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**WO 01/67842 A1**

(54) Title: APPARATUS AND PROCESS FOR MAKING PROSTHETIC SUCTION SLEEVE

(57) Abstract: The method of making a tubular member having a continuous and uninterrupted cured elastomeric resin coating on an outer surface of the member includes forming a continuous uninterrupted tubular layer of uncured elastomeric resin and drawing the resin layer against the surface of the tubular member to be coated by applying suction between the resin layer and the surface of the tubular member so that the resin adheres to the surface of the tubular member. The elastomeric resin may then be cured to produce the final product. Apparatus for carrying out the process is disclosed and includes, in sequence, a coating zone including a sub-atmospheric chamber, a heating zone and a feed mechanism for advancing the tubular member relative to the coating and heating zones. A method is also disclosed for molding a distal end cap on an open end of a length of a preformed tubular sleeve member that may be used for prosthetic applications. A process is also disclosed for molding a sleeve member having prosthetic applications using male and female die elements used to distribute uncured elastomer resin as a layer on a tubular elasticized fabric sleeve element.

## APPARATUS AND PROCESS FOR MAKING PROSTHETIC SUCTION SLEEVE

### 1. Field of the Invention

This invention relates to the process and apparatus for making prosthetic suction liners and coating tubular substrates.

### 2. Background of the Invention

Prosthetic suction liners have been described in U.S. Patent No. 4,923,474 granted to Klasson and Kristinsson on May 8, 1990; U.S. Patent No. 5,728,168 granted March 17, 1998 to Laghi et al.; and U.S. Patent No. 5,830,237 granted to Kania November 3, 1998.

The original suction liner as described in U.S. Patent No. 4,923,474 was formed of a silicone elastomer and was adapted to the rolled over residual limb of a prosthetic user in a manner fully described in the patent.

The manufacturing process for making suction liners with a fabric exterior covering adhered to one or more cured elastomer inner layers typically involves multiple injection molding procedures and possibly laminating procedures that are designed to build-up the various layers constituting the suction liner. Obtaining an intimate bond between the silicone and fabric layers is particularly important, particularly when it is necessary to maintain full elasticity of the suction liner to enable it to closely fit over and conform to a residual limb of a prosthetic user.

The process is more complicated when a distal prosthetic connector fitting must be incorporated in the distal end of the suction liner, particularly when an injection molding procedure is utilized.

Injection molding procedures are time consuming and require complex equipment to ensure accurate shapes and thicknesses of various size suction liners. Injection molding thick, soft elastomeric layers on the inner surfaces of suction liners also present a challenge using injection molding techniques.

Prior art procedures for continuously coating tubular substrates with a cured elastomer coating or film involve many different procedures that tend to be expensive and time consuming. It is highly desirable to continuously coat tubular substrates with an elastomer layer intimately bonded or adhered to the substrate in a convenient, low cost procedure, particularly where the substrate is an elasticized, porous fabric.

#### BRIEF SUMMARY OF THE INVENTION

The invention relates to a process for forming a generally conical, close ended suction liner having a fabric outer covering, a thin cured silicone elastomer coating preferably provided on the interior surface of the fabric and a cured silicone elastomer lining adjacent the intermediate silicone coating. The prosthetic suction liner is formed with a distal end cap in which a prosthetic "umbrella" connector is embedded at the distal end of the suction liner using a process according to the invention described herein. The prosthetic connector is exposed in a central portion to provide access to a prosthetic pin connector in a conventional manner. An optional reinforcement layer may be embedded in the innermost silicone elastomer layer using the inventive process to restrict axial elongation of the distal end portion of the suction liner while permitting lateral distension of the liner material in that portion of the liner in which the reinforcement material is embedded in the silicone elastomer layer.

One aspect of the inventive process involves providing a cylindrical tubular length of elasticized fabric that is stretchable both longitudinally and laterally relative to the axis of the tube; coating the inner surface of the fabric tube with a continuous, thin cured silicone elastomer that partially penetrates and adheres strongly to the fabric but does not extend through the full fabric thickness; optionally attaching a tubular length of reinforcement matrix material to one end of the coated tubular fabric; placing the tubular length of fabric and the optional reinforcement in a molding device; placing the umbrella prosthetic connector element in the molding device; molding and curing a silicone elastomer distal end cap over one end of the tubular length of coated fabric and the optional reinforcement matrix so as to embed the umbrella prosthetic connector in the

distal end cap silicone material while bonding the distal end cap to the end of the tubular length of fabric and the optional reinforcement matrix; removing the tubular length of fabric with the molded distal end cap from the molding device and inserting a premeasured quantity of uncured silicone resin that will form an inner layer of the liner into the closed end of the fabric tube and end cap; inserting the fabric tube with the premeasured quantity of uncured resin and the distal end cap into a female mold cavity having a defined peripheral contour corresponding to a desired outer peripheral contour of the prosthetic suction liner; advancing a male mold member having an external contour corresponding to the desired inner contour of the suction liner into the interior of the tubular fabric and distal end cap assembly from its open end to cold forge the uncured silicone elastomer over the full length of a cavity defined between the male and female molds to fully form the innermost silicone elastomer layer to a desired contour and thickness and carrying out a preliminary cure of the inner most silicone elastomer in the forging device; removing the formed assembly of tubular fabric and partially cured silicone elastomer layer from the forming device and fully curing the innermost silicone elastomer layer.

Apparatus for carrying out the process includes a continuous film casting device configured to continuously cast an uncured elastomer film coating on a tubular substrate using sub-atmospheric suction to draw the film to the surface of the fabric substrate; and a heater in series with the continuous film casting apparatus arranged to cure the cast elastomer film continuously during the coating process to thereby produce a continuous tubular length of substrate coated on one surface thereof with a cured elastomer film.

When the apparatus is used to apply an elastomer coating to a porous material such as an elasticized fabric, the suction applied during casting of the uncured elastomer film is adjusted so that the film partially embeds itself in the intersices or pores of the fabric while avoiding complete penetration of the elastomer throughout the fabric thickness. This leaves the opposed surface of the fabric free of elastomer while producing a continuous sealing film of elastomer on the first surface of the tubular length of fabric.

During curing, the tension applied to the coated substrate is adjusted to produce optimum qualities for the coated length of substrate that are appropriate for the thus

produced product or any subsequent use of the coated substrate in a manufacturing procedure in which the coated substrate is formed into an end product.

The thus coated tubular length of substrate may be reversed with the cured elastomer coating on the inside of the substrate. The tubular coated substrate may then be cut to lengths corresponding approximately to individual lengths of products to be made with the coated lengths of substrate and a tubular matrix of reinforcement material may be attached to one end of the end of the tubular length of substrate for use, for example, in a prosthetic suction liner.

As described previously, a distal end cap may be molded to the one end of a tubular length of coated elasticized fabric substrate with a prosthetic connector fitting or umbrella embedded in the distal end cap.

In a specific example wherein it is desired to use such a continuous coated tubular substrate in a process for making a prosthetic suction liner, the substrate comprises a tubular elasticized fabric such as circular knit fabric that is distensible both lengthwise and widthwise and the elastomer is constituted of a silicone elastomer formulated so that it may be cast as a continuous film in its uncured condition in a temperature range that is practical. The coated fabric maintains its elasticity due to the elasticity of the silicone elastomer in its cured condition. The surface of the cured silicone film may be left in a somewhat tacky condition so as to be readily bondable to a subsequent silicone elastomer layer.

The cold forging apparatus includes a female die that preferably includes suction devices to draw the fabric tube into intimate contact with the interior walls of the female die prior to the advancement of the male member into the female die. The male die member formed in accordance with a desired inner profile of the innermost silicone elastomer layer of the suction liner, is advanced into the uncured silicone elastomer previously deposited into the closed end of the fabric and distal end cap assembly so the elastomer is forced to flow longitudinally through a cavity that is formed between the female die and the male die member from the closed end of the suction liner to the proximal open end thereof. The procedure may be referred to as a cold forging process for convenience.

The rate of advancement of the male die member is controlled to permit complete flow of the uncured silicone elastomer throughout the cavity provided between

the male and female die members, particularly when the gap between the male and female die members varies along the length of the molding device.

A guide pin may be inserted into the prosthetic connector element embedded in the distal end cap of the pre-formed tubular length of coated fabric, distal end cap and prosthetic connector. The female die includes an aperture at its distal end arranged to receive the guide pin to thereby center and locate the length of coated fabric and distal end cap in the female die before the male die member is advanced into the female die to cold forge the uncured silicone elastomer resin into the die cavity between the male and female die members.

The male and female dies may be heated to perform a preliminary curing of the silicone elastomer of the silicone elastomer in the mold cavity before the laminated assembly of elasticized fabric, thin coating of silicone elastomer and final inner layer of silicone elastomer are removed from the die.

The process and apparatus constituting the inventive subject matter will be described in more detail in the drawings and description that follow.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a longitudinal section view of a suction liner formed in accordance with the process according to the present invention;

Figure 2 is a distal end view of the suction liner shown in Figure 1;

Figure 3 is a section view taken along line III-III of Figure 1;

Figure 4 is an enlarged view of Figure 3 to show the details of the suction liner side wall;

Figure 5 shows a tubular sealing sleeve formed by using a coating process according to the present invention;

Figures 6 - 10 show the geometry of the cured silicone elastomer inner layer of a suction sleeve shown in Figure 1;

Figure 11 is a schematic view of a flat section of elasticized fabric in process of being folded and stitched to form a length of tubular elasticized fabric;

Figure 12 schematically shows a continuous coating system for applying a cast elastomer film onto one surface of the tubular substrate in a continuous process;

Figures 13 and 14 show details of the apparatus illustrated in Figure 12;

Figure 15 shows a reinforcement matrix stitched to one end of a length of

elasticized fabric that has been coated with a continuous cured silicone elastomer film;

Figure 16 shows a molding device for molding a distal end cap onto the length of tubular elasticized fabric that has been previously coated and provided with a tubular length of reinforcement matrix at one end thereof;

Figures 17 - 21 schematically illustrate a procedure for molding a distal end cap onto the tubular fabric using the apparatus shown in Figure 17;

Figure 22 is a detailed view showing the distal end of an assembly of elasticized tubular fabric coated with a continuous silicone elastomer film on the inner surface thereof, a reinforcement matrix, a distal end cap and an embedded prosthetic connector in the distal end cap;

Figure 23 schematically illustrates a procedure to dispense a predetermined quantity of uncured silicone elastomer into the closed end of the preformed assembly illustrated in Figure 23;

Figure 24 shows a cold forging system utilizing a female mold cavity and a male mold element that are brought together to form a mold cavity into which previously inserted uncured silicone elastomer is cold forged to completely fill the mold cavity;

Figure 25 shows the die system illustrated in Figure 24 in a closed condition; and Figure 26 shows the detail XXVI in Figure 25.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

Figure 1 schematically illustrates in a cross-section view a prosthetic suction liner 10 that may be formed using the process and apparatus described herein. The liner is formed in part of a composite elastic material 12 on its interior surface and an elasticized fabric layer 14 on its exterior surface at least up to its distal end area 16, where a distal end cap 18 having embedded therein a rigid prosthetic connector 20 formed, for example, of aluminum or other metal, or rigid plastic such as Nylon, is provided.

The liner 10 is formed as a close ended tapered tubular element, as is conventional for such suction liners. The distal end cap 18 firmly joins the prosthetic connector 20 to the suction liner 10 while providing a cushioning and stabilizing surface at the distal end of the liner. The prosthetic connector 20 includes preferably a threaded aperture 22 for providing access to a threaded prosthetic pin connector in a

manner well known in the art.

Figure 2 shows the suction liner in an end view as seen from the distal end of the liner.

Figure 3 is a cross-section view taken along line III-III of Figure 1 and shows the composite elastic material 12, the elasticized fabric layer 14, and a second thin continuous coating of silicone elastomer material 24 partially embedded in the elasticized fabric layer 14 while not completely penetrating the fabric layer. The intermediate coating 24 is bonded on its opposite side to the composite elastic material 12, whereby the entire assembly of composite elastic material 12, elastomer coating 24 and elasticized fabric 14 is at least freely radially elastically distensible.

The composite elastic material layer 12 may have embedded therein a matrix of reinforcement fibers 26 or other suitable reinforcement having properties such that the composite elastic layer 12 strongly resists longitudinal elongation while it is freely distensible radially of the suction liner for use in liner applications when axial elongation of the liner must be limited. A circular knit glass fiber or Nylon material is preferred.

Figure 4 is an enlarged view of Figure 3 and shows the composite elastic material made in accordance with the present invention in more detail as well as a wall section of suction liner 40 made with such material. Layer 12 may be a novel composite elastic material comprising a cured silicone elastomer containing silicone oil and hollow microspheres 28 dispersed throughout the silicone elastomer layer.

The illustrations in Figures 3 and 4 also show the reinforcement matrix fibers 26 embedded in the silicone elastomer layer, but it should be understood that such reinforcement fibers are optional and extend over a distal portion of the liner to limit axial distension of the liner in such distal portion. The reinforcement fibers 26, of course, do not constitute a portion of the basic composite elastic material described above.

More specifically, the composite elastic material layer 12 itself is regarded as a new and useful proprietary composite elastic material independently of the fibers 28, the outer fabric 14 and the intermediate coating.

In a preferred example, the composite elastic material 12 is formed principally of a silicone elastomer obtainable from NuSil Technology of Carpinteria, California



under Product Designation CF13-2188. For a fuller description of the silicone material, reference may be made to pending U.S. Patent No. 6,136,039 granted October 24, 2000 owned by the assignee of the invention described herein.

Embedded within the silicone elastomer material of layer 12 are hollow thermoplastic microspheres consisting of a polymeric shell with an enclosed blowing agent. The specific thermoplastic microspheres utilized in this example of the invention are expanded microspheres obtained from AKZO NOBEL of Sweden under the trade name EXPANCEL®, Product No. 551DE.

The microspheres 28 preferably have a density of  $.005 \text{ g/cm}^3$  to  $1.25 \text{ g/cm}^3$ , preferably  $.05 \text{ g/cm}^3$ .

For a fuller understanding of the formulation of EXPANCEL® microspheres, reference may be made to EXPANCEL® Technical Bulletin 29 and the EXPANCEL® product specification and material safety data sheets, all of which are available from AKZO NOBEL, S-850, 13 Sundsvall, Sweden.

The silicone oil included in the composite elastic material may be obtained from GE Bayer Silicones GmbH of D 51 368 Leverkusen, Germany under Product Name Baysilone Fluid M350.

In a preferred form, the composite elastic layer 12 comprises 50 - 99.4% by weight of silicone elastomer, preferably 77.25%; .5 - 45% by weight of silicone oil, preferably 10%; and .1 - 5% by weight of microspheres, preferably .75%.

The composite elastic layer 12 also may include one or more skin treatment agents blended into the silicone elastomer, for example Vaseline and aloe vera. In a preferred example, up to 20% by weight of the composite elastic layer, preferably 11.9%, may be Vaseline and up to 3%, preferably .1%, may be a secondary skin treatment agent such as aloe vera.

While EXPANCEL® hollow microspheres as described above are preferred, it should be understood that other hollow microspheres having a density range of  $.005 \text{ g/cm}^3$  to  $1.24 \text{ g/cm}^3$ , preferably  $.05 \text{ g/cm}^3$ , could be used.

When prepared as described above, a preferred embodiment of the composite elastic layer will have a density of  $.5 \text{ g/cm}^3$  to  $1.3 \text{ g/cm}^3$ , preferably  $.94 \text{ g/cm}^3$ ; a tensile strength greater than .1 Pa, preferably greater than .5 Pa; a durometer (00) of 13 to 62, preferably 22; a 100% modulus of 5 kPa to 250, preferably 20 kPa; and a compression

set of 0 to 30, preferably 8.

It should be understood that different or additional skin treating agents may be utilized, depending upon the skin condition to be treated by the skin treating agent. For use as a typical suction sleeve, Vaseline and aloe vera are believed to provide good properties for the composite elastic layer that typically directly contacts or is in close proximity with the skin of a prosthetic user.

When the composite elastic material 12 is laminated or bonded with an elasticized textile layer 14, such layer 14, in a preferred embodiment, may be described as a Supplex Nylon circular knit of 87% Nylon, 13% Spandex fibers using 28 needles per 2.5 cm having a weight per square yard of 6.9 ozs. and a weight per linear yard of 12 ozs. Such a Supplex Nylon is obtainable from Agmont Inc. of Montreal, Quebec, Canada under Style Name 5095. This material has a finished width of 60" (152.4 cm) and is substantially elastically distendable along its length and width in a manner appropriate for a prosthetic suction liner.

The reinforcing fibers 26 may be a circular knit textile formed of relatively non-distendable interlocked fibers (at least within the load ranges contemplated for use in a prosthetic suction liner) wherein the knit construction is such that the layer 26 strongly resists elongation in a longitudinal direction while being freely distendable laterally in a radial direction when it is embedded in the composite elastic layer 12. Any appropriate reinforcement matrix that would provide such properties could be used for layer 26, but as a practical matter a circular knit glass fiber or Nylon material is appropriate, provided it has the anisotropic properties described above.

The textile layer 14 is normally air permeable and is usually formed from a flat knit elasticized fabric that has been rolled into a tube and stitched along abutting side edges along the length of the tube. The inside surface of the fabric layer 14 facing the composite elastic layer 12 is coated with a thin layer of cured silicone elastomer 24 that is partially embedded in the fibers of the textile 14 without completely penetrating the textile 14. The silicone elastomer layer 24 is cured while embedded in the textile so that it is firmly adhered to the textile and preferably renders the textile and silicone layer 24 impermeable to air. The thin coating of silicone elastomer 24 provides a good bonding surface for the composite elastic layer 12 described above.

Preferably, the silicone layer 24 is obtainable under Product No. CF15-2188 from

NuSil Technology of Carpinteria, California. Physical properties of the combined composite elastic layer 12, coating 24 and elasticized fabric 14 include a tensile strength greater than 1 Pa, preferably greater than 2 Pa; and a 100% modulus of 5 to 300 kPa, preferably 55 kPa.

The distal end cap 18 may be formed of a silicone elastomer including 98% by weight silicone rubber, type MED-4950 or type MED-4050 or type CF15-2188, all available from NuSil Technology, with the balance (2%) constituted of a color mixture, for example a color powder blended from 12.5 parts Lucas color No. 2408, 12.5 parts Lucas color No. 2439 and 75 parts Lucas color No. 2510 all obtainable from Fr. Schoenfeld GmbH and Co. include: the material uses a platinum cure system; a press cure time of 50 minutes at 150° C; durometer 45 - 55; tensile strength 1000 psi (6.9 Mpa); elongation 400%; and a tear strength 230 ppi (40.3 kN/M).

As illustrated in Figure 5, a sealing sleeve 30, for example a sleeve capable of sealing the gap between the upper end of a prosthetic socket and a residual limb as illustrated in Patent No. 5,571,208 includes an outer textile layer 32 that is an elasticized, porous or air permeable fabric on which a continuous cured silicone coating 34 has been applied and bonded thereto in the same manner as the coating 24 attached to the layer 14 of the suction sleeve material as illustrated in Figures 1 - 4 and described above.

The interior surface of the sleeve 30 includes a composite elastic material 36 formed in the same manner as the composite elastic layer 12 illustrated in Figures 1 - 4 and described above. The thickness of the composite elastic material 36 may be adjusted to fit the requirements of a sealing sleeve. The composite elastic layer 36 is intimately bonded and adhered to the coating 34. The combined assembly of the textile 32, coating 34 and composite elastic layer 36 is fully distendable both radially and longitudinally in accordance with the requirements of a sealing sleeve for prosthetic applications.

The outer fabric layer 32, in a preferred embodiment, may be a circular rib knit fabric made of 95% Nylon and 5% Lycra, knit as a 1X1 rib using 220 needles per 2.5 cm for a 12 cm width tube and 264 needles per 2.5 cm for a 14 cm tube. This fabric may be obtained from RX-Textile of Monroe, North Carolina.

A preferred form of the suction liner made with the composite elastic material

layer 12 is illustrated in Figures 6 - 10 (the fabric is omitted in the views as being nonessential). The composite elastic material including the cured silicone elastomer layer with silicone oil and hollow microspheres and outer fabric is molded or formed as a tapered suction liner 40 having a closed distal end 42 of uniform thickness, an external profile 44 (see Figure 10) that is circular with the radii of curvature of the external surface 44 centered on a first central longitudinal axis 46 extending through the suction liner 40. The geometry of such suction liner is illustrated in Figures 6 - 10. Moreover, the following table 1 describes the variables shown in Figures 6 - 10 and also describes typical values of some of the variables for different size suction liners listed in the left column of the table entitled "Typical Values of Variables".

TABLE 1

VARIABLE DESCRIPTION

| Variable name | Description                                  |
|---------------|--|
| Angle         | Angle of socket opening                      |
| H_fl_prox     | Height of flange in proximal area            |
| HH1           | Height to flange in distal area              |
| HH2           | Height of flange in distal area              |
| HH3           | Height of second cut                         |
| HHtot         | Total height of socket                       |
| Hst           | Height from radius to start of distal flange |
| Offset        | Offset in lathe                              |
| Rrad1         | Radius on Distal end                         |
| RRad2         | Radius on proximal end                       |
| Tha           | Thickness in anterior area                   |
| Thp           | Thickness in posterior area                  |
| Thtop         | Thickness of socket in top                   |

TYPICAL VALUES OF VARIABLES

| Size | Rrad1 | HH1         | HH2 | HH3             | Hhtot | RRad2 | Tha | Angle | Hfh prox | Offset | Thp | Hst | Thtop |
|------|-------|-------------|-----|-----------------|-------|-------|-----|-------|----------|--------|-----|-----|-------|
| 12   | 19    | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 44.1  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 14   | 22.5  | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 48.1  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 16   | 25.5  | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 51    | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 18   | 28.5  | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 53.8  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 20   | 31.5  | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 56.7  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 21   | 33.5  | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 58.6  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 22   | 35.5  | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 60.5  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 23.5 | 37.5  | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 62.4  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 25   | 40    | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 64.7  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 26.5 | 42.5  | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 67.1  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 28   | 45    | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 69.5  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 30   | 48    | $rrad1+Hst$ | 80  | $Hhtot-HH1-Tha$ | 450   | 72.3  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |

| Size | Rrad1 | HH1       | HH2 | HH3           | Hhtot | RRad2 | Tha | Angle | Hfh prox | Offset | Thp | Hst | Thtop |
|------|-------|-----------|-----|---------------|-------|-------|-----|-------|----------|--------|-----|-----|-------|
| 32   | 51    | rrad1+Hst | 80  | Hhtot-HH1-Tha | 450   | 75.1  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 34   | 54    | rrad1+Hst | 80  | Hhtot-HH1-Tha | 450   | 78    | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 36   | 57    | rrad1+Hst | 80  | Hhtot-HH1-Tha | 450   | 80.8  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 38   | 60.5  | rrad1+Hst | 80  | Hhtot-HH1-Tha | 450   | 84.2  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 40   | 64    | rrad1+Hst | 80  | Hhtot-HH1-Tha | 450   | 87.5  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 42.5 | 67.5  | rrad1+Hst | 80  | Hhtot-HH1-Tha | 450   | 90.8  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |
| 45   | 71.5  | rrad1+Hst | 80  | Hhtot-HH1-Tha | 450   | 94.6  | 6   | 3     | 40       | 3      | 3   | 20  | 1     |

The suction sleeve 40 includes a circular curved inside anterior wall portion 50 having first radii of curvature centered on a second longitudinal axis of anterior curvature 52 extending longitudinally through the suction sleeve towards the anterior side of the first central axis 46 and a posterior wall portion 54 having second radii of curvature centered on a third longitudinal axis 56 located in the posterior direction relative to the central axis 46, said first, second and third longitudinal axes 46,52 and 56 all lying in a common longitudinally and transversely extending imaginary plane 60 (Figure 10) bisecting the anterior and posterior wall portions 50,54 and wherein the second and third axes 52 and 56 are spaced apart a predetermined offset distance from each other on opposed sides of the first axis 46. Thus, this arrangement produces a posterior wall that is thinner than the anterior wall as shown in Figure 10.

The anterior and posterior wall portions 50,54 intersect each other along inner diametrically opposed transition wall portions 62 that extend tangentially relative to the adjoining anterior and posterior wall portions along the sleeve length, so that the interior wall surface of the suction liner along the transition areas 62 are free of rapid changes in thickness, curvature or cross-section profile, as seen best in Figure 10.

In the example illustrated, the radii of curvature of the inside surfaces of the anterior and posterior portions of the sleeve are equal to each other along their respective second and third axes, as observable in Figure 10. A formula for generating the interior profile of the suction sleeve shown in Figures 6 - 10 is indicated at the bottom of Figure 6, and such formula is used to control a computer assisted machine tool (e.g., lathe) used to form a male mold element that shapes the inner profile of the liner.

At the proximal area of the suction sleeve 40 (the open end of the sleeve) a flange area 66 is provided wherein the thickness of the composite elastic material progressively thins as the top edge 68 is approached. The inside surface of the flange portion 66 of the anterior wall 50, as seen in Figure 9, tapers inwardly as the top edge 68 is approached as shown at 70 and the outer surface of the proximal end of the flange portion 66 of posterior wall 54 also tapers inwardly as shown at 72 in Figure 9. Preferably, the top edge 68 of the sleeve is relatively thin as compared with the thickness of the remainder of the sleeve.

The distal end 42 of the sleeve is spherical in curvature and joins the adjoining side wall of the sleeve along a tangent so as to provide a smooth interior and exterior contour as the sleeve transitions between the tapered conical upper portion and the spherically curved closed end portion 42. The thickness of the end portion 42 may be the same thickness as the anterior wall 50. The posterior wall 54 transitions from the same thickness as the anterior wall at the distal end of the sleeve to a thinner wall section over the length of the sleeve in which the thinner wall section is desired. A smooth transition area 74 is provided between the thinner posterior wall section 54 and the full thickness of the wall portion of the sleeve at the distal end of the sleeve.

The suction liner as illustrated in Figure 1 may be made in accordance with the process described below using the apparatus also described below for carrying out the process.

A textile layer corresponding to layer 14 is initially made as a flat strip 100 as illustrated in Figure 11. The flat strip is rolled into a tubular form so that opposed side edges of the strip are abutted together and then stitched at 102 along the abutting edges to form continuous lengths 101 of tubular elasticized fabric that may be utilized in the external cover of a suction liner such as suction liner 10.

A continuous film casting device for coating the tubes 101 includes a vertically extending rod 103 having a conduit 104 extending therethrough in communication with a suction pump 106, the operation of which is controlled by a controller element 107 in a manner to be described in more detail below.

Along the length of the vertical rod 103, there is provided a casting zone 105 along which is located continuous annular film casting device 108 through which an uncured tubular elastomeric film or layer may be expressed as a continuous, generally

vertical uninterrupted film generally coaxially surrounding the rod 102 or any substrate material that may be advanced along the surface of the rod 102 through the film casting device 108.

A source 110 of coating material to be expressed through the film casting device 108 is connected to the latter by means of conduit 112, pump 114 and a control system 116 for governing the operation of the pump 114.

The film casting device 108 may be provided with a heating and cooling system 118, which may include a circulating system for circulating a heating or cooling medium through the film casting device 108 by means of a pump 120 governed by a control system 122.

A suction or sub-atmosphere chamber 124 is connected to the upper surface of the film casting device 108 to create a sub-atmospheric pressure chamber 126 when a suction is applied to the chamber 126 via conduit 128. The conduit 128, for example, may be connected to suction pump 106 via conduit 104 during operation of the film casting device to create a sub-atmospheric pressure in chamber 126, or a separate suction line 109 may be used for this purpose.

The lower end of the rod 102 extends through a heating or curing zone including heating furnace 130 which may contain, for example, radiant or electrical heating elements 132 that provide a source of heat for curing a film expressed through the film casting device 108.

Annular tension control washers 136 spaced axially along the length of rod 102 are provided to control tension of a substrate coated in the apparatus described in a manner to be explained in more detail below.

An annular array of suction orifices 140 or the equivalent are provided on the rod 102 and which are in communication with air passages 144 which are in turn in communication with air passage 104 within rod 102. Orifices 140 may be incorporated in an annular member affixed to the rod 102 at a location where apertures 144 are provided in the rod 102 enabling communication between the orifices 140 and the passage 104. Suction applied by pump 106 can thereby be applied at orifices 140 over an area surrounding the rod 102.

Textile advancing drive elements 150 are provided adjacent the rod 102 above the suction housing 124 for cooperating with a relatively fixed guide element 152 affixed



to rod 102. The drive element 150 is rotatable by a motor 154 operable under the control of a controller 55 connected to the motor. When a substrate is inserted between the drive element 150 and the seat 152, the substrate will be advanced along the rod 102 in accordance with the driving direction of the rotatable element 150.

The orifices in film casting device 108 for expressing or discharging a tubular film or coating material 155 supplied from source 110 is configured in accordance with desired properties of the film or coating to be applied by the coating system as shown. Relatively thin coatings may be expressed through a continuous annular slot provided in the film casting device 108 or relatively thick coatings may be applied in the same fashion.

The vacuum in chamber 126 is adjusted to provide initial contact between a film 155 expressed through the film casting device 108 and the substrate advanced through the film casting device in a manner to be described below. Subsequently, when the substrate is air permeable, the suction device 140 draws the uncured film material into the substrate to a desired extent, for example only partially through the substrate thickness if it is desired to maintain uncoated substrate on the opposed surface of the substrate advanced through the film casting device. Higher suction applied at suction device 140 could be applied if it was desired to fully penetrate a porous substrate advance through the film casting device.

The heater 130 is regulated to fully cure a film expressed through the film casting device 108 and the time and temperature of such curing may be regulated by regulating the speed of advancement of the coated substrate through the heating device in accordance with known principles related to curing of curable films in coatings such as silicone elastomer, for example.

The operation of the film casting system as shown in Figure 12 will now be explained in the context of coating an elasticized tubular fabric with a cured silicone elastomer film. A previously formed length of tubular, elasticized fabric such as porous or air permeable fabric length 101 is threaded vertically upwardly over rod 102 with a lower end of the fabric threaded over element 152, through suction chamber 126, through the film coating device 108, over suction device 140, through heater 130 and onto a take-up spool 160 that is rotatable at a controlled speed by motor 162 in accordance with signals received from controller 164. Idler rollers 166 may be provided

to enable the direction of the coated fabric to be turned at the lower end of rod 102 to advance the fabric to the take-up spool 160.

With a length of fabric 101 thus threaded over rod 102, the fabric is drawn at a controlled speed downwardly over the rod 102 while suction chamber 106 is activated and an uncured tubular silicone elastomer resin film is expressed outwardly as a thin annular sheet of film from casting device 108 towards the fabric 101 that is drawn through the film casting device 108. Initially, the inner edge of the film expressed through the film casting device 108 may be manually adhered to the surface of fabric 101, whereupon the film 126 effectively closes the bottom of the suction chamber 126 so that the film is thereafter drawn inwardly by sub-atmospheric pressure communicated to the outer surface of the fabric 101 via the interstices of the fabric against the surface of the fabric uniformly over its entire periphery as the fabric is advanced through the film casting device 108.

The fabric is threaded through the advancing mechanism 150, 152 by rotating the roller 150 in a direction to advance the fabric downwardly over the rod 102. The positive feeding of the fabric 101 through the suction device 126 prevents undue tension from being applied to the fabric upon rotation of the take-up spool 160. It is desirable to maintain the fabric substrate in a relatively relaxed condition to the extent possible, although a pretension may be applied to the fabric if desired as it is advanced through the film casting device 108 or through the heater 130.

The suction device 140, as shown in detail in Figure 14, draws the uncured and pliable continuous, uninterrupted elastomeric film layer intimately into contact with and adhered to the air permeable substrate fabric 14 to the extent desired for the specific application of the coated fabric.

The fabric with the uncured resin coating then passes through the heater 130 where the coating is cured for a desired time at a desired temperature, all dictated by the properties of the cast film to be cured, and in accordance with known principles.

Within the heater 130, the tension on the coated fabric is controlled by the annular tension control washer elements 136 which apply a predetermined frictional drag on the fabric on its inner side as it is advanced over the rod 102 and also maintain the fabric extended radially somewhat as it passes through the heater 130. The number of annular elements 136 may be adjusted in accordance with the fabric and the

coating applied thereto.

The film casting device 108 may be selectively heated or cooled by using the heating and cooling system illustrated at 118, 120, 122. The degree of heating or cooling will depend upon the composition of the film to be cast on the surface of the fabric 101.

The resultant coated tubular fabric collected on spool 160 is now available to be used in a subsequent process to make a suction liner or may be available for any other application wherein a continuous cured coating applied to an elasticized tubular substrate is desired.

In this example, the film to be cast on fabric 101 corresponds to film 24 described previously and the fabric 101 corresponds to the fabric outer layer 14 of the silicone liner described above in Figures 1 - 4.

After coating of the elasticized fabric 101 using the apparatus described above, the coated fabric is cut into lengths as shown in Figure 15 and a length of tubular reinforcement matrix material 169 is affixed, for example by sewing, to the end of the coated fabric. The matrix 170 may correspond to layer 26 in the suction liner of Figure 1. Preferably the reinforcement matrix comprises interlocked fibers such as a circular knit tubular fabric that strongly resist longitudinal elongation but readily distends radially.

Individual lengths of the coated fabric and reinforcement matrix are then prepared to receive a distal end cap (to be described below) that will be molded to one end of the coated length of fabric 101 to close said end and to embed a portion of the matrix 170 in the interior of the coated tubular fabric, as will become evident following a review of the description of the distal end cap molding apparatus shown in Figure 16.

The coating apparatus described above may be used to form multiple continuous coatings on a tubular substrate simply by advancing a previously coated tubular substrate through the coating apparatus in the same manner as described above. For example, the sealing sleeve illustrated in Figure 5 may be formed using the coating apparatus illustrated in Figure 12 by first providing a continuous coating of silicone elastomer on one surface of a tubular elasticized fabric and then subsequently passing the thus coated fabric through the film casting device 108 while expressing a composite elastic material corresponding to layer 36 in Figure 5 through the casting device 108. The layer 36 may then be cured in the heater 130.

In Figure 16, a compression molding apparatus is illustrated for use in molding

a distal end cap on one end of a length 101 of coated elasticized fabric with a reinforcement matrix 169 attached thereto. The molding apparatus includes a lower female mold cavity 170 configured to form an external shape on a distal end cap to be molded in the cavity and including a central guiding aperture 172, heating elements 174, preferably electrically energized, and a pressure chamber 176 that is in communication with a pneumatic pump 178 that is controllable by controller 180 in combination with a shut-off valve 182 that selectively pressurizes pressure chamber 176. Pneumatic pressure orifices 184 are spaced peripherally around the support 186 for the female mold 170.

The support 186 is rotatably mounted on a base 187 by means of bearings 188 so that the female mold support 186 may be rotated about an axis of rotation relative to the base 187 and the upper part of the molding device to be described below. Vertical support members 189 are schematically illustrated extending between the base 187 and the upper part of the molding device. The support members 189 may be rods or pillars with open areas between them to provide access to the female mold 170 and the upper part of the molding device.

The upper part of the molding device supported above the female mold 170 includes a male mold plug and clamping element 190 and a cooperating clamping cylinder 192 that slidably supports the male mold and clamping device 190 for reciprocal movement relative to the clamping cylinder 192. The mold and clamping device 190 is supported, for example, by a rod 194 or equivalent that is connected to a pneumatic cylinder 196 that is operable to control movement of the male mold and clamping element 190 towards and away from the distal end of the clamping cylinder 192 to effectively open or close the distal or lower end of the clamping cylinder 192.

The interior of clamping cylinder 192 is provided with a suction chamber 196 that communicates with a suction pump 198 via conduit 200 and shut-off valve 202. Pump 198 and shut-off valve 202 are operated under the control of a controller 204 such that a suction can be applied to suction chamber 196 by pump 198 selectively to create an inflow of air between the mold and clamping device 190 and the distal end of the clamping cylinder 192 through a gap 195.

The entire assembly of the clamping cylinder 192 and the mold and clamping device 190 may be reciprocally moved towards and away from the female mold 170 by

a second pneumatic or hydraulic cylinder 208, the operation of which is controlled by a controller 210 and appropriate valving 212, whereby the clamping cylinder 192 and the mold and clamping device 190 may be advanced into cooperation with the female mold 170 to create a mold cavity between the bottom surface of the mold and clamping device 190 and the surface of the female mold 170.

A guide rod and orifice plug 214 optionally extends centrally through the male mold and clamping device 190 for cooperation with the guide opening 172 in the female mold 170 when it is desired to maintain an aperture in a distal end cap to be molded between the male and female molds 190,170. Such an aperture is desired if a prosthetic connector is to be molded into the end cap.

The various pumps, valves and controllers, as well as the heating elements 174 all may be controlled and operated from a central control panel 220 using conventional control technology including digital computer processors.

The operation of the molding device described in Figure 17 will now be described in conjunction with Figures 18 - 22 when it is desired to mold an end cap on a coated elasticized fabric with a prosthetic connector and a distension controlling reinforcement matrix as previously described. Initially, a length of the coated elasticized fabric 101 with a reinforcement matrix 169 attached thereto as shown in Figure 15 is threaded over the female mold support 186 with the free end of the reinforcement matrix 170 threaded over the distal end area of the clamping cylinder 192, as illustrated in Figure 17. The mold and clamping device 190 is in the extended position thereby exposing the gap 195 between the mold and clamping device 190 and the distal end of clamping cylinder 192. A suction is then applied to the suction chamber 196 by pump 106 which draws in the free end of the reinforcement matrix 170 through the gap 195.

The mold and clamping element 190 is then moved to its upper or closed position relative to the clamping cylinder 192 to effectively close the gap 195 and to clamp the free end of the reinforcement matrix 170 between the mold and clamping device 190 and the clamping cylinder 192, as illustrated in Figure 18.

The female mold support 186 is then rotated 1/4 turn or so relative to the base 187 to introduce a twist constriction 218 in the tubular reinforcement matrix 170 that effectively forms a closure at the one end of the length of coated elasticized fabric 101 and leaves a free tubular length of reinforcement matrix 170 within the clamping

cylinder 192. The rod element 214 in this example extends through the central area of the twisted section 218 of reinforcement matrix 170.

As shown in Figure 20, a sudden pressure is then applied to pressure chamber 176 that blows the length of coated elasticized textile outwardly and upwardly over the external surface of the clamping cylinder 192, which may be provided with suction orifices 219 to assist in this procedure as seen in Figure 20.

A rigid prosthetic connector "umbrella" element 224 is next primed or coated with an uncured elastomer that forms an intimate bond with the connector element and with the elastomer to be used for the distal end cap to be molded in the cavity to be provided between the male mold and clamping element 190 and the female mold 170. The thus primed and coated prosthetic connector element 224 is placed in the female mold 170 so that it is spaced away from the bottom of the mold surface with a connector portion thereof 226 extending through aperture 172. A premeasured portion 225 of uncured elastomer material (which may be the same as the primer) is then placed in the female mold cavity 170 on the connector element 224 and thereafter the clamping cylinder 192 and the associated mold and clamping device 190 with the coated elasticized fabric 101 and reinforcement matrix 170 is advanced towards the female mold 170 to compress and shape the uncured elastomer material in the mold cavity so that it conforms on one side to the surface of the female mold 170 and on its other side to the surface of the male mold and clamping element 190. In this process, the prosthetic connector 224 becomes totally embedded in the silicone material in the mold cavity so that it is completely covered by the elastomer. This is illustrated in Figure 21, for example.

The heater element 174 is activated at the appropriate time to heat the female mold 170 to an appropriate curing temperature for the silicone elastomer used to form the distal end cap and the priming elastomer applied on the prosthetic connector 224. The elastomer is then cured to produce a relatively firm distal end cap 230 as shown in Figure 23, with a free length of reinforcement matrix 170 within the coated elasticized fabric 101. The distal end cap 230 bonds together the twisted reinforcement matrix 218 while the male and female molding surfaces together shape the inside and outside contours of the distal end of the coated fabric 101. The elastomer selected for the end cap 230 provides desired properties for the distal end cap as part of a prosthetic suction liner.

The pre-formed assembly of coated tubular elasticized fabric 101, end cap 230 and reinforcement matrix 170 are then placed in a holder 234 as shown in Figure 23 to expose the internal distal end of the length of coated fabric 101 and the reinforcement matrix 170 so that a pre-measured quantity of uncured elastomer liner resin material 232, for example, a silicone elastomer corresponding to the composite elastic material 12 shown in Figure 1, can be dispensed into the open distal end as shown in Figure 24. A source of the silicone elastomer resin is provided at 236 and a precision measuring pump 238 is operated via controller 240 to dispense a precise quantity of uncured elastomer 232 into the holder 234 and within the open distal end of the length of tubular elasticized fabric 101 that has been closed by the end cap 230.

The partially filled pre-form is now placed in a female molding or shaping die cavity 242 as shown in Figure 24 with the length of coated fabric 101 fully extended over the length of the female die cavity 242. The female die cavity 242 is defined within a female die support structure 244 that may include suction orifices 246 to which a suction may be applied via valve 248 to draw the pre-formed coated elasticized fabric 101 and the distal end cap 230 into close conformity with the female die cavity 242. The support 244 includes a heater 250 that may be energized to raise the temperature of the female die support up to the curing temperature of the elastomer deposited in the distal end of the coated fabric sleeve 14.

A male die element or plug 252 is reciprocally mounted relative to the female die support 244 so as to be axially movable into and out of the cavity defined by the female die 242. A pneumatic or hydraulic cylinder arrangement 254 may be provided to advance the male die element 252 towards and away from the female die cavity 242 under the control of a controller 256 that may be integrated with the controller for the heater 250.

The external contour of the male die 252 is configured to provide a defined shape to produce a die cavity that results when the male die 252 is fully advanced towards the female die cavity 242 to form a die cavity as shown in Figure 25. As the male die 252 advances into female die cavity 242, the uncured elastomer 232 is cold forged or driven into the die cavity between the male die 252 and the inner walls of the female cavity 242 progressively from the distal end of the pre-formed coated fabric and distal end cap to the proximal open end of the tubular fabric 101. The external surface

of the male die 252 is contoured to define the internal shape of the elastomer material occupying the die cavity between the male die 252 and the female die cavity 242 while the female die cavity 242 is shaped to define the external contour of the fabric 101 to be joined with the elastomer in the mold cavity. The contour of the male die 252 also includes appropriate surface areas designed to enhance the uniform flow of uncured elastomer from the distal end of the pre-form to the proximal end thereof to ensure that the die cavity between the male and female die elements is completely and uniformly filled with the uncured elastomer material that previously was introduced into the tubular elasticized fabric 101 in a quantity sufficient to fill the die cavity.

To assist in guiding the length of coated fabric 101 into the female die cavity 242, a guide pin 253 having a threaded proximal end may be threaded into the prosthetic connector 224 prior to insertion of the fabric length 101 into the female die cavity. An aperture 253' is provided in the bottom of the support 244 to receive the guide pin 253 as the fabric length 101 is lowered into the female die cavity.

To assure uniform lengths of finished cold forged products, a locking ring 251 may be provided at one end of the fabric sleeve 101 that cooperates with the male die 252 to limit the length of the cold forged liner formed from the uncured silicone elastomer 232 when the male and female dies are brought together.

The heater 250 is activated at the appropriate time to cure the elastomer 232 in the die cavity for an appropriate length of time and at an appropriate temperature in accordance with the elastomer material selected to fill the mold cavity. Heaters 257 may be used in the male die 252 as well.

Figure 26 shows an enlargement of a detail of the female die cavity 242, the heater 250, the coated fabric 101, the coating 155 on the fabric and the innermost layer 232 of elastomer containing an embedded reinforcement matrix and the position of the male die 252. Upon curing of the elastomer in the mold cavity, the male die 252 is withdrawn and the now fully integrated assembly of fabric 101, elastomer coating 155, and innermost elastomer layer 232 is removed from the female mold 242. The guide pin is then removed, leaving a fully formed suction liner corresponding to suction liner 10 in Figure 1 ready for final detailing and eventual use.

When the innermost layer of elastomer 232 is constituted of the composite elastic material described above in connection with Figures 1 - 4, the male and female



dies may be heated to a temperature of 100° C and the elastomer may be cured for a cure time of 6 minutes.

The exterior contour of the male die 252 may be shaped in accordance with the inner peripheral contour of layer 12 of suction sleeve 10 as described in connection with Figures 6 - 10 as described previously.

While a specific embodiment of the inventive process and apparatus constituting the inventive subject matter have been described previously, it should be understood that various modifications to the process and apparatus can be made without departing from the spirit and scope of the invention.

The tubular fabric 101 may be produced in various lengths with or without a longitudinal seam and instead of a reinforcement matrix 170, any appropriate material can be utilized to form a twisting closure in the apparatus shown in Figure 16, including the fabric 101 itself if no matrix is used.

The coating apparatus of Figures 12 - 15 may be utilized to coat any tubular material, including a non-porous or non-permeable tubular material. When non-porous material is coated, the suction applied in suction chamber 126 is adjusted to ensure appropriate adhesive to the exterior surface of the moving tubular substrate and the suction orifices 140 do not need to be used. Likewise, the tension controlling elements 136 may be adjusted to accommodate the specific tubular substrate to be coated in the apparatus.

The premeasured quantity of uncured silicone elastomer could be directly deposited into the open tube 101 after the latter has been set into the female die cavity 242.

Other various departures from the specific embodiment described above can be envisioned within the skill of the person skilled in the art and it is to be understood that the specific steps and apparatus disclosed herein are to be exemplary only.

## I CLAIM:

1. A method for making a tubular member having a continuous and uninterrupted cured elastomeric resin coating on one of two opposed surfaces of the tubular member comprising:

forming a continuous vertically extending uninterrupted tubular layer of uncured elastomeric resin;

drawing the layer of resin against one of said surfaces of the tubular member to be coated by applying suction below atmospheric pressure between the resin layer and the said one surface of the tubular member to which the resin layer is to be applied while continuously moving the tubular member relative to the continuously formed resin layer with the tubular member generally vertically oriented and in generally coaxial relationship with the tubular layer of the elastomeric resin until said one surface is coated with said uncured resin layer and said layer of uncured resin is adhered to said one surface; and

curing said elastomeric resin while it is adhered to the one surface of the tubular member.

2. The method according to claim 1, wherein said tubular member consists of a material that is porous, comprising drawing the tubular layer of uncured elastomeric resin against the one surface to be coated by applying sub-atmospheric pressure to the surface of said tubular member opposed to the surface to be coated by the tubular layer of uncured elastomeric resin to thereby create a sub-atmospheric pressure condition across the porous material of the tubular member and between the tubular member and the uncured layer of elastomeric resin.

3. The method according to claim 2, including drawing said uncured elastomeric resin layer at least partly into the pores of the porous material of said tubular member during said drawing step to thereby further adhere the uncured elastomeric resin layer to the one surface of the tubular member.

4. The method according to claim 2 or 3, including selecting an elasticized fabric

as the material forming said tubular member.

5. The method according to claim 1, including selected a silicone resin as said uncured elastomeric resin layer.

6. The method according to claim 2 or 3, including selecting an elasticized fabric material for use as the material of said tubular member.

7. A tubular member having a continuous and uninterrupted cured elastomeric resin layer adhered to one of the opposed surfaces of the tubular member made by the process according to any one of claims 1 - 6.

8. A composite tubular member comprising a continuous length of a tubular member formed of porous material coated on one side with a continuous uninterrupted elastomeric resin layer that extends only partly into the pores of the porous material.

9. A composite tubular member as claimed in claim 8, wherein the resin layer is silicone.

10. A composite tubular member comprising a continuous length of a tubular member formed of an elasticized porous fabric coated on one side with a continuous uninterrupted layer of cured elastomeric resin that extends only partly into the pores of the fabric.

11. A resin coated tubular member as claimed in claim 10, wherein said elasticized fabric is a tubular knit material.

12. A process for forming a length of a continuous tubular member with an uninterrupted continuous layer of elastomeric resin covering and adhered to one of two opposing sides thereof, comprising:

continuously feeding a tubular member in a generally longitudinal and vertically downward direction relative to and through a coating zone maintained at a

sub-atmospheric pressure;

while carrying out said feeding step, applying and adhering a continuous, uninterrupted tubular uncured elastomeric resin layer to said one side of said tubular member within said coating zone by applying sub-atmospheric pressure between said elastomeric resin layer and said one side of said tubular member; and

curing said elastomeric resin while it is adhered to said one side of said tubular member.

13. The process as claimed in claim 12, wherein said tubular member is formed of an air permeable material having interstices, further comprising supplying sub-atmospheric pressure between said elastomeric resin layer and said one side of said tubular member by exposing the opposed side of said tubular member to said sub-atmospheric pressure and communicating the sub-atmospheric pressure to the side of the tubular member to be coated via interstices of the air permeable member.

14. The process as claimed in claim 12, including selecting an air permeable material having interstices as the material constituting the tubular member, and further drawing the uncured elastomeric resin layer at least partly into the interstices of the air permeable material on said one side of the tubular member by applying a sub-atmospheric pressure to the opposed side of the tubular member and communicating the sub-atmospheric pressure to the uncured elastomeric resin layer via the interstices after the uncured elastomeric resin layer has been adhered to one side of the tubular member.

15. The process as claimed in claim 12, 13 or 14, including the step of selecting an elasticized fabric as the material constituting the tubular member, and radially distending and longitudinally tensioning the tubular member during the curing step.

16. Apparatus for applying a continuous uninterrupted resin layer on one surface of a continuous tubular substrate, comprising:

a coating zone including a continuous resin casting device arranged to dispense a continuous, uninterrupted, tubular coating material layer of uncured

elastomeric resin into the coating zone;

said coating zone including a sub-atmospheric chamber arranged so as to provide a sub-atmospheric pressure within the chamber to which said coating material layer is subjected during operation of the apparatus;

a heating zone located adjacent said coating zone, said heating zone including a heater device; and

a feed mechanism arranged to engage and feed a continuous tubular substrate along a longitudinal direction of the substrate through said sub-atmospheric chamber and coating zone, and said heating zone in the recited order.

17. Apparatus as claimed in claim 16, including a vertically extending rod member;

said rod member extending centrally through said sub-atmospheric chamber, coating zone and heating zone in the recited order;

said rod member arranged to support a tubular substrate to be coated along a length of said rod member extending through said sub-atmospheric chamber, coating zone and heating zone.

18. Apparatus as claimed in claim 17, said rod member including a conduit having a section terminating in said sub-atmospheric chamber and a device for supplying sub-atmospheric pressure to said conduit.

19. Apparatus as claimed in claim 17 or 18, said rod member including a conduit having a section terminating at at least one suction orifice located at an external area of said rod between the coating zone and the heating zone.

20. Apparatus as claimed in claim 17, 18 or 19, including longitudinally spaced friction washer elements disposed along said rod member, said washers comprising annular members each having an outside diameter related to a desired inside diameter of a tubular member to be coated, at least one of said washer elements disposed in said heater.

21. Apparatus as claimed in one of claim 16 - 20, said feed mechanism comprising drive rollers disposed and arranged to frictionally engage the tubular member and to advance the tubular member relative to and along said rod member through said coating zone and heater.

22. Apparatus as claimed in claim 16, said resin casting device including a heating device arranged so as to provide heating energy to a resin material supplied to the casting device.

23. Apparatus as claimed in claim 16, said resin coating device including a cooling device arranged so as to provide cooling energy to a resin material supplied to the casting device.

24. A method for molding a distal end cap on an open end of a length of a pre-formed tubular sleeve member formed of an elasticized fabric with a porous tubular reinforcement matrix integrated with said end cap, comprising the steps:

providing a length of a pre-formed tubular sleeve member formed of elasticized fabric and having an open end;

securing a length of a tubular reinforcement matrix element formed of interlocked fibers that are arranged so the matrix member is porous and strongly resists elongation in the sleeve longitudinal direction but is readily stretchable in transverse radial directions to an open end of the tubular sleeve member so the sleeve member and matrix element extend generally coaxially;

twisting the matrix element about its central axis adjacent the open end of the sleeve member to effectively close the open end of the sleeve member by the twisted matrix element;

providing a female mold having a female mold cavity dimensioned and configured to correspond with a desired outer contour of a distal end cap to be joined to the sleeve member;

placing a predetermined quantity of an uncured end cap elastomeric resin in the female mold cavity;

providing a male mold element dimensioned and configured to cooperate

with the female mold so that, when the male mold element located in molding relationship with the female mold, a closed mold cavity defining the external contour of a distal end cap is formed;

locating the portion of the matrix element extending beyond the twisted portion inside the adjacent open end of the tubular sleeve;

locating the male mold element inside the matrix sleeve portion located inside the tubular sleeve;

advancing the male mold element, matrix sleeve and tubular sleeve into molding relationship with the female mold so that the twisted portion of the matrix element extends within the closed mold cavity along with the uncured distal end cap resin so that the resin penetrates the porous material of the matrix element and closes the open end of the sleeve member;

curing the resin in the mold cavity; and

removing the molded distal end cap and reinforcement matrix from the mold cavity, wherein the former open end of the sleeve member is closed by the molded distal end cap and the reinforcement matrix is located concentrically inside the end area of the sleeve adjacent the distal end cap.

25. The method as claimed in claim 24, said tubular sleeve including an inner wall, and including providing the inner wall of said tubular sleeve with a continuous, uninterrupted elastomeric resin film coating before molding said distal end cap to the open end of the sleeve member.

26. The method as claimed in claim 24, including placing a rigid umbrella prosthetic connector element in said female mold cavity with said predetermined quantity of uncured distal end cap resin and curing the distal end cap with the connector element embedded in the distal end cap resin.

27. A preform for a prosthetic suspension sleeve comprising:

a tubular sleeve comprising an elasticized fabric, said tubular sleeve including an open end;

a distal end cap molded on and closing the open end of the tubular

sleeve;

a tubular matrix reinforcement element secured coaxially to the open end of the sleeve member and having a portion embedded in the distal end cap and a portion extending coaxially within the open end area of the sleeve member.

28. A preform as claimed in claim 27, including a prosthetic umbrella connector element embedded in the distal end cap.

29. A preform as claimed in claim 27, said sleeve member having an inner wall, and including a continuous, uninterrupted cured elastomeric resin film coating on the inside wall surface of said sleeve member.

30. A preform as claimed in claim 29, wherein said film coating and distal end cap comprise silicone elastomer material.

31. A preform as claimed in claim 27, wherein said matrix reinforcement element is circular knit fabric material selected from the group consisting of glass fiber and Nylon.

32. A process for forming a sleeve member suitable for prosthetic applications, said sleeve members comprising a tubular elasticized fabric element having a distal end cap attached to and closing one end of the sleeve element, comprising the steps of:

placing a predetermined quantity of uncured elastomeric resin intended to form said cured elastomer layer in the interior of the closed end of the sleeve member;

placing the sleeve member and uncured elastomer resin in a female molding die cavity having an interior contour corresponding to the desired outer contour of said sleeve member;

placing a male mold die member having an outer contour corresponding with the desired inner contour of the sleeve member within the sleeve member and advancing the male mold die member into the sleeve member and female mold die



cavity until it reaches a molding position relative to the female mold die cavity, at which position a closed die cavity between the male mold die member and the female mold die cavity is defined, said sleeve is located in the mold cavity adjacent inner walls female mold die and the uncured elastomer resin occupies the remainder of the closed die cavity, said resin having been distributed throughout the closed die cavity and against the interior of the sleeve member by movement of the male mold die member relative to the female mold die cavity and the uncured resin;

said predetermined quantity of uncured elastomer resin being calculated to fill said closed die cavity;

curing the elastomer resin in the closed die cavity in bonded relationship with the interior of the sleeve member;

withdrawing the male mold die member, tubular sleeve member, distal end cap and cured elastomer layer from the female mold die cavity.

33. The process as claimed in claim 32, including securing a tubular reinforcement matrix member to the closed end of said sleeve member so that the matrix member extends loosely within the sleeve member adjacent the interior surface of said sleeve member; said matrix member comprising interlocked fibers that are arranged so that the matrix member is porous and strongly resists elongation along the sleeve longitudinal direction but is readily stretchable in the transverse radial direction; and the step placing said predetermined quantity of uncured elastomer resin in the sleeve member includes placing said quantity within the matrix member, whereby, upon distribution of said uncured elastomer resin within the closed die cavity by the movement of the male die member, said matrix member is embedded in the uncured elastomer resin material and is integrated with the elastomer resin upon curing thereof.

34. The process as claimed in claim 32, including drawing said tubular sleeve member against the interior wall of the female mold die cavity during advancement of the male mold die member into the female mold die cavity by using suction of air from the area between the tubular sleeve and the female die cavity interior walls.

35. The process as claimed in claim 32, including covering the interior surface

of said tubular sleeve member with a cured, continuous, uninterrupted elastomeric resin layer prior to placing said predetermined quantity of uncured elastomer resin in said sleeve member, whereby said cured elastomeric resin layer seals the interior surface of said elasticized fabric constituting said sleeve member prior to the placement of the sleeve member in the female molding die cavity, and whereby said uncured elastomer resin filling said die cavity is cured in bonded relationship with said continuous elastomeric resin layer.

36. The process as claimed in claim 32, including selecting silicone resin as the uncured elastomer resin.

37. The process as claimed in claim 35, including selecting silicone resins for said continuous layer of cured elastomer extending over the interior of said sleeve member and for said uncured elastomer resin placed in the interior of the closed end of the sleeve member.

38. A preform for a prosthetic suspension sleeve comprising:  
a tubular sleeve comprising elasticized fabric;  
a tubular matrix reinforcement element secured coaxially to the open end of the sleeve member, said matrix reinforcement element comprising interlocked fibers that are arranged so that the matrix reinforcement element is porous and strongly resists elongation in the sleeve longitudinal direction but is readily elastically stretchable in transverse radial directions;  
said tubular sleeve having an inner wall coated with an uninterrupted, continuous elastomeric layer.

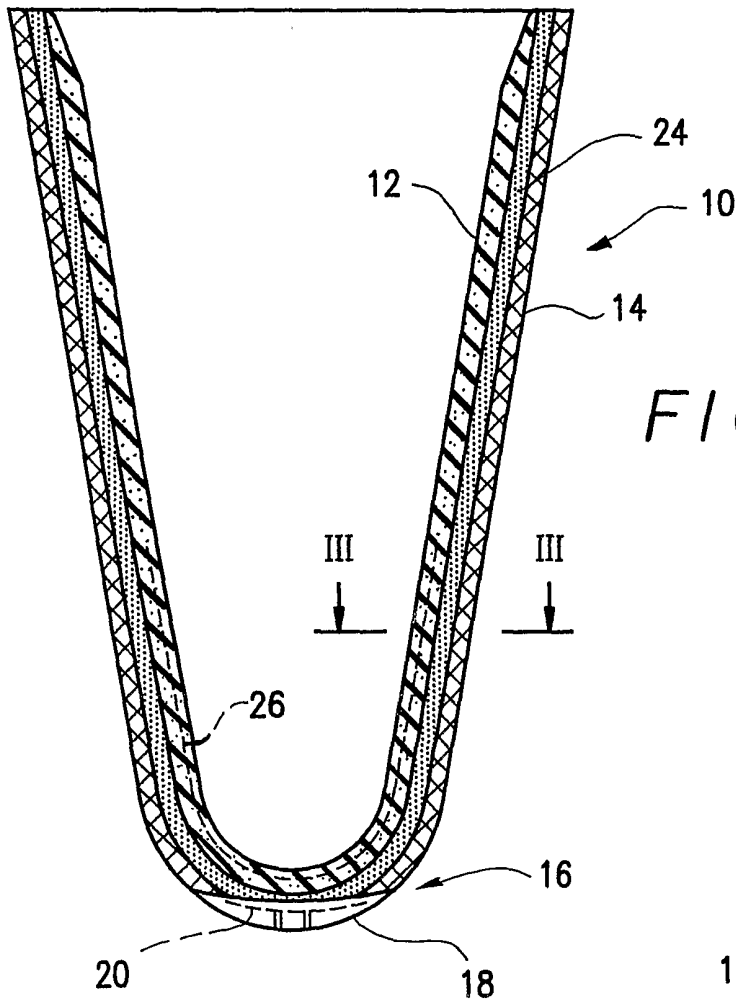


FIG. 1

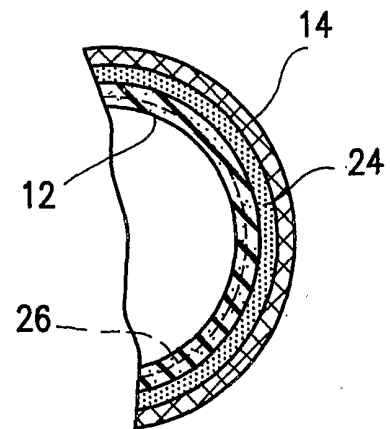


FIG. 3

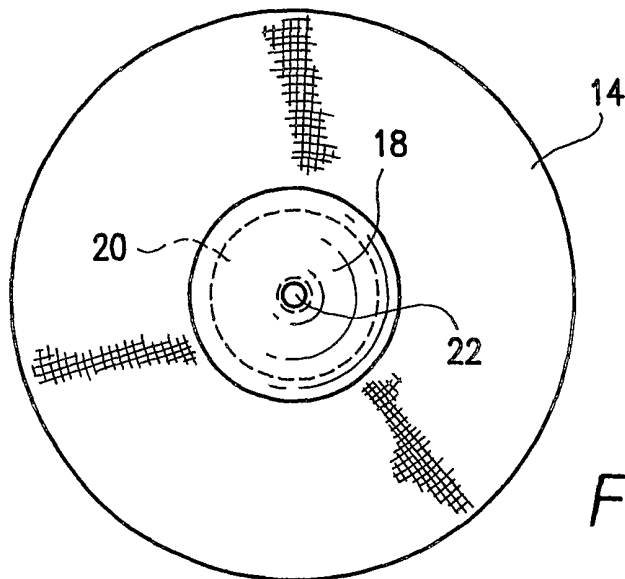


FIG. 2

FIG. 4

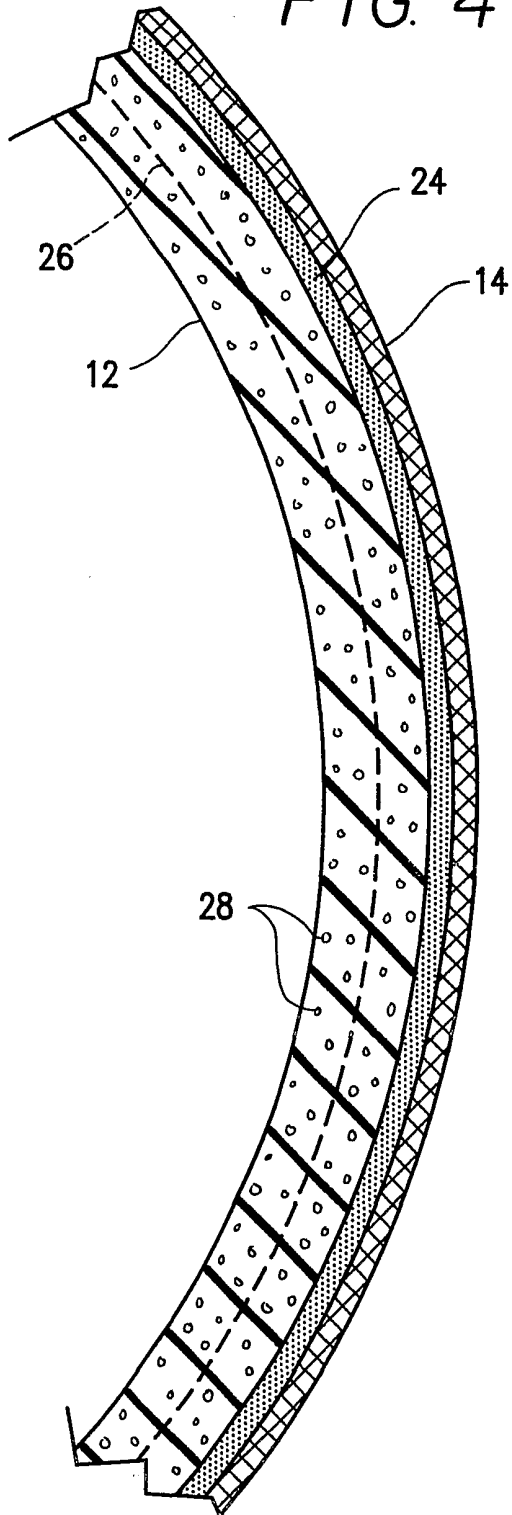


FIG. 5

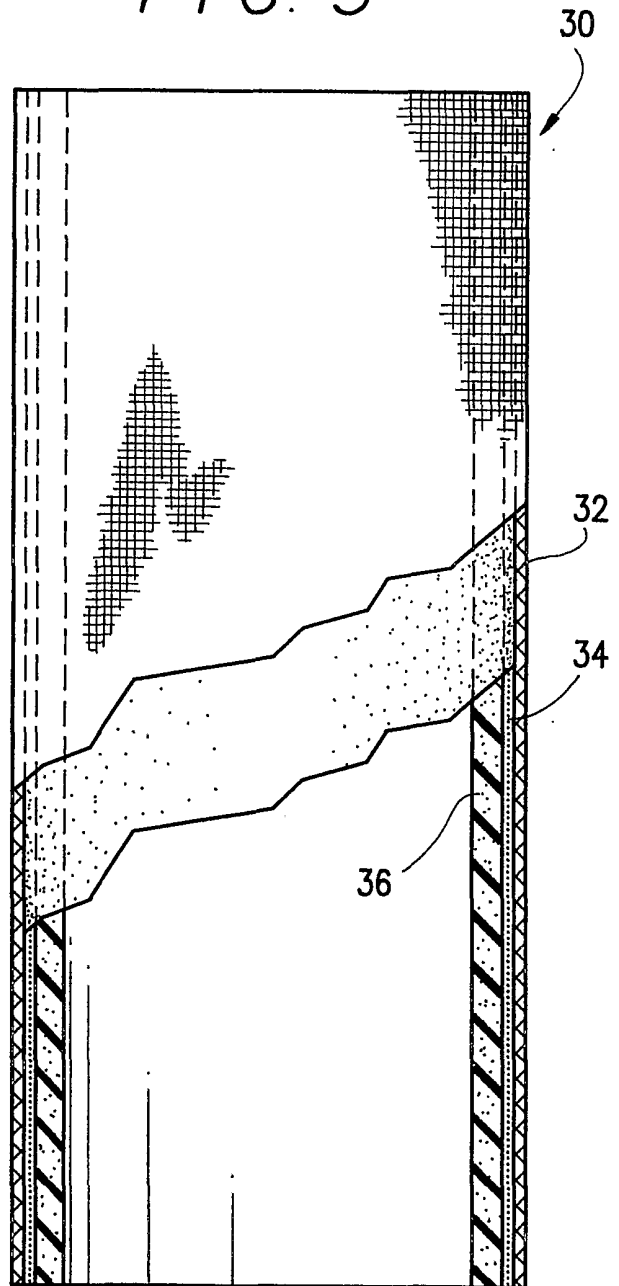
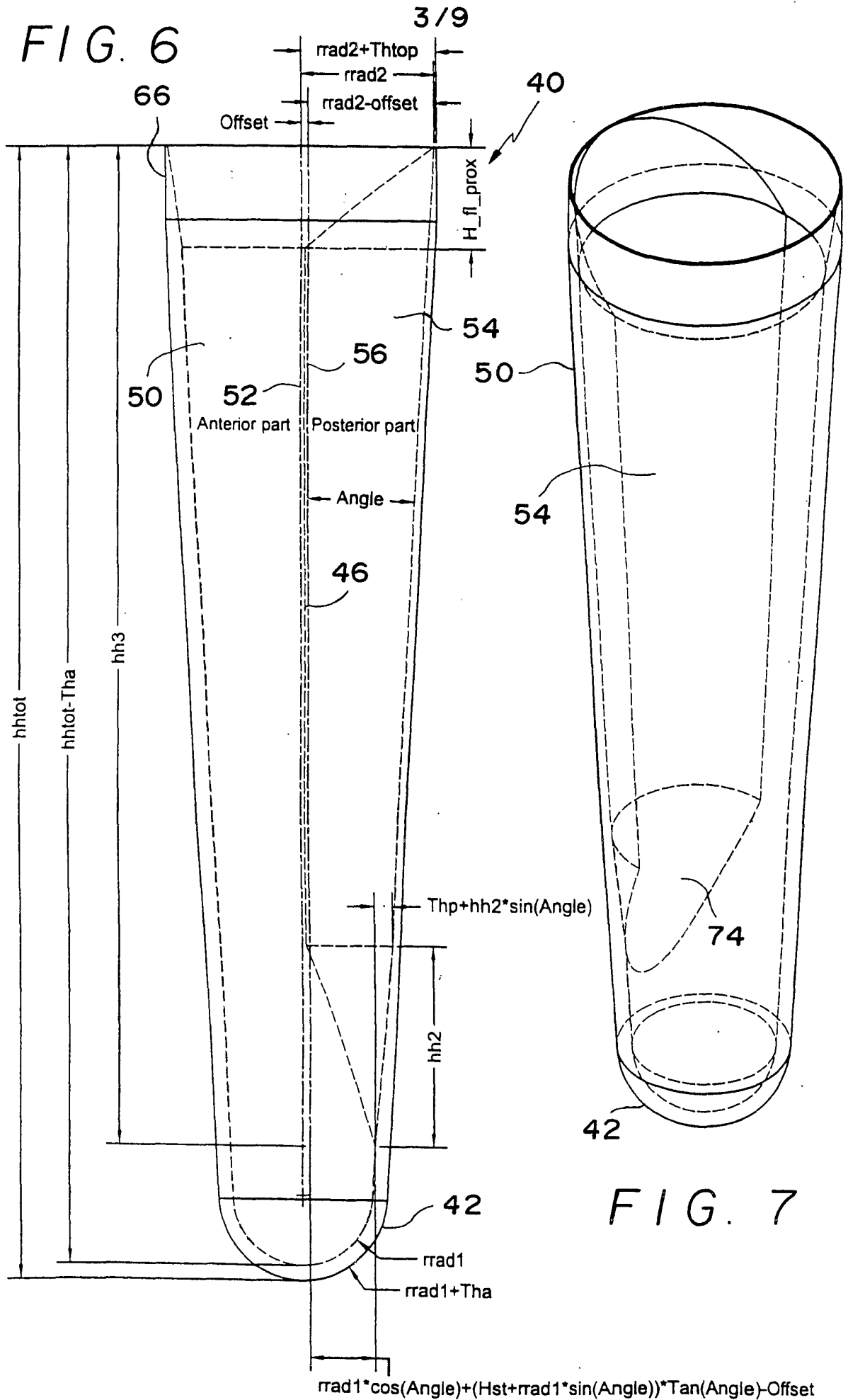


FIG. 6



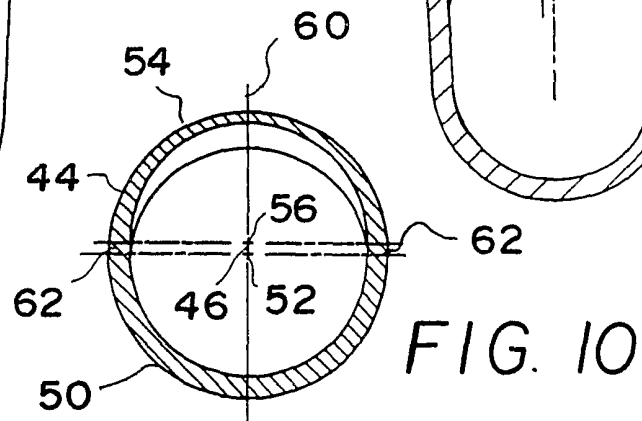
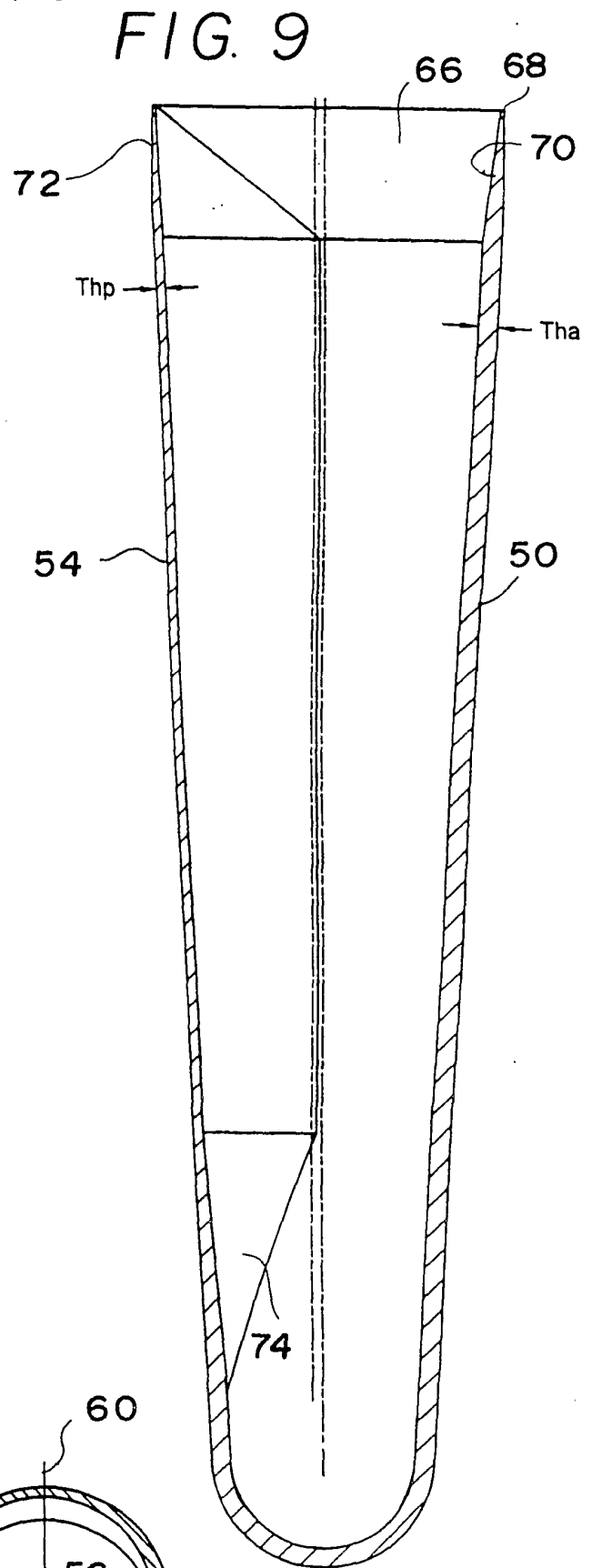
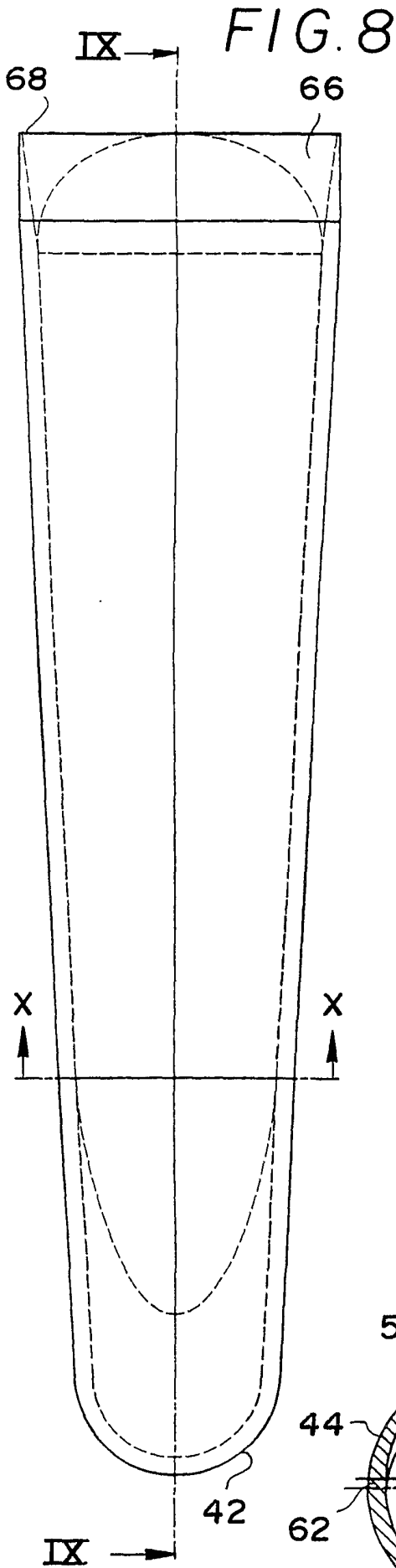


FIG. 12

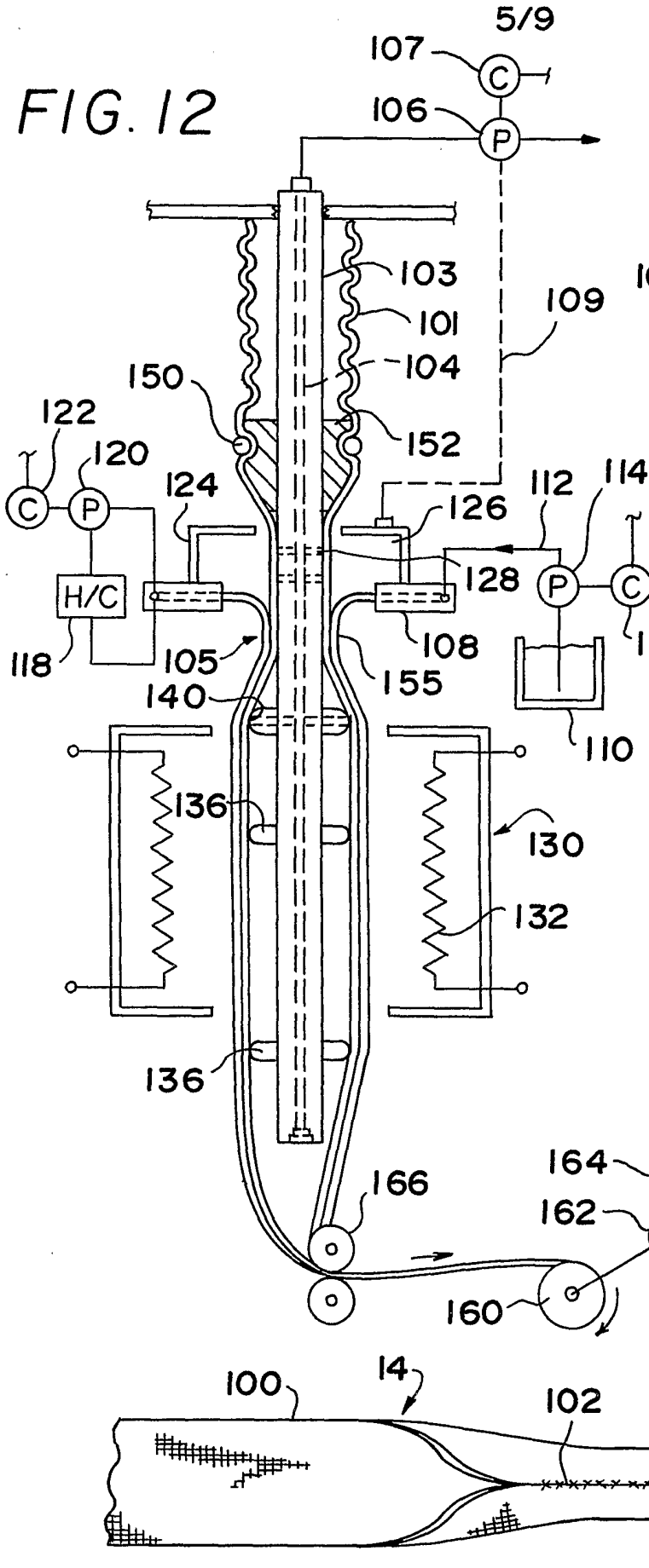


FIG. 13

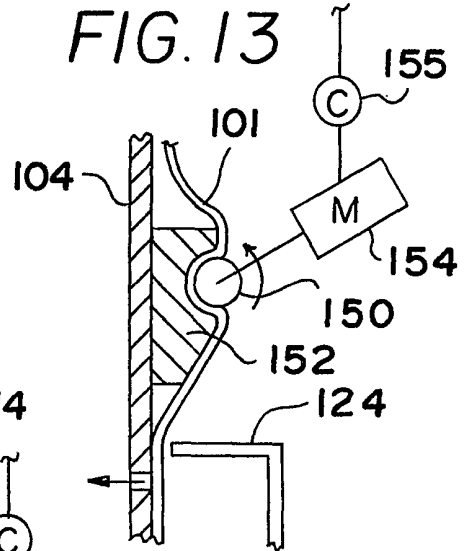


FIG. 14

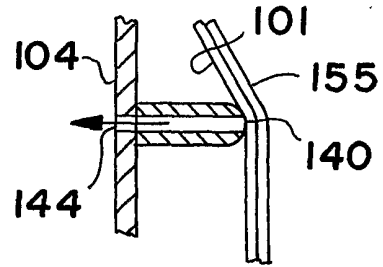


FIG. 15

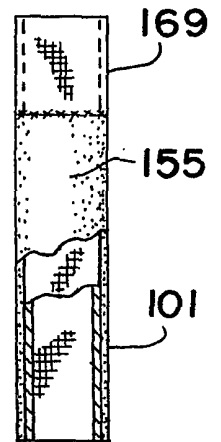
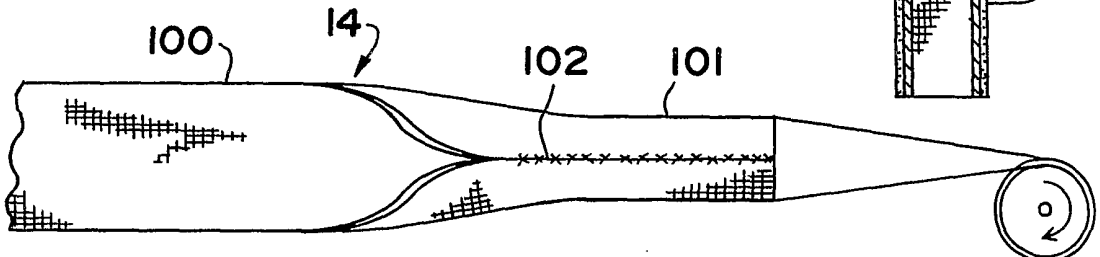


FIG. 11



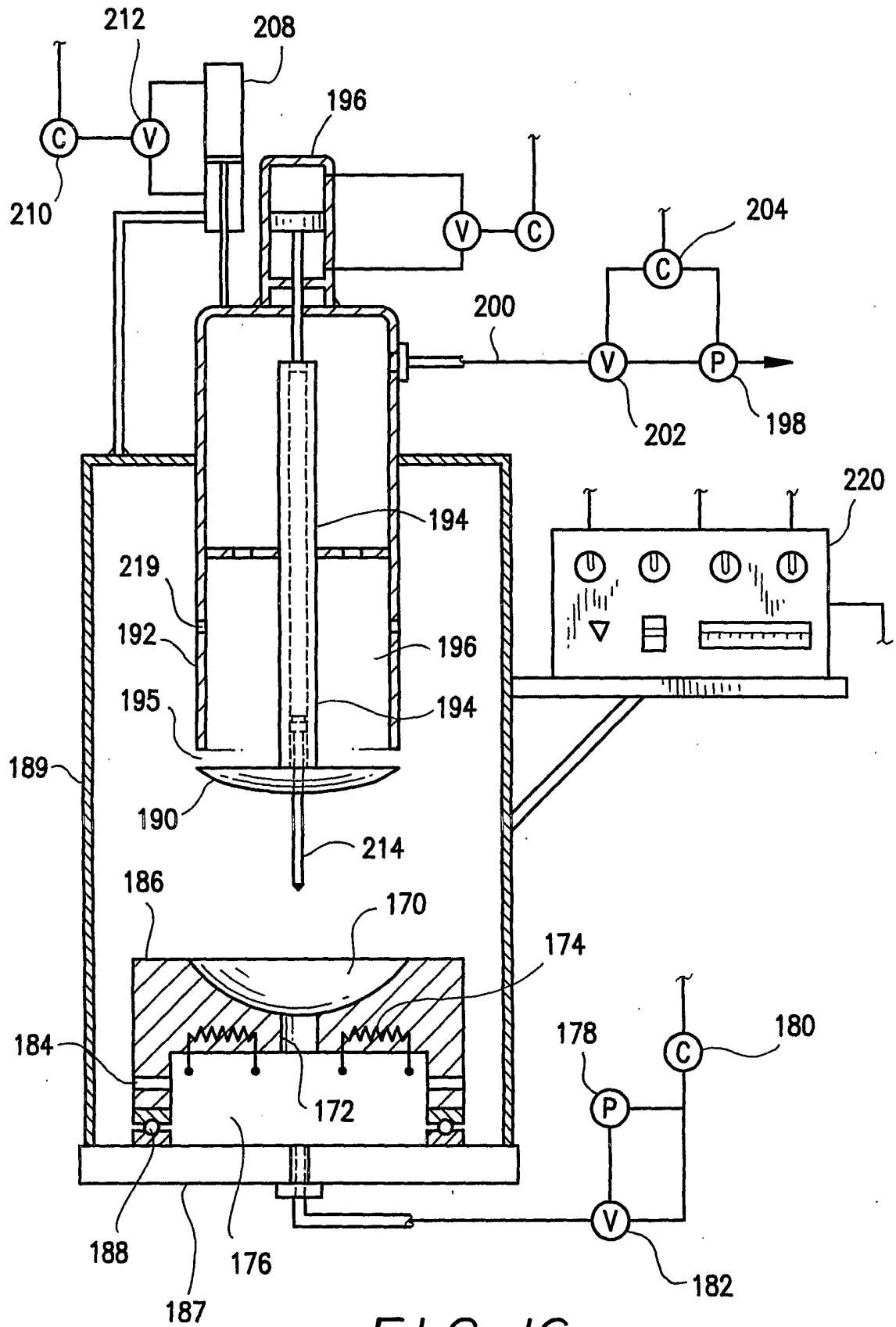


FIG. 16



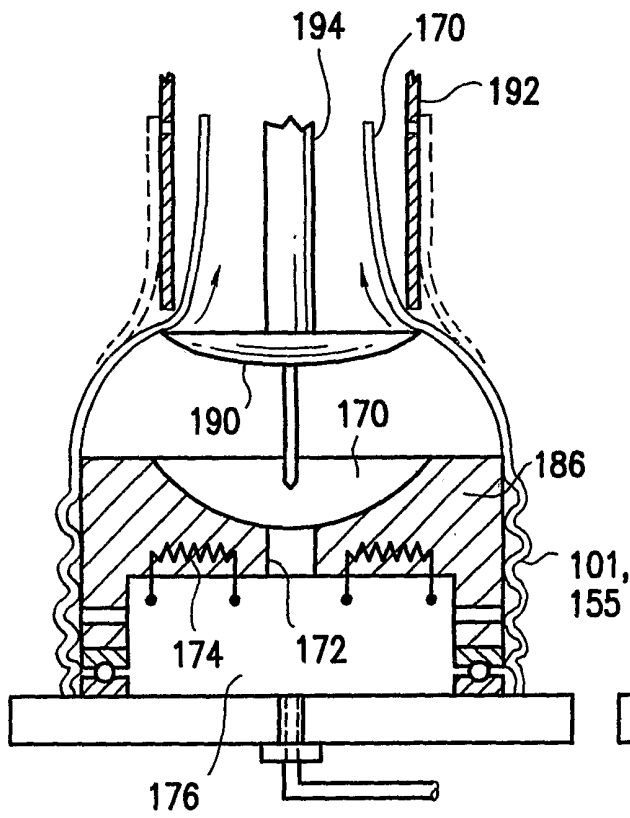


FIG. 17

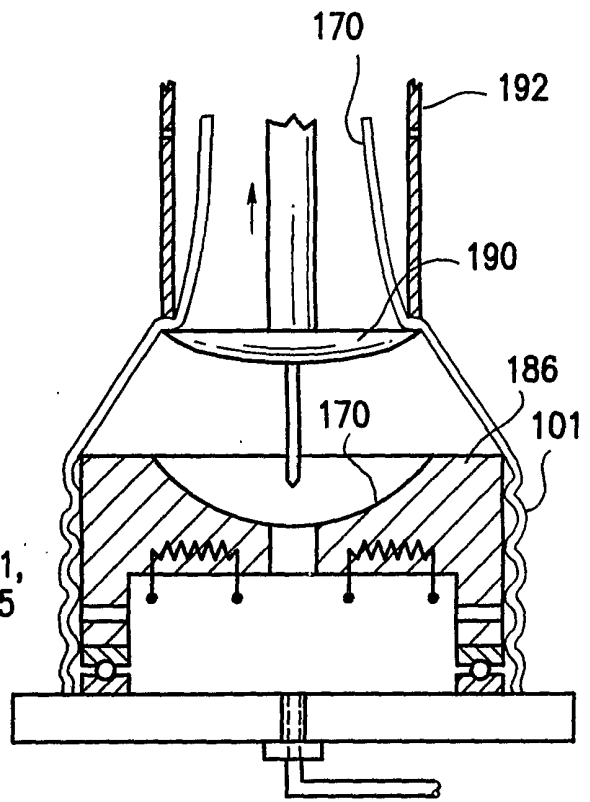


FIG. 18

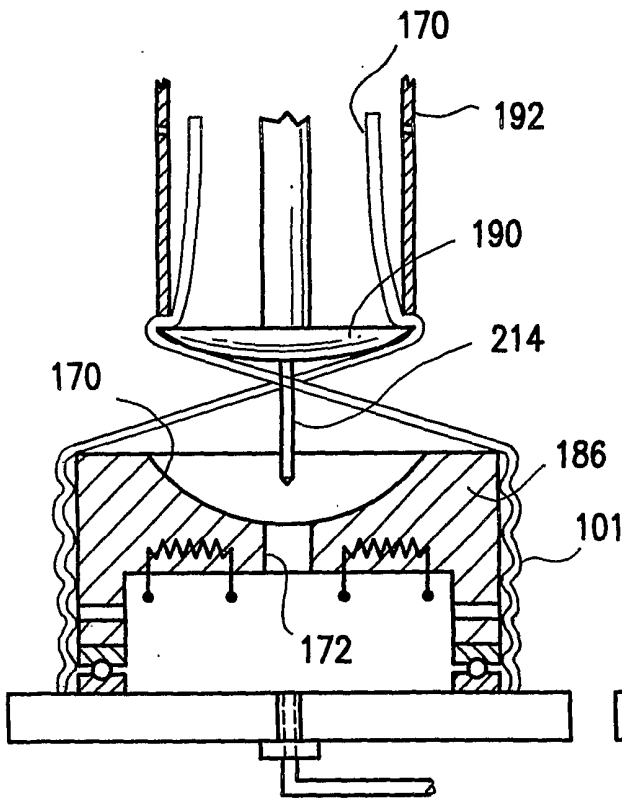


FIG. 19

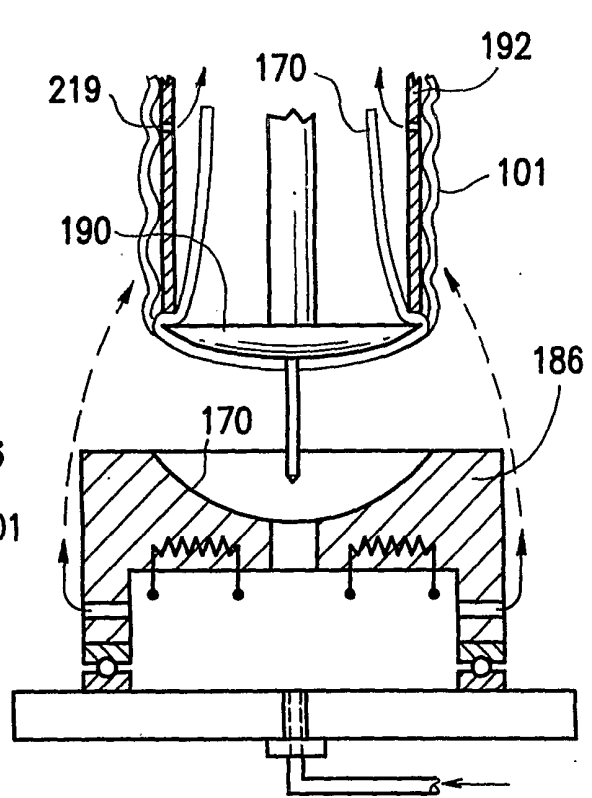


FIG. 20

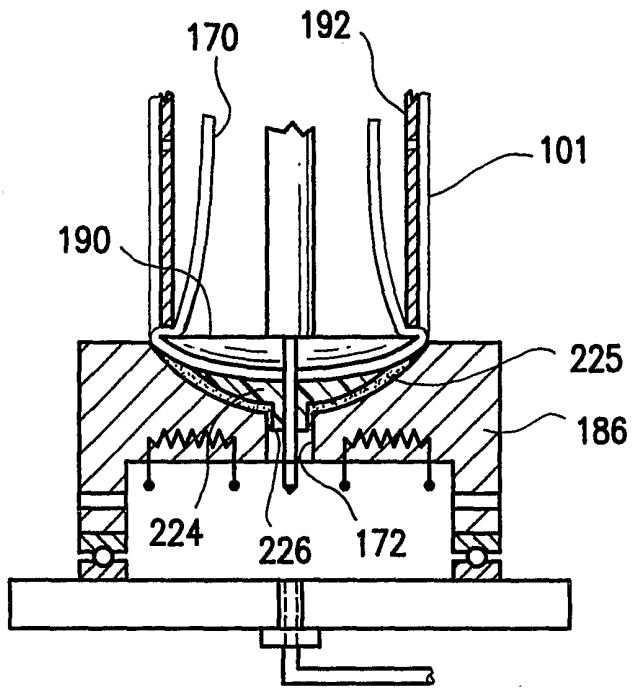


FIG. 21

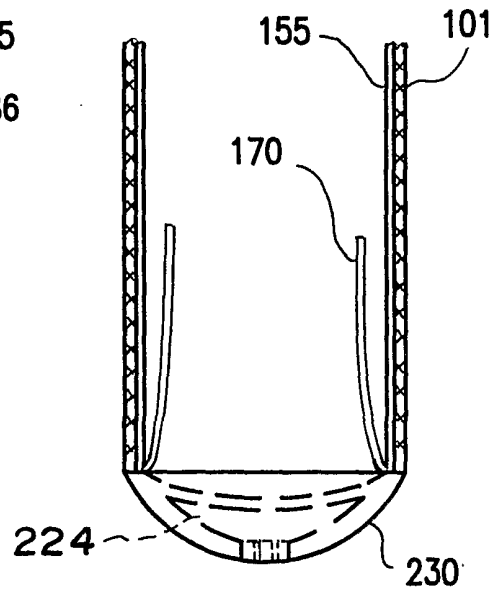


FIG. 22

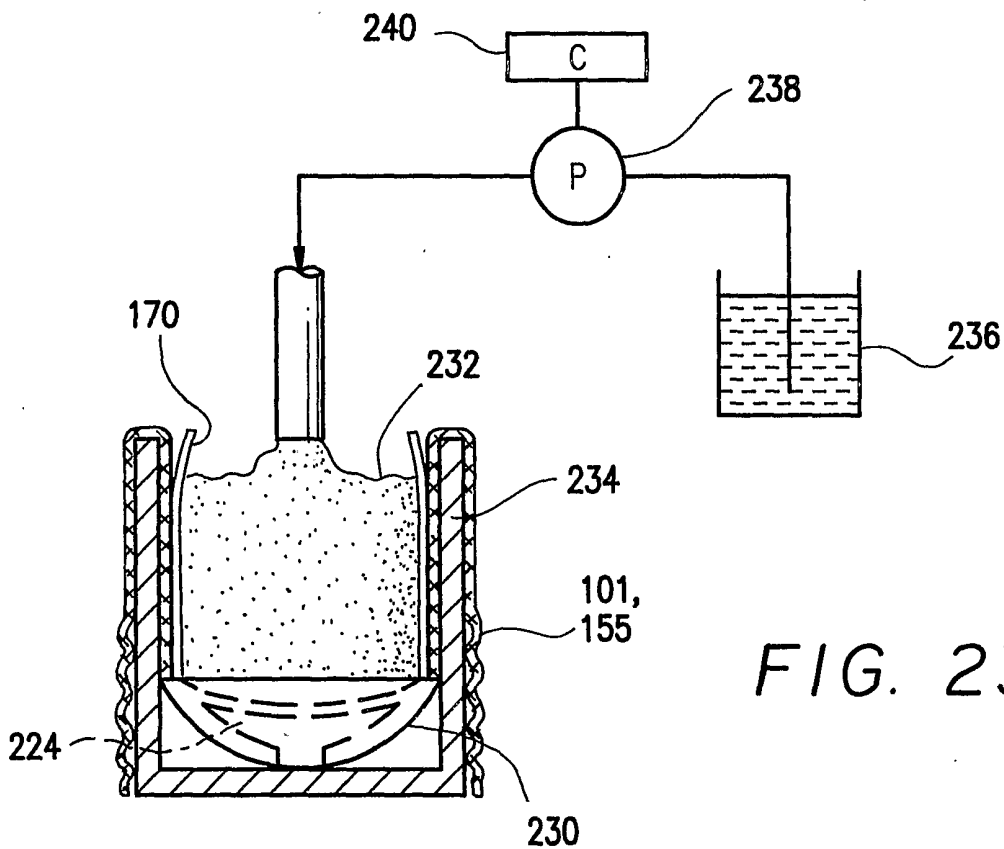


FIG. 23

FIG. 24

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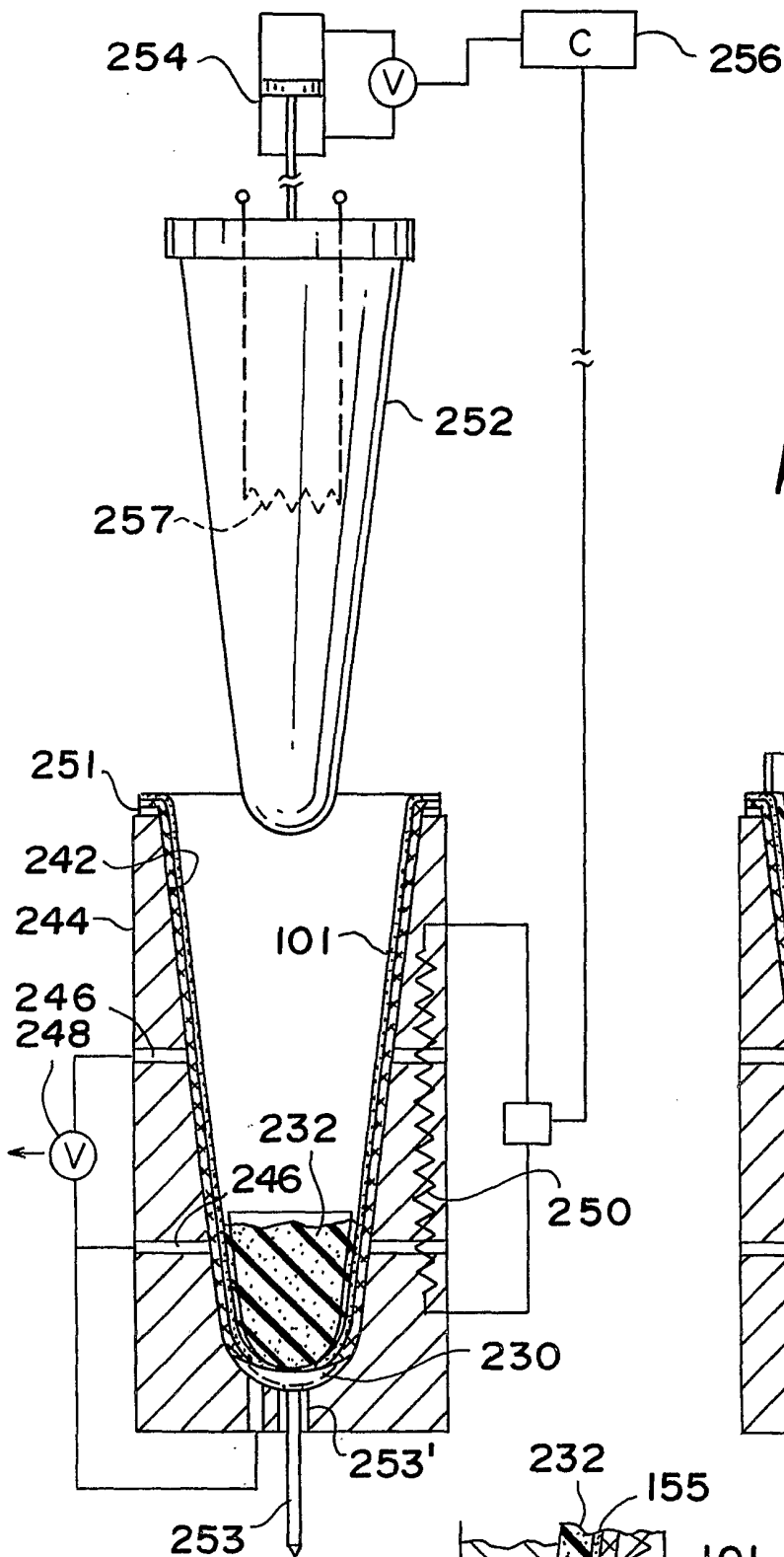


FIG. 25

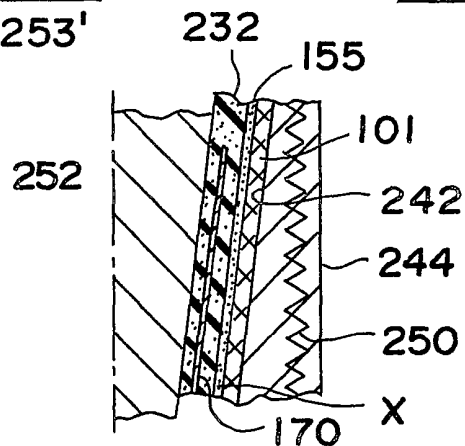
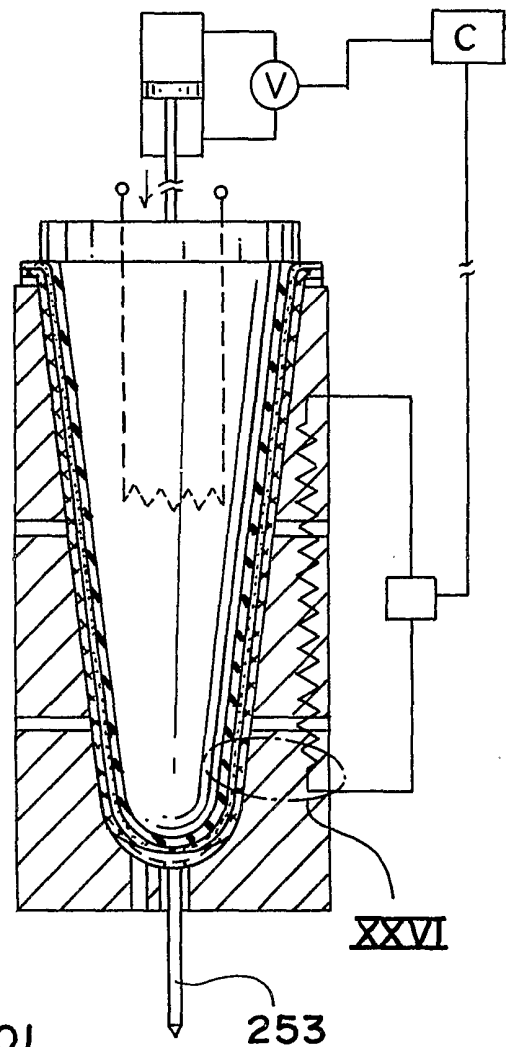


FIG. 26

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/05802

|   |   |  |
|---|---|--|
| <b>A. CLASSIFICATION OF SUBJECT MATTER</b>  |   |  |
| IPC(7) :  |   |  |
| US CL : Please See Extra Sheet.   |   |  |
| According to International Patent Classification (IPC) or to both national classification and IPC   |   |  |
| <b>B. FIELDS SEARCHED</b>   |   |  |
| Minimum documentation searched (classification system followed by classification symbols)   |   |  |
| U.S. : 427/2.1, 2.25, 2.28, 2.3, 2.31, 238, 294, 296; 264/103, 168, 171.12, 242, 248, 251, 257, 259, 261, 295; 623/1  |   |  |
| 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)  |   |  |
| EAST<br>search terms: (suction or vacuum or sub\$1atmospheric); (elongate or tube or tubular); (extrud\$ or extrus\$); elastomer, medical                               |   |  |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>   |   |  |
| Category*   | Citation of document, with indication, where appropriate, of the relevant passages                                      | Relevant to claim No.  |
| Y, P  | US 6,136,039 A (Kristinsson et al.) 24 October 2000, col. 2, line 4, col. 2, line 48, col. 3, abstract, claims.         | 1-38   |
| A   | US 5,571,208 A (CASPERs et al.) 5 November 1996, abstract, col. 4, lines 26-31, col. 10, line 63, col. 11, lines 60-65. | 38   |
| Y   | US 4,923,474 A (Klasson et al.) 8 May 1990, col. 3, line 38, col. 6, line 18.   | 7-11   |
| A   | US 5,728,168 A (LAGHI et al.) 17 March 1998, col. 2, line 17.   | 1  |
| A   | US 4,347,204 (TAKAGI et al.) 31 August 1982, col. 4, line 6 and abstract.   | 1 and 38   |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.                        |   |  |
| * Special categories of cited documents:  | "T"   | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |
| "A" document defining the general state of the art which is not considered to be of particular relevance  | "X"   | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |
| "E" earlier document published on or after the international filing date  | "Y"   | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&"   | document member of the same patent family  |
| "O" document referring to an oral disclosure, use, exhibition or other means  |   |  |
| "P" document published prior to the international filing date but later than the priority date claimed  |   |  |
| Date of the actual completion of the international search   | Date of mailing of the international search report  |  |
| 04 MAY 2001   | 10 JUL 2001   |  |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231   | Authorized officer<br>JENNIFER L. KOLB<br>DEBORAH THOMAS <i>Dut</i><br>PARALEGAL SPECIALIST                             |  |
| Facsimile No. (703) 305-3230  | Telephone No. (703) 308-1495  |  |

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US01/05802

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| Y         | US 5,376,129 A (FAULKNER et al.) 27 December 1994, columns 11-12.                  | 24-31                 |
| Y         | US 4,635,626 A (LERMAN) 13 January 1987, col. 4, line 31 and abstract.             | 1-11 and 38           |

INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US01/05802

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

427/2.1, 2.25, 2.28, 2.3, 2.31, 238, 294, 296; 264/103, 168, 171.12, 242, 248, 251, 257, 259, 261, 295; 623/1

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-11, drawn to a method of making a tubular member having a continuous and uninterrupted cured elastomeric resin coating wherein the "special technical feature" is the combination of steps of forming, drawing, and curing.

Group II, claim(s) 8-23, drawn to a method of making a tubular member having a continuous and uninterrupted cured elastomeric resin coating wherein the "special technical feature" is the combination of steps of feeding, applying a sub-atmospheric pressure, adhering, and curing.

Group III, claim(s) 24-37, drawn to a molded distal end cap on an open end of a length of a pre-formed tubular sleeve member wherein a preform sleeve comprising a tubular sleeve; a distal end cap; and a tubular matrix reinforcement element is formed.

Group IV, claim 38, drawn to a preform wherein the "special technical feature" is the combination of elements that include a matrix reinforcement element having interlocked fibers that are arranged so that the matrix reinforcement is porous.

Note that claims 8-11 are generic to both Group I and Group II.

The inventions listed as Groups I, II, III, and IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Group I is the combination of forming, drawing, and curing. Groups II, III, and IV lack this special technical feature. The special technical feature of Group II is the combination of feeding, applying a sub-atmospheric pressure, adhering, and curing. Groups I, III, and IV lack this special technical feature. The special technical feature of Group III is a distal end cap on an open end of a length of a pre-formed tubular sleeve member wherein a preform sleeve comprises a tubular sleeve; a distal end cap; and a tubular matrix reinforcement element. Groups I, II, and IV lack this feature. The special technical feature of Group IV is the combination of elements that include a matrix reinforcement element having interlocked fibers that are arranged so that the matrix reinforcement is porous. Groups I, II, and III lack this feature.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US01/05802**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.