PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 : A61F 5/44	A1	(11) International Publication Number: WO 87/ 03192
		(43) International Publication Date: 4 June 1987 (04.06.87)

(21) International Application Number: PCT/SE85/00476

(22) International Filing Date: 21 November 1985 (21.11.85)

(71) Applicant *(for all designated States except US)*: FUTURAPRODUKTER HB [SE/SE]; Box 80, S-152 01 Strängnäs (SE).

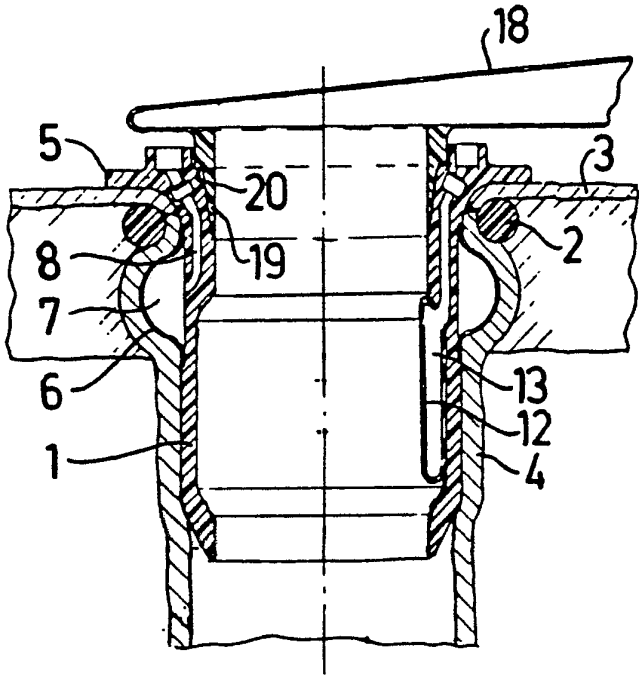
(72) Inventor; and
(75) Inventor/Applicant *(for US only)* : ANDERSSON, Bruno, Sivert [SE/SE]; Sturegatan 2, S-152 00 Strängnäs (SE).

(74) Agents: ONN, Christer et al.; AB Stockholms Patentbyrå, Box 3129, S-103 62 Stockholm (SE).

(81) Designated States: AT (European patent), AU, BE (European patent), BR, DE (European patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), JP, NL (European patent), NO, SE (European patent), US.

Published
With international search report.
In English translation (filed in Swedish).

(54) Title: FIXING DEVICE FOR STOMY BAG



(57) Abstract

At a fixing device for a stomy bag a counter-holding ring (2) is intended to be operated under a patient's outer skin (3) when the intestine (4) is sewed on. A tubular body (1), one end of which is provided with a flange (5) and to which the stomy bag (18) is intended to be connected and whose outer diameter will permit the body (1) to be moved through the counter-holding ring (2) with the flange (5) until contact with the outer skin (3), is provided with an outer peripheral portion (6) of an elastically ductile material and an annular cavity (7) arranged inside this and associated with the outside of the body (1) via a first channel (8).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	**FR**	France	**ML**	Mali
AU	Australia	**GA**	Gabon	**MR**	Mauritania
BB	Barbados	**GB**	United Kingdom	**MW**	Malawi
BE	Belgium	**HU**	Hungary	**NL**	Netherlands
BG	Bulgaria	**IT**	Italy	**NO**	Norway
BJ	Benin	**JP**	Japan	**RO**	Romania
BR	Brazil	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SN**	Senegal
CH	Switzerland	**LI**	Liechtenstein	**SU**	Soviet Union
CM	Cameroon	**LK**	Sri Lanka	**TD**	Chad
DE	Germany, Federal Republic of	**LU**	Luxembourg	**TG**	Togo
DK	Denmark	**MC**	Monaco	**US**	United States of America
FI	Finland	**MG**	Madagascar		

Fixing device for stomy bag

This invention relates to a fixing device for a stomy bag (enterostomy) intended to improve the situation for stomy-operated persons.

The fixing means for stomy bags found on the market have great disadvantages. Thus, fixing devices or attaching plates for stomy bags are used, which plates must be attached to the skin by means of adhesive ties. Moreover, self-adhering bags without attaching plate occur as well as plates attached to belts which must also be sealed against the carrier's skin by means of adhesive ties. These means of attachment have such after-effects that wounds arise on the skin caused by allergy or mechanical irritation. Leakage of intestinal contents will often arise and become a plague to the patient.

As a rule, the connection between stomy bag and attaching plate or attaching means is so embodied that a great force is needed for the connection of the bag to the attaching means in order to obtain the best possible sealing. Further, the commonly used sealing groove of the connection must be carefully cleaned to obtain the best possible sealing at exchange of bag. There has been no possibility of sealing the intestinal orifice at removed stomy bag.

It is the object of this invention to eliminate the above-mentioned disadvantages which has been brought about by means of the characteristic features of the invention defined in the claims.

The invention will be described in greater detail in the form of an example with reference to the drawing, in which Fig. 1 is a lateral section of the invention, Fig. 2 is a top plan view of the device according to Fig. 1, Fig. 3 is a section of the device according to the invention shown in Figs. 1 and 2 and inserted in the intestinal orifice, Fig. 4 is a section of the device

fixed in the intestinal orifice and with applied stomy bag (only a part thereof is shown), Fig. 5 is a section of the device secured in position in the intestinal orifice and with activated cut-off valve, Fig. 6 is a schematic cross-section of the function of the cut-off device, Figs. 7, 8 and 9 show schematically the function of a valve included in the device, Fig. 10 is a top plan view and Fig. 11 a lateral view of a cover which can be applied to the device instead of the stomy bag.

In principle, the very fixing device of the invention can be said to consist of two parts, viz. a substantially tubular body 1 and a counter-holding ring 2.

The counter-holding ring 2 shown in Figs. 3-5 can for instance consist of a plastic or similar material. The ring 2 is operated under the carrier's outer skin 3 when the intestine 4 is sewed on to the outer skin.

The tubular body 1 has a diameter permitting insertion of the body through the counter-holding ring to a position shown in Fig. 3 where a flange 5 of the body 1 will get in contact with the outer skin 3. As is apparent from the figures the intestine 4 will be placed around the inwardly directed tubular body 1 which, therefore, has well-rounded edges like, of course, the counter-holding ring 2. The tubular body 1 is provided with an outer peripheral portion 6 of an elastically ductile material with an annular cavity 7 lying inside thereof. This cavity is via a channel 8 and a nonreturn valve 9 associated with the outside of the flange 5, where the channel 8 ends in a socket-like opening 10.

The channel in the tubular body 1 has an enlarged diameter along a portion 11. On one side of the channel wall and along said portion 11 a gas-tight bladder 12 is arranged, the interior 13 of which is associated with a socket-like opening 16 on the outside of the flange 5 via a channel 14 and a nonreturn valve 15.

When the fixing device or the tubular body 1 has been positioned with the flange 5 in contact with the carrier's skin, as is apparent from fig. 3, the annular cavity 7 is set under pressure, whereby the peripheral portion 6 which will be inside the counter-holding ring 2 in this position will extend fixing the body 1 in position in the intestine 4. The pressure in the annular cavity 7 is for instance brought about by blowing air through the channel 8 by means of a pump, the nozzle of which is applied to the socket-like opening 10. The non-return valve 9 prevents the blown air from leaving the cavity 7. It is also possible instead of a pump to blow directly in a hose, the free end of which is applied to the socket 10.

In this mounted state the intestine 4 is clamped to the counter-holding ring 2, a good sealing and fixing of the body 1 thus being obtained.

The flange 5 has on its outside a bayonet catch in the form of four lugs 17. Of course the bayonet catch can be formed in several different manners within the scope of the knowledge of one skilled in the art and is here no part of the invention.

Fig. 4 shows the body 1 fixed in the intestinal orifice in the way described above with a stomy bag 18 adapted via the bayonet catch 17. Only part of the stomy bag is shown. Besides the parts corresponding to the bayonet catch 17 the stomy bag 18 has a tapered connection 19 with a sealing shoulder 20, the tapered connection being intended to be received in a corresponding tapered part of the mouth of the channel of the body 1. The connection and the shoulder are of a coarser material than the stomy bag but can of course be formed of the same material and integrally with the stomy bag.

Thus, as will be understood Fig. 4 shows a section

of the whole fixing device with mounted stomy bag adapted to the carrier's body and ready for use.

In case it is desirable to seal the intestinal orifice, i.e. to seal the channel of the tubular body 1, air is for instance introduced under pressure via the nozzle 16, the nonreturn valve 15 and the channel 14 to the interior 13 of the bladder 12. When enough air has been introduced into the interior of the bladder, the bladder 12 will quite stop up the channel of the tubular body 1, which is shown in Fig. 5. By forming the portion 11 with an enlarged diameter a good guiding and sealing contact of the bladder to the whole peripheral inside of the channel is obtained. In Fig. 6 the phases of the expansion of the bladder 12 at inflation are shown with dashed lines. The nonreturn valve 15 prevents the air in the bladder from streaming out. A reliable sealing of the intestinal channel has now been achieved. The bladder 12 can be inflated in the same way and by the same means as applies to the portion 6.

It is now possible instead of the stomy bag 18 to apply a cover 21 on the bayonet catch 17 of the tubular body 1, as shown in Figs. 10 and 11. The connection of the cover to the opening of the body 1 corresponds to the connection of the stomy bag and the cover is provided with a grip 23 arranged in a recess 22. The recess 22 can be filled with a soft material permitting access to the grip 23 and the cover can be skin-colored. The carrier of the device according to the invention is here given a possibility of being together with other persons in a freer and easier fashion, e.g. bathing, without being troubled with a stomy bag.

Figs. 7-9 show schematically the function of the nonreturn valves 9 and 15. The nonreturn valves are indicated in the figures in the form of simple membrane valves and the valve can be easily opened for release

of air in the space 7 or 13 by the aid of a thin rod 24 or the like which is applied to the spring tongue.

Thus, the tubular body 1 is formed with a certain thickness and stiffness while the outer peripheral portion 6 as well as the bladder 12 are made of a thin, ductile material.

It will be understood that it is possible within the scope of the invention to embody the different parts described above in other ways than those shown here and several bladders, for example three, can for instance be used evenly distributed along the inner periphery of the portion 11 instead of one single bladder 12. Of course the fixing device can be designed with merely the locking means, i.e. the inflatable peripheral portion 6 engaging inside the ring 2 and the cut-off device 12 being omitted.

Claims

1. Fixing device for a stomy bag, c h a r a c - t e r i z e d by a counter-holding ring (2) intended to be operated under a patient's outer skin (3) when the intestine (4) is sewed on, and a tubular body (1), one end of which is provided with a flange (5) and to which the stomy bag (18) is intended to be connected and the outer diameter of which will permit the body (1) to be moved through the counter-holding ring (2) with the flange (5) until contact with the outer skin (3), said body (1) being provided with an outer peripheral portion (6) of an elastically ductile material and an annular cavity (7) arranged inside this and associated with the outside of the body (1) by means of a first channel (8).

2. The fixing device of claim 1, c h a r a c - t e r i z e d in that the channel of the tubular body (1) has at least one inflatable bladder (12) which encloses said channel completely in inflated state and the interior (13) of which is associated with the outside of the body (1) by means of a second channel (14).

3. The fixing device of claim 1 or 2, c h a - r a c t e r i z e d in that a nonreturn valve (9; 15) is arranged in the first (8) and second (14) channel.

4. The fixing device of claim 2 or 3, c h a - r a c t e r i z e d in that the bladder (12) is arranged in a portion (11) of said channel with a larger diameter than that of the channel.

5. The fixing device of any one of the preceding claims, c h a r a c t e r i z e d in that the flange (5) is provided with a bayonet socket (17) for engagement with the corresponding socket of the stomy bag (18).

FIG.1

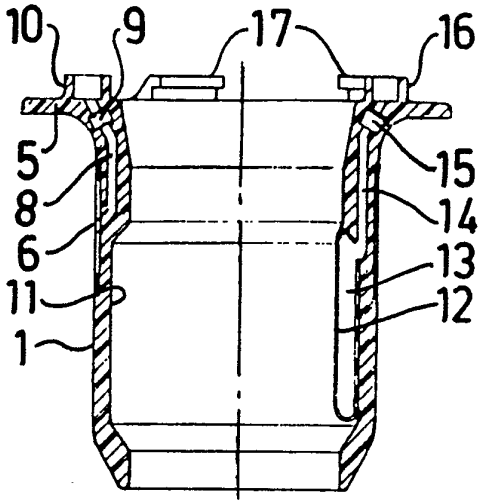


FIG.2

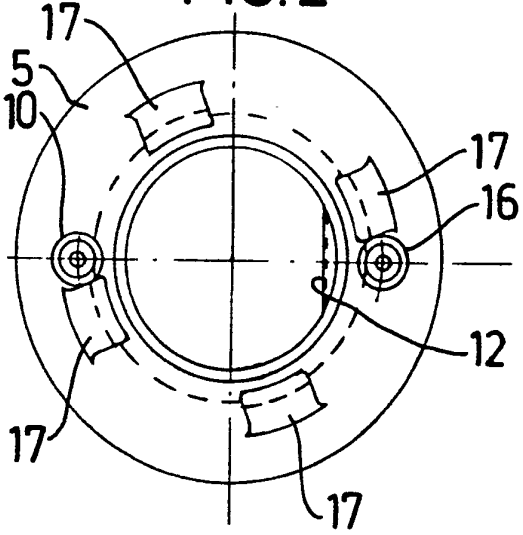


FIG.10

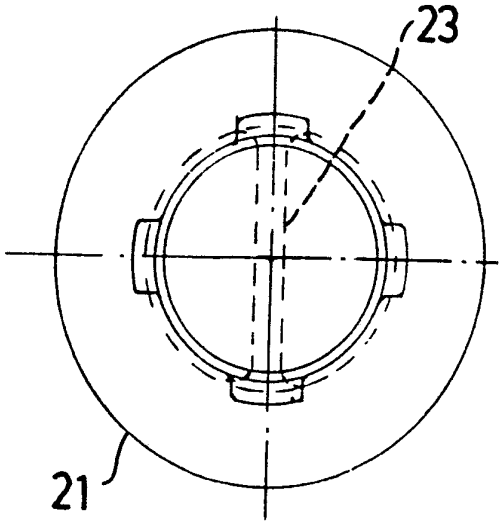


FIG.6

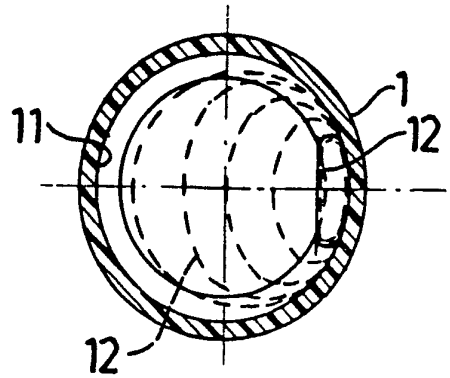


FIG.11

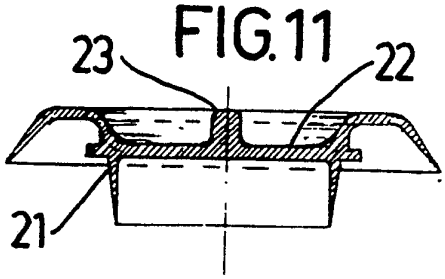


FIG.3

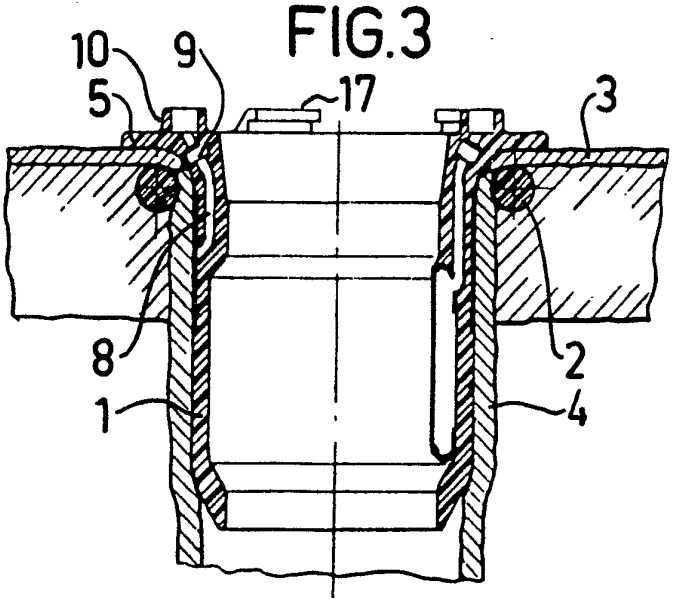


FIG.4

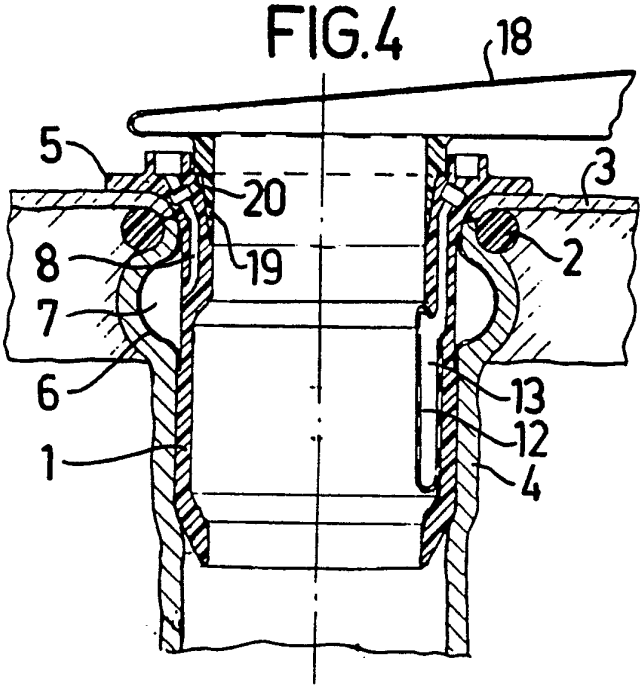


FIG.5

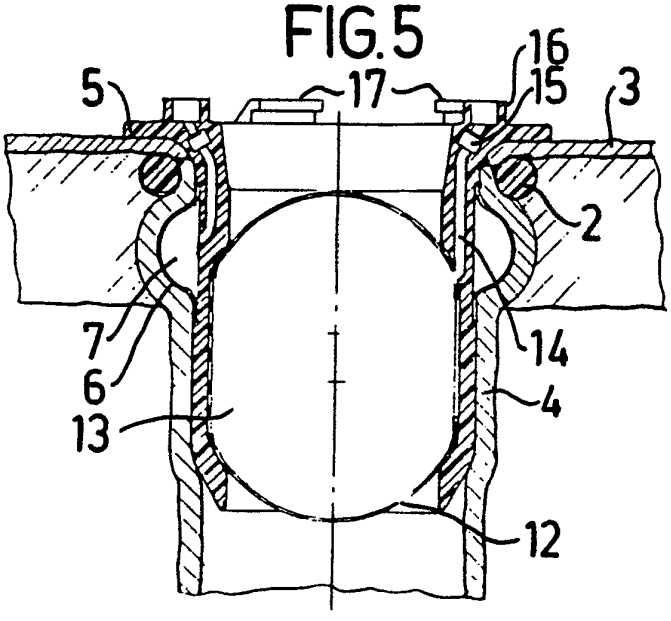


FIG.7

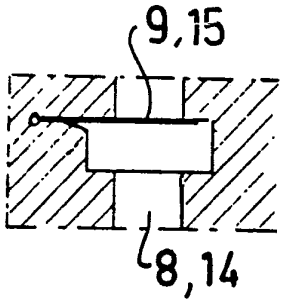


FIG.8

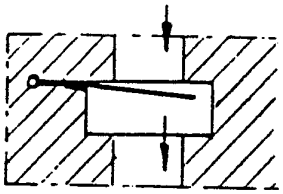
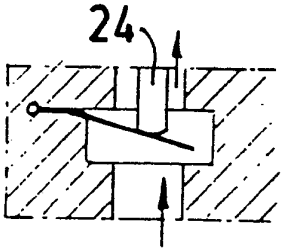


FIG.9



INTERNATIONAL SEARCH REPORT

International Application No PCT/SE85/00476

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC 4

A 61 F 5/44

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC 3,4	A 61 F 5/44, /445, /449
US Cl	3:1; 128:275, 283, 294, 295

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	SE, B, 401 974 (S.B. JOHNSON) 12 June 1978	1,3,5
A	DE, A, 2 722 286 (G. HENNING) 30 November 1978	1
A	US, A, 2 324 520 (O.F. LAMSON) 20 July 1943	1
A	US, A, 4 013 077 (M.C. RITOTA ET AL) 22 March 1977	1,3

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
1986-06-02	1986 -06- 23
International Searching Authority	**Signature of Authorized Officer**
Swedish Patent Office	Leif Karnsäter

L.E