

A DEVICE AND METHOD FOR PREVENTING LEAKAGE OF FLUIDS FROM A BODY DURING AN EMBALMING PROCEDURE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from pending U.S. Provisional Patent Application 61/318,375 filed on March 28, 2010, the disclosure of which is included by reference herein in its entirety.

TECHNICAL FIELD

[0002] The present invention relates generally to the field of preservation of human tissue in the field of mortuary science and more particularly to embalming procedures. Specifically, but not exclusively, the present invention concerns an accessory to a method of embalming that pertains to preventing embalming solutions from extruding or leaking from orifices, both natural and man-made, and restoring and maintaining the natural structural configuration of the body following the embalming procedure.

BACKGROUND OF THE INVENTION

[0003] Arterial embalming as a mortuary practice has existed for many years. The embalming process includes the controlled disinfection of the body by saturating the body with a sufficient level of germicidal arterial fluid. More specifically, the body is drained of all blood from the circulatory system and replaced with an embalming solution injected into at least one of the main arteries of the body. Typically, during the embalming process various openings are formed through the skin and tissue to facilitate the administration of the embalming fluids. Additionally, natural orifices are present and incisions may have been made for performing an autopsy or for tissue donation purposes resulting in skin openings that lead to the extrusion or leakage of the embalming fluid following the injection process.

[0004] Typically, cotton and other absorbent materials have been used to pack and fill any orifice or opening in an attempt to prevent the leakage of the embalming fluid.

Such materials have been found to be inadequate and fail to permanently close the openings. A need exists for a device to be used in conjunction with a material to securely close all openings and maintain cavity structures to ensure the embalming fluid is retained and the body structure is restored and preserved.

BRIEF SUMMARY OF THE INVENTION

[0005] Advancement of the state of the embalming process is believed desirable. One example of an embodiment of the invention that satisfies the need for improvements to the embalming process is a flowable material to prevent leakage and maintain and restore the structure of tissue and cavities within a cadaver. The embodiment of the invention also includes a device that is used to inject or deliver into an opening a material that functions to seal the opening and prevent the leakage of any residual bodily fluid and injected embalming solution from the opening. The aspects of the invention disclosed herein use a flowable material that, among other things, closes and seals an opening and also restores and maintains the desired structural shape of any internal cavity within a cadaver.

[0006] One embodiment of the invention is a method for preventing the leakage of fluids from a body during an embalming procedure. The method may include the step of disinfecting the body using a cleansing solution. The method may also include the step of examining the body to identify areas requiring remedial treatment. Further included in the method may be the step of obtaining a device for preventing leakage of fluids from a body. The method may also include the step of applying a flowable material into at least one opening in the body to prevent the leakage of fluids from the body. It is contemplated that the method may also include the step of injecting the body with an embalming solution.

[0007] An additional embodiment of the invention is a device for preventing leakage of fluid from a cadaver. The device includes a container with a quantity of flowable material stored within the container. The device also includes a means for delivering the flowable material connected to the container into an opening in the cadaver to prevent leakage of fluid. The means for delivering the flowable material

attached to the container includes a first tube member that has a first end, a second end and an inner passage connecting the first end and the second end with the first end being attached to the container and the second end having an opening that is adapted to dispense the flowable material. The first tube member is made from either a flexible material or a rigid material. The means for delivering the flowable material also includes a second tube member that has a first end, a second end and an inner hollow portion connecting the first end and the second end. The inner hollow portion is sized to receive the first tube member. The device also includes a valve that is operatively coupled to the container and functions to control the amount of flowable material exiting from the container through first tube member and into at least one opening in the cadaver.

[0008] An even further embodiment of the invention is a kit including any one of the containers described herein and one or more of the tubular members of varying dimensions. The kit may also include a plurality of sheath members of varying length and diameters. Further, the kit may include at least one finishing tool that is used to position and shape the flowable material. In another aspect of this embodiment of the invention, the kit includes an enclosure adapted to retain the container, the plurality of tubular members, the plurality of sheath members and at least one finishing tool.

[0009] Further additional features and advantages are realized through the techniques of the present invention. Other embodiments and aspects of the invention are described in detail herein and are considered a part of the claimed invention.

Brief Description of the Drawings

[0010] The subject matter which is regarded as the invention is particularly pointed out and distinctly claimed in the claims at the conclusion of the specification. The foregoing and other objects, features and advantages of the invention are apparent from the following detailed description taken in conjunction with the accompanying drawings in which:

[0011] FIG. 1 is a flow chart showing a method for preventing leakage of fluids from a body during the embalming injection process, in accordance with an aspect of the present invention;

[0012] FIG. 2 is a flow chart of an alternative method for preventing leakage of fluids from a post-autopsied body during the embalming injection process, in accordance with an aspect of the present invention;

[0013] FIG. 3 is a flow chart of an alternative method for preventing leakage of fluids from a body, from which organs have been donated, during the embalming injection process, in accordance with an aspect of the present invention;

[0014] FIG. 4A is an elevational, perspective view of a device and a means for delivering the flowable material to an opening in a body, in accordance with an aspect of the present invention;

[0015] FIG. 4B is a cross-sectional view of the means for delivering the flowable material taken along line 4B-4B, in accordance with an aspect of the present invention;

[0016] FIG. 5 is an exploded view of the device and the means for delivering the flowable material as shown in FIG. 4A, in accordance with an aspect of the present invention;

[0017] FIG. 6 is an elevational, perspective view of a sheath member that is part of the means for delivering the flowable material as shown in FIG. 4A, in accordance with an aspect of the present invention;

[0018] FIG. 7A is an anterior view of a cadaver showing possible injection sites generally employed during the embalming injection process and locations of possible areas needing remedial treatment, in accordance with an aspect of the present invention;

[0019] FIG. 7B is a posterior view of a cadaver showing possible injection sites generally employed during the embalming injection process and locations of possible areas needing remedial treatment, in accordance with an aspect of the present invention;

[0020] FIG. 8 is a sagittal view of the means for delivering the flowable material positioned within the oral cavity of a cadaver to fill and seal the mouth, esophagus and trachea, in accordance with an aspect of the present invention;

[0021] FIG. 9 is a sagittal view of the means for delivering the flowable material positioned within the nasal cavity of a cadaver to fill and seal the sinus cavities and upper trachea, in accordance with an aspect of the present invention;

[0022] FIG. 10 is an anterior view of the superior portion of the face of a cadaver showing the means for delivering the flowable material positioned adjacent to the eye sockets to seal the eyes closed and maintain the shape of the eye sockets, in accordance with an aspect of the present invention;

[0023] FIG. 11 is a rear perspective view of the skull of a cadaver showing the means for delivering the flowable material positioned inside an opening to fill the cranial cavity to maintain the cavity integrity, fuse the calvarium or any bone fragments together to close the skull prior to the embalming injection process, in accordance with an aspect of the present invention;

[0024] FIG. 12A is an anterior view of an upper extremity following the donation of the internal supporting bone structure, in accordance with an aspect of the present invention;

[0025] FIG. 12B is an anterior view of the upper extremity following the injection of the flowable material into the cavity/space resulting from the removal of the bones of the upper extremity, in accordance with an aspect of the present invention;

[0026] FIG. 13A is an anterior view of a lower extremity following the donation of the internal supporting bone structure, in accordance with an aspect of the present invention;

[0027] FIG. 13B is an anterior view of the lower extremity following the injection of the flowable material into the cavity/space resulting from the removal of the bones of the lower extremity, in accordance with an aspect of the present invention; and

[0028] FIG. 14 is an elevational, perspective view of a cutting/finishing tool used during the method of preventing leakage of fluids from a body during the embalming injection process, in accordance with an aspect of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0029] Disclosed herein is a method for preventing the leakage of fluids from a body during an embalming procedure, a device for preventing the leakage of fluid from a cadaver and a kit for preventing leakage of fluids during an embalming procedure.

[0030] In this detailed description and the following claims, the words proximal, distal, anterior, posterior, medial, lateral, superior and inferior are defined by their standard usage for indicating a particular part of a bone or body part or directional terms of reference. For example, "proximal" means the portion of an object or body part positioned nearest the torso, while "distal" indicates the part of an object or body part farthest from the torso. As for directional terms, "anterior" is a direction towards the front side of the body, "posterior" means a direction towards the back side of the body, "medial" means towards the midline of the body, "lateral" is a direction towards the sides or away from the midline of the body, "superior" means a direction above and "inferior" means a direction below another object or structure.

[0031] The purpose of embalming a cadaver is to disinfect, temporarily preserve and restore a person's body to a more natural appearance to allow for the public viewing of the body. The process or procedure of embalming will depend upon several factors, including but not limited to, the embalmer's embalming style, the condition of the body, the deceased's age, weight, sex, cause of death, elapsed time since death and environmental factors. Typically, the deceased's body is brought to a funeral home and placed in a preparation room which contains the required instruments, proper ventilation and cleanable surfaces for the purpose of body preparation by embalming. The body is then placed on the embalming table for the process to commence.

[0032] FIG. 1 is a flow chart that generally describes a method for preventing the leakage of fluids from a body during and after the embalming process 500. Typically, method 500 includes the step of disinfecting the body using some sort of a cleansing solution 501.

[0033] The method 500 may further include the step of examining the body to identify areas or locations that require remedial treatment or focused attention 502. For example, checking the body for bed sores, bullet holes, trauma or gangrene 301 (see FIGS. 7A and 7B).

[0034] Generally, the next step of method 500 is to obtain a device for preventing leakage of fluids from the body 503. As seen in FIG. 4A, the device 100 will generally include a storage reservoir or container 101, a valve 102 for controlling the stream of flowable material 103 from storage reservoir 101 and a means for delivering the flowable material 104.

[0035] Determining the amount of flowable material to be dispensed in the above described openings 504 may be another step in method 500. The array of possible openings in the body 301, 302 (See FIGS. 7A and 7B) are of various shapes, sizes and depths and will likely require a means for controllably discharging a finite amount of flowable material 103 into the target opening. Various configurations of insertion tips, diameters of sheath members 110 or tubular members 105 and a measurement scale may be used to calculate and ensure the accurate amount of flowable material 103 to be delivered into and over the openings. A more complete description of the elements for the means for delivering the flowable material 104 will be described below.

[0036] It is contemplated that the next step of method 500 may be applying flowable material 103 into at least one of the openings found in the body to prevent leakage of any fluids from the body 505. Examples of non-natural openings in the body may include, as noted above, bullet holes, incisions, stab wounds, and IV portals 301 (See FIGS. 7A and 7B). Natural openings into which flowable material 103 may need to be dispensed to prevent the leakage of fluids include, but are not limited, to the mouth, eyes, ears, nose, top of the skull or calvarium (for a post-autopsied body), vagina (for females) and anus 302 of the body (See FIGS. 7A and 7B). All of these different natural openings need to be initially cleaned prior to the injection of flowable material 103.

[0037] The present method invention 500 provides for the step of applying the flowable material 103 into the numerous openings found in the body to create a rigid and fixed plug-like structure to prevent the leakage of any fluids from the body 504.

[0038] More specifically, as shown in FIGS. 8, 9, 10 and 11, the embalmer may use device 100 to deliver flowable material 103 into these various natural openings to close these orifices to prevent any further flow of fluids or liquid material from the openings pre and post injection of the embalming solution.

[0039] As seen in the sagittal view of FIG. 8, means for delivering the flowable material 104 may be inserted into the oral cavity 201 of the cadaver and dispense flowable material 103 into the esophagus 202 and/or trachea 202 and also oral cavity 201. Currently, the mouth is either closed by a suture method or with small wires. Both techniques involve bringing the upper and lower jaw together and fixating these two structures to ensure that no securement devices are noticed. Cotton or other absorbent materials have been used to close or plug the mouth, although such materials become saturated during the infusion of the embalming solution resulting in leakage from the body.

[0040] As seen in FIG. 8, flowable material 103 may be initially in a moldable phase or form similar to a foam-like substance that moves into the passages of esophagus and/or trachea 202. Flowable material 103 may act to expand and block these passages. Upon coming in contact with the moist tissue of the passage, flowable material 103 is activated causing it to transition to a second phase which is a rigid structure that mirrors and maintains the confines of the passage in which it has been

dispensed. It is contemplated that flowable material 103 would fill the trachea, esophagus and oral cavity to seal these openings and guard against any “purge” that may occur following the embalming injection step.

[0041] FIG. 9 shows means for delivering the flowable material 104 positioned within the nasal cavity 203. Following the discharge of flowable material 103 into the sinus cavities (not shown), nasal cavity 203 and into the superior aspect of trachea 202, flowable material 103 will expand and support the surrounding structures and be activated to transition from the moldable phase to the rigid phase by the adjacent tissue. Following the change in phase of flowable material 103 from the moldable consistency to the rigid structure, flowable material will block these openings and prevent any “purge” or discharge of fluid from the mouth or nose following the embalming solution injection step. It is further contemplated that flowable material 103 following the phase change (foam to solid) will also function to restore and maintain the structure of the nose and will assist in maintaining closure of the mouth in conjunction with the above described mechanisms that may be used. Although not shown, it should be understood that flowable material 103 may also be dispensed into the ears of the cadaver to prevent any flow of fluids from these openings.

[0042] As seen in FIG. 10, means for delivering flowable material 104 may also be used to inject flowable material 103 into the eye socket 204 of the cadaver. Typically, eye caps are used to provide support to the eye socket and closure of the eyes. Eye caps are plastic devices and are inserted in a similar fashion to contact lenses. Flowable material 103 when injected into eye socket 204 may replace or supplement the eye caps and function to provide the required restorative support and closure functionality.

[0043] As depicted FIG. 11, flowable material 103 may also be used to assist with the closure and/or reconstruction of the skull 206. In the event skull 206 has been damaged due to trauma, flowable material 103 may be used to support and facilitate the reconstruction of skull 206 by fusing or adhering together numerous bony fragments 207. Further, for autopsy cases, means for delivering flowable material 104 may be positioned within cranial cavity 205 and then be used to fill up cranial cavity 205 with flowable material 103. Flowable material 103 may function in two capacities for this application, first, closing and sealing any openings within cranial

cavity 205 and second, holding and securing calvarium 212 in position, thereby eliminating the need for mechanical intervention and fixation.

[0044] Generally the next step of method 500 may be for injecting the body with an embalming solution 506. Typically, step 506 is the arterial injection of formaldehyde or like chemical solution. This step may be compared to a blood transfusion, wherein the blood is exchanged for a solution of water and formaldehyde. The embalmer strives to remove as much blood as possible to eliminate possible sources of bacteria growth and skin discoloration. The exchange is achieved by using the body's natural circulation system. A vein and artery are raised out of the body, most commonly the carotid artery and jugular vein on the left side of the body, with a small incision made near the clavicle bone. This location is most common for embalmers because it is closest to the heart and typically results in the best fluid distribution. However, blockages in the circulation system may occur due to blood clots or tumors for example, which may result in the need to inject a lower extremity or upper extremity separately in order for a thorough distribution of the embalming solution.

[0045] The embalming solution may be injected with the help of a pumping machine that includes a tank to hold the solution and a motor with controls for volume and pressure. Usually a tube is connected and is inserted into the raised artery with the pumping machine effectively acting as the heart and gently pumping the solution into the body's circulatory systems which then diffuses into the surrounding tissues.

[0046] The small incision made on the raised vein acts as an exit point because two liquids cannot occupy the same space, thus the blood is pushed out by the arterial embalming solution. The embalming solution functions to remove the blood, disinfect the body, help return the skin to a more natural color and at the cellular level, encapsulate the lysosome. Additional chemicals may be added to the arterial embalming solution to combat conditions like jaundice, edema, dehydration and emaciation. Also, before the arterial injection is complete a pre-injection solution may be injected to condition the arterial systems to better accept the formaldehyde embalming solution by lubricating vessels, loosening blood clots and adjusting the pH level of the body.

[0047] Method 500 may further include the step of treating the organs of the body 507. The stomach, intestines, liver and other organs will have bacteria within them,

therefore using a trocar and aspirator, the embalmer will suction all of the body's organs to remove any residual liquids and gasses. The trocar is usually inserted into the body near the belly button 303 (See FIG. 7A). After the cleaning step is completed, a second trocar is used to inject the formaldehyde based embalming solution into the various organs. It is contemplated that in the event that any tumors or other cavity creating structures are present within the body cavity 211 (See FIG. 7A), flowable material 103 may be injected into such a space to act as a filler. Flowable material 103 following the transition to its rigid phase will facilitate the restoration of the proper internal supporting structure of the body.

[0048] Following the completion of the organ treatment 507, method 500 may include the step of applying flowable material 103 to the various incisions used for the arterial injection and aspiration procedures and sealing these openings to prevent any leakage of fluids 508. FIGS. 7A and 7B exhibit the typical injection sites 300 used by embalmers. Several other locations are shown (301, 302), although these sites may be related to openings that have been addressed pre-arterial injection in step 504 above. The size and location of the incisions may dictate the amount of flowable material 103 that is used to close and seal the incision. As described above, flowable material 103 will be applied to the openings in an initial flowable/moldable state or phase and that upon contact with the internal wet tissue of the vessel will transition to a second, rigid phase that functions to close and seal the opening.

[0049] Method 500 may also include the step of making the final preparations for viewing the body 509. These preparations typically include washing, dressing and placing the body in the casket, as well as apply cosmetics as needed, and preparing the hair for public viewing.

[0050] FIG. 2 is a flow chart showing an alternative method of preventing the leakage of fluids from a body on which an autopsy has been performed 600. The sequence of steps may vary depending upon the preference of the embalmer as well as the condition of the body. Generally, the embalming process for autopsy cases differs from standard embalming because of the invasive nature of the post-mortem examination. Specifically, the circulatory system is significantly disrupted because of the removal of the organs and viscera. In a full autopsy, all of the internal organs, as well as the brain, will be removed and examined. When the autopsy is completed, and

the organs have been examined, they are usually placed in a plastic bag, which is then placed in the body cavity. Calvarium 212 is placed back in position with the scalp being pulled back over to hold calvarium 212 in place. Body cavity 211 is then sutured closed with a few large sutures.

[0051] Method 600 usually includes the step of cleaning the body 601 including cranial cavity 205. The viscera bag is emptied and the organs are drained and cleaned. Body cavity 211 is exposed and dried.

[0052] Method 600 will further include the step of locating and identifying all the major vessels and injecting each limb with the embalming solution 602. Typically, the embalming solution is injected into the lower extremities through the femoral arteries, the upper extremities through the sub-clavian arteries and the head through the left and right carotid arteries.

[0053] Method 600 may also include the step of treating the torso 603. For this step, a six-point injection is made through the two iliac or femoral arteries, subclavian or axillary vessels, and common carotids. The flaps of skin that fold back to expose the body cavity are typically about an inch thick and full of fatty tissue. The embalmer uses a special trocar or hypodermic needle to deliver the embalming solution to the flaps and surrounding tissue in an attempt to achieve adequate perfusion of the entire torso.

[0054] Method 600 may also include the step of preparing the skull and applying flowable material 103 inside cranial cavity 604. As described above, calvarium 212 may be put back into position and secured to the skull with flowable material 103. The scalp is pulled back down over the top of the skull following the filing of cranial cavity 205 with flowable material 103 being applied to the suture line 306 to seal the skull.

[0055] The step of applying flowable material 103 to the voided areas within the thoracic cavity and cervical region 605 may also be included in method 600.

Following the drying and cleaning of the thoracic cavity, flowable material 103 will be dispensed into the cavity to provide support and facilitate maintaining the proper volume. Flowable material 103 may be manually manipulated to optimize tissue coverage prior to the subsequent phase change to its rigid state after activation of the material by coming in contact with the surrounding tissue.

[0056] Depending upon the preference of the embalmer, method 600 may include the subsequent step of placing the viscera (internal organs) back into body cavity 211 and closing the body 606. The organs may be placed individually into the cavity, or alternatively, within a container bag that is placed in its entirety into the cavity. Following the placement of the organs into the cavity, the body is closed using either sutures and glue, or alternatively, using flowable material 103 as an adhesive to close the cavity along the pre-existing incision lines.

[0057] Method 600 may also include the step of making the final preparations for viewing the body 607. These preparations typically include washing, dressing and placing the body in the casket, as well as apply cosmetics as needed and preparing the hair for public viewing.

[0058] FIG. 3 is a flow chart that further exhibits an alternative method for preventing leakage of fluids from a body from which organs have been donated 700. Because of the numerous types of organ donations that can occur, like for example internal organs (i.e., heart, lung, liver, kidneys, pancreas, eyes, etc.), skin, bone and connective tissue and blood vessels, the embalmer may be faced with numerous challenges in properly preparing a body for public viewing.

[0059] As with methods 500, 600 already described above, the initial step upon receipt of the body from the hospital is for the embalmer to disinfect and generally clean the body 701.

[0060] Method 700 includes the further step of identifying the type of organ donation that has occurred 702, as this will generally dictate the next step of the embalming process. Typically, the step of injecting the embalming solution may include using the available arterial system for the procedure, or alternatively, injecting directly into the available body portions (i.e., torso, upper extremities and lower extremities) 703. Several iterations of this step are discussed below.

[0061] For example, if internal organs have been harvested then the procedure will likely vary slightly for each organ, however, usually in all cases the initial operative procedure begins with a long midline incision 304 entering the thoracic and abdominal cavities, so all organs can be easily removed by the surgeon. If kidneys are the only organs being recovered, only the abdominal cavity will be incised. Typically, the embalming

method for an organ donor is similar to embalming procedure for an autopsy case as described in FIG. 2 with method 600. As such, embalmers may choose to inject the embalming solution from multiple sites, as described in step 602 and not open midline incision 304.

[0062] Should the embalmer choose to open midline incision 304, then the iliac arteries and carotid arteries should be tied off for identification and later use. If the body is that of a heart and/or lung donor, the embalming solution may be injected into the left and right subclavian arteries from inside the thoracic cavity to preserve the arms and shoulders, injected into the left and right common carotids to preserve the head and injected into the abdominal aorta to preserve remaining abdominal viscera, trunk and legs.

[0063] If the liver, kidneys, intestines and pancreas have been donated, the body can be embalmed using the commonly used six-point injection method. The embalmer may also hypodermically inject the trunk walls as needed to ensure tissue perfusion. The thoracic cavity may be filled with flowable material 103 to restore the volume of the cavity and inhibit any further leakage of fluid from the abdominal cavity.

[0064] For skin donations, the arterial embalming procedure is generally followed as discussed in method 500 above, including the use of flowable material 103 to seal any openings in the body prior to the arterial injection. Following the completion of the arterial embalming process, the removed tissue sites 305 may be treated with flowable material 103 to inhibit further fluid seepage.

[0065] For bone and connective tissue donation cases, including the removal of the long bones in the upper and lower extremities and the various bones of the pelvis, maintaining the integrity of blood vessels is difficult. In an effort to assist with the embalming process, the remaining arteries and veins may be identified and used for the injection of the embalming solution. In cases where arterial or venous injection is not possible, hypodermic injection of the extremities may be the only method by which to achieve tissue preservation.

[0066] FIG. 12A shows the upper extremity 208 following the removal of the long bones 209 in the arm which results in a large unsupported cavity (Outline of removed long bones 209 are shown in dashed lines). Currently, dowels or PVC piping are used to replace bones 209. As seen in FIGS. 12B, flowable material 103 of the present

invention may be injected into the cavity and allowed to cure, resulting in a rigid structure that would restore the shape of the arm and support the surrounding tissue.

[0067] As exhibited in FIG. 13A, a lower extremity 210 is shown without the supporting bone structures (Outline of removed long bones 209 are shown in dashed lines). Like with upper extremities 208, embalmers have used wooden dowels or plastic piping to support the tissue of the leg. FIG. 13B depicts the use of flowable material 103 injected in the cavity that is the result of the removal of long bone 209. Flowable material 103 may be dispensed into the cavity and restore the natural shape of lower limbs 210.

[0068] It is contemplated that the step of filling the cavities with flowable material 103 in both the upper and lower extremities post-bone harvest could also take place at the hospital. The surgeon upon removal of the bone structures, could immediately inject flowable material 103 into the created cavity, therefore eliminating this step in the embalming procedure. Alternatively, bone shaped forms fabricated from flowable material 103 may be inserted into the existing cavities.

[0069] Generally, for all types of donation cases, a possible further step in method 700 would include evaluating the body to determine the adequacy of the embalming solution saturation of the tissue 704 following whatever injection technique has been employed as described above. Because of the various types of donations that may occur, the embalmer may be required to use varying techniques to achieve the proper amount of perfusion necessary to preserve the body.

[0070] As a result of the wide variation in embalming techniques used for donation cases, method 700 may further include the step of applying flowable material to a wide range of openings and cavities, including the thoracic cavity, the cranial cavity and the cavities of the extremities 705. Depending upon the condition of the body following the donation procedure, it is contemplated that applying flowable material may occur upwards of three times in method 700; once before any embalming solution has been injected, like in the case where arterial injection is possible, and then a second time into the various cavities 705 and a third time following the injection of the embalming solution, to seal the incision sites and eliminate any fluid leakage 706.

[0071] As with methods 500, 600, method 700 may also include the step of making the final preparations for viewing the body 707. These preparations typically include washing, dressing and placing the body in the casket, as well as apply cosmetics as needed and preparing the hair for public viewing.

[0072] For any of the methods described above, the use of flowable material 103 to restore the shape of various anatomic features and seal the plurality of openings present in a cadaver is a time-saving accessory to the embalming process. An additional benefit of using flowable material 103 is the reduction in exposure time to the embalmer following the injection of the embalming solution because of the efficiency of flowable material 103 in sealing openings in the body and reducing or eliminating any fluid leakage.

[0073] Table 1 lists the various common procedures performed by an embalmer during the embalming procedure. Also included in Table 1 are the typical ranges of the elapsed time necessary to complete certain procedures using current techniques. Further listed in Table 1 are the ranges of elapsed times using the flowable material for the corresponding same procedure, as described above for methods 500, 600, 700.

TABLE 1

<i>Procedure</i>	<i>Time Current Technique</i>	<i>Flowable Material</i>
<i>Technique</i>		
Trocar punctures	3 – 5 mins.	5 - 10 secs.
Vaginal, Anal cavity Closure	3 – 5 mins.	10 - 15 secs.
Nose, Ear and Mouth Closure	4 – 6 mins.	15 – 20 secs.
Ulcers and Gangrene Remediation	5 – 7 mins.	25 – 30 secs.
Chemical Injection Site Closure	6 – 8 mins.	15 – 20 secs.
Cranium Restoration-Autopsy/Donation Methods	30-60 mins.	10 - 12 mins.

Thoracic Restoration-Autopsy/Donation Methods	45-70 mins.	15 – 20 mins.
Bone and Tissue-Autopsy/Donation Methods	180-240 mins.	30 – 120 mins.
Body Closure/Trauma Repair with Suturing-Autopsy/Donation Methods	180-960 mins.	60 – 180 mins.

[0074] It is contemplated that flowable material 103 may also be used in any of the above methods 500, 600, 700 to create pre-existing anatomic part forms. For example, if the body is missing an ear, finger or a bone, flowable material could be injected into a mold. Following the activation of the material, a replacement part is created for attachment or insertion into the body.

[0075] In one aspect of the invention, flowable material 103 is or comprises a hydrophilic substance. In some aspects, this hydrophilic substance changes from a first phase to a second phase when the substance comes in contact with moisture or tissue. For example, in certain embodiments, in the first phase the material is moldable, and in the second phase the material is rigid.

[0076] In one aspect of the invention, flowable material 103 is or comprises a foam, such as polyurethane foam. Such foams are known in the art, and are described, for example, in U.S. Patent Publication US 2010-0227151, as well as in Pinto, “Formulation, Preparation, and Characterization of Polyurethane Foams”, Journal of Chemical Education 87(2) (February 2010), 212-214, and Lampman *et al.*, “Polymer Preparations in the Laboratory”, Journal of Chemical Education 56(9) (September 1979) 626-628. The entire contents of each of these references are incorporated herein by reference. It is contemplated that an alternative flowable material 103 may comprise caulk or like viscous material that has flow properties initially and over time cures to a hardened material.

[0077] In certain aspects of the invention, flowable material 103 is a foam which comprises one or more isocyanates, such as aliphatic, cycloaliphatic, arylaliphatic,

and/or aromatic isocyanates; one or more polyols, such as natural oil based polyols; and one or more blowing agents, such as water or other suitable blowing agents.

[0078] In certain aspects of the invention, the isocyanate is a diisocyanate, or, more particularly, an aromatic diisocyanate such as methylene diphenyl diisocyanate (MDI) or toluene diisocyanate (TDI).

[0079] In certain aspects of the invention, the polyol may be a polyether or polyester polyol, or may be hydroxyl-terminated polyolefins or hydroxyl-containing vegetable oils.

[0080] In some aspects of the invention, flowable material 103 is a foam as described above, which, in addition to an isocyanate, polyol, and a blowing agent, further comprises a catalyst (e.g. tin and/or tertiary amine catalysts, and combinations thereof); and/or a stabilizer, such as silicone.

[0081] In some aspects of the invention, flowable material 103 is a foam which comprises: an isocyanate such as MDI or TMI, or any combination thereof, which represents, for example, 30-45% of the foam; a polyol, such as polyether or polyester polyol, and/or hydroxyl-terminated polyolefin(s), and/or hydroxyl-containing vegetable oils, representing, for example, 55-65% of the foam; water (e.g., for use in producing carbon dioxide), representing, for example, 2-5% of the foam; tin and tertiary amine catalysts or a combination thereof, representing, for example, 0.3-3 % of the foam; and silicone, representing, for example, 0.6-3% of the foam.

[0082] Skilled artisans will recognize that when flowable material 103 is a foam, additional components may be added thereto to achieve desired properties. Such additional components may include, for example, antioxidants, fillers, colorants, chain extenders, and cross linkers. Further, it is contemplated that additives may be included into flowable material 103 that would change the color of the foam to allow the embalmer to match the color with the skin color of the body. Additionally, additives that would combat a foul stench or include certain scents may also be included in the composition of flowable material 103.

[0083] In some aspects, when flowable material is a foam, it will have an index of over 100, wherein the index is defined as: (The amount of isocyanate in the foam, e.g. MDI or TDI) divided by (the sum of the rest of the components in the foam) x 100, such that an index of over 100 represents an excess of isocyanate. In some embodiments, the index is in the range of 100-110.

[0084] FIG. 4A is an elevational, perspective view of the assembled device 100 that shows storage reservoir 101, valve 102 and means for delivering the flowable material 104. It should be understood that the term “storage reservoir” and “container” may be used interchangeably herein. Although not shown, flowable material 103 is contained within storage reservoir 101 and may be released into means for delivering the flowable material 104 by actuating valve 102. For example purposes, storage reservoir 101 is shown as an aerosol can or pressurized device. It is contemplated that storage reservoir may also be a syringe or like structure, that would allow for the manual discharge of flowable material 103 from the container.

[0085] As seen in the exploded view of FIG. 5, device 100 includes a means for delivering flowable material 104 that includes a tubular member 105. Tubular member 105 is typically fabricated from a flexible polymer or plastic material which allows the embalmer to manipulate tubular member 105. A further embodiment of tubular member 105 may include being fabricated from a more rigid material like metal or hard plastic. Tubular member 105 has a first end 106 and a second end 107 with an internal or inner bore 108 that extend the entire length of tubular member 105. Inner bore 108 is sized to accommodate the stream of flowable material 103 when valve 102 is actuated. First end 106 is configured to facilitate attachment either directly to container 101 or via an intermediate valve stem 109. Second end 107 is generally configured to facilitate insertion into an opening in the cadaver or into the sheath member 110. Second end 107 may be arcuate shaped or alternatively, more pointed geometry to facilitate the entry of tubular member 105 into the appropriate location in the body or sheath member 110. It is contemplated that tubular member 105 may be constructed in varying lengths and diameters. Having tubular member 105 available with different dimensional attributes allows the embalmer to choose for

the presented situation, which tubular member 105 best facilitates the delivery of flowable material 103.

[0086] Also shown in FIGS. 5 and 6 is sheath member 110, a further element of the means for delivering the flowable material 104. Sheath member 110 includes a first end 111 and a second end 112. Extending from first end 111 to second end 112 is an inner hollow portion 113. Inner hollow 113 is sized to receive tubular member 105. First end 111 is configured to facilitate the insertion of tubular member 105 into sheath member 110, while second end 112 is shaped to assist with the insertion of sheath member 110 into various sized openings in the body. Although not shown, second end 112 may accommodate modular tips that will allow the embalmer to change the bead size or width of the discharged flowable material 103 as well as facilitate insertion into certain body openings. Alternatively, various sized or shaped (e.g., length, diameter and ends) sheath members 110 may be used during the course of the embalming process to modify the discharged stream size and bead shape. The various sheath members 110 may be interchanged over tubular member 105 depending upon the particular situation that is encountered.

[0087] FIG. 4B is a cross-sectional view of means for delivering the flowable material 104 that shows inner hollow 113 sized to house tubular member 105 within inner hollow 113. Inner hollow 113 also functions to support tubular member 105 when device 100 is in use. Inner hollow 113 and tubular member 105 are shown as having circular cross-sections, although other geometric shapes may be used such as rectangular, square or other polygonal configurations. Such other cross-sectional shapes may allow the embalmer to modify the bead of discharged flowable material to address certain situations. For example, inner hollow 113 and tubular member may have a cross-sectional geometry that produces a flattened broad swath of flowable material 103 that is then utilized to cover a suture line.

[0088] FIG. 6 is a perspective view of sheath member 110. Sheath member 110 is generally configured as a hollow tube-like structure into which tubular member 105 is inserted. Disposed on the outer surface of sheath member 110 is a finger hold 114 that allows the embalmer to manipulate and move sheath member 110 into position.

Finger hold 114 can also be used to actuate valve 102 to discharge flowable material 103. Also shown is a stop mechanism 115, which for example purposes is depicted as a set screw 115. When the knob 117 of stop mechanism 115 is actuated, a member 120 is advanced or extended into inner hollow 113 and would apply pressure to tubular member 105 causing the stream of flowable material 103 to slow or stop. Flow rates of flowable material 103 may be varied by making adjustments to stop mechanism 115. Although not shown, other embodiments of stop mechanism 115 may include a camming device or thumb switch. A measuring scale 118 may be disposed on the outer surface of sheath member 110 near second end 112. Measuring scale 118 allows the embalmer to discharge a set amount of flowable material 103 to a location in a controlled fashion. Additionally, sheath member 110 may include a slot or window 119 that will allow the embalmer to visualize the amount of flowable material 103 inside sheath member 110 prior to the dispensing process. Window 119 may be completely transparent and include graduated markings which depict certain measured amounts of flowable material 103 that may be discharged. Sheath member 110 is typically fabricated from a rigid material, for example, a hardened plastic or metal.

[0089] FIG. 14 shows a finishing tool 150 to be used by the embalmer when manipulating and refining flowable material 103 during its first and second phases. Finishing tool 150 operates in a closed position and an open position. When in the open position, a cutting mechanism 151 extends from one end of the body 153 of finishing tool 150. Cutting mechanism 151 may be configured to operate in a similar manner as scissors with two cutting blades 152 that are hinged and may be closed together to trim and shape flowable material 103 that has entered the second, rigid phase. The top aspect 154 of body 153 is configured as a flat edge-like structure to allow the embalmer to the evenly spread flowable material 103 while in its first phase. Top aspect 154 may be used to smooth over openings and ensure coverage of suture lines prior to flowable material 103 being activated and becoming rigid. Top aspect 154 may be used when finishing tool 150 is either in its open or closed position.

[0090] Body 153 also has a bottom aspect 155 that for the embodiment shown in FIG. 14 is configured to include cutting elements. The cutting elements seen are configured as a plurality of cutting teeth 156. To use bottom aspect 155, the embalmer may hold finishing tool 150 in the open position and place bottom aspect 155 onto the surface that is to be cut. The embalmer would then move finishing tool 150 in a back and forth direction, engaging cutting teeth 156 into the rigid flowable material resulting in the material being cut.

[0091] As further seen in FIG. 14, located at the opposite end from cutting mechanism 151 of finishing tool 150 is a blunt element 157 that the embalmer may be able to use to push and pack flowable material into cavities and openings to enhance and enable the supportive and restorative functionality of flowable material 103. Blunt element 157 may also be used to assist in filling cadaver openings by bluntly forcing as much flowable material into the opening as the opening will hold. By filling any internal cavities (nasal, oral, thoracic, cranial) to full capacity this will assist in restoring and maintaining these cavities shape post-injection of the embalming solution. Blunt element 157 may have a flat or slightly convexly curved surface to maximize surface to material contact, while limiting over-flow. Blunt element 157 may be used in either the open or closed position of finishing tool 150. Finishing tool 150 may be fabricated from a composite of materials including hardened polymers and metal to ensure durability and toughness of the tool.

[0092] It is also contemplated that a kit that includes at least one container 101 that is adapted to attach to a means for delivery the flowable material is provided. The kit further includes a plurality of tubular members 105 with various cross-sectional sizes and shapes and longitudinal lengths. Also included in the kit is a plurality of sheath members 110 with various inner bore sizes, shapes and longitudinal lengths. The kit may also include at least one finishing tool 150 that may be used to position and shape the flowable material following the injection of the material into an opening and/or cavity. Kits according to aspects of the invention may include an enclosure adapted to retain elements of the kit, including the container, the plurality of tubular members and sheath members and at least one finishing tool. The

enclosure that houses all of the components of the kit will allow the embalmer to pick and choose the various elements of device 100 including the type of container 101 and the means for delivering the flowable material 104 that are necessary to address the presented death care situation and any anatomical deformity found in the cadaver. Device 100 and the means for delivering the flowable material 104 may typically include the above described elements and components that, for the sake of brevity sake, will not be discussed again here, and include the same structural and functionality characteristics as described previously herein.

[0093] Although the various embodiments have been depicted and described in detail herein, it will be apparent to those skilled in the relevant art that additional modifications, and substitutions can be made without departing from its essence and therefore these are to be considered to be within the scope of the following claims.

CLAIMS

What is claimed is:

1. A method for preventing the leakage of fluids from a body during an embalming procedure, the method comprising:
 - disinfecting the body using a cleansing solution;
 - examining the body to identify areas requiring remedial treatment;
 - obtaining a device for preventing leakage of fluids from a body;
 - applying a flowable material into at least one opening in the body to prevent the leakage of fluids from the body; and
 - injecting the body with an embalming solution.
2. The method as recited in claim 1, wherein the device comprises a storage reservoir, a valve and a means for delivering the flowable material.
3. The method as recited in claim 2, wherein the storage reservoir contains the flowable material.
4. The method as recited in claim 1, wherein applying a flowable material comprises inserting a means for delivering the flowable material into the at least one opening and actuating the valve.
5. The method as recited in claim 4, wherein actuating the valve comprises releasing the flowable material into the means for delivering the flowable material.
6. The method as recited in claim 2, wherein the means for delivering the flowable material comprises a tubular member with a first end, a second end and an inner bore connecting the first end and the second end with the first end coupled to the storage reservoir and the second end having an opening adapted to dispense the flowable material.

7. The method as recited in claim 6, wherein the means for delivering the flowable material further comprises a sheath member with a first end, a second end and an inner hollow portion connecting the first end and the second end with the inner hollow portion adapted to receive the tubular member.

8. The method as recited in claim 1, further comprising determining the amount of flowable material to be dispensed into the at least one opening in the body.

9. The method as recited in claim 8, wherein determining the amount of flowable material to be dispensed is practiced using a scale on the sheath member.

10. The method as recited in claim 7, wherein the sheath member comprise a rigid material.

11. The method as recited in claim 7, wherein the second end is configured to facilitate insertion of the second end into the at least one opening in the body.

12. The method as recited in claim 7, wherein the sheath member further comprise a stop mechanism.

13. The method as recited in claim 12, wherein the stop mechanism comprises a member and a knob operatively connected to the member, the knob when actuated advances the member into the inner hollow portion of the sheath member to restrict the passage of the flowable material.

14. The method as recited in claim 2, wherein the means for delivering the flowable material comprises a flexible tube member with a first end, a second end and an inner passage connecting the first end and the second end with the first end coupled to the storage reservoir and the second end having an opening adapted to dispense the flowable material.

15. The method as recited in claim 1, wherein the flowable material comprises a hydrophilic substance that changes from a first phase to a second phase when the substance comes in contact with moisture.

16. The method as recited in claim 15, wherein during the first phase the material is moldable and during the second phase the material is rigid.

17. The method as recited in claim 15, wherein the material comprises foam.

18. The method as recited in claim 1, further comprising sealing at least one opening in the body with the flowable material preventing the leakage of fluids from the body.

19. A device for preventing leakage of fluid from a cadaver, the device comprising:

a container;

a quantity of flowable material within the container; and

a means for delivering the flowable material connected to the container.

20. The device as recited in claim 19, wherein the means for delivering the flowable material comprises a first tube member with a first end, a second end and an inner passage connecting the first end and the second end with the first end coupled to the container and the second end having an opening adapted to dispense the flowable material, wherein the first tube member is fabricated from at least one of a flexible material and a rigid material.

21. The device as recited in claim 20, wherein the means for delivering the flowable material further comprises a second tube member with a first end, a second end and an inner hollow portion connecting the first end and the second end with the inner hollow portion adapted to receive the first tube member.

22. The device as recited in claim 19, further comprising a valve, the valve is operatively coupled to the container and is adapted to control the amount of

flowable material exiting from the container through the means for delivering the flowable material and into at least one opening in the cadaver.

23. A kit comprising:

at least one container having a quantity of flowable material disposed within the container and adapted to couple to a means for delivering the flowable material to an opening in a cadaver;

a plurality of tubular members each having a first end, a second end and an inner bore connecting the first end and the second end with the first end adapted to couple to the container and the second end having an opening configured to dispense the flowable material; and

a plurality of a sheath members each with a first end, a second end and an inner bore connecting the first end and the second end with the inner bore configured to receive a tubular member.

24. The kit recited in claim 23, further comprising at least one finishing tool adapted to position and shape the flowable material after the flowable material is dispensed into at least one opening in the cadaver.

25. The kit recited in claim 24, further comprising an enclosure adapted to retain the at least one container, the plurality of tubular members, the plurality of sheath members and the at least one finishing tool.

* * * * *

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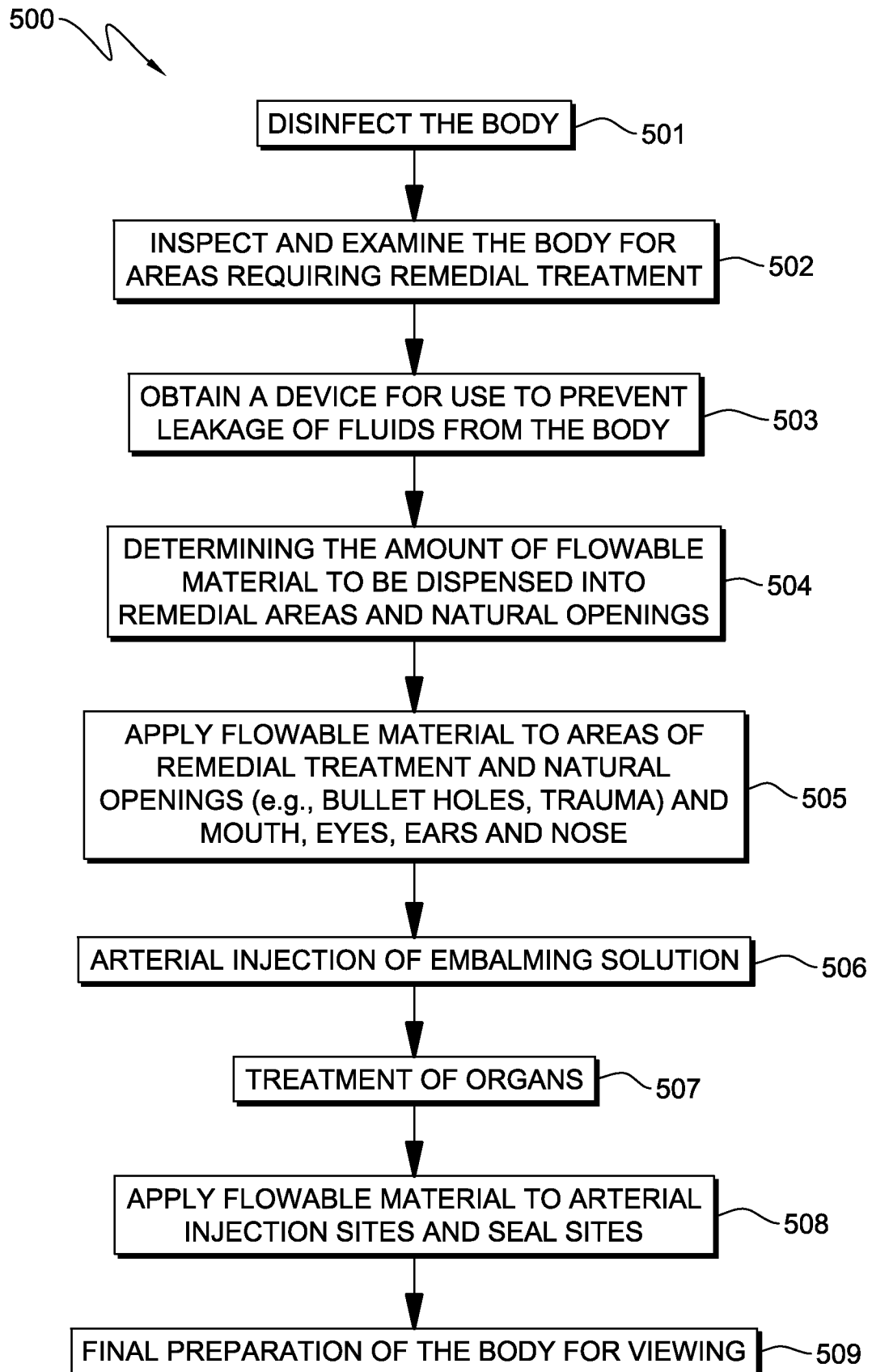


FIG. 1

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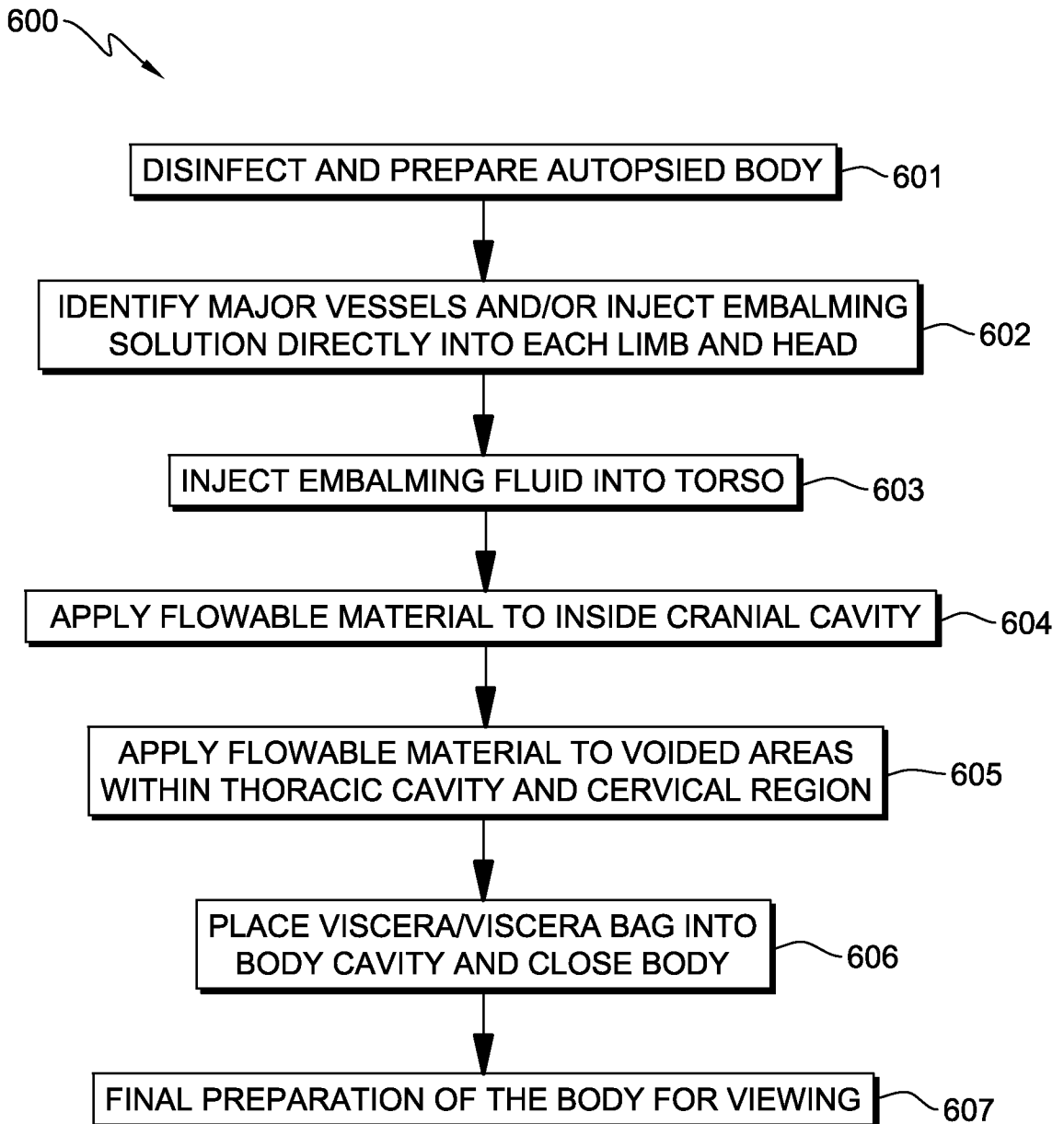


FIG. 2

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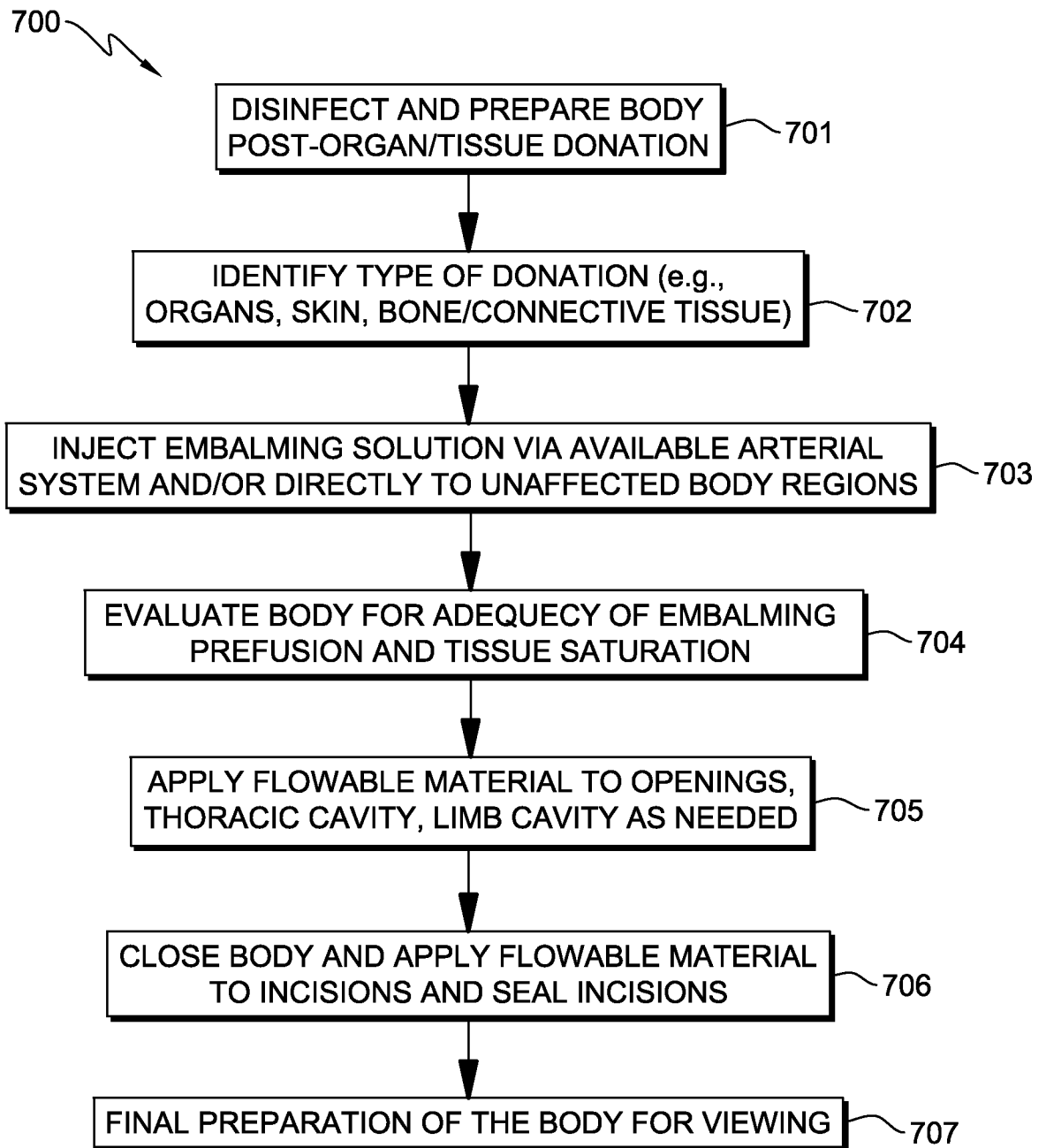
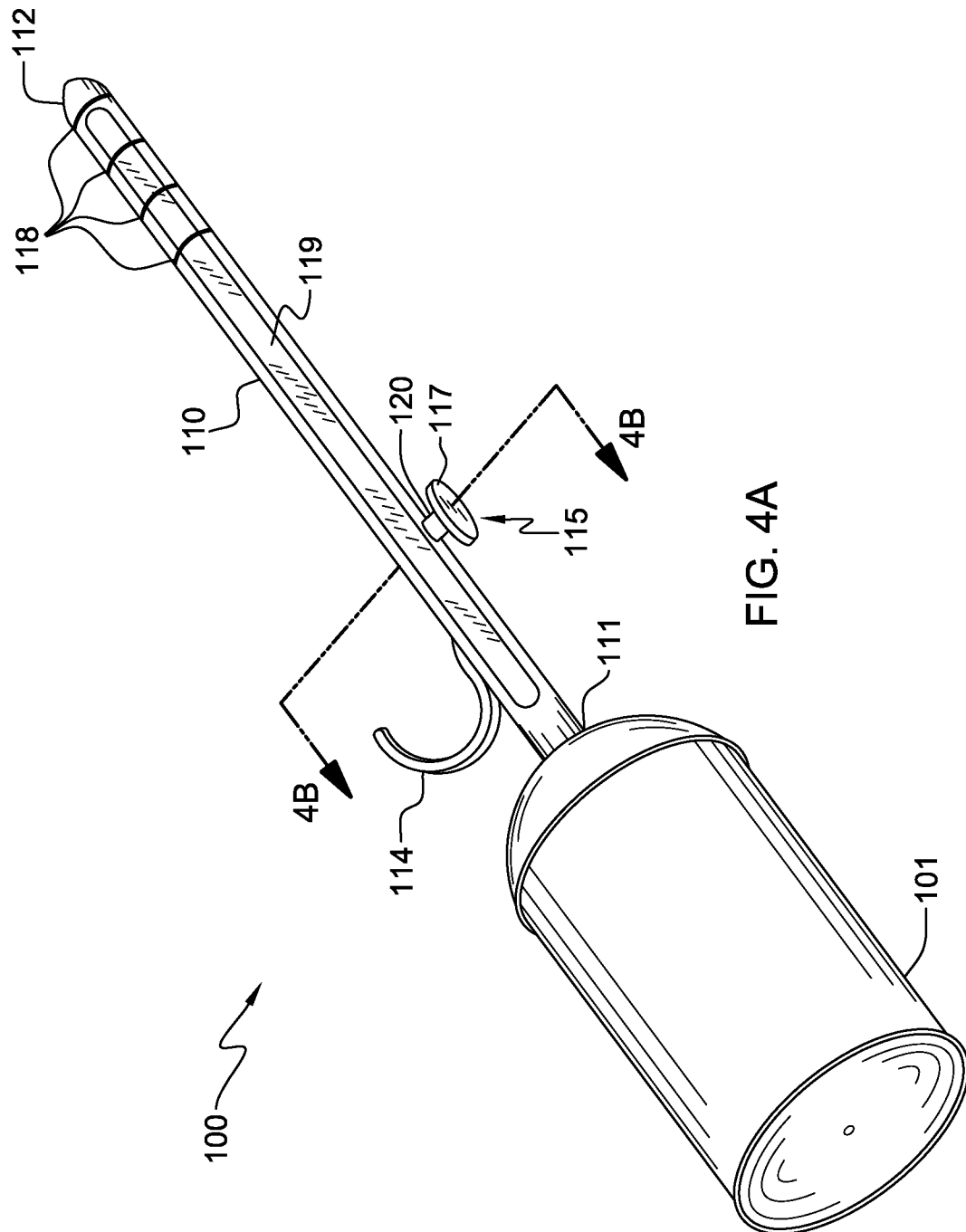


FIG. 3



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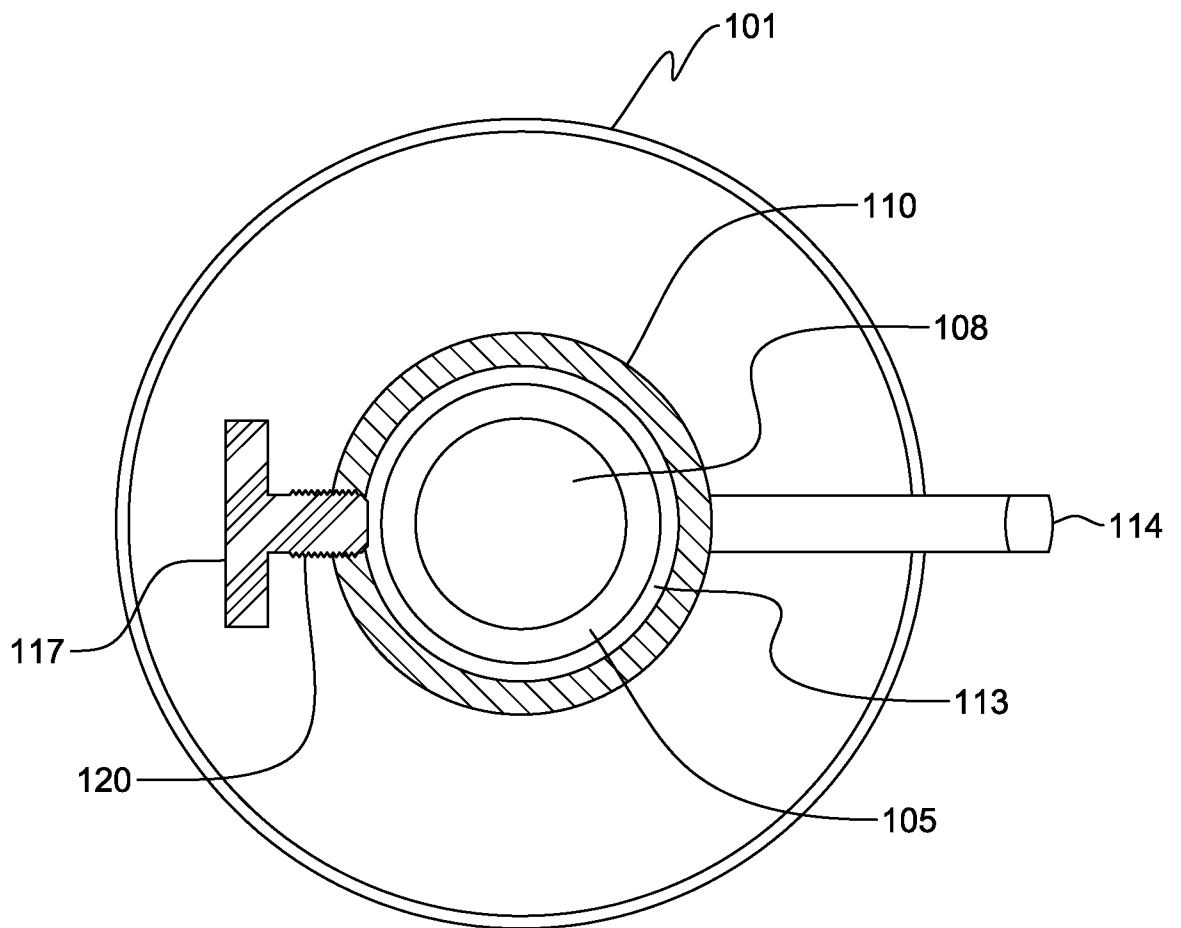


FIG. 4B

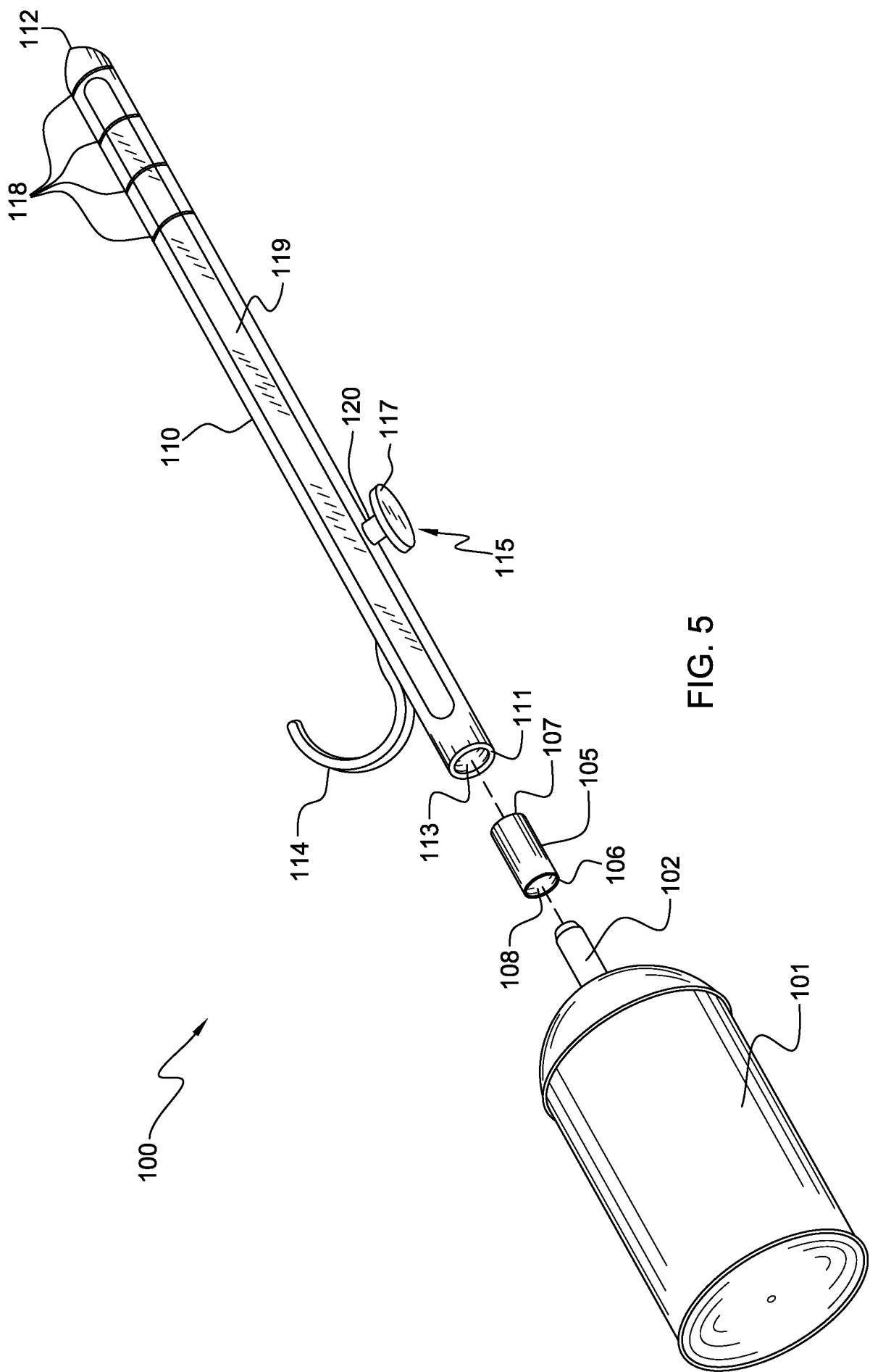
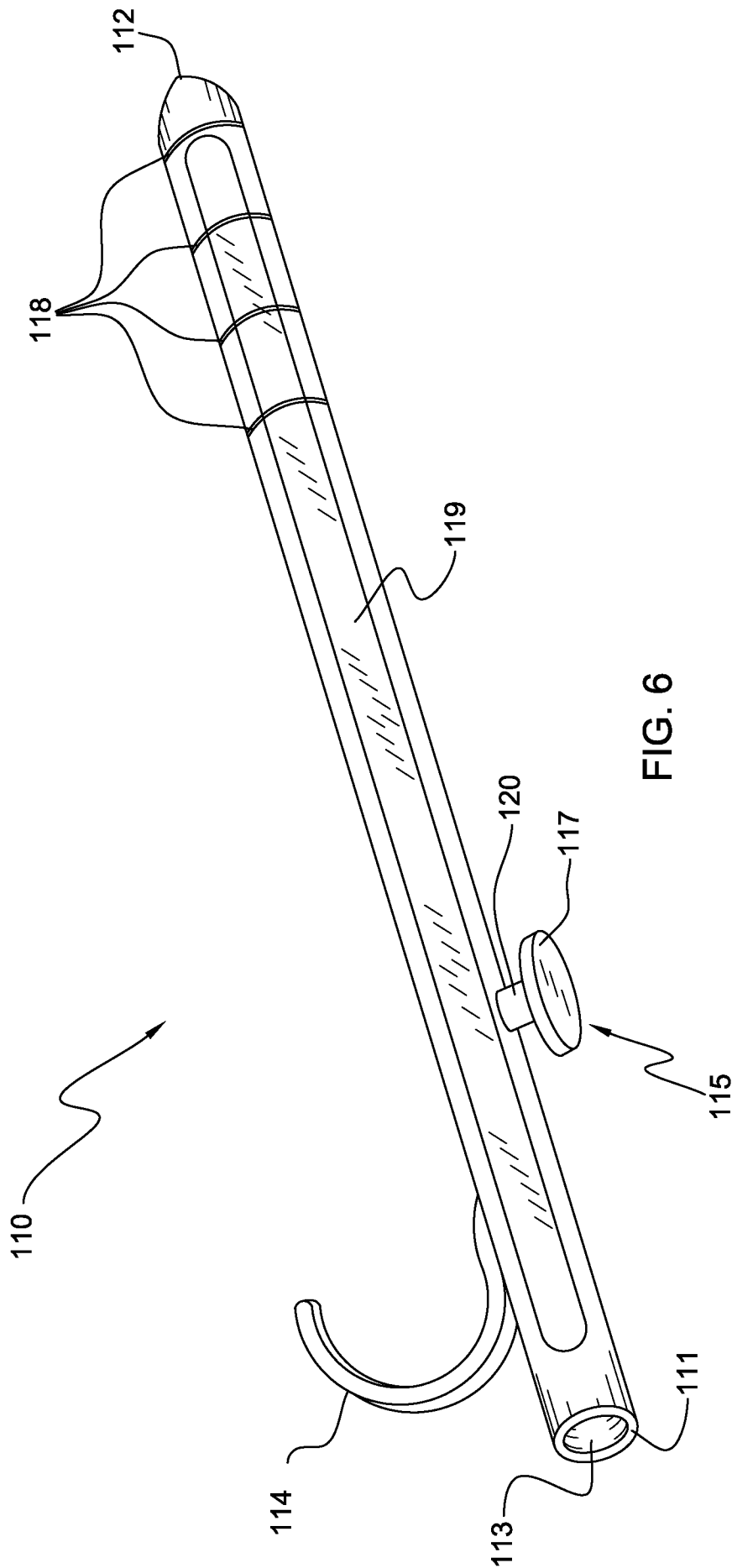


FIG. 5

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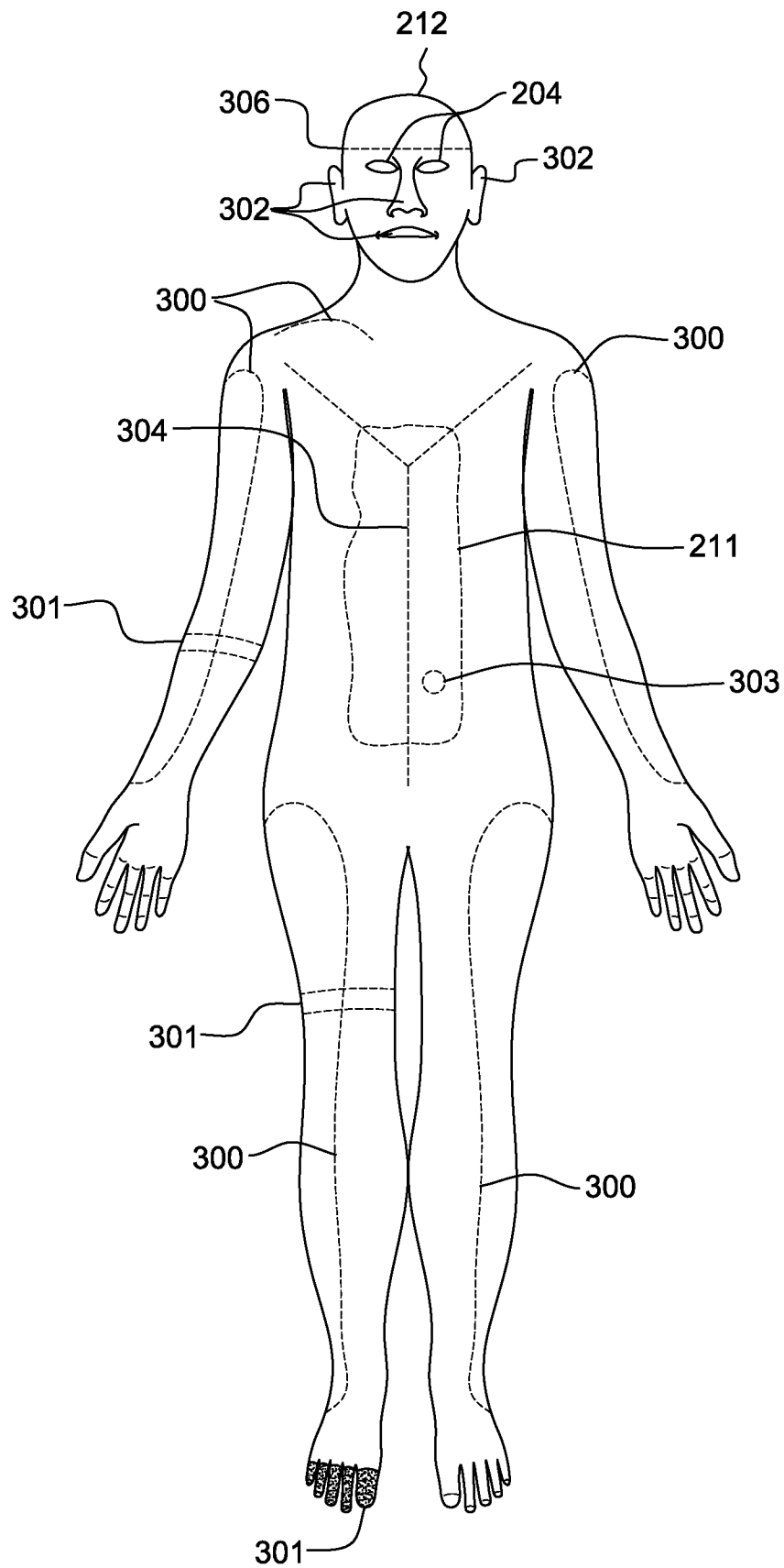


FIG. 7A

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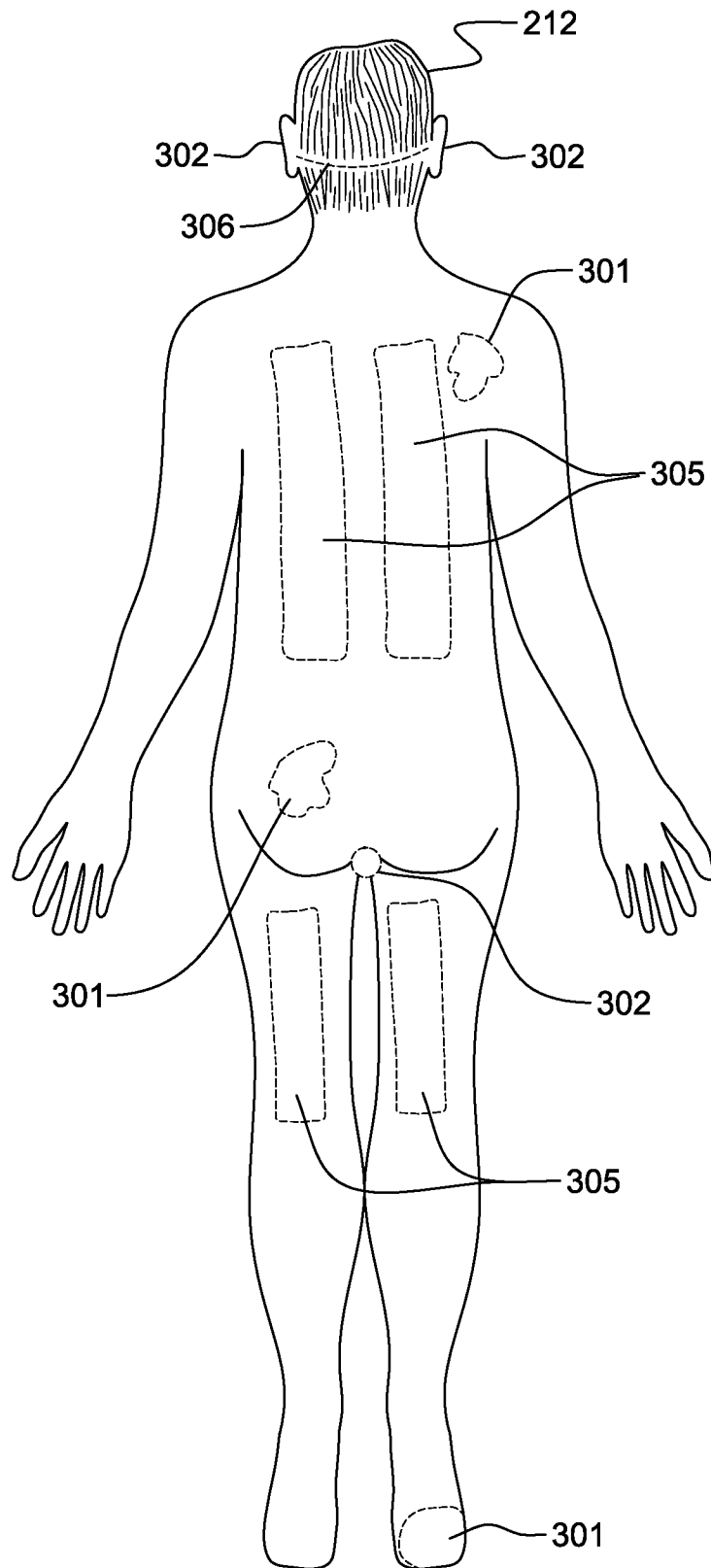


FIG. 7B

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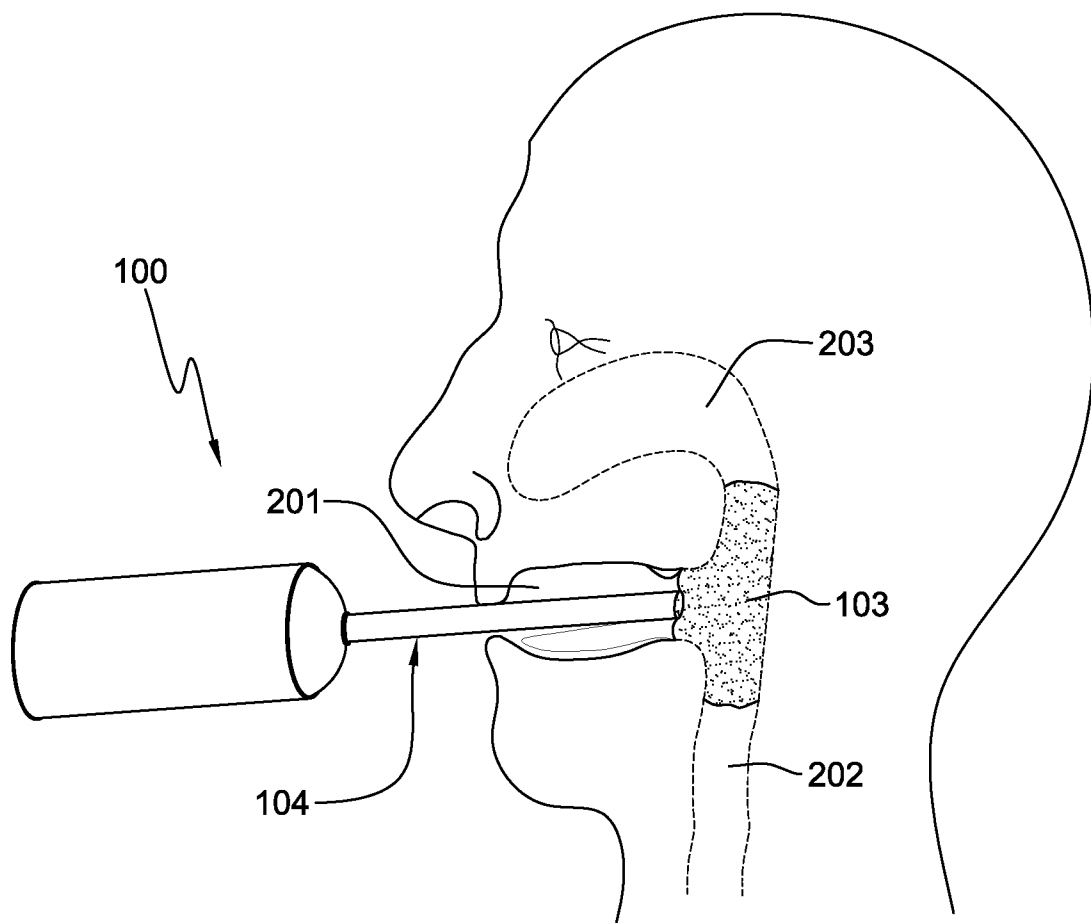


FIG. 8

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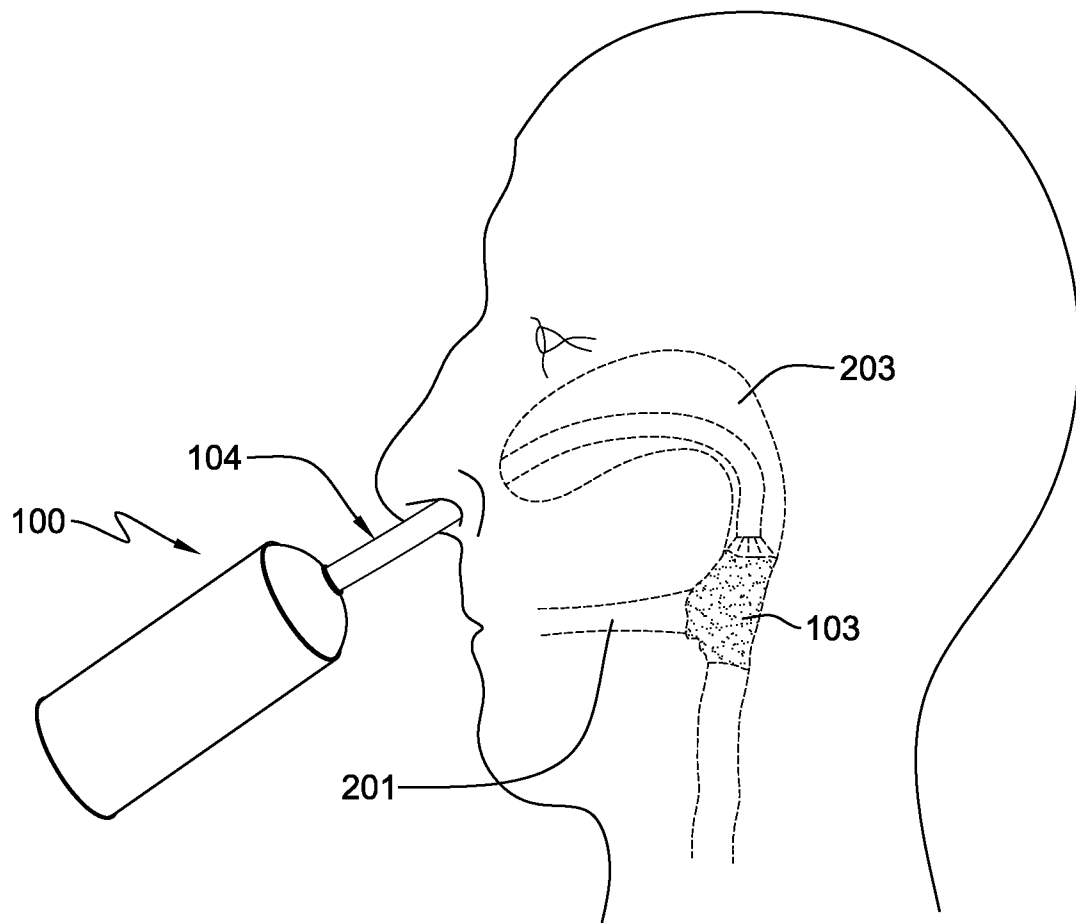
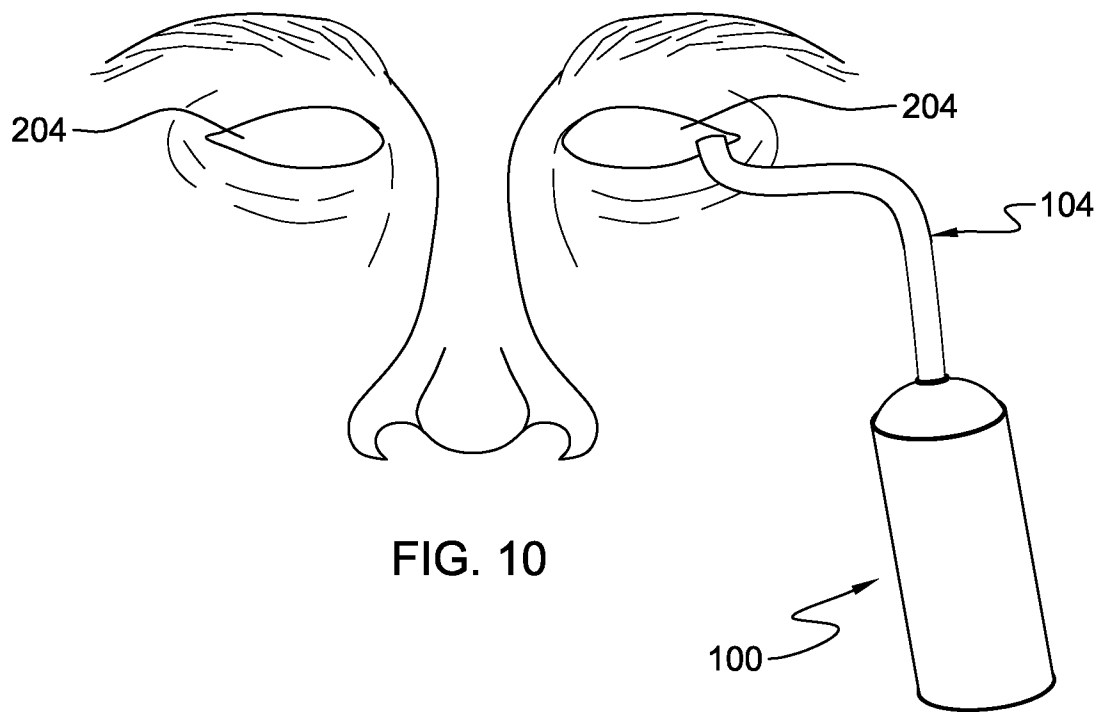


FIG. 9

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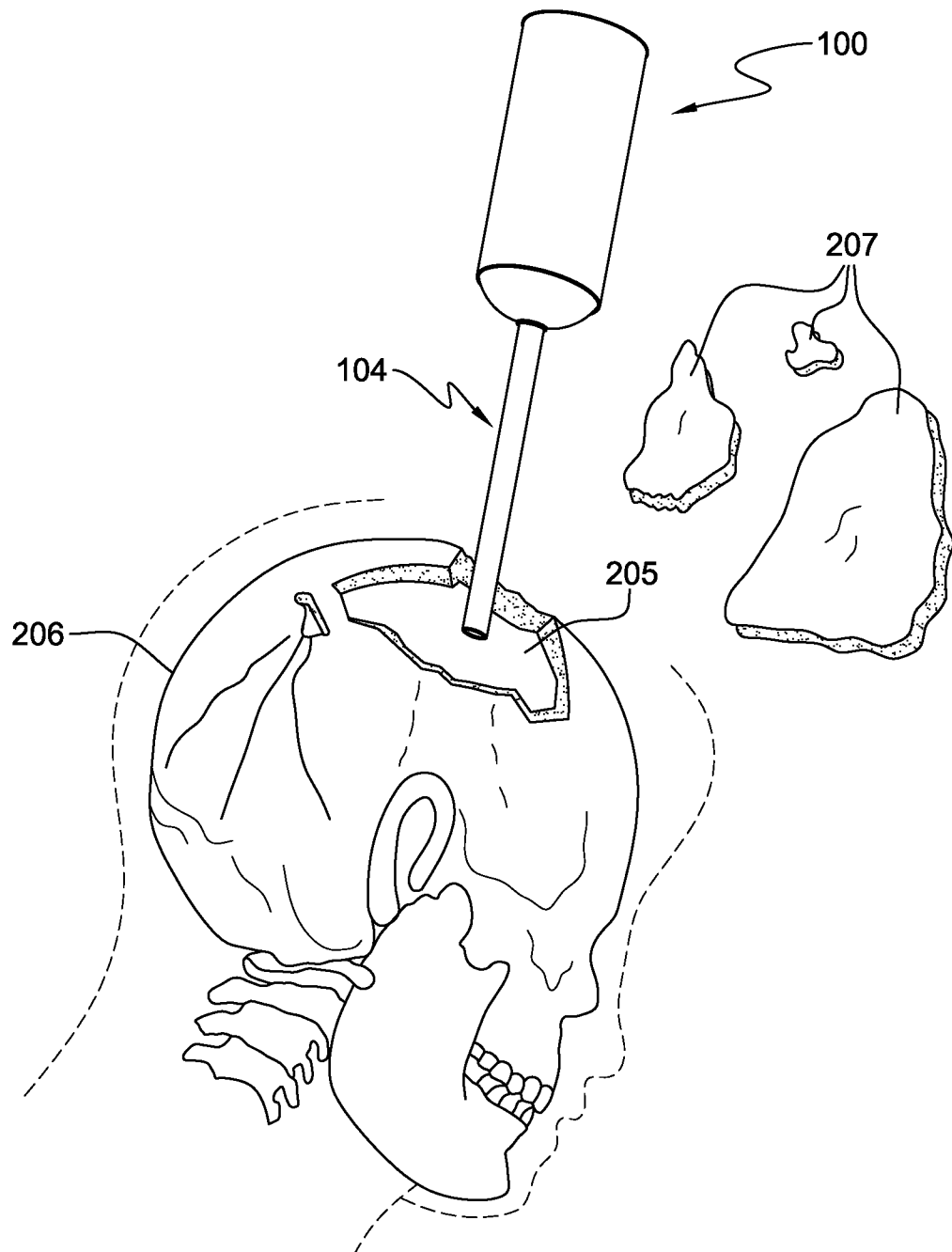


FIG. 11

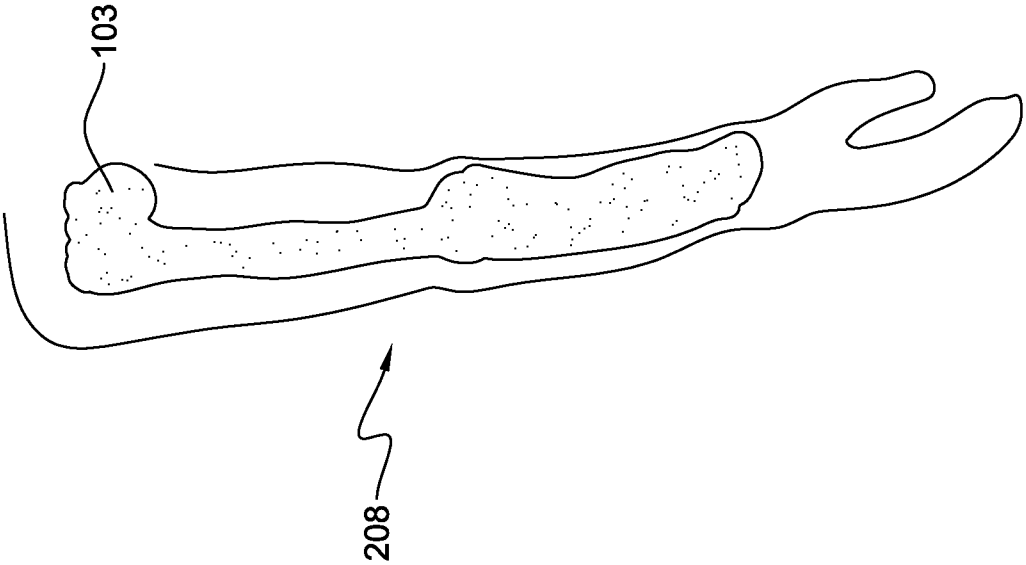


FIG. 12B

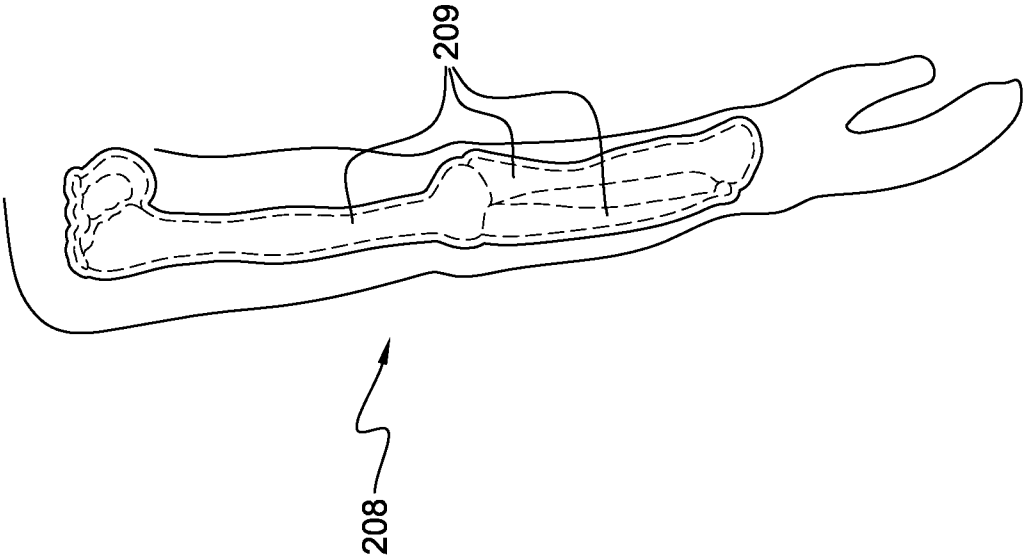


FIG. 12A

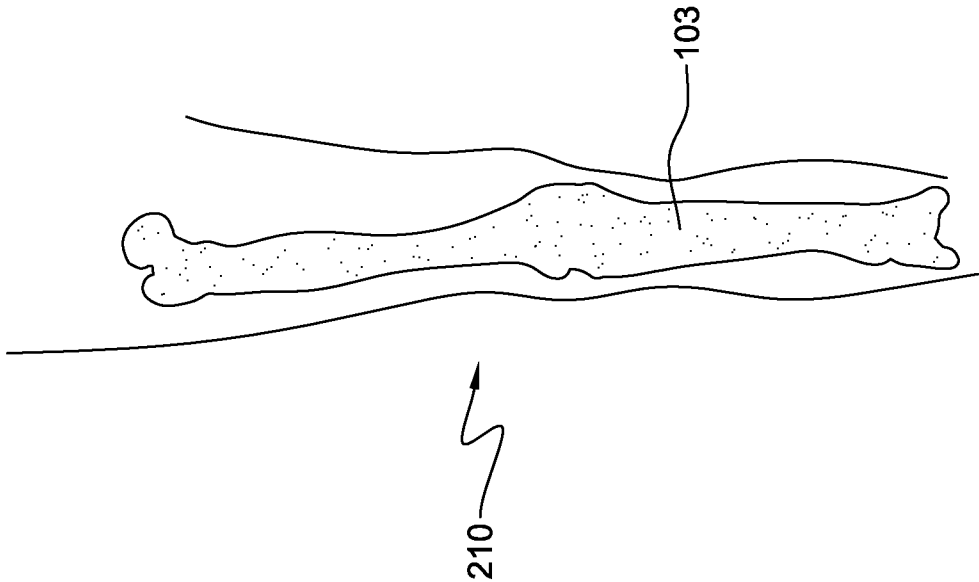


FIG. 13B

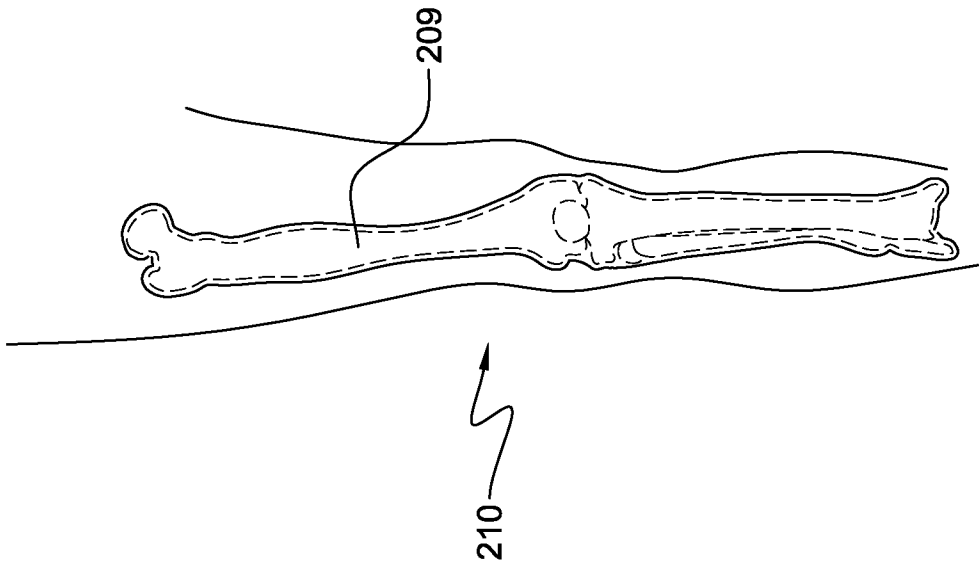


FIG. 13A

