The present invention refers to a surgical closure in accordance with the preamble to Claim 1.

A surgical closure of that kind is known, for example, from the DE-PS 34 44 782. This surgical closure serves especially as a closure affording easier access to the abdominal cavity, preferably in the post-operational treatment of peritonitis.

Peritonitis as a secondary form which develops because of a perforation of a hollow organ or as a postoperative complication, even today still exhibits a high lethality. With rising incidence it represents a central surgical problem.

The abdominal cavity is subjected to a physiological directed flow of liquid which finds its discharge above all via small openings in the peritoneal underside of the diaphragm. In this way the bacteria are fed via the lymphatic vessel to the systemic defence. The capacity of resorption of the intraperitoneal liquid is increased by the mobility of the diaphragm and the intraperitoneal pressure. Within the frame of peritonitis this discharge becomes clogged by the pathophysiological occurrence of fibrin and bacteria and impedes the circulation through fibrin-caused coalescences. The defence system is disturbed and a rise occurs in the bacterial masses or their toxins and fibrin. If there is no success in stopping the progress of the peritonitis in good time, a pathophysiological cascade starts which constantly increases in dynamic and from a certain point can no longer be braked.

For cleansing the abdominal cavities lavage is already being done intraoperatively with physiological cooking salt solution until the lavage liquid remains clear. By this mechanical cleaning bacterial masses, fibrin, devitalized tissue, toxins and also blood residues (even haemoglobin promotes the starting of an infection) have to be removed as completely as possible in order together with the surgical focal sanitation to create an optimum prerequisite for healing.

What is decisive in the postoperative phase, in which the fate of the patient is usually decided, is to recognise a worsening in the situation as early as possible and if necessary remove the cause immediately

(e.g., correction of an insufficiency of stitching after stitching over a perforated stomach ulcer) and through an effective lavage, as far as possible from the 1st postoperative day on, to attend to clear conditions (blood, fibrin and bacteria arising afresh must be laved away).

In postoperative lavage the strategy is known of the open abdomen with lavage at intervals and lavage treatment with the abdomen closed.

This socalled open abdomen is made possible through the rail slide closure and through the zip closure as a closure affording easier access to the abdominal cavity with the advantages that repeated intraabdominal accessibility is guaranteed and at each lavage the operator can satisfy himself of the success of the focal sanitation and hence check the course of the peritonitis. In doing so, postoperative intraabdominal coalescences may be dissolved and coatings of fibrin removed. Typical drainage complications (sealing of the drains with respect to the abdominal wall, clogging or removal of the drains, sources of infection) are eliminated. A relaparotomy is no longer necessary.

What is disadvantageous in that case is that lavage cannot be effected directly after the operation and no continuous lavage is possible. Lavage at intervals is then above all relatively frequent and at the same time burdensome to the patient, for the patient's state is critical. Lavage at intervals must be carefully prepared, it is performed in the operating theatre (during the lavage the abdomen is open) and with full anaesthesia. The advantages of the principle of peritoneal dialysis must be waived since the former closures affording easier access to the abdominal cavity do not close the abdomen tightly. The lavage effect remains restricted since a desirable intraabdominal pressure no longer exists and the lavage liquid preferably flows only in preformed lavage channels. Furthermore after the temporary closure of the abdominal wall part of the lavage liquid trickles into the bed which besides an additional source of infection means ineffective lavage, an additional burden upon the patient and a considerable additional outlay for the nursing staff. Patients with an open abdomen belong for the time to the intensive care patients. If a socalled zip closure or rail slide closure is stitched in as a closure affording easier access to the abdominal cavity, a further disadvantage has to be borne. Once the cutting and sewing in has been done no

adaptation to the conditions of stress in the abdominal wall is any longer posible. But through oedematous swelling of inner organs in the course of a peritonitis the stress in the abdominal wall may increase considerably with the risk of the stitches tearing out. On the other hand, later in the phase of convalescence, in which the inner organs subside, the edges of the wound must be brought together again in steps for the definite stitching of the abdominal wall. Furthermore account must be taken of typical zip-closure complications (jamming, catching). There is no special edge structure for sewing into the fascia, so that only the individual stitches hold. These are often not tight and easily tear out.

Continuous peritoneal lavage with a closed abdomen offers the advantages that a start may be made immediately after the operation with an effective lavage treatment, and thereby the problem of the usual Redon-suction drainage may be replaced considerably more effectively. This has a weak suction capacity and only sucks at points where it is actually lying. Furthermore it easily clogs and then leads to the assumption that the wound space has already been sucked empty. Through the tight system an intraperitoneal pressure may be built up and regulated. The lavage liquid (possibly with the addition of antibiotics) thereby even arrives at the critical "weather corners" of the abdomen. It is not just lavage channels only which arise as in the case of trickling through without pressure. Fewer fibrin-caused coalescences are formed, since the contents of the abdomen "float" and fibrin (*inter alia*) is effectively flushed out (with it at the same time ileac prophylaxis).

Peritoneal dialysis is possible. A rise in the retention values (creatinine, urea, potassium) in the case of a threatened kidney insufficiency may thereby be caught conceivably simply through the employment of a commercial dialysis liquid as the lavage liquid. The patient may be readily dialysed without having to be admitted to the elaborate programme of haemodialysis. The disadvantages connected with that also fall away, such as may arise, say, through the manipulation of the volume of blood. A machine can take over the lavage according to a desired scheme, whereby a distinct relief of the nursing staff is possible. Through chamber counting of the leucosytes in the lavage liquid a simple check of the result of the peritonitis is possible. A judgement of the outlet may

conceivably be performed simply through inspection (turbidity, fibrin or blood impurities). Via the catheter lavage water samples for resistance determination of the bacteria may be taken off at any time and also other substances applied (e.g., electrolytes, albumen, heparin).

What is disadvantageous in doing so is that the abdomen is no longer accessible and thereby a direct sight check no longer exists, which is important if the outlet alters pathologically, or the clinical state of the patient worsens. Sealing and source of infection at the places where the drains pass through, as well as clogging or removal of the drains represent typical complications. In the event of access to the abdomen becoming necessary again a relaparotomy must be effected.

In spite of the very promising start the strategy of the closed abdomen has not prevailed in practice since the disadvantages are prominent.

The problem of the present invention is to improve a temporary intracorporeal surgical closure of the kind mentioned initially, in such a way that a totally pressuretight closure is obtained which, however, may be opened at option at any time as often as necessary. Furthermore the possibility shall exist of repeatable stepless regulation of the stress in the abdominal wall and thereby also of the intra peritoneal pressure without the critical connection between the edge of the fixing element and the corresponding layer of body tissue having to be separated.

This problem is solved by the features specified in the characterizing portion of Claim 1.

By the present invention the advantages of both the strategies described above may be combined so that new widened possibilities of therapy, for example, in abdominal surgery, are available, the use of which does not remain restricted only to the treatment of peritonitis but, for example, appears to promise success even in the treatment of pancreatitis.
A closure affording easier access to the abdominal cavity comes principally into question when postoperative complications are to be expected.
The use is also possible as a closure affording easier access to other body cavities.

Through integrated terminals for drainage tubes the advantages may at the same time be utilised, of a continuous closed lavage system or peritoneal dialysis. A further improvement may be achieved through a special construction and through the shaping of the edge structure which enables a frictional and tight connection between the baseplate and the fascia. In addition a fibrin adhesive may be employed.

Preferred embodiments of the invention follow from the Sub-Claims.

Further advantagous details of the invention are explained in greater detail below with the aid of the embodiments illustrated in the drawing. There is shown in:

Figure 1 - an elevation of a surgical enclosure in accordance with the invention;

Figure 2 - a plan of the surgical closure in accordance with Figure 1 in the open state;

Figure 3 - a cross-section through the surgical closure in accordance with Figure 1, along the line of section I-I in Figure 2;

Figure 3a - a sectional enlargement of detail E in Figure 3;

Figure 3b - further possibilities of connection of the fixing element
and 3c/ to the fascia in the form of a clamp closure;

Figure 4 - a plan of the surgical closure in accordance with Figure 1 in the closed state;

Figure 5 - a cross-section through the surgical closure in accordance with Figure 1, along the line of section II-II in Figure 4; and

Figure 5a - an enlargement of a detail from Figure 5, concerning the rod 26.

The surgical closure in accordance with the invention may, for example,

be stitched as a closure affording easier access to the abdominal cavity, into the fascia 1 which is the ligament plate of the abdominal wall, on the underside of the abdominal wall 2.

For doing this, after a choice of the right size from a plurality of types of surgical closure, with regard to the length of the cut in the abdomen. the edge 3 of a single fixing element 15 surrounding the wound on all sides, designated hereinafter the base area 15a, is pushed on all sides under the fascia 1, with its opening 4 to be provided above the wound, and according to one possible embodiment corresponding with the Figures 3 and 3a is stitched to the fascia 1. In doing so the opening 4 chosen to correspond with the length of cut, may be adapted to the wound gaping according to the stress in the abdominal wall. This is achieved above all when the opening 4 is made as a cutout reaching far into the corners in the form of a spearhead or approximately an ellipse or a wide gap with rounded ends. A prerequisite for this possible adaptation of the opening 4 is moreover that the base area 15a consist of flexible material which may also in addition be elastically extensible. But the elasticity should not be too great in order to be able still to generate an adequate cross-tension in the direction to pull the wound together.

The opening 4 is surrounded by a tubus 5 in the form, for example, of a hose or funnel which is arranged standing up perpendicularly to the base area 15a and consists of flexible material with, if necessary, low elasticity. What is to be understood by the term tubus is a tubular structure of any cross-sectional shape which extends from the opening 4, thus away from the wound, and forms over its whole length a liquidtight sleeve.

On the outside of the tubus 5 at one side of it a cover flap 6 is provided on the base area 15a or on the tubus 5 which after collapsing the tubus 5, for example, by folding it together and/or rolling it up, is laid over the folded tubus or over the roll 19 of the tubus and may be fastened to the base area 15a on the other side of the tubus 5 in such a way that the length of overlay may be altered.

But an embodiment is also conceivable in which the material for the base area 15a, for the tubus 5 and also for the cover flap 6 is so chosen as regards elasticity that an intraabdominal rise in pressure which occurs

suddenly such, say, as a sudden cough, may be at least partially caught. The forces occurring upon the connection between the base area 15a and fascia 1 may in any case be thereby reduced.

In order to make a positive connection possible between the base area 15a and the fascia 1, which engages over an area and is tissue-compatible, the edge 3 of the fixing element must reach or engage under the fascia 1 adequately far on all sides, consist of biocompatible or tissue-compatible material and exhibit a suitable structure. As a biocompatible material a textile material is particularly suitable which is known under the tradename "Gore-tex" such as is already employed in vascular surgery. Blood vessel prostheses of that kind may be stitched in tightly and withstand peaks in blood pressure up to over 200 mmHg systolic.

Within the scope of the present invention a number of possibilities exist in the construction of the edge 3. If a simple execution does not satisfy the requirements of a stable and tight connection between the base area 15a and the fascia 1, not even with the assistance of an adhesive, preferably a fibrin adhesive, then the edge 3 may be made as represented in Figure 3a. An adequately stiff bottom layer 7 distributes the pressure which is generated by the seam or respectively by a number of seams 10, over a large area against the fascia 1 and offers at the same time a bearer layer for the fine points or teeth 9 which engage in the fascia 1 over an area. The points or teeth 9 penetrate a soft sealing layer 8 which is laid above the bottom layer 7. In the simplest case the seam 10 catches only the fascia 1 but also according to stitching techniques, as in the case of a paunch, can seize all of the layers of the abdominal wall 2 and bear against the skin 12 via a pressure-distributor disk 13 (Figure 1). For the production of a tight seam to the fascia 1 it is moreover conceivable for a sewing machine or stapler to come into use. The connection may also be assisted and sealed additionally by a fibrin adhesive. In this connection the use of silicone is also conceivable as an additional sealing material.

What is particularly advantageous in the production of the seam 10 between the fascia 1 and the base area 15a is that through the central opening 4 there is unimpeded access to the operation wound, since the opened tubus 5 because of its flexibility may be folded or laid together

flat. Guidance of the needle on the intraperitoneal side may be seen for checking. If necessary the contents of the abdominal cavity, for example portions of the intestines, may be pressed out of the way of the intraperitoneal guidance of the needle. On one side of the fixing element 15 next the edge 3 a number of drain terminals 14 are preferably integrated into the base area 15a or may be fitted to it subsequently, which are equipped with a screw thread, both for the upper stubs 16 leading outwards and for the lower stubs 17 leading inwards. If no drains are in use the upper stubs 16 are closed by screw plugs. In a preferred embodiment the drainage passages are incoporated into two reinforcement plates 18 which border the base area 15a above and below over an area and in a pressuretight manner. If one or more drains are in use, with the tubus 5 opened they may be placed in the abdominal cavity and screwed onto the lower stub 17. The extracorporeal drain 28 may be screwed as a continuation onto the upper stub 16 even with the tubus 5 closed. Since in this case the problems of tighness and a source of infection at a point of passage of drainage which is not tight is eliminated, such as occur partially in the case of leading through the abdominal wall by separate catheter, a simpler decision may be to utilize a number of drains via the integrated drain terminals 14 and to design the system fundamentally for drains of greater bore. Through the simple intraabdominal accessibility one has here the possibility even in the case of a loss of function of the intracorporeal drains 29, to remove the intraabdominal cause through the opening 4.

Adjoining the inner edge of the base area 15a rises the tubus 5 open upwards. This is connected firmly and in a pressuretight manner to the base area 15a and can shut off the central opening 4 and thereby the abdominal cavity in a pressuretight manner.

In accordance with a preferred embodiment the tubus 5 is closed by a rolling-in process over a rod 26 which, for example, is in two parts.

Figure 5a shows that the one half 21 of the rod is set with sharp pins 31 which pierce the two walls 22, 23 of the tubus 5 laid together, where the walls 22, 23 of the tubus which have been laid together may first have been folded. The second half 24 of the rod is forced by corresponding recesses or holes 25 onto the pins 31 of the first half 21 of the rod.

Fixed in this way, the collapsed tubus 5 may be rolled in over the rod 26 made as a round rod, and shaped into the rolled tubus 19. Depending upon how far it is rolled and how the longitudinal sectional profile of the rod 26 is shaped, different partial stresses may be generated upon the edges of the wound. In conclusion the rolled-in tubus 19 is now fixed by a cover flap 6. This cover flap 6 is connected firmly to the base area 15a on the side with the drain terminals 14. It engages over the rolled-in tubus 19 and is secured on the opposite side. For this purpose an adhesive closure such as a velcro closure 30 is preferably employed.

In another embodiment the rod 26 may be employed exclusively as an aid to rolling and be withdrawn after the rolling-in process. The ends of the rolled tubus 19 may also be folded inwards and thus fixed by the overlapping cover flap 6. In special cases a kind of abdominal belt may also be logical as an additional security.

According to a further embodiment as represented in Figure 3b, the tight closure between the fascia 1 and the base area 33a of the fixing element 33 may be made as a clamp closure 32 as follows.

In order to make possible a tight positive connection, or if necessary one combining a positive and close fit, engaging over an area between the base area 33a of the fixing element 33 and the fascia 1, the inner edge 34 of the fixing element 33 must reach or engage under the fascia 1 adequately far on all sides, so that clamps 35 forced from above onto the inner edge 34 are able to clamp the fascia 1 adequately strongly and tightly.

As shown in Figure 3b, the inner edge 34 of the clamp closure 32 has preferably a width of about 2 cm and is set with barbs 36 which are preferably one to two cm long. When forced against a clamp 35 mounted from above, these barbs 36 pierce the fascia 1 from below and possibly also part of the layer of muscle adjoining it above. In the clamps 35 which are preferably made as a grid block 40, the barbs 36 may snap into the individual openings in the grid block 40 to different distances depending upon the pressure, into the corresponding horizontal layers or planes 41 of the grid block 40. Additional inner and outer seals 37, 38 seal the clamp closure 32 to be liquidtight. It is possible in a simple way to

force the pair of complementary clamping parts 35, 36 together simultaneously by the thumb and forefinger of one hand, since the forefinger can engage through the central opening 4 round the collapsed tubus 5 under the base area 33a. The individual clamps 35, cut to fit in shape and length by a suitable cutting tool, seal the edge of the wound all round.

Where grid blocks 40 are employed as clamps 35 they consist of one more grid planes 41 which for the production of a firm snap connection are provided with openings 42 which correspond with the prongs 39 of the barbs 36.

In order to ensure secure sealing of the clamp closure in accordance with Figure 3b, in the region 34 at the edge of the fixing element 33 where it engages underneath, sealing elements 37, 38 are provided between it and the fascia 1 on the one hand and between the fascia 1 and the clamps 35 on the other so that they completely embrace the wound opening 4.

What is important is that when a number of grid blocks 40 are employed along the wound opening 4 they are spaced far enough apart for them to be able to shift sideways with respect to one another along the wound opening 4.

According to another variant embodiment the clamps 35 may consist of elastically yielding solid material, for example, a material having the elasticity of rubber or of a plastics having the elasticity of rubber, into which the barbs 36 may be pressed in order to produce an adeuately positive connection.

The release of the grid blocks 40 or in general of the clamps 35 from the inner edge of the base area 33a of the fixing element 33 is usefully effected by a lever tool known in itself.

In accordance with the embodiment as in Figure 3c the inner edge 34 of the base area 33a of the fixing element 33 exhibits a recess 43 which completely surrounds the wound opening 4 and at the surface tapers in cross-section in the direction towards the fascia 1 so that one or more clamps 35 may be snapped into this recess 43 with the fascia 1 laid between, if necessary in combination with further structures of the body

tissue, as a sealing element. Preferably the clamps 35 have a circular cross-section so that they may be snapped into the likewise at least approximately circular recess 43 and because of the elastic construction of the fixing element 33 are fixed in this position positively and with a close fit. This atraumatic clamp closure is distinguished in that a preferably straight flexible cuttable rod, preferably a round rod, may be forced into the said recess 43 and that with this clamp connection it is ensured that the fascia 1 lying in between is not injured.

In completion of the executions up to now it may also be useful to apply to the base area 15a or respectively 33a of the fixing element 15 or 33 respectively, markings in the form, for example, of numbers, letters, symbols or the like.

It is also favourable if the whole surgical closure, or at least those parts of it which come or can come into direct contact with the bodily tissue, consist of a biocompatible material such, for example, as the earlier mentioned textile material known under the commerical name of "Gore-tex".

Although as may be seen in particular from Figures 3 and 5 the tubus 5 and fixing element 15 are preferably made in one piece, it is within the scope of a possible modification of the invention to design the tubus 5 and fixing element 15 as separate components and to connect them tightly together later.

According to a preferred embodiment the fixing element 15 consists of one single component. But this does not exclude the fixing element 15 from being produced from a number of fixing element parts and these being connected tightly together.

Materials which come especially into consideration for the tubus 5 are resilient plastics foils or textile plastics which at the surface may be provided with plastics or other sealing and/or tissue-compatible materials.

Further advantages of the surgical closure in accordance with the invention may be seen in the application of laparoscopy. For this purpose,

for example, adaptor pieces may be fitted to the drain terminals 14, through which laparoscopic examinations and/or engagements may be performed.

Finally it is also of advantage that the surgical closure in accordance with the invention opens up the possibility of different schemes of lavage or lavage-suction. Also postoperative continuous open dorsoventral abdominal lavage may easily be realised with the abdominal wall closure in accordance with the invention, which affords easier access. Clumsy and disadvantagous palisade stabilization of the wound opening is done away with in this case. The drain terminals 14 may be employed as lavage inlet and one large-bore drain placed in the central opening 4 of the tubus and sealed to the tubus 5 by, for example, a hose clamp or a high-speed connector, be employed as the suction pipe. Furthermore a probe for measurement and continuous checking of the intraperitoneal pressure may be connected via one drain terminal 14 as permanent access.

Finally, through the clamp closure in accordance with the invention more rapid implantation is possible than through time-consuming sewing in.

C L A I M S

1. A surgical closure which may be opened and closed repeatedly, in particular a closure for an incision in the abdominal wall, and consists of flexible fixing elements in the form of cloth or plates, which may be connected firmly but detachably to the body tissue adjacent to the incision, and a closure which closes the free end regions of the said fixing elements above the incision and may be opened and closed at any time, characterized in that only one single fixing element (15) is provided, which encloses the incision all round and exhibits an opening (4) to be fitted above the incision, and consists of a tube (5) of flexible material, which surrounds the opening (4) and extends away from the wall from the opening (4), and the tube (5) itself acts as closure or is provided with one.

2. A surgical closure as in Claim 1, characterized in that the opening (4) is made lanceolate or elliptical.

3. A surgical closure as in Claim 1 or 2, characterized in that the tube (5) is arranged on the fixing element (15) to be pressuretight.

4. A surgical closure as in one of the Claims 1 to 3, characterized in that the fixing element (15) in the region surrounding the outside of the tube (5) exhibits at least one terminal (14) for a drainage tube or the fixing element (15) is armed with at least one such terminal.

5. A surgical closure as in one of the Claims 1 to 4, characterized in that a cover flap (6) is fitted next the outside of the tube (5) on one side and can cover over the collapsed tube and at the side opposite the side where it is fixed can be fastened detachably in such a way that its length of cover is adjustable.

6. A surgical closure as in Claim 5, characterized in that for fastening the free end of the cover flap (6) a cling closure (30) is provided.

7. A surgical closure as in one of the Claims 1 to 6, characterized in that the tube (5) may be folded together.

8. A surgical closure as in one of the Claims 1 to 6, characterized in that the tube (5) may be rolled together.

9. A surgical closure as in one of the Claims 1 to 8, characterized

* C L M S *

in that starting at the free edge the tube (5) may be folded together over a rod (26).

10. A surgical closure as in Claim 9, characterized in that in the region of its free edge the tube (5) exhibits fixing means of fastening and/or tacking the rod (26).

11. A surgical closure as in Claim 9 or 10, characterized in that the rod (26) has different diameters along its longitudinal axis.

12. A surgical closure as in one of the Claims 9 to 11, characterized in that with the tube (5) rolled together a fixing device (30) is provided in the region of the rolled tube (19) so formed, for holding the rolled tube (19).

13. A surgical closure as in Claim 12, characterized in that a cling closure (30) is provided for the fixing.

14. A surgical closure as in one of the Claims 1 to 13, characterized in that at least in the region which comes directly into direct contact with body tissue it consists of biocompatible material.

15. A surgical closure as in one of the Claims 1 to 14, characterized in that the fixing element (15) exhibits one or more marking signs.

16. A surgical closure as in one of the Claims 4 to 15, characterized in that drainage tube terminals (14) of different diameters are provided or may be fitted.

17. A surgical closure as in one of the Claims 4 to 15, characterized in that the drainage tube terminals (14) are arranged so as to be secured against twisting.

18. A surgical closure as in one of the Claims 1 to 17, characterized in that for rolling it together a rod (26) divided lengthwise is provided, one half-rod (21) of which exhibits pins (31) which project inwards and may be inserted or jammed in holes (25) drilled in the other half-rod (24) and pierce the dividing walls (22, 23) of the tube (5).

19. A surgical closure as in Claim 1, characterized in that the connection to the fascia (1) is produced (Figures 3b and 3c)

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via a clamp closure (32).

20. A surgical closure as in Claim 19, characterized in that that region (34) which engages under the fascia (1), of the edge of the base (33a) of the fixing element (33), is provided with barbs (36) which are aligned at the fascia (1) and may be connected positively or frictionally to clamping-pieces (35) which may be applied to the fascia (1) from above.

21. A surgical closure as in Claim 19 or 20, characterized in that the clamping-pieces (35) are made as a grid block (40).

22. A surgical closure as in Claim 21, characterized in that the grid blocks (40) consist of one or more grid planes (41) which for the purpose of a snap-connection to the teeth (39) of the barbs exhibit corresponding openings (42).

23. A surgical closure as in one of the Claims 19 to 22, characterized in that in the region (34) engaging under the fascia (1), of the edge of the fixing element (33), between the latter and the fascia (1) on the one hand and between the fascia (1) and the clamping-pieces (35) on the other, sealing elements (37, 38) are provided, which completely enclose the incised opening (4).

24. A surgical closure as in one of the Claims 20 to 23, characterized in that the clamping-pieces (35) are spaced apart so that they may be shifted mutually sideways along the incised opening (4).

25. A surgical closure as in Claim 20, characterized in that the clamping-pieces (35) consist of elastically yielding solid material into which the barbs (36) may be forced.

26. A surgical closure as in Claim 19, characterized in that the inner edge (34) of the base (33a) of the fixing element (33) exhibits a recess (43) which completely surrounds the incised opening (4) and at the surface narrows in cross-section in the direction towards the fascia (1) so that one or more clamping-pieces (35) may be snapped as sealing and/or retainer elements into this recess (43) with the interposition of the fascia (1), if necessary in combination with other layers of body tissue (Figure 3c).

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