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Description**Technical Field**

[0001] This invention relates to a prosthetic sleeve and socket combination, and
5 more particularly, to a prosthetic sleeve having dual flaps or skirts concentrically
arranged about the sleeve and configured to form a sealed chamber between
the sleeve and socket when the sleeve is inserted into the socket.

Background Art

10 [0002] An amputee is a person who has lost part of an extremity or limb such as
a leg or arm. That which remains is commonly referred to as a residual limb.
Residual limbs come in various sizes and shapes with respect to the stump. For
instance, new amputations are often slightly bulbous or cylindrical in shape
while older amputations that have atrophied are generally more conical in
15 shape. Residual limbs may also be characterized by their various individual
configurations including the volume and shape of a stump, bony prominence,
uneven limb volume or soft tissue configurations. For example, a leg severed
above the knee generally terminates in a fleshy stump while a leg severed be-
low the knee generally terminates in a bony stump.

20

[0003] More particularly, referring to Figure 1, a below the knee residual limb 18
is shown and described as a leg 20 having been severed below the knee termi-
nating in a stump 22 also referred to as a leg terminus. In this case stump 22 is
formed by the severed tibia 28 and fibula 30 and the smaller, less voluminous
25 muscles of the lower leg. Thus, a below the knee residual limb 18 has its stump
22 generally characterized as being a more bony structure while an above the
knee residual limb (not shown) is characterized as including more soft tissue.

[0004] Artificial limbs typically used by a leg amputee have sockets to put the
30 amputee's stump into. 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 are opened ended sockets having a hollow chamber in the bottom.

[0005] 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, leather lacers or lacings. However, these types of suspension systems are bulky and uncomfortable to wear, and when the residual limb was a leg severed above the knee, the socket had to include an ischial flare which only increased bulk and discomfort. Another method of suspending artificial limbs required the amputee to use a latex rubber tube formed into a rubber-like sleeve which would be rolled on over both the top of the artificial limb and onto the amputee's thigh. In some instances, a negative pressure system was used in combination with the rubber sleeve which required forming a negative pressure chamber between the leg and socket using a vacuum pump. The sleeve acted as a seal between the limb and socket thereby suspending the socket from the limb. However, since the seal was formed on the outside of the socket it was prone to puncturing which resulted in suction loss within the sealed chamber and detachment of the socket from the residual limb.

[0006] US 2007/0123998A discloses a sleeve to fit between a residual limb and a prosthetic socket, and having the features of the pre-characterizing portion of claim 1 appended thereto.

Disclosure of the Invention

[0007] The present invention is directed to a prosthetic sleeve and socket system, and more particularly, to a prosthetic sleeve having dual skirts or flaps concentrically arranged about the sleeve and configured to form a sealed chamber between the sleeve and socket when the sleeve is inserted into the socket. In addition, a method of attaching a prosthesis to a residual limb is presented consisting of placing the improved prosthetic sleeve with dual skirts about a residual limb, inserting the residual limb and prosthetic sleeve into a socket conforming to the shape of the residual limb, forming a continuous seal between the sleeve and an interior surface of the socket, evacuating air from a

chamber contained between the residual limb and an interior surface of the socket and creating a partial vacuum within the chamber sufficient to maintain the socket coupled to and suspendable from the residual limb. The dual skirts about the sleeve cooperate with the interior surface of the socket to form the seal and create a continuous connection along an upper margin of these skirts around the sleeve. The method further includes pushing air from the chamber through an expulsion valve coupled to an opening in the socket by inserting the residual limb into the socket and simultaneously and continually purging air from the chamber through a vacuum pump coupled to an opening in the socket. Preferably, the air contained between the sleeve and the inner or lower skirt is removed by a "wicking" positioned therebetween. Suitable wicking can be an air permeable cotton sock fitted onto the residual limb over a portion of the sleeve.

Brief Description of the Drawings

15 [0008]

Figure 1 is a side elevational view of the tissue and skeletal structure of an amputee's residual leg severed below the knee;
Figure 2 is an exploded perspective view of a prosthetic sleeve and socket system in accordance with a preferred embodiment of the present invention;
20 Figure 3 is a cross-sectional view of the prosthetic sleeve and socket system of Figure 2;
Figure 4 is perspective view of an air wick in partial cross-section in accordance with the sleeve and socket system of Figure 2;
Figure 5 is a plan view of the open end of the socket of Figure 2;
25 Figure 6 is a cross-sectional view of the sleeve and socket system of Figure 2 suspended from an amputee's residual leg below the knee and showing the inner or lower skirt against the liner and the outer or upper skirt manipulated up and away from the sleeve; and,
Figure 7 is a cross-sectional view of the sleeve and socket system of Figure 6 illustrating formation of a seal between the sleeve and socket during installation upon a residual limb.
30

Best Mode for Carrying Out Invention

5 [0009] Figure 1 illustrates a below the knee residual limb 10 showing relatively low amount of residual flesh around the residual bone and potentially elongated portion.

10 [0010] Preferred embodiments of the present invention are illustrated in Figures 2-7, where like portions share like numbering. Generally, as illustrated in Figure 2, the prosthetic sleeve and socket system includes a pliable, silicone sleeve 40 conformable to the shape of an amputee's residual limb, pliable, dual skirts or flaps 42,43 concentrically arranged about sleeve 40, an air wick 44 and a prosthetic socket 46 conforming to the shape of the amputee's residual limb. "Air wick" is hereby defined as an air permeable material, said material including air permeation characteristics in all directions. For example, a cotton sock would be one form of an air wick. The purpose of the air wick is to avoid the entrapment of air between sleeve 40 and socket 46 and to allow a smooth flow of air over all parts of the sleeve 40 to facilitate the creation of downward suction force caused by the manual insertion of a leg into socket 46 or a discrete vacuum pump 90.

20

[0011] Referring also to Figure 3, sleeve 40 includes a cylindrical, continuous sidewall 48 having an upper circumferential extent 50 and a closed bottom end 52. The sleeve 40 includes a limb receiving opening 54 defined and bounded by extent 50, an inner surface 56 of sleeve sidewall 48, and a closed bottom end 52. Since sidewall 48 and closed bottom 52 are constructed of pliable, silicone sheeting, sleeve 40 is sufficiently pliable to fit snugly around an amputee's residual limb, whether it is an arm, leg, or other appendage. Preferably, sleeve sidewall 48 has a uniform thickness of between 3 mm to 6 mm and has surface characteristics that lends itself to comfortably gripping a user's skin.

30

[0012] Lower or inner skirt 42, which is positioned concentrically about sleeve 40, connects to and is fused with outer surface 58 of sleeve sidewall 48 at fused margin 62, and upper or outer skirt 43 connects to and is fused with outer sur-

face 58 at the same point 62 in coextensive integration. Specifically, inner and outer skirts 42,43 consist of a substantially, tubular silicone sheet having an attached margin at 62 that defines the inner skirt proceeding directly downward therefrom and the outer skirt 43 arcing slightly over inner skirt 42 and downward. Inner skirt freely descends downward to define a free margin 64 and outer skirt descends a similar, but greater distance defining a free margin 65. The combination of both skirts extend over sleeve 40 an area equal to margin 61 (see Fig. 7) and define two continuous circumferential envelopes 59,60 underneath each free margin 64,65, respectively, with each skirt overlapping one another as shown.

[0013] Attachment of the skirts 42,43 at 62 to sidewall 48 is accomplished through either using an adhesive or by stitching, or producing sleeve 40 and skirts 42,43 as a single piece. Preferably, fused margin 62 is attached to sidewall 48 by affixing it directly on the outer surface 58 and allowing the skirts 42,43 to extending downward in the general direction of closed bottom 52, such that envelope spaces 59,60 are left between the two. In this manner each skirt 42,43 can be easily folded downward to lie against outer surface 58 of sidewall 48 without creating an otherwise bulky fold about fuse margin 62. Preferably, both skirts 42,43 have uniform thicknesses of between 1 mm and 3 mm, and preferably both skirts are integral with one another at the point of fusing 62.

[0014] As may be understood, while fused margin 62 is shown to be affixed to sleeve 40 at an approximate upper-point along sidewall 48, this fused margin may be moved up or down sleeve 40 to provide a variable placement of free margins 64,65, and the free margins 64,65 themselves may be varied by moving the point of fusing on the skirts 42,43 so that 42 and 43 may vary in length with respect to one another. Also, the width of fuse margin 62 itself may be varied. Such variations allow for the extension of these free upper margins over more surface area of sleeve wall 48 to allow for additional contact and stability of sleeve 40 over limb 91. In this manner, various sizes and configurations of sleeve 40 may be manufactured to fit various sizes and shapes of residual limbs, including residual limbs on arms, legs, fingers, etc. Similarly, various siz-

es and shapes of sockets 46 cooperatively shaped with sleeves 40 would be utilized to accommodate various shapes and sizes of residual limbs.

[0015] Referring now to Figure 4, air wick 44 is constructed of a thin, air permeable fabric formed into a sock. Wick 44 therefore includes a cylindrical continuous wall 66, an open top 68 and a closed bottom 70. It is preferred that wall 66 has a height substantially equal to the distance between the lowermost point of fused margin 62 plus gap 45 downward to closed bottom end 52 and covering same. This positions air wick 44 over bottom end 52 and sidewall 48 of sleeve 40, with wall 66 continuously extended between skirt 42 and outer surface 58 of sidewall 48 when skirt 42 is pressed against sleeve 40. Hence, wick 44 fills envelope 59 when inserted into socket 46 as will be discussed.

[0016] While not shown, the inventors contemplate the usage of a similar portion of an air wick shaped into a tube or cylinder and configured to fill envelope 60 of outer skirt 43 between the lowermost point of fused margin 62 to the lowermost extent of skirt 42. While this type of tubular wick configuration is sufficient to avoid the entrapment of air within envelope 60 during donning of the invention upon a residual limb, it may be preferable, and simpler, to utilize an integrally formed vertically oriented series of parallel ridges (not shown) formed upon the inner surface of the free margin portion 64 of outer skirt 43. Such ridges would necessarily create a series of vertical air channels, thereby facilitating the escape of air from underneath free margin portion 65 upon donning. Irrespective of the inclusion of these additional wicking elements, the lack of a wicking structure between skirts 42 and 43 does not substantively impair the operation of the invention.

[0017] Referring to Figure 5, socket 46 is composed of a socket wall 72 having an interior surface 74 and an exterior surface 76 and a socket distal end 78. Socket distal end 78 merges integrally into socket wall 72 at the lower end of the wall. Jointly with the interior surface 74, distal end 78 forms a substantially cup-shaped inner volume 80 which is accessible through a proximal residual limb insertion opening 82 at the proximal end. Since socket 46 is configured to

attach to an amputee's residual limb by a partial vacuum it is a so-called suction-socket.

[0018] A pair of openings 84 and 86 are formed through socket distal end 78 for
5 allowing air within inner volume 80 to selectively escape from inner volume 80
ahead of an amputee's residual limb 91 when the latter is inserted into inner
volume 80. In particular, opening 84 is coupled to a selectively actuated expulsion
valve 88 for allowing, air under pressure to exit inner volume 80 via short
conduit 87. An example expulsion valve suitable for use in the herein described
10 system is a V4 or V5 expulsion valve offered by Otto Bock HealthCare, Inc.
Opening 86 is connected to a vacuum source 90 via line 89 for pulling air out of
inner volume 80 to form a partial vacuum. Vacuum source 90 is preferably self-
contained and includes a power source, a release valve, a vacuum pump and a
pressure control means configured to maintain pressure within inner volume 80
15 at a predetermined pressure. An exemplary vacuum source includes the
"eVAC" model no. DF-100 manufactured by Smith Global, located in Laurie,
Missouri.

[0019] Referring to Fig. 6, there is shown the prosthetic sleeve and socket sys-
20 tem suspended from a leg severed below the knee near the upper ankle. An
amputee's severed or residual limb 91 includes a lower end 92 that is inserted
through open top end 50 and into limb receiving opening 54 of sleeve 40. Lower
end 92 of the amputee's limb is fully engaged with inner surface 56 of sleeve
sidewall 48 and closed bottom end 52, with sidewall 48 exerting pressure
25 against the leg sufficient to maintain sleeve 40 suspended from lower end 92 of
the amputee's limb when sleeve 40 is coupled to socket 46 and the desired
prosthetic appendage 100. The diameter and length of sleeve 40 are deter-
mined based upon the length and diameter of lower end 92 and the amount of
flesh present about lower end 92. The amount of flesh present can also dictate
30 the thickness of sleeve sidewall 48 since the abundance or lack of flesh can de-
termine how well sleeve 40 engages and remains engaged with socket 46. For
example, in those instances where sleeve 40 and socket 46 are to be coupled
with a leg severed below the knee the thickness of sleeve sidewall 48 may be

increased to make up for the lack of flesh typically found about that part of the leg. Alternatively, when sleeve 40 and socket 46 are to be placed on a leg severed above the knee, the thickness of sleeve sidewall 48 may be less since the upper leg typically includes a relatively substantial amount of flesh.

5

[0020] With sleeve 40 positioned on lower end of the residual limb 91, air wick 44 is then positioned over closed bottom end 52 of sleeve 40 with closed bottom 70 of wick 44 being located adjacent to and in contact with closed bottom end 52. Further, wick 44 extends upwardly along sleeve sidewall 48 to a point
10 near fused margin 62, but leaving a slight gap 45 (see Fig. 7). Skirt 43 to this point may be positioned up and out of the way of wick 44 and skirt 42 to facilitate their smooth integration. This allows easy manipulation of skirt 42 downward to lie flat against the outer surface of air wick 44 along inner skirt 42's interior surface, and prevents almost all direct contact between the sidewall 48 and
15 skirt 42. Once wick 44 and skirt 42 are smoothly secured against sleeve 40, skirt 43 may be folded down and manipulated to smoothly flow over skirt 42 to a form as shown in Fig. 7.

[0021] Referring now to Fig. 7, the lower end of the amputee's residual leg 91,
20 along with sleeve 40 and air wick 44, are positioned within inner volume 80 of socket 46. In particular, closed bottom 70 of wick 44, along with sleeve 40, is positioned immediately above distal end 78 of socket 46 with sleeve sidewall 48 being located substantially parallel to socket sidewall 72. As is now apparent, skirt 42 is first manipulated to lie flat against and between interior surface 74 of
25 socket 46 and air wick 44, and skirt 43 is similarly manipulated to lie flat against skirt 42 outer surface and in between interior socket surface 74 and skirt 42. If desirable, the vertical channels formed on the inner surface of outer skirt 43 will now lie flat against the outer surface of skirt 42, thereby creating a series of vertical air passages between each skirt such that air entrapment is prevented
30 therebetween. The interaction of skirts 42,43 with interior surface 74 acts to create a double continuous seal 94 between sleeve 40 and socket 46 along margin 65. Seal 94 therefore encloses inner volume 80 within socket 46, defining inner volume 80 by interior surface 74, skirts 42,43, and sleeve sidewall 48.

[0022] The seal 94 is first created when skirt 42 is initially inserted into inner volume 80. This occurs as soon as skirt 42 makes a continuous connection with interior surface 74 of socket 46 with skirt 43 also making a continuous connection to the inner surface of skirt 43. Thus, as sleeve 40 and skirts 42,43 are pressed into inner volume 80, seal 94 is created, maintained and moved downwardly toward distal end 78 thereby causing the air within socket 46 to be compressed. This further helps to press skirts 42,43 against interior surface 74 thus strengthening the interaction between skirts 42,43 and socket 46 and ultimately seal 94. Once the air reaches a predetermined pressure, the compressed air is allowed to escape from inner volume 80 through opening 84 and expulsion valve 88. Expulsion valve 88 typically includes a small manual release to control the timing and volume of air that might be expelled through it. Air can also escape through a release valve contained within vacuum source 90, if present, but vacuum source 90 itself will tend to evacuate the air held by seal 94 in response to and at a rate characterized by the operational specifications of the vacuum unit. By increasing the number of openings through which the compressed air can be selectively evacuated from inner volume 80, sleeve 40 is more easily inserted into and coupled with socket 46 since the compressed air can escape at a faster rate. Hence, it is anticipated that multiple expulsion orifices and vacuum conduit openings might be incorporated into the socket 46.

[0023] Once lower end 92 of the amputee's residual limb, along with sleeve 40 and air wick 44, are fully seated within inner volume 80 of socket 46, a partial vacuum is created within inner volume 80. In particular, vacuum source 90 acts to pull air within inner volume 80 out of socket 46 through opening 86 to create a regulated partial vacuum. Since air wick 44 is provided between skirt 42 and sleeve sidewall 48, and, if desired, the air channels that separate skirts 42 and 43, the air located between these elements is more easily removed from inner volume 80. By interposing the air wick 44 along the entire surface of sleeve 40, up to skirt fuse juncture 62 between skirt 42 and the sleeve 40 as shown, and including any vertical air channels, pockets of isolated air are avoided in envelopes 59 and 60 so that the full retention force of the created vacuum extends

along the entire outer surface 58 of sleeve 40 such that socket 46 and residual limb 91 are continuously drawn together. The retention of a vacuum attraction between socket 46 and limb 91 allows socket 46 to be of a substantially reduced size over conventional sockets and permits, in many cases, the disposal
5 of bulky suspending straps.

[0024] As will be apparent to one skilled in the art, various modifications can be made within the scope of the appended claims. For example, air wicking, that ensures air permeation over the entire surface area 58 of sleeve 40, is currently
10 satisfied through the utilization of a sock placed over sleeve 40. However, the inventor envisions that other structures may be employed to promote air permeation and avoid the creation of air pockets over the surface area of sleeve 40. Surface texture and molded structures in the surface 58 of sleeve 40 may be employed to promote air permeation across surface 58. Further, intervening
15 substances, such as granularized powders, might also be employed to promote air permeation. Similarly, various textures, molded structures, and substances may be interspersed between skirts 42,43 to facilitate air removal.

Patentkrav

1. Apparat til fastgørelse af en protese til et rest-lem, hvilket apparat omfatter:

- 5 (a) en bøsning (40) til anbringelse omkring en nedre del af et lem, hvilken bøsning (40) har en yderflade, som er forsynet med en ensartet, lukket lufttæt membran med en lukket bundende;
- (b) et første rundtgående skørt (42), som er udformet ud i ét med den øvre del af bøsningen, og hvor dette rundtgående skørt har en inderflade og
10 en yderflade;
- (c) et andet rundtgående skørt (43), som er udformet ud i ét med den øvre del af bøsningen, og hvor dette andet rundtgående skørt har en inderflade og en yderflade; en protese-fatning (46),
- (d) hvilken fatning (46) i sin nedre del har en vakuum-åbning (86) til tilveje-
15 bringelse af en forbindelse til en vakuum-kilde, **kendetegnet ved, at** det første rundtgående skørt rager ned fra en øvre del af bøsningen, og **at** det andet rundtgående skørt rager ned fra en øvre del af bøsningen, og at det første skørt og andet skørt overlapper hinanden, og at apparatet yderligere omfatter:
- 20 (e) et første luftgennemtrængeligt organ (44), som er anbragt mellem bøsningens (40) yderflade og det første skørts (42) inderflade med henblik på at tillade luft at trænge igennem mellem bøsningens yderside og det første skørt;
- 25 (f) at en protese-fatning (46) har en inderflade, som er anbragt uden på bøsningen (40) og de nævnte skørter (42, 43), så at det første skørts inderflade hviler mod det første luftgennemtrængelige organ (44), og en yderflade på det andet skørt (43) hviler mod en inderflade i fatningen
- 30 (46), idet der findes en lufttæt forsegling mellem inderfladen i fatningen (46) og yderfladen af nævnte andet skørt (43).

2. Apparat ifølge krav 1, hvor det første luftgennemtrængelige organ (44) omfatter en stof-sok, som er indrettet til at kunne glider hen over bøsningen (40).
3. Apparat ifølge krav 1, hvor det første luftgennemtrængelige organ (44) omfatter en grannuleret substans.
4. Apparat ifølge et hvert af de foregående krav, og som yderligere omfatter et andet luftgennemtrængeligt organ, der er anbragt mellem det andet skørt (43) og det første skørt (42) for at tillade gennemtrængning af luft mellem det første skørt og det andet skørt.
5. Apparat ifølge krav 4, hvor det andet luftgennemtrængelige organ omfatter en stof-sok.
6. Apparat ifølge ethvert af de foregående krav, hvilket apparat yderligere omfatter en smeltet randdel (62), som forbinder det første og andet skørt (42, 43) med bøsningen (40), og hvor stillingen af den smeltede randdel (62) kan bevæges op eller ned på bøsningen for tilvejebringelse af en tilpasning til forskellige størrelser af rest-lemmet.
7. Apparat ifølge ethvert af de foregående krav, hvor indersiden af det andet skørt (43) yderligere er forsynet med et antal lodrette kanaler, hvilke kanaler er dannet på indersiden af dette andet skørt for at lette udpresning af skørt-luft mellem delene.
8. Apparat ifølge ethvert af de foregående krav, hvor det første og andet skørt (42, 43) omfatter et integreret rør, som er fastgjort til bøsningen ved en integrerende udformet kantdel (51), og hvor det andet skørt (43) er foldet ned over det første skørt (42).
9. Apparat ifølge ethvert af de foregående krav, hvor det første skørt (42) og andet skørt (43) rager lige langt ned fra bøsningen (40).

10. Apparat ifølge ethvert af de foregående krav, og som yderligere omfatter en vakuum-pumpe (90), som er forbundet med en vakuum-åbning (86) og anbragt på fatningen (46).
- 5 11. Apparat ifølge ethvert af de foregående krav, hvor bøsningen (40) omfatter silikone.
12. Apparat ifølge ethvert af de foregående krav, hvor det første og andet skørt (42, 43) omfatter silikone.
- 10 13. Apparat ifølge ethvert af de foregående krav, hvor apparatet yderligere omfatter en lem-protese (100), som rager ned fra fatningen (46).
14. Fremgangsmåde til fastgørelse af en protese til et rest-lem med en proksi-
 15 mal ende og en distal ende, hvilken fremgangsmåde omfatter:
- a. at man anbringer en foldelig bøsning – som er udformet i overensstemmelse med apparatet ifølge ethvert af de foregående krav – omkring rest-lemmet;
 - 20 b. at man manipulerer de nævnte skørter, så at hvert af disse positioneres i forhold til nævnte proksimale ende;
 - c. at man anbringer en luftvæge uden på det dækkede rest-lem, men under de nævnte skørter, så at man i hovedsagen dækker nævnte luftvæge;
 - d. at man i det mindste manipulerer et af de nævnte skørter, så at det i ho-
 25 vedsagen dækker nævnte luft-væge;
 - e. at man manipulerer det tilbageværende skørt, så at dette i hovedsagen overlapper det andet skørt, som i hovedsagen dækker luft-vægen;
 - f. at man indfører det dækkede rest-lem i en protesefatning, som har sam-
 me form som rest-lemmet samtidigt med, at man bevarer den udform-
 30 ning, som er tilvejebragt ved de tidligere trin a til e;
 - g. at man tilvejebringer en kontinuerlig tætning mellem skørterne og den in-
 dre flade af fatningen, så at et isoleret vakuum-kar dannes mellem fat-
 ningen og skørterne; og

h. at man evakuerer luft fra nævnte kar, så at der opretholdes en sugevirkning mellem rest-lemmet og fatningen.

15. Fremgangsmåde ifølge krav 14, hvor det trin, at man evakuerer luft fra karret omfatter, at man presser luft fra karret gennem en uddrivningsventil, som er
5 koblet til en åbning i nævnte fatning, og dette ved at man indfører rest-lemmet i den nævnte fatning, og at fremgangsmåden yderligere omfatter det trin, at man udtrækker luft fra karret ved hjælp af en vakuum-pumpe, som er koblet til åbningen i fatningen.

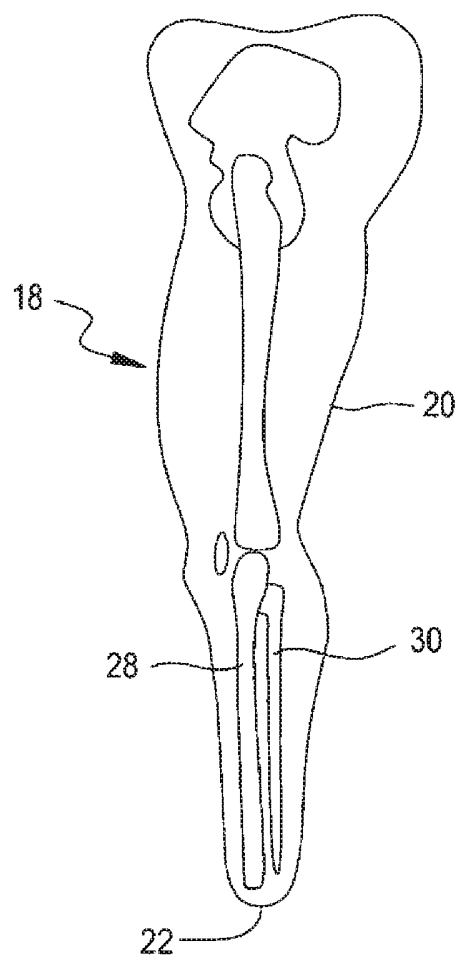


FIG. 1

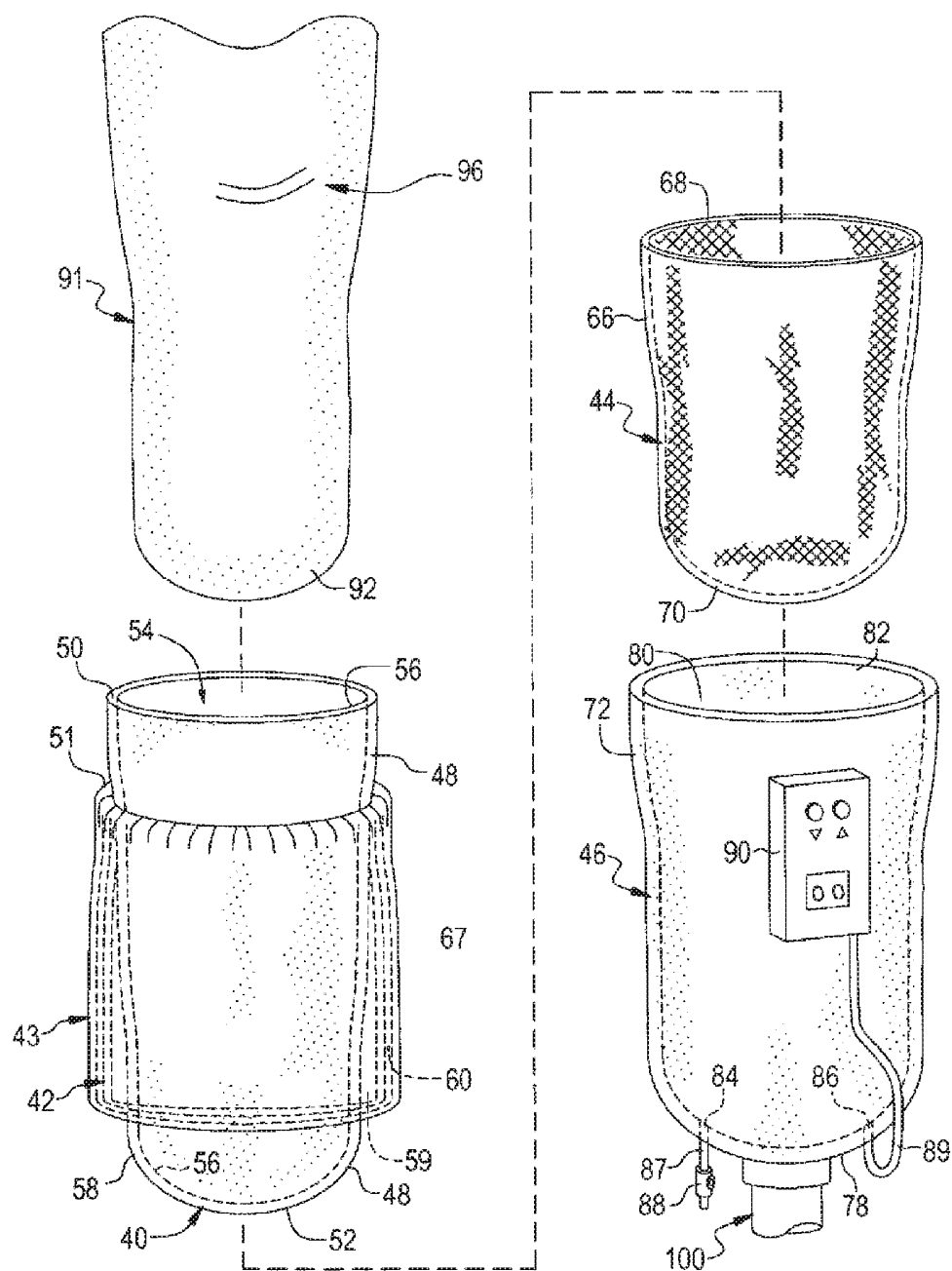


FIG. 2

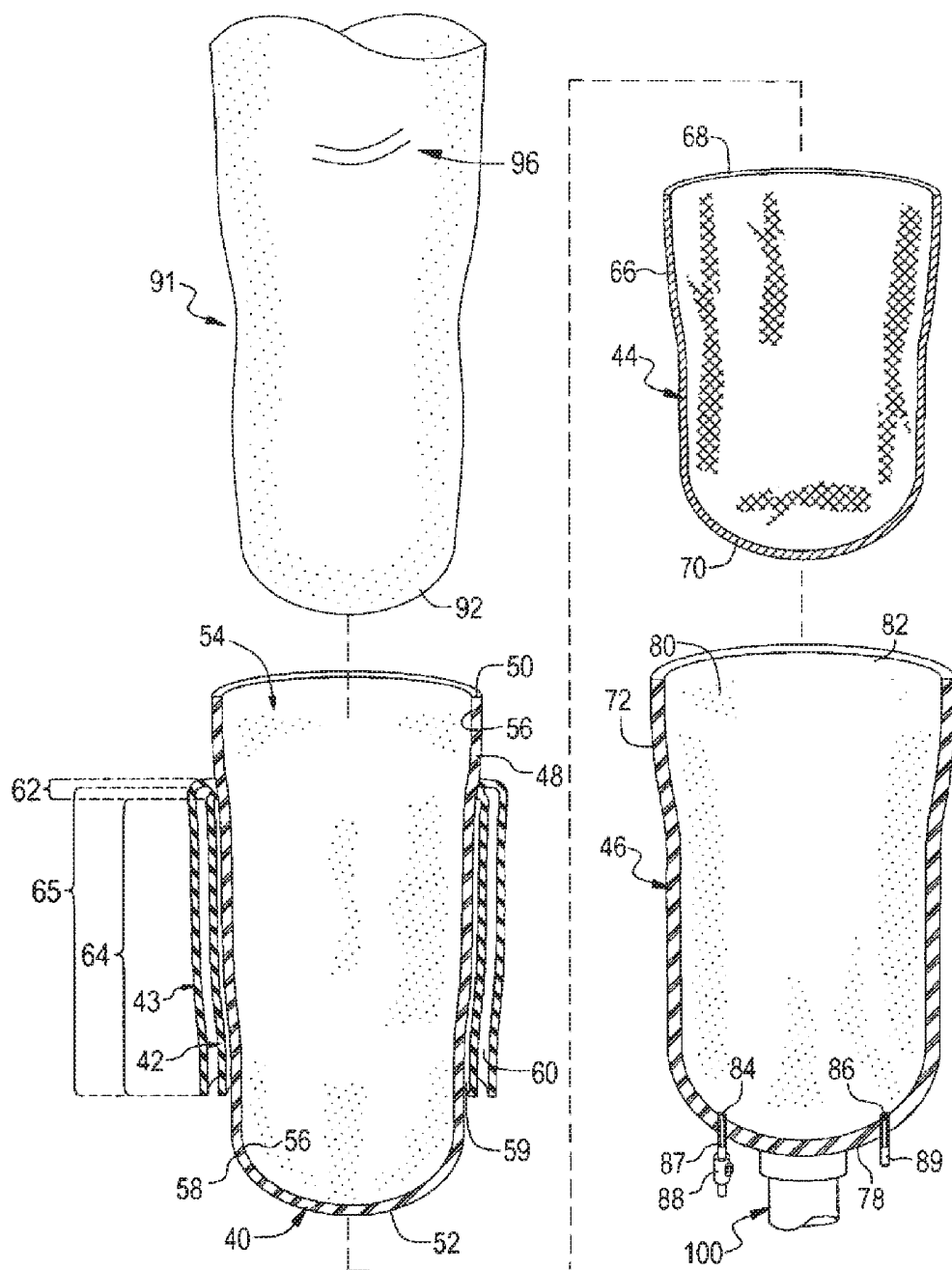


FIG. 3

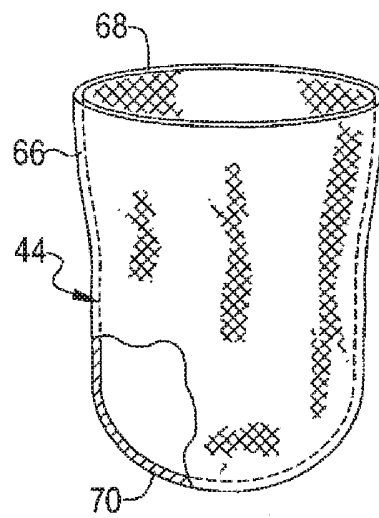


FIG. 4

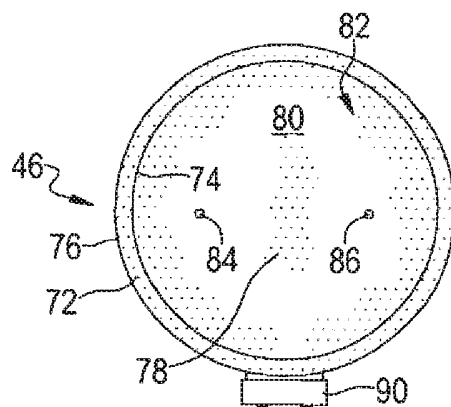


FIG. 5

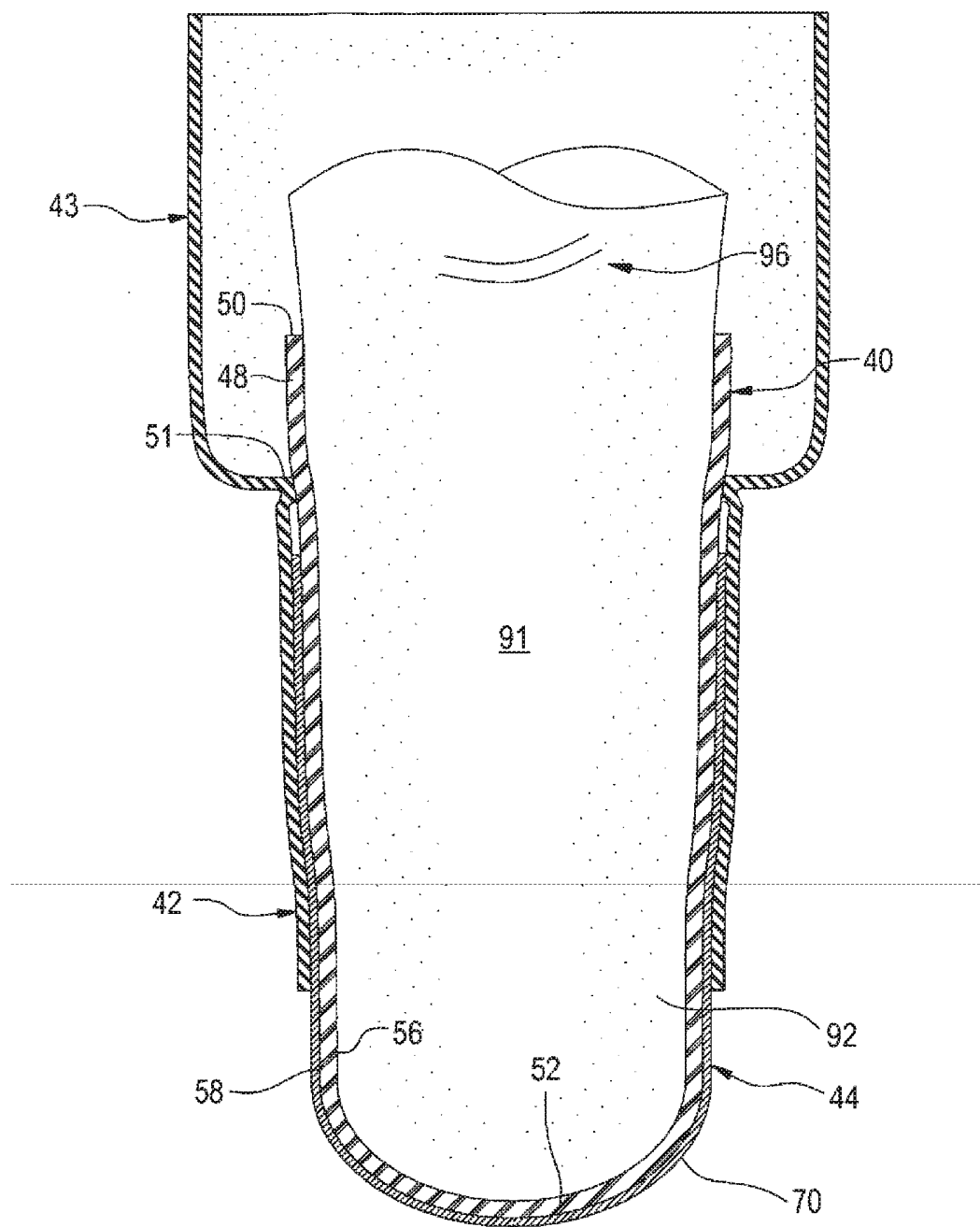


FIG. 6

