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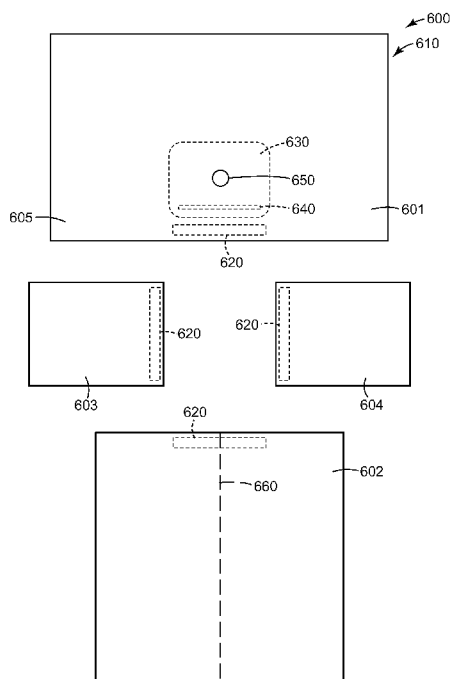
(54) **Title:** MULTI-SECTIONAL TEMPERATURE REGULATING SURGICAL BARRIER DEVICE

FIG. 6

(57) **Abstract:** At least some aspects of the present disclosure feature a temperature regulating surgical barrier device comprising a surgical drape and an attachment device. The surgical drape includes a plurality of drape sections. At least one of the drape sections includes an air impermeable drape sheet and an air permeable base sheet attached to the drape sheet to form an inflatable portion. The attachment device is configured to attach at least a portion of the surgical drape to a patient.

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MULTI-SECTIONAL TEMPERATURE REGULATING SURGICAL BARRIER DEVICE**Technical Field**

[0001] This disclosure relates generally to medical devices used during surgery to provide warming to patients and barrier functions to protect sterile field.

Summary

[0002] At least some aspects of the present disclosure feature a combination for use during surgery on a patient. The combination includes a surgical drape, an inflatable thermal blanket, a first attachment device, and a second attachment device. The surgical drape includes a plurality of drape sections, each drape section comprising a drape sheet of flexible material. The inflatable thermal blanket includes a base sheet, a material sheet attached to a first surface of the base sheet by a plurality of seals to form an inflatable portion, and a plurality of apertures through the base sheet within the inflatable portion. The first attachment device configured to attach the inflatable thermal blanket to the patient. The second attachment device configured to attach at least a portion of the surgical drape to the patient. At least one of the plurality of drape sections is integrated with or attached to the inflatable thermal blanket.

[0003] At least some aspects of the present disclosure feature a temperature regulating surgical barrier device comprising a surgical drape and an attachment device. The surgical drape includes a plurality of drape sections. At least one of the drape sections includes an air impermeable drape sheet and an air permeable base sheet attached to a first surface of the drape sheet via a plurality of seals to form an inflatable portion. The attachment device is configured to attach at least a portion of the surgical drape to a patient.

Brief Description of Drawings

[0004] The accompanying drawings are incorporated in and constitute a part of this specification and, together with the description, explain the advantages and principles of the invention. In the drawings,

[0005] Figure 1A is a side elevation view of an inflatable thermal blanket, with the blanket in use, and associated thermal apparatus indicated schematically; Figure 1B is an enlarged top plan view of the inflatable thermal blanket of Figure 1, opened flat;

[0006] Figure 2A is a perspective view of another embodiment of an inflatable thermal blanket;

[0007] Figure 2B is a bottom view of the embodiment illustrated in Figure 2A;

[0008] Figure 2C shows a cross sectional view of the embodiment of the inflatable thermal blanket illustrated in Figures 2A and 2B;

- [0009] Figures 2D is an enlarged view of a portion of the inflatable thermal blanket illustrated in Figure 2C;
- [0010] Figure 3 is an enlarged sectional view taken along line 3-3 of Figure 1B;
- [0011] Figure 4 is a further enlarged sectional view taken along line 4-4 of Figure 3;
- [0012] Figure 5 is a partial underside view of the inflatable thermal blanket of Figure 1A;
- [0013] Figure 6 illustrates a plan view of an embodiment of a multi-sectional temperature regulating surgical barrier device;
- [0014] Figures 7A and 7B illustrate two configuration of an adhesive area of an adhesive strip;
- [0015] Figures 8A and 8B are cross-sectional views of two embodiments of a surgical barrier device;
- [0016] Figures 9A and 9B illustrate diagrammatic cross-sectional views of embodiments of a surgical barrier device when the inflatable thermal blanket is inflated;
- [0017] Figures 9C and 9D illustrate various sizes and shapes of drape sections;
- [0018] Figure 10A is a diagrammatic plan view of an embodiment of a multi-sectional temperature regulating surgical barrier device;
- [0019] Figure 10B is a perspective view of the surgical barrier device of Figure 10A;
- [0020] Figure 11A is a diagrammatic plan view of another embodiment of a multi-sectional temperature regulating surgical barrier device;
- [0021] Figure 11B is a perspective view of the surgical barrier device of Figure 11A;
- [0022] Figure 12A is a diagrammatic cross sectional view of an embodiment of a surgical barrier device;
- [0023] Figure 12B is an enlargement of a portion of the surgical barrier device of Figure 12A;
- [0024] Figure 13A is a diagrammatic cross sectional view of another embodiment of a surgical barrier device;
- [0025] Figure 13B is an enlargement of a portion of the surgical barrier device of Figure 13A;
- [0026] Figure 14A is a diagrammatic cross sectional view of one other embodiment of a surgical barrier device; and
- [0027] Figure 14B is an enlargement of a portion of the surgical barrier device of Figure 14A.

Detailed Description

[0028] An inflatable thermal blanket is typically placed over a patient and inflated by a thermally controlled inflating medium, such as warmed air. The pressure of the inflating medium causes the blanket to expel the warmed air through holes in the underside of the blanket, thereby creating an ambient environment about the patient, the thermal characteristics of which are determined by the temperature of the inflating medium. Such an inflatable thermal blanket is intended, among other things, for the treatment or prevention of hypothermia, as might occur intraoperatively, or postoperatively. They also are used preoperatively to warm the patient to help prevent intraoperative hypothermia.

[0029] A surgical drape is the usual means employed for provision of a barrier between a surgical site and other fields, during surgery. Typically, a surgical drape is employed for such purposes as keeping fluids confined to the surgical site, maintaining sterility of the surgical site, and screening the anesthesia work area.

[0030] Embodiments of the present disclosure direct to a multi-sectional temperature regulating surgical barrier device that can be configured to use with various surgical procedure types and patient sizes. In some embodiments, the multi-sectional temperature regulating surgical barrier device includes a surgical drape having multiple drape sections, at least one drape section integrated with or attached to an inflatable thermal blanket, a first attachment device configured to attach the inflatable thermal blanket to the patient, and a second attachment device configured to attach at least a portion of the surgical drape to the patient. The drape sections can be disposed to form a surgical access with various configurations suitable to the surgical site. For example, the surgical access can have different shapes and disposed at different sites.

[0031] Inflatable Thermal Blankets:

[0032] Inflatable thermal blanket refers to an inflatable structure for delivering a thermally controlled inflating medium to space occupied by at least a portion of a patient's body when the inflatable thermal blanket is inflated. The purpose of the inflatable thermal blanket is to efficiently administer a uniformly thermally-controlled bath of the inflating medium to a patient within space beneath the blanket. As used herein the term "inflatable" refers to a structure which increases in volume when air or other gas is supplied a pressure greater than atmospheric pressure to the interior of the structure. Typically these structures inflate at relatively low pressures such as pressures less than 100mmHg, preferably at pressures less than 50mmHg, more preferably at pressures less than 25mmHg. Typically the volume will increase by greater than 100% volume.

[0033] An embodiment of inflatable thermal blanket is illustrated in Figure 1A. In Figure 1A, an inflatable thermal blanket **10** has a head end **12**, a foot end **14** and two lateral edges, one such lateral edge indicated by **15**. In the embodiment as illustrated, the blanket **10** is inflated via an inflation inlet cuff **16** that is connected to a heater/blower assembly **18**. In some cases, the heater/blower assembly **18** has a compressor **18a**, a heater **18b** and a control unit **18c** which may include user-selectable fan speeds, controllable heat amounts and temperature control. The heater/blower assembly **18** provides a stream of heated air through a connecting hose **20**. When the heater/blower assembly **18** is operated, the stream of heated airflows through the inflation cuff **16**. Figure 1B is a plan view of the inflatable thermal blanket **10** opened flat to show details of its structure. Figure 1B illustrates the upper surface of the inflatable thermal blanket, that is, the side that is visible in Figure 1A. As seen, the upper surface consists of a parallel array of elongated channels of which **30** and **32** are the lateral most channels, **34** is the center channel, and the channels **38** are arrayed between one of the lateral most channels and the center channel. Each channel is separated from an adjacent channel by a seam, which can be continuous or discontinuous, one of which is indicated by **40**. The seam **40** separates the channel **32** and its nearest adjacent neighbor **38**. The

discontinuous seam **40** is interrupted by passageways **42** communicating between the channels. An interrupted seam separates every channel from one adjacent neighboring channel. The seams permit the inflatable thermal blanket, when inflated, to assume a tubular structure on the upper surface, while the ports **42** permit full circulation of the inflating medium throughout the array of channels. The foot-end seam **45** is continuous. The channels are inflated through the center channel **34** which transitions to a port **36**, through which the inflation cuff **16** is inserted. A seal can be made between the inflation port **36** and the inflation cuff **16** by any conventional means, for example, an o-ring, or even tape. When the inflating medium is introduced into the center channel **34**, it flows laterally from the center channel into all of the other channels through the ports **42**.

[0034] Construction details of embodiments of the inflatable thermal blanket **10** are illustrated in Figures 3 and 4. In some embodiments, the inflatable thermal blanket **10** is assembled from a base sheet and a top sheet. The base sheet consists of an underside layer **50** formed from a flexible, fibrous, preferably non-woven structure composed of synthetic or natural materials capable of bonding to an upper side layer **52** of a heat-sealable synthetic material such as plastic. For example, the underside layer **50** may be a non-woven, hydroentangled polyester material and the upper side layer **52** may include a polyolefin such as a polypropylene film which is extrusion-coated, thermally laminated, or adhesively laminated onto the polyester layer **50**. Alternatively, the underside layer **50** may comprise a non-woven, paper-based material to which the upper side layer **52**, including either a polyethylene or polypropylene film, has been glue laminated. In one embodiment, the layers **50** and **52** are made with a stratum of absorbent tissue paper prelaminated with a layer of heat-sealable plastic has been used.

[0035] The top sheet **53** of the inflatable thermal blanket preferably comprises the same material as the upper side layer **52** of the base sheet. The top sheet **53** thus may consist of a sheet of plastic bonded to the plastic upper side **52** of the base sheet. It is preferably attached by a continuously-running web process including stations that provide an interruptible heat-sealing process. This interruptible heat sealing process can be controlled to form elongate heat seals that define the inflatable channels therebetween. The seals can be formed as continuous air impervious seals or discontinuous air permeable seals. The interruptible heat sealing process is used to form the continuous seams, one of which is the seam **40** in Figure 1B, the interrupted seams, one of which is indicated by **54**, and the inflatable channels, one of which is indicated by **55**. As can be seen in Figure 3, the interruption of the seam **54** forms a passageway **56** between adjacent channels **55** and **57**. In some cases, absorbent material can be applied to the thermal blanket, for example, applied as a single material layer **60**. The absorbent material can be bonded to the upper plastic layer by heat processing or by gluing.

[0036] The inflatable thermal blanket is enabled to bathe a patient in the thermally controlled inflating medium introduced into the inflatable thermal blanket, when inflated, by means of a plurality of apertures **62** shown in Figures 4 and 5. The apertures extend through the underside of the blanket, which includes the layers **50** and **52**. In some implementations, the apertures **62** are made in the footprints of the channels

of the blanket upper side according to a pattern which has been determined to deliver a very uniform thermal bath. In this regard, no apertures are provided through the underside into the lateral most channels **30** and **32**, or into the center channel **34**. In addition, the apertures **62** are provided through the underside to the channels in a density which varies inversely with the proximity of the channel to the center channel **34**. Thus, the density of apertures increases from the channel **38a** through the channel **38d**. The varying density of the apertures **62** tends to reduce this gradient further by forcing hotter air to the edges of the blanket. Thus, the thermal bath delivered to the patient is of a generally uniform temperature. The aperture density variation also equalizes the flow of inflating medium out of the apertures. As will be evident, the inflating pressure will be greatest at the center channel **34** and will tend to diminish toward the lateral edges of the inflatable thermal blanket. Therefore, fewer apertures are required for the channels near the center channel **34** to deliver the same amount of air as the relatively greater number of apertures in the channels at a greater distance from the center channel **34**. The apertures comprise openings which can be of any appropriate shape.

[0037] Figures 2A and 2B illustrate another embodiment of an inflatable thermal blanket **210**. Figure 2A is a perspective view of the embodiment of the inflatable thermal blanket **210** and Figure 2B is a bottom view of the embodiment illustrated in Figure 2A. The inflatable thermal blanket **210** includes a material layer **212** and a base layer **213** brought together at a periphery **214**. The top layer **212** is attached to the bottom layer **213** at least one location within the periphery **214**. In some embodiments, the top layer **212** is attached to the bottom layer **213** at a plurality of locations **216**. The top layer **212** and/or the bottom layer **213** are air permeable using various materials or mechanical structures, for example, air-permeable materials, apertures, interstices, slits, or the like. In order to provide an input of pressurized and thermally regulated air to inflate the blanket **210**, one or more openings are provided in the blanket **210**. For example, the openings can include one or more inlet ports (**218** illustrated in Figure 2A), cuffs (e.g. **16** illustrated in Figure 1A), sleeve openings at the edge of the top and bottom layers, or the like. A relatively stiff collar **219** of material is provided for receiving the end of an air hose **A**. Another end (not shown) of the air hose **A** may be connected to a source of pressurized, warmed air, such as the heater/blower that is illustrated in Figure 1A. The air is conducted through the air hose **A** through the inlet port **218** whence it flows throughout the interior of the blanket **210** between the top and bottom layers of the blanket **210** and causes the blanket **210** to inflate. More than one inflation port may be provided. For example, the port **220** with inflation collar **221** is shown in Figure 2A. The unused inflation port or ports would, of course, be sealed in order to prevent the exit of the pressurized gas during operation of the blanket **210**.

[0038] Figure 2C shows a cross sectional view of the embodiment of the inflatable thermal blanket illustrated in Figures 2A and 2B. Figure 2D is an enlarged view of a portion of the inflatable thermal blanket illustrated in Figure 2C. In some embodiments, the top layer **212** and/or bottom layer **213** are made from a polyester non-woven extrusion **212p** and **213p**, each with a coating of polypropylene **212c** and **213c** on one side. One of the top layer **212** and bottom layer **213** may have holes **229** formed by

punching, slitting, or cutting to permit the flow of pressurized air from the pad through the layer. In some cases, the holes **229** can be opened through both layers **212** and **213**. When the pad is assembled, the polypropylene-coated side **212c** of the top layer **212** is sealed to the polypropylene-coated side **213c** of the bottom layer **213** at the periphery **214**, and the one or more locations **216** to form the pad. The sealing process can use various techniques, for example, ultrasonic welding, radio frequency welding, heat sealing, or the like. Alternatively, the top layer **212** and bottom layer **213** may each include a laminate of polypropylene and polyolefin web with holes formed in at least one of the layers to support passage of pressurized air. In yet another embodiment, at least one of the layers **212** and **213** can use air permeable material, for example, spunbond-meltblown-spunbond (SMS) nonwoven material, or the like.

[0039] Multi-sectional temperature regulating surgical barrier device

[0040] Figure 6 illustrates a plan view of an embodiment of a multi-sectional temperature regulating surgical barrier device **600**. The surgical barrier device **600** includes a surgical drape **610** and an inflatable thermal blanket **630**. The surgical drape **610** includes a plurality of drape sections, **601**, **602**, **603**, and **604** as illustrated in Figure 6. Each drape section includes a drape sheet of flexible material **605** that is configured to provide barrier for a surgical site on a patient's body to protect the sterile field. The inflatable thermal blanket **630** is configured to cover a portion of the patient's body and can be any of the embodiments as described above. The surgical barrier device **600** can optionally include a first attachment device **640** disposed on one or both surfaces of the inflatable thermal blanket **630** and configured to attach the inflatable thermal blanket **630** to the patient and/or the surgical drape **610**. The first attachment device **640** may be disposed on either the patient side of the thermal blanket **630** or on the drape side of the thermal blanket or both. In some cases, the first attachment device **640** can be applied to the thermal blanket **630**. In some other cases, the first attachment device **640** can be provided separately from the thermal blanket **630**. Additionally, the attachment device **640** may include one or more adhesive and/or mechanical attachment means. In some configurations, the attachment device **640** can include a plurality of attachment segments on one or both sides of the thermal warming blanket allowing a health care provider to reposition the thermal blanket relative to the surgical drape **610** during the operation. When used to secure the thermal blanket **630** to the patient, the attachment device **640** may include one or more individual sections of skin compatible adhesive, each section with an individual release liner. When used to secure the thermal blanket **630** to the surgical drape **610**, the attachment device **640** may include one or more individual sections of repositionable pressure sensitive adhesive, each section with an individual release liner, or mechanical fasteners such as those described below related to the attachment device **809** in Figures 8A and 8B.

[0041] In some embodiments, the surgical barrier device **600** can optionally include a second attachment device **620** disposed on a surface of the surgical drape **610** and configured to attach at least a portion of the surgical drape **610** to the patient. In some cases, the second attachment device **620** can be provided separately from the surgical drape **610**. In the embodiment illustrated in Figure 6, the second attachment

device **620** can include a plurality of adhesive strips, where each strip is configured to attach a portion of a drape section to the patient. In some cases, at least one of the drape sections includes a mark to identify a portion of the drape section, the location and/or perimeter of the inflatable warming blanket, for example, such as **650** and **660** illustrated in Figure 6. For example, mark **650** can be used to show the center of the inflatable thermal blanket **630**. As another example, mark **660** can be used to show the vertical middle line of the drape section **602**. Additionally, the surgical drape **610** can be shaded, colored, marked, or labeled with an adhesive label in an area, areas, or pattern that represents the location of the underlying inflatable thermal blanket **630**. As illustrated in Figure 6, the drape sections are generally rectangular. In some alternative embodiments, the surgical drape **610** can have drape sections with various sizes and shapes.

[0042] The first attachment device **640** and /or second attachment device **620** can include skin compatible adhesive that provides an adequate seal between the surgical site and the rest of the patient, portions of which may be warmed by the inflatable thermal blanket. As illustrated in Figure 7A, the adhesive of an adhesive strip can be continuous. Alternatively, as illustrated in Figure 7B, an adhesive strip can have patterned adhesive areas, where one or more adhesive areas may include adhesives of various properties and compositions to enable optimal adhesion to either skin, drape materials, or other surfaces. In addition, such patterned adhesive areas can have better insulation capability to prevent inflating medium from leaking through the adhesive strip. Preferred adhesives are relatively unaffected by the warm air and do not build adhesion excessively with exposed to this heat for two hours or more. Preferred adhesives include acrylates and silicone pressure sensitive adhesives.

[0043] Figures 8A and 8B are cross-sectional views of two embodiments of a surgical barrier device **800** with a surgical drape attached to or integrated with an inflatable thermal blanket. As illustrated in Figure 8A, the surgical barrier device **800** includes a drape sheet **810**, a material sheet **803**, a base sheet **804**, and an attachment device **809**. The drape sheet **810** includes a barrier sheet **802** and an optional top sheet **801**. The barrier sheet **802** is impermeable to liquid penetration. Preferred barrier sheets are free of pin holes. The top sheet **801** is typically a nonwoven fabric, such as a spunbond, hydroentangled or carded web. The top sheet **801** may be hydrophilic or hydrophobic and may have treatment in or on the fibers to impart this property. In some cases, the base sheet **804** is air permeable and the material sheet **803** is not air permeable. The material sheet **803** is attached to a surface of the base sheet **804** to form an inflatable portion. The attachment device **809** can use any permanent or releasable attachment means, for example, two-sided adhesive, perforated tear-away tabs, hook and loop, sewing, snaps, heat, ultrasonic, rivets, repositionable adhesives, mechanical reclosable fasteners, or the like. In some cases, the drape sheet **810** has a first drape surface **810a** and a second drape surface **810b**, where the first drape surface has greater friction coefficient than the second drape surface. In some embodiments, the coefficient of friction of either surface **810a** or **810b** can be selectively varied to create areas that can retain or be adapted to retain surgical related instruments, cables, or hoses.

[0044] Alternatively, as illustrated in Figure 8B, the surgical barrier device **800** includes a drape sheet **810**, a base sheet **804**, and an attachment device **809**. In such embodiment, the drape sheet **810** is not air permeable. The drape sheet **810** is attached to a surface of the base sheet **804** to form an inflatable portion by the attachment device **809**.

[0045] Figure 9A illustrates a diagrammatic cross-sectional view of an embodiment of a surgical barrier device **900** when the inflatable thermal blanket is inflated. The surgical barrier device **900** includes a surgical drape **910**, an inflatable thermal blanket **920**, an attachment device **906** configured to attach the drape **910** to a patient **902**. The surgical drape includes a drape sheet **905**. The inflatable thermal blanket **920** includes a base sheet **908** and a material sheet **907**. The inflatable portion **921** formed by a base sheet **908** and a material sheet **907** is configured to have a recess **926** close to the location where the surgical drape **910** is attached to the patient **902** via the attachment device **906**. In some cases, this recess may be formed by joining or sealing portions of base sheet **908** and material sheet **907** at one or more locations in order to limit the inflatable loft of the thermal blanket **920** at discrete locations. In some cases, the blanket **920** can be attached to the patient **902** via an attachment device **924**.

[0046] In some cases, the inflatable portion may have sections with various volumes when inflated. As an example, the inflatable portion may have a section **931** with lower volume than the volume of the other sections **932** and **933**, as illustrated in Figure 9B. In some configurations, the section **931** is in the middle of the warming blanket. Such configurations can provide uniform warming across the blanket. In some other configurations, the volume of the section **932** can be different from the volume of the section **933**.

[0047] In some cases, a surgical barrier device can include more than one inflatable thermal blanket and various numbers and shapes of drape sections, as illustrated in Figures 9C and 9D. Referring to Figure 9C, a surgical barrier device **940** can include two drape sections **951b** and **952b** and two inflatable thermal blankets **960a** and **960b**. The inflatable thermal blankets **960a** and **960b** can be attached to or integrated with the drape sections as any of the embodiments described above. In some cases, the inflatable thermal blankets **960a** or **960b** may extend beyond the perimeter of the drape sections **951b** or **951b**, to cover the patient. The drape sections **951b** and **952b** are generally L-shape. Referring to Figure 9D, a surgical barrier device **940** can include two drape sections **951c** and **952c** and an inflatable thermal blanket **960c**. The drape section **951c** is generally rectangular and the drape section **952c** is generally U-shape.

[0048] Figures 10A and 10B show one embodiment of the multi-sectional temperature regulating surgical barrier device, in which the inflatable thermal blanket is deployed over the pelvic area and lower extremities of the patient. In Figure 10A, a patient **300** reclines on an examination table **302**. The patient's head **304** lies prone on the table **302**, as do the patient's torso **306**, arms **308**, legs **310**, and feet **312**. The patient's arms **308** lie at the patient's side and the patient's feet **312** are slightly apart. A surgical barrier device **319** includes an inflatable thermal blanket **320**, constructed to warm convectively by exhausting warm air onto the patient **300**, and a surgical drape **321** constructed to provide a fluid barrier

between a surgical site on a patient's body and the remainder of the patient's body. The surgical drape **321** includes two drape sections **321a** and **321b**. As illustrated, the sides **326a** and **327a** of the drape section **321a** can overlap with the sides **326b** and **327b** of the drape section **321b**. The inflatable thermal blanket **320** is configured to cover the patient's pelvic area and lower extremities, while the drape **321** provides barrier functions, in addition to covering additional portions of the patient and providing access to a surgical site. The surgical barrier device **319** includes two ends **322** and **324** and an inflation inlet port **328** that opens into the inflatable thermal blanket **320**. The inlet port **328** may be connected through a flexible heater hose, such as the hose **20** shown in Figure 1, to a heater/blower assembly such as the assembly **18** shown in Figure 1A. In Figures 10A and 10B, the inlet port **328** is shown mounted on the underside of the inflatable thermal blanket **320**, but it could also be mounted on the upper side or the edge of the blanket.

[0049] The inflatable thermal blanket **320** is formed as an inflatable covering that includes a flexible upper sheet **340** and a flexible base sheet **342**, as shown in Figures 12A and 12B. These sheets are secured to each other along a peripheral seam **344** that extends around the periphery of the inflatable thermal blanket. The peripheral seam **344** can be formed by a heat sealing process, as described above. It is preferably continuous, but may also be formed with interruptions at selected locations thereof to facilitate egress of the inflating medium, e.g., heated air, for the purposes described above. The upper sheet **340** and the base sheet **342** are constructed using the materials and techniques described above, forming a parallel array of elongated channels using seams formed by elongated heat seals as shown in Figures 1A and 1B, an array of quasi-discrete inflatable spaces **348** formed using point seals **350**, as shown in Figures 10A and 10B, or other equivalent embodiments. As Figures 12A and 12B show, a plurality of apertures **352** (identical to the apertures **62** shown in Figure 5) open through the base sheet **342** into the inflatable thermal blanket **320**. The apertures allow convective delivery of the inflating medium into the space surrounding the patient, which is enclosed by the surgical barrier device **319**. The base sheet **342** of the inflatable thermal blanket **320** can be constructed like the base sheet of Figure 3, which comprises an underside layer **50** made from a flexible, fibrous material, and an upper side layer **52** made from a heat-sealable synthetic material. The apertures may be formed as holes extending through both of the layers **50** and **52** of this base sheet. Alternatively, the apertures may be formed as holes extending through the upper layer **52** of the base sheet, and as spaces which naturally occur between the fibers of the fibrous material used to form the underside layer **50**.

[0050] Returning to Figures 10A and 10B, the inflatable thermal blanket **320** is attached to, or integrally formed with, one or more drape sections of the surgical drape **321**. The drape **321** including drape sections **321a** and **321b**, extends from the periphery of the inflatable thermal blanket **320**, extends outwardly to define the ends **322** and **324** and the sides **326** and **327** of the surgical barrier device **319**. As shown in Figure 10A, the drape sections **321a** and **321b** are generally L-shape. The surgical drape **321** is preferably sized so that it extends over the entire upper surface of the table **302**, so as to completely cover

the patient **300**. As such, the end **322** extends at least to cover the patient's head, the end **324** extends at least to cover the patient's feet, and the sides **326** and **327** extend at least to cover the patient's sides, arms and legs. More preferably, the drape **321**, at the foot end **324** and sides **326** and **327**, hangs well below the edge of the table **302**.

[0051] In order to provide access to the patient **300** for performing surgery at a surgical site **362**, the drape sections of the surgical drape **321** can form a surgical access window **364**. With a surgical drape **321** having multiple drape sections, a health care provider can lay down each drape section to form a surgical access window **364** at a desired location and with a suitable size and shape. Additionally, one or more drape sections can have a warming blanket integrated with or attached to the drape sheet such that the health care provider can control the warming configuration. Optionally, the surgical barrier device **319** can include a surgical incise drape **365** (i.e., an adhesive coated flexible plastic barrier drape adhered to the patient through which a surgeon makes an incision) that can be attached to the patient covering the surgical site **362**. The surgical incise drape **365** is configured to cover at least a portion of the surgical access **364**. An attachment device **366**, such as one or more pressure sensitive adhesive strips, may be provided around the edges of the surgical access **364** in order to secure the drape **321** to the patient and to provide a seal that isolates the surgical site and keeps the inflating medium away from it. Because the drape **321** is not inflatable, it may be pressed flush against the patient **300** around the periphery of the surgical access **364**, and optionally secured, so that unobstructed access to the patient is ensured. Optionally, another attachment device **352**, such as one or more surgical adhesive strips, may be provided at the edge of the inflatable thermal blanket **320** proximate to the surgical access window **364** that can keep the inflating medium away from the surgical site. In the implementation as illustrated, the inflatable thermal blanket **320** is attached to the patient at a location that is covered by the surgical drape **321**. Optionally, a third attachment device (not shown), which may be applied on one or more drape sections or provided separately, can be used to releasably attach at least two of the drape sections to one another. The third attachment device can use pressure sensitive adhesive materials, nontacky adhesive materials, perforated connections, static clings, and a combination thereof.

[0052] The drape **321** is employed for the same purposes as surgical drapes that are known in the art. The drape **321** also helps retain the inflating medium proximate to the patient body, after it has been exhausted from the blanket **320** through apertures in the base sheet thereof. Air that is exhausted from the inflatable thermal blanket **320** flows beyond the edge thereof and beneath the drape **321**, where it is maintained in proximity to the patient **300**. At the head end **322**, it is necessary to keep the drape **321** away from the patient's nose and mouth, so that respiration is not impaired. For that purpose, a frame structure, which may be formed by a pair of vertical posts **368** mounted on the table **302**, is provided. The head end **322** of the surgical barrier structure **319** may be wrapped around the posts **368** and secured using tape **370** or any other appropriate fastening device, such as clips, etc.

[0053] A drape section can be formed in a variety of ways. As shown in Figures 12A and 12B, a drape section **321x** of the drape **321** can be formed as an extension of the material forming the upper sheet **340** of the inflatable thermal blanket **320**. Alternatively, as shown in Figures 13A and 13B, the drape section **321x** can be formed as an extension of the material forming the base sheet **342** of the inflatable thermal blanket **320**. A drape section can also be formed as an extension of both of the aforementioned sheets **340** and **342**. This is shown by the dotted line **340a**, which represents extension of the upper sheet **340**, if desired. In these embodiments, the drape section **321x** is formed integrally with the inflatable thermal blanket **320**.

[0054] Alternatively, as shown in Figures 14A and 14B, the drape section **321x** can be formed as one or more separate sheets of material **372** that are attached by heat sealing, gluing, welding or the like, around the periphery of the upper sheet **340** (or the base sheet **342**) at the location of the edge seam **344**. Each sheet **372** may be configured as fringe sheet that is attached at an edge portion thereof to the upper sheet **340** (or the base sheet **342**). More preferably, however, one or more single large sheets may be placed over and attached to the top of the upper sheet **340**.

[0055] Figure 11A illustrates a plan view of one embodiment of a surgical barrier device **419** used on a patient. Figure 11B is a perspective view of the embodiment depicted in Figure 11A. As illustrated in Figures 11A and 11B, the surgical barrier device **419** is used in abdominal surgery, in which an inflatable thermal blanket **420** is deployed for thermally bathing the chest and upper extremities of a patient, and a surgical drape **421** is deployed for covering portions of the patient's body, while performing barrier functions and providing access to a surgical site in the patient's abdomen and lower chest area.

[0056] In Figure 11A, a patient **400** is laid on an examination table **402**. The patient's head **404** lies prone on the table **402**, as do the patient's torso **406**, arms **408**, legs **410** and feet **412**. The patient's feet **412** are slightly apart. The patient's arms **408** are spread apart laterally at approximate right angles to the patient **400** and are supported on lateral arm rests **414** that are attached to the table **402**. The surgical barrier device **419** (that includes the inflatable thermal blanket **420** and the surgical drape **421**) is deployed over the patient. In some implementations, the drape **421** and blanket **420** are deployed together. In some cases, the combination is folded for easy deployment over the patient. For example, in one embodiment, the combination is placed at the incision site and may or may not be secured to the patient. The drape/blanket combination then is deployed by pulling the upper section up and over the patient and anesthesia screen and the lower section down over the lower part of the patient. In some cases, the drape/blanket combination is folded to provide simple and smooth unfolding in this manner.

[0057] The thermal blanket **420** is constructed to convectively warm by exhausting warm air onto the patient **400**. The inflatable thermal blanket **420** is similar in most respects to the inflatable thermal blankets shown in the preceding embodiments, except that it is configured to have an inflatable portion that extends over the patient's chest and upper extremities, while the surgical drape **421** covers additional portions of the patient. In some embodiments, the drape and/or blanket comprises means to prevent

exhausting air flow from contaminating the surgical wound. For example, pressure sensitive adhesive strips may be used to seal off the heated air section from the incision site. The surgical drape **421** includes ends **422** and **424**. In one embodiment as illustrated in Figure 11A, the surgical drape **421** has four drape sections **421a**, **421b**, **421c**, and **421d**. Each drape sections cover a portion of the patient **400** respectively. As illustrated in Figures 11A and 11B, the drape section **421a** covers the upper portion, the drape section **421b** covers the lower portion, and the drape sections **421c** and **421d** cover two sides. The surgical barrier device **421** has an inflation inlet cuff **428** that opens into the inflatable thermal blanket **420**. The inlet cuff **428** may be connected through a flexible heater hose, such as the heater hose **20**, to the heater/blower assembly **18**, the construction of which is described above in connection with Figure 1A. In Figures 11A and 11B, the inlet cuff **428** is shown mounted to the underside of the blanket **420**, but it could also be mounted to the upper side of the blanket.

[0058] The inflatable thermal blanket **420** is elongated at **430** and **432** so as to traverse substantially all of the patient's arms **408** as they lie on the arm rests **414** of the table **402**. In some embodiments, the inflatable thermal blanket **420** is formed as an inflatable covering that includes a flexible upper sheet and a flexible base sheet that are identical to the upper and base sheets **340** and **342** shown in Figures 12A and 12B. These sheets are secured to each other along a peripheral seam **444** that extends around the periphery of the inflatable portion. The peripheral seam **444** can be formed by a heat sealing process as described above. It is preferably continuous, but may also be formed with interruptions at selected locations thereof to facilitate egress of the inflating medium, e.g., heated air, as described above. The upper and base sheets of the inflatable thermal blanket **420** can be constructed, for example, using the materials and techniques described above in connection with Figures 2-4, forming a parallel array of elongated channels using seams formed by elongated heat seals as shown in Figures 1A and 1B, or an array of quasi-discrete inflatable chambers **448** formed using point seals **450**, as shown in Figures 10A and 10B, or other equivalent embodiments. A plurality of apertures identical to the apertures **352** shown in Figures 12A and 12B open through the base sheet into the inflatable thermal blanket **420**. The apertures convectively deliver the inflating medium into space surrounding the patient, which is enclosed by the surgical barrier device **419**. The base sheet of the inflatable thermal blanket **420** is preferably constructed like the base sheet of Figure 3, which comprises an underside layer **50** made from a flexible, fibrous material, and an upper side layer **52** made from a heat-sealable synthetic material. The apertures may be formed as holes extending through both of the layers **50** and **52** of this base sheet. Alternatively, the apertures may be formed as holes extending through the upper layer **52**, and as spaces which naturally occur between the fibers of the fibrous material used to form the underside layer **50**.

[0059] The inflatable thermal blanket **420** is attached to, or formed integrally with, one or more drape sections of the surgical drape **421**. The drape section **421a** extends from the periphery of the inflatable thermal blanket **420** outwardly to define the head end **422**, the foot end **424a**, the sides **426a** and **427a** of the drape section **421a**. As shown in Figure 11B, the surgical drape **421** is preferably sized so that it

extends over the entire upper surface of the table **402** so as to completely cover the patient **400**. As such, the end **422** will extend at least to cover the patient's-head, the foot end **424** of the surgical drape **421** will extend at least to cover the patient's feet, the sides **426a** and **427a** of the drape section **421a** can extend at least to cover the patient's torso and legs, and the sides **426b** and **427b** of the drape section **421b** can extend at least to cover the patient's extended arms. More preferably, the drape section **421b**, at the foot end **424**, hangs well below the edge of the table **402**.

[0060] In order to provide access to the patient **400** for performing surgery at a surgical site **462**, the drape sections **421a**, **421b**, **421c**, and **421d** of the surgical drape **421** can form a surgical access **464** by the edges of the drape sections. An attachment device **466**, such as one or more adhesive strips, may be provided close to the edges of the surgical access **464** in order to secure the drape **421** to the patient, and provide a seal that isolates the surgical site and keeps the inflating medium away from it. Because the drape **421** is not inflatable, it may be pressed flush against the patient **400** around the periphery of the surgical access **464**, and optionally secured, so that unobstructed access to the patient is ensured.

[0061] The drape **421** is employed for the same purposes as surgical drapes that are known in the art. The drape **421** also helps retain the inflating medium proximate to the patient body. Air that is exhausted from the inflatable thermal blanket **420** flows beyond the edge thereof and beneath the drape **421**, where it is maintained in proximity to the patient **400**. At the head end **422**, it is necessary to keep the drape **421** away from the patient's nose and mouth, so that respiration is not affected. For that purpose, a frame structure, which may be formed by a pair of vertical posts **468** mounted on the table **402**, is provided. The head end **422** of the surgical barrier device **419** may be wrapped around the posts **468** and secured using tape **470** or any other appropriate fastening device, such as clips, etc.

[0062] In one embodiment, an inflatable thermal blanket is folded within one of the drape sections of the surgical drapes but it is not attached to any of the drape sections. With such embodiment, the inflatable thermal blanket and the surgical drape can be disposed on a patient at the same time.

Exemplary Embodiments

[0063] Embodiment 1. A combination for use during surgery on a patient, comprising:

a surgical drape comprising a plurality of drape sections, each drape section comprising a drape sheet of flexible material;

an inflatable thermal blanket comprising:

a flexible base sheet;

a material sheet attached to a first surface of the base sheet by a plurality of seals to form an inflatable portion; and

a plurality of apertures through the base sheet within the inflatable portion;

a first attachment device configured to attach the inflatable thermal blanket to the patient; and

a second attachment device configured to attach at least a portion of the surgical drape to the patient,

wherein at least one of the plurality of drape sections is integrated with or attached to the inflatable thermal blanket.

[0064] Embodiment 2. The combination of Embodiment 1, wherein the first attachment device comprises one or more adhesive strips.

[0065] Embodiment 3. The combination of Embodiment 1 or Embodiment 2, wherein the second attachment device comprises one or more adhesive strips.

[0066] Embodiment 4. The combination of any one of the Embodiment 1 to Embodiment 3, wherein the plurality of drape sections comprise a large sized drape section, a medium sized drape section, and two small sized drape sections.

[0067] Embodiment 5. The combination of any one of the Embodiment 1 to Embodiment 4, wherein the drape sheet of at least one of the plurality of drape sections comprises a first drape surface and a second drape surface, the first drape surface having greater friction coefficient than the second drape surface.

[0068] Embodiment 6. The combination of any one of the Embodiment 1 to Embodiment 5, wherein at least one of the drape sections comprises a mark.

[0069] Embodiment 7. The combination of any one of the Embodiment 1 to Embodiment 6, wherein the plurality of drape sections are configured to provide a surgical access among two or more edges of the drape sections for accessing a surgical site on the patient.

[0070] Embodiment 8. The combination of any one of the Embodiment 1 to Embodiment 7, wherein the first attachment device is configured to be applied to the inflatable thermal blanket at a location, wherein the location is covered by the surgical drape.

[0071] Embodiment 9. The combination of Embodiment 8, wherein the inflatable portion is configured to have a recess proximate to the location when it is inflated.

[0072] Embodiment 10. The combination of any one of the Embodiment 1 to Embodiment 9, further comprising: a surgical incise drape configured to cover at least a portion of the surgical access.

[0073] Embodiment 11. The combination of any one of the Embodiment 1 to Embodiment 10, further comprising: a third attachment device configured to releasably attach at least two of the drape sections to one another.

[0074] Embodiment 12. The combination of Embodiment 11, wherein the third attachment device comprises at least one of adhesive material, perforated connections, and static cling.

[0075] Embodiment 13. The combination of Embodiment 4, wherein the large sized drape section and the medium sized drape section are configured to cover a head end and a foot end of the patient, and wherein the two small sized drape section are configured to cover two sides of the patient.

[0076] Embodiment 14. A temperature regulating surgical barrier device, comprising:

a surgical drape comprising a plurality of drape sections, at least one of the drape sections comprising an air impermeable drape sheet, the at least one of the drape sections further comprising:

an air permeable base sheet attached to a first surface of the drape sheet via a plurality of seals to form an inflatable portion;

a first attachment device configured to attach at least a portion of the surgical drape to a patient.

[0077] Embodiment 15. The temperature regulating surgical barrier device of Embodiment 14, wherein the first attachment device comprises one or more adhesive strips.

[0078] Embodiment 16. The temperature regulating surgical barrier device of Embodiment 14 or Embodiment 15, wherein the plurality of drape sections comprise a large sized drape section, a medium sized drape section, and two small sized drape sections.

[0079] Embodiment 17. The temperature regulating surgical barrier device of any one of the Embodiment 14 to Embodiment 16, wherein the drape sheet comprises a first drape surface and a second drape surface, the first drape surface having greater friction coefficient than the second drape surface.

[0080] Embodiment 18. The temperature regulating surgical barrier device of any one of the Embodiment 14 to Embodiment 17, wherein at least one of the drape sections comprises a mark.

[0081] Embodiment 19. The temperature regulating surgical barrier device of any one of the Embodiment 14 to Embodiment 18, wherein the plurality of drape sections are configured to provide a surgical access among two or more edges of the drape sections for accessing a surgical site on the patient.

[0082] Embodiment 20. The temperature regulating surgical barrier device of any one of the Embodiment 14 to Embodiment 19, wherein the inflatable portion is configured to have a recess when it is inflated, wherein the recess is proximate to a location where the first attachment device is applied.

[0083] Embodiment 21. The temperature regulating surgical barrier device of any one of the Embodiment 14 to Embodiment 20, further comprising: a surgical incise drape configured to cover at least a portion of the surgical access.

[0084] Embodiment 22. The temperature regulating surgical barrier device of any one of the Embodiment 14 to Embodiment 21, further comprising: a second attachment device configured to releasably attach at least two of the drape sections to one another.

[0085] Embodiment 23. The temperature regulating surgical barrier device of Embodiment 22, wherein the second attachment device comprises at least one of adhesive material, perforated connections, and static cling.

[0086] Embodiment 24. The temperature regulating surgical barrier device of Embodiment 16, wherein the large sized drape section and the medium sized drape section are configured to cover a head end and a foot end of the patient, and wherein the two small sized drape section are configured to cover two sides of the patient.

[0087] Embodiment 25. The temperature regulating surgical barrier device of any one of the Embodiment 14 to Embodiment 23, wherein the plurality of drape sections comprise an L-shape drape section.

[0088] Embodiment 26. The temperature regulating surgical barrier device of any one of the Embodiment 14 to Embodiment 25, wherein the plurality of drape sections comprise a U-shape drape section.

[0089] The present invention should not be considered limited to the particular examples and embodiments described above, as such embodiments are described in detail to facilitate explanation of various aspects of the invention. Rather the present invention should be understood to cover all aspects of the invention, including various modifications, equivalent processes, and alternative devices falling within the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A combination for use during surgery on a patient, comprising:
 - a surgical drape comprising a plurality of drape sections, each drape section comprising a drape sheet of flexible material;
 - an inflatable thermal blanket comprising:
 - a flexible base sheet;
 - a material sheet attached to a first surface of the base sheet by a plurality of seals to form an inflatable portion; and
 - a plurality of apertures through the base sheet within the inflatable portion;
 - a first attachment device configured to attach the inflatable thermal blanket to the patient; and
 - a second attachment device configured to attach at least a portion of the surgical drape to the patient,wherein at least one of the plurality of drape sections is integrated with or attached to the inflatable thermal blanket.
2. The combination of claim 1, wherein the first attachment device comprises one or more adhesive strips.
3. The combination of claim 1, wherein the second attachment device comprises one or more adhesive strips.
4. The combination of claim 1, wherein the drape sheet of at least one of the plurality of drape sections comprises a first drape surface and a second drape surface, the first drape surface having greater friction coefficient than the second drape surface.
5. The combination of claim 1, wherein the first attachment device is configured to be applied to the inflatable thermal blanket at a location, wherein the location is covered by the surgical drape.
6. The combination of claim 5, wherein the inflatable portion is configured to have a recess proximate to the location when it is inflated.
7. The combination of claim 1, further comprising:
 - a surgical incise drape configured to cover at least a portion of the surgical access.
8. A temperature regulating surgical barrier device, comprising:

a surgical drape comprising a plurality of drape sections, at least one of the drape sections comprising an air impermeable drape sheet, the at least one of the drape sections further comprising:

an air permeable base sheet attached to a first surface of the drape sheet via a plurality of seals to form an inflatable portion;

a first attachment device configured to attach at least a portion of the surgical drape to a patient.

9. The temperature regulating surgical barrier device of claim 8, wherein the first attachment device comprises one or more adhesive strips.

10. The temperature regulating surgical barrier device of claim 8, wherein at least one of the drape sections comprises a mark.

11. The temperature regulating surgical barrier device of claim 8, wherein the inflatable portion is configured to have a recess when it is inflated, wherein the recess is proximate to a location where the first attachment device is applied.

12. The temperature regulating surgical barrier device of claim 8, further comprising:
a second attachment device configured to releasably attach at least two of the drape sections to one another.

13. The temperature regulating surgical barrier device of claim 12, wherein the second attachment device comprises at least one of adhesive material, perforated connections, and static cling.

14. The temperature regulating surgical barrier device of claim 8, wherein the plurality of drape sections comprise an L-shape drape section.

15. The temperature regulating surgical barrier device of claim 8, wherein the plurality of drape sections comprise a U-shape drape section.

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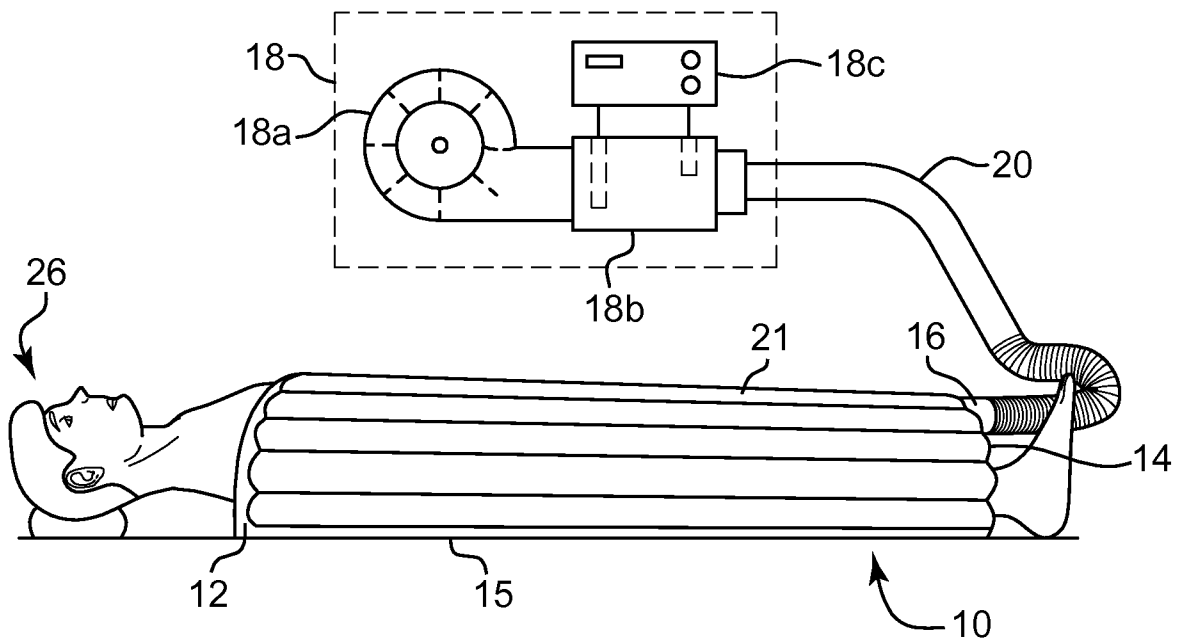


FIG. 1A

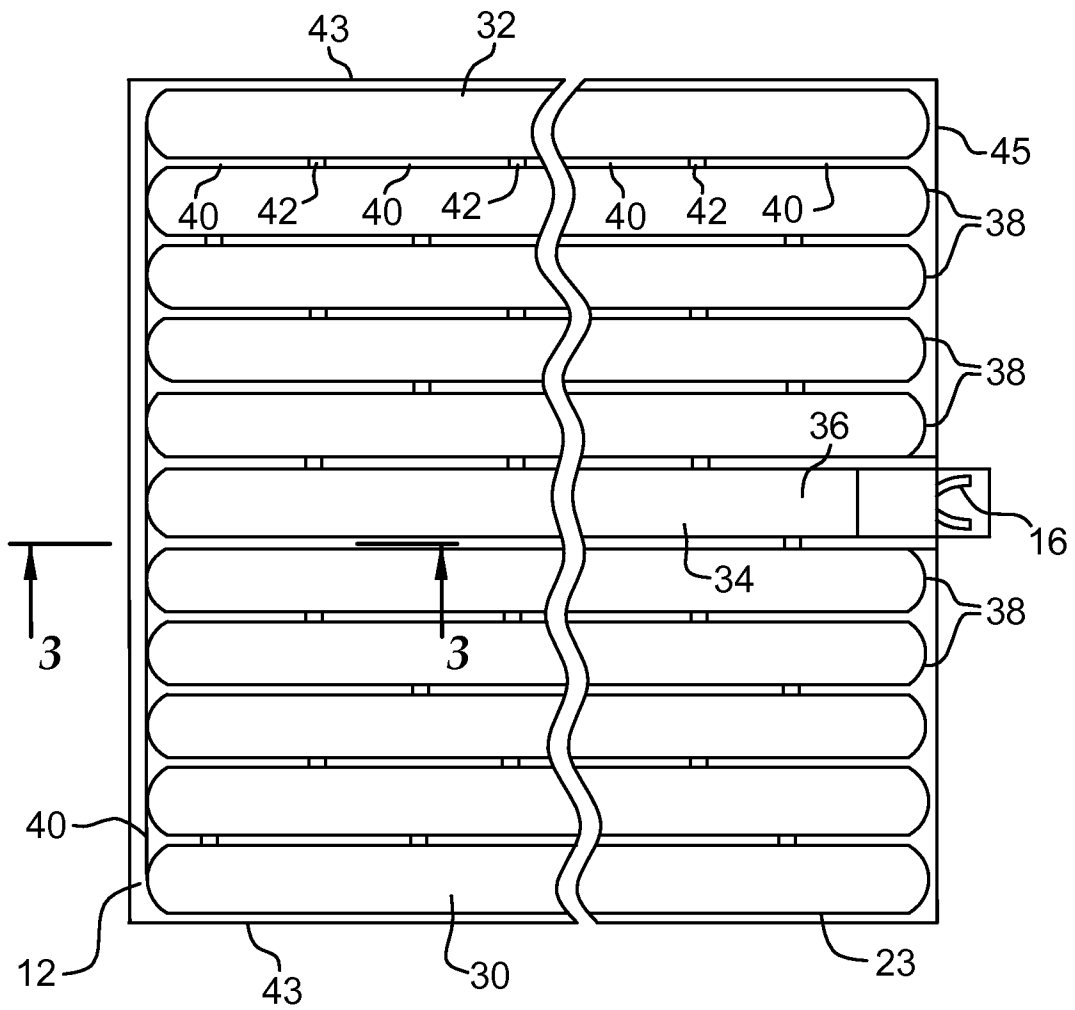


FIG. 1B

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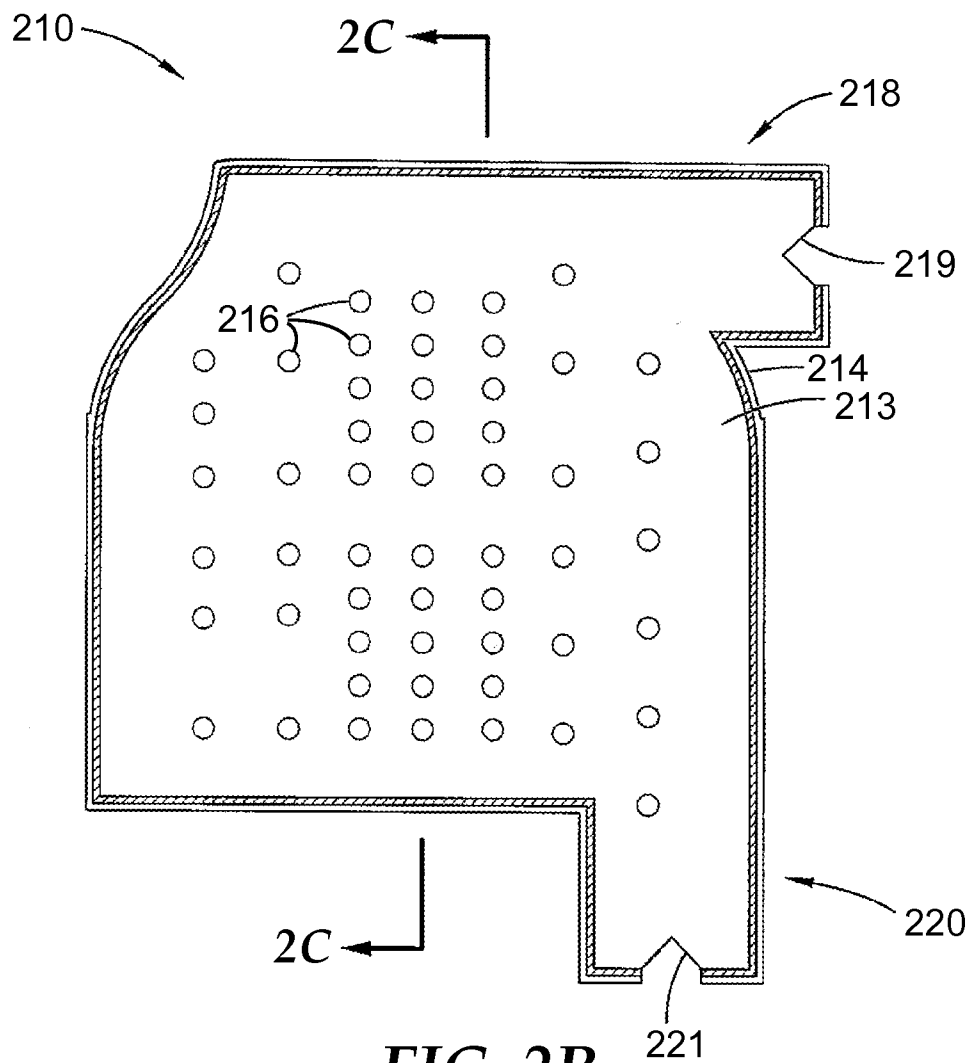
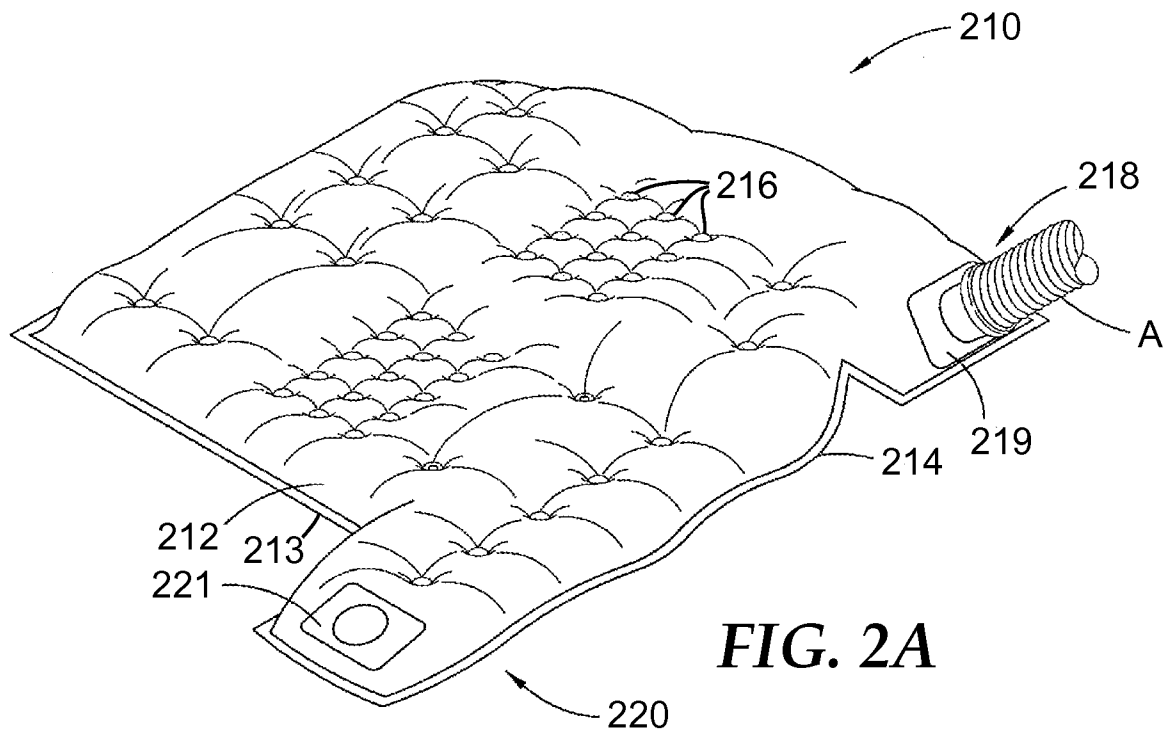


FIG. 2B

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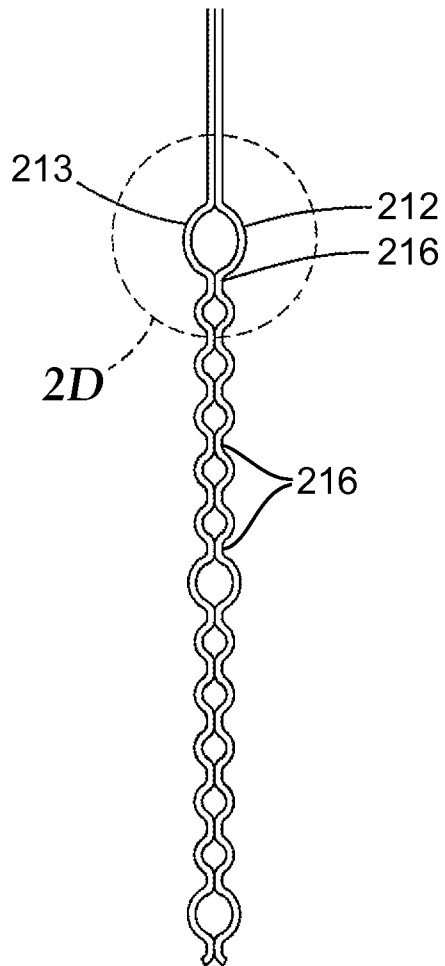


FIG. 2C

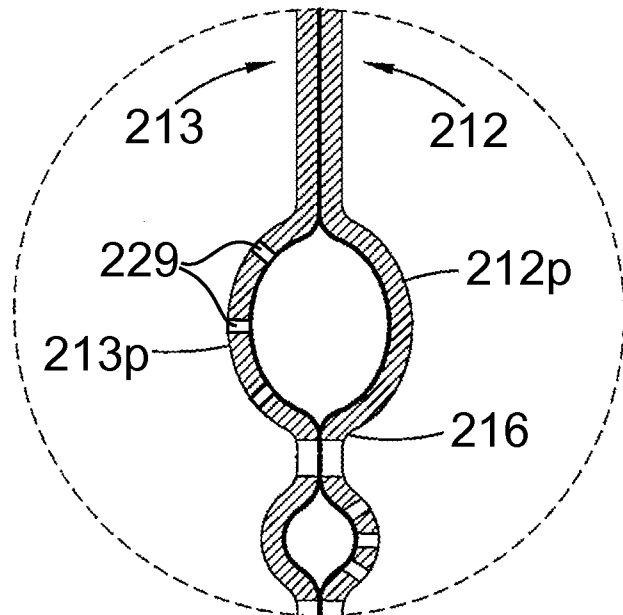


FIG. 2D

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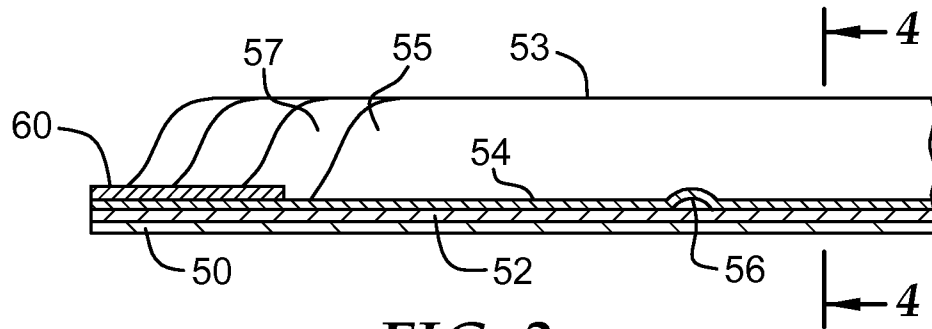


FIG. 3

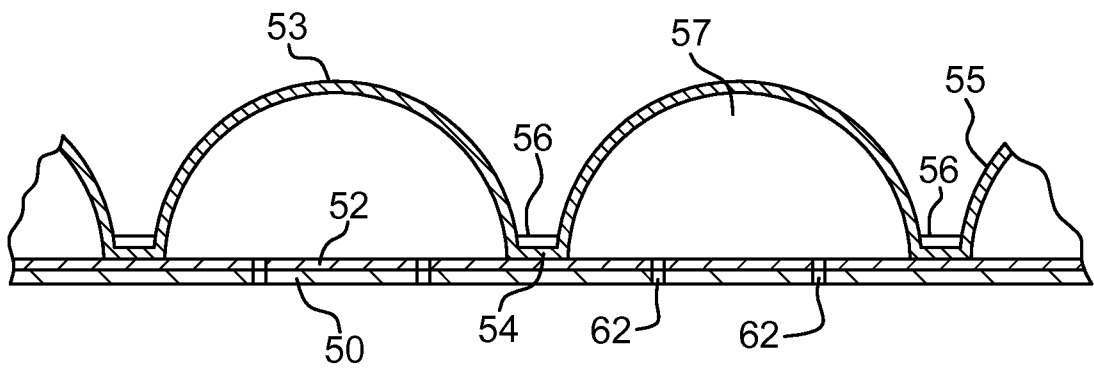


FIG. 4

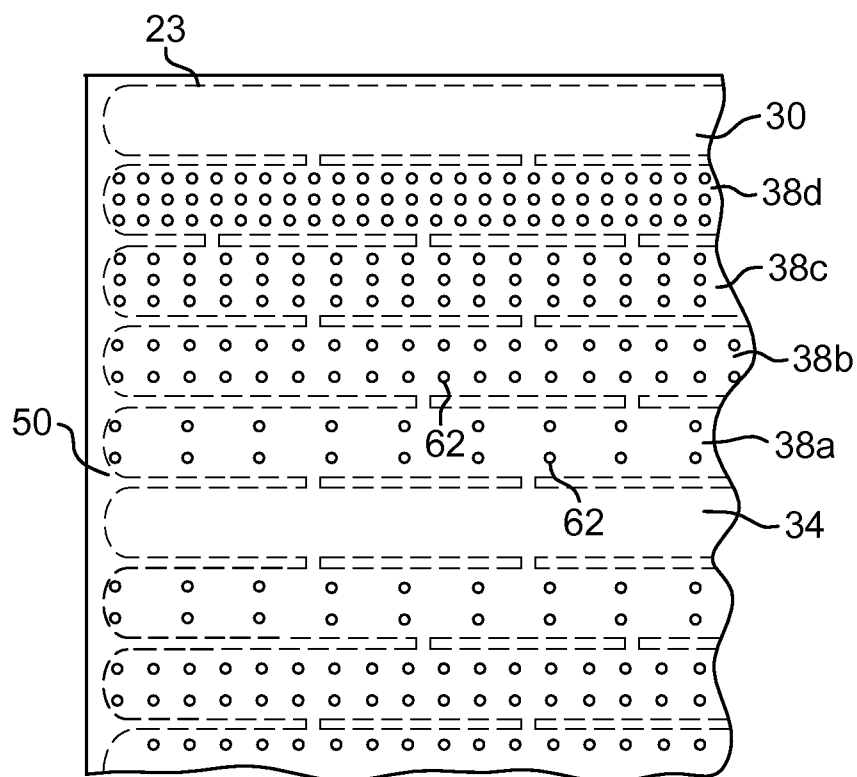
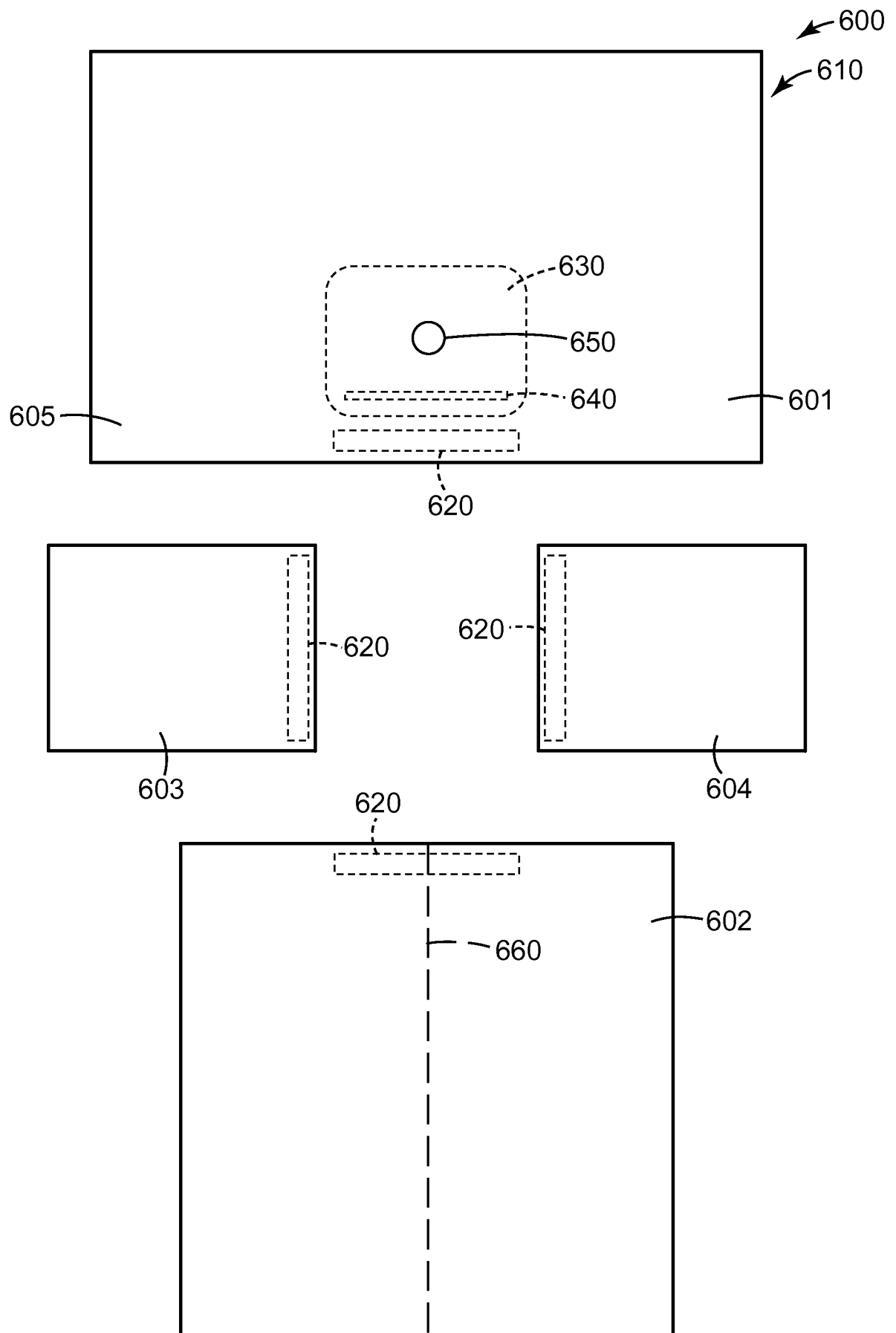


FIG. 5

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**FIG. 6**

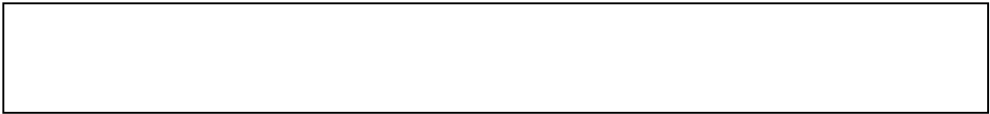


FIG. 7A

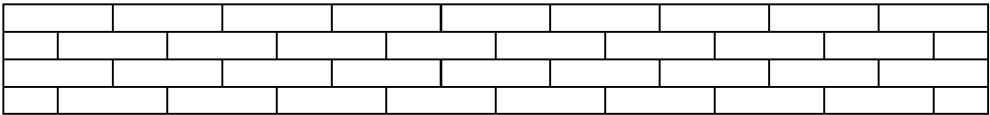


FIG. 7B

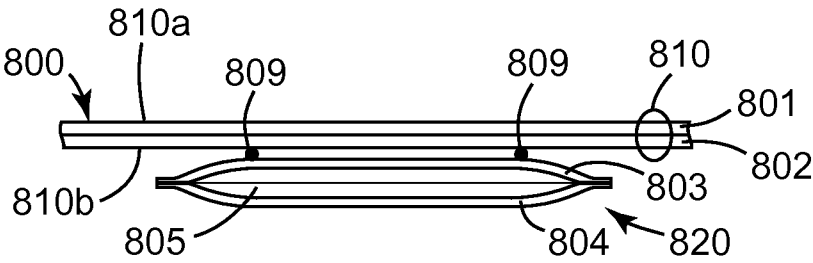


FIG. 8A

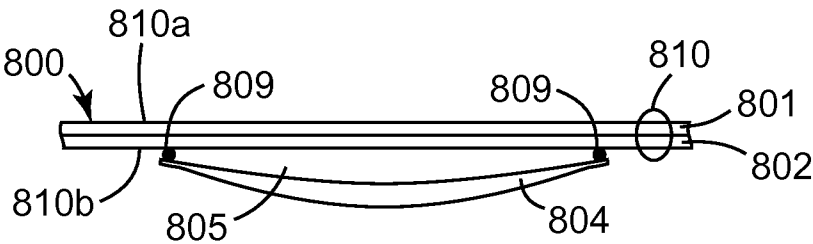


FIG. 8B

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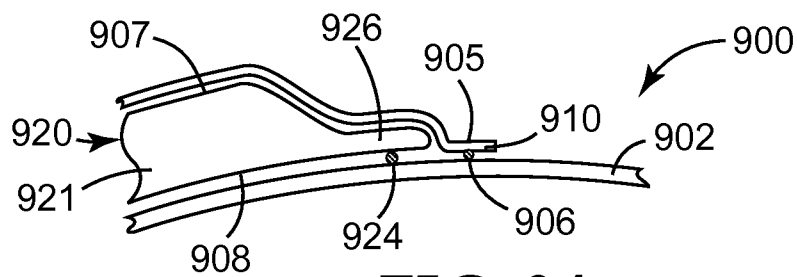


FIG. 9A

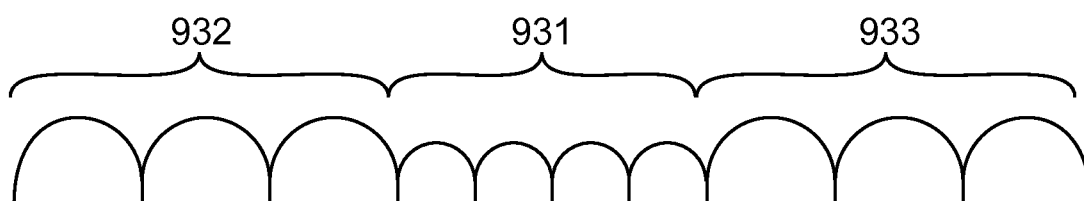


FIG. 9B

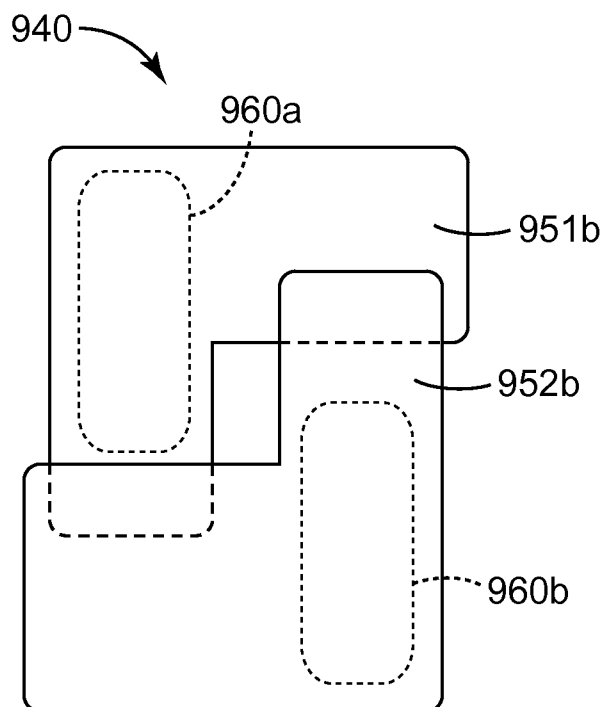


FIG. 9C

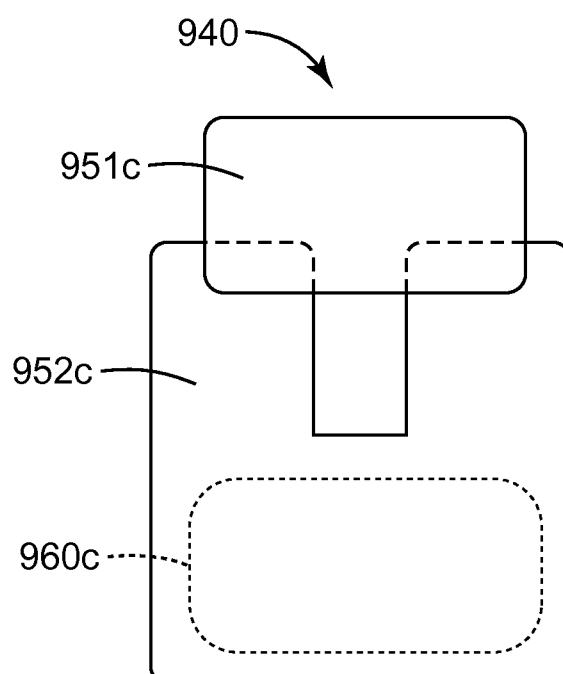


FIG. 9D

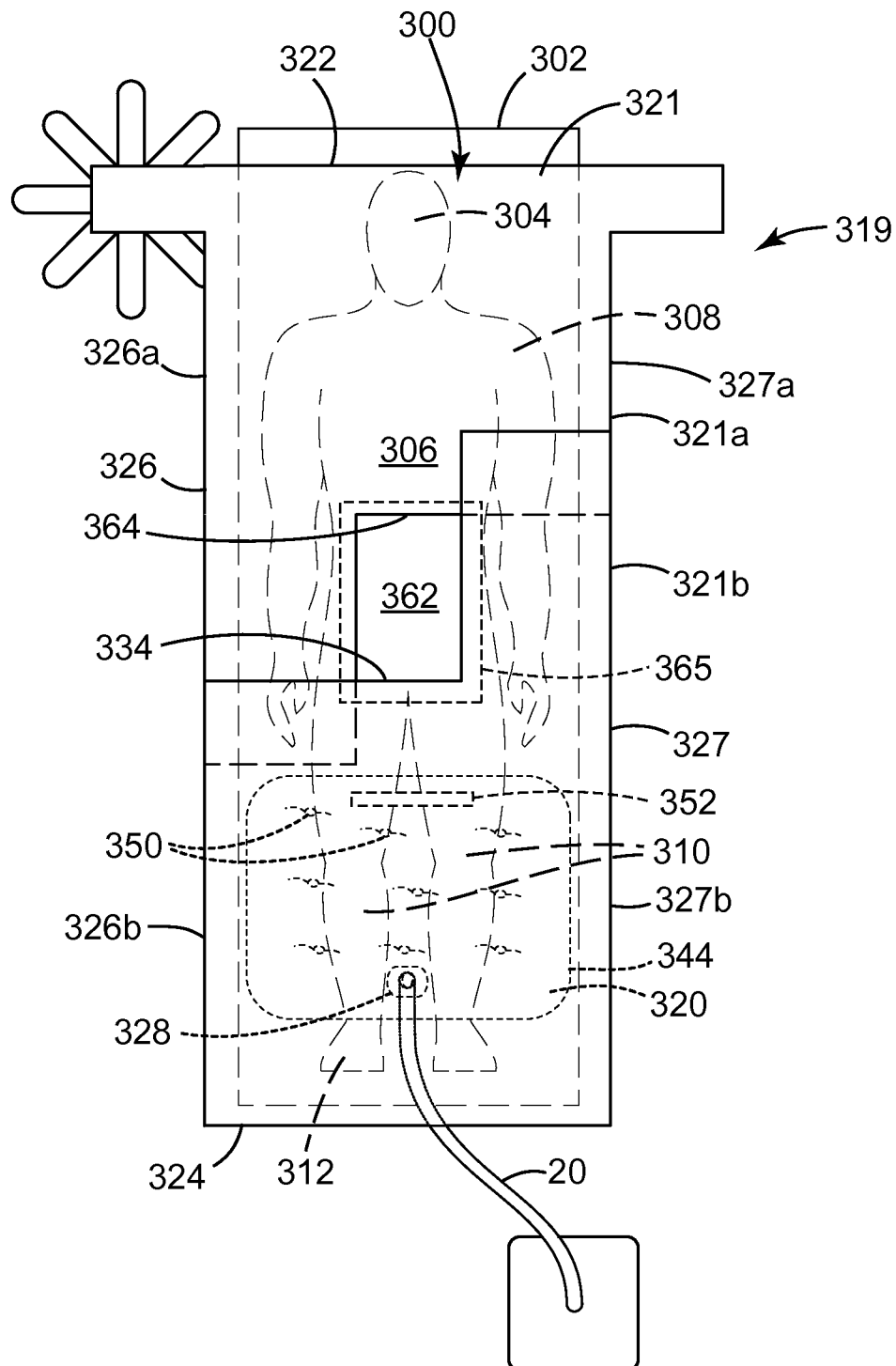


FIG. 10A

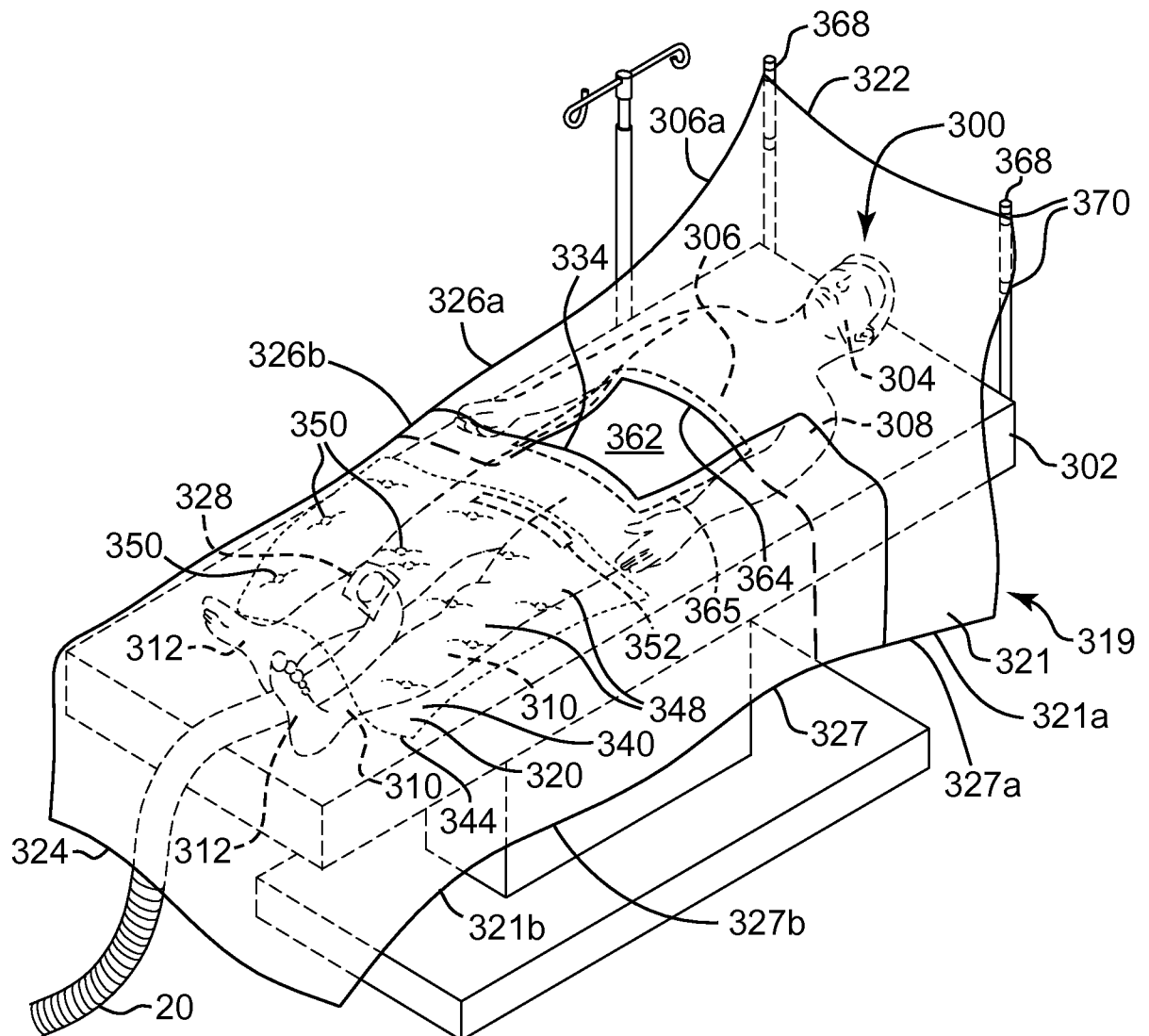
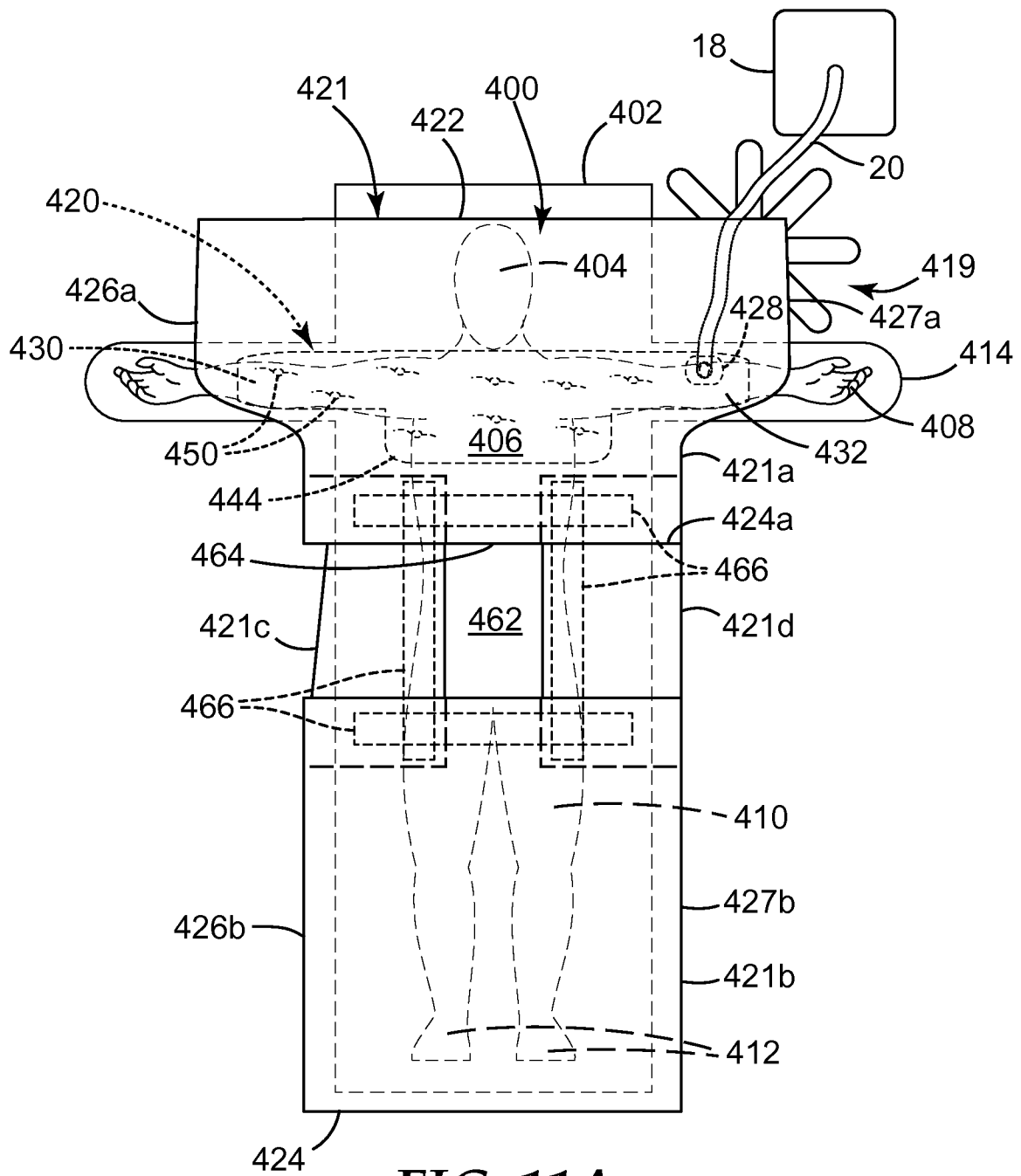
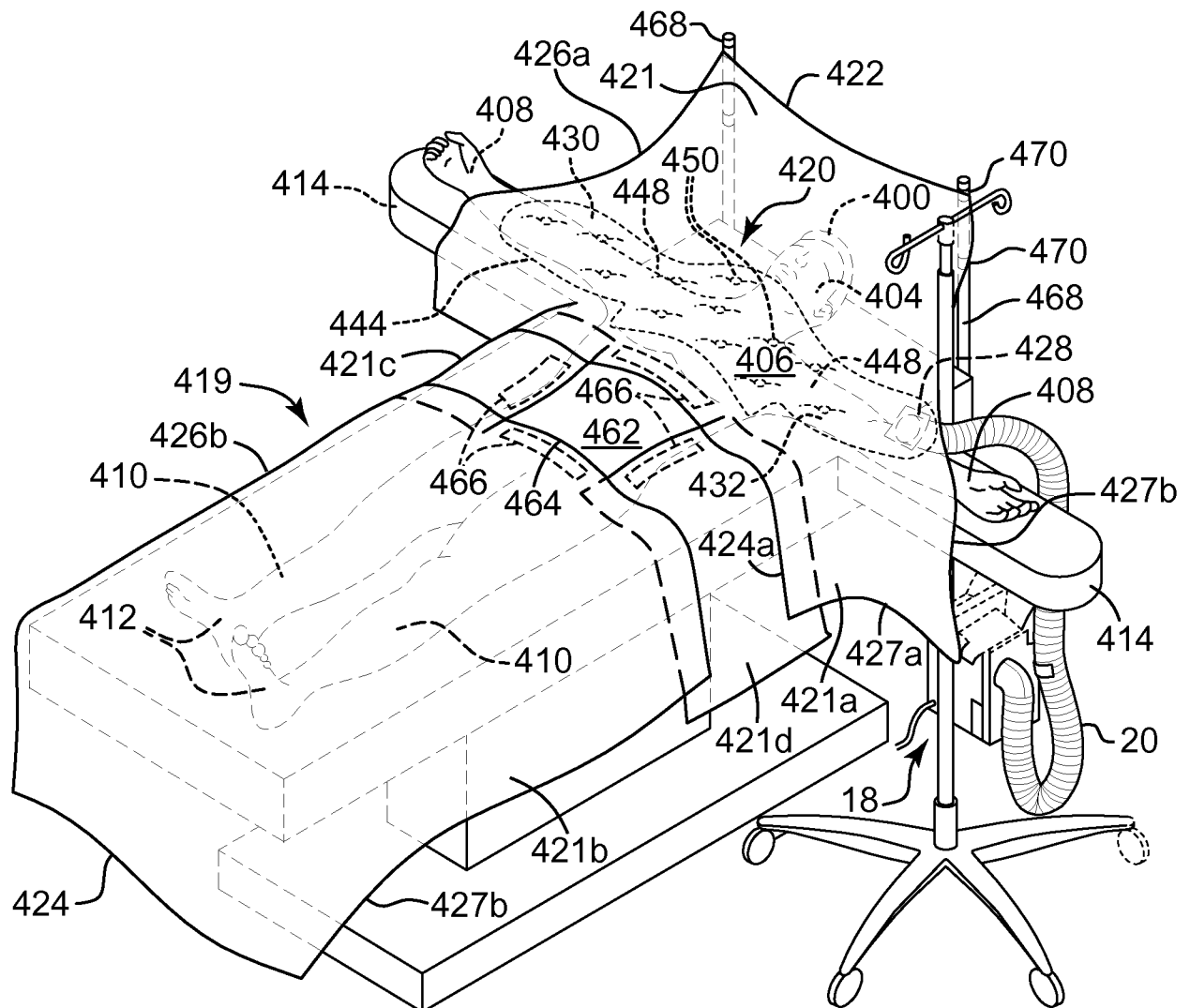


FIG. 10B

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**FIG. 11A**

**FIG. 11B**

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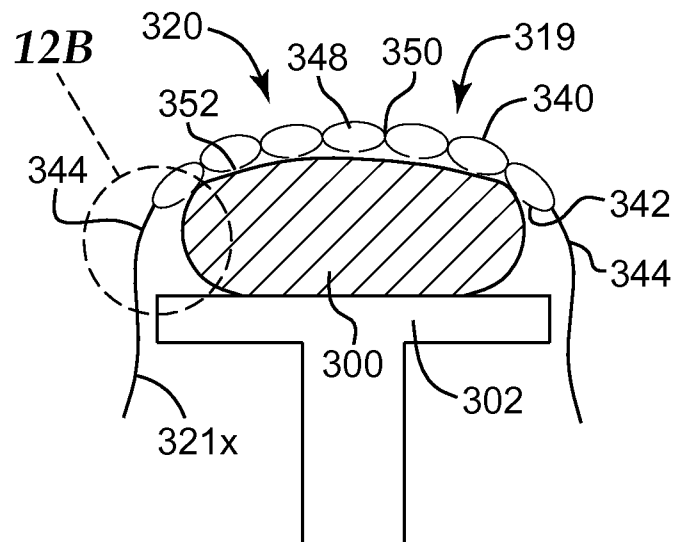


FIG. 12A

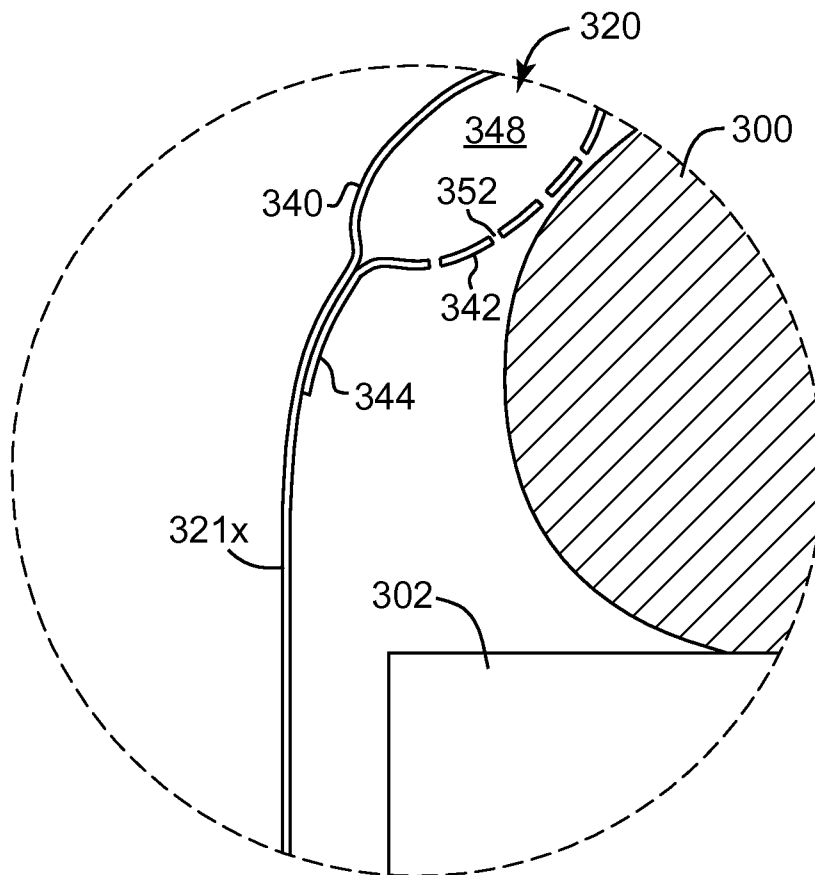
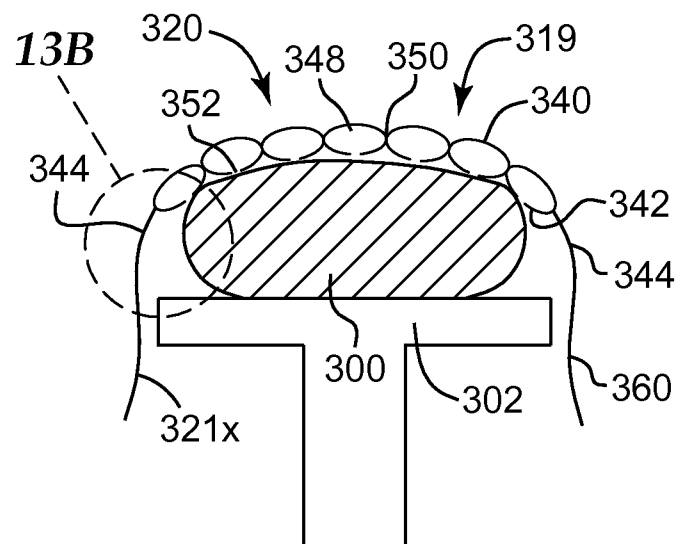
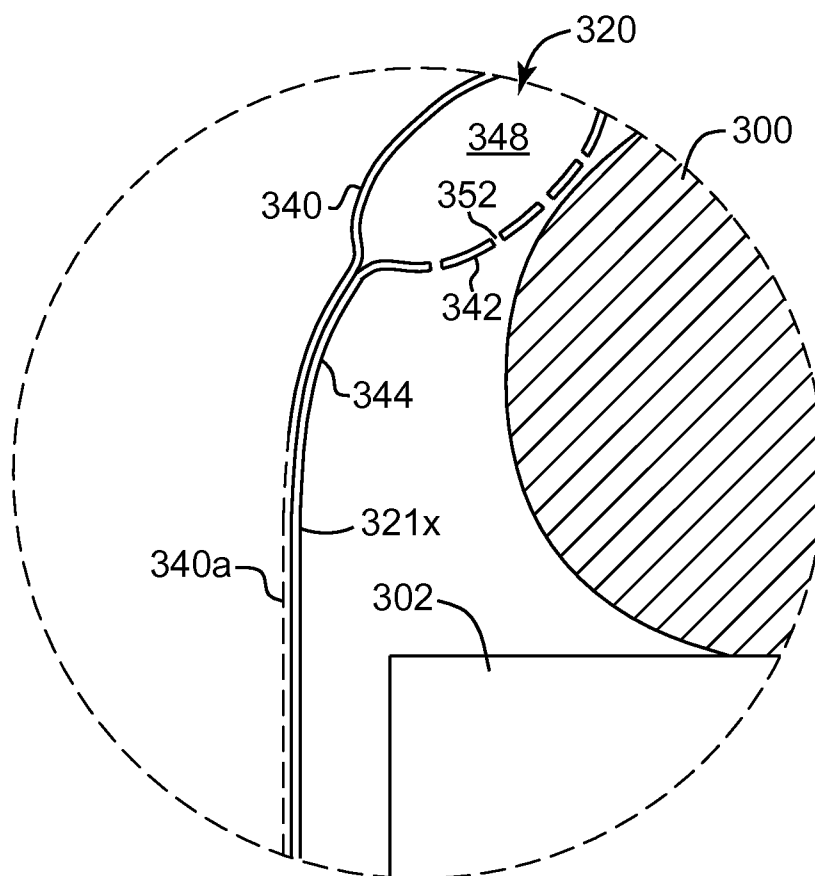
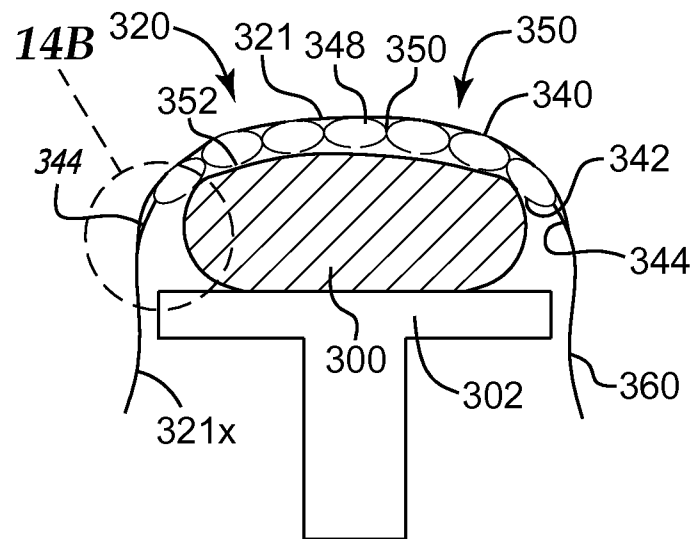
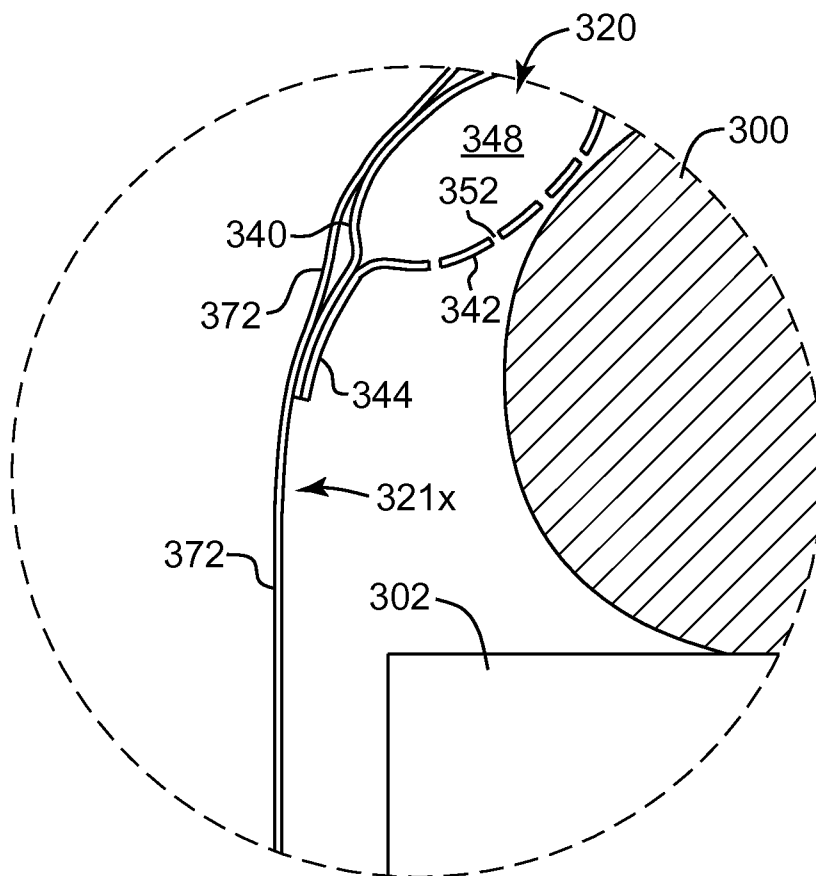


FIG. 12B

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**FIG. 13A****FIG. 13B**

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**FIG. 14A****FIG. 14B**

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2014/038071

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61B19/08 A61B19/10 A61F7/00
 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)

A61F A61B

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 203 567 B1 (AUGUSTINE SCOTT DOUGLAS [US]) 20 March 2001 (2001-03-20) column 5, line 63 - column 6, line 10; figures 1-22 column 9, line 48 - column 11, line 19 -----	1-15
X	US 6 176 870 B1 (AUGUSTINE SCOTT D [US]) 23 January 2001 (2001-01-23) column 3, line 59 - line 65; figures 1-19 column 10, line 35 - column 11, line 16 -----	1-15
X	US 2005/125047 A1 (GAMMONS CLIFFORD E [US]) 9 June 2005 (2005-06-09) paragraphs [0017], [0023], [0029]; figures 1-3 -----	8-15
A		1-7



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

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search

20 August 2014

Date of mailing of the international search report

26/08/2014

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2014/038071

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US 6176870	B1	23-01-2001	NONE
US 2005125047	A1	09-06-2005	NONE