



(43) International Publication Date
8 December 2016 (08.12.2016)

- (51) International Patent Classification:
A61H 9/00 (2006.01)
- (21) International Application Number:
PCT/US2016/032196
- (22) International Filing Date:
12 May 2016 (12.05.2016)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
14/732,067 5 June 2015 (05.06.2015) US
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- (81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG,
MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM,
PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC,
SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

- (84) Designated States (*unless otherwise indicated, for every
kind of regional protection available*): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ,
TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU,
TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE,
DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,
LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,
SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, KM, ML, MR, NE, SN, TD, TG).

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments (Rule 48.2(h))*

(54) Title: COMPRESSION DEVICE IN COMBINATION WITH LOWER LIMB PROTECTION

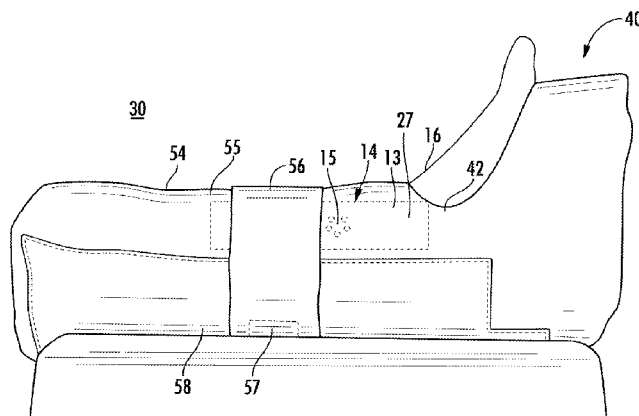


FIG. 1A

(57) Abstract: The present invention relates to a support system for a body part including a compression device in combination with a lower leg protection system. The support system comprises: an inner positioner (14) formed of bladder (13) including fluidized material therein which can retain its shape after sculpting; an outer support (52) comprising a top layer, a first intermediate layer, a second intermediate layer, and a bottom layer; a first plenum formed between the top layer and the first intermediate layer, the top layer includes perforations; a first valve connected to the first plenum and a first pump, said first pump providing air through the first valve to said first plenum to create air flow into the plenum and out through the perforations; a second plenum formed between the first intermediate layer and the second intermediate layer and second pump, a second valve connecting to the second pump, said second pump provides air to the second plenum to inflate said second plenum in an intermittent or sequential manner; and a third plenum formed between the second intermediate layer and the bottom layer, said third plenum containing a fixed amount of static air. The outer support can include a rigid outer shell for providing support.



COMPRESSION DEVICE IN COMBINATION WITH LOWER LIMB PROTECTION

Background of the Invention

Conventional supports provide a polyester filled or foam boot for support of a
5 lower leg. Other conventional supports include an ankle foot orthotic (AFO) or foot
wrap. Another conventional support includes an air chamber in a boot configuration.
The air chamber supports a leg and heel above a surface of a bed patient when lying in a
supine and side lying position, such as in a hospital bed.

The conventional supports have the disadvantage that pressure is applied to the
10 heel or leg for maintaining the heel above the surface of the bed. In addition, the leg can
be raised too high such that joints can lock, nerves can be potentially entrapped and the
circulation to the leg can be compromised. In addition, the intraluminal pressure of
conventional supports minimizes its ability to contour to the object applying the force.

Sequential or intermittent compression devices have been described which
15 include inflatable sleeves. The sleeve is placed over the leg or foot. Pressure modulation
is used in order to reduce risk of clot formation in the leg or foot.

It is desirable to provide a sequential or intermittent compression device in
combination with a lower leg protection system for supporting the leg and heel when a
patient is recumbent while maintaining neutral leg alignment without lifting the leg and
20 heel from the resting surface.

Summary of the Invention

The present invention relates to a support for a body part including a compression
device in combination with a lower leg protection system. The compression device can
be inflated sequentially or intermittently. The compression device can be inlaid into a
25 support boot and attached to the boot with a flexible material. A valve is combined with
the compression device for increasing and reducing pressure within the compression
device in a sequential or intermittent manner. It is optimal to barely elevate the heel from
the surface of the bed. This helps to minimize leg rotation and locking of the knee.

In one embodiment, the compression device is combined with a fluidized lower
30 protection system including an inner positioner and an outer support. The inner

positioner includes a bladder, preferably filled with a fluidized particulate material, to provide three-dimensional contouring to the lower leg and heel. The inner positioner has low pressure and is not sufficient alone to support the leg. The inner positioner has little or no flow characteristics unless an outside force is applied other than gravity. The inner positioner can displace and contour three-dimensionally as though it was fluid to the sides and top of the leg while not having flow characteristics that would result in migration of the medium under the force of gravity. The inner positioner can provide three-dimensional contouring to the Achilles tendon. The inner positioner can include a temperature regulating material for keeping the leg in an optimal range of skin temperature to keep the leg comfortable longer. The inner positioner can be shaped as a pad to mold to the underside portion of the lower leg and heel. Alternatively, the inner positioner can include various shapes to support the lower leg and heel. In one embodiment, the inner positioner also includes a portion which extends over a top portion of the leg, such as the shin.

The outer support is received over the inner positioner. The outer support can be in the shape of an open boot. In one embodiment, the compression device can be integral with the outer support at a position received over the lower leg. One or more valves can extend from a compression bladder for attachment to a pneumatic device. Inflation of the compression bladder positioner adjacent the lower leg also displaces air in the outer support toward the foot which causes simultaneous massaging of the foot. The pneumatic device can be adjusted to provide either sequential or intermittent therapies.

In one embodiment, a first plenum is formed between a top layer and a first intermediate layer that can include dynamic air. The top layer can be perforated with apertures. A second plenum is formed between the first intermediate layer and a second intermediate layer. Air is pumped into the second plenum in a sequential manner or . intermittent manner. A third plenum can be formed between the bottom layer and the second intermediate layer and can include a fixed amount of static air.

In one embodiment, an outer shell can be formed around or integral with leg protection and support system having compression. The outer shell can be formed of a rigid material. One or more valves can extend through the outer shell. The valves can also

be connected to a compression device. The compression device can provide pneumatic pressure for inflating and deflating a compression bladder in a sequential or intermittent manner. The outer shell can be used to make the leg protection and support system having compression a ankle foot orthosis (AFO).

5 The outer support can include an ultra low pressure plenum. The ultra low pressure plenum is filled at a predetermined low pressure for distributing pressure along the length of the outer support, but not providing significant elevation of the lower leg and heel by itself. In this embodiment, the inner positioner is partially filled with the fluidized particulate material so it cannot support a leg on its own. For example, the
10 inner positioner can be filled up to 2/3 of its capacity. The outer portion of the inner positioner contours to the inner portion of the ultra low pressure plenum for providing more air displacement of the outer support than if the inner positioner was not present.

 In one embodiment the system is strapless. In an alternate embodiment, the system includes a strap for attachment of the outer support to the leg. The strap can be
15 sufficiently wide and cushioned to protect the skin. In one embodiment, the strap is air bearing. In one embodiment, a rear end of the outer support includes a gate, which can be opened to allow access to the foot and heel from the rear of the boot.

 The inner positioner or outer support can include a fluidized thermal regulating medium. In one embodiment, a phase change material can be used for adjusting the
20 temperature of the system.

 The system of the present invention can be a one size fits all and adapts to the size and shape of a patient's leg. The system maintains neutral alignment and helps prevent foot drop. The system gently but securely wraps the leg, helping to maintain constant heel position. The system promotes proper dorsiflexion without causing undue pressure
25 on the lower limb.

 The combination of the inner positioner including a fluidized medium along with the outer support including a ultra low pressure plenum creates sufficient support of the lower leg while responding to normal patient movement. The combination of the inner positioner and the outer support provides three-dimensional contouring to the lower leg
30 and heel for micro adjustment while the outer support or boot is closed for minimizing

friction and shear. This is not possible in conventional devices where the inner chamber is not free to communicate with the leg without negatively affecting the functionality of the outer chamber. In general, the custom fitting protection can be used in such a way as to elevate the foot without "locking out the knee" due to three-dimensional molding and provide comfort to the skin. The natural contour of the leg can be maintained while eliminating harmful pressure to the heel, ankle, Achilles and foot. The system of the present invention can respond to the twisting of the leg without causing movement of the outer support. The system of the present invention can minimize shear forces that would be associated with a non-fluidized medium.

The invention will be more fully described by reference to the following drawings.

Brief Description of the Drawings

Fig. 1A is a side schematic diagram of an embodiment of a compression device in combination with a fluidized lower leg protection and support system including an outer support.

Fig. 1B is a rear schematic diagram of the compression device in combination with a fluidized lower leg protection and support system including an outer support, as shown in Fig. 1A.

Fig. 2 is a schematic diagram of the embodiment of the compression device in combination with a fluidized lower leg protection and support system shown in Fig. 1A from an opposite side.

Fig. 3 is a schematic diagram of the embodiment of the compression device in combination with a fluidized lower leg protection and support system shown in Fig. 1A from a rear side.

Fig. 4 is a schematic diagram of the embodiment of the compression device in combination with a fluidized lower leg protection and support system shown in Fig. 1A from a rear side in an open position.

Fig. 5 is a schematic plan view of the embodiment of the compression device in combination with a fluidized lower leg protection and support system shown in Fig. 1A.

Fig. 6 is a schematic diagram of an alternate embodiment of the compression device in combination with a fluidized lower leg protection and support system including an outer support and support strap.

Fig. 7 is a schematic diagram of an alternate embodiment of the compression device in combination with a fluidized lower leg protection and support system including
5 an outer support, support strap and ankle strap.

Fig. 8 is a schematic diagram of the embodiment of the compression device in combination with a fluidized lower leg protection and support system shown in Fig. 7 from an opposite side.

Fig. 9 is a schematic diagram of an alternate embodiment of the compression device in combination with a fluidized lower leg protection and support system including
10 an opening between side portions of the outer support.

Fig. 10A is a top perspective view of an alternate embodiment of the compression device in combination with a fluidized lower leg protection and support system in a fully
15 open position.

Fig. 10B is a bottom perspective view of the embodiment shown in Fig. 10A.

Fig. 11 is a top perspective view of the embodiment of Fig. 10A including an inner positioner.

Fig. 12 is a top perspective view of the embodiment of Fig. 11 in which the rear end of the compression device in combination with a fluidized lower leg protection and support system is closed.
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Fig. 13 is a top perspective view of the embodiment of Fig. 12 in which a lower leg is placed adjacent the rear end of the compression device in combination with a fluidized lower leg protection and support system.

Fig. 14 is a top perspective view of the embodiment of Fig. 13 in which a flap of the compression device in combination with a fluidized lower leg protection and support system is closed over the received lower leg.
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Fig. 15 is a top plan view of a valve extending through the compression device in combination with a fluidized lower leg protection and support system for attachment to
30 the compression device.

Fig. 16A is a schematic diagram of the compression device in combination with a fluidized lower leg protection and support system including a plenum providing low air loss.

Fig. 16B is a top perspective view of an outer support of the compression device in combination with a fluidized lower leg protection and support system shown in Fig. 16A.

Fig. 17A is an alternate embodiment of the compression device in combination with a fluidized lower leg protection and support system operated in a sequential manner.

Fig. 17B is an alternate embodiment of the compression device in combination with a fluidized lower leg protection and support system operated in an intermittent manner.

Fig. 17 C is a top perspective view of an outer support of the compression device in combination with a fluidized lower leg protection and support system of Figs. 17A and 17B,

Fig. 18A is an alternate embodiment of a fluidized lower leg protection and support system including a compression device and a rigid outer shell.

Fig. 18B is an alternate embodiment of a fluidized lower leg protection and support system including a compression device and a rigid outer shell.

Fig. 18C is an alternate embodiment of a fluidized lower leg protection and support system including a compression device and a rigid outer shell.

Detailed Description

Reference will now be made in greater detail to a preferred embodiment of the invention, an example of which is illustrated in the accompanying drawings. Wherever possible, the same reference numerals will be used throughout the drawings and the description to refer to the same or like parts.

Figs. 1-5 illustrate an embodiment of a compression device in combination with a lower leg protection and support system 30.

Compression system 40 is combined with fluidized lower leg support system 50. In one embodiment, compression system 40 can be inlaid into lower leg protection and support system 50 and attached thereto with coupling member 42. Lower leg protection

and support system 50 can be a conventional support boot. In one embodiment, lower leg protection and support system 50 includes outer support 52 and inner positioner 14. Compression system 40 can include bladder 44 attached with coupling member 42 to outer support 52. Valve 46 can be associated with compression system 40 for inflating and deflating compression system 40 in a sequential or intermittent manner.

Outer support 52 can include a plurality of rows of parallel ultra low pressure plenums 53. For example, ultra low pressure plenums 53 can be positioned within outer support 52 along the length L_1 of outer support 52. Flap 54 can extend over front of lower leg 16. Flap 54 can include ultra low pressure air plenums 55, which protect lower leg 16 from strap 56. Flap 54 can also provide anti-rotation of fluidized lower leg protection and support system 50. Strap 56 can be adjustable for closing flap 54 for different sizes of legs. Strap 54 can include a coupling portion 57 at one end thereof for attaching to attachment section 58. Strap 56 can include a cushioning material. In one embodiment, strap 56 is air bearing. Coupling portion 57 can be formed of a hook and loop material. Attachment section 58 can be formed of a hook and loop material. Attachment section 58 can be positioned along length L_1 of outer support 52. Outer support 52 can be received under U-shaped base 59, as shown in Fig. 3. U-shaped base 59 provides anti-rotation of outer support 52. Air pressure within ultra low pressure plenum 53 is reduced sufficiently to provide reduced pressure for conforming outer support 52 to the shape of lower leg 16 and optionally heel 17 for distributing pressure along the length of outer support 52, but is not providing support of lower leg 16 and heel 17.

Inner positioner 14 is formed of bladder 13 including fluidized material 15 therein which can retain its shape after sculpting. Fluidized material 15 can be a particulate material including interstitial spaces between the particles. A lubricant can be present in the interstitial spaces. For example, the lubricant can be a particulate material having a lower coefficient of friction, such as a powder. The volume of the particulate material can be controlled for controlling the interstitial air within the fluidized medium.

Bladder 13 is filled with fluidized material 15 which can retain its shape after sculpting. The flowability or lubricity of fluidized material 15 can be increased by

adding a lubricant or by the removal of air from the interstitial spaces or both. The preferred medium of fluidized material 15 is a particulate material that has been modified in such a way that it acts like a fluid. Fluidized material 15 refers to a compound or composition which can be sculpted and retain its shape and has no memory or substantially no memory. The no memory or substantially no memory feature enables bladder 13 to increase in height and maintain support of a body part. Fluidized material 15 is made of a viscosity that will allow it to contour but not collapse under the weight of the body part.

At sea level, the normal interstitial air pressure would exceed about 760 millibars of mercury. This increases or decreases marginally as altitude varies. Depending on the nature of the particulate fluidized material 15, the pressure can be lowered below about 500 millibars, preferably, about 350 millibars to about 5 millibars, while still maintaining the necessary flow characteristics of the product. The amount the pressure is lowered is dependent on the interstitial spaces needed to provide desired flow characteristics of the product.

Fluidized material 15 can include beads, such as polyethylene or polystyrene (PS) beads, expanded polyethylene (PE), crosslinked expanded polyethylene (PE), polypropylene (PP) pellets, closed cell foams, microspheres, encapsulated phase changing materials (PCM). The beads can be hard shelled or flexible. In one embodiment, the beads are flexible and air can be evacuated from the beads. In one embodiment, hard beads can be mixed with flexible beads in which air can be evacuated from the flexible beads. In an alternative embodiment, fluidized material 15 can be a porous foam substance including pockets of interstitial air. In one embodiment, fluidized material 15 can be a polyurethane foam. The polyurethane foam can be open or closed cell and cut into small shapes such as spheres or blocks. For example, a sphere of polyurethane foam can have a size of 2 inches in diameter. For example, a block of polyurethane foam can be a 1x1x1 inch block.

Suitable examples of fluidized material 15 can be formed of a mixture of microspheres and lubricant. The microspheres can include hollow or gas-filled structural bubbles (typically of glass or plastic) with an average diameter of less than 200 microns.

The composition flows and stresses in response to a deforming pressure exerted on it and the composition ceases to flow and stresses when the deforming pressure is terminated. For example, fluidized material 15 can be formed of a product referenced to as Floam™. A flowable compound comprising lubricated microspheres, including the compound itself, formulations for making the compound, methods for making the compound, products made from the compound and methods for making products from the compound as defined by U.S. Patent Nos. 5,421,874, 5,549,743, 5,626,657, 6,020,055, 6,197,099, and 8,171,585, each of which is hereby incorporated by reference into this application. Bladder 13 provides micro-contouring because fluidized material 15 can respond three-dimensionally.

For example, bladder 13 can be formed of a flexible plastic, such as urethane. Upon removal of residual air from fluidized material 15 bladder 13 flows concurrent with the flow of fluidized material 15 such that bladder 13 moves with movement of fluidized material 15. Bladder 13 can have a size and shape to support lower leg 16 and heel 17 of a user. Bladder 13 can include portion 18 which extends over top portion 19 of lower leg 16. Optionally, air can communicate throughout the whole bladder 13 for allowing maximum contouring and functional displacement of both the air and the fluidized chamber thereby providing maximum contouring to a desired body part.

Inner positioner 14 or outer support 52 can include thermo-regulating medium 27. Thermo-regulating medium 27 can be a phase change material for adjusting the temperature to adapt support system 10 to temperature changes of a body part of a user. Thermo-regulating material 27 can be associated with fluidized material 15 or cover (not shown) placed over inner positioner 14. An example material for thermo-regulating material 27 is manufactured by Outlast Technologies as fibers, fabrics, and foams comprising micro-encapsulated phase changing materials referred to as Thermocules, which store and release heat as further described in U.S. Patent Nos. 7,790,283, 7,666,502 and 7,579,078, hereby incorporated by reference into this application.

For example, the pressure in ultra low pressure plenum 53 can be below 20 mm of water. It will be appreciated that all equivalents such as mm Hg and PSI can be used for measuring the pressure within ultra low pressure plenum 53.

The pressure within ultra low pressure plenum 53 can be below about 20 mm of water if no inner positioner is used or if an area of less than about 30% of outer support 52 is covered by inner positioner 14. The pressure within ultra low pressure plenum 54 can be below about 10 mm of water if an area of between about 30% to about 5 60% of outer support 52 is covered by inner positioner 14. The pressure within ultra low pressure plenum 53 can be below about 5 mm of water if an area of greater than about 60% of outer support 52 is covered by inner positioner 14.

Rear end 60 of outer support 52 can include overlapping flap members 62 and 63 for forming a gate to allow access to foot 19 including heel 17, as shown in Figs. 3A-3B. 10 Flap members 62 and 63 can include respective coupling portions 64 and 65 for attaching flap members 62 and 63 to one another. For example, coupling portions 64 and 65 can be formed of a hook and loop material. Flap members 62 and 63 can be opened to allow access to foot 19, as shown in Fig. 4.

Fig. 6 illustrates an alternate embodiment of a fluidized lower leg protection support system 70, including support strap 72. Support strap 72 can extend around rear end 60 for providing support, for example, in supporting a patient with foot drop. Support strap 72 can include coupling portion 77 at one end thereof. Coupling portion 77 15 can be formed of a hook and loop material. Coupling portion 77 can attach to attachment section 58.

Figs. 7 and 8 illustrate an alternate embodiment of a fluidized lower leg protection and support system 80. Support strap 82 can include coupling portion 87 at one end thereof. Coupling portion 87 can be formed of a hook and loop material. Coupling portion 87 can attach to attachment section 88. Attachment section 88 can be positioned circumferentially around top portion 89. Coupling portion 87 can be coupled at various 20 locations on attachment section 88. Ankle strap 92 can attach to attachment section 94. Ankle strap 92 can include coupling portion 93 at one end thereof. Coupling portion 93 can be formed of a hook and loop material. Attachment section 94 can be formed of a hook and loop material. Ankle strap 92 can be positioned above ankle 95. Attachment section 94 can be positioned adjacent or below ankle 95. 25

Fig. 9 illustrates an alternate embodiment of a fluidized lower leg protection and support system 100 which includes opening 102 between side portions 103 and 104 for allowing air to contact lower leg 16 and allowing cooling of lower leg 16 while providing support. Straps 105 and 106 can attach to respective attachment sections 107 and 108. Straps 105 and 106 can include coupling portion 109 at one end thereof. Coupling portion 109 can be formed of a hook and loop material. Attachment section 107 and 108 can be formed of a hook and loop material.

Inner positioner 14 described above can be used with each of the fluidized lower leg protection and support systems 50, 70, 80 and 100. In one embodiment, inner positioner 14 is positioned horizontally at ankle 19 and wraps around the Achilles to protect the ankle.

Figs. 10-15 illustrate leg protection and support system having compression 200. Outer support 202 includes one or more of parallel rows of ultra low pressure plenums 203 forming outer support bladder 201. For example, ultra low pressure plenums 203 can be positioned within outer support 202 along the length L_1 of outer support 202. Flap 204 can include ultra low pressure air plenums 205.

Compression bladder 214 can be positioned on inner surface 215 of outer support 202, as shown in Fig. 10A. Compression bladder 214 can be integral with outer support 202 in which compression bladder is joined at edges 216 of outer support bladder 201. Support bladder 214 can extend into flap 204.

Valve 210 extends through outer support 202 to provide access to end 211 of valve 210, as shown in Fig. 10B and Fig. 11. End 212 of valve 210 extends into compression bladder 214. Valve 220 extends through flap 204 of outer support 202 to provide access to end 221 of valve 220. End 222 of valve 220 extends into flap 204. Rear end 230 of outer support 202 can include flap members 232 and 233, as shown in Figs. 10A-10B. Flap members 232 and 233 can include respective coupling portions 234 and 235 for attaching flap members 232 and 233 to one another. In one embodiment, coupling portion 234 is attached to inner surface 237 of flap member 232 and coupling portion 235 is attached to outer surface 238 of flap member 235, as shown in Fig. 12. For example, coupling portions 234 and 235 can be formed of a hook and loop material.

During use, inner positioner 14 can be placed over outer support 202, as shown in Fig. 12. Flap members 232 and 233 are attached to one another for closing leg protection and support system having compression 200 and forming foot and heel support portion 240 of outer support 202, as shown in Fig. 13. Lower leg 16 is received in leg protection and support system having compression 200 adjacent to heel support 240, as shown in Fig. 14. Inner positioner 14 provides three dimensional contouring to the received lower leg 16 and heel 17. Flap 204 can be closed over lower leg 16, as shown in Fig. 15. Strap 206 can be adjusted for closing flap 204. End 221 of valve 220 can be connected to compression device 250. Compression device 250 can provide pneumatic pressure for inflating and deflating compression bladder 214 in a sequential or intermittent manner.

Figs. 16A-16B illustrate an alternate embodiment of compression device in combination with lower leg support system 1000. Outer support 1001 of system 1000 has a three layer construction. Outer support 1001 can have a similar shape as outer support 202. Top layer 1020, intermediate layer 1030 and bottom layer 1040 are sealed to one another along outside edge 1050. For example, top layer 1020, intermediate layer 1030 and bottom layer 1040 can be formed of urethane.

Plenum 1100 formed between top layer 1020 and intermediate layer 1030 can include dynamic air. Air 1150 is pumped into plenum 1100 through valve 1110 by pump 1120. Air 1150 is pumped beneath top layer 1020. Top layer 1020 is perforated with apertures 1180. Plenum 1100 provides a dynamic amount of air to system 1000 for adjusting the amount of air in plenum 1140 and providing low air loss.

Plenum 1140 formed between bottom layer 1040 and intermediate layer 1030 can include a fixed amount of static air. In one embodiment, plenum 1140 is filled with an ultra low pressure of a pressure of about 500 millibars through about 10 millibars or in some cases even lower pressures can be used. Valve 1160 can be used to adjust the pressure in plenum 1140.

Figs. 17A-17C illustrate an alternate embodiment of compression device in combination with lower leg support system 2000. Outer support 2001 of system 2000 has a four layer construction. Outer support 1001 can have a similar shape as outer

support 202. Top layer 1020, first intermediate layer 1060, second intermediate layer 1061, and bottom layer 1040 are sealed to one another along outside edge 1050. For example, top layer 1020, first intermediate layer 1060, second intermediate layer 1061, and bottom layer 1040 can be formed of urethane.

5 Plenum 1100 formed between top layer 1020 and first intermediate layer 1060 can include dynamic air. Air 1150 is pumped into plenum 1100 through valve 1110 by pump 1120. Air 1150 is pumped beneath top layer 1020. Top layer 1020 is perforated with apertures 1180. Plenum 1100 provides a dynamic amount of air to system 1000 for adjusting the amount of air in plenum 1100 and providing low air loss.

10 Plenum 1170 is formed between first intermediate layer 1060 and second intermediate layer 1061. Air 1175 is pumped into plenum 1170 through valve 1180 by pump 1190. Pump 1190 can be operated in a sequential manner. Alternatively, pump 1190 can be operated in an intermittent manner as shown in Fig. 17B.

Plenum 1140 formed between bottom layer 1040 and second intermediate layer 1061 can include a fixed amount of static air. In one embodiment, plenum 1140 is filled with an ultra low pressure of a pressure of about 500 millibars through about 10 millibars or in some cases even lower pressures can be used. Valve 1160 can be used to adjust the pressure in plenum 1140.

Figs. 18A-18C illustrate an alternate embodiment of a fluidized lower leg protection and support system including a compression device 3000. Outer shell 3001 is formed around or integral with leg protection and support system having compression 200 as shown in Fig. 18A. Outer shell 3001 can be formed of a rigid material. For example, outer shell 3001 can be formed of a rigid plastic such as for example acrylic polyvinyl chloride thermoplastic. End 221 of valve 220 can extend through outer shell 3001 and be connected to compression device 250. Compression device 250 can provide pneumatic pressure for inflating and deflating compression bladder 214 in a sequential or intermittent manner. Alternatively, outer shell 3001 is formed around or integral with leg protection and support system having compression 1000 as shown in Fig. 18B. End 1115 of valve 1110 and end 1165 of valve 1160 can extend through outer shell 3001.

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25
30 Alternatively, outer shell 3001 is formed around or integral with leg protection and

support system having compression 1000 as shown in Fig. 18B. End 1115 of valve 1110 and end 1165 of valve 1160 can extend through outer shell 3001. Alternatively, outer shell 3001 is formed around or integral with leg protection and support system having compression 2000 as shown in Fig. 18C. End 1115 of valve 1110, end 1185 of valve 1180 and end 1165 of valve 1160 can extend through outer shell 3001. Outer shell 3001 can be used to make leg protection and support system having compression 200, 1000 or 2000 a ankle foot orthosis (AFO).

It is to be understood that the above-described embodiments are illustrative of only a few of the many possible specific embodiments, which can represent applications of the principles of the invention. Numerous and varied other arrangements can be readily devised in accordance with these principles by those skilled in the art without departing from the spirit and scope of the invention.

What is claimed is:

1. A support system for a body part comprising:
an inner positioner, said inner positioner adapted to provide three-dimensional
contouring of the received body part;
5 an outer support comprising a first plenum and a second plenum, said second
plenum positioned on an inner surface of said first plenum, and
a first valve connected to the first plenum and a compression device connected to
said valve, said compression device providing a dynamic amount of air through said
valve to the first plenum to inflate said first plenum in a sequential manner, and the
10 second plenum formed including a fixed amount of static air,
wherein said inner positioner is received over said outer support and displaces gas
within said first plenum.
2. The support system of claim 1 wherein said inner positioner comprises a
bladder filled with a fluidized particulate material.
- 15 3. The support system of claim 2 wherein said fluidized material is selected
from the group comprising beads, polyethylene beads, polystyrene (PS) beads, expanded
polyethylene (PE), crosslinked expanded polyethylene (PE), polypropylene (PP) pellets,
closed cell foams cut into a plurality of shapes, microspheres, and encapsulated phase
changing materials (PCM).
- 20 4. The support system of claim 1 wherein said outer support comprises a top
layer, intermediate layer, and bottom layer coupled to one another along respective edges
and said first plenum is formed between said top layer and said intermediate layer and
said second plenum is formed between said bottom layer and said intermediate layer.
5. The support system of claim 1 wherein said outer support has an opening
25 in a front portion and further comprises a flap for closing the opening.
6. The support system of claim 1 wherein a rear end of said outer support
includes overlapping flap members, each of said flap members including a coupling
portion, said coupling portions attaching said flap members to one another, wherein said
flap members are adapted to be opened to provide access to a foot received on the support
30 system.

7. The support system of claim 1 further comprising a support strap, said support strap extending from each side of said outer support around the rear end of said outer support.

8. The support system of claim 1 further comprising an ankle strap, said
5 ankle strap including a coupling portion at one end thereof, the coupling portion of the ankle strap being coupled to an attachment section of said outer support.

9. The support system of claim 1 wherein said outer support includes an opening between side portions, one or more straps being attached to attachment portions of said side portions, said straps extending over said opening, wherein said opening is
10 adapted to allow air to contact a lower leg received in said outer support.

10. The support system of claim 1 further comprising a cover positioned over the outer support, a rear of said cover includes overlapping flap members, each of said flap members including a coupling portion, said coupling portion attaching said flap members to one another, wherein said flap members are adapted to be opened to provide
15 access to a foot received in the support system.

11. The support system of claim 1 further comprising a rigid outer shell surrounding or integral with the outer support, the first valve extending through the rigid outer shell.

12. The support system of claim 11 wherein the outer shell comprises acrylic
20 polyvinyl chloride thermoplastic.

13. A support system for a body part comprising:
an inner positioner, said inner positioner adapted to provide three-dimensional contouring of the received body part;
an outer support comprising a first plenum and a second plenum, said second
25 plenum positioned on an inner surface of said first plenum; and
a valve connected to the first plenum and a compression device connected to said first valve, said compression device providing a dynamic amount of air through said first valve to the first plenum to inflate said first plenum in an intermittent manner,
wherein the second plenum includes a fixed amount of static air,

wherein said inner positioner is received over said outer support and displaces gas within said first plenum.

14. The support system of claim 13 wherein said inner positioner comprises a bladder filled with a fluidized particulate material.

5 15. The support system of claim 14 wherein said fluidized material is selected from the group comprising beads, polyethylene beads, polystyrene (PS) beads, expanded polyethylene (PE), crosslinked expanded polyethylene (PE), polypropylene (PP) pellets, closed cell foams cut into a plurality of shapes, microspheres, and encapsulated phase changing materials (PCM).

10 16. The support system of claim 13 wherein said outer support comprises a top layer, intermediate layer, and bottom layer coupled to one another along respective edges and said first plenum is formed between said top layer and said intermediate layer and said second plenum is formed between said bottom layer and said intermediate layer.

15 17. The support system of claim 13 wherein said outer support has an opening in a front portion and further comprises a flap for closing the opening.

18. The support system of claim 13 wherein a rear end of said outer support includes overlapping flap members, each of said flap members including a coupling portion, said coupling portions attaching said flap members to one another, wherein said flap members are adapted to be opened to provide access to a foot received on the support
20 system.

19. The support system of claim 13 further comprising a support strap, said support strap extending from each side of said outer support around the rear end of said outer support.

20. The support system of claim 13 further comprising an ankle strap, said
25 ankle strap including a coupling portion at one end thereof, the coupling portion of the ankle strap being coupled to an attachment section of said outer support.

21. The support system of claim 13 wherein said outer support includes an opening between side portions, one or more straps being attached to attachment portions of said side portions, said straps extending over said opening, wherein said opening is
30 adapted to allow air to contact a lower leg received in said outer support.

22. The support system of claim 13 further comprising a cover positioned over the outer support, a rear of said cover includes overlapping flap members, each of said flap members including a coupling portion, said coupling portion attaching said flap members to one another, wherein said flap members are adapted to be opened to provide
5 access to a foot received in the support system.

23. The support system of claim 13 further comprising a rigid outer shell surrounding or integral with the outer support, the first valve extending through the rigid outer shell.

24. The support system of claim 23 wherein the outer shell comprises acrylic
10 polyvinyl chloride thermoplastic.

25. A support system for a body part comprising:
an inner positioner, said inner positioner adapted to provide three-dimensional contouring of the received body part;
an outer support comprising a top layer, a first intermediate layer, a second
15 intermediate layer, and a bottom layer sealed together along respective edges and/or at corresponding non-air bearing sections;
a first plenum formed between the top layer and the first intermediate layer, said top layer of said first plenum includes perforations,
a first valve connected to the first plenum and a first pump, said first pump
20 providing a dynamic amount of air through the first valve to said first plenum sufficient to create air flow into the plenum and out through the perforations at a controlled rate determined by the first pump;
a second plenum formed between the first intermediate layer and the second intermediate layer and second pump, a second valve connecting to the second pump, said
25 second pump provides dynamic air to said second plenum to inflate said second plenum in a sequential manner; and
a third plenum formed between the second intermediate layer and the bottom layer, said third plenum containing a fixed amount of static air,

wherein said second plenum provides sequential compression to a received body part and said inner positioner is received over said top layer and displaces gas within said first plenum.

26. The support system of claim 25 further comprising a rigid outer shell surrounding or integral with the outer support, the first valve and the second valve extending through the rigid outer shell.

27. A support system for a body part comprising:
an inner positioner, said inner positioner adapted to provide three-dimensional contouring of the received body part; and
10 an outer support comprising a top layer, a first intermediate layer, a second intermediate layer, and a bottom layer sealed together along respective edges and/or at corresponding non-air bearing sections;

a first plenum formed between the top layer and the first intermediate layer, said top layer of said first plenum includes perforations,
15 a first valve connected to the first plenum and a first pump, said first pump providing a dynamic amount of air through the first valve to said first plenum sufficient to create air flow into the plenum and out through the perforations at a controlled rate determined by the first pump;

a second plenum formed between the first intermediate layer and the second intermediate layer and second pump, a second valve connecting to the second pump, said second pump provides dynamic air to said second plenum to inflate said second plenum in an intermittent manner and

a third plenum formed between the second intermediate layer and the bottom layer, said third plenum containing a fixed amount of static air

25 wherein said second plenum provides intermittent compression to a received body part and said inner positioner is received over said top layer and displaces gas within said first plenum.

28. The support system of claim 27 further comprising a rigid outer shell surrounding or integral with the outer support, the first valve and the second valve
30 extending through the rigid outer shell.

29. The support system of claim 28 wherein the outer shell comprises acrylic polyvinyl chloride thermoplastic.

30. A method of supporting a body part comprising the steps of:
providing a support system having compression for a body part, said support
5 system comprising an inner positioner, said inner positioner adapted to provide three dimensional contouring of the received body part,
an outer support comprising a first plenum and a second plenum, said second plenum positioned on an inner surface of said first plenum, and
a first valve connected to the first plenum and a compression device connected to
10 said valve, said compression device providing a dynamic amount of air through said valve to the first plenum to inflate said first plenum in a sequential or intermittent manner, and the second plenum formed including a fixed amount of static air,
a flap for closing the opening,
placing said body part over said inner positioner;
15 closing said flap for closing said outer support over the received body part, and
inflating said compression bladder support in a sequential or intermittent manner.

31. The method of claim 30 wherein the support system further comprises a rigid outer shell surrounding or integral with the outer support, the first valve extending through the rigid outer shell.

20 32. A method of supporting a body part comprising the steps of:
providing a support system having compression for a body part, said support system comprising an inner positioner, said inner positioner adapted to provide three dimensional contouring of the received body part, and
an outer support comprising a top layer, a first intermediate layer, a second
25 intermediate layer, and a bottom layer sealed together along respective edges and/or at corresponding non-air bearing sections;
a first plenum formed between the top layer and the first intermediate layer, said top layer of said first plenum includes perforations,
a first valve connected to the first plenum and a first pump, said first pump
30 providing a dynamic amount of air through the first valve to said first plenum sufficient

to create air flow into the plenum and out through the perforations at a controlled rate determined by the first pump;

5 a second plenum formed between the first intermediate layer and the second intermediate layer, a second valve connecting to the second pump, said second pump provides dynamic air to said second plenum to inflate said second plenum in a sequential manner,

a third plenum formed between the second intermediate layer and the bottom layer, said third plenum containing a fixed amount of static air

a flap for closing the opening,

10 placing said body part over said inner positioner;

closing said flap for closing said outer support over the received body part, and

inflating said compression bladder support in a sequential or intermittent manner.

33. The method of claim 32 wherein the support system further comprises a rigid outer shell surrounding or integral with the outer support, the first valve and the
15 second valve extending through the rigid outer shell.

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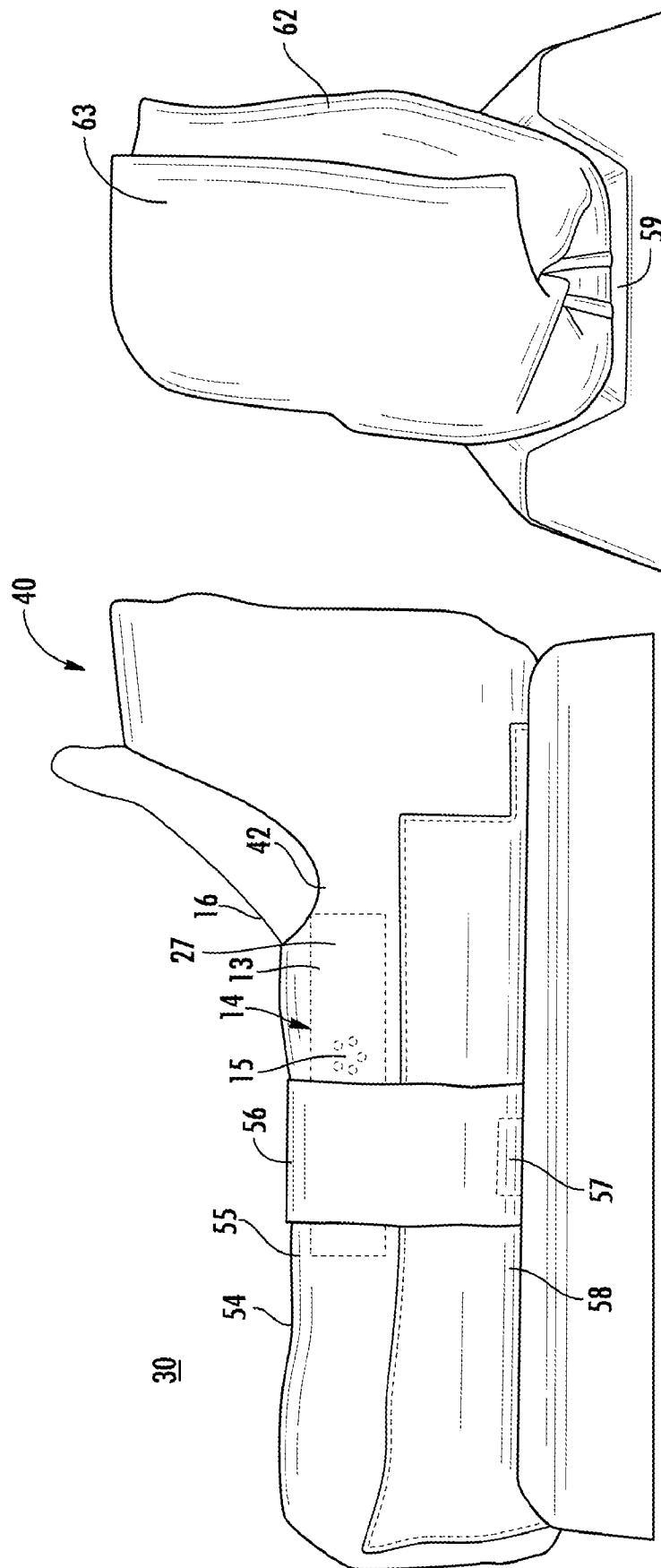


FIG. 1B

FIG. 1A

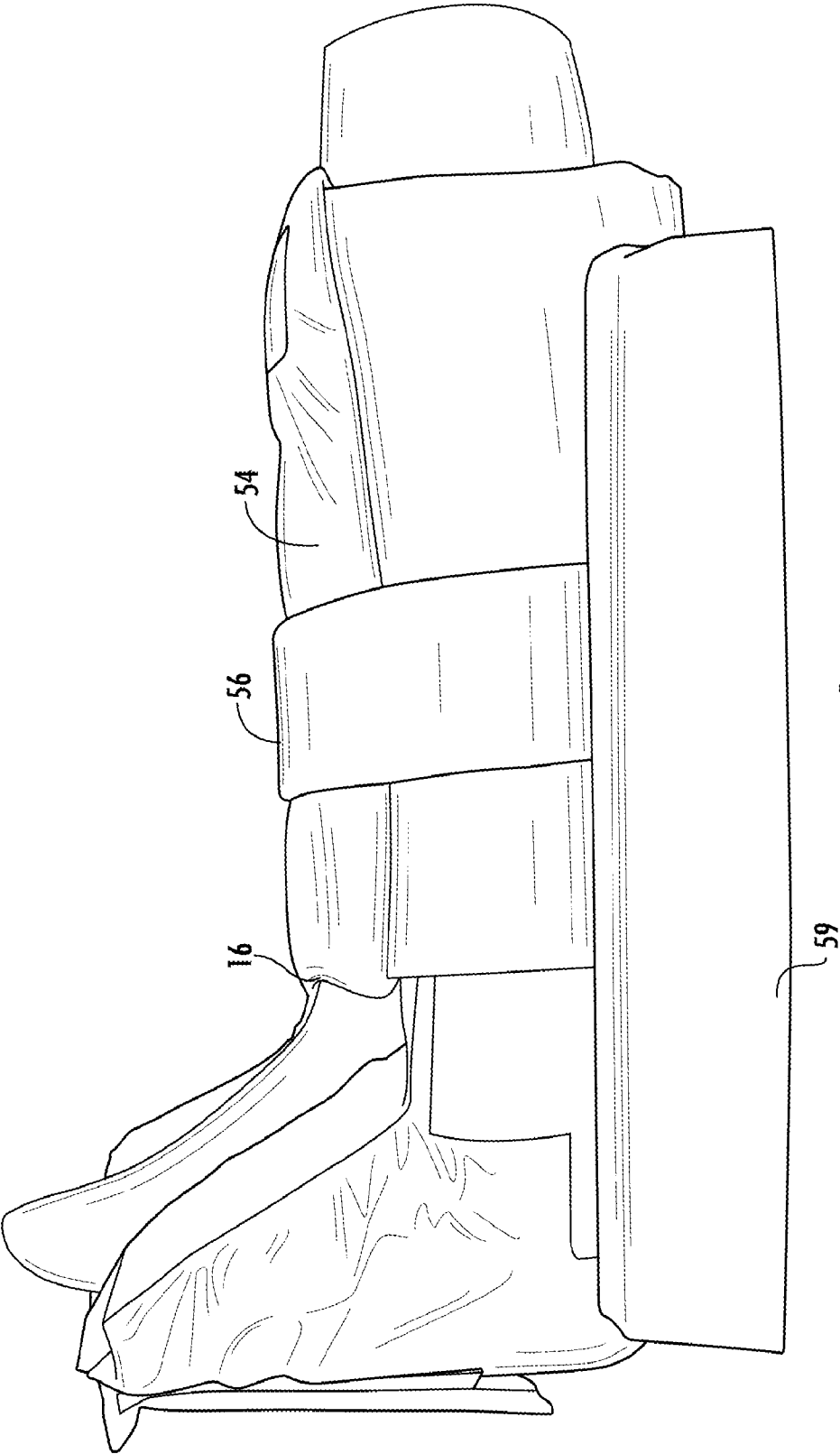
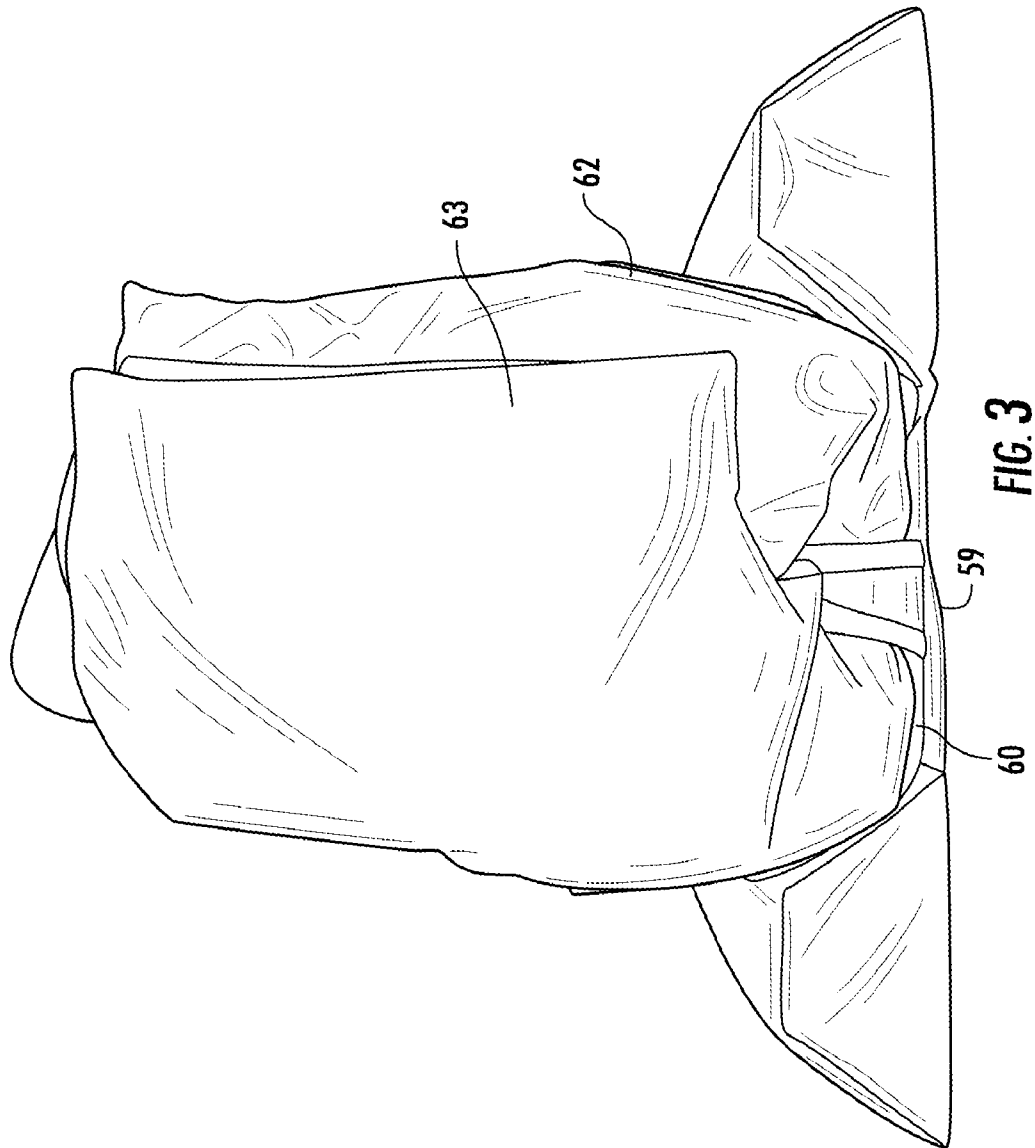


FIG. 2



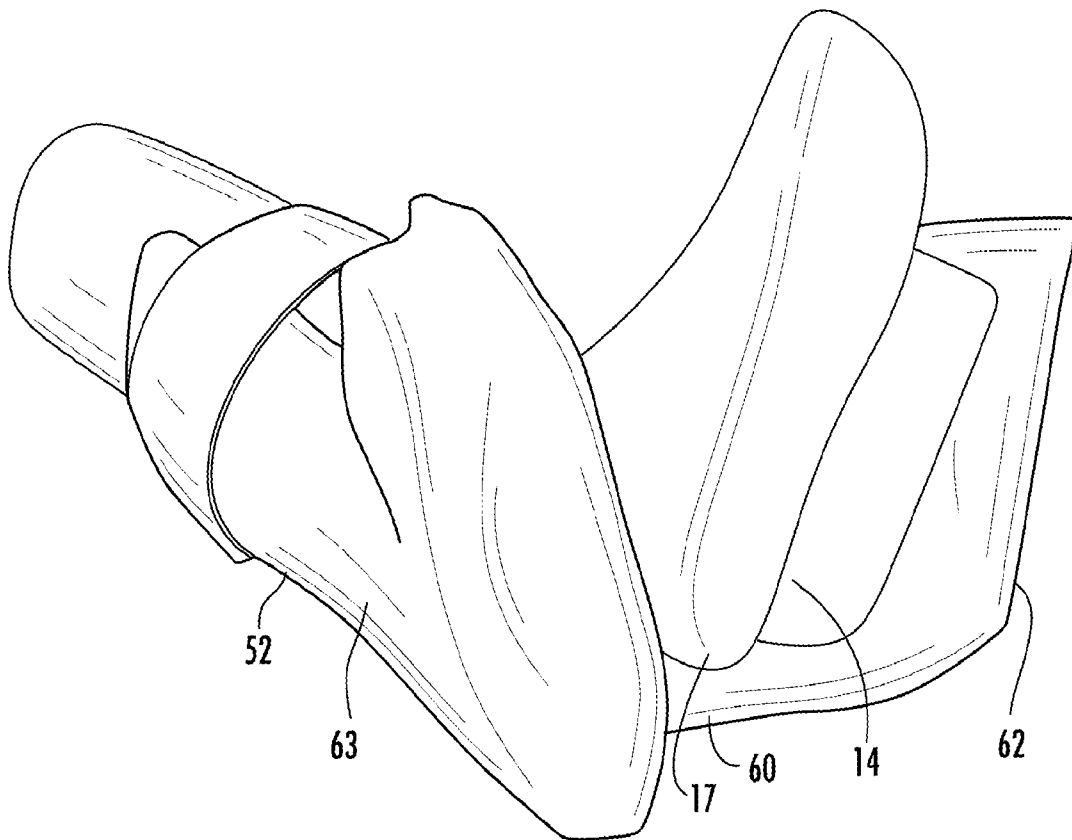


FIG. 4

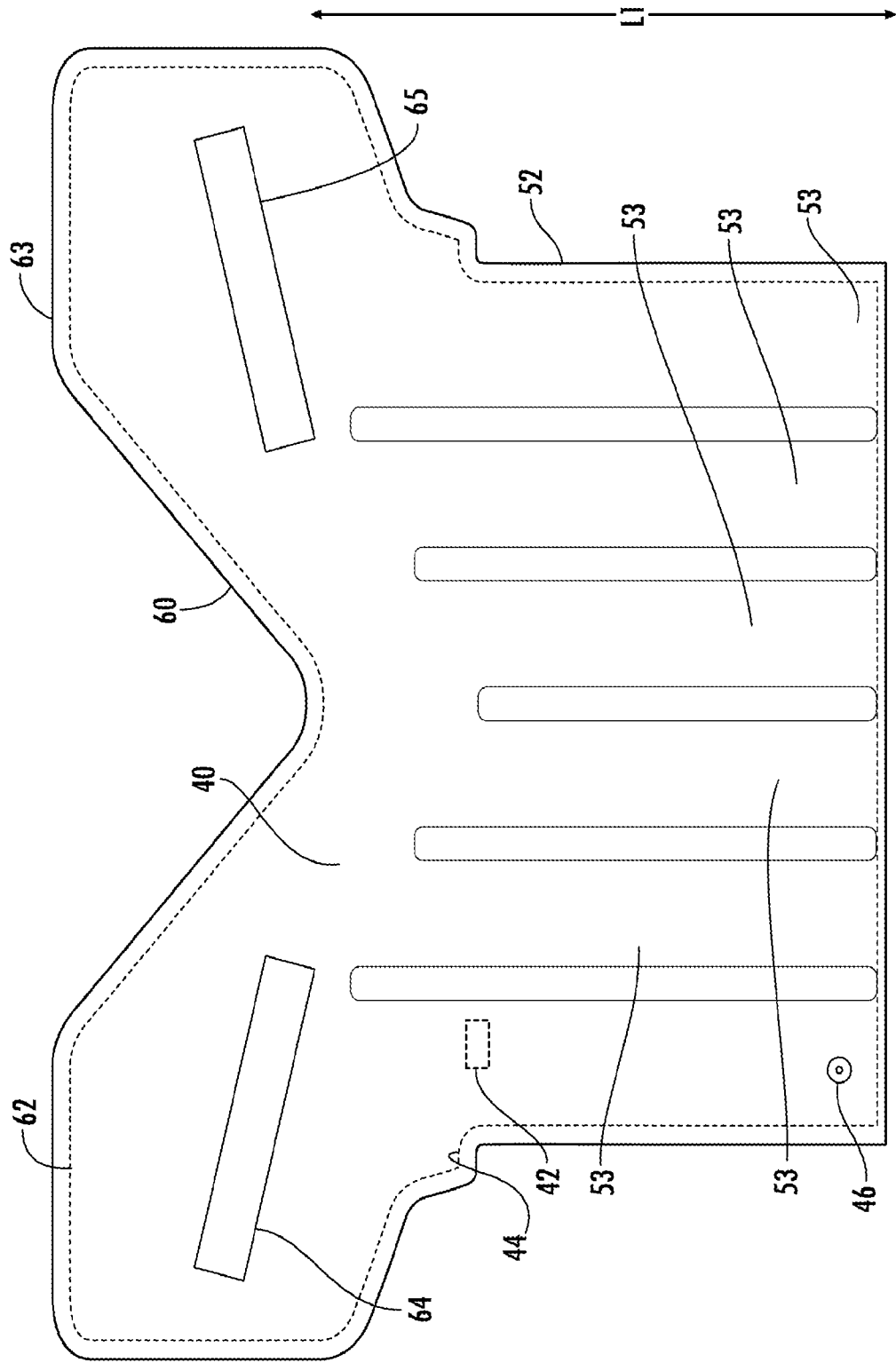


FIG. 5

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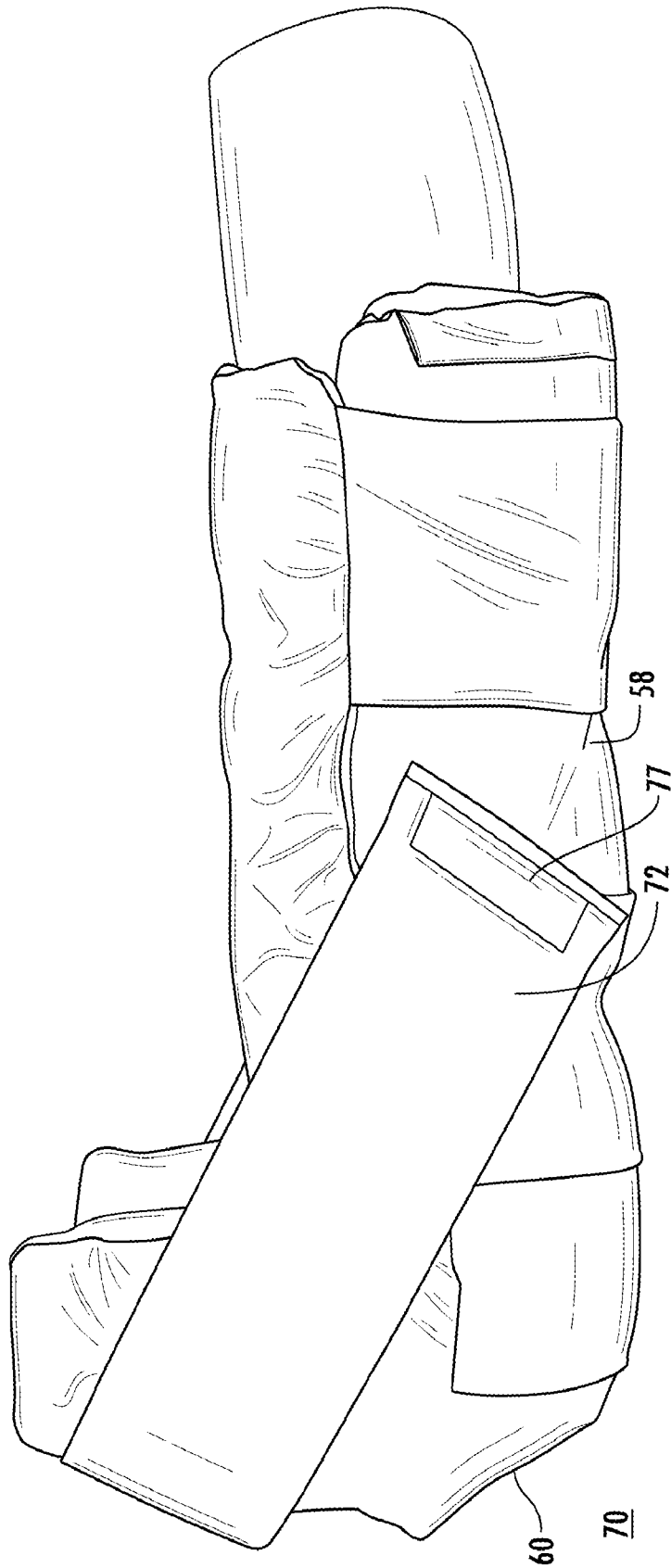
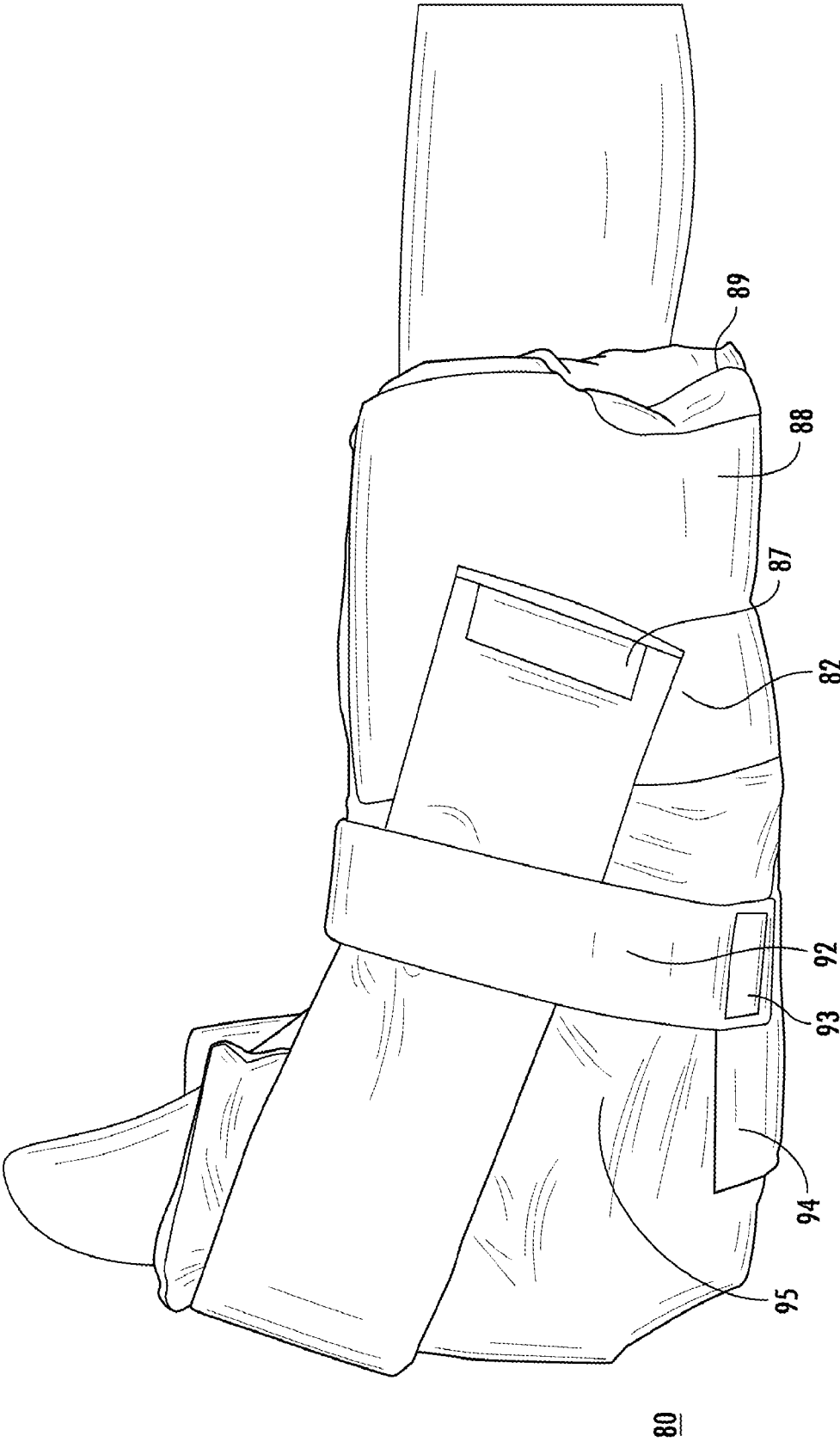


FIG. 6



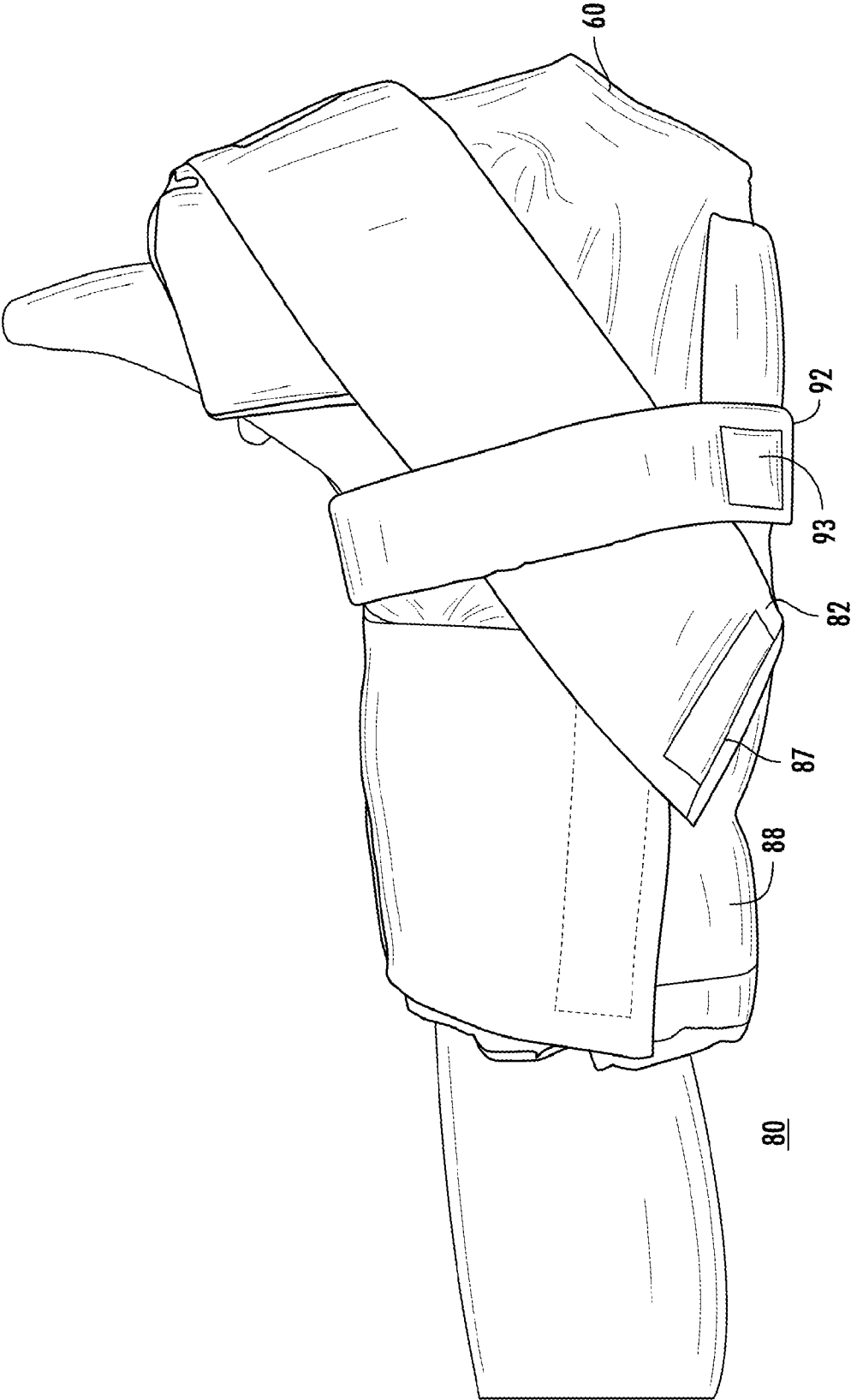
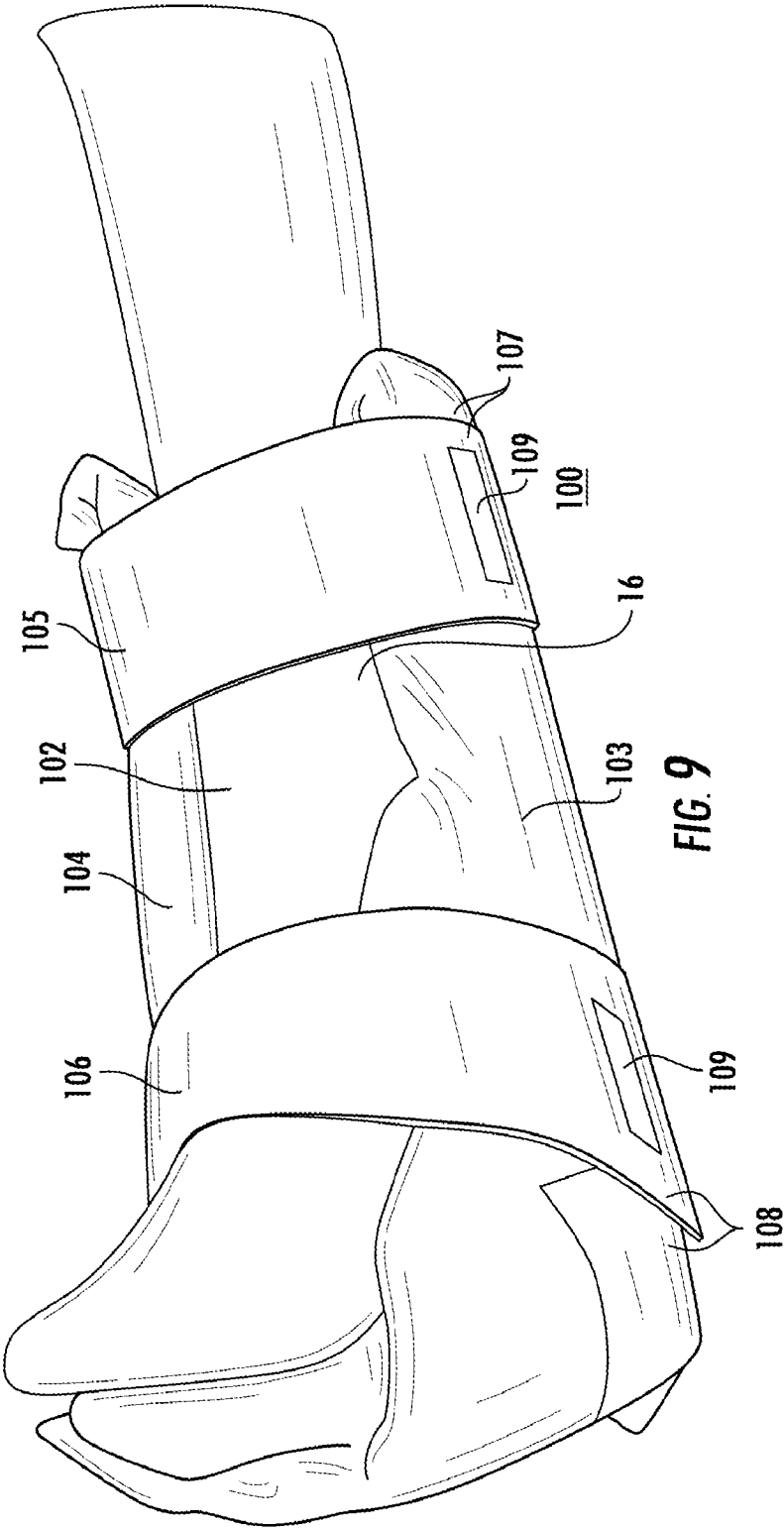


FIG. 8



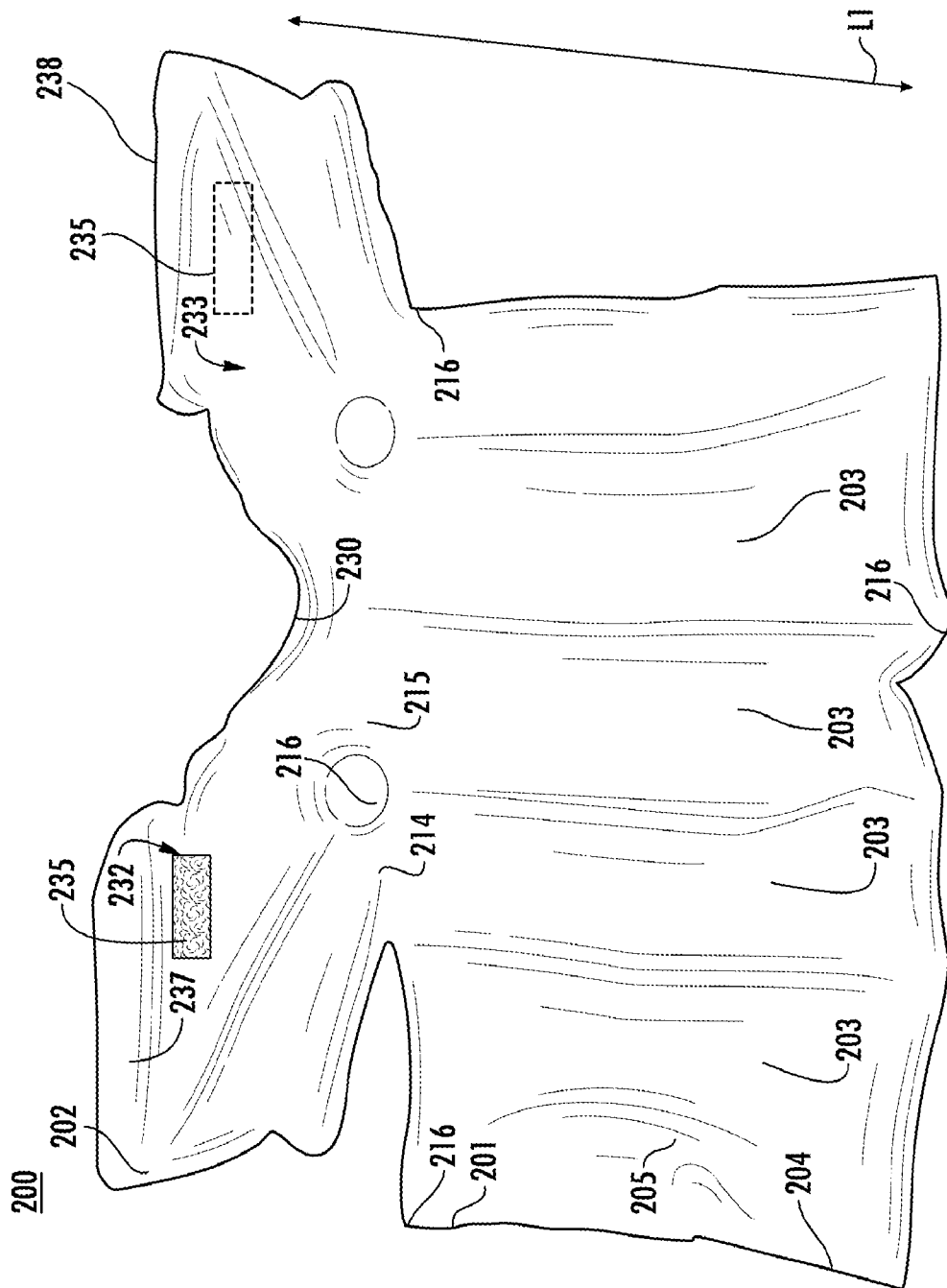


FIG. 10A

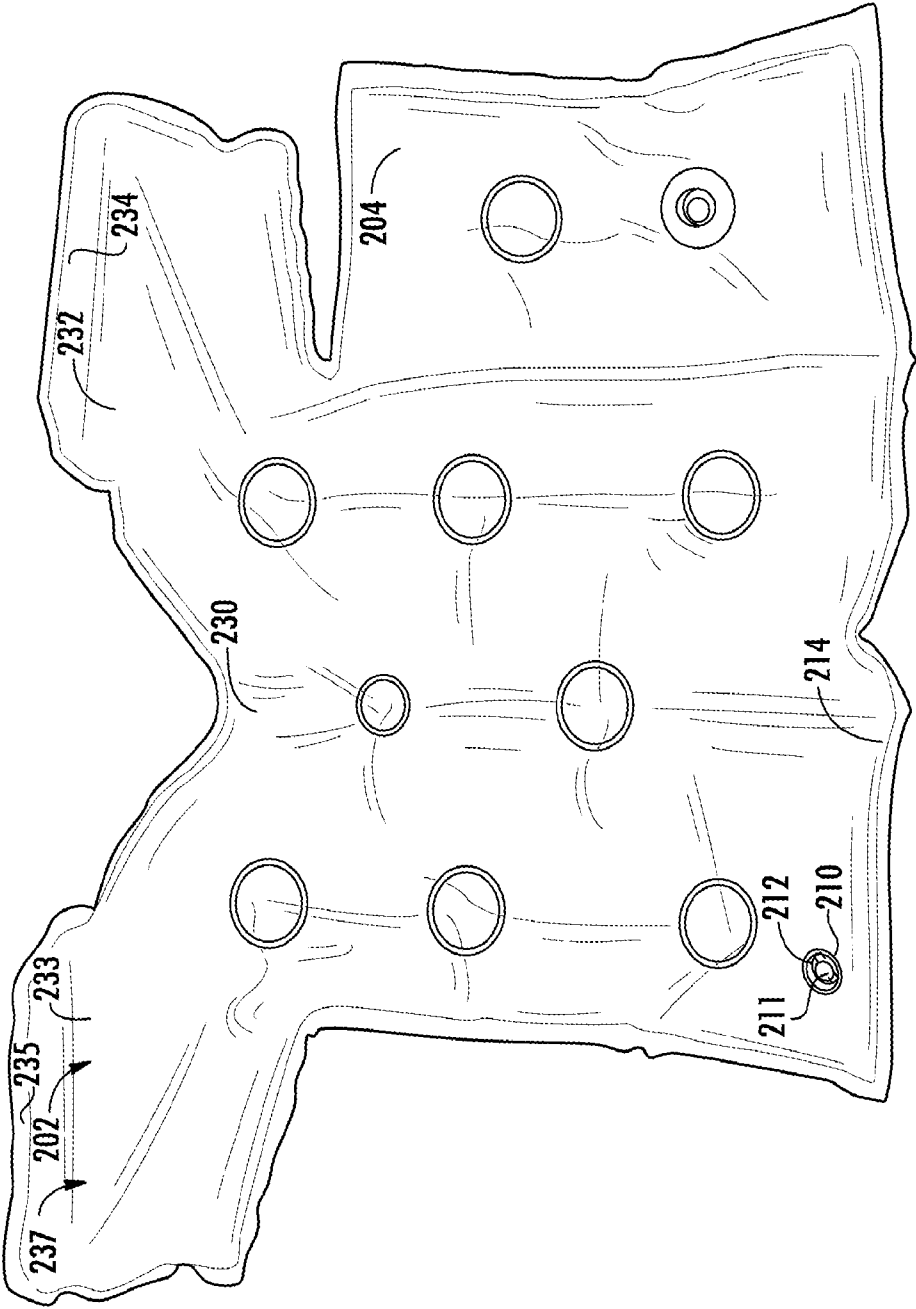


FIG. 10B

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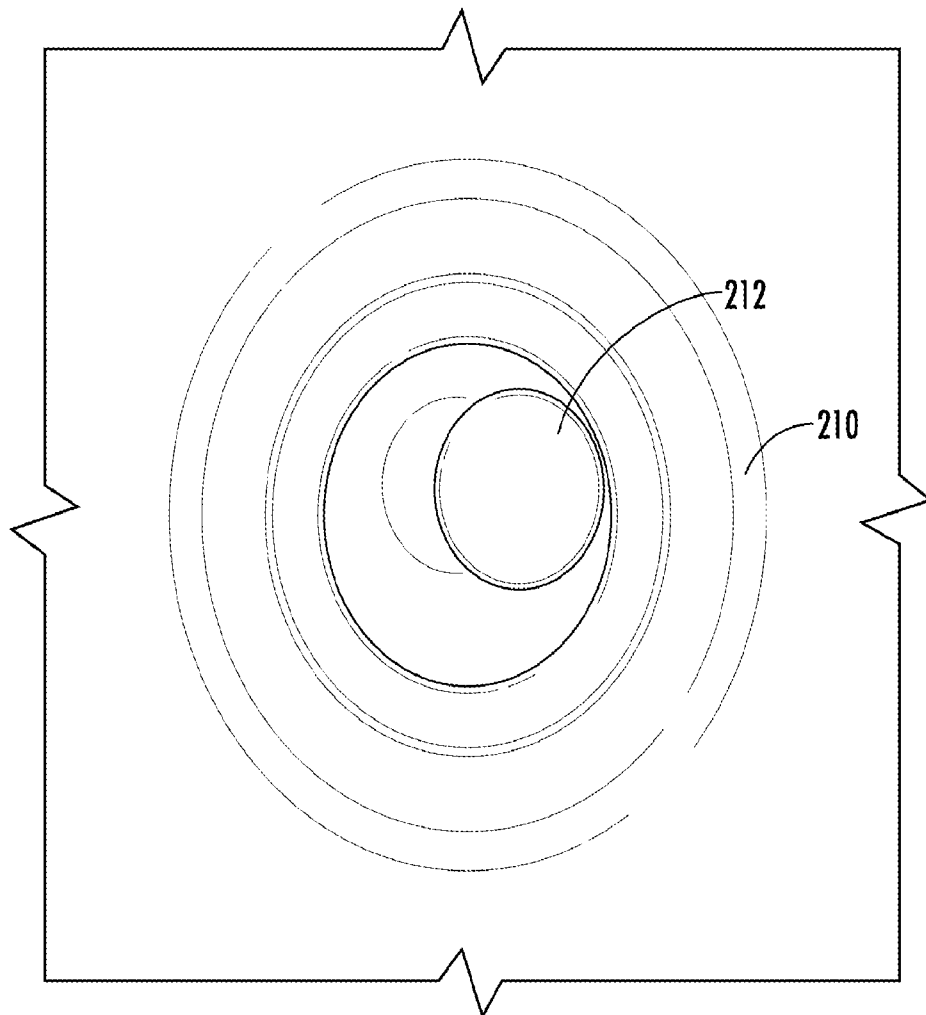


FIG. 11

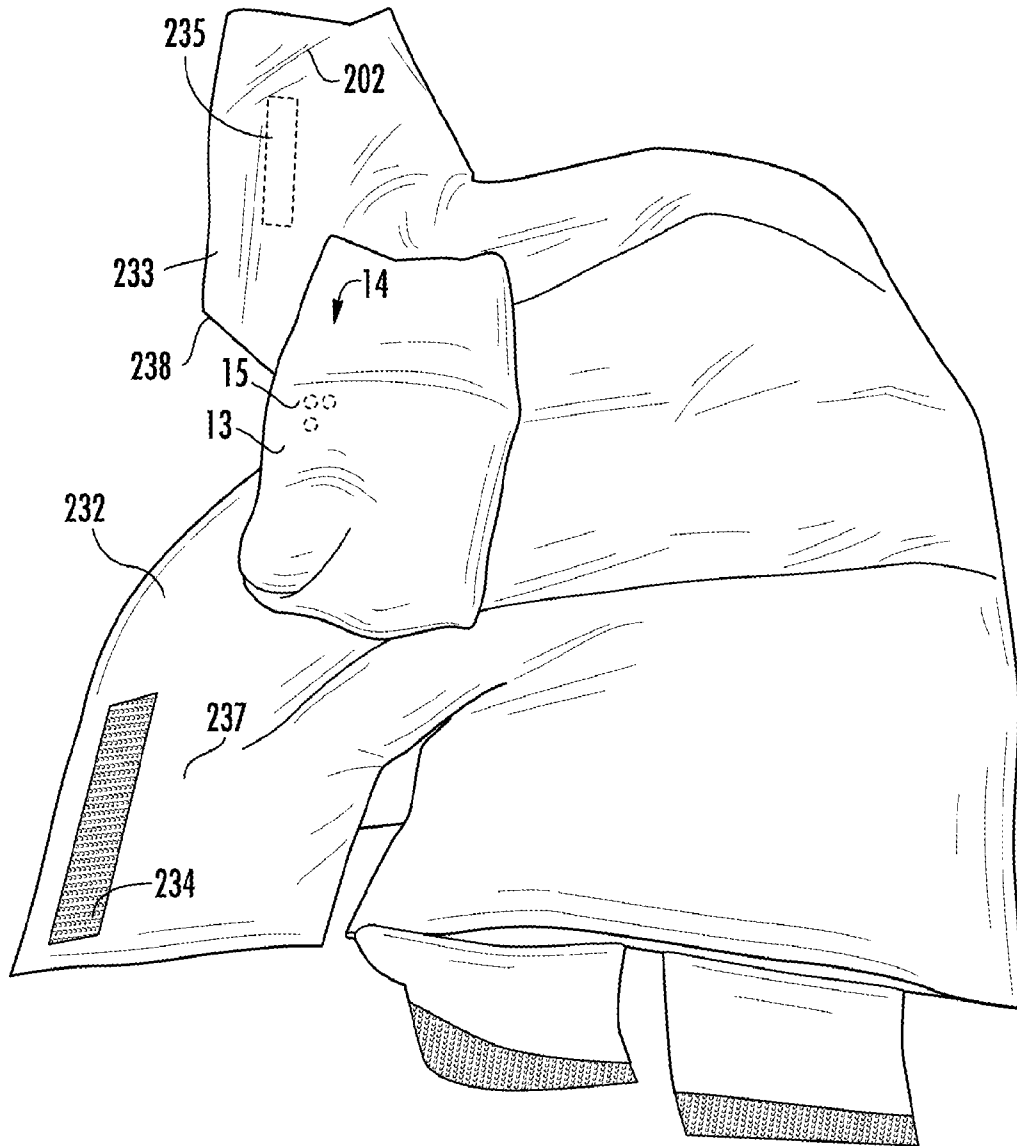
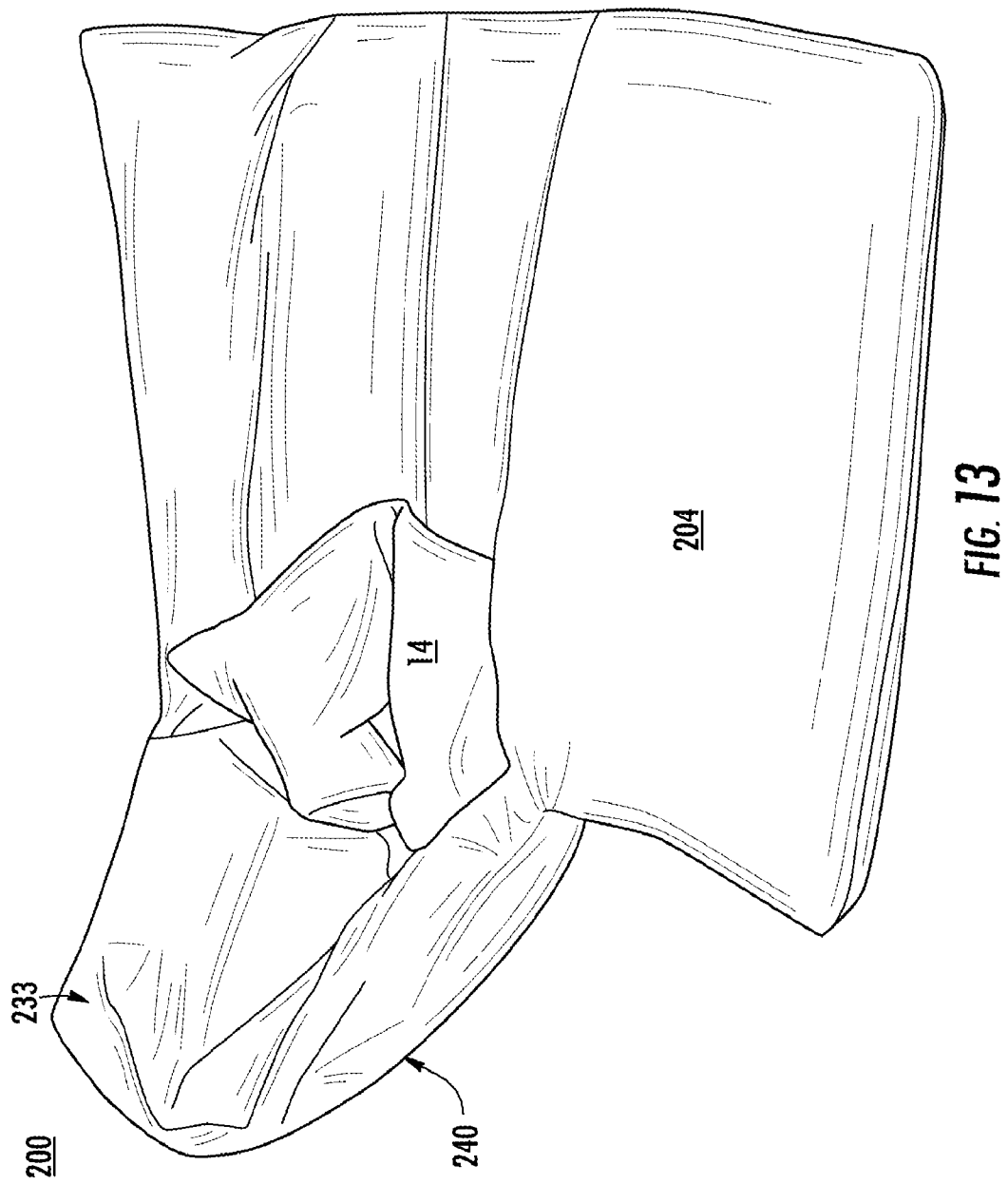
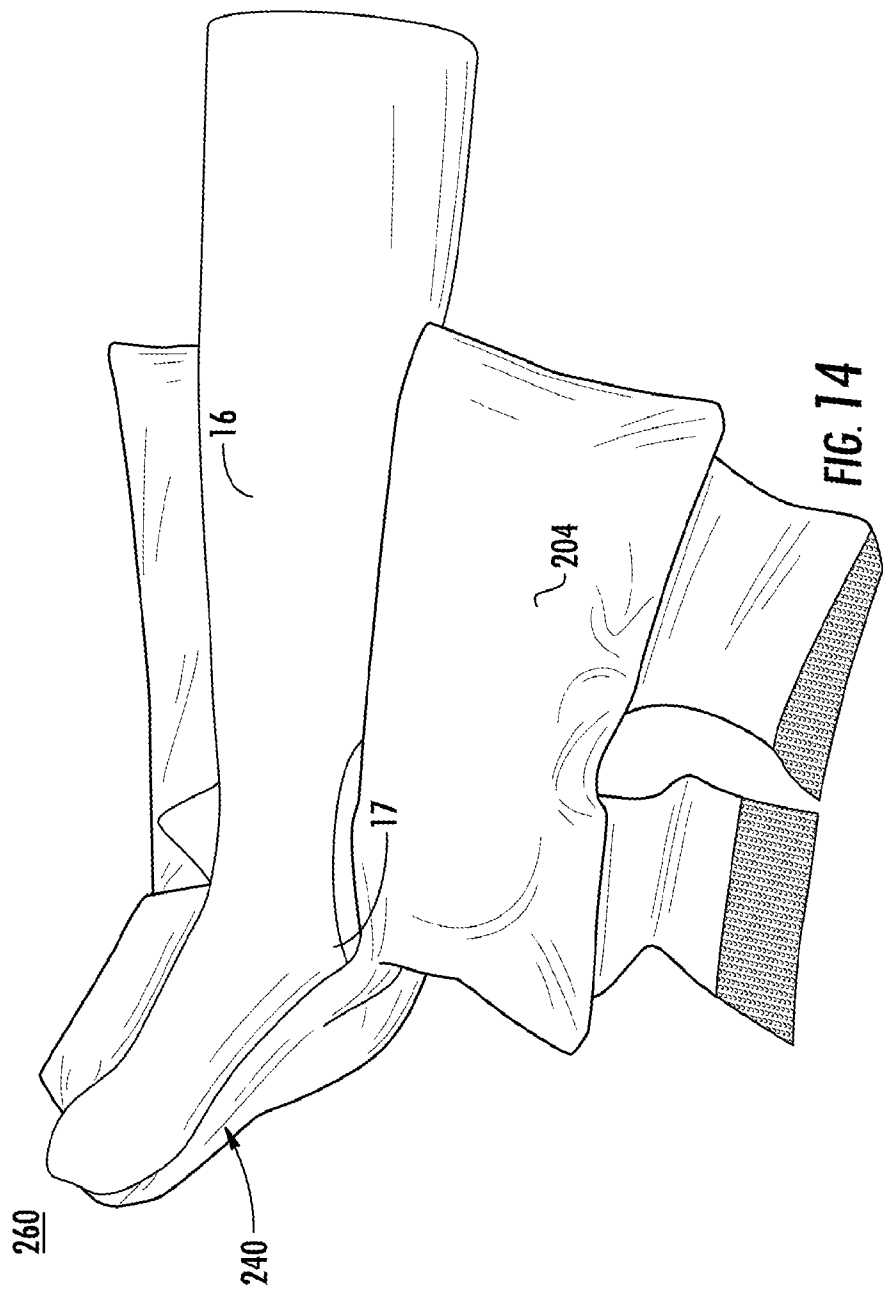


FIG. 12





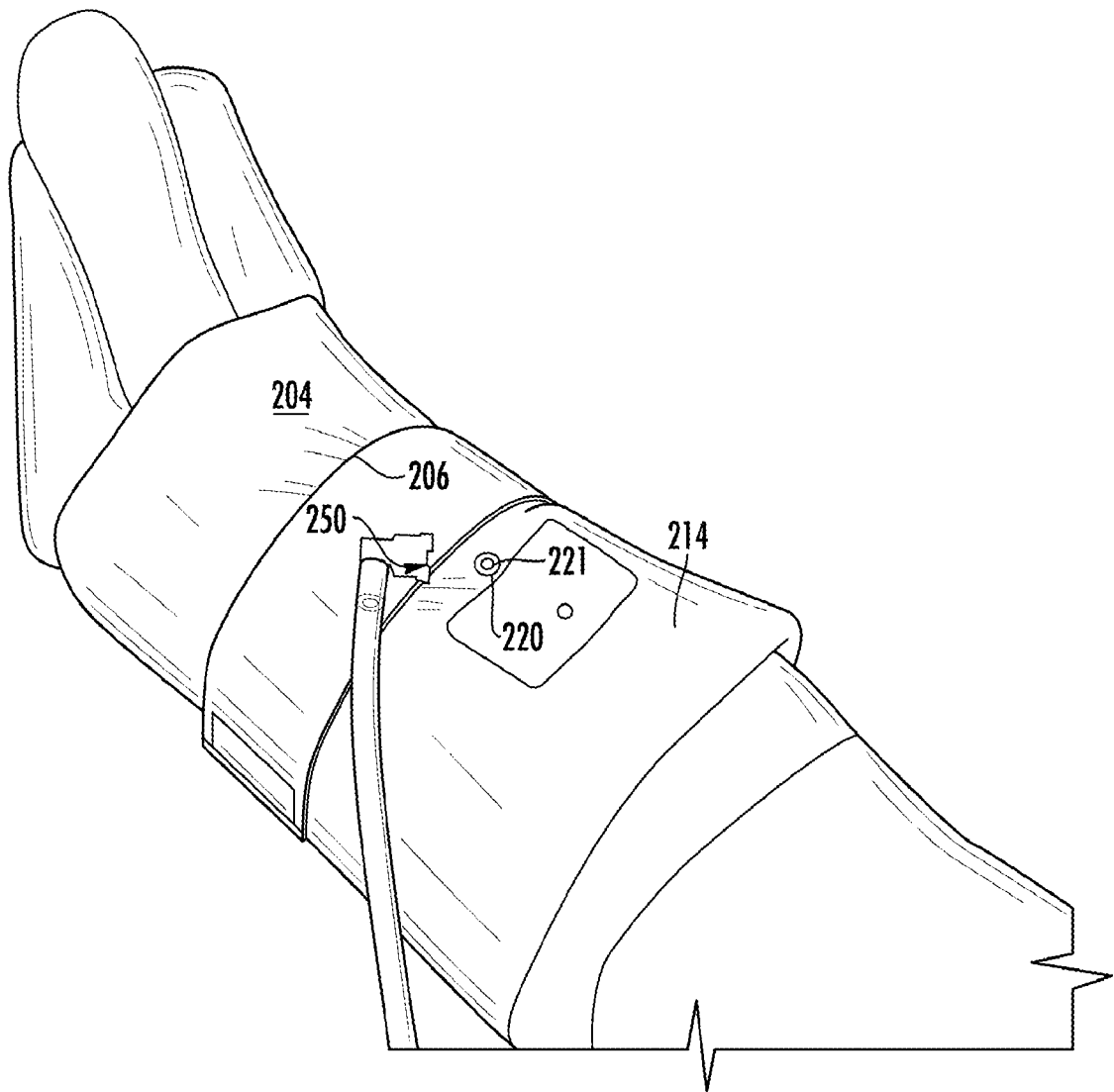
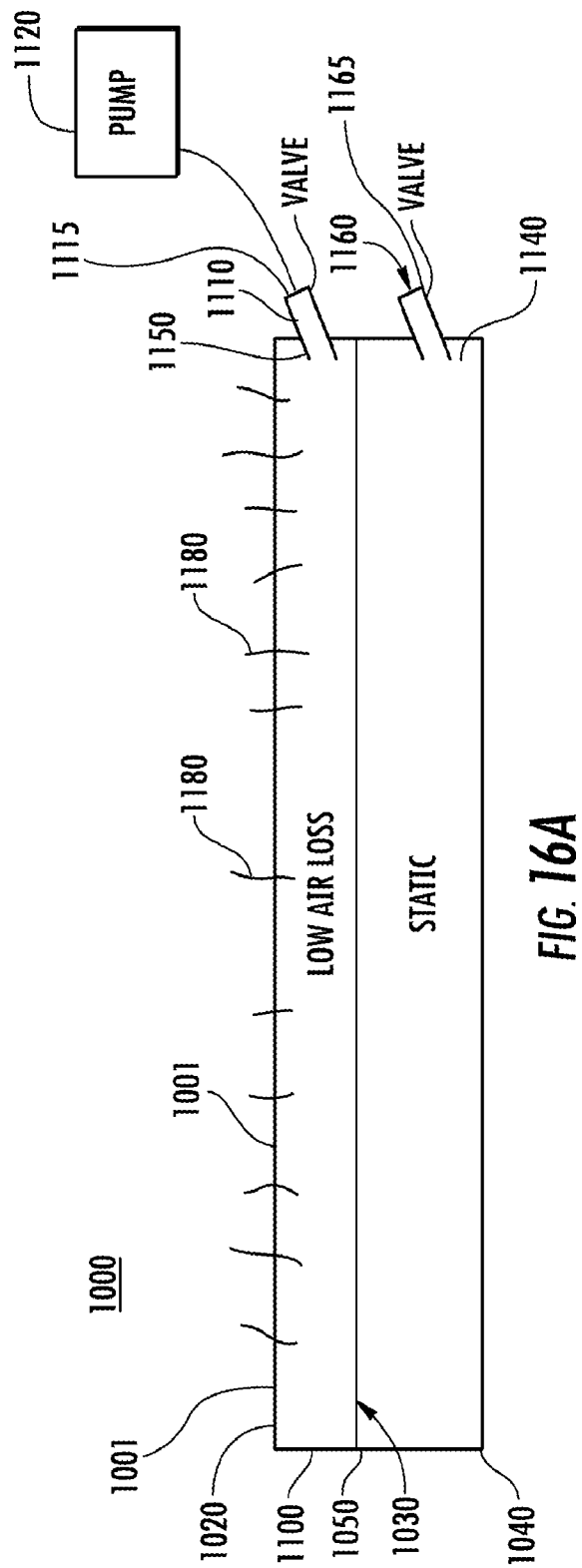


FIG. 15



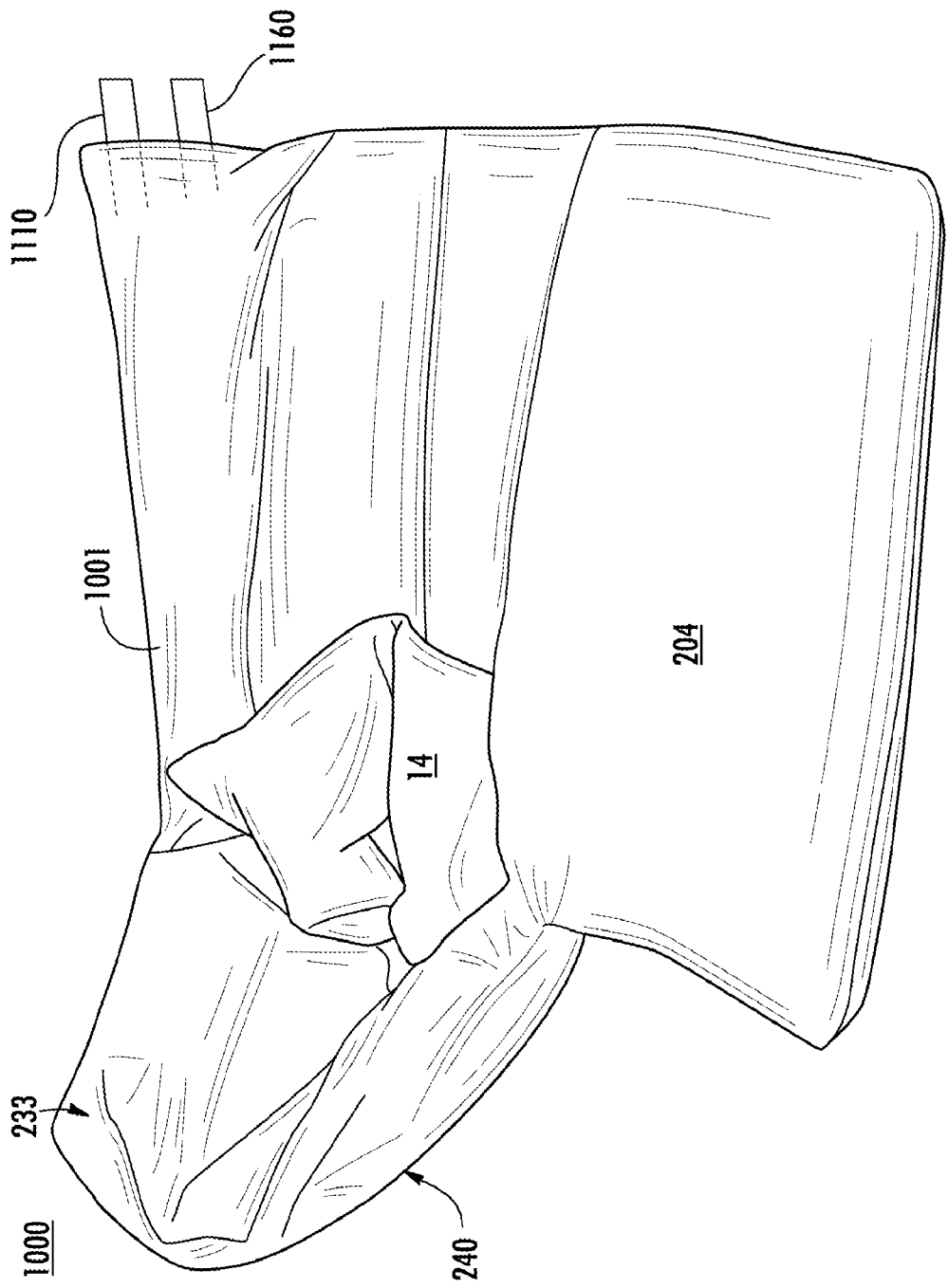


FIG. 16B

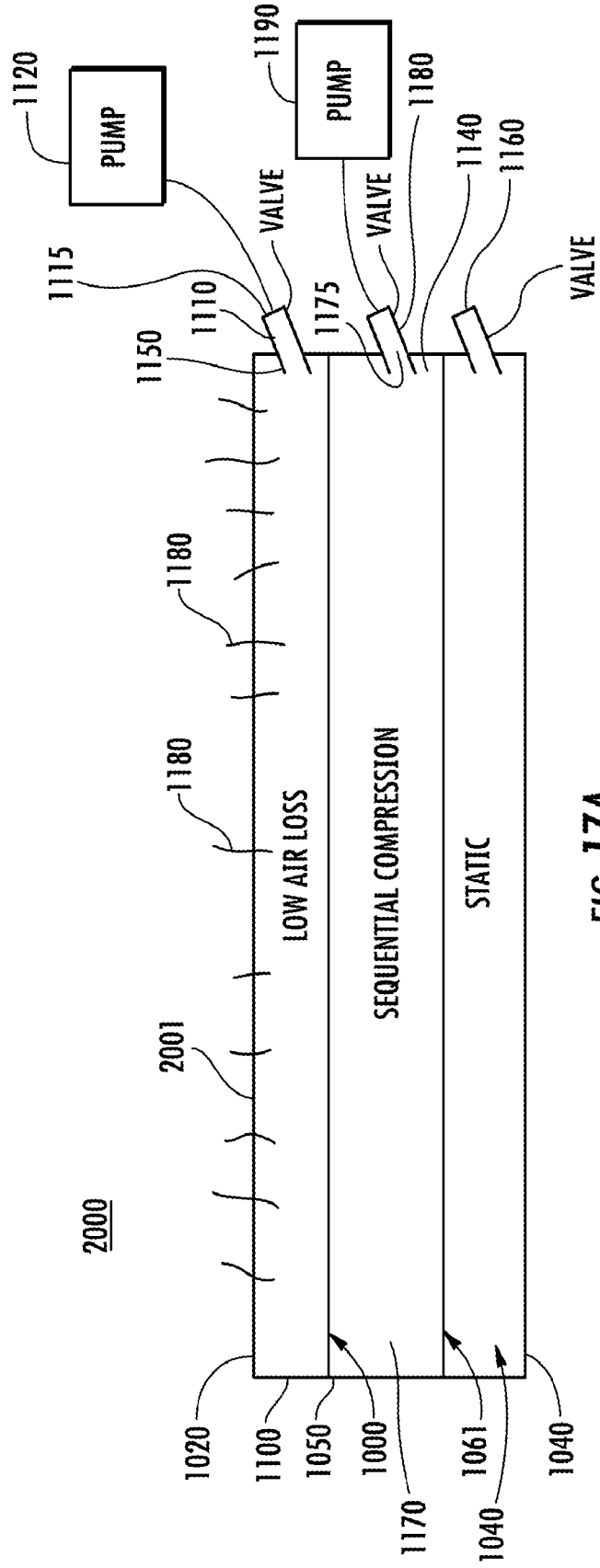


FIG. 17A

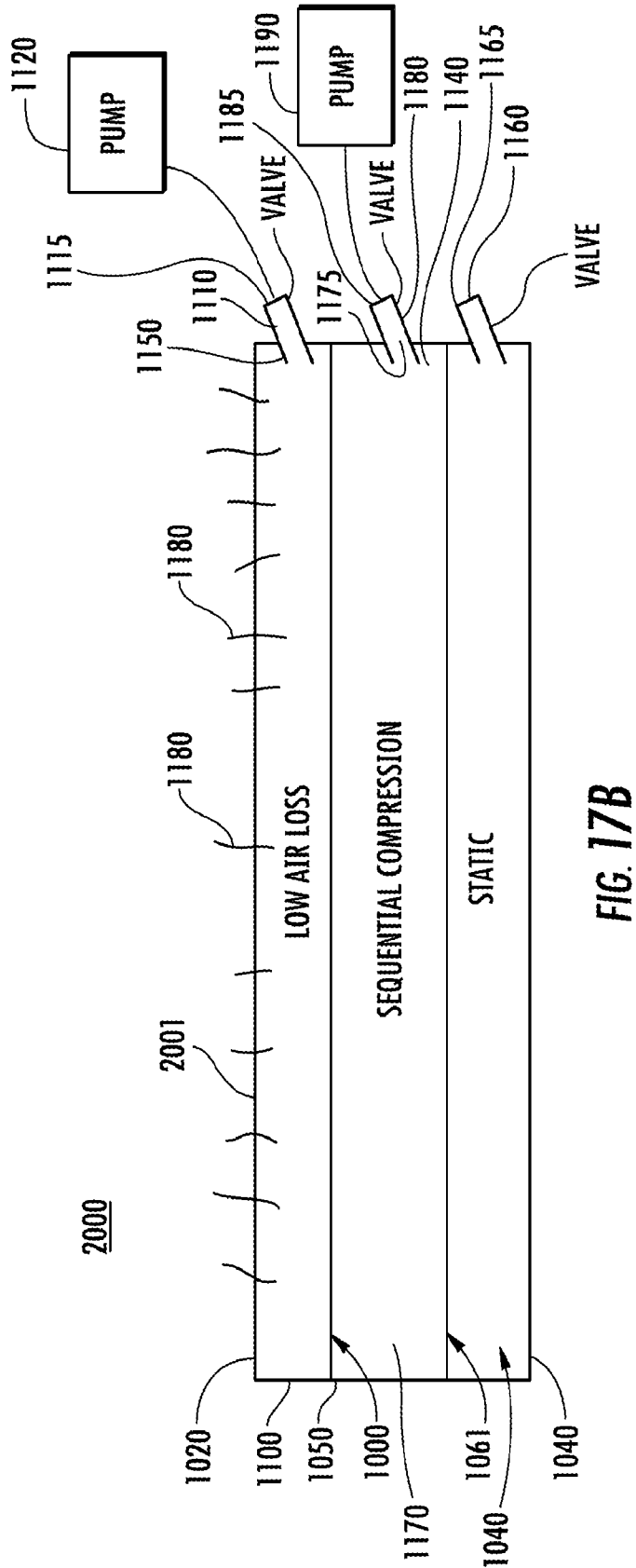


FIG. 17B

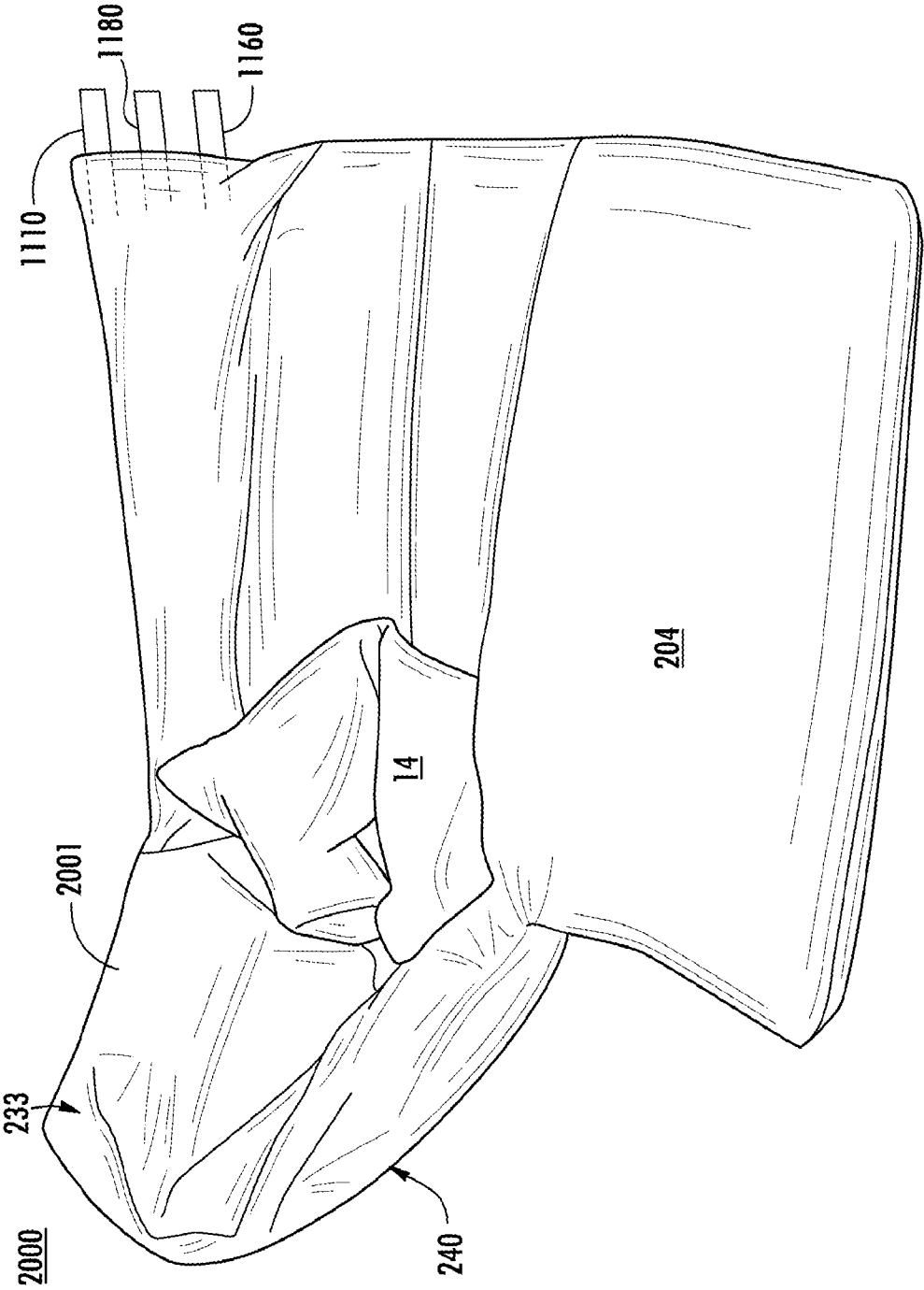


FIG. 17C

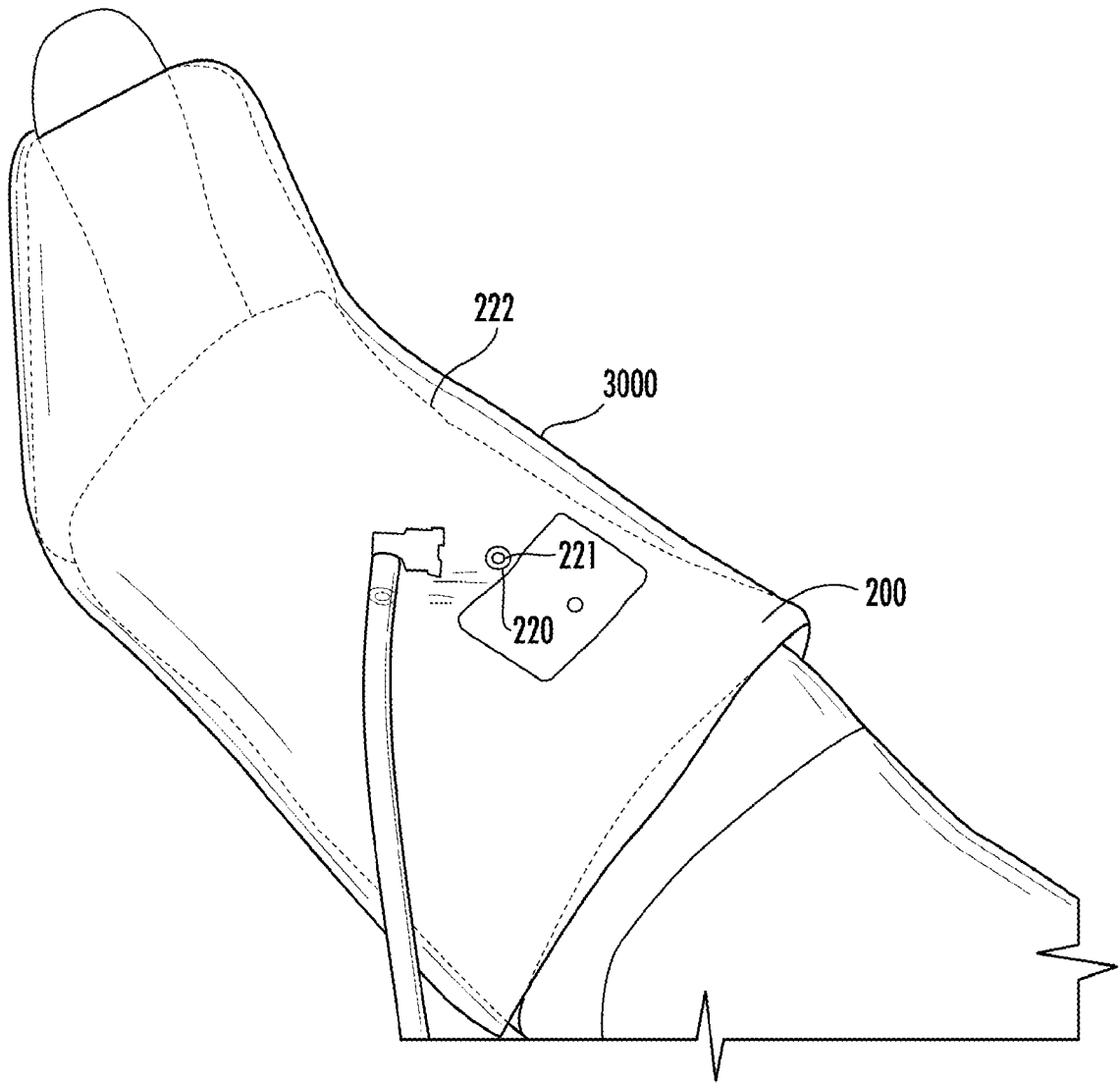


FIG. 18A

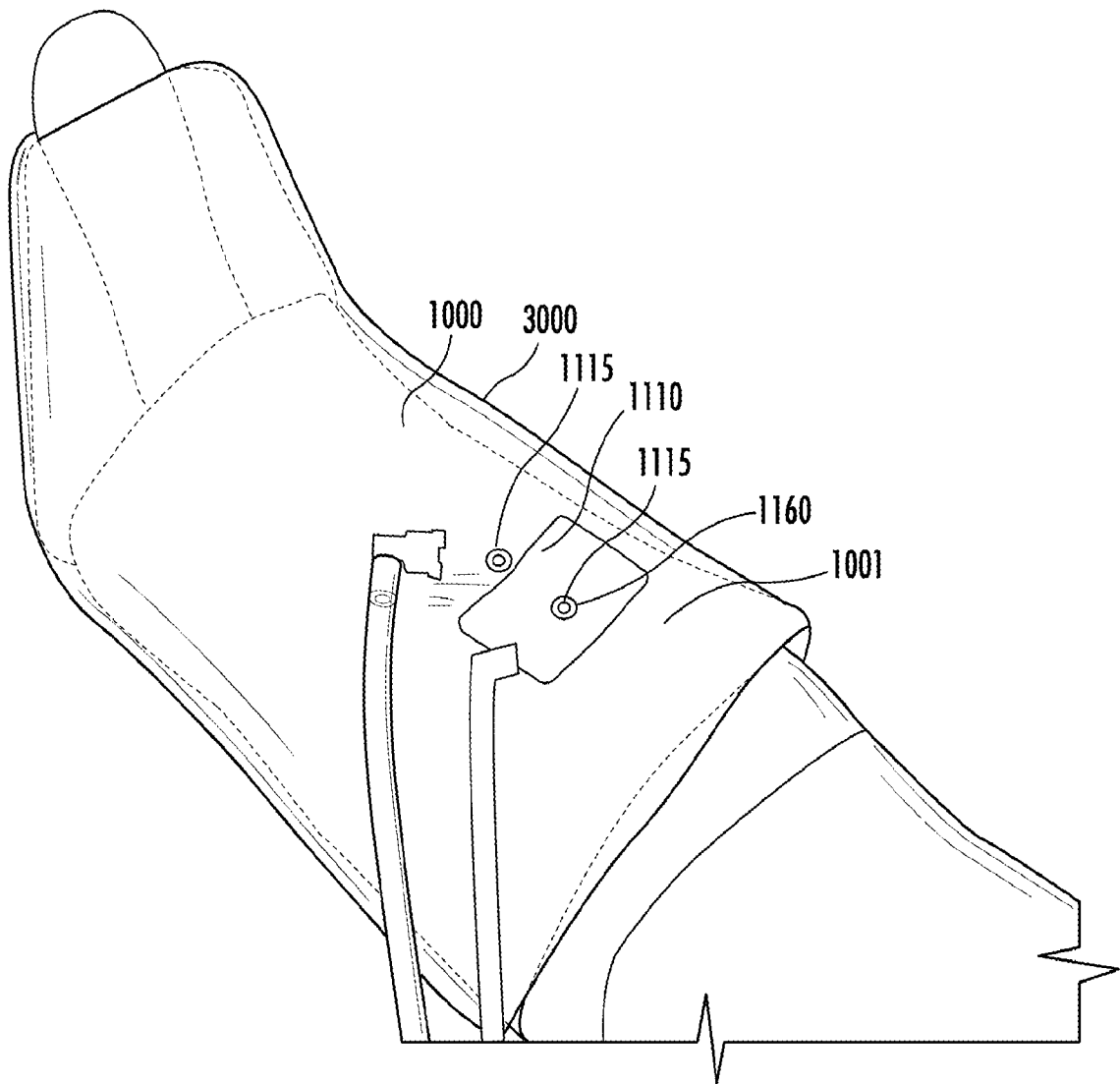


FIG. 18B

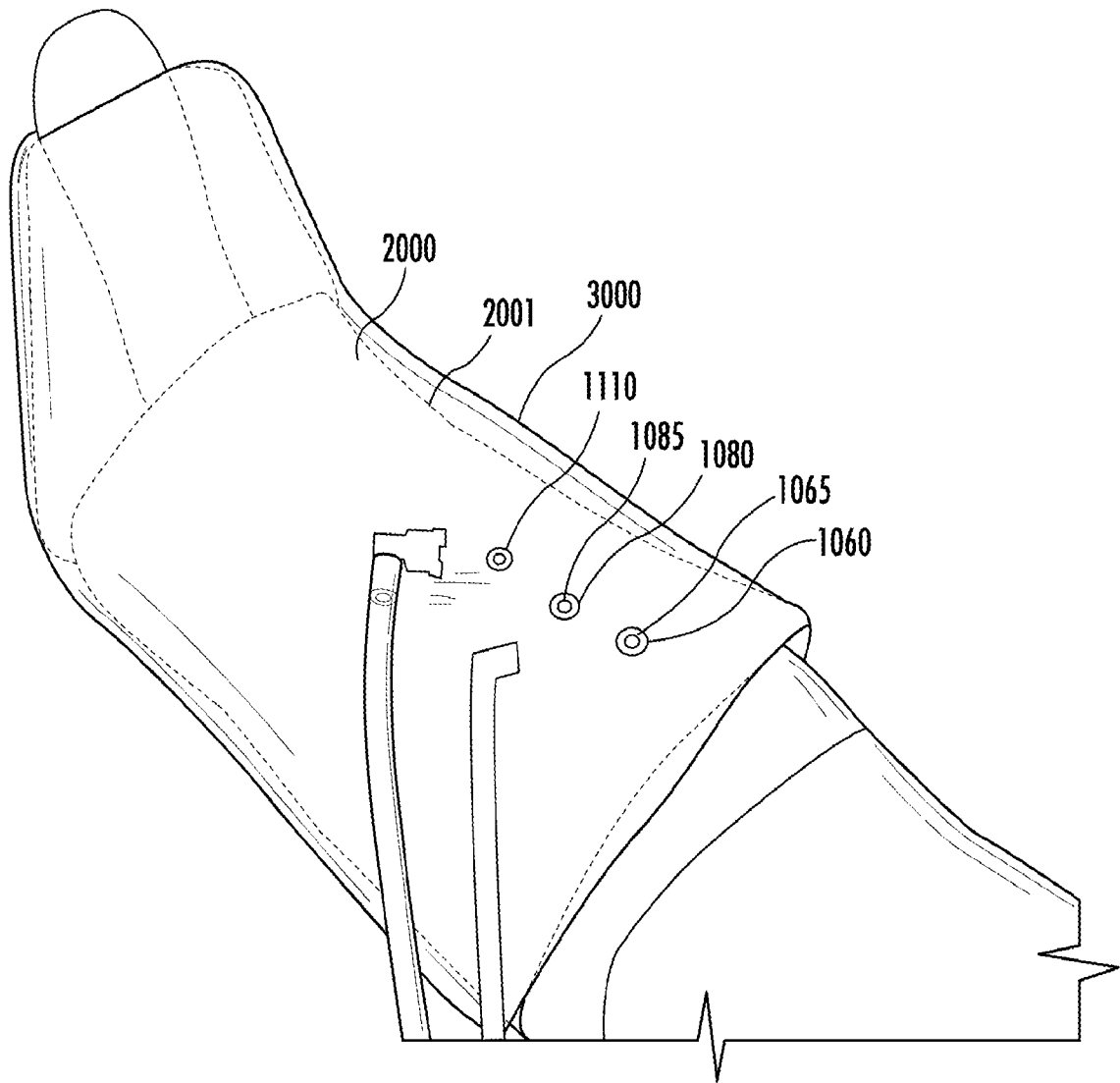


FIG. 18C

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2016/032196

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61H9/00

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/316481 A1 (PURDY WILLIAM [US] ET AL) 13 December 2012 (2012-12-13)	1-10, 13-22,30
Y	the whole document	11,12, 23,24,31
Y	US 2007/282230 A1 (VALDERRABANO VICTOR [CH] ET AL) 6 December 2007 (2007-12-06) paragraphs [0039], [0040]; figure 1	11,12, 23,24,31



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

26 August 2016

Date of mailing of the international search report

28/10/2016

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Schut, Timen

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/032196

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

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

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

see additional sheet

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

1-24, 30, 31

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-24, 30, 31

A support system for a body part comprising: an inner positioner, an outer support comprising a first plenum and a second plenum and a rigid outer shell surrounding or integral with the outer support and the corresponding method

2. claims: 25-29, 32, 33

A support system for a body part comprising: an inner positioner, an outer support comprising a first plenum, a second plenum and a third plenum and the corresponding method.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2016/032196

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012316481	A1	13-12-2012	NONE

US 2007282230	A1	06-12-2007	US 2007282230 A1 06-12-2007
		WO 2007078845 A2	12-07-2007
