United States Patent [19]

Arluck

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[54] **ORTHOPEDIC DEVICE**

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[52] **U.S. Cl.** ..... **128/90**; 128/87 R; 161/88; 161/227

[51] **Int. Cl.**[2] **A61F 5/04**

[58] **Field of Search** 128/90, 89, 87; 161/88, 161/89, 227, 257

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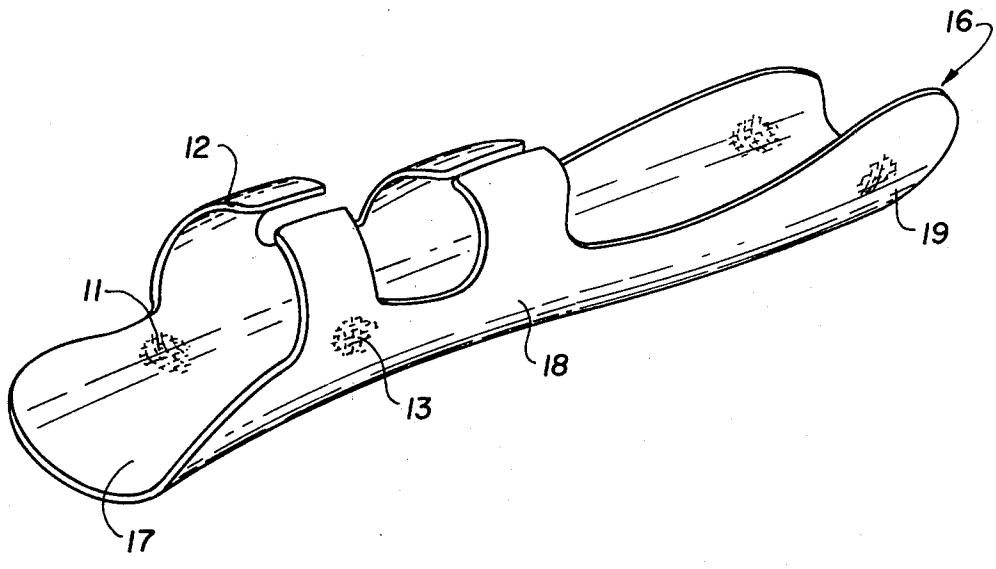
[57] **ABSTRACT**

An orthopedic device comprising a plastic sheet member having one side covered with an insulating fabric layer which is substantially thinner than said plastic sheet member. The plastic sheet member has a tensile strength of at least 2,000 psi. The orthopedic device preferably comprises a plastic sheet member having one side covered with a thin insulating fabric and the other side covered with a thin protective fabric. The orthopedic device is formable at temperatures above 130°F.

35 Claims, 5 Drawing Figures



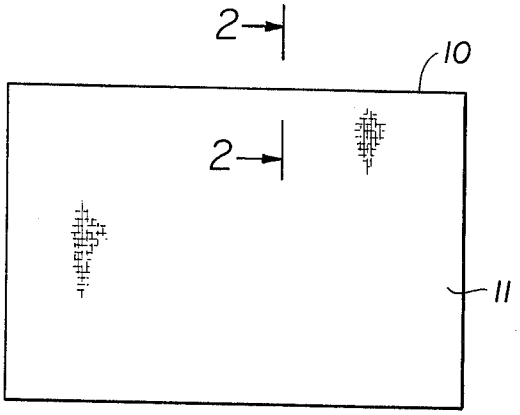


FIG.1

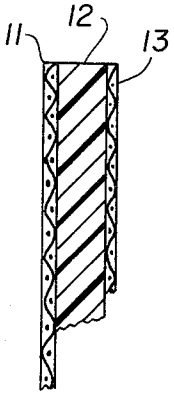


FIG.2a

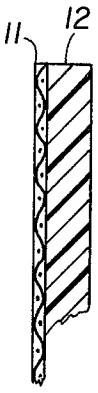


FIG.2b

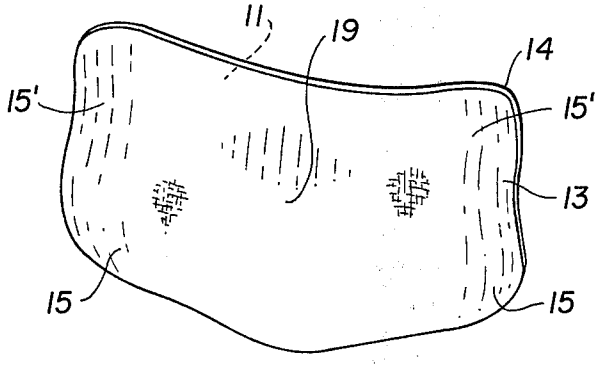


FIG.3

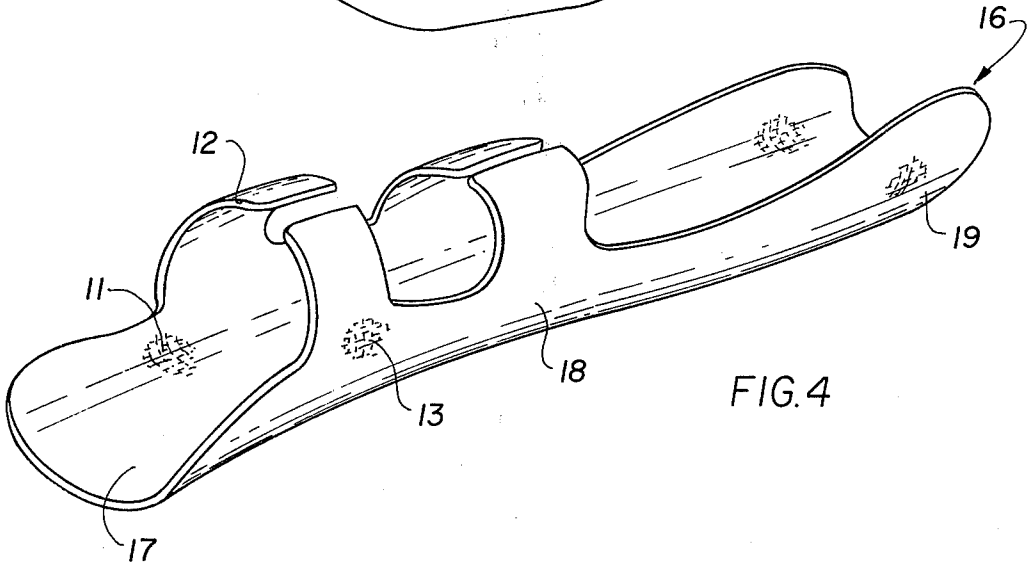


FIG.4

ORTHOPEDIC DEVICE

BACKGROUND OF THE INVENTION

This invention relates to orthopedic devices having broad medical applications. These devices are used to support, position, protect, immobilize and/or restrain portions of the body.

Orthopedic devices is a broad term that is used to described medical structures such as casts, splints, supports, braces and other means utilized to support, immobilize restrain, protect and position body portions. They are used in many fields, including the physical medicine and rehabilitation field, general medicine, neurological field, and the veterinary field. They are also used to prevent recurrance of previous disabilities, and to prevent discomfiture and subsequent disability.

Different types of the known orthopedic devices have specific uses and it has been necessary to select a specific type of orthopedic device to meet the requirements of a specific intended usage. The treatement of fractures usually requires total immobilization. Casts made of Plaster of Paris (plaster) are commonly used for this purpose. Plaster casts have the disadvantage that it takes hours to harden, the cast is excessively heavy, it has poor compression strength and is readily crushed or broken, and it has poor resistance to water and poor x-ray penetrability. Splints have been made of wood and metal and even plastic. Those synthetic base orthopedic devices which have been proposed and/or introduced commercially have had disadvantages inherent in some or all uses of the material.

Orthopedic devices should desirably be lightweight. They should be capable of immobilizing a portion of the body when that is the intended purpose. Similarly, they should be capable of resiliant support when that is required. The orthopedic device should be capable of being formed in a practical manner and without discomfort to the patient. Additionally, the orthopedic device should not have properties which irritate the patient during the period in which it is in service.

It is an object of this invention to provide an orthopedic device having wide applicability and a unique combination of desirable properties.

SUBJECT MATTER OF THE INVENTION

The orthopedic device of the present invention is a plastic sheet member having at least one side covered with a thermally insulating fabric layer. The plastic sheet member is between about 50 mils and 120 mils thick. The insulating fabric layer is between about 10 mils and 22 mils thick. It is capable of being molded (formed) with application of normal finger pressure when the plastic is at a temperature above 129°–130°F. When the device is heated to substantially above 130°F, e.g., 165°–350°F, and allowed to cool in air and ultimately on the patient as it is being formed, the temperature at the outside of the insulating fabric is at least about 25°F cooler than the plastic member.

The orthopedic device preferably has both sides of the plastic sheet member covered with fabric. The side covered with the insulating fabric is the inside surface of the device and is the side intended to be placed against the body surface during service. The other side (the outside of the device) is covered with a fabric layer (referred to herein as the "outside" or "other" fabric layer) which protects the plastic. The insulating layer is bonded to the plastic and preferably the outside

fabric layer is bonded to the plastic sheet member. The bonding is preferably accomplished by bonding the plastic sheet member and the fabric layer with an adhesive which may partially impregnate the fabric layer. The outside fabric layer is between about 4 and 22 mils thick.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a rectangular blank having a construction in accordance with the present invention.

FIG. 2*a* is an enlarged cross section along the line 2—2 of FIG. 1 of one embodiment of the invention.

FIG. 2*b* is an enlarged cross section along the line 2—2 of FIG. 1 of another embodiment of the invention.

FIG. 3 is a perspective of a formed back support having a construction in accordance with the embodiment of FIG. 2*a;* and

FIG. 4 is a perspective of a formed arm splint having a construction in accordance with the embodiment of FIG. 2*a*.

The insulating layer of fabric is a woven, felted, matted, batted or knitted fabric between about 10 mils and 22 mils thick. The preferred insulating fabric is a woven blend, preferably 50:50, of a high-temperature aromatic polyamide, now generically classified as an aramid, and a high-temperature cross-linked phenol-formaldehyde fiber such as the no-burn fabrics marketed by Collins & Aikman Corp. which are blends of 50% Kynol and 50% Nomex. Nomex is a trademarked product of the Du Pont Company and is the high-temperature aromatic polyamide. Kynol is a trademarked product of the Carborundum Company and is a cross-linked phenol-formaldehyde fiber, such as that described in U.S. Pat. No. 3,650,102. An aramid fabric may also be used.

The insulated fabrics may be used in weights of about 4 oz. per square yard, up to about 16 oz. per square yard. The preferred weight is about 5 to 8 oz. per square yard.

The insulating fabric preferably should have a coefficient of heat transfer below about 2 cal/-sec/cm^2/cm/°C$\times 10^{-4}$, and more preferably below about 1.6 cal/sec/cm^2/cm/°C$\times 10^{-4}$.

The insulating fabric layer is affixed to the central plastic member with an adhesive, preferably a thermoplastic adhesive. Since relatively high shaping and molding temperatures, e.g., 400°F, may be used to shape the orthopedic device, the thermoplastic adhesive should be one which will remain bonded to the fabric and to the central plastic member at the temperatures used to heat and form the device. It is preferred that it should retain said property at temperatures above 200°F and for an added safety factor, it is preferred that it should retain said property at above about 350°F for devices which will be shaped before service.

The outside adhesive may be a polyurethane; preferably a flexible thermoplastic polyester type polyurethane adhesive. This material also has the advantages of good resistance to perspiration, washing and dry cleaning. Although the polyester type polyurethanes are preferred, polyether types may also be used. Thermosetting polyurethane adhesives may also be used, such as hydroxyl terminated hexanediol adipate polyester cross linked with about 4% of 4,4'-diphenyl methane diisocyanate.

An extruded polyester sheet about 2½–3 mils thick is also a preferred adhesive. It is positioned between the

central plastic sheet and the fabric layer and the materials heated to about 350°F at a pressure of 1–2 psi to affix the fabric to the central plastic member.

Alternate but less preferred adhesives include the acrylates, such as polyethyl acrylate, polybutyl acrylate, and polyethylhexyl acrylate; and a polyvinyl acetate homopolymer and a copolymer of ethylene and vinyl acetate. The adhesive may also be blends of the foregoing.

The adhesive may be coated as a thin layer on the central plastic member and the fabric layer positioned on the adhesive, usually with the application of pressure. This will usually result in the adhesive penetrating into the fabric layer. With a combination of a sufficiently thin adhesive layer and sufficient pressure during application, there may be some direct contact of some of the fabric with the central plastic member. The adhesive should not be a thick foamed layer; it is preferably thin and not a foamed material.

The fabric, particularly when woven, may be partially or wholly impregnated with a plastic adhesive before being applied to the central plastic layer. The preferred insulating fabric layers are partially impreganted, with the impregnating plastic being applied from one surface to a depth of between about 0.1 mil and 7 mils and preferably between about 0.05 and 5 mils. This results in a thin coating on the surface of the fabric, which is applied hot (or heated after application) and affixes the impregnated fabric to the central plastic member.

The fabric layer may also be bonded to the plastic member by fusing, i.e., heating until the plastic is viscous, at a temperature above about 325°F, and then contacting the fabric with pressure so that the surface of the plastic partially impregnates the fabric and upon cooling is bonded thereto.

The strength and flexural properties of the orthopedic device at ambient temperatures are largely contributed by the plastic central member. This member is strong and has the ability to be resilient in some configurations and sizes. It has the ability to be substantially rigid in specific configurations, i.e., O-sections, L-sections, U-sections, etc. A device may include several different configurations and be substantially rigid in a specific area and quite resilient in another area thereof.

The versatility of the orthopedic devices is illustrated by the following properties of the plastic sheet. Different configurations were prepared from sheet (90–93 mils thick) having the composition illustrated hereinafter. The sheet was 6⅜ inches long.

An O configuration was prepared with a radius of tube of thirteen-sixteenths inches. The tube was held with clamps at each end. The tube was supported at each end and on the bottom. The load was supported on two focal points 4 inches apart at the bottom, and the load applied from the top to the center of the tube. The deflection follows:

Machine Deflection[a] in Inches	Load in Pounds
0.1	49.5
0.2	51.2
0.3	80.5
0.4	104.0
0.5	125.0
0.6	142.0

[a]The machine deflection includes bending of the tube over its entire length, and flattening of the tube at all three focal points.

A U-configuration was prepared with a 2⅜ inches width of configuration and a twenty-nine thirty-seconds inch radius of bend. The arms of the U were mounted parallel to the horizontal (held in vice) and the load applied to the upper arm. A constant load test provided the following:

Points at which Constant Load (1 lb.) was Applied, Measured in Inches from Center of "U"	Deflection in Inches at Constant Load (logarithm)
1.15	0.050
1.75	0.095
2.75	0.135
3.75	0.175
4.75	1.145

A constant deflection test provided the following data:

Points at which Constant Deflection (0.45 inches) was Obtained, Measured in Inches from Center of "U"	Load in Pounds at Constant Deflection (logarithm)
4.75	0.30
3.75	0.60
2.75	1.18
1.75	8.60
1.15	10.73

Two L-shaped configurations were prepared by holding in a vice vertically and bending to form a right angle. The load was applied vertically and placed on horizontal arm.

The results of a constant load test on a sample having a 2 7/16 inches width of configuration and one-fourth inch radius follows:

Points at which Constant Load (2 lbs.) was Applied, Measured in Inches from Center of Bend	Deflection in Inches at Constant Load (logarithm)
0.5	0.010
1.0	0.025
1.5	0.070
2.5	0.280
3.5	0.680
4.5	1.150

The results of a constant deflection test on a sample having a 2⅜ inches width of configuration and a twenty-nine thirty-seconds inch radius follows:

Points at which Constant Deflection (0.35 inches) was Obtained, Measured in Inches from Center of Bend	Load in Pounds at Constant Deflection (logarithm)
4.5	0.50
3.5	1.00
2.5	2.27
1.5	12.00
1.0	40.00

The physical properties of the plastics vary somewhat with the thickness of section tested. Specific physical properties such rigidity and/or resilience of the orthopedic support vary with the thickness and overall size dimensions of the plastic central layer. The central plastic layer is usually between about 50 mils and about 120 mils, although thicker layers may be utilized for

large sections, such as a major body cast where substantial rigidity is required to support a large weight. Devices (in blank form, i.e., flat) used for preparing back supports, are preferably about 65–80 mils thick. Blanks for splints and braces are preferably about 80–120 mils thick. The preferred blanks for highly shaped casts may be of a variety of widths dependent upon the final configuration and service requirements.

The plastic preferably has a tensile strength (at yield) of between 2,000 and 10,000 psi and more preferably between 5,000 and 8,000 psi (ASTM D-638). The central plastic layer is relatively stiff as reflected by a percent elongation at yield of between about 3 and 30% and preferably between about 4 and 8%. The properties to yield are more important than to rupture since the properties should not exceed yield in service.

The flexural strength (ASTM-790) is between 3,000 and 14,000 psi and preferably between 8,000 and 12,000 psi. The flexural modulus (ASTM-790) is between 0.5×10^5 and 7×10^5 psi and preferably between 2×10^5 and 5×10^5 psi. The notched Izod (ASTM D-256) in foot-pounds per inch is between 0.3 and 30 and preferably between 0.5 and 15.

The Rockwell hardness is between 15 R scale and 55 D scale and preferably between 90 and 100 R scale. The Vicat softening point (ASTM D-1525-70) is between 60°C and 80°C.

A sample of the preferred impact modified polyvinyl chloride plastic member which is illustrated in the Example has an average tensile (± 100 psi) at yield of about 7,550 psi and at rupture of about 3,800 psi (ASTM D-638). The average (± 0.5% percent elongation at yield is 5% and the average percent elongation at rupture is 14.2%. The average flexural strength is 10.8×10^3 psi and the Flexural Modulus is 4.1×10^5 psi (ASTM D-790).

Another sample of the same composition had a tensile strength at yield of 6,785 psi; an elongation at yield of 5.6%; a flexural modulus of 3.94×10^5 psi; a flexural strength of 11,612 psi; a Rockwell R of 94; a Vicat of 74°C; and a notched Izod of 0.91 foot pounds per inch.

Another sample of the same composition which had been severely worked during processing, but found operative had a tensile strength at yield of 3,620 psi; an elongation at yield of 4.5%; a flexural modulus of 1.06×10^5; a flexural strength of 3,724 psi; a Rockwell R of 19; a Vicat of 63°C; and a notched Izod of 12.5 foot pounds per inch.

The central plastic member may be formulated from various polymer systems, such vinyl-chloride-propylene copolymers, vinyl-chloride-ethylene copolymers, or the corresponding interpolymer containing diallyl maleate. It is preferred to utilize an impact modified polyvinyl chloride (PVC) composition utilizing a PVC resin having a number average molecular weight of 20,000–23,000. The composition contains between about 10 and 14 parts of an impact modifier, between 1¼ and 2 parts of lubricant, and between 7½ and 8½ parts of a plasticizer, per 100 parts of polyvinyl chloride homopolymer resin. The composition will also contain stabilizers (6–9) parts and various processing aids (1.5–2.1 parts) and usually pigments (up to 5 parts).

A preferred PVC composition and exemplified composition follow:

COMPONENTS	Preferred Range (parts)	Preferred Composition (parts)
PVC homopolymer resin (20,000-23,000)	100	100
impact modifier (methylmethacrylate butadiene-styrene polymer	10–14	12.0
processing aid (acrylic type)*	1.5–2.1	1.8
lubricant		
blend of olefinic monoglyceride and hydrogenated olein	1–1.5	1.25
tri-stearyl citrate	0.25–0.35	0.3
plasticizer (di-2-ethylhexyl phthalate)	7.5–8.5	8.0
stabilizer boosters		
epoxidized soybean oil	4–6	5.0
mixed di- and tri-nonylphenyl phosphite	1.25–1.75	1.5
polyvinyl alcohol	0.05–0.08	0.0675
stabilizers		
calcium stearate	0.24–0.30	0.27
stannous stearate	0.37–0.43	0.40
zinc stearate	0.28–0.34	0.31
pigments	2.5–3.5	
rutile grade TiO_2		3.25
Hosterperm Red		0.0054
Indofast Orange		0.0135

*Rohm & Haas K-120 N

A sheet of the polyvinyl chloride having a thickness of about 80–90 mils was prepared from small pellets about one-eighth × three-sixteenth in diameter. The pellets were heated in an extruder and the resin composition extruded in the form of a rope-shaped material of a diameter of about one-half inch which is then milled in rollers and calendered into sheet about 15–20 mils thick. Four sections of such sheet were laminated together in a press with a heated die to form sheets about 80–90 mils thick. The physical properties of this test sheet were reported hereinbefore. Additional details concerning the said plastic compositions and the manner of producing them are disclosed in copending application, Ser. No. 465,403 filed Apr. 29, 1974, entitled "POLYVINYL CHLORIDE COMPOSITION" and naming AXEL W. TYBUS and LEONARD A. FABRIZIO as the inventors. The disclosure of said compending application is incorporated herein by reference.

The polyvinyl chloride sheet material may be formed in production by heating the small PVC composition pellets in an extruder and directly extruding in sheet form having the desired thickness. An alternate procedure is to mill and calendar rope-shape material of a diameter from about ½ to 4 inch. Sheet material taken from such processes and particularly direct extrusion is stressed and is preferably stress relieved by annealing at temperatures of about 320°F. It is possible to anneal simultaneously with the application of an adhesive or an adhesive and fabric.

The outside fabric layer protects the plastic surface from damage during shipment, storage and handling of the flat orthopedic device before it is molded and also to protect it after it has been shaped. It also protects the plastic layer during heating. If a heating element is used, for example, a hot iron, directly in contact with the orthopedic support, the outside fabric layer serves to prevent adherence of the plastic to the heating element.

This outside fabric layer also functions together with the insulating fabric layer to maintain the coherency of the orthopedic device when it is heated to elevated

temperatures. Since the outside fabric layer is bonded to the plastic, it will be in tension when the orthopedic device is shaped into a curve with the outer fabric layer on the outside of the curve. It is therefore preferably of a resiliant or stretch material which will not apply pressure on and tend to distort the plastic layer at ambient and particularly at elevated shaping and/or forming temperatures.

During heating, the outside fabric layer may be subjected to very high temperatures. The preferred fabrics are those resistant to prolonged heating at 250°F and short term heating to substantially higher temperatures. These high temperature resistant fabrics include the high temperature stabilized nylons: the high temperature stabilized polyesters; the Spandexs (polyurethanes); the armids; such as Nomex; high temperature acrylics; the aforedescribed Collins & Aikman blends of 50% Kynol and 50% Nomex and particularly the lighter weight fabrics; and linen. The said nylons, polyesters, and aramids, are preferred.

For devices which are not to be heated to elevated temperatures, i.e., they are available in blanks generally conforming to the desired end shape, and which are only heated for forming, lower temperature fabrics, such as cotton and wool may be used.

The other fabric layer is between about 4 and 22 mils thick and preferably between about 10 and 15 mils thick. It is preferably affixed to the plastic central member by an adhesive such as a thermoplastic polyurethane resin.

The other fabric layer may be fixed to the central plastic member by fusing with an adhesive in the same manner as that described hereinbefore for affixing the insulating fabric layer to the central plastic member. The same adhesive may be used in both instances, or different adhesives particularly when the two fabric layers comprise different types of fabric.

The orthopedic device may be made by sequentially affixing each of the fabric layers to the central plastic layer. Orthopedic devices have been prepared by first affixing a insulating fabric layer to the central plastic member by passing a three-layered material comprising the central plastic member and extruded polyester film of about 2½–3 mil thickness and the 7 oz. Collins & Aikman fabric described hereinbefore through a Reliant roll press which was at 350°F and applying 1–2 psi for 18 seconds. The extruded polyester film was a thermoplastic. The other fabric film, the 4 oz. Collins & Aikman fabric described hereinbefore, was then affixed to the other side of the central plastic member by passing the aforedescribed insulated fabric coated central plastic member together with said fabric and an interposed 2½–3 mil sheet of the polyester film through the Reliant roll press under the aforesaid conditions. It is preferred to produce the orthopedic device by passing the two fabrics and the central plastic member and the respective adhesive layers, which may be preapplied to the fabric, through the roll press simultaneously to produce the integral orthopedic device in a single pass. The blank orthopedic device may also be prepared by extruding the plastic sheet member onto a coated fabric or even coextruding the fabric layers and the plastic sheet together with the intervening adhesives.

At the shaping and forming temperatures the orthopedic device is readily cut. The cutting may be carried out by shears, for example, a scissors or other sharp edge. Those orthopedic devices having both sides of the plastic member covered by fabric layers retain integrity even at elevated temperatures. When it is desirable to carry out extensive shaping and forming of the orthopedic device such as forming a coil by wrapping various layers of the orthopedic device about each other in a spiral, the temperatures may be elevated, e.g., up to about 250°–400°F. At these temperatures the device maintains its integrity but becomes highly pliable. The orthopedic device may be cut and the plastic does not run out from between the fabric layers. When the orthopedic device is heated to such high temperatures and removed from the source of heat, it may be shaped and molded and formed over a period up to about 6–10 minutes. The rough shaping is carried out as the orthopedic device begins to cool from this elevated temperature. When the outer surface of the insulating fiber is cooled sufficiently, it may be pressed against the body portion to be formed into its final shape, generally under finger pressure. After the orthopedic device is applied against the body, there is still sufficient time during which final molding to conform to the desired body and/or device shape may be carried out.

The orthopedic device may be heated in a constant temperature fluid bath, such as a water bath or a hot oven or radiant energy. It is preferred that heat be applied only to the side of the orthopedic device which will not be applied against the patient. This may be accomplished by radiant heat, a hot air gun or hairdryer and preferably because of their ready availability, a hot plate or tray and an iron in the form of the familar hot tray, home iron or even a special round or curved iron. Surprisingly, it has been found that the hot surface of an iron which may be as hot as 300°–500°F, may be applied to the fabric layer of the orthopedic device and heat it to temperatures at which it becomes extremely pliable so that it may be cut and shaped to extremely complex shapes. The heat source is removed and/or intermittently applied and the orthopedic device applied against the body portion and molded to the desired shape. The molding or forming may be carried out by finger pressure. The person applying and forming the orthopedic device may wear gloves.

The upper temperature limit which may be applied against a portion of the human body varies dependent upon the area of skin in contact with the heat, the time of contact, and the individual tolerance to high temperature. For the purpose of applying orthopedic devices, the temperature should not be above about 120°–125°F for short term contact and preferably below 120°F for contact of several minutes.

When the orthopedic device in blank form is pre-cut and requires only forming, it may be heated to a temperature between about 165°–185°F from one side, and when the outside of the insulating fabric layer is sufficiently cool, applied to the patient's body and formed into the desired contoured shape.

The central plastic member of the orthopedic device solidifies at a temperature of about 120°–130°F. As a consequence, it is necessary that the temperature of the plastic central member should be above about 130°F during forming. Since application of this temperature to the patient's skin for more than a very short time is uncomfortable and possibly dangerous, the outer temperture of the insulating fabric layer should be at least 25°F cooler than the temperature of the plastic central

member during forming, and is preferably at least 30°F cooler. It is even more preferred that the outer temperature be at least 350°F or 40°F cooler than the plastic. The foregoing particularly applies during the plastic forming range of 130°F up to about 160°F.

In a preferred embodiment of the invention, the heat is applied against the side of the orthopedic device covered by the other fabric layer. For some service conditions it is contemplated that both sides of the plastic central member may be covered by insulating fabric. This would permit the entire member to be heated to an elevated temperature and retain the heat for a longer period of time.

The molded orthopedic device may be in many forms dependent upon the intended service and particularly the portion of the body to which is applied. The orthopedic device when manufactured will be in the form of sheet material. For most purposes, these sheet blanks will be in a variety of sizes such as squares from about 4 inches on a side up to about 2 feet on a side and even larger sizes. Rectangular and even oval or round blanks may be prepared. These blanks will have the central plastic member in sheet form with the insulating fabric bonded on one side and preferably the other fabric layer bonded on the other side. Such blanks may have a total overall thickness somewhat less than the sum of the thickness of the plastic central member plus the two fabric coatings as a result of the manufacturing process which involves the application of pressure either in the form of a press or more usually in the form of pressure rolls.

The invention is further illustrated by the following Example and drawings:

FIG. 1 of the drawing illustrates a rectangularshaped blank (flat orthopedic device) **10** having the insulating fabric layer **11** on one side of the plastic sheet.

FIGS. 2*a* and 2*b* illustrate two embodiments of the invention along line 2—2 of FIG. 1.

FIG. 2*a* illustrates the preferred embodiment of the invention in which the insulating layer **11** is on one side of the plastic sheet **12** and the other side of the plastic sheet **12** is covered by the other fabric layer **13**. The relative thickness of the layers in the drawing is for illustrative purposes only.

FIG. 2*b* depicts the embodiment of the invention in which one side of the plastic sheet **12** is not covered by a fabric layer. Such an orthopedic device may be used by positioning the insulated fabric side **11** against the body portion and then covering the exposed plastic with a loose sheet material and applying a hot iron against the sheet until the plastic is sufficiently soft so that it may be molded to the desired body shape. It may also be preheated.

FIG. 3 illustrates a shaped and formed back support **14** with formed contours such as those illustrated at **15** and **15'**. The central portion **19** is relatively fixed and supports the spinal area and portions **15** and **15'** are more resilient and support the back and related lower body portions.

FIG. 4 illustrates an arm splint **16** having hand section **17**, wrist section **18**, and forearm section **19**.

A flat blank orthopedic device was formed from a plastic sheet member of a thickness of 91–93 mils and having the composition set forth in the righthand column of the table hereinbefore was coated on one side with the woven insulating fabric which is the nonburning blend of 50% Nomex and 50% Nomax described hereinbefore. This insulating fabric had a weight of about 7 ounces per square yard and was about 14 mils thick. It was impregnated from one side with a polyester flexible polyurethane thermoplastic adhesive to a depth of about 3 mils on one side. A thin coating remained on the side to which the impregnant was applied. It was bonded to the plastic member by heating the impregnated insulating fabric to a temperature of about 325°F and then covering the plastic sheet and applying light pressure. The other side of the plastic sheet was covered by a knit stabilized nylon fabric of a thickness of about 14 mils similarly impregnated with the same adhesive. It was similarly bonded to the plastic member.

The thermocooling characteristics of the various components of the orthopedic device when heated to high temperatures, for example, about 300°F are illustrated in the following time-temperature profile of a flat (blank) about 6½ × 6½ inches. The central plastic member was about 69 mils thick. The insulating fabric was the aforedescribed Collins & Aikman no-burn fabric (7 oz. weight) about 15–18 mils thick. The other fabric was a knit (tricot) stabilized nylon about 12 mils thick. Both of the fabrics were applied to the plastic member by spreading an adhesive on one side of the plastic member and then applying the fabric and applying a heated iron to heat the fabric and adhesive to the temperature range to about 350°–380°F. The adhesive was spread to a thickness of about 3 mils. The insulating fabric was applied using the thermoplastic polyurethane adhesive described hereinbefore. The nylon adhesive was the thermosetting polyurethane described hereinbefore containing about 4% of the cross-linking diisocyanate.

The thermal properties were determined by first heating the device and then allowing it to cool in air (room temperature 69°–71°F) and measuring the rates thereof. The device was positioned with the nylon fabric face about three-eighths of an inch away from the hot plate and parallel thereto. The hot plate was measured to have a surface temperature of about 409°F. The device was heated to the temperatures noted in the following table and then permitted to cool. A thermocouple T_3 was positioned on the central plastic member face which is bonded to the nylon, and a thermocouple T_4 was on the side of the plastic member which is bonded to the insulating fabric. The time-temperature profile follows:

	Time (minutes)	Temperature °F T_4	T_3
Heating	0	82	82
	10	192	209
	17	224	234
Heat Source Removed	21.5	268	323
Cooling	0.5	263	284
	1.0	252	267
	1.5	242	251
	2.0	227	237
	2.5	219	225
	3.0	206	213
	3.5	195	201
	4.0	186	192
	4.5	177	182
	5.0	168	173
	5.5	161	166
	5.8	157	161
	8.0	131	134
	10.0	115	118
	11.5	106	108

Physical manipulation of the device established that the forming period ended, i.e., the plastic had solidified when the plastic temperature was about 130°F. In some cases this appeard closer to 129°F which is within the range of accuracy of measurement. The same device was reheated several times and each time it solidifies at about 130°F. Similar results were obtained with other samples. This data is consistent with the developmental experience that the same device may be completely or partially reformed and even reshaped, in whole or in part, many times. This provides means for correcting "fitting" errors, and also means for adjusting the shape of the device during its service life. It also provides the possibility of reusing the device which is particularly important in the poorer countries.

The aforesaid time-temperature profile establishes that there was more than eight minutes of shaping and forming time, i.e., the time starting with the removal of the heat source, until solidification occurs. Pratical testing of numerous samples having the nylon fabric on one side and the no-burn Collins & Aikman insulating fabric on the other side has established that when the device has been heated to over 300°F and preferably to 325°F, there is at least 7½ minutes of shaping and forming time. Tests with other experimental devices in which the other fabric is not nylon, for example, cotton, have established that the cooling time to solidification may be different and in some cases appreciably shorter, for example, as little as 4½ minutes.

The actual cooling time for a given device may vary with the overall thickness and other dimensions of the device as well as the amount of heating time and ultimate temperature and and the cooling conditions.

Temperature determinations were also made on the outside of the insulated fabric layer during the time-temperature profile, and during other heating and cooling tests. It was found that when using the aforesaid 7 oz. Collins & Aikman no-burn fabric, the temperature differential between the outside of the fabric and the plastic was about 40°F. The temperature measurements sometimes indicated a variation of ±10°F, but were usually within ±5°F.

When the "blank" orthopedic device is severely shaped at temperatures above about 325°F, e.g., some portions bent around one axis and other portions bent around a perpendicular or other intersecting axis, there may be some displacement of plastic within the fabric layers so that the resultant shaped (and usually formed) device may no longer be of a consistent uniform thickness.

Some practitioners who apply the orthopedic devices may wish to outline the shape, particularly when the shape is relatively intricate, in a pattern on the blank (flat) orthopedic device before cutting it into the rough shape and forming. This may be accomplished in several methods depending upon the fabrics involved. Certain fabrics, e.g., the woven blend of Kynol and Nomex described hereinbefore, may be marked with a marker, e.g., pen, pencil, crayon, etc. Alternately, a paper layer may be affixed to one of the fabric layers by a pressure-sensitive adhesive. The surface of the paper may be marked and used as a pattern and the orthopedic device cut and shaped. The paper may be removed immediately after cutting or in some cases desirably retained until rough shaping is completed. It would then be stripped from the fabric layer.

The orthopedic devices of the present invention have many advantages. When used as a relatively large support without severe bending, such as a back support, the orthopedic device supplies resilient support. When used as a cast it will immobilize. When used to keep a body part in bent position such as a knee cage, restraint in only direction is required. The orthopedic devices have special utility for service where adjustment in the shape of the device is desirable during a protracted period of time. Thus, as the patient responds to treatment, change in position may be desirable. In the past with plaster casts, the old cast had to be removed and a new cast formed. The orthopedic devices of the present invention may be partially reshaped even when attached to the body by localized application of heat and molding.

One of the most important uses of orthopedic devices is support of the lumbo-sacral region of the back. Immobilization of the lower body area risks a number of ill effects including shrinkage of tendons, and elasticity loss and weakening of muscles. The orthopedic devices of the present invention provide effective support and permit stabilization and immobilization of the lower spine without the foregoing adverse effects. This results from the unique combination of physical properties which provide substantial immobilization by those portions of the device which are highly contoured and at the same time provide resilient support by other less contoured portions of the back support and thereby permit body movement. Because of the ability to be formed and molded directly upon the patient, it is possible to provide back supports (which have been impossible or very difficult to make using prior materials) which cover relatively diverse and/or large portions of the back and, in some cases, may overlap around the sides of the body or over the shoulder.

The orthopedic devices may be used in the veterinary field in a manner parallel to their use with humans.

The orthopedic devices may be placed in a pocket or pouch of a garment which encircles a part of the body and thereby positions the orthopedic device. For many applications it will be desirable that the orthopedic device should be placed directly against the body portion and encircle it, and therefore it is self attaching. For other applications, the orthopedic device should have loops or other means of attachment for belts and other types of bindings such as Velcro fasteners, etc. These may be affixed to or even incorporated into one or both of the fabric layers. In such instances they will be affixed to the fabric layer which is on the side of the orthopedic device away from the patient's skin, i.e., in most instances the outside fabric layer. Orthopedic devices may be formed in self-closing and fastening configurations or may be fastened in any and all ways known in the art today.

The orthopedic devices may be provided as flat blanks for molding and shaping by the ultimate user. They may also be provided in preformed shapes, such as a series of preformed back supports which will generally conform to the body portions of the appropriate size. These orthopedic devices would have the advantage over other preformed devices in that final adjustment to individual variations may be made. They will also have the advantages over prior orthopedic devices in their combination of rigidity and resilience in different directions.

Although orthopedic devices will generally be conformed to the shape of the body, they may sometimes be shaped differently so as to make the body conform to the shape of the orthopedic device during service, e.g., a correctly formed arch support for use by a person having a fallen arch.

The discussion hereinbefore is primarily in connection with orthopedic devices which will be attached to the body. They may also be used in equipment which is not attached to the body but comes into contact with the body such as the seat of a chair, particularly an orthopedic chair, foot supports such as arch supports, and other portions of shoes and boots. They may be used in ski boots wherein relative rigidity in certain directions is desired in combination with resiliance in other directions of movement.

I claim:

1. A formable orthopedic device comprising a plastic sheet member having one side covered with an insulating fabric layer which is affixed to said plastic sheet member;

said plastic sheet member being at least about 50 mils thick, and having a tensile strength at yield of between 2,000 and 10,000 psi, an elongation at yield of between 3 and 30%, a flexural strength of between 3,000 and 14,000 psi, a flexural modulus of between about 0.5×10^5 and 7×10^5 psi, a notched Izod of between 0.3 and 30 foot pounds per inch, a Rockwell hardness of between 15 on the R scale and 55 on the D scale, and a Vicat softening point of between 60° and 80°C;

said insulating fabric layer being at least about 10 mils thick, and is a fabric comprising fibers selected from the group consisting of aramid fibers and high temperature cross-linked phenolformaldehyde fibers, which has a coefficient of heat transfer below about 2 cal/sec/cm^2/cm/°C$\times 10^{-4}$.

2. The orthopedic device of claim **1,** wherein said plastic sheet member is between 50 and 120 mils thick and has the tensile strength at yield of between 5,000 and 8,000 psi, an elongation at yield of between about 4 and 8%, a flexural strength of between about 8,000 and 12,000 psi, a flexural modulus of between about 2×10^5 and 5×10^5 psi, a notched Izod of between 0.5 and 15 foot pounds per inch, and a Rockwell of between 90 and 100 R.

3. The orthopedic device of claim **2,** wherein said insulating fabric is between about 10 and 22 mils thick.

4. The orthopedic device of claim **3,** wherein said plastic sheet member is between about 65 and 80 mils thick, and wherein said insulating fabric layer is a woven 50:50 blend of an aramid and a high-temperature cross-linked phenolformaldehyde fiber.

5. The orthopedic device of claim **3,** wherein said plastic sheet member is an impact-modified polyvinyl chloride composition between about 80 and 120 mils thick, and wherein said insulating fabric layer is a woven 50:50 blend of an aramid and a high-temperature cross-linked phenolformaldehyde fiber.

6. The orthopedic device of claim **1,** wherein said plastic sheet member is between about 65 and 80 mils thick, and wherein said insulating fabric layer is a blend of an aramid and a high-temperature cross-linked phenolformaldehyde fiber.

7. The orthopedic device of claim **1,** wherein said plastic sheet member is between about 80 and 120 mils thick, and wherein said insulating fabric layer is a blend of an aramid and a high-temperature cross-linked phenolformaldehyde fiber.

8. The orthopedic device of claim **1,** wherein said device is heated by application of heat to the side of the plastic sheet member not covered with the insulating fabric layer and said plastic sheet member is heated to temperatures of above about 160°F, the insulating fabric has insulating characteristics such that the temperature of the outside surface of said insulating fabric layer is at least 25°F below the temperature of said plastic sheet member.

9. An orthopedic device comprising a central plastic sheet member having one side covered with a fabric insulating layer and the other side covered with a fabric layer, both of said fabric layers being bonded to said plastic sheet member;

said plastic sheet member being between 50 and 120 mils thick, and having a tensile strength at yield of above about 2,000 psi, and an elongation at yield of between 3 and 30%, a flexural strength of between 3,000 and 14,000 psi, and a flexural modulus of between about 0.5×10^5 and 7×10^5 psi;

said insulating fabric layer being between about 10 and 22 mils thick;

said other fabric layer being about 4 and 22 mils thick and functioning to protect said plastic layer; and

said orthopedic device being formable at temperatures above about 130°F.

10. The orthopedic device of claim **9,** wherein said plastic sheet member has a tensile strength at yield of between 2,000 and 10,000 psi, a notched Izod of between 0.3 and 30 foot pounds per inch, a Rockwell hardness of between 15 on the R scale and 55 on the D scale, and a Vicat softening point of between 60° and 80°C; and

said insulating fabric layer has a coefficient of heat transfer below about 2 cal/sec/cm^2/cm/°C$\times 10^{-4}$.

11. The orthopedic device of claim **10,** wherein said plastic sheet member has the tensile strength at yield of between 5,000 and 8,000 psi, an elongation at yield of between about 4 and 8%, a flexural strength of between about 8,000 and 12,000 psi, a flexural modulus of between about 2×10^5 and 5×10^5 psi, a notched Izod of between 0.5 and 15 foot pounds per inch, and a Rockwell of between 90 and 100 R; and

wherein said insulating fabric layer has a coefficient of heat transfer below about 1.6 cal/sec/cm^2/cm/°C$\times 10^{-4}$.

12. The orthopedic device of claim **11,** wherein said other fabric layer is a fabric selected from the group consisting of high temperature stabilized nylons, high temperature stabilized polyesters, and aramids.

13. The orthopedic device of claim **12** wherein when said device is heated by application of heat to the side opposite that covered by the insulating fabric layer and said plastic sheet member is heated to temperatures above about 160°F, the insulating fabric has insulating characteristics such that the temperature of the outside surface of said insulating fabric layer is at least 35°F below the temperature of said plastic sheet member.

14. The orthopedic device of claim **12** wherein said insulating fabric layer is a fabric comprising fibers selected from the group consisting of aramid fibers and high temperature cross-linked phenol-formaldehyde fibers.

15. The orthopedic device of claim 10 wherein said device is heated by application of heat to the side opposite that covered by the insulating fabric layer and said plastic sheet member is heated to temperatures above about 160°F, the insulating fabric has insulating characteristics such that the temperature of the outside surface of said insulating fabric layer is at least 25°F below the temperature of said plastic sheet member.

16. An orthopedic device comprising a central plastic sheet member having one side covered with an insulating fabric layer and the other side covered with a high temperature knitted fabric comprising fibers selected from stabilized nylon fibers and stabilized polyester fibers, said fabric layers being bonded to said plastic sheet member;

said plastic sheet member being between 50 and 120 mils thick, and having a tensile strength at yield of between about 2,000 and 10,000 psi, and an elongation at yield of between 3 and 30%, a flexural strength of between 3,000 and 14,000 psi, and a flexural modulus of between about 0.5×10^5 and 7×10^5 psi;

said insulating fabric layer being between about 10 and 22 mils thick;

said knitted fabric layer being between about 4 and 22 mils thick and functioning to protect said plastic sheet member; and

when said layer device is heated by the application of heat to the knitted side and said plastic sheet member is heated to temperatures above about 300°F, said orthopedic device has thermal characteristics such that it may be shaped and molded for a period of at least about 4½ minutes before it solidifies.

17. The orthopedic device of claim 16, wherein said plastic sheet member is an impact-modified polyvinyl chloride composition and has a tensile strength at yield of between 5,000 and 8,000 psi, an elongation at yield of between about 4 and 8%, a flexural strength of between about 8,000 and 12,000 psi, a flexural modulus of between about 2×10^5 and 5×10^5 psi , and a notched Izod of between 0.5 and 15 foot pounds per inch; and

wherein said insulating fabric layer has a coefficient of heat transfer below about 1.6 cal/sec/cm²/cm/°C10^{-4}; and

wherein said orthopedic device has a shaping and molding time of at least about 7½ minutes.

18. The orthopedic device of claim 17, wherein said insulating fabric layer is a woven 50:50 blend of an aramid and a high temperature cross-linked phenol-formaldehyde fiber.

19. The orthopedic device of claim 18 wherein when said device is heated by application of heat to the knitted side, the insulating fabric has insulating characteristics such that the temperature of the outside surface of said insulating fabric layer is at least 25°F below the temperature of said plastic sheet member.

20. The orthopedic device of claim 18 wherein when said device is heated by application of heat to the knitted side, the insulating fabric has insulating characteristics such that the temperature of the outside surface of said insulating fabric layer is at least 40°F below the temperature of said plastic sheet member.

21. An orthopedic device formable at elevated temperatures comprising a central plastic sheet member having one side covered with a fabric insulating layer and the other side covered with a stretch fabric which will not tend to distort the plastic sheet member when said device is formed, said fabric layers being bonded to said plastic sheet member;

said plastic sheet member being at least 50 mils thick, and having a tensile strength at yield of above about 2,000 psi, a flexural strength of between 3,000 and 14,000 psi, and a flexural modulus of between about 0.5×10^5 and 7×10^5 psi;

said insulating fabric layer being at least about 10 mils thick and being substantially thinner than said plastic sheet member;

said stretch fabric layer being at least 4 mils thick and functioning to protect said plastic sheet member.

22. The orthopedic device of claim 21, wherein said plastic sheet member has a tensile strength at yield of between 2,000 and 10,000 psi, an elongation at yield of between about 3 and 30%, a notched Izod of between 0.3 and 30 foot pounds per inch, and a Rockwell hardness of between 15 on the R scale and 55 on the D scale.

23. The orthopedic device of claim 22, wherein said plastic sheet member has the tensile strength at yield of between 5,000 and 8,000 psi, an elongation at yield of between about 4 and 8%, a flexural strength of between about 8,000 and 12,000 psi, a flexural modulus of between about 2×10^5 and 5×10^5 psi, a notched Izod of between 0.5 and 15 foot pounds per inch, and a Rockwell of between 90 and 100 R; and

wherein said insulating fabric layer has a coefficient of heat transfer below about 2 cal/sec/cm²/cm/°C$\times 10^{-4}$.

24. The orthopedic device of claim 23 wherein said other fabric layer is a fabric comprising fibers selected from the group consisting of high temperature stabilized nylon fibers, and high temperature stabilized polyester fibers.

25. The orthopedic device of claim 24 wherein said insulated fabric comprises fibers selected from the group consisting of aramid fibers and high temperature cross-linked phenol-formaldehyde fibers.

26. The orthopedic device of claim 25 wherein said plastic sheet member is a thermoplastic.

27. An orthopedic device shapeable at elevated temperatures comprising a central plastic sheet member having one side covered with a fabric insulating layer and the other side covered with a knit fabric which will not tend to distort the plastic sheet member when said device is shaped, said fabric layers being bonded to said plastic sheet member;

said plastic sheet member being at least 50 mils thick, and having a tensile strength at yield of above about 2,000 psi, and an elongation at yield of between 3 and 30%, a flexural strength of between 3,000 and 14,000 psi, and a flexural modulus of between about 0.5×10^5 and 7×10^5 psi; said insulating fabric layer being at least about 10 mils thick and is a fabric composed of fibers selected from the group consisting of aramid fibers and high temperature cross-linked phenol-formaldehyde fibers;

said stretch fabric layer being at least about 4 mils thick and functioning to protect said plastic sheet member.

28. The orthopedic device of claim 27 wherein said stretch fabric which will not tend to distort the plastic sheet member is a knitted fabric comprising fibers selected from the group consisting of stabilized nylon fibers and stabilized polyester fibers.

29. The orthopedic device of claim **28,** wherein said plastic sheet member has the tensile strength at yield of between 5,000 and 8,000 psi, an elongation at yield of between about 4 and 8% a flexural strength of between about 8,000 and 12,000 psi, a flexural modulus of between about 2×10^5 and 5×10^5 psi, a notched Izod of between 0.5 and 15 foot pounds per inch, and a Rockwell of between 90 and 100 R.

30. The orthopedic device of claim **29,** wherein when said device is heated by application of heat to the side of the plastic sheet member not covered with the insulating fabric layer and said plastic sheet member is heated to temperatures of above about 160°F, the insulating fabric has insulating characteristics such that the temperature of the outside surface of said insulating fabric layer is at least 25°F below the temperature of said plastic sheet member.

31. An orthopedic device shapeable at elevated temperatures comprising a central plastic sheet member having one side covered with a fabric insulating layer and the other side covered with a high temperature knitted fabric which will not tend to distort the plastic sheet member when it is shaped, said fabric layers being bonded to said plastic sheet member;

said plastic sheet member being at least 50 mils thick, and having a tensile strength at yield of above about 2,000 psi, and an elongation at yield of between 3 and 30%, a flexural strength of between 3,000 and 14,000 psi, and a flexural modulus of between about 0.5×10^5 and 7×10^5 psi;

said insulating fabric layer being at least about 10 mils thick;

said knitted fabric layer is a fabric composed of fibers selected from the group consisting of stabilized nylon fibers and stabilized polyester fibers and being at least about 4 mils thick and functioning to protect said plastic sheet member; and

when said device is heated by the application of heat to the knitted side and said plastic sheet member is heated to temperatures above about 300°F, said orthopedic device has thermal properties such that it may be shaped and molded for a period of at least about 4½ minutes before it solidifies.

32. The orthopedic device of claim **31** wherein said plastic sheet member has a tensile strength at yield of between 5,000 and 8,000 psi, an elongation at yield of between about 4 and 8%, a flexural strength of between about 8,000 and 12,000 psi, a flexural modulus of between about 2×10^5 and 5×10^5 psi, and a notched Izod of between 0.5 and 15 foot pounds per inch.

33. The orthopedic device of claim **32** wherein said plastic sheet member is an impact modified polyvinyl chloride plastic sheet having a thickness between about 50 and 120 mils.

34. The orthopedic device of claim **33** wherein said insulating layer is a fabric comprising fibers selected from the group consisting of aramid fibers and high temperature cross-linked phenyl-formaldehyde fibers.

35. The orthopedic device of claim **34** wherein said insulating fabric layer is a blend of said aramid and said phenyl-formaldehyde fibers.

* * * * *

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,906,943 Dated Sept. 23, 1975

Inventor(s) ELMER M. ARLUCK

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 9, line 3, replace "350°F" with --35°F--.

Column 9, last line, replace "50% Nomex and 50% Nomax" with --50% Kynol and 50% Nomex--.

Column 11, line 4, correct the spelling of "appeared".

Column 11, line 19, correct the spelling of "practical".

Signed and Sealed this

seventeenth Day of *February 1976*

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks