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(19) **United States**(12) **Patent Application Publication****Caspers**(10) **Pub. No.: US 2004/0181290 A1**(43) **Pub. Date: Sep. 16, 2004**(54) **VACUUM APPARATUS AND METHOD FOR  
MANAGING RESIDUAL LIMB VOLUME IN  
AN ARTIFICIAL LIMB**(75) Inventor: **Carl A. Caspers, Avon, MN (US)**

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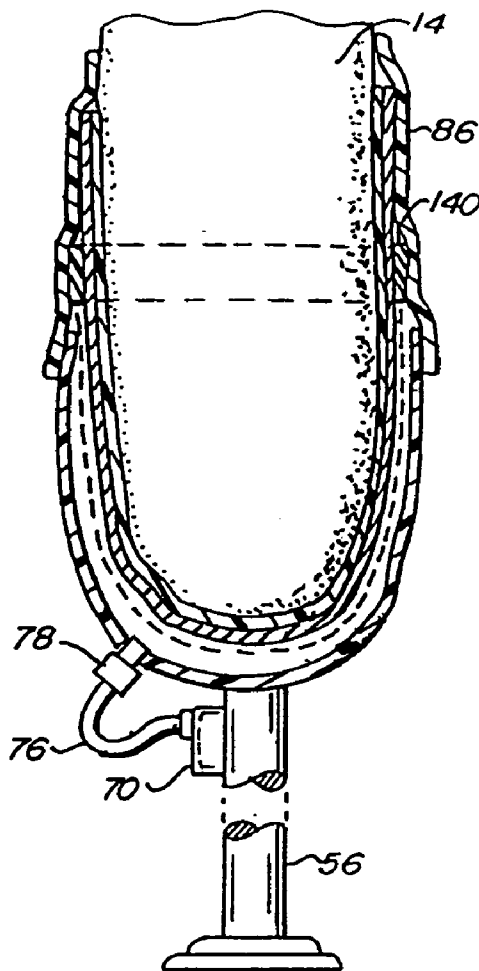
(63) Continuation of application No. 09/785,714, filed on Feb. 16, 2001, now Pat. No. 6,726,726, which is a continuation-in-part of application No. 09/492,406, filed on Jan. 27, 2000, now Pat. No. 6,508,842, which is a continuation-in-part of application No. 09/325,

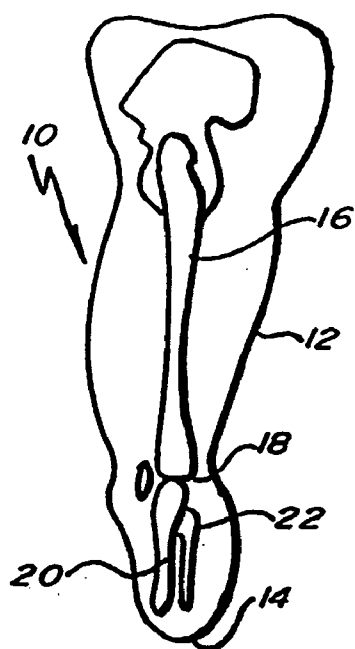
297, filed on Jun. 3, 1999, now abandoned.

Said application No. 09/785,714 is a continuation-in-part of application No. 09/534,274, filed on Mar. 23, 2000, now Pat. No. 6,554,868, which is a continuation-in-part of application No. 09/325,297, filed on Jun. 3, 1999, now abandoned.

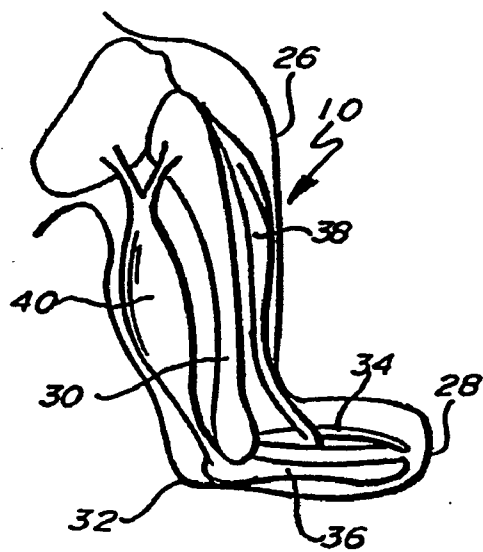
**Publication Classification**(51) **Int. Cl.<sup>7</sup> ..... A61F 2/80**(52) **U.S. Cl. .... 623/34**(57) **ABSTRACT**

A hypobarically-controlled artificial limb for amputees includes a single socket with a volume and shape to receive a substantial portion of the residual limb. A liner with a volume less than the residual limb is donned over the residual limb, with the liner tensioned into a total contact relationship with the residual limb. A sealed cavity is formed between the socket and the liner. A vacuum source is connected to the socket cavity thereby drawing the residual limb and liner into firm and total contact with the socket. To compensate for some air leakage past the seal, there is a mechanism to maintain the vacuum in the cavity.

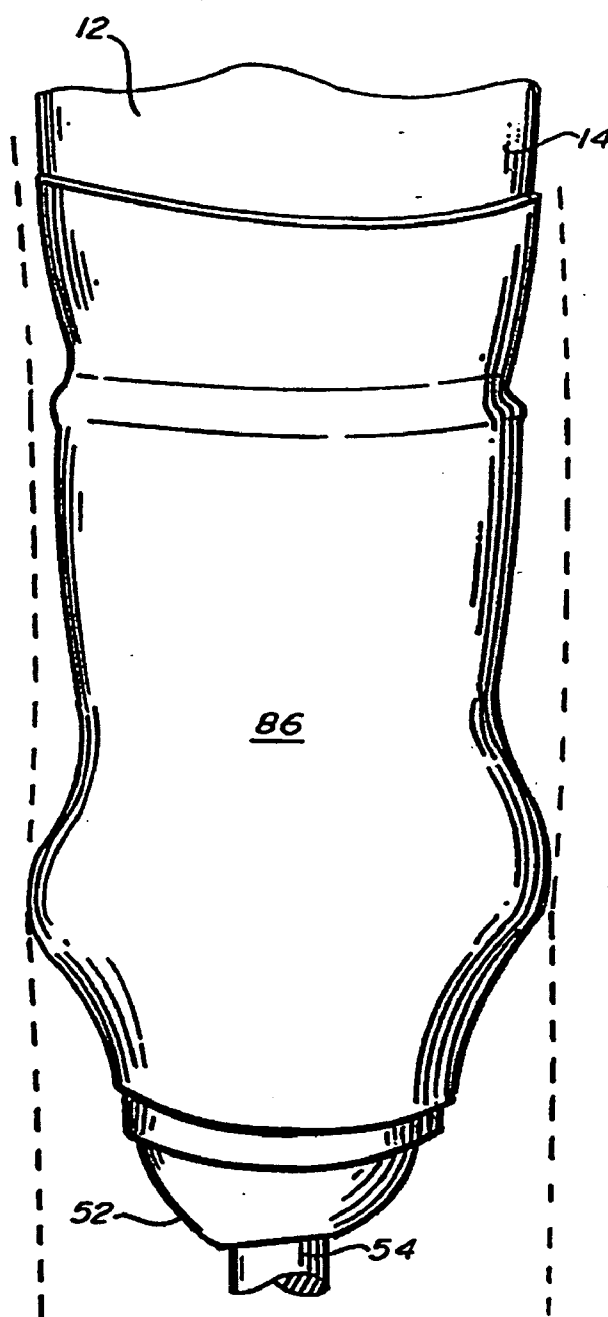




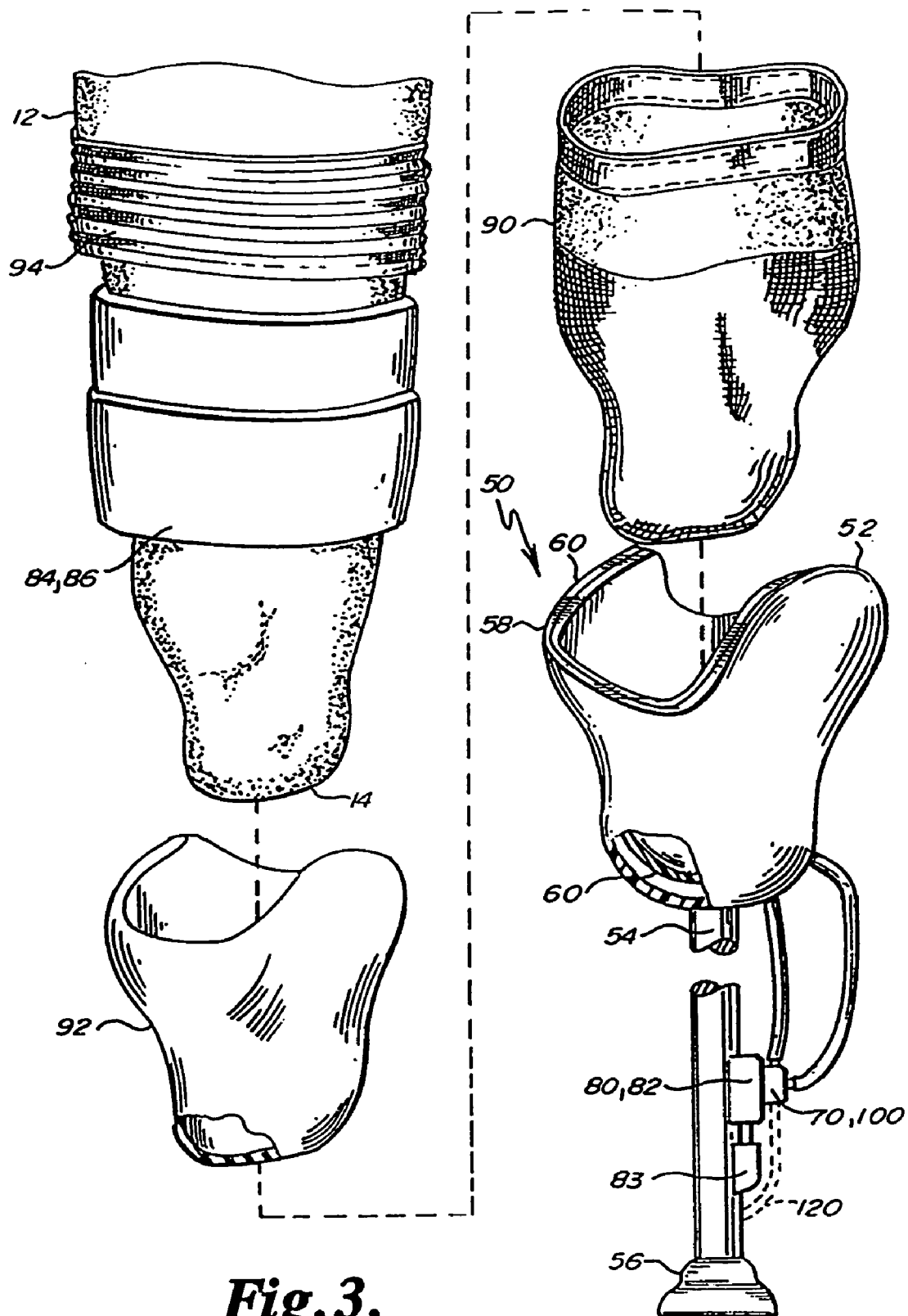
**Fig. 1.**



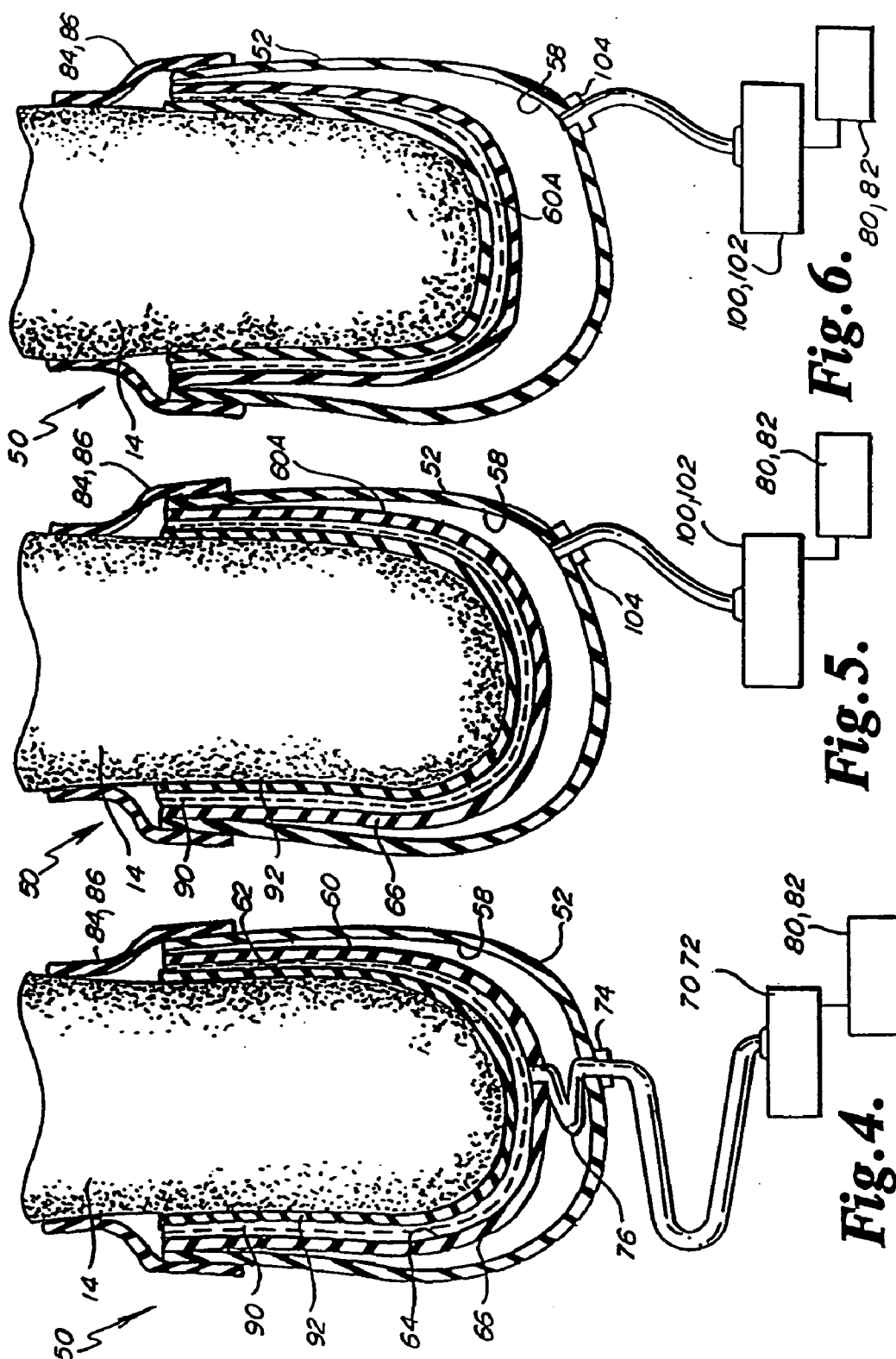
**Fig. 2.**

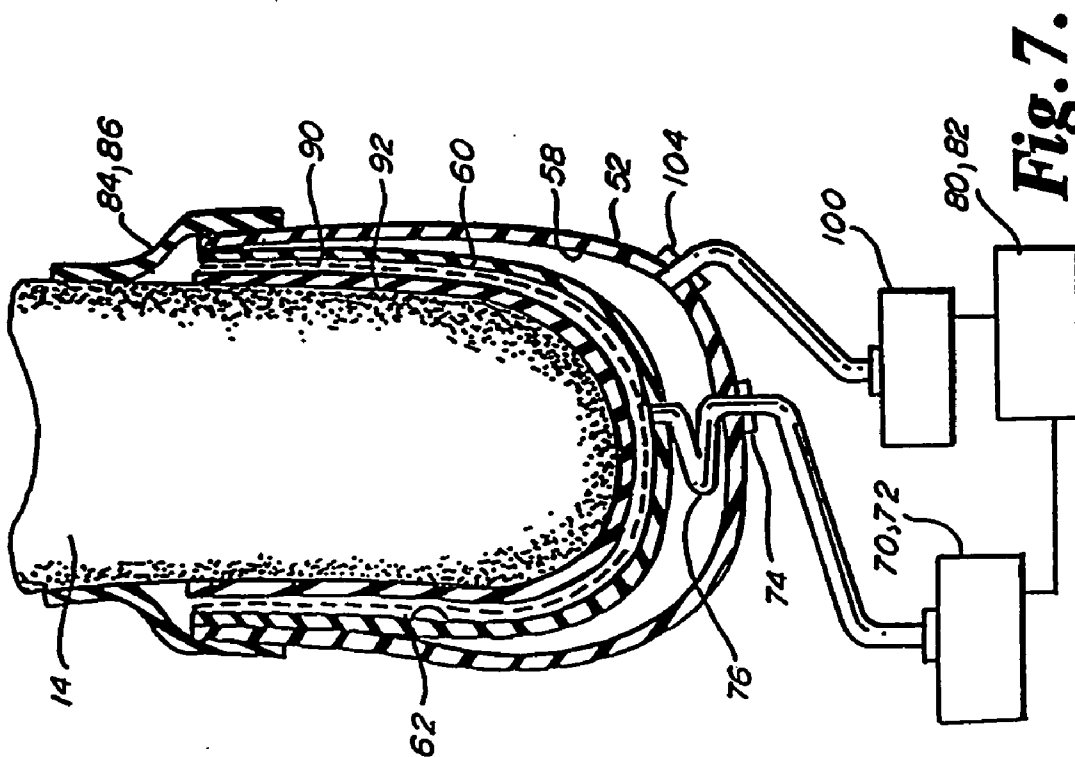
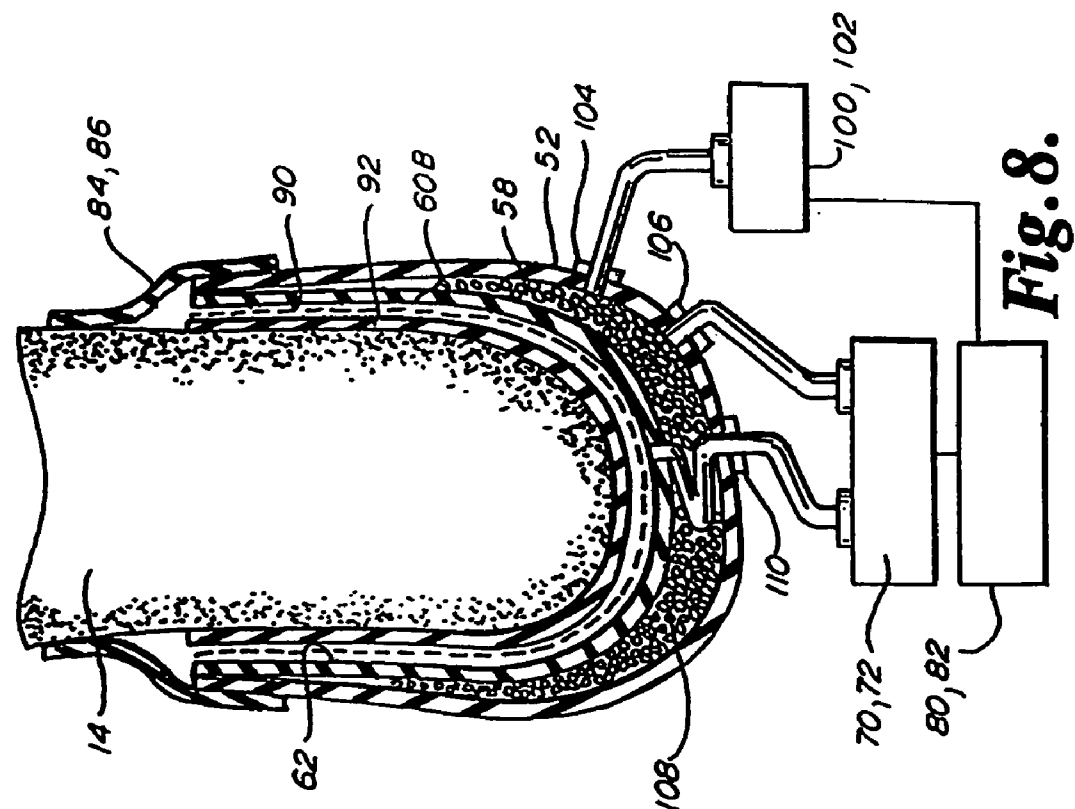


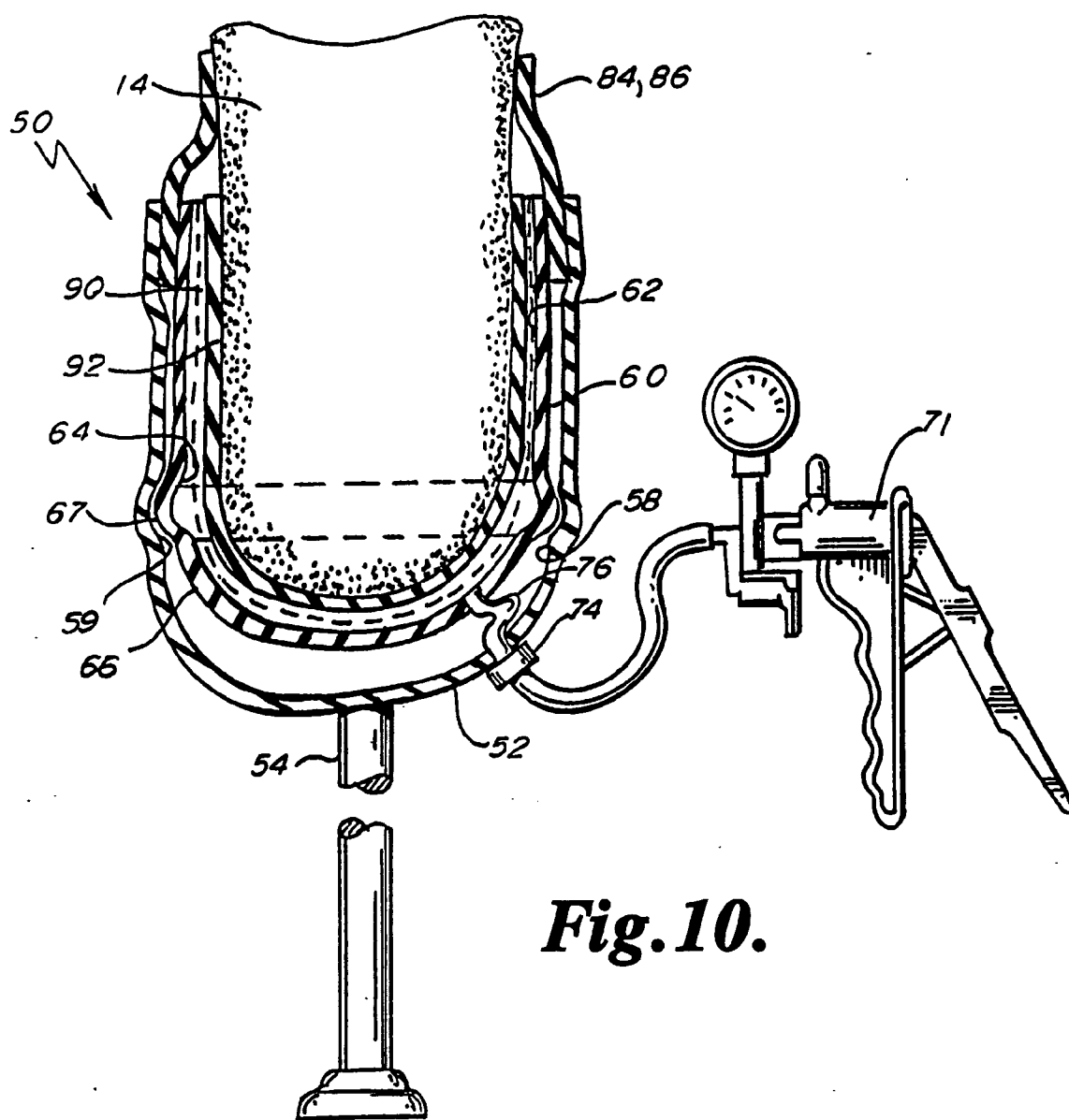
**Fig. 9.**



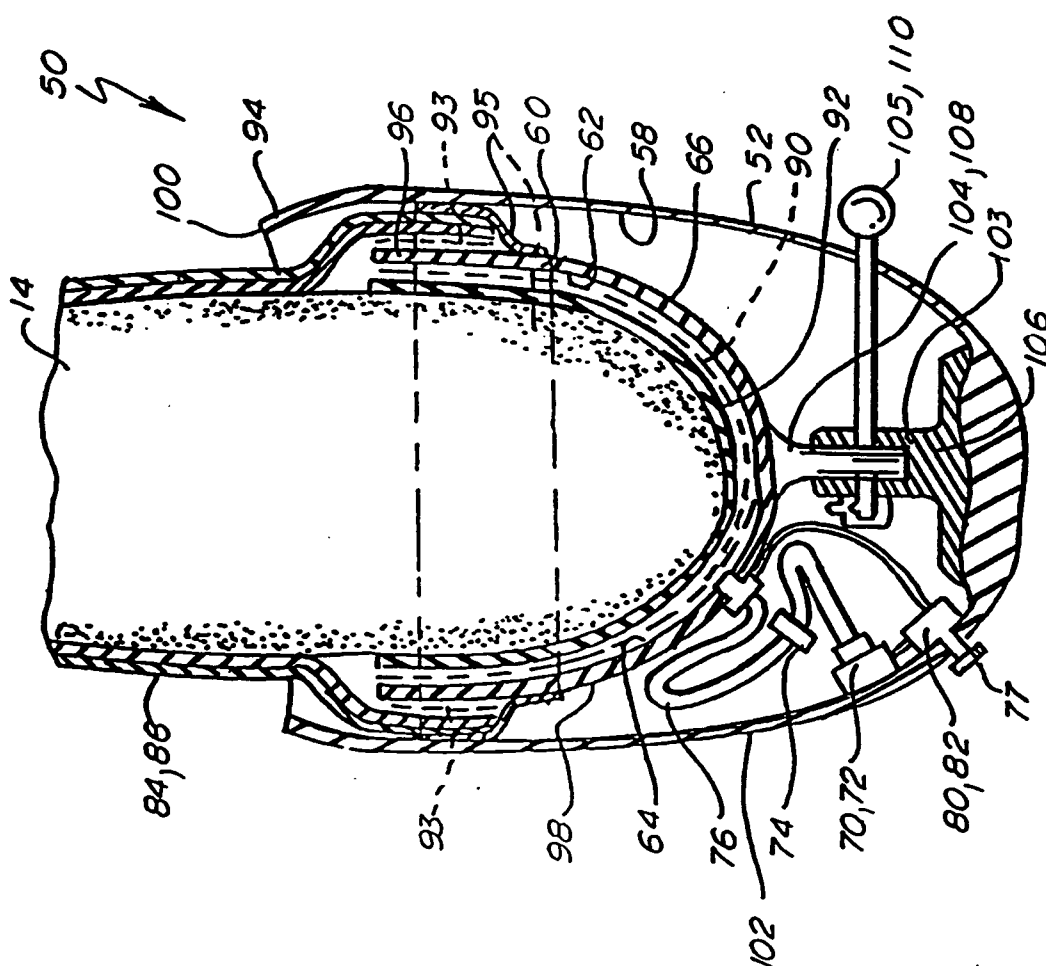
**Fig. 3.**



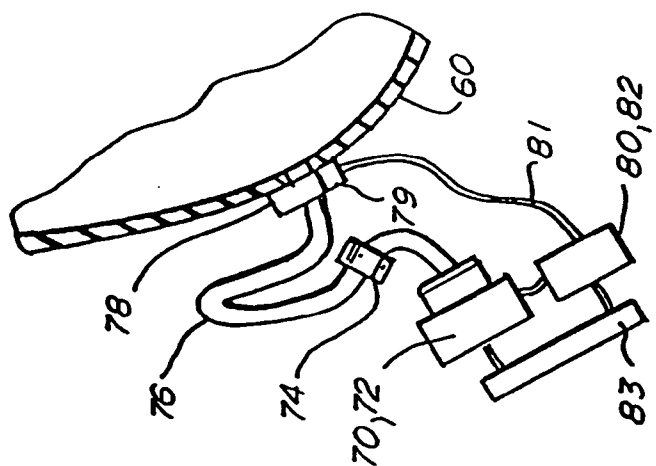




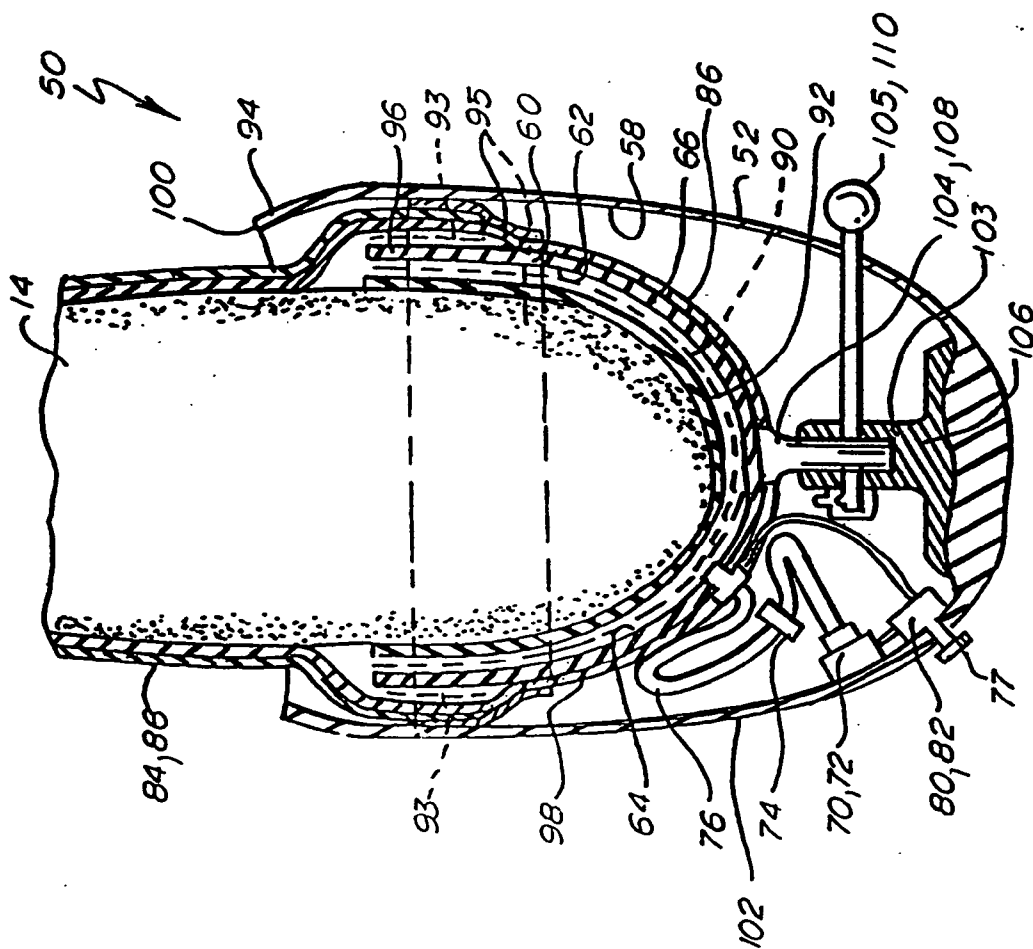
**Fig. 10.**



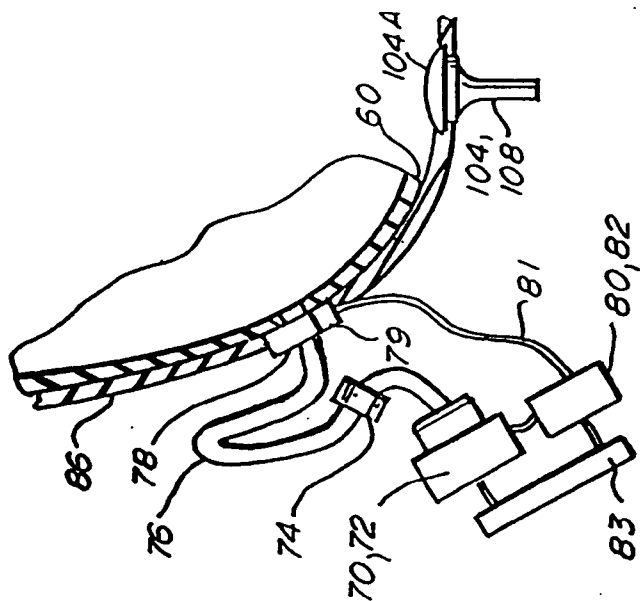
**Fig. 11.**



**Fig. 12.**

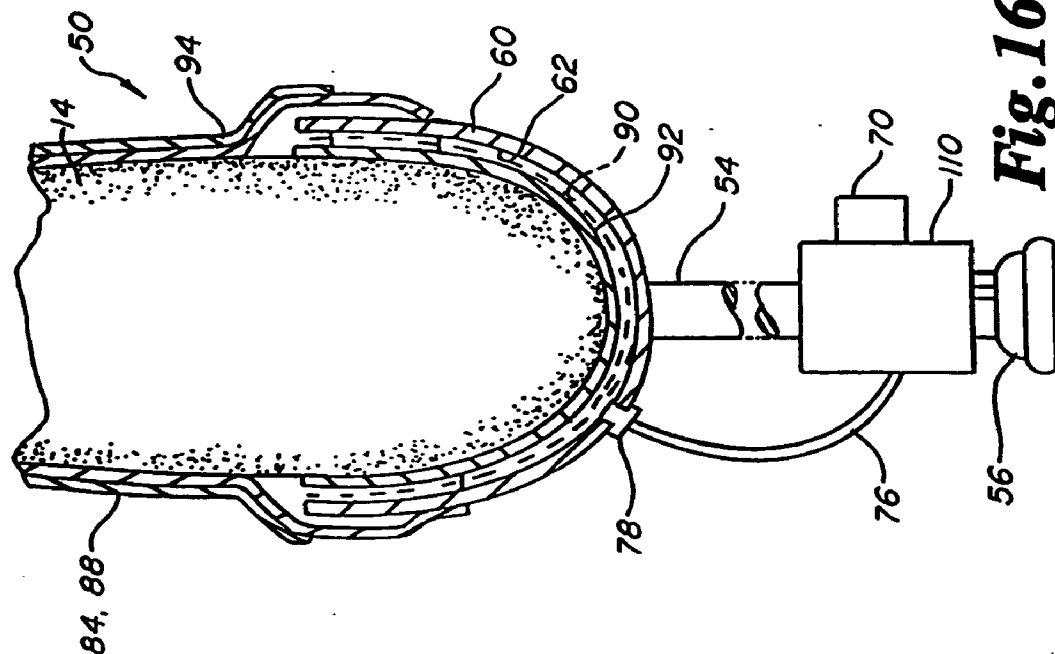


**Fig. 13.**

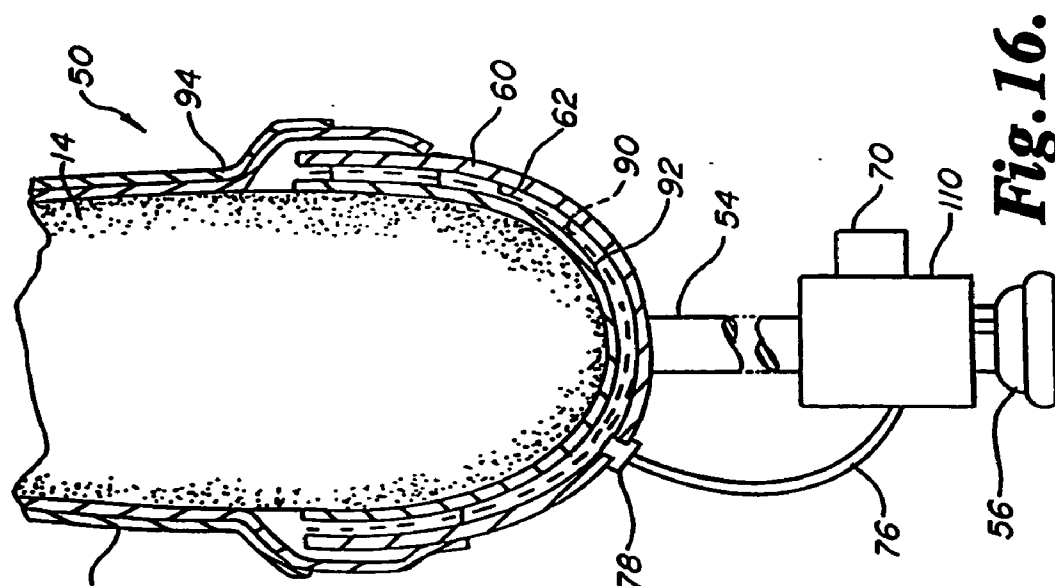


**Fig. 14.**

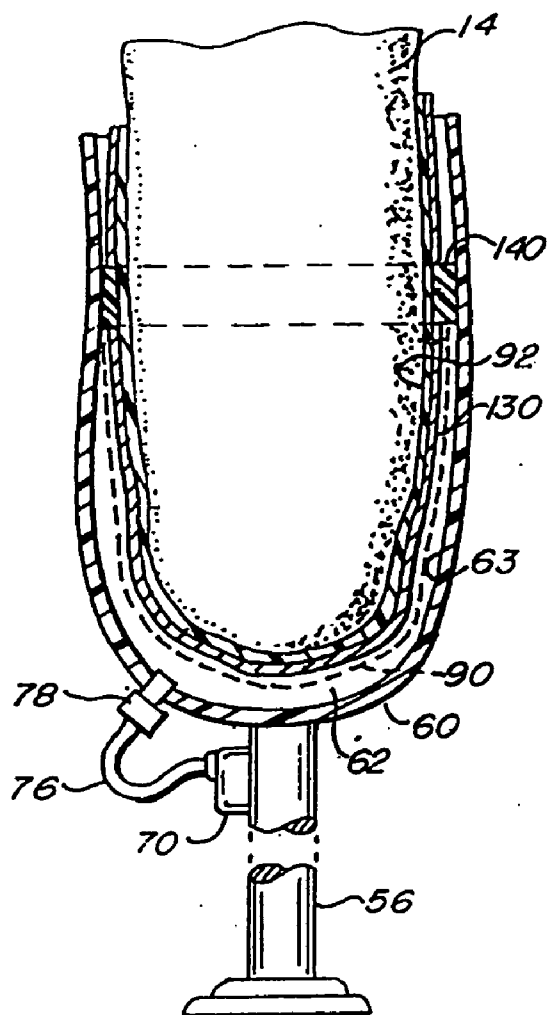




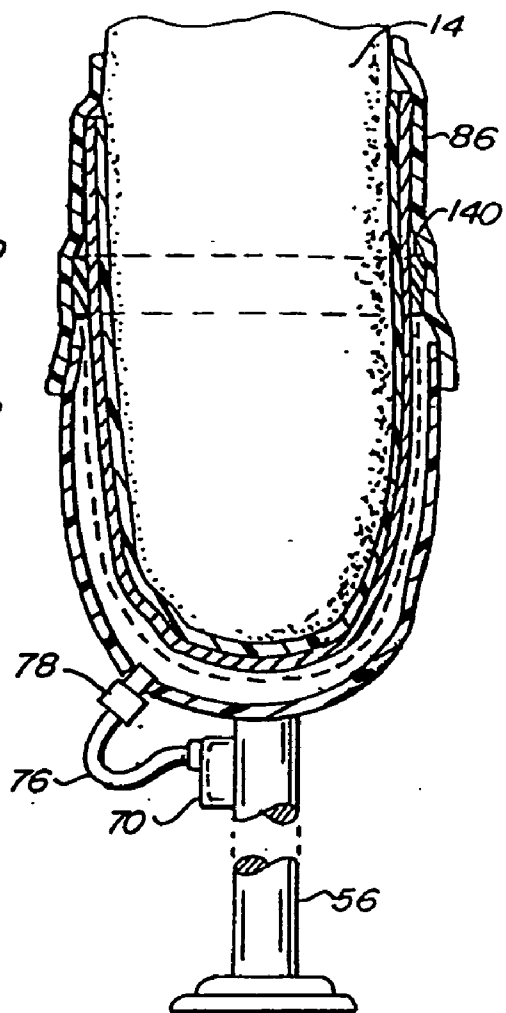
**Fig. 15.**



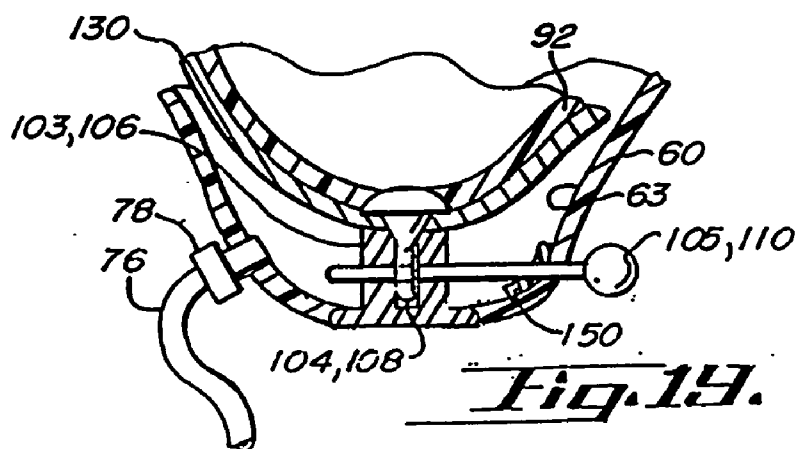
**Fig. 16.**



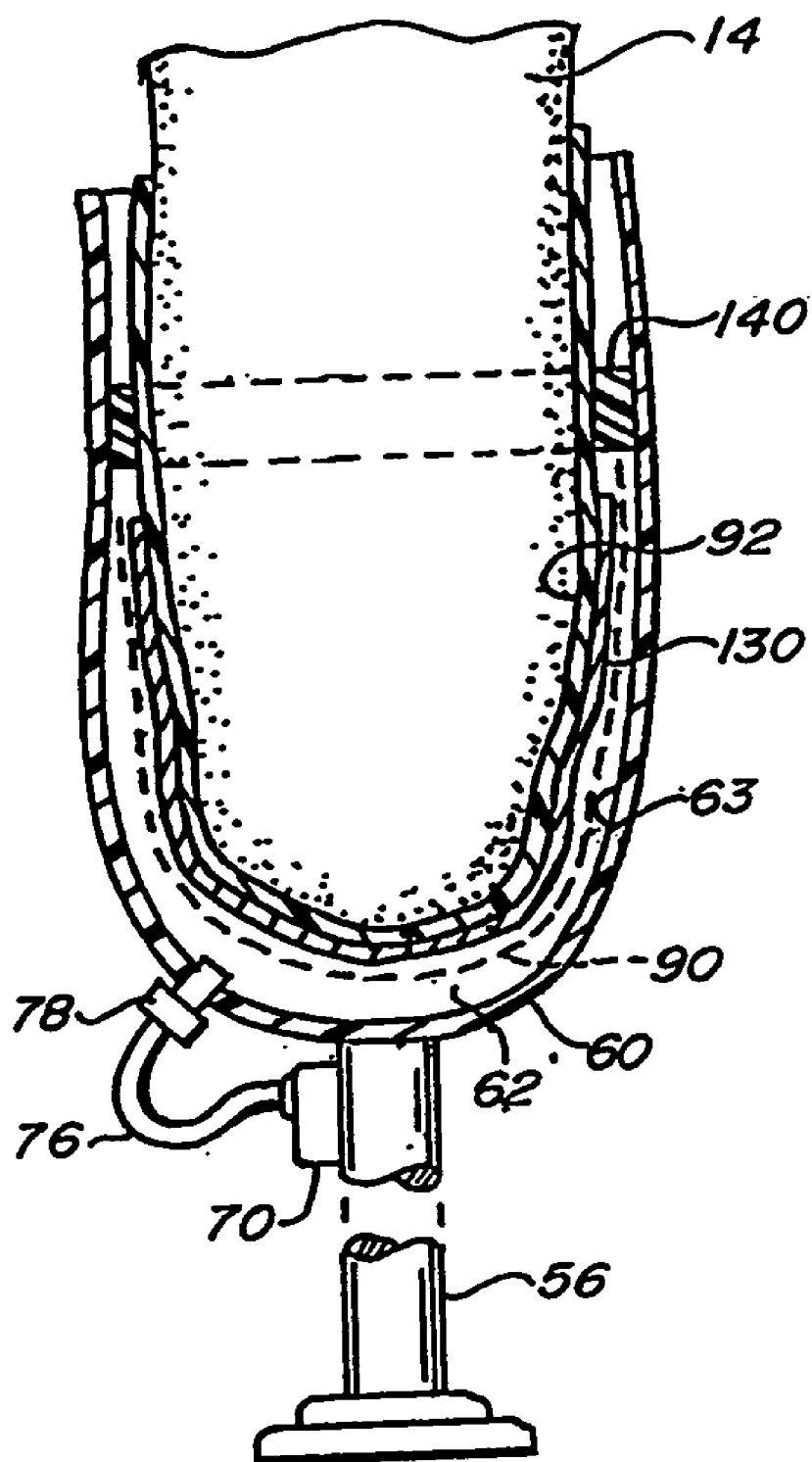
**Fig. 18.**



**Fig. 17.**



**Fig. 19.**



***Fig. 20.***

## VACUUM APPARATUS AND METHOD FOR MANAGING RESIDUAL LIMB VOLUME IN AN ARTIFICIAL LIMB

[0001] This is a continuation of U.S. patent application Ser. No. 09/785,714, filed on Feb. 16, 2001, which is a continuation-in-part of U.S. patent application Ser. No. 09/492,406, filed Jan. 27, 2000, issued as U.S. Pat. No. 6,508,842, which is a continuation-in-part of U.S. patent application Ser. No. 09/325,297, filed Jun. 3, 1999, now abandoned, and a continuation-in-part of U.S. Pat. No. 09/534,274, filed Mar. 23, 2000, issued as U.S. Pat. No. 6,554,868, which is also a continuation-in-part of U.S. patent application Ser. No. 09/325,297, filed Jun. 3, 1999, now abandoned.

### BACKGROUND OF THE INVENTION

[0002] The present invention relates to prosthetic devices and more particularly to a hypobarically-controlled artificial limb for amputees and to a method for preventing loss of residual limb volume due to weight-bearing pressures.

[0003] An amputee is a person who has lost part of an extremity or limb such as a leg or arm which commonly may be termed as a residual limb. Residual limbs come in various sizes and shapes with respect to the stump. That is, most new amputations are either slightly bulbous or cylindrical in shape while older amputations that may have had a lot of atrophy are generally more conical in shape. Residual limbs may further be characterized by their various individual problems or configurations including the volume and shape of a stump and possible scar, skin graft, bony prominence, uneven limb volume, neuroma, pain, edema or soft tissue configurations.

[0004] Referring to **FIGS. 1 and 2**, a below the knee residual limb **10** is shown and described as a leg **12** having been severed below the knee terminating in a stump **14**. In this case, the residual limb **10** includes soft tissue as well as the femur **16**, knee joint **18**, and severed tibia **20** and fibula **22**. Along these bone structures surrounded by soft tissue are nerve bundles and vascular routes which must be protected against external pressure to avoid neuromas, numbness and discomfort as well as other kinds of problems. A below the knee residual limb **10** has its stump **14** generally characterized as being a more bony structure while an above the knee residual limb may be characterized as including more soft tissue as well as the vascular routes and nerve bundles.

[0005] Referring to **FIG. 2**, amputees who have lost a part of their arm **26**, which terminates in a stump **28** also may be characterized as having vascular routes, nerve bundles as well as soft and bony tissues. The residual limb **10** includes the humerus bone **30** which extends from below the shoulder to the elbow from which the radius **34** and ulna **36** bones may pivotally extend to the point of severance. Along the humerus bone **30** are the biceps muscle **38** and the triceps muscle **40** which still yet may be connected to the radius **34** and the ulna, **36**, respectively.

[0006] In some respects, the residual limb amputee that has a severed arm **26** does not have the pressure bearing considerations for an artificial limb but rather is concerned with having an artificial limb that is articulable to offer functions typical of a full arm, such as bending at the elbow and grasping capabilities. An individual who has a paralyzed

limb would also have similar considerations wherein he or she would desire the paralyzed limb to having some degree of mobility and thus functionality.

[0007] Historically, artificial limbs typically used by a leg amputee were for the most part all made out of wood such as an Upland Willow. The limbs were hand carved with sockets for receiving the stump **14** of the residual limb **10**. Below the socket would be the shin portion with the foot below the shin. These wooden artificial limbs were covered with rawhide which often were painted. The sockets of most wood limbs were hollow as the limbs were typically supported in the artificial limb by the circumferential tissue adjacent the stump **14** rather than at the distal end of the stump **14**.

[0008] Some artificial limbs in Europe were also made from forged pieces of metal that were hollow. Fiber artificial limbs were also used which were stretched around a mold after which they were permitted to dry and cure. Again, these artificial limbs were hollow and pretty much supported the residual limb about the circumferential tissue adjacent the stump **14**.

[0009] All of these various artificial limbs have sockets to put the amputee's stump **14** therein. There are generally two categories of sockets. There are hard sockets wherein the stump goes right into the socket actually touching the socket wall without any type of liner or stump sock. Another category of sockets is a socket that utilizes a liner or insert. Both categories of sockets typically were opened ended sockets where they had a hollow chamber in the bottom and no portion of the socket touched the distal end of the stump **14**. So, the stump was supported about its circumferential sides as it fits against the inside wall of the sockets.

[0010] These types of sockets caused a lot of shear force on the stump **14** as well as had pressure or restriction problems on the nerve bundles and vascular flow of fluid by way of the circumferential pressure effect of the socket on the limb. This pressure effect could cause a swelling into the ends of the socket where an amputee may develop severe edema and draining nodules at the end of their stump **14**.

[0011] With time, prosthetists learned that by filling in the socket's hollow chamber and encouraging a more total contact with the stump and the socket, the swelling and edema problems could be eliminated. However, the problematic tissue configurations, such as bony prominences, required special consideration such as the addition of soft or pliable materials to be put into the socket.

[0012] Today, most artificial limbs are constructed from thermoset plastics such as polyester resins, acrylic resins, polypropylenes and polyethylenes, which are perhaps laminated over a nylon stockinette which also may be impregnated by the various resins.

[0013] In the past, most artificial limbs were suspended from the amputee's body by some form of pulley, belt or strap suspension often used with various harnesses and perhaps leather lacers or lacings. Another method of suspending artificial limbs is known as the wedge suspension wherein an actual wedge is built into the socket which is more closed at its top opening. The wedge in the socket cups the medial femoral condyle or knuckle at the abductor tubical. Yet another form of suspension is referred to as the shuttle system or a mechanical hookup or linkup wherein a

thin suction liner is donned over the stump that has a docking device on the distal end which mechanically links up with its cooperative part in the bottom of the socket chamber. Sleeve suspensions were also used wherein the amputee may use a latex rubber tube which forms into a rubber-like sleeve which would be rolled on over both the top of the artificial limb and onto the amputee's thigh. The sleeve suspensions have been used in combination with other forms of suspensions techniques.

[0014] Both the use of a positive pressure system and the use of a negative pressure system (or hypobaric closed chamber) have been utilized in the field of prosthetics. At one time, for pressure systems "inflatable inner tubes" were used to fit into sockets. Presently, there are pneumatic "bags" which are strategically placed over what people consider to be good weight-bearing areas to increase pressure to help accommodate for volume changes within the socket.

[0015] The problem with this is that it is a very specific pressure and creates atrophy and loss of tissue dramatically over these high pressure areas. None of these systems employs positive pressure distributed over the total contact area between the residual limb and the artificial limb socket to accommodate volume changes within the socket.

[0016] The negative pressure aspects have been utilized for a closed chamber in that a socket is donned by pulling in with a sock, pulling the sock out of the socket and then closing the opening with a valve. This creates a seal at the bottom and the stump is held into the socket by the hypobaric seal.

[0017] The older systems were initially started in Germany. They were an open-ended socket, meaning there was an air chamber in the bottom of the socket. This did not work particularly well because it would cause swelling of the residual limb into the chamber created by the negative draw of suspending the weight of the leg and being under a confined area. This would lead to significance edema which would be severe enough to cause stump breakdown and drainage.

[0018] It was later discovered in America that total contact was essential between the residual limb and the socket and once you had total contact the weight was distributed evenly or the suspension was distributed over the whole surface of the limb rather than just over the open chamber portion of the socket.

[0019] The human body as a whole is under approximately one atmosphere of pressure at sea level. It keeps and maintains a normal fluid system throughout the body. When an amputee dons a prosthesis and begins taking the pressures of transmitting the weight of the body through the surface area of the residual limb to the bone, there is increased pressure on the residual limb equal to one atmosphere plus whatever additional pressures are created by weight bearing. This increased pressure causes the eventual loss of fluids within the residual limb to the larger portion of the body which is under less pressure. This loss of fluids causes the volume of the residual limb to decrease during the day. It varies from amputee to amputee, but it is a constant among all amputee and the more "fleshy" and the softer the residual limb, the more volume fluctuation there will be. The greater the weight and the smaller the surface area, the greater the pressures will be and the more "swings" there will be in

fluids. In the past, the amputee had to compensate for this volume decrease by removing the artificial limb and donning additional stump socks to make up for the decreased residual limb volume.

[0020] U.S. Pat. No. 5,888,230 discloses the use of a vacuum pump connected between the limb and a liner. However, this invention is essentially inoperable because the liner will conform to the stump at all times, by an interference fit, so that there is no space between the residual limb and the liner against which to draw a vacuum. In any case, the patent does not disclose application of vacuum to the socket cavity in such a manner as to draw the residual limb firmly and totally against the interior of the socket. Instead, the patent discloses the use of shims between the liner and the socket. Without total contact between the residual limb and the socket, the limb may swell into the space between the limb and the socket. Also, the patent does not disclose the use of vacuum to prevent reduction in volume of the artificial limb due to weight-bearing pressures.

[0021] While some of these devices addressed some of the problems associated with prosthetics, none of the artificial limbs, liners and socket, individually or in combination, offered a prosthesis that presented a total contact relationship with the residual limb; absorbed and dissipated shear, shock and mechanical forces transmitted to the limb tissues by the artificial limb; controlled residual limb volume; and used negative pressure as a locking device to hold the residual limb into the socket.

[0022] There is a need for an improved hypobarically-controlled artificial limb that will offer total contact relationship with the residual limb; absorb and dissipate shock, mechanical and shear forces typically associated with ambulation, twisting and turning and weight bearing with an artificial limb; control residual limb volume by way of even weight distribution; use negative pressure as a locking device to hold the residual limb into the socket without causing swelling of the residual limb into the socket; and control residual limb volume changes by a negative pressure system. Ideally, the vacuum system should be automatically regulated.

[0023] U.S. Pat. No. 5,549,709 discloses several embodiments of a hypobarically controlled artificial limb. However, all of these embodiments required two sockets: an outer socket and an inner socket. Applicant has found that the present invention offers improved performance without the requirement for two sockets. A single socket works equally well or better than two sockets. Also, this patent does not disclose a mechanism for maintaining vacuum in the presence of air leakage into the socket.

[0024] It has been found that it is essentially impossible to maintain a perfect, airtight seal between the residual limb and the sockets disclosed in U.S. Pat. No. 5,549,709, with the result that slow air leakage into the sockets diminishes the vacuum in the sockets. With the reduction in vacuum, the beneficial effects of the vacuum also slowly diminish. Consequently, there is a need for a means for maintaining the vacuum in the socket cavity in the presence of some air leakage past the seal.

#### SUMMARY OF THE INVENTION

[0025] The present invention provides an artificial limb for an amputee who has a residual limb. The artificial limb

includes a flexible liner adapted to encase a portion of a residual limb and a single, substantially rigid socket configured to receive the residual limb encased in the liner and to form a cavity between the liner and the socket. A support member is coupled to the socket with the support member adapted to provide support for the weight of the amputee when the residual limb is received within the socket. A seal member is also included to seal the cavity between the liner and the socket. A vacuum source fluidly coupled to the cavity between the liner and the socket is also included. The vacuum source is configured to apply a designated vacuum pressure evenly over the liner encasing the residual limb so as to securely couple the artificial limb to the residual limb and to maintain the designated vacuum pressure within desired limits during use of the artificial limb by the amputee.

[0026] A method for managing volume loss in a residual limb of an amputee when wearing an artificial limb is also provided by the present invention. The method includes the steps of encasing a portion of a residual limb in a flexible liner and inserting the encased residual limb into a single, substantially rigid socket of an artificial limb and thereby forming a cavity between the liner and the socket. The socket is adapted to be coupled to a structure capable of supporting and facilitating walking by the amputee. Further steps includes sealing the cavity, supplying vacuum to the cavity so as to apply vacuum pressure evenly over the liner encasing the residual limb, and maintaining vacuum within the cavity during both a weight-bearing phase of walking by the amputee and a non-weight bearing phase of walking by the amputee.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0027] FIG. 1 is a side elevational view of the tissue and skeletal structure of an amputee's residual limb;

[0028] FIG. 2 is a side elevational view of a residual limb in the form of an amputated arm showing the skeletal and muscular structure of the residual limb;

[0029] FIG. 3 is an exploded elevational view of the residual limb donning the polyurethane sleeve, stretchable nylon sleeve, liner, nylon sheath and socket of an artificial limb;

[0030] FIG. 4 is a cross-section of the artificial limb in FIG. 3, which is a first embodiment of the artificial limb;

[0031] FIG. 5 is a cross-section of the artificial limb similar to FIG. 4, showing a second embodiment of the artificial limb;

[0032] FIG. 6 is the same as FIG. 5, but showing compression of the inner socket under the influence of positive air pressure;

[0033] FIG. 7 is a cross-section of the artificial limb showing a third embodiment of the artificial limb;

[0034] FIG. 8 is a cross-section of the artificial limb showing a fourth embodiment of the artificial limb;

[0035] FIG. 9 is an elevational view of the polyurethane sleeve and second stretchable nylon sleeve rolled over the socket and residual limb with clothing shown in broken outline;

[0036] FIG. 10 is a cross-section of the artificial limb showing a fifth embodiment of the artificial limb;

[0037] FIG. 11 is a cross-section of the artificial limb showing a sixth embodiment of the artificial limb;

[0038] FIG. 12 is a detailed view of the vacuum mechanism in FIG. 11;

[0039] FIG. 13 is a cross-section of the artificial limb showing a seventh embodiment of the artificial limb;

[0040] FIG. 14 is a detailed view of the vacuum mechanism and suspension sleeve of FIG. 13;

[0041] FIG. 15 is a cross-section of the artificial limb showing an eighth embodiment of the artificial limb; and

[0042] FIG. 16 is a cross-section of the artificial limb showing a ninth embodiment of the artificial limb.

[0043] FIG. 17 is a cross section of the artificial limb showing a liner with an annular seal.

[0044] FIG. 18 is a cross-section of the artificial limb showing a second embodiment of the liner of FIG. 17.

[0045] FIG. 19 is a partial cross-section of the artificial limb showing a third embodiment of the liner of FIG. 17.

[0046] FIG. 20 is a partial cross-section of the artificial limb showing a fourth embodiment of the liner of FIG. 17.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

[0047] The drawings show a number of different embodiments of an apparatus and method for managing the volume of a residual limb within an artificial limb, by applying a vacuum source to the artificial limb cavity. It will be seen that application of the vacuum to the cavity draws the residual limb (which may be encased in a liner) firmly and totally against the socket, thereby preventing swelling of the residual limb into the socket, because there is no open chamber into which the residual limb may be drawn by the vacuum. Importantly, application of the vacuum to the cavity also opposes the loss of fluids from the residual limb due to weight-bearing pressures.

[0048] FIGS. 3 and 4 show one embodiment of the apparatus 50 of the present invention. The hypobarically-controlled artificial limb 50 includes an outer socket 52, shin 54, and foot 56. The outer socket 52 has a volume and shape to receive a substantial portion of the residual limb 14 with a space 58 therebetween.

[0049] The apparatus 50 further includes a flexible inner socket 60 with a cavity 62 with a volume and shape for receiving a substantial portion of the residual limb 14 and fitting in the space 58 between the outer socket 52 and the residual limb 14. The inner socket 60 has an inner surface 64 opposing the residual limb 14 and an outer surface 66 opposing the outer socket 52.

[0050] A vacuum source 70 may conveniently be attached to the shin or pylon 54. The vacuum source 70 may preferably be a mechanical or motor-driven pump 72. The vacuum source 70 may be connected to a power source 83, which may be a battery.

[0051] A vacuum valve 74 is suitably connected to the vacuum source 70. The vacuum valve 74 may preferably be

disposed on the outer socket **52**. A vacuum tube **76** connects the vacuum valve **74** to the cavity **62**. It will be seen that the vacuum source will cause the residual limb **14** to be drawn into firm contact with the inner surface **64** of the inner socket **60**.

[0052] The hypobarically-controlled artificial limb **50** also includes a regulator means **80** for controlling the vacuum source **70**. Preferably, the regulator means **80** may be a digital computer **82**. Alternately, the regulator means may be a vacuum regulator. The regulator means **80** is connected to a power source **83**, which may be a battery.

[0053] A seal means **84** makes an airtight seal between the residual limb **14** and the outer socket **52**. Preferably, the seal means **84** is a nonfoamed, nonporous polyurethane suspension sleeve **86** which rolls over and covers the outer socket **52** and a portion of the residual limb **14**. Alternatively, the seal means **84** may be any type of seal which is airtight.

[0054] The hypobarically-controlled artificial limb **50** may also include a thin sheath **90** between the residual limb **14** and the inner surface **64** of the inner socket **60**. As vacuum is applied to the cavity **62**, the sheath **90** will allow the vacuum to be evenly applied throughout the cavity **62**. Without the sheath **90**, the residual limb **14** might "tack up" against the inner surface **64** and form a seal which might prevent even application of the vacuum to the cavity **62**. The sheath **90** may also be used to assist the amputee into a smooth and easy fitting into the inner socket **60**. The sheath **90** is preferably made of thin knitted nylon.

[0055] The apparatus **50** may also include a nonfoamed, nonporous polyurethane liner **92** receiving the residual limb **14** and disposed between the sheath **90** and the residual limb **14**. The liner **92** provides a total-contact hypobaric suction, equal weight distribution socket liner. The liner **92** readily tacks up to the skin of the residual limb **14** and provides total contact with the limb **14**. The liner **92** absorbs and dissipates shock, mechanical and shear forces typically associated with ambulation.

[0056] The hypobarically-controlled artificial limb **50** may also include a stretchable nylon second sleeve **94** for rolling over and covering the suspension sleeve **86** to prevent clothing from sticking to and catching the suspension sleeve **86**.

[0057] Referring to FIG. 3, the polyurethane tubular sleeve **86** may be appreciated alone and in combination with the urethane liner **92** together with the optional nylon sheath **90** and second stretchable nylon sleeve **94**.

[0058] More specifically, the amputee takes the stretchable nylon second sleeve **94**, suitably made of a spandex-like material and rolls it up over the stump **14** to the upper portions of the residual limb suitably as the thigh of a leg **12**. Next, the polyurethane sleeve **86** is also rolled upwardly over the residual limb **10**. Thereafter, the liner **92** is optionally donned.

[0059] Next, the amputee may optionally utilize the nylon sheath **90** which is suitably of a non-stretching, thin, friction reducing nylon. As stated, this sheath **90** optionally may be used to assist the amputee into a smooth and easy fitting into the inner socket **60**. Alternatively, the sheath **90** may be avoided and the liner **92** simply inserted into the inner socket **60** of the artificial limb **50**.

[0060] Next, the amputee simply grasps the rolled over portion of the polyurethane sleeve **86** and rolls it over a substantial portion of the outer socket **52**. The sleeve **86** makes an airtight seal between the residual limb **14** and the outer socket **52**.

[0061] As can be appreciated, the polyurethane sleeve **86** is tacky. Consequently, the stretchable nylon second sleeve **94** may be utilized and rolled over the polyurethane sleeve **86**.

[0062] The amputee then sets the regulator means **80** to cause the vacuum source **70** to apply vacuum through the vacuum valve **74** and vacuum tube **76** to the cavity **62**. Enough vacuum is applied to cause the residual limb (with optional coverings) to be drawn firmly against the inner surface **64** of the inner socket **60**, which is flexible. The vacuum source **70** may preferably maintain a vacuum in the range of 0 to 25 inches of mercury (ideally ten to twenty five inches).

[0063] It will be seen that the vacuum within the inner socket **60** will cause the hypobarically-controlled artificial limb **50** to be suspended from the residual limb **14**. The vacuum will lock the residual limb **14** into the inner socket **60** without causing swelling of the residual limb into the socket, because of the total contact of the residual limb **14** with the inner socket **60**. That is, there is no open chamber between the residual limb **14** and the inner socket **60** which would draw on the residual limb.

[0064] As the volume of the residual limb **14** decreases during the day due to weight-bearing pressures, the regulator means **80** may appropriately adjust the vacuum source **70** to draw the residual limb **14** more firmly against the inner socket **60** and thus compensate for the loss of residual limb volume. The vacuum may also partially or completely oppose the loss of fluids from the residual limb caused by weight-bearing pressures.

[0065] A second embodiment of the apparatus **50** is shown in FIGS. 5 and 6. The second embodiment of the apparatus **50** is as described above, with the exception that the inner socket **60A** is compressible as well as being flexible. Instead of a vacuum source, the second embodiment has a positive air pressure source **100**, which may preferably be a motor-driven pump **102**. The regulator means **80**, which may be a digital computer **82**, controls the positive air pressure source **100**. The regulator means and positive air pressure source **100** are connected to a power source **83**, which may be a battery. A positive pressure valve **104** connects the space **58** to the positive air pressure source **100**, for compressing the inner socket **60A** as the volume of the residual limb decreases.

[0066] It will be seen that as the volume of the residual limb **14** decreases during the day due to weight-bearing pressures, the regulator means **80** may control the positive air pressure source **100** to cause air pressure to compress the inner socket **60A** to compensate for the decreased volume of the residual limb, as shown in FIG. 6.

[0067] A third embodiment of the hypobarically-controlled artificial limb **50** is shown in FIG. 7. The third embodiment is a combination of the first and second embodiments described above.

[0068] The mechanical motor-driven pump **72** may act as both the vacuum source **70** and the positive air pressure

source **100**. The regulator means **80**, vacuum source **70** and positive air pressure source **100** are connected to a power source (not shown), which may be a battery.

[0069] The vacuum source **70**, under control of the regulator means **80**, will compensate for reduced residual limb volume up to a certain point. From that point on, the regulator means **80** will cause the positive air pressure source **100** to further compensate for reduced residual limb volume as described above. The third embodiment thus uses both vacuum and positive air pressure working together to lock the residual limb **14** into the inner socket **60** and reduce socket volume to compensate for fluid loss in the residual limb **14**. The exact point at which the changeover is made between vacuum compensation and positive air pressure compensation is controlled by the regulator means **80**, which as described may be a digital computer appropriately programmed for the socket environment.

[0070] A fourth embodiment of the apparatus **50** is shown in FIG. 8. The fourth embodiment is like the first embodiment, but includes two vacuum valves: a first vacuum valve **106** and a second vacuum valve **110**, both connected to the vacuum source **70**. The first vacuum valve **106** connects the vacuum source **70** to the space **58**. The space **58** contains a semicompressible material **108**, such as polystyrene beads, as disclosed in U.S. Pat. No. 4,828,325, herein incorporated by reference.

[0071] To don the artificial limb **50**, the amputee proceeds as described above. After inserting the residual limb **14** (with optional coverings) into the inner socket **60B**, which is both compressible and expandable, and rolling the suspension sleeve **86** over the outer socket **52**, the amputee activates the regulator means **80**, causing the vacuum source **70** to apply a vacuum to the space **58**. This causes the material **108** to lock mechanically together into a rigid mass, conforming to the shape of the residual limb **14**. The inner socket **60B** may expand slightly under the weight of the residual limb **14** and under the influence of vacuum.

[0072] It will be seen that the semi-compressible molding material **108** can be molded to the contours of the residual limb **14** without using a custom-building process to produce a custom socket. The outer socket **52** may appropriately occur in standard sizes, such as small, medium, and large. The inner socket **60B** may also occur in standard sizes such as small, medium, and large. Adaptation of the inner socket **60B** to the contours of the residual limb **14** occurs through solidifying the material **108** under the influence of vacuum.

[0073] The second vacuum valve **110** connects the vacuum source **70** to the cavity **62** as previously described, for locking the residual limb **14** into the inner socket **60B**.

[0074] The fourth embodiment may also include a positive air pressure source **100** as previously described, to adjust the size of the inner socket **60B** to compensate for decreased residual limb volume.

[0075] The fourth embodiment may also include a thin sheath **90**, liner **92**, and second sleeve **94**, as previously described.

[0076] The positive air pressure source **100** may also be used for shock absorption and a dynamic response in the ankle and foot sections of the artificial limb **50**, by means of a connection **120**.

[0077] A fifth embodiment of the hypobarically-controlled artificial limb **50** is shown in FIG. 10. This embodiment is the same as the first embodiment shown in FIG. 4, with some changes. First, vacuum source **71** may be a hand-operated vacuum pump **71** which may remove air from the cavity **62** down to approximately 10-25 inches of mercury. A suitable hand-operated vacuum pump is marketed under the trademark MITY VAC II® by Neward Enterprises, Inc. of Cucamonga, Calif.

[0078] The fifth embodiment also includes the seal means **84** which preferably consists of a non-foamed, nonporous polyurethane suspension sleeve **86** for rolling over and covering a portion of the residual limb **14**. A portion of the seal means **86** is adapted to be disposed between the outer socket **52** and the inner socket **60**. The sleeve may be made of any of a variety of air-impervious elastomers.

[0079] The fifth embodiment, shown in FIG. 10 also includes a mechanical interlock **67**, **59** for interlocking the inner socket **62** with the outer socket **52**. Preferably, the mechanical interlock consists of a first detent **67** in the inner socket **62** and a second detent **59** in the outer socket **52**. The first detent **67** engages the second detent **59** to lock the inner socket **60** into the outer socket **52**.

[0080] A sixth embodiment of the apparatus of the present invention is shown in FIGS. 11 and 12. The sixth embodiment is like the first embodiment shown in FIG. 4, with some changes.

[0081] First, the inner socket is specifically intended to be removably from the outer socket. To provide a positive mechanical connection between the inner socket and outer socket and yet allow the inner socket to be easily removed, the sixth embodiment includes a mechanical interlock **103** engaging the inner socket **60** and the outer socket **52**. Preferably, the mechanical interlock may be an extension **104** which is attached to the inner socket **60** and a docking device **106** attached to the outer socket **52** and receiving the extension **104**, and a locking mechanism **105** engaging the extension **104** and the docking device **106**.

[0082] The extension may be any sort of protrusion from the inner socket, such as a bulge or tab. Preferably, the extension **104** comprises a shuttle pin **108**.

[0083] The locking mechanism may be any sort of member which engages both the extension **104** and the docking device **106**, such as a screw, wire, or pin. Preferably, the locking mechanism **105** comprises a second pin **110** which extends outside the outer socket **52** as to be accessible.

[0084] Second, the sixth embodiment includes two thin sheaths, rather than one. A first inner sheath **90** may preferably be disposed between the residual limb **14** and the inner surface **64** of the inner socket **60**. As vacuum is applied to the cavity **62**, the inner sheath **90** will allow the vacuum to be evenly applied throughout the cavity **62**. Without the inner sheath **90**, the residual limb **14** might "tack up" against the inner surface **64** and form a seal which might prevent even application of the vacuum to the cavity **62**. The inner sheath **90** may also be used to assist the amputee into a smooth and easy fitting into the inner socket **60**.

[0085] An outer sheath **93** is preferably disposed between the suspension sleeve **86** and the inner socket **60**, thereby preventing the suspension sleeve from tacking to the inner



socket 60. Such tacking would cause friction between the inner socket 60 and the sleeve 86 which would cause the sleeve to wear out. Such tacking might also cause restrictions in the movement of the residual limb. The outer sheath 93 also protects the suspension sleeve 86 from being damaged by friction with the inner socket 60.

[0086] The sixth embodiment also preferably includes an adhesive pressure tape 95 adapted to cover the outer sheath 93, suspension sleeve 86, and the second sleeve 94 and sealing the outer sheath 93, suspension sleeve 86, and the second sleeve 94 to the inner socket 60. The tape 95 locks all of these layers to the inner socket so that they do not come loose during movement.

[0087] In the sixth embodiment, the suspension sleeve 86 goes between the inner socket 60 and the outer socket 52, so that the sleeve 86 is protected from damage.

[0088] In the sixth embodiment, the inner socket 60 has a rigid lower portion 98 and a substantially flexible upper portion 96. The rigid lower portion assists in weight-bearing while the substantially flexible upper portion allows for movement of the residual limb 14. As the knee is bent from fully straight to fully flexed, the width of the knee changes rather significantly and in a hard, non-flexible socket brim, there can be excessive pressure on the residual limb 14. The substantially flexible upper portion 96 makes the artificial limb 50 more comfortable and more adaptive to these changes. For the same reason, the outer socket 52 has a rigid lower portion 102 and a substantially flexible upper portion 100.

[0089] Preferably, the top edge of the inner socket 60 is below the top edge of the outer socket 52 so that the sleeve 86 is protected from impact. Preferably, the top edge of the inner socket 60 may be  $\frac{3}{16}$  inch below the top edge of the outer socket 52.

[0090] The sixth embodiment includes extensive modifications to the vacuum system.

[0091] First, a vacuum fitting 78 has been added to the inner socket 60 to attach the vacuum tube 76. The vacuum fitting 78 allows the attachment of a vacuum sensor 79 adapted to sense the amount of vacuum in the cavity 62 and a sensor lead 81 is attached to the sensor 79 connecting the sensor 79 to the regulator means 80, thus conveying the sensed vacuum to the regulator means 80.

[0092] A vacuum valve 74 is placed between the cavity 62 and the vacuum source 70 to maintain vacuum in the cavity 62. Typically, the vacuum valve 74 is a one-way valve or non-return valve.

[0093] In the sixth embodiment, the vacuum source 70, vacuum tube 76, vacuum valve 74, regulator means 80, and power source 83 are all attached to the outer socket 52 in the space 58 between the outer socket 52 and inner socket 60. In this way, these delicate components are protected against being damaged by impact. Because of the placement of the regulator means 80 within the outer socket 52, a vacuum control 77 is provided extending outside the outer socket 52 to allow manual control of the regulator means 80.

[0094] The amputee dons the sixth embodiment in a manner similar to that earlier described, with some modifications. First, the outer sheath 93 is put on the residual limb 14 after rolling the suspension sleeve 86 upward over the

residual limb and before donning the liner 92. After donning the inner sheath 90 over the liner 92, the amputee inserts the residual limb 14 into the inner socket 60. Next, the outer sheath 93, suspension sleeve 86, and second sleeve 94 are rolled down over the inner socket 60, and the adhesive pressure tape 95 is applied. Next, the wearer sets the regulator means 80 to an appropriate vacuum level by means of the vacuum control 77, and connects the vacuum tube 76 to the vacuum fitting 78. The inner socket 60 is then placed within the outer socket 52 so that the shuttle pin 108 engages the docking device 106 and the locking pin 110 is set to engage the shuttle pin 108 and the docking device 106, providing a positive mechanical interlock.

[0095] A seventh embodiment of the hypobarically-controlled artificial limb of the present invention is shown in FIG. 13. The seventh embodiment is similar to the sixth embodiment, with some changes.

[0096] First, the mechanical interlock 103 does not engage the inner socket 60. Instead, the mechanical interlock engages the outer socket 52 and the suspension sleeve 86. To accomplish this, the suspension sleeve 86 covers the entire inner socket 60, and the suspension sleeve 86 has the extension 104 or shuttle pin 108 embedded in the suspension sleeve at the distal end of the suspension sleeve, as shown in FIG. 14. Preferably, the extension 104 has a portion 104A embedded in the suspension sleeve. This portion 104A may be a disk or umbrella 104A. The extension 104 then engages the docking device 106 as previously described.

[0097] Second, the suspension sleeve 86 is modified to support the additional weight imposed on the suspension sleeve 86 due to the outer socket 52 and artificial limb. In particular, the suspension sleeve 86 is fabricated from a material which allows circumferential expansion but resists longitudinal stretching under the weight of the artificial limb. Such a material is described in U.S. Pat. No. 5,571,208, herein incorporated by reference.

[0098] The sleeve 86 preferably contains fabric threads which may be oriented circumferentially around the sleeve. The threads preferably are comprised of double-knit polyurethane. The threads may also include nylon. The threads permit the sleeve 86 to expand circumferentially so that the sleeve may be slipped onto the residual limb 14 and so that the lower portion may be slipped over the inner socket 52. The threads are preferably connected together with cross-links, which also may be preferably comprised of polyurethane. The cross-links and threads form a matrix which allows circumferential expansion but resists longitudinal stretching under the weight of the artificial limb. By example, the sleeve 86 may have a 4-to-1 ratio of circumferential stretch relative to longitudinal stretch.

[0099] The sleeve 86 may have a portion above the inner socket 52 which is manufactured of material which allows both vertical and horizontal stretching, to increase flexibility.

[0100] An eighth embodiment of the hypobarically-controlled artificial limb of the present invention is shown in FIG. 15.

[0101] Unlike earlier embodiments, the artificial limb 50 of the eighth embodiment has only a single socket 60 rather than inner and outer sockets and is thus considerably simpler.

[0102] The socket **60** has a volume and shape to receive a substantial portion of the residual limb **14** with a cavity **62** therebetween.

[0103] A nonfoamed, nonporous polyurethane liner **92** is preferably adapted to receive the residual limb **14** and to be disposed between the residual limb **14** and the socket **60**.

[0104] A vacuum source **70** is connected to the cavity **62** by a vacuum valve **78**, thereby drawing the residual limb **14** into firm contact with the socket **60**.

[0105] A seal means **84** makes a seal between the residual limb **14** and the socket **60** to minimize air leakage into the cavity **62**. It has been found that it is impossible to make a perfect seal, with the result that air leakage can occur at rates up to 30 cc per minute. As air leaks into the cavity **62**, it is necessary to activate the vacuum source **70** to restore vacuum in the cavity. Furthermore, it has been found that when the vacuum in the cavity is about 5 inches of mercury, the residual limb may lose up to 6 to 15% of its volume during the day, whereas if the vacuum in the cavity is 10-25 inches of mercury, the residual limb loses only about 1% of its volume during the day.

[0106] To minimize the time that the vacuum source, such as a vacuum pump **72**, needs to run to maintain vacuum in the cavity, a ninth embodiment of the artificial limb **50** is shown in **FIG. 16**. The ninth embodiment is the same as the eighth embodiment, but a vacuum reservoir **110** is added between the vacuum source **70** and the vacuum valve **78**. The vacuum reservoir **110** has a volume substantially larger than the cavity **62**. Suitably, the vacuum reservoir may have a volume of 2 gallons or 9000 cc while the volume of the cavity **62** may be only about 100 cc or even less.

[0107] It will be seen that as air leaks into the cavity **62**, the air will be pulled into the vacuum reservoir **110**, thereby maintaining the vacuum in the cavity **62**.

[0108] When the vacuum in the reservoir **110** reaches a certain minimum threshold, the vacuum source **70** may be activated to restore vacuum to the vacuum reservoir **110**. The vacuum source **70** may be activated either manually or by a regulator means (not shown).

[0109] The artificial limb **50** typically includes a shin or pylon **54** and a foot **56**, as shown in **FIG. 3**. Preferably, the vacuum reservoir **110** is attached to the shin **54** between the socket **60** and the foot **56**. However, the vacuum reservoir may also be carried separately, as for example in a backpack. Depending on the placement of the vacuum reservoir **110**, a vacuum tube **76** may be necessary to connect the vacuum reservoir **110** to the vacuum valve **78**.

[0110] If the volume of the vacuum reservoir **110** is about 9000 cc and air leaks into the cavity **62** at about 75 cc per minute, it will be seen that the intervals between activation of the vacuum source **70** can be up to about 120 minutes.

[0111] The artificial limb **50** of the eighth and ninth embodiments may preferably further comprise the following.

[0112] An inner sheath **90** may be adapted to be disposed between the liner **92** and the socket, to ensure even distribution of vacuum in the cavity **62**, as earlier described. Preferably, the inner sheath **90** may be thin knitted nylon. The sheath **90** may also be affixed to the outside of the liner **92**.

[0113] The seal means **84** is preferably a nonfoamed, nonporous polyurethane suspension sleeve **86** for rolling over and covering the socket **60** and a portion of the artificial limb **14**, as earlier described.

[0114] A stretchable nylon second sleeve **94** for rolling over and covering the suspension sleeve **86** may be added to prevent clothing from sticking to and catching on the suspension sleeve **86**, as earlier described.

[0115] The vacuum source **70** is preferably a motor or mechanical driven vacuum pump **72**, as earlier described. A vacuum tube **76** may be necessary to connect the vacuum pump **72** to the vacuum valve **78**, depending on the placement of the vacuum pump **72**.

[0116] The vacuum source **70** may also be a weight-actuated vacuum pump and shock absorber as disclosed in U.S. patent application Ser. No. 09/534,274, filed Mar. 23, 2000, and issued as U.S. Pat. No. 6,554,868, and herein incorporated by reference.

[0117] To maintain the vacuum in the cavity, either a regulator means **80**, a vacuum reservoir **110**, or a weight-actuated vacuum pump and shock absorber as disclosed in U.S. Pat. No. 6,445,868 may be employed.

[0118] Applicant has found that many of the embodiments discussed earlier share a common problem. The vacuum which holds the residual limb (and liner) in firm contact with the socket tends to cause edema and blistering at the point on the residual limb where the suspension sleeve contacts the residual limb. This problem occurs because the vacuum (perhaps 7½ pounds of negative pressure) in cavity **62** draws against the suspension sleeve **86** at the point where the suspension sleeve **86** contacts the skin of the residual limb. However, because the liner **92** often has an outer fabric cover **130** to prevent the liner from adhering to the socket **60** or clothing, the suspension sleeve cannot make a good seal at the point where it contacts the outer fabric cover **120**. This has left the residual limb as the only point at which to make the seal.

[0119] **FIG. 17** shows one solution to this problem. The liner **92** is improved by adding an annular seal **140** extending outwardly from the fabric cover **130**. The annular seal, which may be made from the same material as the inner layer **92** of the liner, is adapted to sealingly engage the suspension sleeve **86**, producing a seal against the vacuum in cavity **62** at the point of contact with the suspension sleeve **86**. Therefore, the vacuum in cavity **62** now draws against the annular seal **130** rather than against the skin of the residual limb **14**.

[0120] An alternative solution to the above problem is shown in **FIG. 18**. Here, the annular seal **140** does not make contact with the suspension sleeve **86**, but rather makes contact with the inner wall **63** of the socket **60**, and makes a seal at that point. No suspension sleeve is used in this variation, it being found that sufficient holding force is provided by the vacuum in cavity **62**.

[0121] A second alternative is shown in **FIG. 19**. This alternative is like that of **FIG. 18**, with the exception that a mechanical interlock **103** is provided which is adapted to interlock with the socket **60**. Preferably, as shown, the mechanical interlock **103** comprises a shuttle pin **108** adapted to connect the liner **92** with the socket **60**, and a

locking mechanism **105** such as a second pin **110** extending through the socket **60** to the exterior of the socket **60** for access by the amputee as earlier described. More particularly, the liner **92** may have an extension **104** or shuttle pin **108** embedded in the liner at the distal end of the liner. Preferably, the extension **104** has a portion **104A** which may be a disk or umbrella which engages a docking device **106** as earlier described.

[0122] To keep air from entering the cavity **62**, the invention of **FIG. 19** also preferably includes a locking mechanism seal **150** adapted to engage the inner wall **63** of the socket **60** about the locking mechanism **105**. The seal **150** could alternatively be on the outer surface of the socket **60**.

[0123] Another alternative is shown in **FIG. 20**. Here, the fabric cover **130** stops below the annular seal **140**. The annular seal **140** may also be made of the same material as the liner **92**.

[0124] A very important advantage, in all of the above embodiments, is the use of vacuum within the socket to prevent fluids from migrating out of the distal end of the residual limb due to weight-bearing pressures. Although the exact mechanism is not precisely known at this time, Applicant believes this limb vacuum volume management system to function as follows.

[0125] Application of a vacuum to the socket cavity **62** sucks the liner **92** tightly against the inner wall of the socket **60**. The liner has a tight interference fit with the residual limb **14**, so that the residual limb is also butted tightly up against the inner wall of the socket. During the weight-bearing phase of walking, the wearer's body weight will force the limb and liner even more tightly against the inner wall of the socket. However, during the non-weight-bearing phase, or swing phase, of walking, the weight of the artificial limb will have a tendency to cause the socket **60** to pull away from the liner **92**. This is prevented by the vacuum in the socket cavity. Because the vacuum keeps the liner tightly opposed to the inner wall of the socket, this tendency will also cause the liner **92** to pull away from the residual limb, creating a small, partial vacuum between the liner **92** and the residual limb **14**. This small, partial vacuum, perhaps on the order of 2 inches of mercury, will then oppose the migration of fluids out of the residual limb.

[0126] In order for this beneficial effect of vacuum to occur, the vacuum in the socket cavity **62** needs to be at least about 10 to 25 inches of mercury. At this level of vacuum, it has been found that the residual limb loses only about 1% of its volume during the day.

[0127] The present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof, and it is therefore desired that the present embodiment be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than to the foregoing description to indicate the scope of the invention.

What is claimed:

1. An artificial limb for an amputee who has a residual limb comprising:

a means for receiving a portion of a residual limb of an amputee;

a means for supporting the weight of the amputee when the residual limb is received within the receiving means;

a means for applying vacuum to the residual limb when the residual limb is received within the receiving means;

a means for reducing loss of vacuum against the residual limb during a weight-bearing phase of walking by the amputee; and

a means for reducing loss of vacuum against the residual limb during a non-weight bearing phase of walking by the amputee.

2. The artificial limb of claim 1, wherein the supporting means comprises a prosthetic foot.

3. The artificial limb of claim 1, wherein the means for applying vacuum comprises a vacuum pump.

4. The artificial limb of claim 1, wherein the means for applying vacuum comprises a vacuum reservoir.

5. The artificial limb of claim 1, wherein the receiving means comprises a socket.

6. The artificial limb of claim 1, wherein the means for reducing loss of vacuum comprises a seal.

7. The artificial limb of claim 1, wherein the means for reducing loss of vacuum comprises a suspension sleeve.

8. The artificial limb of claim 1, wherein the means for reducing loss of vacuum comprises a means for maintaining vacuum during both the weight-bearing and non-weight bearing phases of walking by the amputee.

9. The artificial limb of claim 8, wherein the means for maintaining vacuum comprises a vacuum pump adapted to regulate a level of vacuum against the residual limb.

10. An artificial limb for an amputee who has a residual limb comprising:

a flexible liner adapted to encase a portion of a residual limb

a single, substantially rigid socket configured to receive the residual limb encased in the liner and to form a cavity between the liner and the socket;

a support member coupled to the socket, the support member adapted to provide support for the weight of the amputee when the residual limb is received within the socket;

a seal member adapted to seal the cavity between the liner and the socket; and

a vacuum source fluidly coupled to the cavity between the liner and the socket, the vacuum source configured to apply a designated vacuum pressure evenly over the liner encasing the residual limb so as to securely couple the artificial limb to the residual limb and to maintain the designated vacuum pressure within desired limits during use of the artificial limb by the amputee.

11. The artificial limb of claim 10, wherein the support member comprises a prosthetic foot.

12. The artificial limb of claim 10, wherein the vacuum source comprises a vacuum pump.

13. The artificial limb of claim 12, wherein the vacuum pump comprises shock absorption.

14. The artificial limb of claim 12, wherein the vacuum pump is weight actuated.

**15.** The artificial limb of claim 10, wherein the vacuum source comprises a vacuum reservoir.

**16.** The artificial limb of claim 10, wherein the seal member comprises a suspension sleeve.

**17.** The artificial limb of claim 10, wherein the seal member is formed integral with the flexible liner.

**18.** A method for managing volume loss in a residual limb of an amputee when wearing an artificial limb, the method comprising the steps of:

encasing a portion of a residual limb in a flexible liner;

inserting the encased residual limb into a single, substantially rigid socket of an artificial limb and thereby forming a cavity between the liner and the socket, the socket adapted to be coupled to a structure capable of supporting and facilitating walking by the amputee;

sealing the cavity;

supplying vacuum to the cavity so as to apply vacuum pressure evenly over the liner encasing the residual limb; and

maintaining vacuum within the cavity during both a weight-bearing phase of walking by the amputee and a non-weight bearing phase of walking by the amputee.

**19.** The method of claim 18, wherein the step of maintaining vacuum comprises reducing the loss of vacuum within the cavity.

**20.** The method of claim 18, wherein the step of sealing the cavity comprises placing a suspension sleeve over a portion of the residual limb and over a portion of the socket.

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