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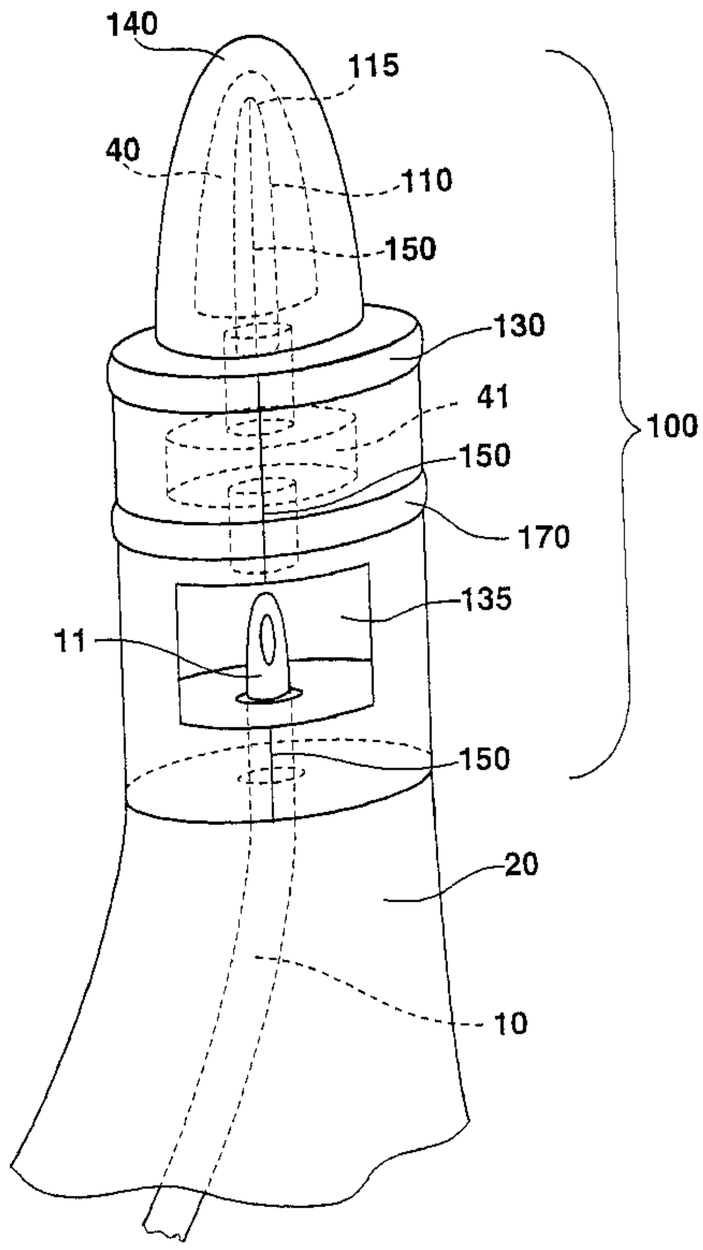

(57) Abrégé/Abstract:
Disclosed is a catheter application system comprising preferably a permanently applicable urinary catheter that is provided with a catheter tip, a hollow envelope in which the catheter is slidably disposed, and an insertion aid located at the distal end of the envelope. Said insertion aid is designed such that the catheter can be passed therethrough. The insertion aid encompasses insertion aid parts, i.e. an insertion sleeve with a closing element that can be opened for passing the catheter through, and a stop element which preferably extends outside the envelope and limits insertion of the insertion sleeve into an orifice. The insertion sleeve and/or the stop element are embodied as splittable insertion aid parts so as to be removable from the catheter once the catheter has been passed through.

Abstract

The invention proposes a catheter application system comprising preferably a urinary catheter for long-term application, comprising a catheter tip, a hollow sheath in which the catheter is slidably disposed, and an insertion aid at the distal end of the sheath. The insertion aid is provided for passage of the catheter through it. The insertion aid comprises insertion aid components, namely an insertion sleeve provided with a sealing element which can be opened for passage of the catheter, and a stop element extending preferably outside the envelope and limits insertion of the insertion sleeve into an orifice. The insertion sleeve and/or the stop element are formed as splittable insertion aid components in such a way that said insertion aid components are removable from the catheter after its passage.

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CATHETER APPLICATION SYSTEM

The invention relates to a catheter application system, in particular, for introducing a urinary catheter into the urethra. The catheter system has an insertion sleeve to facilitate introduction of the catheter, wherein the catheter remains a sterile as possible when introduced and, in particular, no microorganisms are imported from the anterior section of the urethra into the bladder.

Catheters are used for diagnosis and treatment purposes, e.g., for suprapubic bladder drainage or urine elimination via the urethra. The catheters are supplied by the manufacturer in sterile packages ready for application. Prior to the application of a catheter, the area around the body orifice into which the catheter is to be introduced is washed and disinfected. However, absolute disinfection is practically impossible to achieve, in particular with respect to the urethral orifice and the anterior section of the urethra. Microbial contamination always lingers, especially in the anterior section of the urethra adjacent to the orifice, so that the sterile catheter must traverse a non-sterile area when introduced into the urethra. Microorganisms must be prevented from spreading from this urethral area into the bladder or posterior urethral areas to the greatest extent possible. Special precautions must therefore be taken during introduction, particularly in the case of long-term catheters, which remain in place for several days.

It is known that sliding friction can be reduced during catheterization by wetting the outer surface of the catheter with a liquid, e.g., a lubricant or an aqueous saline solution, so that the catheter can be introduced into a hollow organ of the human body causing as little pain as possible and without triggering further irritations. This can also be accomplished with other coatings to improve sliding characteristics. A hydrophilic outer surface over the length of the catheter shaft is also frequently used for this purpose, and is activated by means of an aqueous liquid prior to catheter application. Water molecules bind to the hydrophilic surface when the surface is wetted with water. This yields a soft, smooth surface that enables comfortable introduction of the catheter. These embodiments have in the past been proven effective in preventing discomfort during introduction and application of a catheter.

It is also known to provide both the inner surface and the outer surface with an

anti-microbial coating, e.g., a coating of silver, to reduce bacterial adherence.

The documents DT 2456980 Al, US 3,421,509 and US 4,652,259, disclose catheter application systems with an insertion sleeve for urethral catheters, which is introduced into the anterior area of the urethra infected with bacteria until a stop element, e.g., a ring, restricts the introduction of the insertion sleeve into the urethra. After the insertion sleeve has been introduced into the urethra, a catheter can be pushed through the insertion sleeve. The catheter opens a slit at the distal end of the insertion sleeve, and can then be advanced into the bladder. The insertion aid restricts the transport of microorganisms within the terminal urethra to a short distance and creates a sterile passage for introducing the catheter through the microbial contaminated area of the urethra.

Catheter application systems for intermittent catheterization in the prior art provide insertion aids that completely surround the catheter shaft like a ring, and consequently remain on the catheter after application of the catheter.

It is the underlying object of the invention to provide a catheter application system that avoids the disadvantages of prior art, which is particularly easy, quick and inexpensive to use, and which helps to avoid or reduce catheter-associated infections, in particular, urethral infections.

This object is achieved by the device of the independent claim. The dependent claims represent advantageous embodiments of the invention.

This object is achieved in accordance with the invention by providing a catheter application system with a catheter (urinary catheter) which can be applied preferably for long-term bladder drainage, comprising a catheter tip, a hollow sheath in which the catheter is slidably disposed, and an insertion aid at the distal end of the sheath. The sheath also guarantees primarily sterile packaging of the catheter and of the insertion aid components provided within the sheath. The insertion aid is adapted for passage of the catheter, wherein the insertion aid comprises insertion aid components, i.e. an insertion sleeve comprising a sealing element which can be opened for passage of the catheter, and a stop element, preferably extending outside of the sheath, for limiting insertion of the insertion sleeve into a body orifice. The sealing element is thereby preferably an integral component of the insertion sleeve. The insertion sleeve and/or the stop element are designed as splittable insertion aid components, so that they can be removed from the catheter when the catheter has passed through. The splittable insertion

aid components hence are formed as separate parts, and can therefore be removed from the catheter. Upon application, the catheter is guided through the insertion aid and therefore through the insertion aid components. The insertion aid components have a through hole. After passage of the catheter through the insertion aid, the insertion aid components surround the catheter like a ring. Splittable means that the insertion aid components of this embodiment can be taken apart into individual parts so that they no longer encompass the catheter after disassembly. The split insertion aid embodiment has the advantage that the insertion aid can be easily removed from the catheter without having to pass the entire catheter through the insertion aid which would e.g. not be possible if the urine bag was fixed to the catheter. This facilitates removal of the microbial contaminated insertion aid, or at least of the contaminated insertion sleeve, from the catheter following its application, making it possible to avoid an ascending infection.

After preparing the catheter application system according to the invention, the urinary catheter is applied by introducing the insertion sleeve, which is supported from inside by the catheter tip, into the anterior area of the urethra of the patient adjacent the orifice until the stop element prevents further insertion. The catheter is then passed through the insertion aid, catheter tip first, whereby the catheter tip opens the sealing element. The catheter is then advanced through the insertion aid until the catheter tip reaches the bladder of the patient. When the retaining system (balloon) of the catheter is locked, the insertion sleeve is pulled out of the patient's urethra, and the insertion sleeve, preferably the entire insertion aid, is disassembled by splitting it, so that it can be removed from the catheter.

In a further embodiment, the sealing element of the catheter application system has a perforation or cross-shaped slit, so that opening becomes possible by penetrating the perforation or cross-shaped slit while passing through the catheter. The advantage of the sealing element provided with a perforation or cross-shaped slit is that no additional parts are required to ensure penetrability of the sealing element, and that the sealing element retains its primarily closed tip shape.

The splittable insertion aid components each consist preferably of at least two segments which surround the introduced catheter like a ring when they are assembled. The segments hence each have an area adjacent to the through hole. In the simplest case, each of the splittable insertion aid components consists of

two symmetrical segments. For example, if the stop element is designed as a ring, each of its two segments constitutes half a ring. The advantage to the segmented embodiment is that a simple partition of insertion aid components ensures splittability. As a result, this embodiment is simple and inexpensive to manufacture.

The splittable insertion aid component segments may be held together at predetermined breaking lines, in particular perforations and/or adhesive tape and/or crepe tape. Particularly advantageous is an embodiment with interlocking elements, thereby obviating additional components for the inventive splittable insertion aid of the catheter application system. No additional production costs are incurred. In addition, catheter application is no more difficult than in the case of conventional catheters.

The insertion aid of the catheter application system, in particular the stop element, is preferably designed as a handle, wherein the handle preferably incorporates a through hole. The through hole can be formed on one or both sides. To this end, the stop element can be composed of several assembled parts. A bilateral through hole in the handle can be used to grip the catheter in the through hole as it is passed through the insertion aid, e.g., with two fingers, thereby facilitating catheter application. In a unilateral through hole, the catheter inside the handle can be pressed against the inside of the handle, e.g., with a finger of the person applying the catheter, and thereby be held fast.

The insertion aid preferably has a removable protective cover over the insertion sleeve. This protects the insertion sleeve against mechanical damage and keeps the insertion sleeve sterile. The protective cover can also simultaneously cover the surface of the stop element.

The catheter preferably has a hydrophobic/oleophobic outer surface and/or an antimicrobial, preferably silver coating, on its outer and/or inner surfaces.

The protective cover and/or insertion sleeve are each preferably filled with a liquid. In addition, the insertion aid can incorporate a liquid reservoir filled with liquid that can be penetrated by the catheter during its application. These embodiments ensure that the catheter is wetted with liquid during introduction into a body orifice. This permits a largely pain-free insertion. The liquid reservoir guarantees that enough liquid is metered based on the personal needs of the user. Gentle catheterization without additional aids and catheter preparations is

enabled.

The liquids preferably include a lubricant gel and/or water and/or physiological saline solution (0.9 w/w solution).

A pre-connected collection container, e.g., a urine bag, is preferably secured to the catheter of the catheter application system. During use of the catheter application system, this prevents the inner surface of the catheter from being exposed to microbial contamination when connecting the catheter with a collection container.

In an indwelling urinary catheter, the tip area of the catheter has an activatable retaining system, e.g., an inflatable balloon or cuff, which, when inflated, locks the catheter tip in the bladder of the patient. For this purpose, a hollow space is provided around the catheter tip, which can be filled with a fluid through a tubular line that runs along the catheter. As a result, reliable placement of an indwelling catheter in the bladder can be ensured.

In particular for urinary catheters, the insertion sleeve has a sleeve length between 1.55 and 2 cm, and a diameter adjusted to the respective outer diameter of the used indwelling catheter. These dimensions correspond to those of the urethra, and in particular the length of the part of the urethra that is naturally contaminated with microbes.

A locking device that allows the catheter to move through the insertion aid in only the insertion direction, is preferably provided inside the insertion aid of the catheter application system. Such a locking device prevents the catheter from unintentionally sliding back e.g. out of the urethra during introduction, which can very easily result in contamination thereof.

Additional advantages can be extracted from the description and attached drawings. The previously mentioned, and yet to be specified, features of the invention can each be used individually or in combination. The cited embodiments are not to be considered as a comprehensive listing, but rather as being of an exemplary nature.

The invention will be explained in greater detail below based on exemplary embodiments with reference to the drawings.

FIG. 1 shows a catheter application system according to the invention;
FIG. 2a is an exploded view of the insertion aid of a catheter system according to the invention;
FIG. 2b shows the insertion aid of FIG. 2a in its assembled condition; and
FIG. 3 shows one embodiment of a stop element with a unilateral through hole.

The figures in the drawings provide a highly diagrammatic representation of the invention, and are not to scale. The individual components of the invention are shown in such a way as to effectively illustrate their structure.

FIG. 1 shows the catheter application system according to the invention. The entire system consists of a closed, sterile catheter system comprising a catheter 10 made of silicone, PVC, polyurethane (PU), or latex, which enables sterile catheterization to prevent urethral infections induced by the catheter, which is further assisted by the closed, sterile system, a silver coating and a hydrophobic/oleophobic coating on both the outer and inner surfaces of the catheter 10. The coating is applied using nano-coating technology. The catheter 10 can preferably be applied for long-term bladder drainage. The catheter 10 has a catheter tip 11 with at least one drainage hole, or "eye," provided with rounded edges to improve the sliding characteristics of the catheter. The catheter 10 is disposed within a hollow sheath 20 in which it can slide. This inner package consists of a plastic film. A distal end of the sheath 20 is provided with an insertion aid 100, through which the catheter can be passed. The sheath 20 consists of a plastic bag (polyethylene bag) mounted to the insertion aid e.g. using an adhesive tape or shrinkable tubing. This plastic bag envelops the remaining components of the catheter application system and keeps them in a sterile condition. The insertion aid is assembled from insertion aid components, namely an insertion sleeve 110 which includes a sealing element 115, and a stop element 130 to limit introduction of the insertion sleeve into a body orifice. The sealing element 115 can be opened for passage of the catheter, preferably by penetrating the sealing element 115 with the catheter tip 11. To this end, the sealing element 115 may be, for example, a perforation in the insertion sleeve 110, or a cross-shaped slit in the insertion sleeve, that serves as predetermined breaking point. The insertion sleeve (insertion membrane) is composed of a soft plastic. The stop element 130 extends outside the sheath 20. The insertion sleeve 110 and stop element 130 are splittable, i.e. they can be divided into at least two segments, making them removable from the catheter when the catheter is introduced. To this end, a predetermined breaking point 150 is provided both in the stop element 130 and in the insertion sleeve 110. The dividable tip or

insertion sleeve 110 serves as an insertion aid for the catheter, additionally bridging the initial centimeters of the urethra. The stop element 130 is preferably formed so that it can be easily gripped with one hand. To this end, the stop element is elongated on its side facing away from the insertion sleeve 110. A liquid reservoir 41 and a through hole 135 are disposed within this elongation. The catheter is guided through the stop element 130 in such a way that it can e.g. be gripped by two fingers via the through hole 135 and the catheter penetrates the liquid reservoir 41. The basic element of the insertion aid, ie., the stop element, is made out of hard plastic. A retaining band 170, with cooperating hook-and-loop fasteners (crepe tape), holds the segments of the stop element 130 together, while simultaneously securely binding the sheath 20 to the stop element 130, which can also be accomplished with a shrinkable tubing. The insertion sleeve 110 is provided with a protective cover 140 that has an enlarged base, and hence also covers at least part of the stop element. The hollow space 40 formed by the protective cover over the insertion sleeve 110 is filled with a liquid, e.g., a water-based lubricant gel. The insertion sleeve 110 is preferably also filled with lubricant gel in advance. Thus, a sufficient quantity of lubricant gel is provided on the catheter and on the insertion tip, i.e. the insertion sleeve. The protective cover 140 is made out of hard plastic, and can be easily removed by simply turning and pulling it off. The end of the catheter remote from the catheter tip usually has a funnel. This funnel may be pre-connected to a urine drainage system such as a collection container, e.g. a urine bag, by the manufacturer. The urine bag is preferably secured to the catheter by means of a shrinkable tubing. The sheath of the catheter application system ends at the funnel of the catheter.

The catheter application system can also comprise a urine reflux protection system and/or a loop secured to or integral with the urine bag, or a hole for holding and hanging the bag. Indwelling urinary catheters usually also have a urine collecting site at the point where the urine bag is connected to the catheter, a Pasteur drip chamber for flow interruption, an anti-reflux valve, a vent with anti-microbial function and/or a drip-free outlet.

The catheter application system is provided in a sterile outer packaging. This outer packaging is configured in such a way that it can be peeled back from the insertion aid toward the urine bag for the purpose of catheter application.

FIG. 2 shows the insertion aid of an inventive catheter application system. Fig. 2a shows the insertion aid in an exploded view and Fig. 2b shows the assembled insertion aid. A protective cover 140, an insertion aid 110 and a splittable stop element are shown. The dimensions of the stop element are such that it can be

used as a handle. The stop element consists of several parts, specifically two wing segments 111 and 112, two handle segments 131 and 132, and a sealing ring 200. The wing segments together yield a surface area forming the stop at the penis tip.

FIG. 3 shows an embodiment of a stop element with a unilateral through hole 135. The stop element consists of two wing segments 111 and 112, and two handle segments 131 and 132. The stop element consists of two parts in all, which are shown split apart in the figure. The surface of the stop element, which touches the body of the patient during introduction to limit the introduction of the insertion aid, is ribbed. The two parts comprise locking means via which they can be splittably connected. The locking means consist of peg-shaped noses on one part that fit into matching holes on the opposite part. When assembled, the parts form a hollow space. This hollow space incorporates an arrangement of bridges ensuring precise guidance of a catheter. A first part is formed in one piece from a handle segment 131 and a wing segment 111. This first part has a through hole 135. Four noise-receiving holes are formed in this first part. The second part is also a single piece comprising a handle segment 132 and a wing segment 112. However, it has no through hole. The through hole is therefore unilateral. The four noses are formed on the second part.

In a further embodiment, at least the handle segments 131 and 132 are made out of a soft, deformable material, preferably with elastic characteristics. Users can employ their fingers to deform such handle segments without exerting much force, to an extent where a catheter passed through the stop element can be held fixed in any position. Unintentional slipping of the catheter in the stop element is impossible, and there is no need for a through hole, as shown in FIG. 1 and FIG. 3.

List of Reference Numerals

10	catheter
11	catheter tip
20	sheath
40	hollow space
41	liquid reservoir
100	insertion aid
110	insertion sleeve
111,112	wing segment
115	sealing element
130	stop element
131,132	handle segment
135	through hole
140	protective cover
150	predetermined breaking point
170	hook-and-loop fastener
200	sealing ring

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NEW CLAIMS

1. A catheter application system comprising
a catheter (10) being applicable for long-term bladder drainage and comprising a catheter tip (11) and an inflatable balloon disposed in the region of the catheter tip (11), wherein the balloon, in its inflated state, effects locking of the catheter tip (11), preferably in the bladder of the patient,
a hollow sheath (20) in which the catheter is slidably disposed, and an insertion aid (100) at the distal end of said sheath provided for passage of the catheter (10) through it, wherein the insertion aid comprises insertion aid components, namely
an insertion sleeve (110) with a sealing element (115) which can be opened for passage of the catheter (10) and
a stop element (130) extending outside of said sheath for limiting insertion of the insertion sleeve (110) into a body orifice, characterized in that the insertion aid comprises a removable protective cover (140) over the insertion sleeve (110), and the insertion sleeve (110) and/or the stop element (130) are formed as splittable insertion aid components in such a way that said insertion aid components are removable from the catheter (10) after its passage, and the stop element comprises handle segments, wherein the handle segments are made from a soft, deformable material with preferably elastic characteristics.

2. The catheter application system according to claim 1, characterized in that the sealing element (115) comprises a perforation formed in such a way that a penetration of said perforation enables the opening during the passage of the catheter (10), or the sealing element (115) comprises a cross-shaped slit in such a way that a penetration of said cross-shaped slit enables the opening during the passage of the catheter (10).

3. The catheter application system according to at least one of the claims 1 to 2, characterized in that the splittable insertion aid components each consist of at least two segments (111, 112, 131, 132), which, in the assembled state, encompass the catheter (10) after its passage like a ring.

4. The catheter application system according to claim 3, characterized in that the segments (111, 112, 131, 132) of the splittable insertion aid components are

held together by predetermined breaking points (150), in particular perforations and/or adhesive tape and/or crepe tape and/or locking elements.

5. The catheter application system according to at least one of the claims 1 to 4, characterized in that the insertion aid, in particular, the stop element (130) is formed as part having the size of a handle, wherein a preferably unilateral or bilateral through hole (135) is formed within said part.

6. The catheter application system according to at least one of the claims 1 to 5, characterized in that the catheter (10) comprises a hydrophobic/oleophobic outer surface and/or an antimicrobial, preferably silver coating on its outer and/or inner surfaces.

7. The catheter application system according to at least one of the claims 1 to 6, characterized in that the protective cover (140) and/or the insertion sleeve (110) are filled with a liquid each, and/or a liquid reservoir (41) filled with a liquid is disposed in the insertion aid (10), said liquid reservoir (41) being penetratable by the catheter (10) during its application.

8. The catheter application system according to claim 7, characterized in that the liquids are a lubricant gel and/or water and/or physiological saline solution.

9. The catheter application system according to at least one of the claims 1 to 8, characterized in that a pre-connected collection container is mounted to the catheter (10).

10. The catheter application system according to at least one of the claims 1 to 9, characterized in that the insertion sleeve (110) has a sleeve length between 1.55 and 2 cm.

11. The catheter application system according to at least one of the claims 1 to 10, characterized in that a locking device is provided within the insertion aid, said locking device allowing displacement of the catheter through the insertion aid in only the insertion direction.

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Annexes to the preliminary examination report

NEW CLAIMS

1. A catheter application system comprising
a catheter (10), being preferably applicable for long-term bladder drainage and comprising a catheter tip (11),
a hollow sheath (20) in which the catheter is slidably disposed, and an insertion aid (100) at the distal end of said sheath provided for passage of the catheter (10) through it, wherein the insertion aid comprises insertion aid components, namely
an insertion sleeve (110) with a sealing element (115) which can be opened for passage of the catheter (10) and
a stop element (130) extending outside of said sheath for limiting insertion of the insertion sleeve (110) into a body orifice,
characterized in that
the insertion sleeve (110) and/or the stop element (130) are formed as splittable insertion aid components in such a way that said insertion aid components are removable from the catheter (10) after its passage, characterized in that the stop element comprises handle segments, wherein the handle segments are made from a soft, deformable material with preferably elastic characteristics.

2. The catheter application system according to claim 1, characterized in that the sealing element (115) comprises a perforation formed in such a way that a penetration of said perforation enables the opening during the passage of the catheter (10), or the sealing element (115) comprises a cross-shaped slit in such a way that a penetration of said cross-shaped slit enables the opening during the passage of the catheter (10).

3. The catheter application system according to at least one of the claims 1 to 2, characterized in that the splittable insertion aid components each consist of at least two segments (111, 112, 131, 132), which, in the assembled state, encompass the catheter (10) after its passage like a ring.

4. The catheter application system according to claim 3, characterized in that the segments (111, 112, 131, 132) of the splittable insertion aid components are

held together by predetermined breaking points (150), in particular perforations and/or adhesive tape and/or crepe tape and/or locking elements.

5. The catheter application system according to at least one of the claims 1 to 4, characterized in that the insertion aid, in particular, the stop element (130) is formed as part having the size of a handle, wherein a preferably unilateral or bilateral through hole (135) is formed within said part.

6. The catheter application system according to at least one of the claims 1 to 5, characterized in that the insertion aid comprises a removable protective cover (140) over the insertion sleeve (110).

7. The catheter application system according to at least one of the claims 1 to 6, characterized in that the catheter (10) comprises a hydrophobic/oleophobic outer surface and/or an antimicrobial, preferably silver coating on its outer and/or inner surfaces.

8. The catheter application system according to at least one of the claims 1 to 7, characterized in that the protective cover (140) and/or the insertion sleeve (110) are filled with a liquid each, and/or a liquid reservoir (41) filled with a liquid is disposed in the insertion aid (10), said liquid reservoir (41) being penetratable by the catheter (10) during its application.

9. The catheter application system according to claim 8, characterized in that the liquids are a lubricant gel and/or water and/or physiological saline solution.

10. The catheter application system according to at least one of the claims 1 to 9, characterized in that a pre-connected collection container is mounted to the catheter (10).

11. The catheter application system according to at least one of the claims 1 to 10, characterized in that the catheter (10) comprises an activatable retaining system, preferably an inflatable balloon, in the region of the catheter tip (11), wherein the balloon, in its inflated state, effects locking of the catheter tip (11), preferably in the bladder of the patient.

12. The catheter application system according to at least one of the claims 1 to 11, characterized in that the insertion sleeve (110) has a sleeve length between 1.55 and 2 cm.

13. The catheter application system according to at least one of the claims 1 to 12, characterized in that a locking device is provided within the insertion aid, said locking device allowing displacement of the catheter through the insertion aid in only the insertion direction.

14. A method of application of a catheter on a patient using the catheter application system according to at least one of the claims 1 to 13, comprising the following steps:

- providing a catheter application system comprising a catheter (10) with a catheter tip (11), a hollow sheath (20) in which the catheter (10) is slidably disposed, and an insertion aid (100) at the distal end of the sheath (20), said sheath being provided for passage of the catheter (10) through it, wherein the insertion aid (110) comprises an insertion sleeve with a sealing element (115) which can be opened for passage of the catheter (10), and a stop element (130) extending preferably outside of the sheath (20) for limiting insertion of the insertion sleeve (110) into a body orifice,
- inserting the insertion sleeve (110) into the anterior section of the patient's urethra adjacent to the orifice until the stop element (130) prevents further inserting,
- passing the catheter (10) through the insertion aid, catheter tip (11) first, and penetrating the sealing element (115) with the catheter tip (11),
- displacing the catheter (10) through the insertion aid until the catheter tip (11) has advanced into the bladder of the patient,
- activating the retaining system
- removing the insertion sleeve (110) from the urethra of the patient and
- disassembly and removal of the insertion sleeve (110), preferably of the total insertion sleeve (100) from the catheter (10).

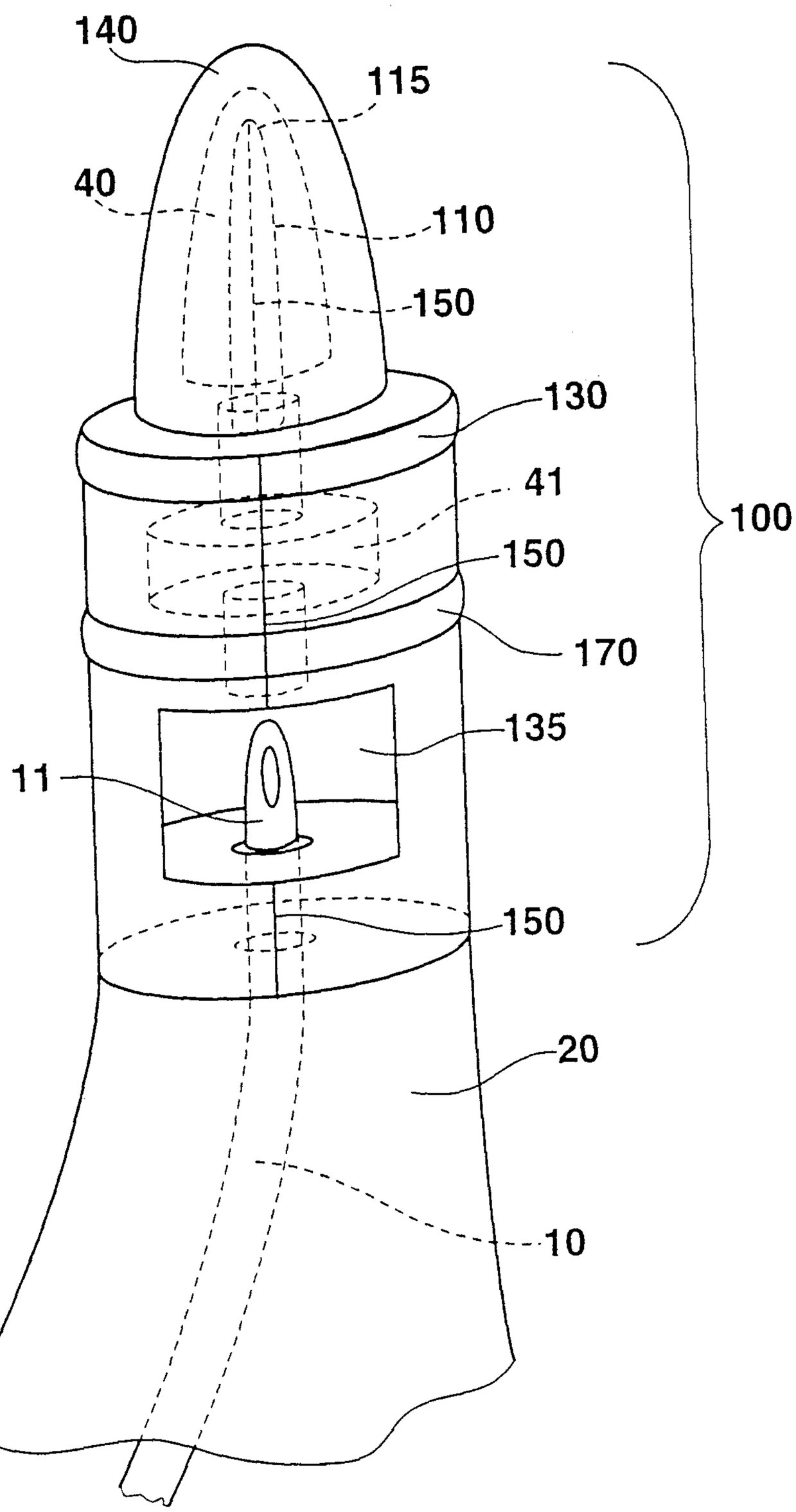


Fig. 1

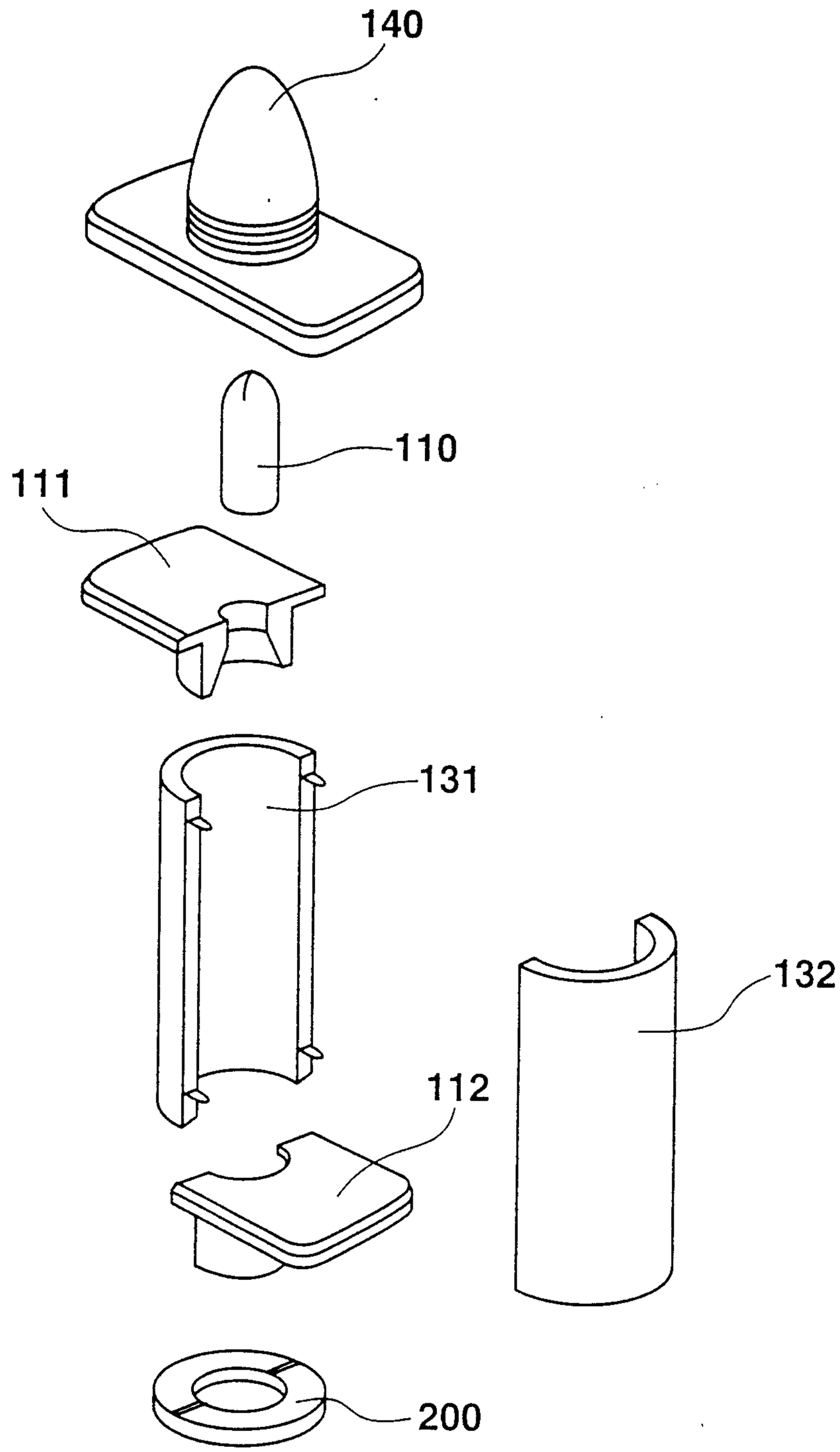


Fig. 2a

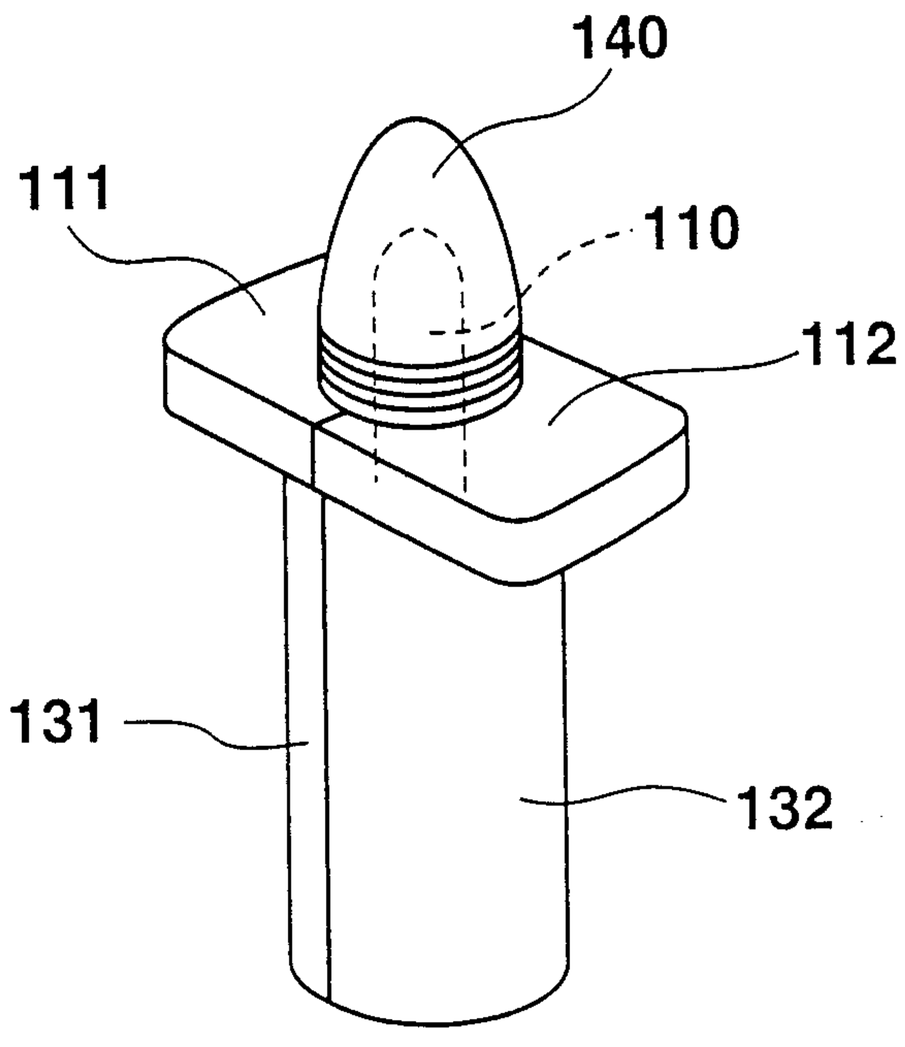


Fig. 2b

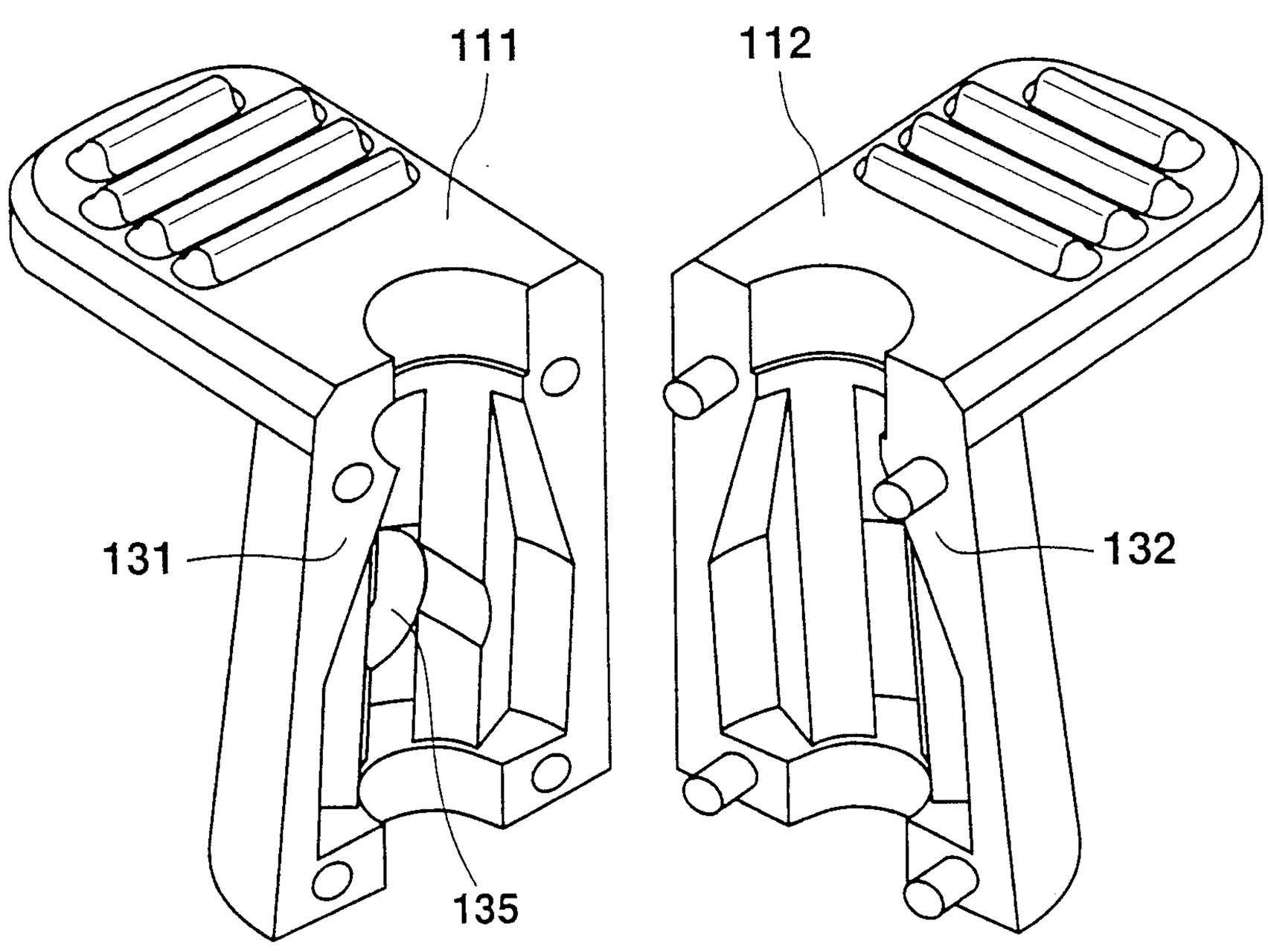
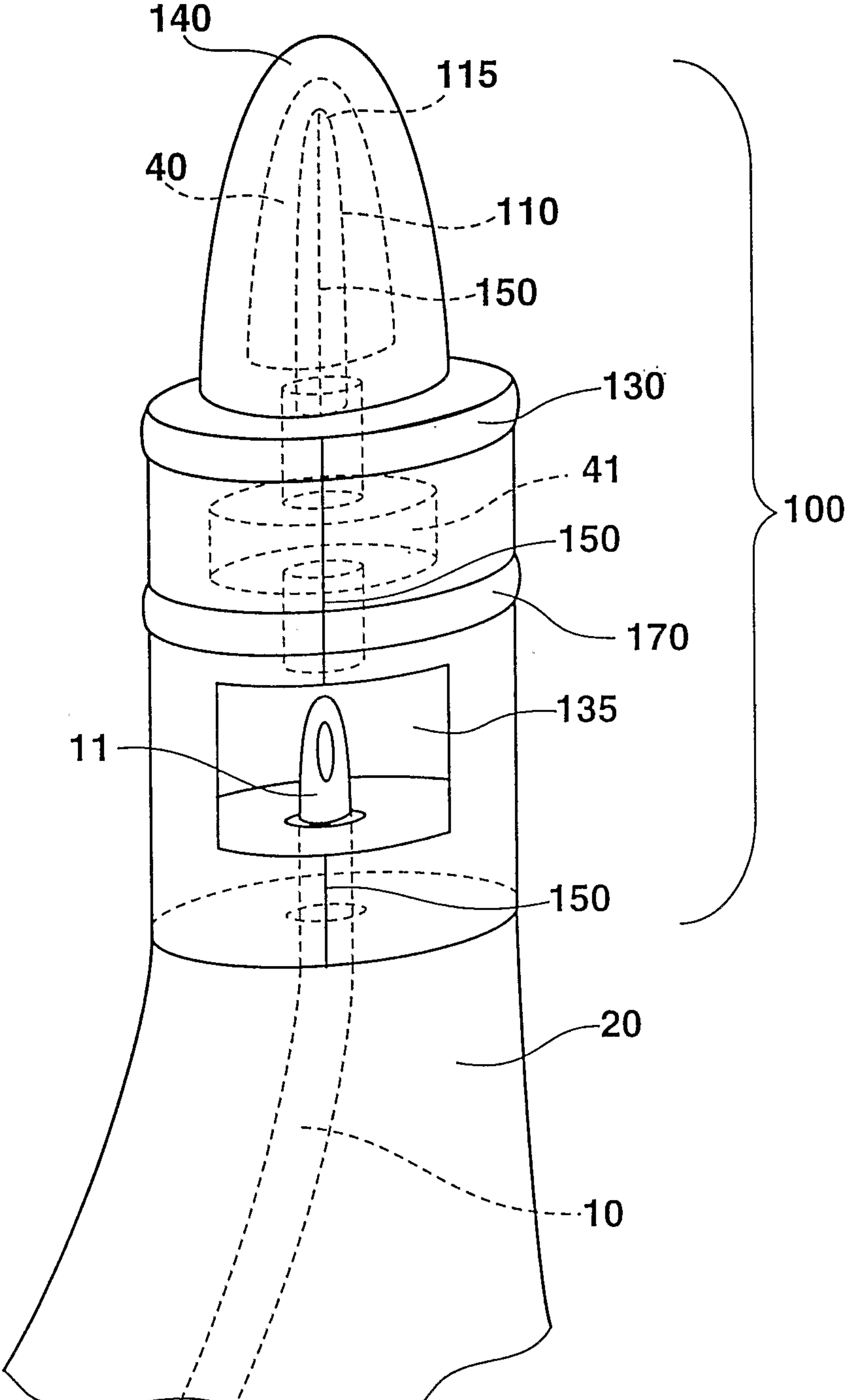


Fig. 3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