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(56) Related Art

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COMPRESSION APPARATUS

Abstract

A compression apparatus (10) is described having a sleeve (12) and an inflatable member (14) disposed within the sleeve (12), the inflatable member (14) being movable in relation to the sleeve (12). The compression apparatus (10) includes a hook and loop features attached to the foot sleeve (12) for securing compression apparatus (10) to the feet.

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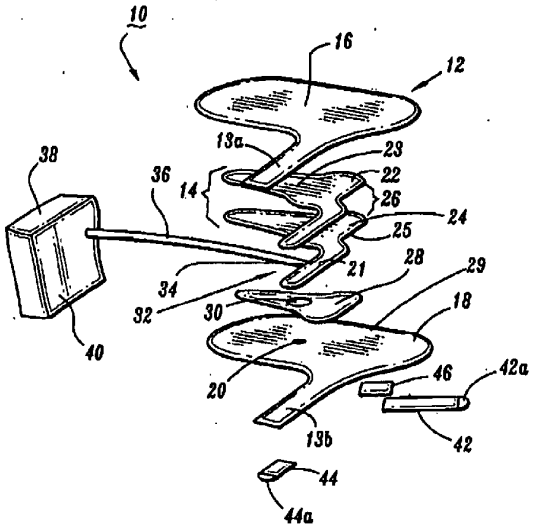

FIG. 1

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PATENTS ACT 1990

COMPLETE SPECIFICATION

FOR A STANDARD PATENT

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Invention Title:	Compression apparatus

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

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COMPRESSION APPARATUS

BACKGROUND

1. Technical Field

The present disclosure relates generally to compression apparatus. In particular, the present disclosure relates to a compression apparatus configured for applying compressive forces to a portion of a patient's anatomy.

2. Description of the Related Art

Compression devices for applying compressive forces to a selected area of a person's anatomy are generally employed to improve blood flow in the selected area. Compression devices that provide intermittent pulses of a compressed fluid (i.e. air) to inflate at least one inflatable chamber in a sleeve are particularly useful. This cyclic application of pressure provides a non-invasive method of prophylaxis to reduce the incidence of deep vein thrombosis (DVT), and the like. These compression devices find particular use during surgery on patients with high-risk conditions such as obesity, advanced age, malignancy, or prior thromboembolism. Patients who develop this condition often have swelling (edema) and tissue breakdown (venous stasis ulcer) in the lower leg. When a DVT occurs, the valves that are located within the veins of the leg can be damaged, which in turn can cause stasis and high pressure in the veins of the lower leg.

Generally, these compression devices are fluidly coupled to a source of pressurized fluid by one or more air tubes. Additionally, each compression device includes a flexible shell having one or more inflatable members disposed therein. The compression device is placed around the patient's foot or other selected portion whereupon a pressurized fluid is delivered into the inflatable member creating pressure at the part or parts of the body in contact with the inflatable member.

Compression sleeves adapted for use with a patient's foot may be combined with one or more additional compression sleeves that are disposed on portions of a patient's leg for improving the treatment regimen. In general, each of the additional compression sleeves includes a plurality of separate inflatable chambers that are progressively arranged along a longitudinal axis of the sleeve from a lower portion to an upper portion of the limb. A pressure source, e.g. a controller, is provided for intermittently forming a pressure pulse within these inflatable chambers from a source of pressurized fluid during periodic compression cycles. The compression sleeves provide a pressure gradient along

the patient's limbs during these compression cycles which progressively decreases from the lower portion to the upper portion of the limb (e.g. from the ankle to the thigh).

Compression sleeves that are adapted for use with a patient's foot generally include a heel strap with a tab portion that is adapted to fit around a portion of the patient's heel. This arrangement allows the compression sleeve to be releasably attached to the patient's foot.

Examples of compression sleeves are disclosed in U.S. Pat. Nos. 4,013,069 and 4,030,488 to Hasty, U.S. Pat. Nos. 4,029,087 and 5,795,312 to Dye, and U.S. Pat. No. 5,626,556 to Tobler *et al.*, all of which are currently owned by Tyco Healthcare Group LP and are incorporated by reference herein in their entirety. Other examples of compression sleeves are disclosed in U.S. Patent Nos. 4,696,289 to Gardner et al. and 5,989,204 to Lina. An example of compression treatment method is disclosed in U.S. Pat. No. 6,231,532 to Watson *et al.*, which is currently owned by Tyco Healthcare Group LP, the contents of which are hereby incorporated by reference herein in their entirety.

Some prior art devices are bulky and may irritate portions of the limb undergoing treatment which may increase patient discomfort and may increase the possibility that the patient may not complete the treatment regimen.

Object of the Invention

It is an object of the present invention to substantially overcome or ameliorate one or more of the disadvantages of the prior art, or to at least provide a useful alternative.

Summary of the Invention

The present disclosure provides a compression apparatus for applying DVT prophylaxis therapy to a body part of a patient, the compression apparatus comprising:

an outer layer;

an inner layer overlying the outer layer and secured thereto to define a space therebetween; and

a solitary inflatable member defining a solitary chamber for receiving a pressurized fluid, the solitary inflatable member being disposed in the space defined by the inner and outer layers and having an inner face facing the inner layer and an outer face facing the outer layer, wherein the outer face of the solitary inflatable member is secured to the outer layer, and wherein the inner face of the inflatable member is in direct contact with and is free from direct securement to the inner layer so that the inflatable member is freely movable in relation to the inner layer when disposed on the body part of the patient for providing DVT prophylaxis therapy to the body part of the patient.

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In one preferred embodiment, the compression apparatus includes a foot sleeve for applying compressive forces to a patient's foot. The foot sleeve includes an inflatable member disposed therewithin, the inflatable member being freely movable in relation to the foot sleeve. The foot sleeve includes a contact layer and an outer layer. The contact layer and the outer layer are fixedly joined by radio frequency (RF) welding, or by other suitable methods, along their corresponding perimeters thereby defining a space therebetween. The outer surface of the contact layer contacts the bottom portion of the foot and it may be fabricated from a chemically treated material having a mesh-like fabric with wicking ability. The outer layer may be fabricated from a laminated material having a soft material for cushioning effect against the skin. In addition, the outer layer provides the attachment surface for the hook and loop features.

The inflatable member is preferably configured for receiving and retaining a pressurized fluid from a pressurized fluid source for exerting compressive pressure on a portion of the patient's foot during successive pressure applying cycles. In addition, the inflatable member is preferably dimensioned for being disposed within the space defined by the contact and outer layers of the foot sleeve. The inflatable member includes an upper layer having a two part laminated material for sliding against the foot contact layer and a lower layer configured for anchoring to the outside layer of the foot sleeve. Alternatively, the inflatable member is configured and adapted to be freely movable with respect to the contact and outer layers of the foot sleeve.

In a second embodiment, the compression apparatus includes a compression sleeve for applying compressive pressure against a portion of a patient's limbs, such as, for example, the legs. The compression sleeve includes a sleeve having a pair of opposed sheets attached to one another along their respective perimeters and defining at least one chamber. The at least one chamber is configured for receiving at least one inflatable member wherein the at least one inflatable member is freely movable or repositionable in relation to the sleeve. The inflatable member is configured for receiving and retaining a pressurized fluid from a pressurized fluid source for exerting compressive pressure on a portion of a patient's leg during successive pressure applying cycles.

Other features will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the presently disclosed compression apparatus.

Brief Description of the Drawings

The features of the presently disclosed compression apparatus will become more readily apparent by referring to the following detailed description of embodiments, which are described hereinbelow with reference to the drawings, wherein:

FIG. 1 is a perspective view, with parts separated, of a first embodiment of the compression apparatus in accordance with the present disclosure;

FIGS. 2-3 are top and bottom plan views respectively, of the compression apparatus illustrated in FIG. 1;

FIG. 4 is a bottom plan view of the compression apparatus of FIG. 1, illustrating a foot of a patient disposed thereon, in accordance with the present disclosure;

FIG. 5 is a bottom plan view of an alternative embodiment of a compression apparatus, in accordance with the present disclosure;

FIGS. 6-7 are top plan views of further alternative embodiments of a compression apparatus, in accordance with the present disclosure;

FIG. 8 is a top plan view of the compression apparatus of FIG. 1 disposed about a foot of a patient;

FIG. 9 is a side plan view of the compression apparatus of FIG. 1 disposed about a foot of a patient;

FIG. 10 is a perspective view of another embodiment of the compression apparatus, in accordance with the present disclosure; and

FIG. 11 is a perspective view illustrating the compression apparatus of FIG. 10 wrapped around a leg of a patient.

DETAILED DESCRIPTION

With reference to the drawing figures, in which like references numerals identify identical or corresponding elements, various embodiments of the presently disclosed compression apparatus will now be described in detail.

With initial reference to FIGS. 1-4, a first embodiment of a compression apparatus in accordance with the present disclosure is illustrated and is designated generally as compression apparatus 10. Compression apparatus 10 is adapted for use in a system for applying compressive pressure to a portion of a body, such as, for example, a foot of a person. Compression apparatus 10 generally includes a foot sleeve 12 configured for disposal about a foot and an inflatable member 14 disposed within foot sleeve 12 and being freely movable or repositionable in relation to foot sleeve 12. Moreover, foot sleeve 12 is configured and dimensioned for disposing about the right or left foot of the subject.

Foot sleeve 12 includes a contact layer 16 and an outer layer 18 fixedly joined at seams adjacent corresponding perimeters thereof and defining a space for receiving

inflatable member 14 therein. Contact layer 16 and outer layer 18 may be joined by radio frequency (RF) welding, sewing, adhesives, etc. Contact layer 16 and outer layer 18 include strap portions 13a and 13b respectively. Strap portions 13a, 13b have a longitudinally projecting configuration for wrapping about a portion of the foot adjacent to the ankle. Contact layer 16 is adapted for contacting the bottom portion of the foot and providing a fabric on fabric slide with inflatable member 14, in accordance with the present disclosure. Strap portions 13a, 13b (FIG. 1) are joined together to form a strap portion 13 (FIG. 3). Strap portions 13a, 13b can be sewn, RF welded, or sonic welded. Contact layer 16 is fabricated from a chemically treated material, with wicking ability, for wicking away moisture from the skin. In one embodiment, contact layer 16 includes a mesh-like fabric capable of wicking moisture away from the patient's skin. Furthermore, the contact layer 16 can be faced with a soft material toward the treatment surface of the patient. The material can be a thin layer of open celled porous foam, napped cloth, or a layer of vapor permeable cloth permeable.

Outer layer 18 includes an opening 20 for permitting a pressurized fluid inlet passage therethrough, in a manner described herein below. Outer layer 18 is configured for providing the attachment surface for a hook and loop feature of compression apparatus 10, as will be described in detail hereinbelow. Moreover, outer layer 18 provides a soft material for cushioning effect against the top portion of the feet and may be fabricated from similar materials as contact layer 16 and in similar dimensions therewith for corresponding geometry. Alternatively, outer layer 18 may be fabricated from a laminated material, such as, for example, sontara fabric, open cell urethane foam, or loop fabric.

With particular reference to FIG. 1, inflatable member 14 is disposed within the space defined by contact layer 16 and outer layer 18 and is configured for moving independently relative to foot sleeve 12. Inflatable member 14 is configured for positioning against the bottom portion of the feet and the ankle portion. Inflatable member 14 is adapted for receiving and retaining a pressurized fluid (e.g. air) for exerting compressive pressure to the foot during successive pressure applying cycles. An inflatable strap portion 21 is in fluid communication with inflatable member 14 and extends substantially within the space defined by strap portions 13a and 13b of contact layer 16 and outer layer 18 respectively. Inflatable member 14 includes upper and lower inflatable layers 22, 24 overlaid to form an inflatable portion. Upper and lower layers 22,

24 are fixedly joined via sealing lines 26 along their perimeters to define the inflatable portion. Sealing lines 26 may be formed by radio frequency (RF) welding. Alternatively, sealing lines 26 may be sewn, formed by adhesive, heat sealing, etc.

A first surface 23 of upper inflatable layer 22 is positioned just below contact layer 16 for providing the largest compression effect on the foot. Surface 23 of upper inflatable layer 22 releasably engages contact layer 16 for facilitating application of pressure for vascular therapy to the foot. Upper inflatable layer 22 includes material for wicking away moisture from the bottom of the feet. In one embodiment, upper inflatable layer 22 includes a two-part laminated material that is formed from a chemically treated wicking fabric or sontara material combined with a suede finish thereby allowing layer 22 to move with respect to contact layer 16.

Lower inflatable layer 24 includes a single material such as a polyvinyl chloride (PVC) having a suede finish. It is envisioned that the material used to fabricate lower inflatable layer 24 may include at least two different thicknesses for providing directional inflation of inflatable member 14. Thus, inflation of inflatable member 14 yields different shapes as determined by the thickness of inflatable member 14.

An adhesive layer 28 is provided for anchoring an outer surface 25 of lower inflatable layer 24 to an interior surface 29 of outside layer 18 of foot sleeve 12. Therefore, inflatable member 14 is freely movable or repositionable with respect to contact layer 16. An opening 30 positioned on adhesive layer 28 is aligned with opening 20 of outer layer 18 of foot sleeve 12 for permitting the pressurized fluid inlet therethrough. Adhesive layer 28 may be fabricated from a double sided adhesive material. In an alternative embodiment, inflatable member 14 may be freely movable or repositionable with respect to both contact layer 16 and outside layer 18, eliminating adhesive layer 28. Additionally, adhesive layer 28 may be positioned between contact layer 16 and surface 23. This arrangement allows outer layer 18 to move freely with respect to outer surface 25.

With continued reference to FIG. 1, inflatable member 14 further includes an inflation assembly 32 for supplying or removing a pressurized fluid (i.e. air) to inflatable member 14. Inflation assembly 32 includes a valve connector (not shown) having a port 34 (FIGS. 2 and 3) coupled to lower inflatable layer 24 and a lumen 36. Lumen 36 fluidly connects the inflatable member 14 to a pressurized fluid source 38. It is noted that the valve connector (not shown) protrudes from openings 30 and 20 for providing access

to inflatable member 14. An example of a suitable valve connector is disclosed in U.S. Patent No. 5,478,119 to Dye, currently owned by and assigned to Tyco Healthcare Group LP, the entire contents of which is hereby incorporated by reference herein. Pressurized fluid source 38 is disposed within a controller 40 that is adapted for delivering fluid under pressure for performing vascular therapy. An example of a suitable controller 40 is disclosed in U.S. Patent No. 5,876,359 to Bock et al., currently owned by and assigned to Tyco Healthcare Group LP, the entire contents of which is hereby incorporated by reference herein. It is contemplated that controller 40 may include the necessary electronics and/or computer software to provide vascular therapy, in accordance with the present disclosure, and may be stationary or portable. Alternatively, controller 40 does not include a source of pressurized fluid, but fluidly couples pressurized fluid source 38 to foot sleeve 12, wherein controller 40 controls the delivery of pressurized fluid to foot sleeve 12 for performing vascular therapy.

Referring now to FIGS. 1 and 4, a plurality of hook fasteners 42, 44 are provided for attaching compression apparatus 10 to a foot F, and are positioned on outer layer 18 of foot sleeve 12. Hook 44 is mounted to strap portion 13b of outer layer 18 of foot sleeve 12 while hook 42 is mounted on a surface of outer layer 18. In use, when strap portion 13 is wrapped about foot F, hook element 44 engages outer layer 18 to facilitate mounting of foot sleeve 12 to foot F. In addition, inflatable strap portion 21 of inflatable member 14 is disposed about foot F for compression therapy. An identification tab 46 may also be included for providing information such as the model number and manufacturer name. Hook fasteners 42, 44 have tabs 42a, 44a without fastening material thereon. This provides convenient gripping locations on hook fasteners 42, 44, thereby allowing the practitioner to easily remove hooks 42, 44 from the surface of outer layer 18.

With reference to FIGS. 5-7, alternative embodiments of the compression apparatus 10 of FIGS. 1-4 are illustrated. These embodiments are similar to the embodiment illustrated in FIGS. 1-4 and will only be discussed in detail to the extent necessary to identify differences in construction and operation.

With particular reference to FIG. 5, compression apparatus 200 includes foot sleeve 212 and inflatable member 214, shown in phantom. Foot sleeve 212 includes first and second layers defining a space therebetween for receiving inflatable member 214 therein, which are similar to upper and lower inflatable layers 22, 24 (FIG.1). Inflatable member 214 is configured for independent movement relative to at least one of first or

second layers. Inflatable member 214 includes a valve connector 216 for connecting inflatable member 214 to a pressurized fluid source. Valve connector 216 protrudes through an opening positioned on the outer sleeve portion of foot sleeve 212, in a manner described hereinabove with respect to compression apparatus 10. Foot sleeve 212 includes strap portion 218 extending longitudinally therethrough. A hook element 220 attached to a distal end of strap portion 218, and a hook element 222 is mounted to a portion of the foot sleeve 212. Inflatable member 214 is configured and dimensioned for substantial fit within foot sleeve 212, wherein foot sleeve 212 is configured to be wrapped around the bottom portion of the foot.

With reference to FIG. 6, compression apparatus 300 includes foot sleeve 312 and inflatable member 314, shown in phantom. Foot sleeve 312 includes first and second layers defining a space therebetween that receives inflatable member 314 therein, which are similar to upper and lower inflatable layers 22, 24 (FIG.1). Inflatable member 314 is configured for independent movement relative to at least one of first or second layers. Foot sleeve 312 further includes an elongated strap 316 extending longitudinally therethrough. Hook element 318 is mounted to elongated strap 316, while hook element 320 is mounted on foot sleeve 312. Foot sleeve 312 further includes a plurality of curvatures 322 for custom fitting about the foot.

With reference to FIG. 7, compression apparatus 400 includes foot sleeve 412 and inflatable member 414 shown in phantom. Foot sleeve 412 includes first and second layers defining a space therebetween that receives inflatable member 414 therein. Inflatable member 414 is configured for independent movement relative to at least one of first or second layers. Foot sleeve 412 includes an elongated strap 416 extending longitudinally therethrough. Hook element 418 is mounted to elongated strap 416, while hook element 420 is mounted on foot sleeve 412. Foot sleeve 412 further includes a plurality of curvatures 422 for custom fitting about the foot. Inflatable member 414 includes inflatable elongated strap portion 424 extending substantially along strap portion 416.

In use, compression apparatus 10, in accordance with the present disclosure, is configured to apply compressive forces to a patient's foot. With reference to FIGS. 8-9, in conjunction with FIGS. 1-4, compression apparatus 10 is positioned about foot F of a patient. Foot sleeve 12 is disposed about foot F by wrapping elongated strap portion 13 around an ankle A, wherein hook element 44 is configured for engaging the surface of

outer layer 18. After placement of foot sleeve 12 about foot F and connecting movable inflatable member 14 to pressurized fluid source 38 via inflation assembly 32, controller 40 may then be actuated for supply pressurized air to compression apparatus 10 and initiating compression therapy. Controller 40 intermittently inflates inflatable member 14 sequentially during periodic compression cycles in a pressure gradient profile. As compression therapy is applied, contact layer 16 and inflatable member 14 move independently, while outer layer 18 remains fixed against the foot throughout the compression therapy. The wicking properties of contact layer 16 will facilitate keeping feet F dry during prolonged periods of compression therapy. Deflation between successive inflation cycles occurs by return of air through inflatable member 14 to controller 40, as known in the art. FIGS. 2-7 show various orientations of the several embodiments of the presently disclosed compression apparatus.

With reference to FIGS. 10-11, another embodiment of a compression apparatus in accordance with the present disclosure is illustrated and is designated generally as compression apparatus 500. Compression apparatus 500 is adapted for use in a system for applying compressive pressure to a portion of a patient's body, such as, for example, the legs. Compression apparatus 500 is similar to the compression sleeve disclosed in U.S. Patent Nos. 5,626,556 to Tobler et al. and 5,795,312 to Dye that are currently owned by Tyco Healthcare Group LP and are incorporated herein by reference in their entirety.

With particular reference to FIG. 10, the compression apparatus 500, in accordance with the present disclosure, includes sleeve 510 having first or outer sheet 512 and second or inner sheet 514 connected by a plurality of laterally extending sealing lines 516 and longitudinally extending sealing lines 518 connecting the ends of lateral sealing lines 516. Outer sheet 512 is adapted as an outer gas-impervious sheet and second sheet 514 is adapted as an inner gas-impervious sheet, for placement against the person's limbs. Sealing lines 516, 518 may be formed by radio frequency (RF) welding, etc. An elongated opening 521 is provided for extending through what would be the knee region. Opening 521 is defined by peripheral edges 523 extending around opening 521.

Sealing lines 516, 518 define a plurality of spaces or chambers 520a, 520b, and 520c that are adapted for receiving movable inflatable members 522a, 522b and 522c. Inflatable members 522a, 522b, and 522c are configured for moving independently relative to sleeve 510. Similar to inflatable member 14 of compressive sleeve 10, inflatable members 522a, 522b and 522c are adapted for receiving and retaining a

pressurized fluid, such as, for example, air, for exerting compressive pressure to the leg of the patient during successive pressure applying cycles. A plurality of lumens 524a, 524b, 524c, and 524d having a valve connector 525 is included for operably connecting inflatable members 522a, 522b and 522c to a controller (not shown) having a source of pressurized fluid, such as, air.

First or outer sheet 512 may, for example, comprise a suitable flexible polymeric material, such as, for example, polyvinyl chloride (PVC) on the order of 5-10 mils thick. Second or inner sheet 514 will preferably comprise a similar polymeric material, e.g. 5-10 mil PVC having laminated to the inner surface to be placed against the limb a non-women material such as polyester for added comfort to the wearer.

Compression apparatus 500 further includes a plurality of hook fasteners for attaching the sleeve about the patient's limb. Hook fasteners include a set of spaced strips, such as loop material, positioned on first or outer sheet 512 and cooperating with a set of spaced hook material 526a, 526b, and 526c disposed on second or inner sheet 514 for releasably fastening compression apparatus 500 encircling the limb.

With particular reference to FIG. 11, in use, after placement of sleeve 510 on the patient's leg and connection to the controller via connector 525 and plurality of lumens 524a, 524b, 524c and 524d, the controller intermittently inflates inflatable members 522a, 522b and 522c sequentially during periodic compression cycles in a pressure gradient profile. As compression therapy is applied, first or outer sheet 512 and inflatable members 522a, 522b and 522c move independently, while second or inner sheet 514 remains fixed against the leg throughout the compression therapy. Deflation between successive inflation cycles occurs by return of air through inflatable members 522a, 522b, and 522c to the controller, as known in the art.

It will be understood that numerous modifications and changes in form and detail may be made to the embodiments of the present disclosure. It is contemplated that numerous other configuration of the compression apparatus and geometries and orientation of the inflatable member may be used, and the material of the sleeve and/or inflatable member may be selected from numerous materials other than those specifically disclosed. Therefore, the above description should not be construed as limiting the disclosed compression apparatus but merely as exemplifications of embodiments thereof. Those skilled in the art will envision numerous modifications within the scope of the present disclosure as defined by the claims appended hereto.

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The claims defining the invention are as follows:-

1. A compression apparatus for applying DVT prophylaxis therapy to a body part of a patient, the compression apparatus comprising:

an outer layer;

an inner layer overlying the outer layer and secured thereto to define a space therebetween; and

a solitary inflatable member defining a solitary chamber for receiving a pressurized fluid, the solitary inflatable member being disposed in the space defined by the inner and outer layers and having an inner face facing the inner layer and an outer face facing the outer layer, wherein the outer face of the solitary inflatable member is secured to the outer layer, and wherein the inner face of the inflatable member is in direct contact with and is free from direct securement to the inner layer so that the inflatable member is freely movable in relation to the inner layer when disposed on the body part of the patient for providing DVT prophylaxis therapy to the body part of the patient.

2. The compression apparatus as set forth in claim 1, wherein the inner face of the inflatable member is secured to the inner layer by an adhesive layer selected from the group consisting of:

at least one strip of adhesive tape;

an adhesive fluid;

a gel; and

combinations thereof.

3. The compression apparatus as set forth in claim 2, wherein the adhesive layer comprises plural, spaced apart strips of double-sided adhesive tape joining the inner face of the inflatable member to the inner layer.

4. The compression apparatus as set forth claim 2, wherein the adhesive fluid is selected from the group consisting of glue, a thermoplastic adhesive, a thermosetting adhesive, a rubber-resin blend, ultraviolet curable adhesives and mixtures thereof.

5. The compression apparatus as set forth in claim 2, wherein the gel comprises silicone gels, hydrocolloidal gels, cyanoacrylate gels, thixotropic gels and mixtures thereof.

6. The compression apparatus as set forth in claim 2, wherein the compression apparatus has a body portion and a strap portion, the body portion adapted to engage a foot and the strap portion adapted to engage an ankle.

7. The compression apparatus as set forth in claim 2, wherein the inflatable member has a body portion that is adapted to engage a foot.

8. The compression apparatus as set forth in claim 2 further comprising a rigid sole element.

Dated: 20 May, 2009
Tyco Healthcare Group LP
Patent Attorneys for the Applicant/Nominated Person
SPRUSON & FERGUSON

AH21(2051053_2):PRW

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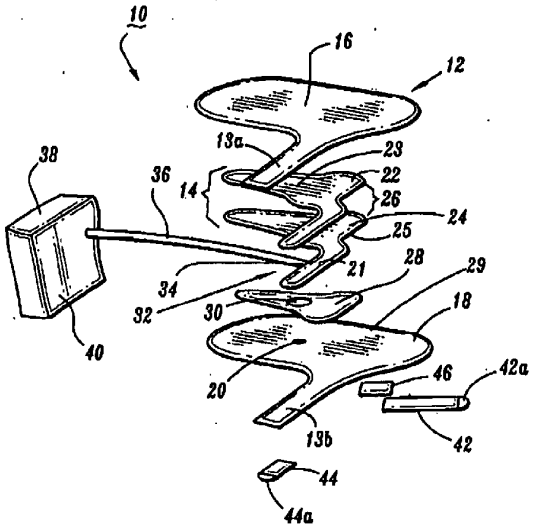

FIG. 1

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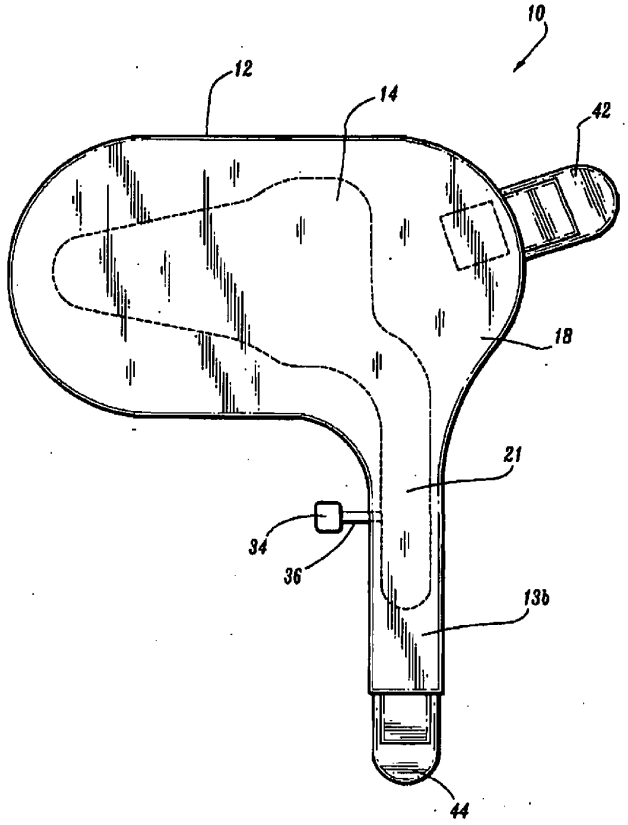

FIG. 2

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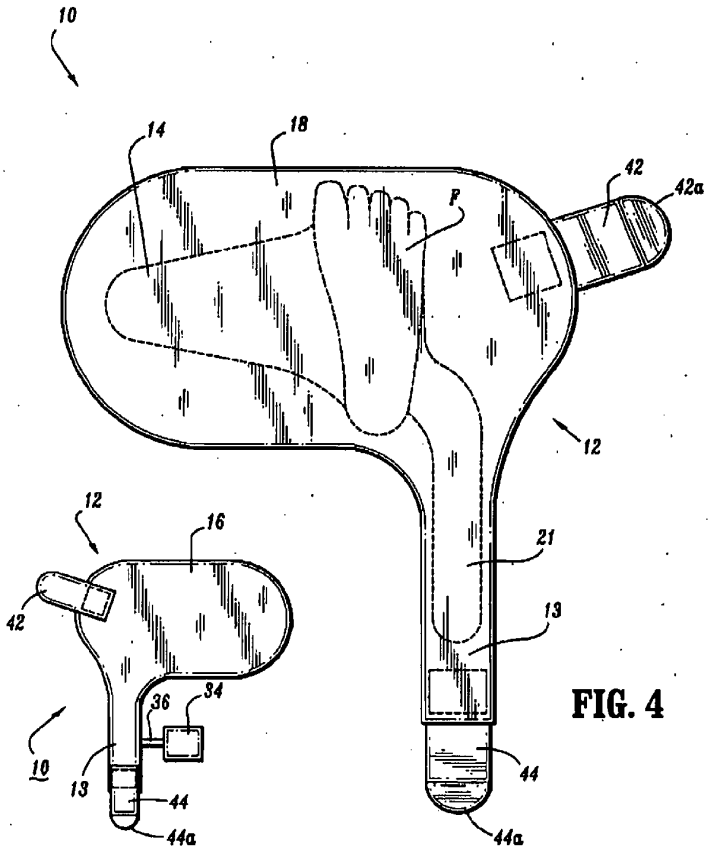

FIG. 4

FIG. 3

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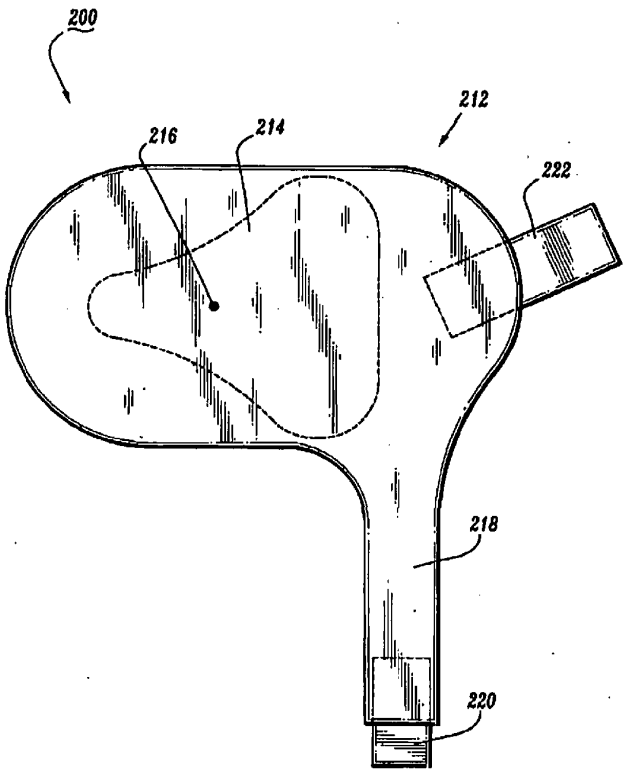

FIG. 5

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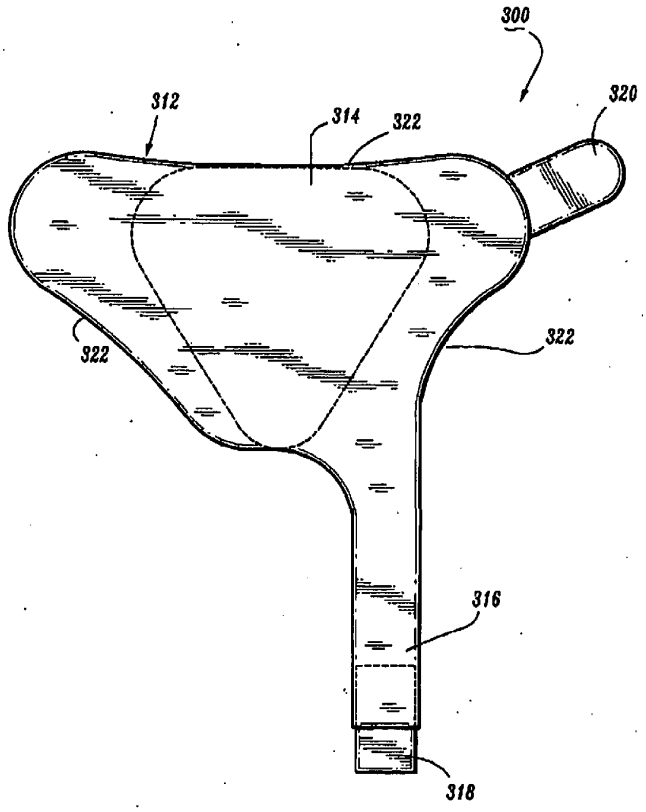

FIG. 6

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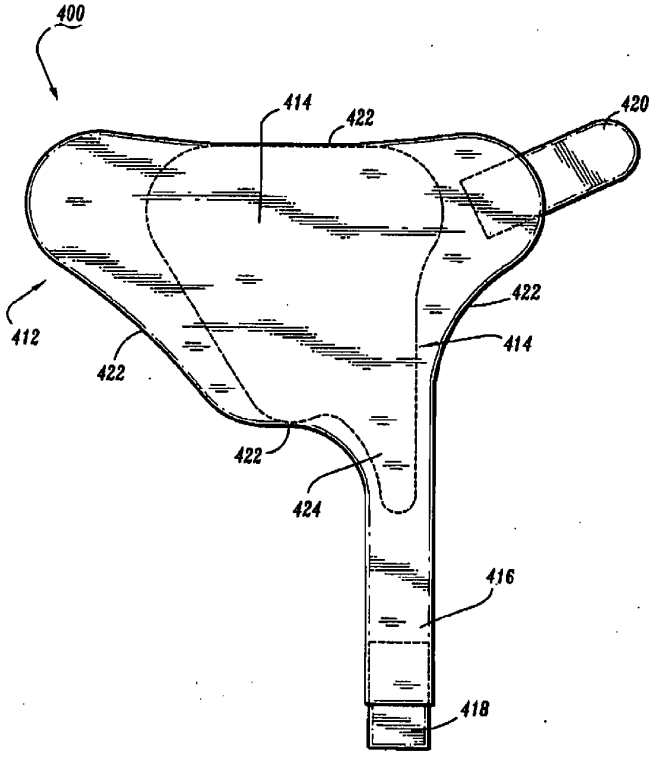

FIG. 7

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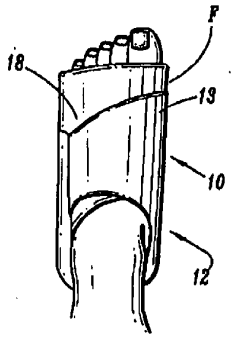

FIG. 8

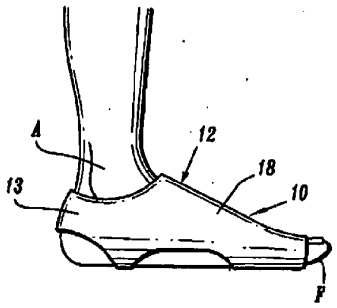

FIG. 9

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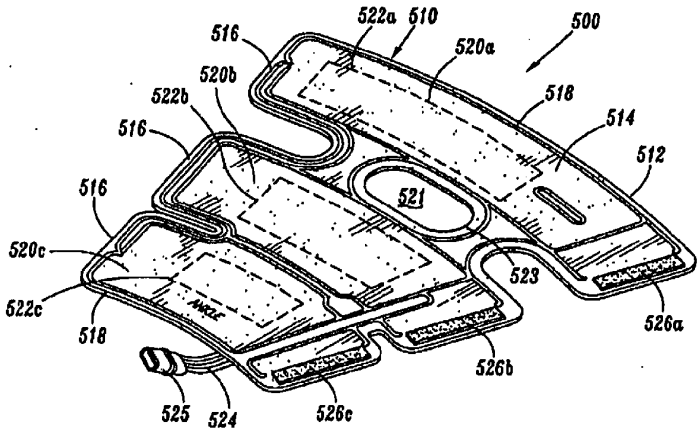

FIG. 10

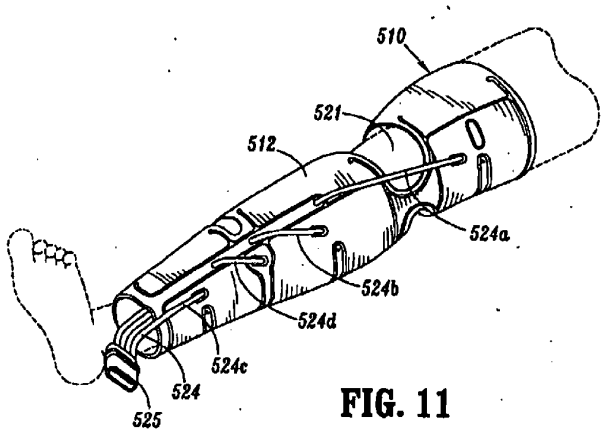

FIG. 11