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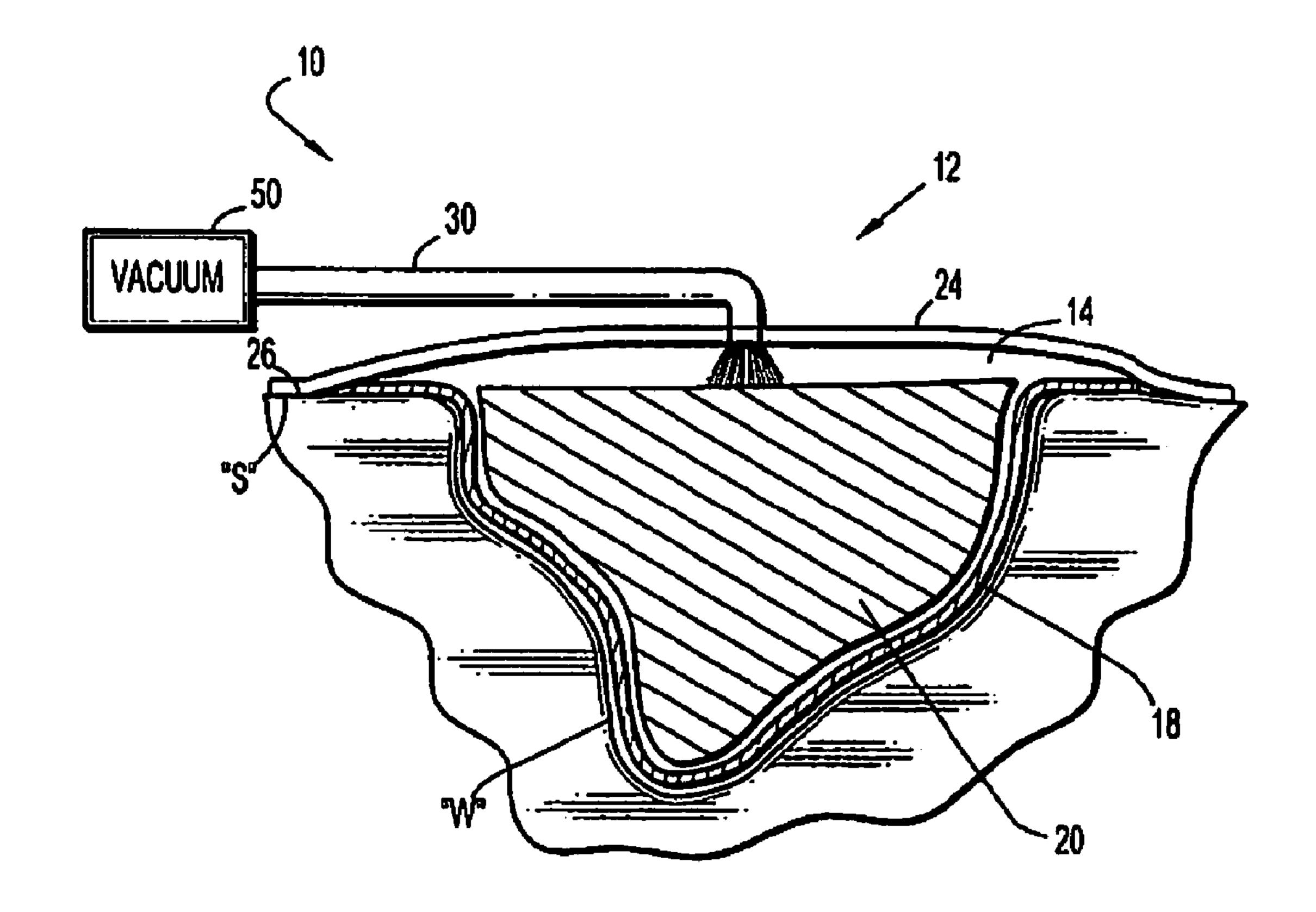


FIG. 1

(57) Abrégé/Abstract:

An apparatus for promoting the healing of an exuding wound includes a cover layer for positioning over a wound to define a reservoir over the wound. An exudate conduit having a fibrous core includes a plurality of fibers communicates with the reservoir for wicking fluids away from the wound.



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(54) Title: APPARATUS FOR VACUUM BRIDGING AND/OR EXUDATE COLLECTION

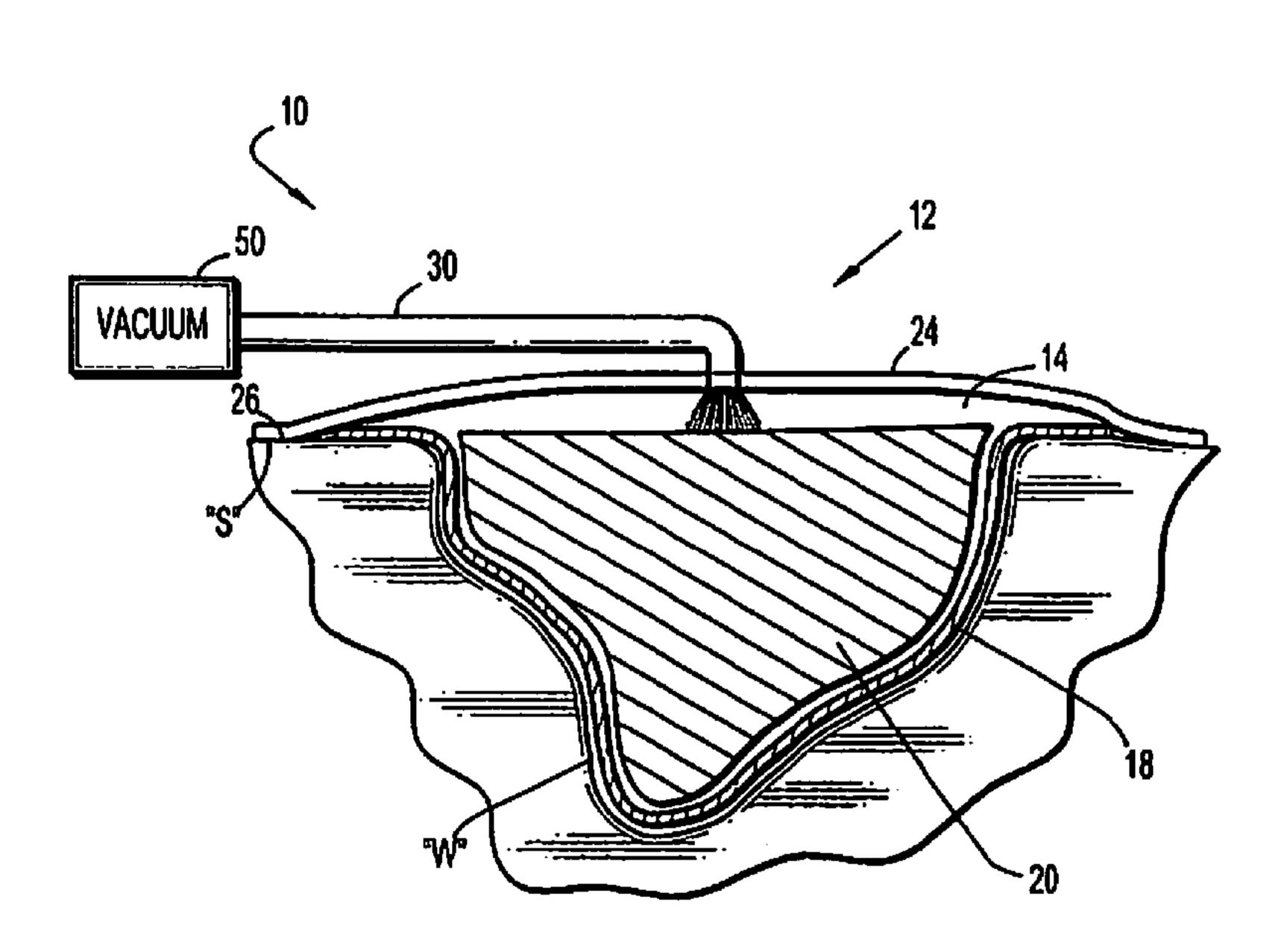


FIG. 1

(57) Abstract: An apparatus for promoting the healing of an exuding wound includes a cover layer for positioning over a wound to define a reservoir over the wound. An exudate conduit having a fibrous core includes a plurality of fibers communicates with the reservoir for wicking fluids away from the wound.



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APPARATUS FOR VACUUM BRIDGING AND/OR EXUDATE COLLECTION

BACKGROUND

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1. Technical Field

The present disclosure relates generally to wound therapy, and, in particular, relates to an apparatus for vacuum bridging and/or exudate collection for managing wound exudates during negative pressure wound therapy.

2. Background of Related Art

Various techniques to promote healing of a wound involve providing suction to the wound. For example, a vacuum source may serve to carry wound exudates away from a wound, which may otherwise harbor bacteria that inhibit the body's natural healing process. One technique for promoting the natural healing process may be described as negative pressure wound therapy (NPWT). This technique involves the application of a reduced pressure, e.g. sub-atmospheric, to a localized reservoir over a wound. Sub-atmospheric pressure has been found to assist in closing the wound by promoting blood flow to the area, which stimulates the formation of granulation tissue and the migration of healthy tissue over the wound. This technique has proven effective for chronic or non-healing wounds, but, has also been used for other purposes such as post-operative wound care.

SUMMARY

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Accordingly, the present disclosure relates to further developments in wound therapy. In accordance with one embodiment, an apparatus for promoting the healing of an exuding wound includes a cover layer for positioning over a wound to define a reservoir over the wound. An exudate conduit having a fibrous core includes a plurality of fibers communicates with the reservoir for wicking fluids away from the wound. The exudate conduit may include a wound end adapted for positioning proximate to the cover layer and a vacuum end adapted for fluid connection with a vacuum source. A vacuum source may be in fluid communication with the vacuum end of the exudate conduit and operable to establish a reduced pressure within the reservoir. A collection canister may be adapted for fluid connection to the vacuum end of the exudate conduit whereby the vacuum source draws a vacuum through the collection canister.

In one embodiment, at least some of the fibers within the exudate conduit may be at least partially exposed adjacent the wound end of the exudate conduit. The exudate conduit may include an outer sleeve for at least partially accommodating the fibrous core with some of the fibers extending beyond the outer sleeve. At least one of the fibers may comprise a hydrophobic material.

The fibrous core may include an inner bundle of fibers and an outer bundle of fibers. The inner bundle may comprise hydrophobic fibers for discouraging fluid absorption and the outer bundle may comprise hydrophilic fibers for promoting fluid absorption. In the alternative, the outer bundle of fibers is knitted, woven, or braided around the inner bundle of fibers. The fibrous core may include at least one additive. The additive may be one of an antimicrobial, an anti-septic, and a surfactant. The fibrous core may include a concentration of

the additive adjacent the wound end which is greater than a concentration of the additive adjacent the vacuum end.

The outer sleeve may comprise a semi-permeable material. In one embodiment, the outer sleeve defines a first cross-sectional dimension greater than a second cross-sectional dimension to thereby reduce the profile of the outer sleeve.

A method for facilitating healing of a wound is also disclosed. The method includes the steps:

applying a wound dressing over a wound;

fluidly connecting an exudate conduit having a fibrous core to the wound

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port; and

extending the exudate conduit into a second reservoir that incorporates a vacuum

connecting the second reservoir to a vacuum source via the vacuum port thereby connecting the vacuum source with the first reservoir via the exudate conduit.

According to another aspect of the disclosure, a composite wound dressing apparatus includes a cover layer for defining a reservoir over a wound in which a negative pressure may be maintained by forming a substantially fluid-tight seal around the wound. The cover layer includes an aperture therein through which fluids may be extracted from the reservoir. An elongate wick has a first end and a second end, wherein the first end is in fluid communication with the reservoir through the aperture in the cover layer, and the second end is disposed remotely with respect to the aperture in the cover layer. The elongate wick is adapted for longitudinal transport of fluids therethrough. A flexible wick cover extends over the elongate

wick and has a first end and a second end. The first end of the wick cover is configured for forming a substantially fluid tight seal over the aperture in the cover layer, the second end including an aperture therein through which fluids may be extracted from the elongate wick. A fluid port is coupled to the wick cover and is in fluid communication with the second end of the elongate wick through the aperture in the wick cover. The fluid port is configured to receive a fluid conduit at the remote location with respect to the wound.

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The apparatus may include a skin covering positioned beneath at least a portion of the elongated wick to substantially minimize contact of fluids with a skin surface adjacent the wound. The skin covering may be adapted to define an enclosure for accommodating the portion of the elongated wick.

The wick cover may include indicia thereon to indicate a distance from the fluid port. The indicia may include rule marks centrally located on the wick cover. The fluid port may include a flange coupled to an underside of the wick cover.

The elongate wick may be constructed of continuous synthetic fibers arranged as an elongate rope. The elongate wick may be treated with an antimicrobial agent such as polyhexamethylene biguanide.

According to another aspect of the disclosure, a composite bridge dressing and delivery apparatus includes a wick cover having a lower surface and an upper surface, wherein the lower surface is at least partially coated with a pressure sensitive adhesive such that the wick cover may form a fluid tight seal with the skin of a patient. An elongate wick is adhered to the lower surface of the wick cover, wherein the elongate wick is adapted for longitudinal transport of fluids therethrough. A backing layer is adhered to the lower surface of the wick cover in a

releasable manner such that the elongate wick is interposed between the wick cover and the backing layer.

The wick cover may include an aperture therein through which wound fluids may be drawn. A fluid port may be coupled to the wick cover, wherein the fluid port is configured to provide fluid communication between a vacuum source and the elongate wick through the wick cover. A releasable delivery layer may be adhered to the upper surface of the wick cover. At least one of the wick cover, the backing layer and the delivery layer may include indicia thereon to indicate a length along the apparatus. Identifiers may be included to provide visual queues to indicate the order in which layers of the apparatus should be separated. The apparatus may have a length in excess of 9 inches.

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According to another aspect of the disclosure, a negative pressure wound therapy apparatus includes a cover layer for defining a reservoir over a wound in which a negative pressure may be maintained by forming a substantially fluid-tight seal around the wound. The cover layer includes an aperture therein through which fluids may be extracted from the reservoir. An elongate wick has a first end and a second end, wherein the first end is in fluid communication with the reservoir through the aperture in the cover layer, and the second end is disposed remotely with respect to the aperture in the cover layer. The elongate wick is adapted for longitudinal transport of fluids therethrough. A flexible wick cover extends over the elongate wick and has a first end and a second end. The first end of the wick cover is configured for forming a substantially fluid tight seal over the aperture in the cover layer, and the second end of the wick cover includes an aperture therein through which fluids may be extracted from the

elongate wick. A vacuum source is in fluid communication with the reservoir, wherein the vacuum source is suitable for generating the negative pressure in the reservoir.

According to another aspect of the invention there is provided use of a wound dressing for facilitating wound treatment, the wound dressing comprising: a cover layer for positioning over a wound and define a reservoir over the wound, and an exudate conduit including a fibrous core having a plurality of fibers communicating with the reservoir for wicking fluids away from the wound, the fibrous core including an inner bundle of fibers and an outer bundle of fibers, and the inner bundle comprising hydrophobic fibers for discouraging fluid absorption and the outer bundle comprises hydrophilic fibers for promoting fluid absorption.

BRIEF DESCRIPTION OF THE DRAWINGS

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The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the present disclosure and, together with the detailed description of the embodiments given below, serve to explain the principles of the disclosure.

- FIG. 1 is a cross sectional view of an NPWT apparatus in accordance with the present disclosure;
- FIG. 2 is a cross sectional view of an NPWT apparatus in accordance with another embodiment of the present disclosure;
 - FIG. 3 is perspective view of an exudate conduit containing a fibrous core which forms the connection between the wound and vacuum source of FIG. 1;

FIGS. 4A-4F are schematic views depicting various cross sections of individual fibers of the exudate conduit of the present disclosure;

FIGS. 5A-5G are schematic views depicting various co-extrusion arrangements for individual fibers of the exudate conduit of the present disclosure;

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FIGS. 6A-6J are partial orthogonal views depicting various configurations of the fibrous core of the exudate conduit of the present disclosure;

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FIG. 7 is a perspective view, with parts separated, of the exudate conduit and wound dressing in accordance with the present disclosure;

- FIG. 8A is a cross sectional view of an NPWT treatment apparatus including a fluid port in the vicinity of a vacuum reservoir for treating a wound;
- FIG. 8B is a partial cross sectional view of the fluid port of FIG. 8A affixed in an alternate configuration;
 - FIG. 8C is a partial cross sectional view of the fluid port of FIG. 8A affixed in another alternate configuration;
- FIG. 9 is a sectional view of an NPWT apparatus in accordance with another embodiment of the present disclosure;
 - FIG. 10A is a cross sectional view of a composite wound dressing and bridging dressing with the fluid port in a remote location in accordance with the present disclosure as applied on the wound;
 - FIG. 10B is a partial cross-sectional view of an alternate configuration of a bridging dressing applied without a fluid port; and

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FIG. 11 is an exploded perspective view of a composite bridging dressing and delivery system in accordance with the present disclosure.

DETAILED DESCRIPTION OF THE EMBODIMENTS

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The NPWT system of the present disclosure incorporates a flexible, low profile exudate conduit having an appropriate fitting for connection to a vacuum source. The sleeve of the exudate conduit includes a collection of fibers disposed therein for wicking fluid away from a wound under vacuum. The sleeve may also hold wound fluid as it is drawn towards the vacuum source thereby acting as a fluid collection vessel.

One NPWT protocol involves covering the wound with a flexible cover layer such as a polymeric film, for example, to establish a vacuum reservoir over the wound where a reduced pressure may be applied by individual or cyclic evacuation procedures. Two methods of delivering the reduced pressure to a wound are either by placing a tube structure through the cover layer into the wound bed such that the tube is surrounded by a suitable fill material, such as gauze or foam, and covering the wound with an adhesive coated thin film to seal the wound area, or by packing and sealing the wound with a suitable fill material, covering the wound with an adhesive coated thin film to seal the wound, and attaching a vacuum connection to the outer film surface of the cover layer. The vacuum connections that are attached to the film dressing may be molded polymer materials that can be rigid or semi-rigid. Often times, however, the location of the wound makes it undesirable to use a tube or rigid vacuum connection because resultant pressure points from the connection may potentially cause further damage to the wound area or impede wound healing. In this situation, a technique known as bridging, in which the same or similar materials are used to fill and seal the wound to form a low-profile channel running away from the wound site to an area where connection to the vacuum source, may be less problematic for the patient and potentially less damaging to the wound. A conventional

technique requires a significant amount of the clinician's time custom building the structure. It also requires an increase in treatment costs through the consumption of more and sometimes different dressing materials.

Referring initially to **FIG. 1**, an NPWT apparatus according to the present disclosure is depicted generally as **10** for use on a wound "w" surrounded by healthy skin "s."

The NPWT apparatus **10** includes a wound dressing **12** positioned relative to the wound "w" to define a reservoir **14** in which a negative pressure appropriate to stimulate healing may be maintained.

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Wound dressing 12 may include a contact layer 18 positioned in direct contact with the bed of wound "w" and may be formed from perforated film material. An appropriate perforated material permits the negative pressure applied to the reservoir to penetrate into the wound "w," and also permits exudates to be drawn through the contact layer 18. A non-adherent material may be selected such that contact layer 18 does not tend to cling to the wound "w" or surrounding tissue when it is removed. Exemplary materials that may be used as a contact layer 18 is sold under the trademark XEROFORM®, CURITY®, and VENTEX® by Tyco Healthcare Group LP (d/b/a Covidien).

Wound filler 20 is positioned in the wound "w," over the optional contact layer 18, and is intended to allow wound dressing 12 to absorb and capture wound exudates. Wound filler 20 is conformable such that it may assume the shape of any wound "w" and may be packed up to the level of healthy skin "s." Exemplary materials that may be used as wound filler 20 are

sold under the trademarks KERLIX®, EXCILON®, and WEBRIL®, all by Tyco Healthcare Group LP (d/b/a Covidien).

Wound dressing 12 also includes a cover layer 24 in the form of a flexible membrane. Cover layer 24 may be positioned over the wound "w" such that a biocompatible adhesive at the periphery 26 of the cover layer 24 forms a substantially fluid-tight seal with the surrounding skin "s." Thus, cover layer 24 may act as both a microbial barrier to prevent contaminants from entering the wound "w," and also a fluid barrier maintaining the integrity of vacuum reservoir 14. Cover layer 24 may be formed from a moisture vapor permeable membrane to promote the exchange of oxygen and moisture between the wound "w" and the atmosphere. A membrane that provides a sufficient moisture vapor transmission rate (MVTR) is a transparent membrane sold under the trade name POLYSKIN®II by Tyco Healthcare Group LP (d/b/a Covidien). A transparent membrane permits an assessment of wound conditions to be made without requiring removal of the cover layer 24. Alternatively, cover layer 24 may comprise an impermeable membrane 24. Cover layer 24 may be a substantially rigid member.

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Exudate conduit 30 provides a fluid flow path leading through apparatus 10.

Exudate conduit 30 may be positioned within or proximate to reservoir 14 through cover layer 24 which is adapted to receive the exudate conduit 30 in a releasable and fluid-tight manner.

Exudate conduit 30 extends from the reservoir 14 to provide fluid communication between the reservoir 14 and vacuum source 50. Exudate conduit 30 may be low profile and flexible to allow for easy adaptation by the user to connect the wound dressing 12 to the vacuum source 50. The low profile reduces pressure points on the patient's skin, thereby reducing the risk of pressure irritation of the skin surface or on the wound itself.

In embodiments, a collection canister 52 may extend between reservoir 14 and vacuum source 50 as illustrated in FIG. 2. Fluid conduit 54 extends from collection canister 52 providing fluid communication with vacuum source 50. Any suitable conduit may be used for fluid conduit 54 including those fabricated from elastomeric or polymeric materials. Fluid conduit 54 may connect to vacuum source 50, collection canister 52, or other apparatus components by conventional air tight means such as friction fit, bayonet coupling, or barbed connectors. The conduit connections may be made permanent, or alternatively a quick-disconnect or other releasable means may be used to provide some adjustment flexibility to apparatus 10.

The optional collection canister 52 may comprise any container suitable for containing wound fluids. For example, a rigid bottle may be used as shown or alternatively a flexible polymeric pouch may be appropriate. Collection canister 52 may contain an absorbent material to consolidate or contain the wound drainage or debris. For example, super absorbent polymers (SAP), silica gel, sodium polyacrylate, potassium polyacrylamide or related compounds may be provided within canister 52. At least a portion of canister 52 may be transparent to assist in evaluating the color, quality or quantity of wound exudates. A transparent canister may thus assist in determining the remaining capacity of the canister or when the canister should be replaced.

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Vacuum source 50 generates or otherwise provides a negative pressure to the NPWT apparatus 10. Vacuum source 50 may comprise a peristaltic pump, a diaphragmatic pump or other mechanism that is biocompatible and draws fluids, e.g. atmospheric gases and wound exudates, from the reservoir 14 appropriate to stimulate healing of the wound "w." The

PCT/US2009/047877

CA 02765455 2011-12-14

vacuum source 50 may be adapted to produce a sub-atmospheric pressure in the reservoir 14 ranging between about 20 mmHg and about 500 mmHg, in embodiments, from about 75 mmHg to about 125 mmHg, in other embodiments from about 50 mmHg to about 80mmHg. Vacuum source 50 may be a peristaltic pump, a diaphragmatic pump or other mechanism that draws fluids, e.g. atmospheric gasses and wound exudates, from the reservoir 14 appropriate to stimulate healing of the wound "w." One suitable peristaltic pump is the Kangaroo PET Enteral Feeding Pump manufactured by Tyco Healthcare Group LP (d/b/a Covidien).

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Referring now to FIG. 3, exudate conduit 30 includes outer member of sleeve 32 defining lumen 33. Exudate conduit 30 has first or proximal end 34, second or distal end 36, and fibrous core 38 disposed within lumen 33 of outer sleeve 32. Outer sleeve 32 may be fabricated from flexible polymer and/or elastomeric materials, for example, polyolefins such as polypropylene and polyethylene, polyesters such as polyethylene terephthalate, polyamides such as nylon, and polyurethanes. Outer sleeve 32 may be constructed from materials which are nonirritating and biocompatible. In embodiments, outer sleeve 32 may be fabricated from a breathable material, such as a material with a high moisture vapor transmission rate to allow for vapor transmission and evaporation thus increasing the fluid retention capacity of the exudate conduit 30.

The wall 31 of outer sleeve 32 may range in thickness from about 0.002" to about 0.020". The diameter of outer sleeve 32 may be from about 0.1" to about 3" depending on the application. Additionally, outer sleeve 32 may be clear or translucent in color to permit visualization of wound fluid. Exudate conduit 30 may also be opaque and define a transparent window for visualizing the wound fluid. In embodiments, the window may be from about 15%

to about 25% of the periphery of outer sleeve 32. Outer sleeve 32 may define a reduced profile with respect to the longitudinal axis "k" of the sleeve 32. For example, outer sleeve 32 defines a first transverse dimension "b" which is substantially greater than a second transverse dimension "m" relative to the longitudinal axis "k." These dimensions provide a generally flattened, planar or elliptical profile to exudate conduit 32. The reduced profile may assist in a bridging technique as will be discussed.

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Exudate conduit 30 includes connection member or fitting 40 at the second or distal end 36 that connects to vacuum source 50. Connection member or fitting 40 may be any conventional fitting for forming a fluid and air tight connection between exudate conduit 30 and vacuum source 50. In embodiments, connection member 40 may include a check valve (schematically as reference numeral 40v) and/or filter to prevent fluid contamination of vacuum source 50. Check valves include duck bill style valves that are held in the open position during connection to vacuum source 50 and assume a closed position in the absence of the vacuum pressure thereby preventing wound fluid leakage. Connection member 40 may include electronic moisture sensing capability to signal that the fluid capacity of the conduit is full, thereby triggering an alarm and/or turning the vacuum source off until the conduit is replaced.

Exudate conduit 30 contains fibers 42 therein. A plurality of fibers 44 is disposed within exudate conduit 30 for maintaining the shape and/or preventing the flexible conduit 30 from collapsing. Fibers 42 also facilitates wound fluid movement. Fibers 42 may be any size from a micro denier of about 0.002 to a larger denier of about 0.1. In embodiments, fibers 42 may extend from first or proximal end 34 of exudate conduit 30 into reservoir 14 or wound bed "w."

Referring now to FIGS. 4A-4F, the fibers may exhibit various cross-sections to enhance wicking capabilities or other fluid handling characteristics of the exudate conduit 30. In embodiments, the fibers may be constructed to promote fluid movement without the aid of vacuum or gravity. A solid flat 42a or round 42b cross section as depicted in FIGS. 4A and 4B, respectively, may be a standard for most fibers due to a relatively low cost when compared to modified cross sections. Fiber 42c is depicted in FIG. 4C having a void 41 in its cross section. Void 41 runs the entire length of fiber 42c yielding a reduced density and rigidity of fiber 42c and permitting air to be trapped within. Such a cross section may facilitate crimping, entangling and/or lofting processes which may further enhance fluid handling properties of the fiber. A multi-lobal cross section may also be used as depicted in FIG. 4D. Tri-lobal fiber 42d exhibits three arms 43 projecting from a central region offering rigidity and resilience to the fiber 42d.

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Highly modified cross section fibers 42e as depicted in FIG. 4E are sold under the trade name 4DGTM by Fiber Innovation Technology, Inc. Deep channels 45 of various sizes and configurations are provided along a longitudinal axis of the fiber 42e to help promote capillary wicking with its relatively large surface area. For example, fibers 42e having a 4DGTM cross section have demonstrated a capability to transport up to 2 liters of water per hour per gram of fiber. A fiber 42f having a bowtie cross section as depicted in FIG. 4F may be well suited for use in self-crimping fibers.

Referring now to FIGS. 5A through 5G, two or more distinct polymers may be co-extruded to generate fibers with complex profiles and specialized characteristics. The co-extruded fibers may have any of the cross-sections as described above, among others. A fiber 42g exhibiting a concentric sheath-core arrangement is depicted in FIG. 5A. A core polymer

47g is surrounded by a sheath polymer 49g. A sheath polymer may exhibit a lower melting temperature than a core polymer such that the sheath polymer may be melted to provide a binder for individual fibers. Other applications for a sheath-core arrangement may include providing a high strength structural core polymer 47g and a sheath polymer 49g with surface characteristics appropriate to help promote wicking of wound fluid or to accept any of the beneficial polymer additives discussed below. A fiber 42h exhibiting an eccentric sheath-core arrangement is depicted in FIG. 5B including an off-center core polymer 47h and corresponding sheath polymer 49h. This arrangement may be used to provide a self-crimping fiber when the core polymer and sheath polymer are provided with differing shrinkage characteristics when subject to a temperature change. When heated, the fibers may curl into a helix that is retained when the filament is cooled, thus developing a crimp or bulk in an otherwise flat fiber. Such a selfcrimping procedure may be further facilitated by using a side-by-side arrangement as depicted in FIG. 5C. Fiber 42i is similar to fiber 42h, but differs in that core polymer 47i and sheath polymer 49i each occupy a portion of the outer surface of the fiber 42i. With a proper polymer selection, the side-by-side arrangement of fiber 42i may yield higher levels of latent crimp than the eccentric sheath-core arrangement of fiber 42h. As shown in FIG. 5D, a fiber 42j having a pie-wedge arrangement may include alternating wedges comprising polymers 47j and 49j. A fiber 42k exhibiting a hollow pie wedge arrangement including a hollow center core is depicted in FIG. 5E.

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With reference to FIG. 5F, fiber 42m exhibits an islands-in-the-sea arrangement where one or more "island" polymers 47m are surrounded by a soluble "sea" polymer 49m. This arrangement may provide for very fine strands of island polymers 47m to be effectively handled by manufacturing equipment. Once the island polymers 47m are in place, the soluble sea

polymer is dissolved away. For example, as many as about 37 or more island polymers 47m having a denier of about 0.04 (roughly 2 microns in diameter) may thus be handled effectively as a single fiber 42m. A fiber 42n exhibits a "three island" arrangement, as depicted in FIG. 5G. This arrangement includes three island polymers 47n surrounded by a sea polymer 49n. Fiber 42n may be used in a manner similar to fiber 42m exhibiting an islands-in-the-sea arrangement, but may be more commonly used in a manner similar to fibers 42g, 42h, and 42i described above exhibiting a sheath-core arrangement. Fiber 42n may be described as including three core polymers 47n collectively having an increased surface area to discourage de-lamination from a potentially incompatible sheath polymer 49n.

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Various suppliers may produce fibers as described above, as any commercial fiber or suture material may advantageously be employed in exudate conduit 30. A non-exhaustive list of materials includes, but are not limited to, polymers and polymer blends selected from the group consisting of polyolefins (such as polyethylene and polypropylene including atactic, isotactic, syndiotactic, and blends thereof as well as, polyisobutylene and ethylene-alphaolefins copolymers, and fluorinated polyolefin such as polytetrafluoroethylene); polyesters (such as polyethylene terephthalate and polybutylene terephthalate); acrylic polymers and copolymers; modacrylics; vinyl halide polymers and copolymers (such as polyvinyl chloride); polyvinyl ethers (such as polyvinyl methyl ether); polyvinylidene halides (such as polyvinylidene fluoride and polyvinylidene chloride); polyacrylonitrile; polyvinyl ketones; polyvinyl aromatics (such as polystyrene); polyvinyl esters (such as polyvinyl acetate); copolymers of vinyl monomers with cach other and olefins (such as etheylene-methyl methacrylate copolymers, acrylonitrile-styrene copolymers, ABS resins and ethylene-vinyl acetate copolymers); polyamides (such as nylon 4, nylon 6, nylon 610, nylon 11, nylon 12 and polycaprolactam); alkyd resins;

polycarbonates; polyoxymethylenes; polyimides; polyethers; epoxy resins; aramids, polyurethanes; rayon; rayon-triacetate; and spandex.

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Fibers 30 may be bundled into a plurality of fibers 44 to form fibrous core 38. An outer bundle of fibers 46 may be selectively arranged around an inner core or bundle 48 of various fiber combinations and sizes to optimize fluid handling and to reduce the propensity for clogging of wound fluid. It is envisioned that the fibers that comprise the bundles may be varied to facilitate optimal fluid handling. For example, the inner bundle fibers 48 may be a hydrophobic polymer to discourage fluid absorption while the outer bundle fibers 46 may be hydrophilic to promote some absorption.

Typical fiber bundle 44 arrangements are illustrated in FIGS. 6A-6E. Referring now to FIG. 6A, fibers 42 may be arranged so as to be generally non-intersecting along their length. Although not necessarily parallel, fibers 42 may be generally free from entanglement or interlacing over a substantial portion of their length. Outer bundle of fibers 46a may be included to help prevent separation of fibers 42 which form inner bundle 48. A single outer bundle 46a may be formed from a separate continuous fiber wrapped or tied around inner bundle 48 to compress bundle 48 in a localized region. Alternatively, outer bundle 46b may be placed intermittently along inner bundle 48, as shown in FIG. 6B, to help secure fibers 42 at multiple locations, or separate continuous fibers may be wrapped helically around inner bundle 48 as in FIG. 6C to form outer bundle 46c.

Fibers 42 may also be enclosed in a knitted, woven, or braided outer bundle 46d as illustrated in FIG. 6D. The knitted, woven, or braided outer bundle 46d may be adjusted to provide a greater or lesser diameter and conduit patency under vacuum or kinking of the exudate

conduit. Fibers may also be twisted, as in a rope, to provide an outer bundle 46e as illustrated in FIG. 6E.

Alternatively, fibers 42 may be arranged or constructed as shown in FIGS. 6F-6J to help the inner bundle 48 resist separation of individual fibers 42. Fibers 42 may be enclosed with a self-scaling, non-woven mesh or other porous sheet to form bonding feature 51a as shown in FIG. 6F. A self-scaling bonding feature 51a may be an elastic or slightly undersized band such that individual fibers 42 may be inserted through an open end of the band to be constrained under compression. Alternatively, bonding features may include an adhesive component such that a flat strip may be wrapped around the fibers and the flat strip may be affixed by adhering either to itself or to the individual fibers 42 with the adhesive component. As depicted in FIG. 6G, a bonding feature 51b may be formed with a substantial length of a non-woven mesh or a porous sheet to enclose a substantial length of the fibers. Bonding features 51a and 51b may be porous to promote absorption of wound fluids and exudates.

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Fibers 42 which form inner bundle 48 may be entangled by various processes to form a bonding feature 51c (FIG. 6H). Jets of steam, air, or water may be directed at localized regions in the bundle 48 to entangle fibers 42 and provide bonding feature 51c. The entangling process may involve application of heat in a localized area to entangle or bond fibers 42. Another example of an entangling process involves needles used in a manner similar to needle punching to entangle fibers 42. A bonding feature 51d (FIG. 6I) may be provided simply by bonding fibers 42 with an adhesive, or by incorporating a binding material having a lower melting temperature than fibers 42. By heating the bundle, the binding material may melt and bind fibers 42 together upon cooling. A binding material may be provided along with one or

more of the individual fibers in a co-extrusion such as a core-sheath arrangement, as described above. As depicted in FIG. 6J, a bonding feature 51e may also be provided by crimping individual fibers to provide some degree of entanglement thereby providing additional surface area, as described in greater detail above. It is also envisioned that the arrangement of individual fibers may include two or more of the features shown in FIGS. 6A through 6J.

Various polymer additives may be applied to individual fibers 42, the inner bundle 48, the outer bundle 46, or the entire plurality of fibers 44 or a selective subset of fibers therein. Further, the additive may be imparted to a section of each fiber such as the sheath construction of a sheath-core fiber construct. The additive may be any substance or mixture of substances that have clinical use. Consequently, the additives may or may not have pharmacological activity per se, e.g., a dye. Alternatively an additive could be any agent that provides a therapeutic or prophylactic effect, a compound that affects or participates in tissue growth, cell growth, cell differentiation, a compound that may be able to invoke a biological action such as an immune response, or could play any other role in one or more biological processes. It is envisioned that the additive may be applied to the fibers 42 in any suitable form of matter, e.g., films, powders, liquids, gels and the like. The additive could also be formed to activate only on contact with moisture such as wound fluids and exudates.

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Examples of classes of additives which may be utilized in accordance with the present disclosure include anti-adhesives, antimicrobials, antibacterials, antiobiotics, anti-virals, anti-fungals, anti-septics, anti-inflammatories, and anesthetics. Additionally, odor control technology may also be incorporated into fibers 42 as an additive. It is also intended that combinations of additives may be used. For example, an anti-adhesive, to prevent adhesions

from forming between the fibers and the surrounding tissue, may be utilized with an antimicrobial, such as polyhexamethylene biguanide, to reduce the bio burden in the wound bed.

Other additives, such as surfactants like silicone or floropolymers such as PTFE may be added to provide fiber 42 with a slicker surface. A slicker or surfactant treated surface may facilitate optimal fluid handling properties. For example, a surfactant or combination of surfactants may create a highly hydrophobic surface on the fiber and/or bundle to encourage directional wicking and fluid movement away from the wound dressing. Surfactant treatment may be selective along the length of fiber 42 such that the portions located within or adjacent the proximal end 34 of exudate conduit 30 could be processed in a combination of materials or concentration of materials to promote more rapid fluid movement away from the wound where the portions of fibers 42 located in or towards the distal end 36 of exudate conduit 30 would allow slower movement thus increasing its capacity of holding and containing wound fluid.

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In embodiments, exudate conduit 30 may be treated with a moisture sensitive material on the inside of sleeve 32 and/or fiber bundle 44 that could change color in the presence of moisture, thus indicating a filled conduit. The color sensitive material could be continuous providing a visual indication of the remaining fluid capacity of the conduit. The distal end 36 of sleeve 32 may be treated to provide an early indication of the conduit's capacity. As such, exudate conduit 30 may act as a fluid reservoir thus eliminating the need for collection canister 52 at or near vacuum source 50. The exudate conduit 30 may vary in length to accommodate larger quantities of wound fluid.

Referring now to FIG. 7, the fibers 42 of exudate conduit 30 are at least partially inserted through an aperture or access hole 25 in cover layer 24 thereby positioning the fibers

proximate to the wound "w." Access hole 25 may be provided as a prefabricated feature of cover layer 24, or alternatively, access hole 25 may be cut as appropriate by a clinician at the time cover layer 24 is installed. Proximal end 34 of sleeve 32 may then be inserted into or adjacent to access hole 25. Sleeve 32 may be provided with an adhesive for securing the exudate conduit 30 to cover layer 24 in order to form an air and fluid tight connection with cover layer 24. Alternatively, an adhesive coated thin film, thin film dressing, or other provisions may be made for sealing the connection between exudate conduit 30 and access hole 25 of cover layer 24. Distal end of sleeve 32 may then be routed to the vacuum source or collection canister as discussed above.

The size, shape, and/or location of the wound "w" may influence the manner in which exudate conduit 30 is routed relative to wound dressing 12 and the vacuum source 50. For example, some wounds "w" may accommodate a fluid port or a vacuum port in the vicinity of a vacuum reservoir as depicted in FIG. 8A.

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FIG. 8A generally depicts an NPWT apparatus 60 for use on a wound "w" surrounded by healthy skin "s." The NPWT apparatus 60 includes a wound dressing 62 positioned relative to the wound "w" to define a reservoir 14 in which a negative pressure appropriate to stimulate healing may be maintained.

Wound dressing 62 includes a contact layer 18 positioned in direct contact with the bed of wound "w." Contact layer 18 may be formed from perforated film material as described above with reference to FIG. 1. Also, passage of wound fluid through the contact layer 18 is preferably unidirectional such that exudates do not flow back into the wound bed. Unidirectional flow may be encouraged by conical or directional apertures formed in the contact

layer 18, or a lamination of materials having absorption properties differing from those of contact layer 18. Wound dressing 62 also includes a wound filler 20 and a cover layer 24 as described above with reference to FIG. 1. Cover layer 24 includes access hole 25 therein, through which wound fluids and atmospheric gasses may be removed from the dressing 62.

A fluid port 66 having a flange 68 may also be included in wound dressing 62 to facilitate connection of the wound dressing 62 to fluid conduit 54. The fluid port 66 may be configured as a rigid or flexible, low-profile component, and may be adapted to receive a fluid conduit 54 in a releasable and fluid-tight manner. An adhesive on the underside of flange 68 may provide a mechanism for affixing the fluid port 66 to the dressing 62, or alternatively the flange 68 may be positioned within reservoir 14 (FIG. 8B) such that an adhesive on an upper side of the flange 68 affixes the fluid port 66. As depicted in FIG. 8C, an additional alternative for affixing the fluid port to the cover layer 24 involves securing the flange 68 to the cover layer 24 with a skirt 24a. The skirt 24a may be constructed of an adhesively coated polymeric film similar to the cover layer 24. However it is affixed to the dressing 62, a hollow interior of the fluid port 66 provides fluid communication between the fluid conduit 54 and the reservoir 14.

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Fluid conduit 54 extends from the fluid port 66 to provide fluid communication between the reservoir 14 and collection canister 52. Any suitable conduit may be used including exudate conduit 30 described above with reference to FIG. 3. Leading from collection canister 54 is another section of fluid conduit 54 providing fluid communication with vacuum source 50.

In some applications, providing a fluid port or exudate conduit at a remote location with respect to the wound "w" may be beneficial. For example, wounds formed on contoured body parts, such as the foot or elbow, or other parts of the body in which the fluid port

or exudate conduit would inhibit the patient's movement or comfort may require a different and sometimes indirect method of routing exudate conduit 30. The exudate conduit 30, then, may be routed from the wound site to a second site where connection to the vacuum source is less problematic for the patient and less damaging to the wound.

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As illustrated in FIG. 9, a wound dressing 12 is positioned relative to a wound "w" to define a reservoir 14 in which a negative pressure appropriate to stimulate healing may be maintained as described above with reference to FIGS. 1 and 2. Exudate conduit 30 may be positioned through cover layer 24 in any manner and position which will not interfere with the patient or wound healing. As illustrated, the proximal end 34 of sleeve 32 is positioned within reservoir 14 by scaling the conduit 30 between skin "s" and cover layer 24 in a fluid and air tight manner. Exudate conduit 30 may then be routed to run along the healthy skin "s" of the patient to prevent or minimize any unnecessary winding or flexure that could tend to kink the exudate conduit 30. In embodiments, an exudate conduit 30 having an outer sleeve 32 with a reduced profile as discussed above may be positioned with the "flattened" side having the first transverse dimension "b" substantially flush with skin "s" to maximize the exudate conduit's contour along skin "s" of the body. Thus, exudate conduit 30 may be placed along the patient's skin "s", such as up a leg, down an arm, or across a chest, towards a second site which does not interfere with the patient's movement or comfort, such as an such as a portion of healthy skin "h" that is relatively flat, for connection to vacuum source 50.

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The second site may be any area where a vacuum port 70 may be placed for connection to a vacuum source 50. As illustrated, a second cover layer 24' may be placed over skin "h" to form a second reservoir 14'. The distal end 36 of the exudate conduit 30 may be sealed within the reservoir 14' by cover layer 24' in a similar or different manner than that of

proximal end 34 with cover layer 24. A vacuum port 70 having a flange 73 may be provided to facilitate connection of the reservoir 14' to vacuum source 50 via fluid conduit 54. The vacuum port 70 is affixed to cover layer 24' and a hollow interior of the vacuum port 70 provides fluid communication between the fluid conduit 54 and the reservoir 14'. The fluid conduit 54 may then be routed to a canister or vacuum source as described in detail above.

Referring now to **FIG. 10**A, an alternate embodiment includes a composite wound dressing 100. Compound dressing **100** permits a fluid port **66** to be placed remotely with respect to the wound "w." Composite wound dressing 100 includes a contact layer **18**, a wound filler **20** and a cover layer **24** applied to the wound "w" in a manner similar to wound dressing **12** discussed. The fluid port **66**, however, is affixed to the composite wound dressing **100** at a location "r" that is remote from the wound "w," rather than being affixed to the cover layer **24** at the access hole **25**.

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To provide fluid communication, or a "bridge," between access hole **25** and the remote location "r," a bridging dressing 102 is positioned partially over the cover layer **24** and partially over the healthy skin "s." The remote location "r" may be an area of the healthy skin "s" where the fluid port **66** will tend not to irritate the wound "w" or to cause discomfort for the patient. If the wound "w" is located on the back of a patient, the remote location "r" may be, for example, at the chest or shoulder of the patient. This permits the patient to lie comfortably without placing undue pressure on the fluid port **66**. To provide this functionality, a bridging dressing **102** may exhibit a length in the range from about 2 inches to about 12 inches, or more.

The bridging dressing 102 includes a, skin lining or film 103, an elongate wick 104, a wick cover 106, and the fluid port 66. The film or lining 103 will be placed in contact

CA 02765455 2011-12-14

with skin, typically, the healthy skin along a portion of the "bridge". The lining or film 103 may be any suitable film adapted for patient contact, and may or may not have an adhesive backing for securement to the skin. The film or lining 103 may overlap a peripheral portion of the cover 24. The film or lining 103 may or may not be adhesively coated, and, in some embodiments is a thin, transparent, polymeric membrane such as polyurethane, elastomeric polyester or polyethylene. The elongate wick 104 defines a longitudinal direction therealong between a first end 110 positioned near the access hole 25 in the cover layer 24, and a second end 112 near the remote location "r." The elongate wick 104 is adapted for longitudinal transport of fluids therethrough. The elongate wick 104 may promote capillary action in a longitudinal direction to provide for the longitudinal transport of fluids. A cross section of individual fibers, or an arrangement of fibers may serve to transport fluids longitudinally. The elongate wick 104 may be constructed from materials suitable for use as wound filler 20 and/or exudate conduit 30. The elongate wick 104 may, for example, be constructed of hydrophobic fibers, such as continuous synthetic fibers, arranged as an elongate rope or cord. The fibers may be crimped, bulked or lofted to influence the absorptive, wicking or comfort characteristics of the elongate wick 104. U.S. Provisional Application No. 61/188,370, filed August 8, 2008, the entire content of which is hereby incorporated by reference, describes various such processes and arrangements for fibers, which may be employed to construct the elongate wick 104 or the filler 20.

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Alternatively, elongate wick 104 may be constructed from staple fibers, and may be arranged as woven or kitted fabrics. The fibers may be treated with antibacterial agents such as polyhexamethylene biguanide (PHMB) to decrease the incidence of infection, or other medicaments to promote healing of the wound "w." The fibers may also include combinations

of materials or chemicals to tailor the wick for specific fluid transport, comfort or other specific requirements.

The wick cover 106 has a first end 114 positioned near the access hole 25 in the cover layer 24 and beyond the first end 110 of the elongate wick 104. A second end 116 of the wick cover 106 is positioned near the remote location "r." The first end 114 of wick cover 106 forms a substantially fluid-tight seal with the cover layer 24, and the second end 116 of the wick cover 106 forms a substantially fluid tight seal with the lining 103 or the skin in the absence of the lining 103. The second end 114 of wick cover 106 may contact or be secured to lining 103 thereby assisting in securement of the lining relative to the subject and optionally forming an enclosure 105 between the wick cover 106 and the lining 103 substantially enclosing the a portion of the elongated wick 103 preventing exudate from contacting the skin.

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Wick cover 106 may be constructed from any of the materials used to fabricate cover layer 24. For example, wick cover 106 may be constructed of an adhesively coated, thin, transparent, polymeric membrane such as polyurethane, elastomeric polyester or polyethylene. The thickness of the wick cover 106 may, for example, be in the range of about 0.8 mils to about 1.2 mils. Thicknesses in this range may permit wick cover 106 to conform comfortably to the contours of a patient's skin surrounding the elongate wick 104, and accommodate evacuation cycles associated with an NPWT procedure. The adhesive coating should provide firm, continuous adhesion to the skin "s" and/or the cover layer 24 such that leak paths are not readily formed as reservoir 14 is subjected to the evacuation cycles of an NPWT treatment. The adhesive should also not unduly interfere with the MVTR of the wick cover, and should peel away from the skin "s" easily when the wick cover 106 is no longer required.

An aperture 118 in the wick cover 106 facilitates fluid communication between fluid port 66 and the elongate wick 104. The fluid port 66 forms a substantially fluid tight seal with the wick cover 106 near the aperture 118 and receives fluid conduit 54. Fluid conduit 54 may be coupled to a vacuum source 50 as described above with reference to FIG. 2.

In this manner, fluids such as wound exudates and atmospheric gasses may be drawn from the reservoir 14, through the access hole 25 in the cover layer 24, and into the first end 110 of the elongate wick 104. The fluids are transported longitudinally through the wick 104 under the influence of the reduced pressure and the fluid transport properties of the wick 104 to the second end 112 of the wick 104 near the remote location "r." The fluids may then be removed from the bridging dressing 102 through the fluid port 66. Since the wick 104 and the wick cover 106 are generally more flexible and conformable to the contours of the patient's body, and also to the movements of the patient than fluid port 66, these components of bridging dressing 102 are typically more comfortable positioned adjacent to the wound "w."

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Referring now to FIG. 10B, an alternate embodiment of the disclosure permits fluid communication between the fluid conduit 54 and the second end 112 of the wick 104 near the remote location "r" to be established without the use of a fluid port. A wick cover 106a includes a second end 116a devoid of an aperture for the attachment of a fluid port. Rather, the wick cover 106a forms a substantially fluid tight seal with the fluid conduit 54 and the lining 103 surrounding the remote location "r." This configuration allows fluid conduit 54 to be placed comfortably at the remote location "r" rather than near the wound "w." Since the fluid conduit 54 may be generally less conformable or more rigid than the wick 104 and the wick cover 106a,

placement of the fluid conduit 54 remote from the wound "w" may be more comfortable than adjacent the wound "w."

Referring now to FIG. 11, bridging dressing 102 is depicted as provided with a delivery system attached. While the composite dressing and delivery system 120 may be manufactured in any desired size or shape, the particular location of the wound "w" to be treated may prompt customization of each individual bridging dressing 102. As provided, composite dressing and delivery system 120 may be generally rectangular having a length of about 6 inches and a width of about 4 inches as shown. The composite dressing and delivery system 120 may be provided with a greater length than is anticipated to be necessary to permit the bridging dressing 102 to be cut to length at the time of application.

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A backing layer 124 has a firm but releasable affinity for the adhesively coated lower surface 126 of the wick cover 106. Backing layer 124 covers the adhesive coating on the wick cover 106 and maintains the wick 104 in position against the lower surface 126 wick cover 106. The backing layer 124 includes a peripheral region 128 that extends substantially beyond at least one edge of the wick cover 106. Peripheral region 128 thus provides a gripping surface to facilitate the separation of the backing layer 124 from the wick cover 106. Peripheral region 128 includes an indicator, such as first numerical indicator 132, printed or otherwise applied thereto. First numerical indicator 132 provides a prominent visual queue to indicate the order in which the layers of the composite dressing and delivery system 120 should be separated.

A delivery layer 136 is adhered to an upper surface 138 of the wick cover 106 in a releasable manner. Delivery layer 136 is substantially rigid in relation to wick cover 106 to maintain the wick cover 106 in a relatively smooth and unwrinkled configuration while the wick

layer 106 is applied over the lining 103 positioned to cover the skin "s" and/or the cover layer 24 (FIG. 10A). Delivery layer 136 is, however, sufficiently flexible to conform to irregular contours of the skin "s" such that the wick cover 106 may be pressed onto the skin "s" and/or the cover layer 24 to form a substantially fluid tight seal therewith. Thereafter, the delivery layer 136 may be separated from the wick cover 106.

Preferably, both delivery layer 136 and upper surface 138 are non-adhesive, and may be adhered by heat lamination contact or similar means. Alternately, the delivery layer may include an adhesive to provide appropriate adhesion to the cover layer during application. A peripheral region 140 of delivery layer 136 overlies wick cover 106, but is not adhered to wick cover 106. Peripheral region 140 thus provides a gripping surface to facilitate separation of the delivery layer 106 from the dressing layer 102. An indicator such as second numerical indicator 142 is positioned on the peripheral region 140 to indicate the order in which the layers of the composite dressing and delivery system 120 should be separated. Delivery layer 136 also includes a central opening 146 to accommodate fluid port 66. Fluid port 66 may be adhered to the upper surface 138, the lower surface 126, or removed all together.

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In use, a bridging dressing 102 may be applied subsequent to the application of a cover layer 24 to a wound "w" (FIG. 10A). Once the desired length of the bridging dressing 102 is determined, the composite dressing and delivery system 120 may be cut to length. Indicia such as rule marks 148 may be printed or otherwise applied to the wick cover 106 to facilitate customizing the length of the bridging dressing 102. Alternatively, indicia may be applied to the backing layer 124 or the delivery layer 136, particularly when these layers are substantially transparent.

CA 02765455 2011-12-14

While the disclosure has been illustrated and described, it is not intended to be limited to the details shown, since various modifications and substitutions can be made without departing in any way from the spirit of the present disclosure. For example, in the embodiment of **FIG. 1**, the vacuum source **50** may be optional whereby wound exudate is conveyed through exudate tube via gravity, wicking or the like. In the embodiment of **FIG. 2**, the canister **52** may be optional whereby the exudate is contained within the exudate tube. In this embodiment, a filter or check valve may be utilized to prevent fluid communication into the vacuum source. It is further envisioned that a check valve could be positioned adjacent the wound end of exudate conduit to prevent fluid regress into the wound area. As such, further modifications and equivalents of the disclosure can occur to persons skilled in the art, and all such modifications and equivalents are intended to be within the spirit and scope of the disclosure as defined by the following claims.

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WHAT IS CLAIMED IS:

1. An apparatus to promote the healing of a wound comprising:

a cover layer for positioning over a wound to define a reservoir over the wound; and
an exudate conduit including a fibrous core having a plurality of fibers communicating

wherein the fibrous core includes an inner bundle of fibers and an outer bundle of fibers, and

with the reservoir for wicking fluids away from the wound,

wherein the inner bundle comprises hydrophobic fibers for discouraging fluid absorption and the outer bundle comprises hydrophilic fibers for promoting fluid absorption.

- 2. The apparatus according to claim 1, wherein at least a portion of the plurality of fibers are at least partially exposed adjacent a wound end of the exudate conduit.
- 3. The apparatus according to claim 2, wherein the exudate conduit includes an outer sleeve for at least partially accommodating the fibrous core, the at least some of the fibers extending beyond the outer sleeve.
- 4. The apparatus according to claim 1, wherein at least one of the plurality of fibers comprises a hydrophobic material.
- 5. The apparatus according to claim 1, wherein the outer bundle of fibers is knitted, woven, or braided around the inner bundle of fibers.

- 6. The apparatus according to claim 1, wherein the fibrous core includes at least one additive selected from the group consisting of an antimicrobial, an anti-septic, and a surfactant.
- 7. The apparatus according to claim 6, wherein the exudates conduit has a wound end adapted to be positioned proximate the cover layer, and a vacuum end adapted to be fluidly connected to a vacuum source, and wherein a concentration of the at least one additive in a region of the fibrous core adjacent the wound end is greater than a concentration of the at least one additive in the fibrous core adjacent the vacuum end.
- 8. The apparatus of claim 1, wherein the fibrous core defines an elongate wick having a first end and a second end, the first end in fluid communication with the reservoir through an aperture in the cover layer, the second end disposed remotely with respect to the aperture, the elongate wick adapted for longitudinal transport of fluids therethrough; and wherein the apparatus further comprises a flexible wick cover extending over the elongate wick and having a first end and a second end, the first end configured for forming a substantially fluid tight seal over the aperture in the cover layer, the second end including an wick cover aperture therein through which fluids may be extracted from the elongate wick; and a fluid port coupled to the wick cover and in fluid communication with the second end of the elongate wick through the wick cover aperture, the fluid port configured to receive a fluid conduit.
- 9. The apparatus according to claim 8, wherein the wick cover includes indicia thereon that is indicative of a distance from the fluid port.

- 10. The apparatus according to claim 9, wherein the indicia include rule marks on the wick cover.
- 11. The apparatus according to claim 8, wherein the fluid port includes a flange coupled to an underside of the wick cover.
- 12. The apparatus according to claim 8, wherein the elongate wick is treated with an antimicrobial agent comprising polyhexamethylene biguanide.
- 13. The apparatus according to claim 8 further comprising a backing layer adhered to the lower surface of the wick cover in a releasable manner such that the elongate wick is interposed between the wick cover and the backing layer.
- 14. The apparatus according to claim 13 wherein the wick cover comprises an aperture therein through which wound fluids may be drawn.
- 15. Use of a wound dressing for facilitating wound treatment, said wound dressing comprising:

a cover layer for positioning over a wound and define a reservoir over the wound, and an exudate conduit including a fibrous core having a plurality of fibers communicating with the reservoir for wicking fluids away from the wound, the fibrous core including an inner bundle of fibers and an outer bundle of fibers, and the inner bundle comprising hydrophobic fibers for discouraging fluid absorption and the outer bundle comprises hydrophilic fibers for promoting fluid absorption.

1/9

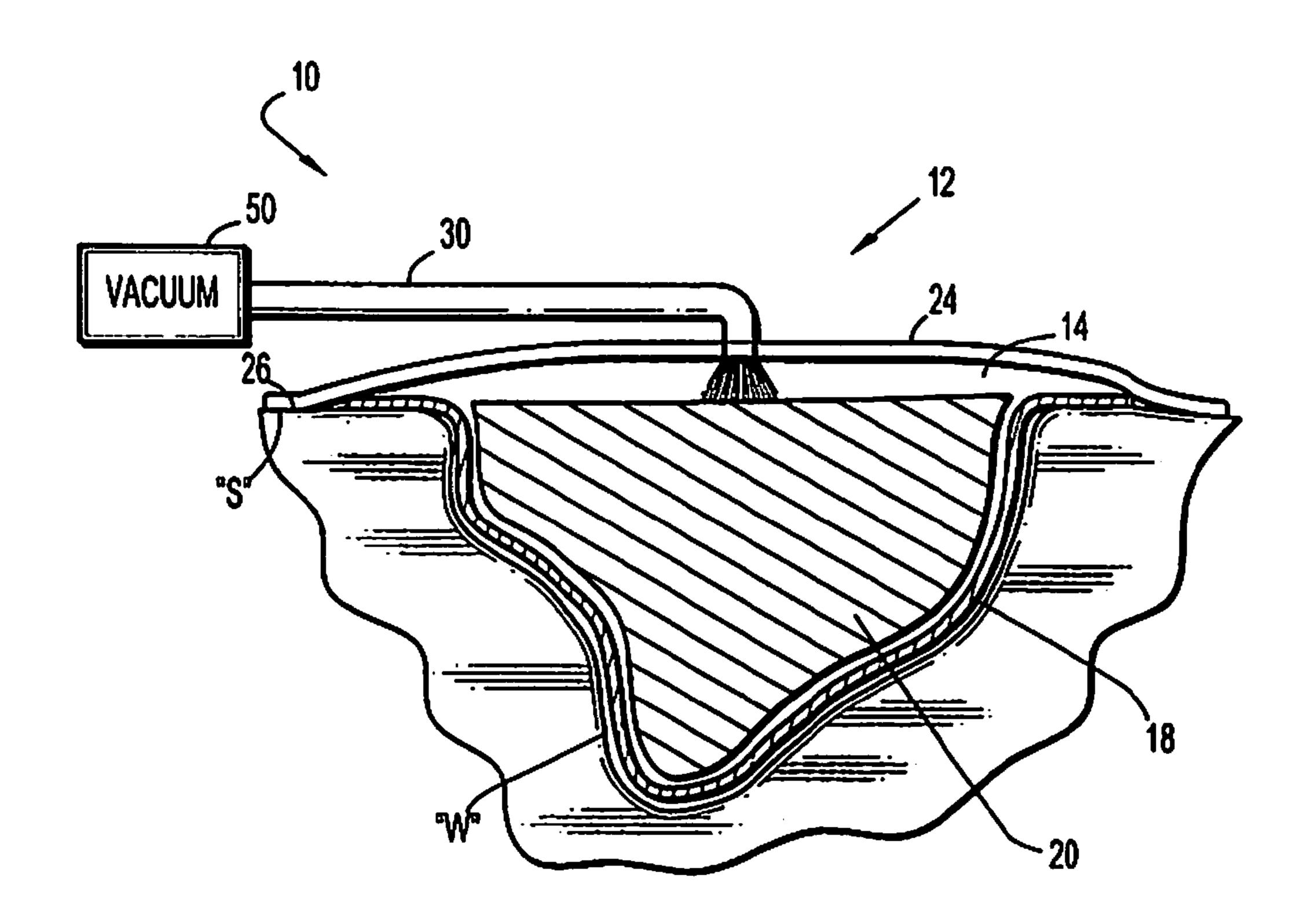


FIG. 1

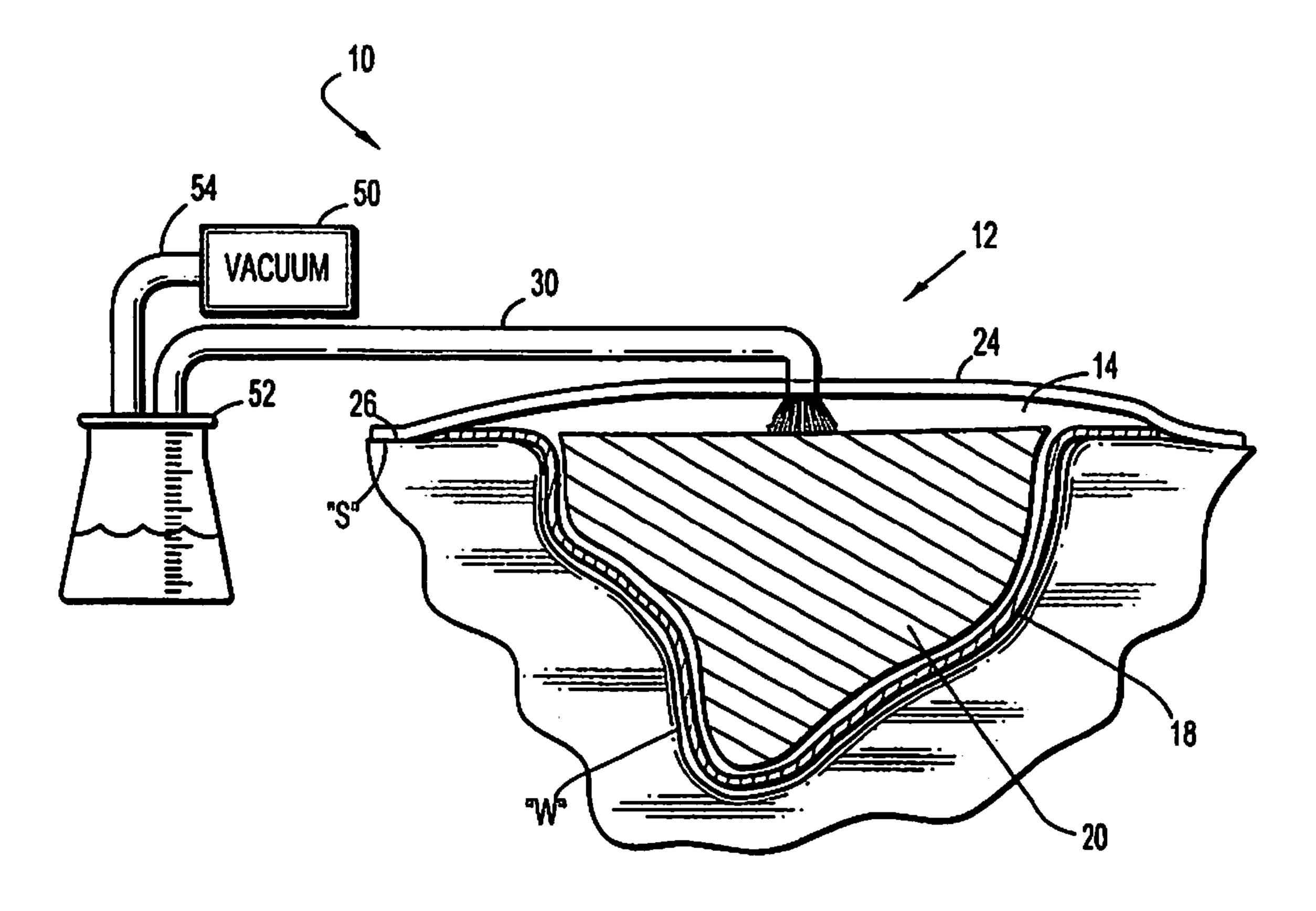
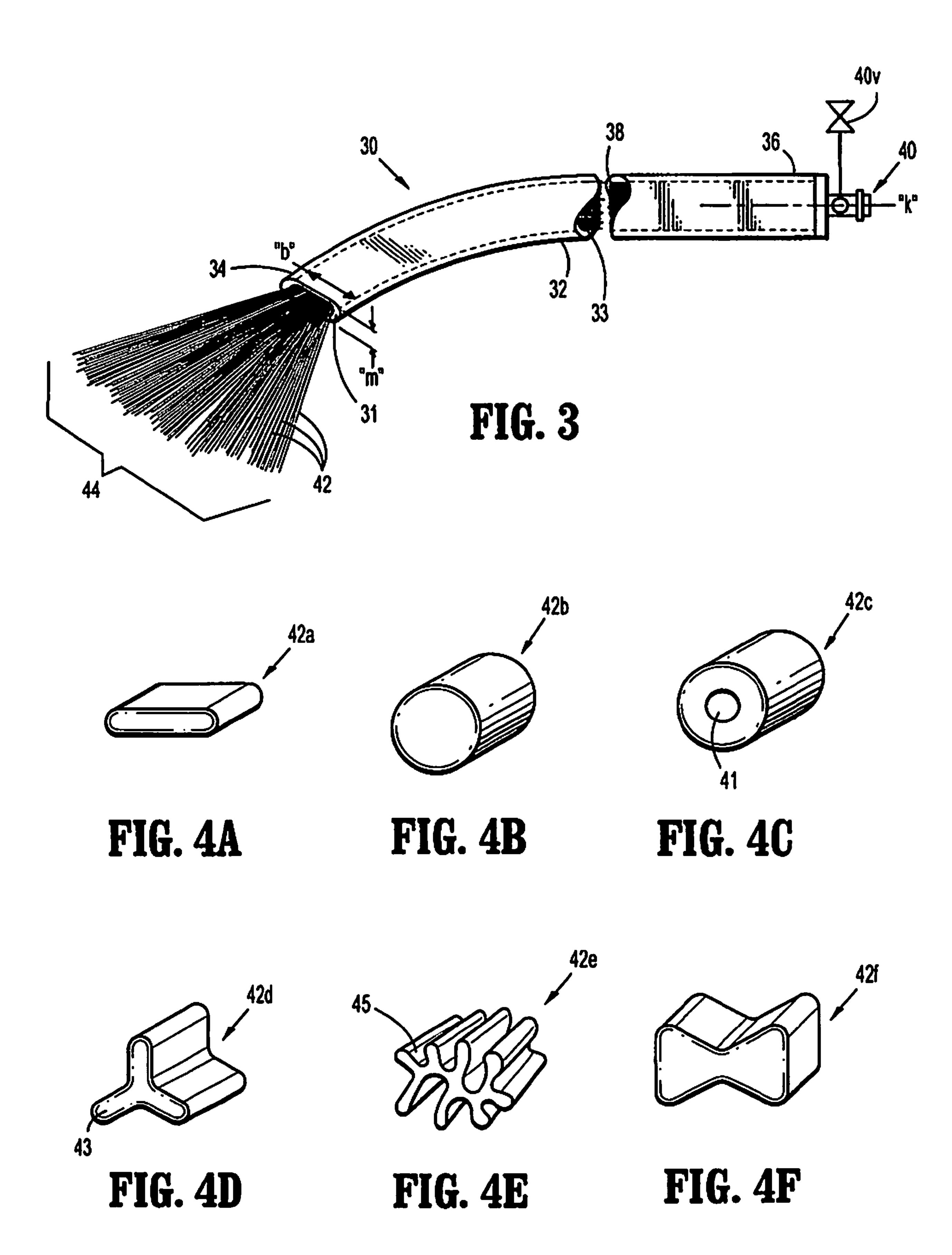
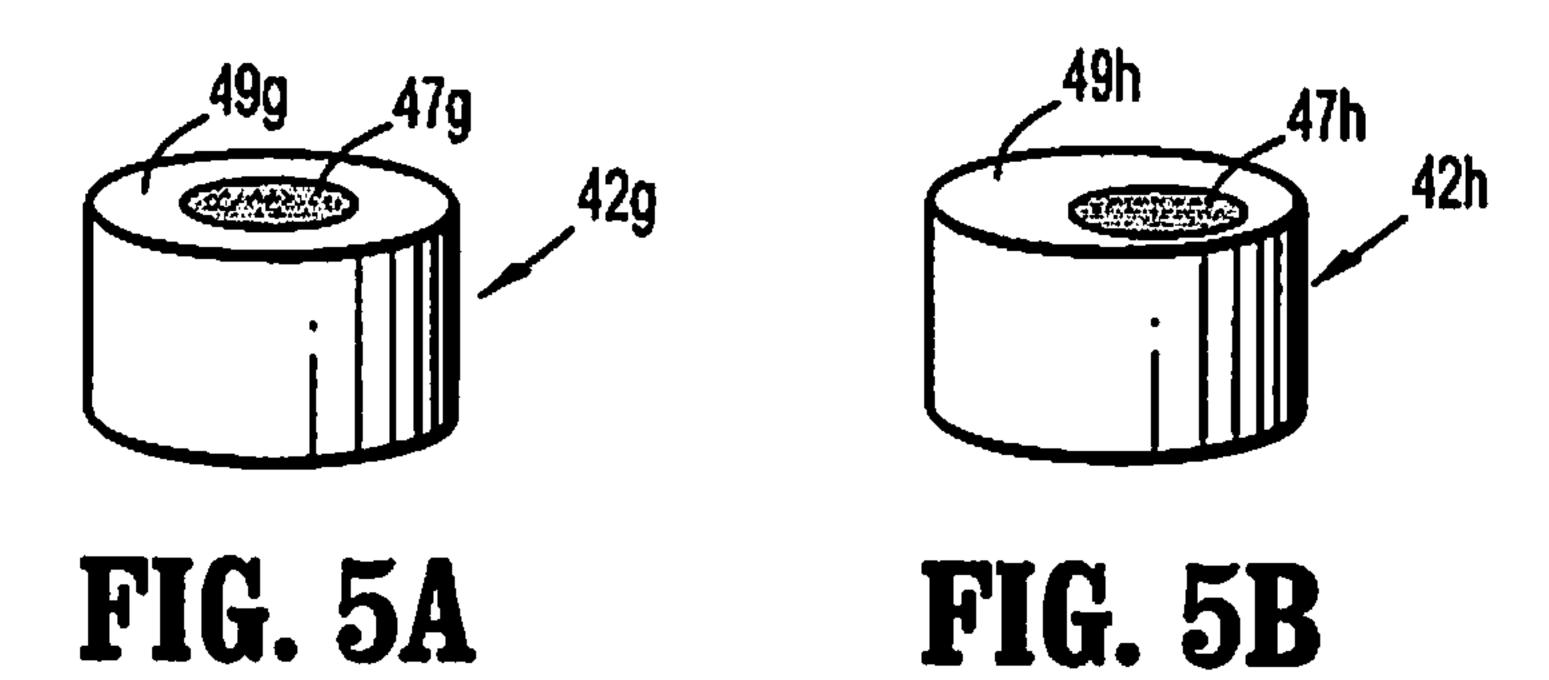


FIG. 2

2/9





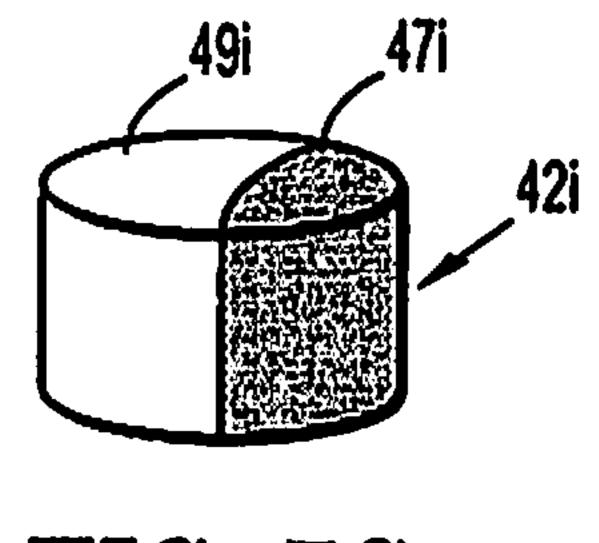


FIG. 5C

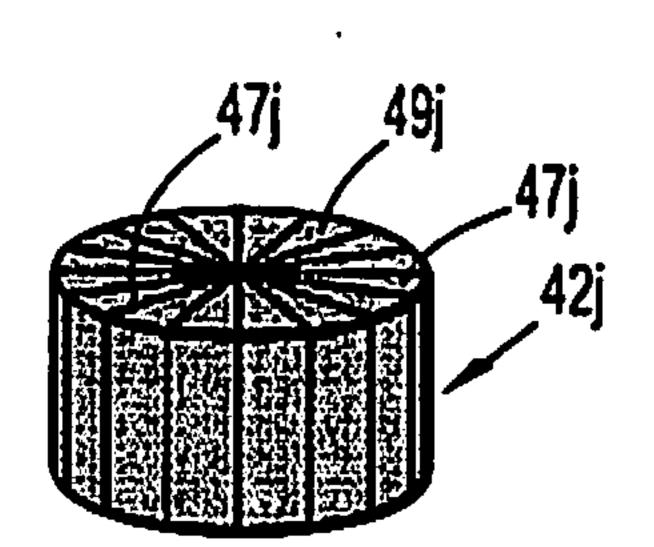


FIG. 5D

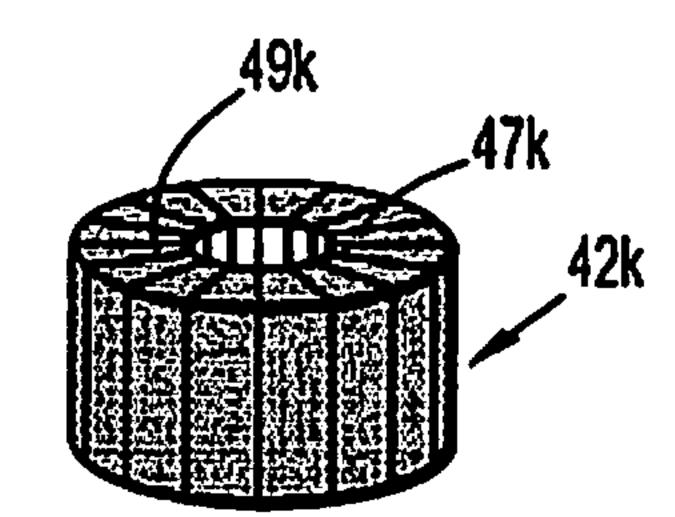


FIG. 5E

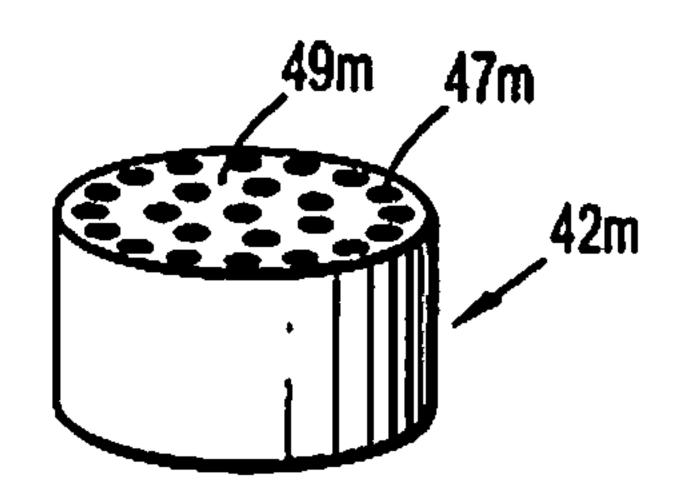


FIG. 5F

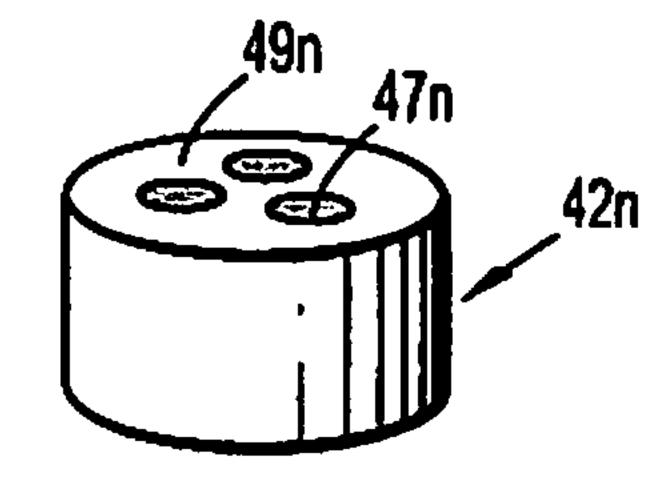
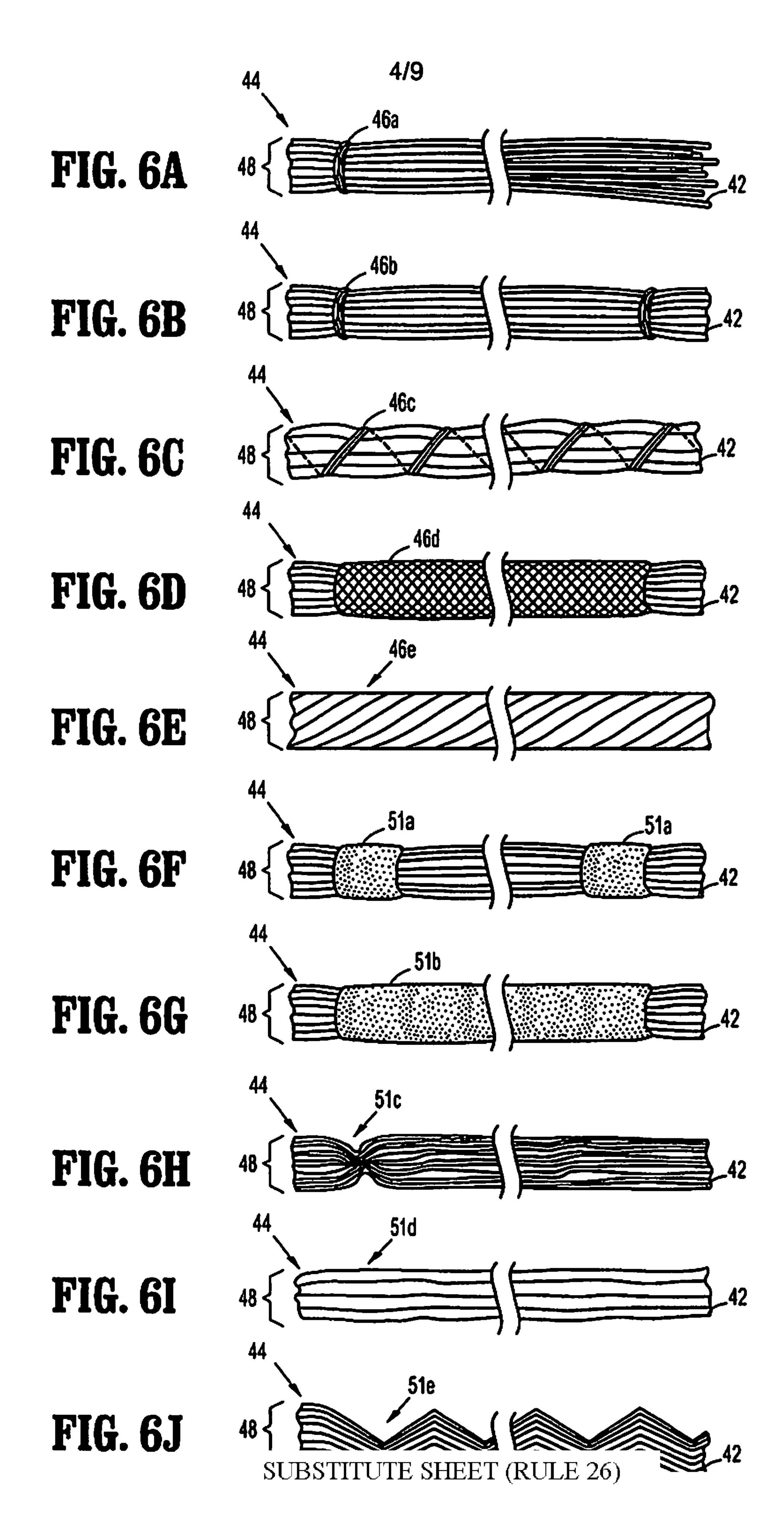


FIG. 5G



5/9

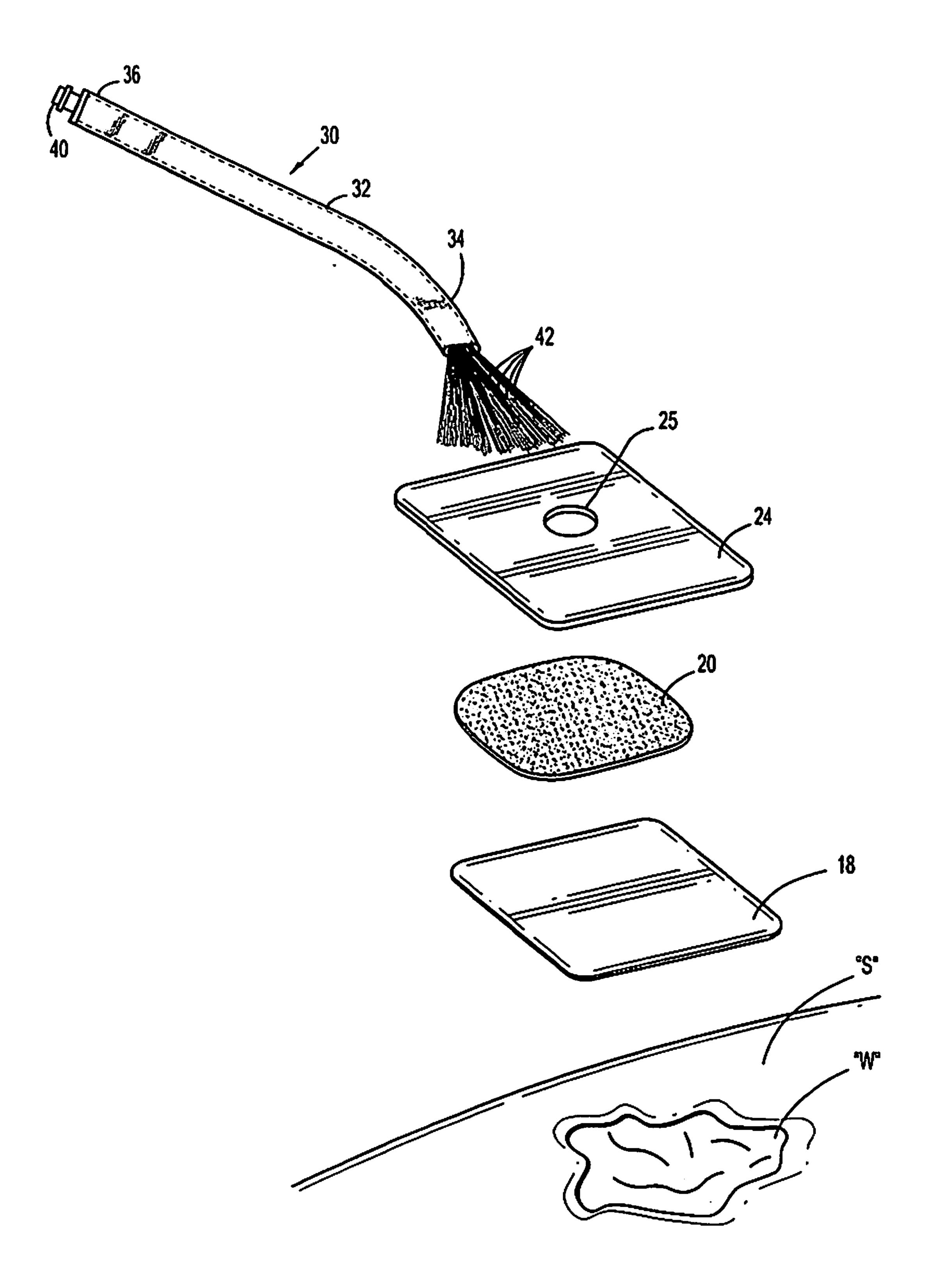
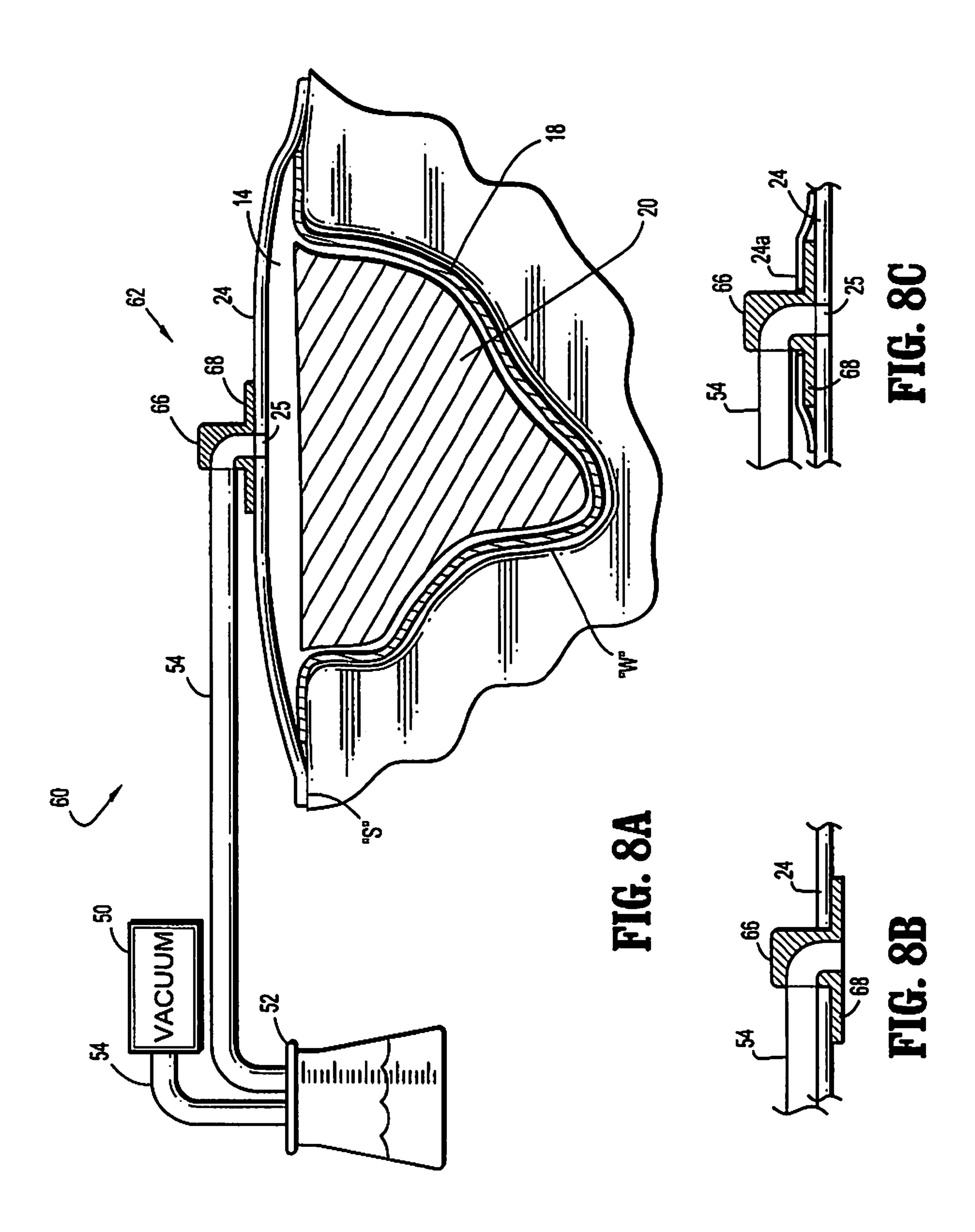
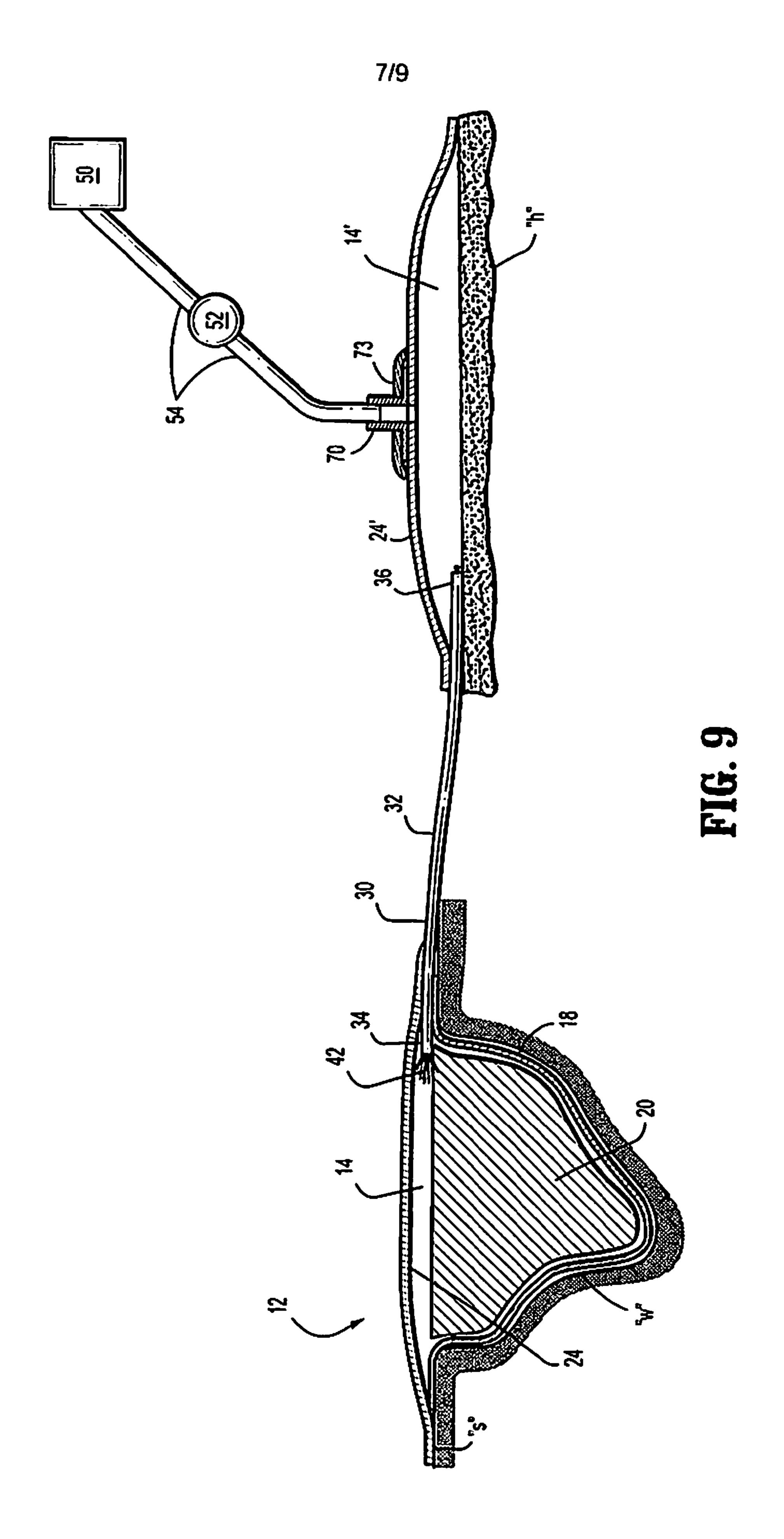


FIG. 7

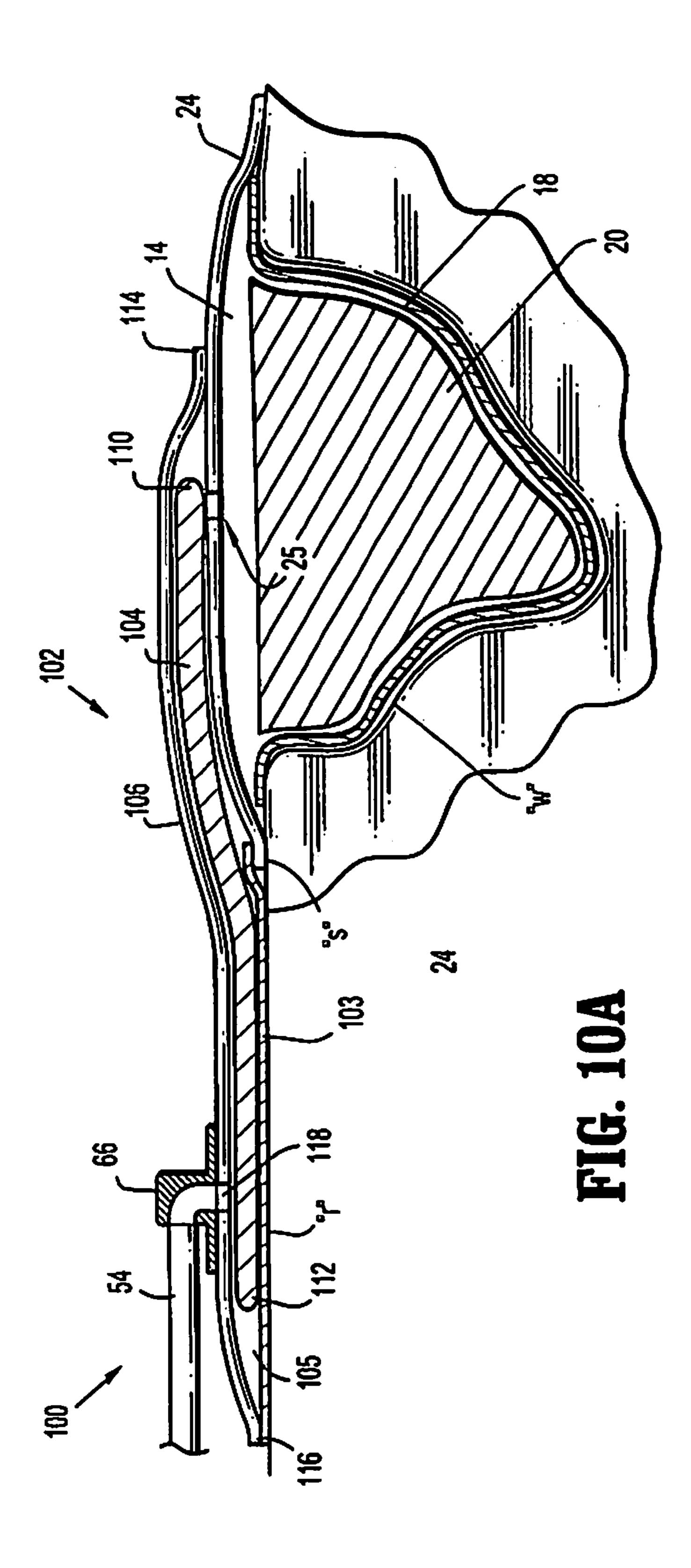
6/9

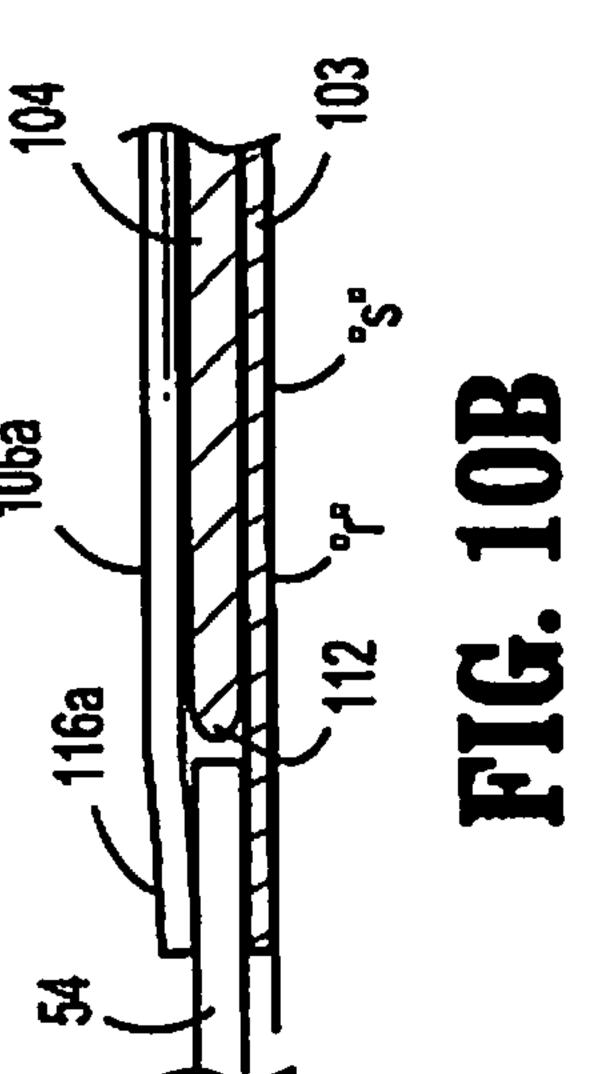




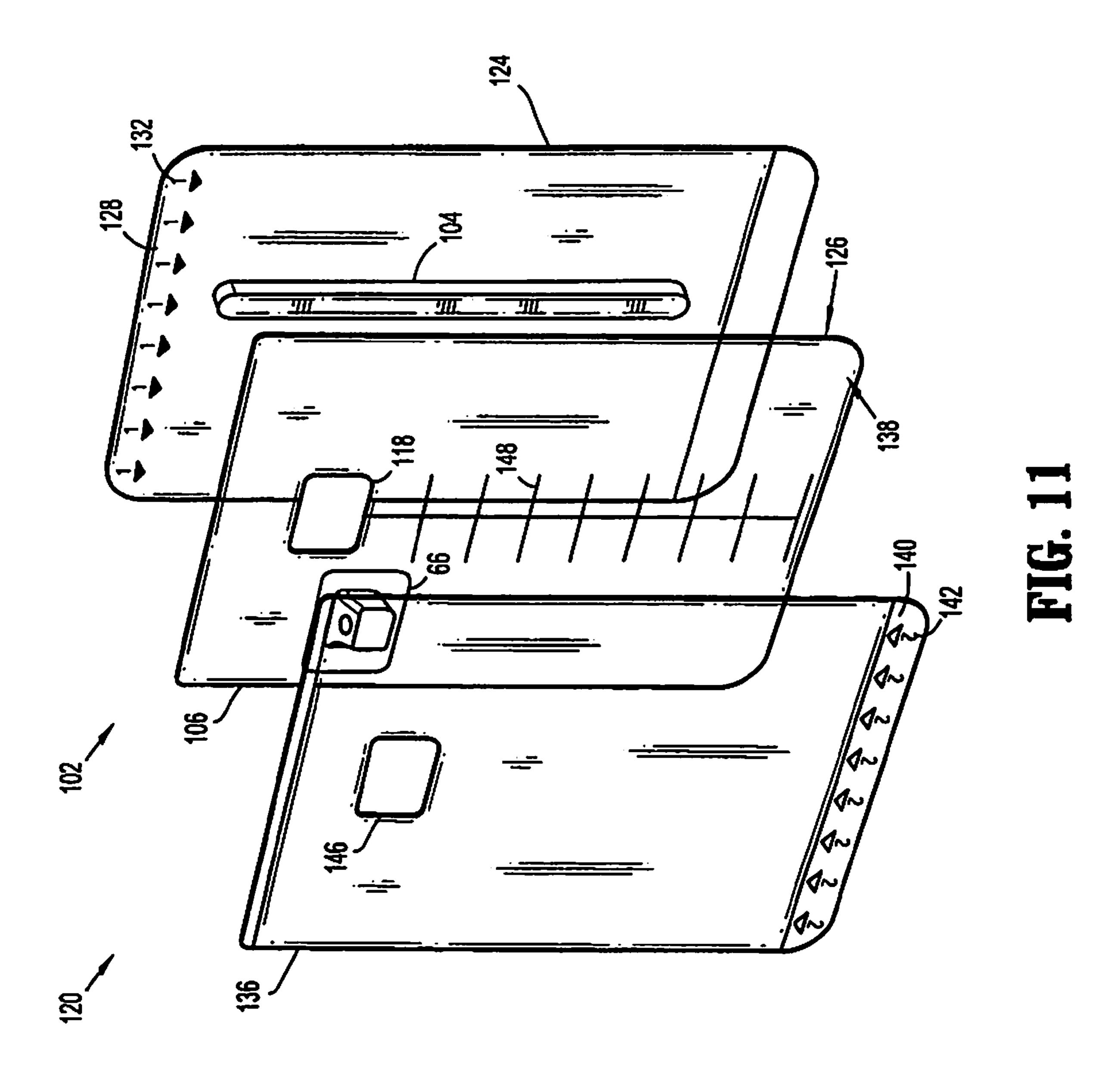
SUBSTITUTE SHEET (RULE 26)

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9/9



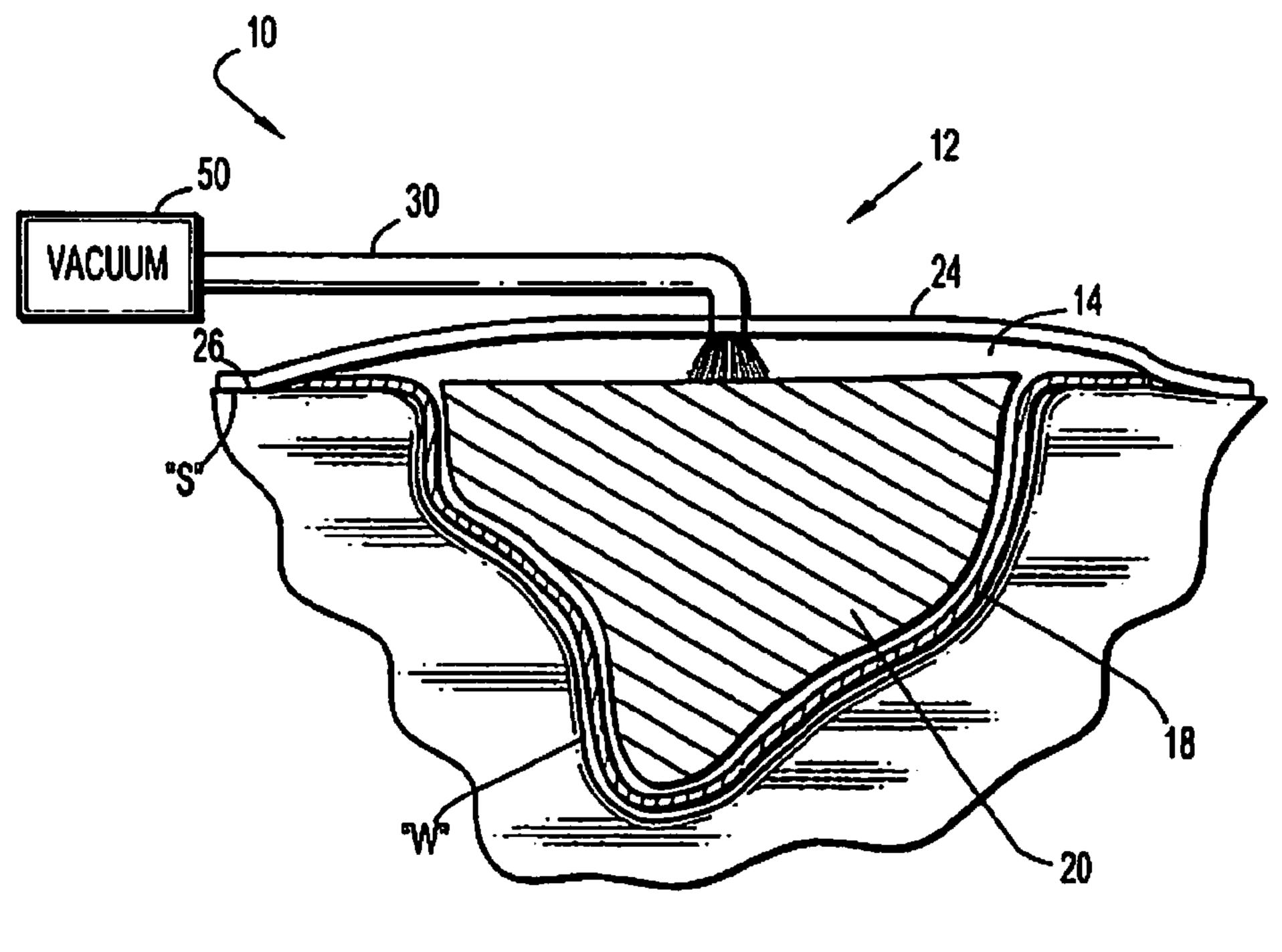


FIG. 1