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(54) Titre : CONDITIONNEMENT POUR CATHETER URINAIRE
(54) Title: A PACKAGE FOR A URINARY CATHETER

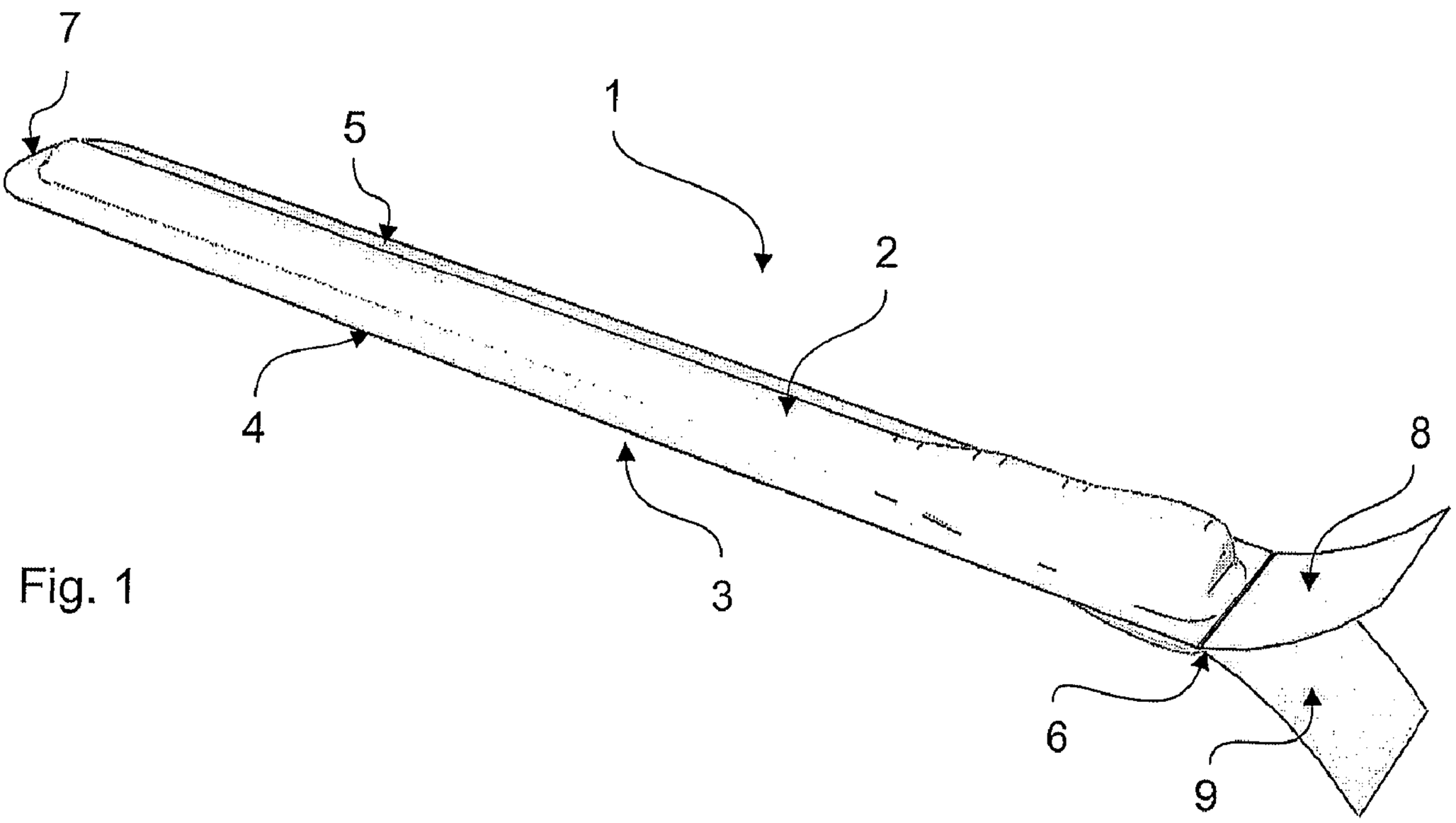


Fig. 1

(57) Abrégé/Abstract:
A package including an intermittent urinary catheter and a protective sleeve is provided. The protective sleeve is adapted to cover the surface of the catheter prior to use, thereby preventing contamination of the surface. The protective sleeve is compressed in a storage-position, and in a use-position it is extended to cover most of the insertable length of the catheter. In the compressed state, the urinary catheter may be wetted if the catheter is provided with a hydrophilic coating. The protective sleeve may be made of flexible material, which may be folded or pre-folded into a concertina-like configuration. A package which includes an intermittent urinary catheter with a protective sleeve is provided. An assembly, which includes a package with an intermittent urinary catheter, and a compartment containing a fluid medium, is provided. Finally, a method for wetting an intermittent urinary catheter including a protective sleeve is provided.

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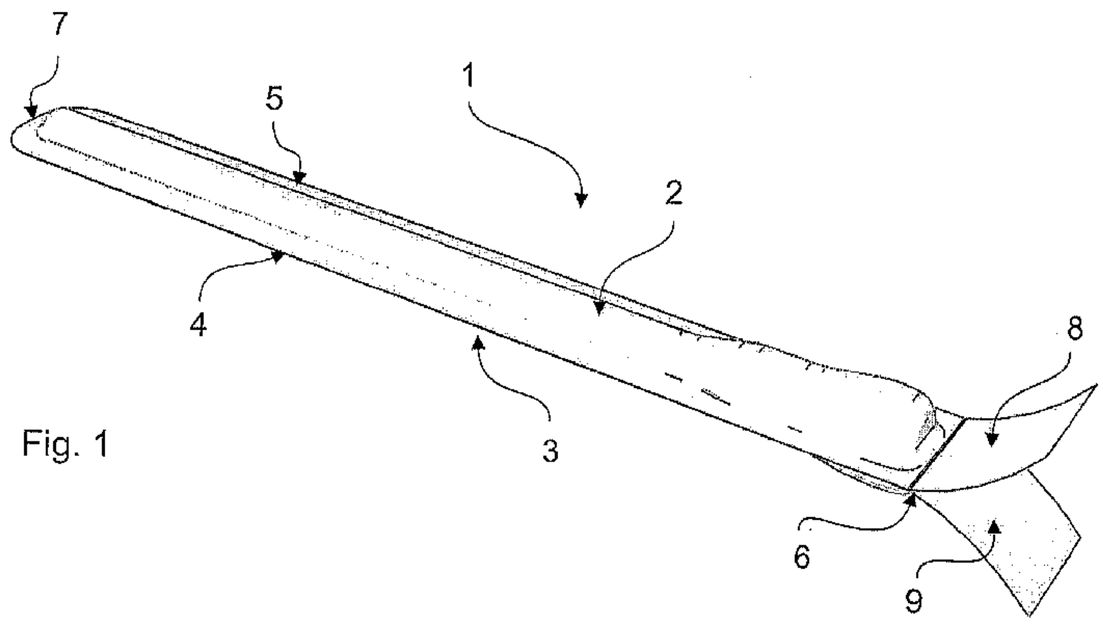


Fig. 1

(57) Abstract: A package including an intermittent urinary catheter and a protective sleeve is provided. The protective sleeve is adapted to cover the surface of the catheter prior to use, thereby preventing contamination of the surface. The protective sleeve is compressed in a storage-position, and in a use-position it is extended to cover most of the insertable length of the catheter. In the compressed state, the urinary catheter may be wetted if the catheter is provided with a hydrophilic coating. The protective sleeve may be made of flexible material, which may be folded or pre-folded into a concertina-like configuration. A package which includes an intermittent urinary catheter with a protective sleeve is provided. An assembly, which includes a package with an intermittent urinary catheter, and a compartment containing a fluid medium, is provided. Finally, a method for wetting an intermittent urinary catheter including a protective sleeve is provided.

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A package for a urinary catheter

This application concerns the provision of a protective sleeve to be used in connection with an intermittent urinary catheter. The catheter with the protective sleeve is wrapped in a package prior to use. The protective sleeve is adapted to cover the surface of the catheter immediately prior to use. Thereby the surface will not be contaminated.

Background

Urinary catheters are widely used for intermittent catherisation, particularly in connection with operative procedures, where the caregiver is performing the intermittent catherisation, and in connection with spinal cord injuries, where the user is left without control of the bladder. In order to reduce the risk of damage to the urethral wall, the catheters are typically coated with a coating imparting an extremely low friction on the surface of the catheters. This coating is normally activated by applying a fluid medium (for example tap water or sterilised water) to the coating – either in the production stage or prior to use.

Some users of catheters often experience Urinary Tract Infections (UTI). 30% experience more than 3 UTIs per year and 10% experience more than 6 UTIs per year.

To reduce risk of infection, the urinary catheter as well as the fluid medium may be sterilised. Furthermore, the surface of the urinary catheter should preferably remain uncontaminated prior to use.

Protective sleeves that cover the surface prior to insertion may be used. Such a protective sleeve enables the user to hold the urinary catheter without it slipping due to the coating and without contaminating the sterilised surface. An example of such an insertion is shown in WO07/050685 relating to a pre-wetted intermittent catheter apparatus that includes a collapsible container with a conduit positioned as well as a wetting fluid. The conduit has a lubricious coating disposed thereon, such that the coating is hydrated upon contact with the wetting fluid in the container, providing a slippery surface for the conduit, which facilitates introduction of the conduit into a user.

Summary of the Invention

The invention relates to a package including an intermittent urinary catheter. A protective sleeve is attached at a distal end to the intermittent urinary catheter. The protective sleeve is used to cover the surface of the catheter prior to use so that a user can use this for holding the catheter. Thereby contamination of the surface is prevented. The protective sleeve has two positions: a compressed position that allows wetting of the urinary catheter, and an extended position that covers the surface of the urinary catheter. The urinary catheter is stored in a package and the proximal end of the protective sleeve is attached to the package by a weak attachment. Thereby when the user has wetted the catheter immediately prior to use, the user grips the connector of the catheter at the distal end and pulls it out of the package. As the proximal end of the protective sleeve is attached to the package, the protective sleeve will be pulled out over the catheter to an extended position where it covers the surface of the urinary catheter.

The invention also concerns an assembly including a package with an intermittent urinary catheter and a compartment for a fluid medium, and a method for wetting an intermittent urinary catheter including a protective sleeve.

Detailed Description of the Invention

In a first aspect, the invention relates to a package comprising a urinary catheter comprising

- a proximal end and a distal end
- a protective sleeve adapted to be compressed into a storage-position when the catheter is stored, and to be extended into a use-position to cover most of the surface of the catheter, when the catheter is to be used
- where the distal end of the protective sleeve is attached to the distal end of the catheter and the proximal end of the protective sleeve is attached to the package by a weak attachment
- where the attachment of the protective sleeve is such that when the catheter is removed from the package, the protective sleeve will pulled over a length of the catheter until the sleeve is extended, where-after the weak attachment between the sleeve and the package will break and the catheter including the sleeve can be completely removed from the package.

The package including the intermittent urinary catheter and the protective sleeve makes it possible to wet the catheter prior to use. After the wetting the catheter can be removed from the package and the protective sleeve will automatically be pulled down over the length of the catheter. This is due to the attachment between the catheter and the protective sleeve. When the sleeve is completely unfolded, further pulling at the catheter will cause the weak attachment between the sleeve and the package to break. Then the catheter including the protective sleeve can be removed completely from the package.

The urinary catheter comprises a proximal end and a distal end. It should be understood herein that by referring to the proximal end of an element or a part, reference is made to a side or a section of an element or a part, which is closest to the user (e.g. the person to whom the emptying of the bladder is performed) right before the catheter is inserted into the urethra. Likewise, the distal end is the end opposite the proximal end. In other words the proximal end corresponds to the tip end of the catheter and the distal end to the connector end.

In storage position, the protective sleeve is compressed in the length direction to be stored at the distal end of the catheter just below the connector. In use-position, the protective sleeve is pulled down over the catheter so that it covers most of the catheter.

Intermittent urinary catheters are well-known in the art. An example of a urinary catheter is a catheter provided as a tube that is made of Polyurethane (PU) or Poly Vinyl Chloride (PVC), and which is provided with a connector in one end. In the opposite end (the tip end), the catheter is provided with one or more eyelets that let urine enter into the tube. For a male catheter the insertable length is 250-300 mm and for a female catheter the insertable length is between 60-130 mm. The insertable length corresponds to the length of the tubular element except for the 3-5 cm that are closest to the connector. This part of the catheter is uncoated because the catheter is coated by dipping. Furthermore, the uncoated part enables welding or gluing of the connector to the catheter.

The urinary catheter may comprise a hydrophilic coating at the surface thereof. The entire surface or part of the surface may be coated, depending on how the catheter is used.

The protective sleeve ensures the grip on the intermittent urinary catheter because the surface of the device is very slippery due to the coating. Without a protective sleeve, the urinary catheter would be difficult to hold securely.

Intermittent urinary catheters are advantageously provided with a slippery coating, such as a hydrophilic coating, to avoid stressing of the internal surface of the urethra. Furthermore, UTIs are a major problem, which is why it is important to keep urinary catheters as sterile as possible.

In storage-position the catheter and sleeve is stored dry – there is substantially no free liquid in the package. Prior to use, the catheter must be wetted to activate a hydrophilic coating provided on the catheter. The wetting is done using a fluid medium, which may also be stored in the package or provided as an extra compartment to the package. During wetting of the catheter, the protective sleeve will not be wetted because it is placed in a compressed condition near the connector. Only the coated part of the catheter below the connector is to be wetted. Thus, when the catheter has been wetted the sleeve is still dry and easy to hold. Thereby the user will avoid getting his/her hands wet from the fluid medium.

The distal end of the protective sleeve corresponds to the end where the protective sleeve is attached to the connector. The proximal end of the protective sleeve corresponds to the opposite end. The protective sleeve is attached to the connector or urinary catheter in the connector end. The attachment may be done by welding or gluing or by attaching a heat shrinking foil around the protective sleeve. The proximal end of the protective sleeve is attached to the inside of the package by a weak attachment, such as a string or a weak adherence. It may also be attached by welding the protective sleeve to the package, and then providing it with a weak tearing line (for example perforated) next to the welding. In that way, the protective sleeve will separate from the package at the tearing line.

The protective sleeve may comprise a foldable material so that the protective sleeve in a storage-position is folded, and in a use-position the folds are straightened. The protective sleeve may also be pre-folded into a concertina pleated configuration. The pre-folded configuration may be made in a material without any particular demand for flexibility. If the material has no pre-folds and needs to be folded, then the material needs certain flexibility.

The length of the compressed protective sleeve in a storage-position may be approximately 20 mm. The length in the compressed state should be less than the uncoated part of the urinary catheter. If the protective sleeve were compressed into this length then all of the insertable length would be able to be wetted by the fluid medium.

In an embodiment, the length of the extended protective sleeve in a use-position corresponds to at least ¾ of the insertable length of the catheter. The length of the protective sleeve in the extended state should be long enough to minimize the risk of contamination of any part of the outer surface when touched upon. On the other hand, the larger the part of the surface that is covered by the protective sleeve, the lesser the risk of contamination if the surface is accidentally in touch with an object, for example a sink or a towel in the near vicinity of the user.

The largest width of the protective sleeve is preferably between 1 and 15 mm larger than the diameter of the urinary catheter. The lower limit leaves enough room surrounding the swelled coating of the catheter, so that the coating is not disturbed by the protective sleeve. The catheter, including the protective sleeve, should, however, not take up too much space. Therefore, over sizing the protective sleeve with respect to the catheter should be limited. Furthermore, the urinary catheter may be difficult to hold if the protective sleeve is too big, particularly if the catheter is slippery due to the provision of a coating.

The material may be plastic foil such as polyethylene (PE) or polypropylene (PP) or coated paper. The list is not exhaustive. The protective sleeve is only adapted to cover the surface of the intermittent urinary catheter immediately prior to use. Thereby the protective sleeve need not be long-term impermeable. Likewise, the ends of the protective sleeve may be left open. The protective sleeve should not be too permeable because moisture and contamination from the hand should be prevented from permeating through the protective sleeve. However, there is no need for a complete impermeability, because it is only used while the urinary catheter is inserted, that is for a few minutes. This means that many types of material are suited for the purpose, because the only requirement is that the material has to be foldable into a compressed state and from there be extendable with relative ease.

The package may be made of a foil, which is welded along the sides. For this purpose, materials like Poly-Ethylene-Tere-Phtalate (PETP), PETP including a thin layer of aluminum, Low-Density Poly-Ethylene (LDPE), High-Density Poly-Ethylene (HDPE), PP, Poly-Vinyl-Chloride (PVC), Poly-Amide (PA), Amorphous Polyester (PET) and surface-treated paper are suitable.

The urinary catheter may be sterilized prior to packing and then packed in a sterile package. Then the catheter is completely sterile when it exits the package, thereby reducing the risk of getting infected when used.

An aspect of the invention relates to an assembly for wetting an intermittent urinary catheter that comprises a compartment for containing a fluid medium and a package for containing the catheter, wherein the compartment and the package are separate elements joined together, where the compartment comprises an outlet and the package an inlet for the fluid medium, where the package is as described earlier.

The assembly comprises a package and a compartment, which are two separate parts, but attached together. Prior to use the fluid medium is stored in the compartment. The package comprises an inlet and the compartment comprises an outlet for the fluid medium. Prior to use, in a storage-position, the outlet and the inlet are not in contact with each other. When the urinary catheter is ready to be used (the assembly is in a use-position) the outlet and inlet are in contact with each other. In the use-position, the fluid medium is able to flow from the compartment and into the package and wet the surface of the catheter that is stored in the package.

Having the compartment and the package as separate elements but attached together, has the effect that the compartment can be produced at one location and the package at another location. The package and the compartment may also be sterilised separately.

With the assemblies it is possible to wet only a part of the intermittent urinary catheter corresponding to the insertable length. Thereby the top part of the device is left dry and less slippery and may be used for holding the device.

Keeping the two parts separate may also be an advantage, because leakage from the liquid-holding compartment would not interfere with the urinary catheter during storage.

Furthermore, if the compartment were entered into the package including the catheter, contamination, which may be present on the outside of the compartment, would enter into the package. Thereby the catheter may be contaminated.

The compartment may be made as a foil-element similar to the package. Such an element may be made of materials such as aluminium, PETP, LDPE, HDPE, PP, PVC, PA, PET and surface- treated paper. When the package and compartment are made of foil-elements, they are easy to pack and store, because they only take up as much room as the amount of fluid or the urinary catheter demands. In some embodiments, the compartment needs to be able to be squeezed to get the fluid out of the compartment. In such embodiments, foil-elements are also advantageous.

The fluid medium may be water or a saline-solution, for example physiological 0.9% saline-solution. In an embodiment, the fluid may include an anti-microbial such as hydrogen peroxide. Using hydrogen peroxide provides an anti-microbial effect, which helps prevent infections to the intermittent urinary catheter.

Hydrogen peroxide is known to have an anti-microbial effect. It is also known to decompose easily. Hydrogen peroxide reacts with reduced transition metal ions, such as iron (II) and copper (I). It decomposes by the Fenton reaction to form the highly reactive hydroxyl radical. Apart from destroying hydrogen peroxide, and therefore reducing the shelf-life of a product that comprises hydrogen peroxide, hydroxyl radicals from the Fenton reaction may potentially damage a polymer coating. This could be a hydrophilic coating in particular, by way of its reaction with various components of the coating system. Contamination of water with transition metal ions takes place for example by storing the water in steel tanks or in glasses. Even in water that is purified, for example by ion exchange, trace amounts of transitional metal ions are still present. Thus, a polymer coating that comprises a liquid with hydrogen peroxide may generally be considered unsuited for long-time storage.

Another aspect relates to a method of wetting an intermittent urinary catheter including a protective sleeve using a package as described earlier, wherein the method comprises

- wetting the catheter below the compressed protective sleeve;
- extending the protective sleeve to cover the catheter.

Such a method enables wetting of a urinary catheter, which is stored in a dry condition. It also enables the use of a protective sleeve, such that the surface of the catheter is left uncontaminated. 'Below the compressed protective sleeve' means the length of the catheter between the protective sleeve and up to and including the tip portion.

Brief Description of the Drawing

Figure 1 illustrates an intermittent urinary catheter packed in a package.

Figure 2 illustrates the package as it is opened.

Figure 3 illustrates the open package showing the catheter within it.

Figure 4 illustrates the catheter including the protective sleeve.

Figure 5 illustrates the protective sleeve in an extended state.

Detailed Description of the Drawing

Figure 1 illustrates a package **1** that includes an intermittent urinary catheter. The package comprises two layers of foil **2** and **3** that is welded together along the sides **4**, **5** and at the top **6** and the bottom **7**. The package **1** further includes two flaps **8**, **9** for opening the package by peeling the foils **2**, **3** from each other. Figure 2 illustrates the opening of the package **1** showing the catheter **10** inside it, and figure 3 illustrates the package with one of the foils completely removed. Figure 4 illustrates the catheter **10** as it has been completely removed from the package. The catheter **10** comprises two ends, a tip end **11** and a connector end **12**, where a connector **13** is attached to the catheter **10** at the connector end **12**. Typically, the connector **13** is attached by welding it to the outside of the tubing **14** constituting the catheter **10**. The tip end **11** comprises the tip **15** in form of a closing of the tubing **14**. The tip **15** includes eyelets **16** for letting urine flow into the tubing **14** and then out through the connector **13**. This figure also clearly illustrates the protective sleeve **17** in the compressed state where it is entirely folded back towards the connector **13**. When the surface of the catheter **10** corresponding to the insertable length is wetted, the protective sleeve **17** may be moved to the extended position as illustrated in figure 5. In this position, the protective sleeve **17** covers most of the insertable length of the catheter. Thereby, the risk of accidentally touching the sterile surface is reduced. When the catheter **10** is to be used, the user grabs the catheter **10** somewhere along the extended protective sleeve and inserts the tip into the urethra. The protective sleeve **17** is able to be folded back at the same time as the catheter **14** is advanced into the urethra.

Claims

1. A package comprising a urinary catheter comprising
   - a proximal end and a distal end
   - a protective sleeve adapted to be compressed into a storage-position when the catheter is stored, and to be extended into a use-position to cover most of the surface of the catheter, when the catheter is to be used
   - where the distal end of the protective sleeve is attached to the distal end of the catheter and the proximal end of the protective sleeve is attached to the package by a weak attachment
   - where the attachment of the protective sleeve is such that when the catheter is removed from the package, the protective sleeve will pulled over a length of the catheter until the sleeve is extended, where-after the weak attachment between the sleeve and the package will break and the catheter including the sleeve can be completely removed from the package.

2. A package according to claim 1, wherein the catheter comprises a hydrophilic coating at a surface thereof.

3. A package according to any preceding claims, wherein the protective sleeve comprises a foldable material, and where the protective sleeve in a storage-position is folded, and in a use-position the folds are straightened.

4. A package according to any preceding claims, wherein the protective sleeve is pre-folded into a concertina pleated configuration.

5. A package according to any preceding claims, wherein the length of the compressed protective sleeve in a storage-position is approximately 20 mm.

6. A package according to any preceding claims, wherein the length of the extended protective sleeve in a use-position corresponds to at least ¾ of the insertable length of the catheter.

7. A package according to any preceding claims, wherein the largest width of the protective sleeve is between 1 and 15 mm larger than the diameter of the catheter.

8. An assembly for wetting an intermittent urinary catheter comprising a compartment for containing a fluid medium and a package for containing the catheter, wherein the compartment and the package are separate elements joined together, where the compartment comprises an outlet and the package an inlet for the fluid medium, where the package is according to any of claims 1 to 7.

9. An assembly according to claim 8, wherein the fluid medium comprises hydrogen peroxide.

10. A method of wetting an intermittent urinary catheter including an protective sleeve using a package according to claims 1 to 7, wherein the method comprises
    a. wetting the catheter below the compressed protective sleeve;
    b. extending the protective sleeve to cover the catheter.

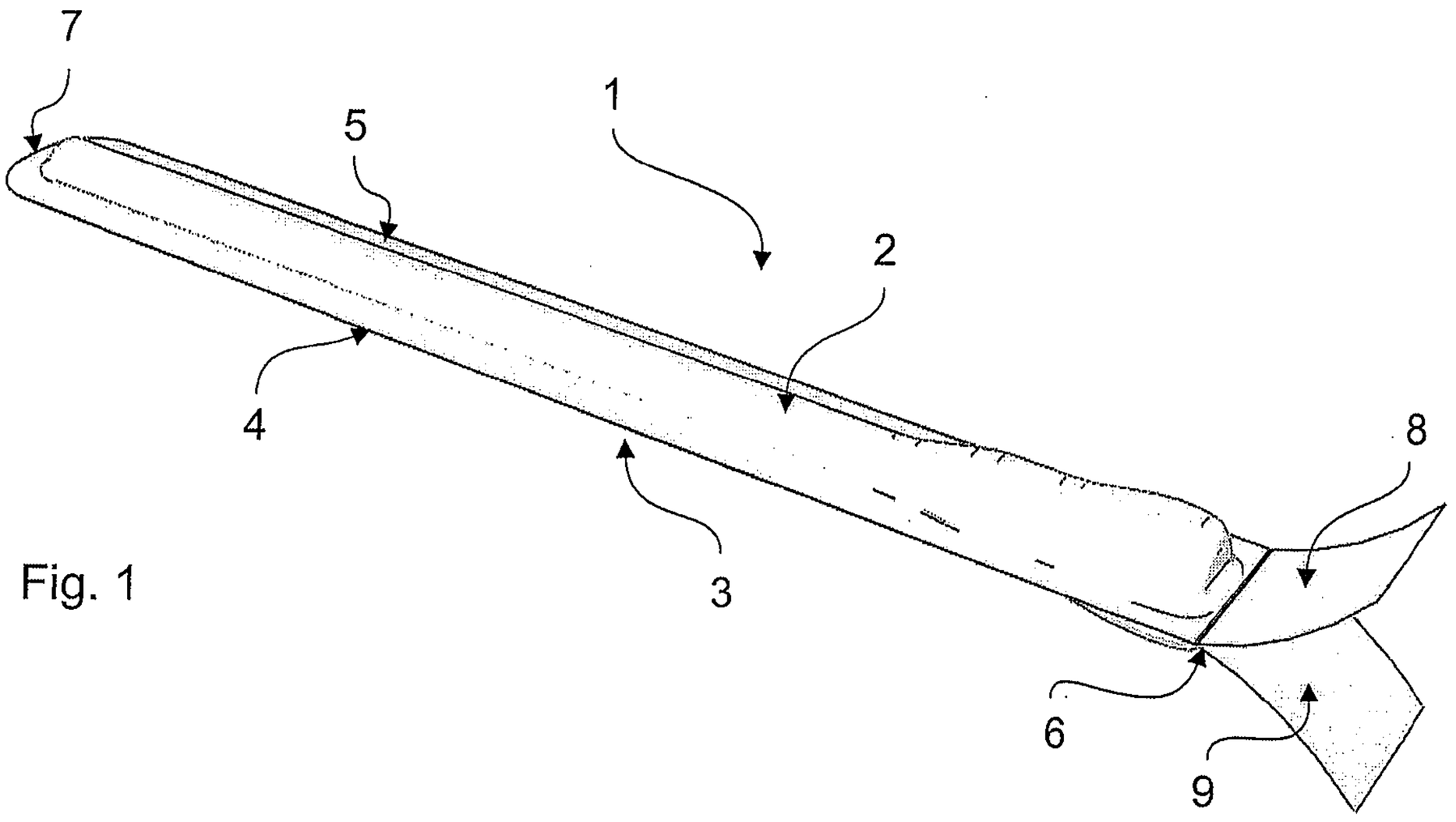


Fig. 1

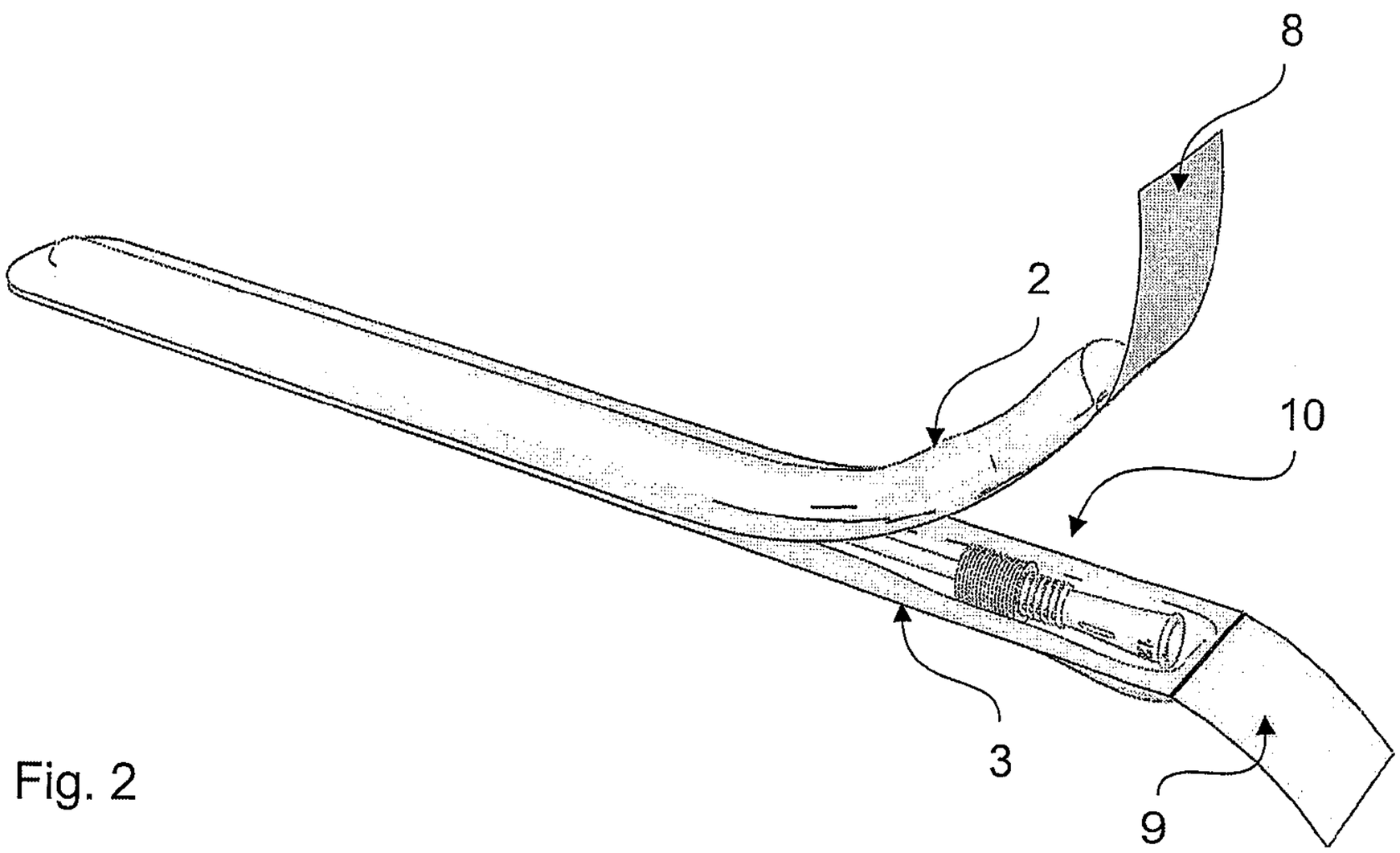


Fig. 2

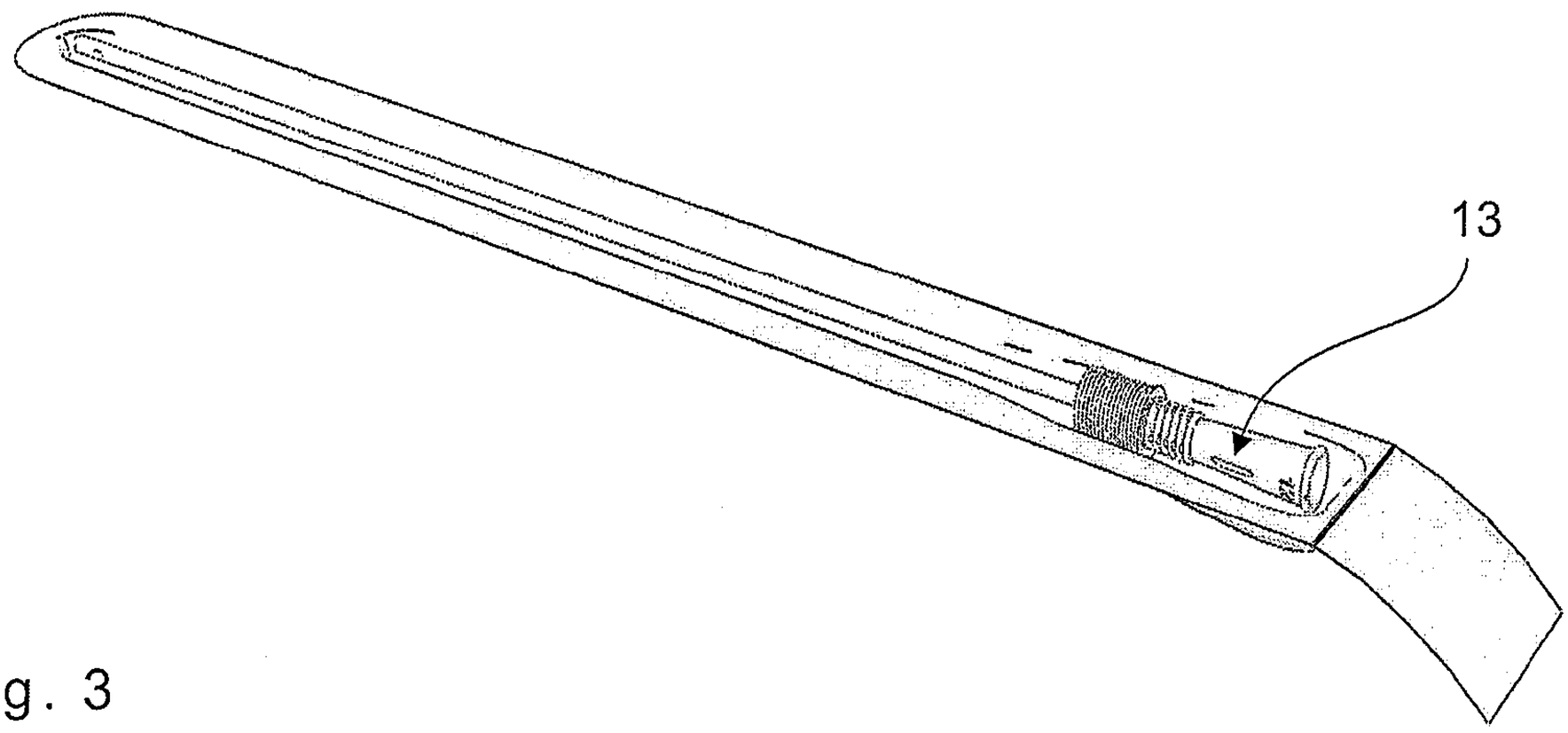


Fig. 3

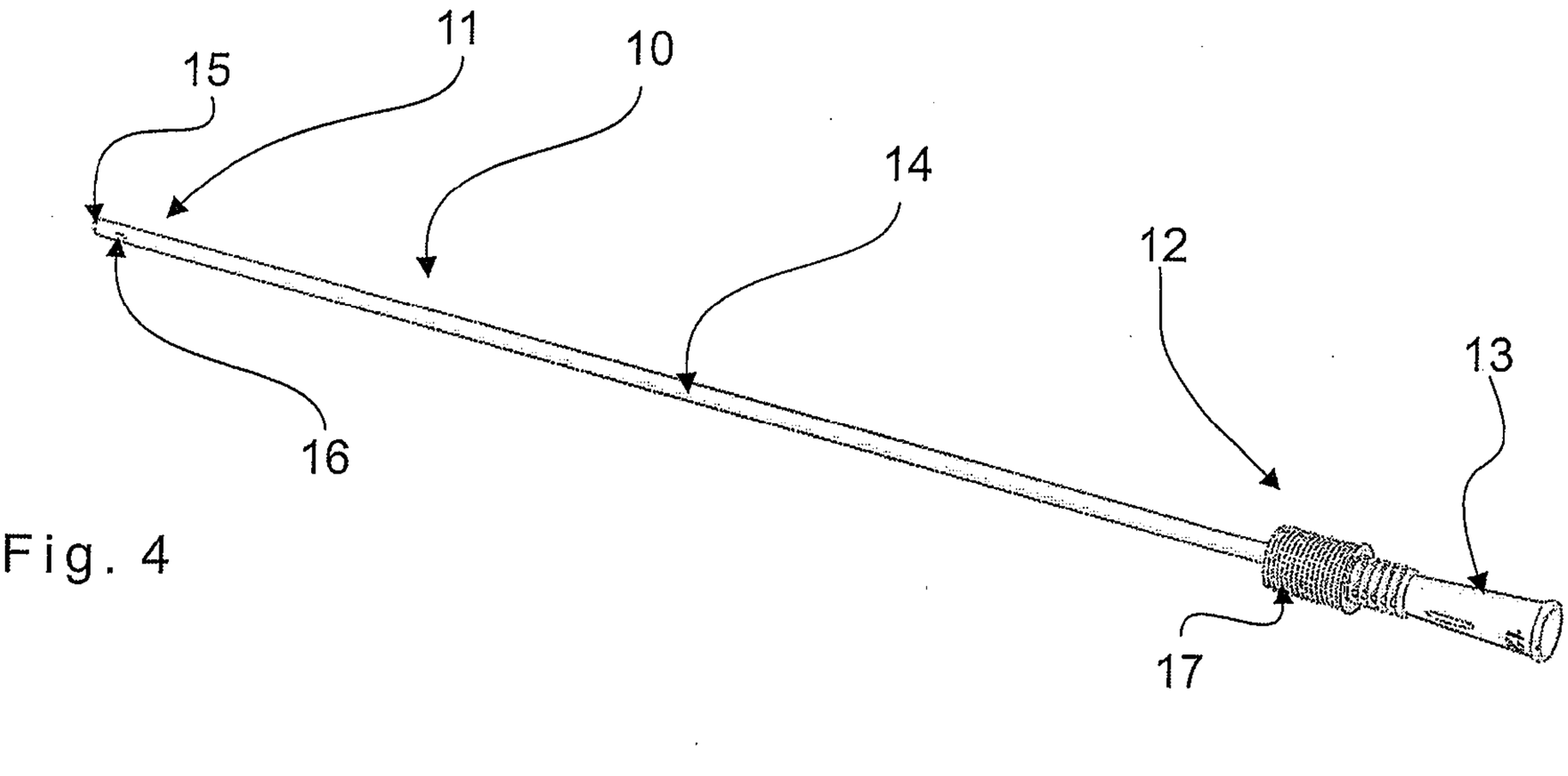


Fig. 4

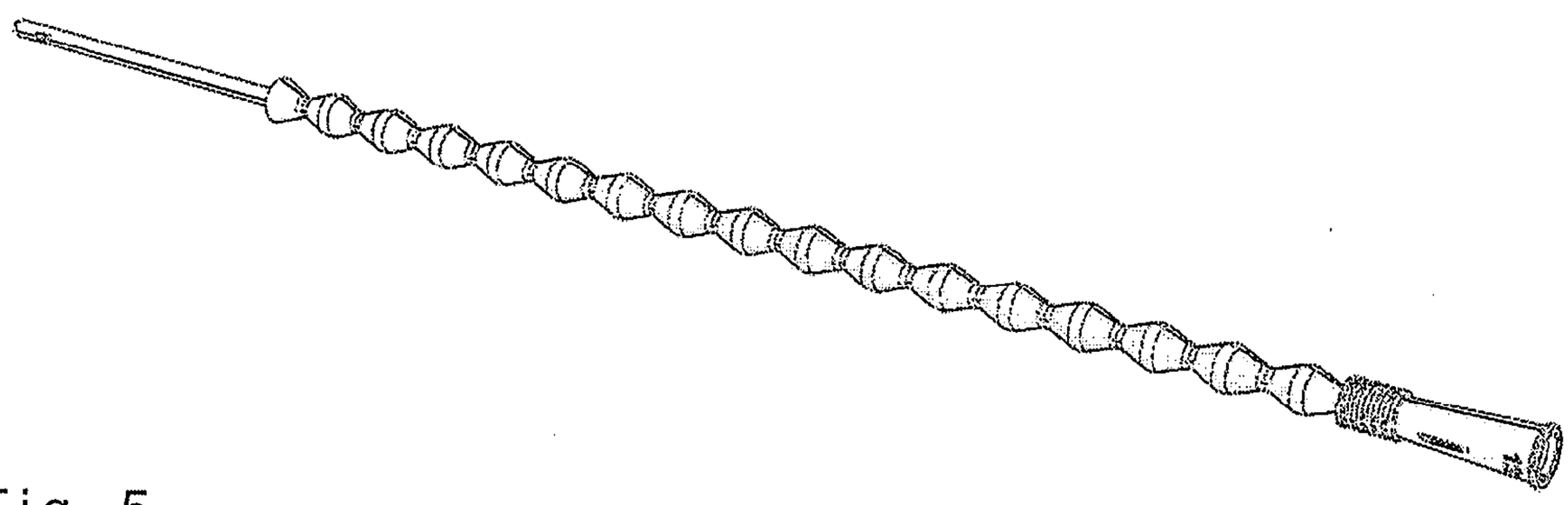


Fig. 5

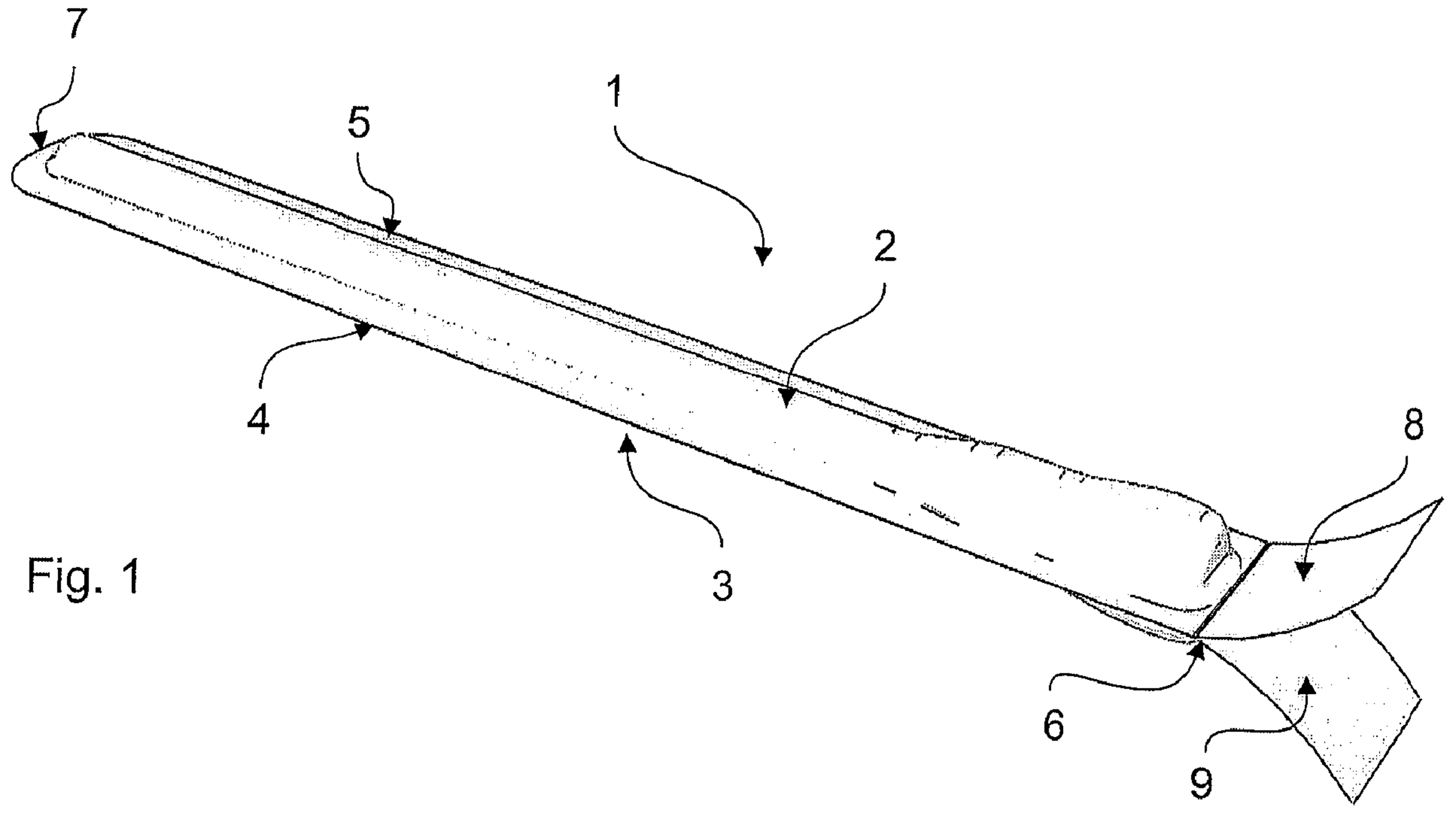


Fig. 1