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(71) Applicant: **KMK ApS** [DK/DK]; Hallebyorevej 21, DK-4450 Jyderup (DK).

(72) Inventor: **KJELDSEN, Kurt Malmbak**; Hallebyorevej 21, Hallebyor, DK-4450 Jyderup (DK).

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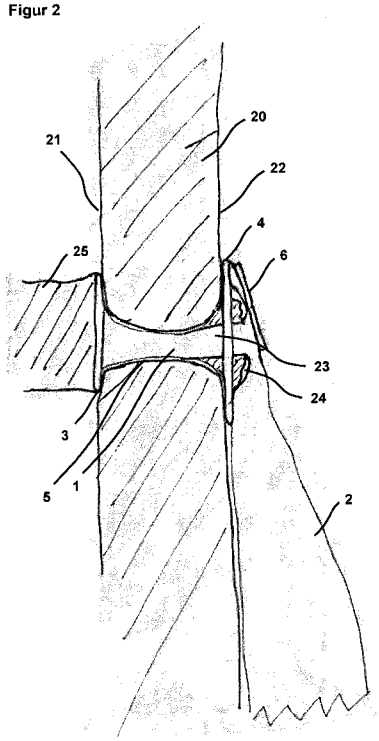
(54) Title: AN OSTOMY BAG

Figur 2



(57) Abstract: An ostomy bag comprising an insertion part and a collection bag, wherein the insertion part comprises a first ring and a second ring and a plastically deformable interspace piece. The first ring can be arranged on the inner side of the abdominal wall and has a diameter which is larger than the stoma, but not so large as to exert an uncomfortable pressure on the inner side of the intestine. The second ring can be arranged on the outer side of the abdominal wall and has a diameter which is larger than the flare of the intestine. The length of the interspace piece is shorter than the profile of the abdominal wall between the first ring and the second ring whereby the interspace piece is deformed plastically when it is mounted. The collection bag constitutes an extension of the insertion part.

An ostomy bag

The invention relates to a flexible ostomy bag for collecting faeces from ostomy patients.

Background of the invention

In case of colostomy and ileostomy the diseased part of the large intestine and the small intestine, respectively, is cut away. The connection to anus is closed, and the mouthing of the remainder of the intestine is drawn through an opening in the abdominal wall where the end of the intestine is sutured into place in the outer epithelium. Owing to the absence of the sphincter, faeces will subsequently flow out of the body passively.

To remedy this, numerous ostomy bags are available on the market. They have various configurations and they all have the feature in common that they consist of several parts and encapsulate the effluent faeces by the bag being adhered to the outer epithelium. As it is, most of the solutions available work quite well following some training and practice. However, on the one hand, the individual adaptation needs to take place by means of scissors, and the assembly of the parts needs to be performed very carefully, and, on the other hand, the glue for the adhesion may often entail undesired skin reactions following prolonged periods of use.

US 2011/0092929 relates to a stoma extender including a first end for insertion into a stoma intended for diverting stomal effluent into the stoma extender before the effluent exits the stoma. Plus a second end covering the remaining external part of the stoma providing a discharge exit for stomal effluent. Also, finally, a conduit portion coupled between the first and second ends for communicating stomal effluent through the stoma extender, wherein the length of the conduit portion is adjustable to permit adaptation of the stoma extender to an individual's stoma.

It is a drawback of the stoma extender that it is to be used in conjunction with several parts, including a wafer that is adhered to the outer epithelium. A further drawback of the stoma extender is that it is kept in place by distension of the intestine.

WO 2012/016575 relates to a stoma prosthesis comprising a rigid interspace piece and an internal flange inserted surgically in the abdominal wall and an external flange screwed onto the interspace piece. The internal and external flanges fixate the prosthesis by applying a pressure around the abdominal wall. A collecting pouch and a cap can be mounted on the stoma prosthesis.

The drawback of the stoma prosthesis to the patient is the rigid interspace piece which will be difficult to conceal due to the way in which the interspace piece protrudes out of the abdominal wall and which may be difficult to ignore when the stomach region moves, the interspace piece not being deformable.

According to the present invention the ostomy bag is a fully integrated bag encapsulating and collecting faeces without using glue and comprising only one part that constitutes an inexpensive, disposable product. The ostomy bag is applied with one hand and without the use of mirror, scissors, and the like. The integration of the bag with the mounting unit safeguards against the occurrence of leak of faeces that may irritate the skin around the stoma. Additionally, fixation of the ostomy bag is accomplished by a pressure around the abdominal wall which is less vulnerable to pressure than the intestinal wall. An inexpensive and readily usable disposable product like the present one will be suitable e.g. to ostomy patients in poor countries.

Description of the invention

The ostomy bag comprises an insertion part and a collection bag, wherein the insertion part comprises a first ring and a second ring and a plastically

deformable interspace piece. The first ring can be arranged on the inner side of the abdominal wall and has a diameter which is larger than the stoma, but not so large as to exert an uncomfortable pressure on the inner side of the intestine. The second ring can be arranged on the outer side of the abdominal wall and has a diameter which is larger than the stoma. Usually, the second ring will also be larger than the flare of the intestine. The length of the interspace piece is shorter than the profile of the abdominal wall between the first ring and the second ring whereby the interspace piece is deformed plastically when it is mounted. The collection bag constitutes an extension of the insertion part.

Thereby the ostomy bag is kept in place by the plastic stress of the interspace piece between the first ring and the second ring. Hereby the use of wafers glued to the skin or distension of the intestine is obviated, both of which may be of great discomfort to the user.

According to a preferred embodiment, the interspace piece is either cylindrical or frusto-conical when it is extended between the first ring and the second ring in non-mounted state.

The collection bag is made of the same material as the interspace piece.

The collection bag may comprise a degassing item consisting of a degassing filter with i.a. activated carbon.

According to a further embodiment, the collection bag may comprise a degassing item consisting of a degassing valve provided with a filter with i.a. activated carbon.

All or parts of the material of the ostomy bag may be biodegradable. Hereby it is enabled that the entire ostomy bag with contents is fully flushable in the toilet.

The distance between the first ring and the second ring can be varied by the second ring being kept in position by a number of circularly or partially circularly disposed ribs that protrude from the inner surface at the external end of the interspace piece. It is thereby possible for the user to fine-tune the pressure of the insertion part around the abdominal wall, e.g. when a higher pressure could be desirable during various physical activities, such as e.g. running and dancing, or when a lower pressure could be desirable if the user has, for a period of time, gained weight with an ensuing increase in the thickness of the abdominal wall.

According to a further embodiment, the second ring has a diameter of 80-150 mm, preferably 110-150 mm. The diameter of the second ring is thereby considerably larger than the stoma.

In this embodiment, the interspace piece may be divided into two parts, an internal part and an external part, wherein the external part of the interspace piece consists of a material that is less elastic than the internal part.

The advantage of that embodiment is that the increased diameter of the second ring and the increased rigidity of the external part of the interspace piece support the tissue around the stoma and thereby reduces the likelihood of the patient suffering from hernia around the ostomy.

The invention also relates to an ostomy plug comprising an insertion part, wherein the insertion part comprises a first ring and a second ring, a plastically deformable interspace piece and at least one degassing filter. The first ring can be arranged on the inner side of the abdominal wall and has a

diameter which is larger than the stoma. The second ring can be arranged on the outer side of the abdominal wall and has a diameter which is larger than the stoma. The length of the interspace piece is shorter than the profile of the abdominal wall between the first ring and the second ring whereby the interspace piece is deformed plastically when it is mounted. The degassing filter closes either the first ring or the second ring.

The ostomy plug is thereby kept in place by the plastic stress on the interspace piece between the first ring and the second ring.

According to a preferred embodiment, the interspace piece is either cylindrical or frusto-conical when it is extended between the first ring and the second ring in non-mounted state.

Both the first ring and the second ring can be closed off by a degassing filter, whereby the ostomy plug comprises two degassing filters, wherein the first ring is closed off by a degassing filter, and the second ring is closed off by a second degassing filter. This may provide added safeguarding to the user against odour nuisance.

All or parts of the material of the ostomy plug may be biodegradable.

Definitions

Elastic: a reversible deformation (i.e. change of shape) of a material whilst under the influence of an external force, whereby by “reversible” is intended that the material reverts to its original shape after the deformation.

Circular: A more or less circle-shaped ring or loop that may be either interrupted or uninterrupted.

Brief description of the figures

Figure 1 shows the ostomy bag in non-mounted state.

Figure 2 shows a cross section of the ostomy bag in mounted state. However, cross-sections of the first ring and the second ring are not provided.

Figure 3 shows a cross section at the external mounting face of the ostomy bag.

Figure 4a shows a cross section along the interspace piece showing an embodiment of the ribs.

Figure 4b shows a cross section transversally of the interspace piece showing an embodiment of the ribs without ring mounted.

Figure 4c shows a cross section transversally of the interspace piece showing an embodiment of the ribs with ring mounted.

Figure 5 shows a cross section of the degassing filter.

Figure 6 shows an embodiment of an insertion tool.

Figure 7 shows an embodiment wherein the bag has been replaced by a degassing filter to the effect that it may serve as an ostomy plug.

Figure 8 shows an embodiment of the ostomy bag wherein the outer ring is substantially larger than the stoma and a two-part interspace piece.

Detailed description

As shown in figure 1, the ostomy bag is, according to the preferred embodiment, a simple and uncomplicated structure consisting of an insertion part **1** and, in extension of that, a collection bag **2**. The insertion part **1**

consists of a first ring **3** and a second ring **4**, both of which are flexible and enclosed and connected by an interspace piece **5** of a thin, flexible and elastic material. Said material continues beyond the second ring **4** and forms the collection bag **2** for collecting faeces. Thereby the ostomy bag is a unit that needs neither gluing to the skin nor assembly with other parts to work.

The first **3** and second **4** rings are not necessarily circular in the rings' own cross sections. They may just as well be oval or have another suitable shape.

The first ring **3** is an elastic ring having a diameter which is slightly larger than the stoma **23** in the abdominal wall **20**, e.g. 30 mm. At the same time, the diameter of the first ring **3** must not be so large as to exert an uncomfortable pressure on the intestinal wall **25**. The rigidity and thickness of the ring as such are adapted to be such that, compressed, it can easily be inserted into the stoma **23** and inside on the inner side of the abdominal wall **21**. This is without the use of mirror, scissors, glue or other aids. Choice of material and thickness may be varied until sufficient elasticity and pressure are accomplished. The thickness of the first ring **3** may be e.g. 1-3 mm.

Also, ring **3** and the entire ostomy bag are removed easily by a skew pull in the second ring **4** and the interspace piece **5**. Optionally after having turned the ring **4** a couple of times to cut off for discharge of faeces.

As shown in figure 2, the interspace piece **5** connects the first ring **3** and the second ring **4** and is made of a thin and elastic material. Choice of material and thickness can be varied until sufficient elasticity and pressure are accomplished. One preferred material could be the polymer known under the designation Latex. The length of the interspace piece depends on the individual abdominal wall **20** and is usually shorter than the thickness of the abdominal wall, whereby the first ring **3** and the second ring **4** are drawn towards each other and connect sealingly to the inner side **22** and the outer

side **21**, respectively, of the abdominal wall **20**. Thus, it is the plastic stress of the interspace piece **5** between the two rings **3**, **4** that keeps the entire ostomy bag in place.

The first ring **3** is welded, rolled or in other way attached to the end of the interspace piece **5**. Internally, the interspace piece **5** is, at the second ring **4**, provided with a circularly or partly circularly arranged rib **7** that secures the otherwise loose ring **4** in the desired position. That a rib is partially circular means that the rib **7** may constitute an interrupted or uninterrupted circle on the inner side of the interspace piece **5**. The rib **7** may be configured as a row of barbs facing towards the first ring **3**. According to a further embodiment, the rib **7** may be replaced by a ring of the same material as the first **3** and the second **4** rings which is welded, rolled or otherwise attached to the inner side of the interspace piece **5**.

The second ring **4** is an elastic ring having a diameter which is somewhat larger than the flare **24** of the intestine on the outer side of the abdominal wall **22**, e.g. 50-70 mm. The second ring **4** may be made of the same material as the first ring **3**. The thickness of the second ring **4** as such is usually larger than that of the first ring **3**, e.g. 3-6 mm. Upon delivery, the ring is usually located in the rib **7** in the interspace piece **5**. The interspace piece **5** can be provided with plural rows of ribs **7**, whereby the distance between the first ring **3** and the second ring **4** can be regulated following insertion of the first ring **3** by the second ring **4** being moved to one of the other ribs **7**. It is thereby possible to fine-tune the length of the interspace piece to optimal fit relative to the thickness of the abdominal wall **20** of the individual user.

As shown in figure 3, the second ring **4** is larger than the flare **24** of the intestine. Thereby it is only the interspace piece **5** which is made of a more flexible and softer material than the ring **4** that comes into contact with the

flare **24** of the intestine. This is advantageous since the flare of the intestine **24** can be very sensitive.

In figures 4a, 4b, and 4c an embodiment is shown, wherein the ribs **7** are configured as a number of barbs **7** that sit at a distance from each other in a circle on the inner side of the interspace piece **5**. Figures 4a and 4c also show the location of the second ring **4** in one of the ribs **7**. By this is intended that, when the ostomy bag is mounted and the second ring **4** is arranged in one of the ribs **7**, the second ring **4** will not be able to fall back onto a rib **7** closer to the collection bag **2**.

The collection bag **2** is made from the same material as the interspace piece **5**. The collection bag **2** may, at the top, be provided with an opening of about 20 by 40 mm covered by a degassing item **6** that allows intestinal gas to leave the collection bag **2** without allowing liquid to seep through and removes the unpleasant odour from the intestinal gas. The degassing item **6** may be a degassing filter **8** or a degassing valve provided with a degassing filter **8**.

A degassing filter is usually constructed from several layers, wherein each layer has the same or a different function; figure 5 shows a degassing filter **8** made in three layers. The three layers comprise an innermost layer **9** consisting of a coarse filter **9** for collecting faeces. It could be e.g. a layer of nylon sponge or other foam material. Then a middlemost layer **10** suitable for adsorption of impurities from liquids and gases, such as e.g. activated carbon **10**, and finally a membrane **11** of a waterproof, but breathable material. A preferred material could be one of the polymers known under the designations Gore-Tex and SympaTex.

By the insertion part **1** and the collection bag **2** being made in one piece, it is prevented that faeces come into contact with the cut-off end of the intestine

25 and the skin on the outside of the abdominal wall **22** when the ostomy bag is mounted. The ostomy bag will thereby be suitable in cases where it is not possible, or for other reasons not advantageous, to make a flare **24** of the intestine **25** on the patient. For instance, it could be necessary to keep as much functional intestine as possible. Or it may be of interest to avoid the sensitive flare.

For the ostomy bag, a lid **30** may advantageously be provided having a face constructed like, or having the same properties as, the degassing filter **8** in the degassing valve **6**. Following insertion of the first ring **3** and optionally adjustment of the second ring **4**, the collection bag **2** is pushed into the insertion part **1,** or merely towards it, and the lid **30** is clicked onto the second ring **4**.

By clicking on the lid **30**, the ostomy bag may quickly be converted into a complete enclosure for faeces. Should the lid **30** fall off the second ring **4**, the collection bag **2** will unfold and operate as usual. This is without a risk of leak of faeces or odour nuisance.

An insertion tool **12** may also be a supplement to the ostomy bag. As shown in figure 6, the insertion tool **12** may be a 10-20 cm long stick **12** with a U-shaped retention part at the one end configured for being positioned on the first ring **3**. A slight pull in the interspace piece **5** will deform the first ring **3** and stay in contact with the engagement of the stick **12** with the first ring **3**, which can then be inserted into the stoma **23**. When ring **3** has, by means of the stick **12**, been inserted just beyond the inner side of the abdominal wall **21**, the stick **12** is withdrawn, the ring **3** straightens out circularly, and a straight pull in the second ring **4** makes the first ring **3** abut on the inner side of the abdominal wall **21**. Following complete withdrawal of the stick **12**, ring **4** is positioned in the correct rib **7** for ensuring sealing.

According to a further advantageous embodiment, the collection bag **2** is removed from the ostomy bag to the effect that the ostomy bag is rather to serve as an ostomy plug **40**. The ostomy plug **40** consists of the insertion part **1** and a first ring **3** and a second ring **4**, both of which are flexible and enclosed and connected by an interspace piece **5** of a thin, flexible material. The access to the insertion part **1** through the first ring **3** is closed off by a degassing filter **8** that could be similar to or have the same properties as the degassing filter **8** in the degassing valve **6**. A lid **30** could be arranged on the second ring **4**, following mounting, as described above. Likewise, the access to the insertion part **1** through the second ring **4** may also be closed off by a degassing filter **8** that could also be similar to or have the same properties as the degassing filter **8** in the degassing valve **6**. By having two degassing filters **8**, one on the first ring **3** and on the second ring **4**, respectively, it is ensured that faeces are retained while simultaneously the intestinal gases are allowed to escape. The advantage of this is that the patient may avoid feeling bloated shortly after mounting of the plug. The aforementioned lid **30** may also be mounted on the second ring **4** if the access to the insertion part **1** through the second ring **4** has been closed off with a degassing filter **8**. That could be relevant during periods when the patient wishes added safeguarding against odour nuisance.

According to a further advantageous embodiment, the second ring **4** has a diameter which is much larger than the stoma **23** in the abdominal wall **20**, e.g. 80-150 mm, preferably 110-150 mm. In this embodiment, the intermediate piece **5** is divided into two parts, an internal part **51** and an external part **52**. The internal part **51** is the part of the interspace piece **5** which sits inside the stoma **23** and covers the flare **24** of the intestine, if a flare is present. The external part **52** is that part of the interspace piece **5** which sits along the outer side of the abdominal wall **22**. The external part **52** of the interspace piece **5** consists of a material which is more rigid than that which the internal part **51** consists of. By more rigid is intended a less flexible

and elastic material. The increased rigidity may be accomplished by use of another, more rigid material than that which was used for the internal part **51**. The two parts **51**, **52** of different materials may be joined by welding. Or the material in the external part **52** may be more rigid due to an increased material thickness. The advantage of this embodiment is that the increased diameter of the second ring **4** and the increased rigidity of the external part **52** of the interspace piece **5** supports the tissue around the stoma **23** and hence reduces the likelihood that the patient will suffer from hernia around the ostomy.

Claims

1. An ostomy bag comprising an insertion part (1) and a collection bag (2), wherein the insertion part (1) comprises a first ring (3) and a second ring (4) and a plastically deformable interspace piece (5),

- the first ring (3) can be arranged on the inner side of the abdominal wall (20) and has a diameter which is larger than the stoma (23);
- the second ring (4) can be arranged on the outer side of the abdominal wall (21) and has a diameter which is larger than the stoma (23);
- the length of the interspace piece (5) is shorter than the profile of the abdominal wall (20) between the first ring (3) and the second ring (4) whereby the interspace piece (5) is deformed plastically when it is mounted;
- the collection bag (2) constitutes an extension of the insertion part (1).

2. An ostomy bag according to claim 1, **characterised in that** the ostomy bag is kept in place by the plastic stress of the interspace piece (5) between the first ring (3) and the second ring (4).

3. An ostomy bag according to one or more of the preceding claims, **characterised in that** the interspace piece (5) is either cylindrical or frusto-conical when it is extended between the first ring (3) and the second ring (4) in non-mounted state.

4. An ostomy bag according to one or more of the preceding claims, **characterised in that** the collection bag (2) is made of the same material as the interspace piece (5).

5. An ostomy bag according to one or more of the preceding claims, **characterised in that** the collection bag (2) comprises a degassing item (6) consisting of a degassing filter (8) with activated carbon (10).

6. An ostomy bag according to one or more of the preceding claims, **characterised in that** the collection bag (2) comprises a degassing item (6) consisting of a degassing valve provided with a filter (8) with activated carbon (10).

7. An ostomy bag according to one or more of the preceding claims, **characterised in that** all or parts of the material of the ostomy bag is/are biodegradable.

8. An ostomy bag according to one or more of the preceding claims, **characterised in that** the distance between the first ring (3) and the second ring (4) can be varied by the second ring (4) being kept in position by a number of circularly or partially circularly disposed ribs (7) that protrude from the inner surface at the external end of the interspace piece (5).

9. An ostomy bag according to one or more of the preceding claims, **characterised in that** the second ring (4) has a diameter of 80-150 mm, preferably 110-150 mm.

10. An ostomy bag according to one or more of the preceding claims, **characterised in that** the interspace piece (5) is divided into two parts, an internal part (51) and an external part (52), where the external part (52) of the interspace piece (5) consists of a material that is less elastic than the internal part (51).

11. An ostomy plug comprising an insertion part (1), wherein the insertion part (1) comprises a first ring (3) and a second ring (4), a plastically deformable interspace piece (5) and a degassing filter (8),

- the first ring (3) can be arranged on the inner side of the abdominal wall (20) and has a diameter which is larger than the stoma (23);
- the second ring (4) can be arranged on the outer side of the abdominal wall (21) and has a diameter which is larger than the stoma (23);
- the length of the interspace piece (5) is shorter than the profile of the abdominal wall (20) between the first ring (3) and the second ring (4) whereby the interspace piece (5) is deformed plastically when it is mounted;
- the degassing filter (8) closes either the first ring (3) or the second ring (4).

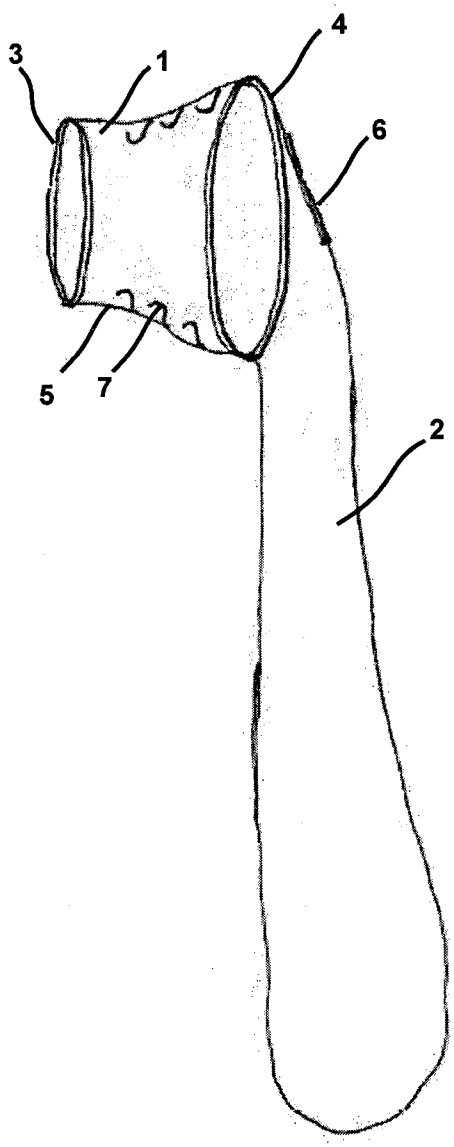
12. An ostomy plug according to claim 11, **characterised in that** the ostomy plug is kept in place by the plastic stress on the interspace piece (5) between the first ring (3) and the second ring (4).

13. An ostomy plug according to claim 11 or 12, **characterised in that** the interspace piece (5) is either cylindrical or frusto-conical when it is extended between the first ring (3) and the second ring (4) in non-mounted state.

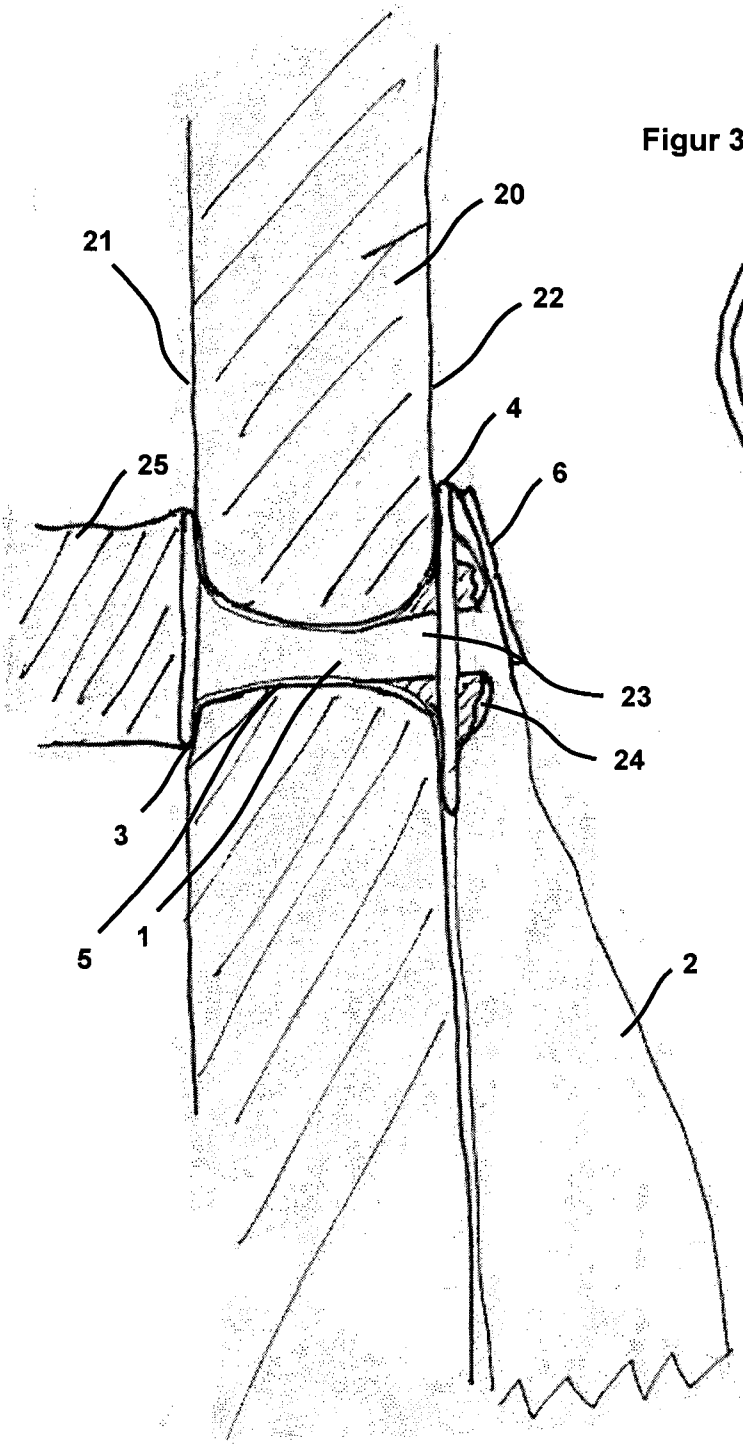
14. An ostomy plug according to one or more of claims 11-13, **characterised in that** the ostomy plug comprises two degassing filters, wherein the first ring (3) is closed off by a degassing filter (8), and the second ring (4) is closed off by a second degassing filter (8).

15. An ostomy plug according to one or more of claims 11-14, **characterised in that** all or parts of the material of the ostomy plug is/are biodegradable.

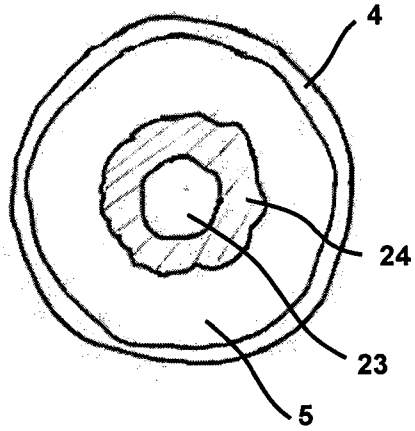
Figur 1



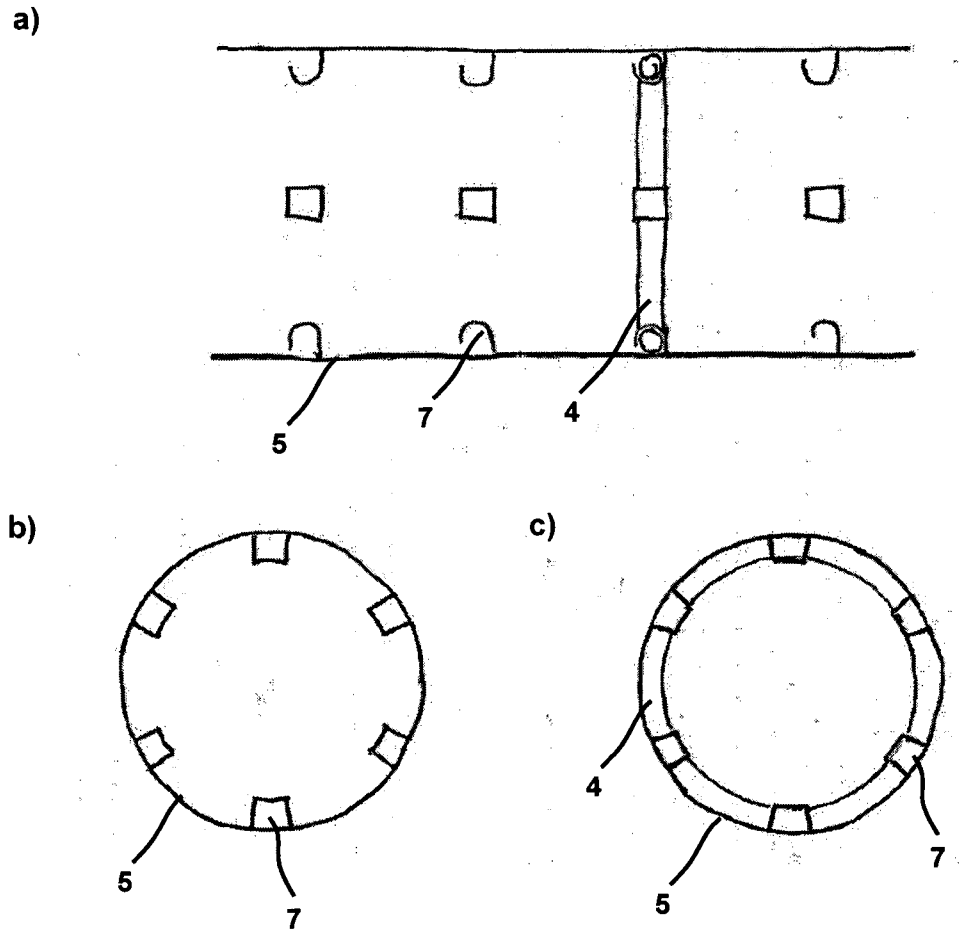
Figur 2



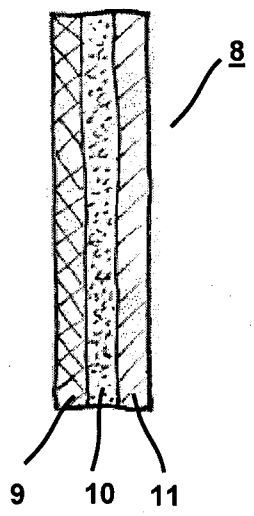
Figur 3



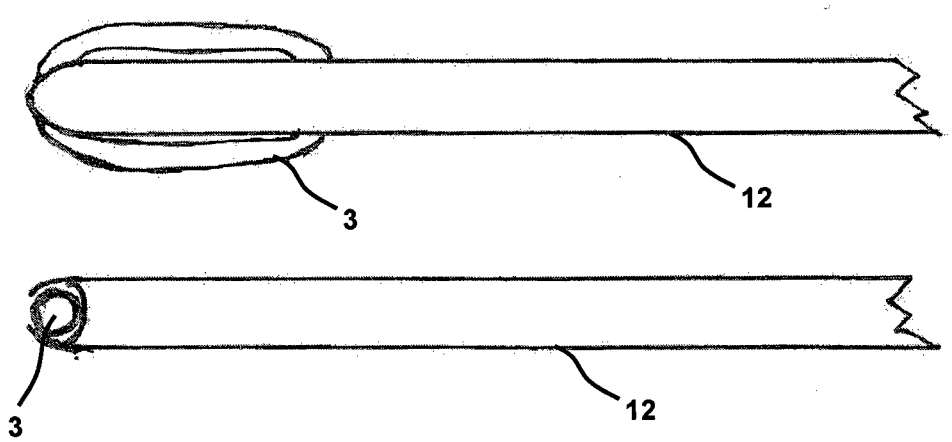
Figur 4



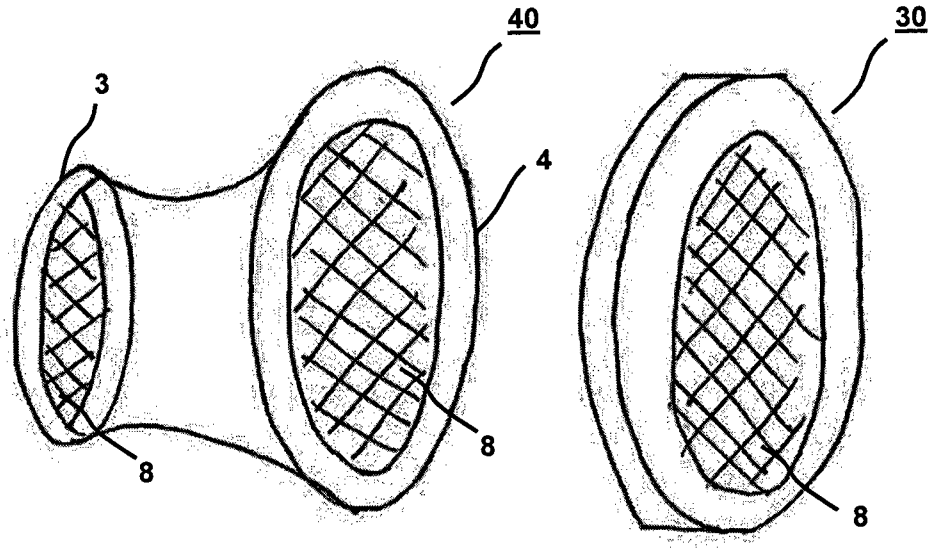
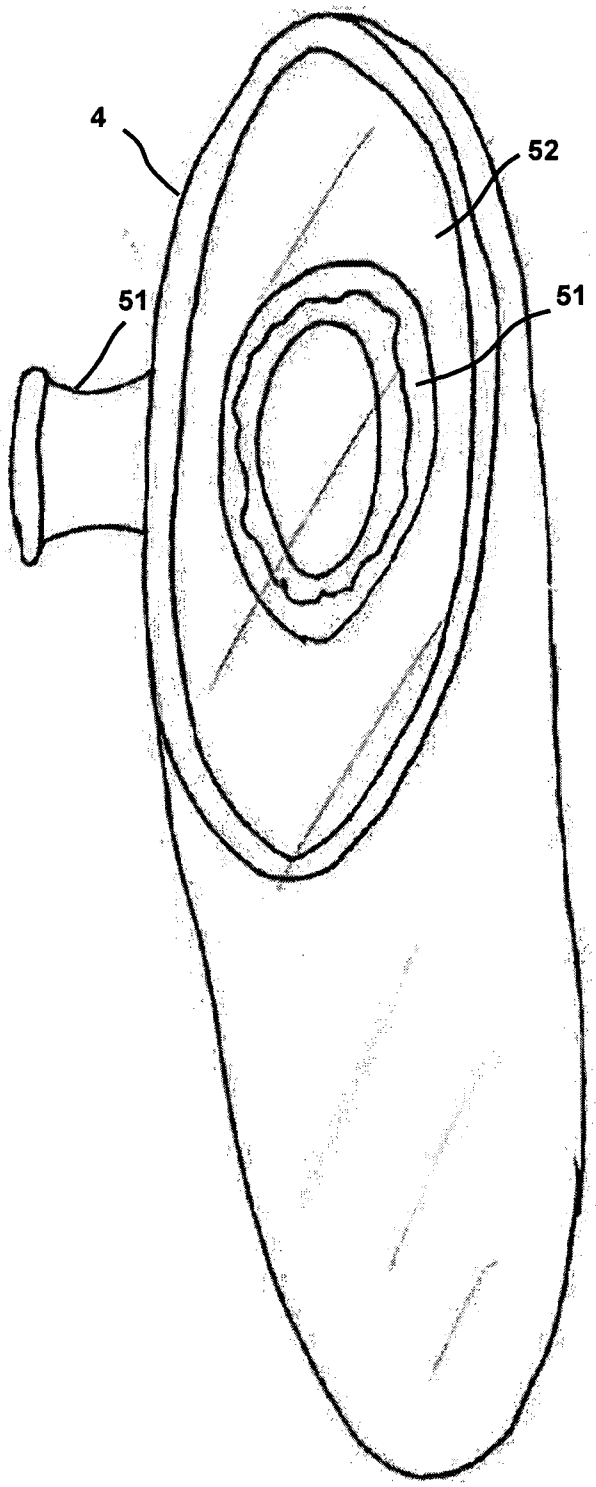
Figur 5



Figur 6



Figur 7



Figur 8