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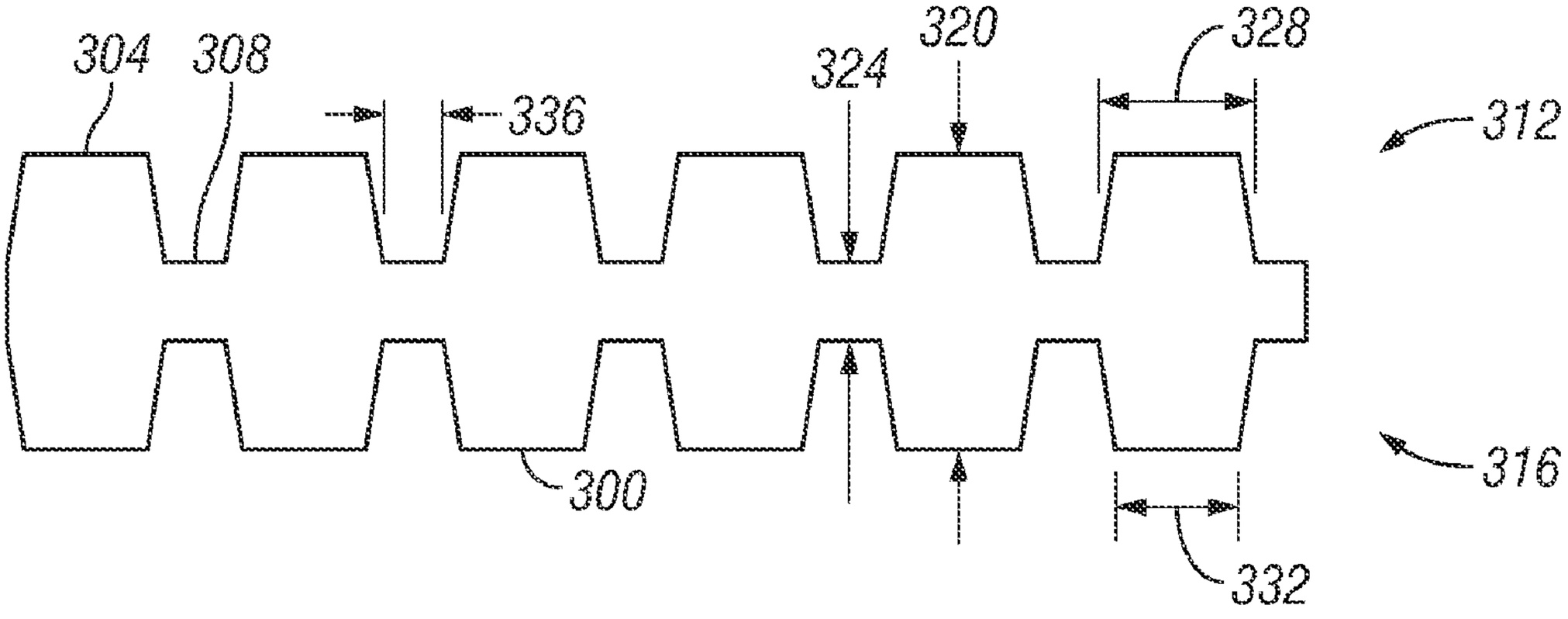
(54) **Titre : GARNITURES EN MOUSSE POUR BLESSURES POURVUES DE REGIONS DE DENSITES SUPERIEURE ET INFERIEURE, PANSEMENTS, ET METHODES**
(54) **Title: FOAM WOUND INSERTS WITH REGIONS OF HIGHER AND LOWER DENSITIES, WOUND DRESSINGS, AND METHODS**



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Foam wound inserts with high-density and low-density regions, methods for making wound inserts, wound-treatment methods, and wound-treatment systems.

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(54) Title: FOAM WOUND INSERTS WITH REGIONS OF HIGHER AND LOWER DENSITIES, WOUND DRESSINGS, AND METHODS

(57) Abstract: Foam wound inserts with high-density and low-density regions, methods for making wound inserts, wound-treatment methods, and wound-treatment systems.

DESCRIPTION

FOAM WOUND INSERTS WITH REGIONS OF HIGHER AND LOWER DENSITIES, WOUND DRESSINGS, AND METHODS

BACKGROUND

1. Field of the Invention

[0002] The present disclosure relates generally to healing of wounds and wound-treatment therapies. More particularly, but not by way of limitation, the present disclosure relates to fluid-instillation and negative-pressure wound therapies.

2. Background Information

[0003] Clinical studies and practice have shown that providing a reduced pressure in proximity to a tissue site augments and accelerates the growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but application of reduced pressure has been particularly successful in treating wounds. This treatment (frequently referred to in the medical community as "negative pressure wound therapy," "reduced pressure therapy," or "vacuum therapy") provides a number of benefits, including faster healing and increased formulation of granulation tissue. Typically, reduced pressure is applied to tissue through a wound insert (e.g., a porous pad or other manifold device). The wound insert typically contains cells or pores that are capable of distributing reduced pressure to the tissue and channeling fluids that are drawn from the tissue. The wound insert can be incorporated into a wound dressing having other components that facilitate treatment, such as, for example, a drape (e.g., adhesive surgical drape).

SUMMARY

[0004] The present disclosure includes embodiments of wound inserts with high-density regions and low-density regions (e.g., unitary high-density regions and low-density regions), wound dressings, methods of making wound inserts, and wound-treatment methods.

[0005] Some embodiments of the present methods of making a wound insert, comprise: compressing at least a portion of a foam having thick portions and thin portions such that the compressed foam has a substantially constant thickness, and such that the thick portions have a density greater than the density of the thin portions; and treating the compressed foam such that the foam remains substantially compressed in the absence of an external compressive force.

[0006] In some embodiments, treating comprises heating the compressed foam to reduce the resiliency of the foam. In some embodiments, prior to compressing the foam, the thick portions and thin portions have substantially the same densities.

[0007] In some embodiments, treating comprises activating a coating that is distributed through at least a portion of the foam. In some embodiments, the coating is activated by heating the foam and the coating. In some embodiments, the coating comprises an adhesive. In some embodiments, the coating comprises a cross-linkable polymer, and where activating comprises exposing the coating to at least one of light and elevated temperature to cause at least some portion of the cross-linkable polymer to become cross-linked.

[0008] Some embodiments further comprise: cooling the foam; where cooling is performed after treating the compressed foam.

[0009] In some embodiments, the compressed thickness of the thick portions is substantially equal to the uncompressed thickness of the thin portions. In some embodiments, after being compressed the foam exhibits anisotropic properties.

[0010] Some embodiments of the present methods of making a wound insert, comprise: providing a foam including thick regions and thin regions having substantially the same densities; compressing at least a portion of the foam such that the foam has a substantially constant thickness, and such that the thick regions have a density greater than the density of the thin regions; heating the foam to an elevated temperature sufficient to reduce resiliency of the foam; and cooling the foam such that the compressed portion remains substantially compressed.

[0011] Some embodiments of the present methods of making a wound insert, comprise: compressing at least a portion of a foam such that the foam has a substantially constant thickness; heating the foam to an elevated temperature sufficient to reduce resiliency of the foam; and cooling the foam such that the compressed portion remains substantially compressed; where prior to being compressed, the foam includes thick regions and thin regions (e.g., unitary thick

regions and thin regions) having substantially the same densities, and after being compressed the thick regions have a density greater than the density of the thin regions.

[0012] In some embodiments, the foam comprises an open-celled foam. In some embodiments, the foam comprises a hydrophilic (or hydrophobic) foam. In some embodiments, prior to being compressed the thick regions of the foam have a uncompressed thickness greater than the uncompressed thickness of the thin regions, and where the compressed thickness of the thick portions is substantially equal to the uncompressed thickness of the thin portions. In some embodiments, after being compressed the foam exhibits anisotropic properties.

[0013] Some embodiments of the present methods of making a wound insert comprise: providing a foam including thick regions and thin regions having substantially the same densities; compressing at least a portion of a foam such that the foam has a substantially constant thickness, and such that the thick regions have a density greater than the density of the thin regions; and activating a coating that is distributed through at least a portion of the foam such that the compressed portion remains at least partially compressed in the absence of an external compressive force.

[0014] Some embodiments of the present methods of making a wound insert comprise: compressing at least a portion of a foam such that the foam has a substantially constant thickness; and activating a coating that is distributed through at least a portion of the foam such that the compressed portion remains at least partially compressed in the absence of an external compressive force; where prior to being compressed, the foam includes thick regions and thin regions (e.g., unitary thick regions and thin regions) having substantially the same densities, and after being compressed the thick regions have a density greater than the density of the thin regions.

[0015] In some embodiments, the coating comprises an adhesive. In some embodiments, the coating comprises a cross-linkable polymer, and activating comprises exposing the coating to at least one of light and elevated temperature to cause at least some portion of the cross-linkable polymer to become cross-linked.

[0016] Some embodiments of the present wound inserts are for use with a wound dressing, and comprise: a foam having high-density regions and low-density regions. In some embodiments, the foam comprises a hydrophilic foam. In some embodiments, the high-density

regions and low-density regions are configured in alternating rows. In some embodiments, the high-density regions and low-density regions are configured in a grid pattern.

[0017] Some embodiments of the present wound dressings are for healing wounds using negative pressure wound therapy, and comprise: any of the present wound inserts; and a drape for coupling to skin of a patient adjacent the wound to which the dressing is applied such that the drape covers the wound insert and the wound, and forms a space between the drape and the wound.

[0018] Some embodiments of the present wound inserts (e.g., for use with a wound dressing) comprise: a foam (e.g., sterile foam) having high-density regions and low-density regions having a density that is less than the density of the high-density regions. In some embodiments, the foam is formed by any of the present methods. In some embodiments, the foam comprises a hydrophilic (or hydrophobic) foam. In some embodiments, the high-density regions and low-density regions are configured in alternating rows. In some embodiments, the high-density regions and low-density regions are configured in a grid pattern.

[0019] Some embodiments of the present wound dressings comprise: a wound insert configured to be positioned on a wound of a patient, the wound insert comprising a foam (e.g., sterile foam) having high-density regions and low-density regions having a density that is less than the density of the high-density regions; and a drape configured to be coupled to skin of the patient adjacent the wound such that the drape covers the wound insert and the wound, and forms a space between the drape and the wound.

[0020] Some embodiments of the present wound-treatment methods comprise: positioning a wound insert on a wound of a patient, the wound insert comprising a sterile (e.g., sterile) foam having high-density regions and low-density regions having a density that is less than the density of the high-density regions; and coupling a drape to skin adjacent the wound such that the drape covers the wound insert and the wound, and forms a space between the drape and the wound. Some embodiments further comprise: applying negative pressure to the wound through the wound dressing. In some embodiments, applying negative pressure comprises activating a vacuum source that is coupled to the wound dressing. Some embodiments further comprise: delivering a fluid to the wound through the wound dressing. In some embodiments, delivering a fluid comprises activating a fluid source that is coupled to the wound dressing.

[0021] Any embodiment of any of the present systems and/or methods can consist of or consist essentially of – rather than comprise/include/contain/have – any of the described steps, elements, and/or features. Thus, in any of the claims, the term "consisting of" or "consisting essentially of" can be substituted for any of the open-ended linking verbs recited above, in order to change the scope of a given claim from what it would otherwise be using the open-ended linking verb.

[0022] Details associated with the embodiments described above and others are presented below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] The following drawings illustrate by way of example and not limitation. For the sake of brevity and clarity, every feature of a given structure is not always labeled in every figure in which that structure appears. Identical reference numbers do not necessarily indicate an identical structure. Rather, the same reference number may be used to indicate a similar feature or a feature with similar functionality, as may non-identical reference numbers.

[0024] **FIG. 1** depicts a side view of one embodiment of the present wound dressings having one of the present wound inserts and coupled to a wound site and to a wound treatment apparatus.

[0025] **FIG. 2** depicts an enlarged side view of the wound insert of **FIG. 1**.

[0026] **FIG. 3** depicts a schematic block diagram of one embodiment of a wound treatment apparatus that can comprise and/or be coupled to and/or be used with the present wound dressings and/or wound inserts.

[0027] **FIG. 4** depicts an end view of an embodiment of the present wound inserts.

[0028] **FIG. 5** depicts an end view of another embodiment of the present wound inserts.

[0029] **FIG. 6** depicts an end view photograph of an embodiment of the present wound inserts in uncompressed and compressed configurations.

[0030] **FIG. 7** depicts a top view photograph of the wound insert of **FIG. 6** in a compressed configuration.

[0031] **FIGS. 8A** and **8B** depict forward looking infrared FLIR images of fluid migration through embodiments of the present wound inserts and through a prior art wound insert.

[0032] **FIG. 9** depicts foam suitable for embodiments of the present wound inserts that has been cut by laser methods.

[0033] **FIG. 10** depicts a top view of an embodiment of the present wound inserts illustrating tearing of the wound insert along a lower-density region.

[0034] **FIG. 11** depicts an embodiment of one of the present wound inserts in a circular configuration.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0035] The term "coupled" is defined as connected, although not necessarily directly, and not necessarily mechanically; two items that are "coupled" may be integral with each other. The terms "a" and "an" are defined as one or more unless this disclosure explicitly requires otherwise. The terms "substantially," "approximately," and "about" are defined as largely but not necessarily wholly what is specified, as understood by a person of ordinary skill in the art.

[0036] The terms "comprise" (and any form of comprise, such as "comprises" and "comprising"), "have" (and any form of have, such as "has" and "having"), "include" (and any form of include, such as "includes" and "including") and "contain" (and any form of contain, such as "contains" and "containing") are open-ended linking verbs. As a result, a method that "comprises," "has," "includes" or "contains" one or more steps possesses those one or more steps, but is not limited to possessing only those one or more steps. Likewise, a wound dressing that "comprises," "has," "includes" or "contains" one or more elements possesses those one or more elements, but is not limited to possessing only those elements. For example, in a wound dressing that comprises a wound insert and a drape, the wound dressing includes the specified elements but is not limited to having only those elements. For example, such a wound dressing could also include a connection pad configured to be coupled to a wound-treatment apparatus.

[0037] Further, a device or structure that is configured in a certain way is configured in at least that way, but it can also be configured in other ways than those specifically described.

[0038] Referring now to the drawings, and more particularly to **FIG. 1**, shown therein is an embodiment of one of the present wound treatment system **10**. In the embodiment shown, apparatus **10** comprises a wound-treatment apparatus **14**, and a wound dressing **18** coupled to apparatus **14** by a conduit **22**. As shown, dressing **18** is configured to be coupled to (and is shown coupled to) a wound **26** of a patient **30**. More particularly, in the embodiment shown, dressing **18** comprises a wound insert **34** and a drape **38**. As shown, wound insert **34** is configured to be positioned (and is shown positioned) on wound **26** (e.g., on or adjacent to wound surface **42**), and/or drape **38** is configured to be coupled to (and is shown coupled to) skin

46 of the patient adjacent to wound **26** such that drape **38** covers wound insert **34** and wound **26**, and forms a space **50** between drape **38** and wound **26** (e.g., wound surface **42**).

[0039] Apparatus **14** can comprise, for example, a vacuum source configured to be actuatable (and/or actuated) to apply negative pressure (e.g., via conduit **22**) to wound dressing **18**, a fluid source configured to be actuatable (and/or actuated) to deliver (e.g., via conduit **22**) a fluid (e.g., an installation fluid such as a medicinal fluid, antibacterial fluid, irrigation fluid, and or the like) to wound dressing **18**. System **10** can be implemented and/or actuated and/or coupled to patient **30** in any of various configurations and/or methods similar to those described in the prior art. For example, various wound therapy systems and components are commercially available through and/or from KCI USA, Inc. of San Antonio, Texas, U.S.A., and/or its subsidiary and related companies (collectively, "KCI").

[0040] Conduit **22** can comprise a single lumen conduit (e.g., switched between a vacuum source and/or a fluid source and apparatus **14**), or can comprise multiple single-lumen conduits or a multi-lumen conduit such that, for example, fluid can be delivered and/or negative pressure can be applied to wound dressing **18** individually and/or simultaneously. Additionally, conduit **22** can comprise, for example, a first lumen for the application of negative pressure and/or fluid delivery, and at least one additional lumen for coupling to pressure sensor(s) to sense pressure or negative pressure between drape 38 and surface 42. In some embodiments, conduit **22** can comprise multiple lumens (e.g., as in a single conduit with a central lumen for application of negative pressure and/or fluid delivery and one or more peripheral lumens disposed adjacent or around the central lumen such that the peripheral lumens can be coupled to a pressure sensor to sense a pressure or negative pressure between drape **38** and surface **42** (e.g. in space **50**). The lumens may be arranged with a central lumen and other lumens disposed radially around the central lumen, or in other suitable arrangements. The lumens may also be provided in separate conduits. In the embodiment shown, system **10** further comprises a wound dressing connection pad **54** configured to be coupled (and is shown coupled) to conduit **22**. One example of a suitable connection pad **54** is the "V.A.C. T.R.A.C.® Pad," commercially available from KCI. One example of a suitable drape **38** includes the "V.A.C.® Drape" commercially available from KCI.

[0041] Referring now to **FIG. 2**, a side view of a wound insert **34** is shown. Wound insert **34** has an upper side **100**, a lower side **104**, lateral sides **108**, **112** and interior volume **116**. Although only one side is shown of wound insert **34**, it will be understood by those of ordinary

skill in the art that wound insert **34** includes a three-dimensional rectangular volume having a depth extending perpendicular to the side shown. In other embodiments, wound insert **34** can have any suitable shape, such as, for example, a round cylindrical shape, a fanciful shape, or may be trimmed to fit an irregular shape of a wound (e.g., **26** and/or wound surface **42**). Wound insert **34** can comprise a foam, such as, for example, open-celled foam (which may also be reticulated).

[0042] Embodiments of the present wound treatment methods may be better understood with reference to **FIG. 3**, which depicts a schematic block diagram of one embodiment of system **10**. In the embodiment shown, wound dressing **18** is coupled to apparatus **14**, and apparatus **14** comprises a vacuum source **200** (e.g., a vacuum pump and/or the like) coupled to a canister **204** (e.g., configured to receive exudate and or the like from wound dressing **18**) by way of a conduit **208**. In the embodiment shown, apparatus **14** further comprises: a pressure sensor **212** having a first pressure transducer **216** coupled to conduit **208** by way of conduit **220** and/or tee-fitting **224**, and a second pressure transducer **228** coupled to canister **204** and/or wound dressing **18** by way of conduit **232**. Pressure sensor **212** is configured to sense the negative pressure in wound dressing **18**, and/or any of the various lumens (e.g., within conduits) coupled to wound dressing **18**, pressure sensor **212**, and/or vacuum source **200**.

[0043] In the embodiment shown, apparatus **14** further comprises a pressure release valve **236** coupled to conduit **232**. Further, in the embodiment shown, canister **204** and vacuum source **200** are coupled to wound dressing **18** by way of conduit **240**; and/or canister **204** can comprise a filter **244** at or near an outlet of canister **204** to prevent liquid or solid particles from entering conduit **208**. Filter **244** can comprise, for example, a bacterial filter that is hydrophobic and/or lipophilic such that aqueous and/or oily liquids will bead on the surface of the filter. Apparatus **14** is typically configured such that, during operation, vacuum source **200** will provide sufficient airflow through a filter **244** that the pressure drop across filter **244** is not substantial (e.g., such that the pressure drop will not substantially interfere with the application of negative pressure from wound dressing **18** from vacuum source **200**).

[0044] In the embodiment shown, apparatus **14** further comprises a fluid source **248** coupled to wound dressing **18** by way of a conduit **252** that is coupled to conduit **240** such as, for example, by way of a tee- or other suitable fitting **256**. In some embodiments, tee fitting **256** can comprise a switch valve and/or the like such that communication can be selectively permitted between wound dressing **18** and vacuum source **200**, or between wound dressing **18** and fluid

source **248**. In some embodiments apparatus **14** comprises only one of vacuum source **200** and fluid source **248**. In embodiments of apparatus **14** that comprise only fluid source **248**, canister **204** and/or pressure sensor **212** can also be omitted. In various embodiments, such as the one shown, conduit **232** and/or conduit **240** and/or conduit **252** can be combined and/or comprised in a single multi-lumen conduit, such as is described above with reference to **FIG. 1**. In some embodiments, fluid source **248** is coupled directly to wound dressing **18** (e.g., conduit **252** is coupled one end to wound dressing **18**, such as via connection pad **54**, and conduit **252** is coupled on the other end to fluid source **248**; and conduit **252** is not coupled to tee fitting **256**).

[0045] In various embodiments, such as the one shown in **FIG. 3**, apparatus **14** can be configured such that as soon as liquid in the canister reaches a level where filter **244** is occluded, a much-increased negative (or subatmospheric) pressure occurs in conduit **208** and is sensed by transducer **216**. Transducer **216** can be connected to circuitry that interprets such a pressure change as a filled canister and signals this by means of a message on an LCD and/or buzzer that canister **204** requires emptying and/or replacement, and/or that automatically shuts off or disables vacuum source **200**.

[0046] Apparatus **14** can also be configured to apply negative (or subatmospheric) pressure (e.g., continuously, intermittently, and/or periodically) to the wound site, and/or such that pressure relief valve **236** enables pressure at the wound site to be brought to atmospheric pressure rapidly. Thus, if apparatus **14** is programmed, for example, to relieve pressure at ten-minute intervals, at these intervals pressure relief valve **236** can open for a specified period, allow the pressure to equalize at the wound site, and then close to restore the negative pressure. It will be appreciated that when constant negative pressure is being applied to the wound site, valve **236** remains closed to prevent leakage to or from the atmosphere. In this state, it is possible to maintain negative pressure at the wound site without running and/or operating pump **200** continuously, but only from time to time or periodically, to maintain a desired level of negative pressure (i.e. a desired pressure below atmospheric pressure), which is sensed by transducer **216**. This saves power and enables the appliance to operate for long periods on its battery power supply.

[0047] Referring now to **FIGS. 4-7**, various views are shown of several embodiments of the present wound inserts. **FIG. 4** depicts an end view of a foam **300** that includes thick regions **304** and thin regions **308** . In the embodiment shown, thick regions **304** and thin regions **308** are

unitary (i.e., are included and defined in a single piece of foam). As shown, the foam is substantially uncompressed such that thick regions **304** and thin regions **308** have substantially the same density. Foam **300** can comprise an open-celled foam (which may also be reticulated), and/or may be hydrophilic and/or hydrophobic. Foam **300** has a trapezoidal configuration in which each thick portion **304** has a trapezoidal shape on each side of thin portions **308**. More particularly, each thick portion **304** has an upper side **312** and a lower side **316**, and each has a trapezoidal shape extending from thin portions **308**. In other embodiments, thick portions **304** may extend from only a single side of thin portions **308** (e.g., only have upper side **312** or lower side **316**). In other embodiments, upper and/or lower sides **312**, **316** of each thick portion **304** can have any shape that permits foam 300 to be compressed, treated, or used as described in this disclosure, such as, for example, square, rectangular, triangular, arcuate, hemispherical, or the like.

[0048] Thick regions **304** have a thickness **320** that is larger or thicker than a thickness **324** of thin regions **308**. For example, thickness **320** of thick regions **304** can be equal to, greater than, less than, or between any of: 120, 140, 160, 180, 200, 220, 240, 260, 280, 300, 320, 340, 360, 380, and/or 400 percent of thickness **324** of thin regions **308**. For example, in some embodiments, thickness **320** is between 200 and 300 percent of thickness **324**, such that, if compressed, to thickness **320**, thick region **304** will have a density of between 2 and 3 times the density of thin region **308**. Thick regions **304** also have a base width **328** (measured at the base of thick region **304** and top of thin regions **308**), and a top width **332**. In the embodiment shown, top width **332** is less than base width **328**, and more particularly, top width **332** is between 70 and 80 percent of base width **328**. In other embodiments, top width **332** can be equal to, less than, greater than, or between any of: 0, 10, 20, 30, 40, 50, 60, 70, 80, 90, and/or 100 percent of base width **328**. Further, thin regions **308** have a width **336** that, in the embodiment shown, is between 30 to 40 percent of base width **328** of thick portions **304**. In other embodiments, width **336** can be equal to, greater than, less than, or between any of: 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, and/or 200 percent of base width 328. For example, in some embodiments, width **336** is between 20 and 50 percent of width 328 such that if compressed, foam 300 will have less low-density regions than high-density regions, and such that the high-density regions wick or draw fluids away from a large wound area, and the low-density regions permit communication of negative pressure to the wound surface.

[0049] **FIG. 5** depicts an end view of another foam **350** including thick regions **354** and thin regions **358** (in the embodiment shown, thick and thin regions **354**, **358** are included and defined in a single piece of foam). As shown, foam **350** is substantially uncompressed such that thick regions **354** and thin regions **358** have substantially the same density. Foam **350** comprises an open-celled foam (which may also be reticulated), such as, for example, a hydrophilic (or hydrophobic) foam. Foam **350** has a sawtooth configuration in which each thick portion **354** has a triangular shape on each side of thin portions **358**. More particularly, each thick portion **354** has an upper side **362** and a lower side **366**, and each has a triangular shape extending from thin portions **358**. In other embodiments, thick portions **354** may extend from only a single side of thin portions **358** (e.g., only have upper side **362** or lower side **366**). In other embodiments, upper and/or lower sides **362**, **366** of each thick portion **354** can have any shape that permits foam 300 to be compressed, treated, or used as described in this disclosure, such as, for example, square, rectangular, arcuate, hemispherical, or the like.

[0050] Thick regions **354** have a thickness **370** that is larger or thicker than a thickness **374** of thin regions **358**. For example, thickness **370** of thick regions **354** can be equal to, greater than, less than, or between any of: 120, 140, 160, 180, 200, 220, 240, 260, 280, 300, 320, 340, 360, 380, and/or 400 percent of thickness **374** of thin regions **358**. Thick regions **354** also have a base width **378** (measured at the base of thick region **354** and top of thin regions **358**). In the embodiment shown, thick portions **354** have a substantially triangular shape such that the width (top width) of each thick portion at the point furthest from thin portions **358** is substantially zero. Thin regions **358** have a width **386** that, in the embodiment shown, is between 30 to 40 percent of base width **378** of thick portions **354**. In other embodiments, width **386** can be equal to, greater than, less than, or between any of: 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, and/or 200 percent of base width **378**.

[0051] **FIG. 6** depicts an end perspective photograph of foam **300** in an uncompressed configuration such as that of **FIG. 4**, and in a compressed configuration in which foam **300** is configured as a wound insert **34a**. As understood with reference to **FIG. 6**, some embodiments of the present methods of making wound inserts comprise: compressing (and/or felting) at least a portion of a foam (e.g., foam **300**) such that the foam has a substantially constant thickness (e.g., thickness **400**). Some embodiments comprise: treating (e.g., by applying heat, or activating a coating that has been applied to) the compressed foam such that the foam remains substantially

compressed in the absence of an external compressive force. For example, in some embodiments, treating comprises heating the foam (e.g., foam) to an elevated temperature sufficient to reduce resiliency of the foam. For example, the foam can be heated to a temperature at which resiliency of the foam is reduced and/or relaxed, but that is below the melting temperature of the foam (e.g., such that the foam is not degraded by the elevated temperature). In this way, the foam can be compression set using heat and pressure (compressive force) to relax compressive strains developed in the foam. Generally, high temperatures are used to achieve the compression set. Examples of foam materials can include polyurethane (e.g., polyethers and/or polyesters), which may be hydrophobic or hydrophylic. To achieve the desired "set" such that resiliency of the foam is reduced and/or the foam remains substantially compressed in the absence of a compressive force, temperatures can range from 158 degrees Fahrenheit to 482 degrees Fahrenheit (e.g., equal to, less than, greater than, or between any of: 140, 160, 180, 200, 220, 240, 260, 280, 300, 320, 340, 360, 380, 400, 420, 440, 460, 480, 500 degrees Fahrenheit, depending upon the particular foam used). The foam may also be put through a cooling cycle to help retain the set introduced. For example, the foam may be cooled to a temperature below room or ambient temperature (e.g., to or in a temperature equal to, less than, greater than, or between any of: 0, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, or 70 degrees Fahrenheit). In some embodiments of the present methods of forming a wound insert, the foam (e.g., foam 300) is disposed between two heated plates or platens (e.g., in a plate or platen press and/or where the plates are heated to a temperature sufficient to reduce the resiliency of the foam); and the press is actuated to move the plates toward one another (e.g., perpendicular to thickness 320 of thick portions 304) such that the foam is compressed to the desired overall thickness or degree of compression). Such a press can be electrically, mechanically, and/or hydraulically operated. Other foams that may be suitable include crosslinked and/or uncrosslinked polyolefin's, ethylene vinyl acetate (EVA), and elastomers such as acrylonitrile butadiene (NBR), polychloroprene (PCP or CR), ethylene propylene rubber (EPR & EPDM), silicones, and fluoro carbon polymers.

[0052] Some embodiments of the present methods of making wound inserts also comprise: cooling the foam (e.g., after heating the foam) such that the compressed portion of the foam remains substantially compressed at room temperature (e.g., at a temperature of 72 degrees Fahrenheit) in the absence of a compressive force. In other embodiments, cooling the foam includes cooling a coating that has been applied to the foam such that the compressed portion

remains substantially compressed in the absence of a compressive force at a temperature or temperature range equal to, less than, greater than, or between any of: 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, and/or 150 degrees Fahrenheit. In some embodiments, prior to being compressed, the foam (e.g., **300**) includes thick regions (e.g., **304**) and thin regions (e.g., **308**) having substantially the same densities, and/or any other characteristics described above for foams **300** or **350** with reference to **FIGS. 4** and **6**; and after being compressed, the thick regions (e.g., **304**) have a density greater than the density of the thin regions (e.g., **304**).

[0053] Thick and thin regions (e.g., **304**, **308** and **354**, **358**) in the foam can be formed by any suitable methods, such as, for example, laser cutting or the like. For example, **FIG. 9** shows a photograph of sheets of foam that have been cut in grid patterns by laser cutting, in a configuration that may be a precursor to certain of the present embodiments. For example, in the embodiment shown, portions of the sheets of foam may be removed along the grid pattern to define the thick portions and thin portions described above..

[0054] In some embodiments, the foam is compressed such that thickness **400** of the compressed foam **300** is substantially equal to the pre-compressed thickness **324** of thin portions **308**. In other embodiments, the foam is compressed such that thickness 400 of the compressed foam **300** (wound insert **34a**) is equal to, less than, greater than, or between any of: 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, and 100 percent of thickness **324** of pre-compressed thin portions **308**. In other embodiments, foam **300** is compressed such that only thick portions **304** are compressed and thickness **400** of the compressed foam **300** (wound insert **34a**) is greater than thickness **324** of pre-compressed thin portions **308**.

[0055] Other embodiments of the present embodiments of making wound inserts comprise: compressing at least a portion of a foam (e.g., **300**) such that the foam (e.g., **300**) has a substantially constant thickness (e.g., **400**). In some embodiments, treating the foam comprises: activating a coating (e.g., a liquid coating such as adhesive or the like) that is applied to or distributed through at least a portion of the foam (e.g., **300**) such that the compressed portion remains at least partially compressed (e.g., remains substantially compressed) in the absence of an external compressive force, such as at room temperature (e.g., at a temperature of 72 degrees Fahrenheit). For example, in some embodiments, a coating (e.g., an adhesive or cross-linkable polymer fluid) can be applied to the foam before or after compressing the foam, such that the coating can be activated (e.g., dried or activated with UV light) to substantially maintain the

compression of the foam. In other embodiments, activating a coating includes activating the coating such that the compressed portion remains substantially compressed in the absence of a compressive force at a temperature or temperature range equal to, less than, greater than, or between any of: 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, and/or 150 degrees Fahrenheit. In some embodiments, prior to being compressed, the foam (e.g., **300**) includes thick regions (e.g., **304**) and thin regions (e.g., **308**) having substantially the same densities, and/or any other characteristics described above for foams **300** or **350** with reference to **FIGS. 4** and **6**; and after being compressed, the thick regions (e.g., **304**) have a density greater than the density of the thin regions (e.g., **304**).

[0056] In some embodiments, the foam is compressed such that thickness **400** of the compressed foam **300** is substantially equal to the pre-compressed thickness **324** of thin portions **308**. In such embodiments, the coating can be dispersed through the foam, such as, for example, by spraying the foam with the coating, dipping the foam in the coating, and/or any other suitable way of dispersing the coating in the foam. In some embodiments, for example, the foam can be coated with a material that has a transition temperature (e.g., melting point, glass transition, etc.) that occurs at a relatively low temperature (e.g., lower than the foam alone), or that develops stiffness as it dries. In some embodiments, the coating can be configured to enable the foam to be compressed (and/or compression set) at lower temperatures (e.g., without heating), such that the coating becomes stiff or otherwise resistant to expansion as it cools or dries to hold the foam in its compressed configuration. For example, a fluid adhesive may be applied to thick portions before compressing the foam and permitted to dry before removing the compressive force, such that the dried adhesive will resist expansion from the compressed thickness. In other embodiments, the coating can be configured to compression set the foam such that the compression is reversible (e.g., at least partially and/or completely reversible) such that the foam can expand (e.g., after placing in or on a wound) as it warms or absorbs water. In some embodiments, the coating comprises a cross-linkable polymer and/or activating comprises exposing the coating to light and/or elevated temperature (e.g., above ambient temperature, such as, for example, a temperature sufficient to cause at least part of the cross-linkable polymer to cross-link) to cause at least some portion of the cross-linkable polymer to become cross-linked.

[0057] Examples of suitable coatings include cross-linkable polymers that contain n-methylol acrylamide (NMA). NMA is a monomer that may be co-polymerized with many other

monomers (such as acrylics & vinyls). On heating, (e.g., to about 140°C), NMA reacts with itself and other hydroxyl-containing groups (e.g., carboxyl). Similarly, urea formaldehyde, melamine formaldehyde, and/or phenol formaldehyde can be caused to react with themselves and other hydroxyl-containing polymers to form crosslinks. Other crosslinking agents may include, for example, modified ethylene ureas, which react with hydroxyl-containing polymers at elevated temperatures to crosslink them. Other crosslinking agents can include peroxides which will crosslink most polymers at elevated temperatures. Polymers containing hydroxyl and carboxyl groups may also be combined, and, when heated, may form polyester crosslinks. Additionally, epoxy prepolymers can be used that have low reactivity at room temperatures, and when heated, react quickly to form an epoxy polymer with crosslinks. Similarly, polymeric isocyanates may be used that will only react significantly fast at elevated temperatures and in presence of hydroxyl groups, amines, or moisture to form polyurethanes or polyureas.

[0058] **FIG. 7** illustrates a side view of wound insert **34a** (compressed foam **300**). As shown, after being compressed, the density of thick regions **304** increases because the foam material of thick regions **304** is compressed into a smaller space. As a result, wound insert **304** comprises compressed foam **300** (at least partially compressed – thin portions **308** may not be compressed at all) having high-density regions **404** and low-density regions **408** having a density that is less than the density of the high-density regions. More particularly, in the embodiment shown, high-density regions **404** and low-density regions are configured in alternating rows. In other embodiments, high-density regions **404** and low-density regions can be configured in any suitable pattern, such as, for example, a grid pattern or the like. The present wound inserts can be formed by any of the present methods described above.

[0059] The combination of high-density regions (e.g., **404**) and low-density regions (e.g., **408**) cooperate to provide various characteristics for the present wound inserts. For example, the high-density regions have a smaller aggregate cell size and increased cell density, such that the high-density regions have improved wicking function and more-effectively transmit fluid (e.g., draw fluids away from the wound surface and/or communicate fluid from a fluid source to the wound surface more effectively than the low-density regions. The high-density regions are generally also mechanically stronger than the low-density regions, such that the high-density regions can provide structural support for the low-density regions and/or the wound insert as a whole (e.g., such that the wound insert is resistant to tearing in directions that are not parallel to

the low-density regions). Additionally, the low-density regions have a larger effective cell or pore size such that the low-density regions are less-susceptible to clogging. Especially when a negative pressure is applied to draw fluid and/or exudate away from the wound and through the wound insert, the larger pore size of the low-density regions may permit fluids to be drawn through the low-density regions at a higher velocity than the fluid is drawn through the high-density regions, such that particulate and granular matter are drawn to and/or through the low-density to discourage and/or decrease the likelihood of clogging in the high-density regions. In some embodiments, the foam can also be coated with a hydrophilic material to improve wicking properties of the wound insert.

[0060] The low-density regions may also be configured to permit the wound dressing to bend and/or otherwise conform to a wound. For example, the low-density regions can be relatively easier to bend (and/or less resilient when the wound insert is bent or folded along a low-density region) such as to double over a wound insert, and/or to conform a wound insert to additional hardware such as plates, pins, or the like. Typical single-density foam wound inserts are isotropic such that under negative pressure, a typical single-density foam wound insert will contract proportionally in all directions. In contract, the present wound inserts are configured to be anisotropic, such that the present wound inserts can be configured to mechanically assist with wound closure. For example, low-density regions **408** are less-dense (and will compress more under negative pressure) than high-density regions. As such, in the embodiment of **FIG. 7**, if negative pressure is applied to wound insert **34a**, low density regions **408** will contract more than high-density regions **404**, such that high-density regions **404** will be drawn together and wound insert **34a** will contract laterally (perpendicular to the rows of regions **404**, **408**) more than longitudinally. As noted, the present wound inserts can be configured to have such anisotropic properties, and the present methods can employ such anisotropic properties, to mechanically assist closure of a wound, and/or apply other therapeutic strains to the wound (e.g., wound surface), while simultaneously applying a negative pressure to the wound and/or delivering fluids to the wound. For example, in other embodiments, the present wound inserts can be configured to have alternating and sequentially larger closed ring-shaped high-density regions **404** and low-density regions **408**, such that under negative pressure, the wound insert will contract laterally inward to its own center.

[0061] **FIGS. 8A** and **8B** illustrate the improved wicking or "wetting" properties of the present wound inserts. More particularly, forward-looking infrared (FLIR) images are shown in **FIG. 8A** of a traditional wound insert **34**, a wound insert **34a** formed from foam **300** (having a trapezoidal or tapered squaretooth configuration) of **FIG. 4**, and a wound insert **34b** formed in similar fashion from foam **350** (having a triangular sawtooth configuration) of **FIG. 5**. **FIG. 8A** shows the wound inserts at an initial time before fluid is delivered to the lower ends of each of the wound inserts **34**, **34a**, and **34b**; and **FIG. 8B** shows the wound inserts after fluid has been delivered to the lower ends of each of the wound inserts **34**, **34a**, and **34b**. As shown, the present wound inserts **34a** and **34b** wick fluid away from their lower ends, and through their respective lengths, more quickly than the traditional wound insert **34**. This improved wicking of the present wound inserts may be even more pronounced where wound inserts **34a** and **34b** comprise hydrophilic foam or are coated with a hydrophilic coating. In some embodiments, thick portions **304**, thin portions **308**, high-density regions **404**, and/or low-density regions **408** can be coated and/or printed (either before or after compression) to enhance the hydrophilic or hydrophobic properties of individual regions of the foam or of the foam as a whole. Such coated regions may also contain and/or be coated with other additives, such as antibiotics, or blockage-reducing agents.

[0062] Referring now to **FIGS. 10-11**, embodiments are shown of the present wound inserts illustrating additional features of the present wound inserts. **FIG. 10** illustrates a photograph of a top view of wound insert **34**. Wound insert **34** is configured to have anisotropic properties. More particularly, high-density regions **404** have a greater tensile strength than low-density regions **408** such that wound insert can be torn along low-density regions **408**, as shown. More specifically, when a tearing force is applied to wound insert **34** (e.g., by pulling two high-density regions **404** in directions away from one another), the foam is more likely to tear along a low-density region **408** between the high-density regions than in any other direction. As such, the low-density regions **408** can be described as zones of relative weakness that permit directional tearing without having to separately perforate the foam (e.g., reducing manufacturing costs and complexity, and eliminating the debris that may be formed by perforating processes). While low-density regions **408** are provided in rows in the embodiments shown, in other embodiments low-density regions can be provided in any suitable configuration. For example, the present wound inserts can comprise low-density regions **408** and high-density regions **404** in

alternating, sequentially larger rectangles (e.g., squares), rings (e.g., circles), or a checker-board pattern.

[0063] **FIG. 11** shows a photograph of a portion of wound insert **34a**, and more-particularly, shows a high-density region **404** that has been torn or otherwise separated to include a single high-density region **404** and portions of the adjacent low-density regions **408** adjoining the high-density region **404**. As shown, the high density region **408** is mechanically strong and/or durable enough to be compressed into various shapes. For example, in the embodiment shown, high-density region **404** has been spiraled into a circular configuration. Additionally, a single high-density region **404** (and adjoining portions of the adjacent low-density regions) can be torn or otherwise removed from a wound insert **34**, such that the high-density region **404** can be inserted into a tunnel-type wound, and/or removed from a tunnel-type wound without breaking the foam and/or losing particles of foam in the wound.

[0064] Some embodiments of the present wound dressings comprise a wound dressing (e.g., any of the present wound dressings, such as **34a**, **34b**) configured to be positioned on a wound (e.g., **26**) of a patient (e.g., **30**) and/or on or in contact with the wound surface (e.g., **42**), where the wound insert comprises a foam (e.g., **300**) having high-density regions (e.g., **404**) and low-density regions (e.g., **408**) having a density that is less than the density of the high-density regions. In some embodiments, the foam is sterile (e.g., substantially free of microbes and/or bacteria). Some embodiments further comprise a drape (e.g., **38**) configured to be coupled to skin (e.g., **46**) of the patient such that the drape covers the wound insert and the wound, and forms a space between the drape and the wound (e.g., in a manner such as that shown in **FIG. 1**).

[0065] Some embodiments of the present wound-treatment methods comprise: positioning a wound insert (e.g., any of the present wound inserts such as **34a**, **34b**) on a wound (e.g., **26**) of a patient (e.g., **30**), where the wound insert comprises a foam (e.g., **300**) having high-density regions (e.g., **404**) and low-density regions (e.g., **408**) having a density that is less than the density of the high-density regions. In some embodiments, the foam is sterile (e.g., substantially free of microbes and/or bacteria). Some embodiments further comprise: coupling a drape (e.g., **38**) to skin (e.g., **46**) adjacent the wound such that the drape covers the wound insert and the wound, and forms a space between the drape and the wound. Some embodiments comprise: applying negative pressure to the wound through the wound dressing (e.g., through the wound insert). In some embodiments, applying negative pressure to the wound comprises

activating a vacuum source (e.g., apparatus **14** of **FIG. 1**, or vacuum source **200** of **FIG. 3**) that is coupled to the wound dressing. Some embodiments comprise: delivering a fluid to the wound through the wound dressing. In some embodiments, delivering a fluid comprises activating a fluid source (e.g., fluid source **248** of **FIG. 3**) that is coupled to the wound dressing.

[0066] Some embodiments of the present wound-treatment systems comprise either embodiment of system **10** (or any subset of components of either embodiment of system **10**), and one or more of the present wound inserts and/or wound dressings.

[0067] The various illustrative embodiments of devices, systems, and methods described herein are not intended to be limited to the particular forms disclosed. Rather, they include all modifications and alternatives falling within the scope of the claims.

[0068] The claims are not intended to include, and should not be interpreted to include, means-plus- or step-plus-function limitations, unless such a limitation is explicitly recited in a given claim using the phrase(s) "means for" or "step for," respectively.

[0069] It will be understood that the benefits and advantages described above may relate to one embodiment or may relate to several embodiments. It will further be understood that reference to 'an' item refers to one or more of those items, unless otherwise specified.

[0070] The steps of the methods described herein may be carried out in any suitable order, or simultaneously where appropriate.

[0071] Where appropriate, aspects of any of the examples described above may be combined with aspects of any of the other examples described to form further examples having comparable or different properties and addressing the same or different problems.

[0072] It will be understood that the above description of preferred embodiments is given by way of example only and that various modifications may be made by those skilled in the art. The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments. Although various embodiments have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of this invention.

CLAIMS:

1. A method of making a wound insert using a foam having thick portions and thin portions that are thinner than the thick portions, comprising:

compressing at least a portion of the foam so that the foam has a substantially constant thickness, and so that a density of the thick portions is greater than a density of the thin portions, wherein prior to compressing the foam, the density of the thick portions is a same density as the density of the thin portions; and

after compressing the foam, treating the foam so that the foam remains substantially compressed in an absence of an external compressive force.

2. The method of claim 1, wherein treating the foam comprises heating the foam to reduce a resiliency of the foam.

3. The method of claim 1, wherein treating the foam comprises activating a coating that is distributed through at least a portion of the foam.

4. The method of claim 3, wherein the coating is activated by heating the foam and the coating.

5. The method of claim 3, wherein the coating comprises an adhesive.

6. The method of claim 3, wherein the coating comprises a cross-linkable polymer, and wherein activating the coating comprises exposing the coating to at least one of light or an elevated temperature to cause at least a portion of the cross-linkable polymer to become cross-linked.

7. The method of any one of claims 1 to 6, further comprising cooling the foam after treating the foam.

8. The method of any one of claims 1 to 7, wherein after compressing the foam, a thickness of the thick portions is substantially equal to an uncompressed thickness of the thin portions.

9. The method of any one of claims 1 to 8, wherein after the foam is compressed, the foam is configured to exhibit anisotropic properties.

10. A wound insert for use with a wound dressing, the wound insert comprising:

a foam having a plurality of regions configured as high-density regions and low-density regions when the foam is at least partially compressed and configured as the wound insert, wherein a density of the high-density regions is greater than a density of the low-density regions, and wherein the plurality of regions of the foam have a density that is substantially the same when the foam is uncompressed.

11. The wound insert of claim 10, wherein the foam comprises a hydrophilic foam.

12. The wound insert of claim 10, wherein the high-density regions and the low-density regions are configured in a grid pattern or in alternating rows.

13. A wound dressing for healing a wound using negative pressure wound therapy, the wound dressing comprising:

the wound insert according to any one of claims 10 to 12; and

a drape configured to couple to skin of a patient adjacent the wound so that the drape covers the wound insert and the wound, and wherein the drape is configured to form a space between the drape and the wound.

14. A method of making a wound insert using a foam having thick regions and thin regions that are thinner than the thick regions, the method comprising:

compressing at least a portion of the foam so that the foam has a substantially constant thickness and so that a density of the thick regions comprises a density that is greater than a density of the thin regions, wherein prior to compressing the foam, the density of the thick regions comprises a density that is substantially the same as a density of the thin regions;

heating the foam to an elevated temperature to reduce a resiliency of the foam; and

cooling the foam so that at least the portion of the foam that is compressed remains substantially compressed.

15. The method of claim 14, wherein the foam comprises an open-celled foam.

16. The method of claim 15, wherein the foam comprises a hydrophilic foam.

17. The method of claim 14, wherein after compressing the foam, a thickness of the thick regions is substantially equal to an uncompressed thickness of the thin regions.

18. The method of claim 14, wherein after compressing the foam, the foam is configured to exhibit anisotropic properties.

19. A method of making a wound insert using a foam comprising thick regions and thin regions that are thinner than the thick regions, the method comprising:

compressing at least a portion of the foam so that the foam has a substantially constant thickness and so that a density of the thick regions comprises a density that is greater than a density of the thin regions, wherein prior to compressing at least the portion of the foam, a density of the thick regions comprises a same density as a density of the thin regions; and

activating a coating that is distributed through at least a portion of the foam so that at least the compressed portion of the foam remains at least partially compressed in an absence of an external compressive force.

20. The method of claim 19, wherein the coating comprises an adhesive.

21. The method of claim 19, wherein the coating comprises a cross-linkable polymer, wherein activating the coating comprises exposing the coating to at least one of light or an elevated temperature to cause at least a portion of the cross-linkable polymer to become cross-linked.

22. A wound insert for use with a wound dressing, the wound insert comprising:

a foam having a plurality of regions configured as high-density regions and low-density regions that have a density that is less than a density of the high-density regions when the foam is at least partially compressed, wherein the plurality of regions of the foam have a density that is substantially the same when the foam is uncompressed, and wherein the high-density regions and the low-density regions are configured in a grid pattern or in alternating rows.

23. The wound insert of claim 22, wherein the foam is formed by the method of claim 15.

24. The wound insert of claim 22, wherein the foam comprises a hydrophilic foam.

25. A wound dressing comprising:

a wound insert configured to be positioned on a wound, the wound insert comprising a foam having a plurality of regions configured as high-density regions and low-density regions that have a density that is less than a density of the high-density regions when the foam is at least partially compressed and configured as the wound insert, wherein the plurality of regions of the foam have a density that is substantially the same when the foam is uncompressed; and

a drape configured to be coupled to skin adjacent the wound so that the drape covers the wound insert and the wound, wherein the drape is configured to form a space between the drape and the wound.

26. Use of a wound dressing for treating a wound on a patient, the wound dressing including a wound insert configurable in a compression state and comprising a foam having a first region and a second region, wherein a density of the first region is the same as a density of the second region when the foam is in an uncompressed state, and wherein the density of the first region is greater than the density of the second region when the foam is in the compressed state,

wherein the wound insert is configured to be positioned on the wound,

wherein the wound dressing includes a drape configured to be coupled to skin adjacent the wound so that the drape covers the wound insert and the wound, wherein the drape is configured to form a space between the drape and the wound.

27. Use of the wound dressing according to claim 26, wherein negative pressure is applicable to the wound through the wound insert.

28. Use of the wound dressing according to claim 27, wherein a vacuum system is couplable to the wound insert and is activatable to apply the negative pressure.

29. Use of the wound dressing according to claim 26, wherein the wound insert is configured for delivery of a fluid to the wound through the wound insert.

30. Use of the wound dressing according to claim 29, wherein a fluid source is couplable to the wound insert and is activatable for delivery of the fluid to the wound.

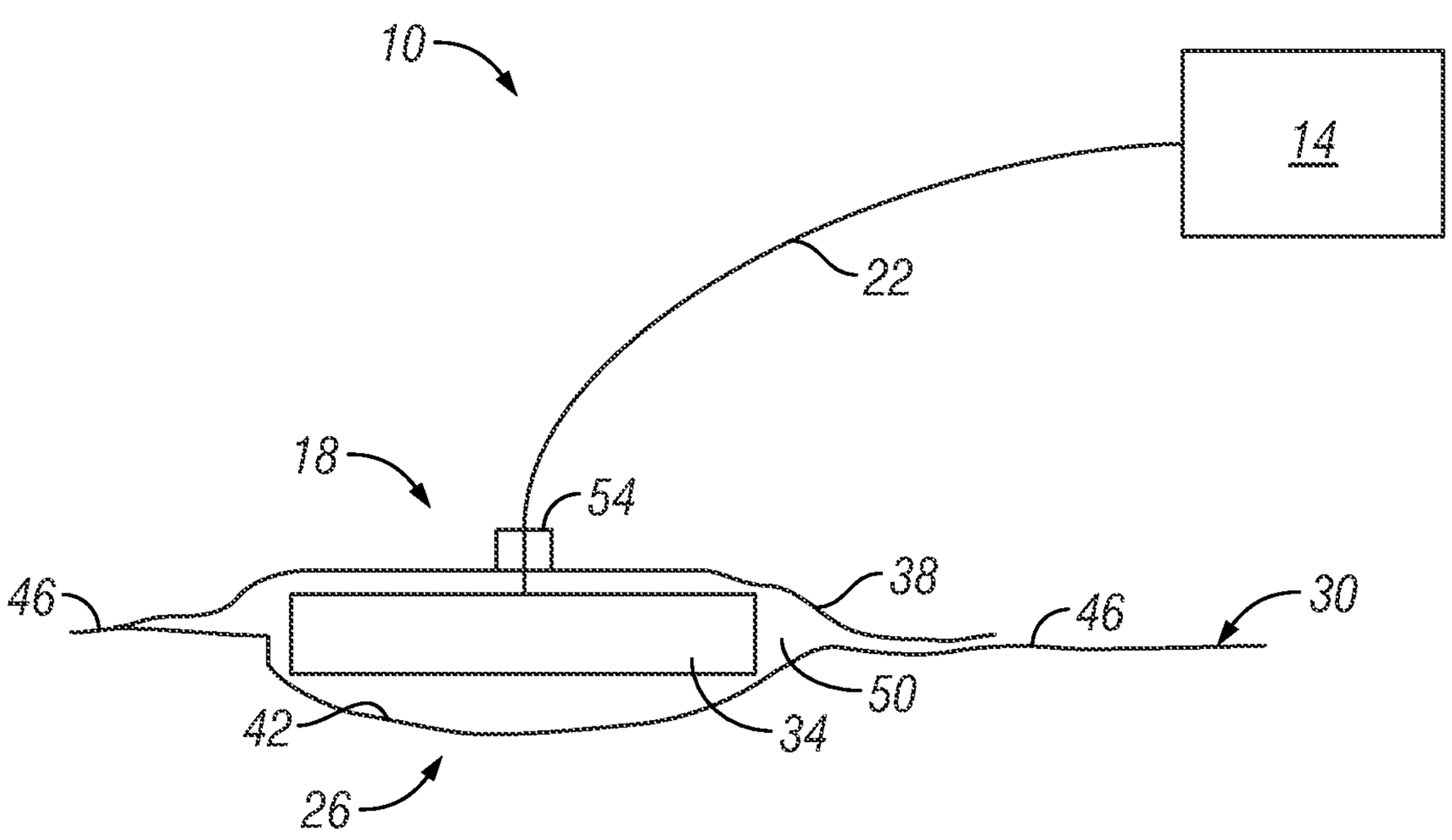


FIG. 1

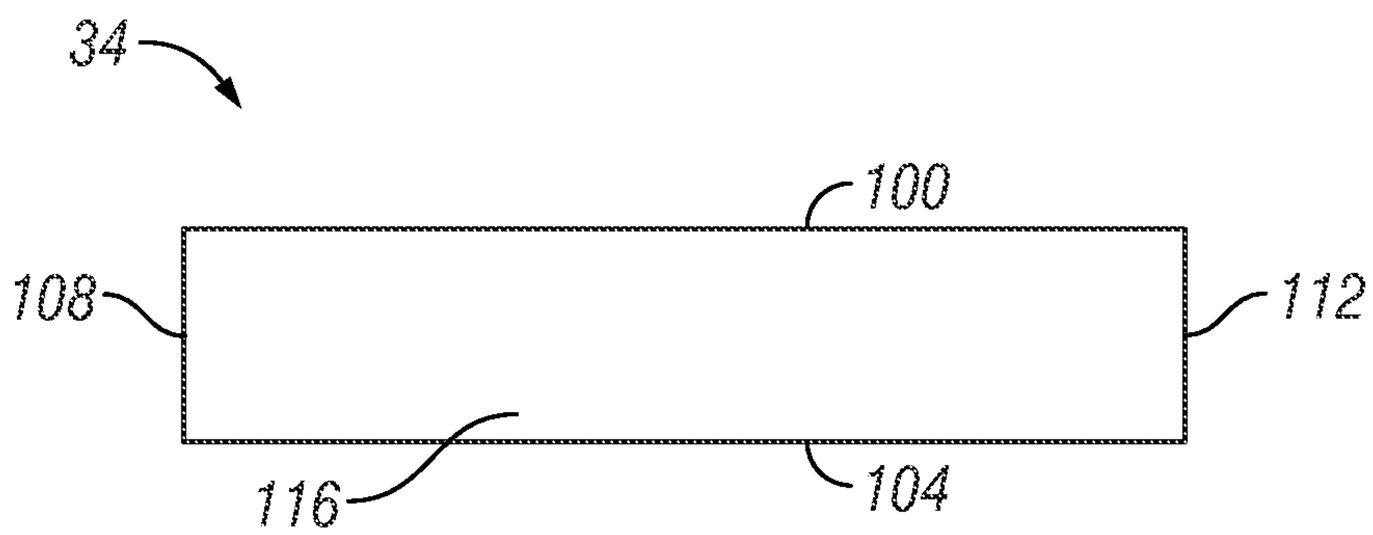


FIG. 2

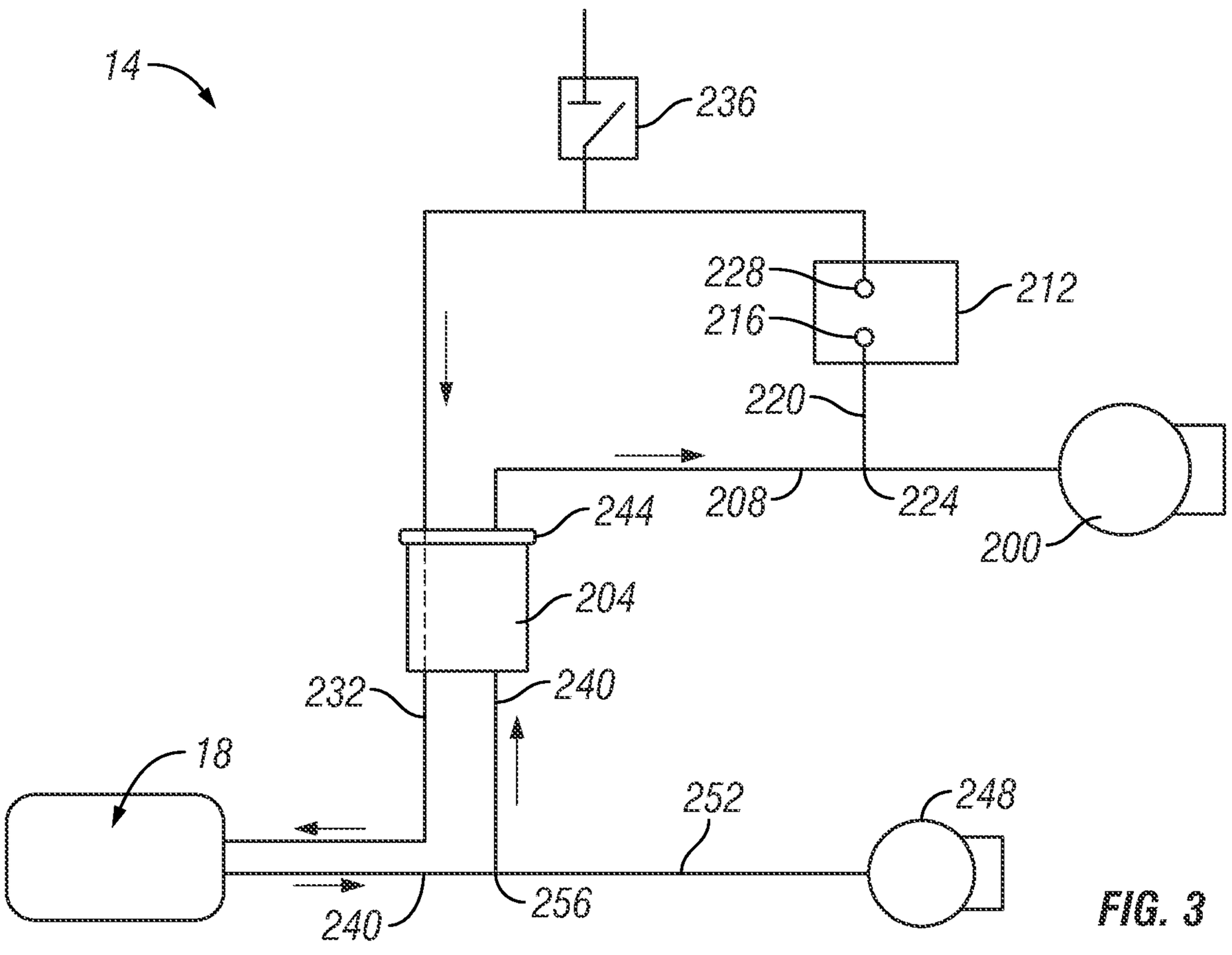

14
236
228
216
212
220
208
224
244
200
204
232
240
18
252
248
240
256

FIG. 3

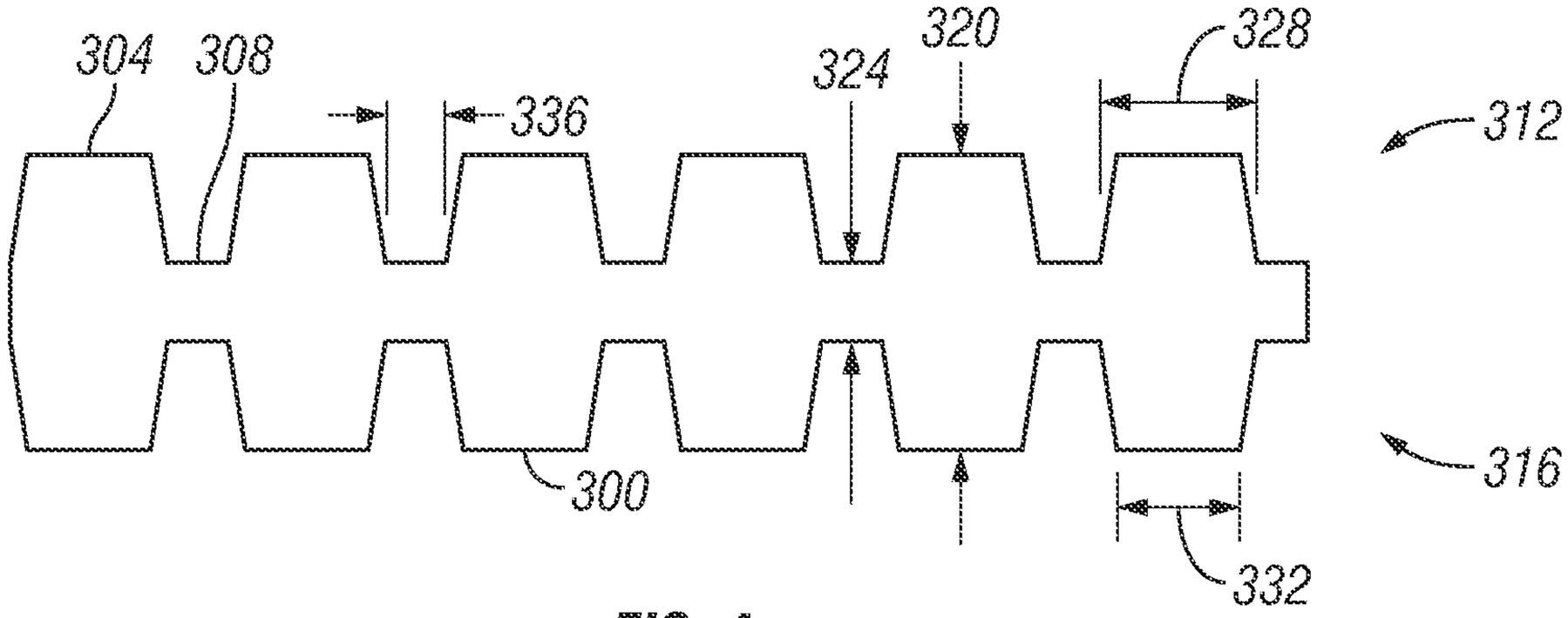

304
308
336
324
320
328
312
300
316
332

FIG. 4

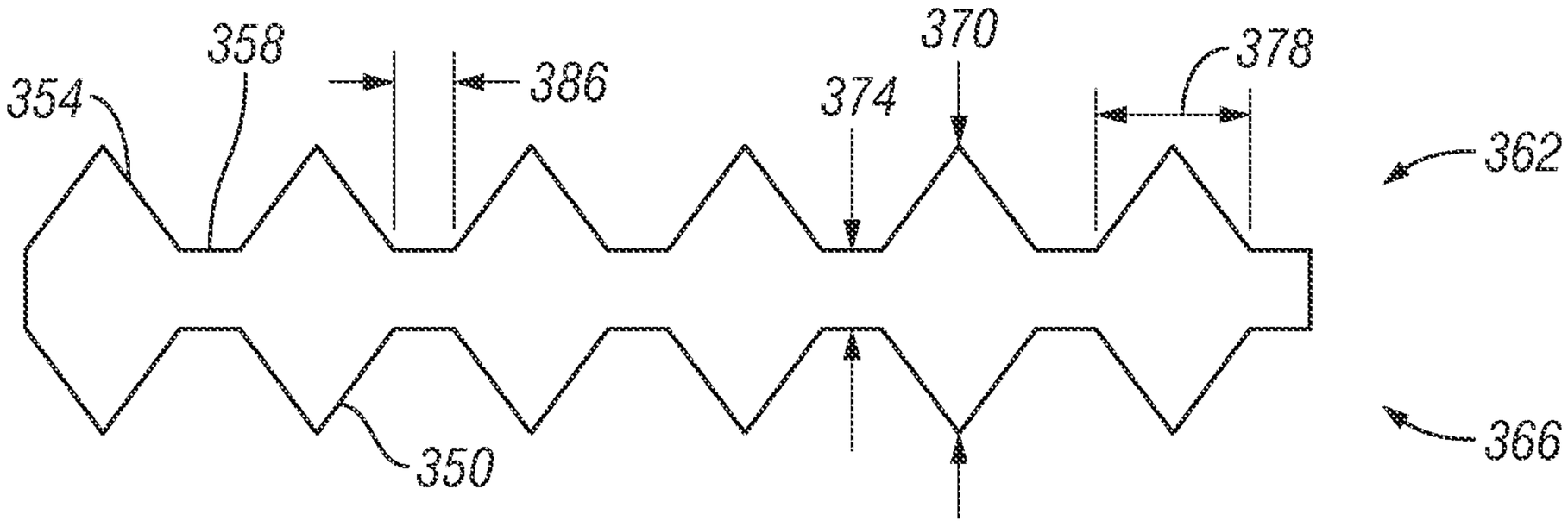

354
358
386
374
370
378
362
350
366

FIG. 5

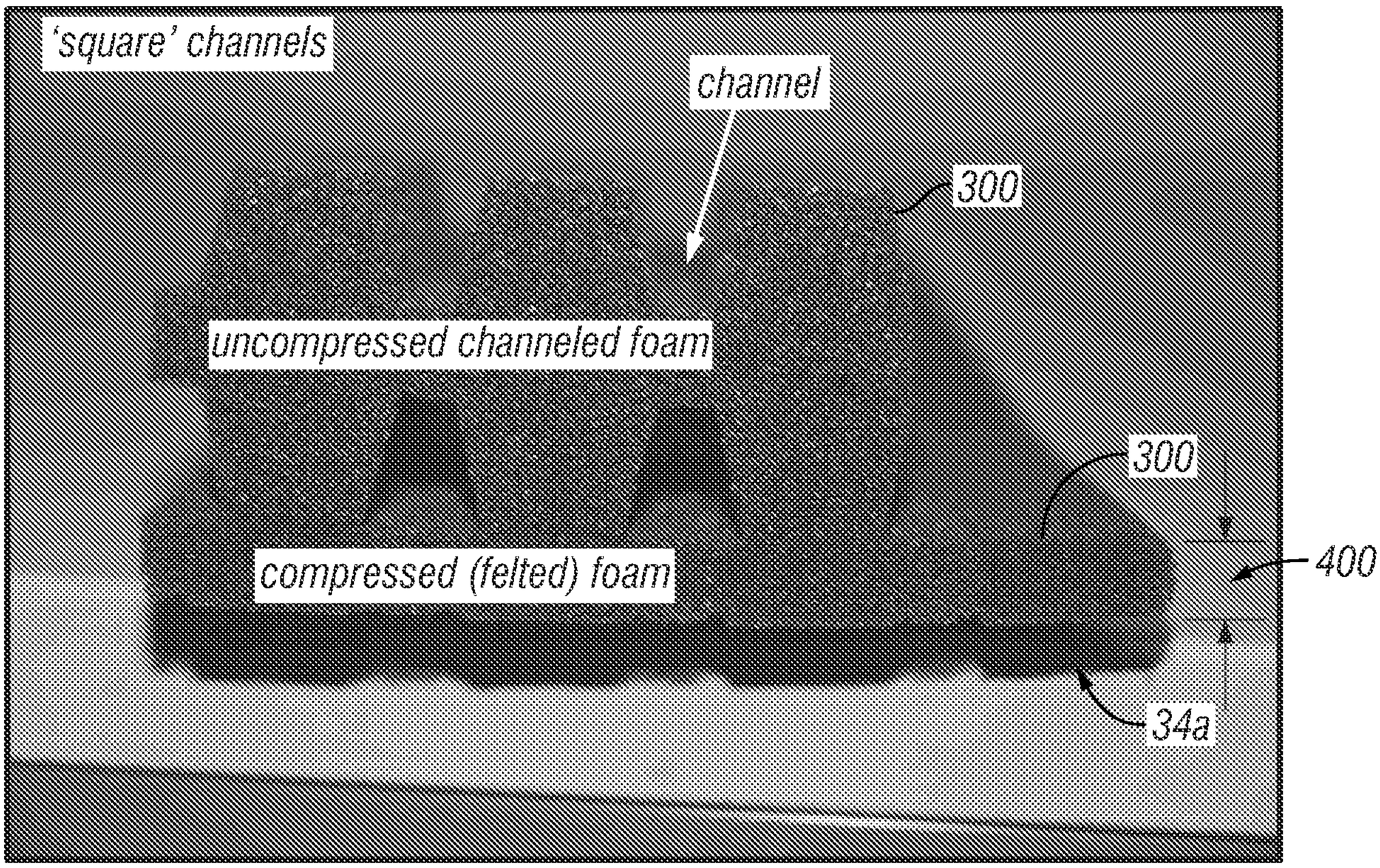

'square' channels
channel
300
uncompressed channeled foam
300
compressed (felted) foam
400
34a

FIG. 6

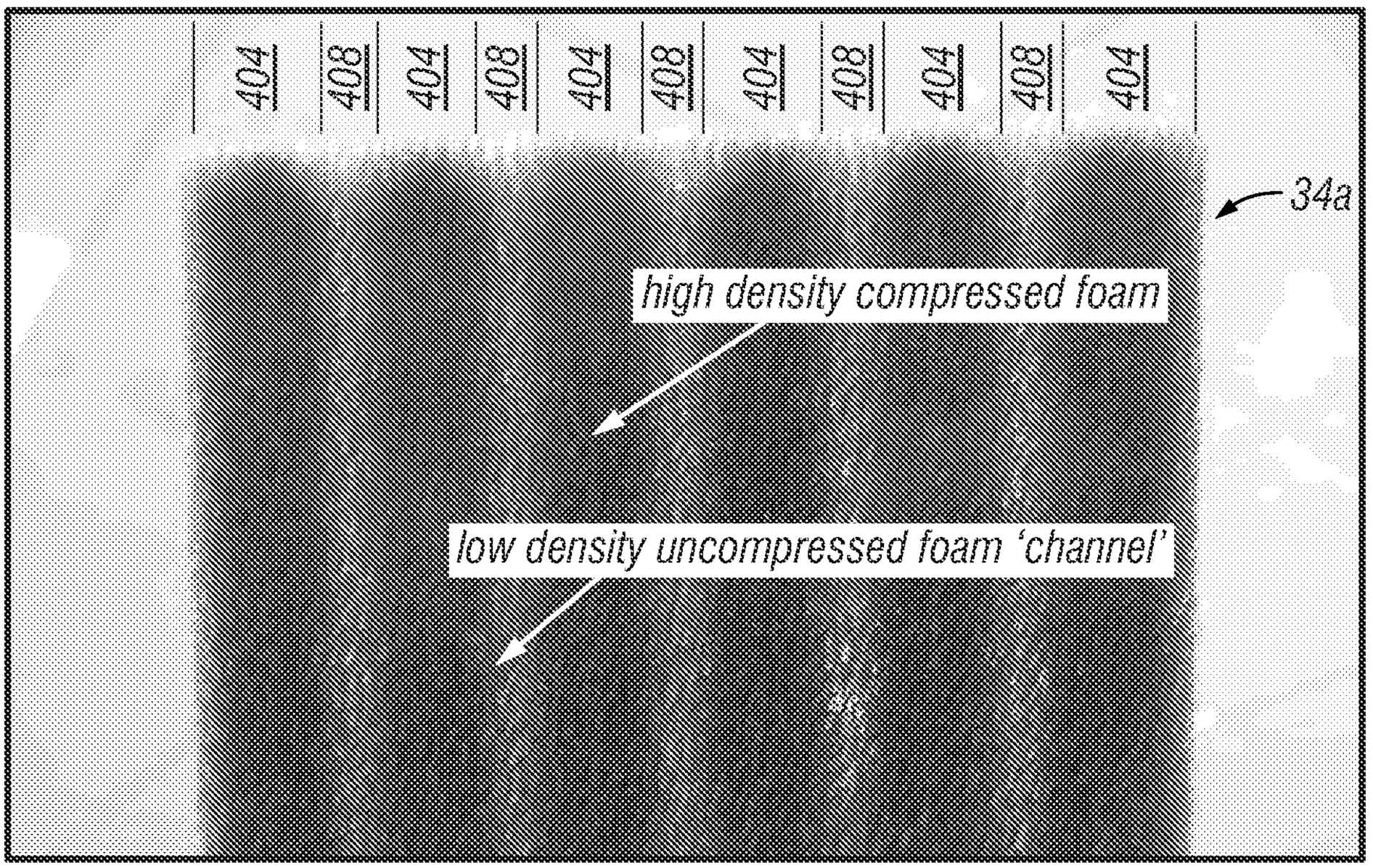

404
408
404
408
404
408
404
408
404
408
404
34a
high density compressed foam
low density uncompressed foam 'channel'

FIG. 7

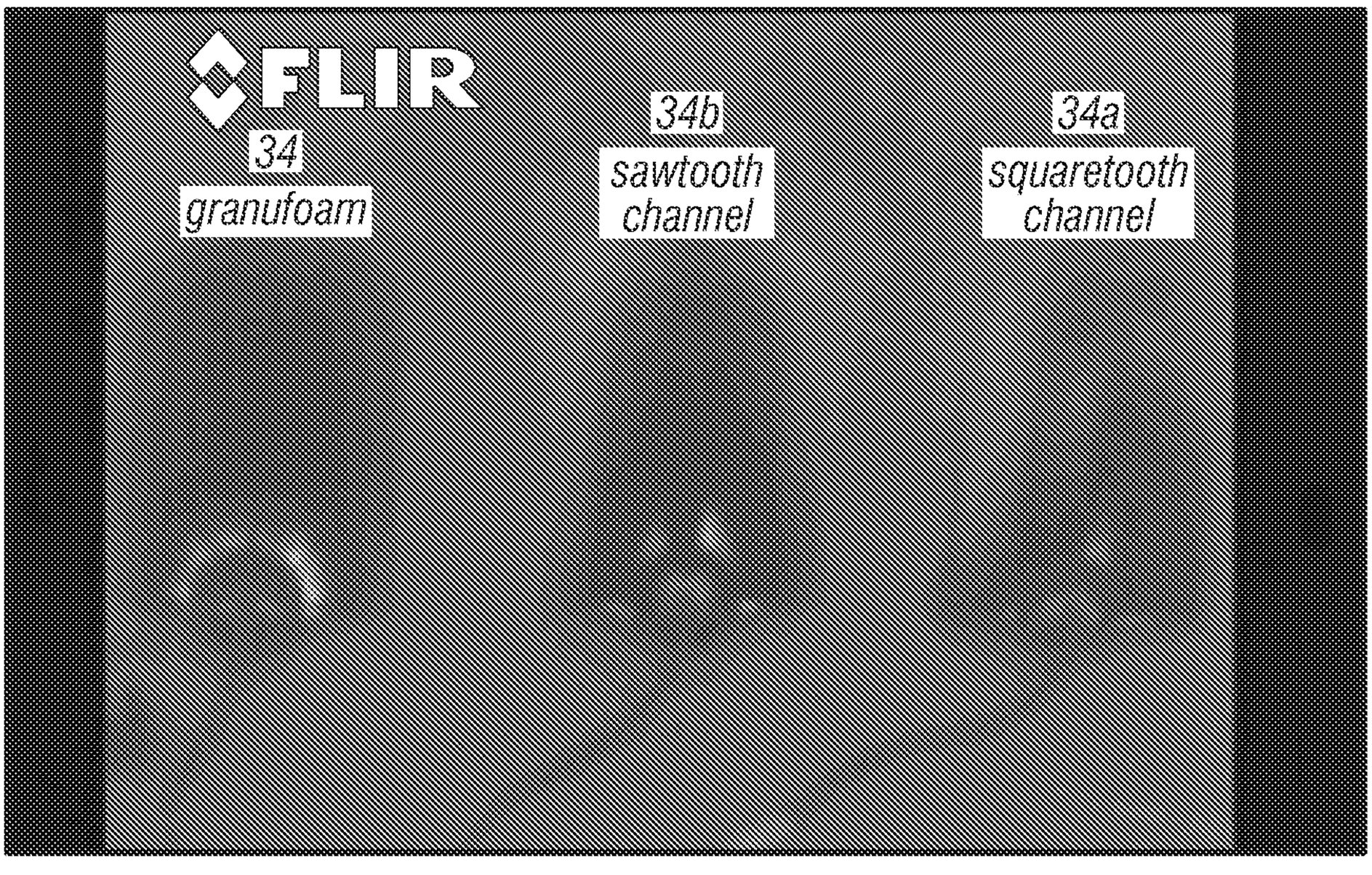

FLIR
34
granufoam
34b
sawtooth
channel
34a
squaretooth
channel

FIG. 8A

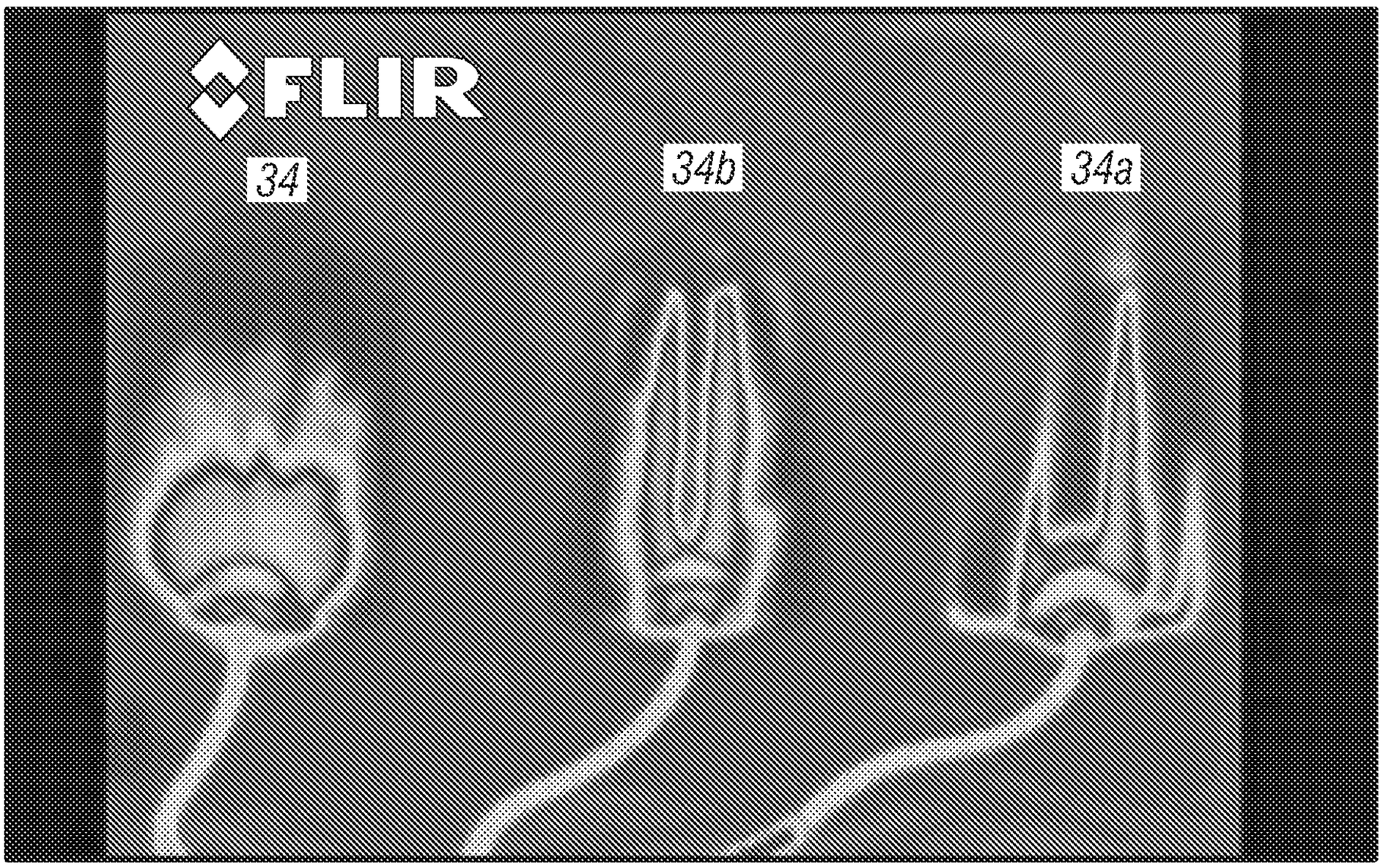

FLIR
34
34b
34a

FIG. 8B

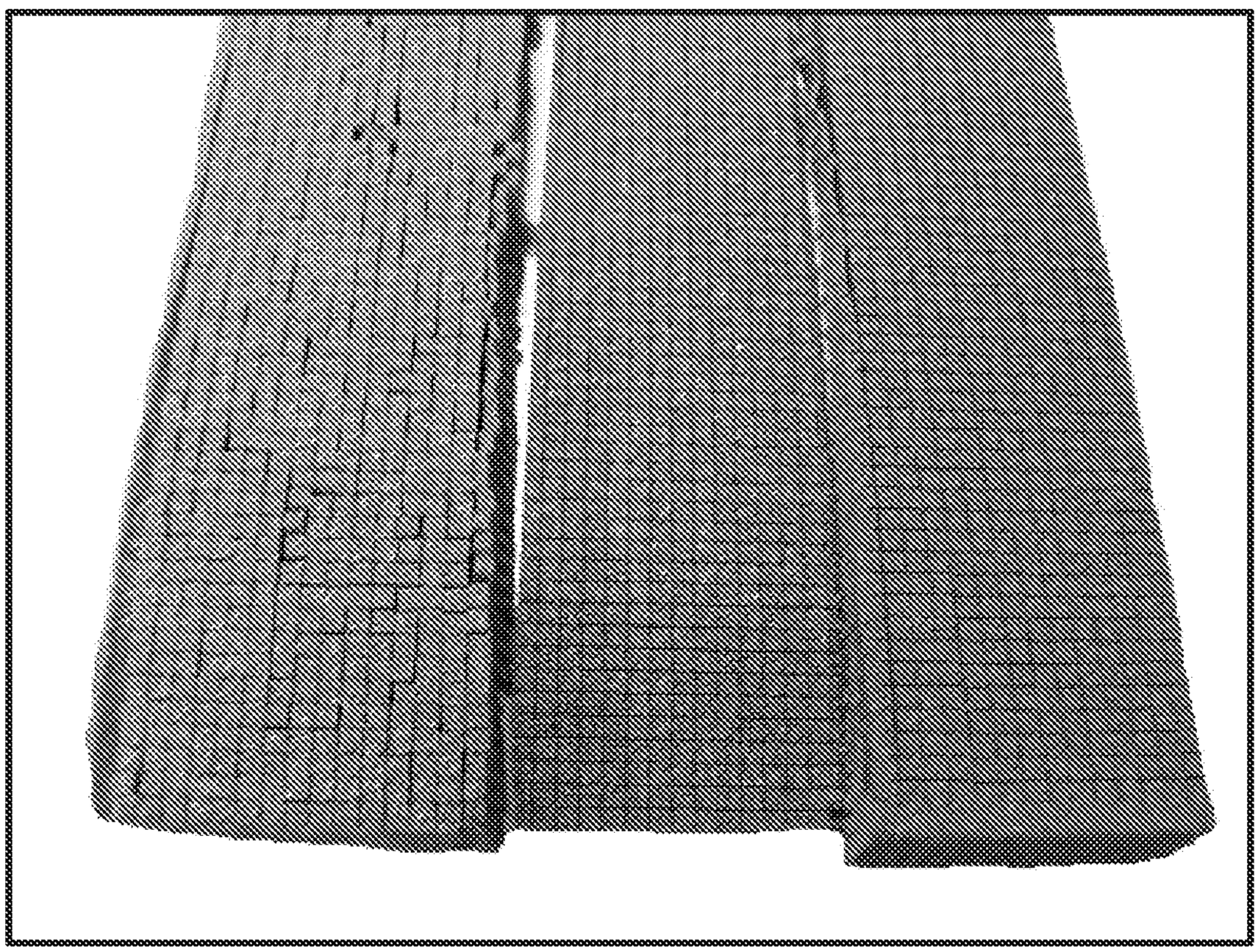


FIG. 9

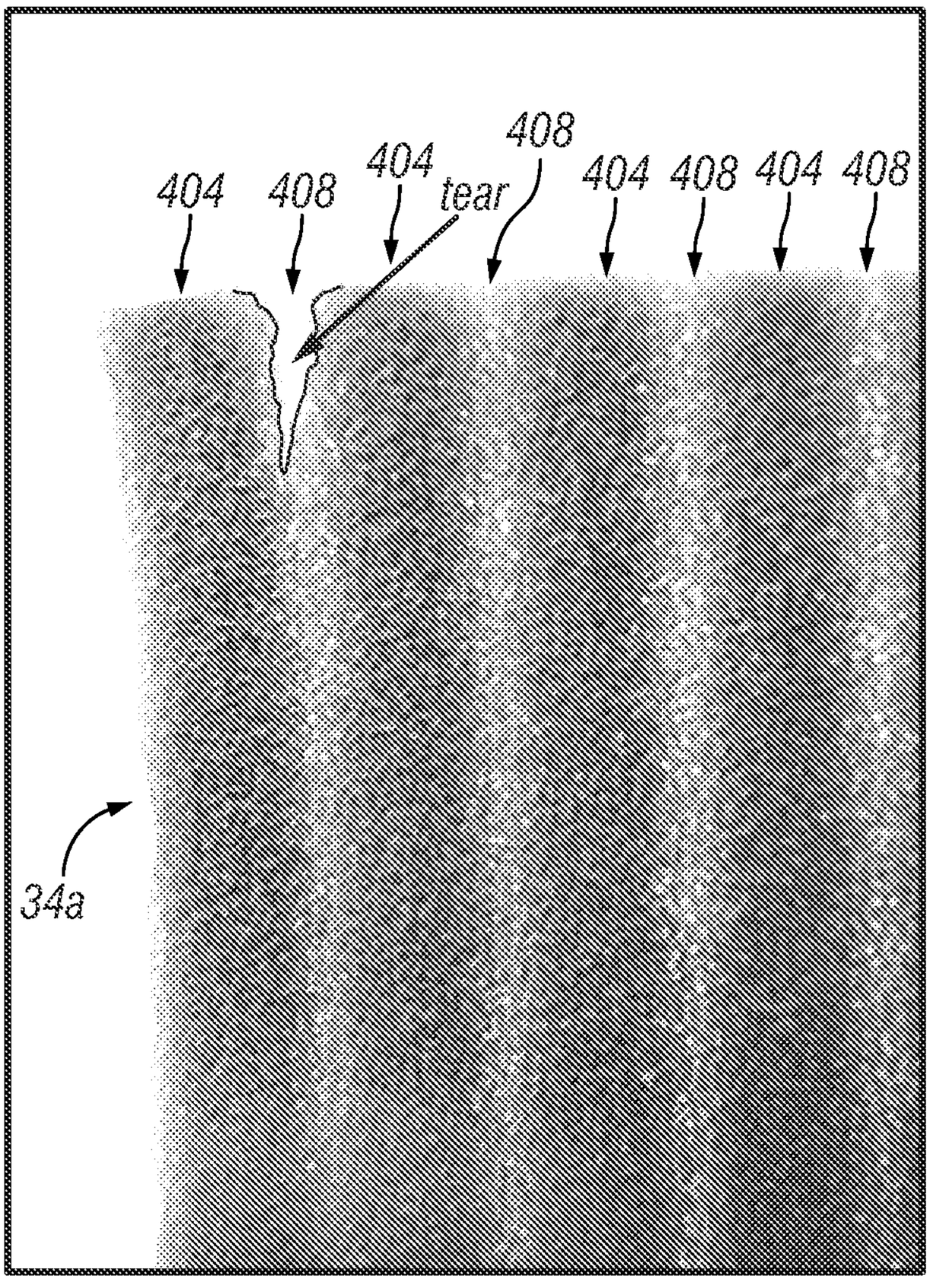


FIG. 10

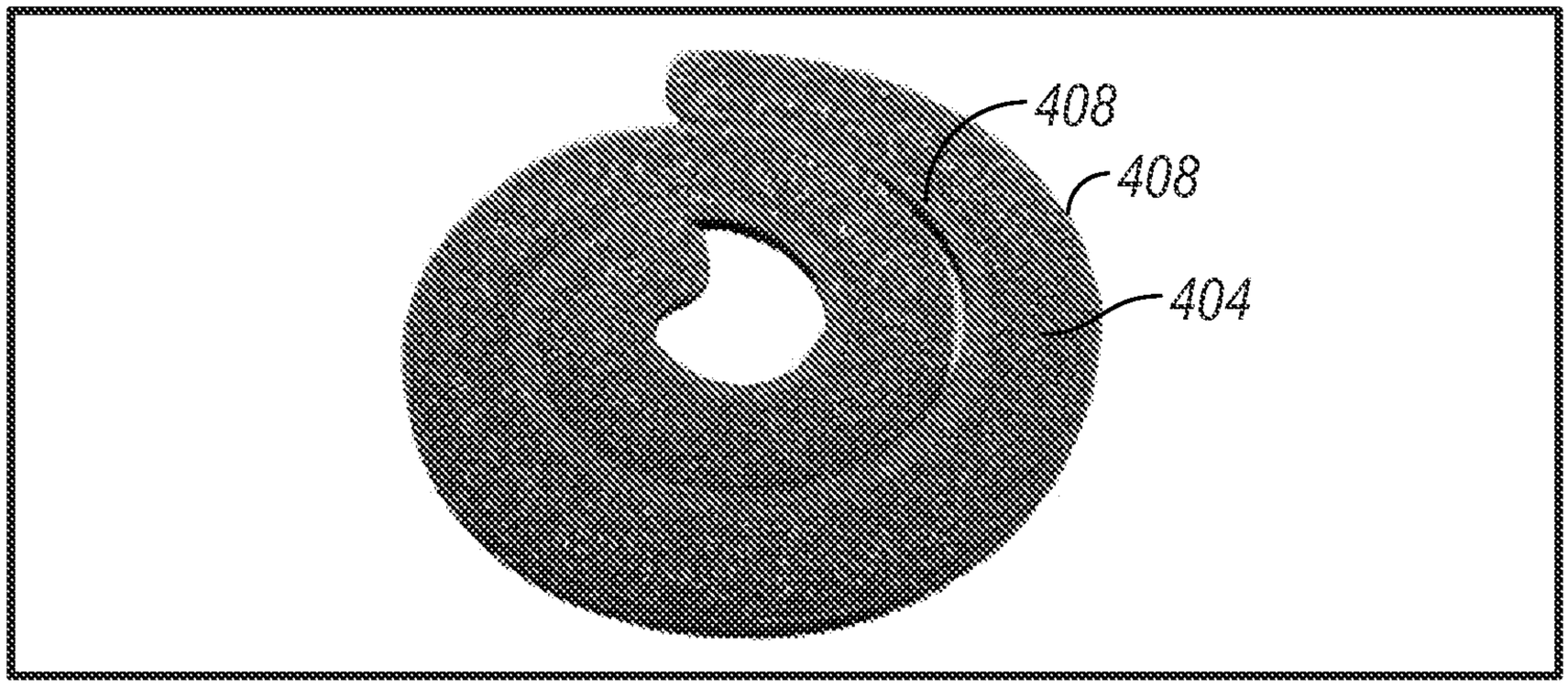
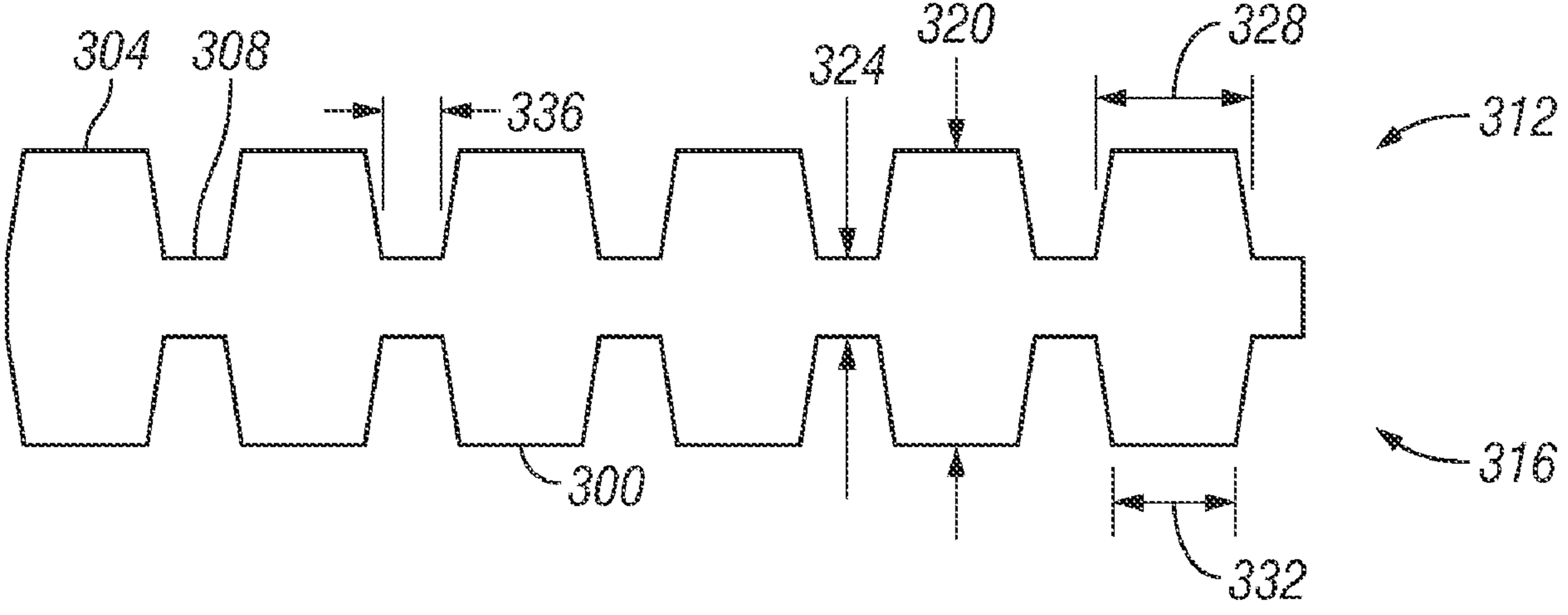


FIG. 11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