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(71)(72) Applicant and Inventor: CENTANNI, Luciano [IT/IT]; Corso Lombardia, 121, I–10151 Torino (IT).

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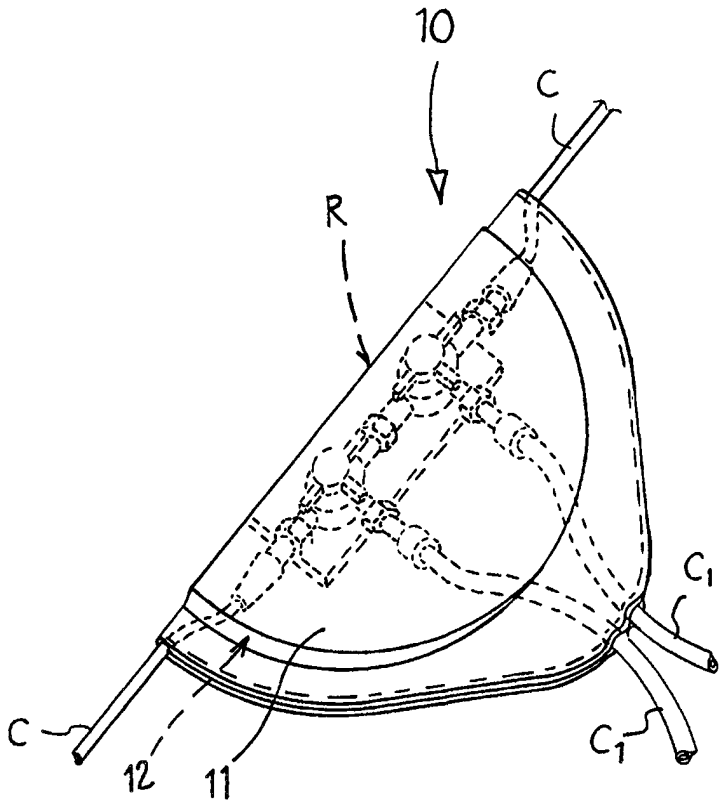
(54) Title: STERILE WRAPPING FOR PROTECTING MEDICAL EQUIPMENT DURING ITS USE

(57) Abstract

Sterile wrapping for medical equipment, including a medium consisting of a film made of flexible and resistant material, and means of closing enabling the wrapping to be kept closed over a piece or part of a piece of equipment to be protected during use against contaminating agents such as microbes, viruses, bacteria and such, characterised by the fact that it includes a padding (12) made of fibres charged electrostatically in a permanent manner, fixed onto one side of said medium (11). When the wrapping is closed over itself, the padding wraps said equipment or piece of equipment at last in part, so as to provide an aseptic field inside the wrapping, forming an effective protection against the contaminating agents, preventing the agents themselves from entering the equipment protected by said wrapping.



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"STERILE WRAPPING FOR PROTECTING MEDICAL EQUIPMENT DURING ITS USE"

This invention concerns a sterile wrapping for protecting medical equipment while it is being used, in particular for the administration, the drainage or the sampling of substances such as liquids, for therapeutic or diagnostic purposes.

While this equipment is being used, it is exposed to the risk of contamination by microbes, viruses, bacteria and such present in the environment. Indeed, contaminating agents can easily get into the equipment referred to above through the fittings for tubes, taps, valves and such that are part of the equipment itself, and cause serious infections in the patient using them.

In order to overcome this serious problem, a known system is to wrap said medical equipment, or parts of same, in a flexible protective wrapping which – according to EP 0.311.532, for example – includes:

- a medium consisting of a film made of a flexible, waterproof and strong material;
- a layer of absorbent, spongy material smaller than the medium to which it is fixed;
- sideways and crosswise means of closure, for example of the so-called "Velcro" (registered trademark) type, enabling the wrapping to be kept closed around a piece of equipment contained inside it.

The layer of spongy material is fixed to the medium by means of thermally adhesive glue. The sideways and crosswise means of closure are also fixed to the medium by means of thermally adhesive glue.

Said flexible protective wrapping, however, has the following main drawbacks:

. the layer of spongy material which, during use, is impregnated with sterilising or anti-contaminant agents in the form of a liquid or paste, easily releases these agents, which then come out of the wrapping, scattering and soiling the medical equipment, the personnel and the patient;

. Due to the effect of the chemical action of the sterilising and anti-contaminant agents, the glue used to fix the spongy layer and the means for closing it onto the medium, easily loses its properties and therefore said parts become detached from the medium;

. Furthermore, said sterilising or anti-contaminant agents with which the layer of spongy material is impregnated form an insufficient barrier against the proliferation of the bacterial, microbial and viral content inside the wrapping and, therefore, on the equipment that is contained inside it. In any case, this barrier is liable to be dispersed and exhausted within a short time.

The main purpose of this invention is to arrange for a sterile wrapping for the protection of medial equipment while it is being used. The wrapping must be capable of guaranteeing safe and lasting protection against contamination with bacterial, viruses and microbes of the equipment and such intended for medical use, used to administer substances to patients and to take sample and/or drain substances from patients, for example by means of infusion and sampling techniques.

Another purpose is to arrange for a sterile wrapping as indicated above, consisting of a simplified structure, safe, handy, reliable to use, and easy to make from an industrial point of view.

In view of said purposes, this invention envisages a sterile wrapping for the protection of medical equipment in use, the basic characteristics of which are the subject-matter of the main claim.

Additional beneficial characteristics are described in the subordinate claims.

The claims referred to above are understood to be given here in full

This invention is described in detail below, with reference to the drawings attached hereto by way of example, in which:

- Figure 1 is a plan view of the sterile wrapping for the protection of medical equipment in use, according to the invention, in an open position and showing its inside surface;
- Figure 2 and 3 are cross-section view on a larger scale, along lines II-II and III-III of Figure 1 respectively;
- Figure 4 is a view in perspective, consisting of a schematic illustration of the sterile wrapping for medical equipment according to Figure 1, on which a fitting with two taps for flexible tubes to be protected against contamination by bacteria, microbes and/or viruses is arranged;
- Figure 5 is a similar view to that shown in Figure 4, but in which the sterile wrapping is folded back over itself and is closed so as to protect said fitting.

In the drawings, 10 (Figure 1) indicates the sterile wrapping for the protection of medical equipment in use, according to this invention, and seen as a whole.

Said wrapping 10 includes, basically, the following components:

. an external flexible laminar medium 11 (Figures 2 and 3) with a high resistance, consisting, for example, of a flexible polyvinylchloride (PVC) film having an elliptical shape in accordance with the example illustrated;

. a cushion-like padding 12, consisting of fibres that are electrostatically charged in a permanent manner. This padding 12, which has a circular profile contained in the laminar medium 11, is centred and fixed on one side of the medium itself (hereinafter referred to

as the internal surface), for example by gluing it with a double-adhesive strip, so as to leave one edge 11.1 free (Figure 2) on the internal surface of said medium 11;

. a flexible finishing sheet 13 (Figure 2), made for example of cloth or non-woven fabric, overlapping said padding 12, having the function of containing the fibres of the padding itself;

. an edge flap 14, made for example of PVC, overlapping the inside surface of said flexible medium 11 along said free edge 11.1 and fixed, by means of seam for example, along the outer peripheral edge of the support 11 itself, so as to form a continuous pocket 15 (Fig. 2). Inside this pocket said padding 12 is partly inserted, along the profile of its circumference;

. means 16, which can be separated, used for closing the wrapping 10 when same is folded back along its median transverse axis X-X (Fig.1) by overlapping the two halves.

Said means of closure 16, consisting for example of means which have grip on each other when overlapped, such as so-called "Velcro", or of means that adhere to each other when overlapping, or means fitted with snap-fasteners, magnetic means or such, which are fixed for example by sewing or heat-welding them onto said edge flap 14.

The fibres forming the cushion-like padding 12 are separate electrostatically charged fibres. The density of the charge is, for example, about 50 nC/cm .the fibres are charged in the two-pole mode. Seen on a cross-section, the rectangular fibres have, for example, a thickness of about 10 m and a width of about 60 m.

The fibres are carded and form an open and uniform non-woven fabric.

The electrostatic charges are located in the mass of the material and are therefore not influenced by external factor.

At one end of said edge flap 14, in a distal position in respect of the X-X axis, there is a slot 17 (Figure 1), the shortest axis of which coincides with the median longitudinal axis of wrapping 10. A through notch 17.1 extends from the slot 17 as far as the peripheral inside edge of the edge flap 14 along said Y-Y axis.

At the height of the slot 17, said Edge flap 14 is reinforced by a stiffening fin 17.2 (Figure 3), made for example of cardboard, coupled with said flap and notched in accordance with the shape of said slot 17 and along said notch 17.1.

According to experiments carried out by the inventor, the cushion- like padding 12, made of fibres with a permanent electrostatic charge, provides an aseptic field inside the wrapping 10, forming an effective protection against contaminating agents such as microbes, viruses and bacteria: The protection prevents said agents from entering the equipment protected by said wrapping.

When the medical equipment to be protected is being used (Figure 4 and 5), the equipment itself or part of it is superimposed on the internal surface of the wrapping 10, in such a way as to arrange it in one half of the surface itself in respect of the X-X axis.

In Figures 4 and 5 the equipment illustrated schematically is a fitting R with two taps R1, from which flexible tubes, C and C1 respectively, branch out.

Through the notch 17.1, the flexible tubes C1 are arranged so that they pass through the slot 17, so that the edge flap 14 overlaps them partially. The flexible tubes C, on the other hand, come out of the wrapping 10 on from opposite bands, parallel to said X-X axis.

The wrapping 10 is then folded back over itself along said X-X axis, until it closes it completely, as illustrated in Figure 5, and the opposite parts of the means of closure 16 overlap each other. Whatever the means of closure 16 may be, on applying a slight pressure on their overlapping parts sealing of the protective wrapping 10 is achieved, and the wrapping is closed peripherally along its edge flap 14, with the equipment R kept stably inside it. It will be noted that the edge flap 14, partially overlapping the tubes C1, enables safe and effective closing of the wrapping 10, also folded back at the height of the tubes themselves, which lead freely out of the wrapping 10 through the slot 17, keeping them stably in position. The flexible tubes C come out of the wrapping 10 along the folding line parallel to the X-X axis.

In said arrangement, the wrapping 10 forms a closed chamber in which the equipment R is protected effectively against contamination by viruses, microbes and bacteria by means of the cushion-like padding 12, in which the equipment itself is wrapped.

Of course, in practice, many variants may be made as compared with the embodiment described and illustrated by way of example only, without exceeding the scope of the invention and therefore the field of this industrial patent.

CLAIMS

1. Sterile wrapping for medical equipment, including a medium consisting of a film made of flexible and resistant material, and means of closing enabling the wrapping to be kept closed over a piece or part of a piece of equipment to be protected during use against contaminating agents such as microbes, viruses, bacteria and such, characterised by the fact that it includes a padding (12) made of fibres charged electrostatically in a permanent manner, fixed onto one side of said medium (11).
   When the wrapping is closed over itself, the padding wraps said equipment or piece of equipment at least in part, so as to provide an aseptic field inside the wrapping, forming an effective protection against the contaminating agents, preventing the agents themselves from entering the equipment protected by said wrapping.
2. Wrapping according to claim 1, characterised by the fact that the fibres forming said padding (12) are electrostatically charged in the two-pole mode.
3. Wrapping according to claims 1 and 2, characterised by the fact that the fibres forming said padding (12) are carded and form an open and uniform non-woven fabric, in which the electrostatic charges are located.
4. Wrapping according to claim1, characterised by the fact that it includes a flexible finishing sheet (13), made, for example, of cloth or non-woven fabric, overlapping said padding (12) and having the function of containing the fibres of the padding itself.
5. Wrapping according to claim 1, characterised by the fact that it includes an edge flap (14) overlapping the internal surface of said flexible medium (11) and fixed along the outer peripheral profile of the medium (11) itself, so as to form a pocket (15) inside which said padding (12) is a partially inserted, along its outer peripheral profile.
6. Wrapping according to claim 5, characterised by the fact that a slot (17) is provided in said edge flap (14), while a through notch (17.1) extends from the slot (17) as far as the peripheral inside edge of the edge flap (14), in such a way that flexible tubes (C1) of the equipment or part of equipment to be protected are arranged through said slot (17) so that the edge flap (14) overlaps them partially. This enables safe and effective closure of the wrapping (10), also folded back at the height of the tubes themselves, which lead out freely from the wrapping through the slot (17), keeping them stably in position.
7. Wrapping according to claim 6, characterised by the fact that at the height of said slot (17) said edge flap (14) is reinforced by means of a stiffening fin (17.2), made for example of cardboard, coupled with said flap (14) and notched in accordance with the profile of said slot (17) and along said notch (17.1).

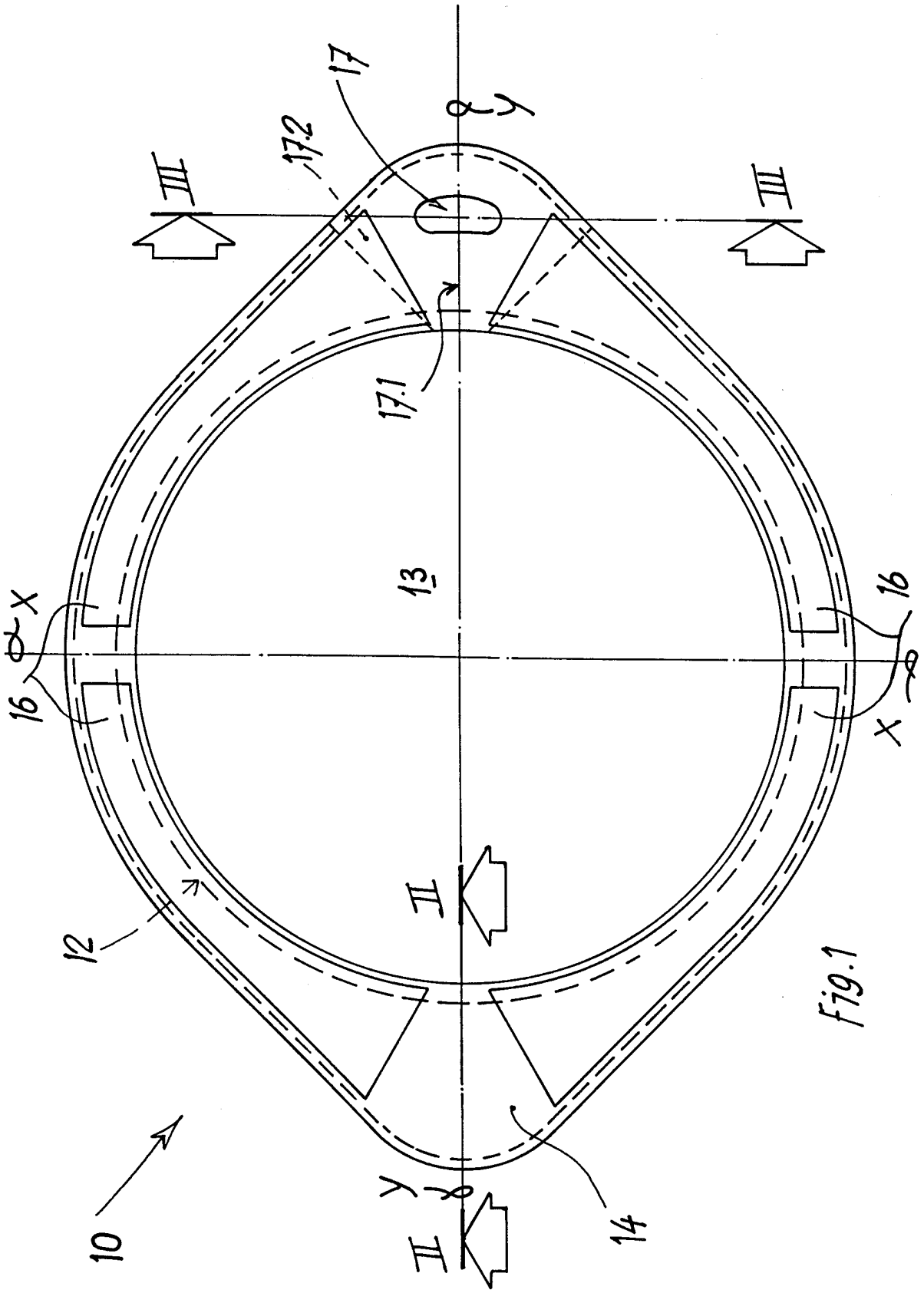

Fig.1

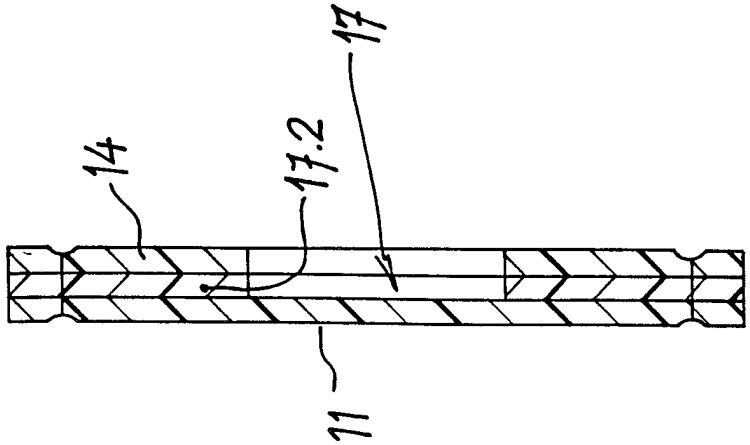

Fig. 3

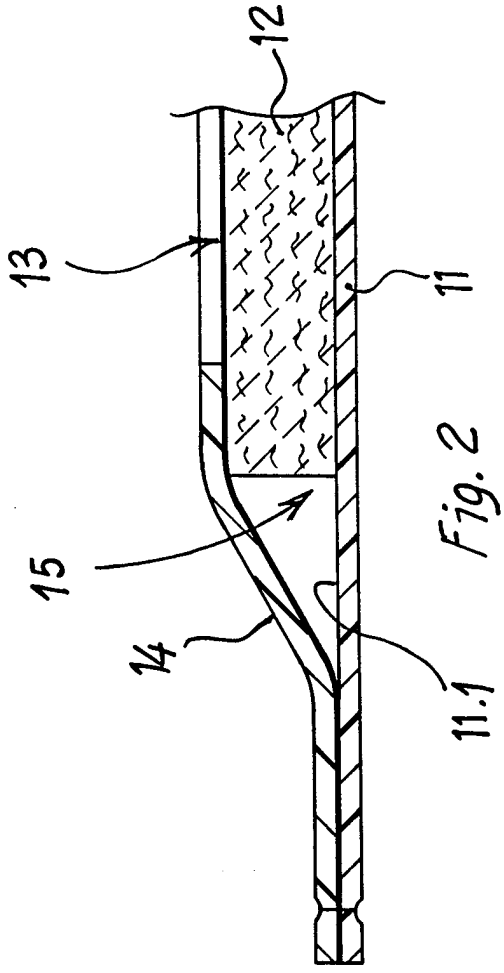

Fig. 2

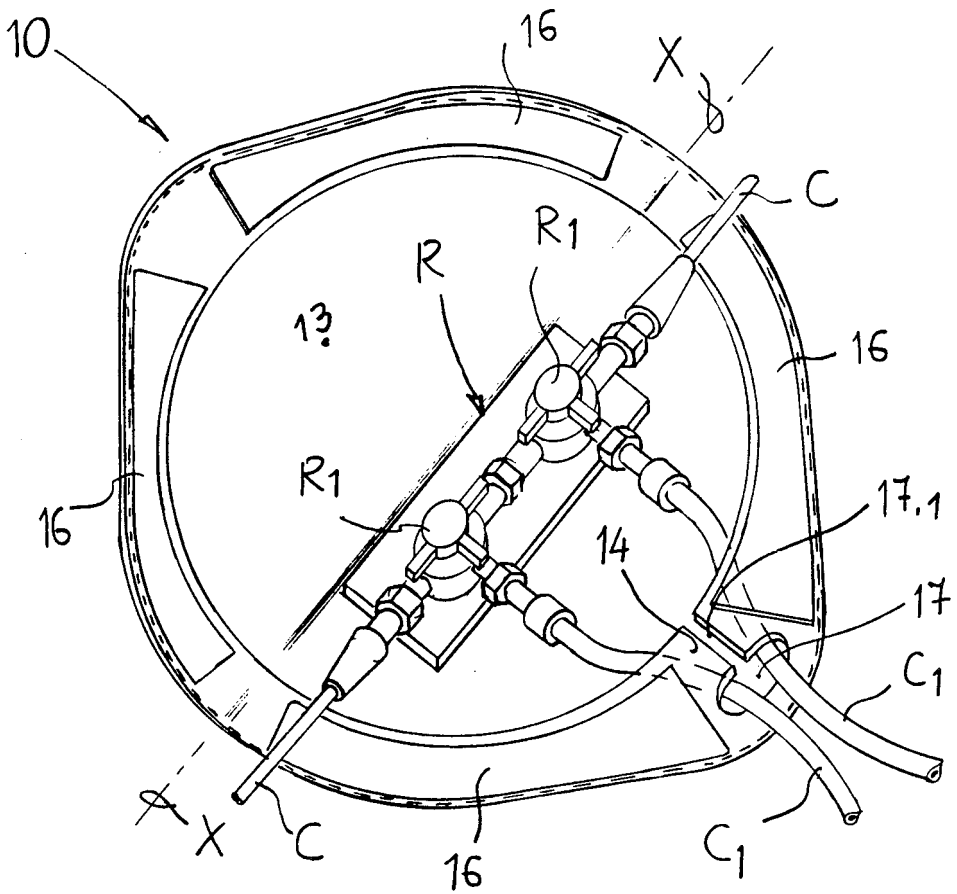

Fig. 4

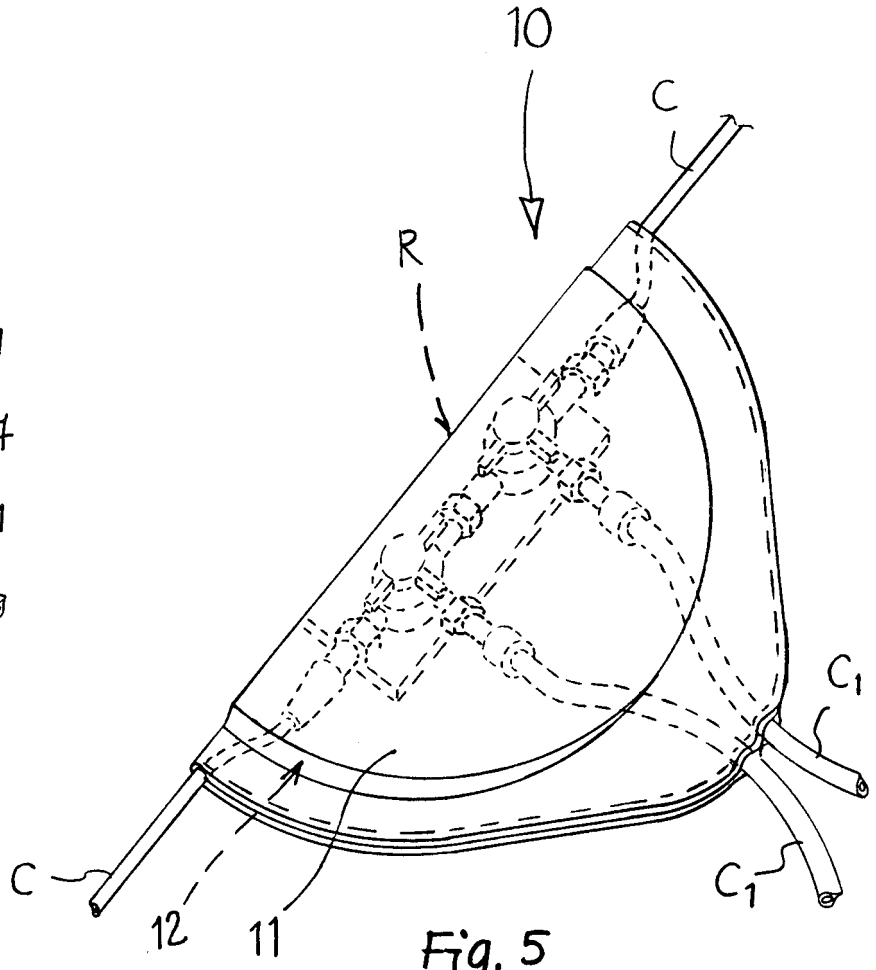

Fig. 5

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/EP 98/03332

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M39/16 A61B19/08

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61B B65D

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

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 311 532 A (GRIVON JOSETTE) 12 April 1989 cited in the application see abstract; claims 1,2; figures 1-4	1-3
Y	WO 96 00093 A (KIMBERLY CLARK CO) 4 January 1996 see page 1, line 7 - line 11 see page 5, line 16 - line 28; claims 11-19	1-3
A	EP 0 391 725 A (JOHNSON & JOHNSON MEDICAL) 10 October 1990 see abstract; claim 1; figures 3,4	1-3
A	US 4 425 126 A (SHEPHERD ROBERT C ET AL) 10 January 1984 see column 4, line 20 - line 31; figure 6	1,4,5

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

[X] Patent family members are listed in annex.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 94 16763 A (ROSSETTI GIOVANNI ;FORINO LUCIANO (IT); GUGLIOTTA VINCENZO (IT)) 4 August 1994 see abstract; figures 1-6	1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/EP 98/03332

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0311532 A	12-04-1989	FR 2621477 A	14-04-1989
		AT 109646 T	15-08-1994
		DE 3851028 D	15-09-1994
		DE 3851028 T	30-03-1995
		ES 2060670 T	01-12-1994
WO 9600093 A	04-01-1996	AU 693215 B	25-06-1998
		AU 2904295 A	19-01-1996
		BR 9508131 A	02-09-1997
		CA 2136576 A	28-12-1995
		EP 0767681 A	16-04-1997
		JP 10505388 T	26-05-1998
		SK 167596 A	06-08-1997
EP 0391725 A	10-10-1990	AT 107494 T	15-07-1994
		AU 5295390 A	11-10-1990
		CA 2014053 A	07-10-1990
		DE 69010051 D	28-07-1994
		ES 2060027 T	16-11-1994
		GR 90100242 A	27-09-1991
		JP 3063046 A	19-03-1991
US 4425126 A	10-01-1984	NONE	
WO 9416763 A	04-08-1994	IT T0930006 U	20-07-1994
		AT 152632 T	15-05-1997
		AU 5882294 A	15-08-1994
		DE 9422087 U	18-12-1997
		DE 69403060 D	12-06-1997
		EP 0680360 A	08-11-1995