United States Patent

[11] **3,631,854**

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[54] **INFLATABLE MEDICAL ASSEMBLIES**
3 Claims, 8 Drawing Figs.

[52] **U.S. Cl.** **128/90,** 128/DIG. 20
[51] **Int. Cl.** **A61f 5/04**
[50] **Field of Search** ..... 128/90, 87, 85, 89, DIG. 20

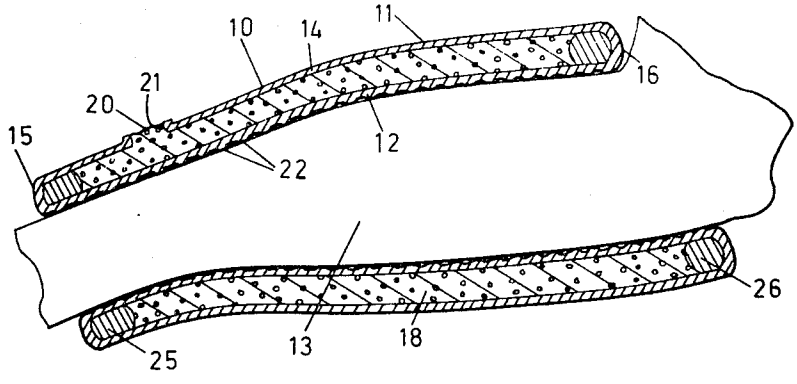
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ABSTRACT: This invention provides inflatable, double-walled resilient sleeves for use in forming surgical casts about human and animal body members. In use, such a sleeve is first disposed about the body member and a liquid-curable material such as a foamable polyurethane prepolymer composition, is introduced into the space between the inner and outer walls of the sleeve to inflate the latter. Curing of the liquid material then provides the required rigidification of the sleeve. The invention also embraces the casts so formed and a method for forming the resilient sleeves, usefully by a dipping technique using a novel forming member.



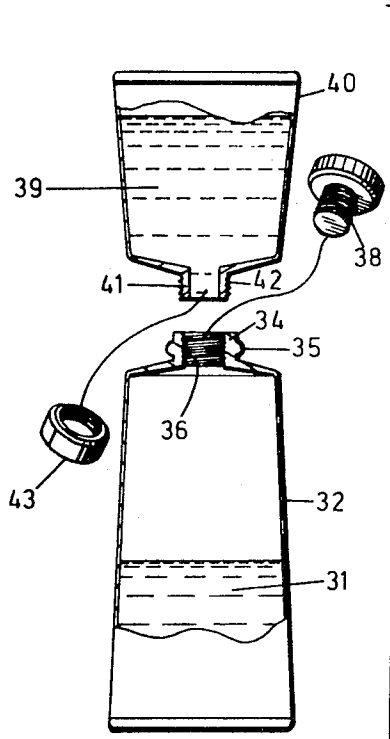


Fig. 5

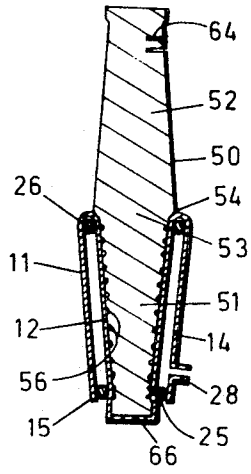


Fig. 7

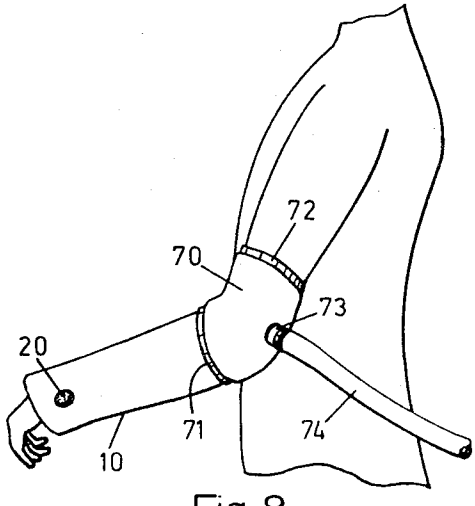


Fig. 8

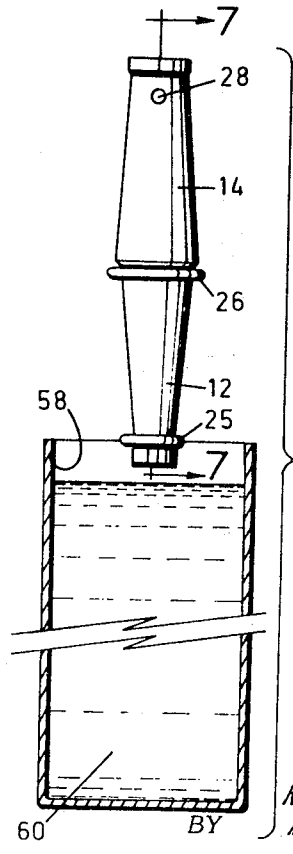


Fig. 6

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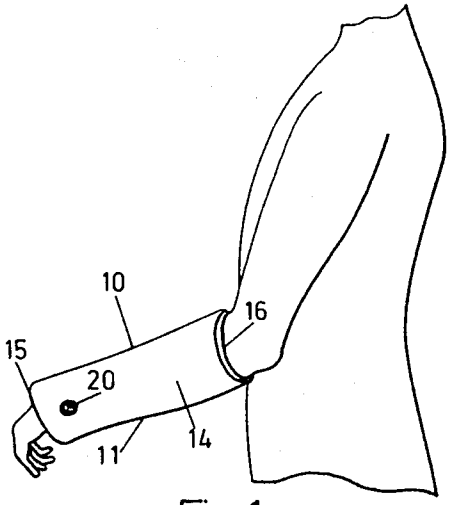


Fig. 1

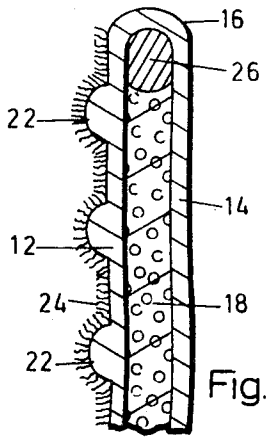


Fig. 3

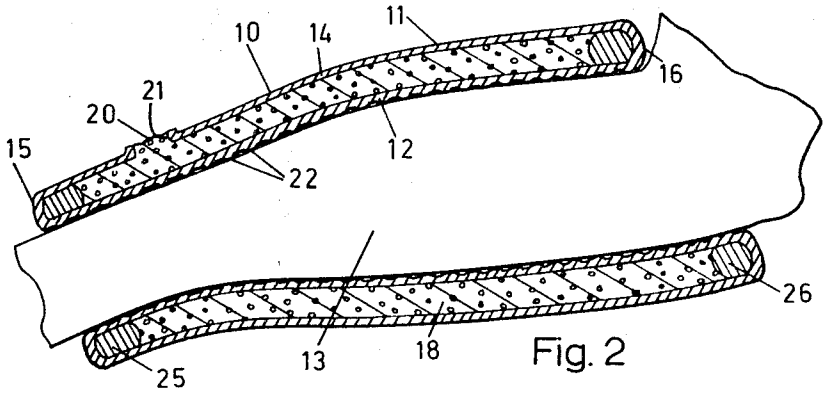


Fig. 2

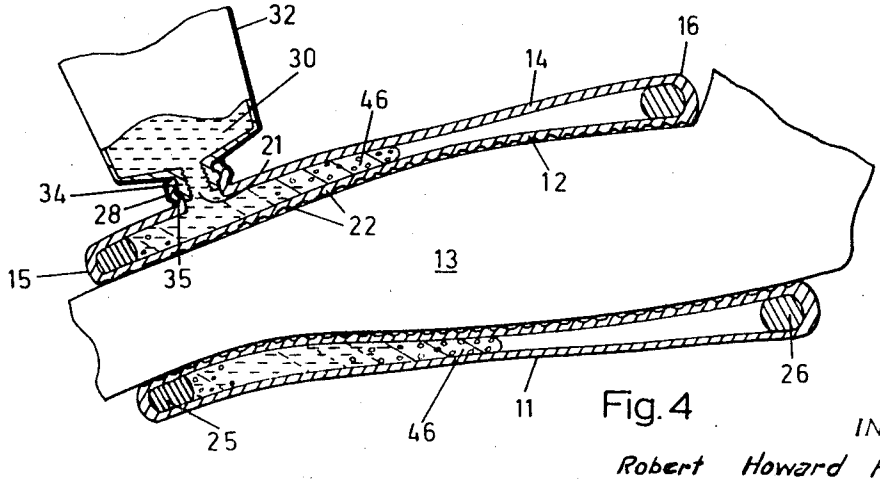


Fig. 4

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INFLATABLE MEDICAL ASSEMBLIES

The present invention relates to surgical casts and to a method of forming such casts whereby the setting of fractures and the like may be facilitated. The invention also relates to inflatable sleeves for use in forming such casts and to forming members for use in the manufacture of such sleeves, as well as to a method for forming such sleeves.

A principal object of the present invention is to provide a surgical cast free of many of the well-known problems and disadvantages associated with the use of plaster of Paris for such purpose.

A more particular object of the present invention is to provide a surgical cast which is convenient to apply, which is lightweight and washable, and which is relatively transparent to X-rays.

It is yet another object of the present invention to provide a surgical cast and a method of applying such a cast to a body member which cast and method are characterized by their ease and rapidity of application.

A further object of the present invention is to provide surgical casts which have wide application in the treatment of both human and animal fractures and the like.

Yet another object of the invention is to provide inflatable sleeves which may be used for forming the surgical casts of the invention.

Other objects of this invention are to provide a method for forming such inflatable sleeves and novel forming members for use in such a method.

It is a further object of the present invention to provide a flexible, generally fluidtight sleeve for use in combination with the novel surgical casts of the invention for drying a body member covered by such a cast.

A novel surgical cast in accordance with the present invention is broadly defined as comprising a double-walled resilient sleeve having an inner wall and an outer wall circumjacent said inner wall, said sleeve being maintained in a rigidified, inflated condition by a solidified material, such as foamed polyurethane, disposed between said inner and outer walls.

The invention also provides a method of forming a surgical cast about a body member which method comprises disposing an inflatable, double-walled resilient sleeve about said body member, introducing a liquid-curable composition, such as a foaming polyurethane composition, into the space between the walls of said sleeve to inflate said sleeve about said body member, and curing said liquid composition to a solid state within said sleeve.

The present invention also embraces in combination with a novel surgical cast as hereinbefore defined, a flexible, generally fluidtight sleeve having first and second resilient end cuffs, said first end cuff encircling said cast in a generally fluidtight manner and said second end cuff being adapted to encircle in a generally fluidtight manner a body member extending from within said cast, and said flexible, generally fluidtight sleeve having an opening through which air may be blown for passage between said body member and the circumjacent surgical cast.

An inflatable sleeve in accordance with the present invention broadly comprises a resilient inner wall adapted to receive therethrough a body member and, circumjacent said inner wall, a resilient outer wall, said inner and outer walls being terminally secured together in a fluidtight manner to define a space therebetween, and an opening being provided into said sleeve to permit the introduction of a liquid-curable composition into said space between said inner and outer walls.

The invention also provides a novel method for forming such a sleeve. Such a method comprises the steps of (a) forming a continuous tubular sleeve of resilient material on and around a forming member comprising terminally adjacent first and second longitudinal portions, said first longitudinal portion having an external configuration corresponding to the desired internal configuration of said double-walled resilient sleeve, and said second longitudinal portion having larger sectional dimensions that said first longitudinal portion and having an external configuration corresponding to the desired, uninflated, external configuration of said double-walled resilient sleeve, (b) peeling said tubular sleeve from said longitudinal second portion of said forming member so that it is disposed as an outer wall circumjacent said tubular sleeve constituting an inner wall on said forming member, (c) bonding said inner and outer walls terminally together to form said inflatable, double-walled resilient sleeve, and (d) forming an opening in said sleeve for the admission into the space between said inner and outer walls of a curable liquid material.

As hereinbefore indicated, the invention also provides a forming member for use in forming the aforementioned resilient sleeves. Such a forming member broadly comprises an elongated body having terminally contiguous, first and second longitudinal portions adapted to support integrally formed inner and outer walls respectively of a resilient sleeve during a forming operation, said first and second longitudinal portions having different sectional dimensions such that, when said sleeve is peeled from said second longitudinal portion and disposed circumjacent said sleeve from said first portion, a desired separation between said inner and outer walls of the sleeve is obtained.

Other objects, features and advantages of the invention will become apparent as the description herein proceeds.

The invention will now be described merely by way of illustration with reference to the accompanying drawings:

FIG. 1 is a perspective view of a surgical cast in accordance with the invention showing it disposed around a patient's forearm;

FIG. 2 is an enlarged, longitudinal sectional view through the surgical cast of FIG. 1;

FIG. 3 is an enlarged, partial longitudinal sectional view through the surgical cast of FIG. 1 showing a particularly useful feature of that cast;

FIG. 4 is a similar sectional view to that of FIG. 2 but illustrating the method according to the invention for forming a surgical cast and more particularly showing the introduction of a foaming liquid composition into the space between the walls of an inflatable, double-walled resilient sleeve disposed around a patient's forearm;

FIG. 5 is a representation of two deformable containers containing a precursor material and an activator material, which materials are intermixed prior to the introduction of the resulting foamable mixture as shown in FIG. 4 into the resilient sleeve of the surgical cast;

FIG. 6 is a front elevation showing the use of a forming member in accordance with the invention for forming the inflatable, double-walled resilient sleeve of FIGS 2, 3 and 4 showing such a sleeve partly formed;

FIG. 7 is a longitudinal sectional view through the forming member of FIG. 6 taken along the line 7 —7 of that figure and showing a subsequent stage in the sleeve-forming operation; and

FIG. 8 is a perspective view similar to that of FIG. 1 but also showing the use with the surgical cast of that figure of a flexible, fluidtight sleeve suitable for drying the patient's forearm under the cast, for example, after bathing.

Referring first to FIGS. 1 to 3, it will be seen that the surgical cast generally indicated therein at **10** and shown in position around a patient's forearm **13** comprises an inflatable, double-walled resilient sleeve **11** having an inner wall **12** and an outer wall **14** circumjacent the inner wall **12**. It will be noted particularly from FIG. 2 that the sleeve **11** is closed at each of its ends **15** and **16**. The walls **12** and **14** are usefully formed from an elastomer and, as will be explained hereinafter, such a sleeve **11** can readily be formed by the novel forming method of the present invention using an elastomer latex dipping procedure.

A solidified liquid material such as a foamed resinous material **18**, for example, foamed polyurethane, is disposed within the space between the walls **12** and **14** and this material **18** serves to maintain the sleeve **11** in inflated condition. Such

material 18 also provides the required rigidification of the sleeve 11. It will also be appreciated that the actual rigidity of the cast 10 will vary according to the resiliencies of the sleeve 11 and of the material 18 as well as on the extent to which the sleeve 11 is inflated on distended by the material 18 contained therein.

It will also be seen from FIGS 1 and 2 that the foamed resinous material 18 extends outwardly at 20 through an opening 21 in the outer wall 14 of the sleeve 11, this opening 21 being provided to permit the introduction of the resinous material 18 into the space between the walls 12 and 14 as will be explained in more detail hereinafter with reference to the application of the cast 10 about a patient's body member, for example, the patient's forearm 13. It will further be understood that, once the cast 10 is formed, the opening 21 is sealed by the "plug" 20 of resinous material.

IN accordance with useful feature of the invention, the inner surface of the inner wall 12 adapted to be disposed in surface contact with a body member, for example, the forearm 13, is formed with a plurality of inwardly projecting protuberances or dimples 22 to permit some circulation of air between the cast 10 and the enclosed body member for such purposes as permitting drying of the skin, for example, after bathing, or for allowing free evaporation of perspiration. If desired, the inner surface of the cast 10 may also be flocked as shown at 24 in FIG. 3.

In accordance with another useful feature of the invention, the cast 10 is also usefully provided at each of its ends 15 and 16 with a resilient, preformed collar 25, 26 respectively, each of which is disposed between the inner and outer walls 12 and 14 respectively. Such collars 25 26 provide some degree of dimensional stability to the cast 10 while it is being positioned and filled about a body member as well as facilitating the introduction of the material 18 into the space between the walls 12 and 14. However another reason is to provide comfort should the wearer flex a limb, by providing resiliency, since the cast is hardened between the ends.

Having described the structure of the surgical cast 10, reference will now be made to FIGS. 4 and 5 to describe the manner in which the cast 10 is formed about a body member such as the forearm 13. In such a procedure, the inflatable, double-walled resilient sleeve 11 in its deflated form is first disposed about the body member. It should be noted that, for the particular sleeve 11 shown in FIG. 4, the collars 25 and 26 are secured between the inner and outer walls 12 and 14 during the manufacture of such sleeve and that the opening 21 already mentioned is defined by an outwardly extending nipple 28. Having disposed the sleeve 11 correctly about the forearm 13, a liquid, curable resinous composition 30 is introduced into the space between the walls 12 and 14. The liquid resinous composition 30 is usefully introduced into the sleeve 11 from a primary deformable container or tube 32 (FIG. 4) having a tubular neck 34 gripped by the nipple 28. Compression or other deformation of the container or tube 32 then forces the liquid composition 30 into the sleeve 11 as will readily be understood by reference to FIG. 4.

In accordance with another useful feature of the present invention, the tubular neck 34 of the primary container 32 is provided with an external annular lip 35 which serves to provide a generally fluidtight engagement with the nipple 28. Once the introduction of the liquid composition 30 into the sleeve 11 has proceeded to the desired extent, the liquid material is cured within the sleeve to a solid state to provide the required rigidification of the cast 10. The primary tube 32 is then removed from the sleeve 11 and the protruding nipple 28 which is plugged with solidified material is then severed to provide a level outer surface for the cast 10.

Many suitable liquid curable compositions can be used for forming surgical casts in accordance with the present invention. For instance, resinous liquid compositions can be used which are self-curing and which are prepared a short time before use in view of their limited shelf lives. Alternatively, compositions may be used which have long shelf lives but which require the application of an external stimulus such as heat, ultraviolet radiation, etc., to initiate or effect their curing to a solid state. Obviously, the liquid material must be one which is capable of being cured to a solid state under conditions which can be tolerated by the body member contained within the cast.

Although the present invention embraces the use of non-foaming liquid compositions, particularly effective casts have been formed by the use of foamable compositions such as those comprising polyurethane materials. With such materials, it is convenient to prepare the liquid composition 30 just prior to use and to introduce such a composition immediately into the sleeve 11 to allow the foaming to proceed the in situ. Such use of polyurethane compositions advantageous in that the curing times of such compositions are very short, being of the order of five minutes or less.

With this procedure, the reactive component materials from which the foamable liquid composition is prepared are usefully supplied in separate containers for intermixing when required. For convenience, such two-component systems will be referred to herein and in the claims appended hereto as comprising a "precursor material" and a separate "activator material." In the case of polyurethane compositions, the precursor material may, for instance, comprise a suitable liquid prepolymer while the activator material may comprise a catalyst effective for completing the curing and foaming of the prepolymer to a solid foamed state. It should be under stood, however, that the invention is not restricted to the use of any specific liquid curable compositions and that many suitable combinations of precursor materials and activator materials which will provide curable liquid compositions having the required properties can be used in the method of the invention.

Referring now, merely by way of further illustration, to FIG. 5 of the accompanying drawings, it can be explained that a precursor material such as a liquid polyurethane prepolymer 31 is supplied in the primary deformable container or tube 32, the tubular neck 34 of which has a female thread 36 for engagement with a male-threaded closure cap 38. A suitable activator material such as a catalyst 39 for use with the particular prepolymer 31 is separately supplied in a secondary deformable container or tub 40 having a neck 41 with a male thread 42 and a cooperating female-threaded closure cap 43. For a reason which will become apparent as the description herein proceeds, the primary container 32 is only partially filled with the prepolymer 31. The threads 36 and 42 of the containers or tubes 32 and 40 respectively are adapted to interengage as will be explained. When it is required to prepare the liquid material 30 for introduction into the sleeve 11 in the manner already described, the closure caps 38 and 43 are removed from the tubes 32 and 40 respectively and the neck 41 of the secondary tube 40 is screwed into the neck 34 of the primary tube 32. The catalyst 39 is then transfered from the secondary tube 40 to the primary tube 32 by squeezing the former for thorough mixing in the primary tube 32 of the catalyst 39 with the prepolymer 31 contained therein. Such mixing can be facilitated by the use of a resilient tube 32. The required mixing can then be effected by kneading the tube 32. It may also be advantageous to incorporate a dye or other coloring agent into one of the component materials 31 and 39 so as to provide a visual indication when the required degree of mixing has been obtained. In this case, the tube 32 may usefully be formed of a transparent or translucent material. When such mixing is complete, the liquid mixture is then transferred from the tube 32 into the sleeve 11 as already described with reference to FIG. 4. Foaming of the liquid composition occurs rapidly as indicated at 46 to inflate the sleeve 11.

Having described the use of the sleeve 11 for forming a surgical cast 10, reference will now be made to FIGS. 6 and 7 to describe a particularly useful procedure and a forming member in accordance with the invention for forming such a sleeve 11.

Referring first to FIG. 7, it will be noted that a forming member or mould indicated generally therein at 50 comprises an elongated body having terminally contiguous, first and second, frustoconical longitudinal portions 51 and 52 with their larger ends disposed generally centrally at 53. For a reason which will be understood as the description herein proceeds, the second portion 52 has sectional dimensions greater than those of the first portion 51. Consequently, a shoulder 54 is provided between the two portions 51 and 52.

The peripheral surface of the first or lower portion 51 of the forming member 50 is provided with surface irregularities 56 which serve to provide the aforementioned protuberances or dimples on the inner surface of the inner wall 12 of the sleeve 11 used in forming the surgical cast 10.

In forming a sleeve such as sleeve 11 using the forming member 50, the latter is first dipped into a bath 58 of rubber or other elastomer latex 60 and then removed therefrom. Such dipping provides a surface coating of latex on the forming member 50. This coating is then dried by any suitable procedure, the coating on the first or lower portion 51 of the forming member 50 providing the inner wall 12 of the sleeve 11 and that on the second portion 52 providing the outer wall 14 of the sleeve 11. After the latex coating on the former 50 has dried sufficiently, resilient collars 25 and 26 are disposed about the first portion 51 of the forming member 50 so as to be circumjacent the longitudinal ends of the inner wall 12. If desired, these collars 25 and 26 may be bonded in any appropriate manner to the underlying inner wall 12, for example, by the use of a suitable adhesive composition.

Referring further to FIG. 7, it will be seen that the upper or second portion 52 of the forming member 50 is provided with an annular recess 64 extending generally radially inwardly from its peripheral surface. During the aforementioned dipping operation, the latex 60 is received within this recess 64 to form the tubular nipple 28 utilized subsequently for introducing the curable liquid composition 30 into the sleeve 11.

With the collars 25 and 26 correctly disposed around the inner wall 12 as shown in FIG. 6, the outer wall 14 is peeled from the second or upper portion 52 of the forming member 50 and disposed circumjacent the inner wall 12 around the lower portion 51 of the forming member 50 as shown in FIG. 7. The adjacent lower ends of the walls 12 and 14 are then bonded to each other in any suitable manner, for example, by a further latex dipping operation or by the use of a suitable adhesive composition.

It will be appreciated that, with the forming operation hereinbefore described with reference to FIGS. 6 and 7, it will be necessary to remove the rubber end portion shown at 66 in first 7. This may be effected before or after removal of the sleeve 11 from the forming member 50. Although the sleeve 11 has been described as having a tapered configuration, it will be understood that sleeves of other configurations, for example, cylindrical ones, may just as readily be formed in the manner described.

Referring finally to FIG. 8 of the accompanying drawings, there is shown therein, in combination with a cast 10 as already described, a flexible, generally fluidtight, fabric or plastic sleeve 70 having first and second, resilient end cuffs 71 and 72. As will be seen, one of these cuffs, for example, cuff 71, may be disposed so as to encircle the cast 10 in a generally fluidtight manner in proximity to the end 16 thereof while the cuff 72 may then be disposed so as to encircle in a generally fluidtight manner the patient's arm extending from within the cast 10. The sleeve 70 has an opening with an associated fitment through which air may be blown for passage between the forearm 13 and the cast 10. Such a sleeve 70 is particularly useful in that it permits air to be blown beneath the cast for drying purposes, for instance, if the body member is wetted, for example, during bathing. The fitment 73 may usefully be adapted to be connected releasably to a hose 74 from a vacuum cleaner, hair dryer or the like.

What is claimed is:

1. A surgical cast comprising a double-walled resilient sleeve having an inner wall and an outer wall circumjacent said inner wall, said sleeve being maintained in a rigidified, inflated condition by a solidified material disposed between said inner and outer walls an opening extending through said outer wall said opening being sealed by said solid material, said inner surface being adapted to be disposed in surface contact with a body member, said inner surface being formed with a plurality of inwardly projecting protuberances to permit circulation of air between said cast and a body member enclosed thereby, and at least one resilient, preformed collar disposed between said inner and outer walls.

2. A surgical cast as defined in claim 1 which cast comprises first and second, resilient, preformed collars disposed between said inner and outer walls terminally thereof.

3. In combination, with a surgical cast comprising a double-walled resilient sleeve having an inner wall and an outer wall circumjacent said inner wall, said sleeve being maintained in a rigidified, inflated condition by a solidified material disposed between said inner and outer walls, a flexible generally fluidtight sleeve having first and second resilient end cuffs, said first end cuff encircling said cast in a generally fluidtight manner and said second end cuff being adapted to encircle in a generally fluidtight manner a body member extending from within said cast, and said flexible, generally fluidtight sleeve having an opening through which air may be blown for passage between said body member and the circumjacent surgical cast.

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