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(54) **Title**: AN ATTACHMENT MEMBER FOR ATTACHING A URINE COLLECTING SYSTEM TO A PENIS

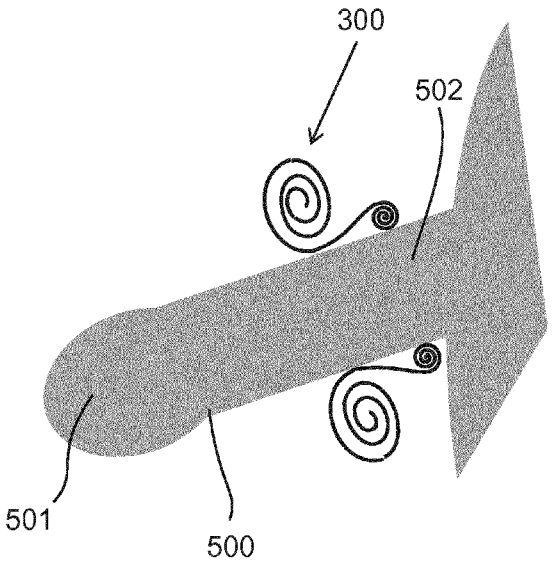

Fig. 6a

(57) **Abstract**: An attachment member suitable for attaching a system to a male human being's penis, said system being suitable for collecting urine from a male human being, said attachment member comprising a substantially cylindrical portion which : comprises an elastic film material, has a first opening at a first end thereof and a second opening at the other end thereof, is arranged such that at least the glans penis of a penis could be arranged inside the substantially cylindrical portion with the first opening being further from the base of the penis than the second opening, and a portion of said substantially cylindrical portion comprising said first opening is rolled up into a first rolled up portion in such a way that the first opening is located inside the first rolled up portion but the second opening is not located in the first rolled up portion. And where a portion of the substantially cylindrical portion comprising the second opening is further rolled up into a second rolled up portion in such a way that the second opening is located inside the second rolled up portion. In this way, an effective and simple to apply attachment member is provided.

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AN ATTACHMENT MEMBER FOR ATTACHING A URINE COLLECTING SYSTEM TO A PENIS

FIELD OF THE INVENTION

The present invention relates to an attachment member for attaching a urine collecting system to a penis and a urine collecting system comprising such an attachment member.

More specifically, the present invention relates to an attachment member suitable for attaching a system for collecting urine from a male human being to a male human being's penis, the attachment member comprising a substantially cylindrical portion which comprises an elastic film material, has a first opening at a first end thereof and a second opening at the other end thereof, is arranged such that at least the glans penis of a penis could be arranged inside the substantially cylindrical portion with the first opening being further from the base of the penis than the second opening, and a portion of said substantially cylindrical portion comprising said first opening is rolled up into a first rolled up portion in such a way that the first opening is located inside the first rolled up portion but the second opening is located outside the first rolled up portion.

Furthermore, the present invention relates to a method of applying an attachment member to a penis and a method of applying a urine collecting system and an attachment member to a penis.

The present specification also discloses methods of manufacturing an attachment member for attaching a system for collecting urine from a male human being to a male human being's penis.

In the context of the present invention the term "attachment member" shall be understood as a member adapted to contact and to be attached to a penis.

In the context of the present invention the term "elastic film" shall be understood as a thin sheet like material that via a force can be expanded and will contract again when the force is removed. The sheet like material may in some cases essentially return to its original shape. Since it is difficult to create a seal against

the skin surface of a penis an elastic film material is used for the attachment member of the current invention. It is important that the material is elastic enough to expand and/or to conform to the changing shape of the penis, but also designed to stay in place, which is why the size and elasticity of the substantially cylindrical portion is important.

In the context of the present invention the term "substantially cylindrical portion" shall be understood as a portion having a shape formed like a pipe, a cylinder, a truncated cone, a diamond shape, a cylindrical shape with varying cross sectional diameter, an oval cylinder, combinations of the above or other cylindrically shaped structures with regular or irregular cross sectional geometries.

BACKGROUND OF THE INVENTION

Urine collecting systems for males can be divided into two main types, internal systems which make use of a catheter or other implement inserted into the urea and external systems where a urisheath is attached to the outside of the penis.

A known problem with external urine collecting systems is that they frequently drop off the penis as the urisheath fails to stay in place. Furthermore a person skilled in the art knows that it can be difficult to apply urisheaths on many patients, for example elderly and overweight persons, as the penis of many patients can be fairly small, can have a non-firm form and can contain wrinkled skin.

The majority of urisheaths in use today are provided in a rolled up configuration and are applied near the exit of the urea and rolled onto the penis in a direction towards the base of the penis in a manner similar to how a condom is applied to the penis. Most of the time this procedure is difficult due to the above described nature of the penis. In contrast to a condom which is rolled onto the penis when the penis is in an erected state, urisheaths are mostly rolled onto the penis when the penis is in a flaccid state, which makes the application procedure more difficult.

Many have tried to solve these issues by improving the flexibility of the urisheath, applying adhesives on the urisheath, optimizing the fit of the urisheath to the penis and building teaching materials for nurses on how to apply urisheaths.

Two examples of urisheaths which try to solve these problems are EP0068712 and FR2752158 which use a flexible condom-like material and an applicator. However they do not overcome the problem of applying a tight urisheath on a relaxed penis.

Co-pending application of the current inventor, WO 2011/098581, which is incorporated by reference in its entirety into the current specification, discloses a new type of urisheath where the urisheath is applied at the base of the penis and then unrolled towards the exit of the urea. This provides a simple way of applying the urisheath to the penis. Combined with the proper choice of dimension and material, a good seal is established between the penis and the urisheath which is also comfortable to the user over time.

SUMMARY OF THE INVENTION

An object of the current invention to further improve the urisheath disclosed in WO 2011/098581.

The present invention solves the above mentioned object by providing an attachment member as mentioned in the introductory paragraph wherein a portion of the substantially cylindrical portion comprising the second opening is further rolled up into a second rolled up portion in such a way that the second opening is located inside the second rolled up portion.

In this way an attachment member is provided which is easy to place on an inner portion of a penis and can then be unrolled in a direction away from the base of the penis. Due to the elasticity of the material and the diameter of the cylindrical portion, the attachment member forms a secure fit on the penis. The second rolled up portion increases the sealing ability of the urisheath. Furthermore, even though the urisheath as mentioned in the introductory paragraph already has a very good sealing ability, the extra presence of the second rolled up portion can also further reassure the user of the urisheath, due to the additional sealing portion.

In one embodiment of the urisheath of the current invention, the inner diameter of the first and second rolled up portions of the substantially cylindrical portion when they are not rolled up and not stretched could be less than 35mm. The value of

35mm has been chosen to reflect the statistical diameters of the average penis diameter. In order to cover the most common penis diameters found in the adult male population, the relaxed inner diameter could be less than 28mm so that an effective seal is provided when applied on the penis. In practise, a series of attachment members could be supplied in different diameters where the diameters will fall within the range of less than 35mm. Of course there are penis diameters which will fall outside this range, but the commercially interesting range is less than 35mm. However, in certain embodiments, the relaxed inner diameter could be less than 32mm, less than 30mm, less than 28mm, less than 27mm, less than 26mm, less than 25mm, less than 24mm or less than 23mm.

In general, it could be said that in most embodiments, the inner diameter of the two openings and the film material should be designed so that the two openings are expandable to a size larger than the outer diameter of the penis, but also designed so that their relaxed diameter is smaller than the outer diameter of the flaccid penis. In this way, it is possible to apply the attachment member onto the penis when the openings are expanded and then create a good seal when the openings are allowed to retract.

In one embodiment, the curvature of the first rolled up portion could be opposite to the curvature of the second rolled up portion and the first rolled up portion could be rolled up on the outside of the substantially cylindrical portion while the second rolled up portion could be rolled up on the inside of the substantially cylindrical portion. In this way, the second rolled up portion when applied to the penis will be located on the inside of the substantially cylindrical portion and lie up against the outer surface of the penis at the base of the penis. The second rolled up portion since it is on the inside will be prevented from unrolling and will create a good seal against the outer surface of the penis. In this embodiment, the rotation direction of rolling of the first rolled up portion and the rotation direction of rolling of the second rolled up portion are the same.

In another embodiment the curvature of the first rolled up portion could be the same as the curvature of the second rolled up portion and the first and second rolled up portions could be rolled up on the outside of the substantially cylindrical portion. In this way, the second rolled up portion would be located on the outside of the substantially cylindrical portion when applied to the penis and could either be used as a way of increasing the sealing force at the end of the substantially

cylindrical portion which is closest to the base of the penis or it could be further unrolled towards the base of the penis thereby increasing the length of the contact area between the penis and the substantially cylindrical portion. In this embodiment, the rotation direction of rolling of the first rolled up portion and the rotation direction of rolling of the second rolled up portion are opposite.

In one embodiment, the length of the portion of the substantially cylindrical portion which forms the second rolled up portion could be between 0.3 cm and 8.0 cm, between 0.5 cm and 5 cm, between 1.0 cm and 5.0 cm or between 1.0 cm and 3 cm.

In one embodiment the length of the portion of the substantially cylindrical portion which forms the first rolled up portion could be between 5.0 cm and 25.0 cm, between 5.0 cm and 15.0 cm or between 8.0 cm and 15.0 cm.

In one embodiment, the second rolled up portion could comprise an adhesive between the layers of the second rolled up portion. In an embodiment where the second rolled up portion is arranged on the inside of the substantially cylindrical portion when the attachment member is applied to a penis, the purpose of the adhesive could be to further prevent the second rolled up portion from unrolling. In this case, the adhesive could be a strong adhesive which forms a bond already during the manufacturing process. In an embodiment where the second rolled up portion is arranged on the outside of the substantially cylindrical portion when the attachment member is applied to a penis, the purpose of the adhesive could be to provide a more effective seal between the substantially cylindrical portion and the skin of the penis. In this case, the adhesive could be of the kind which remains tacky after the manufacturing process and which is arranged to establish a bond between the skin of the penis and the substantially cylindrical portion of the attachment member when the second rolled up portion is unrolled. However, in the case where the second rolled up portion is arranged on the outside of the substantially cylindrical portion when the attachment member is applied to a penis, an adhesive could also be used which prevents unrolling of the second rolled up portion.

In one embodiment, adhesive could be applied to a portion of the substantially cylindrical portion which is located in the first rolled up portion. The adhesive could be applied at a short distance from the first opening. The adhesive could cover a

larger area, or just be a small area. In this way, the unrolling of the first rolled up portion will be stopped once the first rolled up portion is unrolled to the location of the adhesive. In this way, a small rolled up portion can be maintained at the end of the substantially cylindrical member which does not unroll. This can act as a stiffening member to hold the first opening of the substantially cylindrical portion open.

In another embodiment, an area of the first rolled up portion could be provided with an adhesive which is placed on the first rolled up portion such that it is located on the outside of the first rolled up portion when the first rolled up portion is rolled up and such that it is located on the inner side of the substantially cylindrical portion when the first rolled up portion is unrolled. In this way, the adhesive can form an adhesive bond to the skin of the penis when the attachment member is unrolled on a penis.

In one embodiment, or in one step of an application procedure, the first and second rolled up portions could be stretched such that the inner diameter of the rolled up portions are at least 10% greater than the inner diameters of the rolled up portions of the substantially cylindrical portion when the elastic film material of the substantially cylindrical portion is not stretched and not rolled up. In this way, the attachment member is easier to apply on the penis. In one embodiment, the diameters could be stretched at least 20%, at least 30%, at least 40% or at least 50%.

In one embodiment of the attachment member, the substantially cylindrical portion of the attachment member could be essentially liquid impermeable, at least in the areas which are in direct contact with urine during the wear-time of the attachment member.

In a second aspect, the present invention relates to a system suitable for collecting urine from a male human being, the system comprising a urine container for collecting and/or storing urine during wear time; an attachment member as mentioned above for attaching the system to a penis and a connection member for establishing fluid communication between the urine container and the attachment member. The urine container can be formed in many ways as will be clear to the person skilled in the art.

In a third aspect, the present invention relates to a method as mentioned in claim 9. In one embodiment, the method could further comprise the step of unrolling the second rolled up portion in a direction along the penis and towards the base of the penis. This is mainly relevant for those embodiments of an attachment member where the second rolled up portion is arranged on the outside of the substantially cylindrical portion when the attachment member is applied on a penis.

In another embodiment of the method, the method could further comprise the step of releasing the stretching force applied to the first and second rolled up portions of the attachment member and allowing them to retract, after positioning the attachment member on the outer surface of the penis.

In yet a further embodiment, the method could further comprise the steps of determining the approximate outer diameter of the penis and providing an attachment member which is sized appropriately for the approximated outer diameter of the penis.

It should be noted that the above mentioned methods are not methods of treatment by therapy since the above mentioned methods do not cure or stabilize the condition of the user of the system. Furthermore, the methods do not result in a significant health risk to the user if the methods are performed incorrectly. As such, non-trained medical staff can perform the method. Furthermore, while the above mentioned methods might lack industrial applicability when performed in the private home of a patient by the patient him or herself, the methods do have industrial applicability when performed in a hospital or other care facility by a professional health care worker on a patient.

In certain cases, it might be difficult to apply the attachment member correctly on a penis due to the nature of the penis and/or due to the material characteristics of the elastic film. Therefore it may be desirable to use an applicator to apply the attachment member.

The attachment member could therefore be provided in a kit of parts comprising an attachment member as provided above and an applicator which is arranged to stretch the rolled up portion of the substantially cylindrical portion such that the inner diameter of the rolled up portion is increased by at least 10% when compared to its non-stretched inner diameter. In different embodiments, the applicator could

be arranged to increase the inner diameter at least 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90% or 100%.

In the context of the present invention, an "applicator" shall be understood as a physical form and/or shape and/or mechanism adapted to support at least the positioning of at least a part of the attachment member in an inwards position on a penis. The applicator may be a separate element or it may be integrated into the attachment member.

In one embodiment of the first aspect of the present invention the applicator is adapted to: expand the diameter of the substantially cylindrical shape of the elastic film to a size larger than the outer diameter of the penis; and to support the positioning of at least a part of the attachment member on the penis in an inwards position.

In the case where the rolled up portions of the attachment member comprise a soft thermoplastic elastomer which has a tendency to creep over longer periods of time if stored in a stretched configuration or in other cases, it may be desirable to allow the attachment member to be stored in a relatively relaxed position during shelf life and immediately prior to application on a penis be expanded.

In one embodiment, the applicator therefore has two configurations: a first configuration wherein the applicator has a first diameter; and a second configuration wherein the applicator has a second diameter; said second diameter being at least 20% larger than the first diameter. In other embodiments, the second diameter could be at least 30%, 40%, 50%, 60%, 70%, 80%, 90% or 100% larger than the first diameter.

In one embodiment, the applicator is adapted to expand the inner diameters of the rolled up portions of the attachment member by at least 1 mm; at least 2 mm; between 2 and 10 mm or between 5 and 25mm.

In order to ease the unrolling process, it may be necessary to support the unrolling process with an unrolling supportive element. Such unrolling supportive element(s) may also reduce the need to touch the penis during application of the member. This may be particularly desirable if the member is applied by another person than the human being intended to wear the attachment member.

In the context of the present invention, an "unrolling supportive element" shall be understood as a physical form and/or shape and/or mechanism adapted to support the unrolling process of an attachment member in an outwards direction on a penis.

In one embodiment, the attachment member could therefore comprise an unrolling supportive element. In one embodiment, the unrolling supportive element comprises at least one strip. In one embodiment, the unrolling supportive element comprises at least two strips.

In one embodiment, the unrolling supportive element comprises at least one strip, the at least one strip being at least partially rolled up together with the first rolled up portion of the substantially cylindrical portion such that one portion of the strip is located in the rolled up portion and one portion of the strip is located outside the rolled up portion. In this way, when the free portion of the strip is pulled, the rolled up portion unrolls. In one further embodiment, the end of the portion of the strip which is located in the rolled up portion could be arranged at a distance from the first opening of the substantially cylindrical portion. In this way, when the strip is pulled, the first rolled up portion of the substantially cylindrical portion unrolls until the end of the strip is reached. The strip is then removed and the last portion of the first rolled up portion remains rolled up.

In order to ease the unrolling process, it may be advantageous to reduce the adherence of the elastic film material to itself. This may be achieved by introducing a non-adherent layer (which then also needs to be elastic/expandable) or by altering the surface properties of the elastic film material, for example by coating the elastic film material with talc.

Additionally, it may be painful or uncomfortable or irritating if crotch hairs entangle with the attachment member during the unrolling process. It may consequently be convenient to shield crotch hairs from the attachment member with a "shield element".

In the context of the present invention, a "shield element" shall be understood as a physical form and/or shape and/or mechanism adapted to shield at least a portion of the user's crotch hairs during the unrolling process. Such a shield element may be in the form of a separate element or it may be integrally formed with the attachment member and/or applicator.

In one embodiment, the attachment member comprises a shield element. In one embodiment, the applicator comprises a shield element. Furthermore, in one embodiment a kit of parts could be provided which comprises an attachment member as described above or a kit of parts as described above where the kit could further comprise a shield element arranged at the second opening of the substantially cylindrical portion of the attachment member. In one embodiment, said shield element could comprise a flange having an outer diameter which is at least 2cm greater than the inner diameter of the rolled up portion of the substantially cylindrical portion when the rolled up portion is not rolled up and not stretched.

In one embodiment, the shield element comprises a flange portion. The flange portion may be used to shield the crotch hairs, but may also used as an unrolling supportive element as the person applying the attachment member may use the flange as a grip during the unrolling process, thereby ensuring that a portion of the attachment member stays in an inwards position on the penis.

In one embodiment the flange portion is integrally formed with the attachment member. In one embodiment, the flange portion is fastened to the outer surface of the substantially cylindrical portion between the first rolled up portion and the second rolled up portion.

In one embodiment the outer diameter of the flange portion is between 5.0 and 25.0 cm, between 6.0 and 20 cm, between 7.0 and 18.0 cm, between 8.0 and 16.0 cm, between 6.5 and 12.5 cm or between 5.9 and 10.5 cm.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following, the invention will be described in greater detail with reference to embodiments shown by the enclosed figures. It should be emphasized that the embodiments shown are used for example purposes only and should not be used to limit the scope of the invention.

Figures 1a-1d disclose schematic cross sectional views of an attachment member for attaching a system to a penis. The figures show the attachment member in different configurations.

Figure 2 shows a schematic cross sectional view of an attachment member with an unrolling helping element.

Figure 3 shows a schematic cross sectional view of a first embodiment of an attachment member according to the current invention.

Figures 4a-4c show schematic cross sectional views which illustrate the method of applying the attachment member shown in figure 3 to a penis.

Figure 5 shows a schematic cross sectional view of a second embodiment of an attachment member according to the current invention.

Figures 6a-6c show schematic cross sectional views which illustrate the method of applying the attachment member shown in figure 5 to a penis.

Figure 7 shows a schematic cross sectional view of the attachment member of figure 5 integrated with a shield element.

Figure 8 shows a schematic cross sectional view of the attachment member of figure 5 mounted on an applicator.

Figures 9a-9f show schematic cross sectional views which illustrate the method of applying the attachment member with applicator shown in figure 8 to a penis.

Figures 10a-10d show schematic cross sectional views which illustrate one method of producing an attachment member as shown in figure 5.

Figures 11a-11d show schematic cross sectional views which illustrate one method of producing an attachment member with a dip moulding process.

Figure 12 shows a schematic cross sectional view showing how adhesive could be applied to the attachment member.

Figure 13 shows a schematic cross sectional view showing how the attachment member of figure 12 would look like once it was applied to a penis.

Figure 14 shows a schematic cross sectional view showing another method of applying adhesive to the attachment member.

Figure 15 shows a schematic cross sectional view of still another attachment member with adhesive.

Figure 16 shows a schematic cross sectional view of the attachment member of figure 15 when applied to a penis.

Figure 17 shows a schematic cross sectional view of one embodiment of an unrolling supportive member applied to an attachment member.

DETAILED DESCRIPTION OF THE DRAWINGS

Figure 1a shows a side view of a substantially cylindrical attachment member 100 formed from an elastic film material 101. Figure 1b shows a cross section view of the attachment member 100 as defined by the line Ib-Ib in figure 1a. In general, the attachment member of this embodiment has a constant circular cross section with a diameter D and a wall thickness T. It should however be noted that in the current embodiment the elastic film material 101 is not so stiff that the attachment member holds its circular form when unsupported, rather it is soft and flexible and will collapse when not supported. For the sake of this specification, the attachment member 100 is defined as having a first opening 103 at one end of the attachment member and a second opening 102 at the other end of the attachment member. In this embodiment, the inner diameter D1 of the first opening and the inner diameter of the second opening D2 are equal, however other forms and shapes of attachment members are possible.

The attachment member is adapted to receive a penis and allow the elastic film to seal against the surface of the penis. The first and second openings 103,102 are arranged such that when the attachment member 100 is applied on a penis (see for example figure 4b) the first opening 103 is arranged further from the base of the penis than the second opening 102. In this way, the second opening is arranged close to the base of the penis when applied to the penis. The area of the attachment member near the first opening 103 is adapted as a connecting element

which is suitable to receive a connecting member and to be fastened to a connecting member (see for example figure 4c).

It should be noted that in most cases, the attachment member will be longer than the penis length, see for example figure 4c due to the nature of typical connecting members. However, it should be clear to the person skilled in the art, that if a connecting member were to be provided which was larger in diameter than the penis, then the attachment member could be shorter than the length of the penis.

Figure 1c shows the attachment member of figures 1a and 1b when it has been rolled up in a manner similar to a condom, but not stretched. However, in contrast to a condom, the rolled up attachment member as shown in figure 1c is open on both ends. As can be seen from figure 1c, the diameter of the second opening D2 is still the same as before since it is not stretched, however the inner diameter D3 of the rolled up portion 105 of the attachment member is smaller than the diameter D1 and D2 since the process of rolling will cause the diameter to decrease due to the elasticity of the substantially cylindrical portion. As can be seen from figure 1c, the first opening 103 is located inside the rolled up portion 105, while the second opening 102 is located outside the rolled up portion 105.

Figure 1d shows the attachment member in its rolled up configuration and when it has been stretched. As can be seen from the figure, both the inner diameter D3 of the rolled up portion 105 and the diameter D2 of the second opening 102 have been increased with respect to their original non-stretched diameters.

It is important, when choosing the elasticity of the elastic film, that the force of attachment (both in relation to fastening and to discomfort feeling) and easiness to apply are considered. Consequently, the physical properties of the elastic film material are important.

In the context of the present invention, the term "elongation of the elastic film material" describes the elasticity of the material and is measured according to the standard test method ASTM D638 as the elongation at break (measured in percent).

In one embodiment, the substantially cylindrically shaped elastic film material is able to be elongated between 100 and 2000 percent, between 400 and 1900 percent, between 600 and 1700 percent or between 1000 and 1500 percent.

In one embodiment, the substantially cylindrically shaped elastic film material has a modulus 300% between 0.05 and 1.00, between 0.07 and 0.60, between 0.08 and 0.40 or between 0.09 and 0.30. In the context of the present invention, the term "modulus 300%" describes the stress (measured in MPa) required to elongate a sample of given dimensions 300%, measured according to the standard test method ASTM D638.

In one embodiment, the substantially cylindrically shaped elastic film material has a modulus 100% of between 0.02 and 0.50, between 0.03 and 0.30, between 0.04 and 0.20 or between 0.05 and 0.15. In the context of the present invention, the term "modulus 100%" describes the stress (measured in MPa) required to elongate a sample of given dimensions 100%, measured according to the standard test method ASTM D638.

It should be noted that both the type of material used and the thickness of the material used for the elastic film material has an effect on the force of elongation. Consequently, the choice of material and the choice of wall thickness are both important when selecting material for the elastic film.

In one embodiment, the elastic film material is selected from a group comprising thermoplastic elastomers and silicones. In one embodiment the elastic film material has a shore OO hardness between 10 and 90, between 15 and 80, between 20 and 70 or between 25 and 65.

The thickness of the elastic film is furthermore important with respect to avoiding unintended cracks and/or holes in the film, but also in relation to the comfort of the user during wear time.

In one embodiment of the present invention the substantially cylindrically shaped elastic film has a thickness of between 0.01 and 2 mm, between 0.04 and 0.8 mm, between 0.08 and 0.4 mm, between 0.1 and 0.3 mm or between 0.15 and 0.25 mm.

Figure 2 discloses a schematic cross sectional view of another example of an attachment member 100 similar to fig. 1c, but in fig. 2 the attachment member further comprises an unrolling supportive element 198 in the form of a strip, which, when pulled, will unroll the pre-rolled attachment member. In one embodiment (not shown), a portion of the rolled up portion is rolled up first without any unrolling strip, then the next portion is rolled up with an unrolling strip. In this way, when the unrolling strip is pulled, the portion with the strip is unrolled. However, when the unrolling strip reaches the end, there will still be a portion which is not unrolled. This section can then be unrolled further depending on the length of the penis. For a long penis, the portion can be completely unrolled whereas for a short penis, the portion can just be left rolled up.

Figure 3 shows a first embodiment (200) of an attachment member according to the current invention. In contrast to the attachment member shown in figure 1c, there are two rolled up portions, a first rolled up portion 205 and a second rolled up portion 206. The first opening 203 is located inside the first rolled up portion 205 while the second opening 202 is located inside the second rolled up portion 206. Both rolled up portions are located on the outside of the substantially cylindrical portion (201) and the curvatures of the rolled up portions have the same sign, ie both are positive curvature or both are negative curvature depending on the point of view. It can also be seen that the rotational directions of rolling up the first and second rolled up portions are opposite to each other

Figures 4a-4c show a method of application of the attachment member 200 to a penis 500. In a first step (not shown) the two rolled up portions are stretched such that their inner diameter is greater than the outer diameter of the penis. The attachment member is then placed at the base 502 of the penis with the second rolled up portion closer to the base of the penis than the first rolled up portion (figure 4a). The first rolled up portion is then unrolled in a direction along the penis and towards the tip 501 of the penis as shown in figure 4b. A connection member 231 is then attached to the end of the attachment member for establishing fluid communication between the penis and a urine collecting container (figure 4c).

In certain cases (not shown), the second rolled up portion 206 could also be unrolled, however, in the opposite direction of the first rolled up portion, namely towards the base of the penis. This could be useful in cases where the attachment member is not initially placed entirely at the base of the penis. In a situation where

the attachment member were initially placed in the middle of the penis and then unrolled, the contact area between the attachment member and the penis could be increased by unrolling the second rolled up portion, thereby increasing the seal between the attachment member and the penis. Furthermore, for very small penises or for retracted penises, one method of applying the attachment member of figure 3 to a penis could be to place the rolled up attachment member on the middle of the penis, or quite close to the glans penis of the penis. The first portion could then be unrolled with an unrolling supportive element as for example shown in figure 2. The glans penis can now be held and pulled out away from the body, thereby giving access to a larger portion of the main body of the penis. The second rolled up portion can then be unrolled towards the base of the penis. This entire procedure can be performed without actually having to contact the penis itself, rather just the attachment member is contacted.

In figure 5, a second embodiment 300 of an attachment member according to the current invention is shown. In contrast to the first embodiment, the second rolled up portion 306 is rolled up on the inside of the substantially cylindrical portion 301 of the attachment member. When applied on a penis as shown in figure 6a, the first rolled up portion 305 can be unrolled along the penis towards the tip 501 of the penis. However, the second rolled up portion 306 cannot be unrolled further. It does however form an increased seal between the attachment member and the penis. This can be especially seen in figure 6c where it is illustrated what happens should a back flow be generated along the surface of the penis. A pocket 307 would be formed, however, due to the second rolled up portion 306, the pocket would be formed outside the second rolled up portion and a good seal would be maintained.

In another embodiment (not shown), the embodiments shown in figures 3 and 5 could be combined, by providing a second rolled up portion which comprises a rolled up portion which is rolled one way and then another portion which is rolled the other way. In this way, when applying the attachment member on a penis, the second rolled up portion could be rolled a short distance towards the base of the penis until the portion which is rolled the opposite way is exposed.

Figure 7 shows an embodiment where a shield element 400 is attached via an adhesive 401 to an attachment member 300 of the kind which was shown in figure 5. In this embodiment, the shield member is attached to the outer surface of the substantially cylindrical portion of the attachment member between the first rolled

up portion 305 and the second rolled up portion 306. In one embodiment (not shown), an applicator could be incorporated into the shield element as well and be used to stretch the rolled up portions during the application process.

In figure 8, an attachment member 300 as shown in figure 5 is mounted on an applicator 405. The applicator is arranged to have two states, a first state where the attachment member is not stretched or at least only slightly stretched and a second state where the applicator is expanded such that the rolled up portions of the attachment member are stretched to a size which is larger than the outer diameter of the penis. A suitable applicator is described in co pending, but not yet published, Danish patent application PA 2011 70654 and its corresponding PCT application which are incorporated in their entirety by reference into this specification.

In figures 9a-9f the attachment member 300 is applied to a penis 500 with the help of the applicator 405. In the figures it is shown that the first rolled up portion is unrolled while the second rolled up portion remains on the applicator. However, it would also be possible to remove both the first and second rolled up portions from the applicator before the first rolled up portion is unrolled. Furthermore, the method with the applicator is only shown with the attachment member of figure 5. However the same procedure would also be possible with the attachment member of figure 3.

Figures 10a-10d show one method of producing an attachment member as shown in figure 5. In a first step (figure 10a) a mandrel 600 is provided having a diameter which is equal to or at least slightly larger than the relaxed inner diameter of the substantially cylindrical portion 301 of the attachment member 300. The substantially cylindrical portion is applied to the mandrel such that substantially cylindrical portion is smooth. In one embodiment the material is not stretched and in another embodiment the material is slightly stretched. In the figures, the first opening 303 is located to the left and the second opening 302 is located to the right.

The second opening 302 is then folded back along the fold line F such that a portion of the substantially cylindrical portion P now is two layered (see figure 10b). The first opening 303 and the second opening 302 are then rolled towards the right in the figures (figure 10c) thereby generating a first rolled up portion 305 inside which

the first opening 303 is arranged and a second rolled up portion 306 inside which the second opening 302 is arranged (figure 10d).

In one embodiment of the method, the substantially cylindrical portion of the attachment member is formed via an extrusion process. In another embodiment the substantially cylindrical portion of the attachment member is formed via a dip moulding process. An example of a dip moulding process is shown in figures 11a-11d.

In a first step, a dip moulding form 700 and a moulding bath 701 filled with a suitable dipping material 702, for example silicon, is provided. The dip moulding form 700 is then dipped in the bath one or more times depending on the desired thickness of material of the final attachment member. This results in an attachment member which is closed at one end and open at the other. It is therefore necessary to cut the closed end of the attachment member off, or to make a hole in the closed end, in order to provide an attachment member which is open at both ends (see figure 11d). In certain situations, it might also be advantageous to dip the end of the dip moulding form into the dipping material in order to increase the thickness of the attachment member at its end. When the hole is made, the thicker portion is retained which acts as a collar or stiffening element at the end of the attachment member. By inverting the dip moulding form and dipping the other end, a thicker portion can also be formed at the other end.

After the dip moulding process, the rolling process could be performed directly on the dip moulding form before removing the attachment member from the dip moulding form.

While condoms are often manufactured via dip moulding processes, it would not seem obvious at first glance to a person skilled in the art to manufacture a urisheath via a dip moulding process since a urisheath should be open at both ends while a dip moulding process results in a closed shape. This therefore results in a process which requires an extra step to cut the dip moulded product open. However, it has surprisingly been found that via a dip moulding process, a urisheath can be manufactured from a very soft and flexible material which improves the fit of the urisheath and increases the wearing comfort. While the urisheath shown in figures 11a-11d is of the kind which is suitable for placing at the base of the penis and then unrolling towards the tip, a urisheath made from soft

and flexible materials via a dip moulding process could also be used in a more traditional type of urisheath which is applied at the tip of the penis and then rolled towards the base. Thicker portions towards the tip could be provided by dipping the tip portion more times than the main body portion of the urisheath.

Another way of providing a urisheath of the more traditional type with a softer and more flexible penis contacting portion, would be to injection mould the tip portion as is currently done and then fuse or glue a penis contacting portion which is manufactured via an extrusion process or via a dip moulding process to the tip portion. One could also mount the injection moulded tip portion onto a dip moulding form and then dip the form into a bath such that the bath at least partially overlaps the tip portion thereby establishing a strong connection between the tip portion and the penis contacting portion. In one embodiment, the tip portion is provided at the bottom of the form whereby the entire tip portion is covered in the dip moulding operation. An opening then needs to be cut in the tip portion before using. In another embodiment, the tip portion is mounted at the top of the dip moulding form and only the edge of the tip portion is covered. In this embodiment, a hole would need to be cut into the base of the dip moulded product to provide an opening.

In another embodiment, a penis contacting portion made via an extrusion or dip moulding process could be inserted into an injection mould, after which the tip portion is formed via an injection moulding process wherein the material of the tip portion fuses with the material of the penis contacting portion which was inserted into the mould prior to the injection operation.

Figure 12 shows a modification of the attachment member manufactured in the process described with regards to figures 10a-10d. In this embodiment, just before the portion of the substantially cylindrical portion which forms the first rolled up portion and the portion of the substantially cylindrical portion which forms the second rolled up portion are rolled up, adhesive 320 is applied to the outside surface of the foremost portion of the substantially cylindrical portion and adhesive 321 is applied to the "inner surface" of the portion of the substantially cylindrical portion which forms the second rolled up portion. In the current embodiment, it is easy to apply the adhesive to the inner surface, since the portion which will form the second rolled up portion has been folded back. When the first and second rolled up portions are rolled up, the adhesive 320, 321 will come into contact with the

surfaces of the substantially cylindrical portion and form a bond thereto. The rolled up portions will thereby be prevented from unrolling. Since the adhesive in the current embodiment is provided on the entire portion of the second rolled up portion, the entire second rolled up portion is prevented from unrolling. In contrast, adhesive is only applied to the foremost portion of the first rolled up portion. In this way, the majority of the first rolled up portion can still be unrolled, but the foremost portion of the first rolled up portion will remain rolled up. This can be seen in figure 13 where the second rolled up portion is still rolled up due to adhesive 321 and the foremost portion of the first rolled up portion is still rolled up due to the adhesive 320.

It should be noted that in the current embodiment, the entire area at the end of the first rolled up portion is covered with adhesive. However, it could also be that only a portion of the area is covered with adhesive. For example, a dotted pattern could be used, or a striped pattern could be used. Furthermore, a single small area could be covered at the "start" of the rolled up portion which should remain rolled up after unrolling. For example, a thin line of adhesive could be applied around the circumference of the substantially cylindrical portion a certain distance from the first opening 303 of the substantially cylindrical portion. When the first portion is rolled up, then the first portion will roll up until the line of adhesive was reached. The adhesive would then form a bond and future unrolling beyond this point would not be possible.

Figure 14 shows an alternative form of applying adhesive. In this embodiment adhesive 322 is applied to a portion of the outer surface of the substantially cylindrical portion which makes up the first rolled up portion and adhesive 323 is applied to the outer surface of the substantially cylindrical portion which makes up the second rolled up portion. This embodiment provides an attachment member after unrolling which has a rolled up portion located distal to the base of the penis as shown in figure 13, but a second rolled up portion located closest to the base of the penis as shown in figure 4b.

Figure 15 shows an embodiment of an attachment member, where after the first and second rolled up portions have been rolled up, an adhesive 326 is applied to the outer portion of the first rolled up portion. The adhesive is of the kind which is suitable for being in contact with the skin of the penis. When the attachment member is placed on a penis and the first rolled up portion is unrolled, then the

adhesive 326 will form an adhesive connection between the inner surface of the substantially cylindrical portion of the attachment member and the skin of the penis as shown in figure 16. This will increase the reliability of the seal of the attachment member on the penis as well as prevent the attachment member from falling off.

Figure 17 shows an embodiment of an attachment member with a strip 800 used to help unroll the first rolled up portion. This is similar to the embodiment shown in figure 2. However, in contrast to the embodiment of figure 2, in the current embodiment, the end 801 of the strip 800 is arranged at a distance from the first opening. In this way, when the first rolled up portion is rolled up, the foremost portion of the first rolled up portion is not in contact with the strip. When the first rolled up portion is completely rolled up, then pulling on the strip causes most of the first rolled up portion to unroll, but the foremost portion of the first rolled up portion which is not in contact with the strip will not unroll.

It should be clear to the person skilled in the art that the above description has disclosed a number of different inventions which could be the basis of divisional applications. The current claim set is focussed on the embodiments shown in figures 3 and 5 and the method shown in figures 10a-10d, however, one non limiting example of subject matter which would be suitable for potential divisional applications is the dip moulding process methods disclosed above which could all be the basis of potential divisional applications.

CLAIMS

1. An attachment member (300) suitable for attaching a system to a male human being's penis (500), said system being suitable for collecting urine from a male human being, said attachment member comprising a substantially cylindrical portion (301) which:

    a. comprises an elastic film material,

    b. has a first opening (303) at a first end thereof and a second opening (302) at the other end thereof,

    c. is arranged such that at least the glans penis (501) of a penis (500) could be arranged inside the substantially cylindrical portion with the first opening being further from the base of the penis than the second opening, and

    d. a portion of said substantially cylindrical portion comprising said first opening is rolled up into a first rolled up portion (305) in such a way that the first opening (303) is located inside the first rolled up portion but the second opening (302) is located outside the first rolled up portion,

    characterized in that a portion of the substantially cylindrical portion comprising the second opening (302) is further rolled up into a second rolled up portion (306) in such a way that the second opening (302) is located inside the second rolled up portion.

2. An attachment member (300) according to claim 1, **characterized** in that the curvature of the first rolled up portion (305) is opposite to the curvature of the second rolled up portion (306) and in that the first rolled up portion is rolled up on the outside of the substantially cylindrical portion while the second rolled up portion is rolled up on the inside of the substantially cylindrical portion.

3. An attachment member (200) according to claim 1, **characterized** in that the curvature of the first rolled up portion (205) is the same as the curvature of the second rolled up portion (206) and in that the first and second rolled up portions are rolled up on the outside of the substantially cylindrical portion.

4. An attachment member (300) according to any one of claims 1-3, **characterized** in that the second rolled up portion (306) comprises an adhesive (321) between the layers of the second rolled up portion.

5. An attachment member (300) according to any one of claims 1-4, **characterized** in that a portion of the portion of the substantially cylindrical portion which makes up the first rolled up portion (305) comprises an adhesive (320).

6. An attachment member (300) according to any one of claims 1-5 **characterized** in that an outer portion of the first rolled up portion (305) when the first rolled up portion is completely rolled up is provided with a skin friendly adhesive (326).

7. An attachment member according to any one of claims 1 to 6, **characterized in that** the first rolled up portion and the second rolled up portion are stretched such that the inner diameter of the rolled up portions are at least 10% greater than the inner diameters of the rolled up portions of the substantially cylindrical portion when the elastic film material of the substantially cylindrical portion is not stretched and not rolled up.

8. A system for collecting urine from a male user, said system comprising
   a. a urine container for collecting and/or storing urine during wear time,
   b. an attachment member according to any one of claims 1-7 and
   c. a connection member for establishing fluid communication between the urine container and the attachment member.

9. A method of attaching an attachment member (300) according to any one of claims 1-7 to a penis comprising the steps of:
   a. providing an attachment member according to any one of claims 1-7,

b. stretching the first and second rolled up portions (305,306) such that the inner diameters of the rolled up portions are at least 1% greater than the outer diameter of the penis,

c. positioning the first and second rolled up portions of the attachment member on the outer surface of the penis rod at a position between the glans penis and the base of the penis; and

d. unrolling the first rolled up portion of the attachment member in a direction along the penis and away from the base of the penis.

10. A method according to claim 9 when using an attachment member according to claim 3, further comprising the step of unrolling the second rolled up portion in a direction along the penis and towards the base of the penis.

11. A method of manufacturing an attachment member (300) suitable for attaching a system to a male human being's penis, said system being suitable for collecting urine from a male human being, said method comprising the steps of:

a. providing an attachment member comprising a substantially cylindrical portion (301) comprising an elastic film material, said substantially cylindrical portion comprising a first opening (303) at a first end thereof and a second opening (302) at the other end thereof,

b. arranging said substantially cylindrical portion of said attachment member on a substantially cylindrical form (600) which has an outer diameter which is equal to or at least slightly larger than the inner diameter of the unstretched substantially cylindrical portion of the attachment member,

c. folding a portion of said substantially cylindrical portion comprising the second opening (302) back towards the first opening (303) such that a portion (P) of said substantially cylindrical portion comprises two layers,

d. rolling the first opening (303) towards the second opening (302) to form a first rolled up portion (305) where the first opening (302) is arranged inside the first rolled up portion (305), but the second opening (302) is not arranged inside the first rolled up portion and

e. rolling the second opening (302) in the same direction as the first rolled up portion to form a second rolled up portion (306) where the second opening is arranged inside the second rolled up portion.

12. A method according to claim 11, **characterized** in that the step of folding back a portion of the substantially cylindrical portion comprising the second opening provides a two layer portion which is between 0,3 cm and 8 cm long.

13. A method according to claim 11 or 12, **characterized** in that an adhesive (321) is applied to a portion of the portion of the substantially cylindrical portion which makes up the second rolled up portion (306) before rolling up the second rolled up portion.

14. A method according to any one of claims 11-13, **characterized** in that an adhesive (320) is applied to a portion of the portion of the substantially cylindrical portion which makes up the first rolled up portion (305) before rolling up the first rolled up portion.

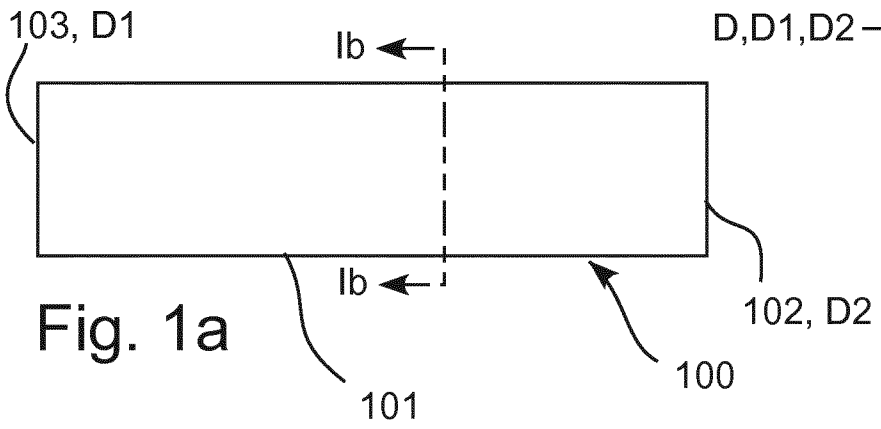


Fig. 1a

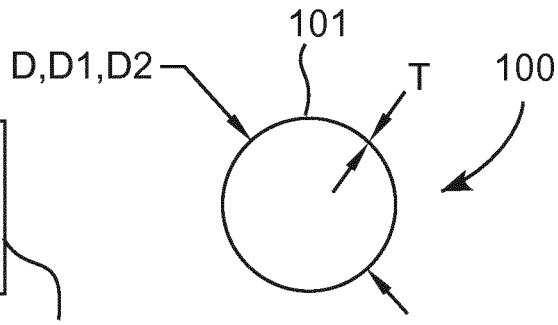


Fig. 1b

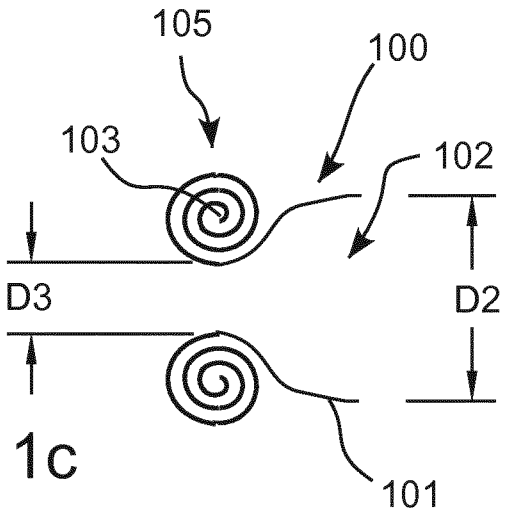


Fig. 1c

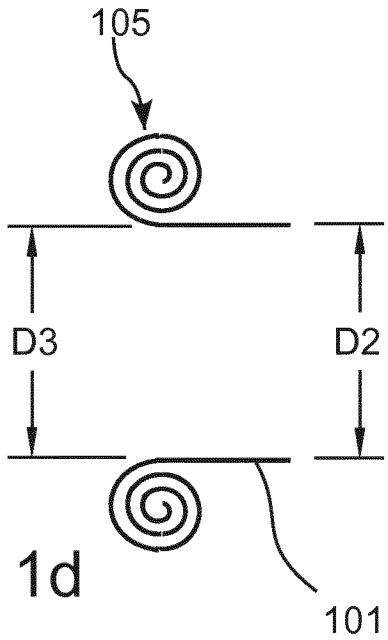


Fig. 1d

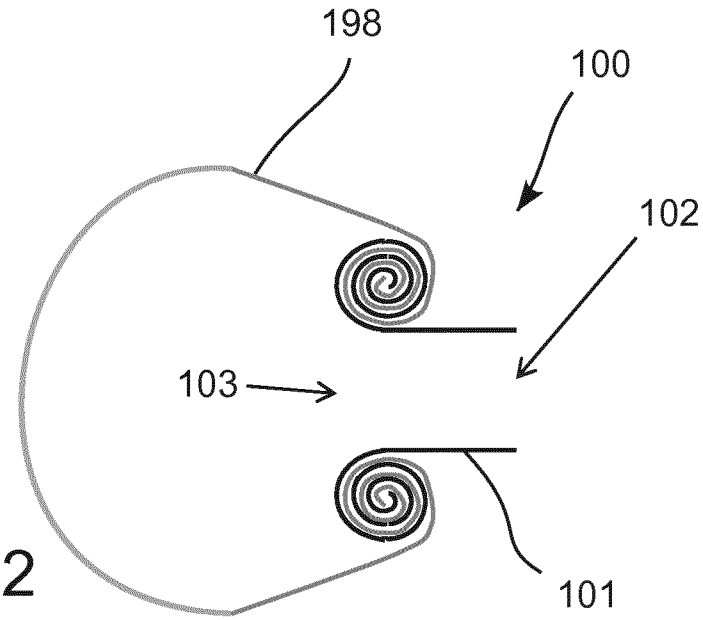


Fig. 2

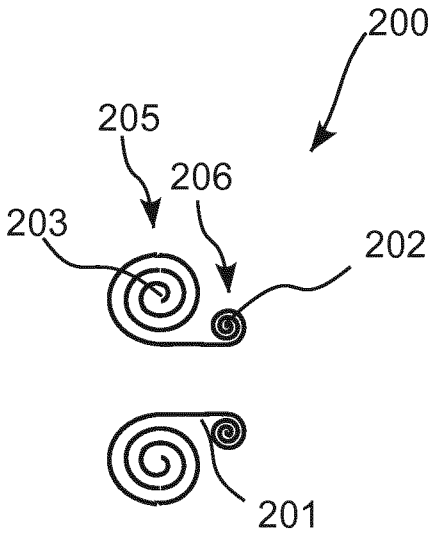


Fig. 3

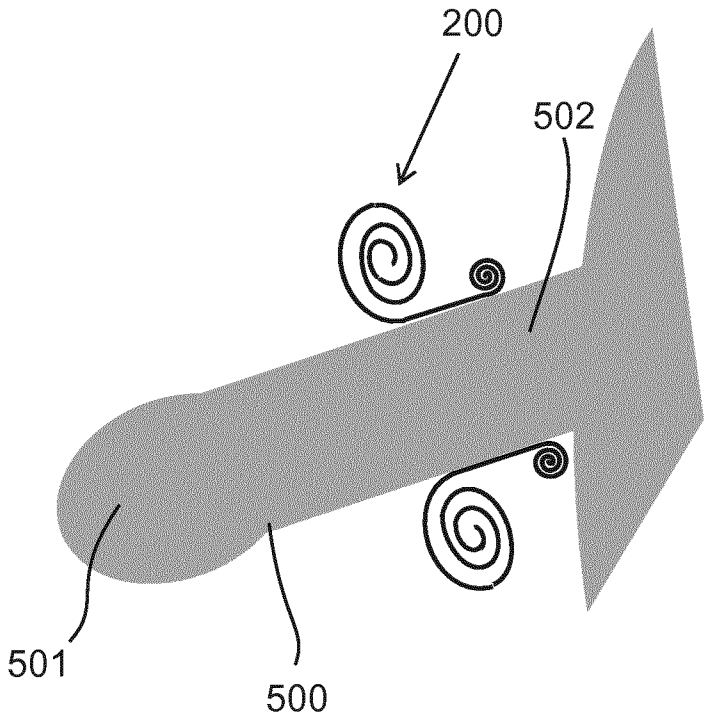


Fig. 4a

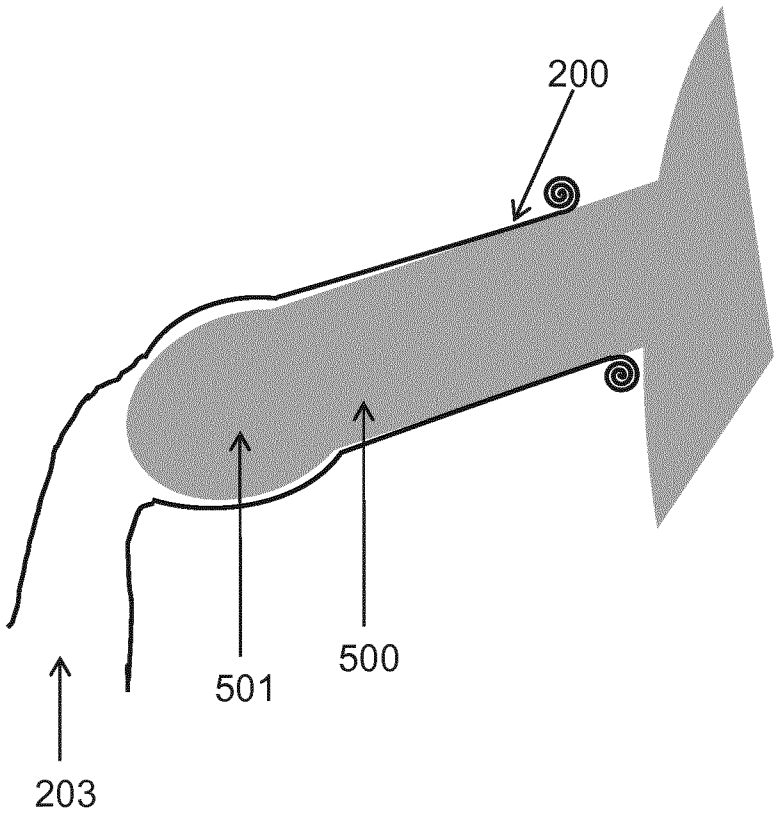


Fig. 4b

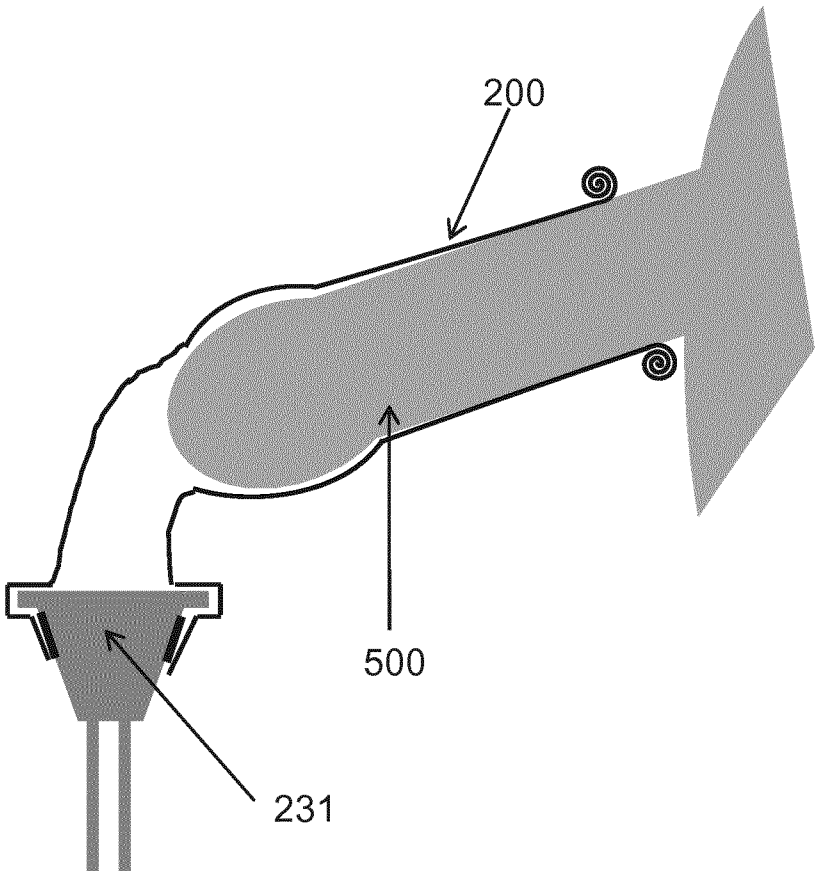


Fig. 4c

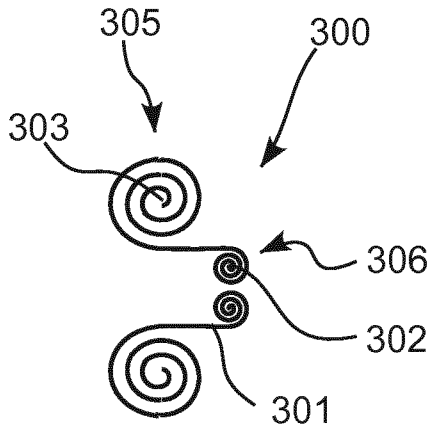


Fig. 5

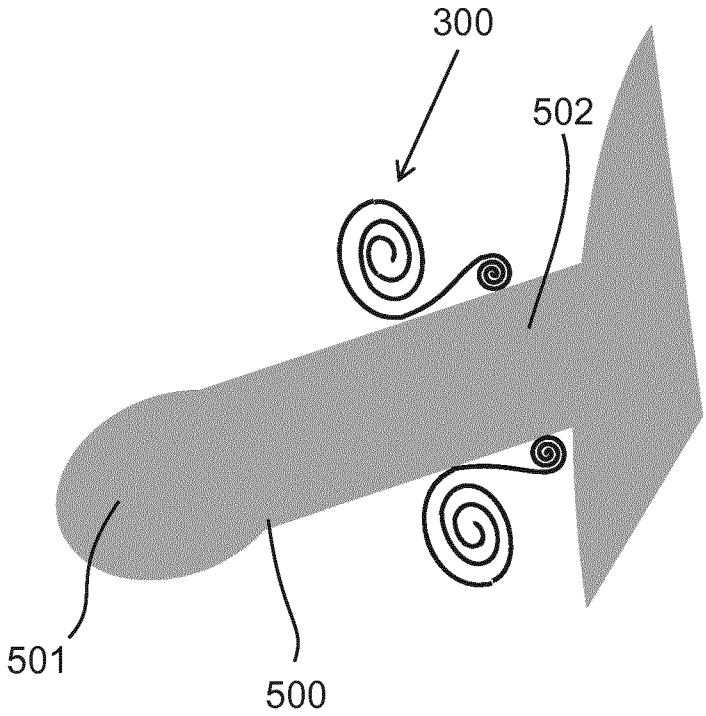


Fig. 6a

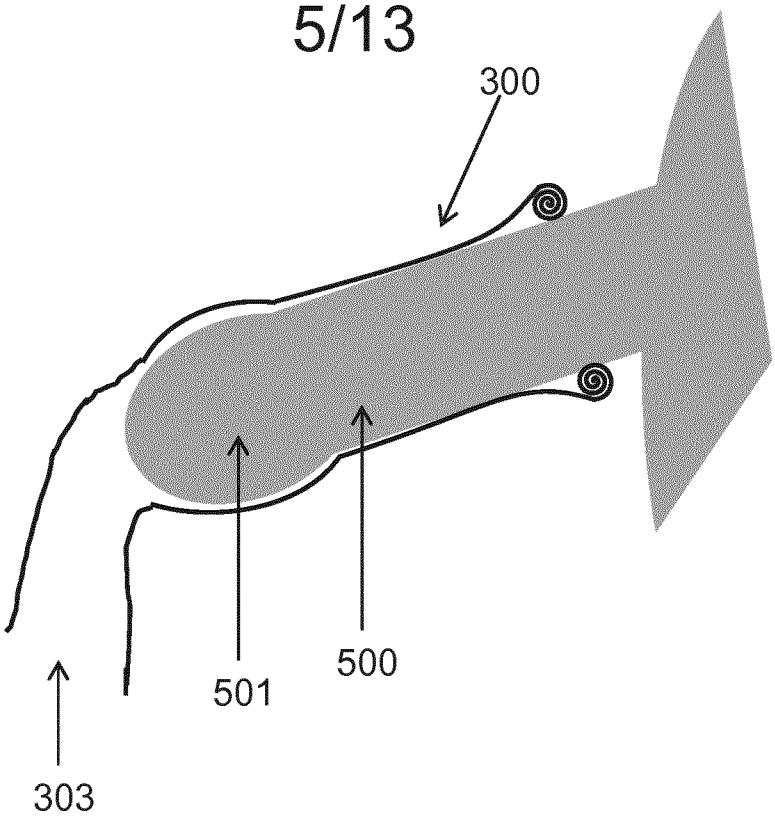


Fig. 6b

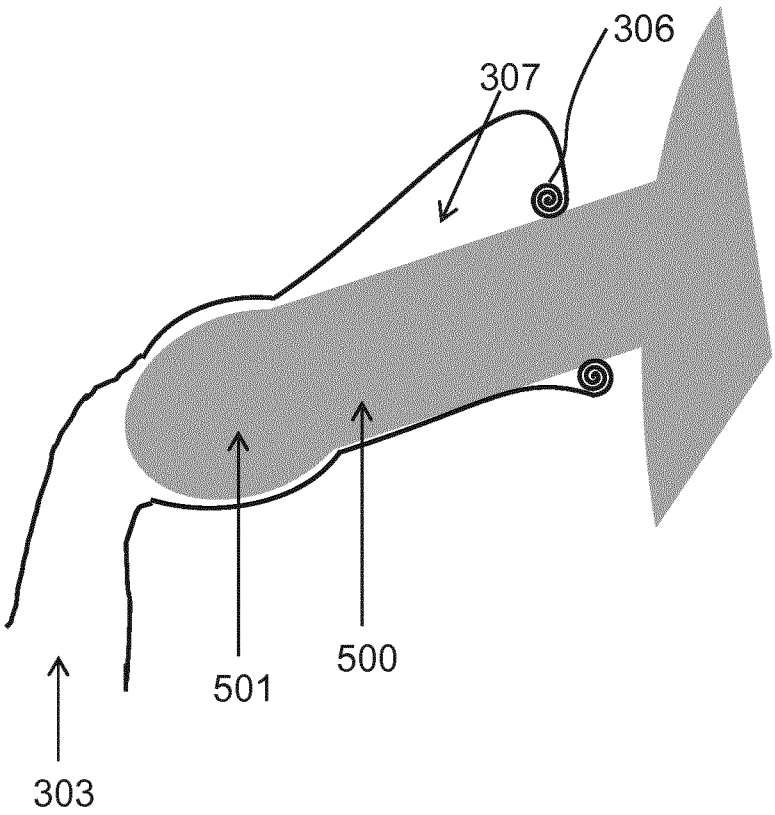


Fig. 6c

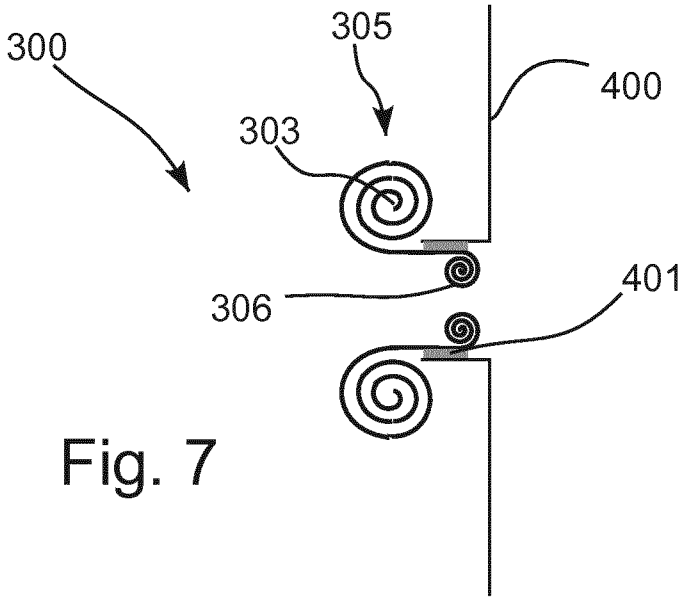


Fig. 7

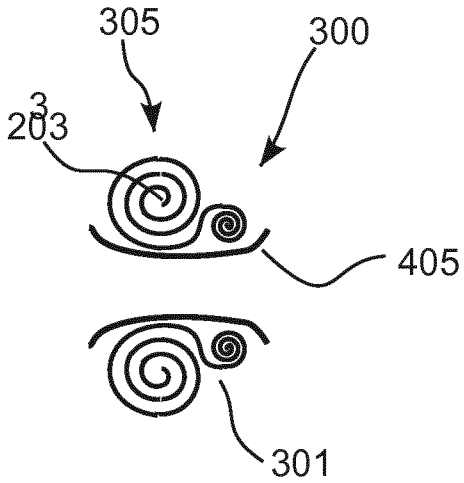


Fig. 8

Fig. 9a

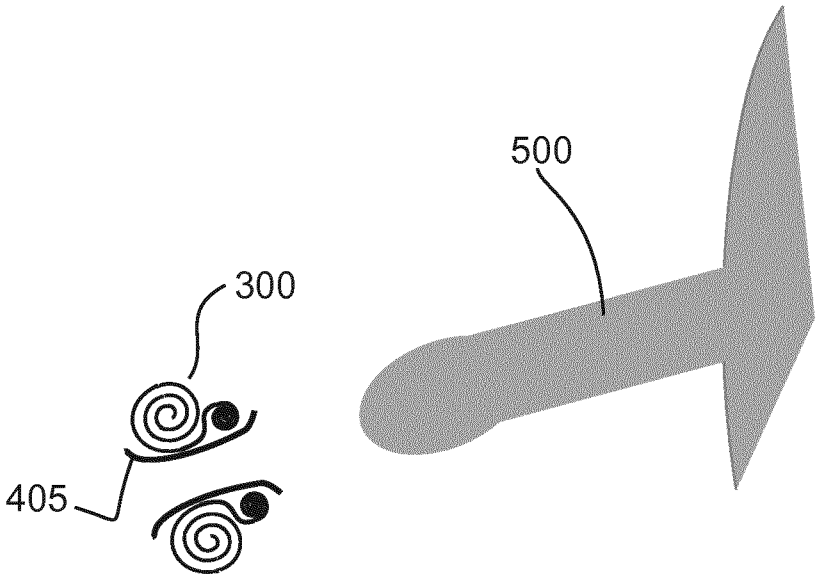


Fig. 9b

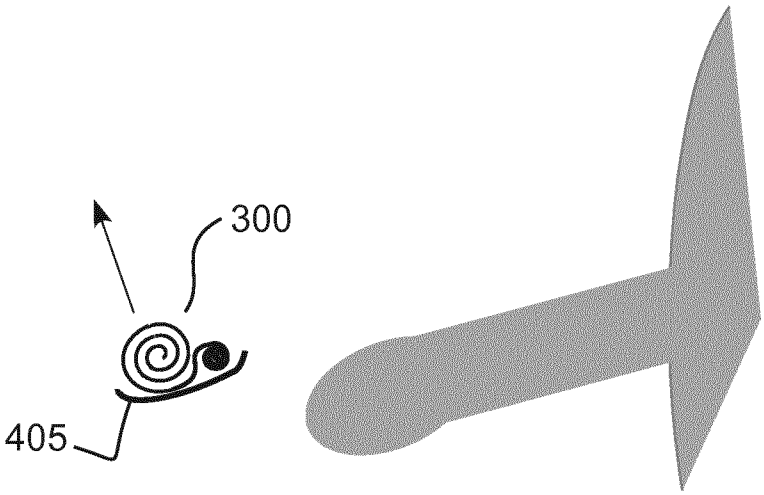
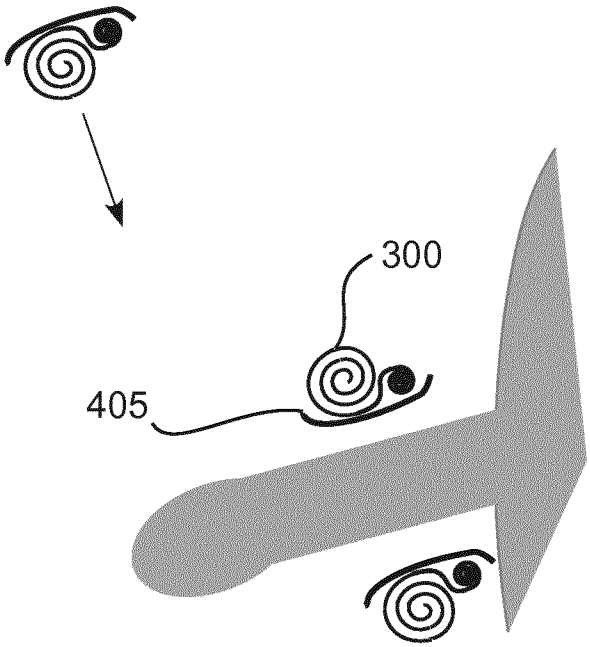


Fig. 9c



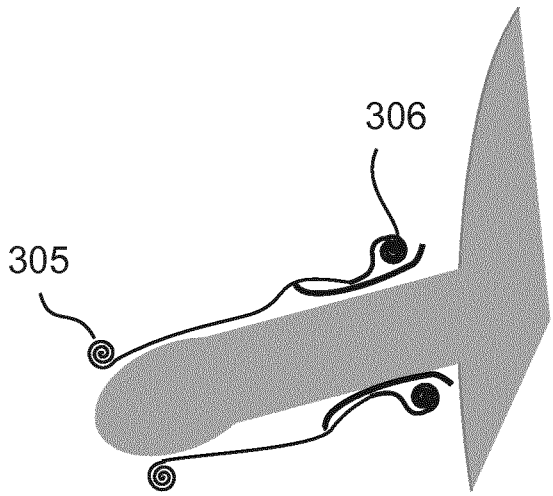


Fig. 9d

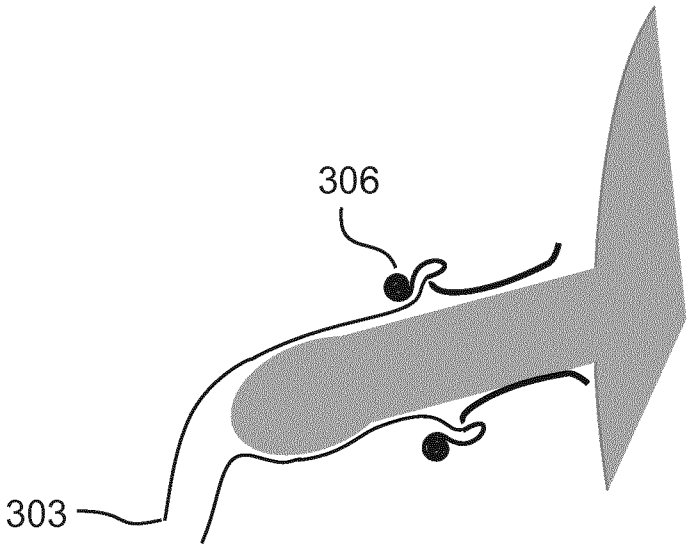


Fig. 9e

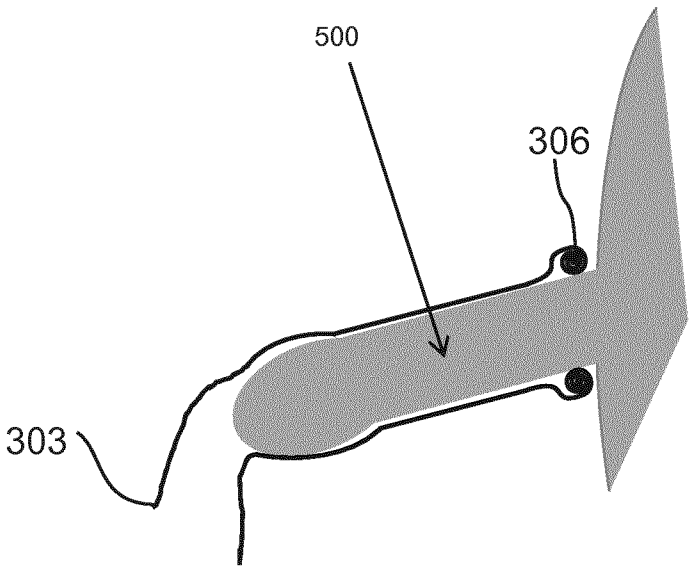


Fig. 9f

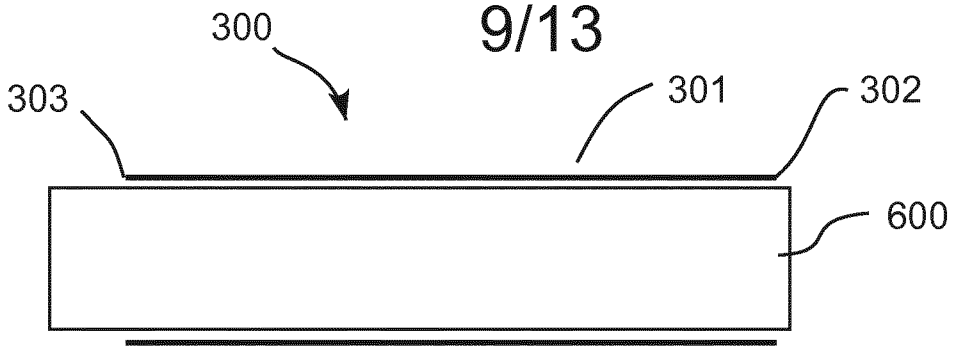


Fig. 10a

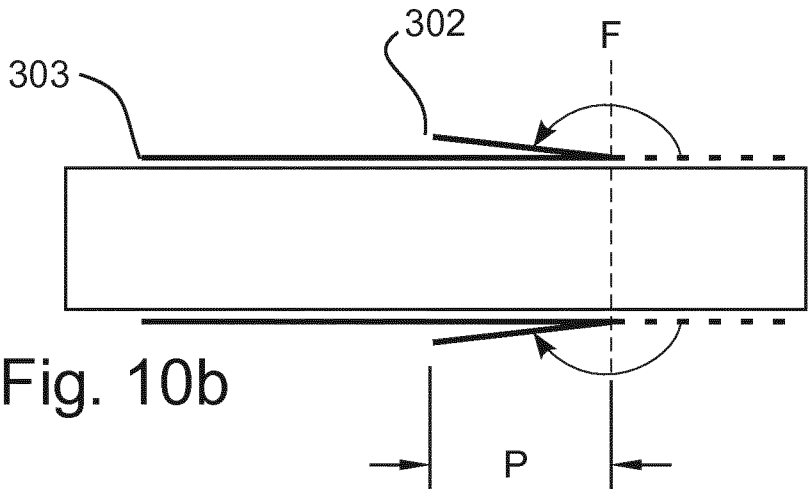


Fig. 10b

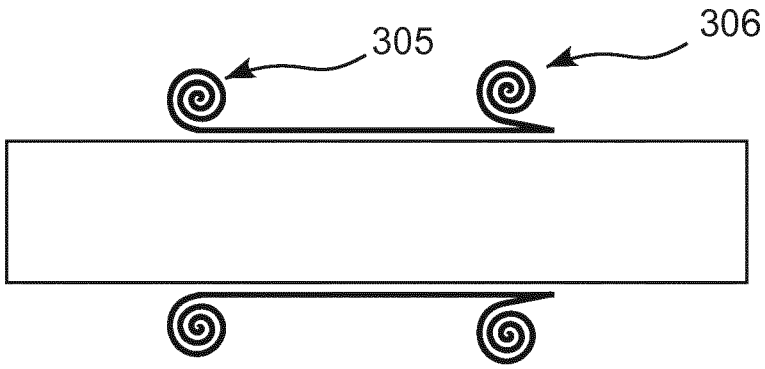


Fig. 10c

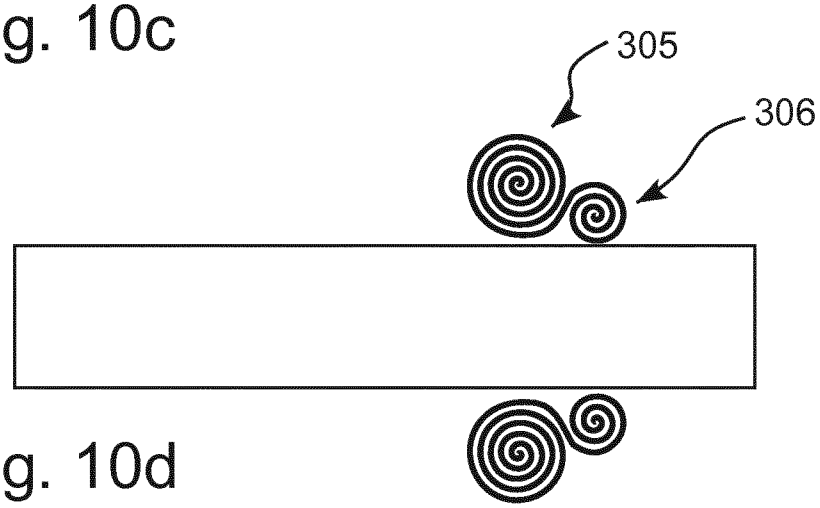


Fig. 10d

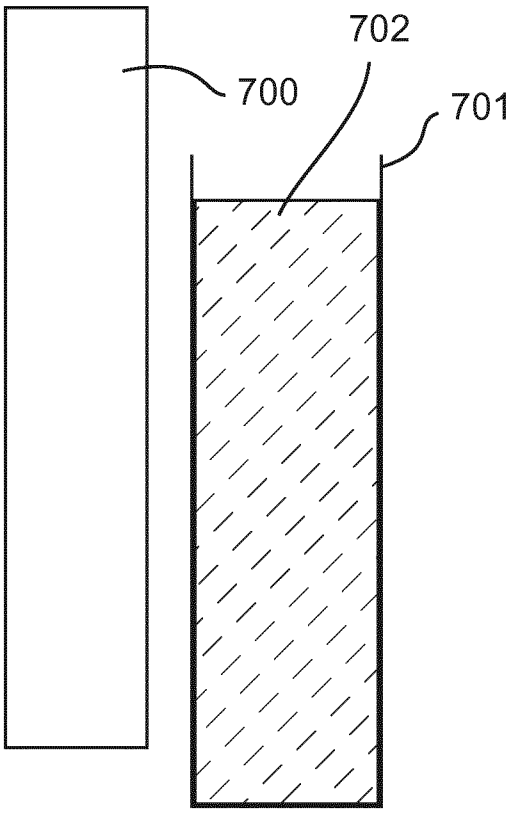


Fig. 11a

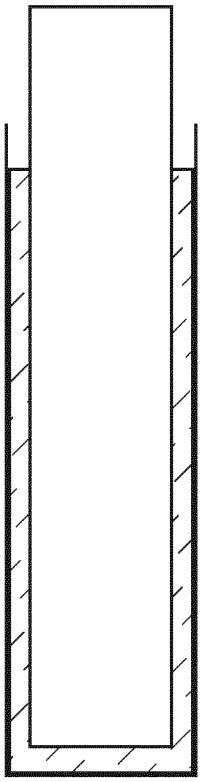


Fig. 11b

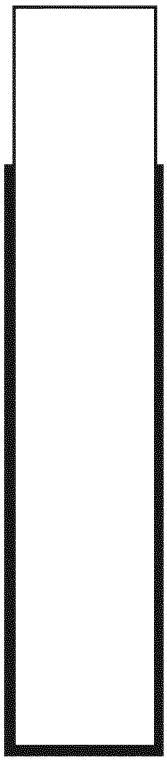


Fig. 11c

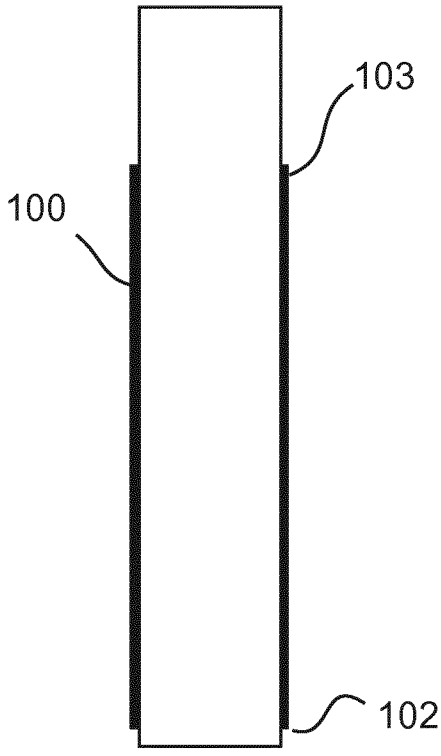


Fig. 11d

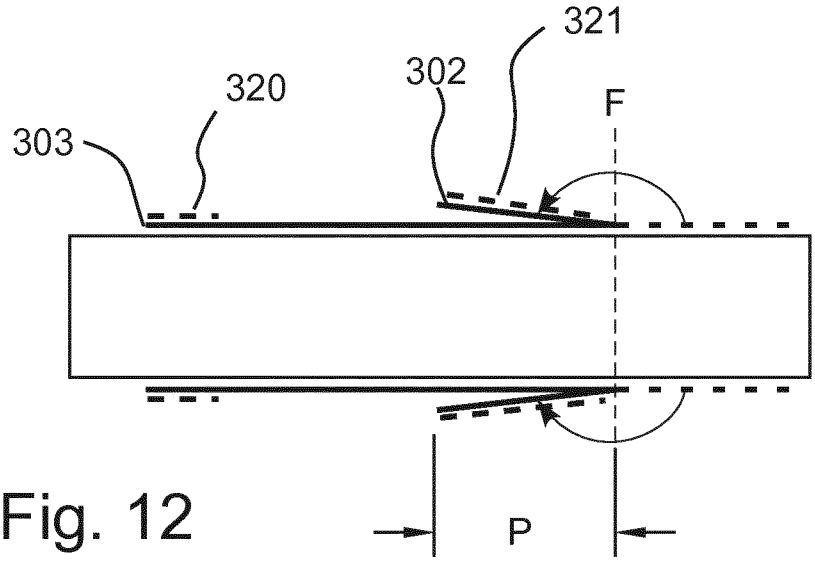


Fig. 12

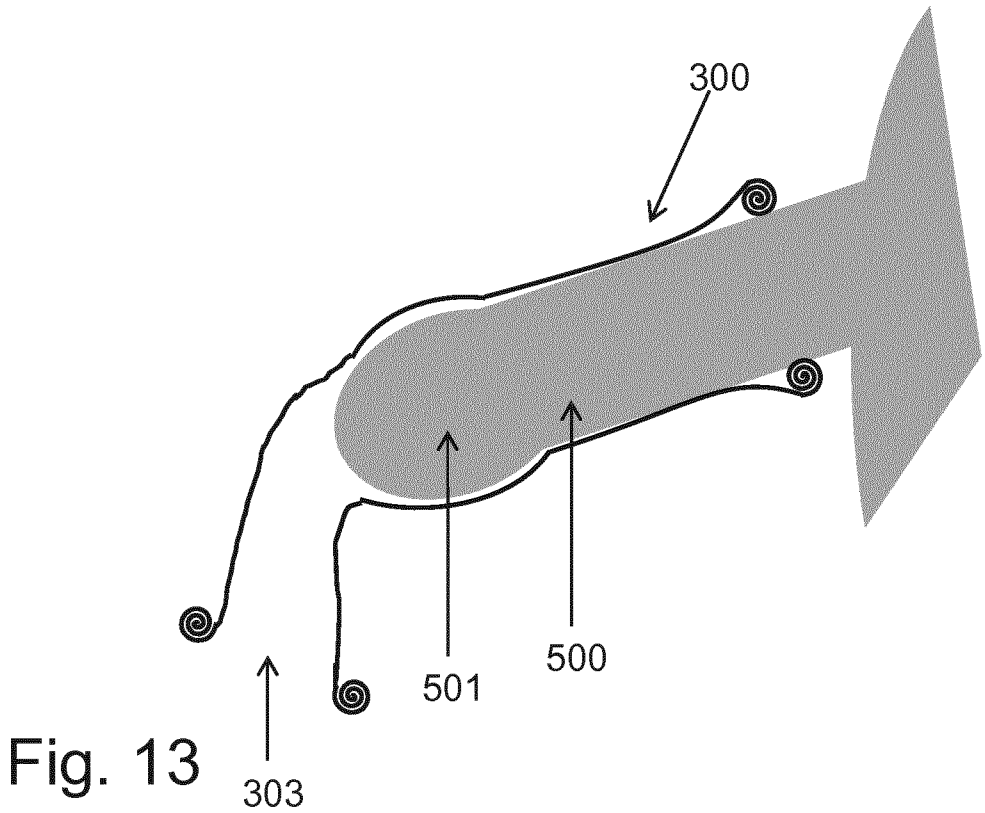


Fig. 13

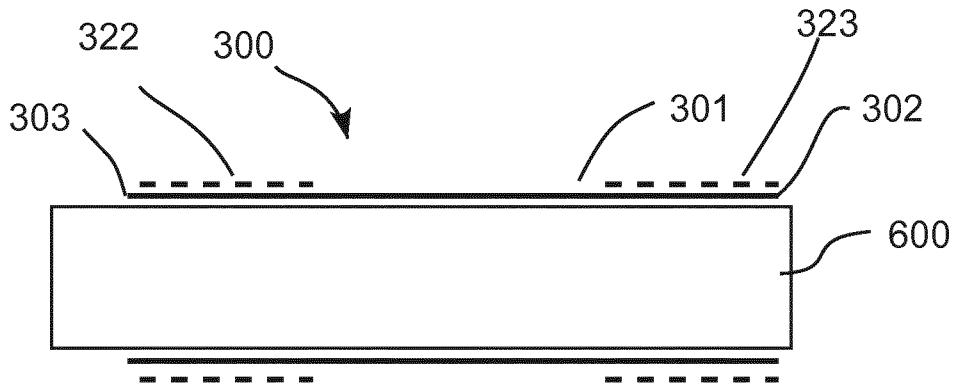


Fig. 14

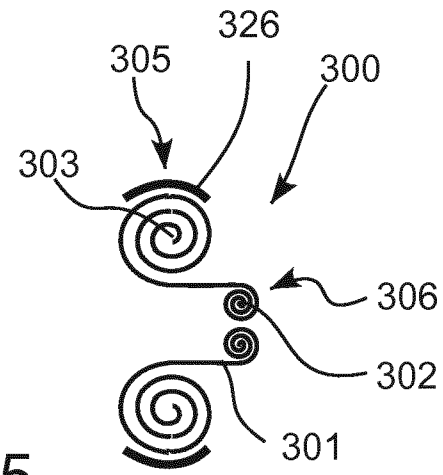


Fig. 15

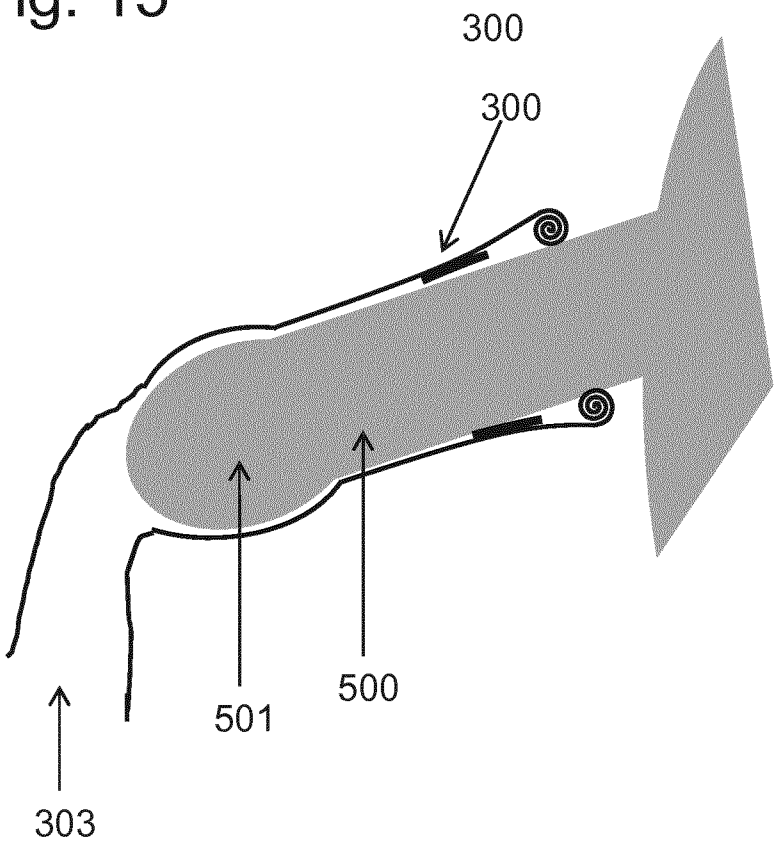


Fig. 16

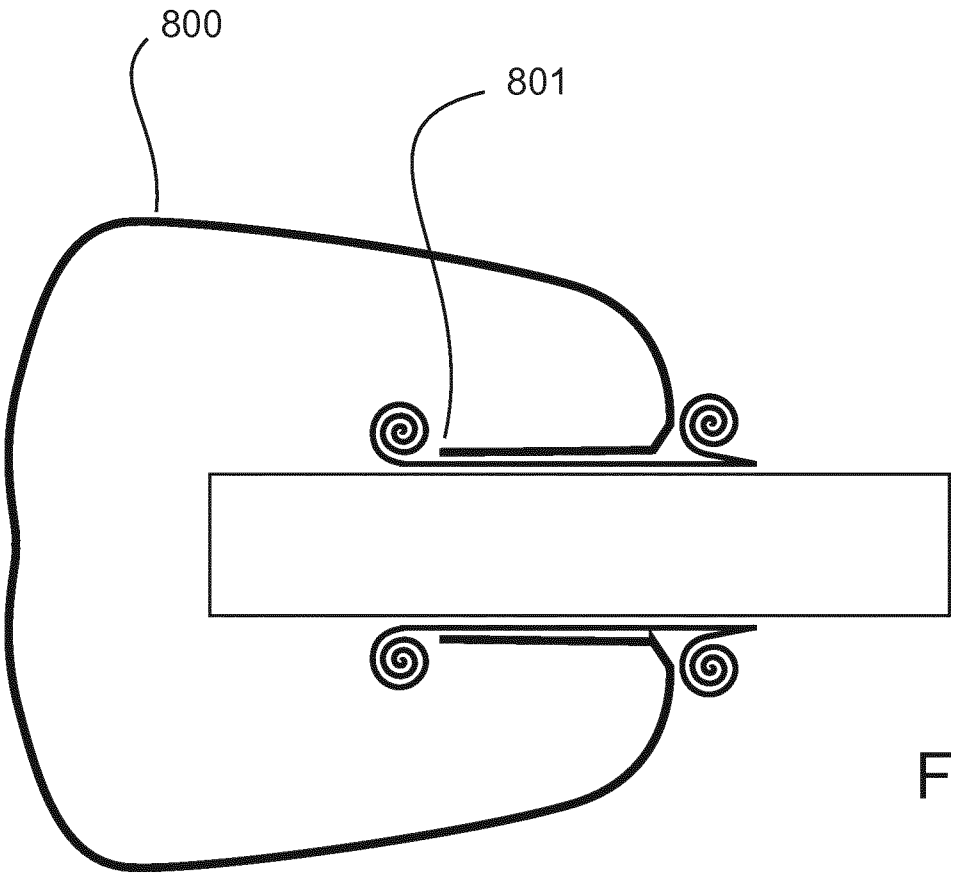


Fig. 17

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/056626

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/453
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)
A61F

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.
X Y	US 2007/142794 A1 (BESTER KENNETH W JR [US] ET AL) 21 June 2007 (2007-06-21) paragraph [0005] - paragraph [0006] paragraph [0024] paragraph [0027] - paragraph [0035] paragraph [0044] - paragraph [0045] paragraph [0046] paragraph [0053]; figures 1-14 -----	1,3-5,7, 9,10 6,8
Y	WO 2011/098581 A1 (SECURIN APS [DK]; NIELSEN BRIAN [DK]; SOERENSEN NICOLAI [DK]) 18 August 2011 (2011-08-18) cited in the application page 33, line 23 - line 28; figure 7 ----- -/--	6,8

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 June 2013	26/06/2013

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

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/056626

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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X	WO 2006/115537 A1 (MALLISON READ ELIZABETH [US]; WILLIAMS JAMES H [GB]) 2 November 2006 (2006-11-02) paragraph [0032] paragraph [0048] - paragraph [0049]; figure 8 -----	1,2,11
A	US 6 916 301 B1 (CLARE KENNETH [US]) 12 July 2005 (2005-07-12) paragraph [0050] - paragraph [0051]; figures 2a-2b -----	1-14

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2013/056626

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		US 2013053804 A1	28-02-2013
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US 6916301 B1	12-07-2005	NONE	