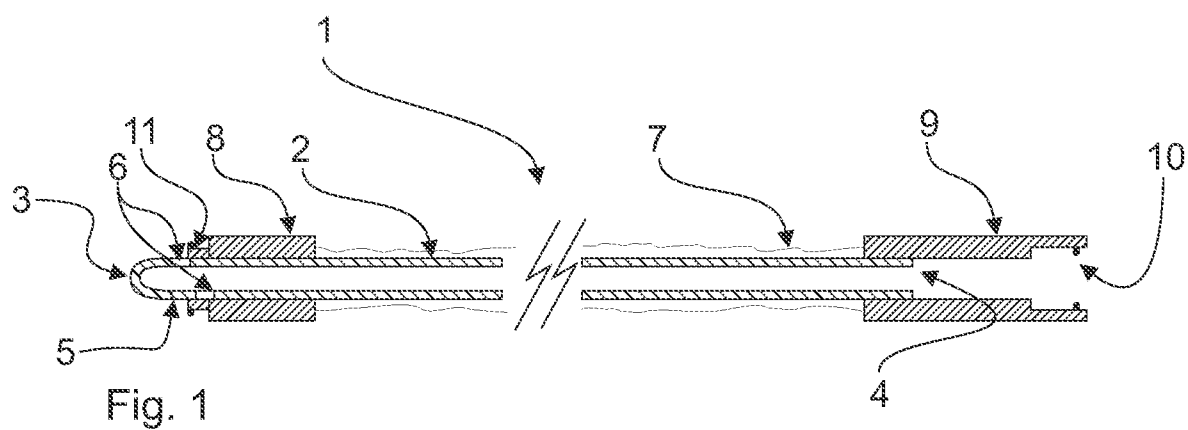


Fig. 2

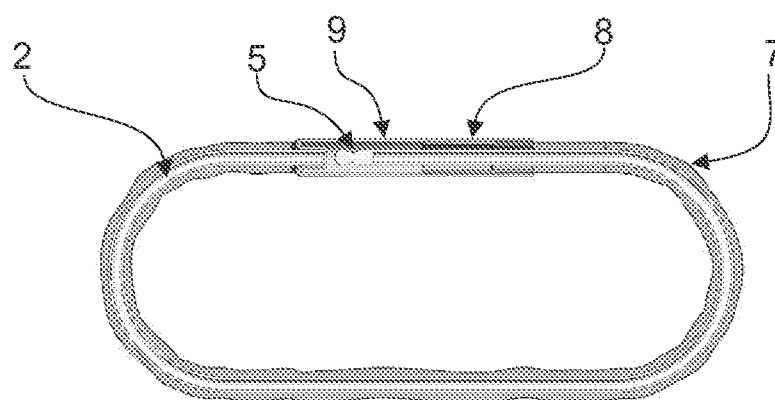
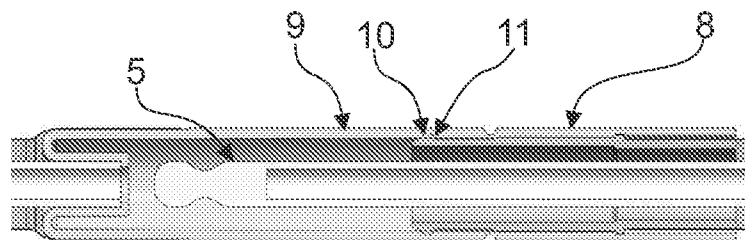
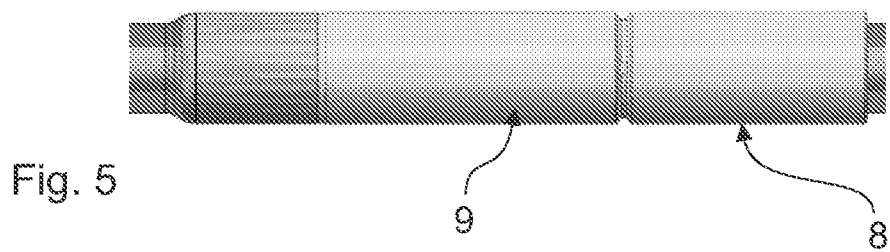
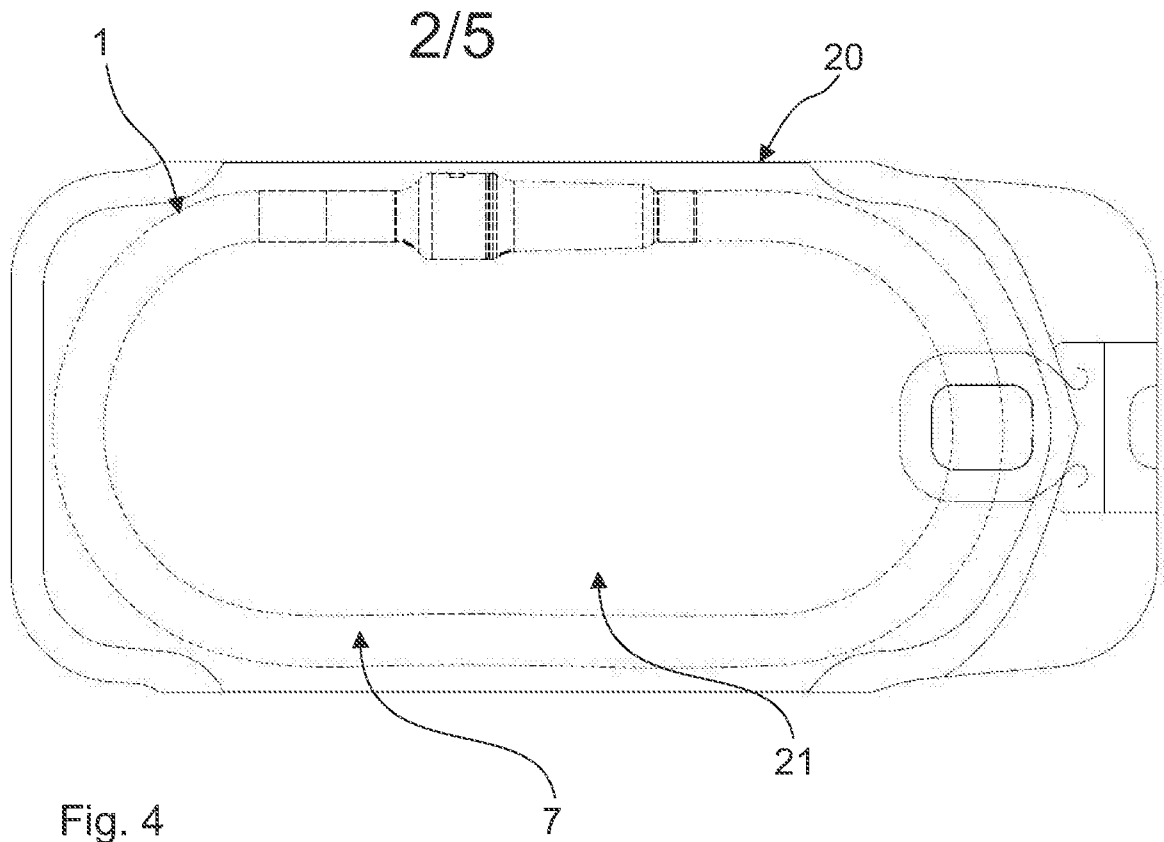


Fig. 3



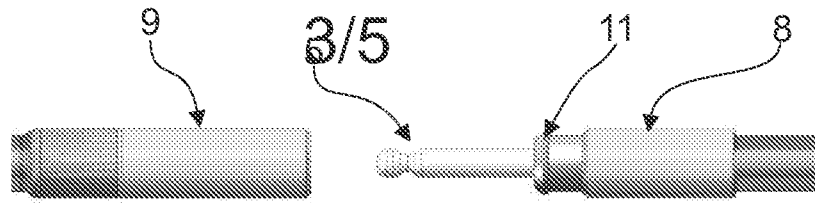


Fig. 7

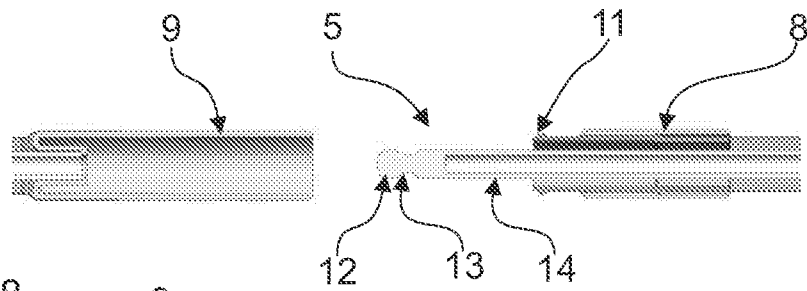


Fig. 8

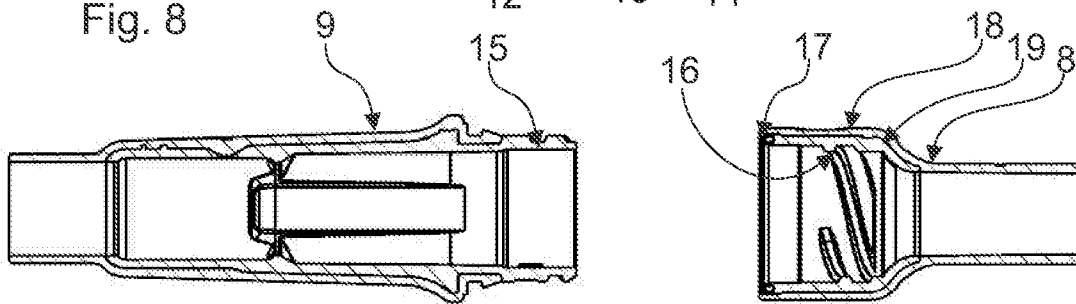


Fig. 9

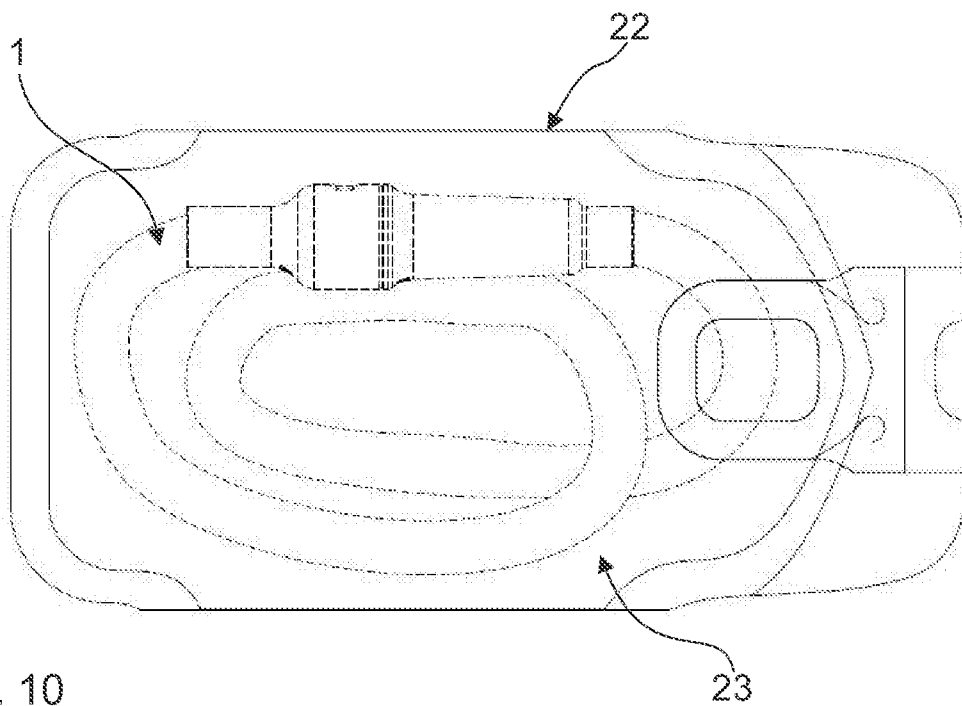


Fig. 10

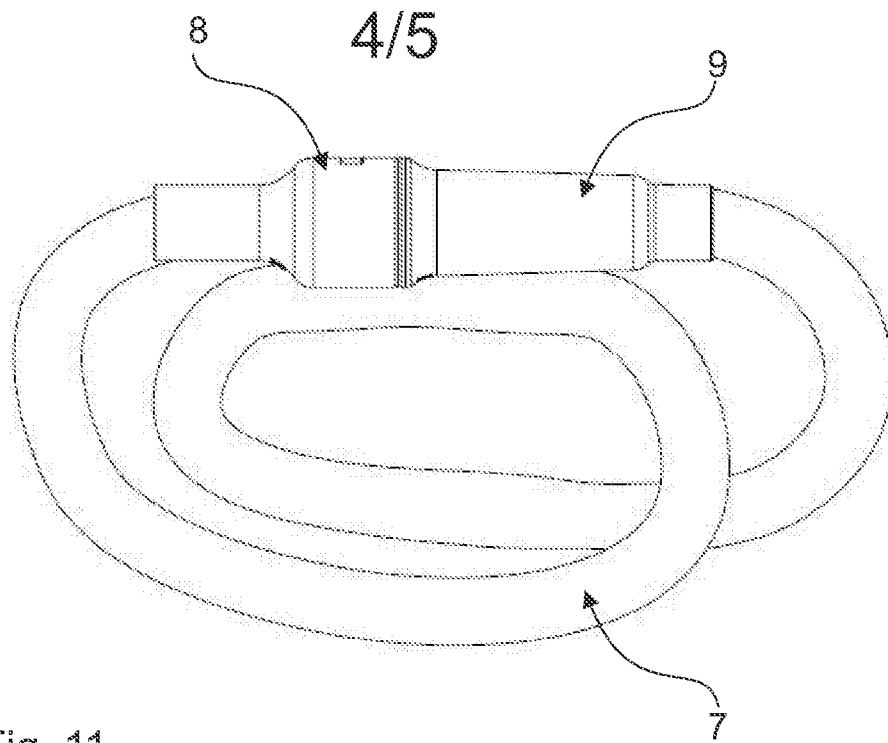


Fig. 11

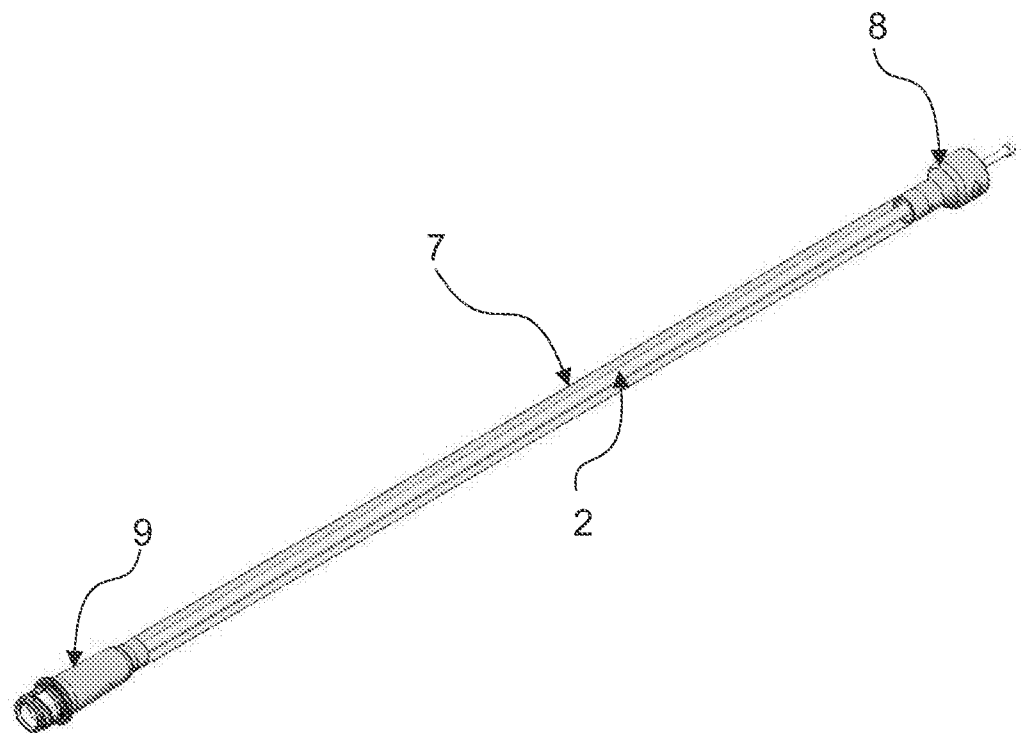


Fig. 12

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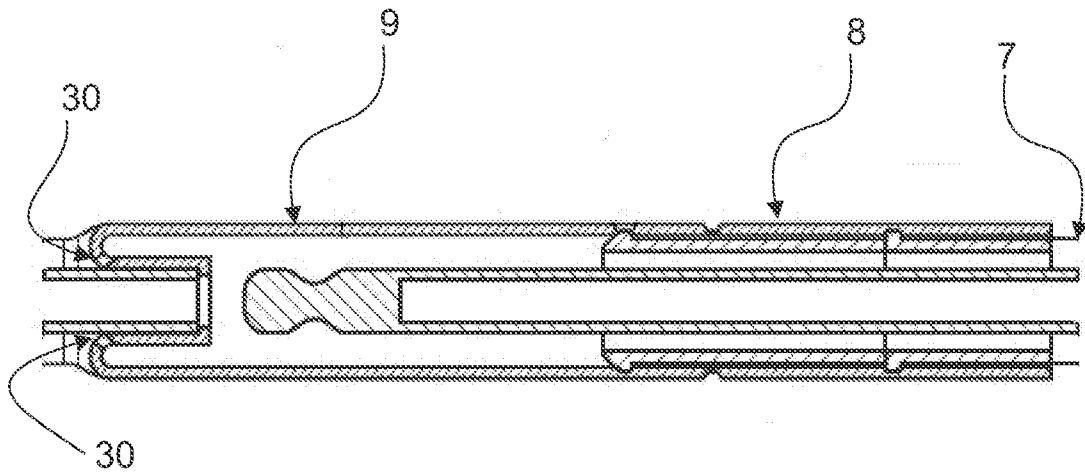


Fig. 13

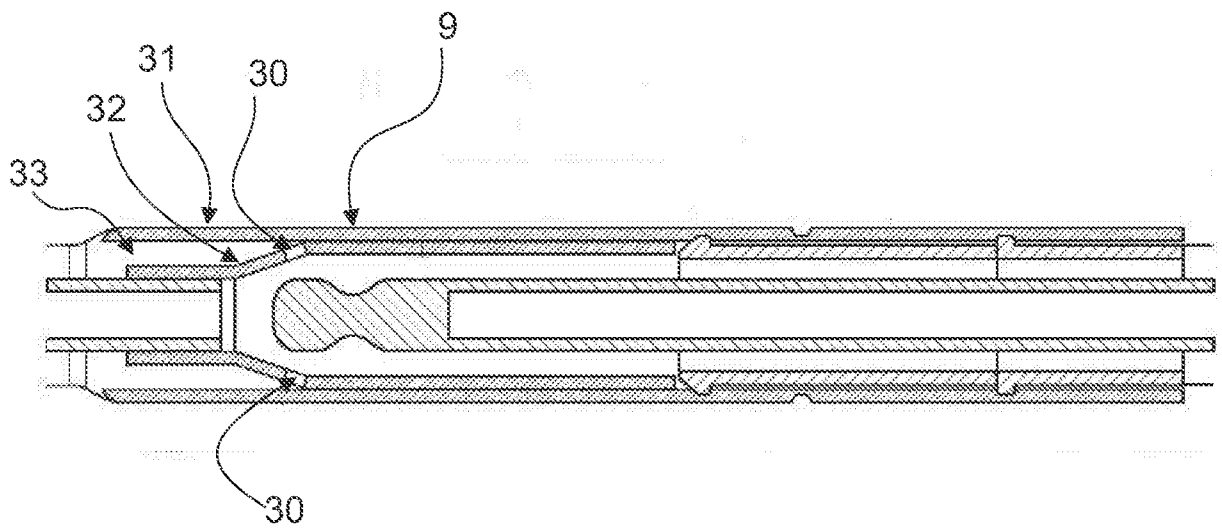


Fig. 14

INTERNATIONAL SEARCH REPORT

International application No

PCT/DK2016/050222

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M25/00 A61M25/01
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2007/106431 A2 (COLORADO CATHETER COMPANY INC [US]; HOUSE JAMIE GLEN [US]) 20 September 2007 (2007-09-20) paragraph [0042] - paragraph [0046] figures 1A-1C	1-7,10, 11,13-18
A	----- paragraph [0042] - paragraph [0046] figures 1A-1C	8,9,12
Y	GB 2 007 507 A (CHICAGO REHABILITATION INST) 23 May 1979 (1979-05-23) page 1, line 1 - page 2, line 79 figures 1-6	1-7,10, 11,13-18
A	----- WO 2013/049733 A2 (SPARKMED RES LLC [US]) 4 April 2013 (2013-04-04) page 13, paragraph second figure 2	1
	----- -/-	



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

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"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

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Date of the actual completion of the international search

19 September 2016

Date of mailing of the international search report

27/09/2016

Name and mailing address of the ISA/

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Authorized officer

Amaro, Henrique

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK2016/050222

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

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

1. ☒ Claims Nos.: 19-23
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/DK2016/050222

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/144920 A1 (SAMUELS SHAUN L W [US]) 10 October 2002 (2002-10-10) paragraph [0020] figures 1-3 -----	1
A	US 2011/230864 A1 (HOUSE JAMIE GLEN [US]) 22 September 2011 (2011-09-22) paragraph [0035] figures 1A,1B -----	3
A	WO 2014/142917 A1 (HOLLISTER INC [US]) 18 September 2014 (2014-09-18) paragraph [0064] figures 1,2 -----	4
A	US 2014/262859 A1 (KNAPP TRACEY E [US] ET AL) 18 September 2014 (2014-09-18) figure 5 -----	10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/DK2016/050222

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