

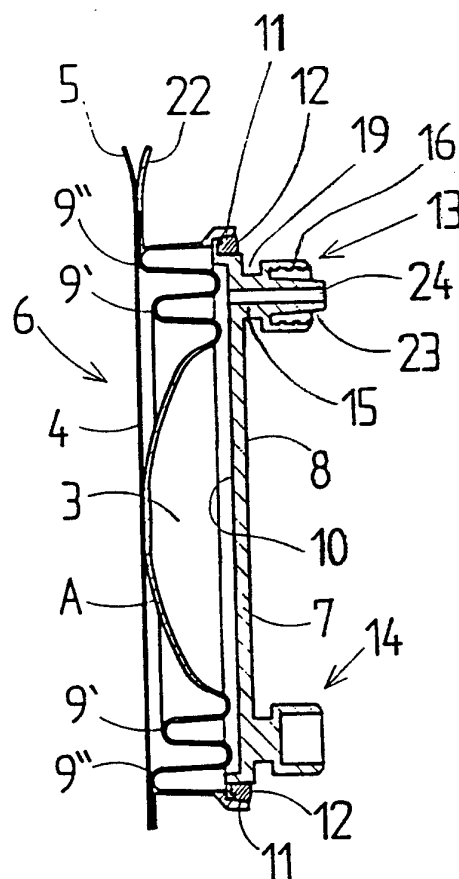
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(21) International Application Number: PCT/SE93/00705 (22) International Filing Date: 25 August 1993 (25.08.93) (30) Priority data: 9202484-3 28 August 1992 (28.08.92) SE (71) Applicant (for all designated States except US): RADI MEDICAL SYSTEMS AB [SE/SE]; Palmbladsgatan 10, S-754 50 Uppsala (SE). (72) Inventor; and (75) Inventor/Applicant (for US only) : ÅKERFELDT, Dan [SE/SE]; Nyvå, S-755 92 Uppsala (SE). (74) Agents: LINDGREN, Anders et al.; Dr. Ludwig Brann Patentbyrå AB, P.O. Box 17912, S-104 62 Stockholm (SE).		(81) Designated States: AU, BB, BG, BR, BY, CA, CZ, FI, HU, JP, KP, KR, KZ, LK, MG, MN, MW, NO, NZ, PL, RO, RU, SD, SK, UA, US, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report. In English translation (filed in Swedish).</i>

(54) Title: DEVICE FOR STERILE PACKAGING OF MEDICAL EQUIPMENT

(57) Abstract

The present invention provides a sterile packaging which considerably reduces the risk for contamination of a part which shall be in contact with an area on the patient's body, and which can be exposed to the risk of infection. More specifically, the invention consists of a single-use air cushion unit (6) for use with a femoral compressor (1). The latter consists of an arch (2) and connecting part (17) on the arch. The air cushion unit (6) consists of a base plate (7) and an inflatable air cushion (8) attached to the baseplate (7). The distinguishing feature of the invention is that a shielding element (4) in the form of a lid made of a flexible material and which can be removed using a tab (5), is fused along the periphery of the air cushion (8). In this way the sterile air cushion's (8) contact surface (A) is protected in a safe way from contamination.



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DEVICE FOR STERILE PACKAGING OF MEDICAL EQUIPMENT

The present invention relates to sterile packaging of medical equipment, and in particular to a device for the simplification of manual handling of parts which shall be sterile when put in contact with an area on the body of a patient, for example, a puncture site or the like.

The invention is especially suitable for use with inflatable cushions which are used for femoral compression by means of a femoral compressor as described in Swedish patent applications no. 9002077-7 and 9003271-5.

In general, sterile, single-use items which are used in health care and especially during surgical procedures, are usually packaged in sealed, gas-permeable pouches (e.g. TYVEC, a du Pont trademark), so that they can be gas sterilized using ethylene oxide gas after the pouches have been sealed. Sterilisation of the sealed item can also be done by means of radiation treatment (electron radiation, that is, beta sterilisation or gamma radiation). A disadvantage with this kind of sterile packaging is that when the part is to be used, it must be removed from the pouch and handled manually, which clearly implies a risk of contamination of the part on the way to the patient, even if the distance is not very great.

Therefore, there is a need to be able to handle a sterile part in a safe way, so that the risk for contamination is reduced as much as possible. This can be done by using a package which is constructed in such a way that the seal need not be broken until just before the part is placed on the patient. In this way, the part, e.g. an air cushion for a femoral compressor, can be handled manually and positioned on the patient with no particular care being necessary to avoid contamination.

The object of the present invention is therefore to provide a sterile package which considerably reduces the risk of contamination of a part which shall be brought into contact with an area on the patient's body, and which can be exposed to the risk of infection.

This purpose is achieved with a device as defined claim 1.

The preferred embodiments are defined in the dependent claims.

Below a detailed description of the preferred embodiments of the invention will be given, applied to a femoral compressor according to Swedish patent applications 9002077-7 and 9003271-5, and with reference to the attached drawings in which:

Figure 1 shows a cross-section of a patient with a femoral compressor of the above-mentioned type attached over a puncture site;

Figure 2 shows a compression arch belonging to the femoral compressor in Figure 1;

Figure 3 shows an embodiment of a sterile lid according to the invention;

Figure 4 shows an air cushion belonging to the femoral compressor in Fig. 1, with a sterile lid according to the invention;

Figure 5 shows in cross-section, and from below, a part of the compression arch in Fig. 2 adapted to rest against the base plate of a replaceable air cushion;

Figure 6 shows the base plate in cross-section and from below; and

Figure 7 shows the air cushion unit in an inflated

state.

The femoral compressor 1 shown in Fig. 1 consists of an arch 2 to which an inflatable air cushion 3 is permanently attached. This arch 3 is applied to the puncture site in the femoral artery in order to stop bleeding and is inflated to a suitable pressure using, for example, a manual inflator. Therefore, there is a risk of infection if the air cushion should be contaminated with infectious material.

The known femoral compressor 1 (according to Swedish patent applications no. 9002077-7 and 9003271-5) is supplied as one unit (arch 2 and air cushion 3) in a sterile package which is opened just prior to application onto the patient. The disadvantage with this construction is that the manufacturing and transport costs are high, and that the waste, i.e. the entire unit, is bulky. For possible reuse, the entire compressor must be resterilised, in e.g. an autoclave, in which case the device's large volume is a disadvantage.

The greatest disadvantage with the known femoral compressor is that there is a risk that the contact surface of the permanently mounted air cushion may be contaminated between the moment that the sterile compressor is removed from the package and the moment when it is applied, e.g. on the bleeding puncture site.

In addition, the waste (the compressor), because of blood contamination, is considered hazardous waste, with accompanying troublesome handling of the bulky unit.

In an alternative form of the compression unit of Swedish patent applications no. 9002077-7 and 9003271-5, the air cushion is a separate part and is mounted on a base plate 7 which is attached to the arch 2 by means of e.g. double adhesive tape.

Even in this case, there is a risk of contaminating the air cushion when attaching it to the arch, since the sterile

packaging enclosing the cushion and its base plate 7, necessarily must be opened before the cushion is mounted manually onto the arch.

Figure 3 shows a sterile lid 4 according to the invention, meant to be used for sealing the air cushion 3 which is part of the air cushion unit 6 (described below). The lid provides a protective element 4, and includes a primary base layer of spray fiber material (spun bonded), or of a gas permeable, or non-gas permeable polymer material, and a second layer of e.g. melt-glue or of a plastic material which is meltable, so that element 4 is fusible with the above-mentioned periphery.

A suitable, commercially available material for the lid is TYVEC (registered trademark of du Pont).

Below the replaceable air cushion unit will be described in detail, with reference to Fig. 4.

The replaceable unit of single use type, is generally shown with the reference number 6, and includes a base plate 7, the upper side 8 of which is attached to the femoral compressor's 1 arch 2. This attachment is achieved by means of a "snap attachment" which will be described in detail below.

On the base plate there is an inflatable air cushion 3 which is mounted by gluing or fusing along the base plate's 7 periphery. The material of which the cushion is made is, seen from a cross sectional view, folded 9', 9" so that the air cushion when not inflated, that is, as it is packaged, takes up as little volume as possible.

Along the periphery of the base plate is a groove 11, wherein melt-glue 12 is placed and after heat and pressure treatment in manner well known to the skilled man, this makes for an airtight sealing of the air cushion 3 against the base plate 7. Two attachment elements 13, 14, stick out from the upper side 8 of

the plate 7, said attachment elements 13, 14 being designed so that their end 15 which connects to the base plate 7 is smaller in diameter than their end 16 which is not connected to the baseplate 7. A web or waist 19 is therefore formed between the baseplate and the thicker end piece 16.

The thicker ends 16 of these attachment elements 13 and 14 are designed to fit precisely into the notches 18 of connecting part 17 shown in Fig. 5. These notches have a narrower part 18' which stretches mainly along a line concentric to the periphery, and has a width equivalent in diameter to the narrower parts 15 of the connecting elements 13, 14. Furthermore, the connecting parts' 17 thickness corresponds to the length of the waist 19. Therefore, if the replaceable air cushion unit's connecting element is fit into the arch's notches 18 and thereafter turned counter-clockwise, then base plate 7 will fit tightly against the connecting part 17.

Furthermore, connecting part 17 is equipped with a protruding element 20, which "snaps" into the corresponding notches 21" in base plate 7 when cushion part 6 is twisted into place. Thus unit 6 is locked to arch 2 and is prevented from loosening from it. In the shown embodiment, the protruding elements 20 are triangular. On the base plate, there are also notches 21' into which the element 20 slides when the air cushion unit 6 is initially placed against the connecting part 17 and the attachment elements 13 and 14 are fit into the larger (wider) part of the notches 18. When the unit 6 is then twisted into place, the element 20 is moved over the part between the notches 21' and 21", whereby the baseplate 7 gives somewhat. Thereafter, the element 20 falls into place in the notches 21", and thereby a locked position is reached and the desired "snap attachment" is achieved.

Alternatively, the protruding element 20 can be attached to the base plate 7, and the notches 21' and 21" can be attached to the connecting part 17.

One of the connecting elements 13 is designed so that it forms an attachment of LUER-LOCK type 23. There is a hole 24 in connecting element 13 through which air can be pumped in order to inflate air cushion 3 after the femoral compressor 1 has been placed on a patient.

In order to ensure that the risk of contaminating the contact surface A of air cushion 3 is reduced as much as possible, it is suggested according to the present invention, that a lid (see Fig. 4), preferably made of a "spun bonded" material (spray fiber material), (e.g. TYVEC^R from du Pont) equipped with a melt-glue layer, or a layer of other material which can be melted so that a seal is formed, is attached to the air cushion 4. The lid 4 is fused or glued along the periphery of the uninflated cushion 3 (see Fig. 3). The fusing is done by using heat and pressure, typically approximately 130°C and 400 kPa. The fusing time is typically approximately 2 s. The desired peel force should be 0.17 - 0.47 N/mm (4.5 - 12 N/inches), preferably 0.31 N/mm (8 N/inch), which is a suitable balance between good strength and unintentional opening and ease of opening the lid by hand. The lid is equipped with a tab 5 which makes it easy to remove the lid from the edge. The stripping force is typically 0.31 N/mm (8 N/inch).

After the lid 4 has been attached, the air cushion unit 6 is sterilised by e.g. radiation with high energy radiation or by gas sterilisation.

When using a femoral compressor with replaceable air cushion unit 6 of the type described, the air cushion unit 6 is first mounted onto the arch 2. Thanks to the lid 4 which protects the contact surface A on air cushion 3, the nurse or physician who applies the compressor to the patient does not need to be as careful, with regard to the manual handling of the entire instrument, as with the known device of Swedish patent applications no. 9002077-7 and 9003271-5. The unit 6 is mounted as described by putting the attachment elements 13, 14 into the notches 18,

whereupon the unit is turned clockwise until it "snaps" into place thanks to the protruding elements' 20 working together with the notches 21 in connecting part 17. The femoral compressor 1 can now be taken to the patient, and immediately before application, the lid 4 is easily torn off by gripping the tab 5 and pulling diametrically over the air cushion. The stripping force is slight enough that this shall not cause any difficulties.

After completed compression, that is when bleeding no longer occurs, the compressor is removed and the single-use air cushion unit 6 is disassembled by turning it counter-clockwise and pulling it out from the notches 18, whereupon it is discarded as waste. To avoid touching the blood-contaminated air cushion, the unit 6 can be loosened from the arch by turning the air cushion unit from behind using the protruding attachment elements 13 and 14.

CLAIMS:

1. An air cushion unit (6) of single use type for use together with a femoral compressor (1) which consists of an arch (2) and on the arch a connecting part (17); said unit (6) comprising a base plate (7) and an inflatable air cushion (8) attached to the base plate (7), characterized by a shielding element (4) of a flexible material sealed along the periphery of the air cushion (8).
2. The air cushion unit as claimed in claim 1, wherein the shielding element (4) is provided with a means (5) which can be gripped with the fingers and used to pull off the sealing element (4).
3. The air cushion element as claimed in claim 1 or 2, comprising a flange (22) running along the edge of the cushion to which the shielding element (4) is permanently fused or glued so that it seals the air cushion (8).
4. The air cushion unit as claimed in any of claims 1, 2 or 3, wherein the shielding element (4) comprises a first and a second layer, and wherein the second layer is made of e.g. melt-glue or a plastic material which is meltable, so that the element (4) is melt-fusible onto the above-mentioned periphery.
5. The air cushion unit as claimed in any preceding claim, wherein the primary layer is made of spun bonded material, or of gas permeable or gas impermeable polymer material.
6. The air cushion unit as claimed in any preceding claim, wherein the stripping force in the fusing seam is 0.17 - 0.47 N/mm (4.5 - 12 N/inch), preferably 0.31 N/mm (8 N/inch).
7. The air cushion unit as claimed in any preceding claim, which is sterilised after the protective element (4) has been attached.

8. The air cushion unit as claimed in any preceding claim, further comprising attachment means (13, 14, 20) provided on the base plate (7) and designed to cooperate with the attachment means (18, 21', 21'') on the femoral compressor's (1) connecting part (17).

9. The air cushion unit as claimed in claim 8, wherein the attachment devices are designed so that either:

a) the base plate (7) has notches (21', 21'') designed to receive the protruding elements (20) on the femoral compressor's (1) arch (2), or

b) the arch (2) has notches (21', 21'') designed to receive the protruding element (20) on the base plate (7),

for locking the unit (6) to the arch (2).

10. The air cushion unit as claimed in any of claims 1-7, wherein the attachment device is made of double-adhesive tape.

11. A femoral compressor adapted to be used together with the single-use air cushion unit as claimed in any of the claims 1-10, comprising a connecting part (17), having attachment means (18, 21', 21''); 20) adapted to cooperate with the air cushion units' (6) attachment means (13, 14, 20; 21', 21'').

12. The femoral compressor as claimed in claim 11, wherein the attachment means (18, 21', 21''); 20) comprises

notches (18) having a diameter corresponding to the diameter of the attachment elements (13,14) for receiving the mentioned attachment elements therethrough, said notches (18) having a narrower part (18') which extends mainly along a line concentric to the connecting part's (17) periphery, and which has a width corresponding to the diameter of the attachment elements'

(13, 14) narrower parts (15), whereby the width of the connecting part (17) corresponds to the attachment elements' waist (19), belonging to the air cushion unit (6), whereby the connecting part (17) either:

a) is equipped with protruding elements (20), designed to fit into notches (21', 21") in the air cushion units' (6) base plate (7) or

b) is equipped with protruding element (20) designed to fit into the notches (21', 21") in the arch's (2) connecting part (17),

for locking the single use unit (6) to the femoral compressor (1).

13. The femoral compressor as claimed in claim 11, wherein the attachment devices (18, 21', 21"; 20) comprises:

notches (18) which have a diameter corresponding to the diameter of the connecting elements (13, 14) for receiving the mentioned attachment elements therethrough, said notches (18) having a narrower part (18') which extends mainly along a line concentric to the periphery of the connecting part (17), and which has a width corresponding to the diameter of the connecting element's (13, 14) narrower parts (15), whereby the connecting part's (17) width is equivalent to the connecting element's waist (19), belonging to the air cushion unit (6), and whereby the connecting part is smooth and designed to fit against the base plate (7) on the arch (6) by means of double-sided adhesive tape.

14. An air cushion unit (6) of single use type for use together with a femoral compressor (1) which consists of an arch (2) and on the arch a connecting part (17), said unit (6) consisting of a base plate (7) and an inflatable air cushion (8) attached to the base plate (7)

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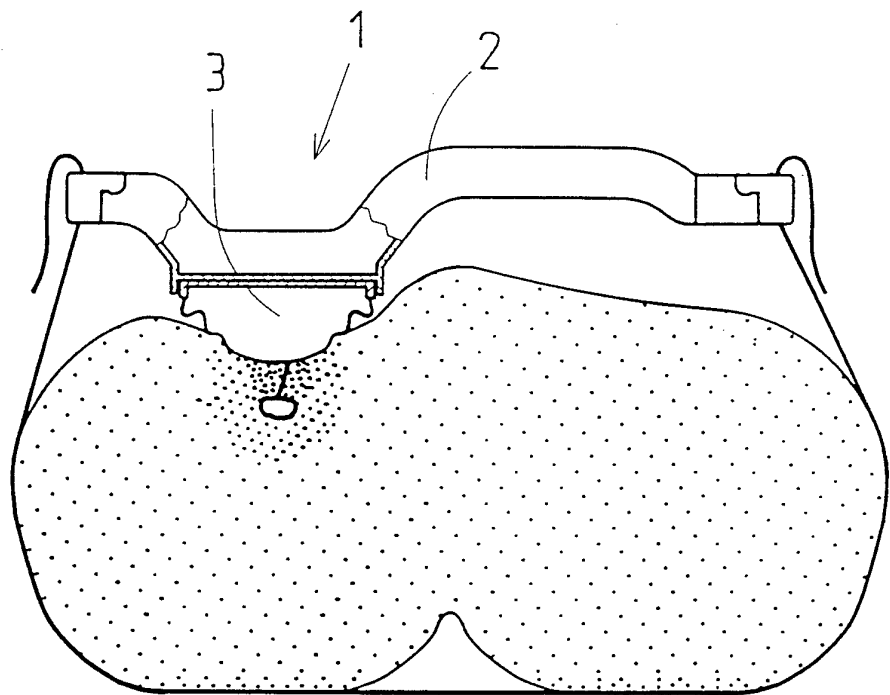


Fig.1

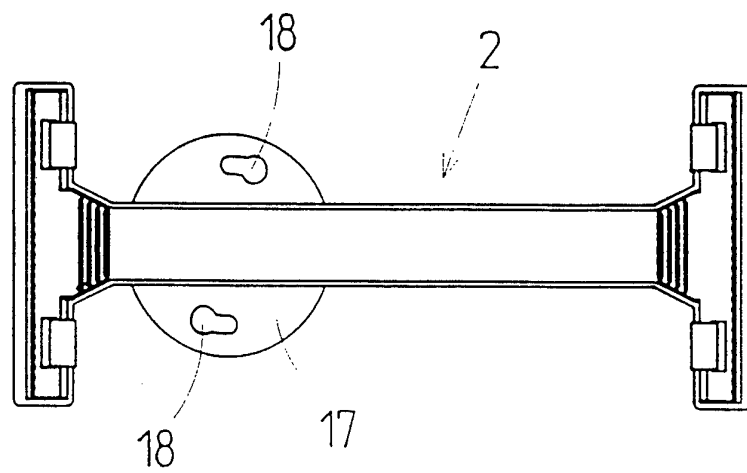


Fig.2

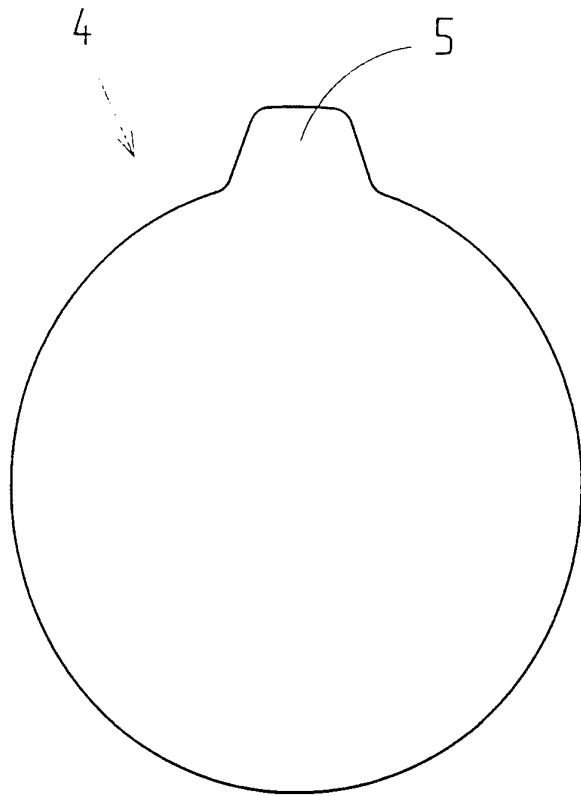


Fig.3

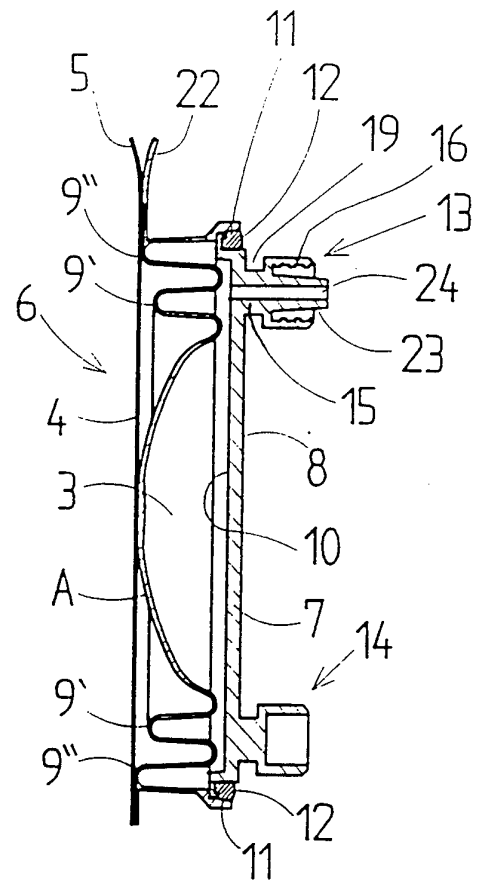


Fig.4

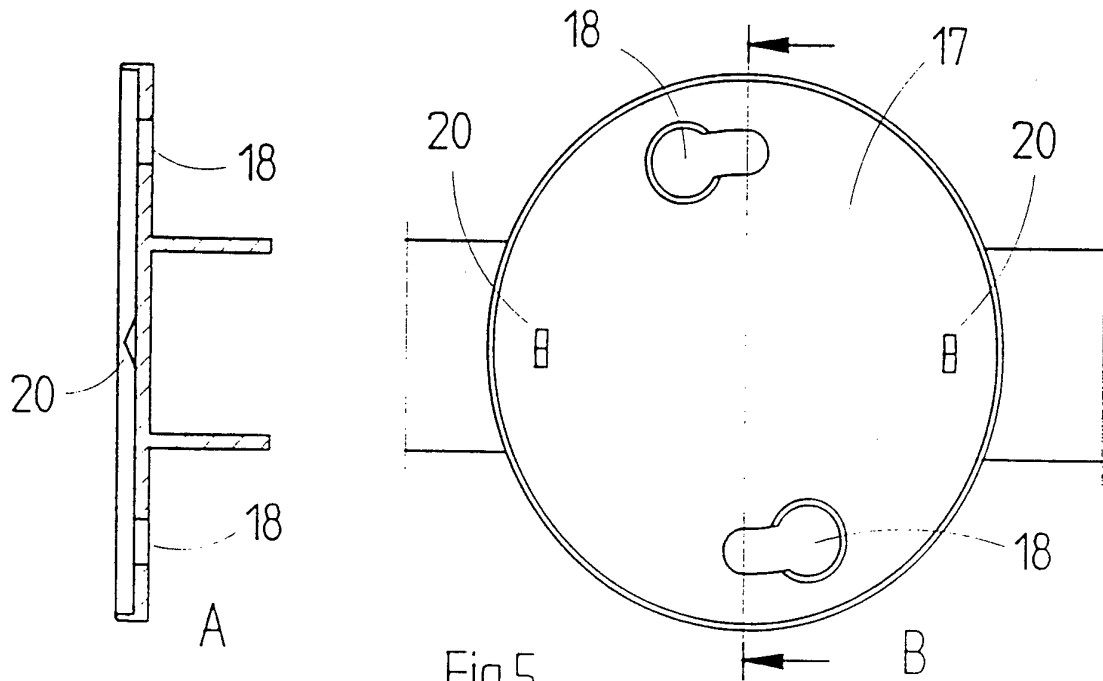
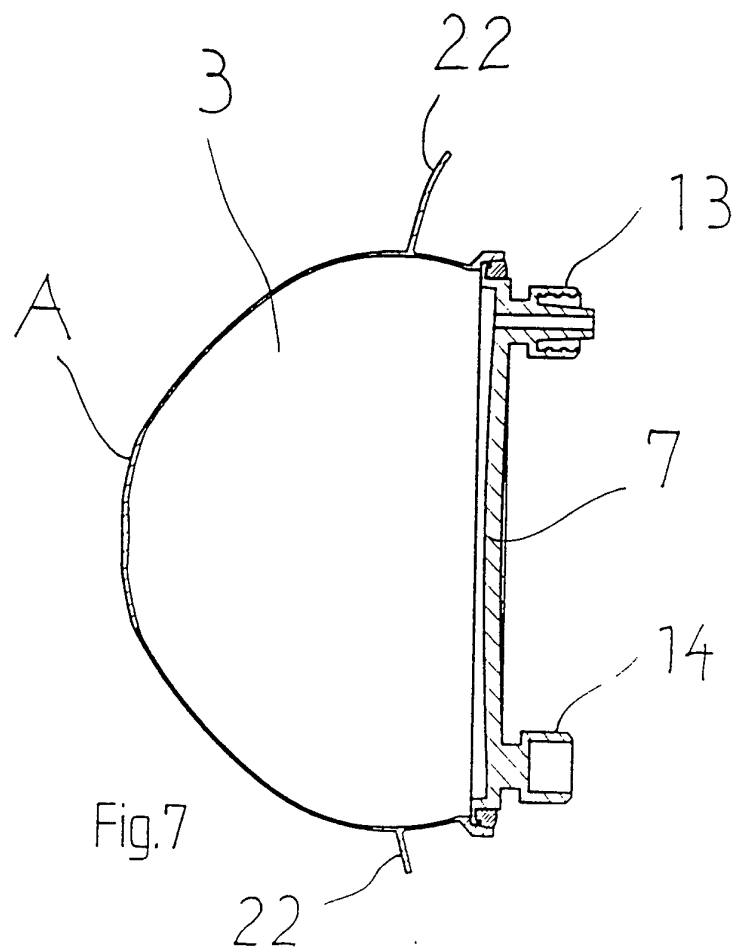
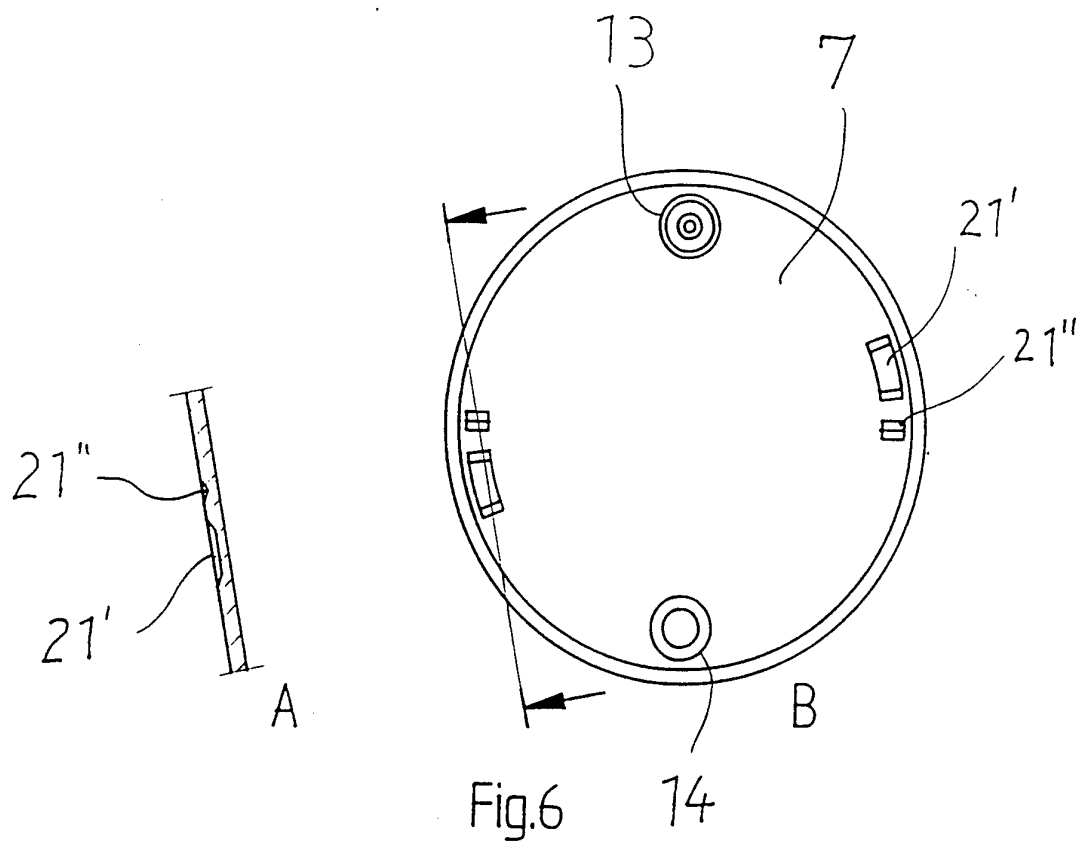


Fig.5



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 93/00705

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61B 17/12

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)

IPC5: A61B, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP, A2, 0462088 (RADI MEDICAL SYSTEMS AB), 18 December 1991 (18.12.91), abstract	14
Y	---	1-7,8,10-11
Y	US, A, 4224945 (J. COHEN), 30 Sept 1980 (30.09.80), column 3, line 15 - line 20; column 3, line 35 - line 37	1-7
Y	US, A, 4233980 (L.P. MCRAE ET AL), 18 November 1980 (18.11.80), claims 1-7, abstract	8,10-11

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

29 November 1993

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INTERNATIONAL SEARCH REPORT

Information on patent family members

16/10/93

International application No.

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A2- 0462088	18/12/91	JP-A- 5115487 SE-A- 9002077 SE-A- 9003271	14/05/93 12/12/91 12/12/91
US-A- 4224945	30/09/80	NONE	
US-A- 4233980	18/11/80	NONE	