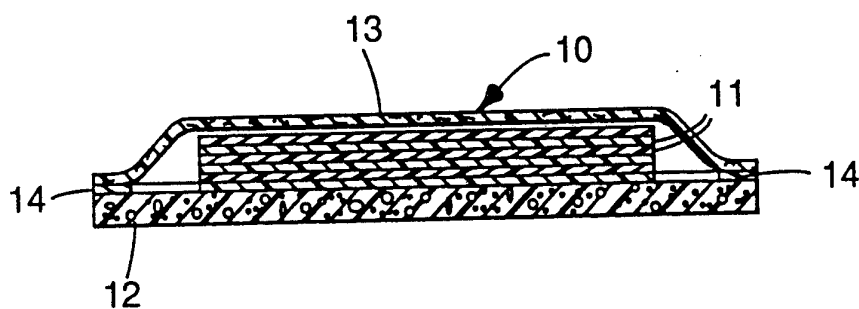




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(54) Title: CONFORMABLE BRACE**(57) Abstract**

The present invention provides a removable brace or splint which is contoured to the shape of the body part which is to be restrained or protected. The brace (10) is formed from a flexible substrate (11) impregnated with a curable resin fitted with a flexible, water-permeable cover (13) made of one component of a two component hook and loop fabric fastener system that is treated with a fluorochemical and a silicone. A properly sized and shaped brace made from the impregnated substrate is placed over a limb or joint and the resin is allowed to cure. After the resin has cured, the hook and loop fabric member is sufficiently adhered to the substrate in order to serve as a fastening surface to hold the orthopedic brace to the limb or joint and to allow multiple removal and reattachment of the brace and repositioning of the bound hook and loop member.

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CONFORMABLE BRACE

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This application is a continuation-in-part of U.S. application Serial Number 07/973,050 filed November 6, 1992, now pending.

The present invention generally relates to apparatus for splinting or bracing limbs and particularly relates to a conformable apparatus for bracing
10 an ankle or wrist.

BACKGROUND OF THE INVENTION

A variety of materials have been used to splint or brace injured body parts, particularly limbs and joints, to aid healing and to provide
15 protection and support for the injured body part. Historically, fractured or injured limbs and joints were completely immobilized in relatively heavy plaster of paris casts. Recently, curable resins have substantially replaced the use of plaster of paris in these types of rigid casts. Both plaster of paris and cured resin casts provided desired immobilization or support for a limb or joint but,
20 of course, these conventional types of casts cannot be easily removed and then reattached or reused.

In addition, conventional casts typically prevent or severely inhibit all movement of the limb or joint. In many cases, however, the inhibition of all movement is not preferred. In cases where limited or controlled
25 movement is acceptable or desired, particularly at joints such as ankles, knees and wrists, various types of braces or splints may be used. Generally, these braces include rigid splints or components which are wrapped or strapped around a limb or joint. Such braces are generally detachable and may be removed for examination, therapy, washing or care of the braced limb or joint
30 and then reattached or reused.

In order for a brace or splint to provide proper protection or support to a body part, it is generally recognized that these apparatus must be capable of closely conforming to the specific shape of a particular patient's limb or joint. Proper fitting of the brace to the affected body part is important to the
35 protection and support of the body part as well as the overall comfort and continued use of the brace.

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A number of approaches have been used to make a standardized, single-shaped brace that properly fits the different contours and shapes of a variety of individuals. For example, U.S. Patent 4,628,945 describes an ankle brace fitted with inflatable bladders that may be expanded to conform more closely to an individual's ankle. U.S. Patent 5,014,691 describes using densified, lubricated battings that are reported to conform more easily to an individual's ankle. U.S. Patents 4,946,726 and 5,002,047 describe a resin impregnated foam which conforms to the shape of a limb or joint and then cures to give a permanently formed mold of the limb or joint. U.S. Patent 4,600,618 describes a splint material formed from a thermoplastic material that becomes moldable when heated. A conformable brace may be formed by heating the thermoplastic material, molding the heated plastic around the body part and then allowing the plastic to harden to the conformed shape.

In another example, U.S. Patent 5,027,803 describes a porous, lightweight, easily handled splinting or casting material. The reported material includes a flexible resin impregnated substrate. When the flexible substrate is formed around a body part and the resin is cured, the resin and substrate form a rigid material molded to the shape of the body part. The above patent also reports that the flexible, impregnated substrate may be covered with a special fluorochemical or silicone treated permeable envelop that allows water to pass into the envelop and contact the resin impregnated substrate but prevents the resin from passing out of the envelop. When such a splint or cast is used, the porosity of both the impregnated substrate and the envelop allows moisture due to perspiration or washing to evaporate and assures good hygiene for the underlying skin.

Simply put, the treated envelop prevents resin from leaking away from the substrate material as the resin is handled, molded and cured. In part, the treated envelop preferably has a low surface energy in order to repel the resin and prevent the resin from passing through the envelop. Thus, the treated envelop enables handling the resin impregnated casting material without the use of gloves or resin leakage. The treatment of the envelop with a fluorochemical or a silicone, however, would be expected to make the treated envelop material extremely difficult to adhere to or bond with the flexible substrate or to other materials.

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SUMMARY OF THE INVENTION

The present invention provides an orthopedic brace for protecting and supporting a body part. The brace is made from a laminate material which includes a lightweight, porous, resin-impregnated substrate that is covered on at least one surface with one component of a two component hook and loop fabric fastener system. The hook and loop fabric component that covers the resin impregnated substrate is selected from a material having a low surface energy sufficient to prevent resin leakage. Preferably, the hook and loop fabric component is initially treated with a material such as a fluorochemical or a silicone and then placed over at least one major surface of the substrate in order to prevent the impregnating resin from leaking or penetrating into and through the treated hook and loop component. In spite of the fluorochemical or silicone treatment, the covering hook and loop component is sufficiently adhered directly to the impregnated substrate when the resin is cured. The adhered cover serves as a structural surface or attachment point for straps made from the complementary hook and loop fastener component. These straps may be used to hold the brace in position to a limb and allow repeated removal and reattachment of the brace.

A brace of this invention may be readily formed from an appropriately sized piece of a laminate material that includes a resin impregnated material having at least one major surface covered with one treated member of a hook and loop fabric fastener system. Typically, a shaped laminate material is selected which will properly cover the desired body part. After the appropriately shaped laminate material is selected, the laminate material is contacted with water to initiate the cure of the resin and then the wet material is fitted around the protected body part. The wet material is held in place around the body part with sufficient pressure to mold the laminate material to the shape of the body part and the laminate material is held in the proper position until the resin is sufficiently cured. Generally, the set time is less than ten minutes and preferably the set time is in the range of three to five minutes. As the resin cures, a bond forms between the hook and loop fastener component and the resin impregnated material.

After the resin is cured, the brace is held in the proper position to the body part with straps made from the complementary member of the hook and loop fastener system. When a loop fabric is adhered to the impregnated material, straps or fasteners made of the hook material are used to secure the brace. Similarly, when a hook material is adhered to the impregnated material,

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straps or fasteners of the loop fabric are used to secure the brace. Preferably, the loop fabric is adhered to the impregnated material and a hook material is used for securing purposes.

5 In a specific embodiment of this invention, one side of the laminate material is covered with a fluorochemically treated loop fabric and the opposing side of the laminate material is covered with a layer of a fluorochemically treated padding material such as a fluorochemically treated open-cell foam. In use, the treated open-cell foam layer directly contacts the braced body part.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a plan view of an ankle brace.

Figure 2 is a perspective view of the ankle brace of Fig. 1 fitted to an ankle.

15 Figure 3 is a cross sectional view of the ankle brace of Fig. 1 taken through section line 3-3.

Figure 4 is a plan view of an ankle brace illustrating, in phantom, a two piece resin impregnated substrate joined with an inelastic strap.

20 Figure 5 is a cross-sectional view of the ankle brace of Figure 4 taken through section line 5-5.

Figure 6 is a plan view of a wrist brace.

Figure 7 is a perspective view of the wrist brace of Fig. 6 fitted to a wrist.

Figure 8 is a perspective view of a strap for use with a brace.

25

DETAILED DESCRIPTION

This invention is particularly related to an orthopedic brace comprising a resin impregnated laminate material having one of the exposed major surfaces of the material covered with a loop fabric. The loop fabric functions to allow an easy, convenient, and secure method of fastening the splint or brace to the limb through the use of hook-type fasteners.

30 During application of an ankle brace 20 illustrated in Fig. 1, a padded foam surface on the brace is applied adjacent to the skin and the brace is carefully fitted and molded to the shape of the patient's ankle and lower leg. In Fig. 1 the narrowed portion of the brace 22 fits under a patient's heel.

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When attached, side-to-side or lateral movement of the ankle is thus inhibited or substantially limited by the brace but extension or flexing of the foot is still possible.

Molding may be accomplished by the steps of wetting the brace to activate the impregnated resin, applying the brace to the lower leg and ankle, wrapping an ACE-type elastic wrap around the brace, forming the resin impregnated material to the contours of the ankle and lower leg and then allowing the activated impregnated resin to set. During application of the brace, pressure is applied by the ACE wrap as well as by the molding pressure applied by the clinician. The ACE elastic wrap is removed after the resin has set or cured and the cured brace may be held in place during use using multiple straps of a hook material.

A fitted ankle brace 30 fastened with hook straps 32 to a patient's ankle and lower leg is illustrated in Fig. 2. Alternatively, the hook material adjacent to the exposed limb could be laminated to a second loop fabric for added comfort and to prevent the hooks from irritating the skin.

Another suitable strap is illustrated in Fig. 8. The strap 80 is made of plain backed loop fabric 82 fitted with a D-ring buckle 84 and a first section of hook fastener 86 (illustrated as the dotted section) is fitted to the back of the loop fabric strap near the D-ring. The other end of the strap is fitted with a second section of hook fastener 88 fitted to the front of the loop fabric strap. In use, the D-ring end of the strap is attached to the loop fabric of the brace with the section of hook fastener 86 fitted to the back of the loop fabric strap and the strap is tightened by wrapping the loop fabric strip around the brace, inserting the unattached end of the strap through the D-ring, and securing the hook fastener 88 attached to this end of the strap to the loop fabric section 82 of the strap.

If additional support of the brace is desired or required, additional hook fastener sections made be attached to the strap or to the loop fabric covering of the brace. In particular, additional hook sections may be placed on the strap so that they will attach to the loop fabric of the covering material as the strap is wrapped around the brace and thus "lock" the laminate material on both sides of the ankle together. Alternatively, the strap may be made of a double sided loop fabric and additional double sided hook fastener sections may be adhered to outside surfaces of the brace. In this embodiment, the double sided loop fabric attaches to the additional hook fasteners as the strap is wrapped around the brace. In either of the above embodiments, the

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loop covering is sufficiently adhered to the impregnated substrate when the resin is cured so that the cover may be used as a structural surface or attachment point for the straps and to allow for repeated removal and reattachment of the straps.

5 In one embodiment of this invention, the ankle brace illustrated in Figs. 1 and 2 is formed from a three-part laminate material 10 as illustrated in Fig. 3. In the laminate material of Fig. 3, a unitary one piece multiple layer, resin impregnated water permeable material 11 is held between a treated porous, open-cell foam 12 and a treated loop fabric 13. A layer of transfer adhesive 14 is used to bond the edge of the loop fabric to the foam. Other conventional methods may also be used to attach the loop fabric to the foam such as sewing, tapes, hot melt adhesives, ultrasonic welding, or heat sealing. The treated loop fabric 13 has an inherently low surface energy or is treated with a material containing a fluorochemical or a silicone in order to provide a low surface energy.

An alternative embodiment of an ankle brace 40 of this invention is illustrated in Figs. 4 and 5. In this embodiment, the multilayer resin impregnated material is in two parts or sections. One section 41 fits the medial side of the ankle and the other section 42 fits the lateral section of the ankle. 20 The medial and lateral sections of the impregnated material are connected along the lower edges of both sections with a flexible inelastic strap 43. Strap 43 is flexible enough to bend and conform to the contour of a foot but is less than about 20% extensible when subject to a load of about 5 lb./in. width (8.8 N/cm width).

25 Both sections of the resin impregnated material and the inelastic strap are held between a porous open cell foam 12 and a treated loop fabric 13. The inelastic strap 43 is preferably inserted between the layers of the resin impregnated material as illustrated in Fig. 5. As the impregnated resin cures during the fitting and molding process, the strap becomes bonded to the resin impregnated material. Fig. 5 also illustrates that it is preferred to fold the resin impregnated material along the edge 51 which contacts the strap. When the resin is cured, the folded edge is smoother and less abrasive as compared to a cut or untreated edge and the wear on the strap at this edge is reduced.

35 A variety of materials may be used for the strap 43. Preferred materials are flexible, inelastic and have enough strength to prevent the ankle from excessively flexing in the medial or lateral directions. Suitable materials include knitted, woven, and non-woven fabrics which are made from natural

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fibers such as cotton, rayon, jute, hemp, or silk as well as fabrics which are made from synthetic fibers such as polyesters, polyolefins, halogenated polyolefins, polyamides, polyaramides, polyetheresters, or blends of these materials. A preferred inelastic strap may be made of woven polypropylene
5 yarns. The strap may also be made from a thin sheet of a thermoplastic or thermoset material. Suitable sheets include polyesters, polyolefins, polyamides, polyurethanes, or natural and synthetic rubbers.

Alternatively, the loop fabric 13 alone may be used to connect the two sections 41 and 42. In this embodiment, no additional strap is needed.
10 When a separate strap 43 is not used, it is beneficial to use a loop fabric which has sufficient strength and integrity to allow for repeated use of such a brace.

Fig. 7 illustrates a wrist brace 70 that is formed from a symmetrically shaped laminate blank 60 illustrated in Fig. 6. The laminate blank 60 is symmetrical along the longitudinal axis in order to allow one blank
15 to be used for both a left and a right wrist. The aperture 62 allows the thumb to extend through the brace and permits use of the thumb and fingers if desired. The wrist brace 70 may also be fastened with hook straps 32 to a patient's wrist and lower arm.

In the laminate material illustrated in Figs. 3 and 5, the surface
20 energy of the loop fabric 13 is selected or modified to allow moisture or water to pass through the loop fabric into the resin impregnated material without allowing the resin to pass into and through the loop fabric. Preferably, the surface energy of the loop fabric is treated to provide a surface energy of about 15-40 dynes per centimeter and more preferably to provide a surface energy
25 less than 30 dynes per centimeter when the surface energy is tested according to the method described in Example 6, below. Surprisingly, the low surface energy of the loop fabric does not prevent the cured resin material from adhering to or bonding with the loop fabric.

The fluorochemical or silicone which is added to a loop fabric or
30 a padding material to impart low surface energy is generally applied at low amounts or levels. Suitable amounts are between 0.1-5.0 wt. % fluorochemical or silicone solids based on the weight of the fabric or padding. A preferred amount is between 0.25-2.0 wt. % solids, i.e., about 0.0025-0.020 grams of solids per gram of the material. The treated loop fabric or padding material
35 prevents the impregnated curable resin from leaking through to the exterior surface of the brace. A benefit thus obtained by the orthopedic brace of this

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invention is that the curable resin does not leak through the loop fabric and transfer or bond to the skin of the person who applies the cast and/or the patient but still allows the covering to be porous.

The curable resin used for impregnating the flexible substrate can
5 be any of the curable resins known for use in orthopedic applications. Suitable curable resins include water-curable prepolymers of polyurethanes, cyanoacrylate esters, free radical cured acrylates, methacrylates, acrylamides, and epoxy resins. Particularly preferred curable resins are isocyanate terminated prepolymers, such as curable resins described in U.S. Patent
10 4,667,661 and the resin described in U.S. Patent 4,871,845, Example 1, except that the catalyst is about 1.75 wt. % of the weight of resin.

The cure may be accomplished by a variety of methods such as reaction or activation by water or other agents. The choice of activation agent depends on the particular type of resin used. The preferred mode of activation
15 for use with an isocyanate-terminated polyurethane resin is water or moisture because it is safe, convenient and offers the ability to control set or cure time through both the temperature of the water and the amount of water delivered to the material. Preferred impregnating resins are reported in U.S. Patents
20 4,433,680 and 4,667,661.

When a water curable liquid resin is used in the brace of this invention, activation may be accomplished by a variety of methods but is preferably done by either dipping and squeezing the brace in water, spraying with water, or pumping a damp sponge on the loop fabric side of the brace followed by application to the limb. The later method is particularly useful
25 because the foam padding remains relatively dry.

Both the foam padding and loop fabric should be porous to air and moisture vapor in order to allow sufficient ventilation for the limb. The preferred means of obtaining porosity while preventing resin leakage through the above materials so that the material can be handled without the need for
30 protective gloves is provided by treating the materials with a fluorochemical or silicone disposed on the surface as described in U.S. Patent 5,027,803.

In order to ensure adequate porosity the resin impregnated material is preferably porous to both air and moisture vapor. This may be accomplished by impregnating a curable resin into a porous fabric. The fabric
35 may be made of natural or synthetic fibers (or a blend of these materials) but is preferably fiberglass, polyolefin, polyester, or open-cell foam. The fabric may be woven, knitted, foam, non-woven, or a composite structure of these

materials but preferably the fabric construction is conformable to the limb. A preferred fabric typically has an elongation of at least 20% under a load of 1.67 lb/in width (2.94 N/cm width). Preferred fabrics are disclosed in U.S. Patents 4,433,680, 4,502,479, 4,841,958, 4,898,159, 5,014,403, and
5 4,668,583. Composite fabrics such as fabrics disclosed in U.S. Patent 4,683,877 are also suitable.

In the laminated material illustrated in Figs. 3 and 5, a padded open-cell foam layer 12 is applied adjacent to the limb. Preferably the foam layer is also porous and sufficiently flexible in order to conform and shape to
10 the limb or body part. Open-cell foam materials suitable for use in a brace of this invention are described in U.S. Patents 4,946,726 and 5,002,047. Alternatively, padding materials such as woven or non-woven cast paddings and felts may be used in the present invention.

The foam or padding material may also be treated with a
15 fluorochemical or silicone to prevent leakage of the resin. In addition, as the resin cures, the foam also bonds directly to the impregnated material. Thus, the completely cured brace is a conformable unitary laminated structure which provides protection and support.

Alternatively, a loop fabric or foam may be employed which has
20 inherently low surface energy to prevent resin leakage. This is especially possible for resin impregnated materials having relatively low amounts of resin. For example, padding and loop fabric materials made of polypropylene, polyethylene, polyvinylidene fluoride, polytetrafluoroethylene, or poly(4-methylpentene) having a low surface energy may be used in combination
25 with a resin impregnated material having a relatively low resin content of an isocyanate functional polyurethane prepolymer system.

The surface energy preferably is controlled such that it is low enough to prevent resin leakage in a passive condition during storage but is not so low that the loop fabric does not bond to the impregnated material during
30 application. The loop fabric sufficiently bonds directly to the impregnated material as the resin is cured to allow the hook material to be used to hold the brace in place as well as for the hook material to be applied and removed multiple times without disrupting the cured bond. Bonding of the loop fabric to the impregnated material may be enhanced by preapplying a suitable adhesive to
35 the loop fabric or to the impregnating material either as a continuous film or in an appropriate pattern. Preferably, the entire surface is not occluded with adhesive which would reduce porosity.

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Preferably, the loop fabric is relatively thin, e.g., less than 0.050"-0.1" thick in order to prevent unnecessary added bulk and insulation to the brace. Nevertheless, any thickness may be suitable including relatively lofty materials capable of being utilized as padding materials for applications
5 where both major surfaces are covered with loop fabric material. Loop fabrics found to be particularly useful in this invention are commercially available from Guilford Mills (Greensboro, NC) as STYLES 19762, 18903, and 19029 and Gehring Textiles (New York, NY) as STYLES 1117, 1171 and 1730. STYLES 16128 and 18203 from Guilford Mills may also be useful.

10 The loop fabric may be colored, dyed, or printed in solid colors or designs for a fashionable appearance.

For ease of understanding and description, Figs. 1-7 illustrate the loop fabric attached to the resin impregnated material. The present invention also includes reversing the loop and hook materials, i.e., applying the hook
15 material to the brace and fastening the brace to the body using a loop fabric. Preferably, loop fabrics are used because these materials are both more comfortable and more conformable. Furthermore, exposed loop fabric is not harsh or abrasive and not likely to cling to or snag clothing. The hook materials used to fasten the brace may be of either the mushroom or "J-hook"
20 style. U.S. Patent 5,077,870 and the documents listed in that patent describe various types of hooks and methods used to make such hooks.

The bond of the hook to the loop fabric must be sufficient to secure the brace in place during normal activity. The hook/loop fabric bond is more difficult to achieve and maintain because the loop fabric is bonded to a
25 rigid splint as compared to typical hook/loop fabric applications where both sides and especially the loop fabric are attached to a flexible substrate which facilitates interlocking the hook with the loop fabric. A strong bond in the shear direction is important in order to properly hold the brace in place. In addition, the various materials which make up the brace should sufficiently
30 adhere to each other even after repeated attachment and detachment of the brace. In a preferred brace, the hook fastener material may be removed from the loop fabric many times without any noticeable loss of the loop fabric bond with the impregnated substrate.

The brace may be supplied in precut lengths in a variety of
35 shapes and sizes or in roll form in a variety of widths. Alternatively, the brace may also be supplied as a slab and cut to the desired shape by the clinician. Moisture curable products of this invention must be packaged in moisture

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impervious materials. The preferred packaging material is a flexible aluminum-foil-polymer laminate. Aluminum and steel cans and composites of aluminum and cardboard are also possible.

In the present invention resin repellency is imparted to both the
5 loop fabric and foam padding as well as other materials by a chemical treatment which provides low surface energy to the exposed surface of the material. It has been found that this may be done with materials having very high porosity without inhibiting adequate cure. In addition, sufficient adhesion of a layer of loop fabric to the cured impregnated laminate is obtained without resin leaking
10 through the loop fabric by adjusting the level of the particular fluorochemical or silicone used on the surface of the material.

Suitable fluorochemicals for use to obtain low surface energy layers include any of the fluorochemicals known to those skilled in the art that conventionally provide oil repellency or water repellency to natural or synthetic
15 fibers and films. In general, fluorochemical agents or compositions useful in this invention include fluorochemical compounds or polymers containing fluoroaliphatic radicals or groups.

Fluoroaliphatic radicals are fluorinated, stable, inert, nonpolar, preferably saturated, monovalent moieties which are both hydrophobic and
20 oleophobic. Suitable radicals may be straight chain, branched chain, or, if sufficiently large, cyclic, or combinations thereof, such as alkylcycloaliphatic radicals. The skeletal chain in the fluoroaliphatic radical may include catenary divalent oxygen atoms and/or trivalent nitrogen atoms bonded only to carbon atoms. Preferred fluoroaliphatic radicals will typically have about 3-20 carbon
25 atoms, preferably about 6-12 carbon atoms, and will contain about 40-78 wt. %, preferably about 50-78 wt. %, carbon-bound fluorine. The terminal portion of preferred fluoroaliphatic radicals have at least one trifluoromethyl group, and preferably have a terminal group of at least three fully fluorinated carbon atoms, e.g., $\text{CF}_3\text{CF}_2\text{CF}_2-$. Highly preferred
30 fluoroaliphatic radicals are fully or substantially fluorinated, for example, as for perfluoroalkyl radicals, $\text{F}_{2n+1}\text{C}_n-$.

Classes of fluorochemical agents or compositions useful in this invention include compounds and polymers containing one or more fluoroaliphatic radicals. Examples of such compounds include, for example,
35 fluorochemical urethanes, ureas, esters, amines (and salts thereof), amides,

acids (and salts thereof), carbodiimides, guanidines, allophanates, biurets, and compounds containing two or more of these groups, as well as blends of these compounds.

Useful fluorochemical polymers containing fluoroaliphatic radicals include copolymers of fluorochemical acrylate and/or methacrylate monomers with copolymerizable monomers, including fluorine-containing and fluorine-free monomers, such as methyl methacrylate, butyl acrylate, octadecyl methacrylate, acrylate and methacrylate esters of poly(oxyalkylene) polyol oligomers and polymers, e.g., poly(oxyethylene) glycol dimethacrylate, glycidyl methacrylate, ethylene, vinyl acetate, vinyl chloride, vinylidene chloride, vinylidene fluoride, acrylonitrile, vinyl chloroacetate, isoprene, chloroprene, styrene, butadiene, vinylpyridine, vinyl alkyl esters, vinyl alkyl ketones, acrylic and methacrylic acid, 2-hydroxyethyl acrylate, N-methylolacrylamide, 2-(N,N,N-trimethylammonium)ethyl methacrylate and the like.

The relative amounts of various comonomers which may be used with a particular fluorochemical monomer will generally be selected empirically, and appropriate amounts will depend on the substrate to be treated, the properties desired from the fluorochemical treatment, i.e., the degree of oil and/or water repellency desired, and the mode of application of the substrate.

Useful fluorochemical agents or compositions also include blends of the various classes of fluorochemical compounds and/or polymers described above. Blends of these fluorochemical compounds or polymers with fluorine-free compounds, e.g., N-acyl aziridines, or fluorine-free polymers, e.g., polyacrylates such as poly(methyl methacrylate) and poly(methyl methacrylate-co-decyl acrylate), polysiloxanes and the like may also be used.

The fluorochemical agents or compositions may include non-interfering adjuvants such as wetting agents, emulsifiers, solvents (aqueous and organic), dyes, biocides, fillers, catalysts, curing agents and the like.

The final fluorochemical agent or composition should contain, on a solids basis, at least about 5 wt. %, preferably at least about 10 wt. % carbon-bound fluorine in order to impart the benefits described in this invention.

Such fluorochemical agents are generally known and commercially available as perfluoroaliphatic group bearing resin repellent agents which contain at least 5 wt. % of fluorine, preferably 7-12 wt. % of fluorine.

Known formulations include compounds formed by the reaction of the perfluoroaliphatic thioglycols with diisocyanates to give perfluoroaliphatic group-bearing polyurethanes. These products are normally applied in aqueous dispersion for fiber treatment. Such reaction products are, e.g., described in

5 U.S. Patent 4,054,592.

Another group of suitable compounds are perfluoroaliphatic group-bearing N-methylol condensation products. These compounds are described in U.S. Patent 4,477,498.

Another group of compounds which may be used in dispersions

10 includes perfluoroaliphatic group-bearing polycarbodimides which may be obtained by reaction of perfluoroaliphatic sulfonamide alkanols with polyisocyanates in the presence of suitable catalysts. This class of compounds can be used by itself, but often is used with other fluoroaliphatic radical bearing compounds, especially with copolymers such as known polymers bearing

15 fluoroaliphatic residues as well as condensation polymers, such as polyesters and polyamides which contain the corresponding perfluoroaliphatic groups. Preferred copolymers include fluorine-containing acrylates and methacrylates which may contain different fluorine-free vinyl compounds as comonomers. See, e.g., patents DE-A 2 310 801 and GB-A 1.413.051/052 which also report

20 the manufacture of fluorine-containing polycarbodimides as well as the combination of these compounds with each other.

Besides the listed perfluoroaliphatic group-bearing agents, other fluorochemical components may be used, for example, fluoroaliphatic radical-bearing guanidines reported in U.S. Patent 4,540,479, fluoroaliphatic

25 radical-bearing allophanates reported in U.S. Patent 4,606,737, and fluoroaliphatic radical-bearing biurets reported in U.S. Patent 4,668,406. These classes are mostly used in combination. Others include fluoralkyl-substituted siloxanes, e.g., $\text{CF}_3(\text{CF}_2)_6\text{CH}_2\text{O}(\text{CH}_2)_3\text{Si}(\text{OC}_2\text{H}_5)_3$. The useful compounds listed above contain, in general, one or more

30 perfluoroaliphatic residues with preferably at least 4 carbon atoms, preferably 6-14 atoms per residue.

An exemplary preferred fluorochemical is a formulation of 70% solvents and 30% emulsified solid fluorochemical polymers. The formulation includes 11% methyl isobutyl ketone, 6% ethylene glycol as organic solvents,

35 and 53% water. The fluorochemical polymers are a 50/50 blend of a 5/95 copolymer of butyl acrylate and $\text{C}_8\text{F}_{17}\text{SO}_2\text{N}(\text{CH}_3)\text{C}_2\text{H}_4\text{OCOCH}=\text{CH}_2$ prepared as described in U.S. Patent 3,816,229. The second component of the 50/50

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blend is a copolymer prepared from one mole of a tri-functional phenyl isocyanate (available from the Upjohn Company, Kalamazoo, MI, under the name PAPI), two moles of $C_8F_{17}N(CH_2CH_3)CH_2CH_2OH$ and one mole of stearyl alcohol prepared as described in U.S. Patent 4,401,780. Emulsifiers
5 used are conventional commercially available materials such as polyethoxylated quaternary ammonium compounds (available under the name 5% ETHOQUAD 18/15) and 7.5% of a 50/50 mixture of $C_8F_{17}SO_2NHC_3H_6N(CH_3)_3Cl$ and a polyethoxylated sorbitan monooleate (available from ICI Limited, Wilmington, DE under the name TWEEN 80). Such fluorochemicals are non-yellowing and
10 non-irritating to the skin as well as providing treated materials that are stable with excellent long term aging properties.

Exemplary fluorochemicals are available commercially and include ready to use formulations such as SCOTCHGARD FABRIC PROTECTORS FC-214 and FC-270, SCOTCH-RELEASE BRAND FABRIC
15 TREATMENT FC-248, SCOTCHGARD BRAND FABRIC PROTECTOR FC-324, 3M BRAND TEXTILE CHEMICAL FC-461, 3M BRAND TEXTILE CHEMICAL FC-210, 3M BRAND TEXTILE CHEMICAL FC-828, 3M BRAND FC-393, FC-326, FC-905 and FC-214B, and SCOTCHGARD BRAND RAIN AND STAIN REPELLER FC-232 (3M, St. Paul, MN).
20 Another commercially available material includes SOIL SHEDD (available from duPont DeNemours and Company, Wilmington, DE).

Suitable silicones for use to obtain the low surface energy layers of this invention include any of the silicones known to those skilled in the art to provide water repellency and oil repellency to fibers and films. Silicone fluids
25 typically consist of linear polymers of rather low molecular weight, typically having average molecular weights of about 4,000-25,000. Most commonly the polymers are polydimethylsiloxanes.

Silicone fluids with enhanced thermal stability include silicone containing both methyl and phenyl groups are used. Generally, the phenyl
30 groups make up 10-45% of the total number of substituent groups present. Such silicones are generally obtained by hydrolysis of mixtures of methyl and phenylchlorosilane.

Silicone fluids for use in textile treatment may incorporate reactive groups so that they may be cross-linked to give a permanent finish.
35 Commonly, these fluids contain silicon-hydrogen bonds (introduced by including methyldichlorosilane in the polymerization system) and cross-linking occurs on heating with alkali.

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Examples of suitable silicones are those available from Dow-Corning Corporation (Midland, MI) such as C2-0563 silicone and from General Electric Corporation such as GE-SS4098 silicone.

5 EXAMPLES

The following examples are provided to illustrate specific embodiments of this invention and should not be considered to limit the invention which is defined in the appended claims.

10 Example 1

Eight layers, each layer 12 inches (30.5 cm) long and 3 inches (7.6 cm) wide of SCOTCHCAST 2 BRAND CASTING TAPE (commercially available from 3M, St. Paul, MN) made with an isocyanate functional water curable resin were laid flat in the center of a 13-inch (33 cm) long, 4.5-inch (11.4 cm) wide and 1/4-inch (0.64 cm) thick layer of open-cell polyurethane foam (commercially available as FOAM A1536M from Foamex, Auburn, IN). The foam had been treated with SCOTCH BRAND FABRIC PROTECTOR FC-270 (commercially available from 3M, St. Paul, MN) by soaking the foam in aqueous suspension of 2.5 wt. % FC-270, squeezing out excess by passing the foam through a nip roller and drying the foam for about 2-5 minutes at 340°F (170°C) and then for about two hours at 250°F (120°C) to provide about 1.25 wt. % solids of FC-270 on the surface of the foam.

A 2-mil (0.051 mm) strip of 1/2-inch (1.3 cm) wide transfer adhesive (commercially available from 3M, St. Paul, MN as SCOTCH BRAND ADHESIVE TAPE NO. 950) was applied to the exposed outer edges of the foam strip. A layer of treated loop fabric 4.5 inches (11.4 cm) wide and 13 inches (33 cm) long was placed over the eight layers of casting tape and adhered to the transfer adhesive to form a brace. This procedure was repeated to provide three braces.

The treated loop fabric was initially pretreated by soaking three pieces of loop fabric (each piece 4.5 inches (11.4 cm) wide and 13 inches (33 cm) long, commercially available from Guilford Mills, Greensboro, NC as STYLE NO. 19762) in three dilutions of SCOTCH BRAND FABRIC PROTECTOR FC-270 (2% solids, 1.5% solids, and 1.0% solids, one piece per dilution) using the procedures described in U.S. Patent No. 5,027,803. The three soaked pieces were dried by heating in a convection oven at 330°F (166°C) for three minutes.

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The three braces were cured by dipping the braces into water at ambient temperature, hand squeezing three times under water, removing the brace from the water, squeezing the brace to remove excess water and forming the brace around a two-inch diameter cylinder.

- 5 Two strips of hook material (woven, mushroom hook, one-inch wide, commercially available from Aplix, Charlotte, NC as No. 200 mushroom hook) were adhered to the loop fabric layer and the brace was allowed to fully cure. After hardening the loop fabric remained adhered to the casting tape. The hook held firmly with good shear strength when fastened to the loop fabric, but released nicely by pulling normal to the loop fabric.

Example 2

- Using the procedure described in Example 1, eight layers, each layer 12 inches (30.5 cm) long and 3 inches (7.6 cm) wide, of SCOTCHCAST 2 BRAND CASTING TAPE were laid flat in the center of a 13-inch (33 cm) long, 4.5-inch (11.4 cm) wide, and 1/4-inch (0.64 cm) thick strip of foam described in Example 1. A 2-mil strip of 1/2-inch (1.3 cm) wide transfer adhesive (SCOTCH BRAND TRANSFER ADHESIVE NO. 950) was again used to adhere a 4.5-inch (11.4 cm) wide and 13-inch (33 cm) long layer of treated loop fabric to the foam.

- 20 The treated loop fabric was Guilford Mills FABRIC STYLE NO. 19762 which had been treated as described in Example 1 with 2% solids SCOTCHGARD BRAND FABRIC PROTECTOR FC-270 using the procedure as described in U.S. Patent No. 5,027,803.

- 25 To the exposed side of the foam layer was adhered two strips of one-inch wide and six-inch long hook material (woven, j-style hook, HOOK PN 194894, commercially available from Velcro Fastening Systems, Manchester, NH).

- 30 The brace was cured as described in Example 1 except that the brace was molded to a wrist and the hooks were found to fasten to the loop fabric layer to hold the brace firmly in place on the wrist and to release smoothly by pulling normal to the loop fabric.

Example 3

- 35 Using the procedure described in Example 1, loop fabric pieces one inch (2.5 cm) wide and six inches (15.2 cm) long (commercially available from Gehring Textiles, New York, NY as STYLE NO. 1171) were treated with

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zero, 1.0, 1.5, and 2.0 wt. % solids (two loop fabric sections at each solids level) of SCOTCH BRAND FABRIC PROTECTOR FC-270 (commercially available from 3M, St. Paul, MN). After drying, the fabric pieces were placed on a 12-inch (30.5 cm) long, 3-inch (7.6 cm) wide section of SCOTCHCAST 2 BRAND CASTING TAPE (commercially available from 3M, St. Paul, MN) which had been dipped in water for 30 seconds.

A 47 g metal plate (1 inch (2.5 cm) x 6 inch (15.2 cm) x 1/8 inch (0.3 cm)) was used to cover each piece of the loop fabric. A five pound (2.3 kg) weight was then placed on the metal strip for 30 seconds. The weight and the metal strip were removed. All of the samples were then allowed to cure under ambient conditions (about 23°C) for several days.

A peel test was run on each cured sample using an Instron Model 1122 instrument equipped with a Sintech Test Works Version 2.1 (available from Instron Corp., Park Ridge, IL and Sintech, Research Triangle Park, NC, respectively). A one-inch section of the loop fabric was peeled back and a tape leader using SCOTCH BRAND DOUBLE COATED FOAM TAPE NO. 401 DCJ (commercially available from 3M, St. Paul, MN) was attached to each loop fabric piece. A 180° peel test was then performed using the Instron instrument and the load required to peel the loop fabric was measured and the average between the 2 samples was calculated. For 0% solids treatment the average load was 256 g, for 1% about 50 g, for 1.5% about 42 g, for 2.0% about 38 g.

This test demonstrates that increasing the amount of solids in the fluorochemical treatment reduces the strength of the bond of the loop fabric to the casting tape, but that a significant strength of bonding surprisingly remains.

Example 4

Eight layers, each layer 12 inches (30.5 cm) long and 3 inches (7.6 cm) wide of SCOTCHCAST 2 BRAND CASTING TAPE (commercially available from 3M, St. Paul, MN) made with an isocyanate functional water curable resin were laid flat in the center of a 13-inch (33 cm) long, 4.5-inch (11.4 cm) wide and 1/4-inch (0.64 cm) thick layer of fluorochemically treated open cell polyurethane foam. A 2-mil (0.051 mm) strip of 1/2-inch (1.3 cm) wide transfer adhesive (available from 3M, St. Paul, MN as SCOTCH BRAND ADHESIVE TAPE NO. 950) was applied to the exposed edges of the foam strip. A layer of treated nylon loop fabric (commercially available from Gehring Textiles, Inc., New York, NY as NYLON NO. 1171) 4.5 inches

(11.4 cm) wide and 13 inches (33 cm) long was placed over the eight layers of casting tape and adhered to the transfer adhesive to form a brace. This procedure was repeated to provide twelve braces. The braces, two sets of six, were sealed in conventional polymer laminate-aluminum foil pouches.

- 5 The loop fabric described above was treated by soaking pieces of 4.5-inch (11.4 cm) wide and 13-inch (33 cm) long loop fabric in 3 dilutions of either SCOTCH BRAND FABRIC PROTECTOR FC-214 (available from 3M, St. Paul, MN) or General Electric Silicone Polymer Solution SS 4098 (available from General Electric, Waterford, NY) (2% solids, 1.0% solids, and 0.5% solids, two pieces per dilution) using the procedures described in U.S. Patent No. 5,027,803. The soaked pieces were dried by heating in a convection oven at 300°F (149°C) for three minutes.

- 15 The fluorochemically treated foam was treated by soaking the foam identified above in a 2% solid solution of SCOTCH BRAND FABRIC PROTECTOR FC-270 (commercially available from 3M, St. Paul, MN) as described in Example 1 above.

- 20 One set of six sealed braces was cured by removing a brace from the pouch, dipping the brace in water (24°C) and squeezing three times while submerged, removing the brace from the water and squeezing to remove excess water, blotting the foam dry on a cotton towel, applying the brace to a volunteer's arm in conventional overlapped wrist splint configuration, covering and supporting the brace with an ACE elastic wrap, molding the brace by hand to fit the arm, and, after about six minutes from the time of dipping, removing the brace from the arm. After drying the molded braces for about four hours under ambient conditions, the bond of the loop fabric of the brace to the cured SCOTCHCAST 2 BRAND CASTING TAPE was measured by repeated attachment and removal of two types of hook strips at the same site on the cured brace. The number of cycles (up to 50) before failure of the loop fabric-casting tape adhesive bond was measured. Surprisingly, both
25 fluorochemical and silicone treated loop fabric adhered well to the casting tapes.

- 35 The second set of six braces was placed in a 120°F (49°C) oven in sealed pouches for two weeks. These pouches were then allowed to cool to ambient temperature and the braces were removed from the pouches in a dry (less than four percent relative humidity) environment. Each brace was inspected for resin leakage. None of the braces showed any sign of resin leakage.

TABLE I
Evaluation of Adhesion of Treated Loop Fabric to Cured Casting Tape

Number of removals per site	FC-214 Treated						Silicone Polymer Treated					
	0.5% Aplix*	Velcro**	1.0% Aplix	Velcro	2.0% Aplix	Velcro	0.5% Aplix	Velcro	1.0% Aplix	Velcro	2.0% Aplix	Velcro
	>50	18	>50	>50	16	>50	>50	>50	25	6	>50	>50
>50		17	>50	>50	18	>50	>50	>50	>50	14	>50	>50
30									14	>50		

* Aplix No. 200, Nylon/polypolypropylene, Product No. MX25M000, Aplix Corp., Charlotte, NC

** Velcro Silver-grey 324, nylon, Hook No. 088, Tape 0199, Product No. 194,894, Velcro USA, Manchester, NH

Example 5

The following experiment established the minimum pressure necessary to bond a fluorochemically treated loop fabric to a cured resin impregnated casting tape.

- 5 In a constant temperature (23°C) constant humidity (45-50% RH) room, a foam (1/4-inch (0.64 cm) open-cell polyurethane foam, STYLE A1536M, Foamex, Auburn, IN) that was fluorochemically treated with SCOTCH BRAND FABRIC PROTECTANT FC-270 (3M, St. Paul, MN) to approximately 1.25 wt. % solids as described in Example 1 was placed on a
10 flat horizontal table. An eight layer casting tape laminate (SCOTCHCAST 2 CASTING TAPE, 3M, St. Paul, MN) was removed from the moisture proof pouch and immediately laid on the foam with the wale side up. On top of the laminate was immediately placed a loop fabric (Gehring Textiles, P.N. 1171, New York, NY) which was fluorochemically treated with SCOTCH BRAND
15 FABRIC PROTECTANT FC-270 (commercially available from 3M, St. Paul, MN) to approximately 1.25 wt. % solids. The loop fabric had been previously marked with a marking pen for placement of stainless steel weights. The weights were spaced four inches apart center to center. The total amount of weights listed in Table 2 below were placed on the fabric immediately after
20 placing the loop fabric over the uncured casting tape. For each weight level, three individual weight sets were applied to the loop fabric. The stainless steel weights were stacked on top of each other to yield the listed amounts.

- For the first set of samples, Set 1, the weights were allowed to stay in place for 2.5 hours. For the second set, Set 2, the weights were
25 allowed to stay in place overnight. In both sets, the bond of the loop fabric to the resin impregnated casting tape was not tested until 24 hours after initially placing the weights. In order to test the cured bond, two hook materials were used; Set 1 used a mushroom-type hook (Aplix, Charlotte, NC, #200 mushroom, 1" (2.5 cm) wide) and Set 2 used a J-type hook (Velcro USA,
30 Manchester, N.H., J Hook #088, 1" (2.5 cm) wide P.N. 194894). For each hook material the bond was tested by gently placing a 1" x 1" piece of the hook fabric in the center of the site where the weight had resided (hook side down) and placing on top of the hook fabric a 1.00 kg weight for five seconds. The weight was removed and the hook pulled off normal to the loop fabric. The
35 number of times the hook was removed without the loop fabric/casting tape bond breaking was recorded and is listed in Table 2.

TABLE 2

	Weight (g) 1" x 2"	Set 1				Set 2			
		1	2	3	Mean	1	2	3	Mean
5	0	0	0	0	0	0	0	0	0
	33	0	0	0	0	0	0	0	0
	50	0	0	2	0.67	0	0	0	0
	68	5	4	2	3.67	0	0	0	0
	100	0	0	2	0.67	6	8	7	7
10	162	6	4	3	4.3	10	32	24	22
	236	4	0	10	4.7	5	5	8	6
	372	20	18	25	21	>50	>50	NA	>50

- 15 The above data indicate that a pressure of about 180 grams per square inch is sufficient to allow the loop fabric to bond to the cured resin.

Example 6

- 20 The method for measuring the surface energy was AATCC Test Method 118-1983, with the modifications described below. Surface energies measured according to this modified test method are hereinafter referred to as "apparent" surface energies. AATCC test method 118-1983 determines the surface energy of a fabric by evaluating the fabric's resistance to wetting by a series of selected hydrocarbon compositions. The hydrocarbons set forth in
- 25 AATCC 118-1983, however, only provide for measurements of surface energy from about 19.8 to 27.3 dynes per centimeter at 25°C. This range is extended by employing various mixtures of methanol and water in the fabric resistance test. The compositions and their representative surface tensions are as follows.

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	Liquid No.	Composition	Surface Tension (dynes/cm at 25°C)
5	1	n-heptane	19.8
	2	n-octane	21.4
	3	n-decane	23.5
	4	n-dodecane	24.7
	5	n-tetradecane	26.4
	6	n-hexadecane	27.3
10			
	Liquid No.	Volume % Methanol/Water	Surface Tension (dynes/cm at 20°C)
15	7	65/45	30
	8	53/47	35
	9	40/60	40
	10	25/75	45
	11	21/79	50
	12	15/85	55
	13	8.5/91.5	60
	14	5/95	65
20	15	0/100	73

The test procedure is as follows. A specimen of the covering material is placed flat on a smooth, horizontal surface. Using the method of AATCC 118-1983 except that beginning with the lowest number test liquid, 5 drops of the liquid are placed on the surface of the fabric on the side which will face the resin impregnated sheet in various locations. If three of the five drops wick into the fabric within 60 seconds, the liquid of the next higher surface energy is used. When at least 3 drops remain on the fabric surface the apparent surface tension is recorded as the range of the last two liquids.

A preferable surface energy has been determined to be about 15-40 dynes per centimeter and more preferably less than 30 dynes per centimeter for the tested polyurethane resins.

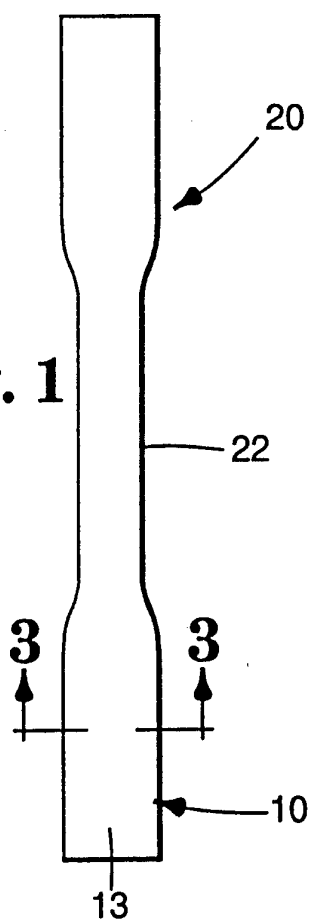
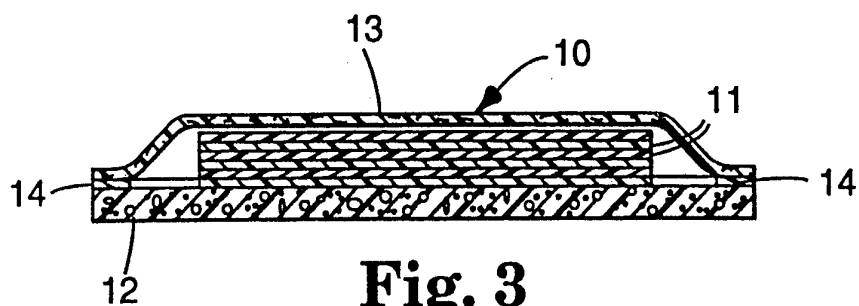
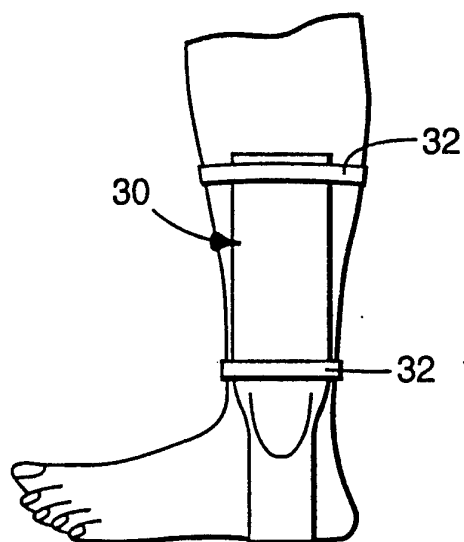
CLAIMS

1. An orthopedic brace adapted to removably immobilize a body part comprising
 - 5 i) a flexible substrate impregnated with a curable resin, and
 - ii) a cover covering at least one major surface of the substrate comprising at least one component of a two component hook and loop fabric fastener system having a low surface energy to prevent resin leakage wherein the hook and loop component is sufficiently adhered directly to the
 - 10 impregnated substrate when the resin is cured in order to provide a fastening surface to hold the orthopedic brace to the immobilized body part and to allow multiple removal and attachment of the brace and repositioning of a fastener to the bound hook and loop member.
- 15 2. The orthopedic brace of claim 1 wherein the hook and loop component is treated with a material selected from the group consisting of a fluorochemical and a silicone.
- 20 3. The orthopedic brace of claim 1 wherein the hook and loop component is made from a low surface energy material selected from the group consisting of polypropylene, polyethylene, polyvinylidene fluoride, polytetrafluoroethylene, poly(4-methylpentene), and nylon.
- 25 4. The orthopedic brace of claim 1 further comprising a padding material attached to a surface of the substrate which contacts a body part.
- 30 5. The orthopedic brace of claim 4 wherein the padding is treated with a sufficient amount of a material selected from the group consisting of a fluorochemical and a silicone to prevent resin leakage.
6. The orthopedic brace of claim 4 wherein the padding material is porous, open-cell foam.
- 35 7. The orthopedic brace of claim 1 wherein the brace is adapted to immobilize an ankle.

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8. The orthopedic brace of claim 7 wherein the flexible substrate impregnated with a curable resin is a first and a second multilayer laminate adapted to fit medial and lateral sides of an ankle and wherein edges of the first and second multilayer laminates are attached to an inelastic strap adapted to fit
- 5 underneath a foot and join the first multilayer laminate to the second multilayer laminate.

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Fig. 1**Fig. 2****Fig. 3**

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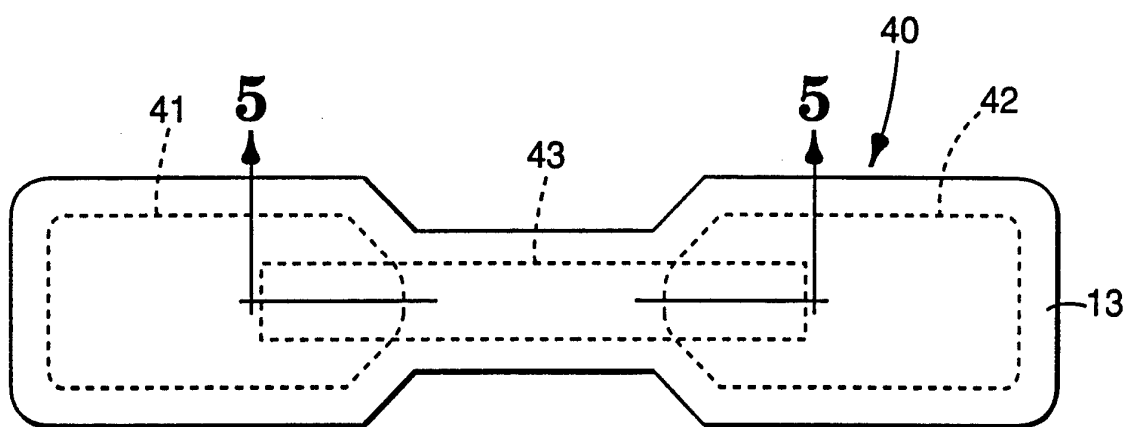


Fig. 4

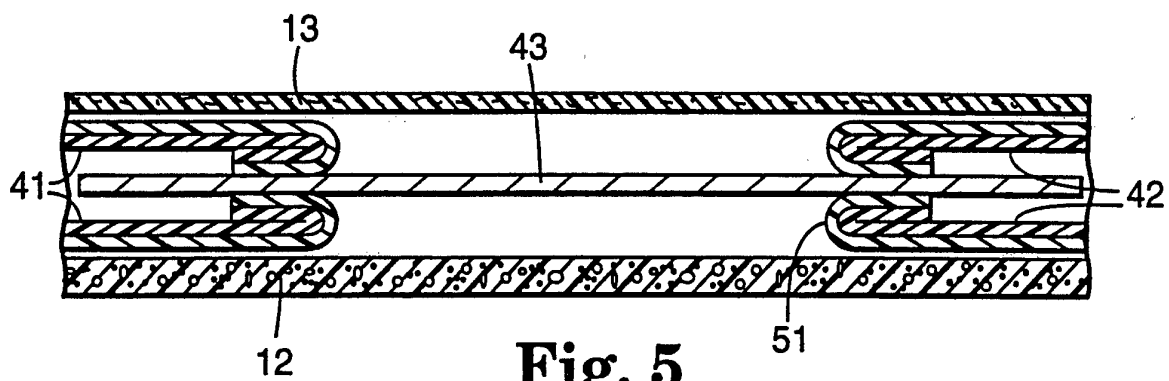


Fig. 5

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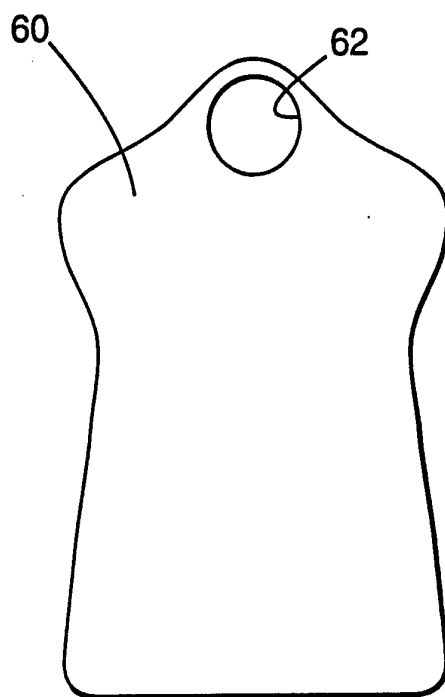


Fig. 6

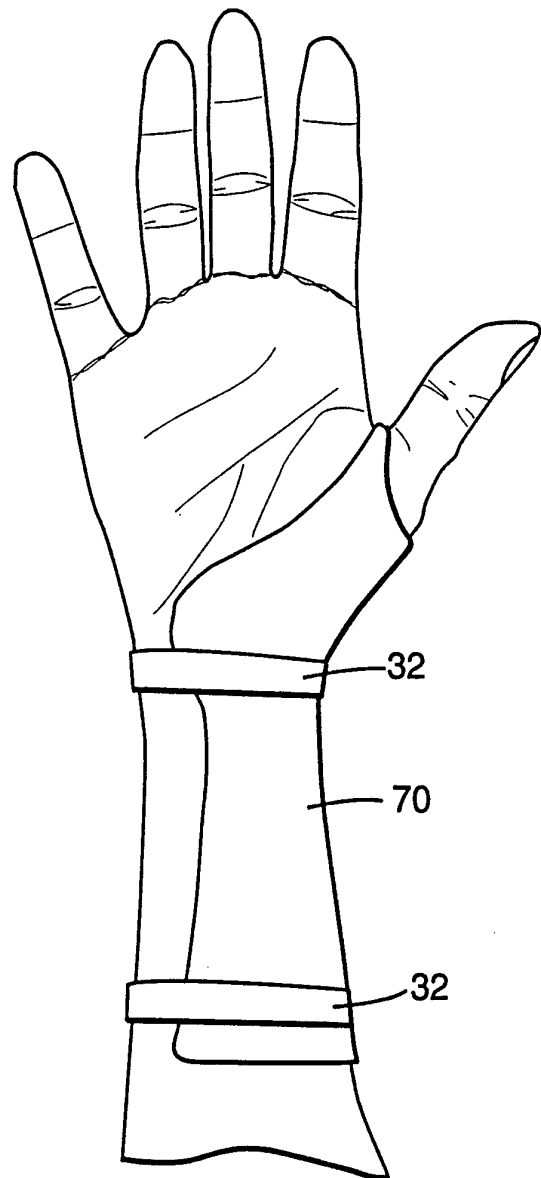
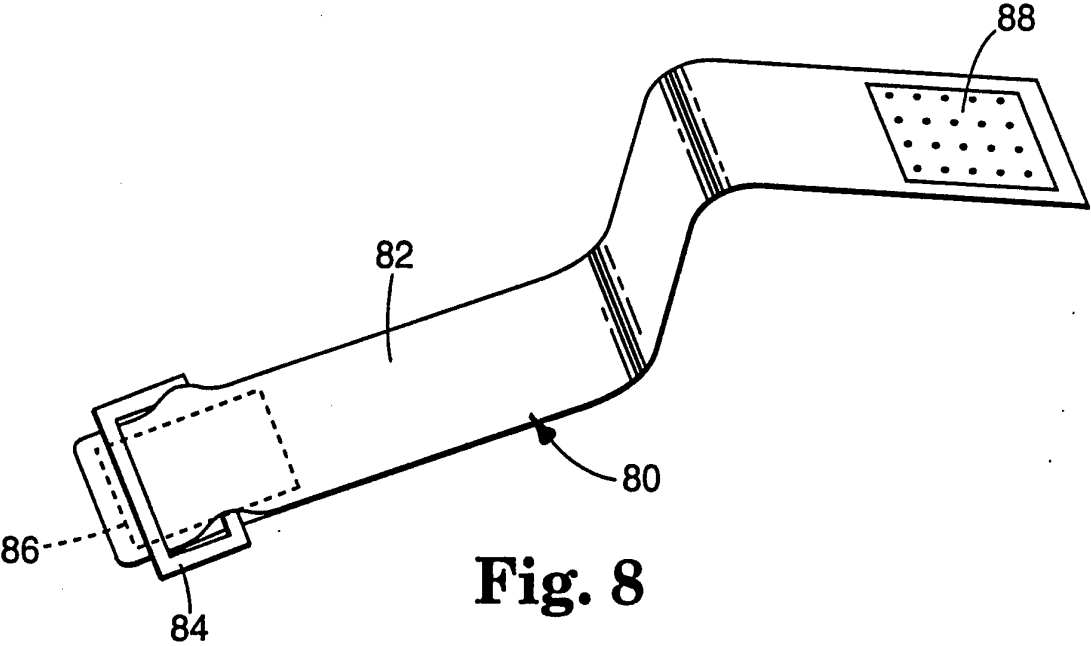


Fig. 7

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 93/08617

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61F 5/04, A61F 13/04 // A61L 15/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61F, A61L

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB, A, 2172806 (TECNOL INC.), 1 October 1986 (01.10.86), page 2, line 14 - line 41, figures 1-2 --	1-2,4-6
Y	US, A, 5027803 (M.T. SCHOLZ ET AL), 2 July 1991 (02.07.91), figure 3, claims 1,3,10 --	1-2,4-6
A	EP, A2, 0061642 (BAYER AG), 6 October 1982 (06.10.82), figure 4, abstract --	1,4,6-7
A	US, A, 4280489 (G.W. JOHNSON, JR.), 28 July 1981 (28.07.81), figures 1,3 --	1,7-8

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

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Date of the actual completion of the international search

Date of mailing of the international search report

3 February 1994

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Name and mailing address of the International Searching Authority

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 93/08617

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4628917 (A.J. CAMPAGNA, JR. ET AL), 16 December 1986 (16.12.86), figures 1,6 -- -----	1,4,6

INTERNATIONAL SEARCH REPORT
Information on patent family members

30/12/93

International application No.
PCT/US 93/08617

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
GB-A-	2172806	01/10/86	NONE		
US-A-	5027803	02/07/91	CA-A-	1316426	20/04/93
			DE-U-	6890436	25/02/93
			EP-A,B-	0352095	24/01/90
			JP-A-	2074253	14/03/90
EP-A2-	0061642	06/10/82	AU-B-	553824	31/07/86
			AU-A-	8189182	30/09/82
			CA-A-	1184817	02/04/85
			US-A-	4442833	17/04/84
US-A-	4280489	28/07/81	CA-A-	1133349	12/10/82
			DE-A,C-	2913606	18/10/79
			FR-A,B-	2421598	02/11/79
			GB-A,B-	2019724	07/11/79
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			JP-A-	54135483	20/10/79
			JP-B-	61030580	14/07/86
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