

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SOLVENTUM CORPORATION,

Petitioner,

v.

WOUND HEALING TECHNOLOGIES, CORP.

Patent Owner.

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IPR2025-01042

U.S. Patent No. 10,639,404

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**DECLARATION OF  
SALVATORE DOMENIC MORGERA, Ph.D., P.Eng.**

## **I. INTRODUCTION**

1. I have been retained in this case by Wound Healing Technologies, Corp. (“WHT”). I was asked to formulate opinions and prepare a report in response to the claims asserted in the above-captioned *Inter Partes* Review of U.S. Patent No. 10,639,404 (“the ’404 patent”).

## **II. BACKGROUND AND QUALIFICATIONS**

2. I am an Engineer with over fifty years of experience and leadership in industry, government, and academia. My curriculum vitae is attached as Exhibit A. I am a retired Professor from the University of South Florida and Florida Atlantic University. I was Chair & Distinguished Professor of Electrical Engineering, Medicine & Bioengineering at the University of South Florida from 2009-2021. I was also an Emeritus Professor of Engineering & Bioengineering at Florida Atlantic University and a Raytheon Fellow. At the time of the effective filing date of the claimed invention, I occupied these positions.

3. Before joining the University of South Florida, I was Professor and Chair of Electrical Engineering & Bioengineering and Founding Director of the Bioengineering Program at Florida Atlantic University. Before joining Florida Atlantic University, I was (1) a Distinguished Professor of Engineering & Biomedical Engineering and Director of the Information Networks and Systems Laboratory in the Department of Electrical and Computer Engineering at McGill

University, Montreal, Canada; (2) a Major Project Leader in the Canadian Institute for Telecommunications Research, a Government of Canada Network of Centres of Excellence; (3) President of the Quebec Research Council, Le Fonds Nature et Technologies; (4) a Distinguished Scientist in the National Research Council, Institute for Information Technology; and (5) Special Assistant to the President, Communications Research Center, Industry Canada, Government of Canada. Before joining McGill University and being appointed to the Government of Quebec and Government of Canada assignments, I was a Senior Scientist and Program Director at Raytheon Company, Submarine Signal Division, Portsmouth, RI, USA.

4. I am a Fellow of the Institute for Electrical and Electronics Engineers (IEEE) for specific contributions to Electrical Engineering; Fellow of the American Association for the Advancement of Science (AAAS) for specific contributions to Electrical Engineering and Life Sciences; Fellow of the National Academy of Inventors; Fellow of the Institute of Engineering and Technology (IET) for contributions to Intelligent Machines; Fellow of the Asia-Pacific Artificial Intelligence Association (AAIA) for contributions to Artificial Intelligence and Autonomous Machines; IEEE Distinguished Lecturer for the Communications Society; Tau Beta Pi Eminent Engineer; member of the Order of Engineers; and a Professional Engineer. I have received commendations from both industry and the United States and Canadian Governments for my Science and Technology

contributions. I have published 166 journal papers and 154 conference papers and have or will publish three books, including Bioengineering – Intersection of Engineering and Medicine (under contract, McGraw Hill). I have published 8 book chapters, including The Primary Role of the Electric Near-Field in Brain Function, Electric Field (M. Sheikholeslami, Ed.), and have received numerous author awards for my publications.

5. I have over four decades of pioneering work in Bioengineering and Biomedical Engineering. I have consistently advanced the intersection of engineering, medicine, and human health. At Florida Atlantic University, I founded and directed one of the nation's first Bioengineering Certificate and Graduate Degree programs, securing over \$10M in direct and in-kind institutional and industrial support. I collaborated extensively with the Scripps Florida Research Institute, the Max Planck Institute, and the Louis and Anne Green Memory and Wellness Center, linking advanced engineering research to neurological and medical applications. At the University of South Florida, I established the Bioengineering Laboratory and played a key leadership role in interdisciplinary initiatives bridging electrical engineering, medicine, and life sciences. My research leadership extends globally, including my directorship of the Global Center for Neurological Networks, dedicated to unraveling the language of the brain and translating discoveries into non-invasive, non-drug therapeutics for neurological dysfunction and mental

disorders (supported by U.S. Patent 11,129,545). Beyond academia, I have influenced federal and defense research agendas by designing biomedical signal processing frameworks and health-oriented intelligent systems that address both clinical and societal needs.

6. I received a Sc.B. degree in Physics with Honors, an Sc.M. degree in Electrical Engineering, and the Ph.D. degree in Electrical Engineering, all from Brown University, Providence, RI, USA. My core expertise in the matter at hand stems from 1983, when I was selected to serve as a Senior Scientist at the Montreal Neurological Institute and Biomedical Engineering Center Director at McGill University. Since that time, I have consistently applied my background and experience to Bioengineering in academic, industrial, and clinical settings. Wound healing, in particular, is a fundamental pillar of Bioengineering because it integrates physiology, materials science, and medical technology to restore tissue integrity and function. I have taught this topic extensively in both Canada and the United States, framing it as a cornerstone of biomedical engineering education. In addition, I have led clinical research and translational teams, applying knowledge from basic science to practical applications, especially in fields like medicine, biology, and engineering, at the University of South Florida and Florida Atlantic University, guiding investigations and applications of advanced wound healing technologies and methods in direct collaboration with physicians and surgeons. These combined roles

underscore my long-standing engagement in advancing wound healing science as both a teaching discipline and a clinical practice.

### **III. COMPENSATION**

7. I am being compensated for my work as an expert with respect to this litigation at a rate of \$450 per hour for review of materials, for the preparation of my report, and for laboratory examination of devices. My compensation is not contingent and does not depend upon the content of my opinion or the outcome of this IPR.

### **IV. MATERIALS CONSIDERED**

8. In preparing this report, I have reviewed the '404 patent and its prosecution history, Solvatum Corporation's Petition (the "Petition" or "Pet."), the Exhibits A-D included in the Petition, WHT's Request for Discretionary Denial, exhibits related thereto, as well as patents and applications relating to the '404 patent. I also rely upon my extensive experience and knowledge as an Bioengineer. I respectfully submit herewith a list of the materials I reviewed in preparation of this report and attach same as Exhibit B. Exhibit B identifies the materials reviewed and considered in preparation of this Expert Report in this proceeding. These materials include:

A) The '404 patent and its complete prosecution history, as well as related patents and applications;

B) Petitioner's IPR petition and supporting exhibits;

C) Patent Owner's Preliminary Response and supporting exhibits, including its Request for Discretionary Denial under 35 U.S.C. §325(d);

D) Related prior art patents and publications cited by both parties;

E) Peer-reviewed literature, textbooks, clinical guidelines, and regulatory standards relevant to wound healing methods, negative pressure wound therapy, and clinical practice.

9. This list is provided to ensure transparency regarding the scope of the technical and scientific materials reviewed in connection with this matter.

10. Please note that Exhibit B is provided as a separate document to be inserted into the Expert Report.

11. I reserve the right to consider and/or rely upon any additional information or materials that may be provided to me.

## **V. RELEVANT LEGAL PRINCIPLES**

### **A. Level of Skill in the Art**

12. I understand that the validity of patents is analyzed from the perspective of a person having ordinary skill in the art at the time of the invention(s) claimed in the patent ("POSITA"). I understand that courts instruct fact finders to consider several factors in determining the level of ordinary skill in the art, including: (1) the

type of problems encountered in the art; (2) prior art solutions to those problems; (3) rapidity with which innovations are made; (4) sophistication of the technology in the art; and (5) the educational level of active workers in the field.

**B. Presumption of Validity**

13. I understand that in deciding whether to issue a patent, the U.S. Patent and Trademark Office (“PTO”) examines the patent specification, its claims, and relevant prior art references to determine whether the patent application and its claims meet the requirements for patentability. I understand that if the PTO then issues the patent, it has determined that the claims are valid. I understand that the law recognizes that the PTO possesses special expertise to conduct such determinations, and that, as a result, each claim of a patent issued by the PTO is presumed valid by law. I understand that this presumption of validity can be overcome only if the party seeking to invalidate a claim proves invalidity by clear and convincing evidence, which I understand to mean evidence that convinces the PTO, including the Patent Trial and Appeal Board (the “Board”) that it is highly probable that the proposition is true.

14. I understand that where the asserted prior art was before the PTO examiner when the patent was being prosecuted, the party challenging the patent’s validity has the added burden of overcoming the deference that is due to the PTO. I understand that this added burden extends to references that are cumulative of those

considered by the PTO examiner during prosecution.

15. I understand that the presumption of validity applies to each issued claim of the asserted patent, and that validity is determined on a claim-by-claim basis. I understand that a finding that one claim is invalid does not necessarily mean that any other claims of the patent are invalid.

16. I understand that patents include independent claims and dependent claims. I understand that dependent claims depend from independent claims, and that the dependent claim incorporates each and every limitation set forth in the independent claim from which it depends.

17. I further understand that if a prior art reference (or combination of references) fails to invalidate an independent claim, it fails to invalidate any claim that depends from that claim. I further understand that a reference does not invalidate a dependent claim merely because it invalidates the underlying independent claim.

### **C. Items That Qualify As Prior Art**

18. I understand that the anticipation and obviousness analyses focus on “prior art.” I understand that what constitutes “prior art” is set forth in the United States patent laws in 35 U.S.C. § 102.

19. I understand that under 35 U.S.C. § 102(a), a person is entitled to a patent unless the invention was known or used by others within the United States, or patented or described in a printed publication in the United States or a foreign

country, before the applicant's invention date.

20. I understand that the applicant's "invention date" is at least as early as the earliest effective filing date of the patent, and that the invention date may be proven to be earlier than the earliest effective filing date. I understand that a patent's "effective filing date" is generally the filing date of the earliest application to which the patent claims priority. I further understand that a claim only receives the effective filing date of an application to which it claims priority if the disclosure in the application meets the requirements of 35 U.S.C. § 112 with respect to the later- filed claims. I understand that these requirements include the written description requirement and the enablement requirement, which I discuss in greater detail below.

21. I understand that under 35 U.S.C. § 102(b), a person is entitled to a patent unless the invention was patented or described in a printed publication in the United States or a foreign country, or if the invention was in public use or on sale in this country, more than one year prior to the effective filing date of the patent.

22. I understand that to constitute a "printed publication," a reference must have been made accessible to the public in the United States or a foreign country.

23. I understand that to qualify as "on sale" for prior art purposes, there must be a commercial offer for sale of a product or process in the United States. I further understand that the product or process must have been "ready for patenting," meaning that the invention was either (1) already reduced to practice, or (2) drawings

or other descriptions of the invention existed that would enable a POSITA to practice the invention.

24. I understand that to qualify as “in public use” for prior art purposes, the use must have been public and in the United States. I understand that secret uses do not qualify as prior art.

25. I understand that under 35 U.S.C. § 102(e), a person is entitled to a patent unless the invention was described (1) in a published United States patent application filed by another whose earliest effective filing date is before the established invention date; or (2) in a United States patent granted on an application filed by another before the established invention date.

#### **D. Obviousness**

26. I understand that the fundamental question in an obviousness analysis is whether, at the time of the invention, the subject matter of the claimed invention as a whole would have been obvious to a POSITA, taking into account the “Graham factors”: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) any objective indicia (sometimes referred to as “secondary considerations”) of non-obviousness.

27. I understand that if the scope and content of the prior art does not include every element of the claim, then the claimed subject matter is not prima facie

obvious.

28. I understand that such “secondary considerations” include evidence of commercial success, long-felt but unsolved needs, the failure of others, recognition of the problem to be solved, industry praise and recognition, copying by others, licensing by others, and unexpected results. I further understand that, where secondary considerations are present, they must be considered in the obviousness analysis.

29. I understand that multiple references can be combined with one another, or with the knowledge of a person of ordinary skill in the art, to render a claim obvious. I understand, however, that obviousness cannot be established by simply combining previously known elements from the prior art and demonstrating that each element was independently known. I understand that it can be important to identify a reason, such as, for example, a teaching, suggestion, or motivation, that would have prompted a person of ordinary skill in the art to combine the elements in the way the claimed invention does.

30. I further understand that, before a motivation to combine the references or a reasonable expectation of success at doing so is considered, it must first be shown that each claim limitation is disclosed in the prior art. I understand that a limitation that is not disclosed expressly in a reference may be disclosed inherently, but that a party attempting to show that a limitation is inherently present for purposes

of an obviousness analysis must meet a high standard. I understand that inherency may not be established by probabilities or possibilities (*i.e.*, the mere fact that a certain thing *may* result from a given set of circumstances is not sufficient). Rather, a limitation is inherently disclosed only if it is necessarily present or the natural result of the combination of elements expressly disclosed by the prior art.

31. I understand that, while individual references do not necessarily need to enable the claimed invention to be used in an obviousness combination, the ultimate combination of references must enable the claimed invention to render the claims obvious.

32. I further understand that, for an obviousness analysis, the prior art includes only analogous art, *i.e.*, art that is either in the same field as the applicant's endeavor or that is pertinent to the particular problem with which the applicant is concerned. Ascertaining the scope and content of the prior art requires interpreting the claim language and considering both the invention and the art as a whole.

33. I understand that, for purposes of the obviousness analysis, a POSITA does not have the benefit of the teachings of the patent and cannot work backwards from what is disclosed by the patent (I understand that this is referred to as "hindsight"). Rather, the pertinent question is whether what is claimed in the patent would be obvious to a POSITA based on the entirety of the relevant prior art at the time of the invention, including art teaching toward and away from the invention.

34. I am also informed that the obviousness is performed in two steps: first, the terms of the claims are construed by the Board to ascertain their scope; and second, the construed claims are compared to the prior art. I understand that the Board will perform this first step, but that it has not yet done so. (Although, I understand that the Board has previously construed one or more terms of the '404 patent in an *ex parte* appeal.) Thus, I have conducted my analysis using the Board's construction. If necessary, I will supplement my expert report to analyze validity under a different construction.

35. I understand that, particularly in a crowded field, even seemingly small innovations may nonetheless be non-obvious innovations that are of significant practical usefulness to those who make and/or use the invention.

## **VI. SUMMARY OF MY OPINIONS**

36. Based on the information currently available to me, and as set forth below, I provide the following opinions I have formed:

37. Claims 1-13 of U.S. Patent No. 10,639,404 (the "'404 patent") are not rendered obvious to a person of ordinary skill in the art at the time of the invention, by any of the prior art references in the Petition, whether taken alone or in combination.

38. The alleged prior art of Argenta 2008 is cumulative of previously considered Argenta references and does not describe a wound dressing as claimed.

39. The alleged prior art of Hu is cumulative of previously considered reference Biggie.

40. Argenta, both Argenta 2008 and Argenta 2010, discuss a technique for distributing the vacuum from the mouth of a tube to the rest of a wound. In order to distribute the vacuum to the rest of the wound, Argenta's technique requires a serial, *in situ*, deployment of NPWT components. Argenta requires cutting a sponge, shaping the sponge and using the sponge to fill a wound bed. Then, Argenta requires covering the custom sponge with a drape. Next, Argenta requires inserting an end of the vacuum tube through, or under, the drape and mating an end of a vacuum tube with the customized sponge. Then, the vacuum tube needs to be fixed in place and a vacuum-induced suction applied through the tube and distributed to the wound through the sponge.

41. The claimed invention, on the other hand, claims a wound dressing for application directly to a wound-bed, without many of the steps required by Argenta.

42. The claimed invention is more efficient, easier to apply, and less painful to a patient. In biomedical engineering and medicine, the claimed invention and its design is known as a superior wound treatment technology that enhances clinical outcomes.

43. Further, in my opinion, there is no reason why a POSITA would have combined any of the references in the Petition.

## VII. BACKGROUND OF THE TECHNOLOGY

44. Negative pressure wound treatment (“NPT” or “NPWT”) has been clinically demonstrated to be therapeutically advantageous for numerous types of wounds.

45. A wound is typically cleansed, debrided, and partially packed with sterile material prior to NPT application.

46. Conventionally, a NPT drain is placed in a wound (*in situ*) while a practitioner is packing the wound with sterile material. Additional sterile material may be placed over the NPT drain. The NPT drain is anchored. A drape or other bandage is placed over the NPT drain and the wound. Replacing the sterile material in conventional NPT practice is difficult because doing so requires risks displacement of the drain, increases the likelihood of traumatizing the wound bed due to adherence of the packing material, complicates the maintenance of sterility, and causes significant patient discomfort. These limitations highlight the inefficiencies and drawbacks of conventional methods compared to improved wound healing technologies designed for easier dressing changes and reduced patient pain.

47. In my opinion, the ‘404 patent correctly sets forth that conventional preparation of a wound for NPT is complicated, from the points of view of both the practitioner and the patient. ‘404 Patent, column 1, lines 36-38. This is, at least in

part, because the conventional wound-fluid NPWT drain is introduced into a first stage of wound packing in the wound-bed. *Id.*, 1:43-44.

48. The NPT drain is thus associated in situ with the first stage of packing material. *Id.*, 1:53-54. The drain is placed on or inserted within the initial packing. *Id.*, 1:55-56. Orientation of the drain within the wound bed or packing will affect the efficiency of the drainage or the quality of the wound-closing. *Id.*, 1:57-58. In fact, orientation of the drain within the wound bed or packing is a critical determinant of drainage efficiency and wound closure quality. Improper placement or angulation of the drain reduces suction uniformity, limits exudate removal, and interferes with tissue approximation, leading to less effective healing outcomes. The exiting tube is taped to the patient's skin. *Id.*, 1:64.

49. The practitioner must be careful to avoid disturbing the placement of the tube, which is held in place by the adhesion of tape to the skin. *Id.*, 2:3-6. Even with the vacuum/drainage skin-anchored close to the wound, "manipulations" involved in completing the wound-packing procedure may deleteriously shift the NPT drain-and-tube.

50. In yet a further stage of NPT preparation, the drain and the tube are draped with an adherent flexible covering that is intended to provide an airtight seal against the perilesional skin. *Id.*, 2:8-12. However, it may be challenging to produce an effective airtight perimeter seal. *Id.*, 2:13-20. Such a procedure may be difficult

and time-consuming. Creating an airtight seal with an adherent flexible covering over the drain and tube is often difficult and time-consuming due to several clinical realities that I have witnessed. Irregular wound shapes and the natural contours of skin make it challenging for adhesive drapes to fully conform, while the presence of moisture, wound exudate, or perspiration frequently undermines adhesion. In addition, patient movement or tension from the tubing can disrupt the seal, requiring repeated adjustments. These difficulties not only prolong the procedure but also increase patient discomfort and risk of contamination, making the process inconsistent with the high standards of care that demand efficiency, reliability, and protection of the wound environment.

51. In yet a further stage of conventional NPT preparation, a sealed egress of the draping material must be formed along the outer surface of the tube. *Id.*, 2:21-26. Each additional taping may be painful to the patient, as well as inconvenient and time-consuming.

52. In conventional NPT regimens, “the number and intricacy of conventional NPT-required manipulations may make it difficult for a practitioner to efficiently carry out the procedure (practical and institutional constraints may limit the number of practitioners and aides available); may lead to the need to repeat part or all of the procedure so as to correct earlier errors and/or later shifting of components; may contribute to incomplete success of the procedure, depriving the

patient of the full benefit of NPT.” *Id.*, 2:44-53. Moreover, the multiple steps described above would, in a typical wound, “be repeatedly applied over several courses of NPT.” *Id.*, 2:54-55. Each course of NPT may include, at the outset, cleansing and assessment of the progressively smaller wound-bed, followed by application of the dressing.” *Id.*, 2:60-63. “Inherent painfulness may attend repeated manipulations of the wound-bed and surrounding wound-site, compounding the difficulties and complications involved in preparation of a wound for NPT by conventional apparatus and methods.” *Id.*, 2:63-66.

53. In my opinion, the claimed invention of the ’404 patent represents a decisive advancement over conventional negative pressure wound treatment regimens. Traditional regimens are inherently piecemeal, relying on loosely associated components that must be manually assembled and applied in ways that are often cumbersome, inconsistent, and prone to failure at critical points of therapy. Such approaches place unnecessary burdens on clinicians, increase the risk of patient discomfort and error, and undermine the reliability of outcomes. By contrast, the ’404 patent embodies a system-level solution, designed holistically rather than as a collection of parts. It is a coordinated structure that enhances efficiency, ensures more consistent application, and directly addresses the central clinical challenges of wound closure and healing. This systemic approach not only mitigates the shortcomings of prior methods but also elevates the standard of care by making

negative pressure therapy more accessible, reliable, and clinically effective.

## **VIII. OVERVIEW OF THE '404 patent**

### **A. U.S. Patent No. 10,639,404**

38. The '404 patent is entitled "Wound Dressing" and issued on May 5, 2020. The '404 patent claims priority to one provisional application: U.S. Provisional Application No. 61/350,988 filed on June 3, 2010. *See*, Exhibit C, '404 patent at Related U.S. Application Data, (63). The named inventor is Isaac Lichtenstein, and the assignee and owner is Wound Healing Technologies, LLC.

39. The claimed invention is a pre-packaged NPT wound dressing ready for application to a wound-bed, avoiding multiple steps necessary in conventional NPT treatment. *See* Ex. C at FIG. 12. A wound dressing according to the embodiments may be applied directly to the wound-site. *See* Ex. C at 4:45-52.

40. When the backing layer of the wound dressing is removed, the dressing is ready for direct application to a wound bed on a patient. FIG. 11 of the '404 patent shows a side view of an exemplary embodiment of the claimed wound dressing in independent claim 3, this direct-application feature is of critical importance in clinical practice. By eliminating multiple preparatory steps and reducing the need for complex assembly, the dressing enables practitioners to apply negative pressure therapy with greater efficiency, saving valuable treatment time and minimizing opportunities for error or contamination. Moreover, direct

application enhances patient safety by lowering infection risk and ensuring a consistent therapeutic seal. Finally, because the system reduces manipulation of the wound and surrounding tissue, it substantially improves patient comfort and mitigates pain compared to conventional approaches that require repeated packing, repositioning, or reassembly of components. This systems-level efficiency, safety, and pain mitigation reflects a higher standard of care and underscores the non-obvious advancement embodied in the '404 patent.

41. FIG. 11 shows a vacuum drainage tube with a terminus, a fluid/absorbing layer, a vapor sealant sheet, a tube-exit-sealant component, and other components of the claimed wound dressing.

42. To initiate treatment, the backing layer is removed from the wound dressing. However, the wound-fluid drain, fluid-absorbing/transferring layer, and tube anchorage component are fixed together, and remain so, after backing layer is applied to a wound bed. Ex. C at 4:45-49.

43. The claimed wound dressing may be applied directly to the wound bed (which may be occupied in part by packing material). That is, the all-in-one dressing may be applied directly to the wound-site. The wound dressing is therefore a pre-packaged unit that is dimensioned prior to application, with the components fixed to and arranged relative to each other, and, when applied to a wound, provides all of the enumerated components.

44. “The dressing may be provided...in sterile over-wrapping. The wrapped dressing may be supplied in a kit with suitable materials and apparatus for wound cleansing and debridement and for initial wound-packing.” Ex. C at 2:21-25.

45. The ’404 patent also describes how the wound dressing may enable NPT with ‘fewer steps’ than conventional NPT regimens. A method for treating a patient with the illustrative dressing includes: 1) Removing the dressing from its sterile over-wrapping; 2) Removing the backing layer; 3) Orienting the dressing for suitable directionality of the vacuum/drainage tube; 4) Centering the fluid-absorbing/transferring material on the wound-bed (centering of the fluid-absorbing/transferring layer is not an act that is independent of the wound; it is a pre-fabricated characteristic of the dressing, because it is centered within the dressing); 5) Applying the dressing to the wound-site; 6) Adhering the draping layer of the dressing to the tissue of the surrounding wound-site; and 7) Connecting a terminus of the vacuum/drainage tube to NPWT equipment.

**B. *Inter Partes* Review Petition Regarding The ’404 patent**

46. I understand that the standard for instituting an *Inter Partes* Review is defined in 35 U.S.C. § 314(a), which states, “The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition... shows that there is a reasonable likelihood

that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

47. I understand that in an *inter partes* review, the petitioner bears the burden to prove unpatentability of the claims of the patent-at-issue by a preponderance of the evidence.

48. I understand that the Petitioner has challenged claims 1-13 (*i.e.*, all claims) of the ‘404 patent. Petitioner’s Ground 1 challenges claims 1-7, 11 and 13; Petitioner Ground 2 challenges claims 8-10; and Petitioner’s Ground 3 challenges claims 1, 4-7 and 12.

49. In my opinion, none of Petitioner’s three grounds are meritorious. Each rests on an overly simplistic reading of the prior art, ignores the system-level nature of the claimed invention, and fails to account for the clinical realities that motivated and validate the ’404 patent. In short, Petitioner’s challenges do not come close to anticipating or rendering obvious the inventive concepts at issue.

#### **IX. THE LEVEL OF ORDINARY SKILL IN THE ART**

50. In my opinion, based on my experience and review of the evidence, a person of ordinary skill in the art at the time of the invention(s) claimed in the ’404 patent would have at least a Bachelor of Science degree in an Engineering discipline, or equivalent industry training and experience. In addition, the person would have at least two years of industry experience with a working knowledge of

medical devices and medical engineering technology.

51. I understand that my opinion of the level of skill in the art is consistent with my own experience, having worked in government, industry, and academia as a bioengineer, biomedical engineer, and medical engineer.

**X. ‘404 PATENT REPRESENTATIVE CLAIM 1**

52. Claim 1 (with elements enumerated as set forth by the Petitioner):

- (a) A wound dressing comprising:
- (b) a wound-fluid drain for use in negative pressure wound treatment (“NPT drain”);
- (c) a vacuum/drainage tube comprising a terminus associated with the NPT drain, said NPT drain being configured to non-simultaneously withdraw fluid from a wound and deliver fluid to the wound;
- (d) fluid-absorbing/transferring layer for distributing negative pressure from the NPT drain, said fluid-absorbing/transferring material being in contact with the NPT drain;
- (e) a vapor sealant sheet from a hydrocolloid material, the vapor sealant that overlies the fluid-absorbing/transferring layer,
- (f) said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-

absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of fluid-absorbing/transferring layer relative to the vapor sealant sheet; and  
(g) a tube-anchorage component that is in contact with at least a portion of the vapor sealant sheet and a portion of the fluid-absorbing/transferring layer, the tube-anchorage component for mechanically maintaining placement of the NPT drain relative to the fluid-absorbing/transferring layer.

## **XI. THE ALLEGED PRIOR ART IS CUMULATIVE**

### **A. Argenta**

53. The Petition relies on Argenta, U.S. Pat. Pub. No. 2008/0208147 (“Argenta 2008”) as its primary reference. Two other Argenta applications and two Argenta patents were considered during the prosecution and Appeal to the PTAB of the ‘404 Patent.

54. In my opinion, there is no relevant subject matter cited from Argenta 2008 that was not in the previously cited, referenced, and considered Argenta patents and applications

55. Below is a list of the Argenta references:

1. U.S. Pat. No. 2008/0208147 (EX1004) (“Argenta 2008”). This is the primary reference for all counts in the Petition.

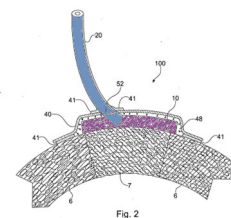
2. U.S. Pub. No. 2010/0042021 (EX2007) (“Argenta 2010”). This was cited during prosecution of the ‘404 Patent by the Examiner. Argenta 2010 was also considered by the PTAB as Primary Reference in reversed rejections. Appears on the face of the ‘404 patent as a considered reference.
3. U.S. Patent No. 5,636,643 (EX2011) (“Argenta 643”). Cited by Patent Owner during prosecution of the ‘404 patent and incorporated by reference in Argenta 2008. Appears on the face of the ‘404 patent as a considered reference.
4. U.S. Patent No. 5,645,081 (EX2012) (“Argenta 081”). Cited by Patent Owner during prosecution of the ‘404 patent and incorporated by reference in Argenta 2008. Appears on the face of the ‘404 patent as a considered reference.
5. U.S. Patent No. 7,216,651 (EX2013) (“Argenta 651”). Cited by Patent Owner during prosecution of the ‘404 patent. Appears on the face of the ‘404 patent as a considered reference.

56. In my opinion, all portions of Argenta 2008 cited in the Petition with respect to exemplary independent claim 3 of the ‘404 patent are present in one or more of the previously cited and considered Argenta references, as shown in Table 1 below. Therefore, in my opinion, Argenta 2008 is cumulative to previously cited

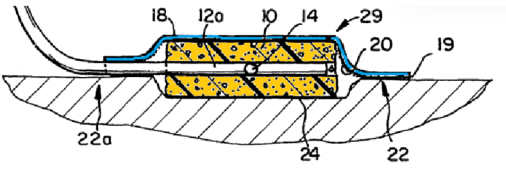
and considered references.

Table 1. Petition Primary Reference Argenta 2008 Cumulative in view of other cited Argenta Documents

| <b>Claimed Element in Claim 3:</b>                 | <b>Petitioner's Reference (Argenta 2008):</b>                                                                                                                                                                 | <b>Previously Considered Argenta References:</b>                                                                                                                                                        |
|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3[a]A wound dressing comprising:                   | Petition, page 31, citing Argenta 2008, ¶¶ 3 and 4.                                                                                                                                                           | To the extent Argenta 2008 discloses a wound cover, Argenta '643, and the other cited Argenta references, also disclose a wound cover, Argenta '643, col. 3:1-2.                                        |
| 3[b] a vacuum/drainage tube comprising a terminus; | <p>“[I]n addition to having an opening at the distal end 32, the tube 30 may be fenestrated along the portion of the tube 30 in communication with the enclosure under cover 10.”</p> <p>Petition, at 32,</p> | <p>Argenta 2010 discloses tube 20 (FIG. 2). “The tube 20 may have one or more fenestrations 23 in that portion of the tube 20 in contact with the porous material 10.”</p> <p>Argenta '2010 at ¶38.</p> |



| Claimed Element in Claim 3:                                                                                                                                                                       | Petitioner's Reference (Argenta 2008):                                                                                                                                     | Previously Considered Argenta References:                                                                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                   | citing Argenta 2008 ¶ 20.                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                           |
| 3[c] fluid-absorbing/transferring layer for distributing negative pressure from the vacuum/drainage tube, said fluid-absorbing/transferring layer being in contact with the vacuum/drainage tube; | Argenta 2008 “discloses screen 20, which is the fluid absorbing/transfer-ring layer that is described by the ‘404 Patent.” Petition at 37, citing Argenta 2008 at ¶¶17-18. | Argenta ‘643 discloses: “FIG. 10 is a schematic cross-sectional view of a reduced or negative pressure appliance comprising an open-cell polymer foam screen, a flexible hose for connecting the foam screen with the vacuum system...” “an end segment 12a of the tubing 12 is embedded within the foam screen 10 for providing suction or reduced pressure.” Col.7:2-3. |
| 3[d] a vapor sealant sheet formed from a hydrocolloid material,                                                                                                                                   | “One of skill in the art would understand that                                                                                                                             | Argenta ‘643 discloses: “The wound cover for the reduced pressure appliance may be in the                                                                                                                                                                                                                                                                                 |

| Claimed Element in Claim 3:                                                                                                             | Petitioner's Reference (Argenta 2008):                                                                                                                               | Previously Considered Argenta References:                                                                                                                                                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>the vapor sealant that overlies the fluid-absorbing/transferring layer,</p>                                                          | <p>Argenta [2008]'s disclosure of a 'self-adhesive' cover that binds to the screen and holds it in place to include adhesive in a central zone." Petition at 42.</p> | <p>form of a gas impermeable covering sheet of flexible polymer material, such polyethylene, having an adhesive backing that provides the seal for securing the sheet over the wound site..." Argenta '643 at col.3:52-56; FIG. 1.</p>  <p style="text-align: center;"><b>FIG. 1</b></p> |
| <p>3[e] Said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor</p> | <p>See 3[d], above. <b>(Bold portion is not taught or suggested by Argenta 2008).</b></p>                                                                            | <p>See 3[d], above. <b>(Bold portion is not taught or suggested by Argenta 2008).</b></p>                                                                                                                                                                                                                                                                                   |

| Claimed Element in Claim 3:                                                                                                                                                                                                                                                                   | Petitioner's Reference (Argenta 2008): | Previously Considered Argenta References: |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|-------------------------------------------|
| sealant sheet, the<br>adhesive for adhering<br>the vapor sealant<br>sheet to the fluid-<br>absorbing/transferring<br>layer, <i>said adhesive that mechanically maintains the placement and orientation of the fluid-absorbing transferring layer relative to the vapor sealant sheet;</i> and |                                        |                                           |
| 3[f] a tube-exit-sealant component for mechanically maintaining the                                                                                                                                                                                                                           | <i>See 3[e], above.</i>                | <i>See 3[e], above.</i>                   |

| <b>Claimed Element in Claim 3:</b>                                                    | <b>Petitioner's Reference (Argenta 2008):</b> | <b>Previously Considered Argenta References:</b> |
|---------------------------------------------------------------------------------------|-----------------------------------------------|--------------------------------------------------|
| vacuum-drainage tube's placement relative to the fluid-absorbing/transfer-ring layer. |                                               |                                                  |

57. In conclusion, it is my opinion that all of the cited portions of Argenta 2008 are wholly cumulative, as the same prior art and arguments have already been considered, weighed, and expressly rejected by the USPTO and the PTAB during earlier proceedings. Petitioner's reliance on Argenta 2008 does not advance the record in any meaningful way; instead, it merely resubmits arguments that have already been examined and dismissed. Allowing such duplicative arguments would undermine the integrity of the IPR process, which is designed to prevent serial harassment of a patent owner through repeated reliance on art and theories that the Office has already addressed.

**B. Hu**

58. The Petition also relies on Hu, U.S. Pat. Pub. No. 2010/0042021 ("Hu") as a secondary reference.

59. In my opinion, Hu is cumulative of Biggie (U.S. Patent No.

7,520,872, EX1008), as set forth in Table 2 below. Because Biggie was considered during the prosecution of the '404 Patent and called out by the Examiner as relevant to the claims of the '404 Patent, it is my opinion that Hu is cumulative.

Table 2 – Secondary Reference Hu is Cumulative in View of Biggie

| <b>Claimed Element:</b>                                                                                                     | <b>Petition’s citation of Hu :</b>                                                              | <b>The citation of Hu is cumulative of Biggie:</b>                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid absorbing layer; | “Hu states that the sealant layer can be ‘made of a hydrocolloid material[.]’”. Petition at 41. | <p>The Petition fails to appreciate that Biggie included an embodiment without a protective cover.</p> <p>Biggie, ¶ 54, states:</p> <p><b>“In Fig. 4</b>, a side cutaway view of the preferred embodiment of FIG. 3 is shown. In this figure, the pouch 1 is secured inside the wound cavity 11 by flexible gel 12. . . . A variety of commercially available gels can be used, such as <b>hydro-colloids</b>, silicones, or a gel, such as a hydrogel.”</p> |

60. It is my opinion that the Petition’s reliance on Hu is fundamentally misplaced. Hu is entirely cumulative of Biggie (U.S. Patent No. 7,520,872), which

was explicitly considered during the prosecution of the '404 patent. Biggie already discloses a draping layer formed of hydrocolloid material, including embodiments both with and without a protective cover (see Biggie ¶ 54). The Petition's assertion that the Examiner only considered an embodiment with a protective cover is factually incorrect and reflects a failure to appreciate the full scope of Biggie. Because Biggie was already before the Office and acknowledged as material to the claims of the '404 patent, the addition of Hu contributes nothing new and does not alter the prior art landscape. Petitioner's reliance on Hu is therefore redundant, cumulative, and contrary to the statutory purpose of inter partes review, which is not intended to permit repetitive challenges on art and arguments that the Office has already evaluated and rejected.

## **XII. THE CHALLENGED CLAIMS ARE NOT OBVIOUS OVER THE PRIOR ART AS THE ALLEGED PRIOR ART DOES NOT SHOW OR SUGGEST CLAIM ELEMENTS**

61. The '404 patent provides a solution that enables easier application of NPT wound dressings than conventional NPT regimens.

62. Conventional NPT systems offer customized wound packing.

63. The '404 Patent, on the other hand, introduces a pre-packaged solution that is far easier to apply to a patient than the conventional methods.

64. Further, the '404 patent reduces the complexity of application of the wound dressing.

65. Each independent claim includes: “*said adhesive that mechanically maintains the placement and orientation of the fluid-absorbing layer relative to the vapor sealant sheet. . .*”

66. The Petition apparently relies on the same prior art to allegedly teach this element for all of the independent claims, namely: “One of skill in the art would understand that Argenta’s disclosure of a “self-adhesive” cover that binds to the screen and holds it in place to include adhesive in a central zone.” Petition, page 42.

67. In my opinion, the Petition is incorrect. Argenta does not disclose, nor even suggest, the claimed element of the independent claims. Argenta merely describes a “self-adhesive” cover that holds a dressing on the patient. This is fundamentally different from the claimed vapor sealant sheet that includes an adhesive specifically configured to mechanically maintain both the *placement* and the *orientation* of the fluid-absorbing layer relative to the vapor sealant sheet itself, prior to deployment on the patient. The adhesive function in the ’404 patent is directed inward—ensuring structural stability and controlled orientation of the internal wound dressing components— during the application of the wound dressing whereas Argenta’s disclosure is related to a post-deployment phase. To equate these two distinct functions is a mischaracterization of Argenta’s teachings and reflects an overextension of its disclosure. Thus, Argenta cannot reasonably be

said to anticipate or render obvious the claimed adhesive feature of the '404 patent.

68. Therefore, in my opinion, applying the claims of the '404 patent to Argenta 2008 would require a fundamental change to Argenta 2008.

69. Paragraph 19 of Argenta 2008 states:

[0019] The screen 20 is desirably cut and shaped to fit into and fill the wound 40. As the wound 40 heals and becomes smaller in size, the size of the screen 20 may be decreased accordingly. The screen 20 may be held in place by contacting an adhesive coated under surface 12 of the cover 10 to assist in securing the screen 20 in a fixed position and to assist in the removal of the screen 20 when the cover 10 is removed. One particularly convenient configuration of cover 10 and screen 20 is the combination of a flexible self-adhesive polymer sheet or drape used in conjunction with an open-cell polymer foam.

70. From this paragraph alone, it is evident that Argenta 2008 describes a piecemeal, manual process of cutting, shaping, and positioning individual dressing components in situ during each application of NPT therapy. This approach inherently introduces variability, complexity, and risk, as it requires repeated manipulation of wound-site materials and is highly dependent on the practitioner's skill and consistency at each step. In contrast, the '404 patent discloses a wound dressing system designed and manufactured as a unitary device that can be applied directly to the wound bed with minimal handling or assembly. A product embodying the '404 Patent technology addresses the standard of care in a way that Argenta never contemplated: it ensures reliability, repeatability, and adherence to

clinical best practices by reducing opportunities for error, decreasing application time, and mitigating patient pain during dressing changes.

71. The fluid-absorbing layer of the '404 Patent, however, has been adhesively placed and oriented relative to the vapor sealant sheet – not in the wound and then covered by an adhesive surface. Once placed relative to the vapor sealant sheet, the recited fluid material absorbing/transferring layer of the '404 patent cannot reasonably be cut, further shaped, or used to then fill a wound.

72. In my opinion, to cut and shape the claimed fluid-absorbing/transferring layer following placement relative to the vapor sealant sheet, as suggested by Argenta 2008, would disturb both the size, shape and operation of the claimed wound dressing. At the minimum, such cutting and shaping would decrease ease of deployment of the claimed fluid-absorbing/transferring layer.

### **XIII. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS**

73. I have analyzed secondary considerations of non-obviousness for the '404 patent. For the reasons I set forth below, this objective evidence further supports my conclusion that the asserted claims of the '404 patent are not obvious in view of the prior art relied upon by the Petition.

74. I have analyzed secondary considerations of non-obviousness for the '404 patent. For the reasons I set forth below, this objective evidence further

supports my conclusion that the asserted claims of the '404 patent are not obvious in view of the prior art relied upon by the Petition.

75. I understand that the commercial success of products that embody a patented invention indicates that the invention was not obvious.

76. In my opinion, the defendant and others have made and marketed wound-healing products that embody the claimed invention in the '404 patent, generating hundreds of millions, if not billions, of dollars in cumulative sales revenue, as evidenced by the substantial global and U.S. negative pressure wound therapy (NPWT) market. See [https://www.grandviewresearch.com/industry-analysis/negative-pressure-wound-therapy-npwt-market#:~:text=The%20global%20negative%20pressure%20wound%20therapy%20market,negative%20pressure%20wound%20therapy%20\(npwt\)%20devices%20market](https://www.grandviewresearch.com/industry-analysis/negative-pressure-wound-therapy-npwt-market#:~:text=The%20global%20negative%20pressure%20wound%20therapy%20market,negative%20pressure%20wound%20therapy%20(npwt)%20devices%20market). See Exhibit D. The global NPWT market is estimated at USD 2,488.2 million in 2023 and is projected to grow to USD 3,872.8 million by 2030 at a compound annual growth rate (CAGR) of 6.5%. In the United States alone, the NPWT market was approximately USD 768.7 million in 2023, with forecasts driving it to about USD 1,143.1 million by 2030. Given that the total addressable market greatly exceeds these figures, a successful product embodying the '404 technology legitimately captures a significant share, supporting the reasonability of a “hundreds of millions to billions” revenue estimation.

77. These numbers strongly support that NPWT as a therapeutic category achieves multi-hundred-million scale sales annually. A competitively advantaged product—especially one with improved convenience and patient comfort as claimed in the '404 patent—could plausibly command a substantially higher market share over its lifetime.

78. In my opinion, the claimed invention is not merely incidental to the commercial success of the accused and related products, but rather *fundamental* to that success. The unique system-level design disclosed in the '404 patent addresses longstanding deficiencies in conventional negative pressure wound therapy, replacing piecemeal, error-prone techniques with a unitary wound dressing that is easier for clinicians to apply, more reliable in maintaining an effective seal, and markedly less painful and distressing for patients. These advantages, efficiency, safety, and patient comfort, are precisely the features that drive clinical adoption, physician preference, and ultimately marketplace success. Thus, there is a direct and undeniable nexus between the asserted claims and the significant revenues realized in the negative pressure wound therapy market. Without the practical improvements embodied in the '404 patent, the widespread acceptance and sustained commercial growth of these products would not have been possible.

79. The commercial success of products embodying WHT's patented invention further supports my opinion that the claims of the '404 patent are not

obvious.

### **RESERVATION OF RIGHT TO SUPPLEMENT**

I reserve the right to supplement my opinion based on additional evidence that may be produced after the date of this report, and in response to other opinions offered in this Reexamination, as appropriate.

DATED: October 3, 2025



Salvatore Domenic Morgera

## **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the **DECLARATION OF SALVATORE MORGERA, Ph. D, and Exhibits A-D** was served on the 3<sup>rd</sup> day of October 2025, by email to counsel for Petitioner:

Daniel L. Moffett  
Akin Gump Strauss Hauer & Feld, LLP  
112 East Pecan, Suite 1010  
San Antonio, TX 78205  
T:210-281-7000  
[dmoffett@akingump.com](mailto:dmoffett@akingump.com)

Respectfully submitted,

/Joel Weiss/

Joel Weiss, Esq. (lead counsel)  
Reg. No. 44,398  
Weiss & Arons LLP  
Attorney for Patent Owner  
63 South Main Street  
Spring Valley, New York  
T: 845-362-6100  
[jweiss@weissarons.com](mailto:jweiss@weissarons.com)

Date: October 3, 2025

# EXHIBIT A

# Salvatore Domenic Morgera

FIEEE, FAAAS, FIET, FAAIA, FAIIA, Raytheon Fellow

Tampa, FL 33647

+1 (561)706-0489 | sdmorgera@usf.edu

## PROFESSIONAL SUMMARY

Dr. Morgera is a retired Distinguished Professor of Engineering and Medicine awarded five Fellowships for his pioneering contributions to Engineering, Bioengineering, and Medicine. He has created higher education degree programs that serve as national models, fostering innovation and excellence in these fields. Dr. Morgera has significantly advanced research at the intersection of engineering and medicine, leading explorations into new frontiers that have garnered international attention. Throughout his illustrious career, he has collaborated extensively with legal professionals on patent litigation and medical device cases. His expertise spans medical device engineering, materials science, electronics, software, and other related disciplines. Known for his ability to distill complex technical concepts, he has been instrumental in aiding judges and juries to comprehend intricate technical details, a skill reflected in the undergraduate and graduate teaching awards he has received. Dr. Morgera's legacy is marked by his dedication to education, research, and the application of engineering principles to solve medical challenges, earning him a distinguished reputation in academic, industrial, government, and legal circles.

## SKILLS

### Engineering/Bioengineering/ Medicine (Brain Networks)

- Academic – 46 years' experience
- Industry – 32 years' experience
- Government -21 years' experience, USA & Canada
- B&L Honorary Science Award
- Tau Beta Pi Eminent Engineer

### Expert, Patent Litigation

- Technical Expertise
- Patent Law
- Analytical Skills
- Objectivity
- Courtroom Experience
- Cross-Examination
- Collaboration

### Expert Witness, Engineering & Medicine

- Medical Device cGMP
- Medical Device Regulatory Compliance
- Medical Device Integrity/Reliability
- Clinical Leader/MC/CC
- Legal Understanding
- Experience Testifying

### JANUARY 2014-CURRENT

Data Scientist SME

Data Analytics & Quality/Data Engineering/Experimental Design/AI,ML,DL Models

Industry Consultant

### JANUARY 2001-CURRENT

Expert Witness, Certified Engineering (all disciplines) and Medicine

Medical Devices, Patent Litigation

### AUGUST 2009-AUGUST 2021

Chair & Distinguished Professor, Electrical Engineering, Medicine & Bioengineering

University of South Florida, Tampa, Florida, United States

Director, Global Center for Neurological Networks | Tampa | NYC | San Diego

JUNE 1998-AUGUST 2009

Chair & Emeritus Professor Engineering & Bioengineering

Director, Bioengineering Program

Florida Atlantic University | Boca Raton, Florida, United States

JANUARY 1985-JUNE 1998

Distinguished Professor Engineering & Biomedical Engineering

Director, Information Networks and Systems Laboratory

Major Project Leader, National Centres of Excellence - CITR

McGill University | Montreal, Quebec, Canada

JANUARY 1992-JANUARY 1998

Senior Vice President

Special Assistant to the President

Industry Canada - CRC | Ottawa, Ontario

JANUARY 1991-JANUARY 1998

Senior Subject Matter Expert

Information Technology Institute

National Research Council Canada | Ottawa, Ontario

JANUARY 1988-JANUARY 1990

President

Le Fonds Nature et Technologies | Quebec, Quebec

JANUARY 1978-JANUARY 1985

Director & Emeritus Professor Electrical Engineering

Concordia University | Montreal, Quebec

JANUARY 1970-JANUARY 1978

Command, Control & Communications (C3) Class C Consultant

US National Security Industrial Association | Washington, DC

JANUARY 1970-JANUARY 1978

Senior Scientist & Technical Director

Raytheon Company | Portsmouth, RI

## EDUCATION

---

Ph.D. in Electrical Engineering

Brown University

Raytheon Advanced Studies Program Award

Sc M. in Electrical Engineering

Brown University

Sc B. in Physics with Honors

Brown University

## PUBLICATIONS

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166 Articles in fully refereed journals, including several highly awarded papers,

154 Articles in fully refereed conference proceedings, including several highly awarded papers, Many papers delivered as Invited, Keynote, and Plenary.

3 Books, *Digital Signal Processing – Applications to Communications and Algebraic Coding Theories* (xx + 233 pp., Academic Press, 1989), *Wireless Integrated Services Networks* (under contract, Artech House), *Bioengineering – Intersection of Engineering and Medicine* (under contract, McGraw Hill), *Communications Systems* (under contract, Oxford University Press).

8 Book Chapters, including several interdisciplinary, highly cited Invited Chapters, *The Intertwining of Abstract Algebra and Structured Estimation Theory* in Advances in Electronics and Electron Physics, Academic Press, and the recently Invited Chapter, *The Primary Role of the Electric Near-Field in Brain Function*, Electric Field (M. Sheikholeslami, Ed.), Intech Publishing, ISBN 978-953-51-5851-6.

72 Industry/Government Research Reports & White Papers, including recent White Papers about Regulatory Compliance for Medical Devices.

A significant number of publications Unclassified Sensitive and Classified.

## WEBSITES, PORTFOLIOS & PROFILES

---

- [https://en.wikipedia.org/wiki/Salvatore\\_D.\\_Morgera](https://en.wikipedia.org/wiki/Salvatore_D._Morgera)
- [https://scholar.google.com/citations?user=7z-nA\\_kAAAAJ](https://scholar.google.com/citations?user=7z-nA_kAAAAJ)
- <https://www.usf.edu/engineering/documents/12182015-sal-morgera.pdf>
- <https://www.globalneuronetworks.com/>

## CAREER ACHIEVEMENTS

---

- Cybersecurity: Major impact on Defense Intelligence Security Agency (DISA), US Special Operations Command (USSOCOM), and defense industry programs. Responsible for intelligent vision system deployed at US airports and MANETS/intelligent robots used on critical missions.
- Bioengineering: Developed Graduate Certificate and Graduate Degree programs; the first of their kind in the nation with over 10M\$ of direct and in-kind institutional and industrial support.
- Telecommunications: As Senior Executive Industry Canada and Canadian Institute for Telecommunications Research (CITR), developed research areas that had an initial impact of more than 2B\$ on worldwide cellular system and network development.
- Aerospace: Responsible for the algorithms and sensors found in a variety of aircraft for a category III C intelligent landing system approach, a precision approach and landing with no decision height and no runway visual range limitation. Cruise missile research & development.

- Underwater Systems: Responsible for the design of several tactical and strategic submarine communications/autonomous systems used by the US Navy and for oceanographic survey vessel acoustic transceiver systems currently deployed in Canadian waters by the Hydrographic Service. U.S. Patent 4207620 A.
- Neurological Networks: Director, Global Center for Neurological Networks, a growing force in the understanding of the networks and language of the brain, with application to noninvasive, non-drug therapeutics for a wide variety of neurological dysfunctions and mental disorders. U.S. Patent 11129545.

## PROFESSIONAL ACTIVITIES AWARDS

---

Named to Board, Academia Medicine – 2023

Named to Board, Industry Alliance for Artificial Intelligence – 2023

Bell Laboratories Prize Finalist, 2015, for discovery of Neurological Network Near-Field Phenomena (a competition of 255 entrants from 30 countries)

NASA Advisory Board – NASA Centers for the Commercial Development of Space

Executive Board - The International Association of Science & Technology for Development (IASTED),

Keynote Speaker, World Conference & Expo on Biomedical Engineering 2018, Miami,

Keynote Speaker, Nanotech France 2018 International Conference and Exhibition, Paris, 2015,

Fellow, Institute of Electrical & Electronics Engineers (IEEE) - 1990,

Fellow, American Institute for the Advancement of Science (AAAS) - 2011,

Fellow, Institute for Engineering and Technology (IET) - 2018,

Fellow, Asia-Pacific Artificial Intelligence Association (AAIA) - 2021,

Fellow, Artificial Intelligence Industry Alliance (AIIA) – 2023,

Italian Scientists and Scholars of North America Foundation - 2016,

National Academy of Inventors – 2014 – present.

The Smithsonian Institution - 2004 - present,

Reginald Aubrey Fessenden Award,

Scuola Superiore G. Reiss Romoli (Telecom Italia Group of Companies),

Order of Engineers Iron Ring (first time bestowed to a non-Canadian University graduate at McGill University,

Associate Editor, Circuits, Systems, & Signal Processing, Birkhauser, 2000 – present,

Associate Editor, International Journal of Research and Reviews in Wireless Sensor Networks (IJRRWSN), 2012 - present,

Guest Editor, Journal of Applied Mathematics, 2013 – present,

Editor & Special Issue Editor, Sensors, MDPI, 2018 – present-

## LANGUAGES

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### English

Native

### French

Conversational

### Italian

Conversational

### German

Conversational

# EXHIBIT B

## **Exhibit B – Materials Considered**

Expert for Wound Healing Technologies, Corp.

IPR2025-01042

U.S. Patent No. 10,639,404

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### **1. The '404 Patent and Prosecution History**

- U.S. Patent No. 10,639,404 and entire prosecution history (including Office Actions, Appeal briefs, PTAB decision, and issued patent).
  - File histories of related applications, including continuations, divisionals, and foreign counterparts.
- 

### **2. Petitioner's Materials (Solventum Corp.)**

- Petition for Inter Partes Review of U.S. Patent No. 10,639,404 (IPR2025-01042).
  - Exhibits filed with Petition, including:
    - Argenta 2008 (U.S. Pub. No. 2008/0208147).
    - Hu (U.S. Pub. No. 2010/0042021).
    - Lockwood.
    - Biggie (U.S. Patent No. 7,520,872).
    - Expert Declaration of [Petitioner's Expert].
    - Any other prior art or secondary references cited by Petitioner.
- 

### **3. Patent Owner's Materials (Wound Healing Technologies, Corp.)**

- Patent Owner's Preliminary Response (POPR), filed Sept. 29, 2025.
- Exhibits filed with POPR, including prior art comparisons and analysis (e.g., Argenta 2010, Argenta '643, Argenta '081, Argenta '651, Biggie prosecution record excerpts).

- Patent Owner's Request for Discretionary Denial under 35 U.S.C. §325(d) and related exhibits.
- 

#### 4. Patents and Applications Related to the '404 Patent

- U.S. Patent Application Nos.:
    - 12/789,446 (parent).
    - Related continuations and divisionals.
  - Related U.S. Patents:
    - Argenta '643 (U.S. Pat. No. 5,636,643).
    - Argenta '081 (U.S. Pat. No. 5,645,081).
    - Argenta '651 (U.S. Pat. No. 7,216,651).
  - Foreign counterparts and PCT applications as cited in prosecution.
- 

#### 5. Peer-Reviewed Literature and Texts on Wound Healing and NPWT

Representative examples (to be supplemented as appropriate):

- Argenta, L.C., et al. (1997). *Vacuum-assisted closure: a new method for wound control and treatment: clinical experience*. *Annals of Plastic Surgery*, 38(6), 563–576.
- Banwell, P.E., & Téot, L. (2007). *Topical negative pressure (TNP): The evolution of a novel wound therapy*. *Journal of Wound Care*, 16(3), 138–142.
- Orgill, D.P., & Bayer, L.R. (2011). *Negative pressure wound therapy: past, present and future*. *International Wound Journal*, 8(1), 1–12.
- Krug, E., et al. (2011). *Evidence-based recommendations for the use of negative pressure wound therapy in traumatic wounds and reconstructive surgery: Steps towards an international consensus*. *Injury*, 42(Suppl 1), S1–S12.
- Textbook: *Wound Healing and Ulcers of the Skin: Diagnosis and Therapy – The Practical Approach* (Springer, latest ed.).

- Textbook: *Mechanisms of Vascular Disease: A Reference Book for Vascular Specialists* (University of Adelaide Press, open access).
- 

## 6. Additional References Considered

- FDA guidance documents related to wound healing devices and NPWT.
- Clinical practice guidelines for wound management (e.g., Wound Healing Society guidelines).
- ISO/ASTM standards relevant to wound dressing materials.

# EXHIBIT C



US010639404B2

(12) **United States Patent**  
**Lichtenstein**

(10) **Patent No.:** **US 10,639,404 B2**

(45) **Date of Patent:** **May 5, 2020**

(54) **WOUND DRESSING**

USPC ..... 604/319  
See application file for complete search history.

(75) Inventor: **Isaac Lichtenstein**, Brooklyn, NY (US)

(73) Assignee: **WOUND HEALING TECHNOLOGIES, LLC**, Brooklyn, NY (US)

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,969,880 A \* 11/1990 Zamierowski ..... 604/305  
5,100,396 A 3/1992 Zamierowski  
5,261,893 A 11/1993 Zamierowski  
5,527,293 A 6/1996 Zamierowski  
5,636,643 A 6/1997 Argenta et al.  
5,645,081 A 7/1997 Argenta et al.  
(Continued)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/152,446**

(22) Filed: **Jun. 3, 2011**

(65) **Prior Publication Data**

US 2011/0301556 A1 Dec. 8, 2011

OTHER PUBLICATIONS

“Hydrocolloid dressing,” Wikipedia, Aug. 28, 2013, San Francisco, California.

**Related U.S. Application Data**

(63) Continuation of application No. 61/350,988, filed on Jun. 3, 2010.

*Primary Examiner* — Ariana Zimbouski

(74) *Attorney, Agent, or Firm* — Weiss & Arons LLP

(51) **Int. Cl.**

**A61F 13/00** (2006.01)

**A61M 1/00** (2006.01)

**A61F 13/06** (2006.01)

(52) **U.S. Cl.**

CPC ..... **A61M 1/0088** (2013.01); **A61F 13/00068** (2013.01); **A61F 13/069** (2013.01); **A61F 2013/0054** (2013.01); **A61F 2013/00157** (2013.01); **A61F 2013/00174** (2013.01); **A61F 2013/00412** (2013.01); **A61F 2013/00519** (2013.01); **A61F 2013/00536** (2013.01)

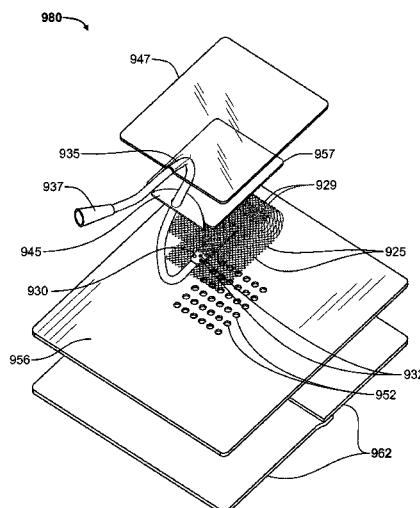
(58) **Field of Classification Search**

CPC ..... A61M 1/0088; A61M 1/0023; A61M 1/0058; A61M 1/0084; A61M 27/00; A61M 1/009; A61F 13/0068; A61F 13/023; A61F 2013/00536; A61F 2013/0054; A61F 2013/00748; A61F 13/00068; A61F 13/0023; A61F 2013/00174

**ABSTRACT**

Apparatus and methods for providing a wound dressing are provided. A wound dressing according to the invention may preferably include a wound-fluid negative pressure treatment (“NPT”) drain and a vacuum/drainage tube comprising a terminus associated with the NPT drain. The dressing may also include a fluid-absorbing/transferring material. The dressing may also include a contour-conforming draping layer for draping over a wound-bed. The draping layer may be in contact with at least a portion of the fluid-absorbing/transferring material. The dressing may also include a vapor sealant sheet that overlies at least a portion of the fluid-absorbing/transferring layer. The material may also include a tube-anchorage component that is in contact with at least a portion of the vapor sealant sheet. The tube-anchorage component may mechanically maintain placement of the NPT drain within the fluid-absorbing/transferring material.

**13 Claims, 16 Drawing Sheets**



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Page 2

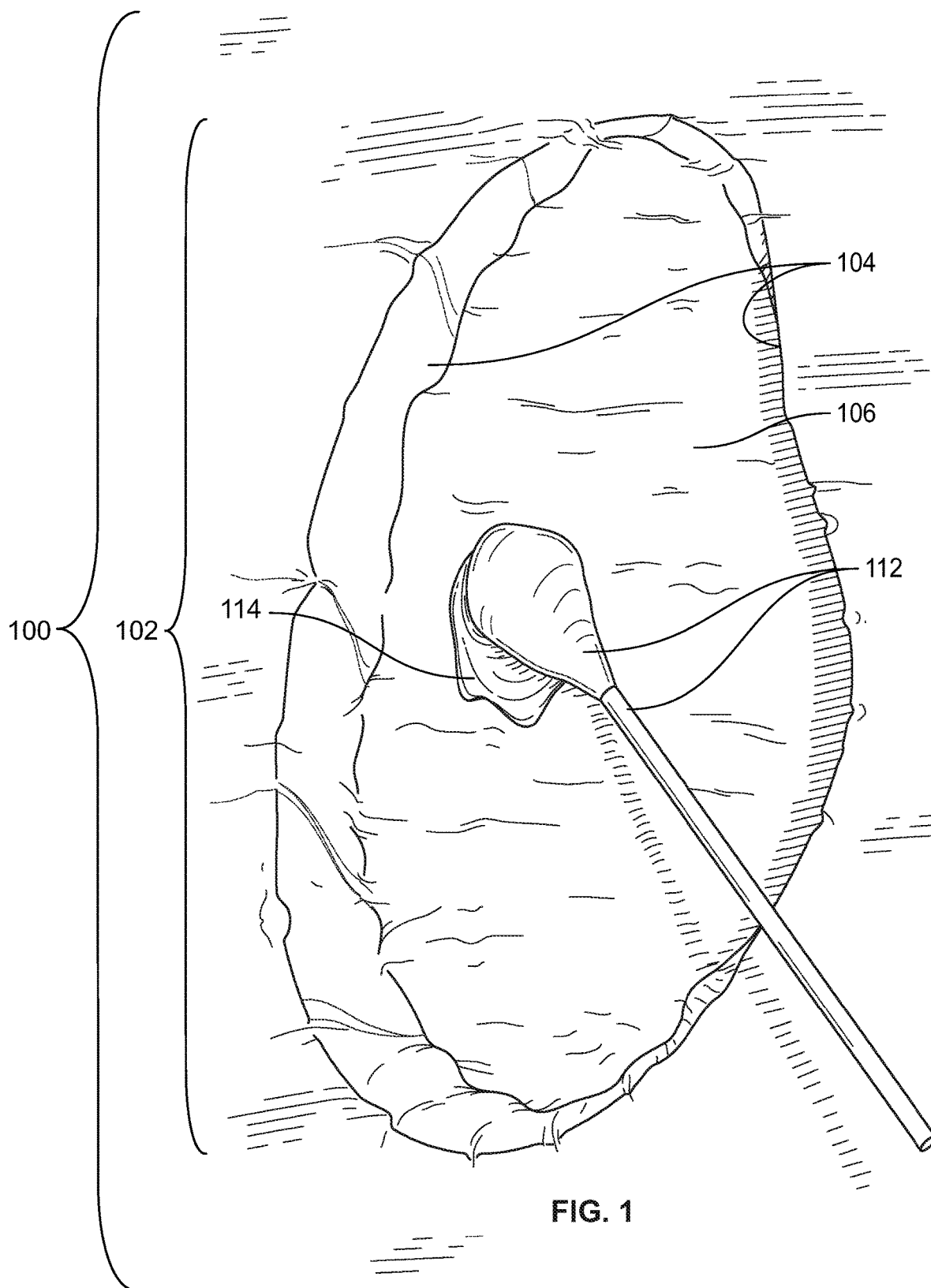
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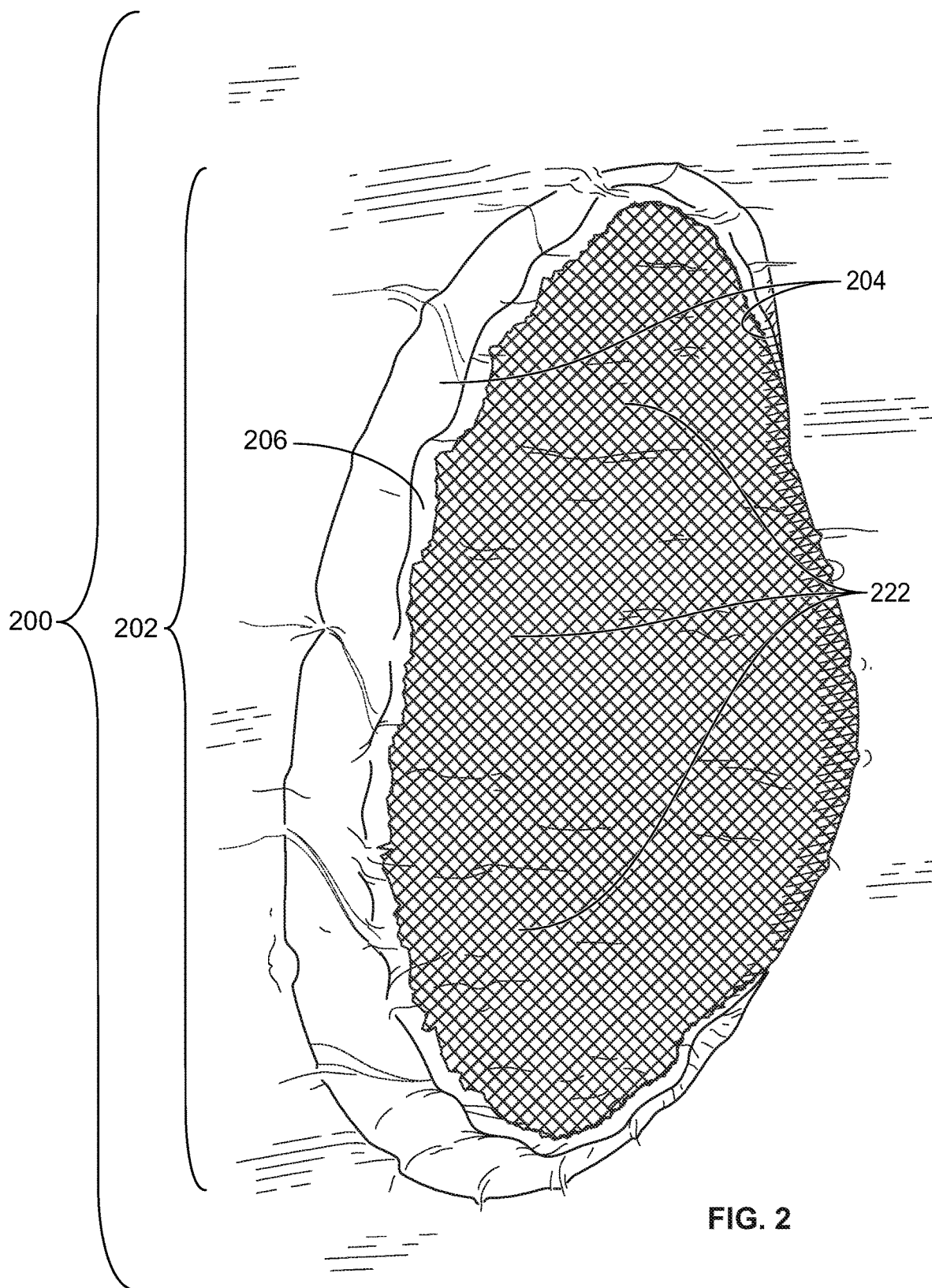
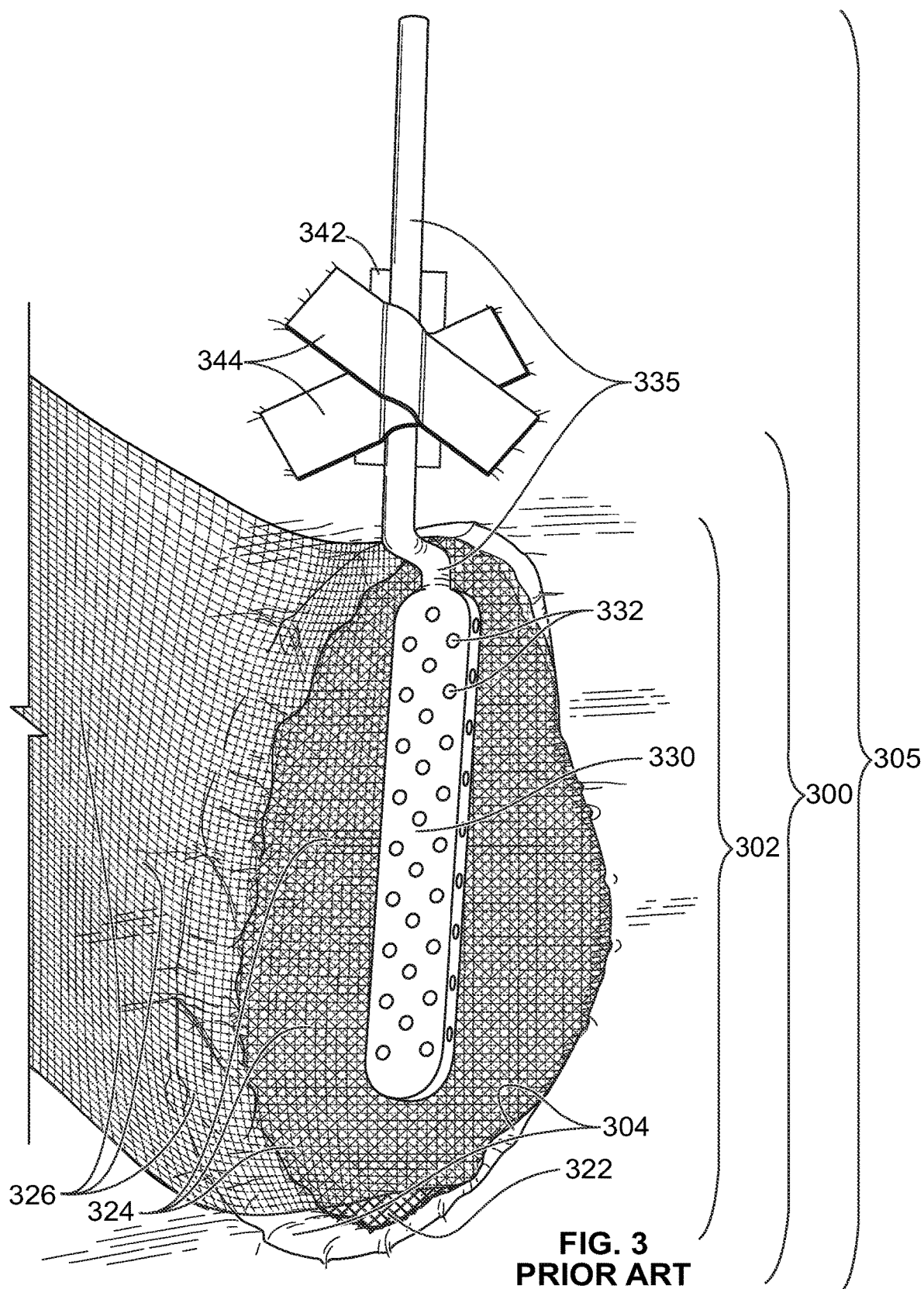


FIG. 2



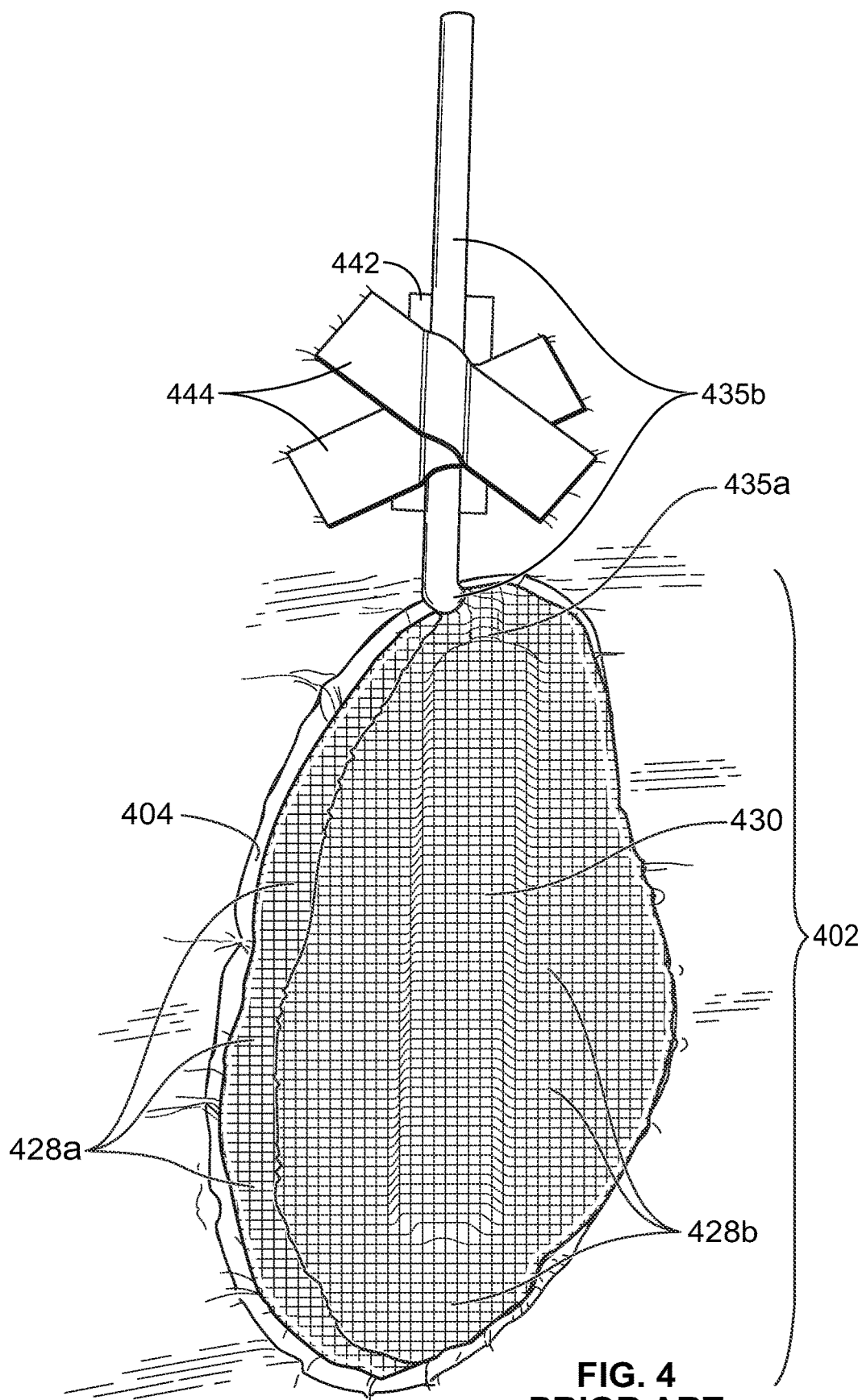
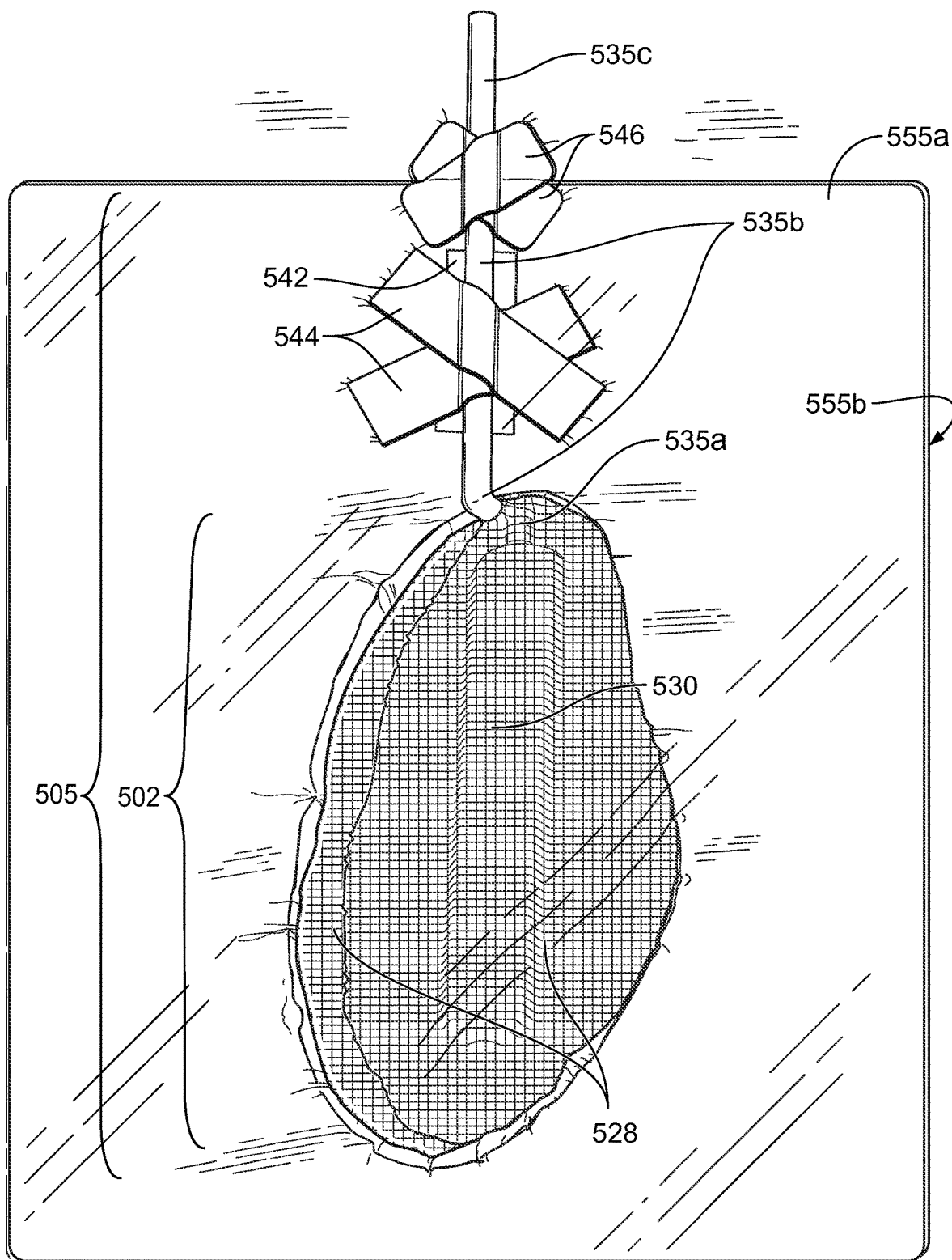
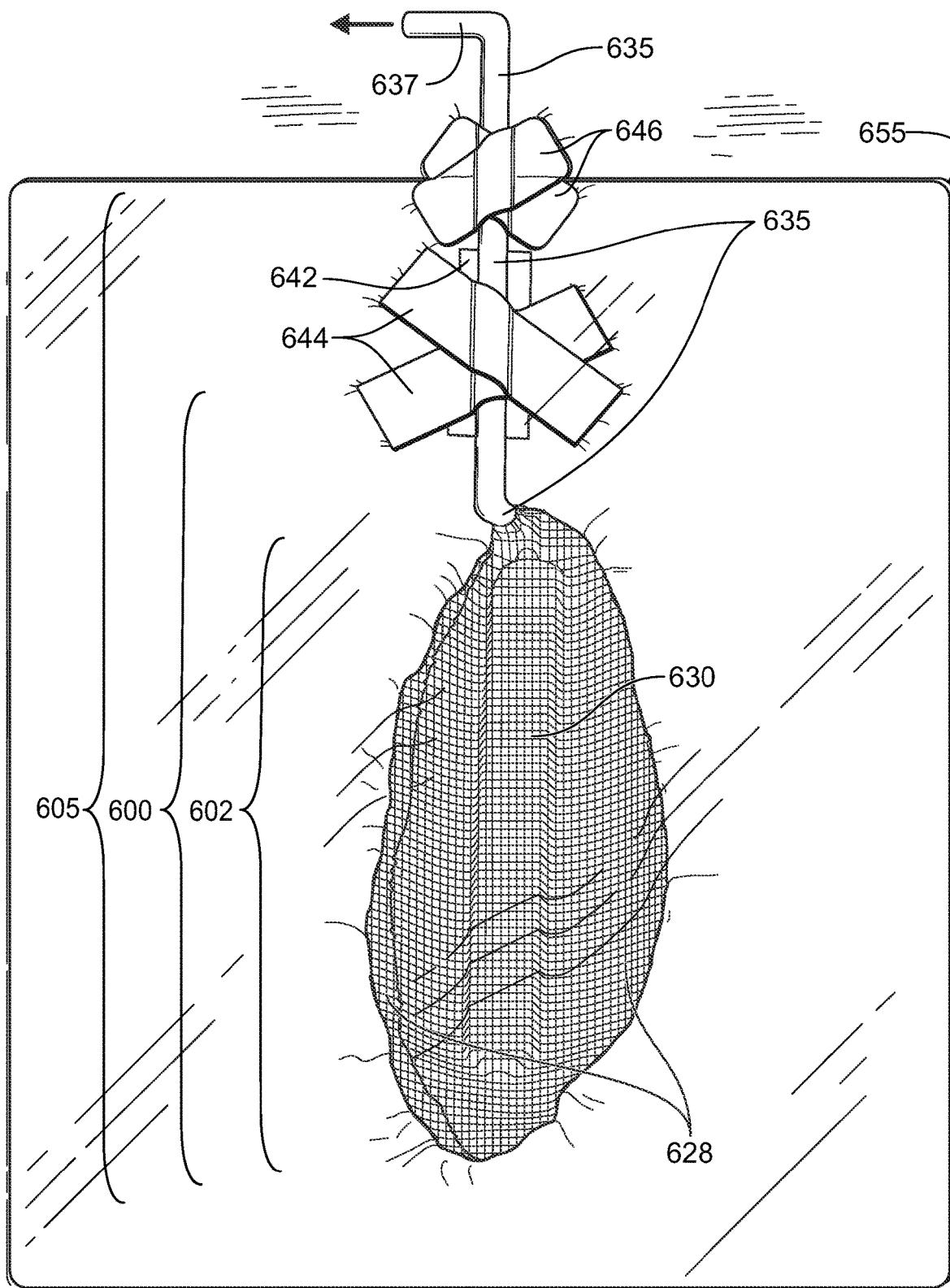


**FIG. 4**  
**PRIOR ART**





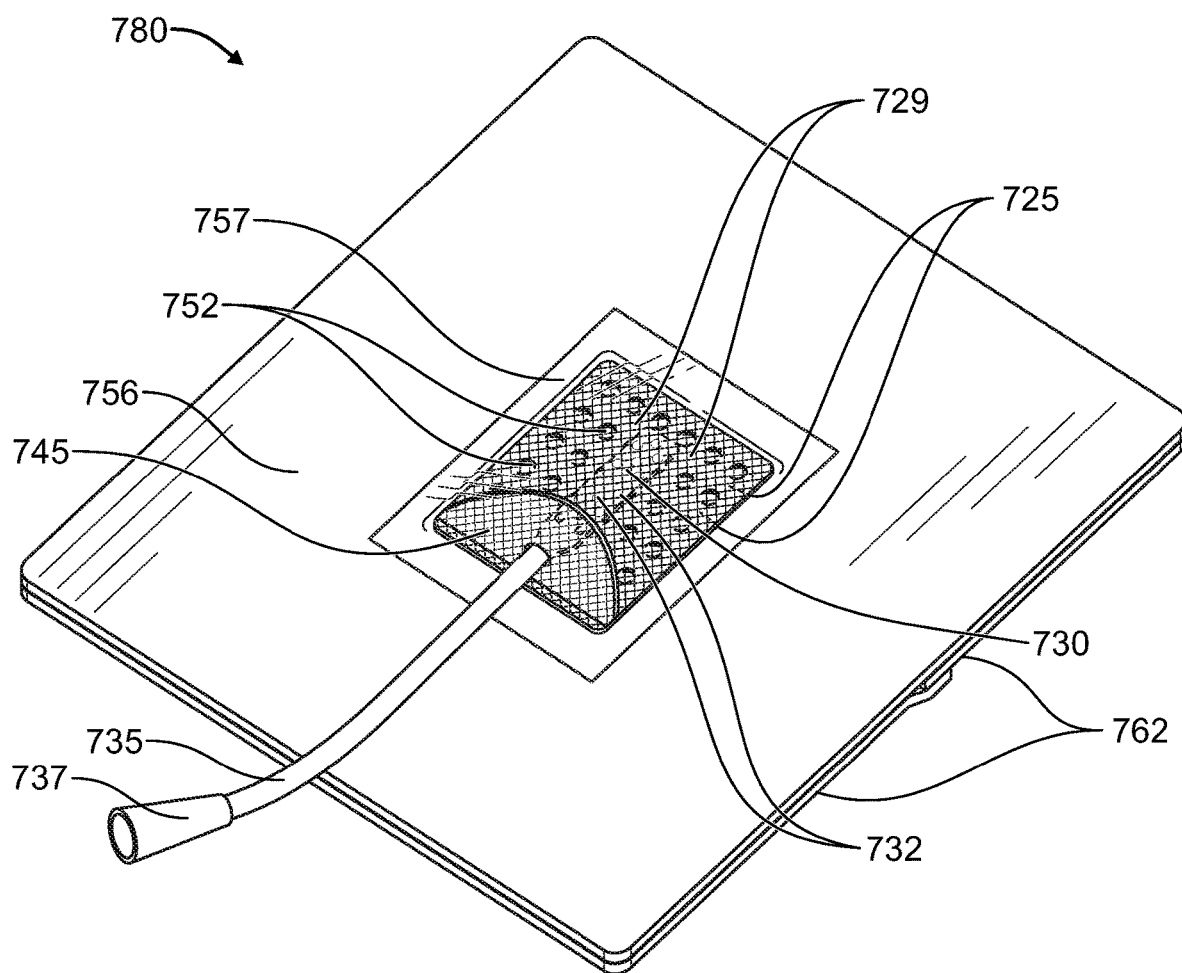


FIG. 7A

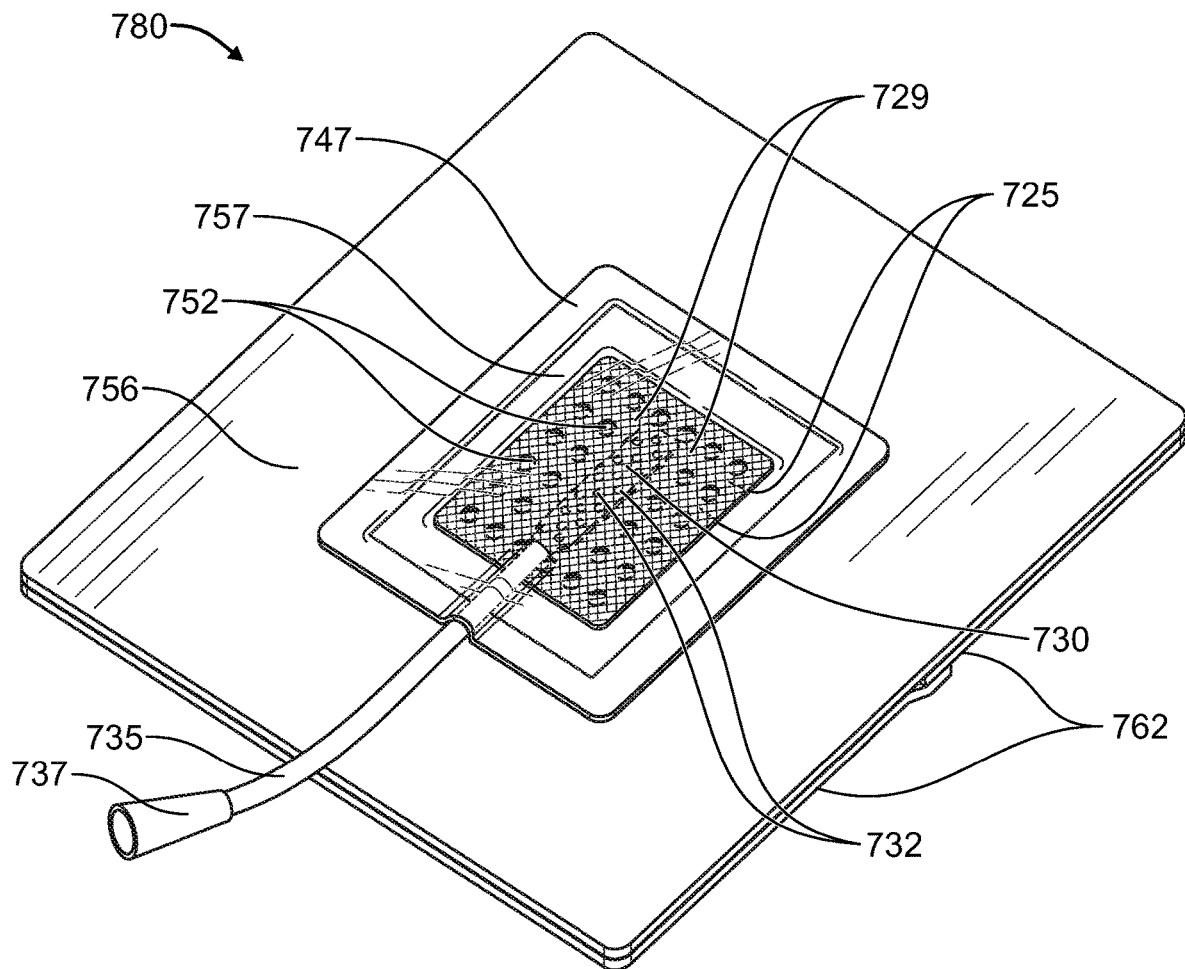


FIG. 7B

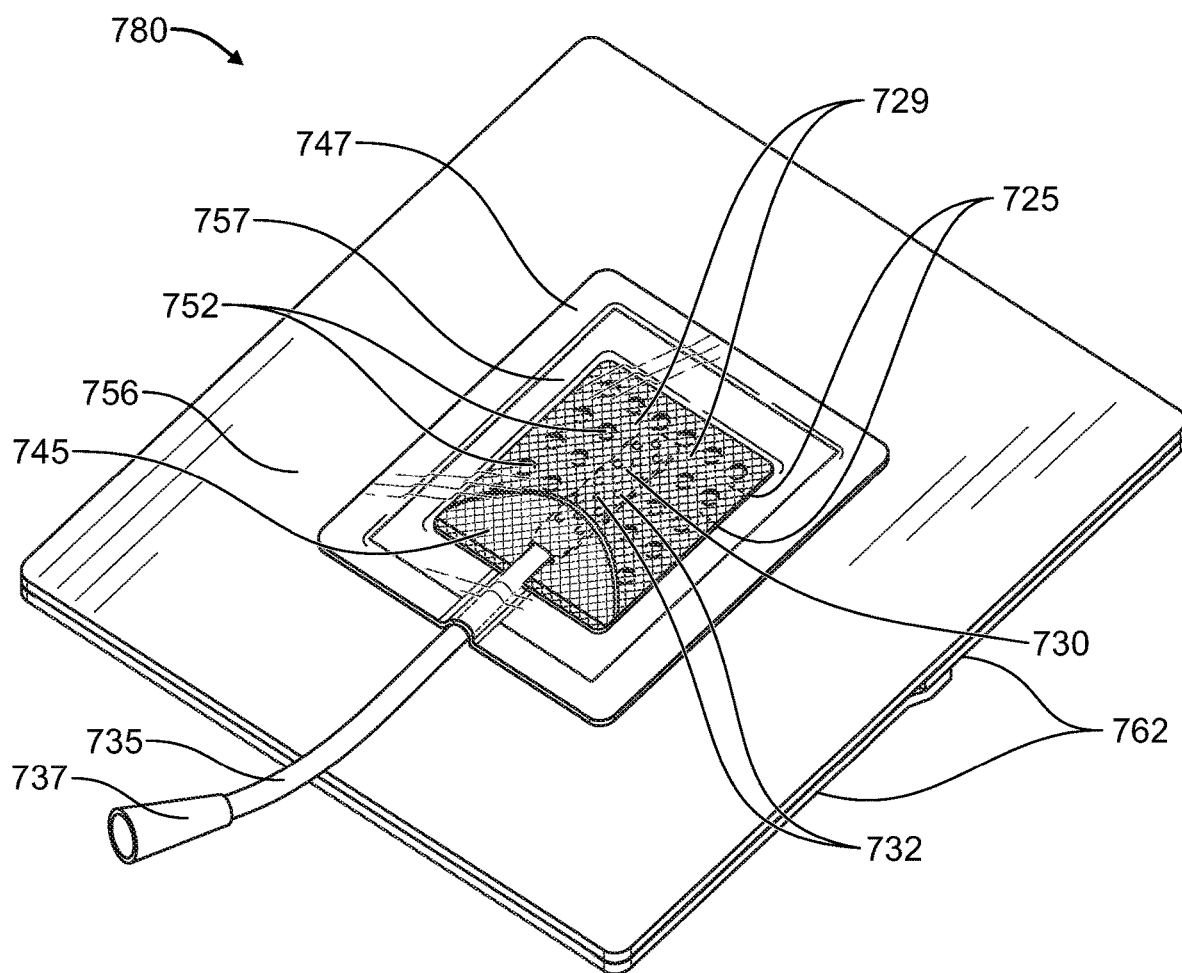


FIG. 7C

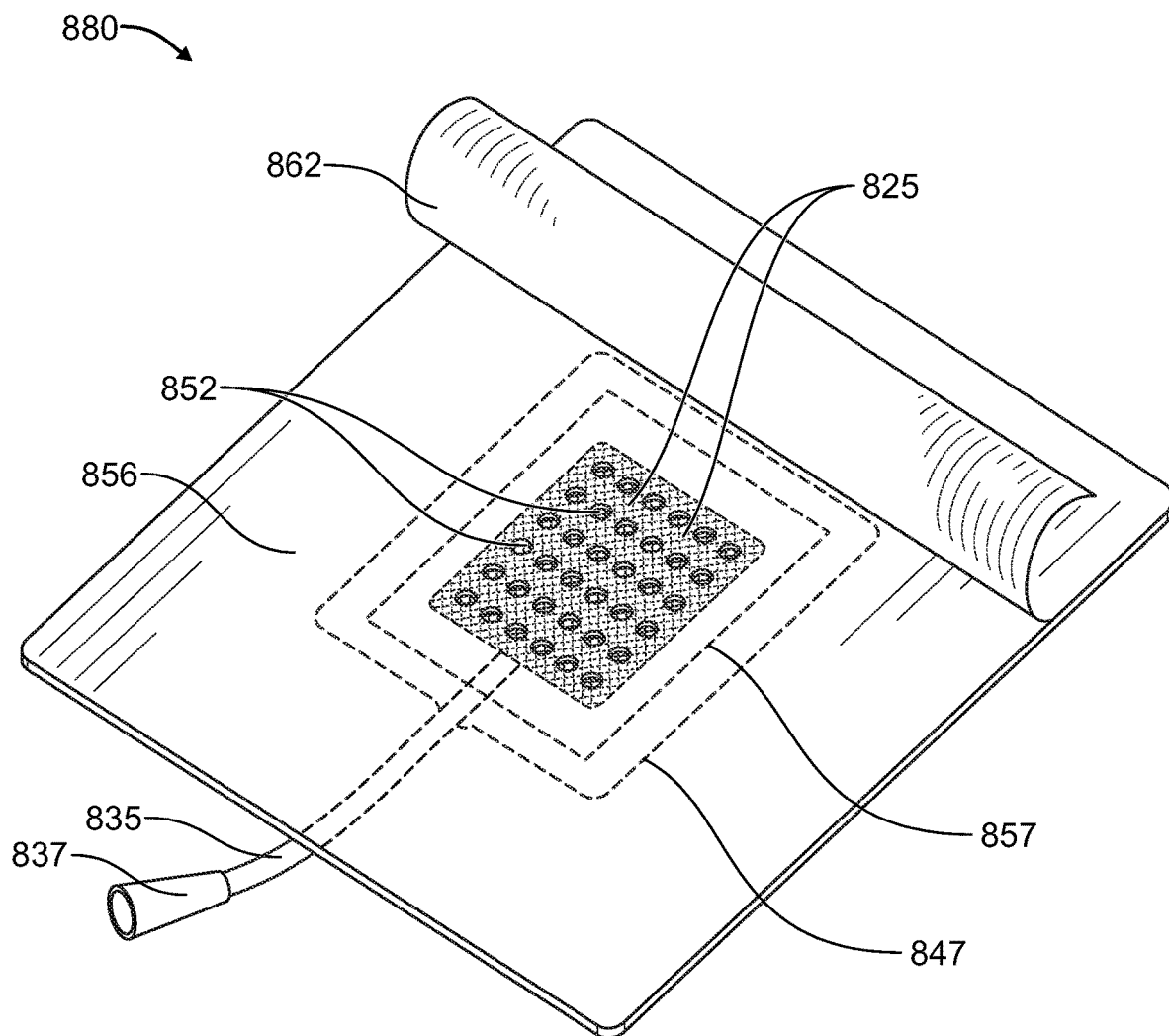


FIG. 8

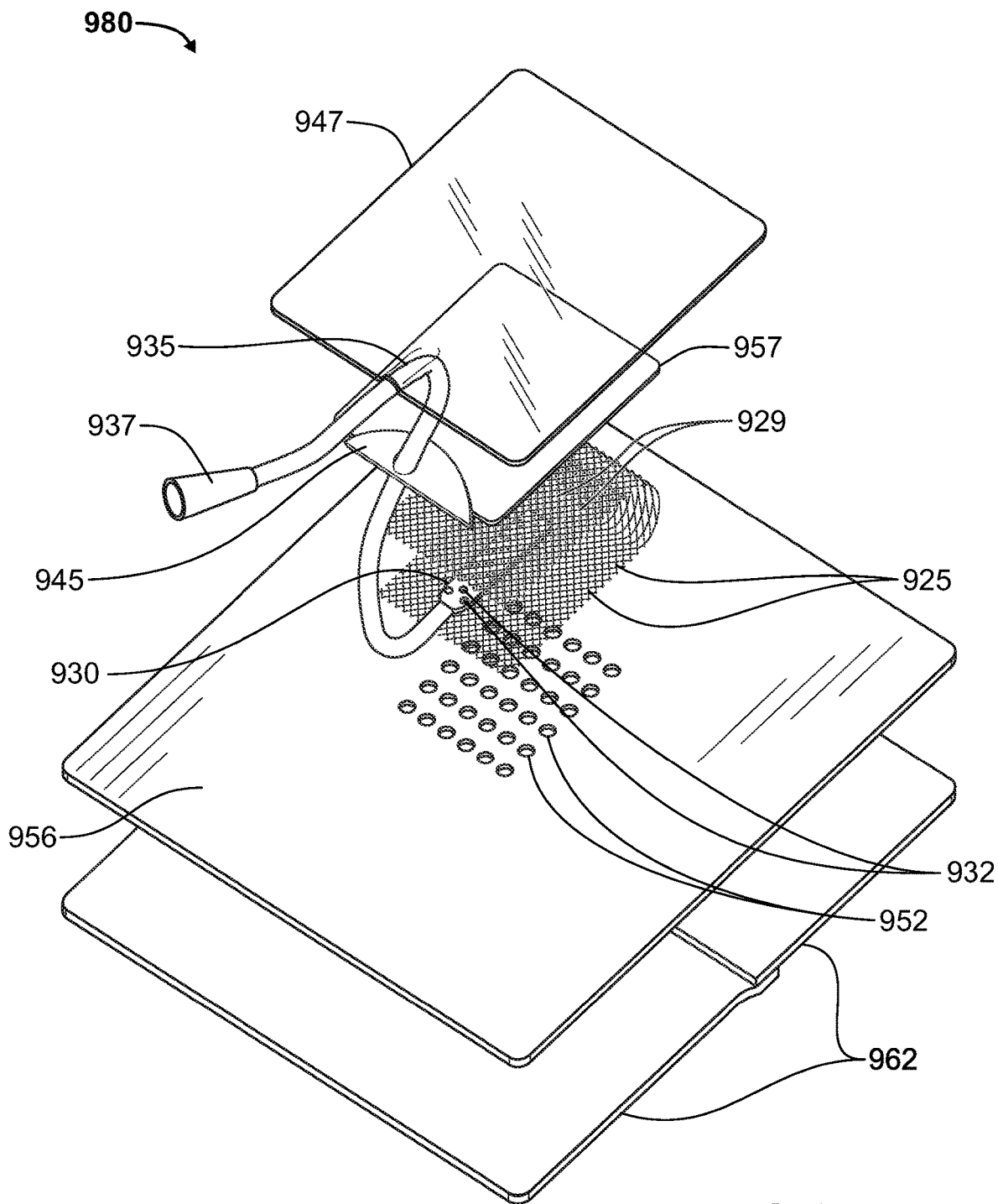


FIG. 9

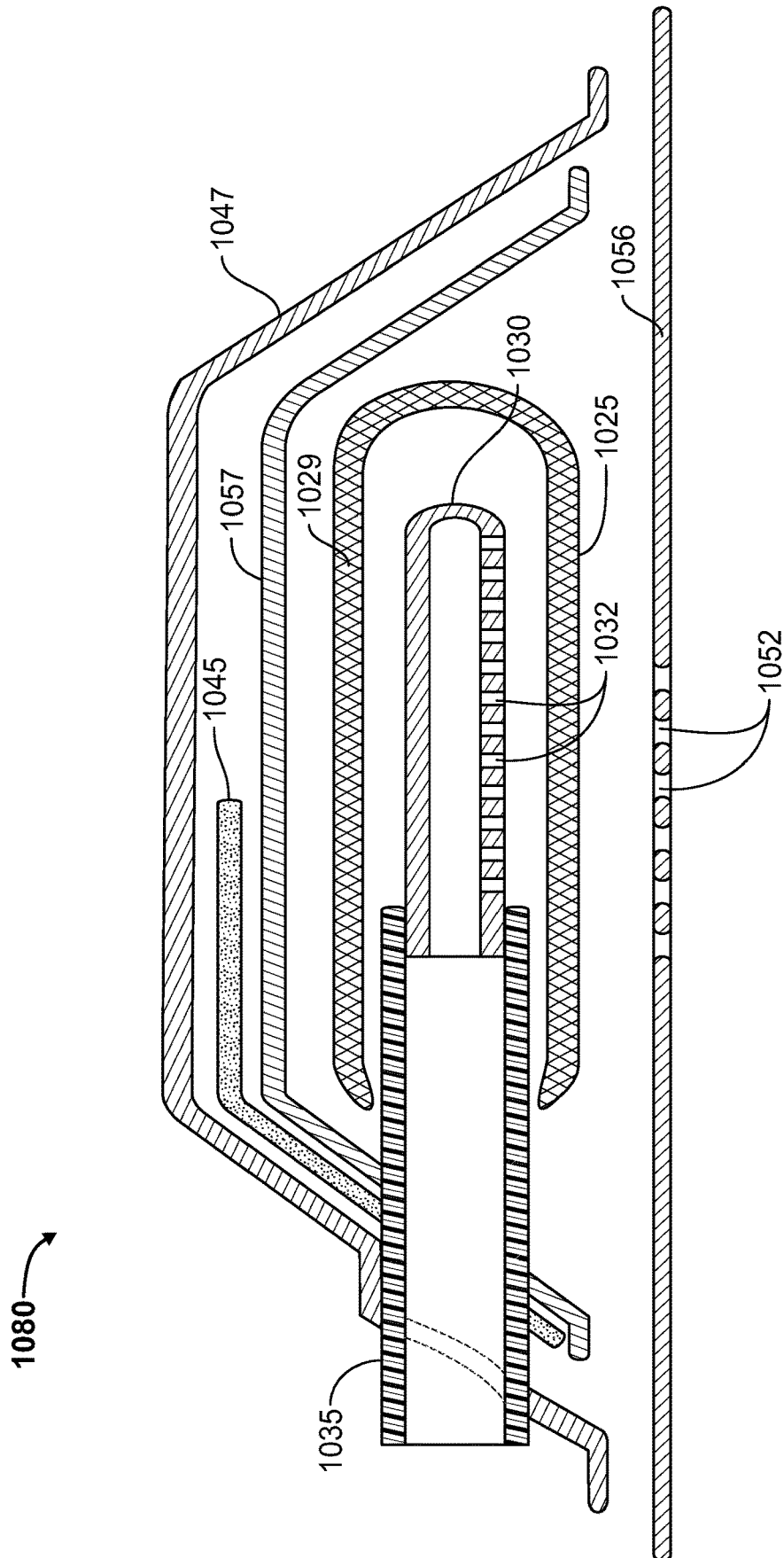


FIG. 10

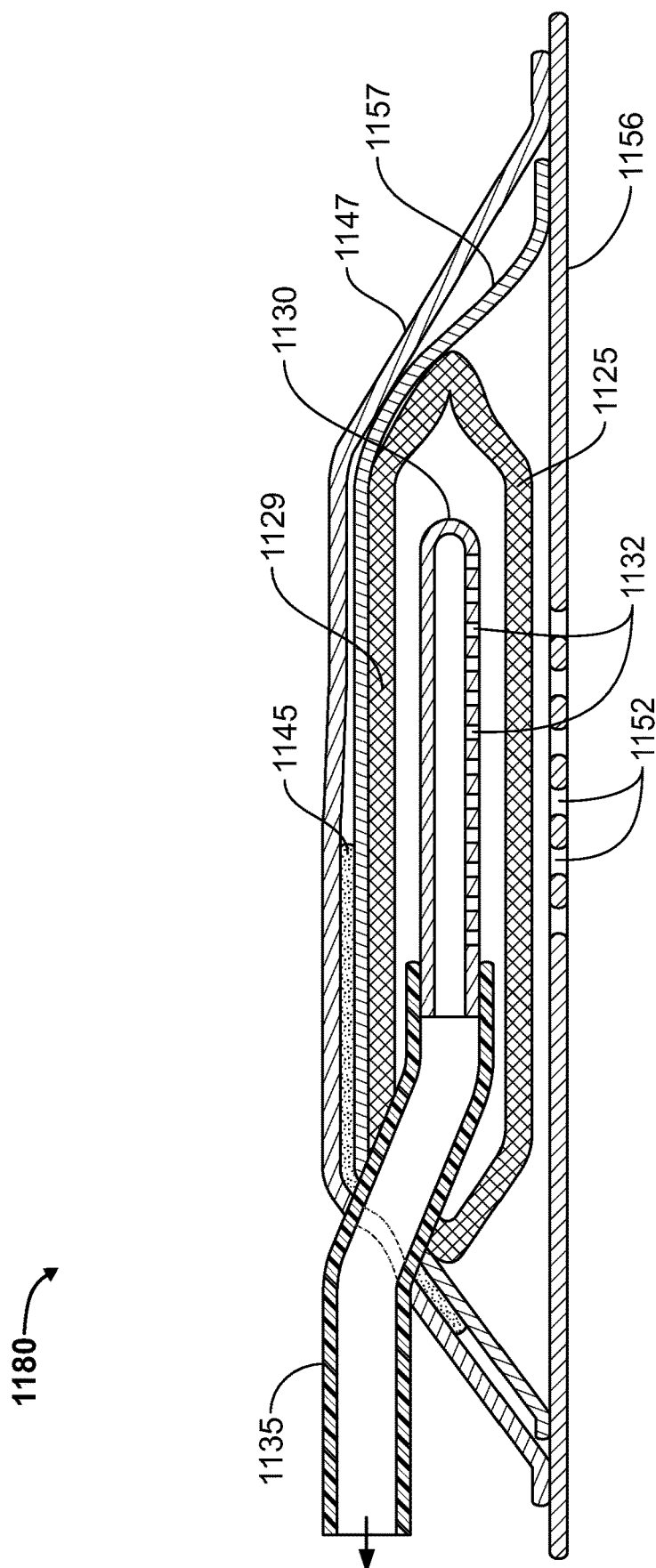


**FIG. 11**

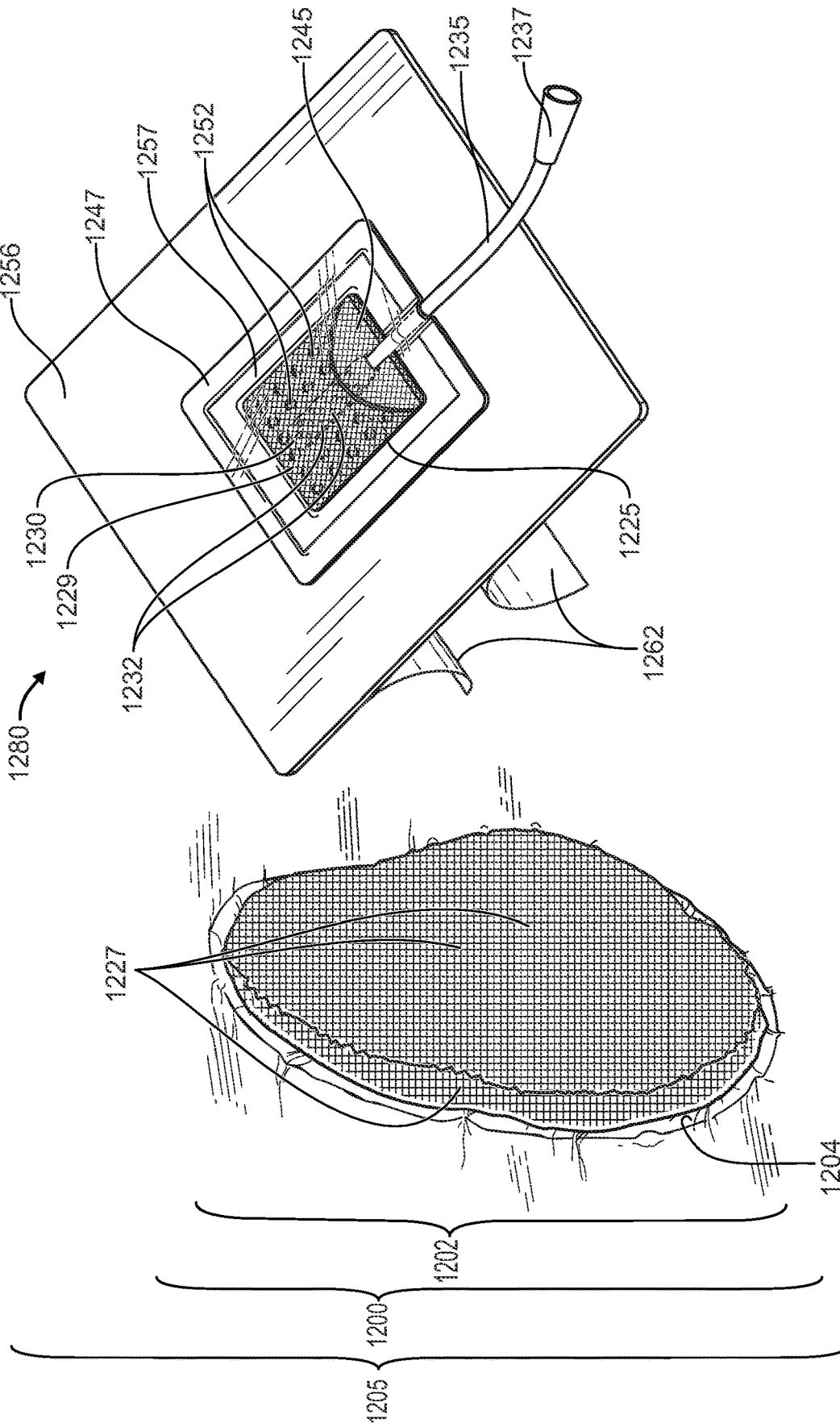


FIG. 12

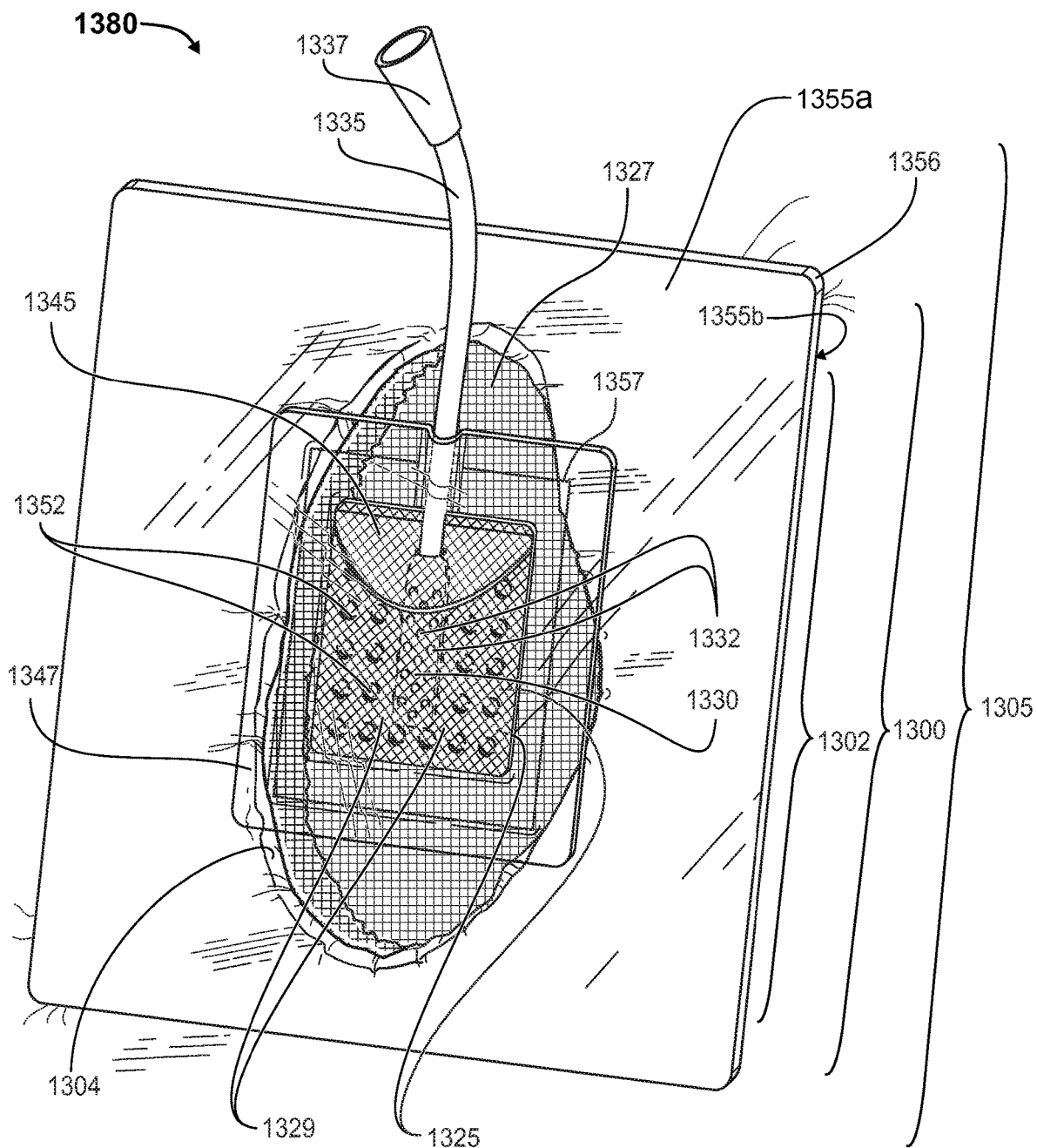


FIG. 13

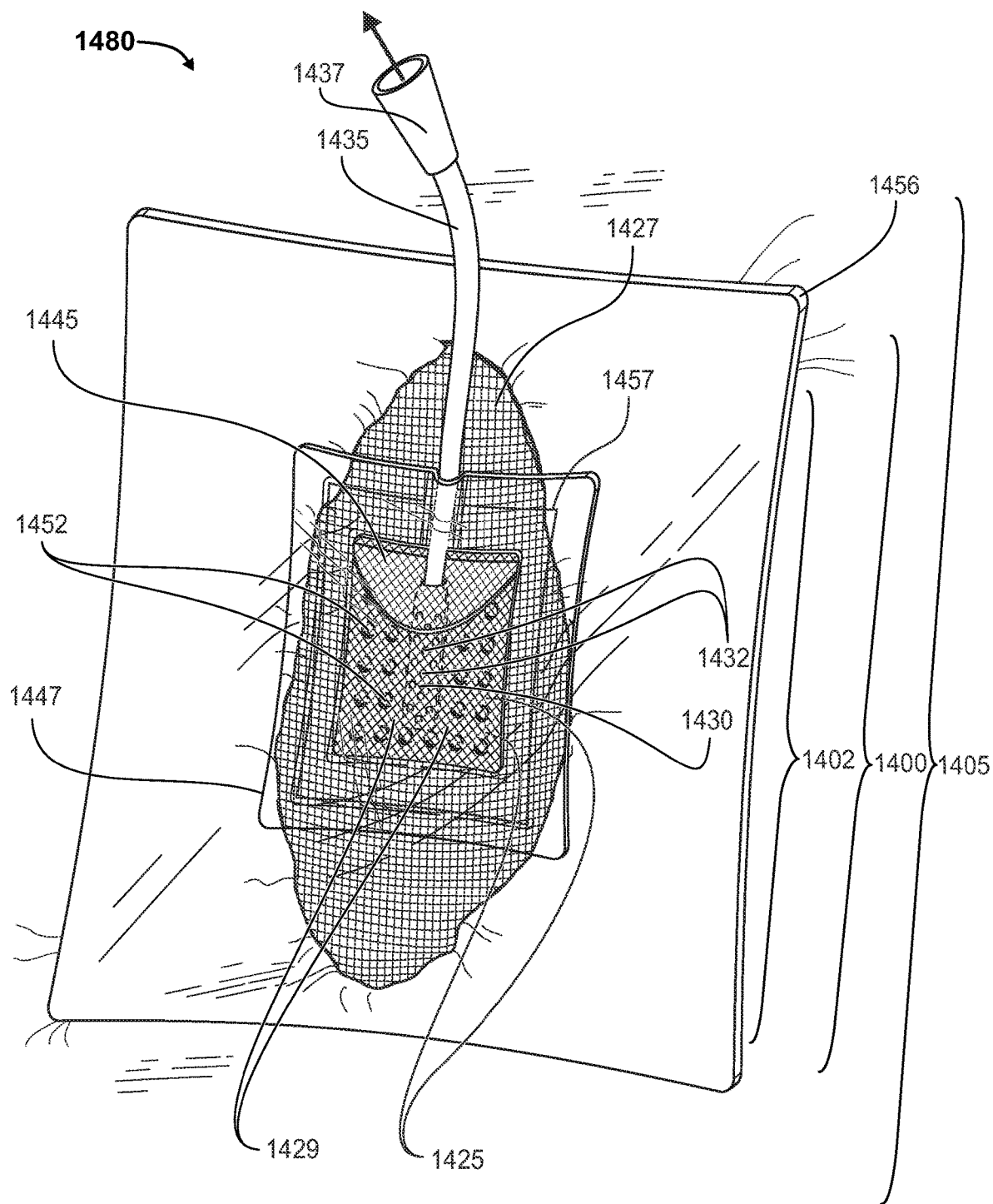


FIG. 14

# 1

## WOUND DRESSING

### CROSS-REFERENCE TO RELATED APPLICATION

This application is a non-provisional application of U.S. Provisional Application No. 61/350,988, filed on Jun. 3, 2010, entitled "Wound Dressing."

### FIELD OF TECHNOLOGY

Aspects of the disclosure relate to systems and methods for therapeutic dressing of medical wounds. In particular, the disclosure relates to apparatus and methods for therapeutic dressing of wounds for their treatment by negative pressure.

### BACKGROUND

Prior to applying a negative pressure dressing, a wound (or other opened-flesh medical condition) is typically cleansed and debrided. Therapeutic treatment of a wound often also involves packing the wound-bed with sterile material. Such material may include gauze, foam or other suitable fluid-absorbing/transferring materials. Application of negative pressure to the packed wound-bed promotes wound-healing.

The term "negative pressure" as used herein refers to lower than ambient air pressure. Widespread clinical experience sets the range of values of negative pressure utilized in wound treatment. Negative pressure treatment (hereinafter referred to as NPT) of wounds has been practiced for more than a decade.

The clinically demonstrated promotion of wound-healing that may be achieved through NPT requires successful practitioner-preparation of the wound and surrounding site. Conventionally, preparation of a wound for NPT complicates the wound-packing procedure for both practitioner and patient.

In conventional preparation for NPT, a practitioner needs to pause the wound-packing procedure at an intermediate stage, with the base of the prepared wound covered but with the wound-bed only partly packed. An appropriately sized wound-fluid NPT drain is introduced into the partly packed wound-bed.

A typical wound-fluid NPT drain may include a hollow tube-like structure featuring transversely perforated walls. Such perforation provides access to the drain's hollow center, which may or may not be capped on one end. A tube for application of negative pressure and for drainage of exuded wound-fluid typically attaches to, or is integrally continuous with, the other end of the drain. This vacuum/drainage tube exits the wound-bed and extends beyond it.

The NPT drain is associated in situ with the initial packing material within the wound-bed. More specifically, the NPT drain is typically placed upon the gauze or inserted within the foam. Location and orientation of the drain within the confines of the wound-bed may affect the efficiency of drainage and the quality of wound-closing.

To maintain the NPT drain's placement and orientation, anchorage of the exiting vacuum/drainage tube may be required. The exiting tube is preferably anchored in close proximity to the wound. Typically, the vacuum/drainage tube is taped to the patient's perilesional and/or other wound-proximal skin.

Conventionally, maintenance of NPT drain-and-tube emplacement and orientation may complicate the remaining stages of the wound-packing procedure. A practitioner lay-

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ing the remaining packing material into the wound-bed may need to exercise caution to accommodate the presence of the NPT drain-and-tube. Even with the vacuum/drainage tube skin-anchored close to the wound, manipulations involved in completing the wound-packing procedure may deleteriously shift the NPT drain-and-tube.

The fully-packed wound-bed, with the emplaced NPT drain and the exiting vacuum/drainage tube, is completely draped with a flexible covering. The draping material closely adheres to sufficient skin area surrounding the wound-site to produce a perimeter seal that remains airtight under NPT conditions of negative wound-bed air pressure.

Particular wound-sites featuring high degrees of local moistness and/or contouring, may present challenges to producing effective airtight perimeter sealing. Practitioner-preparation of the wound for NPT requires smoothly adhering the surface-conforming draping material to the wider site's contours, with minimal disturbance of the packing, drain or tube. Such a procedure may be difficult and time-consuming.

The draping must allow for egress of the vacuum/drainage tube from the vicinity of the wound-site. The tube-egress may be sealed at the edge of the draping material by taping both the draping material and the vacuum/drainage tube at the site of tube-egress to the patient's skin. Such additional taping may be painful to the patient.

The end of the vacuum/drainage tube may be configured to connect to tubing leading to a suitable NPT vacuum controller. Wound-fluid exudate is drained from the sealed, packed wound-bed through the tubing, to a collection/disposal vessel associated with the vacuum controller. Prior to its disposal, collected exudate may be monitored as to volume, volume per time, fluid and cellular composition, bacterial count and/or other parameter(s) of clinical interest.

The therapeutic advantages of NPT have been clinically demonstrated for a broad variety of wound types, including but not limited to burns, lacerations, bed sores, etc. Improved patient-outcomes—including acceleration of wound-healing, decrease of infection and of necrosis, and enhancement of wound-closure quality—have been repeatedly noted in clinical studies.

Attainment of the clinical benefits of NPT depends upon successful practitioner-preparation of the wound-bed, of the surrounding perilesional area, and of the wider site. The number and intricacy of conventional NPT-required manipulations may make it difficult for a lone practitioner to efficiently carry out the procedure (while practical and institutional constraints may limit the number of practitioners and aides available); may lead to the need to repeat part or all of the procedure so as to correct earlier errors and/or later shifting of components; may contribute to incomplete success of the procedure, depriving the patient of the full benefit of NPT.

In the treatment of a typical wound, the above steps may be repeatedly applied over several courses of NPT. (As used herein, the term "course of NPT" refers to all NPT sessions performed on a given wound with a given NPT dressing in place; the term "NPT session" refers to any specific length of time over which the NPT vacuum controller applies continuous and/or intermittent negative pressure.) Each course of NPT may include, at the outset, cleansing and assessment of the progressively smaller wound-bed, followed by application of the dressing. Inherent painfulness may attend repeated manipulations of the wound-bed and surrounding wound-site, compounding the difficulties and complications involved in preparation of a wound for NPT by conventional apparatus and methods.

It would be desirable, therefore, to provide apparatus and methods for streamlining and simplifying preparation of a wound-site for NPT.

### SUMMARY

Apparatus and methods for streamlining and simplifying preparation of a wound-site for NPT are provided. Such apparatus may include a wound dressing. (The term “wound” as used herein includes surgical and traumatic wounds, as well as other medical conditions for which NPT may be beneficial, such as any burns, pressure sores, diabetic ulcers, open abdominal wounds, and other conditions.)

The following description identifies in more detail some aspects of exemplary structure according to the invention. Certain embodiments of apparatus according to the present invention may incorporate in a single dressing some or all of the following components:

1. A preferably airtight, flexible, contour-conforming draping layer. A wound-facing broad surface of such draping may be capable of suitably adhering even to moist tissue surfaces; the same or another surface of such draping that may serve as a platform for other components. A drape may be selectively transversely perforated for transfer of air and/or fluid between the two surfaces; there may be one or more areas of such perforations across the draping layer.

2. One or more wound-fluid NPT drain(s). An NPT drain may be closely associated with and/or partly surrounded by one or more sets of layers of fluid-absorbing/transferring material(s) such as those suitable for wound-packing. Such sets of drain-associated surrounding material(s) may facilitate air/fluid transfer. Such transfer between an NPT drain and a prepared wound may be through draping layer perforations and via the drain-associated surrounding material(s); the area of a set of drain-associated surrounding material(s) may be nominally centered on an area of the draping layer perforations, facilitating such transfer. An NPT drain of the dressing according to the present invention may have functions and capabilities beyond the air/fluid transfer delineated in this paragraph.

3. One or more single-lumen or multi-lumen vacuum/drainage tube(s). One end of a vacuum/drainage tube may be associated with one or more wound-fluid NPT drains; the other end of a vacuum/drainage tube may be equipped with one or more airtight tube-connecting adapters for connection to an NPT vacuum controller and/or other treatment control-and-monitor equipment.

4. One or more preferably airtight vapor sealant sheet(s). Such sheet (s) may closely overlie and extend beyond each material-surrounded wound-fluid NPT drain. Such vapor sealant sheets may feature tube-exit apertures for the vacuum/drainage tube(s) associated with each NPT drain. The perimeter of each vapor sealant sheet associated with an NPT drain may be sealed to the draping layer in an airtight manner and/or to other such perimeter-sealed vapor sealant sheets. Such vapor sealant sheets may be exclusively contacting only other components of the dressing, requiring no contact of the vapor sealant sheets with patient tissue.

5. One or more tube-anchorage and tube-exit-sealant layer(s) associated with the vapor sealant sheet(s) associated with the NPT drain(s). Such layer(s) may mechanically stabilize the placement and orientation within the dressing of the vacuum/drainage tube(s) and of the wound-fluid NPT drain(s). Such layer(s) may seal the tube-exit of the vacuum/drainage tube(s) at and/or along tube-egress from the interior to the exterior of the dressing.

The dressing, basic components and features of which may be summarized above, may be available in several shapes and sizes to accommodate a range of wound types and dimensions. A dressing may contain multiple NPT drains and/or multiple associated vacuum/drainage tubes. Vacuum/drainage tubes of a dressing may be of single-lumen and/or multi-lumen configurations.

The draping layer of the dressing may be configured with areas of wound-facing tissue-adhesive surface alternating (or otherwise mixed) on a given side of the draping layer with areas of non-wound-facing surface. Areas of non-wound-facing surface of the drape may feature full functional sets of the other components as summarized above, coupled with coterminous areas of reverse-side wound-facing tissue adhering surface; each pair of coterminous oppositely sided surfaces may communicate through draping layer perforations as described above.

The draping layer of the dressing may be packaged with a readily removable backing layer protecting and preserving the wound-facing tissue-adhesive surface(s) of the draping layer. A dressing may be provided in appropriately labeled sterile over-wrapping. The wrapped dressing may be supplied in a kit with suitable materials and apparatus for wound-cleansing and debridement and for initial wound-packing.

The dressing that may be described in summary above may streamline and simplify methods for preparation of a wound for NPT. In preparation for application of a dressing to a wound for which NPT is indicated, the wound-site may undergo standard assessment, and irrigation/cleansing of the bed and of the surrounding perilesional area, together with any needed slough-removal/debridement of the wound.

In preparation for application of a dressing, the wound-bed may be slightly under-packed. It should be noted that the wound-bed should not be overpacked. The precaution of slight wound-bed under-packing may accommodate the contraction of the packed wound-bed upon being subjected to negative pressure. The attendant reduction of wound-bed volume may force some of the packing material of a fully packed wound-bed undergoing NPT out onto and/or against the perilesional area, with possible deleterious effects.

The slightly under-packed, almost completely filled wound-bed would not be sealed or draped prior to application of the dressing.

A dressing (of appropriate size, shape and any other characteristics such as, but not limited to, tube lumen configuration and NPT drain number) may be applied directly to the slightly under-packed, almost completely filled wound-bed and to the surrounding wound-site. The following procedural outline is for a representative dressing containing a single drain-associated area of drain-surrounding fluid-absorbing/transferring material(s); adjustments, mainly of repetition, to the following procedural steps may be needed for application of a more complexly configured dressing.)

1. Removing the dressing from its sterile over-wrapping.

2. Removing the backing layer associated with the wound-facing tissue-adhesive surface of the draping layer of the dressing.

3. Orienting the dressing for suitable directionality of its exiting vacuum/drainage tube(s).

4. Approximately centering the drain-surrounding fluid-absorbing/transferring material(s) on the area of the slightly under-packed, almost completely packed wound-bed. Such positioning may yield overlap of the upper surface of the packing material within the wound-bed with the draping layer perforations. The area of drain-surrounding fluid-

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absorbing/transferring material(s) may be nominally centered within the dressing on the area of the drain layer perforations.

5. Applying the dressing to the wound-site. The tissue-adhesive wound-facing surface of the draping layer should be placed directly over and/or upon the uppermost layer of wound-packing material within the slightly under-packed wound-bed. The dressing should preferably be approximately centered (as described in the previous step) on the wound-bed.

6. Adhering the contour-conforming draping layer of the dressing to the tissue of the surrounding wound-site.

7. Connecting a drain-distal terminus of the vacuum/drainage tube to tubing from a suitable NPT vacuum controller and/or to other treatment control-and-monitor equipment that may be set to enhance NPT wound-healing.

The above-outlined steps involved in preparation of wounds for NPT by means of the dressing may enhance wound-healing using NPT. Further, such a dressing according to the invention may mitigate difficulties, complications and pain associated with preparation of a wound for NPT.

Thus, the dressing provides apparatus that may streamline and simplify methods for readily preparing a wound-site for NPT.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The objects and advantages of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout, and in which:

FIGS. 1-6 show a representative wound typical of wounds for which NPT may be clinically indicated.

FIG. 1 shows the representative wound at a stage of pre-treatment cleansing prior to wound-packing.

FIG. 2 shows the representative wound with a layer of non-adhering sterile material having been laid upon the base of the wound-bed.

FIG. 3 shows the wound at a typical early stage in conventional procedures for preparation of a wound for NPT, with drain and attached tube in place.

FIG. 4 shows the wound at a subsequent stage of conventional procedures for preparation of a wound for NPT, with wound-packing completed.

FIG. 5 shows the packed wound having been further prepared for NPT by conventional procedures, with the wound and the surrounding wound-site having been covered with an airtight draping material.

FIG. 6 shows the conventionally prepared wound and surrounding wound-site under NPT conditions. The portrayal of the tube-terminus beyond the draping material indicates the functioning of an NPT vacuum controller (not shown).

FIGS. 7A-C show views from "above" of embodiments of a dressing according to the present invention.

FIG. 8 shows a view from "below" of an embodiment of a dressing according to the present invention.

FIG. 9 shows an exploded, multi-tiered view from "above" of layers of components of an embodiment of the dressing according to the present invention.

FIGS. 10-11 show exploded, cross-sectional schematic views of layers of components of embodiments of the dressing according to the present invention.

FIGS. 12-14 show embodiments of the dressing according to the present invention (as per FIGS. 7-11) in conjunction with a representative wound (the latter, as per FIGS. 1-2).

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FIG. 12 shows the representative wound prepared beyond the stage of FIG. 2, having been readied by wound-packing for application of the dressing according to the present invention.

FIG. 13 shows a dressing according to the present invention having been representatively applied to the representative wound and to the surrounding wound-site.

FIG. 14 shows the representative wound (and the surrounding wound-site) and a dressing according to the present invention applied thereto, under NPT conditions.

#### DETAILED DESCRIPTION OF THE DISCLOSURE

In systems and methods according to the present invention, a dressing may be utilized in preparing a wound for NPT.

The dressing may provide apparatus that may be utilized for preparation of wounds for NPT via a number of steps. By providing apparatus that may reduce the number and complexity of steps involved in wound-preparation for NPT, use of the dressing may streamline and simplify wound preparation for NPT.

Details of systems and methods according to the present invention may be clarified as set forth in the following figures. FIGS. 1-6 portray representative wounds either alone or in association with representative NPT dressings in various stages of conventional preparation or use. FIGS. 7-14 portray representative dressings according to the present invention, either alone or in association with wounds.

FIG. 1 is a perspective view of a representative wound. The wounds represented may be surgical or traumatic wounds, acute or chronic wounds, or other wounds, including but not limited to wounds produced by surgical excision, specific degloving injuries, particular burns, diabetic extremity ulcers, and pressure sores. Such wounds may be on and/or in non-human surfaces. All such wounds are considered for application of the dressing according to the present invention.

The representative wound of FIG. 1 is portrayed as a wound-bed **102** surrounded proximally by an area **100** of perilesional tissue. Considering FIG. 1 as a flat horizontal field, the portrayal is seen by a viewer stationed beyond the field's "FIG." number-bearing edge, that edge of the figure being the edge closest to the viewer. The viewer is taken as facing in the direction of area **100**, lined up approximately with the "FIG." number, and peering down at wound-bed **102** from directly above. In the rendering of FIG. 1, overhead illumination is taken as being incident upon area **100** and wound-bed **102** from the viewer's right. In this application, wound-figure illustrations and perspective-view illustrations of the present invention may utilize this perspective view.

The terms "right" and "left" as used herein for orientation and to distinguish aspects of designated illustrated features, refer to the right and left, respectively, of the above described viewer. Likewise, the terms "near" and "far" as used herein to distinguish aspects of designated illustrated features, refer to those aspects' relative closeness to the viewer's station beyond the "FIG." number-bearing near edge of each figure. The terms "below" (or "beneath") and "above" as used herein to distinguish aspects of designated illustrated features associated with the wound-bed and/or the wound-dressing, refer to those aspects' being, respectively, vertically proximal to and vertically distant from the wound-base, as per the perspective view utilized and along the line-of-sight of the viewer, along which a displacement from

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“below” to “above” would be toward the viewer. Likewise, the terms “lower” (or “down” or “downward”) and “upper” (or “up” or “upward”) as used herein to distinguish aspects of designated illustrated features associated with the wound-bed and/or the wound-dressing, refer to those aspects’ being, respectively, vertically proximal to and vertically distant from the wound-base, as defined for “below” and “above.”

In FIG. 1, wound-bed 102 features a base 106 surrounded and defined by a set of walls 104. The portrayal of wound-base 106 and wound-walls 104 features texturing typical of exposed subcutaneous tissue. Such choice of tissue and its associated texturing are representative and not limiting; any wound surfaces for which NPT may be clinically indicated are considered.

In FIG. 1, wound-base 106 is lower than the perilesional skin of proximal area 100 by the depth of wound-walls 104.

FIG. 1 shows wound-bed 102 at a representative stage of pre-treatment cleansing prior to wound-packing. The representative cleansing of wound-bed 102 in FIG. 1 portrays an area of wound-base 106 having a medicinal salve (or cleansing agent) 114 being applied to it by means of a stick-and-swab 112. Pre-treatment methods may be utilized in various combinations to achieve the desired preparation of wound-bed 102. Pre-treatment cleansing may typically involve all surfaces of wound-bed 102. Area 100 may also be suitably cleansed in preparation for wound treatment.

FIG. 2 is a perspective view showing the representative wound subsequent to the pre-treatment procedures representatively portrayed in FIG. 1. In FIG. 2, perilesional area 200 and wound-bed 202 may have been prepared for wound-packing by appropriate pre-treatment procedures. Typically, the wound-bed is clinically assessed before being packed. Preparatory to the scene portrayed in FIG. 2, an initial layer of dressing material may have been shaped (typically, cut) to closely match the contours of wound-base 106 of FIG. 1. Usually, the shaped material may have been prepared slightly undersized relative to wound-base 106, allowing for ease of placement within the wound-bed and for anticipated subsequent reduction of wound-base area through healing. The dressing material may typically have been treated, possibly during manufacture, to be non-adhering to wound surfaces and to have other clinically appropriate characteristics.

FIG. 2 shows gauze 222 having been laid down across much of the wound-base. Gauze 222 is representative of a wound-shaped, slightly under-sized, non-adhering initial dressing material laid into wound-bed 202 prior to wound-packing. Gauze 222 is representative of any such suitable material, including but not limited to knitted fabrics such as Smith and Nephew’s ADAPTIC™ dressing and non-woven polymer surfaces such as Boehringer’s BIO-DOME™ dressing.

In FIG. 2, gauze 222 is portrayed as having been inserted within wound-bed 202, laying upon and across the wound-base with some clearance from wound-walls 204 roundabout the wound-base. Exemplary non-covered wound-base 206 is shown proximal to the left wound-wall 204.

FIG. 3 is a perspective view of a typical early stage in conventional procedures for preparation of a wound for NPT. On top of non-adhering initial dressing 322, a wound-packing material 324 is shown in wound-bed 302. To the left of wound-bed 302, exiting packing material 324 is shown as continuous with a supplementary section of packing material 326, perspective portrayed as suspended above the left side of area 300.

In FIG. 3, packing materials 324 and 326 are portrayed as gauze. Alternate conventional procedures of wound-packing

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preparation for NPT may utilize other varieties of packing material such as various shapeable sponge-like foams, such as V.A.C.® GRANUFOAM™.

FIG. 3 portrays an early stage in conventional procedures for preparation of a wound. A representative conventional NPT drain 330 is shown having been emplaced upon the early layering of packing material 324 within wound-bed 302. NPT drain 330 typically features a hollow interior surrounded by walls transversely perforated by one or more holes represented by a set of NPT drain holes 332. Holes 332 provide access from outside NPT drain 330 to the hollow core of NPT drain 330. NPT drain 330 may be any suitable shape—e.g., cylindrical, flat, flattened cylindrical, etc.

In FIG. 3, the near terminus of a vacuum/drainage tube 335 is shown associated with and exiting from NPT drain 330, the hollow core of tube 335 understood to be continuous with the hollow core of drain 330. Tube 335 is shown extending from area 300 to a region of a wider wound-site 305 where the far tube-terminus is portrayed as located.

In FIG. 3, NPT drain 330 is representatively portrayed oriented with vacuum/drainage tube 335 exiting up out of wound-bed 302 at far wound-wall 304 to lie along far perilesional area 300.

The location and orientation of drain 330 within wound-bed 302 may impact the effectiveness of NPT. Any of holes 332 being highly proximal to a section of wound-walls 304 may, under the negative pressure conditions of NPT within wound-bed 302, damage tissue of wound-walls 304. Drain 330 drawing exudate preferentially from one side of the wound-bed may thwart promotion of symmetric wound-healing. These and similar considerations underscore the need for fixity of NPT drain location and orientation after emplacement by practitioner-manipulation. Ideally, drain 330 would be fixed in location and orientation by some apparatus directly within the defined borders of wound-bed 302. In conventional wound-preparation procedures for NPT, such apparatus-placement within wound-bed 302 may, however, interfere with subsequent wound-packing, exudate-drainage and/or wound-healing.

As shown in FIG. 3, anchoring drainage/vacuum tube 335 to the patient’s skin may be the approach used to maintain the location and orientation of NPT drain 330 relative to wound-bed 302. While high proximity of tube-anchorage to wound-bed 302 may improve drain-fixity, perilesional skin of area 300 proximal to wound-bed 302 may be too frail or sensitive to serve as a tube-anchorage site. In addition, the usual apparatus for tube-anchorage, a set of skin-adhesive (and, possibly, tube-adhesive) strips 344, typically tape, but which may also be formed from another suitable sealant such as pliable putty, may interfere with perilesional participation in wound-healing. As presented, adhesive strips 344 anchor vacuum/drainage tube 335 onto the patient’s skin at a far region of perilesional area 300 that is part of a region of wider wound-site 305. A layer of skin-protective material 342, such as pliable putty, laid down upon the patient’s skin prior to laying tube 335 across it, is shown running under the section of tube 335 below the set of adhesive strips 344. Layer 342 and adhesive strips 344 shown are representative of a range of suitable materials including skin-adhesive ostomy strips and surgical tape.

Even with anchorage of tube 335 in proximity to wound-bed 302, the location and orientation of NPT drain 330 relative to wound-bed 302 may be subject to shifting. Such shifting may result from practitioner-manipulations involved in subsequent steps of conventional procedures for wound-preparation for NPT. Even in circumstances that allow for correction of such shifting within conventional

procedures for wound-preparation for NPT, sub-optimality of care may result. Such corrections may involve adjustment or replacement of components of dressing, drain and/or anchorage, which may contribute to patient discomfort.

FIG. 4 is a perspective view of a typical stage in conventional procedures for preparation of a wound for NPT, subsequent to wound-bed packing and preparatory to wound-site draping. In FIG. 4's portrayal of almost fully packed wound-bed 402, material 428b is representative of an uppermost layer of packing material; material 428a is representative of lower layers of packing material.

In FIG. 4's portrayal of almost completely packed representative wound-bed 402 prior to draping, NPT drain 430 within wound-bed 402 is directly indicated as covered by packing material 428b; below layer 428b, NPT drain 430 may be covered by layers 428a. Proximal to the far end of covered NPT drain 430, a section of vacuum/drainage tube 435a associated with the drain is indicated as covered by material 428a-b. A near section of vacuum/drainage tube 435b, continuous with the gauze-covered tube section 435a, is portrayed exiting from packing material 428a-b in the vicinity of far wound-wall 404. The near section of vacuum/drainage tube 435b is portrayed as completing its climb up and out of wound-bed 402 in the vicinity of far wound-wall 404, to lie upon the surrounding perilesional area (as depicted in FIG. 3 for vacuum/drainage tube 335 exiting wound-bed 302 to lie upon area 300). Wound-site skin-anchorage of tube-section 435b via skin-adhesive strips 444, typically tape, but which may also be formed from another suitable sealant such as pliable putty, and skin-protective material 442 is as described in FIG. 3 for strips 344 and material 342, respectively.

FIG. 5 is a perspective view of a typical stage in conventional procedures for preparation of a wound for NPT. The stage portrayed may be subsequent to wound-bed draping and preparatory to reduction of wound-bed ambient air pressure by use of an NPT vacuum controller. The wider wound-site 505, inclusive of wound-bed 502 and its associated perilesional area, is shown as having been draped with a representative contour-conforming material 555a-b. The lower surface of draping material 555a-b, designated 555b, may typically be skin-adhesive. Draping material 555a-b may typically be flexible, facilitating close conforming of 555a-b to the underlying contours of site 505.

Draping material 555a-b portrayed in FIG. 5 is typically impermeable to liquids and gases. By conventional practice, practitioner-smoothing of skin-adhesive material 555a-b to conform to site 505 contouring, may effect an airtight perimeter seal between surface 555b and the patient's skin across draped surfaces of site 505 roundabout wound-bed 502.

Draping material 555a-b may be transparent, as portrayed in FIG. 5. Visible beneath draping material 555a-b, wound-bed 502 is portrayed with drain 530 and its associated section of vacuum/drainage tube 535a indicated as present beneath layers of packing material 528. The section of vacuum/drainage tube 535b running from the wound-bed across the patient's skin of wider wound-site 505 is portrayed beneath draping material 555a-b. Wound-site skin-anchorage of tube-section 535b via skin-adhesive strips 544 and skin-protective material 542 is as described in FIG. 3 for strips 344 and material 342, respectively. The egress of the section of vacuum/drainage tube 535c from the perimeter of the drape is shown as having been sealed by an adhesive material 546, typically tape.

FIG. 6 is a perspective view of a conventionally prepared representative wound-site 605 under NPT conditions.

Beneath contour-conforming draping material 655, wound-site skin-anchorage of tube 635 via skin-adhesive strips 644 and skin-protective material 642 is portrayed as described in FIG. 3 for strips 344 and material 342, respectively; airtight sealing via adhesive material 646 of the tube-egress from drape 655 is portrayed as described for adhesive material 546 of FIG. 5. In FIG. 6, the terminus of tube 635 shown beyond drape 655, is designated 637, and displays an outward-directed arrow.

FIG. 6 portrays conventionally prepared wound-site 605 under NPT conditions of partial vacuum within wound-bed 602. Those conditions are produced by the NPT vacuum controller acting through tube-terminus 637 upon suitably prepared wound-bed 602 and wound-site 605. In FIG. 6, wound-bed 602 is portrayed as contracted, smaller than the same-scale portrayal of wound-bed 502 of FIG. 5. Perilesional area 600 proximal to wound bed 602 is portrayed distorted, its edge is drawn inward toward the contracted wound-bed.

In FIG. 6, draping material 655 above packed wound-bed 602 is shown pulled downward into the wound-bed, pressed against packing material 628; packing material 628 is shown distorted (relative to the portrayal of packing material 528 of FIG. 5), compressed within the vacuum-reduced volume of wound-bed 602.

Under NPT conditions portrayed in FIG. 6, exudate would be drawn from the wound-base and wound-walls through packing material 628 to NPT drain 630 and out through vacuum/drainage tube 635 toward the NPT vacuum controller.

Pressure-settings and time-duration of NPT treatment (including use of ON/OFF cycling to produce intermittent NPT within a course of treatment) may vary as functions of several parameters. Such parameters may include wound-type, accepted institutional procedures, wound-packing material, vacuum controller, and practitioner training and predilections.

The apparatus of the present invention preferably reduces time and increases efficiency of implementation of NPT. Specifically, certain embodiments of the invention provide a first dressing layer and a second dressing layer. These two layers may preferably trap one or more layers of fluid-absorbing/transferring material in between the two dressing layers.

In one of the layers, perforations may exist that roughly correspond to the location of the fluid-absorbing/transferring material within the layers. A drain for removing fluid may be located in between the fluid-absorbing/transferring material layers, or proximal a single fluid-absorbing/transferring material layer.

In the other dressing layer, an aperture may exist that allows a drainage tube to pass through the other dressing layer. The tube connects to the wound-fluid drain. The structure of such a dressing may preferably promote efficient implementation of NPT on a wound at least because it allows the dressing to be more easily, and more quickly, applied to a patient.

Alternative embodiments of the dressing may include a single perforation in one of the dressing layers and the perimeter of the fluid-absorbing/transferring material affixed to the edges of the perforation. The structure of such an embodiment may also promote efficient NPT on a wound. Specifically, such a structure may promote efficient NPT at least because the structure can be applied in fewer steps than a conventional dressing which, typically, requires application in a component-by-component fashion.

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Alternatively, one or more layers of the fluid-absorbing/transferring material may only be fixed to the dressing layer that does not include the perforation. In yet other embodiments, the fluid-absorbing/transferring material may be adhered both to the edges of the perforation and to the dressing layer that does not include the perforation.

FIGS. 7-13 are views of embodiments of a dressing according to the present invention. The dressing according to the present invention, components and functionality of which may be portrayed in FIGS. 7-13, may be available in several shapes and sizes to accommodate a range of wound types and dimensions; the embodiments in FIGS. 7-13 are representative.

The dressing may be provided in an appropriately labeled sterile over-wrapping. Such over-wrapping may be provided for shipping, storage, protection and/or maintenance of sterile conditions. Such over-wrapping may indicate various characteristics of the components of the over-wrapped dressing as may be useful in selecting a particular dressing for matching to a given wound-type on or in a given wound-site. Additionally, the wrapped or unwrapped dressing may be supplied in (association with) a kit with suitable materials and apparatus for wound-cleansing and debridement and for initial wound-packing. The outer packaging of such kit may provide identification of contents of the kit, including those characteristics of the dressing that may be useful in selecting for matching of dressing to wound. The embodiments of the dressing according to the present invention in FIGS. 7-13 are shown independent of any such kit and without any over-wrap.

FIGS. 7A-C are perspective views from above of embodiments of a dressing 780 according to the present invention. Perspective views of the dressing in this application maintain the linked set of view, orientation and directionality utilized for portrayal of wounds in FIGS. 1-6.

In FIGS. 7A-C, dressing 780 may also incorporate components not typically assembled in conventional NPT wound-preparation procedures. Components of dressing 780 may be suitably rated and/or approved for their use in patient care and/or for their use under NPT conditions of low air pressure.

FIGS. 7A-C representatively present the components of dressing 780 according to the present invention. As portrayed in FIGS. 7A-C, these components may include (with select components specifically presented in only two of the three FIGS. 7A, 7B and 7C, to be specified below as such):

1. A wound-fluid NPT drain 730. Wound-fluid NPT drain 730 of dressing 780 according to the present invention may be a hollow tube-like structure featuring transversely perforated walls, the perforations represented by a set of holes 732. Holes 732 represent one or more transverse perforations that may provide access, possibly through a wall of drain 730, to the hollow core of drain 730. Such perforations 732 may be of a range of suitable sizes and shapes, and may be variously and selectively located along the wall(s) of drain 730. Drain perforations 732 may be or may include the open terminus of a tube-like drain. In certain embodiments, drain 730 may be shaped as a flattened tube or in any other suitable configuration that allows for draining exudates.

Drain 730 of dressing 780 according to the present invention may be flexible and may be of a variety of materials, shapes, sizes and configurations. Drain 730 may be as structurally straightforward as a section of tube featuring a single hole 732; drain 730 may be as structurally complex as a multi-part, multi-functional manifold featuring multiple, uniquely shaped and spaced holes 732, and featuring flow-control modalities (e.g., anti-clogging), sensing

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capabilities (e.g., pressure-monitoring), signaling functions (e.g., indication of dressing-change time), and/or anti-bacterial or anti-microbial properties.

A dressing 780 according to the present invention may feature more than one wound-fluid NPT drain; each may be described as presented above in the description of wound-fluid NPT drain 730. The location and orientation of each NPT drain 730 within a dressing 780 may be indicated on the dressing (and on and/or through any packaging over-wrapping of the dressing).

2. A vacuum/drainage tube 735. Vacuum/drainage tube 735 of dressing 780 according to the present invention may provide a conduit through which low air pressure may be applied (via drain 730) to a wound-bed and through which wound-fluid exudate may be drawn (via drain 730) from a wound-bed. One terminus of vacuum/drainage tube 735 may be associated with NPT drain 730. The association of tube 735 with drain 730 may be by structural attachment to drain 730. The hollow core of tube 735 may be continuous with the hollow core of drain 730. The hollow core of drain 730 may or may not be capped on the end of drain 730 opposite its juncture of continuity with tube 735.

Vacuum/drainage tube 735 of dressing 780 according to the present invention may be available in a variety of materials (such as silicon tubing, plastic tubing or other suitable tubing material), strengths, flexibilities, lengths and carrying capacities. Vacuum/drainage tube 735 of dressing 780 may feature a single lumen of a range of cross-sections or a multiple set of lumens of various ranges of cross-section. Multi-lumen vacuum/drainage tube 735 may be of various configurations including, but not limited to, coaxial lumens and side-by-side lumens. Multi-lumen vacuum/drainage tube 735 may be configured at tube-termini with unique connectors and connections for specific sets of lumens or for each lumen, facilitating multiple uses of tube 735.

Non-standard uses of vacuum/drainage tube 735 may be facilitated by the availability of multiple lumens. Such uses may or may not be carried out simultaneously with the standard use of at least one lumen of tube 735 for application of negative pressure to a wound-bed and for exudate-drainage from the wound-bed. Such multi-lumen uses include, but are not limited to, measurement via a lumen of ambient pressure within a wound-bed; flushing via a lumen of clogged drain holes 732; delivery via a lumen of medicinal fluids to a wound-bed as part of a course of treatment; delivery via a lumen of apparatus or agents capable of providing information relative to ambient conditions, such as temperature, within the wound-bed; access via a lumen to a wound-bed by catheter-borne equipment of diagnostic, therapeutic and/or interventional utility; and delivery via a lumen of flushes of surfactant, cleansing and/or irrigating fluids to a wound-site preparatory to wound-dressing changes.

In dressing 780 according to the present invention, the terminus of tube 735 distal to drain 730 may feature a tube-connector adapter 737 that may be available in a variety of sizes and configurations. Adapter 737 may facilitate airtight connection to tubing leading to an NPT vacuum controller as well as connection to other treatment control-and-monitor equipment. Tube-terminus adapter 737 is representative of single and multiple tube-terminus adapters. For a multi-lumen tube 735, a set of one or more adapters 737 may terminate the drain-distal end of tube 735, each adapter of the set containing the connection(s) needed for one or more lumens connected to it and each adapter of the set possibly uniquely oriented as per its associated lumen(s).

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A dressing **780** according to the present invention may feature more than one vacuum/drainage tube; each may be described as presented above in the description of vacuum/drainage tube **735**. Each such vacuum/drainage tube may be associated with one or more NPT drains; each of the latter

3. A set of layering of fluid-absorbing/transferring materials **725** and **729**, which may surround drain **730**, enfolding the drain between a lower layer **725** and an upper layer **729**. As portrayed, fluid-absorbing/transferring layers **725** and **729** may be nominally centered within the larger overall area of dressing **780** according to the present invention; drain **730** may be nominally centered on the area of layers **725** and **729**, from which vacuum/drainage tube **735** may exit. Such portrayed centering is representative and not limiting; the location of drain **730** relative to layers **725** and **729** and of layers **725** and **729** relative to the larger overall area of dressing **780** may be varied to accommodate different shapes and configurations of the dressing.

Fluid-absorbing/transferring layers **725** and **729** of dressing **780** according to the present invention may feature a variety of shapes, areas and thicknesses. Different shapes and configurations of the dressing featuring variously configured fluid-absorbing/transferring layers **725** and **729** associated with variously configured NPT drains **730**, may be optimized for wounds of different types, sizes and/or shapes. Layers **725** and **729** of dressing **780** may be flexible and may be comprised of gauze or other suitable materials. Layer **725** and layer **729** may differ from each other as to compositional materials and as to characteristic shapes, areas and thicknesses. Layers **725** and **729** may be of materials different from that of the packing within the wound-bed. For materials such as foam, layers **725** and **729** may represent the lower and upper segments, respectively, of such materials in which drain **730** is located. Layers **725** and **729** may or may not bear antimicrobial, bacteriostatic, surfactant, cleansing or ameliorative medicinal agents.

Fluid-absorbing/transferring layers **725** and **729** of dressing **780** are representative of one or more sets of such materials, each set containing one or more drains **730** each featuring one or more exiting tubes **735**; the dressing according to the present invention may incorporate multiple drains **730** associated with layers **725** and **729**. Layers **725** and **729** may or may not be structurally integral to drain **730**. The dressing according to the present invention may feature a drain **730** comprised of and built into suitable material layers **725** and **729**; the dressing according to the present invention may feature layers **725** and **729** configured from and linked to the material of drain **730**.

A dressing **780** according to the present invention may feature multiple sets of fluid-absorbing/transferring layers **725** and **729**. Such sets may differ from each other with respect to characteristic shape, area, thickness, orientation and/or compositional material(s), as well as with respect to the number and characteristics of the NPT drains surrounded and/or enfolding thereby and/or comprised thereof.

4. A contour-conforming draping layer **756**. Contour-conforming draping layer **756** of dressing **780** according to the present invention may serve as draping material for a wound-bed. Contour-conforming draping layer **756** may be transparent or translucent, with such transparency/translucency useful in positioning dressing **780** relative to a wound-bed to which it may be applied and, after application of dressing **780**, in visually monitoring the condition of said wound-bed during a course of NPT. Contour-conforming draping layer **756** may be comprised of one or more mate-

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rials that confer flexibility and airtightness on draping layer **756**; draping layer **756** may be comprised of one or more materials that confer on a surface of the drape the capability of adhering even to moist, contoured surfaces of a patient's body, generally to perilesional skin and other wider wound-site skin. Such transparent/translucent, airtight, flexible, contour-conforming, tissue-adhering materials may include, but are not limited to, such hydrocolloids as ER Squibb's Duoderm® and 3M's Tegaderm™ or any other suitable hydrocolloid material or other suitable material. The composition and geometry of draping layer **756** may allow for repeated applications to and smoothing manipulations upon patient body surfaces, resulting in NPT-suitable tissue-adhesion and airtightness, even on moist contoured surfaces. Such airtight, flexible, contour-conforming, tissue-adhering draping layer **756** may be of suitable composition and geometry to maintain such characteristics under NPT conditions.

Contour-conforming draping layer **756** of dressing **780** according to the present invention may be directly associated with other components of dressing **780**. As portrayed (more explicitly in FIGS. 9-11, presentations in which emphasize components' relative spatial locations), fluid-absorbing/transferring layers **725** and **729**, and drain **730** that may be surrounded thereby, may be associated with a surface of contour-conforming draping layer **756**. Fluid-absorbing/transferring layer **725**, as the lower of layers **725** and **729**, may be in physical contact with and lie along the surface of draping layer **756** with which layers **725** and **729** are directly associated.

Contour-conforming draping layer **756** of dressing **780** according to the present invention may feature a set of transverse perforations, the perforations represented by a set of holes **752**. Holes **752** represent one or more transverse perforations that may provide access through draping layer **756** from below layer **756** to drain **730** located within fluid-absorbing/transferring layers **725** and **729**. Draping layer perforations **752** may be of a range of individual sizes and shapes, and of suitable overall number and geometric arrangement, to provide such access to various configurations of layers **725** and **729** and of drain **730**. Draping layer perforations **752** may be variously located along the area of draping layer **756**, providing access to layers **725** and **729**. The access provided by draping layer perforations **752** may allow transfer of air and fluid between a packed wound-bed (situated below draping layer **756**) and drain **730** (situated above draping layer **756**).

Draping layer perforation **752** may be a single opening of geometry and area approximating the geometry and area of overlying fluid-absorbing/transferring layer **725**. This may facilitate direct contact of all or most of layer **725** with a packed wound-bed independent of intervening section of draping layer **756**.

In such embodiments where perforation **752** is a single opening of geometry and area approximating the geometry and area of overlying fluid-absorbing/transferring layer(s) **725**, or some other suitable geometry, then the perimeter of fluid-absorbing/transferring layer(s) **725** and/or **729** may be trapped between the draping layer **756** and/or vapor sealant sheet **757**. Alternatively, the perimeter of fluid-absorbing/transferring layer(s) **725** and/or **729** may be affixed to draping layer **756** by adhesive on the draping layer or in some suitable fashion. Alternatively, any suitable portion of fluid-absorbing/transferring layer(s) **725** and/or **729** may be affixed to vapor sealant sheet **757** by adhesive on vapor sealant sheet **757** or in some other suitable fashion.

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Contour-conforming draping layer **756** of dressing **780** according to the present invention may allow for flexible, airtight adhesion to it of other components of dressing **780**. One such component may be a vapor sealant sheet **757**.

5. Vapor sealant sheet **757** may overlie all of the area of fluid-absorbing/transferring layer **729**. Vapor sealant sheet(s) **757** may be transparent or translucent, providing a view of overlain layer **729**, with such transparency/translucency useful in positioning dressing **780** relative to a wound to which it may be applied. Vapor sealant sheet **757** may extend beyond the area of layer **729** to provide a perimeter roundabout the area of layer **729**. The perimeter of vapor sealant sheet **757** roundabout layer **729** may flexibly adhere to a surface of draping layer **756** in an airtight fashion. Vapor sealant sheet **757** may be of thickness and of preferably airtight material to serve as an airtight sealing above and roundabout layer **729**. Flexible, transparent/translucent, airtight vapor sealant sheet **757** may be of materials including a suitable hydrocolloid material or other suitable material that is non-hydrocolloid.

Airtight vapor sealant sheet **757** may form an airtight seal roundabout layer **729** by adhering directly to the material(s) of the surface of draping layer **756** and/or to other such perimeter-sealed vapor sealant sheets. Additionally or alternatively, airtight vapor sealant sheet **757** may form an airtight seal roundabout layer **729** by adhering to the material(s) of a surface of draping layer **756** (or to other vapor sealant sheets) by means of one or more sealing agents.

Perimeter-sealed vapor sealant sheet **757** may mechanically maintain the placement and orientation of fluid-absorbing/transferring layers **725** and **729** within the larger area of drape **756**. Within the area of drape **756**, perimeter-sealed vapor sealant sheet **757** may mechanically maintain the placement and orientation of several sets of layers **725** and **729**. Dressing **780** according to the present invention may feature several perimeter-sealed vapor sealant sheets **757**, each overlying one or more sets of layers **725** and **729**.

A vapor sealant sheet **757** may provide an exit for vacuum/drainage tube **735**. Maintenance of the airtight seal provided by vapor sealant sheet **757** notwithstanding the presence of the aperture necessitated by vacuum/drainage tube **735** exiting through sheet **757**, is dealt with below in the description of tube-anchorage and tube-exit-sealant components **745** and **747**.

Contour-conforming draping layer **756** of dressing **780** according to the present invention may feature a variety of shapes, areas and thicknesses to accommodate different types of wounds and NPT conditions. Contour-conforming draping layer **756** may be provided with a set of readily removable backing layer **762**. Backing layer **762** may be associated with and protect and preserve tissue-adhesive surface(s) of draping layer **756** until ready for application to a wound-site; such backing layer may prevent unintentional adhesion and/or contamination of draping layer **756**. Protective backing layer **762** may be comprised of suitable material including, but not limited, to paper and plastic sheeting.

6. A tube-anchorage and tube-exit-sealant component **745** and/or **747**. Tube-anchorage and tube-exit-sealant components **745** and **747** are featured together in FIG. 7C, in an embodiment of dressing **780** according to the present invention in which the functioning of each of components **745** and **747** may reinforce each other. Tube-anchorage and tube-exit-sealant component **745** is featured without component **747** in the embodiment of dressing **780** according to the present invention presented in FIG. 7A; tube-anchorage and tube-exit-sealant component **747** is featured without com-

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ponent **745** in the embodiment of dressing **780** according to the present invention presented in FIG. 7B.

In embodiments of the dressing shown in FIG. 7A-C, either one or both of tube-anchorage and tube-exit-sealant components may mechanically maintain drain **730**'s placement and orientation within fluid-absorbing/transferring layers **725** and **729**. Either one or both tube-anchorage and tube-exit-sealant components may maintain drain **730**'s placement and orientation preferably by reinforcing the fixation of tube **735** proximal to the tube's (or tubes') exit(s) from sheet **757** overlying layer **729**. Such reinforcement may be achieved by the sealing of such tube-anchoring components to other components of the dressing, requiring substantially no contact of the dressing's tube-anchoring components with a patient's tissues.

As presented in FIG. 7A, tube-anchorage and tube-exit-sealant component **745** may provide anchorage for vacuum/drainage tube **735** exiting vapor sealant sheet **757**. As portrayed, such tube-anchorage may be provided by component **745** proximally to the exit of tube **735** from sheet **757**, by component **745** sealing around and upon the vicinity of the tube-exit aperture in sheet **757**. Such tube-anchorage sealing may mechanically contribute to tube-fixity and may confer airtightness to the tube-exit. Such mechanical anchorage of tube **735** may also contribute to maintenance of the placement and orientation of NPT drain(s) **730** within dressing **780**. It should be noted that the operation of tube-anchorage and tube-exit-sealant components **745** and **747**, respectively, may be enhanced by the application of a preferably pliable putty. Such putty may be applied about the exit point of tube **735** from one or both of tube-anchorage and tube-exit-sealant components **745** and **747**.

In certain embodiments, there may be no affixing of fluid-absorbing/transferring layer(s) **725** to draping layer **756** and/or vapor sealant sheet **757** by tube-exit-sealant components **745** and **747**. In such embodiments, a seal between tube and vapor sealant sheet **757** may be obtained with a pliable putty, or some other suitable substance, applied at the exit point of tube **735** from vapor sealant sheet.

Tube-anchorage and tube-exit-sealant component **745** may overlie part or all of vapor sealant sheet **757** and may extend beyond sheet **757** in area. Component **745** may be transparent or translucent, providing a view of and through overlain vapor sealant sheet **757**. Additionally or alternatively, the area-footprint of component **745** overlying vapor sealant sheet **757** may be sufficiently smaller than the area of sheet **757** that a view of and through transparent/translucent sheet **757** adequate for purposes of positioning dressing **780** may be obtained without need to see below the area-footprint of component **745**.

Component **745** may be comprised of one or more materials that confer a suitable range of flexibilities, thicknesses, anchorage-strengths, (transparency/translucency) and airtightness-sealing to the component. Such materials include, but are not limited to, ER Squibb's Duoderm® and 3M's Tegaderm™ or any other suitable hydrocolloid material or any other suitable material which may not be a hydrocolloid material. Component **745** may be sealed onto vapor sealant sheet **757** by adhesion of the materials of component **745** and sheet **757**. Additionally or alternatively, component **745** may be sealed onto draping layer **756** by adhering directly to the material(s) of the surface of draping layer **756**. Additionally or alternatively, component **745** may be sealed onto vapor sealant sheet **757** and/or draping layer **756** by means of one or more sealing agents.

As presented in FIG. 7B, tube-anchorage and tube-exit-sealant component **747** may provide anchorage for vacuum/

drainage tube 735 exiting vapor sealant sheet 757. As portrayed, such tube-anchorage may be provided by component 747 both proximally to the exit of tube 735 from sheet 757 and along a suitable length of section of tube 735 running over vapor sealant sheet 757 and over draping layer 756. Tube-anchorage and tube-exit-sealant component 747 may provide such anchorage by overlying (and possibly flexibly sealing to) all of the area of vapor sealant sheet 757 and by extending beyond the area of sheet 757 to provide a perimeter roundabout vapor sealant sheet 757. The perimeter of component 747 roundabout the edges of vapor sealant sheet 757 may flexibly adhere to and seal a surface of draping layer 756 roundabout vapor sealant sheet 757. Such perimeter-sealed overlying of vapor sealant 757 may reinforce the airtightness of vapor sealant sheet 757 across its area. Tube-anchorage and tube-exit-sealant component 747 may be transparent or translucent, providing a view of and through overlain vapor sealant sheet(s) 757.

As presented in FIG. 7C, tube-anchorage and tube-exit-sealant components 745 and 747 may both be incorporated into dressing 780, and may both provide anchorage and tube-exit-airtightness for vacuum/drainage tube 735 exiting vapor sealant sheet 757. As presented in FIG. 7C, component 745 may be as described above in FIG. 7A. As presented in FIG. 7C, component 747 may be as described above in FIG. 7B, with the additional functional feature that it may also overlie (and possibly seal with) component 745.

As presented in FIGS. 7B-C, tube-anchorage and tube-exit-sealant component 747 may conform to the section of underlying tube 735, extending the area of tube-exit into a channel, the upper surfaces of which may be defined as part of the lower surface of component 747. The lower surfaces of such tube-exit channel may be defined proximally to the tube-exit aperture in sheet 757 as part of the upper surface of vapor sealant sheet 757 and, beyond the perimeter of 757, by part of the upper surface of drape 756. Component 747 may flexibly adhere to the section of tube 735 running within the tube-exit channel and may seal that section of tube with the other surfaces defining the channel. Additionally or alternatively, such channel may be sealed by means of one or more sealing agent(s).

Component 747 may be comprised of one or more materials that confer a suitable range of flexibilities, thicknesses, transparency/translucency, anchorage-strengths, and airtightness-sealing to the component. Such materials include, but are not limited to, Tegaderm, DuoDerm or any other suitable hydrocolloid material or other suitable non-hydrocolloid material. Component 747 may be sealed onto vapor sealant sheet 757, onto component 745, onto draping layer 756 and/or onto vacuum/drainage tube 735 by adhesion of the materials of component 745 with the materials of those other components. Additionally or alternatively, component 747 may be sealed to any or all of vapor sealant sheet 757, component 745, draping layer 756 and tube 735 by one or more sealing agents.

A dressing 780 according to the present invention may feature a contour-conforming draping layer 756 of dressing 780 may feature, on a given side, both areas of wound-facing surface and areas of non-wound facing surface. Areas of wound-facing surface of such drape layer 756 may be associated with and protected and preserved by sections of backing layer 762. Preferably coterminous with any or all of those areas on either side of such drape 756, but on the reverse-side of such drape 756 from the wound-facing tissue-adhesive surfaced areas that may be associated with protective backing layer 762, areas of non-wound-facing surface of such drape 756 may feature fully assembled,

sealed and functional sets of the other non-draping-material components of dressing 780. Each pair of coterminous surfaces on opposite sides of such drape layer 756 may communicate through one or more sets of draping layer perforations 752 as described above.

FIG. 8 is a perspective view from below of an embodiment of a dressing 880 according to the present invention. Protective backing layer 862 is portrayed partially peeled back from the tissue-adhesive face of draping layer 856 to show transverse draping layer perforations 852 running through layer 856, such perforations being representatively nominally centered on the area of layer 856.

On the reverse surface of draping 856, aspects of components that may be in proximal contact with that surface are shown. On the reverse surface of draping 856, representatively shaped area of fluid-absorbing/transferring layer 825 is indicated as extensively overlapped by the area of draping layer perforations 852. Layer 825 is representatively presented as a gauze layer, part of the mesh of which may be directly visible through draping layer perforations 852. Also indicated on the reverse surface of drape 856 are the draped-sealed perimeter of vapor sealant sheet 857 and the draped-sealed perimeter of tube-anchorage and tube-exit-sealant component 847. (The embodiment viewed from below in FIG. 8 may correspond to the embodiments viewed from above in FIGS. 7B-C.)

Indicated as running between sheet 857 and layer 847 along the reverse surface of drape 856 is a section of vacuum/drainage tube 835 proximal to layer 825. Tube 835 is shown exiting the channel formed by part of the reverse surface of drape 856 and part of component 847. A terminus of vacuum/drainage tube 835 and its associated tube-terminus adapter 837 are shown beyond the edge of draping sheet 856.

FIG. 9 is an exploded perspective view from above of an embodiment of a dressing 980 according to the present invention (corresponding to the embodiment in FIG. 7C). From above, the tiered components presented may be:

1. Tube-terminus adapter 937 that may be connected to a terminus of vacuum/drainage tube 935.
2. Vacuum/drainage tube 935 that may run partly under tube-anchorage and tube-exit-sealant component 947 (and then may proceed downward to and/or through other, lower components).
3. Tube-anchorage and tube-exit-sealant component 947 that may be above, and may extend in area beyond the areas of, component 945 and component 957.
4. Tube-anchorage and tube-exit-sealant component 945 (through which tube 935 may run) that may be above component 957.
5. Vapor sealant sheet 957 (through which tube 935 may run) that may be associated at its tube-exit aperture with tube-anchorage and tube-exit-sealant component 945; vapor sealant sheet 957 may be above, and may extend in area beyond the area of, component 929.
6. Fluid-absorbing/transferring layer 929 (through or below which tube 935 may run) that may be above drain 930 and may be continuous with layer 925.
7. NPT drain 930 that may be attached to or may be integrally continuous with vacuum/drainage tube 935; drain 930, which may feature drain perforations 932, may be above layer 925.
8. Fluid-absorbing/transferring layer 925 (through or above which tube 935 may run) that may be above, and may overlie perforations 952 of, draping layer 956.

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9. Draping layer **956** that may be below all the above-listed components of dressing **980**. Draping layer **956** may be above, and be as extensive in effective area as, component **962**.

10. Layer **962** that may be backing the tissue-adhesive surface of layer **956**. Protective backing layer **962** may be removed prior to application of dressing **980** to a wound, such that draping layer **956** may be the most wound-proximal component of a dressing **980** applied to a wound.

FIG. **10** and FIG. **11** are exploded, cross-sectional schematic views of embodiments of a dressing according to the present invention.

FIG. **10** schematically portrays in exploded cross-section the components of a dressing **1080** according to the present invention (corresponding to the embodiment in FIG. **9**). In FIG. **10**, draping layer **1056**, with associated perforations **1052**, is portrayed as serving as a platform for the other portrayed components. NPT drain **1030**, with associated perforations **1032**, is portrayed nested between fluid-absorbing/transferring layers **1025** and **1029**; NPT drain **1030** is portrayed associated with vacuum/drainage tube **1035**. Following along drain-associated tube **1035** away from its association with NPT drain **1030**, tube **1035** is portrayed as passing between fluid-absorbing/transferring layers **1025** and **1029**, through vapor sealant sheet **1057**, through tube-anchorage and tube-exit-sealant component **1045**, and through tube-anchorage and tube-exit-sealant component **1047**. Tube-anchorage and tube-exit-sealant component **1047** is portrayed as wrapping around tube **1035**, such wrapping representing the anchorage and airtightness that either or both tube-anchorage and tube-exit-sealant components **1045** and **1047** may provide.

In FIG. **10**, drain-containing fluid-absorbing/transferring layers **1025** and **1029** are portrayed as nested within vapor sealant sheet **1057**. Tube-anchorage and tube-exit-sealant component **1045** is portrayed as overlying sheet **1057** proximal to the exit of tube **1035** from sheet **1057**, in which vicinity component **1045** may both stabilize fixation of tube-position and contribute to airtight sealing of said tube-exit. Drain **1030**, layers **1025** and **1029**, sheet **1057**, and component **1045** are portrayed as nested within the tube-anchorage and tube-exit-sealant component **1047**.

FIG. **11** schematically portrays in exploded cross-section the components of a dressing **1180** according to the present invention (corresponding to the embodiment in FIG. **9**). FIG. **11** may present the components presented in FIG. **10** less vertically separated than in FIG. **10**. In FIG. **11**, draping layer **1156** is portrayed as serving as a platform for the other portrayed components, and as the contact-surface against which some components may be sealed. NPT drain **1130** is portrayed as closely surrounded by fluid-absorbing/transferring layers **1125** and **1129**; NPT drain **1130** is portrayed associated with vacuum/drainage tube **1135**. Following along drain-associated tube **1135** away from its association with NPT drain **1130**, tube **1135** is portrayed as passing between or through fluid-absorbing/transferring layers **1125** and/or **1129**, through vapor sealant sheet **1157**, through tube-anchorage and tube-exit-sealant component **1145**, and through tube-anchorage and tube-exit-sealant component **1147**.

In FIG. **11**, drain-containing fluid-absorbing/transferring layers **1125** and **1129** are portrayed as closely nested within vapor sealant sheet **1157**; layer **1129** is portrayed as closely overlain by vapor sealant sheet **1157**. The edges of vapor sealant sheet **1157** that extend beyond sheet **1157**'s overlying of layer **1129** are portrayed lying along draping layer **1156**; vapor sealant sheet **1157** may form airtight seals along

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the areas of its contact with the surface of draping layer **1156**. Tube-anchorage and tube-exit-sealant component **1145** is portrayed as closely overlying vapor sealant sheet **1157** proximal to the exit of tube **1135** from vapor sealant sheet **1157**, in which vicinity component tube-anchorage and tube-exit-sealant component **1145** may both stabilize fixation of tube-position (and, thereby, stabilize fixity of drain-position) and contribute to airtight sealing of said tube-exit.

In FIG. **11**, tube-anchorage and tube-exit-sealant component **1145** and vapor sealant sheet **1157** are portrayed as closely overlain by tube-anchorage and tube-exit-sealant component **1147**. The edges of tube-anchorage and tube-exit-sealant component **1147** that extend beyond components **1147**'s overlying of component **1145** and of fluid-absorbing/transferring layer **1129** are portrayed lying along draping layer **1156**; tube-anchorage and tube-exit-sealant component **1147** may form airtight seals along the areas of its contact with the surface of draping layer **1156**.

As per the portrayals in FIG. **11** and the descriptions presented in FIGS. **7-10** of components' features and functions, the tube-exit from the interior to the exterior of dressing **1180** may be sealed by tube-anchorage and tube-exit-sealant component **1145** and/or by tube-anchorage and tube-exit-sealant component **1147** (either or both, possibly, by means of sealing agent(s)); airtight component **1147** may closely overlie component **1145** and vapor sealant sheet **1157**; airtight component **1147** may be sealed at its edges against the surface of draping layer **1156** (possibly by means of sealing agent(s)); airtight vapor sealant sheet **1157** may overlie fluid-absorbing/transferring layers **1125** and **1129**, closely overlying layer **1129**; airtight vapor sealant sheet **1157** may be sealed at its edges against the surface of draping layer **1156** (possibly by means of sealing agent(s)); the airtight material(s) of draping layer **1156** may underlie drain-containing fluid-absorbing/transferring layers **1125** and **1129**, closely underlying layer **1125**. Thus, air/fluid-flow access to drain **1130** from the exterior of dressing **1180** may be obtained only via draping layer **1156**'s perforations **1152** and through vacuum/drainage tube **1135**.

The portrayed drain-distal terminus of vacuum/drainage tube **1135** displays an outward-directed arrow. The arrow may indicate the direction within tube **1135** of outward flow of air and/or fluid. Such air/fluid-flow may originate exterior to dressing **1180** along the wound-facing surface of draping layer **1156**; may traverse draping layer **1156** to the non-wound-facing surface of draping layer **1156** through its associated perforations **1152**; may travel via fluid-absorbing/transferring layers **1125** and **1129** to the interior of drain **1130** through its associated perforations **1132**; and, from the interior of drain **1130**, may travel to the exterior of dressing **1180** via vacuum/drainage tube **1135**. When applied to a wound, the dressing as schematically represented in FIG. **11** as **1180** would have draping layer **1156** overlying and sealing a wound-bed. Flow of air and/or of wound-fluid exudate from the wound-bed may then follow the route outlined above, passing through draping layer perforations **1152** to travel into drain **1130** and then outward through tube **1135**.

Dressing **1180** according to the present invention may feature modalities beyond the standard application of negative pressure to wound-beds and drainage of wound-fluid exudate from wound-beds. Among those modalities may be capabilities of wound-flushing, possibly via multi-lumen tube(s) **1135**. Such capability may allow for reversal of the standard direction of fluid flow. Such capability of reverse-flow may be utilized to selectively deliver medicinal or other fluids to a sealed wound-bed at a pause between NPT

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sessions of a course of NPT; or to partially irrigate a sealed wound-bed to wet its packing material and wound-bed surfaces (possibly with surfactants) prior to a wound-dressing change upon the conclusion of a course of NPT.

As reverse-flow modalities may be mediated by vacuum/ drainage tube 1135, they and several other non-standard advantages of use of dressings according to the present invention over conventional apparatus and methods may be addressed in the description of vacuum/drainage tube 735 of FIGS. 7A-C.

As portrayed in FIG. 11, fixation of position of vacuum/ drainage tube 1135 (and, thereby, fixation of position of NPT drain 1030) may be stabilized by tube-anchorage and tube-exit-sealant component 1145 and/or tube-anchorage and tube-exit-sealant component 1147. Those tube-anchorage and tube-exit-sealant components may also contribute to the airtightness of dressing 1180, particularly at and/or along the tube-exit of vacuum/drainage tube 1135 from the interior to the exterior of dressing 1180. The functionality of tube-anchorage and tube-exit-sealant component 1145 and tube-anchorage and tube-exit-sealant component 1147 may be attained by the sealing of those components exclusively to other components of dressing 1180, with no contact with patients' skin or other tissues.

FIGS. 12-14 return to the perspective view utilized in FIGS. 1-9, linked to the assumed directionality of illumination and the orientation of the viewer given in description of FIG. 1. FIGS. 12-14 are perspective views from above of embodiments of a dressing according to the present invention (as per FIGS. 7-11) in conjunction with a representative wound (the latter, as per FIGS. 1-2).

FIG. 12 is a perspective view from above of an embodiment of a dressing 1280 according to the present invention, in conjunction with a representative wound-bed 1202 that may be ready for application of dressing 1280. As portrayed, wound-bed 1202 may be proximally surrounded by a perilesional area 1200; both wound-bed 1202 and surrounding perilesional area may be contained within a wider wound-site 1205.

In FIG. 12, wound-bed 1202 is portrayed ready for application of dressing 1280, such state of readiness attained by preparation of wound-bed 1202 and of an appropriate portion of wider wound-site 1205 beyond wound-bed 1280. Initial preparation of wound-bed 1202 and of wider wound-site 1205 beyond wound-bed 1280 prior to the stage portrayed in FIG. 12 may be representatively portrayed in FIGS. 1-2 and detailed in the corresponding descriptions of FIGS. 1-2. In FIG. 12, wound-bed 1202 is portrayed as having been further readied for application of dressing 1280 by the expedient of wound-packing, with packing material within wound-bed 1202 designated as 1227.

A precautionary accommodation that may have been made in packing wound-bed 1202 with packing material 1227 as part of preparing wound-bed 1202 for application of dressing 1280, may have been a slight under-packing of wound-bed 1202. Such under-packing of prepared wound-bed 1202 is depicted in FIG. 12 by packing material 1227 portrayed as almost but not completely filling wound-bed 1202. Uppermost edges of wound-walls 1204 of slightly under-packed, almost completely filled wound-bed 1202 are shown as not covered by packing material 1227. (Wound-walls 1204 may be continuous roundabout the entire inner perimeter of wound-bed 1202. Given the perspective view utilized, sections of right wound-wall 1204 may be blocked from view by the perilesional upper edge of right wound-wall 1204.)

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In FIG. 12, packing material 1227 is portrayed as comprised of layers of gauze. The right-most region of packing material 1227 is portrayed as the uppermost layer of packing material 1227 within prepared, slightly under-packed wound-bed 1202. Depiction of wound-packing material 1227 as gauze is not limiting; dressing 1280 may be applied to and used in treating wound-beds filled or packed with materials other than gauze, e.g. foam or other suitable material.

The portrayed dressing 1280 is representative of a range of such dressings differing in the size, shape, capabilities, characteristics, numbers and/or relative orientations of their constituent components. Such variation may be in any or all of, but not limited to, draping layer 1256, draping layer perforations 1252, NPT drain 1230, drain perforations 1232, fluid-absorbing/transferring layers 1225 and 1229, vapor sealant sheet 1257, tube-anchorage and tube-exit-sealant component 1245, tube-anchorage and tube-exit-sealant component 1247, vacuum/drainage tube 1235, and drain-distal tube-terminus adapter 1237. Description of the range of such variations in such constituent components of NPT drain 1280 may be addressed, partially and representatively, in the description of constituent components of NPT drain 780 of FIGS. 7A-C.

One of the sets of choices made in selecting dressing 1280 may have been as to the lumen number and functional capabilities of vacuum/drainage tube 1235. Linked to that set of choices may have been selection for the number, size, shape, capacity and functional capabilities of NPT drain 1230, along with the number and characteristics of drain-distal tube-terminus adapter 1237.

The material of draping layer 1256 well beyond the borders of tube-anchorage and tube-exit-sealant component 1247 (or, for dressings 1280 lacking such tube-anchorage and tube-exit-sealant component 1247, well beyond the borders of vapor sealant sheet 1257) may have been selectively trimmed to accommodate the body location and contouring of wider wound-site 1205. (Such trimming of the material of draping layer 1256 may be carried out with consideration of the area of tissue-adhesive surface of such material required to effect an airtight NPT seal roundabout wound-bed 1202 upon application of dressing 1280 to wound-site 1205.)

FIG. 12 portrays dressing 1280 with backing layer 1262 protective of the wound-facing tissue-adhesive broad surface of draping layer 1256 having been partly removed. Procedurally, backing layer 1262 may be completely removed from wound-facing tissue-adhesive surface(s) of draping layer 1256 prior to application of dressing 1280 to prepared wound-bed 1202 and to an appropriate portion of wider wound-site 1205 beyond wound-bed 1202.

Additional steps may be taken before application of the dressing 1280 to wound-bed 1202 and to an appropriate portion of wider wound-site 1205 beyond wound-bed 1202. The additional steps may include finalization of selection of the positioning and orientation of dressing 1280 relative to wound-bed 1202. Tissue-adhesive characteristics of the wound-facing surface of draping layer 1256 may allow dressing 1280 to be removed, repositioned and re-applied several times before finalization of application to wound-bed 1202 and to the finalized dressing-covered portion of wider wound-site 1205 beyond wound-bed 1202 for a given course of NPT; tissue-adhesive characteristics of the wound-facing surface of draping layer 1256 may allow dressing 1280 to be removed, repositioned and re-applied to wound-site 1205 between NPT sessions of a given course of NPT.

The position and orientation of an NPT drain **1230** within a dressing **1280** may be labeled through visible/tactile marking(s) that may be readily perceived on or through the uppermost surface of a dressing **1280**. With fluid absorbing/transferring layer **1229** possibly blocking NPT drain **1230** from view through the transparent/translucent overlying layer(s), such indication of position and orientation of an NPT drain **1230** within a dressing **1280** may be useful in positioning and orienting the dressing during its application to wound-site **1205**.

FIG. **13** is a perspective view from above of an embodiment of a dressing **1380** according to the present invention, as representatively applied to a representative wound-bed **1302** and to an appropriate portion of a wider wound-site **1305** beyond wound-bed **1302**. FIG. **13** distinguishes between the lower, wound-facing tissue-adhesive surface of draping layer **1356** (designated as wound-facing surface **1355b**) and the upper, non-wound-facing surface of draping layer **1356** (designated as non-wound-facing surface **1355a**). FIG. **13** portrays representative positioning and orientation of dressing **1380** relative to wound-bed **1302** and to the wider wound-site **1305** beyond wound-bed **1302**. The portrayed positioning and orientation of dressing **1380** with respect to relevant features of wound-bed **1305**, display several features of diverse roles and levels of significance relative to the functionality of dressing **1380**:

Extensive contact-area of tissue-adhesive wound-facing surface **1355b** with the tissue-surface of wound-site **1305** roundabout wound-bed **1302**, inclusive of perilesional area **1300**.

Extensive overlap of the area of draping layer perforations **1352** with the area of packing material **1327** within wound-bed **1302**. (The term "area of draping layer perforations" as used herein refers to the area across the broad surface of the draping layer occupied by the transverse perforations through the draping layer, with inclusion of the areas between individual perforations. In the portrayal in FIG. **13**, the area of draping layer perforations **1352** is depicted as closely bounded from without by the area of fluid-absorbing/transferring layer **1329**.)

Approximate centering of the area of draping layer perforations **1352** on the area of wound-packing material **1327** within wound-bed **1302**.

Approximate orientation of NPT drain **1330** along the long axis of wound-bed **1302**.

Orientation of vacuum/drainage tube **1335** relative to wound-site **1305**.

The extent of contact of tissue-adhesive wound-facing surface **1355b** with the tissue-surface of wound-site **1305** roundabout wound-bed **1302**, and the extent and geometry of overlap of the area of draping layer perforations **1352** with the area of packing material **1327** within wound-bed **1302**, may be factors to have been taken into consideration in selecting a dressing **1380** of specific characteristics. Relevant characteristics may include the sizes and shapes of draping layer **1356**, of fluid-absorbing/transferring layers **1325** and **1329**, and of the area of draping layer perforations **1352**. As constrained by wound-site **1305**'s contours and proximal body-parts, an extensive and close interface of contact between wound-facing surface **1355b** and the patient's tissue-surface may contribute to obtaining an NPT-required quality of airtight sealing roundabout wound-bed **1302**. With wound-site **1305**'s local conditions of moistness as a factor that may have to be contended with, other characteristics that may have been selected relative to obtaining a high quality interface of dressing **1380** with

wound-site **1305**, may include the tissue-adhesion characteristics of wound-facing surface **1355b**.

With an appropriately selected dressing **1380** in hand, the practitioner may have taken into consideration in initial positioning and orienting of the dressing for its application to wound-site **1305**, the attainment of extensive contact of tissue-adhesive wound-facing surface **1355b** with the tissue-surface of wound-site **1305** roundabout wound-bed **1302**. Likewise, in such initial positioning and orienting of the dressing, the practitioner may have considered attainment of an extensive overlap of the area of draping layer perforations **1352** with the area of packing material **1327**. Other considerations for such initial, coarse adjustments of general positioning and orientation may include suitability of the direction of vacuum/drainage tube(s) **1335** and drain-distal tube-terminus adapter(s) **1337**, relative both to proximal body-parts and to the NPT vacuum controller and/or other treatment control-and-monitor equipment.

In making fine adjustments for precise positioning and orientation of dressing **1380** prior to finalizing its application to wound-site **1305**, the practitioner may have been guided by considerations of attainment of an overlap of the area of draping layer perforations **1352** with the area of packing material **1327** within wound-bed **1302**, and of a particular orientation of NPT drain **1330** within that geometry. As portrayed in FIG. **13**, the area of draping layer perforations **1352** may be approximately centered on the area of packing material **1327** within wound-bed **1302**. In addition, FIG. **13**'s portrayal of a representatively applied dressing **1380** shows no overlying of draping layer perforations **1352** upon perilesional area **1300**; the outer edges of the area of draping layer perforations **1352**, as portrayed in FIG. **13**, may be well within wound-walls **1304**, with a perimeter of packing material **1327** visible roundabout the area of draping layer perforations **1352**, showcasing a lateral gap between draping layer perforations **1352** and surrounding perilesional area **1300**.

As per the dressing-internal spatial relationships among components of dressings **980**, **1080** and **1180** portrayed in FIGS. **9**, **10** and **11**, respectively, draping layer perforations **1352** on non-wound-facing surface **1355a** may be directly overlain by fluid absorbing/transferring layer **1325** that may be directly overlain by NPT drain **1330**; during NPT sessions, negative pressure may be applied to wound-bed **1302** via NPT drain **1330**'s drain perforations **1332**. Thus, NPT negative pressure may be most directly applied to packing material **1327** within wound-bed **1302**, and drainage of wound-fluid exudate may be most directly effected, in the region of overlap of the area of packing material **1327** with the area of draping layer perforations **1352**.

A high degree of overlap of the two areas close to their mutual centers may yield an evenly balanced drainage of wound-fluid exudate from all parts of packing material **1327** within wound-bed **1302** under NPT conditions. Mutual centering of the areas may contribute to an even distribution of contraction of wound-walls **1304** under NPT conditions, which may positively impact rapidity and quality of wound-healing. Minimization of overlying of drain layer perforations **1352** upon perilesional area **1300** may minimize contact of wound-fluid exudate with tissues of perilesional area **1300** during NPT sessions; such contact, particularly under NPT conditions, may be deleterious to tissue health. Thus, the extent and geometry of overlap of the area of draping layer perforations **1352** with the area of packing material **1327** within wound-bed **1302** may impact the effectiveness of exudate-drainage, quality of wound-closure, and health of perilesional area **1300**.

An additional consideration during fine adjustments for precise positioning and orientation of dressing **1380** prior to finalizing its application to wound-site **1305**, particularly for surgical wounds, may have been the orientation of NPT drain **1330** relative to the geometry of wound-bed **1302**. In FIG. **13**, NPT drain **1330** is portrayed as oriented approximately along the long axis of wound-bed **1302**, as delimited by surrounding wound-walls **1304**. Wound-bed healing may naturally tend to preferentially promote wound-closure orthogonal to particular cleavage lines (such as Langer's, Kraissl's or Borges's cleavage lines) that lie along particular orientations in different regions of the body. Particularly in surgical wounds, where incisions may have been made parallel to such cleavage lines to take advantage of the preferential directionality of natural wound-closure in a given region of the body, approximate alignment of the NPT drain **1330** with the wound-axis of wound-bed **1302** may be advantageous to the wound-healing process. (Such orientation of NPT drain **1330** as portrayed in FIG. **13** is representative and not limiting; NPT drain(s) **1330** of dressing **1380** according to the present invention may be associated with a wide range of wound-bed shapes, including those with no discernable long axis, such as circular wounds and various irregular wounds. Orientation and location of NPT drain **1330** within wound-bed **1302** may be constrained by many clinical factors, even in the case of surgical wounds; such factors may include the three-dimensional shape of the volume of wound-bed **1302** and the specifics of the contouring of wider wound-site **1305**.)

In application to wound-site **1305** of dressing **1380** according to the present invention, establishment of the position and orientation of dressing **1380** relative to relevant features of wound-bed **1305**, including the geometry of wound-bed **1302**, may have been straightforward, as may be portrayed in FIG. **13**.

With comprehensive visual knowledge of wound-site **1305** obtained through transparent/translucent tube-anchorage and tube-exit-sealant component(s) **1347** (and/or **1345**), and/or through transparent/translucent vapor sealant sheet **1357**, and through transparent/translucent draping layer **1356**; with visual/tactile marking(s) of the position and orientation of NPT drain(s) **1330** within dressing **1380**, perceivable on or through overlying component(s) **1347** (and/or **1345**) and/or overlying sheet **1357**; with edges of all or any of component(s) **1347** (and/or **1345**), of sheet **1357**, of fluid absorbing/transferring layer **1329**, and of layer **1356**, perceivable relative to geometries of relevant features of wound-site **1305** during application of dressing **1380**, the practitioner may have established a set of position and orientation of dressing **1380** with relative ease and precision. Maintenance of the position and orientation of applied dressing **1380** may be effected by the tissue-adhesion characteristics of wound-facing surface **1355b**. Establishment and maintenance of mutual positions and orientations of constituent components within applied, positioned and oriented dressing **1380**, may be obtained as consequences of the set of structural functionalities of those components preassembled with fixity of position and of orientation within dressing **1380**.

In FIG. **13**, draping layer **1356** of dressing **1380** may be conformed and adhered to the contours of perilesional area **1300** and of the rest of dressing-covered regions of wound-site **1305**. Practitioner manipulation across non-wound-facing surface **1355a**, smoothing draping layer **1356** over the underlying contours, may have been readily accomplished and may have been guided and facilitated by the transparency/translucency of draping layer **1356**.

As shown in FIG. **13**, the contact-area of tissue-adhesive wound-facing surface **1355b** with the tissue-surface of wound-site **1305** roundabout wound-bed **1302**, inclusive of perilesional area **1300**, may be extensive. FIG. **13**'s portrayal of an applied dressing **1380** shows no perilesional area **1300** not overlain by draping layer **1356**; in addition, extensive regions of the wider wound-site **1305** beyond perilesion area **1300** may be overlain, and conformed to, by the material of draping layer **1356**, and adhered to by tissue-adhesive wound-facing surface **1355b**. The extent and quality of the contact-area of tissue-adhesive wound-facing surface **1355b** with the tissue surface roundabout wound-bed **1302**, may impact production of effective airtight perimeter sealing of wound-bed **1302** under NPT conditions of low wound-bed air pressure.

FIG. **14** is a perspective view from above of an embodiment of a dressing **1480** (corresponding to the embodiment in FIG. **13**) representatively applied, conformed and adhered to a representative prepared wound-site **1405**, under NPT conditions of low air pressure within wound-bed **1402**. The portrayed tube-terminus adapter **1437** of vacuum/drainage tube **1435** displays an outward-directed arrow. The arrow may indicate airtight connection of tube-terminus adapter **1437** to a functioning NPT vacuum controller (not shown) and/or suitable connections for obtaining wound-bed NPT conditions by mean of other treatment control-and-monitor equipment (not shown); such other treatment control-and-monitor equipment may facilitate also such non-standard functionalities of representative dressing **1480** according to the present invention as may be addressed, partially and representatively, in the description of vacuum/drainage tube **735** of FIGS. **7A-C**.

In FIG. **14**, the outward-directed arrow associated with tube-terminus adapter **1437** may indicate, also, the direction of exudate-flow within vacuum/drainage tube **1435** outward from wound-bed **1402**; such outward flow may be consequent to NPT conditions of partial vacuum obtaining within wound-bed **1402**. Those conditions may be produced by an NPT vacuum controller (or an operational vacuum-functionality of other suitable treatment control-and-monitor equipment) connected to tube-terminus adapter **1437**, acting through vacuum/drainage tube **1435** upon the interior of NPT drain **1430**; through drain perforations **1432**, acting upon fluid-absorbing/transferring layers **1425** and **1429**; through draping layer perforations **1452**, acting upon and within packing material **1427** within wound-bed **1402**.

NPT conditions of partial vacuum obtaining within packing material **1427** may contract packing material **1427** and may subject the wound-base and wound-walls of wound-bed **1402** to the effects of such negative pressure. Such effects may include the drawing out of wound-fluid exudate from the wound-base and wound-walls of wound-bed **1402** into and through packing material **1427**; wound-fluid exudate in packing material **1427** may retrace the path of application of partial vacuum, flowing up and out of wound-bed through vacuum/drainage tube **1435**.

With the contraction of packing material **1427** and the application of partial vacuum to the wound-base and wound-walls of wound-bed **1402**, wound-bed **1402** may be contracted; as portrayed in FIG. **14**, wound-bed **1402** may be smaller than the same-scale portrayal of wound-bed **1302** of FIG. **13**, particularly orthogonal to, and approximately symmetrically medially toward, the long axis of wound-bed **1402**, along which NPT drain **1430** may be centered and oriented. In FIG. **14**, the edges of perilesional area **1400** proximal to wound-bed **1402** are portrayed as pulled inward toward the center of wound-bed **1402**, mostly medially

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toward the long axis of wound-bed **1402**; skin-tension lines in perilesional area **1400** proximal to wound-bed **1402** may indicate the mainly medial stretching of the upper edges of the wound-walls toward contracted wound-bed **1402**. Regions of wider wound-site **1405** beyond perilesional area **1400** may, as portrayed in FIG. **14**, be somewhat distorted as consequent to NPT conditions of partial vacuum obtaining within wound-bed **1402**.

Contraction of wound-bed **1402** vertically downward along the viewer's line-of-sight, may also typically occur under NPT conditions of partial vacuum obtaining within wound-bed **1402**. In FIG. **14**, draping layer **1456**, particularly above contracted wound-bed **1402**, may be pulled downward into the depth of wound-bed **1402**, pressed against contracted packing material **1427**; packing material **1427** may be portrayed distorted (relative to the portrayal of packing material **1327** of FIG. **13**), compressed within the vacuum-reduced volume of wound-bed **1402**. Likewise, through a set of distortions of their area-borders (relative to their portrayals in FIG. **13**), FIG. **14** shows the distortions medially inward and vertically downward of tube-anchorage and tube-exit-sealant components **1447** and **1445**, of vapor sealant sheet **1457**, and of fluid-absorbing/transferring layers **1429** and **1425**. Likewise, vacuum/drain tube **1435** proximal to its exit from below tube-anchorage and tube-exit-sealant component **1447**, and following along the tube-exit channel beneath component **1447** in the direction of the viewer's station beyond and approximately in line with the figure's "FIG. **14**," may be distorted downward toward NPT drain **1430**. Depending on the characteristics of flexibility of NPT drain **1430**, NPT drain **1430** may be distorted by NPT conditions of partial vacuum obtaining within wound-bed **1402**.

The wound-base and wound-walls of wound-bed **1402** may be under mechanical strain consequent to NPT conditions of partial vacuum ("NPT negative pressure") obtaining within wound base **1402**. While such strain may be contributory to NPT-enhancement of wound-healing, the intensity of the strain may need to be limited to accommodate the sensitivities and strengths of the tissues of the wound-base and wound-walls of wound-bed **1402**. NPT sessions featuring NPT drain **1430** according to the present invention applied to a prepared wound-site **1405**, may accelerate NPT-enhancement of wound-healing without over-straining wound-walls and wound-base tissues of wound-bed **1402**.

Thus, apparatus and methods that streamline and simplify preparing a wound-site for negative pressure treatment have been provided. Persons skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, which are presented for purposes of illustration rather than of limitation, and that the present invention is limited only by the claims that follow.

The invention claimed is:

1. A wound dressing comprising:

a wound-fluid drain for use in negative pressure wound treatment ("NPT drain");

a vacuum/drainage tube comprising a terminus associated with the NPT drain, said NPT drain being configured to non-simultaneously withdraw fluid from a wound and deliver fluid to the wound;

fluid-absorbing/transferring layer for distributing negative pressure from the NPT drain, said fluid-absorbing/transferring material being in contact with the NPT drain;

a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer, said vapor sealant sheet

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comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of fluid-absorbing/transferring layer relative to the vapor sealant sheet; and

a tube-anchorage component that is in contact with at least a portion of the vapor sealant sheet and a portion of the fluid-absorbing/transferring layer, the tube-anchorage component for mechanically maintaining placement of the NPT drain relative to the fluid-absorbing/transferring layer.

2. A wound dressing comprising:

a wound-fluid negative pressure treatment ("NPT") drain; a vacuum/drainage tube comprising a terminus associated with the NPT drain;

fluid-absorbing/transferring layer for distributing negative pressure from the vacuum/drainage tube, said fluid-absorbing/transferring layer being in contact with the vacuum/drainage tube;

a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer, said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of the fluid-absorbing transferring layer relative to the vapor sealant sheet;

a first tube-anchorage component that is in contact with at least a portion of the vapor sealant sheet; and

a second tube-anchorage component, the first and second tube-anchorage components for mechanically maintaining the NPT drain's placement relative to the fluid-absorbing/transferring layer.

3. A wound dressing comprising:

a vacuum/drainage tube comprising a terminus;

a fluid-absorbing/transferring layer for distributing negative pressure from the vacuum/drainage tube, said fluid-absorbing/transferring layer being in contact with the vacuum/drainage tube;

a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer, said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of the fluid-absorbing transferring layer relative to the vapor sealant sheet; and

a tube-exit-sealant component for mechanically maintaining the vacuum/drainage tube's placement relative to the fluid-absorbing/transferring layer.

4. The wound dressing of claim 1 wherein the fluid-absorbing/transferring layer comprises gauze.

5. The wound dressing of claim 1 wherein the fluid-absorbing/transferring layer comprises foam.

6. The wound dressing of claim 1 wherein the fluid-absorbing/transferring layer comprises an upper layer and a lower layer.

7. The wound dressing of claim 6 wherein the NPT drain is enfolded between the lower layer and the upper layer.

8. The wound dressing of claim 2 wherein the vacuum/drainage tube comprises a plurality of lumens.

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9. The wound dressing of claim 8 wherein the plurality of lumens comprises at least one lumen configured to deliver fluid to a wound and at least one lumen configured to withdraw fluid from the wound.

10. The wound dressing of claim 8 wherein at least one lumen is configured to convey a medical device.

11. The wound dressing of claim 3 wherein the vacuum/drainage tube terminus is associated with a negative pressure treatment ("NPT") drain.

12. The wound dressing of claim 11 wherein the NPT drain comprises a plurality of NPT drains.

13. The wound dressing of claim 3 wherein the vacuum/drainage tube is further associated with an external vacuum source.

\* \* \* \* \*

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# EXHIBIT D



# Negative Pressure Wound Therapy Market (2024 - 2030)

Size, Share & Trends Analysis Report By Product (Conventional NPWT Devices, Single-Use NPWT Devices, NPWT Accessories), By Wound Type (Chronic Wounds, Acute Wounds), By End-use, By Region, And Segment Forecasts

[Report Summary](#)

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[Segmentation](#)

[Methodology](#)

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## Negative Pressure Wound Therapy Market Summary

The global negative pressure wound therapy market size was estimated at USD 2,488.2 million in 2023 and is projected to reach USD 3,872.8 million by 2030, growing at a CAGR of 6.5% from 2024 to 2030. Increasing demand for advanced wound care is expected to propel negative pressure wound therapy (npwt) devices market.

### Key Market Trends & Insights

In terms of region, North America was the largest revenue generating market in 2023.

Country-wise, Denmark is expected to register the highest CAGR from 2024 to 2030.

In terms of segment, conventional npwt devices accounted for a revenue of USD 2,095.3 million in 2023.

Herbal Tea is the most lucrative product segment registering the fastest growth during the forecast period.

### Market Size & Forecast

2023 Market Size: USD 2,488.2 Million

2030 Projected Market Size: USD 3,872.8 Million

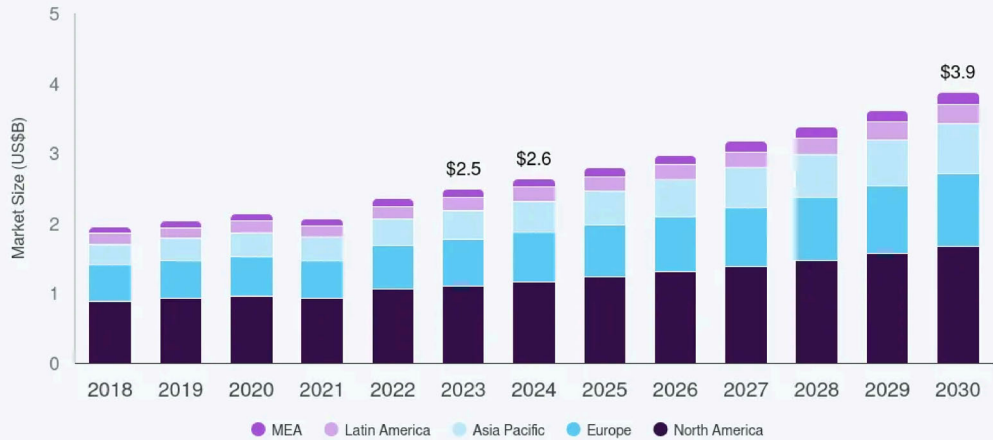
CAGR (2024-2030): 6.5%

North America: Largest market in 2023

Single-use NPWT devices are gaining traction in the field of wound care management over conventional products. For instance, in January 2022, Smith+Nephew announced that the FDA cleared its Single Use Negative Pressure Wound Therapy (sNPWT) Systems PICO 7 and PICO 14 for new indications in closed surgical incisions, which can help lower the occurrence of dehiscence, postoperative seroma, and superficial and deep incisional Surgical Site Infections (SSIs).

## Negative Pressure Wound Therapy Market

Size, by Region, 2018 - 2030



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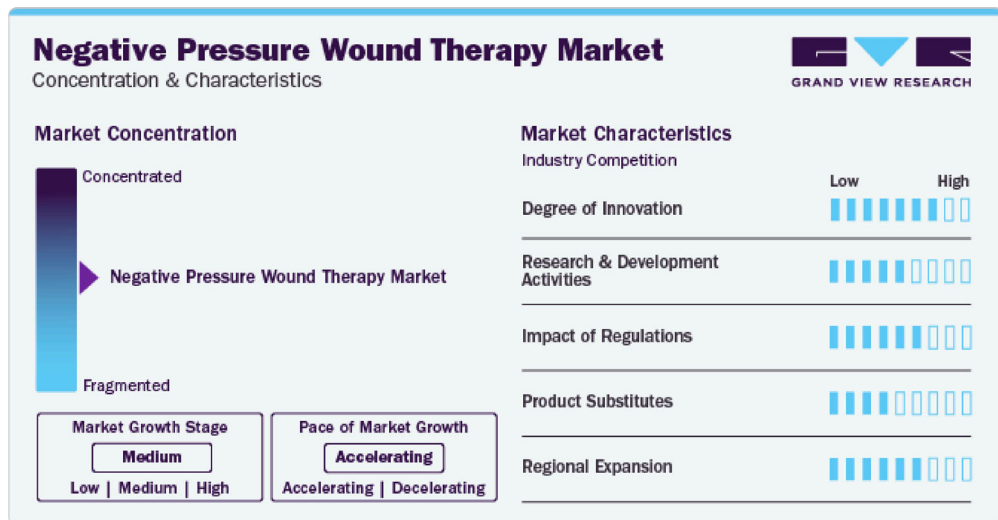
The increasing prevalence of chronic diseases, such as diabetes, cancer, and autoimmune conditions, is further anticipated to propel the market over the forecast period. This is primarily attributable to the fact that diabetes often results in complications such as diabetic foot ulcers. As per a report by WHO, in March 2023, about 422 million live with diabetes globally in 2023, Diabetes can contribute to an increased occurrence and complexity of various wounds, including infections, ulcerations (such as leg or foot ulcers), and acute wounds like surgical and traumatic wounds.

In addition, the increasing prevalence of obesity is another key factor likely to drive market growth, as it is associated with lower extremity amputations and chronic wounds. According to the World Obesity Federation, estimated that around 1 billion people globally, including 1 in 7 men and 1 in 5 women, will be living with obesity by 2030. Obese people are at a higher risk of pressure ulcers, with lowered vascular action in adipose tissue. Thus, this factor will likely boost the demand for these products, leading to market growth.

Elderly people have low immunity levels and thus, are prone to chronic disorders, such as diabetes, cancers, and heart diseases. Rising geriatric population is a significant factor propelling the growth of the negative pressure wound therapy devices market. According to the WHO data published in October 2022, by 2030, one out of every six people worldwide will be 60 years or older. During this period, the number of individuals in this age group will rise from 1 billion in 2020 to 1.4 billion. By 2050, the global population of those aged 60 and above is anticipated to double, reaching 2.1 billion. Moreover, the number of people aged 80 years or older is projected to triple by 2050, reaching a total of 426 million, compared to the figures recorded in 2020. These abovementioned factors are expected to drive the demand for negative pressure wound therapy devices over the forecast period.

### Market Concentration & Characteristics

The market growth stage is moderate, and the pace of the market growth is accelerating. The negative pressure wound therapy market is characterized by a moderate-to-high degree of growth. Key drivers include the global aging population, prevalence of chronic diseases, and advancements in NPWT devices. Regulatory compliance, reimbursement policies, and trend towards home healthcare also shape the market dynamics.



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Key strategies implemented by players in negative pressure wound therapy market are new product launches, expansion, acquisitions, partnerships, and other strategies. In April 2023, Convatec Group PLC acquired 30 Technology Limited's anti-infective nitric oxide technology platform, which includes new product assets and R&D. In addition to enhanced **wound care** (<https://www.grandviewresearch.com/industry-analysis/wound-care-market>), Convatec plans to explore the technical platform for use in other businesses.

The market is witnessing a substantial degree of innovation driven by rapid technological advancements and the increasing adoption of advanced products, particularly in home care settings. Companies investing significantly in these advanced technologies are gaining a competitive edge, contributing to the overall market growth. Thesingle-use systems, wireless remote monitoring, and enhanced patient mobility, the latest NPWT devices are designed to provide more effective and efficient wound healing solutions. Such advancements and innovations in negative pressure wound therapy drive market growth.

The market is significantly influenced by stringent quality protocols and regulatory norms enforced by various nations, aimed at ensuring patient safety and data integrity. Market participants with robust compliance measures and a proven track record of meeting regulatory standards not only enhance patient trust but also gain preference from MedTech sponsors.

Companies are actively acquiring development-stage firms to broaden their product portfolios, catering to a larger patient base. These collaborative efforts aim to strengthen relationships and improve the implementation of clinical programs pitched towards reducing hospitalizations for members. For instance, in March 2022, Convatec Group PLC completed the acquisition of Triad Life Sciences, Inc. to enter the wound biologics segment. Triad's team, current portfolio, and product pipeline were transitioned to Convatec's Advanced Wound Care (AWC) business, known as Convatec Advanced Tissue Technologies.

The market comprises a large number of medical device manufacturers leads to a highly fragmented market scenario.

Negative pressure wound therapy companies are increasingly prioritizing regional expansion to gain a competitive edge and expand their market reach. This involves forming partnerships, making acquisitions, and adopting localized marketing strategies to establish a stronger presence in key geographical areas. By customizing their products and services to cater to the unique healthcare requirements of different regions, these companies aim to improve accessibility and responsiveness, which in turn can lead to better market penetration. Overall, regional expansion is a crucial element for industry leaders to explore new markets, address specific healthcare demands, and drive sustained growth.

## Report Coverage & Deliverables

PDF report & online dashboard will help you understand:

- ✓ Competitive benchmarking
- ✓ Historical data & forecasts
- ✓ Company revenue shares
- ✓ Regional opportunities
- ✓ Latest trends & dynamics

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## Product Insights

On the basis of product, the market has been segmented into conventional NPWT devices, single-use NPWT devices, and NPWT accessories. The conventional segment accounted for the largest market share of 84.21% in 2023. This can be attributed to their high price and increasing adoption globally. Conventional NPWT devices reduce the length of hospital stay for patients, reducing the total cost of treatment and favoring the adoption of this device over single use. Furthermore, it can be rented and purchased, which is expected to increase the usage rate of conventional NPWT in developing countries owing to its low purchasing power, thereby driving segment growth.

The Single-use NPWT devices segment is expected to witness the fastest growth over the forecast period. This is due to its wide applicability in home care settings, prompting major companies to focus on increasing their cost-effectiveness. According to the National Center for Biotechnology Information (NCBI), the estimated cost of sNPWT per patient was 19,986 compared to USD 20,572 for surgical complications (SC). This cost-effectiveness has proved an added advantage for single-use NPWT devices in developing countries, these factors are driving segment growth.

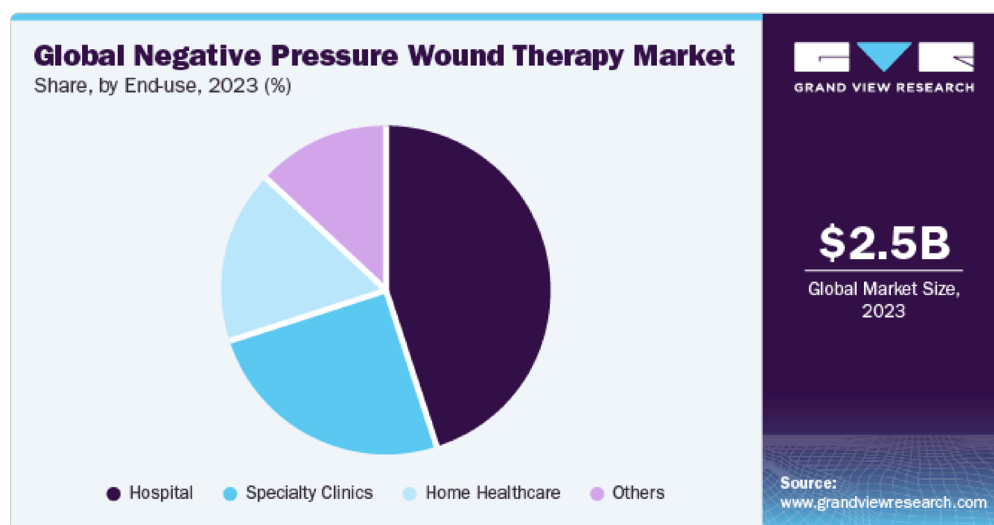
## Wound Type Insights

The chronic wounds segment dominated the market in 2023. This can be attributed to an increasing number of geriatric populations and an increase in the prevalence of chronic wounds, such as diabetic foot ulcers and venous pressure ulcers, are expected to drive segment growth. As per data published by Wound Care Advantage, in May 2023, about 8.2 million people over the age of 65 and above have chronic wounds in America. Thus, increasing geriatric population with chronic wounds is anticipated to drive segment growth during the forecast period.

The acute wounds segment is expected to witness the fastest growth over the forecast period. The rising incidences of burns injuries across the globe and rising number of SSIs is one of the major driving factors for the segment growth. For instance, according to data published by Rosenfeld Injury Lawyers, in March 2023, about 450,000 people suffer from burn injuries each year in America. These factors are propelling the segment growth.

## End-use Insights

Hospitals segment dominated the market in 2023 on account of a high volume of patients due to the increasing chronic diseases globally. In addition, NPWT devices are widely used in hospital settings, which include acute care centers and community hospitals. Moreover, the rising number of hospitals is anticipated the segment growth. According to the American Hospital Association, in 2023, around 6,129 hospitals were available in the U.S. Thus, introducing new healthcare hospitals and new patients for wound treatment spurs the demand for negative pressure wound therapy devices in the forecast period.



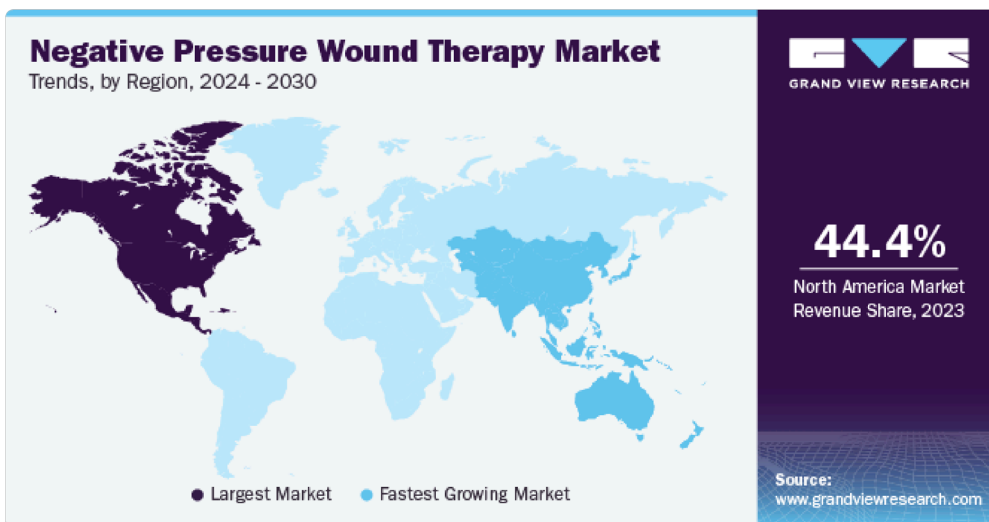
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The home healthcare segment is expected to witness the fastest growth over the forecast period. NPWT therapy designed for home use is emerging, owing to the introduction of technologically advanced single-use and traditional NPWT systems. These innovations eliminate the necessity for hospitalization, making the overall therapy cost-efficient when applied in a home setting.

## Regional Insights

North America accounted for the highest market share in 2023. This can be attributed to the rising number of road accidents, sports injuries, and the presence of several key players in the region is anticipated to drive the market in North America. The region is continuously developing cost-efficient and advanced devices for the patients to capture a huge share of the market. In addition, the rise in the number of hospitals and the growing geriatric population are factors responsible for the regional market growth.



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U.S. accounts for the largest market share in North America market. This can be attributed to the high incidence rate of chronic wounds in the U.S. and the rising geriatric population in U.S. is expected to boost the market growth. For instance, in May 2023, the CDC estimates that 6 in 10 adults in the U.S. currently live with a chronic disease such as cancer, heart disease, or diabetes.

Asia Pacific is expected to be the fastest-growing region during the forecast period because of the rising target population base with increasing chronic diseases, the need for medical equipment by the patients, and supportive government initiatives. In addition, the rapidly growing medical tourism industry in these countries can also be attributed to the increase in demand for NPWT in this region coupled with improvements in healthcare infrastructure will contribute to the region's growth.

China accounts for the largest market share in Asia Pacific market. As per the National Library of Medicine report, the proportion of elderly people in China's population is increasing, indicating a demographic shift towards an aging society. As a result, the incidences of diabetes and diabetic foot have been increasing. These factors are expected to drive the segment's growth over the forecast period.

## Key Negative Pressure Wound Therapy Company Insights

Market trends are shaping negative pressure wound therapy company's strategies. Heavy investments in research and development for technological innovations reflect a commitment to connected healthcare solutions. Top negative pressure wound therapy brands are adapting to the shift towards home healthcare through strategic partnerships and acquisitions, expanding their offerings for patients seeking accessible solutions.

### Key Negative Pressure Wound Therapy Companies:

The following are the leading companies in the **negative pressure wound therapy market**. These companies collectively hold the largest market share and dictate industry trends. Financials, strategy maps & products of these **NPWT companies** are analyzed to map the supply network.

3M

Talley Group Ltd (Direct Healthcare Group)

Smith+Nephew

Mölnlycke Health Care

Medela AG

DeRoyal Industries, Inc.

Convatec Inc.

Recent Developments

- In May 2023, **Smith+Nephew** (<https://www.smith-nephew.com/en/news/2023/05/02/20230502-smith-nephew-receives-innovative-technology-contract-from-vizient-for-pico>) received an innovative technology contract for its PICO Single Use Negative Pressure Wound Therapy Systems from Vizient, Inc. This contract will strengthen research and development related to NPWT, thereby driving market growth.
- In April 2023, **Convatec Group PLC** (<https://www.convatecgroup.com/media/press-releases/2023/convatec-secures-a-highly-innovative-technology-platform-in-the-anti-infective-space/>) acquired 30 Technology Limited's anti-infective nitric oxide technology platform, which includes new product assets and R&D. In addition to enhanced wound care, Convatec plans to explore the technical platform for use in other businesses.
- In August 2023, Medela launched novel Invia Integrated Dressing for different types of wounds.
- In January 2022, Smith+Nephew announced that the FDA cleared its Single Use Negative Pressure Wound Therapy (sNPWT) Systems PICO 7 and PICO 14 for new indications in closed surgical incisions, which can help lower the occurrence of dehiscence, postoperative seroma, and superficial and deep incisional Surgical Site Infections (SSIs)

Negative Pressure Wound Therapy Market Report Scope

| Report Attribute          | Details                                                                                               |
|---------------------------|-------------------------------------------------------------------------------------------------------|
| Market size value in 2024 | USD 2.63 billion                                                                                      |
| Revenue forecast in 2030  | USD 3.87 billion                                                                                      |
| Growth rate               | CAGR of 6.64% from 2024 to 2030                                                                       |
| Actual data               | 2018 - 2023                                                                                           |
| Forecast period           | 2024 - 2030                                                                                           |
| Report updated            | January 2024                                                                                          |
| Quantitative units        | Revenue in USD million/billion and CAGR from 2024 to 2030                                             |
| Report coverage           | Revenue forecast, company ranking, competitive landscape, growth factors, and trends, product outlook |
| Segments covered          | Product, wound type, end-use, region                                                                  |
| Regional scope            | North America; Europe; Asia Pacific; Latin America; MEA                                               |

|                              |                                                                                                                                                                                                                                                                                                                           |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Country Scope                | U.S.; Canada; UK; Germany; Italy; France; Spain; Denmark; Sweden; Norway; Japan; China; India; South Korea; Australia; Thailand; Brazil; Mexico; Argentina; South Africa; Saudi Arabia; UAE; Kuwait                                                                                                                       |
| Key companies profiled       | 3M; Talley Group Ltd (Direct Healthcare Group); Smith+Nephew; Mölnlycke Health Care<br>Medela AG; DeRoyal Industries, Inc.; Convatec Inc.<br>Cardinal Health; Paul Hartmann AG                                                                                                                                            |
| Customization scope          | Free report customization (equivalent up to 8 analysts working days) with purchase. Addition or alteration to country, & segment scope.                                                                                                                                                                                   |
| Pricing and purchase options | Avail customized purchase options to meet your exact research needs. <a href="https://www.grandviewresearch.com/checkout/select-license/negative-pressure-wound-therapy-npwt-market">Explore purchase options (https://www.grandviewresearch.com/checkout/select-license/negative-pressure-wound-therapy-npwt-market)</a> |

## Global Negative Pressure Wound Therapy Market Report Segmentation

This report forecasts revenue growth at regional and country levels and provides an analysis of the latest industry trends in each of the sub-segments from 2018 to 2030. For this study, Grand View Research has segmented the global negative pressure wound therapy market report based on product, application, end-use, and region:

 Global Negative Pressure Wound Therapy Market Report Segmentation

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### • Product Outlook (Revenue, USD Million, 2018 - 2030)

- Conventional NPWT Devices
- Single-use NPWT Devices
- NPWT Accessories

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- **Wound Type Outlook (Revenue, USD Million, 2018 - 2030)**

- Chronic Wounds
  - Pressure Ulcer
  - Diabetic Foot Ulcer
  - Venous Leg Ulcer
  - Others
- Acute Wounds
  - Surgical & Traumatic Wounds
  - Burns

- **End-use Outlook (Revenue, USD Million, 2018 - 2030)**

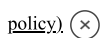
- Hospital
- Specialty Clinics
- Home Healthcare
- Others

- **Regional Outlook (Revenue, USD Million, 2018 - 2030)**

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  - Canada
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  - Italy
  - France
  - Spain
  - Denmark
  - Sweden
  - Norway
- Asia Pacific
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  - South Africa
  - Kuwait

## Frequently Asked Questions About This Report

Who are the key players in negative pressure wound therapy market? ▼

What are the factors driving the negative pressure wound therapy market? ▼

How big is the negative pressure wound therapy market? ▼

What is the negative pressure wound therapy market growth? ▼

Which segment accounted for the largest negative pressure wound therapy market share? ▼

 Key questions answered by the report

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## Office Address

📍 Grand View Research is registered in the State of California at Grand View Research, Inc. 201 Spear Street 1100, San Francisco, CA 94105, United States

☎ +1-415-349-0058 (tel:1-415-349-0058) or 1-888-202-9519 (tel:1-888-202-9519)

✉ [sales@grandviewresearch.com](mailto:sales@grandviewresearch.com) (mailto:sales@grandviewresearch.com)

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