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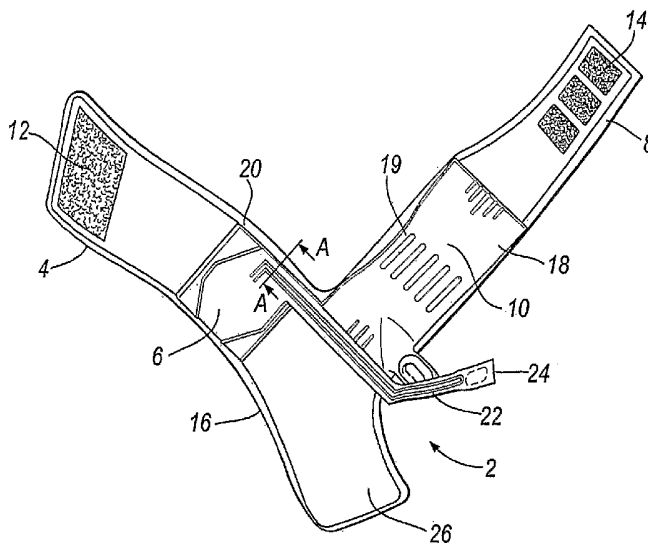
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(54) Title: A CUFF FOR PROVIDING COMPRESSION TO A LIMB



(57) Abstract: A cuff for providing compression to a limb, the cuff comprising an outer wall joined to an inner wall to form a bladder, the bladder being provided with means to separate the walls to maintain a path for fluid flow into and out of the bladder characterised in that the separating means are a spacer provided on the interior of at least one wall, which separates the walls when the bladder is deflated.

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## A CUFF FOR PROVIDING COMPRESSION TO A LIMB

This invention relates to a compression device for the limb and particularly to a device for use on the foot. The device is particularly  
5 suited for use in the type of compression therapy used in the treatment of venous foot ulcers or venous heel ulcers.

Various compression devices are known for applying compressive pressure to a patient's limb. These types of devices are used to assist  
10 mainly in the prevention of deep vein thrombosis (DVT), vascular disorders and the reduction of oedema. Prior art devices are adapted for use in a hospital setting in which they are used predominantly for the prevention of DVT in patients with a high risk for developing the same. US 5117812, US 5022387 and US 5263473 (The Kendall Company), US  
15 6231532 (Tyco International Inc), US 6440093 (McEwen et al) and US 6463934(Aircast Inc) disclose such devices.

Compression therapy is used in the treatment of venous leg ulcers. The treatment relies on the compression achieving a reduction in oedema and  
20 improved return of blood via the venous system. This in turn reduces the residence time for blood supplied to the lower limb and the severity of ischaemic episodes within the limb that can result in tissue breakdown.

Compression of the foot can be achieved by a pneumatic compression  
25 device. The known devices apply pressure to the foot and to the rest of the limb through a thick cuff which is large, bulky and powered by mains electricity. The known devices not only affect patient mobility but are also aesthetically unacceptable to many patients. For instance the device can prevent the wearing of the patient's ordinary shoes and clothes  
30 meaning that the patient is housebound and unable to walk. In the

hospital devices, these disadvantages are not apparent because the patient is largely confined to bed.

5 A problem in providing an aesthetically acceptable foot cuff is one of supplying the pneumatic fluid to the cuff. In the hospital devices of the prior art, pneumatic fluid is supplied to the cuffs through a network of pipes without consideration to the patient being mobile, wearing normal clothing or wearing a shoe. Even if the patient is able to put their shoe on with the cuff in place in a deflated state, the shoe may prevent  
10 inflation of the cuff in the areas where pressure is required as the shoe may block the path for the passage of pneumatic fluid. If a tube is used to supply the fluid to for instance the arch of the foot, the shoe may collapse or kink the tube and may cause pressure points on the foot.

15 In addition a problem with the devices of the prior art is that the cuff is generally cylindrical and applies pressure over the whole of its surface to the foot meaning that the mobility of the ankle is reduced making walking difficult even if the patient can wear a shoe and inflate the cuff.

20 Pneumatic compression devices do however have advantages in particular over compression bandages. They provide an effective treatment, while deflated, the inflatable cuff or cuffs are easy to apply to the patient's foot and the pressure is more readily controlled and monitored. Also they are not subject to the effect of radius where the level of compression depends  
25 on the circumference of the limb so that high pressure and low pressure spots occur at the ankle where the radius under the bandage varies. The effect of radius is a fundamental limitation of elasticated bandages and stockings. In addition it is difficult to apply pressure to the heel of the foot with an elastic bandage and this is an area in which ulcers occur.

30 With elastic bandages applying pressure to the heel means that mobility in the ankle is reduced as the bandage applies pressure over the whole ankle.

This reduction in mobility impairs venous return as the patient is unable to walk normally.

There thus exists a need for a foot cuff, which focuses the pressure applied by the cuff to those areas where ulcers are prevalent and limits inflation of the cuff in the surrounding areas so that the patient is able to wear their ordinary shoes and clothes with the cuff inflated. There is also a need for a means of supplying pneumatic fluid to a foot cuff so that inflation is focused on certain areas and the patient is allowed to be mobile and wear ordinary shoes without interrupting the supply of fluid to the cuff. There is also a need for a foot cuff that enables the application of pressure in a manner that is flexible enough to allow the treatment of various indications from one device.

We have now invented a device for applying compression against a patient's foot which alleviates the above problems by providing a device which is simple to apply to the foot, focuses pressure on certain areas of the foot, is low profile and lightweight and has a discreet pneumatic fluid supply. A first aspect of the present invention provides a compression device for the foot comprising:

- a wrap adapted to surround the foot, the wrap comprising at least two bladders which when inflated conform to the shape of the foot to provide compression, the bladders being positioned on the wrap so that a first bladder focuses compression on the heel of the foot and a second bladder focuses compression on the arch of the foot;
- a channel attached to each bladder for independently delivering fluid to each bladder and
- a controller attached to the channels that generates and independently controls the flow of fluid to the bladders.

We have found that such a device may bring the advantages of applying pressure to the heel and arch of the patient without reducing mobility.

The pressure can also be targeted on the area of the heel where ulcers are most prevalent. Independent supply and control of fluid to two bladders  
5 means that the device can be operated in a number of ways. This flexibility enables a range of treatments to be provided by the device and thus allows one device to treat a number of different indications.

The device may be operated so that the pressures applied by the heel and  
10 arch bladders may be the same as or different from each other or may be the same or different to the pressures applied by an associated device. The heel bladder for example may be at the same pressure as bladders located in an associated leg sleeve and may be attached thereto.

15 Preferably the controller comprises a microprocessor control system and a pump. More preferably the device comprises at least one pressure sensor in the channel or positioned in the device, the sensors providing readings of the pressure experienced by the foot due to the inflation of the wrap by the controller.

20 The wrap comprises two or more individually inflatable bladders. The bladders may be formed from an outer wall and an inner wall, the inner wall contacting the foot in use. The wrap may comprise an inelastic fabric to which the bladders are fixed or the fabric may form the outer  
25 wall of the bladder. Preferably the bladder walls are elastic and are joined to the wrap by welding.

Preferably the bladder is provided with means to separate the walls in use to maintain a path for fluid flow into and out of the bladder. This has the  
30 advantage that the inflation of the bladder may be localised to the area of the foot where pressure needs to be applied, for instance the heel and the

arch of the foot, and may be limited in those areas where pressure need not be applied, for instance the sides of the foot. In this way the patient is able to be mobile, has mobility in the ankle and may wear their ordinary clothes and shoes.

5

The separation means in the bladder may be a spacer provided on the interior of at least one bladder wall. By this means it is not necessary to have a tube supplying fluid running into the patient's shoe and causing possible pressure points or blockages. The spacer is preferably made  
10 from a flexible material that is relatively incompressible and is elongate to create a channel for the supply of fluid into and out of the bladder.

Preferably the wrap has a Y-shaped outline when in an unwrapped state. One arm of the Y is provided with a bladder to apply pressure to the heel  
15 of the foot in use and the other arm of the Y is provided with a bladder to apply pressure to the arch of the foot when in use. The Y-shaped wrap may be opened to a flat state making application to the patient's foot easy enough that the patient may apply the device unaided.

20 The wrap may be applied to the foot by the patient placing the arch of their foot on the arch bladder located on one arm of the Y (the arch arm) and with their heel in the fork of the Y. The tail of the Y may then be wrapped over the top of the foot and the other arm of the Y (the heel arm) wrapped around the heel and fixed to the tail by loop and hook  
25 fastening. The free end of the arch arm is then folded over the top of the foot and attached to the heel arm and tail of the Y by hook and loop fastenings. Preferably the heel and arch bladders are located close to the junction of the arms.

30 Alternatively, in another embodiment, the wrap may comprise a one strap fastening, fastened over the top of the foot, the heel and arch parts of the

wrap being integral. The foot may be inserted in such a device and the strap fastened over the instep.

5 The heel bladder is preferably divided into two parts which may be connected and provides pressure in the areas between the malleoli and the achilles on either side of the heel. This bladder can be permanently fixed in position on the wrap or can be repositionable to customise the fit to individual patients.

10 The wrap may be used in conjunction with a compression sleeve for the lower limb such as that described in GB 0307097.6 or GB 0423410.0. When such a sleeve is present the wrap may be integral with it or be connectable to it. The pressures applied by the heel and arch bladders may be the same or different from each other or may be the same or  
15 different to the pressures in the cuffs of the sleeve.

The heel and/or arch bladders can connect directly to the controller that generates and controls the flow of fluid in the sleeve or can connect to one of the bladders in the sleeve and thus be at the same pressure as that  
20 bladder or at different pressures.

Preferably the channels connecting the heel and arch bladders to the sleeve or controller are low in profile and resistant to crushing or kinking for instance by the wearer's shoe. The channels may have a similar  
25 construction to the bladder and comprise an outer wall and an inner wall in the form of elongate strips provided with means to separate the walls in use to create a path for fluid flow from the sleeve or controller. In this way the separating means maintain a path for fluid flow despite crushing or kinking of the channel. The separation means in the channel can be  
30 the same as that used in the bladder and preferably is an elongate flexible strip, narrower than the width of the channel walls.

The channel walls are preferably made of the same material as the bladders and may be welded to a window in the bladder wall of the sleeve or wrap or cuff to make an air tight connection.

5

Preferably there are one or more individual sensors associated with each bladder to monitor the pressure from that bladder. This allows the controller to precisely control the pressure in that bladder and the device to comply with a predetermined pressure profile.

10

In a second embodiment, the invention provides a cuff for providing compression to a limb, the cuff comprising an outer wall joined to an inner wall to form a bladder, the bladder being provided with a spacer to separate the walls to create a channel for fluid to flow into and out of the bladder.

15

The advantage of the cuff of the invention is that the separating means allow the bladders to be shaped so that the compression generated by the device can be focused on those areas where ulcers are more prevalent without compromising the path for fluid movement.

20

The spacer is made from a relatively incompressible material that spaces the walls apart but does not allow the bladder or channel to become obstructed in the manner that a tube may become obstructed by kinking or collapsing or being flattened against, for instance a shoe.

25

Preferably the bladder walls are selectively welded together so that inflation of the bladder is limited in the welded areas which can in use contact those parts of the foot where compression is not required, for example the sides of the foot or over bony prominences in the heel.

30

The spacer is preferably provided on the inside of at least one wall of the bladder and even more preferably a spacer is provided on the inner wall of the bladder and a spacer is provided on the outer wall of the bladder which spacers abut when the bladder is deflated.

5

The spacers allow pneumatic fluid to flow into the bladders and have the advantage that they are easily constructed on the bladder walls. The spacers may be elongate and flexible so that the bladder may be shaped to provide an elongate channel for connection to a conduit of the device.

10

In a third embodiment, the invention provides a channel for connecting one or more bladders to each other or to a controller, the channel comprising an elongate outer wall joined to an elongate inner wall, the channel being provided with means to separate the walls to create a path for fluid to flow into and out of the channel.

15

The separating means are preferably a spacer provided on at least one wall of the channel and even more preferably a spacer provided on the inner wall of the channel and a spacer provided on the outer wall of the channel which spacers abut when the channel is deflated.

20

Having spacers on opposing walls means that each spacer need only be half the thickness of a single spacer on one wall yet achieve the same separation of the walls. This makes the channel or bladder more flexible and, as the spacers can slide against each other, enables the bladder and channels to conform readily to curved surfaces.

25

The spacers are preferably made from the same material as the bladders or channels and are preferably about 4mm wide and 0.4mm thick and arranged in opposing pairs.

30

Preferred embodiments of the invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a plan view of the wrap of one embodiment of the present invention;

Figure 2 is a perspective view of the heel part of another embodiment of the wrap of the invention;

Figure 3 is a cross-sectional view on a plane horizontally through the ankle of the patient and viewed from above with the device of Figure 2 on the foot showing the position of the heel bladder;

Figure 4 is a perspective view of the first stage of applying the wrap of Figure 1 to a foot;

Figure 5 is a perspective view of the second stage of applying the wrap of Figure 1 to a foot;

Figure 6 is a perspective view of the final stage of applying the wrap of Figure 1 to a foot;

Figure 7 is a cross sectional view taken on the line A-A of Figure 1 showing the spacing means in the channel;

Figures 8, 9 and 10 are perspective views of a low profile air channel according to another embodiment of the invention and in particular showing the connection of a channel to a bladder.

In Figure 1 the wrap of the invention is shown open in plan view with the surface that will contact the foot in use uppermost. The wrap (2) is generally Y-shaped and comprises a first arm (4) provided with a bladder (6), which contacts the arch of the foot in use and a second arm (8) provided with a bladder (10), which contacts the heel of the foot in use. The first arm (4), the arch arm, is provided at its extremity with one part of the hook and loop fastening material (12). The second arm (8), the heel arm, is provided at its extremity with one part of a hook and loop fastening material (14). The heel bladder (10) and the arch bladder (6)

are located close to the junction of the arms but may be repositionable on the wrap by the use of hook and loop fastening material.

In the wrap of Figure 1 the bladders are constructed from an outer wall, which is welded to the wrap and an inner wall (18, 20) welded to the outer wall. Pneumatic fluid, usually air, is supplied to the bladders through channels (22) formed by spacers (23) on both the inner and outer walls which abut when the bladder is in a deflated state, best seen in Figure 7.

10

The channels (22) run across the fork in the Y and are terminated by a connector (24), which attaches to a conduit (not shown) and a control unit. Alternatively, the channels can be elongated further still and connect directly to the controller. The tail of the wrap (26) is provided on its outer surface with one part of a hook and loop fastening (28) best seen in Figure 5.

15

Figure 2 shows a single strap embodiment of the wrap of the present invention where the heel bladder (30) is integral with a strap (32), which fastens the device over the instep of the foot. The heel bladder (30) is in two connected parts so that pressure is applied by the bladder on either side of the posterior tibiofibular ligament. The separation of the bladder (30) into two parts may be achieved by a series of welds of the inner and outer walls of the bladder, as shown in Figure 1 at 19. The welds are interspersed with spacers to provide a path for fluid flow. Similarly spacers can be provided in any region where a bladder or channel is likely to kink or block for instance over a bony prominence.

25

In use, the heel bladder (30) applies pressure to the heel in the manner shown in Figure 3. In Figure 3, the heel bladder (30) is shown in an inflated state with pressure being applied on either side of the heel.

30

Figures 4, 5 and 6 show the application of the wrap of Figure 1 to the foot of a patient. Figure 4 shows the first stage of application where the patient places the arch of their foot over the arch bladder (6), the heel  
5 being positioned in the fork of the Y. Figure 5 shows the second stage of application where the tail of the Y (26) is wrapped over the in step of the foot and the heel arm (8) is lifted up and around the heel of the foot so that the fastening (14) comes into contact with the fastening (28) on the outer surface of the tail (26). Figure 6 shows the final stage in applying  
10 the wrap where the heel arm (4) is folded over the foot to bring the fastening (12) in contact with the fastening (28).

Figure 6 also shows the positioning of the connector (24) and channels (22) at the top of the foot, which allows the conduit to be attached to the  
15 wrap without a tube having to be run down the side of the foot to the arch bladder (6) and without a tube having to be run around the edge of the foot to the heel bladder (10). The channels (22) create a reliable passage of fluid to the bladders (6, 10) without causing pressure points, without the risk of a tube that kinks or collapses, and discreetly, so that a network  
20 of tubes is not apparent to others. The channels (22) also allow the patient to wear their ordinary shoes.

The wrap of Figure 1 allows the patient mobility in their ankle, as the device does not restrict hinge or rotational movement of the ankle.

25

Figures 8, 9 and 10 show an embodiment of the invention in the form of an elongate channel 60 where the channel walls 62,64 are each provided with a spacing strip 66,68 attached to the inner surface of each wall so that they abut when the walls 62,64 are welded together on their long  
30 sides to form the channel 60. The channel 60 provides a lower profile and is more discrete than a conventional tube. The lower profile means

that the flat channel will not create pressure points against the patient's limb, when for instance a shoe is worn.

To join the channel 60 to bladder wall 69, the wall 62 is made shorter  
5 than wall 64 as shown in Figure 8 so that when the walls are welded  
together to form channel 60 part of wall 64 and strip 68 is left exposed.  
The channel wall 64, is folded back at its top edge to expose the channel  
interior as shown in Figure 9. The channel wall 62 is placed on the  
bladder wall 69 under opening 73 and welded along its upper edge 70 to  
10 the bladder wall 69. The channel wall 64 is folded up over the opening  
73 in bladder wall 69 and welded in place around its free edges shown as  
lines 72 in Figure 10. The welded connection of the air channel 60 to  
bladder wall 69 provides a more secure fluid connection than the use of  
conventional tubing and air connectors.

15

Although the present invention has been shown and described with respect  
to several preferred embodiments thereof, various changes, omissions and  
additions to the form and detail thereof may be made without departing  
from the spirit and scope of the invention.

20

## Claims

5

1. A cuff for providing compression to a limb, the cuff comprising an outer wall joined to an inner wall to form a bladder, the bladder being provided with means to separate the walls to maintain a path for fluid flow into and out of the bladder characterised in that the separating means  
10 are a spacer provided on the interior of at least one wall, which separates the walls when the bladder is deflated.

2. A cuff as claimed in Claim 1, characterised in that the inner wall of the bladder is provided with a spacer and the outer wall of the bladder  
15 is provided with a spacer which spacers abut when the bladder is deflated.

3. A cuff as claimed in Claim 2 characterised in that the spacer is in the form of an elongated, flexible strip welded to the bladder wall.

20 4. A cuff as claimed in any preceding claim characterised in that the bladder walls are selectively welded to limit the inflation of the bladder in certain areas so that the pressure applied by the bladder is focused on selected areas of the patient.

25 5. A cuff as claimed in any preceding claim characterised in that the bladder walls are welded to create elongate channels for the passage of air into and out of the bladder, the separating means being positioned in the channels.

30 6. A cuff as claimed in any preceding claim characterised in that the cuff is a foot cuff.

7. Use of a spacer in the manufacture of a cuff for providing  
compression to the foot, the cuff comprising an outer wall joined to an  
inner wall to form a bladder, the spacer separating the walls when the  
5 bladder is deflated or constricted to maintain a path for fluid flow into  
and out of the bladder.

8. A channel for use in a compression device for connecting one or more  
bladders to each other or to a controller, the channel comprising an  
10 elongate outer wall joined to an elongate inner wall, the channel being  
provided with means to separate the walls to create a path for fluid to  
flow into and out of the channel and into and out of the bladder.

9. A channel as claimed in Claim 8 characterised in that the separating  
15 means is in the form of an elongate, flexible strip welded to the channel  
wall.

10. A channel as claimed in Claims 8 or 9 characterised in that the  
channel is connected to the bladder by welding.

20

11. A channel as claimed in Claims 8 to 10 characterised in that the  
channel walls are made from the same material as the bladders.

12. Use of a spacer in the manufacture of a channel for connecting one or  
25 more bladders to each other or to a controller in a compression device for  
providing compression to a limb, the channel comprising an elongate  
outer wall joined to an elongate inner wall, the channel being provided  
with means to separate the walls to maintain a path for fluid to flow into  
and out of the channel and into and out of the bladder.

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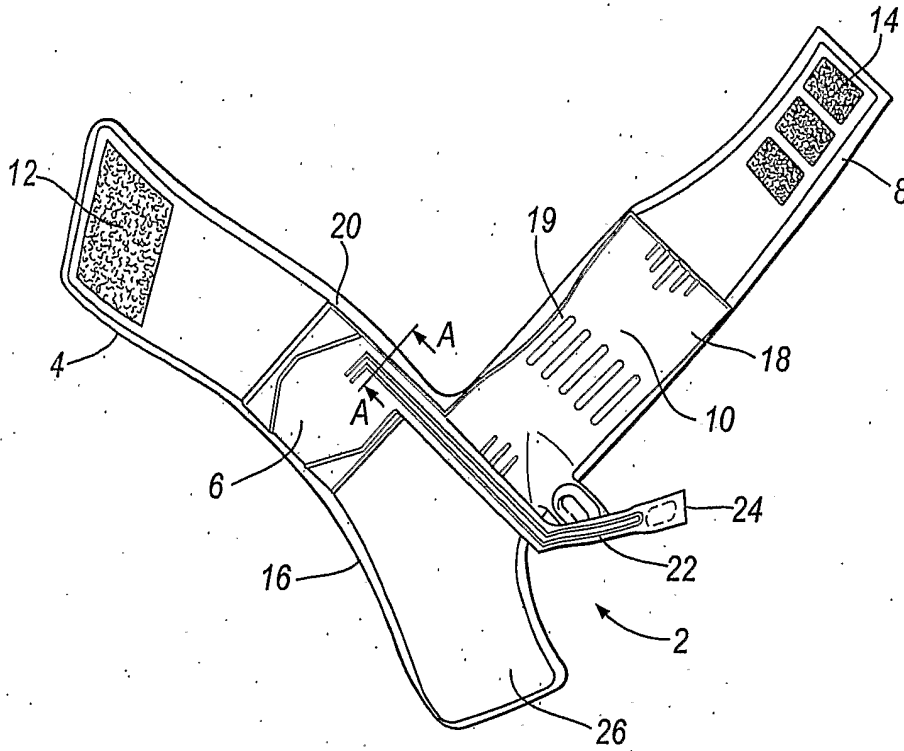


Fig. 1

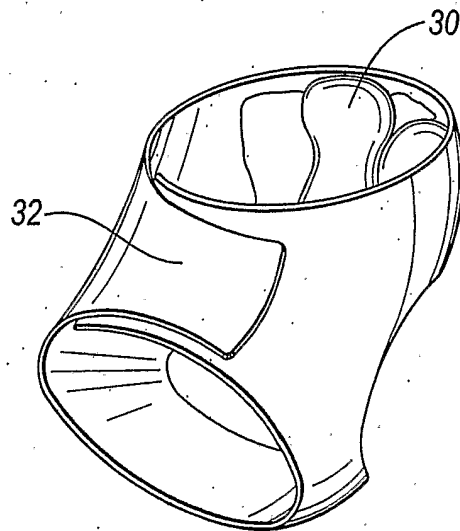


Fig. 2

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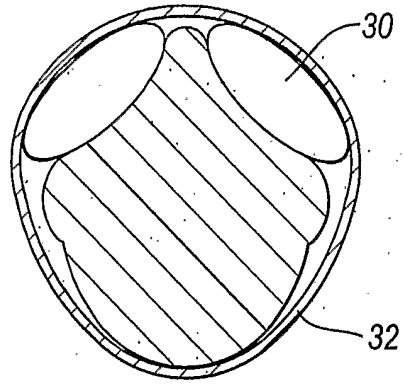


Fig.3

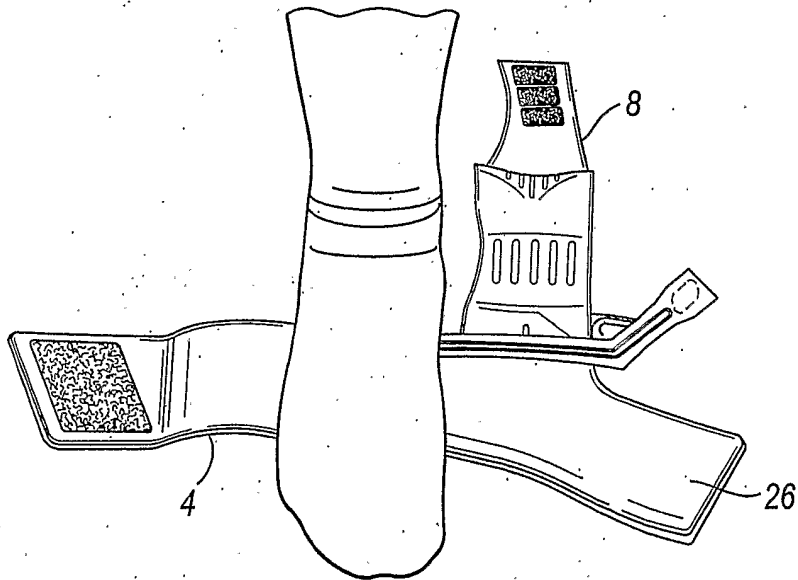


Fig.4

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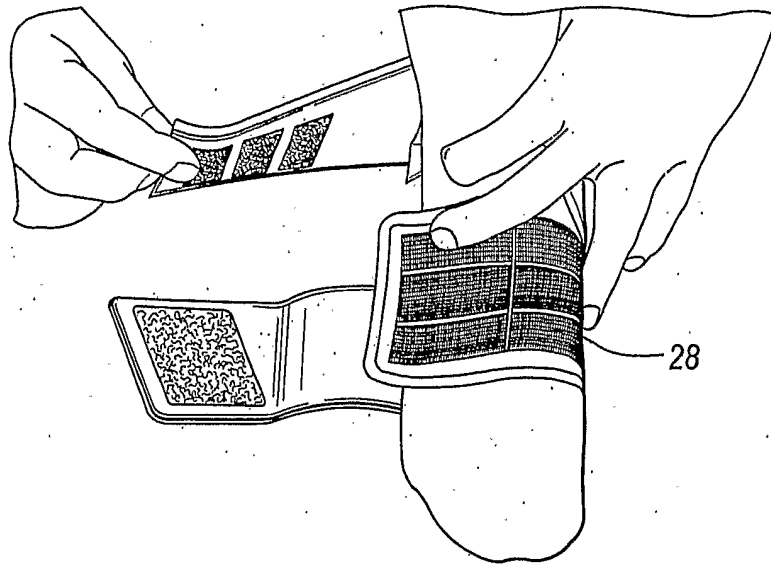


Fig. 5

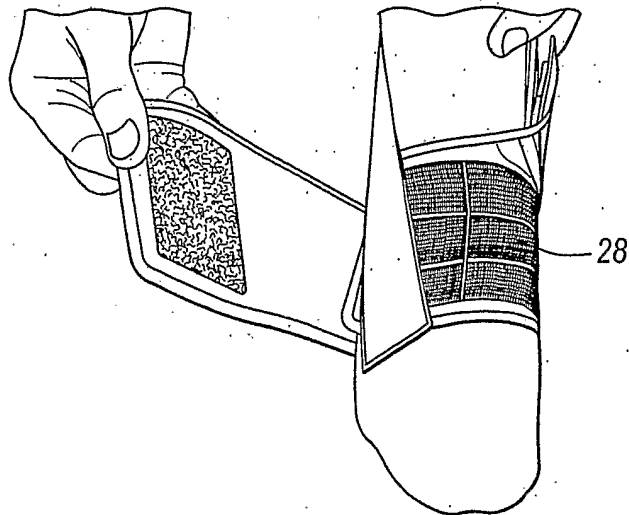


Fig. 6

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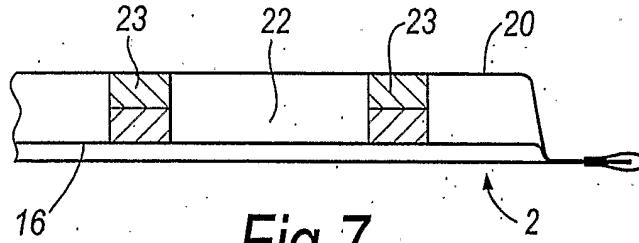


Fig. 7

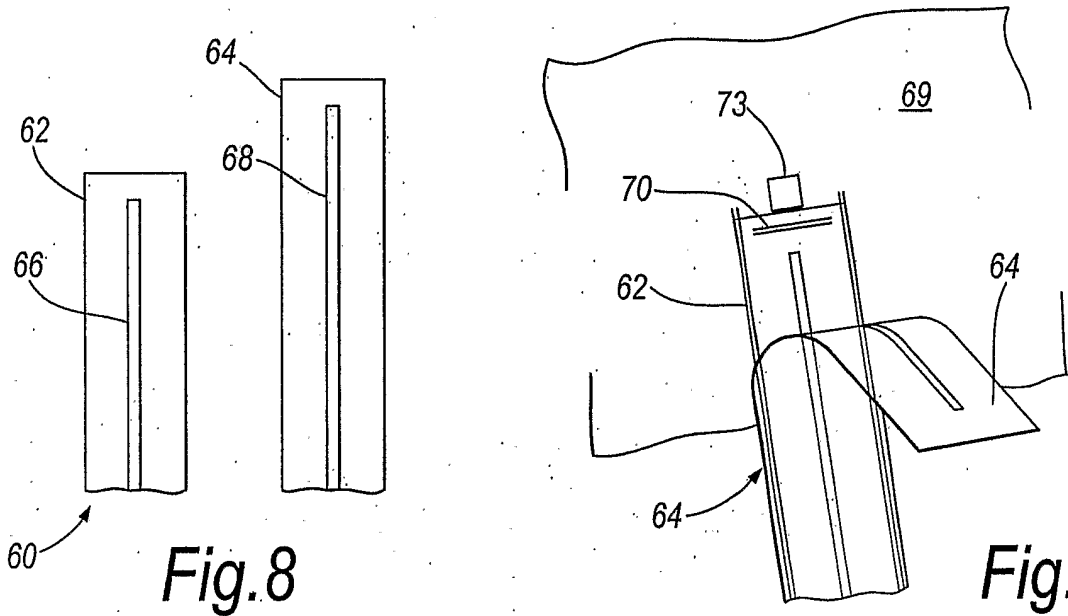


Fig. 8

Fig. 9

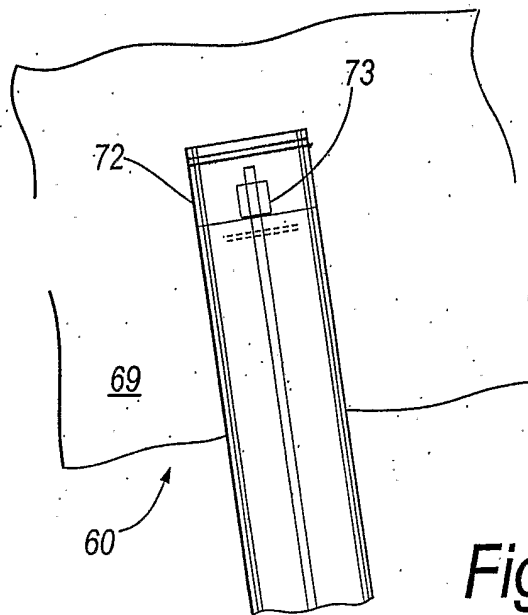


Fig. 10