(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 December 2019 (26.12.2019)

WIPO | PCT

(10) International Publication Number
WO 2019/245591 A1

(51) International Patent Classification:
A61F 2/12 (2006.01) *F21V 21/092* (2006.01)
A47L 5/16 (2006.01)

(21) International Application Number:
PCT/US2018/047724

(22) International Filing Date:
23 August 2018 (23.08.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/687,288 20 June 2018 (20.06.2018) US
62/695,418 09 July 2018 (09.07.2018) US

(71) Applicant: **KIM MEDICAL DESIGN LLC** [US/GB]; 1230 Beimar Lane, Lexington, KY 40515 (US).

(72) Inventors: **KIM, David, S.**; 4858 Hartland Parkway, Lexington, KY 40515 (US). **MAUDSLEY, Kevin, J.**; 3821 Gillespies Glen, Lexington, KY 40515 (US).

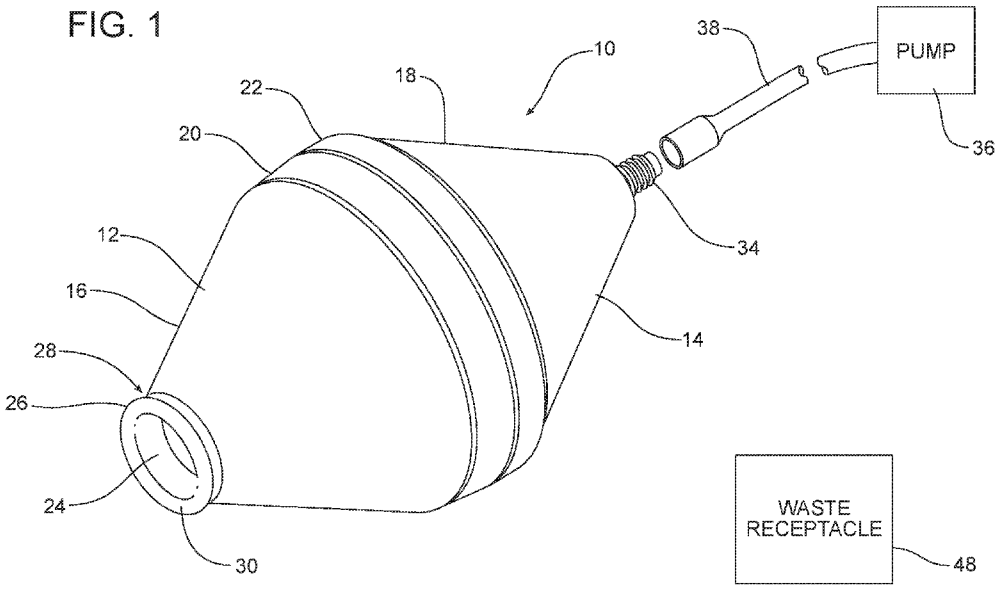
(74) Agent: **HARGIS, Michael, S.** et al.; King & Schickli, PLLC, 800 Corporate Drive, Suite 200, Lexington, KY 40503 (US).

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

WO 2019/245591 A1

(54) Title: BREAST IMPLANT REMOVAL DEVICE AND RELATED METHODS

FIG. 1



(57) Abstract: A device for removing a breast implant from a patient includes a housing defining an interior chamber for receiving the breast implant. The housing includes a distal portion, a proximal portion defining an orifice through which the breast implant passes during removal, and a suction port. The orifice is defined such that a seal is formed between the housing and the breast implant during removal of the breast implant. A related method of removing a breast implant of a patient includes the steps of exposing the breast implant, positioning the orifice of the housing in contact with the breast implant, and applying suction to the housing sufficient to draw the breast implant through the orifice.

[Continued on next page]

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

Published:

— *with international search report (Art. 21(3))*

BREAST IMPLANT REMOVAL DEVICE AND RELATED METHODS

[0001] This application claims the benefit of U.S. Provisional Patent Application Nos. 62/687,288, filed June 20, 2018, and 62/695,418, filed July 9, 2018, the disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] This document relates generally to breast prostheses or implants, and more specifically with the removal of breast implants.

BACKGROUND OF THE INVENTION

[0003] Breast implants, also known as breast prostheses, have been successfully utilized since the 1960's. The implants consist of an outer elastomeric shell and a fill material. In most implants, the fill material is a silicone polymer. From time to time, it may become necessary to remove a breast implant. The most often encountered reason for doing so is a malfunction of the implant, for example, a leak of the silicone fill material outside of the outer shell.

[0004] As time progresses, the outer elastomer shell of some breast implants may deteriorate allowing the fill material to leak out. This process is commonly known as gel bleed. In other circumstances, a frank disruption of the outer elastomeric shell occurs leading to direct leakage of the fill material. Other circumstances can also be indications for implant removal including, but not limited to, capsular contracture, implant malposition, a patient's desire for size change, and/or a patient's desire for implant removal.

[0005] Regardless of the indication for removal, actually removing the breast implant from the scar pocket, commonly known as a capsule, which naturally forms and surrounds the breast implant can present a technical and often time-consuming challenge in the operating room. More specifically, the breast implant must be brought out through a small opening in the scar pocket and skin and, preferably, removed intact. Grasping the implant digitally or with an instrument such as a clamp can lead to, or enlarge, an existing tear in the outer elastomeric shell of the implant. This is particularly true in cases of ruptured or leaking implants where the outer shell can be extremely

fragile and/or partially or fully disintegrated. In such cases, removal of a ruptured or leaking breast implant and leaked material can require significant amounts of operating room time to complete.

[0006] The difficulty of removal is exacerbated by the fill material, which is commonly a silicone polymer and has a tendency to adhere to everything including, for example, breast tissue, skin, surgeon's gloves, and/or surgical instruments. As such, the silicone polymer fill material is difficult to work with and contain and requires a significant effort to clean from breast tissue and surgical instruments. Further complicating matters, fill material or gel left within the breast pocket can lead to granuloma formation which can create palpable and visible irregularities.

[0007] Accordingly, a need exists for a device and related method of efficiently removing an intact or a ruptured breast implant while containing the fill material.

SUMMARY OF THE INVENTION

[0008] In accordance with the purposes and benefits described herein, a method of removing a breast implant of a patient, includes the steps of: exposing the breast implant; positioning an orifice of a housing in contact with the breast implant; and applying suction to the housing sufficient to draw the breast implant through the orifice.

[0009] In another possible embodiment, the step of applying a positive air pressure to the housing includes connecting an air line to a connector attached to the housing.

[0010] In yet another possible embodiment, the method further includes the step of assembling first and second portions of the housing.

[0011] In another possible embodiment, the housing defines an interior chamber for receiving the breast implant.

[0012] In yet another possible embodiment, the housing includes a proximal portion defining the orifice.

[0013] In still another possible embodiment, the housing includes a suction port.

[0014] In yet still another possible embodiment, the step of applying suction to the housing sufficient to draw the breast implant through the orifice includes the step of connecting in-wall suction to the suction port.

[0015] In one other possible embodiment, the step of applying suction to the housing sufficient to draw the breast implant through the orifice includes the step of connecting one of a vacuum pump, a syringe, or a hand operated pump to the suction port.

[0016] In another possible embodiment, the suction port is positioned on a distal portion of the housing.

[0017] In yet one other possible embodiment, the suction port is positioned on a distal end of the housing.

[0018] In another possible embodiment, the suction port extends from a distal end of the housing.

[0019] In yet another possible embodiment, the suction port is a barbed connector.

[0020] In still another possible embodiment, the step of connecting in-wall suction to the suction port includes connecting tubing between the in-wall suction and the suction port.

[0021] In yet still another possible embodiment, the step of connecting one of a vacuum pump, a syringe, and a hand operated pump a vacuum pump to the suction port includes connecting tubing between the one of the vacuum pump, the syringe, and the hand operated pump and the suction port.

[0022] In one other possible embodiment, the step of connecting one of a vacuum pump, a syringe, and a hand operated pump to the suction port includes connecting tubing between the one of the vacuum pump, the syringe, and the hand operated pump and the barbed connector.

[0023] In another possible embodiment, the step of exposing the breast implant includes the step of making an incision through the patient's skin.

[0024] In yet another possible embodiment, the step of exposing the breast implant includes the step of making an incision through a capsule at least partially surrounding the breast implant.

[0025] In one other possible embodiment, the housing includes a ring.

[0026] In another possible embodiment, the ring extends from the housing.

[0027] In yet another possible embodiment, the ring includes a rounded inner edge defining the orifice of the housing.

[0028] In still another possible embodiment, the ring includes an outer lip.

[0029] In yet still another possible embodiment, the step of positioning an orifice of a housing in contact with the breast implant includes positioning the ring in contact with the breast implant.

[0030] In one other possible embodiment, the step of exposing the breast implant includes the step of making an incision through the patient's skin, and wherein the step of positioning the ring in contact with the breast implant includes the step of inserting the ring through the incision in the patient's skin.

[0031] In another possible embodiment, the step of positioning the ring in contact with the breast implant includes the step of positioning the ring such that edges created by the incision in the patient's skin rest behind the ring during removal of the breast implant.

[0032] In yet one other possible embodiment, the step of exposing the breast implant includes the step of making an incision through the patient's skin and a capsule at least partially surrounding the breast implant, and wherein the step of positioning the ring in contact with the breast implant includes the step of inserting the ring through the incisions in the patient's skin and the capsule.

[0033] In another possible embodiment, the step of positioning the ring in contact with the breast implant includes the step of positioning the ring such that edges created by the incision in the capsule rest behind the ring during removal of the breast implant.

[0034] In yet another possible embodiment, the ring is integrally formed with the housing.

[0035] In yet still another possible embodiment, the step of assembling first and second portions of the housing.

[0036] In one other possible embodiment, the method further includes the step of performing a partial capsulectomy.

[0037] In another possible embodiment, the step of performing a partial capsulectomy occurs prior to removal of the breast implant.

[0038] In yet one other possible embodiment, the method further includes the step of performing a total capsulectomy.

[0039] In another possible embodiment, the step of performing a total capsulectomy occurs prior to removal of the breast implant.

[0040] In yet another possible embodiment, the step of applying suction to the housing sufficient to draw the breast implant through the orifice includes the step of applying suction to the housing sufficient to draw the breast implant and the capsule through the orifice.

[0041] In yet still another possible embodiment, the method further includes the step of disposing of the breast implant into a waste receptacle.

[0042] In yet still another possible embodiment, the method further includes the step of disposing of the housing, including the removed breast implant, into a waste receptacle.

[0043] In an additional embodiment, a device for removing a breast implant from a patient is provided. The device includes a housing defining an interior chamber for receiving the breast implant. The housing includes a distal portion, a proximal portion defining an orifice through which the breast implant passes during removal, and a suction port, wherein the orifice is defined such that a seal is formed between the housing and the breast implant during removal of the breast implant.

[0044] In another possible embodiment, the housing includes a ring.

[0045] In yet another possible embodiment, the ring is fixed in position.

[0046] In yet still another possible embodiment, the ring extends from the housing.

[0047] In one other possible embodiment, a neck is formed between the ring and the proximal portion of the housing.

[0048] In another possible embodiment, the neck extends the ring and the orifice away from the distal portion of the housing.

[0049] In yet one other possible embodiment, the ring includes a rounded inner edge defining the orifice of the housing.

[0050] In another possible embodiment, the ring includes an outer lip.

[0051] In yet another possible embodiment, the ring is integrally formed with the housing.

[0052] In yet still another possible embodiment, the suction port extends from the distal portion of the housing.

[0053] In one other possible embodiment, the proximal portion and the distal portion are separable.

[0054] In another possible embodiment, the proximal portion and the distal portion are halves.

[0055] In yet one other possible embodiment, the proximal portion and the distal portion are frustoconically shaped.

[0056] In yet still another possible embodiment, the proximal portion and the distal portion are shaped to accommodate nesting one within the other when not in use.

[0057] In one other possible embodiment, the suction port extends through the orifice when the distal and proximal portions are in a nested position.

[0058] In another possible embodiment, the proximal portion and the distal portion are threaded for connecting the proximal portion and the distal portion.

[0059] In yet one other possible embodiment, the device further includes one of a vacuum pump, a syringe, and a hand operated pump.

[0060] In another possible embodiment, the device further includes tubing for connecting the one of the vacuum pump, the syringe, and the hand operated pump to the suction port.

[0061] In yet another possible embodiment, the device further includes at least one grip.

[0062] In yet still another possible embodiment, the at least one grip is a detent formed in the housing.

[0063] In one other possible embodiment, the at least one grip is elevated.

[0064] In another possible embodiment, the elevated grip is a rubber material.

[0065] In an additional embodiment, a device for removing a breast implant from a patient is provided. The device includes a housing defining an interior chamber for receiving the breast implant. The housing includes distal and proximal portions, a ring attached to the proximal portion and defining an orifice through which the breast implant passes during removal, and a suction port. The orifice is defined such that a seal is formed between the ring and the breast implant during removal of the breast implant.

[0066] In another possible embodiment, the ring is fixed in position.

[0067] In yet another possible embodiment, the ring extends from the housing.

[0068] In yet still another possible embodiment, a neck is formed between the ring and the proximal portion of the housing.

[0069] In one other possible embodiment, the neck extends the ring away from the distal portion of the housing.

[0070] In another possible embodiment, the ring includes a rounded inner edge defining the orifice.

[0071] In yet one other possible embodiment, the ring includes an outer lip.

[0072] In still yet another possible embodiment, the ring is integrally formed with the housing.

[0073] In one other possible embodiment, the suction port extends from the distal portion of the housing.

[0074] In another possible embodiment, the proximal portion and the distal portion are separable.

[0075] In yet another possible embodiment, the proximal portion and the distal portion are halves.

[0076] In another possible embodiment, the proximal portion and the distal portion are frustoconically shaped.

[0077] In yet one other possible embodiment, the proximal portion and the distal portion are shaped to accommodate nesting one within the other when not in use.

[0078] In yet still another possible embodiment, the suction port extends at least partially through the ring when the distal and proximal portions are in a nested position.

[0079] In one other possible embodiment, the proximal portion and the distal portion are threaded for connecting the proximal portion and the distal portion.

[0080] In another possible embodiment, the device further includes one of a vacuum pump, a syringe, and a hand operated pump.

[0081] In still another possible embodiment, the device further includes tubing for connecting the one of the vacuum pump, the syringe, and the hand operated pump to the suction port.

[0082] In yet still another possible embodiment, the device further includes at least one grip.

[0083] In still another possible embodiment, the at least one grip is a detent formed in the housing.

[0084] In one other possible embodiment, the at least one grip is elevated. In another, the elevated grip is a rubber material.

[0085] In the following description, there are shown and described several preferred embodiments of a device for removing a breast implant and related methods of removing a breast implant of a patient. As it should be realized, the devices and methods are capable of other, different embodiments and their several details are capable of modification in various, obvious aspects all without departing from the methods and devices as set forth and described in the following claims. Accordingly, the drawings and descriptions should be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

[0086] The accompanying drawing figures incorporated herein and forming a part of the specification, illustrate several aspects of the invention and together with the description serve to explain certain principles thereof. In the drawing figures:

[0087] Figure 1 is a perspective view of a device for removing a breast implant;

[0088] Figure 2 is a perspective view of an end of the breast implant removal device showing a proximal orifice having a rounded lip; and

[0089] Figure 3 is a perspective view of a side of the breast implant removal device shown in a partially disassembled state;

[0090] Figure 4 is a cross sectional view of the breast implant removal device showing the proximal orifice in contact with a breast implant at an initial stage of the implant removal process; and

[0091] Figure 5 is a perspective view of an alternate embodiment of a unitary breast removal device.

[0092] Reference will now be made in detail to the present preferred embodiments of the device and related methods for removing breast implants, examples of which are illustrated in the accompanying drawing figures, wherein like numerals are used to represent like elements.

DETAILED DESCRIPTION

[0093] Reference is now made to Figure 1 which illustrates a device 10 for removing a breast implant (I) from a patient. The breast implant may be removed intact or when leaking fill material. References to breast implants within this specification refer to the breast implant including the outer elastomeric shell and the fill material, whether the shell is intact or the fill material has leaked out of the shell, and/or a capsule which naturally forms at least partially around breast implants. In other words, a reference to contacting the breast implant (I) includes contacting the fill material if leaked out, the outer shell, and/or the capsule.

[0094] The device 10 consists of a first, proximal portion 12 and a second, distal portion 14 which together form a housing. In the described embodiment, the proximal and distal portions are generally halves which are separable. Each portion 12, 14 consists primarily of a solid wall 16, 18 and together define an interior chamber for receiving the breast implant (I). Other embodiments of the device 10, however, may include a unitary housing wherein the proximal and distal portions are not separable.

[0095] Each of the proximal and distal portions 12, 14 are generally frustoconical in shape, in the described embodiment, and join together to form the housing along base ends 20, 22. Of course, other shapes (e.g., round, oval, oblong, conical, at least partially cylindrical, etc.) may be utilized. Overall, any shape may be utilized, and the shape of the proximal and distal portions 12, 14 should be selected to accommodate the volume of the breast implant (I) and provide sufficient mechanical strength to avoid a collapse of the device 10 under vacuum pressure which is the driving force for removal or extraction of the breast implant.

[0096] The total volume of the interior chamber, adding both proximal and distal portions 12, 14 together, should be sufficient to remove large-sized breast implants. In other words, the volume of the chamber is at least 600 cc capacity or greater, in the described embodiment, to accommodate the removal of large-sized breast implants. Of course, other embodiments may utilize smaller chamber volumes and/or specifically sized chamber volumes on a patient to patient basis.

[0097] As shown in Figures 1 and 2, the proximal portion 12 of the housing defines an orifice, designated reference numeral 24, through which the breast implant (I) passes during removal. More specifically, the orifice 24 is positioned in contact with the breast implant (I) during the removal process such that a seal is formed between the housing and the breast implant sufficient to allow vacuum pressure to draw the breast implant from the patient and into the housing.

[0098] In the described embodiment, the housing includes an integrally formed ring 26 that is fixed in position and extends from the proximal portion 12 of the housing. In this position, best shown in Figure 3, a neck 28 is formed between the ring 26 and the proximal portion 12 of the housing such that the neck extends the ring and the orifice 24 away from the distal portion 14 of the housing.

[0099] As shown, the described ring 26 includes a rounded inner edge 30 that defines the orifice 24 in one embodiment. Other embodiments may not utilize a ring and the proximal portion itself may define the orifice. The rolled inner edge 30 provides a substantially smooth and mechanically advantageous ingress for the breast implant (I) being removed. The ring 26, including the rolled inner edge 30, may be made of a lubricious material or a medical lubricant may be applied thereto to limit friction between the breast implant (I), possibly leaked/leaking fill material (M), and the rolled inner edge as the implant passes through the orifice 24 during the removal process.

[00100] The described ring 26 also includes a flared, rounded, or rolled outer lip 32 as shown in Figures 1 and 3. The outer lip 32 helps to assist with a smooth insertion into an incision in the patient's skin (D) and, possibly, a capsulotomy incision. Further, the outer lip 32 assists with retention of the device 10 within the incision(s) and maintains edges of incision(s) in an open position when the ring/orifice 24 is positioned in contact with the breast implant (I) during removal. In other words, the ring 26 is inserted through the incision(s) and positioned such that the ring is contacting the breast implant (I). In this position, the incision edges extend around the outer lip 32 and rest behind the ring 26 which is generally adjacent the neck 28. While the ring 26 and defined orifice are described as round in one embodiment, the orifice and/or ring may take essentially any shape including, for example, oval or oblong.

[00101] As shown in Figures 1 and 3, a suction port 34 extends from the distal portion 14 of the housing in the described embodiment. The suction port 34, however, may be positioned in any location on the housing. The suction port 34 is a nipple or barbed connector, in the described embodiment, designed to receive tubing connected to a suction source 36 (e.g., a vacuum pump, a syringe, and/or a hand operated pump). Various other connectors may be used to connect the device 10 to a suction source as is known in the art. In the described embodiment, the suction source 36 is a vacuum pump. Operating rooms typically provide a suction source which may be a vacuum pump located in a remote area or within the operating room itself. In some instances, portable vacuum pumps, syringes, or even hand operated pumps may be supplied with the device 10 for utilization in operating rooms which are void of a suitable suction source. In each instance, however, the device 10 is connected to the suction source 36 utilizing tubing 38 as shown in Figure 1.

[00102] At a distal end 32 of the distal half 14, shown in Figures 1 and 4, a nipple or barbed connector 34 receives a hose (not shown) to provide vacuum pressure for use in removal and/or forced air for use in the insertion process. Vacuum and air sources and/or hoses are universally available for surgical procedures in operating rooms. In alternate embodiments, a tube or hose may extend from the housing with the connector attached thereto for mating with a vacuum/fluid hose or vacuum/fluid source connector.

[00103] As shown in Figure 3 and noted above, the proximal and distal portions 12, 14 are separable and generally frustroconical in shape in the described embodiment. This shape, and others, accommodate nesting of the portions one within the other when not in use. In one embodiment, the suction port 34 extends through the orifice 24 when the distal and proximal portions are in the nested position. Nesting the portions in general is particularly useful for packaging the preoperative device 10. Of course, other shapes may be utilized so long as they provide sufficient mechanical rigidity under vacuum pressure or the device may be a unitary structure as described above.

[00104] As further shown, the proximal portion 12 and the distal portion 14 are connected by a simple threaded mechanism. The connection between the two portions 12, 14 provided by the mechanism is air tight in order to maintain vacuum pressure and also prevent leaking of any silicone polymer fill material received within the device 10. More specifically, a distal end 40 of the proximal portion 12 has a screw thread 42 that combines with a mating screw thread 44 of the distal portion 14 forming the connection. Of course, other types of mechanical connections may be utilized in lieu of the threaded mechanism in alternate embodiments such as, but not limited to, press fit connections, friction fit connections, butt connections with a separate connection ring, or a compression band. Further, gaskets or O rings may be utilized in all such embodiments to ensure an air tight seal or the above-described unitary design may be utilized.

[00105] As an added convenience, one or more grips 46 may be provided on one or both of the proximal and distal portions 12, 14 to assist the user in assembly and disassembly thereof. As best shown in Figures 3 and 4, the grips 46 may be detents formed in the one or both portions 12, 14. While shown as generally oval in shape in the described embodiment, the grips 46 may take any shape sufficient to provide improved gripping of the portions 12, 14 during use and/or assembly/disassembly. Even more, the grips may be elevated (not shown) extending above an

outer surface of the housing. The elevated grips may be made of a rubber or like material and may provide a rigid and/or a tacky feel for the user. Of course, other types and numbers of grips may be utilized in alternate embodiments.

[00106] As noted above, a device 50 may be a unitary structure as shown in Figure 5. In other words, the device 50 may be a single piece unit thereby eliminating threaded mechanism 36 between the proximal and distal portions 12, 14 of the earlier described device 10. The alternate device 50 similarly includes proximal and distal portions 52, 54 which define an interior chamber, and generally includes walls, 56, 58, a defined orifice 60, a suction port 62, and a ring 64 in at least the described embodiment. Other than the unitary nature of the housing, the device 50 is the same as the above described embodiment and alternative embodiments thereof. Even more, the unitary device 50 is intended for disposal after a single use.

[00107] In all embodiments, caps (not shown) may be provided to seal off the proximal opening and/or distal suction port prior to and/or post operation. In addition, the devices 10, 50 may be created using materials suitable for biohazardous waste disposal.

[00108] The method of removing a breast implant (I) of a patient referred to above in describing devices used therein includes the steps of exposing the breast implant, positioning an orifice of the device in contact with the breast implant, and applying suction to the device sufficient to draw the breast implant through the orifice. The method is further described with reference to an embodiment of the device 10 described above.

[00109] The device 10 is supplied in a sterile condition. The user first assembles the two portions 12, 14 of the device 10 together using the threaded mechanism 36. Once together, the device 10 is ready for use. Surgically, a capsule (C) which naturally forms at least partially around the breast implant (I) is exposed via incisions through skin (S), breast tissue (T), and muscle depending on the placement of the breast implant. If a partial or total capsulectomy procedure is to be completed, the desired steps may be performed prior to or after removal of the breast implant (I).

[00110] As part of the described removal process, a capsulotomy incision is created in the capsule (C) thereby directly exposing the breast implant (I). The capsulotomy incision is necessarily sized large enough to admit the ring 26 in the described method. This allows for direct

contact between the device 10 and the breast implant (I) which necessarily includes the outer shell (S) and/or fill material (M) if the outer shell of the breast implant (I) has dissolved or is disrupted. In other words, the orifice 24 of the device 10 is positioned in contact with the breast implant.

[00111] In the described method, the ring 26 defines the orifice and is positioned in contact with the breast implant (I) by inserting the ring through the incision in the patient's skin (D) and capsule (C). In alternate methods, the capsule (C) may not be breached and the ring 26 may be inserted through the incision in the patient's skin (D) and positioned in contact with the capsule.

[00112] With the ring 26 inserted through the incision in the patient's skin (D) and capsule (C) and positioned in contact with the breast implant (I), the outer lip 30 of the ring 26 assists with retention of the device 10 within the incision(s) and maintains edges of the incision(s) in an open position. In other words, edges created by the incision in the patient's skin (D) extend around the outer lip 32 and rest behind the ring 26 during removal of the breast implant (I). Again, if an incision is made in the capsule (C), then edges of the capsule incision likewise rest behind the ring 26. Even more specifically, edges of the incision(s) rest in a recess behind the ring 28 which is generally adjacent the neck 28.

[00113] Subsequent to inserting the ring 26 and positioning the orifice 24 in contact with the breast implant (I), a suction source 36 is connected to the suction port 34. As described above, the suction port 34 may be a nipple or barbed connector 34, for example, which is positioned at the distal end of the distal portion 14 of the device 10 in the described embodiment. In the described embodiment, tubing 38 is utilized to connect the suction port 34 to the suction source 36. Again, the suction source 36 may be a vacuum pump 36 provided with the device 10 or located in an operating room or in a basement of a building wherein the operating room is located. In alternative embodiments, a syringe or hand operated vacuum source may be utilized as the suction source. In other words, a suction source may be provided with the device or an existing suction source may be utilized by connecting the device thereto.

[00114] Once connected, the suction source 36 is initiated applying suction to the housing sufficient to draw the breast implant (I) through the orifice. In other words, the suction source 36 is initiated drawing air out of the internal chamber of the device 10 through the tubing 38. The negative pressure created by the vacuum draws the implant (I) through the orifice 26 in the ring

26 or proximal portion 12 and into the internal chamber of the device (10). For reference, the breast implant (I) being removed will move along a proximal to distal direction during the removal process.

[00115] The natural cohesivity of the implant (I) including its outer shell (S) and fill material (M) ensure that the entire implant, including any leaked fill material or gel, is drawn into the interior chamber of the housing. In addition, if the capsule (C) has been fully mobilized from its surrounding soft tissue attachments prior to removal of the implant (I), the capsule typically accompanies the breast implant (I) into the interior chamber. In other words, the suction applied to the housing is sufficient to draw the breast implant (I) and the capsule (C) through the orifice. It should be noted that the suction source 36 can be connected to the suction port 34 prior to insertion of the ring 26 and/or positioning of the orifice in contact with the breast implant (I). Similarly, the suction source 36 may be initiated at any time throughout the process.

[00116] If the user desires to inspect the breast implant (I) now contained in the interior chamber of the device 10, then the proximal and distal portions 12, 14 may be separated opening the device and granting access to the breast implant. If the breast implant (I) is intact, it may be removed from the interior chamber for further inspection and/or disposal into a suitable biohazardous waste receptacle 48. The two portions 12, 14 of the device 10 may then be reassembled, and the same device may be used to remove a contralateral breast implant, if desired.

[00117] In the event the breast implant (I) is ruptured or there has been substantial gel bleed, it is recommended not to remove the breast implant from the interior chamber as doing so may expose the operative field to the sticky polymer fill material (M) or gel. Rather, the breast implant (I) and device 10 may be disposed of within the biohazardous waste receptacle 48 with or without caps applied to the ring 26 and/or distal suction port 34 as desired to seal the breast implant (I) within the interior chamber. A new removal device 10 may be used for extraction of the contralateral breast implant. In the event the one-piece alternate embodiment of the device 50 is utilized, it is preferable to use one removal device 50 per breast implant (I). In this scenario, the breast implant (I) resident in the interior chamber of the device 50 may not be taken out for inspection or otherwise.

[00118] The foregoing has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the embodiments to the precise form disclosed. Obvious modifications and variations are possible in light of the above teachings. For instance, the integrally formed ring that is fixed in position and extends from the proximal portion of the housing may not be integrally formed. The ring and a neck section extending therefrom may be attached to the proximal portion 12 of the device 10. For example, the ring and neck section may be screwed into the proximal portion 12 such that removal is possible. In this manner, the ring may extend any desired distance from the proximal portion 12 subject only to the length of the neck.

[00119] In another possible modification, if a partial or total capsulectomy procedure is to be completed, the desired procedure may be performed prior to or after removal of the breast implant (I). Even more, the above-described devices may be sized to accommodate two breast implants such that removal of a first removed implant prior to removal of a contralateral implant or utilization of two devices is unnecessary. All such modifications and variations are within the scope of the appended claims when interpreted in accordance with the breadth to which they are fairly, legally and equitably entitled.

WHAT IS CLAIMED:

1. A method of removing a breast implant of a patient comprising the steps of:
exposing the breast implant;
positioning an orifice of a housing in contact with the breast implant; and
applying suction to the housing sufficient to draw the breast implant through the orifice.

2. The method of removing a breast implant of a patient of claim 1, wherein the housing defines an interior chamber for receiving the breast implant.

3. The method of removing a breast implant of a patient of any of claims 1-2, wherein the housing includes a proximal portion defining the orifice.

4. The method of removing a breast implant of a patient of any of claims 1-3, wherein the housing includes a suction port.

5. The method of removing a breast implant of a patient of claim 4, wherein the step of applying suction to the housing sufficient to draw the breast implant through the orifice includes the step of connecting in-wall suction to the suction port.

6. The method of removing a breast implant of a patient of claim 4, wherein the step of applying suction to the housing sufficient to draw the breast implant through the orifice includes the step of connecting one of a vacuum pump, a syringe, and a hand operated pump to the suction port.

7. The method of removing a breast implant of a patient of any of claims 4-6, wherein the suction port is positioned on a distal portion of the housing.

8. The method of removing a breast implant of a patient of any of claims 4-7, wherein the suction port is positioned on a distal end of the housing.

9. The method of removing a breast implant of a patient of any of claims 4-7, wherein the suction port extends from a distal end of the housing.

10. The method of removing a breast implant of a patient of any of claims 4-9, wherein the suction port is a barbed connector.

11. The method of removing a breast implant of a patient of claim 5, wherein the step of connecting in-wall suction to the suction port includes connecting tubing between the in-wall suction and the suction port.

12. The method of removing a breast implant of a patient of claim 6, wherein the step of connecting a vacuum pump to the suction port includes connecting tubing between one of the vacuum pump, the syringe, and the hand operated pump and the suction port.

13. The method of removing a breast implant of a patient of claim 10, wherein the step of connecting one of a vacuum pump, a syringe, and a hand operated pump to the suction port includes connecting tubing between the one of the vacuum pump, the syringe, and the hand operated pump and the barbed connector.

14. The method of removing a breast implant of a patient of claim 1, wherein the step of exposing the breast implant includes the step of making an incision through the patient's skin.

15. The method of removing a breast implant of a patient of claim 14, wherein the step of exposing the breast implant includes the step of making an incision through a capsule at least partially surrounding the breast implant.

16. The method of removing a breast implant of a patient of any of claims 14-15, wherein the housing defines an interior chamber for receiving the breast implant.

17. The method of removing a breast implant of a patient of any of claims 14-16, wherein the housing includes a proximal portion defining the orifice.

18. The method of removing a breast implant of a patient of any of claims 14-17, wherein the housing includes a suction port.

19. The method of removing a breast implant of a patient of claim 18, wherein the step of applying suction to the housing sufficient to draw the breast implant through the orifice includes the step of connecting in-wall suction to the suction port.

20. The method of removing a breast implant of a patient of claim 18, wherein the step of applying suction to the housing sufficient to draw the breast implant through the orifice includes

the step of connecting one of a vacuum pump, a syringe, and a hand operated pump to the suction port.

21. The method of removing a breast implant of a patient of any of claims 18-20, wherein the suction port is positioned on a distal portion of the housing.

22. The method of removing a breast implant of a patient of any of claims 18-20, wherein the suction port is positioned on a distal end of the housing.

23. The method of removing a breast implant of a patient of any of claims 18-20, wherein the suction port extends from a distal end of the housing.

24. The method of removing a breast implant of a patient of any of the claims 18-23, wherein the suction port is a barbed connector.

25. The method of removing a breast implant of a patient of claim 19, wherein the step of connecting in-wall suction to the suction port includes connecting tubing between the in-wall suction and the suction port.

26. The method of removing a breast implant of a patient claim 20, wherein the step of connecting one of a vacuum pump, a syringe, and a hand operated pump to the suction port includes connecting tubing between the one of the vacuum pump, the syringe, and the hand operated pump and the suction port.

27. The method of removing a breast implant of a patient of any of claims 1-26, wherein the housing includes a ring.

28. The method of removing a breast implant of a patient of claim 27, wherein the ring extends from the housing.

29. The method of removing a breast implant of a patient of any of claims 27-28, wherein the ring includes a rounded inner edge defining the orifice of the housing.

30. The method of removing a breast implant of a patient of any of claims 27-29, wherein the ring includes an outer lip.

31. The method of removing a breast implant of a patient of any of claims 27-30, wherein the step of positioning an orifice of a housing in contact with the breast implant includes positioning the ring in contact with the breast implant.

32. The method of removing a breast implant of a patient of claim 31, wherein the step of exposing the breast implant includes the step of making an incision through the patient's skin, and wherein the step of positioning the ring in contact with the breast implant includes the step of inserting the ring through the incision in the patient's skin.

33. The method of removing a breast implant of a patient of claim 32, wherein the step of positioning the ring in contact with the breast implant includes the step of positioning the ring such that edges created by the incision in the patient's skin rest behind the ring during removal of the breast implant.

34. The method of removing a breast implant of a patient of claim 31, wherein the step of exposing the breast implant includes the step of making an incision through the patient's skin and a capsule at least partially surrounding the breast implant, and wherein the step of positioning the ring in contact with the breast implant includes the step of inserting the ring through the incisions in the patient's skin and the capsule.

35. The method of removing a breast implant of a patient of claim 34, wherein the step of positioning the ring in contact with the breast implant includes the step of positioning the ring such that edges created by the incision in the capsule rest behind the ring during removal of the breast implant.

36. The method of removing a breast implant of a patient of any of claims 27-35, wherein the ring is integrally formed with the housing.

37. The method of removing a breast implant of a patient of any of claims 1-36, further comprising the step of assembling first and second portions of the housing.

38. The method of removing a breast implant of a patient of any of claims 1-37, further comprising the step of performing a partial capsulectomy.

39. The method of removing a breast implant of a patient of claim 38, wherein the step of performing a partial capsulectomy occurs prior to removal of the breast implant.

40. The method of removing a breast implant of a patient of any of claims 1-37, further comprising the step of performing a total capsulectomy.

41. The method of removing a breast implant of a patient of claim 38, wherein the step of performing a total capsulectomy occurs prior to removal of the breast implant.

42. The method of removing a breast implant of a patient of any of claims 38-41, wherein the step of applying suction to the housing sufficient to draw the breast implant through the orifice includes the step of applying suction to the housing sufficient to draw the breast implant and the capsule through the orifice.

43. The method of removing a breast implant of a patient of any of claims 37-42, further comprising the step of disposing of the breast implant into a waste receptacle.

44. The method of removing a breast implant of a patient of any of claims 37-42, further comprising the step of disposing of the housing, including the removed breast implant, into a waste receptacle.

45. A device for removing a breast implant from a patient, comprising:

a housing defining an interior chamber for receiving the breast implant, the housing having a distal portion, a proximal portion defining an orifice through which the breast implant passes during removal, and a suction port, wherein the orifice is defined such that a seal is formed between the housing and the breast implant during removal of the breast implant.

46. The device for removing a breast implant from a patient of claim 45, wherein the housing includes a ring.

47. The device for removing a breast implant from a patient of claim 46, wherein the ring is fixed in position.

48. The device for removing a breast implant from a patient of claim 47, wherein the ring extends from the housing.

49. The device for removing a breast implant from a patient of claim 48, wherein a neck is formed between the ring and the proximal portion of the housing.

50. The device for removing a breast implant from a patient of claim 49, wherein the neck extends the ring and the orifice away from the distal portion of the housing.

51. The device for removing a breast implant from a patient of any of claims 46-50, wherein the ring includes a rounded inner edge defining the orifice of the housing.

52. The device for removing a breast implant from a patient of any of claims 46-51, wherein the ring includes an outer lip.

53. The device for removing a breast implant from a patient of any of claims 46-52, wherein the ring is integrally formed with the housing.

54. The device for removing a breast implant from a patient of any of claims 45-53, wherein the suction port extends from the distal portion of the housing.

55. The device for removing a breast implant from a patient of claims 45-54, wherein the proximal portion and the distal portion are separable.

56. The device for removing a breast implant from a patient of any of claims 45-55, wherein the proximal portion and the distal portion are halves.

57. The device for removing a breast implant from a patient of any of claims 45-56, wherein the proximal portion and the distal portion are frustoconically shaped.

58. The device for removing a breast implant from a patient of any of claims 45-56, wherein the proximal portion and the distal portion are shaped to accommodate nesting one within the other when not in use.

59. The device for removing a breast implant from a patient of claim 58, wherein the suction port extends through the orifice when the distal and proximal portions are in a nested position.

60. The device for removing a breast implant from a patient of claim 55, wherein the proximal portion and the distal portion are threaded for connecting the proximal portion and the distal portion.

61. The device for removing a breast implant from a patient of any of claims 45-60, further comprising one of a vacuum pump, a syringe, and a hand operated pump.

62. The device for removing a breast implant from a patient of claim 61, further comprising tubing for connecting the one of the vacuum pump, the syringe, and the hand operated pump to the suction port.

63. The device for removing a breast implant from a patient of any of claims 45-62, further comprising at least one grip.

64. The device for removing a breast implant from a patient of claim 63, wherein the at least one grip is a detent formed in the housing.

65. The device for removing a breast implant from a patient of claim 63, wherein the at least one grip is elevated.

66. The device for removing a breast implant from a patient of claim 65, wherein the elevated grip is a rubber material.

67. A device for removing a breast implant from a patient, comprising:

a housing defining an interior chamber for receiving the breast implant, the housing having distal and proximal portions, a ring attached to the proximal portion and defining an orifice through which the breast implant passes during removal, and a suction port, wherein the orifice is defined such that a seal is formed between the ring and the breast implant during removal of the breast implant.

68. The device for removing a breast implant from a patient of claim 67, wherein the ring is fixed in position.

69. The device for removing a breast implant from a patient of claim 68, wherein the ring extends from the housing.

70. The device for removing a breast implant from a patient of claim 69, wherein a neck is formed between the ring and the proximal portion of the housing.

71. The device for removing a breast implant from a patient of claim 70, wherein the neck extends the ring away from the distal portion of the housing.

72. The device for removing a breast implant from a patient of any of claims 67-71, wherein the ring includes a rounded inner edge defining the orifice.

73. The device for removing a breast implant from a patient of any of claims 67-72, wherein the ring includes an outer lip.

74. The device for removing a breast implant from a patient of any of claims 67-73, wherein the ring is integrally formed with the housing.

75. The device for removing a breast implant from a patient of any of claims 67-74, wherein the suction port extends from the distal portion of the housing.

76. The device for removing a breast implant from a patient of claims 67-75, wherein the proximal portion and the distal portion are separable.

77. The device for removing a breast implant from a patient of any of claims 67-76, wherein the proximal portion and the distal portion are halves.

78. The device for removing a breast implant from a patient of any of claims 67-77, wherein the proximal portion and the distal portion are frustoconically shaped.

79. The device for removing a breast implant from a patient of any of claims 67-77, wherein the proximal portion and the distal portion are shaped to accommodate nesting one within the other when not in use.

80. The device for removing a breast implant from a patient of claim 79, wherein the suction port extends at least partially through the ring when the distal and proximal portions are in a nested position.

81. The device for removing a breast implant from a patient of claim 76, wherein the proximal portion and the distal portion are threaded for connecting the proximal portion and the distal portion.

82. The device for removing a breast implant from a patient of any of claims 67-81, further comprising one of a vacuum pump, a syringe, and a hand operated pump.

83. The device for removing a breast implant from a patient of claim 82, further comprising tubing for connecting the one of the vacuum pump, the syringe, and the hand operated pump to the suction port.

84. The device for removing a breast implant from a patient of any of claims 67-83, further comprising at least one grip.

85. The device for removing a breast implant from a patient of claim 84, wherein the at least one grip is a detent formed in the housing.

86. The device for removing a breast implant from a patient of claim 84, wherein the at least one grip is elevated.

87. The device for removing a breast implant from a patient of claim 86, wherein the elevated grip is a rubber material.

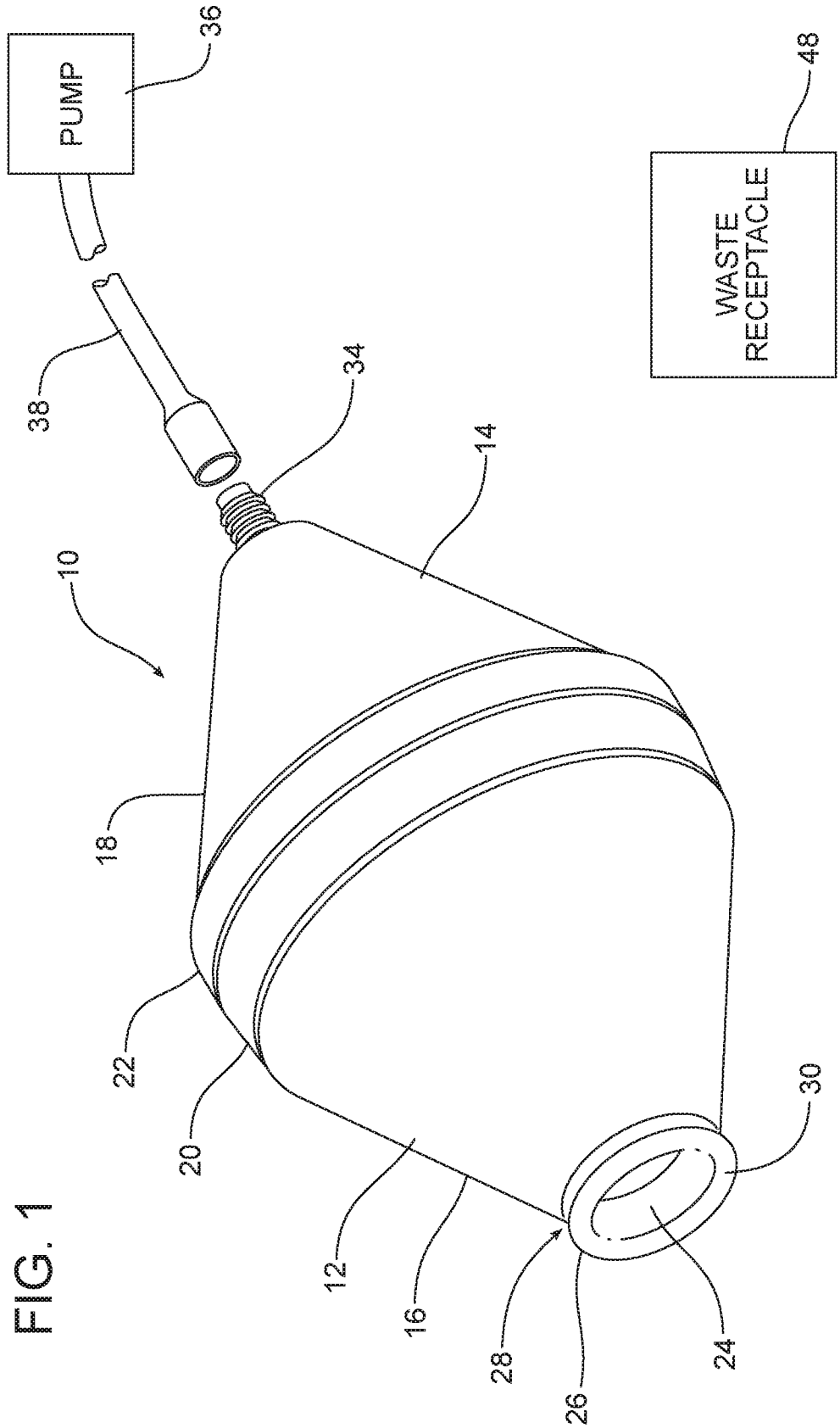
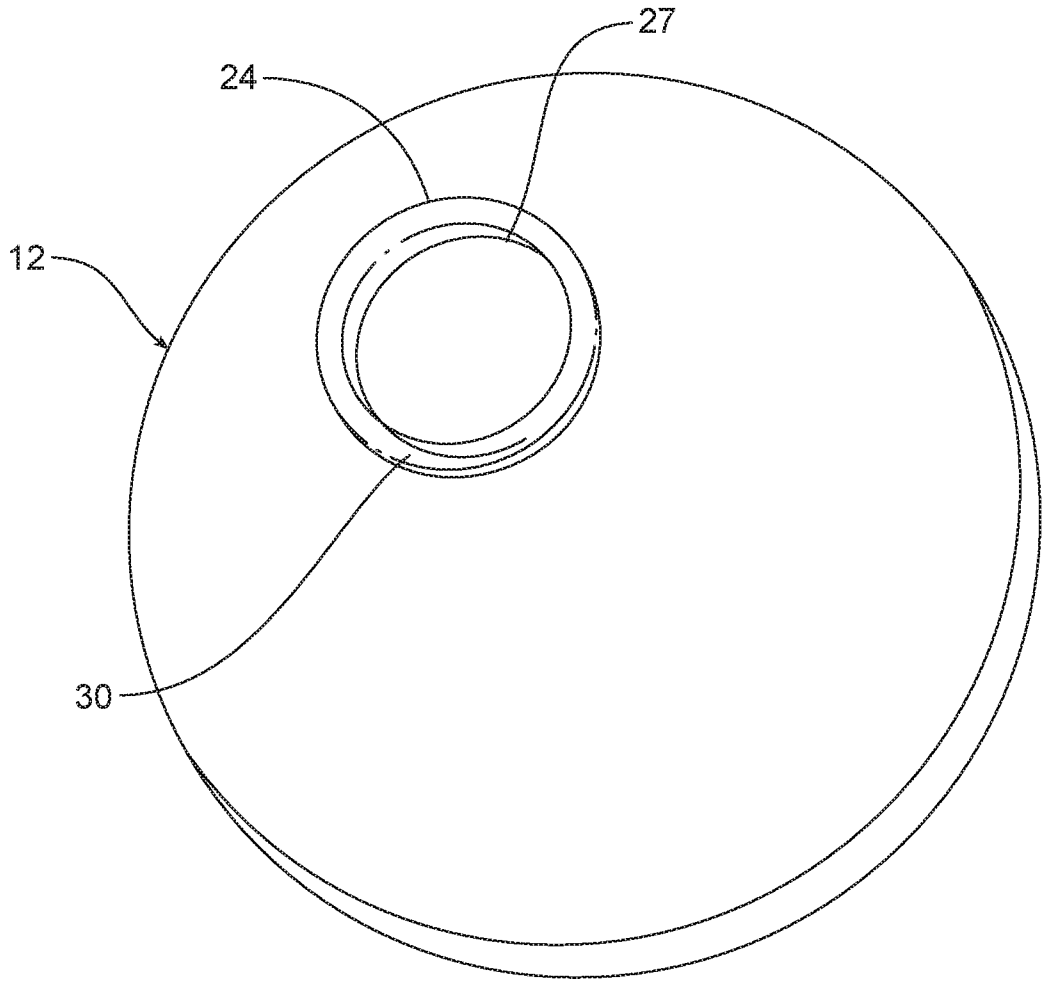


FIG. 1

FIG. 2



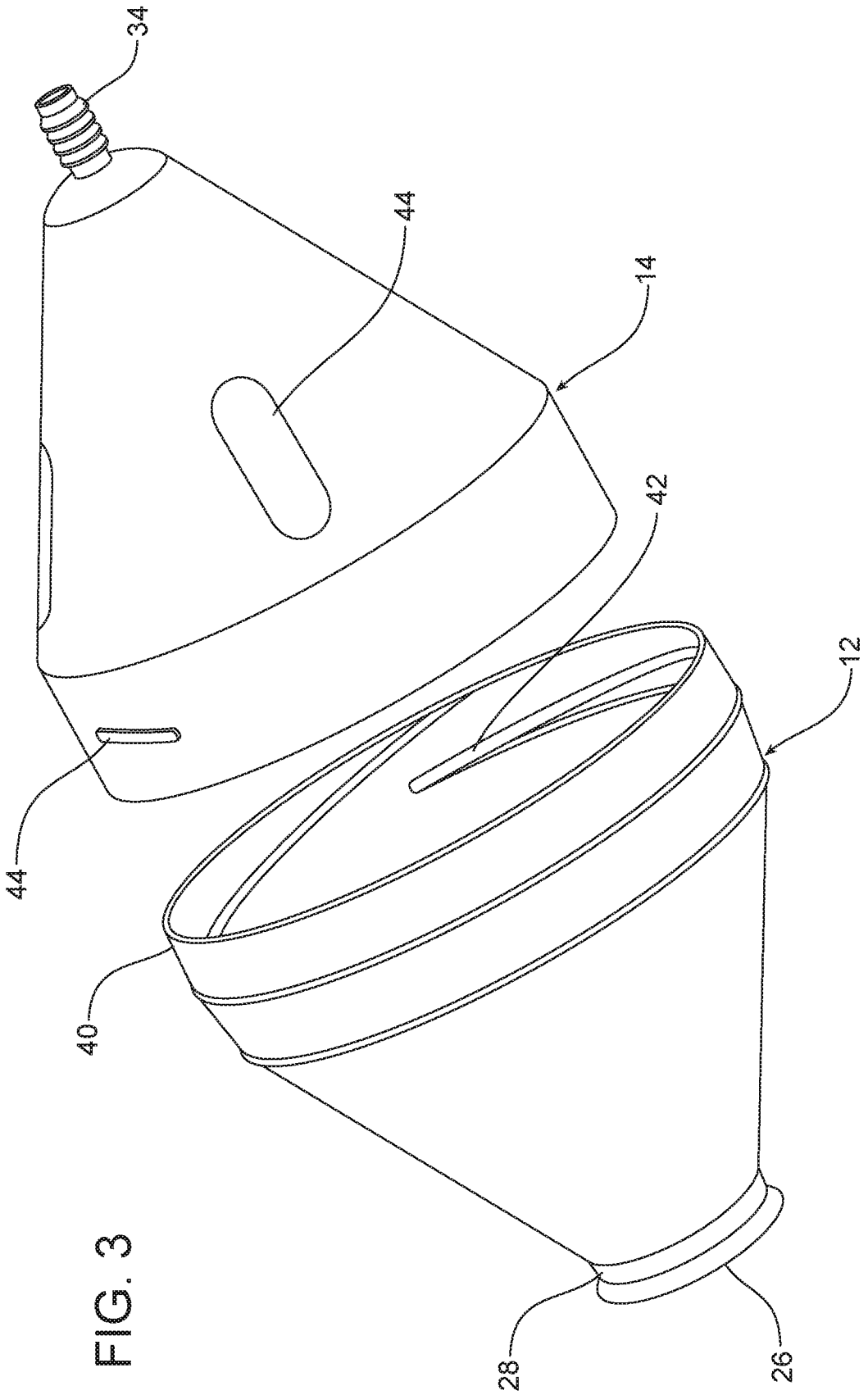


FIG. 3

FIG. 4

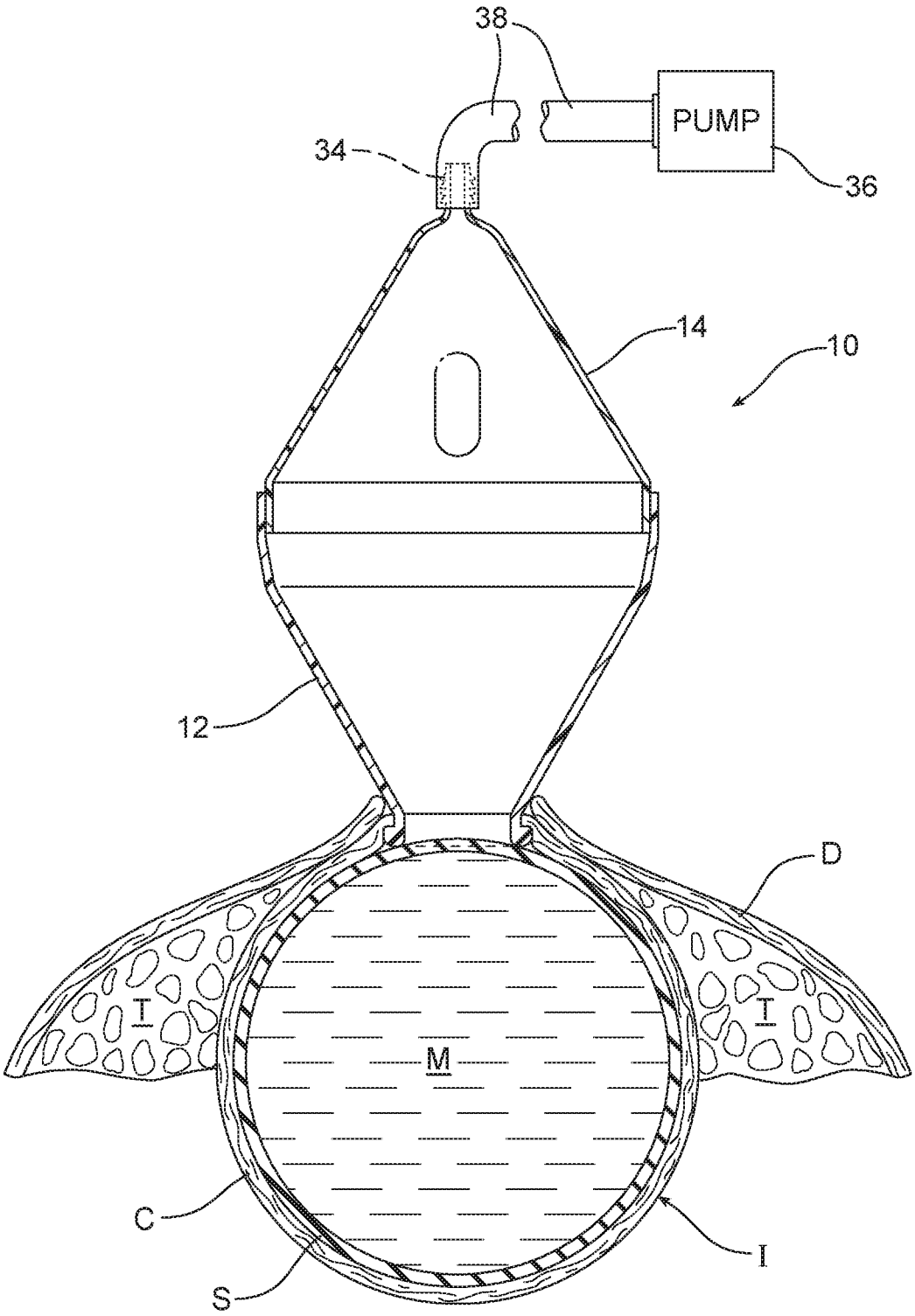
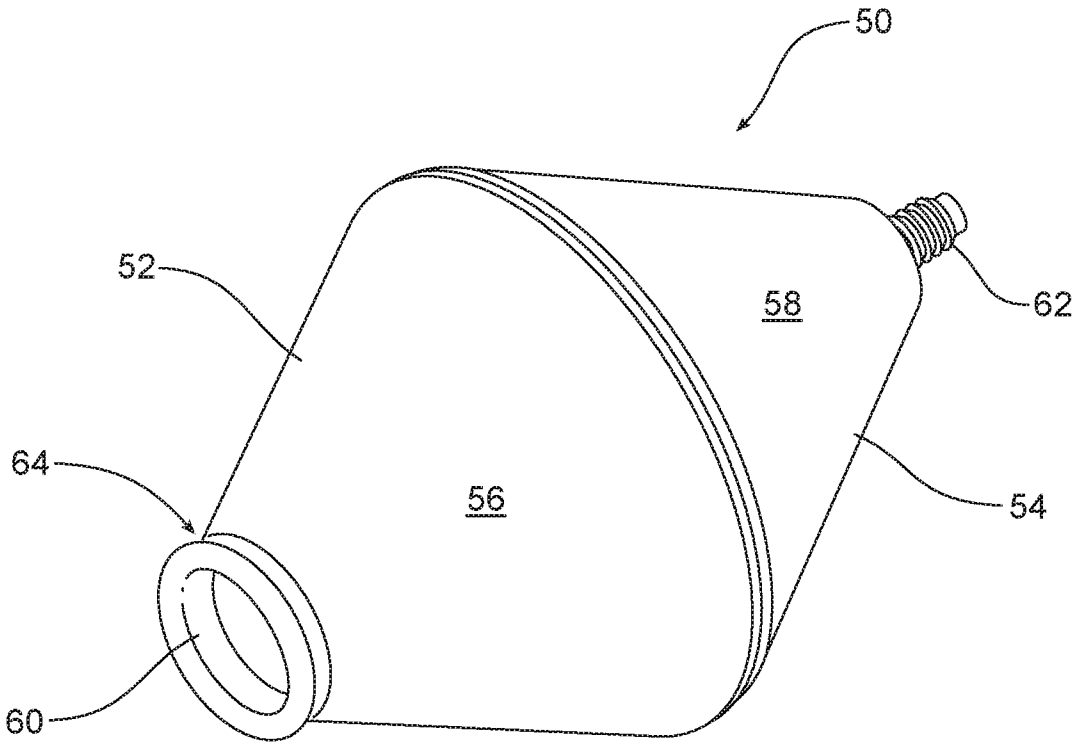


FIG. 5



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/047724

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-13, 17-44, 52-66, 73-87
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/047724

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/12; A47L 5/16; F21V 21/092 (2018.01)
CPC - A61F 2/12; A61B 2017/00796; A61B 90/02 (2018.08)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 601/6; 601/14; 623/8 (keyword delimited)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	O'NEIL et al. A novel method to remove silicone gel after breast implant rupture. The British Association of Plastic Surgeons. Published by Elsivier Ltd. August 2006 Pgs. 889-891	1-3, 14-16, 45-50, 67-71 --- 51, 72
Y	US 6,237,791 B1 (BECK et al) 29 May 2001 (29.05.2001) entire document	51, 72
A	US 2005/0119617 A1 (STECKER et al) 02 June 2005 (02.06.2005) entire document	1-3, 14-16, 45-51, 67-72

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 September 2018	16 OCT 2018
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774