

MECÁNICA IET

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DOCUMENTO D0
SOLICITUD EN ESTUDIO
CASO PRÁCTICO IET

**FUNDA PROTECTORA DE UN SOLO USO DESTINADA A ALOJAR UN
MANGUITO DE UN ESFIGMOMANÓMETRO**

OBJETO DE LA INVENCION

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La presente invención se refiere a una funda protectora de un solo uso en forma de cinta destinada a alojar un manguito de esfigmomanómetro y destinada, además, a adaptarse a la forma del mismo, que se engloba en el campo de dispositivos o accesorios protectores contra el riesgo de infecciones en manguitos de esfigmomanómetros. Más en particular, la presente invención describe una funda protectora de un solo uso adaptada a alojar el manguito del esfigmomanómetro, donde dicha funda protectora está fabricada en una sola pieza de un material hidrofóbico actuando como barrera contra riesgo de infecciones.

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ANTECEDENTES DE LA INVENCION

La toma de la tensión arterial en la práctica clínica es una de las técnicas realizadas más habitualmente para la valoración hemodinámica de los pacientes, ya sea en situaciones de emergencia o en reconocimientos rutinarios. De todos los métodos utilizados para la toma de la tensión arterial, el más exacto, usado, estudiado e investigado es el auscultatorio con la utilización de un esfigmomanómetro.

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El esfigmomanómetro es un aparato para medir la tensión arterial indirectamente utilizando un brazalete (llamado manguito), que es colocado en el brazo, una pera de goma para hinchar el brazalete y un fonendoscopio para escuchar el pulso.

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Tradicionalmente, la toma de la tensión arterial con un esfigmomanómetro se ha considerado un método inocuo, seguro y que aporta información importante sobre el estado de salud del paciente. Sin embargo, estos dispositivos son utilizados de forma repetida en distintos pacientes, sin proceder a su desinfección lo que impide garantizar una atención segura y de calidad, lo cual resulta indispensable tras la pandemia del Covid-19.

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Existen diversos estudios científicos que demuestran que el manguito del esfigmomanómetro incorpora detritus orgánicos y microorganismos de la piel del paciente. Por lo tanto, puede constituir un reservorio y vía de transmisión bacteriana con potencial

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peligro de infección para los pacientes; y un riesgo para la salud de los profesionales sanitarios.

5 El modelo de utilidad U201000015 describe un protector de un solo uso para las campanas y las membranas de los fonendoscopios o estetoscopios, lo que podría constituir un elemento complementario para la presente invención. No obstante, se desconocen en el estado de la técnica dispositivos de protección para los manguitos de esfigmomanómetros.

DESCRIPCIÓN DE LA INVENCION

10 La presente invención pretende solucionar alguno de los problemas mencionados en el estado de la técnica. Más en particular, la presente invención describe una funda protectora de un solo uso en forma de cinta destinada a alojar un manguito de esfigmomanómetro y a adaptarse a la forma del mismo, donde dicha funda protectora está
15 fabricada de una sola pieza de un hidrofóbico actuando como barrera contra el riesgo de infecciones.

En una realización preferente, está fabricada de un material del tipo SMS (“Spunbond Melblown Spunbond fabric”) compuesto por una tela no tejida que comprende una capa
20 superior de polipropileno “Spunbond”, una capa intermedia de polipropileno fundido por soplado y una capa inferior de polipropileno “spunbond”. Mas preferentemente, de SMS 35 gr.

Asimismo, la funda protectora puede estar fabricado también de una tela no-tejida del tipo
25 SMMS (“Spunbond, Meltblown, Meltblown y Spunbond”), SSMMS (“Spunbond, “punbond, Meltblown, Meltblown y Spunbond”) e incluso SMMMS el cual incorpora 3 capas de meltblown.

La funda protectora puede disponer de una cara lateral abierta para insertar el manguito
30 de esfigmomanómetro dentro de la funda protectora.

Preferentemente, la funda protectora comprende además un elemento de unión en una porción inferior o superior de la cara abierta, destinado a unir a cerrar la funda protectora con el manguito de esfigmomanómetro alojado interiormente. En una realización
35 preferente, dicho elemento de unión es un adhesivo doble cara.

Asimismo, la funda protectora puede estar dotada de una marca de posición de la arteria que indica el rango de colocación tanto en una superficie exterior como en una superficie interior.

- 5 La funda protectora puede estar dotada de un agujero pasante en una superficie lateral de la misma.

- 10 La funda protectora de un solo uso se puede realizar para los diferentes tamaños de brazaletes o manguitos existentes en el mercado (XL, adulto, pediátrico) y en diferentes colores.

DESCRIPCIÓN DE LOS DIBUJOS

- 15 Para complementar la descripción que se está realizando y con objeto de ayudar a una mejor comprensión de las características de la invención, de acuerdo con un ejemplo preferente de realización práctica de la misma, se acompaña como parte integrante de dicha descripción, un juego de dibujos en donde con carácter ilustrativo y no limitativo, se ha representado lo siguiente:

- 20 Figura 1.- Muestra una vista frontal de una superficie exterior de la funda protectora de acuerdo con una realización preferente de la invención, donde se ilustra la superficie interna que comprende aberturas para dejar al descubierto el velcro del manguito, así como la marca de posición de la arteria.

- 25 Figura 2.- Muestra una vista frontal de una superficie interior de la funda protectora de acuerdo con una realización preferente de la invención, donde se ilustra la superficie externa que comprende aberturas para dejar al descubierto el velcro del manguito, así como la marca de posición de la arteria y el agujero pasante lateral.

- 30 Figura 3.- Muestra una vista en perspectiva de una porción inferior de la funda protectora donde se muestra que comprende una cara abierta y un adhesivo.

Figura 4.- Muestra una vista en perspectiva de una vista opuesta con respecto a la figura 3, donde se muestra la cara abierta, la abertura y el velcro del manguito.

REALIZACIÓN PREFERENTE DE LA INVENCION

5 A continuación, se describe con la ayuda de las figuras 1-3, una realización preferente de la funda protectora (1) de un solo uso destinada a alojar un manguito de esfigmomanómetro y a adaptarse a la forma del mismo.

10 En la realización preferente descrita, el manguito de esfigmomanómetro destinado a alojarse en la funda protectora (1) es del tipo que comprende velcro (V) para cerrar y adaptarse a la anatomía en forma de brazalete o abrazadera.

15 La figura 1 muestra una vista frontal de la funda protectora (1) donde se muestra que comprende una superficie interna (5) que comprende unas aberturas (2) destinadas a permitir la accesibilidad del velcro (v) del manguito. De esta manera, la porción que presenta velcro (v) del manguito original queda al descubierto para asegurar la correcta colocación del brazalete o manguito en el usuario.

20 En la realización preferente descrita la funda protectora (1) está fabricada de una sola pieza de material hidrofóbico actuando como barrera contra el riesgo de infecciones, donde dicho material es una tela no-tejida del tipo SMS 35 gr ("Spunbond Melblown "punbond fabric") que comprende una capa superior de polipropileno "Spunbond", una capa intermedia de polipropileno fundido por soplado y una capa inferior de polipropileno "spunbond".

25 La figura 2 muestra una vista de la superficie externa (6) que comprende también aberturas (2) destinadas a permitir accesibilidad al velcro (v) del manguito.

30 Asimismo, tanto la superficie interna (6) como externa (5) están dotadas de una marca de posición (4) de la arteria que indica el rango de colocación.

35 La figura 3 muestra una vista en perspectiva de una porción inferior de la funda protectora (1) según la realización preferente, donde se ilustra que la funda protectora (1) presenta una superficie abierta y una línea adhesiva (7) de doble cara para permitir la correcta colocación sobre el manguito.

La figura 4 muestra una vista en perspectiva de la porción opuesta a la figura 3, según la realización preferente de la funda protectora.

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REIVINDICACIONES

1.- Funda protectora (1) de un solo uso destinada a alojar un manguito de esfigmomanómetro y a adaptarse a la forma del mismo, donde dicha funda protectora (1) está **caracterizada por qué** está fabricada de una sola pieza de un material hidrofóbico actuando como barrera contra el riesgo de infecciones.

2.- La funda protectora (1) de la reivindicación 1, en el que el material hidrofóbico es un SMS ("Spunbond Melblown "punbond fabric") compuesto por una tela no tejida que comprende una capa superior de polipropileno "Spunbond", una capa intermedia de polipropileno fundido por soplado y una capa inferior de polipropileno "spunbond".

3.- La funda protectora (1) de la reivindicación 1, que comprende una abertura (2) en una superficie interior (5) y en una superficie exterior (6), donde dichas aberturas (2) están destinadas a dejar al descubierto el velcro (v) del manguito de esfigmomanómetro para asegurar la correcta colocación del mismo con la funda protectora (1).

4.- La funda protectora (1) de la reivindicación 1, que en una porción inferior comprende una cara abierta que permite introducir el manguito de esfigmomanómetro.

5.- La funda protectora (1) de la reivindicación 4, que comprende, además, un elemento de unión (7) en una porción inferior o en una porción superior de la cara abierta destinado a unir la funda protectora (1) con el manguito de esfigmomanómetro.

6.- La funda protectora (1) de la reivindicación 5, en el que el elemento de unión (7) es un adhesivo doble cara.

7.- La funda protectora (1) de la reivindicación 1, que comprende en la superficie interior (5) y en la superficie exterior (6) una marca de posición (4) de la arteria que indica el rango de colocación.

8.- La funda protectora (1) de la reivindicación 1, que comprende un agujero pasante (3) en una porción lateral del mismo.

RESUMEN**FUNDA PROTECTORA DE UN SOLO USO DESTINADA A ALOJAR UN MANGUITO
DE UN ESFIGMOMANÓMETRO**

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Funda protectora (1) de un solo uso destinada a alojar un manguito de esfigmomanómetro y a adaptarse a la forma del mismo, que comprende una porción inferior inferior dotada de una cara abierta que permite introducir el manguito de esfigmomanómetro, donde dicha funda protectora (1) está fabricada de una sola pieza

10 de un material hidrofóbico del tipo SMS compuesto por una tela no tejida que comprende una capa superior de polipropileno "Spunbond", una capa intermedia de polipropileno fundido por soplado y una capa inferior de polipropileno "spunbond", actuando así dicha funda protectora (1) como barrera contra el riesgo de infecciones.

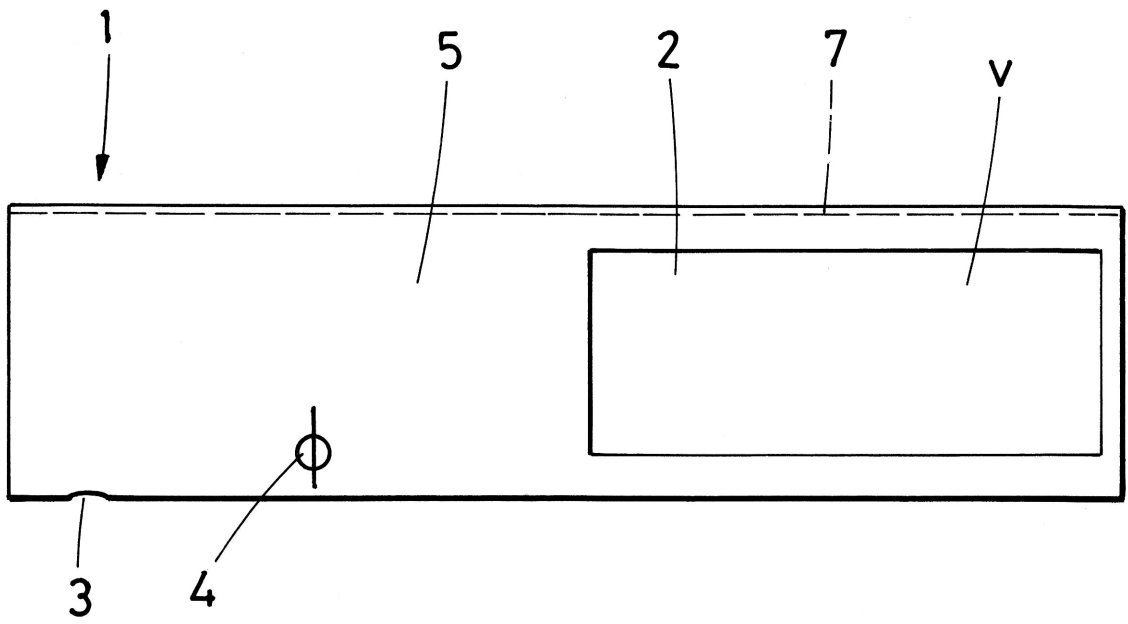


FIG.1

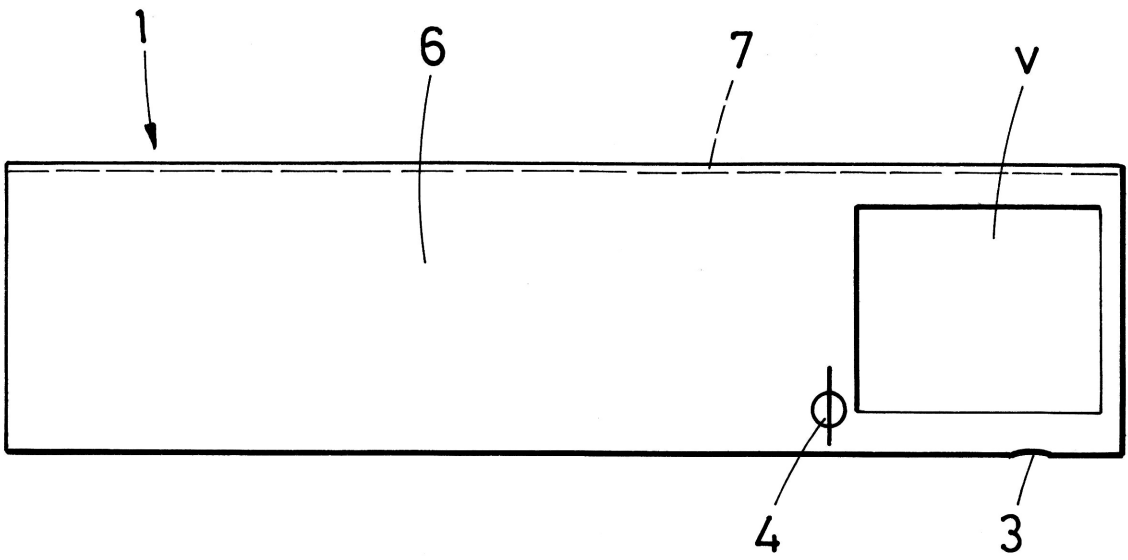


FIG.2

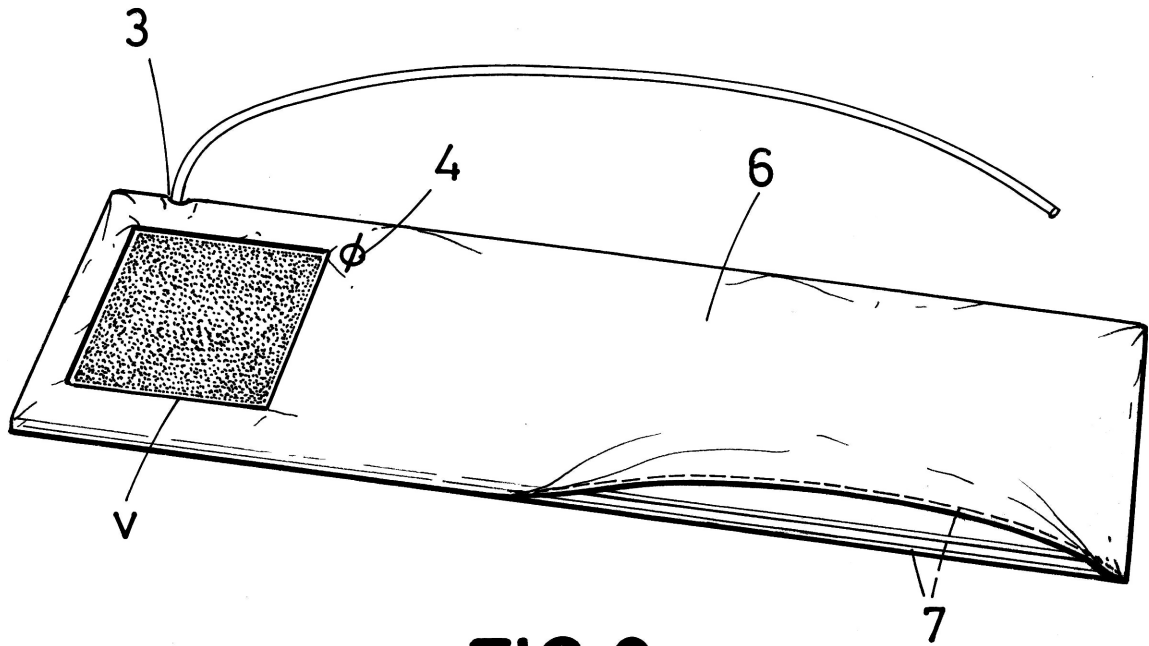


FIG. 3

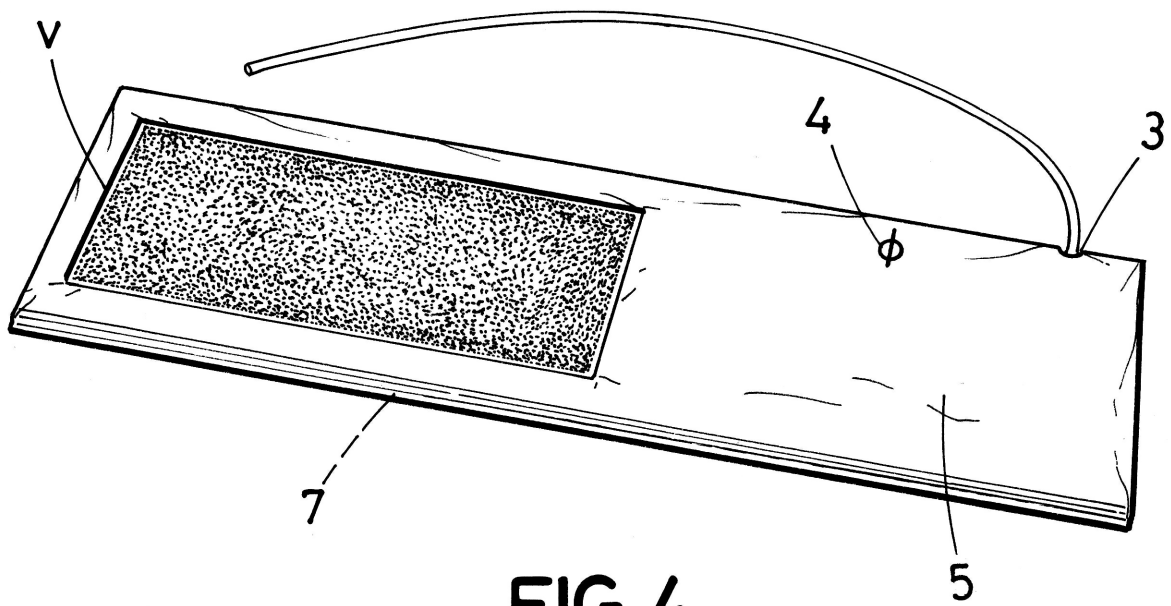
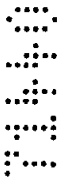


FIG. 4

MECÁNICA
DOCUMENTO D1
AU 736862 B3

(57) Abstract

A protective sleeve (10) for a blood pressure cuff (22) comprises a flexible tube (11a, 11b) of fluid impermeable material adapted to fit around at least that part of a limb of a patient from where a blood pressure measurement is to be taken. The tube (11a, 11b) has a first opening (16) for inserting a blood pressure cuff (22) therethrough, the tube (11a, 11b) being adapted to snugly receive the cuff (22) therein, and has at least one opening (16, 18) through a wall (12, 14) of the tube (11a, 11b) at a location corresponding to the location on the so received cuff of fastening means (32, 34) used to secure one end of the cuff (22) to another end of the cuff (22) when the tube (11a, 11b) is fitted around the limb of the patient. The arrangement is such that, in use, the blood pressure cuff (22) is snugly received in the tube (11a, 11b), and the tube is fitted around the limb of the patient to protect the cuff (22) from fluid.



AUSTRALIA
Patents Act, 1990
ORIGINAL
COMPLETE SPECIFICATION
PETTY PATENT

TO BE COMPLETED BY THE APPLICANT

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INVENTION TITLE: BLOOD PRESSURE CUFF
PROTECTION SLEEVE

DETAILS OF ASSOCIATED
PROVISIONAL APPLICATION NO(S): NIL

The following statement is a full description of this invention including the best
method of performing it known to me:-

The present invention relates to a protective sleeve for a blood pressure cuff, also known as a biohazard cuff protector.

Blood pressure cuffs or sphygmomanometers are one of the most commonly used medical devices. Blood pressure measurements may be taken of a range of patient types, from those undergoing routine blood pressure tests to those in emergency situations, among which the taking of blood pressure measurements may be in circumstances where the patient is undergoing the loss of blood or other body fluids.

Contamination of blood pressure cuffs in the course of their use is not uncommon. As well as the likelihood of contamination by blood, mucus or vomit in emergency situations, blood pressure cuffs may absorb other body fluids, such as sweat, as well as grime that can act as carriers of disease causing agents and which present a generally unhygienic environment to which a patient may be exposed. Even where blood pressure cuffs have only ever been used on patients undergoing routine blood pressure tests, such as in community health clinics or in the surgeries of general practitioners, the gradual accumulation of sweat and grime on the cuff may, over time, pose a threat to the health of patients.

In circumstances where the level of contamination of the cuff has been severe, there may be no alternative but to safely dispose of the cuff, a somewhat expensive measure and a problematic solution in itself.

Where a cuff has been contaminated to a lesser extent, decontamination of the cuff may be effected by routine methods commonly used in hospitals and the like, although these methods must ensure that they do not destroy or compromise the structure and function of the cuff. Many blood pressure cuffs are not designed to withstand the high sterilizing temperatures required to thoroughly decontaminate them. Furthermore,

decontamination methods are time consuming and the use of autoclaves and sterilizers to decontaminate blood pressure cuffs will place an added burden on the use of the resources of the hospital or the like.

It is an object of the present invention to overcome or substantially
5 ameliorate the disadvantages and shortcomings of the prior art.

It is another object of the present invention to provide a means for effectively isolating the blood pressure cuff, when in use, from the body fluids of the patient whose blood pressure is being measured.

It is yet another object of the present invention to provide a protective
10 sleeve that can effectively surround the blood pressure cuff, when in use, and can easily be fitted over the arm of the patient.

It is a still further object of the present invention to provide a protective sleeve for a blood pressure cuff that can be used on a patient's arm to which there is attached drip tubing, without the need to disconnect the drip tubing
15 from the patient's arm before fitting the protective sleeve thereto.

According to the present invention, there is provided a protective sleeve for a blood pressure cuff comprising a flexible tube of fluid impermeable material adapted to fit around at least that part of a limb of a patient from where a blood pressure measurement is to be taken, the tube comprising a first
20 opening through a first wall of the tube for inserting a blood pressure cuff therethrough, the tube being adapted to snugly receive the cuff therein, the first opening being at a location of the tube corresponding to the location on the so received cuff of a first component of fastening means used to secure one end of the cuff to another end of the cuff when the tube is fitted around the limb of
25 the patient, and a second opening through a second wall of the tube opposite the first wall, the second opening being at a location of the tube corresponding to the location on the so received cuff of a second component of the fastening



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means, whereby when the tube is fitted around the limb of the patient, one end of the cuff is secured to another end of the cuff by engagement of the first and second components of the fastening means, thereby protecting the cuff from fluid.

Preferably, the protective sleeve further includes adhesive means for
 5 securing a first end of the tube to the tube when the tube is fitted around the limb.

It is preferred that the flexible tube is transparent over at least that part of the cuff corresponding to the location of an arterial indicator symbol represented on the cuff.

10 In order that the invention may be readily understood and put into practical effect, reference will be made to the accompanying drawings, in which:

Fig 1 is a perspective view of a protective sleeve according to a preferred embodiment of the present invention together with a
 15 blood pressure cuff with its connected air supply tubing prior to inserting the cuff into the sleeve,

Fig 2 is a perspective view of the protective sleeve of Fig 1 with the blood pressure cuff snugly received therein, the view showing the upper surface of the sleeve,

20 Fig 3 is a perspective view of the protective sleeve of Fig 1 with the blood pressure cuff snugly received therein, the view showing the lower surface of the sleeve,

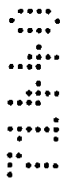
Fig 4 is a sectional side view through IV-IV of the protective sleeve of Fig 2 with the blood pressure cuff snugly received therein,



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Fig 5 is an isometric view of the protective sleeve of Fig 2 with the blood pressure cuff snugly received therein, shown in the process of being fitted around an arm of a patient, and

Fig 6 is a view similar to that of Fig 5 of the protective sleeve of Fig 2 with the blood pressure cuff snugly received therein shown fitted around the arm of the patient.



The protective sleeve 10 shown in Figs 1 to 6 comprises a flexible tube fabricated of a plastic material, such as polyvinyl chloride, that is impermeable to fluid, especially body fluids such as blood and mucus. The tube, which has a substantially rectangular main body 11a and a perpendicularly extending arm 11b, is formed by pressure melting or sealing together two separate, but superimposed strips or sleeve portions 12, 14 of the tube, along the edges 13, 15a, 15b, 17, 19, 21a, 21b of the sleeve portions 12, 14 but leaving the edges 23 unsealed. The upper and lower sleeve portions 12, 14 constitute the wall of the tube, with the upper sleeve portion 12 being transparent and the lower sleeve portion 14 being opaque or coloured.

There is an opening 16 formed through the upper sleeve portion 12 and there is an opening 18 formed through the lower sleeve portion 14. The upper and lower sleeve portions 12, 14 are heat sealed together along a line stretching from edge 13 to edge 15a to form a weld seam 20. The location of the weld seam 20 is such that, when the blood pressure cuff 22 is inserted through the opening 16 and orientated correctly as shown, the cuff 22 is received snugly in the tube and its connected air supply tubing 24 is fed through the arm 11b and exits the tube through an opening 26 defined between the unsealed edges 23 of the arm 11b of the tube.

Attached to the sleeve adjacent the edge 19 are a pair of peelable strip protected adhesive tabs 28, 29.

By virtue of defining an accessible enclosure 30 between the flexible sleeve portions 12, 14, the sleeve can snugly receive therein the cuff 22 and, when so received, the location of opening 16 leaves exposed a patch of hook members 32 of a hook and loop attachment system of the cuff 22, and the location of opening 18 leaves exposed a patch of loop members 34 of the hook and loop attachment system of the cuff 22.

In use, the protective sleeve 10 with cuff 22 snugly received therein is applied to the arm 35 in the normal manner, as shown in Fig 5, with the arterial indicator symbol 36 which is normally printed on the cuff 22 being used to correctly position the sleeve 10 around the arm 35 by aligning the symbol 36 with the patient's brachial artery puncture point opposite the elbow. Wrapping the sleeve 10 over itself will enable the hook members 32 to engage the loop members 34, thereby securing both the sleeve 10 and the cuff 22 snugly received therein around the arm 35 as shown in Fig 6. The strips of the adhesive tabs 28, 29 may then be peeled off and the tabs 28, 29 pressed against the sleeve 10 to ensure edge 19 is not loose.

A blood pressure measurement can be taken in the normal manner with the sleeve 10 protecting the arm fitted cuff 22 as described above.

It is a particular advantage of the sleeve of the present invention that it can be used on a patient's arm to which there is attached drip tubing, without the need to disconnect the drip tubing from the patient's arm before fitting the sleeve thereto.

Various modifications may be made in details of design and construction without departing from the scope and ambit of the invention.

The sleeve 10 may be manufactured as a single use, disposable item or as a multi-use item that can be sterilized or decontaminated after each use.



THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A protective sleeve for a blood pressure cuff comprising a flexible tube of fluid impermeable material adapted to fit around at least that part of a limb of a patient from where a blood pressure measurement is to be taken, the tube comprising a first opening through a first wall of the tube for inserting a blood pressure cuff therethrough, the tube being adapted to snugly receive the cuff therein, the first opening being at a location of the tube corresponding to the location on the so received cuff of a first component of fastening means used to secure one end of the cuff to another end of the cuff when the tube is fitted around the limb of the patient, and a second opening through a second wall of the tube opposite the first wall, the second opening being at a location of the tube corresponding to the location on the so received cuff of a second component of the fastening means, whereby when the tube is fitted around the limb of the patient, one end of the cuff is secured to another end of the cuff by engagement of the first and second components of the fastening means, thereby protecting the cuff from fluid.
2. The protective sleeve of claim 1 further including adhesive means for securing a first end of the tube to the tube when the tube is fitted around the limb.
3. The protective sleeve of claim 1 or claim 2 wherein the flexible tube is transparent over at least that part of the cuff corresponding to the location of an arterial indicator symbol represented on the cuff.

Dated this 2nd day of April, 2001

Process Improvements Pty Limited

Patent Attorneys for the Applicant

PETER MAXWELL & ASSOCIATES



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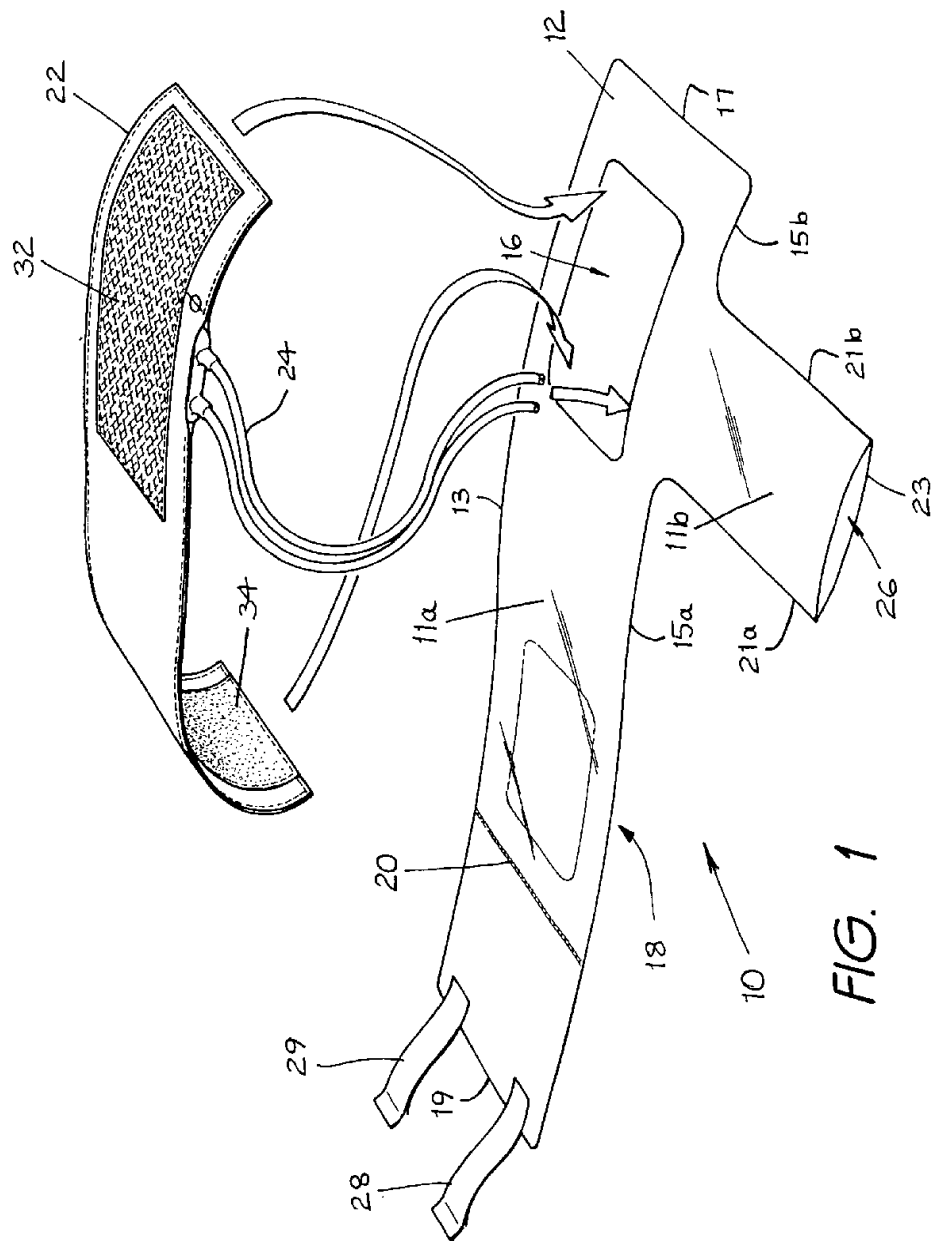


FIG. 1

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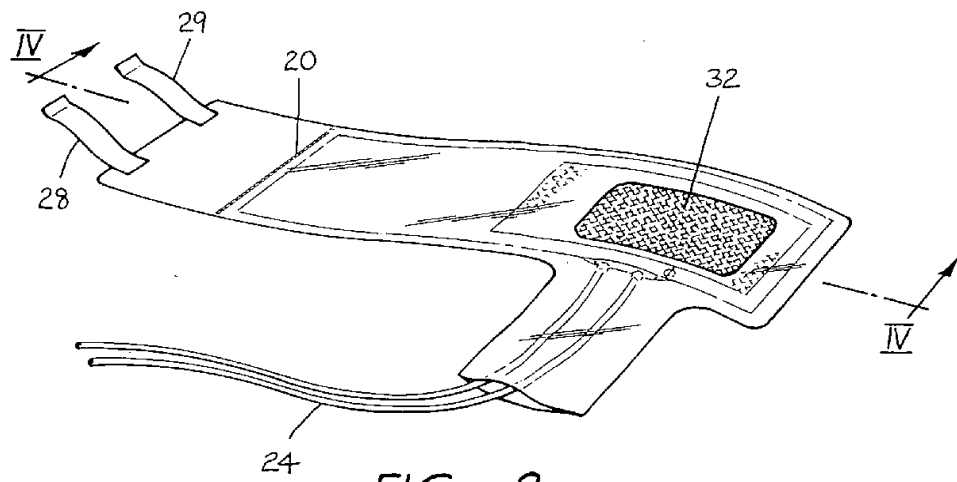


FIG. 2

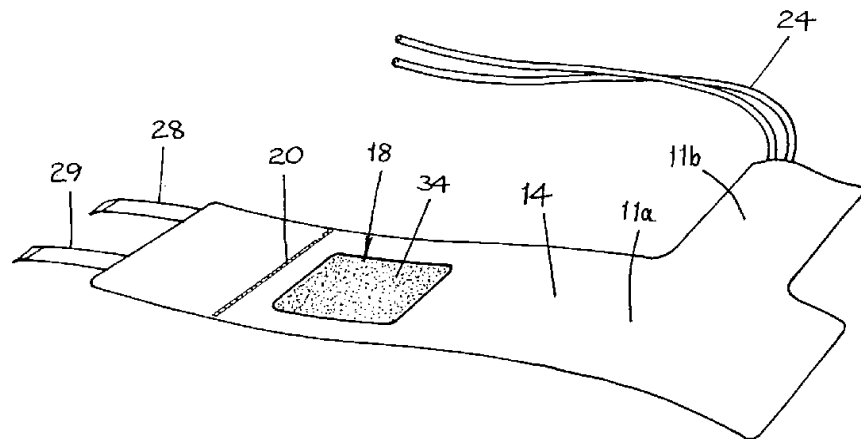


FIG. 3

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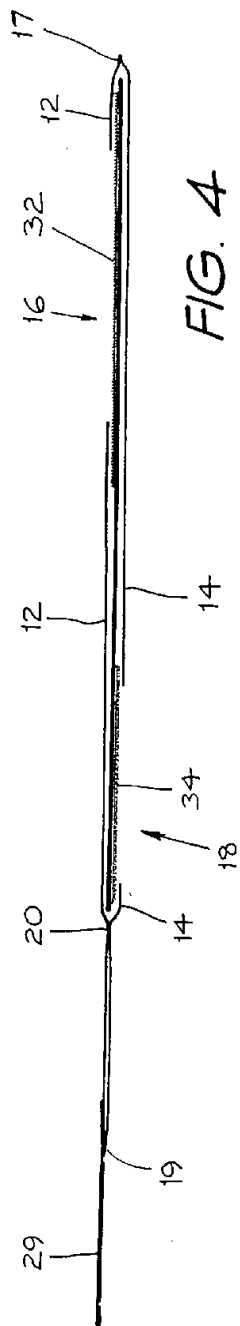


FIG. 4

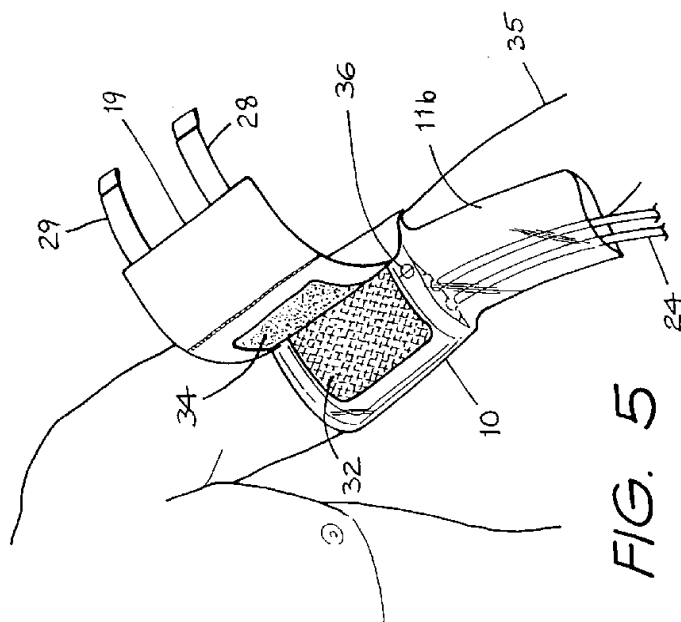


FIG. 5

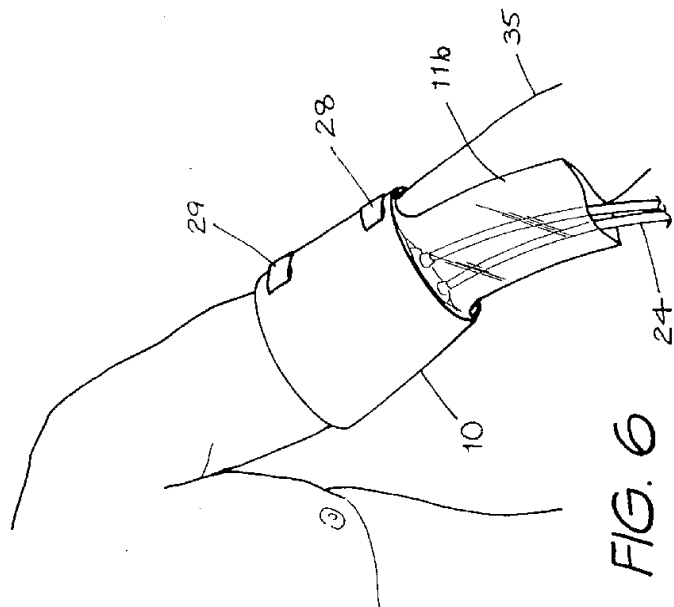


FIG. 6

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WO 2004019759 A2

ENCLOSURE FOR A BLOOD PRESSURE CUFF

FIELD OF THE INVENTION

[0001] The present invention relates generally to an accessory for a device for measuring blood pressure, and more particularly, to a hygienic and sanitary enclosure for a blood pressure cuff of a sphygmomanometer that is reusable and/or disposable.

BACKGROUND OF THE INVENTION

[0002] Most individuals at one time or another have had their blood pressure measured. Typically, measuring one's blood pressure occurs at a physician's office employing a sphygmomanometer. Generally, a sphygmomanometer comprises a ball pump, air delivery lines, a pressure gauge and an inflatable blood pressure cuff. The blood pressure cuff or BP cuff, is wrapped about one's bare arm and inflated and then deflated in the process of measuring one's blood pressure.

[0003] In settings such as a physician's office, it is usually standard practice for an unprotected, common blood pressure cuff to be reused to measure the blood pressure of a plurality of patients. While use of a blood pressure cuff by a plurality of patients may not be commonly associated with the transmission of body fluids or pathogens in a physician's office, in other settings, such as emergency rooms, trauma centers and the like, the common usage of a single blood pressure cuff by a plurality of patients can nevertheless present a health hazard. Indeed, in emergency rooms and trauma centers, for example, a blood pressure cuff may easily become soiled and/or contaminated with various types of body fluids, e.g., blood, microorganisms, bacteria, viruses, etc., which can ultimately lead to transmission of pathogens and disease between patients through use of a common blood pressure cuff.

[0004] To help prevent the transmission of pathogens between patients in emergency room type settings, disposable enclosures for blood pressure cuffs that can be discarded after each use have been developed. Such enclosures generally comprise a pouch or envelope with a large opening for introducing the BP cuff into the interior at one end, wherein the opening
5 generally runs the length of the pouch, and often includes a closure mechanism for retaining the cuff in the interior, consisting of one or more adhesive strips.

[0005] Similarly, in hospital inpatient settings, it is also desirable to utilize a blood pressure cuff enclosure as a safety precaution to help prevent the transmission of disease and pathogens among the patient population. However, since inpatients often have their blood
10 pressure checked several times a day during their stay, it is generally uneconomic to utilize a “fresh” previously unused cuff cover and dispose of the same after each patient’s BP reading. Thus, reusable blood pressure cuff enclosures into which a blood pressure cuff may be inserted each time a patient’s blood pressure is measured have been developed.

[0006] Closure mechanisms relying on adhesives, as a rule, are unsatisfactory in
15 reusable BP cuff enclosures because of their inability to be resealed after the first opening of the seal for removal of the BP cuff. Consequently, reusable enclosures often comprise pouches with openings that are closeable via hook and loop type fasteners, such as VELCRO® brand fastener, or a zipper type closure mechanism (similar to the types of seals associated with plastic sandwich bags and/or plastic freezer bags). However, this inventor
20 found that such closure means are not always reliable, and can often be cumbersome to use. For example, enclosures utilizing VELCRO® type hook and loop fasteners as closure means have a tendency to engage with and snag onto the corresponding hook and loop fastener tabs found on most blood pressure cuffs, when introducing the BP cuff inside the enclosure.

Hence, it can become a tedious and difficult maneuver to insert a blood pressure cuff into these types of enclosures, often discouraging wide acceptance and usage by hospital personnel.

[0007] While zipper type seals seemingly offer the best solution for closing a blood pressure cuff cover, enclosures relying on such seals tend to undergo a separation or “curling” effect, i.e., the propensity of one strip of the zipper seal to separate from the other strip of the zipper seal as the enclosure is wrapped about a patient’s arm or appendage. It is believed this curling effect may be attributed to a difference between the inner and outer circumferences of the zipper seal strips when the enclosure is rolled upon itself during the process of wrapping the enclosed BP cuff around a patient’s arm.

[0008] Accordingly, there is a need for an improved, more reliable and convenient to use blood pressure cuff enclosure which is reusable so it can be assigned to a single patient at the time of admission and reused for the period of the patient’s stay, and also sufficiently economic so that it is also disposable after a single use or after multiple uses.

SUMMARY OF THE INVENTION

[0009] The present invention broadly comprises a reusable and/or disposable enclosure for a blood pressure cuff for a sphygmomanometer. In a preferred embodiment, the enclosure comprises a pouch having an opening therein for holding a blood pressure cuff. The enclosure includes a flexible fastener, e.g., a zipper type seal of the type typically associated with a resealable sandwich bag and/or a resealable freezer bag, that is operatively arranged to open the pouch and at least partially close the pouch when the blood pressure cuff is enclosed therein. In a particularly preferred embodiment, the enclosure includes a flexible fastener, e.g. a zipper seal, having a first strip and a second strip. The first strip includes at

least one male rib portion extending therefrom and along its length. The second strip including at least two female rib portions extending therefrom and along its length. The female rib portions of the second strip form a channel for complementarily accepting the male rib portion of the first strip such that the first strip and the second strip may be matingly engaged with one another to partially close the enclosure. The enclosure may be constructed from at least one ply of a translucent polyolefin comprising a spun, non-woven, fibrous outer surface and a nonporous, liquid impermeable inner surface. The spun, non-woven, fibrous outer surface is operatively arranged for direct contact with a user's skin such that the blood pressure cuff enclosure is comfortable to the user and effectively facilitates evaporative cooling at the surface of the skin. The inner surface is, preferably, impermeable to fluids for purposes of preventing contamination and/or soiling of the blood pressure cuff contained therein and/or to prevent a contaminated blood pressure cuff from contacting a patient. The enclosure also prevents patients from viewing a potentially unsightly and/or soiled blood pressure cuff.

[0010] Thus, a primary object of the present invention is to provide a highly economic "reposable" (i.e., reusable and disposable) blood pressure cuff enclosure with an improved flexible fastener for securing a blood pressure cuff therein while also allowing the unimpeded insertion and removal of a blood pressure cuff to and from the enclosure.

[0011] These and other objects, features and advantages of the invention will become readily apparent to one having ordinary skill in the art upon study of the following detailed description in view of the drawings and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Figure 1 shows a perspective view of a blood pressure cuff enclosure of the present invention wrapped about a patient's arm;

[0013] Figure 2 is a view of the bottom panel (panel in contact with a user's
5 appendage) of a blood pressure cuff enclosure according to the present invention, the enclosure including a blood pressure cuff therein;

[0014] Figure 3 is a view of a top panel of a blood pressure cuff enclosure according to the present invention;

[0015] Figure 4 is a sectional view of the present invention taken generally along line
10 4-4 of Figure 3, illustrating the thickness of the flange of the flexible fastener means; the enclosure including a blood pressure cuff therein;

[0016] Figure 5 is a sectional view of the present invention taken generally along line 5-5 of Figure 3;

[0017] Figure 6 is a perspective view of a blood pressure cuff enclosure including
15 enlarged surface areas to illustrate the non-woven, fibrous outer surface of an embodiment of the present invention;

[0018] Figure 7 is a view of the bottom panel (panel in contact with a user's appendage) of a blood pressure cuff enclosure according to the present invention comprising a fibrous outer surface, the enclosure including a blood pressure cuff therein;

20 [0019] Figure 8 is a view of the top panel of a blood pressure cuff enclosure according to the present invention comprising a fibrous outer surface, the enclosure including a blood pressure cuff therein;

[0020] Figure 9 is a sectional view of the present invention taken generally along line 9-9 of Figure 8;

[0021] Figure 10 is a sectional view of the present invention taken generally along line 10-10 of Figure 8.

5 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0022] At the outset, it should be appreciated that like reference numbers on different drawing figures represent identical structural elements. It should also be appreciated that, while a number of different embodiments and variations of the present invention are shown in the various drawings, the invention as claimed is not intended to be limited to these specific
10 embodiments, as the claims define a broader invention that can take many different shapes and structures. In the description that follows, the term “reposable” is intended to refer to reusable and, optionally, disposable qualities of the enclosure of the present invention. In the description and claims that follow, the term “curling” is intended to mean the propensity of the male and female strips of a flexible fastener, e.g., a zipper seal of a type typically
15 associated with a resealable plastic sandwich bag or freezer bag, to separate from one another when the flexible fastener is rolled or wrapped upon itself, e.g., when the enclosure and the flexible fastener are wrapped about an individual’s arm for purposes of measuring blood pressure.

[0023] Adverting now to the figures, in Figure 1 enclosure 30 of the present invention
20 is shown in association with sphygmomanometer 10, of which blood pressure cuff 20 is a component thereof. The blood pressure cuff enclosure and the blood pressure cuff are shown wrapped about a patient’s arm for purposes of measuring the patient’s blood pressure. A typically sphygmomanometer 10 generally includes pump 12, pressure gauge (not shown), air

delivery tube 22 and blood pressure cuff 20. As is generally the case, the blood pressure cuff of a sphygmomanometer is usually rectangular in shape and comprises hook and loop tab fasteners proximate the terminal ends of the blood pressure cuff. The blood pressure cuff, thus, may be wrapped about a patient's arm and its terminal ends secured to one another by means of the hook and loop fasteners. Once secured about arm 100 of patient 99, the blood pressure cuff is then inflated by means of the pump, which passes air to the blood pressure cuff via air delivery tube 22 until blood flowing through a patient's artery has ceased. Once a patient's arterial blood flow has ceased, further pressurization of the blood pressure cuff is also ceased. Thereafter, the blood pressure cuff is allowed to slowly deflate so that the systolic and diastolic blood pressures of the patient may be measured. It should be appreciated by those having ordinary skill in the art that, while an enclosure for a manually operated sphygmomanometer is disclosed herein, the enclosure of the present invention may be used with sphygmomanometers that are automatically inflated and/or deflated.

Structure of a Preferred Embodiment

[0024] Referring more specifically now to Figures 2-5; enclosure 30 of the present invention generally forms a pouch. The pouch is generally in the manner of an envelope and is operatively arranged to receive an blood pressure cuff of a sphygmomanometer therein such that the blood pressure cuff does not become contaminated by bodily fluids or become soiled. In a preferred embodiment, the enclosure is made from a single sheet of enclosure material that has been folded in half and joined along its edges to form top panel 50 and bottom panel 32. When folded in such manner enclosure 30 comprises first edge 34, second edge 36 (fold edge), third edge 38 and fourth edge 40.

[0025] In the embodiment illustrated in the drawings, the top and bottom panels are secured to one another along first edge 34 and third edge 38 to form seals 70. Seals 70 extend substantially along the first and the third edges between the second and fourth edges. In a preferred embodiment, seals 70 are preferably formed by ultrasonically welding the first and third edges of the top and bottom panels to one another. In this manner an enclosure having interior 74 is provided in which blood pressure cuff 20 may be secured. It should be appreciated that other means for securing the first and third edges to one another are contemplated and may include but are not limited to: heat welding, adhesives, stitching, etc. It should also be appreciated by those having ordinary skill in the art, that while a preferred embodiment comprises a single piece of sheet material that has been folded upon itself to form a pouch or envelope, substantially similar results may be achieved by securing two or more independent sheets together to form a pouch or envelope. Obviously, other methods of folding the enclosure and/or forming a pouch are contemplated and intended to be encompassed by the present claims and disclosure, as are other shapes of pouch.

[0026] Disposed proximate first edge 34 and fixedly secured to top panel 50 is a tab section of loop 62. Disposed proximate third edge 38 of bottom panel 32 is tab section of hook 46. Loop material 62 is provided for binding with hook material 46 when the enclosure and blood pressure cuff are wrapped about a patient's arm or appendage. It should be appreciated that loop material 62 comprises a length such that the enclosure may be adjusted about the arm or appendage for a substantially snug fit. It should also be appreciated by those having ordinary skill in the art that while we disclose a enclosure comprising hook material 46 and loop material 62 disposed on bottom and top panels, 32 and 50, respectively, the locations of the hook and loop material could be reversed to achieve like results.

[0027] As shown in Figures 2-4, fourth edge 40 of the enclosure of the present invention includes flexible fastener 41. Flexible fastener 41 comprises means for resealably opening and closing the enclosure such that a blood pressure cuff may be readily inserted or removed therefrom for the term of a patient's stay. In a preferred embodiment, flexible fastener 41 comprises first strip 43 and second strip 45. First strip 43 is secured to an inner side of bottom panel 32 proximate fourth edge 40 and second strip 45 is secured to an inner surface of top panel 50 proximate fourth edge 40. Each of first strip 43 and second strip 45 extend substantially along the entire length of fourth edge 40 and are disposed opposite one another. Extending from first strip 43 and substantially along the length of fourth edge 40 is at least one male rib 47 and guide means 44. Similarly, extending from second strip 45 and substantially along the length of fourth 40 edge are at least two parallel and spaced female ribs 49. At least two female ribs 49 form channel 42 therebetween, which channel is configured for complementarily accepting male rib 47 therein. Hence, the flexible fastener, and the enclosure, may be closed by means of mating the male rib with the female channel with or without the aid of a zipper clasp means 27 (See Figure 8) for opening and closing the enclosure. It should be appreciated that first strip 43 and second strip 45 of flexible fastener 41 are secured to the enclosure by flanges 51 which may be secured to the bottom and top panels by any appropriate means including but not limited to: heat welding, ultrasonic welding, adhesives, stitching, etc. The inventor discovered that flexible fasteners comprising thick flanges have a tendency to "curl" and open when the enclosure is wrapped about a patient's arm and further found that the problem of curling can be rectified by employing flanges that are sufficiently thin such that the flexible fastener does not have a propensity to curl when the enclosure is closed. More specifically, Figure 4 illustrates that a preferred

thickness, D, of flange 51 of a flexible fastener between 2 and 12 mils, and more preferably, between 4 and 8 mils will eliminate curling and separation of the flexible fastener during the closing and wrapping process. Additionally, other types of flexible fastener, such as hook and loop fasteners, adhesives, etc., are contemplated herein but have been found to be
5 generally ineffective as discussed *supra*.

[0028] Hook and loop type flexible fasteners have a tendency to bind with the hook and loop fasteners of the sphygmomanometer blood pressure cuff such that it can be difficult to insert and remove the blood pressure cuff from the enclosure. Similarly, because the enclosure of the present invention is configured for being reusable, that is, both reusable and
10 disposable, resealable adhesives for opening and closing the enclosure have been found to be largely ineffective as well. Adhesives may become spent or soiled such that the enclosure can no longer be closed or the adhesives may be too strong such that damage to the enclosure may occur when the enclosure is opened for removal of the blood pressure cuff. The improved flexible fastener of the present invention will obviate this problem.

15 [0029] Referring now to Figures 6-10, while the sheet material comprising the top and bottom panels of the enclosure may be constructed from a wide range of materials, a preferred embodiment of the enclosure is constructed from at least a single ply of sheet material that is impermeable to fluids while simultaneously being comfortable to the user. Inner surface 31 of the enclosure comprises at least a single ply of polyolefin film, e.g.
20 polyethylene, which is nonporous to fluids, whereas outer surface 33 has a fibrous texture. In a preferred embodiment, the fibrous texture of the outer surface is provided by a plurality of spun bonded, non-woven fibers, which create a flocked material surface that is soft to the touch. It should be appreciated that while figures 6-10 illustrate outer surface 33 as

comprising enlarged "patches" of the fibrous material, the entire outer surface of the enclosure comprises a fibrous texture and the "patches" shown in the drawings are provided solely for illustration. The inner continuous film surface of the enclosure primarily serves as a fluid and pathogen barrier and is impermeable to blood, bacteria, viruses and the like.

- 5 Thus, the inner surface of the enclosure prevents the blood pressure cuff from becoming contaminated and/or soiled. On the opposite side of the film ply, the fibrous outer surface of the enclosure is soft and allows ambient air to contact the patient's skin, which facilitates evaporation at the skin surface making the enclosure more comfortable to the patient. The fibrous outer surface also prevents any chafing of the skin that may typically occur.
- 10 Additionally, while a preferred embodiment of the present invention comprises section of loop material 62 for binding hook material 46, it should be appreciated that where the outer surface of the enclosure is sufficiently fibrous, hook material 46 may be directly bound to the outer surface of the enclosure such that the tab section of loop may be dispensed with.

- [0030] Referring now to Figures 1-10, in a preferred embodiment, the sheet material
- 15 of the enclosure is translucent such that written indicia appearing on the blood pressure cuff contained therein may be read when the enclosure is engaged with the surface of the blood pressure cuff. For example, written indicia 48 on first edge 24 of the blood pressure cuff 20 may be read through translucent bottom surface 32 and may comprise terms such as "24 cm" and "32 cm," as shown in Figure. 2. Second edge 26 of the blood pressure cuff 20 (Figure 3)
- 20 may also comprise written indicia 48, for example, the term ARTERY. The written indicia are provided for assisting the healthcare provider to align the blood pressure cuff in accordance with the location of a patient's arteries. It should be appreciated that while the enclosure of the present invention is translucent such that written indicia on the surface of the

blood pressure cuff may be viewed, the translucent material is simultaneously sufficiently opaque such that it is difficult for a patient to see contaminants such as dirt, stains, blood, etc. on the blood pressure cuff. Hence, the enclosure of the present invention provides additional comfort to the patient in that the patient is not likely to view dirt, stains, blood and the like on the blood pressure cuff. It should be readily apparent to those having ordinary skill in the art that the written indicia on the blood pressure cuff 20 may comprise virtually any information that is helpful to the healthcare practitioner and is not limited to the written indicia shown in the figures. In a particularly preferred embodiment, the enclosure of the present invention further comprises means for distinguishing one enclosure from another enclosure such that the same enclosure is not used for two different patients. Appropriate means for distinguishing one enclosure from another include labels, color-coding, etc.,

Use of a Preferred Embodiment

[0031] To use the enclosure of the present invention, the healthcare practitioner need merely open the flexible fastener and insert the blood pressure cuff therein. Thereafter, the flexible fastener may be partially closed by mateably securing the male rib with the channel formed by the female ribs; it should be appreciated that the flexible fastener remains partially closed when the blood pressure cuff is secured within the enclosure for purposes of accommodating the passage of air delivery tube 22 to the sphygmomanometer. Once secured within the enclosure, the written indicia on the blood pressure cuff may be viewed through the translucent enclosure material such that the blood pressure cuff may be aligned with a patient's artery. The enclosure and blood pressure cuff may then be wrapped about and secured to the arm or appendage of a patient by means of hook material 46 and loop material 62 fasteners. The blood pressure cuff is then inflated until blood within the artery has ceased

flowing. The blood pressure cuff is then deflated to measure the patient's systolic and diastolic blood pressures. Once completed, the enclosure and blood pressure cuff may be removed from the patient's arm or appendage. Thereafter, the blood pressure cuff may be removed from within the enclosure and inserted in a new enclosure for purposes of measuring
5 another individual's blood pressure. The enclosure used to measure a first patient's blood pressure may be disposed of, or it may be saved for purposes of taking another blood pressure reading from that same patient at a later time. Hence, the enclosure of the present invention is configured to be both reusable and disposable.

[0032] Thus, it is seen that the objects of the present invention are efficiently
10 obtained, although modifications and changes to the invention should be readily apparent to those having ordinary skill in the art, and these modifications are intended to be within the spirit and scope of the invention as claimed.

What Is Claimed Is:

1. An enclosure for a blood pressure cuff comprising:
a pouch having an opening therein to hold said blood pressure cuff; and,
a flexible fastener,
said flexible fastener having a thickness sufficiently thin so as to prevent curling when said enclosure is wrapped upon itself; said flexible fastener adapted to open said pouch and at least partially close said pouch when said blood pressure cuff is enclosed therein.
2. The enclosure of Claim 1 wherein said flexible fastener comprises a first strip having at least one male rib portion extending therefrom and a second strip including at least two female rib portions extending therefrom, said female ribs forming a channel for complementarily accepting said male rib portion therein such that said first strip and second strip may be matingly engaged
3. The enclosure of Claim 1 wherein said flexible fastener comprises a flange having a thickness between 2 and 12 mils.
4. The enclosure of Claim 3 wherein said flexible fastener comprises a flange having a thickness between 4-8 mils.
5. The enclosure of Claim 2 wherein said flexible fastener further comprises a zipper clasp.

6. The enclosure of Claim 1 wherein said enclosure comprises at least a single ply of polyolefin film having an inner surface that is impermeable to liquids.
7. The enclosure of Claim 6 wherein said enclosure comprises at least a single ply of polyolefin film having an outer surface with a fibrous texture.
8. The enclosure of Claim 7 wherein said flexible fastener is disposed proximate said opening.
9. The enclosure of Claim 8 wherein said flexible fastener further comprises:
 - a first strip including at least one male rib portion extending therefrom; and,
 - a second strip including at least two female rib portions extending therefrom, said female ribs forming a channel for complementarily accepting said male rib portion therein such that said first strip and second strip may be matingly engaged.
10. The enclosure of Claim 1 wherein said enclosure is translucent.
11. The enclosure of Claim 8 wherein said enclosure is translucent.
12. The enclosure of Claim 8 wherein said pouch is formed by folding said at least a single ply of polyolefin film upon itself.

13. The enclosure of Claim 12 wherein the at least one edge of said pouch comprises an ultrasonic weld.
14. The enclosure of Claim 1 further comprising securing means for fastening said enclosure to itself when rolled upon itself.
15. The enclosure of Claim 14 wherein said securing means comprises hook and loop.
16. The enclosure of Claim 1 comprising a length sufficient such that said enclosure may be wrapped about an appendage.
17. The enclosure of Claim 1 further comprising means for distinguishing said enclosure from another enclosure.
18. The enclosure of Claim 17 wherein said means for distinguishing comprises a label secured to a top panel of at least one of said enclosures.
19. A method of using a blood pressure cuff for purposes of minimizing contamination between at least two patients using a single blood pressure cuff, said method comprising:
 - providing at least two enclosures having openings therein to hold said blood pressure cuff for said at least two patients; said at least two enclosures having flexible fasteners having a thickness sufficiently thin so as to prevent curling when said enclosures are wrapped upon

themselves; said flexible fastener adapted to open said enclosures and at least partially close said enclosures when said blood pressure cuff is enclosed therein;

securing said blood pressure cuff within a first enclosure and measuring the blood pressure of a first patient;

removing said blood pressure cuff from said first enclosure; and,

securing said blood pressure cuff within a second enclosure and measuring the blood pressure of a second patient.

removing said blood pressure cuff from said second enclosure; and,

20. The method of Claim 19 further comprising securing said blood pressure cuff within said first enclosure and re-measuring the blood pressure of said first patient.

21. The method of Claim 20 wherein said flexible fasteners comprise:

a first strip including at least one male rib portion extending therefrom; and,

a second strip including at least two female rib portions extending therefrom, said female ribs forming a channel for complementarily accepting said male rib portion therein such that said first strip and second strip may be matingly engaged.

22. The method of Claim 21 wherein said flexible fasteners each comprise a flange having a thickness between 2 and 12 mils.

23. The method of Claim 22 wherein said flexible fastener has a flange having a thickness between 4-8 mils.

24. The method of Claim 20 further comprising providing means for distinguishing said at least two enclosures from one another.

25. The method of Claim 24 wherein said means for distinguishing comprises a label secured to a top panel of at least one of said enclosures.

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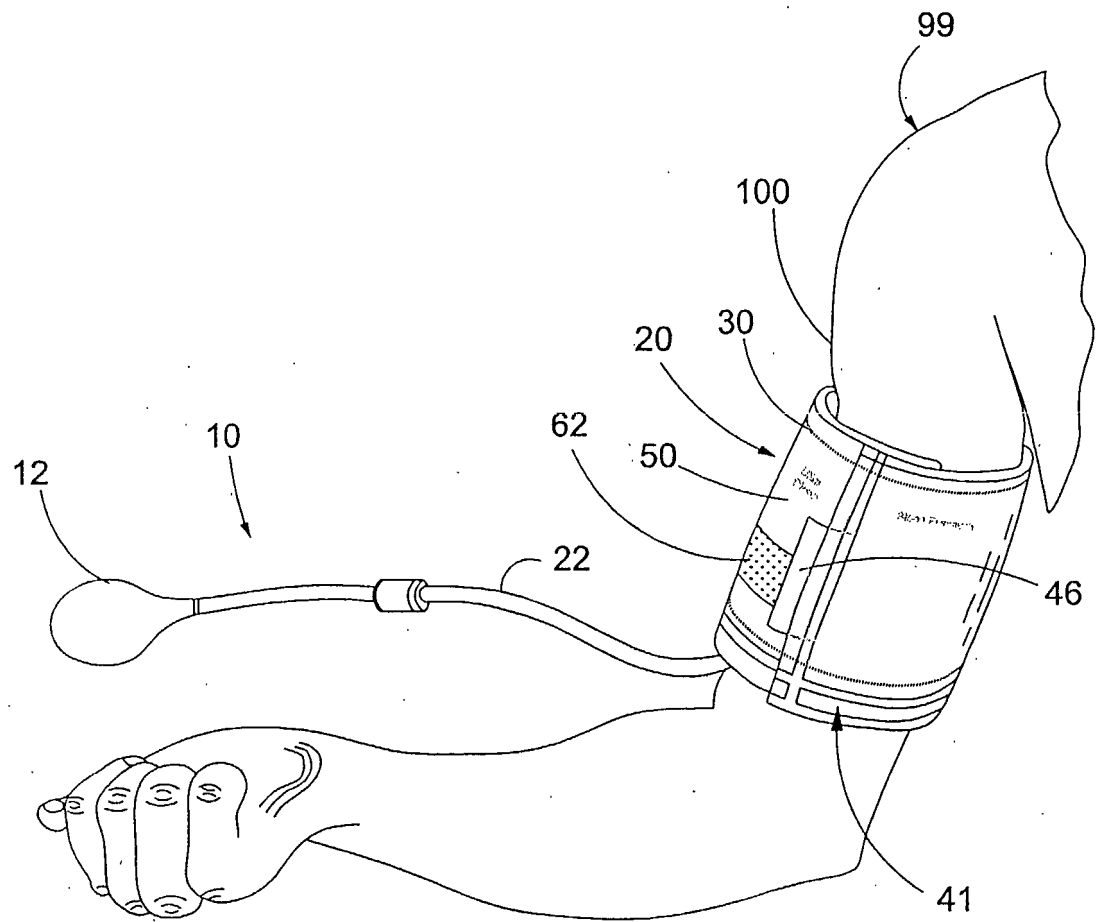


Fig. 1

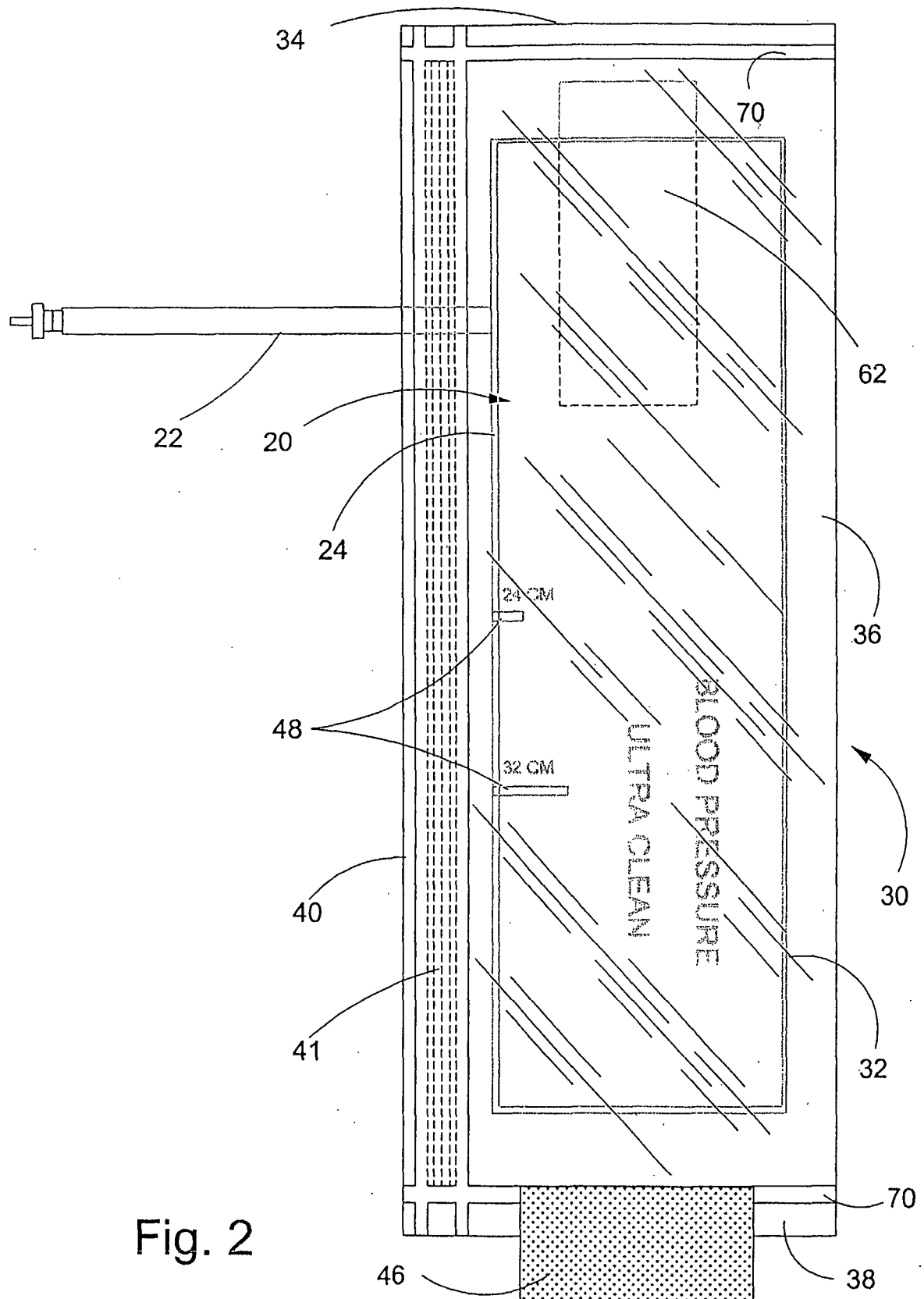


Fig. 2

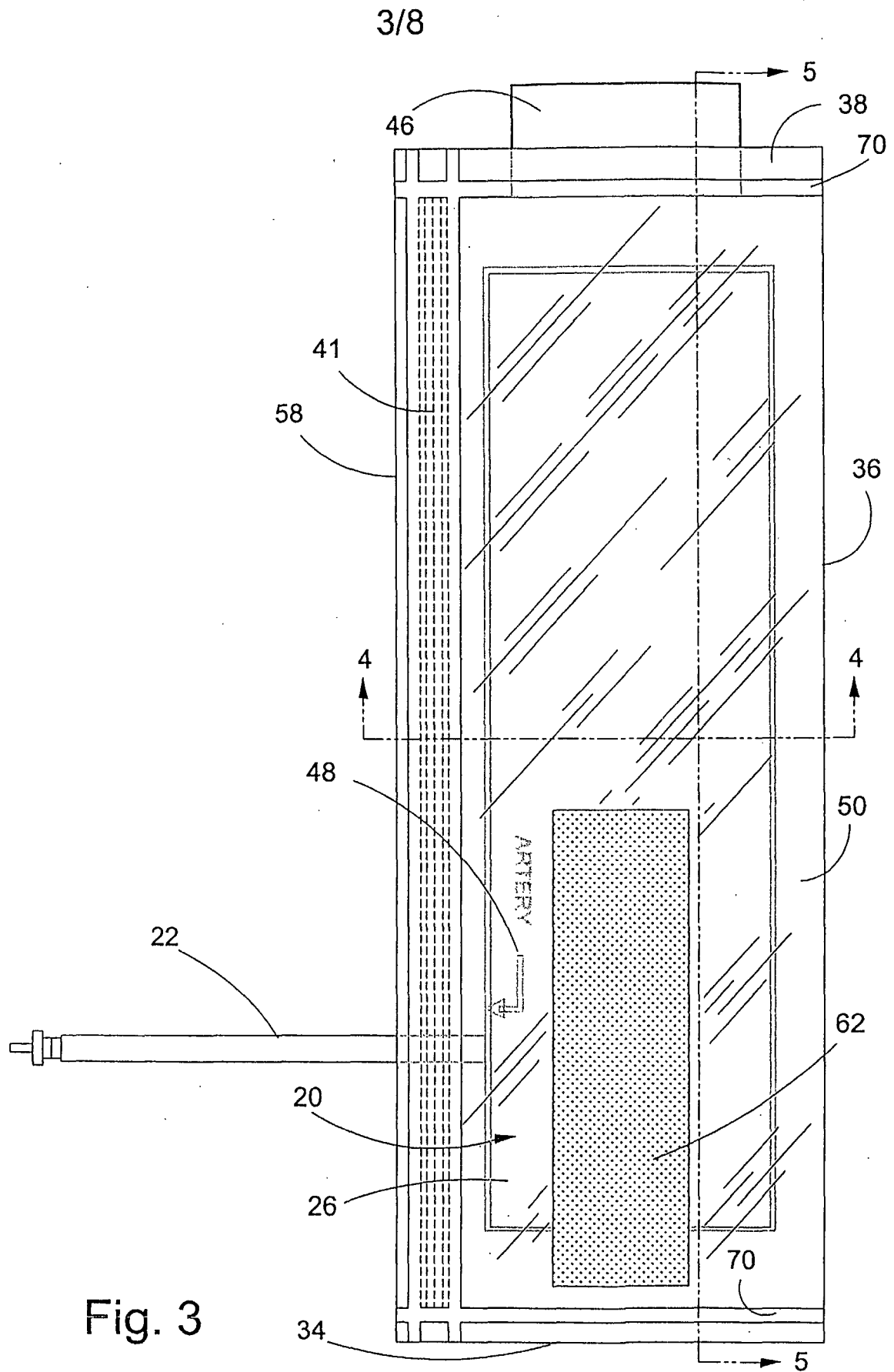


Fig. 3

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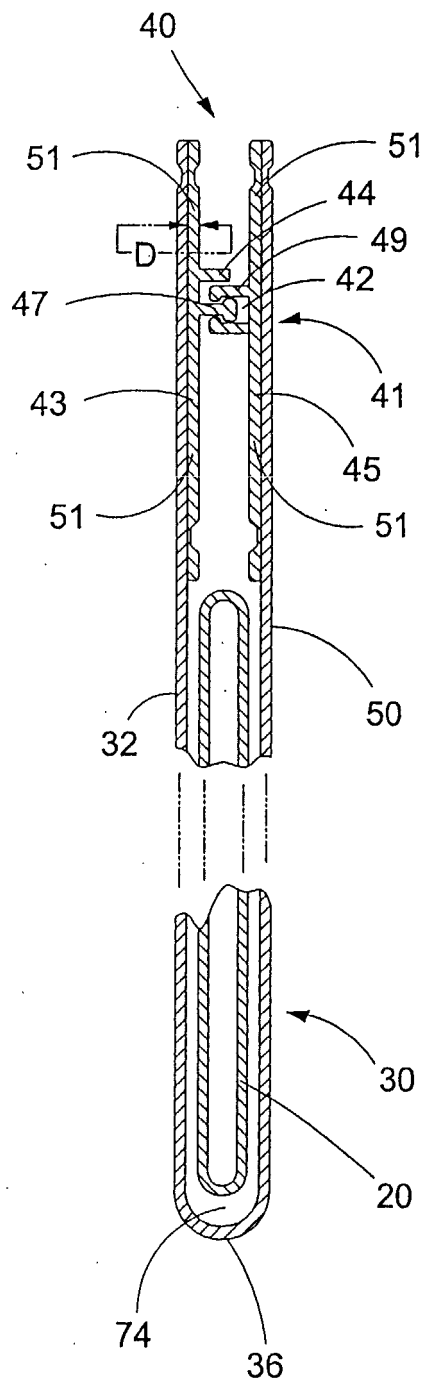


Fig. 4

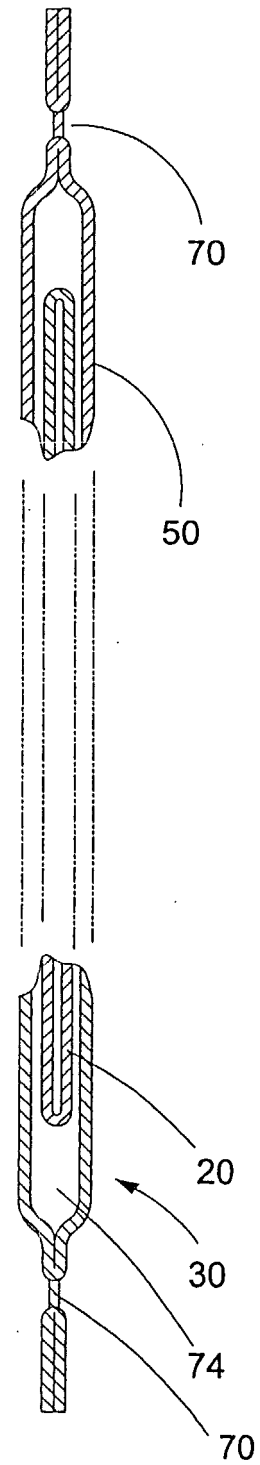


Fig. 5

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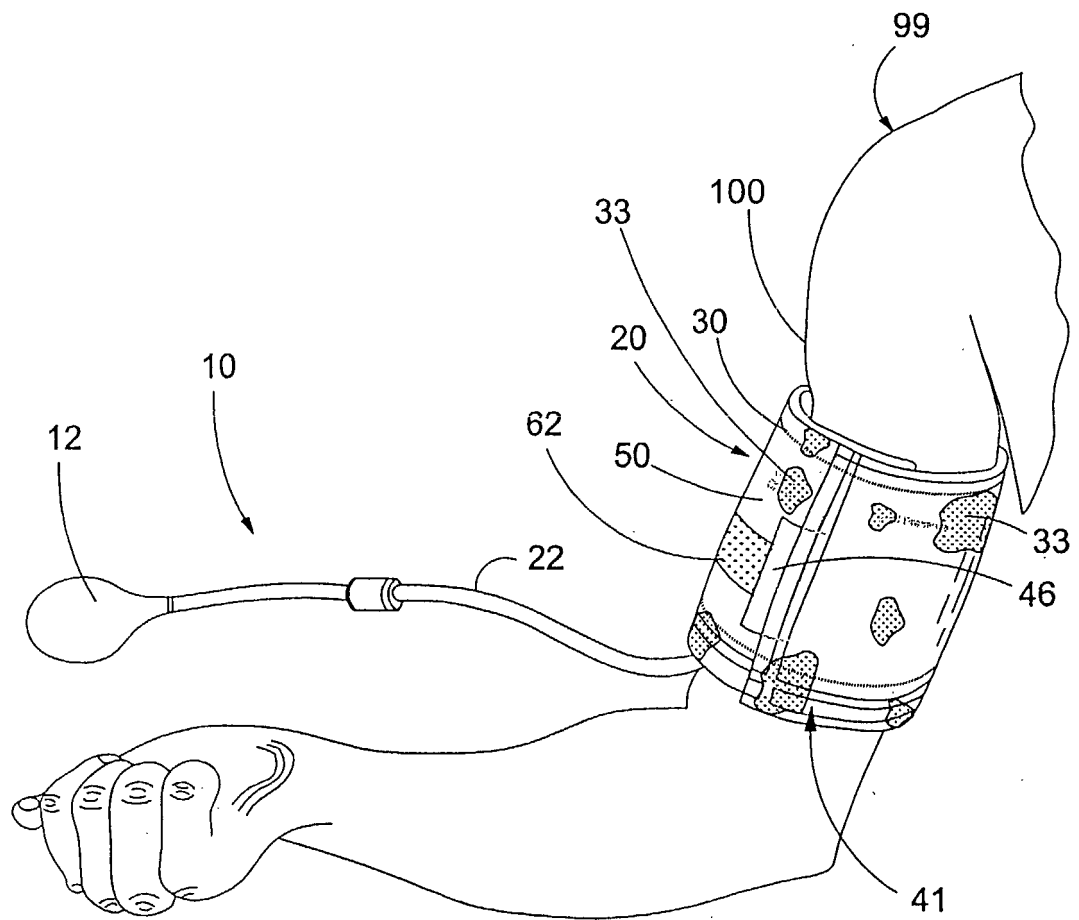


Fig. 6

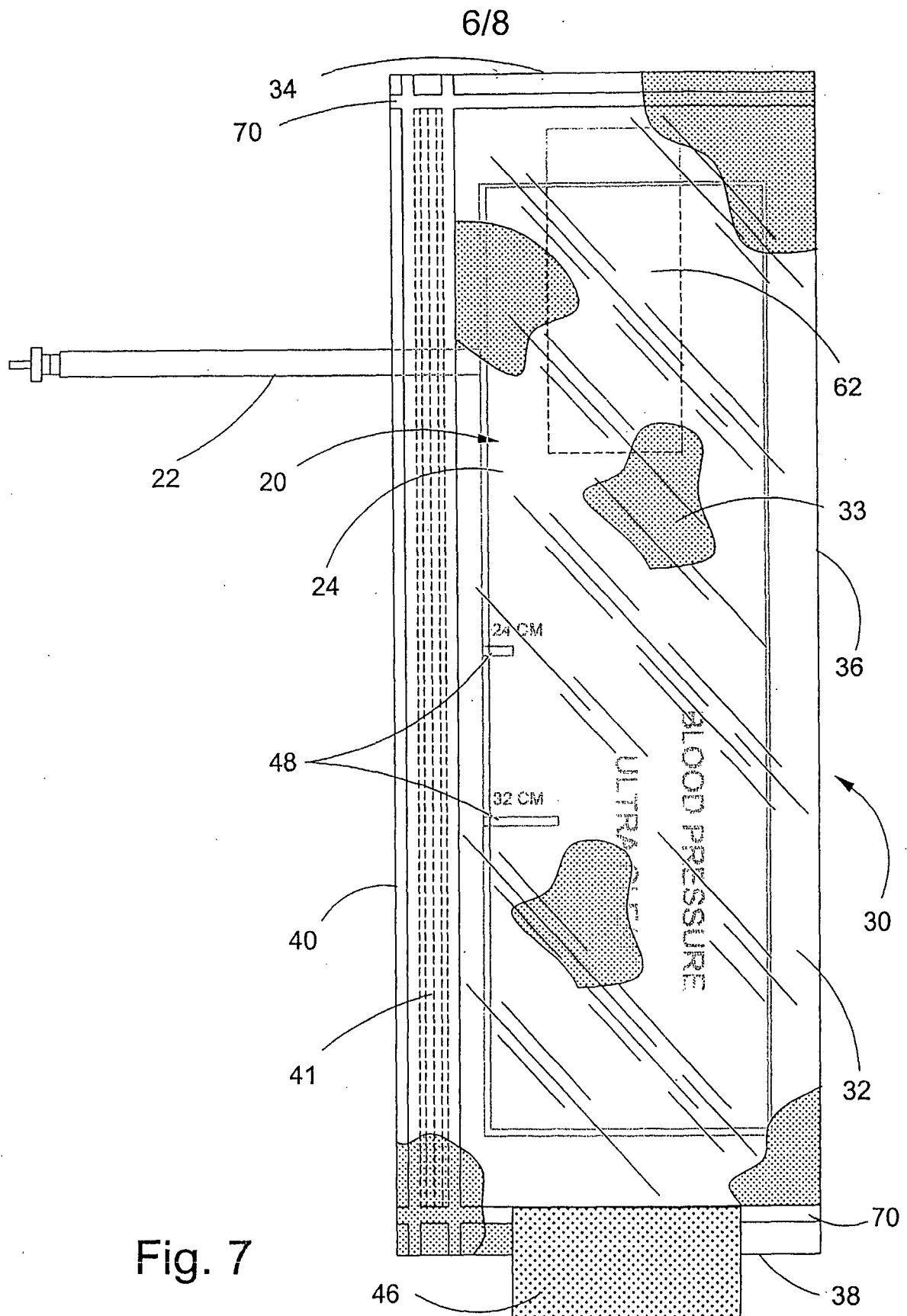


Fig. 7

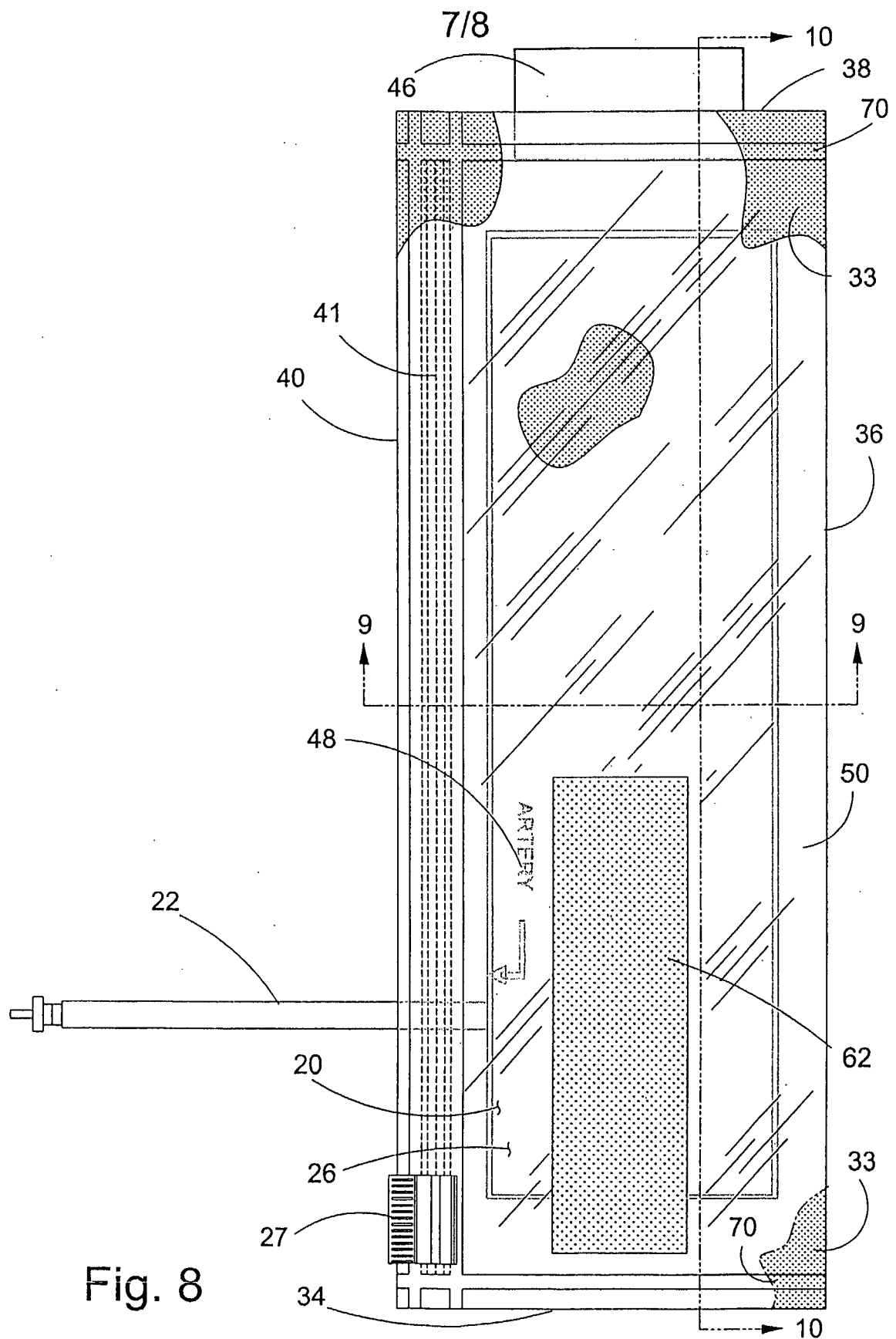


Fig. 8

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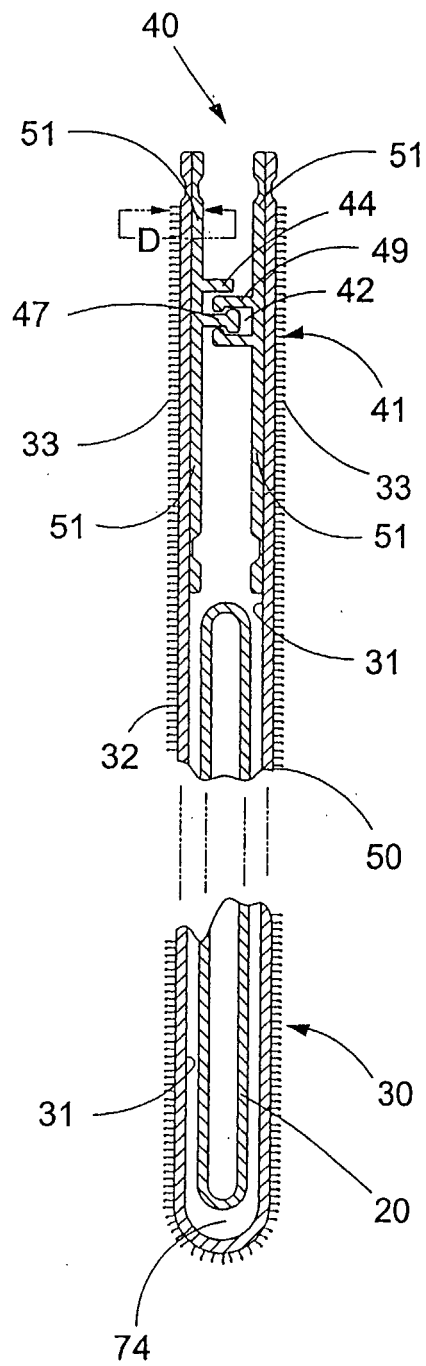


Fig. 9

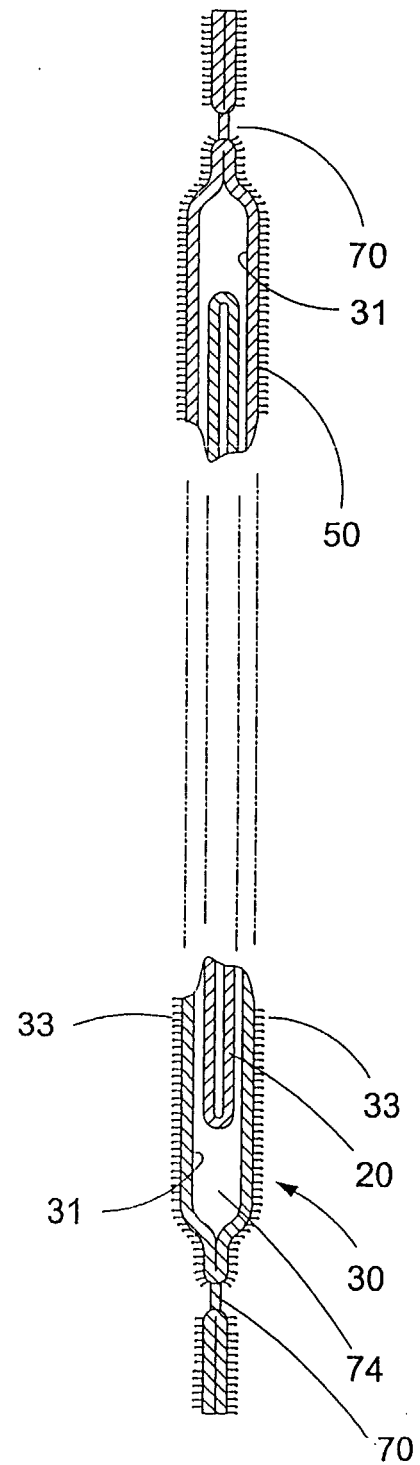


Fig. 10

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DescriptionField of the Invention

5 [0001] The invention relates to nonwoven fabrics and to processes for producing nonwoven fabrics. More specifically, the invention relates to composite nonwoven fabrics having barrier properties which are particularly suited for medical applications.

Background of the Invention

10 [0002] Nonwoven fabrics and fabric laminates are widely used in a variety of applications, for example, as components of absorbent products such as disposable diapers, adult incontinence pads, and sanitary napkins; in medical applications such as surgical gowns, surgical drapes, sterilization wraps, and surgical face masks; and in other numerous applications such as disposable wipes, industrial garments, house wrap, carpets and filtration media.

15 [0003] By combining two or more nonwoven fabrics of different types, nonwoven fabric laminates have been developed for a variety of specific end use applications. For example, nonwoven barrier fabrics have been developed which impede the passage of bacteria and other contaminants and which are used for disposable medical fabrics, such as sterilization wraps for surgical and other health care related instruments, surgical drapes, disposable gowns and the like.

20 [0004] Barrier fabrics can be formed by sandwiching an inner fibrous web of thermoplastic meltblown microfibers between two outer nonwoven webs of substantially continuous thermoplastic spunbonded filaments. The fibrous meltblown web provides a barrier impervious to bacteria or other contaminants in the composite nonwoven fabric. Examples of such fabrics are described in U.S. Patent No. 4,041,203 and U.S. Patent No. 4,863,785, and EP-A-0 674 035. Typically, nonwoven fabric laminates used as disposable medical fabrics include a meltblown layer formed of meltblown microfibers having an average diameter of about 1.8 to 3.0 microns and higher. In addition, the meltblown layer typically

25 has a basis weight of about 20 to 40 grams per square meter.

[0005] Current industry standards require that laminate fabrics used for barrier purposes provide a predetermined level of protection against penetration of the fabric by air borne contaminants. The level of barrier protection required can depend upon the particular end use application of the fabric. Many laminate fabrics currently available cannot meet all of the requirements for a particular end use application. In particular, U.S. Patent No. 4,863,785 to Berman et al.,

30 discloses an improvement in a laminate nonwoven fabric comprised of a meltblown nonwoven sandwiched between two prebonded nonwoven reinforcing layers. The Berman Patent teaches the use of grooved, helical rolls to bond the laminate structure in a continuous fashion, thereby decreasing the incidence of loose fibers contained in the fabric, which in turn yields an improvement in the barrier properties of the laminate fabric. However, the Berman reference does not disclose a method by which to improve barrier properties to such an extent that double wrapping is no longer

35 required. Similarly, EP-A-0 674 035 teaches an improvement in the meltblown layer of a S/M/S construction; however, again, the superior barrier properties of the instant invention are not provided, and dual wrapping is therefore still required.

[0006] For example, a single sheet of currently available barrier laminate fabric typically cannot meet all standards for barrier fabrics used as a sterile wrap. To provide the required degree of protection against penetration of the sterile

40 wrap by air borne contaminants, current industry standards require that surgical instruments, and other items to be sterilized, be "double wrapped," i.e., that at least two sheets of the laminate fabric, cut to a predetermined size and shape, each be individually wrapped about the instruments and secured before sterilization.

[0007] Industry standards have recently allowed the use of a single sterile wrap formed of two sheets of a trilaminate fabric described above sonically bonded about the periphery thereof to form an integrated "single" sheet. This can

45 eliminate time and labor involved in conventional techniques of wrapping and securing a first sheet of sterile wrap, followed by wrapping and securing a second sheet of sterile wrap about the objects to be sterilized. However, there can be problems associated with the integrated double layer sterile wrap, such as increased stiffness along the bonded edges, which can resist lateral folding of the sterile wrap.

[0008] Accordingly, despite these and other laminate fabrics which are currently available, it would be advantageous to provide a laminate fabric having improved barrier properties. In addition, it would be advantageous to provide such a laminate fabric which can be used as a single sheet to wrap objects which are to be subsequently sterilized, and would not require the labor of double wrapping such items. It would further be advantageous if such a laminate fabric were flexible and easily foldable.

Summary of the Invention

55 [0009] The present invention provides nonwoven laminate fabrics which have superior barrier properties, and which are flexible and soft. The laminate fabrics of the invention can be used as components in any variety of nonwoven

products, and are particularly useful as barrier components in medical fabrics, such as sterile wraps, surgical gowns, and the like.

[0010] The laminate fabrics of the invention include a nonwoven web of meltblown microfibers having a basis weight between about one and twenty grams per square meter, and preferably between about one and twelve grams per square meter. The meltblown web further includes a plurality of thermoplastic microfibrillar fibers having an average fiber diameter of less than 1.5 microns, preferably between 0.5 and 1.5 microns and more preferably between 0.8 and 1.3 microns.

[0011] The meltblown web is sandwiched between and bonded to first and second nonwoven webs to form the composite nonwoven fabric of the invention. The outer webs can be, for example, spunbonded nonwoven webs or webs formed of staple fibers. Preferably, the meltblown web is sandwiched between outer spunbonded webs and the layers of the fabric are bonded together via a multiplicity of thermal bonds distributed throughout the laminate.

[0012] The thermoplastic microfibrillar fibers of the meltblown component of the fabric are formed from any of various thermoplastic fiber forming materials known to the skilled artisan, such as polyolefins, polyesters, polyamides, and copolymers and blends thereof. Preferably, the polymer selected has a high melt flow rate as compared to polymers used in conventional meltblowing processes, i.e., at least about 1000, and even up to 1200 and higher.

[0013] The present invention also includes sterile wraps formed of the laminate nonwoven fabrics of the invention for wrapping about objects to be sterilized, as well as wrapped packages of sterilizable objects. Preferably the packages includes a single sheet of the sterile wrap of the invention. The sterile wrap exhibits excellent barrier properties, such as hydro head measurements, i.e., resistance to penetration of the fabric by water, of up to 80 cm water pressure, and up to 95%, and up to 98% and higher, efficiency against the passage of bacteria through the laminate fabric.

[0014] The present invention also includes a process for the manufacture of the nonwoven laminate fabrics of the invention. It has been found that relatively high melt flow rate thermoplastic polymers, i.e., 1000 MFR or higher, can be attenuated in a heated high velocity air stream in such a way suitable for the stable production of microfibrillar fibers and concurrent formation of a low basis weight web. These conditions include controlling the attenuation conditions (e.g. attenuation gas velocity and temperature), as well as selecting an appropriate melt flow rate polymer, to promote formation of microfibrillar fibers and low basis weight webs without significantly impairing or adversely impacting the process conditions, i.e., formation of fly.

[0015] Generally, the process conditions are selected so the attenuation gas velocity and temperature are increased up to ten percent and up to twenty-five percent and higher, relative to conventional processing parameters for a particular polymer system. These parameters can be increased without forming undesirable amounts of fly to form microfibrillar fibers having a greatly reduced average diameter size as compared to conventional meltblown webs.

Brief Description of the Drawings

[0016] Some of features and advantages of the invention having been stated, others will become apparent from the detailed description which follows, and the accompanying drawings which form a part of the original disclosure of this invention, and in which:

Figure 1 is a fragmentary top view of a laminate fabric of the present invention, partially cut away to illustrate components thereof;

Figure 2A is a perspective top view of a conventional "double wrapped" sterile package, partially cut away to illustrate the double sheet construction thereof;

Figure 2B is a perspective top view of a single wrapped sterile package of the present invention, formed of the laminate fabric of Figure 1, partially cut away to illustrate the single sheet construction thereof; and

Figure 3 is a schematic side view of an illustrative process in accordance with the present invention for forming the laminate fabric of Figure 1.

Detailed Description of the Invention

[0017] The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which illustrative embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, this embodiment is provided so that the disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Like numbers refer to like elements throughout. For purposes of clarity, the scale has been exaggerated.

[0018] Figure 1 is a fragmentary top view of a laminate fabric of the present invention, designated generally as 10. Laminate fabric 10 is partially cut away to illustrate the individual components thereof. The fabric is a three ply composite comprising an inner ply 12 sandwiched between outer plies 14 and 16. The composite fabric 10 has good strength,

flexibility and drape and may be formed into various articles or garments such as sterile wraps, surgical gowns, surgical drapes and the like. The barrier properties of the fabric 10 make it particularly suitable for medical applications, but the fabric is also useful for any other application where barrier properties would be desirable.

[0019] Outer ply 14 of the composite fabric 10 is a nonwoven web of spunbonded substantially continuous thermoplastic filaments. The spunbonded web 14 may be produced using well known spunbonding processes, and may suitably have a basis weight in the range of about 10 to about 100 gsm. The thermoplastic filaments of ply 14 can be made of any of a number of known fiber forming polymer compositions. Such polymers include those selected from the group consisting of polyolefins such as polypropylene and polyethylene, polyesters, such as poly(ethylene terephthalate), polyamides such as poly(hexamethylene adipamide) and poly(caproamide), polyethylene, and copolymers and blends thereof.

[0020] Outer ply 16 may be either a web of spunbonded substantially continuous thermoplastic filaments or a web of staple fibers. In the embodiment illustrated, ply 16 is a nonwoven web of spunbonded substantially continuous thermoplastic filaments of a composition and basis weight similar to outer ply 14. The continuous filaments or staple fibers of outer ply 16 may be selected from the same polymers as described above for ply 14. Additionally, the staple fibers may be natural or synthetic fibers having hydrophilic properties to give one surface of the composite fabric absorbent characteristics. Examples of hydrophilic fibers include cotton fibers, wool fibers, rayon fibers, acrylic fibers, and fibers formed of normally hydrophobic polymers which have been treated or chemically modified to render them hydrophilic. When ply 16 is a nonwoven web of staple fibers, the nonwoven web can be a carded web or a wet-laid web of staple fibers.

[0021] In one aspect of this embodiment of the invention, ply 16 is a nonwoven web comprising a mixture of thermoplastic staple fibers and absorbent staple fibers. The nonwoven web comprises the absorbent fibers in an amount sufficient to impart absorbency characteristics to the web.

[0022] Inner ply 12 comprises a nonwoven fibrous web of meltblown thermoplastic microfibers. Specifically, meltblown web 12 is a nonwoven web comprising a plurality of thermoplastic microfibril fibers 18. The microfibril fibers of meltblown web 12 have an average fiber diameter of less than 1.5 microns, preferably an average fiber diameter from 0.5 and 1.5 microns, and more preferably from 0.8 to 1.3 microns. In addition, the basis weight of meltblown web 12 is between about 1 and 20 grams per square meter ("gsm"), and preferably between about 1 and 12 grams per square meter.

[0023] The microfibers 18 of meltblown web 12 can be formed using any of various thermoplastic fiber forming materials known to the skilled artisan. Such materials include polyolefins such as polypropylene and polyethylene, polyesters such as poly(ethylene terephthalate), polyamides, polyacrylates, polystyrene, thermoplastic elastomers, and blends of these and other known fiber forming thermoplastic materials. The polymer selected preferably has a relatively high melt flow rate, as compared to conventional polymers used in meltblowing processes, as explained in more detail below. In a preferred embodiment, meltblown web 12 is a nonwoven web of polypropylene meltblown microfibers.

[0024] Advantageously, meltblown web 12 is electrically treated to improve filtration properties of the web. Such electrically treated fibers are known generally in the art as "electret" fibrous webs. Electret fibrous filters are highly efficient in filtering air because of the combination of mechanical entrapment of particles in the air with the trapping of particles based on the electrical or electrostatic characteristics of the fibers. Both charged and uncharged particles in the air, of a size that would not be mechanically trapped by the filtration medium, will be trapped by the charged nature of the filtration medium. Meltblown web 12 can be electrically treated using techniques and apparatus known in the art.

[0025] Layers 12, 14 and 16 of the laminate fabric of the present invention can be bonded together to form a coherent fabric using techniques and apparatus known in the art. For example, layers 12, 14 and 16 can be bonded together by thermal bonding, mechanical interlocking, adhesive bonding, and the like. Preferably, laminate fabric 10 includes a multiplicity of discrete thermal bonds distributed throughout the fabric, bonding layers 12, 14 and 16 together to form a coherent fabric.

[0026] In addition, as will be appreciated by the skilled artisan, laminate fabric 10 can include one or more additional layers to provide improved barriers to transmission of liquids, airborne contaminants, etc., or additional supporting layers.

[0027] Meltblown web 12 of the invention exhibits a variety of desirable characteristics, which make the web particularly useful as a barrier component in a laminate fabric, such as a sterile wrap. Because the microfibers of the web have extremely small fiber diameters, the surface area of the meltblown microfibers is greatly increased, as compared to conventional microfibers. In contrast, conventional meltblown webs incorporated as a component in a face mask include microfibril fibers having an average fiber diameter of about 1.8 to 3.0 microns, and higher. Further, by incorporating microfibril fibers having an average fiber diameter of less than 1.5 microns, the resultant meltblown web allows a packing density which, combined with the high surface area provided by the microfibril fibers, provides significantly improved barrier properties of the fabric.

[0028] In addition, the basis weight of the meltblown web of the invention is greatly reduced, i.e. between 1 and 20 gsm, and preferably between 1 and 12 gsm. In contrast, the basis weight of conventional meltblown webs used in

barrier applications typically have a basis weight from 20 to 40 gsm. As a result, meltblown web 12 can provide a lightweight component of a laminate fabric, and provide increased flexibility and ability to conform about objects, such as surgical items to be sterilized, without significantly impairing or diminishing the barrier properties of the web, for example, against passage of airborne contaminants and bacteria. Accordingly, although the meltblown web of the

5 laminate of the invention includes both an average fiber diameter and basis weight well below that of conventional meltblown webs, the resultant web has excellent barrier properties.

[0029] The superior barrier properties of the meltblown component 12 of the laminate fabric 10 of the present invention makes the meltblown web a superior candidate as a component for disposable medical fabrics, including sterile wraps, where barrier properties are required but can be poorly delivered by existing commercial products. Accordingly,

10 a laminate fabric 10 as described above can be used as a sterile wrap.

[0030] Referring now to Figure 2A, a perspective top view of a conventional "double wrapped" sterile package, designated generally as 30, is illustrated. The package includes at least two sheets 32 and 34 of a trilaminate fabric, wrapped about items 36 to be sterilized. The items to be sterilized can be surgical instruments, as illustrated, although as the skilled artisan will appreciate, the items can be any of the types of items which are sterilized before use. As

15 noted above, to meet current industry standards of barrier protection, at least two sheets of a trilaminate fabric can be necessary to provide adequate barrier protection in a sterile wrap.

[0031] In contrast, as illustrated in Figure 2B, the present invention also includes a sterile wrap 40 formed of the laminate fabric of the present invention, a single sheet of which can be wrapped about the items to be sterilized to form a single layer sterile wrap package 42. Specifically, Figure 2B is a perspective top view of single sheet sterile wrap

20 package 42 of the present invention, partially cut away to illustrate the single layer construction thereof.

[0032] The sterile wrap 40, and thus the sterile wrap package 42, of the invention exhibit excellent barrier properties and meet current industry standards without the need of "double wrapping" the sterilizable items. Accordingly, the present invention provides not only a superior barrier fabric, but also can provide increased efficiency in preparing items for sterilization by eliminating repetitive folding and securing steps required for double wrapping conventional

25 barrier laminate sheets. Further, because a single sheet of the laminate fabric of the invention is used, bonding about the periphery thereof, which can result in decreased flexibility and increased difficulty in folding, can be avoided.

[0033] Instruments contained within sterile wrap package 42 of the present invention can be sterilized using any of the techniques known in the art for sterilization of surgical instruments and other health care related items. Such sterilization techniques include steam sterilization at a temperature of about 250-280°F (121°C-138°C), ethylene oxide

30 sterilization at a temperature of about 130°F (54°C), gamma irradiation, and the like.

[0034] Referring now to Figure 3, an illustrative process for forming the meltblown web 12 and the laminate fabric 10 of the present invention is illustrated. Figure 3 includes a simplified, diagrammatic illustration of an apparatus, designated generally as 50, capable of carrying out the method of forming a meltblown web in accordance with the invention. Conventional meltblowing apparatus known in the art can be used.

35 [0035] In meltblowing, thermoplastic resin is fed into an extruder where it is melted and heated to the appropriate temperature required for fiber formation. The extruder feeds the molten resin to a special meltblowing die. The die arrangement is generally a plurality of linearly arranged small diameter capillaries. The resin emerges from the die orifices as molten threads or streams into high velocity converging streams of heated gas, usually air. The air attenuates the polymer streams and breaks the attenuated streams into a blast of fine fibers which are collected on a moving

40 screen placed in front of the blast. As the fibers land on the screen, they entangle to form a cohesive web.

[0036] The technique of meltblowing is known in the art and is discussed in various patents, e.g., Buntin et al, U.S. Patent No. 3,978,185; Buntin, U.S. Patent No. 3,972,759; and McAmish et al, U.S. Patent No. 4,622,259.

[0037] In the present invention, process parameters of the meltblowing process are selected and controlled to form the microfine microfibers of the meltblown webs of the invention while minimizing or eliminating processing complications, i.e., without concurrently forming substantial amounts of loose fibers, i.e., fly, which can interfere with processing efficiency and cause defects in the meltblown web.

45 [0038] It has been found that relatively high MFR thermoplastic polymers, i.e., 1000 MFR or higher, can be attenuated in a heated high velocity air stream in such a way suitable for the stable production of microfine microfibers and concurrent formation of a microfibrinous nonwoven low basis weight web. These conditions include controlling the attenuation conditions (e.g. attenuation gas velocity and temperature), as well as selecting an appropriate MFR polymer, to promote formation of microfine microfibers and low basis weight webs without significantly impairing or adversely impacting the process conditions, i.e., formation of fly.

50 [0039] As will be appreciated by the skilled artisan, as the temperature and velocity of the attenuation gas increases, collection of the fibers can become more difficult. Indeed, elevated temperatures and increased attenuation gas velocities can result in the formation of fibers too short to be collected on the collection surface. For example, conventionally, to form microfibrinous meltblown polypropylene webs which can be incorporated as a barrier layer in a nonwoven laminate fabric, attenuation process conditions are adjusted so that attenuation gas temperatures are from 515°F (268°C) to 525°C (274°C). Further, attenuation gas velocities conventionally are about 20 cubic feet per minute ("cfm")

(0.6 cubic meters per minute) per inch (2.54 cm) of the width of the die.

[0040] If the temperature and velocity of the gas is increased beyond these ranges, fibers which are too short to be collected can be formed, known as "fly." These stray fibers tend to float in the air in the area surrounding the meltblowing equipment, and can land on the formed web, thus creating a defect in the fabric. Further, elevated temperatures and gas velocities can result in the formation of "shot" or globules of solid polymer in the web.

[0041] In the present invention, the inventors have found that despite conventional wisdom regarding the use of elevated temperatures and increased velocities of the attenuation gas, these process parameters can be increased up to 10 percent, and even up to 25 percent and higher, relative to conventional processing parameters for a particular polymer system. These parameters can be increased without forming undesirable amounts of fly to form microfibers having a greatly reduced average diameter size as compared to conventional meltblown webs.

[0042] This increase in processing parameters is further adjusted in accordance with the characteristics of the polymer system being processed. That is, polymers having high melt flow rates relative to conventional meltblowing polymers can be processed to form the meltblown webs described above by increasing attenuation gas velocity and temperature. Typically, meltblown webs are formed from polymers having a melt flow rate of about 800 or lower, believed necessary for cohesiveness and strength. Polymers having melt flow rates higher than about 1000 were believed to be too flowable for smooth attenuation. However, the inventors have found that polymers having a melt flow rate up to 1000, and even up to and greater than 1200 can be meltblown using the above attenuation air temperatures and velocities. The melt flow rate is determined according to ASTM test procedure D-1238 and refers to the amount of polymer (in grams) which can be extruded through an orifice of a prescribed diameter under a mass of 2.16 kg at 230°C in 10 minutes. The MFR values as used herein have units of g/10 min. or dg/min.

[0043] As the melt flow rate (MFR) of the polymer increases, for example to levels above 2000, and greater, the attenuation gas velocity and temperature do not necessarily have to increase as much as with polymers having a melt flow rate range from about 1000 to 1200 to achieve the same end product. Accordingly, all of these factors, i.e., the attenuation gas velocity and temperature, as well as the polymer system used (i.e., the type of polymer used, MFR, melt temperature, etc.) are taken into account when determining the process parameters for a particular polymer used to form the meltblown webs of the invention.

[0044] For example, to form meltblown microfibers of a polypropylene polymer having a melt flow rate of about 1000, the temperature of the attenuation gas can be increased to at least about 565°F (295°C) to 575°F (300°C), and even up to about 645°F (335°C) to 655°F (340°C). As noted above, as will be appreciated by the skilled artisan, the temperature of the attenuation gas can vary according the particular polymer system used. For example, to form a polyester meltblown web of the invention, attenuation air temperatures could range from about 580°F (304°C) to about 660°F (350°C), in contrast to conventional temperatures used of about 540°F (282°C) to about 600°F (315°C).

[0045] In addition, the speed of the attenuation gas can be increased to at least about 25 cfm, and up to about 30 cfm, per inch of the width of the meltblowing die, and higher. As the skilled artisan will also appreciate, attenuation gas velocities can be dependent upon the configuration of the meltblowing apparatus. For example, as the distance from the orifice through which the attenuation gas exits to the orifice through which the polymer is extruded increases, for attenuation gas streams supplied at equal velocities, a greater volume of gas will be pushed through the gas supplying nozzles, thus in effect increasing the gas velocity.

[0046] Referring again to Figure 3, as shown, thermoplastic polymer pellets of a polymer are placed in a feed hopper 52 of a screw extruder 54 where they are heated to a temperature sufficient to melt the polymer. Advantageously the polymer has a MFR of at least 1000. Alternatively, as will be appreciated by the skilled artisan, polymers having a MFR of less than 1000 can be used in combination with a visbreaking agent, such as a peroxide, which degrades the polymer and reduces the melt flow rate thereof to form a polymer which exiting the extruder has a MFR of at least 1000. Visbreaking agents and techniques are known in the art. The molten polymer is forced by the screw through conduit 56 into a spinning block 58 and the polymer is extruded from the spin block 58 through a plurality of small diameter capillaries 60 into a high velocity gas stream, such as compressed air designated generally as 62. The temperature and velocity of the air is controlled as described above to form microfine meltblown microfibers having an average fiber diameter of less than about 1.5 microns.

[0047] The meltblown microfibers are deposited onto a foraminous endless belt 64 and form a coherent web 66 which is removed from the belt by a pair of consolidation rolls 68. The rolls optionally may include bonding elements (not shown) in the form of a relief pattern to provide a desired extent of point bonding of the microfibrinous web. At these points where heat and pressure is applied, the fibers fuse together, resulting in strengthening of the web structure.

[0048] The microfibrinous web 66 can then be electrically treated to impart an electrical charge to the fabric, and thus improve its filtration capabilities. Techniques and apparatus for electrically treating a nonwoven web are known in the art.

[0049] The microfibrinous web can then be removed from the assembly and stored on a roll. Alternatively, as illustrated, the microfibrinous web can be passed on to additional manufacturing processes, as described in more detail below.

[0050] As illustrated in Figure 3, the microfibrinous web 66 is fed through consolidation rolls 68 and is combined with a pre-formed web 14 and preformed web 16, drawn from supply rolls 70 and 72, respectively, to form a laminate 74.

[0051] As described above, at least one of pre-formed webs 14 and 16 can be spunbonded webs of continuous filaments. The spunbonding process involves extruding a polymer through a generally linear die head or spinneret for melt spinning substantially continuous filaments. The spinneret preferably produces the filaments in substantially equally spaced arrays and the die orifices are preferably from about 0.002 (.005 cm) to about 0.040 (0.1 cm) inches in diameter.

[0052] The substantially continuous filaments are extruded from the spinneret and quenched by a supply of cooling air. The filaments are directed to an attenuator after they are quenched, and a supply of attenuation air is admitted therein. Although separate quench and attenuation zones can be used, it will be apparent to the skilled artisan that the filaments can exit the spinneret directly into the attenuator where the filaments can be quenched, either by the supply of attenuation air or by a separate supply of quench air.

[0053] The attenuation air may be directed into the attenuator by an air supply above the entrance end, by a vacuum located below a forming wire or by the use of eductors integrally formed in the attenuator. The air proceeds down the attenuator, which narrows in width in the direction away from the spinneret, creating a venturi effect and causing filament attenuation. The air and filaments exit the attenuator, and the filaments are collected on the collection screen. The attenuator used in the spunbonding process may be of any suitable type known in the art, such as a slot draw apparatus or a tube-type (Lurgi) apparatus.

[0054] Alternatively, at least one of webs 14 and 16 can be a carded web formed of staple length textile fibers, or a wet-laid or air-laid web of staple fibers, including bicomponent staple length textile fibers. While pre-formed webs 14 and 16 are shown, it will be appreciated that the webs could be formed in a continuous in-line process and combined with meltblown web 66. It will also be understood that additional webs could be combined with meltblown web 66, on one or both sides thereof.

[0055] The three-layer laminate 74 is conveyed longitudinally as shown in Figure 3 to a conventional thermal fusion station 76 to provide a composite bonded nonwoven fabric 10. The fusion station is constructed in a conventional manner as known to the skilled artisan, and advantageously includes bonding rolls. Preferably, the layers are bonded to provide a multiplicity of thermal bonds distributed throughout the laminate fabric. Because of the wide variety of polymers which can be used in the fabrics of the invention, bonding conditions, including the temperature and pressure of the bonding rolls, vary according to the particular polymers used, and are known in the art for differing polymers.

[0056] Although a thermal fusion station in the form of bonding rolls is illustrated in Figure 3, other thermal treating stations such as ultrasonic, microwave or other RF treatment zones which are capable of bonding the fabric can be substituted for the bonding rolls of Figure 3. Such conventional heating stations are known to those skilled in the art and are capable of effecting substantial thermal fusion of the nonwoven webs. In addition other bonding techniques known in the art can be used, such as by hydroentanglement of the fibers, needling, and the like. It is also possible to achieve bonding through the use of an appropriate bonding agent as known in the art.

[0057] The resultant fabric 10 exits the thermal fusion station and is wound up by conventional means on a roll 78. The resulting laminate provide superior barrier and filtration properties. In addition, the laminate also allows a sterilization medium, such as steam, ethylene oxide gas, and the like, to penetrate the fabric to sterilize objects contained within.

[0058] The present invention is subject to numerous variations. For example, the polymers used in the present invention may be specifically engineered to provide or improve a desired property in the composite. For example, any one of a variety of adhesion-promoting, or "tackifying," agents, such as ethylene vinyl acetate copolymers, may be added to the polymers used in the production of any of the webs of the composite structure, to improve inter-ply adhesion. Further, at least one of the outer webs may be treated with a treatment agent to render any one of a number of desired properties to the fabric, such as flame retardancy, hydrophilic properties, and the like.

[0059] Additionally, the fibers or filaments used in any of the webs of the composite structure may comprise a polymer blend or bicomponent polymeric structure. For example, in one embodiment of the invention, fibers employed in the carded web can be sheath/core or similar bicomponent fibers wherein at least one component of the fiber is polyethylene. The bicomponent fibers can provide improved aesthetics such as hand and softness based on the surface component of the bicomponent fibers, while providing improved strength, tear resistance and the like due to the stronger core component of the fiber. Preferred bicomponent fibers include polyolefin/polyester sheath/core fibers such as a polyethylene/polyethylene terephthalate sheath core fiber.

[0060] Additionally, although the method illustrated in Figure 3 employs a meltblown web sandwiched between two spunbonded webs, it will be apparent that different numbers and arrangements of webs can be employed in the invention. For example, the composite nonwoven fabric of the invention may comprise a spunbonded/meltblown web composite. Alternatively, the meltblown web can be sandwiched between a spunbonded web and a carded web. Additionally, several meltblown layers can be employed in the invention and/or greater numbers of other fibrous webs can be used. Nonwoven webs other than carded webs are also advantageously employed in the nonwoven fabrics of the invention. Nonwoven staple webs can be formed by air laying, garnetting, and similar processes known in the art.

[0061] The present invention will be further illustrated by the following non-limiting example.

Example

[0062] Meltblown webs were formed by meltblowing polypropylene resins having a melt flow rate of about 1250. The resin was meltblown at varying temperatures and air velocity speeds. The webs were electret treated using an apparatus of the University of Tennessee, which can result in a fabric which can maintain the electric charge for a long period of time and maintain the charge to a large degree after the fabric is sterilized, for example using steam and/or gamma sterilization. The drop in pressure across the web (ΔP) as well as filtration efficiency was measured for each web. The results are set forth below in Table 1.

TABLE 1

Trial #	gsm	Diameter, μ	Air Perm cfm (m^3/min)	ΔP	%BFE*
1	1.0	0.8	331 (9.4)	0.3	99.2
2	3.0	1.1	174 (4.9)	0.7	99.5
3	5.0	1.3	144 (4.1)	0.8	99.9
4	20.0	1.7	54 (1.5)	2.0	99.9
5	42.0	2.7	57 (1.6)	2.1	90.4

* electret treated

[0063] The filtration efficiency of each web was tested using a standard BFE (a bacteria filtration efficiency) test, Nelson Labs Test # AB010. *Staphylococcus aureus* was nebulized into a spray mist and forced through an aperture in a closed conduit. The bacteria passing through the aperture were captured on agar plates held in an Andersen sampler. The same procedure was repeated with samples of the meltblown webs blocking the aperture of the conduit. After a period of at least 18 hours, the bacteria colonies were counted. The efficiency of filtration was determined by comparing the colony count on the plates with and without the meltblown web samples. Results are expressed as a percentage which represents the reduction of the bacteria colonies when the meltblown webs were in place.

[0064] The drop in pressure in millimeters ("mm") of water across each of the fabric samples was also measured using a constant flow rate (85 liters per minute) of air through a 100 square centimeter area of the web. As set forth in Table 1, the meltblown webs exhibit a pressure differential from 0.3 to 0.8. Such a low differential in pressure across the webs provides excellent breathability, despite the ability of the webs to filter particles.

[0065] Trilaminate fabrics including outer spunbonded polypropylene webs thermally bonded to various ones of the meltblown webs prepared above were formed. A variety of properties of the laminate fabric were measured, including hydro head, bacteria filtration efficiency (BFE) and the like.

[0066] The trilaminate fabrics exhibited BFE values (measured as described above) up to 95%, and even as high as 98%. Accordingly, using this measurement of barrier efficiency, the laminate fabrics of the invention can exhibit superior barrier and filtration properties.

[0067] In addition, the ability of the laminate fabrics to withstand water pressure applied to one surface of the fabric before breaching or impairing the barrier properties thereof were also measured. Specifically, the barrier protection of the laminate fabrics was evaluated in terms of centimeters of water pressure which can be withstood by the fabric before compromising the barrier thereof (referred to as "hydro head" measurements). A single sheet of the fabric of the invention can exhibit hydro head measurements of up to 80 cm. For purposes of comparison, currently commercially available laminate fabrics having a meltblown component formed of 1.5 to 1.7 micron average diameter microfibers exhibit hydro head measurements of at best about 45 to 55 cm, and two sheets of this material exhibit a hydro head of about 75 to 90 cm.

[0068] Further, the laminate fabrics of the invention exhibit high flexibility (i.e., ease of handling) and superior softness. The fabrics provides sterility penetration and residual value equal to or better than that provided by commercially available products.

[0069] The foregoing example is illustrative of the present invention, and is not to be construed as limiting thereof. The invention is defined by the following claims, with equivalents of the claims to be included therein.

Claims

1. A composite nonwoven laminate fabric (10) comprising first and second nonwoven webs (14, 16), a nonwoven web (12) of meltblown microfibers (18) sandwiched between and bonded to said first and second webs, said meltblown web

- having a basis weight between about one and twenty grams per square meter, and
- further including a plurality of thermoplastic microfibers of an average diameter of less than 1.5 microns and which are formed from a polymer having a melt flow rate of at least about or greater than 1,000.

2. A laminate fabric according to claim 1, wherein first and second nonwoven webs and meltblown web are bonded together via a multiplicity of thermal bonds distributed through out the fabric to form a coherent laminate fabric, said first and second nonwoven webs being of substantially continuous thermoplastic filaments.

3. A laminate fabric according to anyone of claims 1 and 2 wherein the average diameter of the thermoplastic microfibrils is between about 0.5 and 1.5 microns, preferably between about 0.8 and 1.3 microns.

4. A laminate fabric according to anyone of claims 1 to 3 wherein the meltblown web has a basis weight between about one and twelve grams per square meter.

5. A laminate fabric according to anyone of claims 1 to 4 wherein the meltblown web is electrically treated.

6. A laminate fabric according to anyone of claims 1 to 5 wherein the microfibrils of the meltblown web are formed of a polymer having a melt flow rate of greater than 1,200.

7. A laminate fabric according to anyone of claims 1 to 5 wherein the microfibrils of the meltblown web are formed of a polypropylene having a melt flow rate of at least about 1,000.

8. Use of a laminate fabric according to anyone of claims 1 to 7 to form disposable medical fabrics, preferably sterile wraps.

9. A single layer sterile wrap package obtained by wrapping a sterile wrap formed from a laminate fabric according to anyone of claims 1 to 7.

10. A process for the manufacture of a nonwoven laminate fabric according to claim 1 comprising:

- forming a nonwoven meltblown web (12) having a basis weight between about one and twenty grams per square meter, including a plurality of thermoplastic microfibers of an average diameter of less than 1.5 microns and which are formed from a polymer having a melt flow rate of at least about or greater than 1,000,
- sandwiching the obtained meltblown web between opposing nonwoven webs (14, 16) to form a laminate fabric and
- bonding the webs together to form a coherent laminate fabric.

11. A process according to claim 10, wherein the step of bonding is a thermally bonding to form a multiplicity of discrete thermal bonding throughout the laminate fabric.

Patentansprüche

1. Textiles nichtgewebtes Verbundlaminatflächengebilde (10), umfassend erste und zweite nichtgewebte Faserflore bzw. Krempelvliese (14, 16), einen nichtgewebten Faserflor bzw. Krempelvlies (12) aus schmelzgeblasenen Mikrofaseren (18), der sandwichartig zwischen dem ersten und dem zweiten Faserflor angeordnet und damit verbunden ist, wobei der genannte schmelzgeblasene Faserflor

- ein Basisgewicht zwischen etwa ein und zwanzig Gramm pro Quadratmeter hat und
- weiterhin eine Vielzahl von thermoplastischen Mikrofaseren mit einem mittleren Durchmesser von weniger als 1,5 Mikron einschließt, die aus einem Polymeren mit einer Schmelzflußrate von mindestens etwa 1000 oder größer gebildet sind.

2. Textiles Laminatflächengebilde nach Anspruch 1, dadurch **gekennzeichnet**, daß der erste und der zweite nichtgewebte Faserflor und der schmelzgeblasene Faserflor miteinander durch eine Vielzahl von thermischen Bindungen verbunden sind, die durch das Flächengebilde unter Bildung eines kohärenten textilen Laminatflächengebildes verteilt sind, wobei der erste und der zweite nichtgewebte Faserflor aus im wesentlichen kontinuierlichen thermo-

plastischen Filamenten besteht.

3. Textiles Laminatflächengebilde nach einem der Ansprüche 1 und 2, dadurch **gekennzeichnet**, daß der durchschnittliche Durchmesser der thermoplastischen mikrofeinen Fasern zwischen etwa 0,5 und 1,5 Mikron, vorzugsweise zwischen etwa 0,8 und 1,3 Mikron, liegt.
4. Textiles Laminatflächengebilde nach einem der Ansprüche 1 bis 3, dadurch **gekennzeichnet**, daß der schmelzgeblasene Faserflor ein Basisgewicht zwischen etwa ein und zwölf Gramm pro Quadratmeter hat.
5. Textiles Laminatflächengebilde nach einem der Ansprüche 1 bis 4, dadurch **gekennzeichnet**, daß der schmelzgeblasene Faserflor elektrisch behandelt worden ist.
6. Textiles Laminatflächengebilde nach einem der Ansprüche 1 bis 5, dadurch **gekennzeichnet**, daß die mikrofeinen Fasern des schmelzgeblasenen Faserflors aus einem Polymeren mit einer Schmelzflußrate von größer als 1200 gebildet sind.
7. Textiles Laminatflächengebilde nach einem der Ansprüche 1 bis 5, dadurch **gekennzeichnet**, daß die mikrofeinen Fasern des schmelzgeblasenen Gewebes aus einem Polypropylen mit einer Schmelzflußrate von mindestens etwa 1000 gebildet sind.
8. Verwendung des textilen Laminatflächengebildes nach einem der Ansprüche 1 bis 7 zur Bildung von medizinischen textilen Wegwerfgebilden, vorzugsweise sterilen Umhüllungen.
9. Sterile Ein-Schicht-Umhüllungspackung, erhalten durch Einwickeln einer sterilen Umhüllung, die aus einem textilen Laminatflächengebilde nach einem der Ansprüche 1 bis 7 gebildet ist.
10. Verfahren zur Herstellung des textilen nichtgewebten Laminatflächengebildes nach Anspruch 1, umfassend:
 - Bildung eines nichtgewebten schmelzgeblasenen Faserflors bzw. Krempelvlieses (12) mit einem Basisgewicht zwischen etwa ein und zwanzig Gramm pro Quadratmeter, der eine Vielzahl von thermoplastischen Mikrofasern mit einem durchschnittlichen Durchmesser von weniger als 1,5 Mikron einschließt, die aus einem Polymeren mit einer Schmelzflußrate von mindestens etwa 1000 oder größer gebildet sind,
 - sandwichartiges Anordnen des erhaltenen schmelzgeblasenen Faserflors zwischen gegenüberliegende nichtgewebte Faserflore bzw. Krempelvliese (14, 16) zur Bildung eines textilen Laminatflächengebildes und
 - Verbinden der Faserflore miteinander unter Bildung eines textilen kohärenten Flächengebildes.
11. Verfahren nach Anspruch 10, dadurch **gekennzeichnet**, daß die Stufe der Bindung eine thermische Bindung ist, um eine Vielzahl von diskreten thermischen Bindungen durch das textile Laminatflächengebilde hindurch zu bilden.

Revendications

1. Etoffe stratifiée non tissée composite (10) comprenant des première et seconde nappes non tissées (14, 16), une nappe non tissée (12) de microfibres (18) soufflées à l'état fondu placée en sandwich entre lesdites première et seconde nappes et liée à celles-ci, ladite nappe soufflée à l'état fondu :
 - ayant un poids de base compris entre environ 1 et 20 g/m², et
 - comprenant de plus une pluralité de microfibres thermoplastiques ayant un diamètre moyen inférieur à 1,5 µm et qui sont formées à partir d'un polymère ayant un indice de fluidité d'au moins environ 1.000 ou plus.
2. Etoffe stratifiée suivant la revendication 1, dans laquelle les première et seconde nappes non tissées et la nappe soufflée à l'état fondu sont liées ensemble par l'intermédiaire d'une multiplicité de liaisons thermiques distribuées sur l'ensemble de l'étoffe de façon à former une étoffe stratifiée cohérente, lesdites première et seconde nappes non tissées étant faites de filaments thermoplastiques pratiquement continus.
3. Etoffe stratifiée suivant l'une quelconque des revendications 1 et 2, dans laquelle le diamètre moyen des fibres microfines thermoplastiques est compris entre environ 0,5 et 1,5 µm, de préférence entre environ 0,8 et 1,3 µm.

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4. Etoffe stratifiée suivant l'une quelconque des revendications 1 à 3, dans laquelle la nappe soufflée à l'état fondu a un poids de base compris entre environ 1 et 12 g/m².
5. Etoffe stratifiée suivant l'une quelconque des revendications 1 à 4, dans laquelle la nappe soufflée à l'état fondu est soumise à un traitement électrique.
6. Etoffe stratifiée suivant l'une quelconque des revendications 1 à 5, dans laquelle les fibres microfines de la nappe soufflée à l'état fondu sont formées d'un polymère ayant un indice de fluidité supérieur à 1 200.
7. Etoffe stratifiée suivant l'une quelconque des revendications 1 à 5, dans laquelle les fibres microfines de la nappe soufflée à l'état fondu sont formées d'un polypropylène ayant un indice de fluidité d'au moins environ 1 000.
8. Utilisation d'une étoffe stratifiée suivant l'une quelconque des revendications 1 à 7, pour former des étoffes à jeter à usage médical, de préférence des enveloppes stériles.
9. Trousse formée d'une enveloppe stérile à couche unique obtenue par repliement d'une enveloppe stérile formée à partir d'une étoffe stratifiée suivant l'une quelconque des revendications 1 à 7.
10. Procédé pour la fabrication d'une étoffe stratifiée non tissée suivant la revendication 1, comprenant :
 - la formation d'une nappe non tissée (12) soufflée à l'état fondu ayant un poids de base compris entre environ 1 et 20 g/m², comprenant une pluralité de microfibres thermoplastiques ayant un diamètre moyen inférieur à 1,5 µm et qui sont formées à partir d'un polymère ayant un indice de fluidité d'au moins environ 1.000 ou plus;
 - la disposition de la nappe soufflée à l'état fondu ainsi obtenue en sandwich entre des nappes non tissées (14, 16) se faisant face de façon à former une étoffe stratifiée et
 - la liaison des nappes ensemble pour former une étoffe stratifiée cohérente.
11. Procédé suivant la revendication 10, dans lequel l'étape de liaison est une liaison thermique de façon à former une multiplicité de liaisons thermiques discrètes sur l'ensemble de l'étoffe stratifiée.

