Sept. 29, 1953 M. M. GOTTLIEB ET AL 2,653,396

ARCH SUPPORT AND METHOD OF MAKING SAME

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FIG. 1.

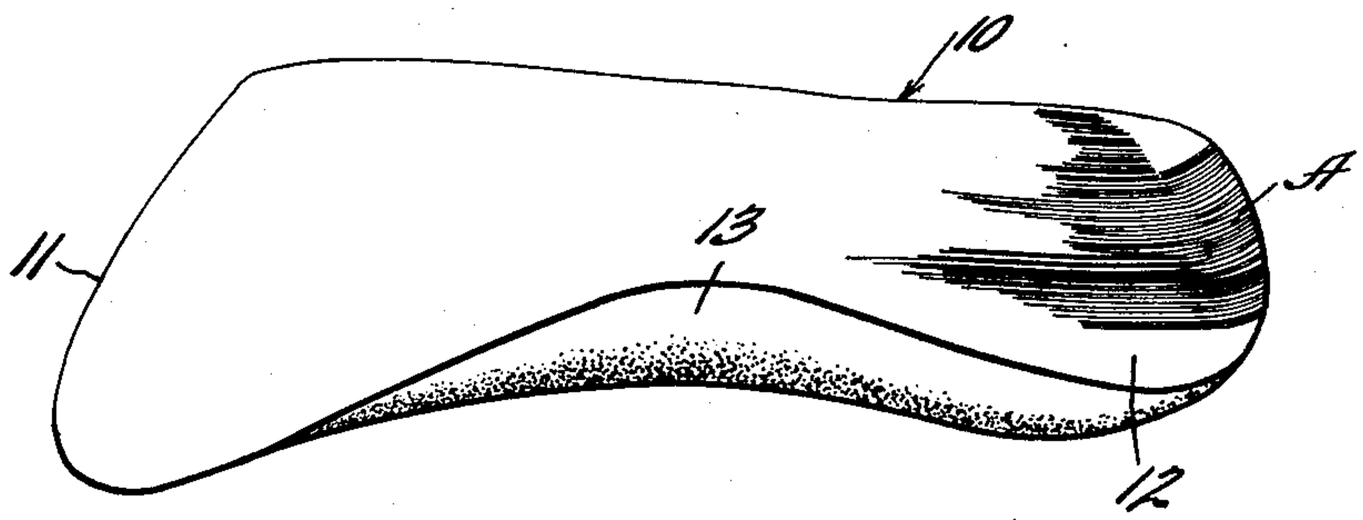

FIG. 2.

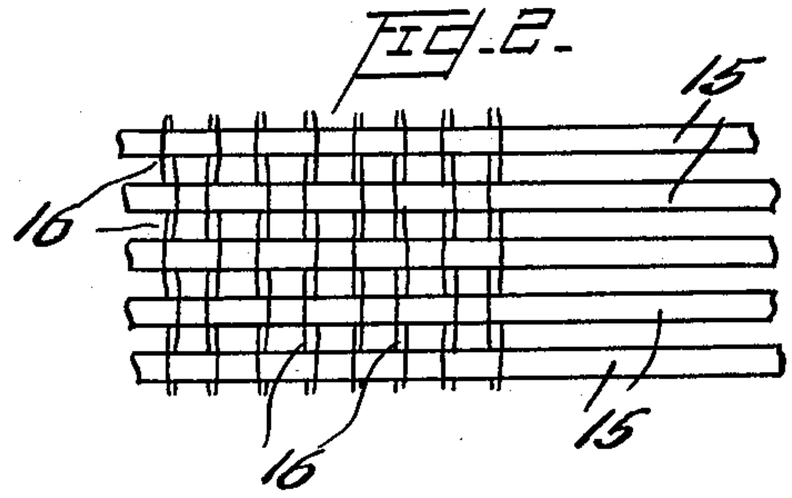

FIG. 3.

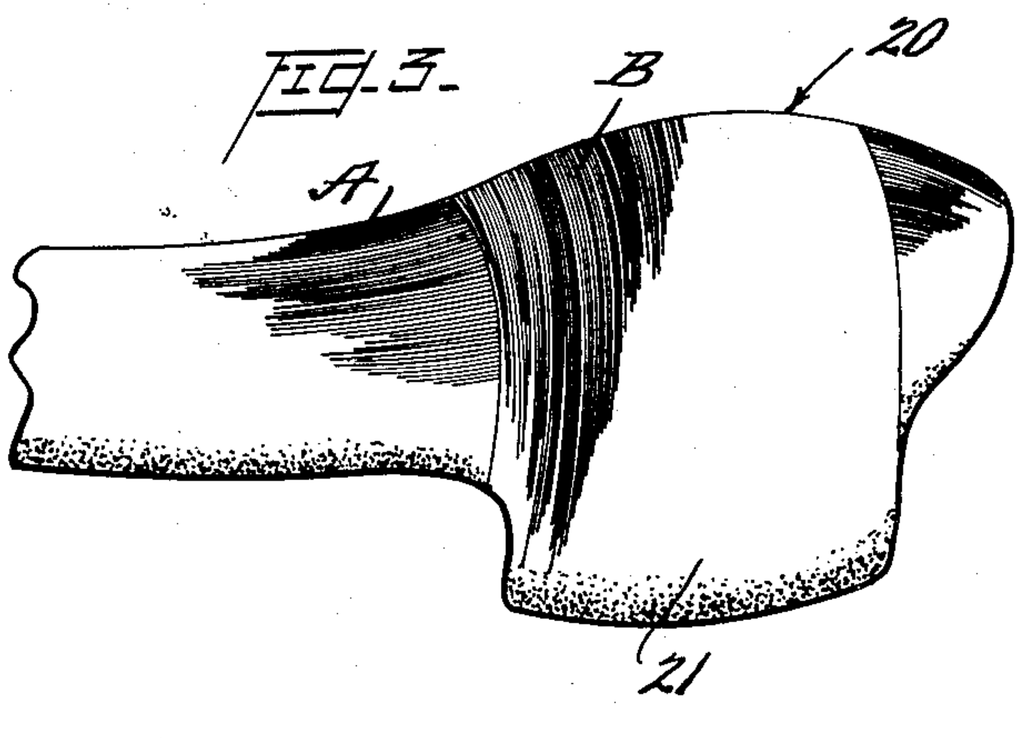

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FIG-4-

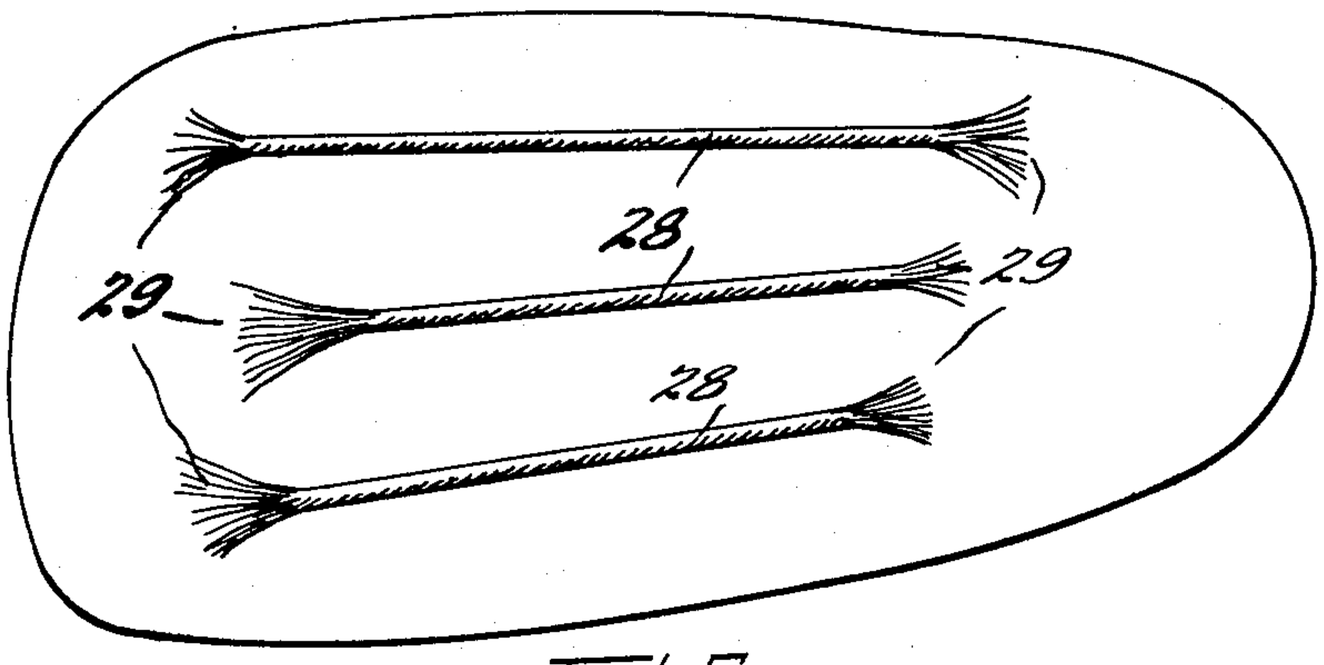


FIG-5-

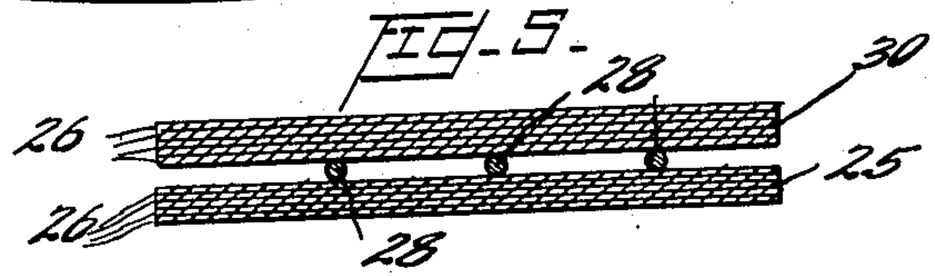


FIG-7-

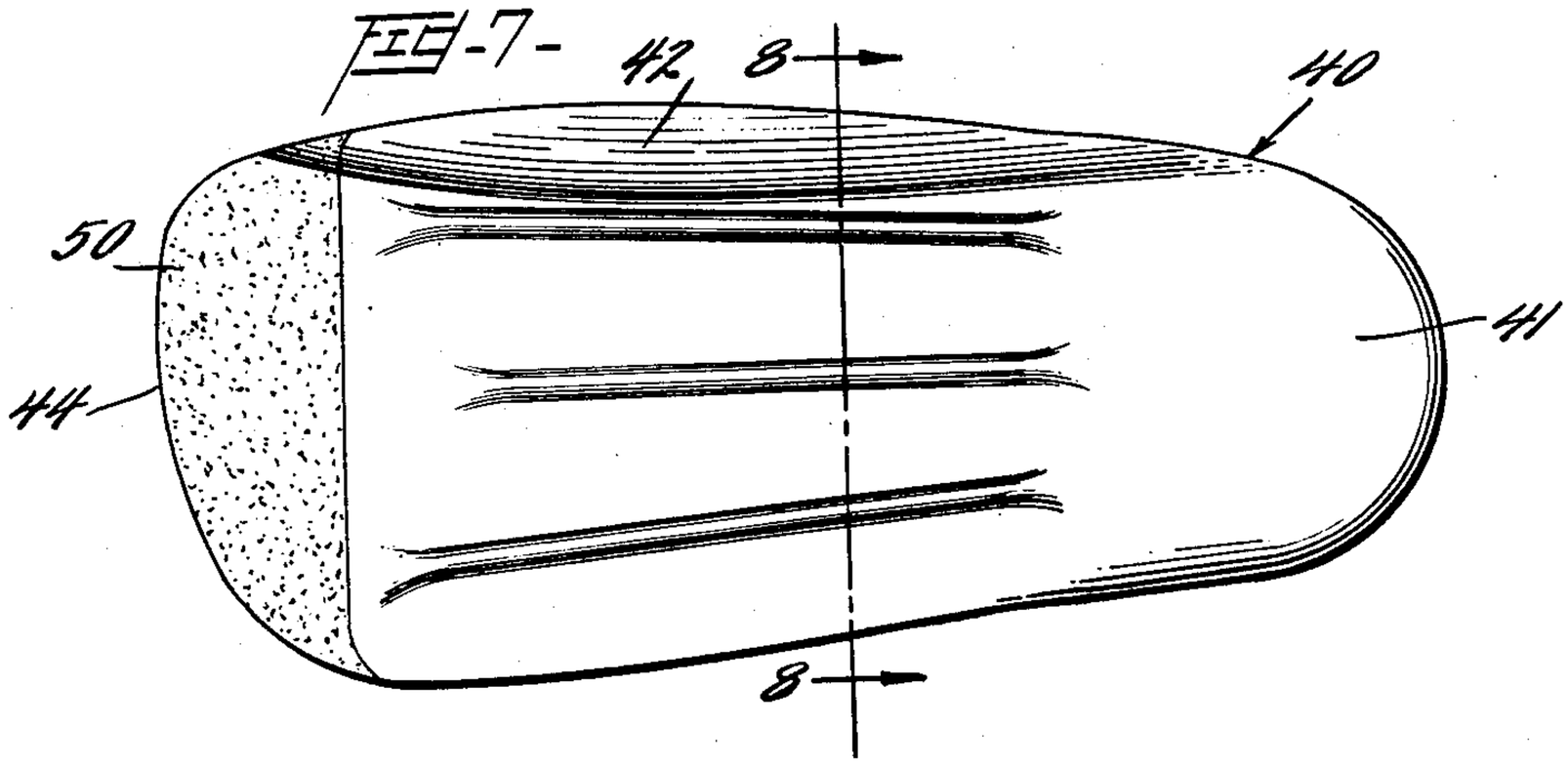


FIG-8-

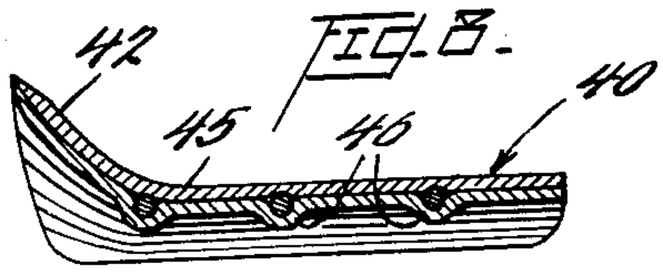
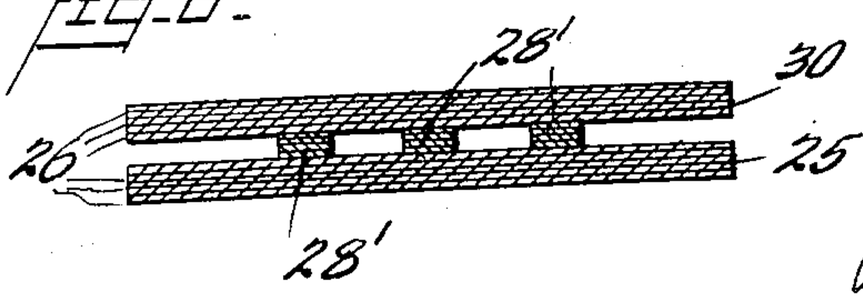


FIG-6-



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2,653,396

ARCH SUPPORT AND METHOD OF MAKING SAME

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4 Claims. (Cl. 36—71)

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This invention relates to surgical devices and more particularly to orthopedic appliances.

It is the general object of the invention to provide novel and improved appliances for use in the field of orthopedics for the feet, whether as rigid devices for the active correction of foot conditions or as non-rigid appliances for passive support.

The present application is a continuation-in-part of my copending application Serial No. 630,834, filed November 26, 1945, now abandoned.

Conventional devices of the rigid type have been made of various metals such as nickel-steel alloys, aluminum and its alloys, German silver, Monel metal, Phosphor bronze, stainless steel, or the like, either as such or for the provision of the basic skeleton or chassis, such basic skeleton being covered with leather or other suitable material. However, such constructions have certain disadvantages, among which may be cited the susceptibility to oxidation or corrosion, crystallization and cracking at points of stress, a high weight factor, and bulkiness. In addition to these drawbacks may be mentioned the difficulties attendant to forging, grinding, and polishing these metal appliances.

The non-rigid type of appliance has conventionally been made of cork, leather, sponge rubber, felt, wood, cellulosic and thermoplastic materials. Although these articles are of lighter weight than the metal or metal-reinforced appliances, they still present disadvantages in their bulkiness, compressibility, absorption of foot odors and perspiration, rapid deterioration from these and other causes, low impact resistance, and a low degree of dimensional stability.

Therefore, the present invention in its preferred embodiments contemplates the provision of foot appliances, whether of the rigid or non-rigid type, which are made of fibrous glass impregnated with a plastic material. Among the advantages of orthopedic appliances constructed basically of fibrous glass are high specific tensile strength and a high degree of dimensional stability. The fibrous glass appliances are also non-toxis, non-allergic, non-sensitizing, and chemically stable, and therefore not subject to oxidation, so that they cannot produce any harmful effects upon the human tissue. Such appliances are also unaffected by body acids and do not absorb perspiration or odors.

The fibrous glass orthopedic or prosthetic appliances are of light weight and occupy a minimum of space in the shoe. The appliances are of high impact resistance and can be made either rigid or flexible as desired. Appliances made of

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these materials are very easily handled and worked, being very readily ground and shaped as, for example, upon a power grinding wheel.

One particular advantage of the appliances made in accordance with the present invention lies in the readiness with which they may be fabricated to the correct form required by the therapeutic indications for the individual patient. The appliance can not only be made rigid for active correction or flexible for passive support, but can be vary readily shaped by the practitioner according to the specific requirements of the individual patient, that is to say each appliance itself is adapted to be molded to the exact configuration necessary, and not merely selected from an assortment of pre-formed or pre-fabricated pressure-molded appliances.

To effect this latter purpose, the plastic material or resin with which the fibrous glass web or sheeet is impregnated is one which can be conformed to the ultimate shape desired without high pressure or high temperature molding. Any thermosetting, polymerizing, non-condensing resin requiring less heat and pressure for setting than would impair or destroy a plaster of Paris or similar relatively fragile cast or mold or other delicate accessory such as the vacuum bag to be described hereafter may be used.

It will be realized that the main structural strength of the appliance is afforded by the fibrous glass base, and that the resin or plastic with which it is impregnated serves fundamentally as a binder, instead of providing the chief source of strength. In this respect the novel appliance provided by the present invention differs from prior articles which have employed resinous or other plastic compositions as the basic structural material, such material being merely bound together before setting by organic or metallic fabrics.

Other objects and features of novelty, including various structural modifications, the use of glass fibers of various fabrications, the use of supplemental rigidifying skeleton structure, and the provision of frictional retaining features, will be apparent from the following specification when read in connection with the accompanying drawings in which certain forms of the invention are illustrated by way of example.

In the drawings,

Figure 1 is a perspective view of an orthopedic appliance comprising an insert to be applied to the shoe of the wearer;

Figure 2 is an enlarged somewhat diagrammatic detail view of one form of fibrous glass fabric suitable for use in pursuing the invention;

Figure 3 is a fragmentary view, substantially in bottom plan, of an appliance of laminated construction for affording better resistance to transverse stresses;

Figure 4 is a plan view of a partially assembled appliance in accordance with a modification of the invention;

Figure 5 is a somewhat diagrammatic transverse sectional view, with exaggerated dimensions in the vertical direction, through an assembled appliance before softening or molding is effected;

Figure 6 is a view similar to that of Figure 5 in which different reinforcing rib elements are used;

Figure 7 is a bottom plan view of a finished appliance of the kind shown in progress of manufacture in Figures 4 and 5; and

Figure 8 is a view in transverse vertical section through Figure 7, as taken on line 8—8 of that figure.

In Figure 1 of the drawings, the appliance is indicated generally by the reference numeral 10, and is of a type designed to afford support for a normal foot, the benefits in this particular instance being more of a prophylactic than of a therapeutic nature. The appliance is provided with a tapered forward edge 11 which merges with the inner surface of the sole of the shoe, and the heel portion 12 is cupped to conform to the normal heel. Curved side edges 13 are provided to correspond with the proper configuration of the inner longitudinal arch portion of the foot. In this suggested example of the use of the invention, the stresses sustained by the appliance are for the most part longitudinal. The appliance is made up of multiple layers of fibrous glass fabric or webbing impregnated with the resin as described, the number of layers depending upon the therapeutic indications for the individual patient.

In Figure 2 there is illustrated in somewhat diagrammatic form the construction of one preferred type of fibrous glass fabric. In this material the larger and of course stronger warp fibers 15 extend from right to left in the figure, and this is the direction of maximum resistance to stress. The transverse fibers 16 which form the woof of the fabric are of a much finer gauge than the warp fibers 15, and serve principally to hold the warp fibers together in web or sheet form. In this way a larger number of longitudinal stress-sustaining warp fibers may be used per square inch of fabric, and this provides a stronger support for the appliance in the longitudinal direction.

In making up a support or appliance of the type shown in Figure 1, the laminations may be applied so that the stronger and larger warp fibers 15 extend generally longitudinally of the appliance, as indicated at A, although the several laminations may be set so that the principal fibers of one lamination may extend at a slight angle to those of another.

In Figure 3 of the drawings, there is illustrated at 20 another form of support in which it is desirable to provide greater resistance to stress transversely of the appliance. In this case one or more of the several laminations which go to make up the device may extend transversely to the remaining laminations so that the larger warp fibers 15 of certain laminations may extend at an angle of up to 90° with the fibers of the other laminations. The layers with longitudinally extending warp fibers are indicated at A and one or more layers having the warp fibers

extending transversely are shown at B. In the embodiment illustrated here, the transverse laminations extend across the heel seat of the appliance and terminate in a flange portion indicated at 21. The determination of the particular angularity of the successive layers going to make up the appliance is to be made in accordance with the individual case.

In addition to the particular fabric illustrated diagrammatically in Figure 2 of the drawings, other forms of fibrous glass sheeting may be employed in the building up of the appliances. For example, an "8-harness" weave of fibrous glass strands provides an excellent material for the purpose. For certain constructions, a knitted glass fabric may be employed, and in still other appliances matted or felted laminations of unspun glass fibers may be utilized. It is understood that these laminations, whatever the weave or fabrication, are impregnated with the selected plastic as will be presently described.

In preparing the appliances in accordance with the individual requirements of the patient, a good positive cast is essential. First of all, a negative cast is made up by any of the usual known methods. For this purpose, plaster-of-Paris-impregnated roller gauze or splints may be immersed in water and then applied to the foot, with the patient or practitioner holding the foot in the desired position while the plaster of Paris sets.

After the negative cast has set, it is slipped off the foot and when it has hardened sufficiently it is filled with plaster of Paris in order to form the positive cast. After the positive cast has been removed from the negative, it may be corrected and smoothed in accordance with the therapeutic indications of the case. Next, an outline of the appliance to be made is drawn on the positive cast, and from this a template is made. The template is used to outline the configuration of the appliance on the piles of uncured, resin-impregnated, fibrous glass material, and a sufficient number of plies of this fabric or material is used to give the necessary thickness and strength of the appliance in the requisite directions.

Figures 1 and 3 of the drawings show finished appliances of the general type described, whereas Figures 4 to 8 inclusive illustrate modifications of the invention in which additional reinforcing ribs are provided longitudinally of the appliance, in order to afford greater strength over the central arch thereof. In Figure 4, there is shown a series of laminations impregnated with the plastic material but uncured, the laminations being approximately one-half of the number making up the finished appliance. About ten layers all together would be the average number required. This series of laminations indicated at 25 in Figure 5 is cut to the proper outline by means of the template just described. The individual laminations making up the pile 25 are indicated at 26. Upon the top of the lower pile 25 there are laid one or more strands, cords, or ropes, of twisted glass fibers. In the example shown there are three of such ropes indicated at 28. These ropes are laid longitudinally of the appliance along lines of maximum strain and, preferably, the ends of the rope sections 28 are unravelled for a short distance and spread or splayed in a sort of fan-shape upon the pile 25 as indicated at 29. The ropes themselves are impregnated with plastic material and the splayed portions blend with the surfaces of the piles of laminations.

Upon the top of the partial assembly shown in Figure 4 there are placed the remaining group **30** of laminations **26**, these laminations also being impregnated with the appropriate plastic substance.

A modification of this arrangement is shown in Figure 6 of the drawings in which the reinforcing rib material interposed between the piles of laminations **25** and **30** are made of narrow elongated strips of material in multiple plies (say from four to six layers) and of substantially the same construction as the laminations **26**. These elongated reinforcing plies are indicated at **28'** in Figure 6 and serve the same purpose as the ropes **28** in the previously described embodiment.

The plastic materials used in impregnating the main laminations **26** may vary somewhat in flexibility, and in cases where the body of the appliance may be relatively flexible or soft, the reinforcing or bridging ribs **28** or **28'** may be impregnated with a hard or rigid resin or plastic but preferably one which is compatible with the impregnating composition used in the body laminations.

The arrangements shown in somewhat exaggerated form in Figures 5 and 6 comprise the built-up laminates which are to be molded to the desired configuration depending upon the therapeutic indications involved in the particular case. A suitable parting material, for example a thin, flexible, cellulose sheet, is applied to the positive cast. Then the built-up laminate is applied to the thus coated surface of the positive cast. In order to cause the laminate to conform exactly to the configuration of the cast and to be hardened and cured in the desired shape, the cast with the applied laminate is inserted and sealed in an air-tight bag made of polyvinyl alcohol or other suitable material, to which an air valve has been fitted. The bag and its contents are placed in the curing oven, the air valve being attached to a vacuum pump which serves to exhaust the air from the bag. The pump is operated to maintain the vacuum throughout the curing of the article. Of course, the time and temperature required to cure the article will vary somewhat according to the type of resin employed. In the case of the thermosetting, polymerizing, non-condensing resin known as "Plaskon 911–11" the curing may be effected at approximately 125° C. to 150° C. in about one to thirty minutes, depending upon the thickness of the appliance.

When the cure is completed, the vacuum bag is cut away and the appliance removed from the mold, and it may be finished off on a sanding wheel or other suitable device. The appliance may then be inserted in the shoe for immediate use, or if desired, may be covered with leather. The latter expedient may be preferred when it is necessary to cover or protect any added underlying raise which is usually made of rubber, cork, or similar material.

A typical completed orthopedic appliance applicable to the foot, is illustrated in Figures 7 and 8 of the drawings. The appliance indicated generally by the reference numeral **40** shows a cupped heel portion **41** and an upwardly curved marginal edge **42** conforming to the proper configuration of the inner longitudinal arch portion of the foot and similar to the edge portion **13** of the embodiment in Figure 1. The appliance has a tapered relatively thin forward edge **44** which merges with the inner surface of the sole of

the shoe. An inspection of Figure 8 will reveal that the two groups of laminations **25** and **30** have merged or fused together and the gentle pressure employed in the molding or forming operation insures that the upper surface **45** of the appliance is smooth and conformed perfectly to the foot, while the reinforcing ribs **46** resulting from the interposition of the ropes **28** or the strips **28'** may bulge the appliance downwardly slightly upon the under surface. These reinforcing ribs **46** form a beam or truss element for the appliance and thus give increased strength where this is necessary.

The plastic material employed in impregnating the glass skeletal structure of the appliance is selected from the large group of polymerization resins, which do not change markedly in volume or give off a great deal of water, and which consequently may be called non-condensing. These materials harden at pressures under fifteen pounds per square inch, and include unsaturated polyesters, allyls, modified alkyds (including alkyd styrene), and other resins of the same or similar properties, all being marketed under various trade names by different manufacturers.

Within the generic group of low-pressure thermosetting resins, certain types or combinations of types may be employed for determining the characteristics of the appliance. For example, there is a matter of post-forming, which is generally a characteristics of thermo-plastic resins. However, some of the thermosetting, unsaturated polyesters are somewhat post-forming. They can be reheated to a temperature in the neighborhood of 135° C., and the molding of the appliances corrected. The operator would in such cases use asbestos gloves in handling the articles and would cool the appliance after the desired corrected configuration is attained, by dipping it in cold water.

Although some of the phenolic plastics are post-forming, these are not readily suitable for use in pursuing the present invention since they require too high a pressure and too high a temperature for molding against plaster of Paris molds according to the provisions for individual fitting and forming of the present appliances. However, plastic compositions within the described category may be selected or mixed to attain different degrees of post-forming susceptibility, as well as flexibility.

Another important advantage of the present method is the ease of adjustment of the appliance by building up certain parts by the addition of laminations.

Another feature of the present invention is shown in Figure 7 of the drawings. This comprises a layer of material **50** which is applied to the under side of the forward portion of the appliance where it is adapted to bear upon the inner surface of the sole of the shoe. This applied material comprises a coating consisting of a flexible base such as a strip of blotting paper, suede leather, or sheet material of similar properties impregnated with a relatively soft or flexible resin such as a polyester of these selected characteristics. The selection of such a resin from the current plastic catalogues should present no difficulty to one skilled in the art, bearing in mind of course that the impregnating friction strip plastic should be of the same generic classification as, or completely compatible with, that of the main arch support, but softer when set. The base material is impregnated with the resin (usually one dipping is

sufficient) and then applied upon the appliance on the mold and cured along with the body portion of the appliance itself. The relatively flexible and rigid resins employed respectively in the friction strip and in the main arch support are of course compatible, and may of course be identical except for the relative softness upon setting; and the coating strip **50** adheres perfectly to the lower forward edge of the main appliance. The cured strip **50** presents a frictional or "non-skid" surface to the sole of the shoe and effectively prevents sliding or displacement of the appliance within the shoe.

It will be understood that there is provided by the present invention a very effective means for use in the treatment of foot defects such as the congenital flaccid foot of the moderate or extreme type, the congenital flat foot, the acquired flat foot or weakening of the arches in their varying degrees of intensity and deformity, the high arch foot, and foot deformities due to disease or to post-operative or traumatic complications. Also, means are provided for supporting the normal foot and maintaining it in its proper condition. It will be obvious that it is infinitely better for the practitioner to be able to conform the appliance with great exactitude to the configuration necessary to the therapeutic indications of the individual patient, rather than effect a mere approximation by selecting an appliance from a stock of stereotyped forms. This advantage is afforded by the provision of the relatively strong glass fiber chassis or skeleton and the use of the low-temperature, low-pressure (or no-pressure) settable resins employed. In the case of the previously used high-pressure, condensing resins the molding of the appliance to the exact configuration needed by means of plaster of Paris molds would be impossible. Furthermore, the appliances provided by the present invention may be very readily produced by the individual practitioner without the use of expensive special equipment or installations.

Various changes and modifications may be made in the embodiments illustrated and described herein without departing from the scope of the invention as defined by the following claims.

Having thus described the invention, what is claimed as new and desired to be secured by Letters Patent is:

1. An arch support adapted to be inserted in the shoe of the wearer and comprising a plate shaped to the proper configuration for the support or correction needed; said plate comprising a plurality of coalesced layers of fibrous glass webs impregnated with a thermoset and polymerized non-condensing resin, said resin being one that in its unset unpolymerized state is capable of setting after heating to a temperature of not over about 150° C. and subjection to pressure of not over 15 pounds per square inch, said support being reinforced internally with one or more elongated strips of fibrous glass material impregnated with a quantity of the above-described resin, said strips being disposed between certain of the layers of impregnated webs and coalesced therewith, said strips extending longitudinally of the support, bridging the shank portion, and terminating adjacent the heel and

ball portions of the support, to provide additional bracing means therefor.

2. The appliance set forth in claim 1 in which the strips comprise a fibrous glass rope, the ends of which are at least partially unravelled and splayed to merge gradually with the adjacent layers of webs.

3. The process of making an orthopedic foot appliance of a high degree of dimensional stability, such as an arch support, adapted for insertion in the shoe of the wearer, said method comprising making a positive cast of the foot requiring orthopedic support or compression, impregnating one or more fibrous glass webs with a low-pressure, low-temperature, non-condensing, thermosetting resin which is capable of setting after heating to a temperature of not over about 150° C. and subjection to pressure of not over 15 pounds per square inch, laying the impregnated web against the corresponding area of the positive cast, pressing the web against the cast with pressure the equivalent of not more than 15 pounds per square inch, and at the same time applying heat to a temperature of from about 125° C. to about 150° C.

4. The process of making an orthopedic foot appliance of a high degree of dimensional stability, such as an arch support, adapted for insertion in the shoe of the wearer, said method comprising making a positive plaster of Paris cast of the foot requiring orthopedic support or compression, impregnating a plurality of fibrous glass webs with a low-pressure, low-temperature, non-condensing, thermosetting resin which is capable of setting after heating to a temperature of not over about 150° C. and subjection to pressure of not over 15 pounds per square inch, trimming said webs to the area to be contacted by the appliance, laying the superposed impregnated webs against the corresponding area of the positive cast, placing the cast and webs in a flexible air-tight bag, evacuating the bag thus collapsing it against the exposed walls of the cast and webs and thus pressing the webs against the cast to conform to the contour thereof, heating the assembly to a temperature of from about 125° C. to about 150° C. for from one to about thirty minutes, removing the bag, and removing the appliance from the cast.

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