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# DESCRIPTION

**Introduction**

**[0001]** Embodiments described herein relate to surgical instrumentation and, more particularly, a retractor according to the preamble of claim 1, forming an unobstructed, illuminated viewing slot for the physician's field of view.

**[0002]** Light sources that interfere with the physicians field of view, or that do not properly illuminate the field of view, inhibit the physician from seeing critical developments. For example, when performing a dissection, potential blood sources may drain blood into the dissection cavity, and without proper treatment, these blood sources can cause post-surgery infection. Such concerns are pertinent when using breast retractors, which are used for breast augmentation or reconstruction.

**[0003]** Conventional breast retractors may cause blood to drain into the dissection cavity due to a lack of proper illumination in the field of view.

**[0004]** Currently, breast retractors require substantial auxiliary lighting. This lighting is expensive, difficult to assemble, requires cleaning and reprocessing after each use, and due to lack of customization for breast retractors, fails to provide sufficient light at desired locations. Namely, practitioners must assemble and secure an independent light source onto the breast retractor prior to the patient procedure. These auxiliary light sources do not provide the physician with the ability to focus the light onto, and illuminate, specific portions of the surgical field without interfering with the physician's field of view.

**[0005]** Further, auxiliary light sources affixed to a retractor require expensive preparation and components that must be reprocessed after each patient procedure in order to ensure no patient cross-contamination. Without adequate reprocessing, cross contamination from one patient to another can occur. Moreover, even with reprocessing of the light sources, effective reprocessing is not 100% guaranteed, and many hospitals have reported patient cross-contamination due to inadequate or errors in reprocessing.

**[0006]** A retractor according to the preamble of independent claim 1 is for example known from US 2008/0108877 A1 and DE 20 2005 019 780 U1.

**[0007]** A further known retractor is disclosed in US 2013/0324801 A1.

**[0008]** Additionally, US 2012/0078060 A1 and US 2014/0364695 A1 disclose known specula.

**[0009]** Therefore, as can be seen, there is a need for a retractor according to claim 1.

**[0010]** The retractor may be made of polymer and according to various embodiments: (1) the polymer is a 50% glass-fiber reinforced polymer; (2) the polymer is a polyarylamide compound; (3) the polymer is a thermoplastic crystalline polymer; (4) the polymer is a thermoplastic crystalline polymer of aromatic diamines and aromatic dicarboxylic anhydrides; (5) the polymer is a glass-fiber reinforced polyarylamide; (6) the polymer is at least 50% glass-fiber reinforced; (7) the polymer has a flexural modulus of at least 17 GPa; (8) the polymer has a flexural strength of at least 375 MPa; (9) the polymer has an impact strength of at least 100 J/m; (10) the illumination assembly is permanently attached to the curved portion; and/or (11) the polymer has a conductivity of less than 10-6 A.

**[0011]** Further features and advantages will be apparent to those skilled in the art after reviewing the drawings and detailed description provided herein.

**Brief Description of the Drawings**

**[0012]**

Figure 1 is a side view of a surgical retractor serving as an example;

Figure 2 is a dimetric view of a surgical retractor serving as an example;

Figure 3 is an exploded view of a surgical retractor serving as an example;

Figure 4 is a perspective view of a surgical retractor serving as an example;

Figure 5 is a rear view of a surgical retractor serving as an example;

Figure 6 is a perspective view of a surgical retractor serving as an example, with the light assembly removed for clarity;

Figure 7 is a front view of a surgical retractor serving as an example;

Figure 8 is a top view of a surgical retractor serving as an example;

Figure 9 is a bottom view of a surgical retractor serving as an example;

Figure 10 is a top view of an exemplary embodiment;

Figure 11 is a front angled view of an exemplary embodiment;

Figure 12 is a rear view of an exemplary embodiment;

Figure 13 is a side perspective view of an exemplary embodiment;

Figure 14 is a top perspective view of an exemplary embodiment;

Figure 15 is an inverted view of an exemplary embodiment;

Figure 16 is a side perspective view of an exemplary embodiment;

Figure 17 is a rear perspective view of an exemplary embodiment;

Figure 18 is a top perspective view of an exemplary embodiment;

Figure 19 is a side view of an exemplary embodiment;

Figure 20 is a side view of an exemplary embodiment;

Figure 21 is a view of an exemplary embodiment;

Figure 22 is another view of an exemplary embodiment;

Figure 23 is a fluoroscopy image illustrating the radiolucency of an embodiment;

Figure 24 illustrates flexural strength and flexural modulus for a variety of plastics.

**[0013]** The invention is particularly shown in figures 10-22.

**Detailed Description of Select Exemplary Embodiments**

**[0014]** The following detailed description is of certain exemplary embodiments. The description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the present retractor.

**[0015]** Broadly, one or more embodiments provide a surgical retractor including an integrated light source and rounded blade forming an unobstructed, illuminated viewing slot for the physician's field of view. The surgical retractor with integrated light source prevents the problem caused by external light sources- namely, the casting of shadows within the operating cavity. To solve this problem, the integral light source of the surgical retractor is pointed in the same direction as the distal end of the retractor, which causes the light to be directed to the same point where the cutting is being performed.

**[0016]** The surgical retractor may provide a handle portion generally perpendicularly joined to a blade portion. The blade portion may form an arcuate (curved) shaped barrel portion defining a viewing slot, wherein the blade portion interconnects a saddle portion and an operative portion. The operative portion is dimensioned and adapted for surgery. The saddle portion attaches to the handle portion, while forming a recessed cavity for receiving the light source. The light source and recessed cavity are disposed, dimensioned, and adapted so that the light beam from the light source is directed down the viewing slot.

**[0017]** Referring now to Figures 1 through 22, one or more exemplary embodiments may include a surgical retractor 100 integrated with a light assembly 205. The surgical retractor 100

may include a handle portion 110 generally perpendicularly joined to a blade portion 120. The handle portion 110 may be joined to the blade portion 120 at saddle portion 210. The blade portion 120 may extend from a proximal end 130 to a distal end 140, wherein the proximal end 130 is joined to the handle portion 110 at saddle portion 210.

**[0018]** The blade portion 120 may be made of any moldable material that is sufficiently resilient including, but not limited to, polystyrene, poly-carbonate, glass filled nylon, or the like, although as explained herein, glass-reinforced polyarylamide is preferred, due its superior strength, radiolucency, and low conductivity.

**[0019]** The blade portion 120 may form a saddle portion 210, a barrel portion 215, and an operative portion 220.

**[0020]** The blade portion 120 may extend from the proximal end 130 to the distal end 140, wherein the barrel portion 215 interconnects the saddle portion 210 and the operative portion 220.

**[0021]** The barrel portion 215 may form an arcuate shape along its length so that the trough of the arcuate shape is upwardly oriented, defining a "viewing slot," as illustrated in the drawings.

**[0022]** The saddle portion 210 may be formed in a bowl-like configuration. The saddle portion 210 may form a recessed cavity 605 for receiving the light assembly 205. A spring or other fastener (not shown) may be provided to secure the light assembly 205 in the recessed cavity 605.

**[0023]** The light assembly 205 may include a light source 305, a switch 310 and a power source 315 connected in series. The power source 315 may include batteries, such as button style batteries, adapted to store only sufficient energy for a single use. Alternatively, the batteries may be reusable or rechargeable batteries for multiple uses. The light source 305 may be enclosed by a housing 320. The light source may include a LED, OLED, incandescent, or other suitable light source for emitting a beam of light. The switch 310 may be a light tab made from a nonconductive material, such as a Mylar tape, adapted to open circuit the serial electrical circuit of the power source 315 and the light source 305, whereby removal of the switch 310 results in the power source 315 activating the light source 305. In certain embodiments, the switch 310 may utilize any known means of activating/powering the light source 305, such as, but not limited to, a push button switch, toggle switch, magnetic reed switch or slider switch.

**[0024]** The recessed cavity 605 and the light source 305 may be dimensioned and adapted so that the beam of light is directed along the viewing slot, toward the distal end 140 of the blade portion 120, as illustrated in FIGS. 2 and 6, which illustrate the light source 305 disposed in the saddle portion 210 and directed down the viewing slot of barrel portion 215. As shown, the housing 320 is disposed below the viewing slot, and therefore out of the field of view of the end user.

**[0025]** The operative portion 220 may be downwardly angled away from the viewing slot so as to not obstruct the above-mentioned field of view. The operative portion 220 may be substantially flat and/or substantially square or rectangular in shape, providing a distal tip with a plurality of ridges 710 opposite the barrel portion 215. The shape of the distal tip and the ridges 710 may be dimensioned and adapted to hold the tissue of the breast recessed cavity away from the area of dissection, which helps the end user in the dissection procedure. Ridges 710 may be of any suitable depth and size in order to hold the breast tissue.

**[0026]** A method of using the retractor, not forming part of the invention, may include the following. The surgical retractor 100 disclosed above may be provided. A user may remove the surgical retractor 100 from a sterile package just prior to the surgical procedure. The user may remove the switch 310 to energize the light source 305. The user may then create an incision in the patient and use the surgical retractor 100 to create a pocket through this incision. The pocket will be used for breast augmentation, reconstruction, or other breast related surgical procedures. When the procedure is over, the retractor 100 may be discarded, because the light source 305 may be designed to not be replaceable and the power source may only be sufficient to power the light source for a single procedure, thereby allowing disposal of the present embodiment after one use.

**[0027]** In certain embodiments, the surgical retractor 100 can be adapted to form a retractor suitable for other procedures such as a nasal retractor spine retractor, orthopedic retractor, and retractors for other surgical procedures. All such retractors maintain the present embodiment of fully assembled, lighted, and single use.

**[0028]** In certain embodiments, the retractor may be used in a medical procedure performed by robots. Such robots will also need lighted retractors to allow visualization of the surgical cavity. Robotic procedures also benefit from enhanced field of view, and from single use components that eliminate the risk of patient cross contamination. An embodiment will contain suitable connecting features for attachment to a medical robot.

**[0029]** FIGS. 10-22 depict the invention comprising a retractor 100 with a light source 1020 located toward or near the distal end 140 of the barrel portion 215. It should be noted that some or all of the features as discussed herein with reference to these embodiment may be used in conjunction with, or in place of, some or all of the features in embodiments previously disclosed.

**[0030]** Referring now to FIGS. 10-20, retractor 100 includes a light source 1020 located nearer to the operative portion 220. The light source 1020 may be located toward the distal end of barrel portion 215. Light source 1020 may be located at any point near the distal end 140, including within the barrel portion 215 and the operative portion 220.

**[0031]** Light source 1020 may include a wide dispersion angle, such as a 100 degree angle, or any suitable variation thereof. The wide dispersion angle may be attained by using a wide

dispersion LED. The use of light source 1020, with a wide dispersion angle, and its location toward the distal end 140 of the blade portion, provides light to the entire operative area located in front of operative portion 220.

**[0032]** As illustrated in FIG. 10, the light source 1020 may be associated with some or all of the features of light assembly 205, including light source 305, a switch 310 and a power source 315.

**[0033]** Further, in this embodiment, operative portion 220 may include integral ridges 710, shown in FIG. 13, which provide for holding back tissue during use of the retractor 100.

**[0034]** A smoke evacuation channel 1105, with channel cover 1010, is located within barrel portion 215, and may extend, at one end, up to operative portion 220. In some embodiments, the smoke evacuation channel 1105 and cover 1010 may extend into a portion of the operative portion 220 at one end. The channel 1105 may be a hollow cavity defining the barrel portion 215.

**[0035]** At a second end, the smoke evacuation channel cover 1010 may be anchored in the saddle portion 210. The smoke evacuation channel 1105 may then extend into a hollow space located within handle 110. Thus, handle 110 may include a hollow space for receiving the smoke evacuation channel 1105 and cover 1010.

**[0036]** As illustrated, the smoke evacuation channel cover 1010 may be angled at certain points. The smoke evacuation channel 1105 also incorporates light source 1020, according to the invention.

**[0037]** Light source 1020 may further include a light holder 1115.

**[0038]** Channel 1105, coupled with cover 1010, provided for air and smoke to enter channel 1105 via a gap between cover 1010 and the barrel portion 215, thereby guiding smoke away from the physician's field of view. The gap may be provided on either side of the light source 1020.

**[0039]** The smoke channel 1105 and cover 1010 may extend from the distal end 140 of the retractor 100, near the operative portion 220, towards handle 110, as shown in FIG. 14.

**[0040]** Channel 1105 conducts air or smoke received at the entrance of the channel 1105, located at the distal end of the blade portion 120, towards the handle portion 110. Channel 1105 therefore acts as an air conduit and moves air/smoke away from the incision site and/or the physician's field of view.

**[0041]** A vacuum source may be attached to the retractor 100. The vacuum source may be connected to any point of the handle portion 110, including the bottom of the handle 110, distal to the saddle portion. Alternatively, the vacuum source may be attached at any suitable

location to the handle portion 110, or may be attached directly to the cover 1010 at the location of the saddle portion 210.

**[0042]** The handle portion 110 may be hollow and act as an air conduit. Smoke or air may leave the channel 1105 at the entrance to the handle portion 110, which may include a hollow chamber that is in communication with channel 1105. The handle portion 110 may include a portion of channel 1105, which is integral with the other portion of cover 1010. Alternatively, the handle portion 110 may include a second cover in communication with channel 1105, and may receive the smoke/air from channel 1105. The vacuum source may be attached at the base of the handle portion 110.

**[0043]** The vacuum source is operable to provide suction, via the channel 1105, in order to move air/smoke away from an incision site or the physician's field of view. The air/smoke enters the channel 1105 at an opening created by the gap between cover 1010 and barrel portion 215, located near the blade tip, traverses the channel 1105 toward the saddle portion 210, and enters the handle portion 110. The vacuum source pulls the air/smoke from the handle.

**[0044]** As illustrated in the inverted view of the retractor 100 in FIG. 15, the channel 1105 and cover 1010 descend to the bottom 1520 of the handle portion 110. The cover 1010 includes a connector 1410 at the bottom 1520, which fluidly connects the channel 1105 to the vacuum source and draws the smoke/air out of the channel.

**[0045]** As illustrated in FIGS. 11-13, the smoke channel 1105 advantageously abuts operative portion 220 in order to provide smoke evacuation from the operative site.

**[0046]** Further, the light source 1020 may be provided at an angle similar to, or substantially the same as, the downward angle of the operative portion 220 relative to the barrel portion 215, in order to focus the light from the light source 1020 onto the area retracted by the operative portion 220.

**[0047]** The light source 1020 may alternatively be provided at an angle substantially similar to the barrel portion 215, and may not slope downward with the operative portion 220. This may still cause the light source to illuminate the operative area, due to the wide dispersion angle of the light source 1020.

**[0048]** Yet further illustrated is the angle of the operative portion 220, particularly at the distal end as it slopes downward. Integral ridges 710 provide, along with the angle of the blade 120 at its operative portion 220 and the square shape of the operative portion 220, for optimal methods and apparatus for holding back tissue during use.

**[0049]** Blade 120 may incorporate one or more retaining slots 1510, shown in FIGS. 15 and 17, on the underside of the blade. The slots 1510 are operable to hold cover 1010 in place. The retaining slots 1510 are also optimally designed to not catch tissue during a surgical

procedure, such as when the blade 120 is inserted into the body cavity.

**[0050]** Each retaining slot 1510 incorporates a hole sized to receive a retaining tab 1605 from cover 1010, as shown in FIG. 16. To hold cover 1010 in place on top of blade 120, the retaining tab 1605 from cover 1010 is inserted into the hole of retaining slot 1510. Retaining slots 1510 are sized such that the hole is smaller than the associated retaining tab 1605. The hole is raised and smoothed, which holds body tissue away from the hole.

**[0051]** As illustrated in FIG. 21, retaining slot 1510 may include a raised and smoothed portion. Based on this feature, the retaining tab 1605, when inserted into and residing within retaining slot 1510, is recessed within the hole, and does not protrude from the hole of retaining slot 1510. This ensures that no tissue is snagged or caught by the end of retaining tab 1605.

**[0052]** FIG. 22 illustrates a cutaway of tab 1605 residing within, and not protruding from, retaining slot 1510. Tab 1605 deforms around shelf 2210, and tab 1605 snaps into place such that contact between the underside of tab 1605 and the top of shelf 2210 prevents the separation of tab 1605 from shelf 2210.

**[0053]** Shelf 2210 is located opposite retaining slot 1510. Retaining slot 1510 is located on the underside of blade portion 120, and is formed from mold structures that penetrate the blade portion 120 from the underside. The penetration of the mold structures forms holes in the blade portion 120, such as retaining slot 1510, which is shown filled in with tab 1605. To prevent retaining slot 1510 from trapping tissue, it is preferable to minimize the size of retaining slot 1510, as well as limit the number of holes to one hole located on the underside of blade portion 120.

**[0054]** Retractor 100 is therefore formed using a mold structure that penetrates blade portion 120 only in the location of shelf 2210. The formed hole of retaining slot 1510 is minimized in size to be of the same, or approximately the same, size as the width of shelf 2210.

**[0055]** In an embodiment, the manufacturing process includes utilizing the mold structures to form a hole in the underside of the blade portion (e.g., in the hole of retaining slot 1510), opposite shelf 2210. By penetrating the blade portion 120 only in the location of the shelf, and in no other location on the underside of the blade portion, the hole on the underside, which may face the patient during a procedure, is only as wide as the shelf. Thus, the hole size is reducing trapping of patient tissue.

**[0056]** Yet, by reducing the hole area for retaining slot 1510, and providing for one hole the same width of shelf 2210, during manufacturing, retaining tab 1605 cannot deform into place to fit around shelf 2210.

**[0057]** As illustrated in FIG. 22, an additional hole 2220 is therefore formed during manufacturing from a mold structure on the top side of blade portion 120, opposite the tissue-facing underside, in order to allow for deformation of retaining tab 1605.

**[0058]** Hole 2220 is formed to provide for deformation of retaining 1605. The location of hole 2220 is optimally located on the top side of blade portion 120, away from tissue contact. Hole 2220 does not proceed through the width of the blade portion 120, thereby minimizing additional hole structures on the patient-facing side of retractor 100.

**[0059]** As illustrated in FIGS. 21-22, retaining slot 1510, is sized to half the width of a conventional hole, due to the use of multiple molds. Therefore, only slot 1510, with a smoothed mound, provides for minimal tissue catch.

**[0060]** In an embodiment, the retractor 100 is formed from an injection mold design. It should be noted that a shrunken hole is smaller than the retaining tab 1605, which is only possible in an injection mold design, and is not feasible with a metal retractor.

**[0061]** Retractor 100 further includes an on/off switch 1705, located at the bottom of handle 110. Switch 1705 may be located adjacent to the connector 1410. Switch 1705 controls one or more of the light source and vacuum source.

**[0062]** FIG. 18 illustrates the retractor 100 with cover 1010 removed. Channel 1105, the cavity, under the smoke evacuation cover 1010, is illustrated extending from a distal end of the barrel portion 215 adjacent to the operative portion 220, past the saddle portion 210, and into a cavity 1810 located in the handle 110. Smoke may travel from the intake adjacent to operative portion 220, under the cover 1010, via channel 1105, into the handle cavity 1810. The smoke traverses the internal cavity 1810 and exits the handle via connector 1410, which is connected to a smoke evacuation hose and uses suction from the vacuum source.

**[0063]** FIGS. 18-20 illustrate the electrical connection to the light source 1020, which is normally held in place in channel 1105 by the smoke evacuation cover 1010. The wires 1820 lead from the light source 1020 into a power source in the handle 110. The power source is controlled by switch 1705. The power source may contain sufficient charge for only a single use.

**[0064]** As illustrated in FIG. 19, retractor 100 may include an assembly 1910. Assembly 1910 may be made or manufactured separate from the retractor body. Assembly 1910 may be include one or more of a power source 1920, wires 1820, switch 1705 and light source 1020.

**[0065]** In an exemplary method of manufacture, assembly 1910 may be inserted, as one pre-formed piece, into the base portion of handle 110. Assembly 1910 may be inserted into the cavity of handle 110 from the bottom, and fed up through handle 110, out the top portion of handle 110, adjacent to the saddle portion 210. The assembly 1910 may then be placed onto the barrel portion 215, within channel 1105, at which point the light source 1020 and wires 1820 of assembly 1910 are placed into receiving slots 1830. The cover 1010 is then placed over the channel 1105, including assembly 1910, and snapped into place.

**[0066]** A method of utilizing the smoke channel 1105 to remove the smoke from a physician's field of view, which is not part of the invention, may include the following. Generating smoke during a surgery or procedure by, for example, use of electro-cauterization tools. This smoke may interfere with the physician's vision, particularly with the field of view. The light source 1020 may be focused on the physician's field of view. During the course of the procedure, a vacuum source may be switched on, and smoke may be drawn into the retractor via the smoke evacuation channel. The smoke may traverse the smoke evacuation channel, into the handle, and out the bottom of the handle.

**[0067]** It should be noted that the entire retractor and associated components as disclosed herein, including the blade/handle, handle cover, and cover, are fully compatible with low-cost injection molding, and are able to be manufactured using low cost plastic. Further, the entire retractor assembly is optimal for use as a single-use and disposable product.

**[0068]** It should be understood that, among the advantages of the retractor, the need for a separate smoke evacuation tool is eliminated. Additionally, a bright light source is provided to illuminate the surgical cavity.

**[0069]** The surgical retractor includes a handle portion joined to a blade portion. The blade portion may be perpendicularly joined to the handle portion, such as at a 90 degree angle or approximately 90 degree angle. Alternatively, the blade portion may be joined to the handle portion at any suitable angle, such as, for example, a 30 degree angle, 45 degree angle, 110 degree angle or any other suitable angle.

**[0070]** Also, the blade portion may include a saddle portion, a curved barrel portion, an operative portion, and a channel cover. The saddle portion may abut the handle portion, forming a recessed cavity. The curved barrel portion may be located distal to the saddle portion and define a channel. Within the barrel portion, a light assembly may be disposed. The operative portion may be located distal to, and downwardly angled from, the barrel portion. The channel cover may be disposed over the channel within the barrel portion, and may be adapted to hold the light assembly in place.

**[0071]** In a variant, the operative portion of the retractor is substantially squared in shape, and includes a plurality of ridges distal to the barrel portion. The ridges may be of any suitable dimension. The ridges may be dimensioned to grip tissue and hold the tissue away from an operative area.

**[0072]** According to an alternative, the light assembly abuts the operative portion and includes a light source, a switch, a single-use power source, and a housing.

**[0073]** The channel of the retractor may be a smoke evacuation channel that extends from the barrel portion, through the saddle portion, and into a hollow space in the handle portion.

**[0074]** The smoke evacuation channel may extend through a length of the handle portion to a

connector located at a bottom of the handle portion. A vacuum source may be coupled, via a connector, to the bottom of the handle portion. The coupling of the vacuum source provides a fluid connection between the smoke evacuation channel and the vacuum source, which provides suction for removing smoke.

**[0075]** The surgical retractor includes a handle portion and a blade portion joined to the handle portion. The blade portion may include a saddle portion abutting the handle portion and forming a recessed cavity; a curved barrel portion located distal to the saddle portion and defining a channel, the barrel portion including a light assembly disposed within the barrel portion; an operative portion located distal to, and downwardly angled from, the barrel portion; a channel cover disposed over the channel, within the barrel portion, and adapted to hold the light assembly in place, the channel cover including a plurality of retaining tabs; and a plurality of retaining slots located on an underside of the blade portion, the retaining slots sized to minimize a size of the hole of the retaining slot and including a smoothed and raised geometry to facilitate tissue movement without catching. Each retaining tab may be sized to fit into one of the plurality of retaining slots, and the retaining slots may be operable to hold the channel cover in place over the channel.

**[0076]** Therefore, provided is a self-lighted retractor with the ability to provide bright, shadow-less light to a surgical cavity. In accordance with the invention, also provided is a dual-purpose smoke evacuation channel and light source holder that couples the light source to the retractor. Further may be provided a single-use battery and high volume moldable plastic components that allow for manufacture of a high- quality retractor that is affordable for single use, reducing infection risk. Yet further may be provided an angled retractor blade that is squared, with integral ridges to hold tissue aside during use of the retractor.

**[0077]** The blade, the handle and the curved section (referred to herein collectively as "the body") may be integrally molded. In at least one exemplary embodiment, the material of which the body is formed is a strong, rigid, lightweight plastic (e.g., a polymer). One example of a suitable plastic is a glass-fiber reinforced polyarylamide compound that provides high strength and rigidity, surface gloss, and creep resistance. An example uses a 50% glass-fiber reinforced polyarylamide compound, but those skilled in the art will understand that other percentages may be used without departing from the scope of the claimed invention.

**[0078]** Polyarylamides are thermoplastic crystalline polymers of aromatic diamines and aromatic dicarboxylic anhydrides having good heat, fire, and chemical resistance, property retention at high temperatures, dielectric and mechanical properties, and stiffness but low light resistance and processability. Those skilled in the art will understand that other plastics with suitable strength and rigidity also may be used.

**[0079]** In one or more examples, the body is made of a plastic (such as glass-fiber reinforced polyarylamide) having properties of at least one of radiolucence and non- conductivity. As used herein, "radiolucence" means high transparency to radiation, so that the device may be used when taking, for example, x-ray images. "Nonconductive," as used herein, means essentially

dielectric.

**[0080]** An advantage of radiolucence is that the device may be used when taking X-ray images, without obscuring essential structures, as shown in FIG. 23. The "OBP" in FIG. 23 resulted from metal lettering placed below the blades of an embodiment to show the radiolucency. The much darker image on the left is of a stainless steel comparison blade, which shows up as black due to its opacity with respect to X-rays.

**[0081]** Examples described herein may provide light to the tip of the retractor and still remain highly (as much as 99%) radiolucent. Prior art devices have, for example, fiber optic cables that obstruct the view when X-ray images are taken, even when the devices are constructed of plastic. Metal devices are, of course, not radiolucent at all.

**[0082]** This radiolucent property means that retractors described herein may not need to be removed prior to the use of imaging techniques in surgical procedures. This can expedite the conduct of a procedure needing anatomic identification and/or device localization.

**[0083]** An advantage of nonconductivity is that it provides improved safety to patients - in contrast to metal retractors. Currents as low as 0.001 A may be felt by a patient, and larger currents may damage the patient. Embodiments described herein limit currents to less than $10^{-6}$ A, and thus greatly reduce electrical hazards.

**[0084]** For example, electro-cautery is used extensively in surgical tissue dissection. The use of metal retractors exposes the operating surgeon and the patient to the risk of retracted tissue damage due to destructive cautery current being conducted inadvertently. Retractors are often used to displace and retract delicate cautery sensitive tissues such small or large bowel (colon), lung, or major blood vessels. Cautery injury to these tissues can create major complications. In addition, retractors are often used to develop surgical tissue pockets in breast and pacemaker surgery. Use of a non-electrical conducting material, such as is described herein with respect to certain embodiments, prevents any stray electrical energy injury to the retracted tissues. Patient safety is thus enhanced.

**[0085]** As those skilled in the art will understand, strength is a function of both the material and the design. Designs using weaker material than is described herein need to be thicker and more rounded. Both of these traits will decrease the favorability of a retractor, which should not block visibility of the body cavity.

**[0086]** Flexural Strength represents the limit before a material will break under stress. Flexural modulus is the tendency of the material to bend under stress. Both of these parameters are critical to retractor design and resulting performance. First, a retractor blade must be thin enough to not interfere with the medical procedure for which it is used. Very thick blades will tend to fill the hole in the body that the physician needs to work in. An optimal design will have a blade thin enough to allow space for the physician to work. Typically metal blades are used because of their high Flexural modulus. They have unlimited flexural strength, because they

bend rather than break. Metal blades as thin as 0.5-2 mm are readily available and this thickness is small enough to not interfere with the physician's work space in a wound or operating cavity. Stainless steel metal can have a flexural modulus of 180 GPa which will inhibit blade deformation of more than 10 mm under 66,7 N (15 lbs of tip pressure) for most retractor designs.

**[0087]** Plastic injection molded blades require a thicker blade because they have a lower Flexural Modulus. Blade strength will increase as the cube of the blade thickness, but blade thicknesses larger than 2 mm are not desirable in most physician applications. Typical plastic materials, such as those shown in Table 1 below, have a Flexural Modulus of just a few GPa and a Flexural Strength of less than 200 MPa. These lower value parameters result in retractor blades that deform more than 10mm under use, and are likely to break with less than 133,5 N (30 lbs of force) placed on the tip of an average length retractor blade (50-150 mm long).

**[0088]** Retractor blades that deform significantly during use increase the physician's difficulty in retracting the tissue during a medical procedure. Retractor blades that break with less than 133,5 N (30 lbs of force) can create a hazard to the patient since a broken blade, or pieces of a broken blade, may fall into the patient and create damage. Retractor blades made from the plastics listed in the following table will typically bend more than 20 mm under 44,5 N (10 lbs of tip force), and will break at 66,7 N (15 lbs of tip force) (or even less).

**TABLE 1: TYPICAL FLEXURAL STRENGTH AND FLEXURAL MODULUS OF POLYMERS**

**[0089]**

| POLYMER TYPE | FLEXURAL STRENGTH (MPa) | FLEXURAL STRENGTH (MPa) |
|---|---|---|
| Polyamide-Imide | 175 | 5 |
| Polycarbonate | 90 | 2.3 |
| Polyethylene, MDPE | 40 | 0.7 |
| Polyethylene Terephthalate (PET) | 80 | 1 |

**[0090]** To increase the flexural modulus and flexural strength of plastic, in an embodiment, glass fiber is added to the plastic material. FIG. 24 shows a variety of plastics with various percentages of glass fiber added.

**[0091]** It can be seen from the above that the addition of glass fiber can increase the Flexural Strength of certain plastics to 300 MPa or above, and increase the Flexural Modulus to 16 GPa or above. In an exemplary embodiment, a certain type of plastic, polyacrylamide, is infused with glass fiber to create a flexural strength of over 375 GPa and a Flexural modulus of over 17 GPa.

**[0092]** Plastics with these properties have the ability to create retractor blades of approximately 2 mm thickness that withstand over 133,5 N (30 lbs of tip force) without breaking and deform less than 10 mm under 66,7 N (15 lbs of force). Additionally, the glass fiber in this material will "glassify" at the surface leaving a very smooth "metal like" finish which is highly desirable in retractor applications.

**[0093]** The glass fiber in the material also will decrease the likelihood of sharp shards of material being created during an overstress and breakage event. This tendency to create dull edges upon breakage decreases the likelihood that a patient will experience damage if the retractor is overstressed and ultimately broken.

**[0094]** Additionally, the way in which a material breaks can be important in medical applications. The breakage characteristics of a material are often measured by Impact Strength. Materials with low impact strength (10-20 J/m) can break under stress into large numbers of sharp shards which can pose a hazard to a patient if material failure occurs during a medical procedure. Sharp shards can cut patient tissue and large numbers of these shards can make it difficult or impossible to remove the broken material from the patient.

**[0095]** Materials (such as glass fiber reinforced polyarylamide) used in certain embodiments described herein have a high impact strength (>100 J/m) and will fail with very few fractured component edges (and the resulting edges will be blunt). This breakage characteristic minimizes potential hazard to a patient during product overstress that results in material breakage.

# REFERENCES CITED IN THE DESCRIPTION

Cited references

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

**Patent documents cited in the description**


- US20080108877A1 **[0006]**
- DE202005019780U1 **[0006]**

- US20130324801A1 **[0007]**
- US20120078060A1 **[0008]**
- US20140364695A1 **[0008]**

## PATENTKRAV

1. Kirurgisk retraktor (100), omfattende:

en klingedel (120) med en øvre overflade og en nedre overflade og omfattende en proximal ende og en distal ende, hvilken klingedel (120) omfatter en røgafledningskanal (1105);
en håndtagsdel (110) forbundet med den proximale ende af klingedelen (120); og
et belysningsarrangement omfattende i det mindste én lyskilde (1020), i det mindste ét batteri og en omskifter (1705) til aktivering af lyskilden (1020), hvor belysningsarrangementet er forbundet med retraktoren (100),
**kendetegnet ved, at** røgafledningskanalen (1105) omfatter lyskilden (1020) i røgafledningskanalen (1105).

2. Kirurgisk retraktor (100) ifølge krav 1, hvor belysningsarrangementet er permanent forbundet med retraktoren (100).

3. Kirurgisk retraktor (100) ifølge ethvert af de foregående krav, hvor omskifteren (1705) kun tillader en enkelt betjening af en bruger.

4. Kirurgisk retraktor (100) ifølge ethvert af de foregående krav, hvor omskifteren (1705) omfatter en ikke-ledende laske.

5. Kirurgisk retraktor (100) ifølge ethvert af de foregående krav, som yderligere omfatter en afdækning (1010) for røgafledningskanalen (1105).

6. Kirurgisk retraktor (100) ifølge krav 5, som yderligere omfatter holdeslidser (1510), som forbinder afdækningen (1010) med klingedelen (120), og hvor afdækningen (1010) omfatter lasker (1605) svarende til holdeslidserne (1510).

7. Kirurgisk retraktor (100) ifølge ethvert af de foregående krav, hvor røgafledningskanalen (1105) strækker sig i det mindste fra den distale ende af klingedelen (120) til håndtagsdelen (110).

8. Kirurgisk retraktor (100) ifølge krav 5 eller 6, som yderligere omfatter en cylinderdel, hvor afdækningen (1010) er placeret over kanalen (1105) i cylinderdelen og er indrettet til at holde lysarrangementet på plads.

# DRAWINGS

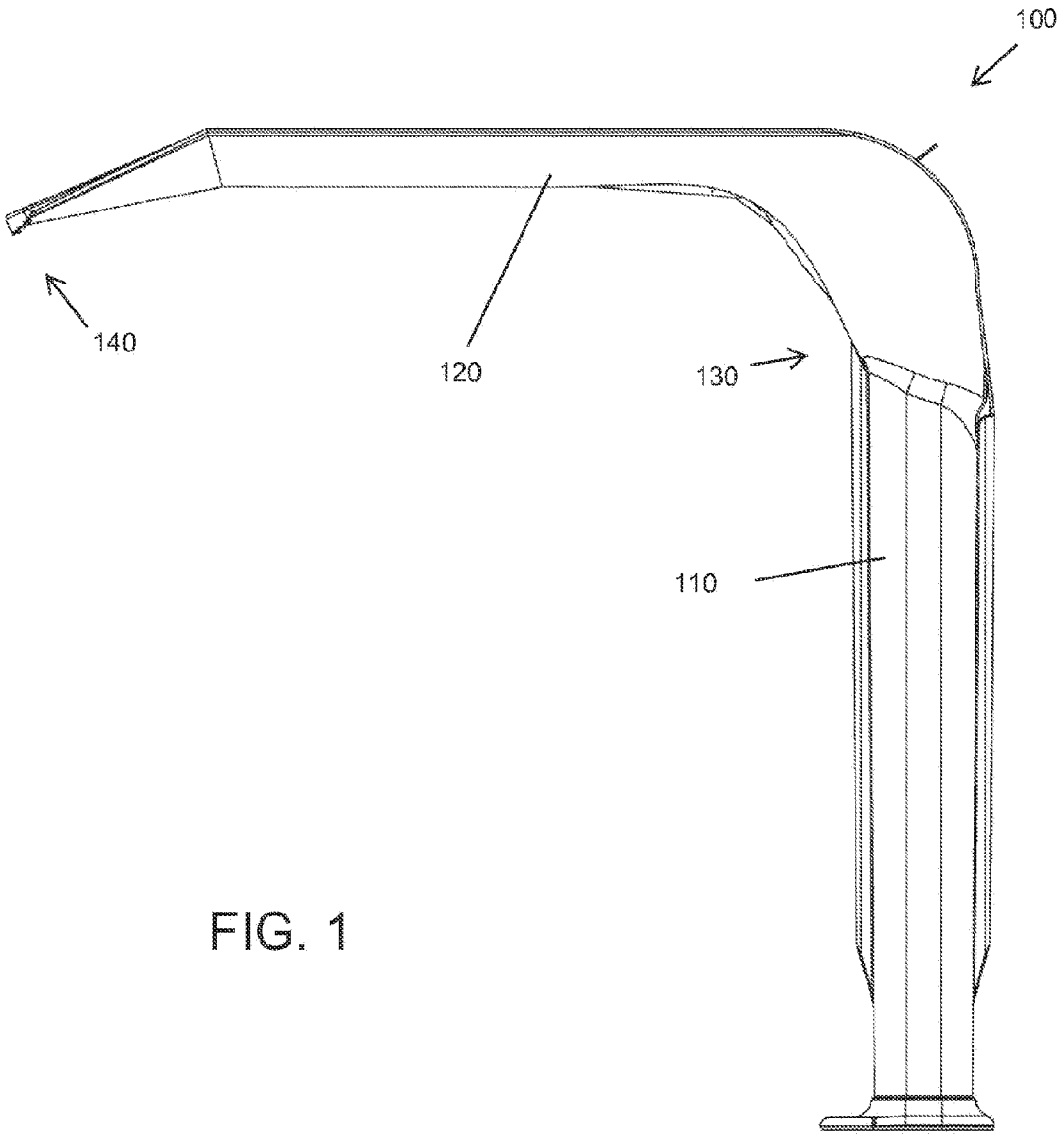



FIG. 1

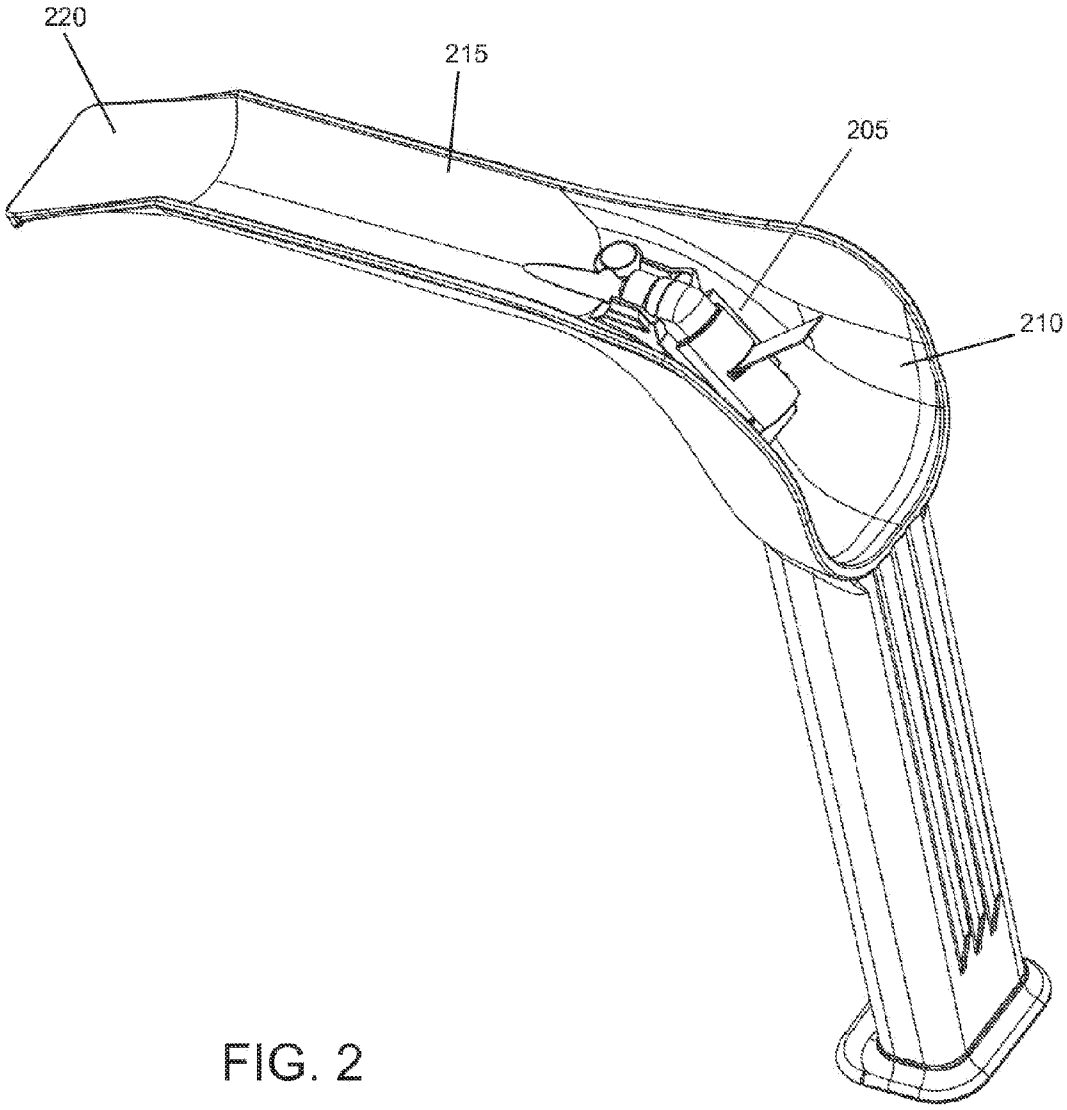



FIG. 2

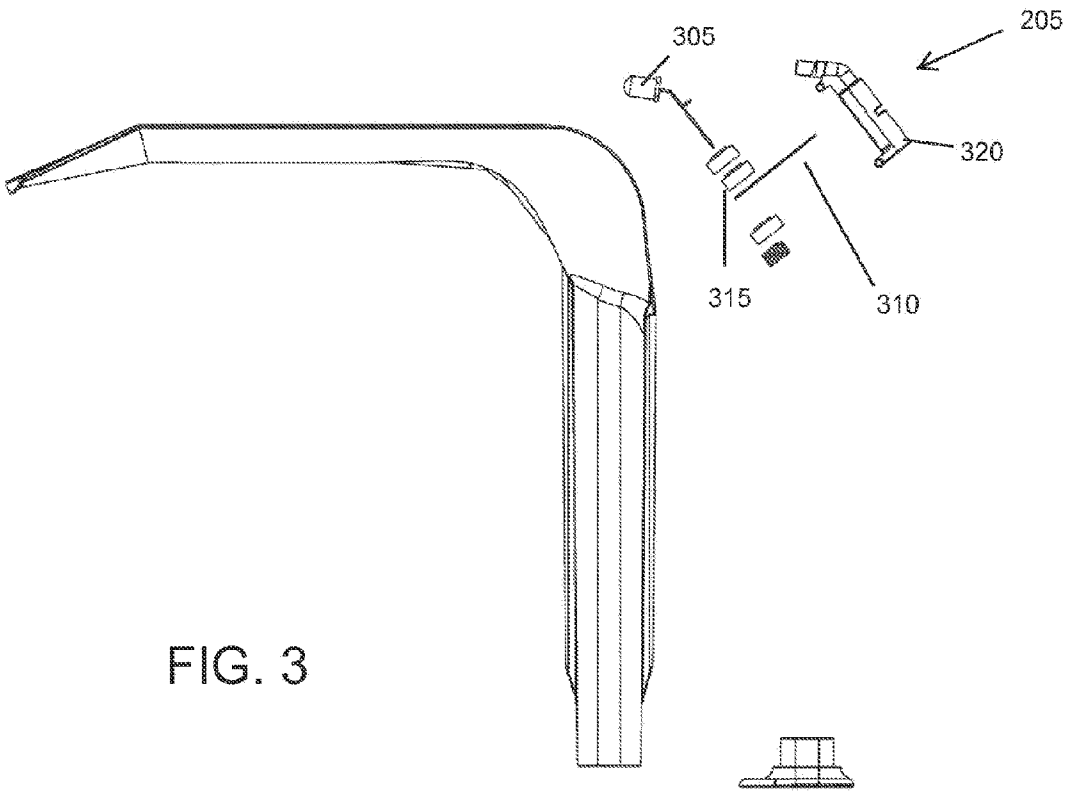



FIG. 3

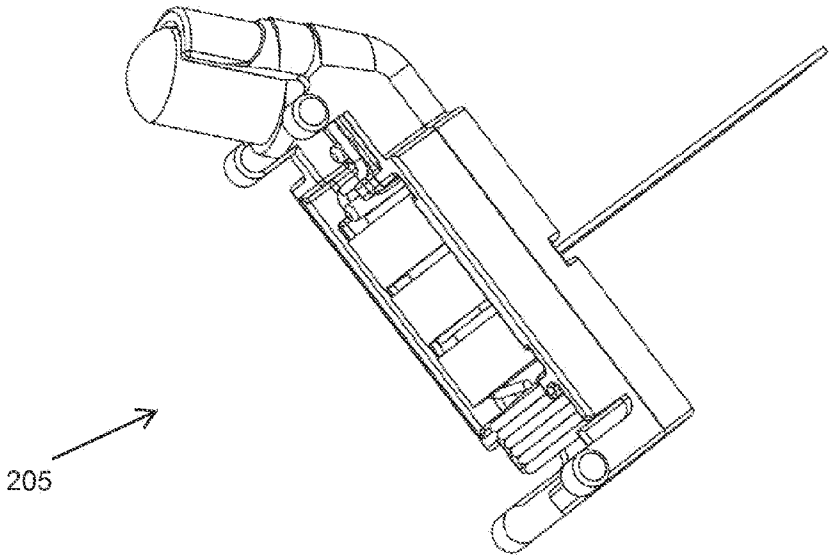



FIG. 4

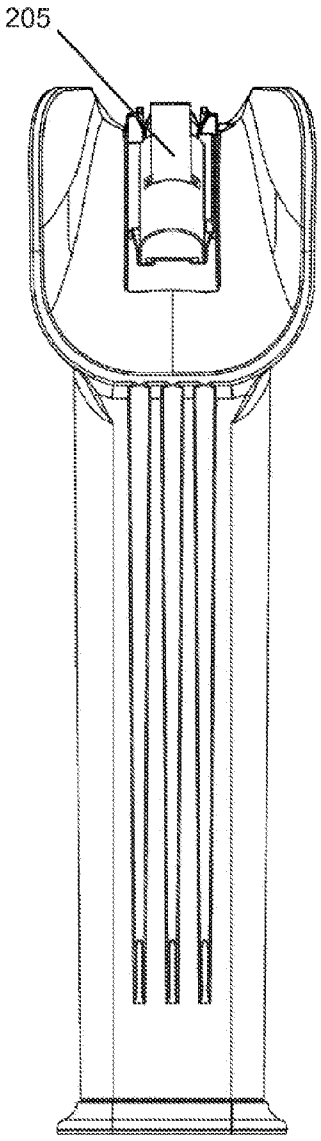



FIG. 5

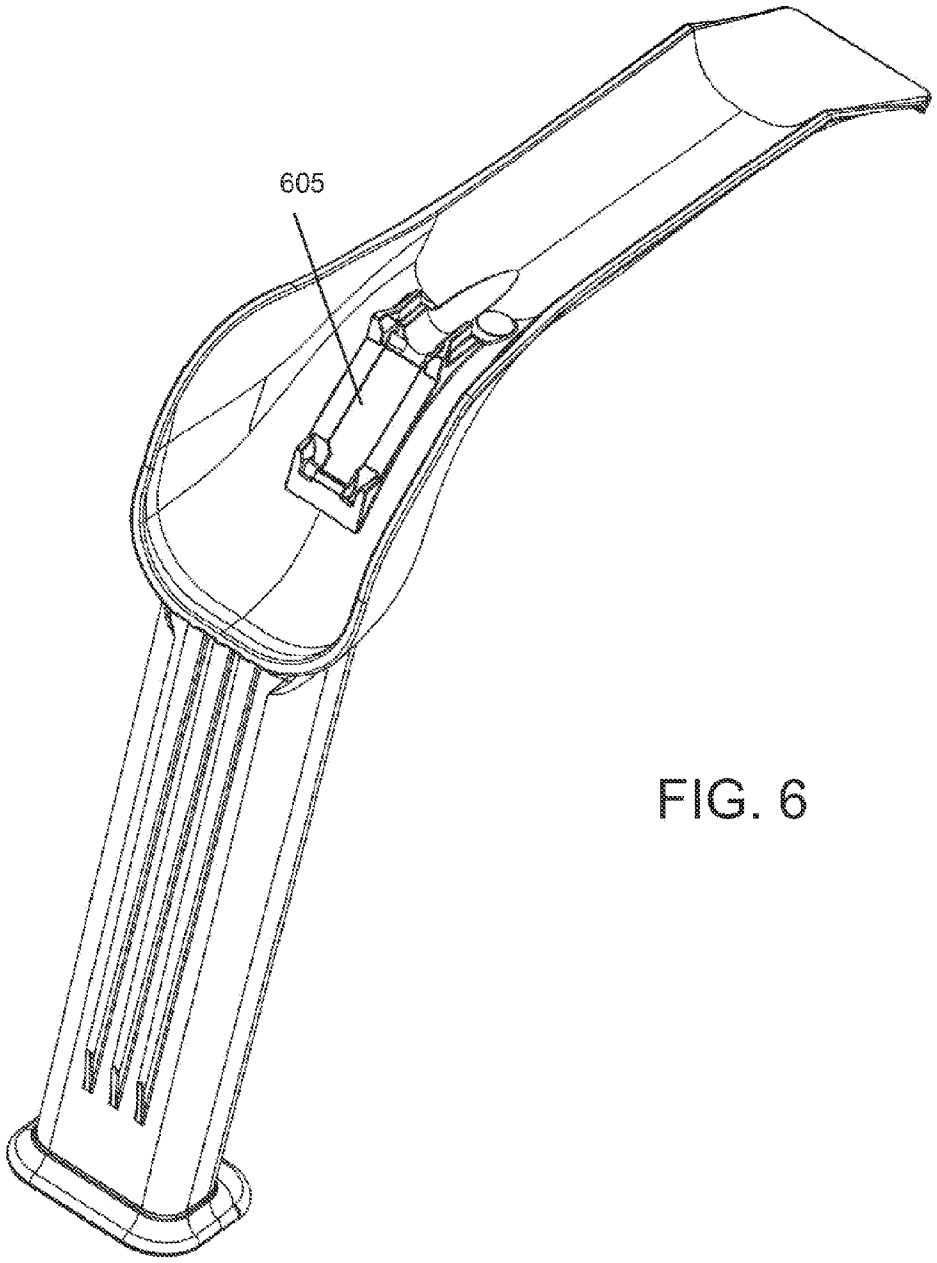



FIG. 6

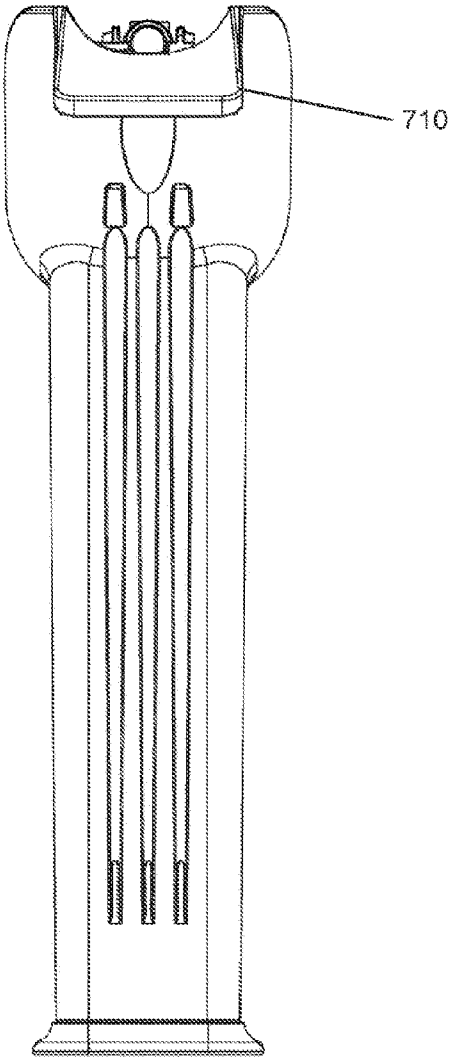



FIG. 7

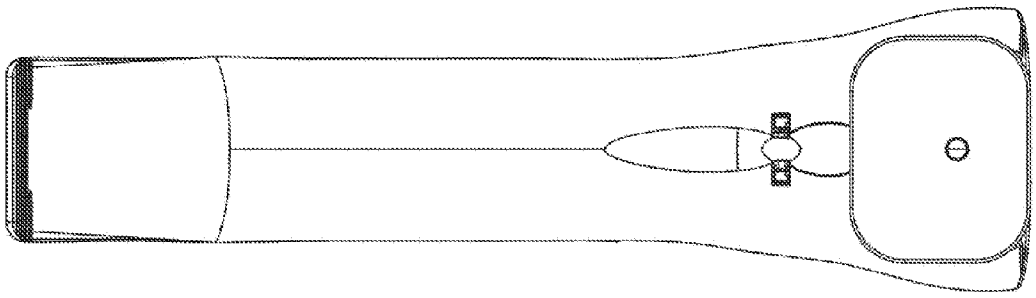


FIG. 8

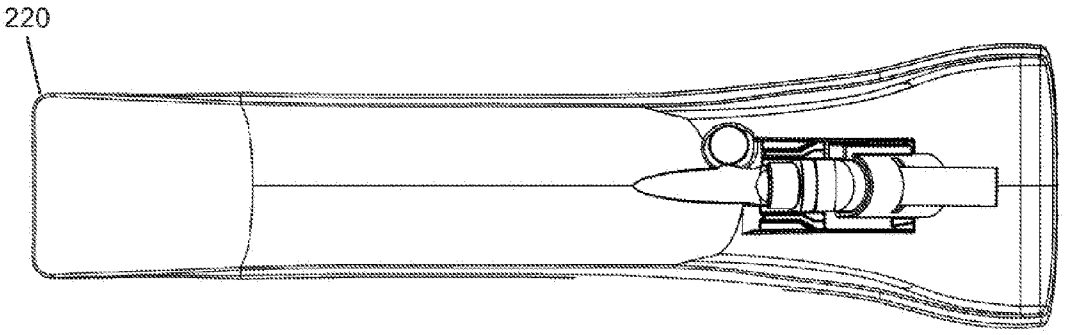



FIG. 9

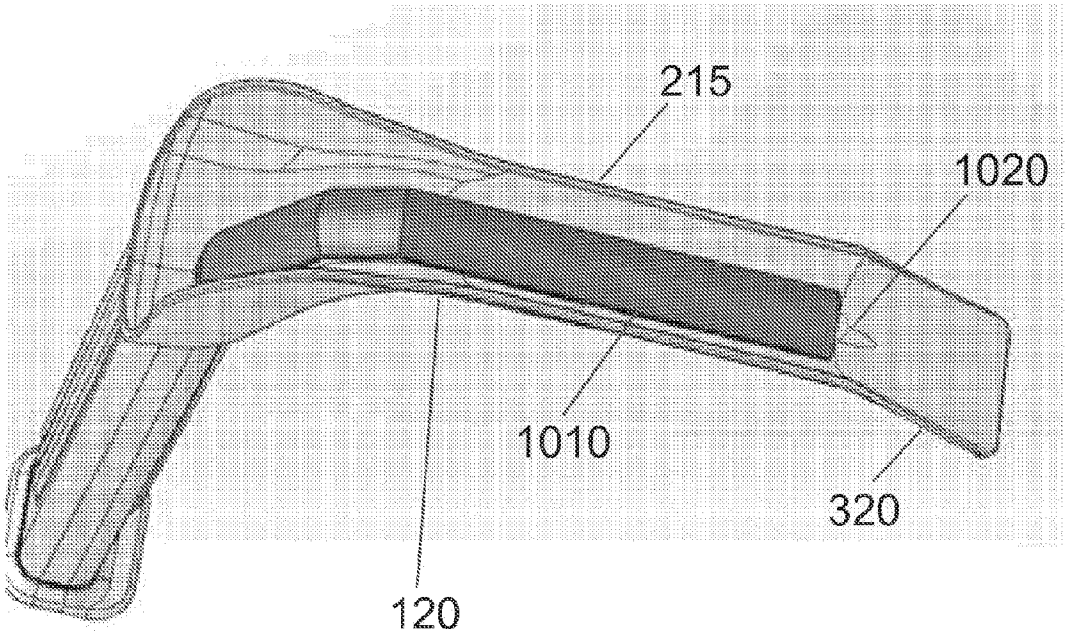



FIG. 10

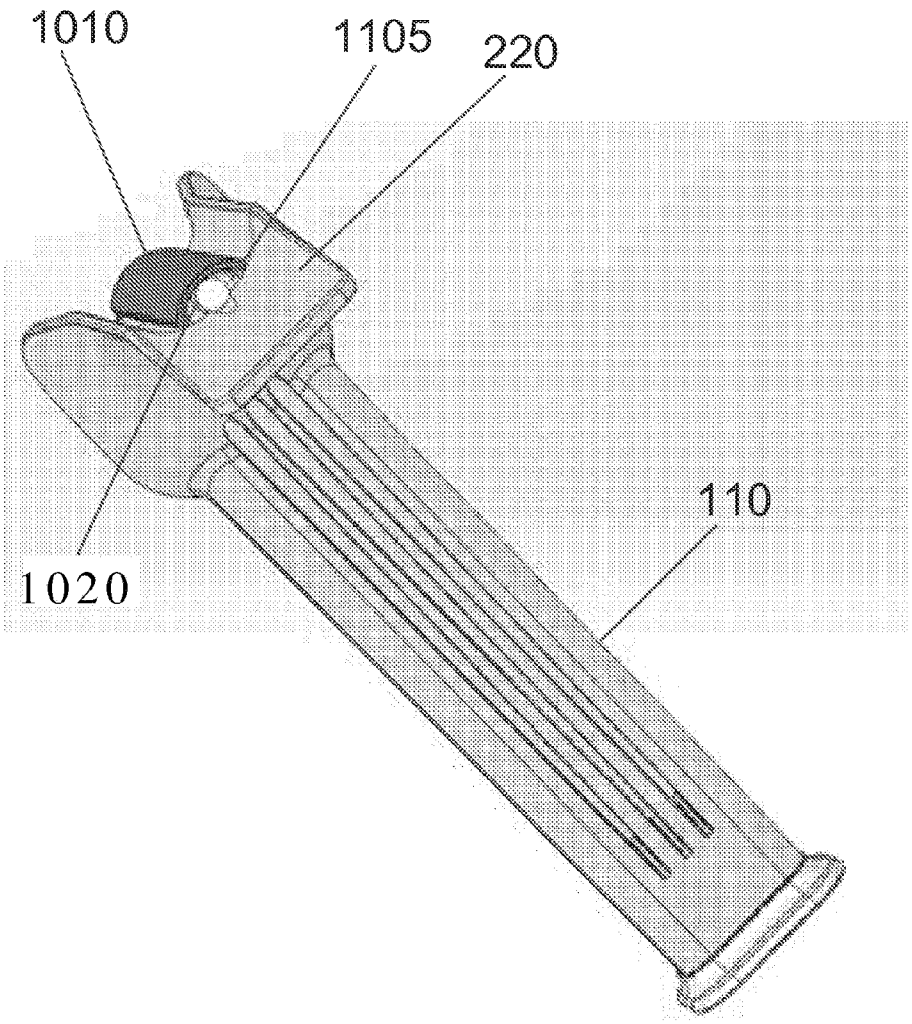



FIG. 11

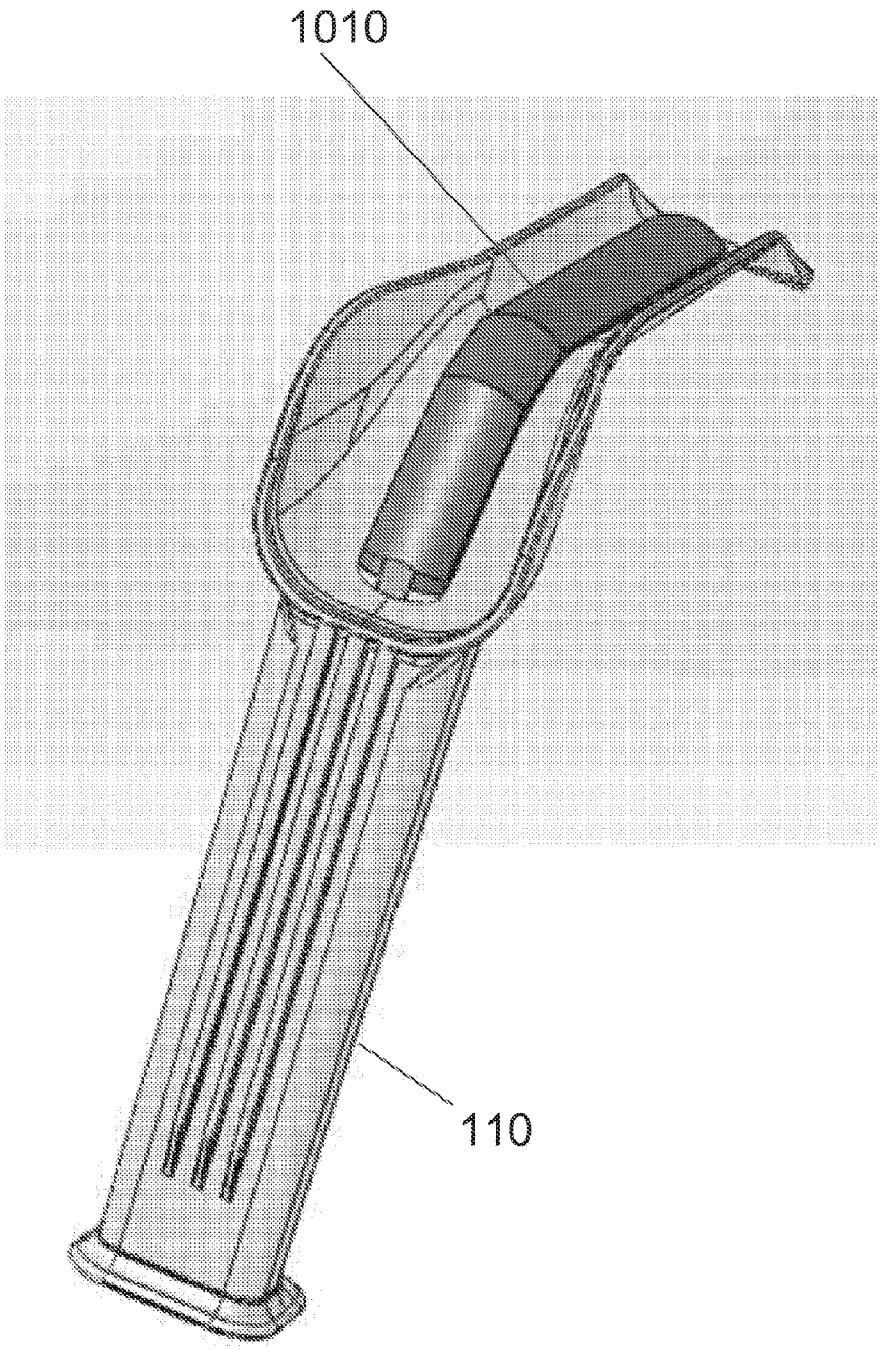



FIG. 12

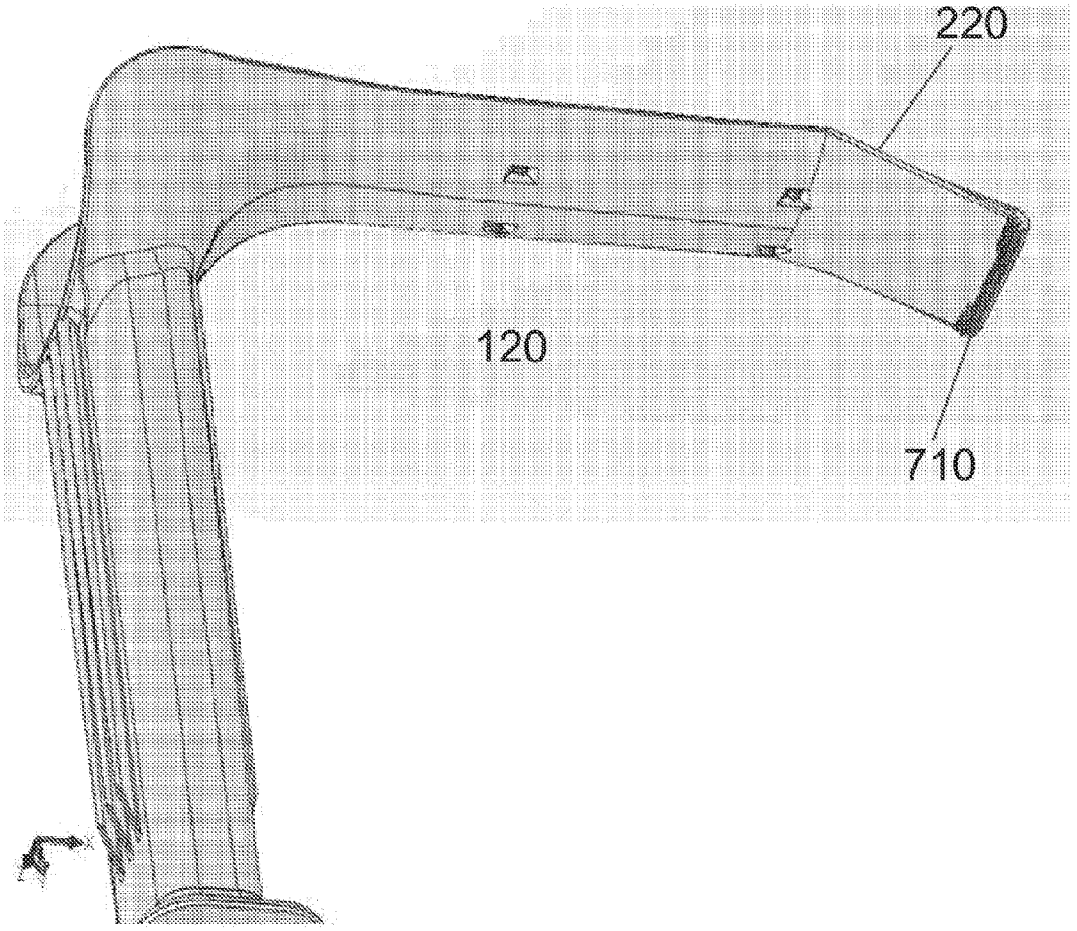



FIG. 13

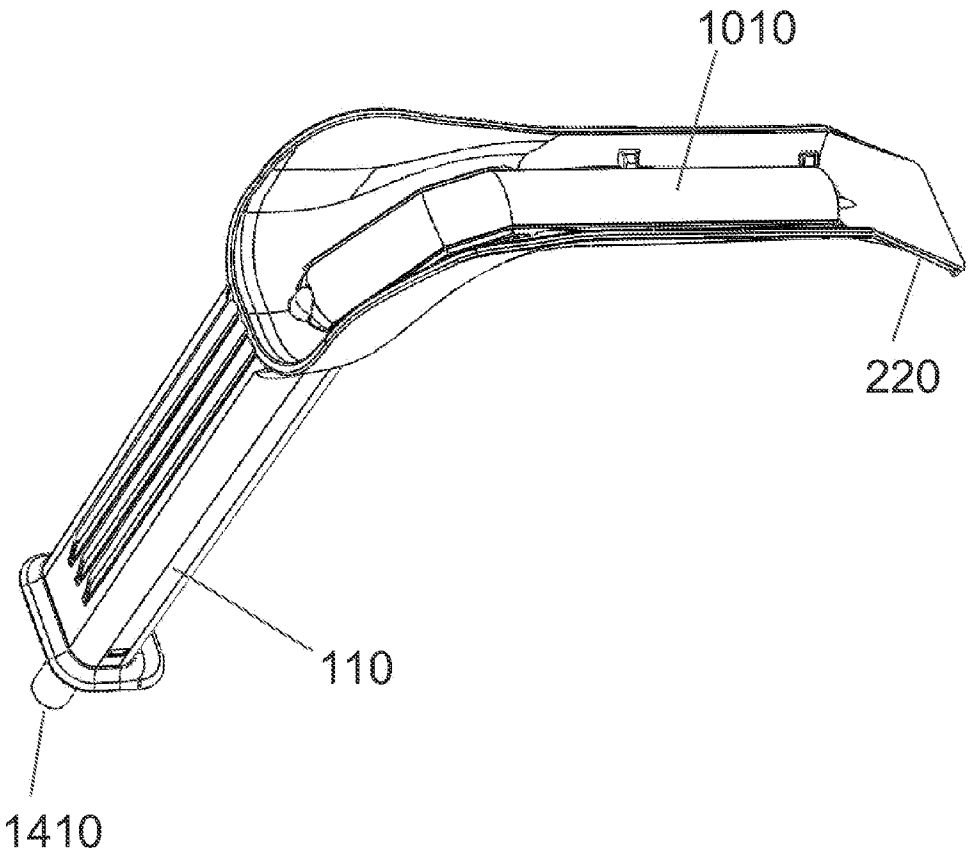



FIG. 14

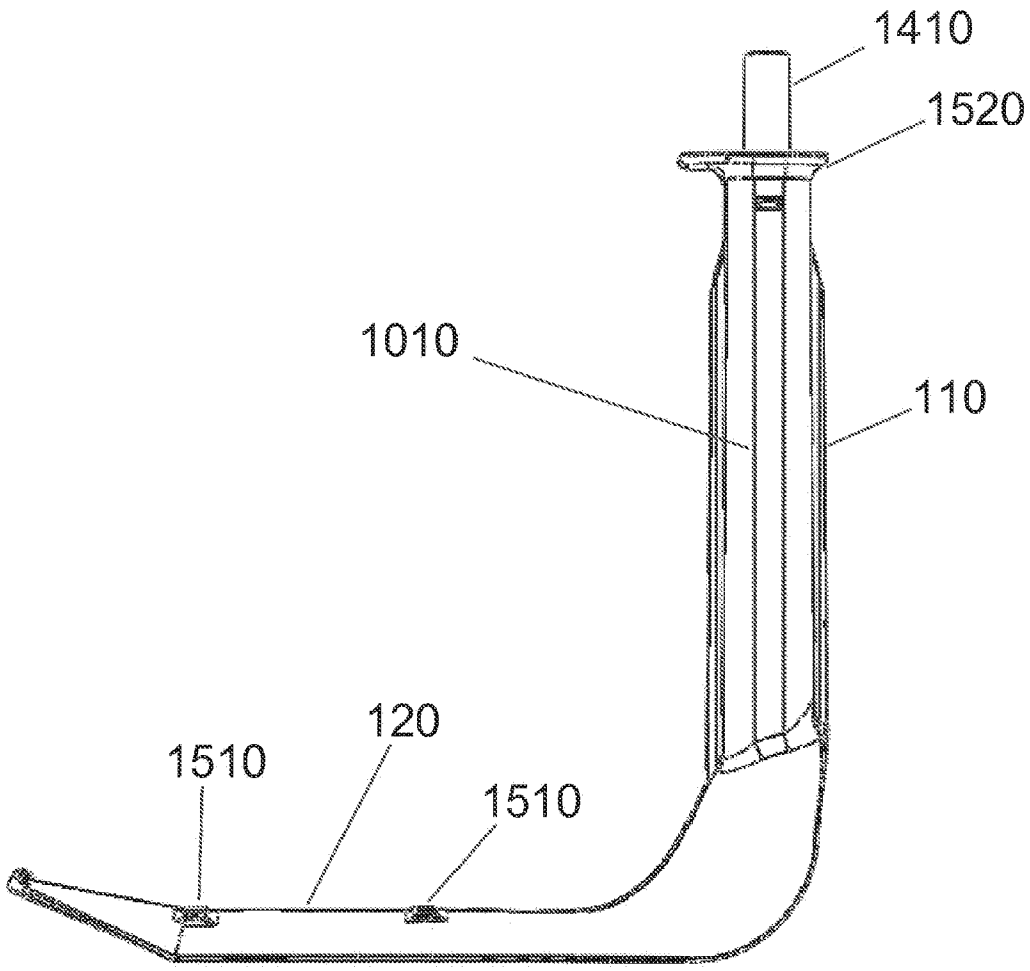



FIG. 15

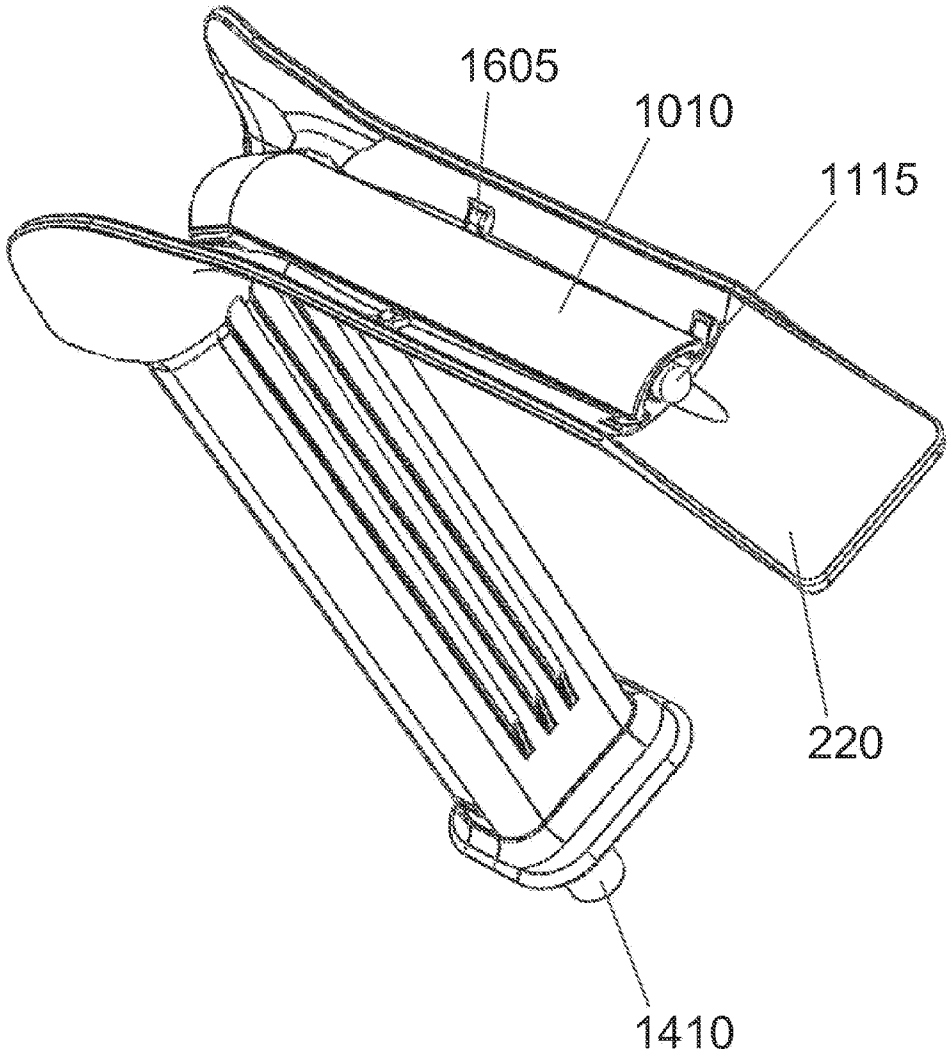



FIG. 16

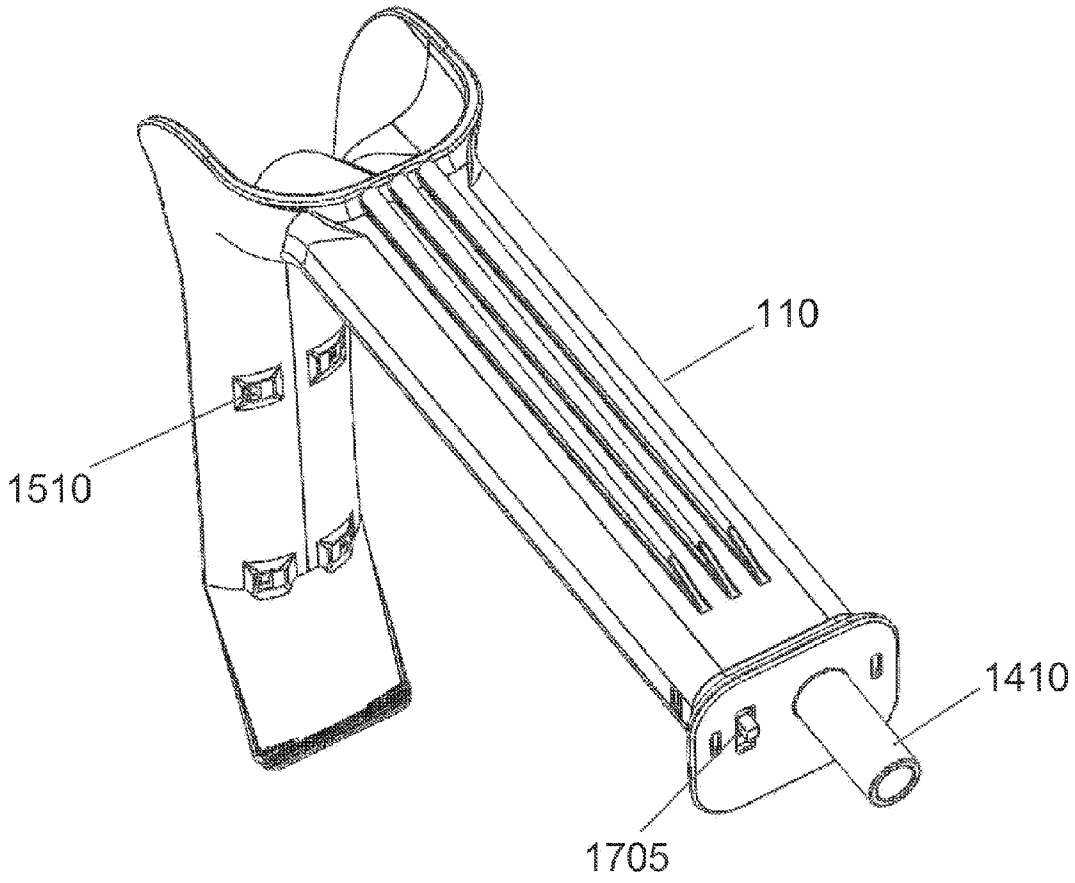



FIG. 17

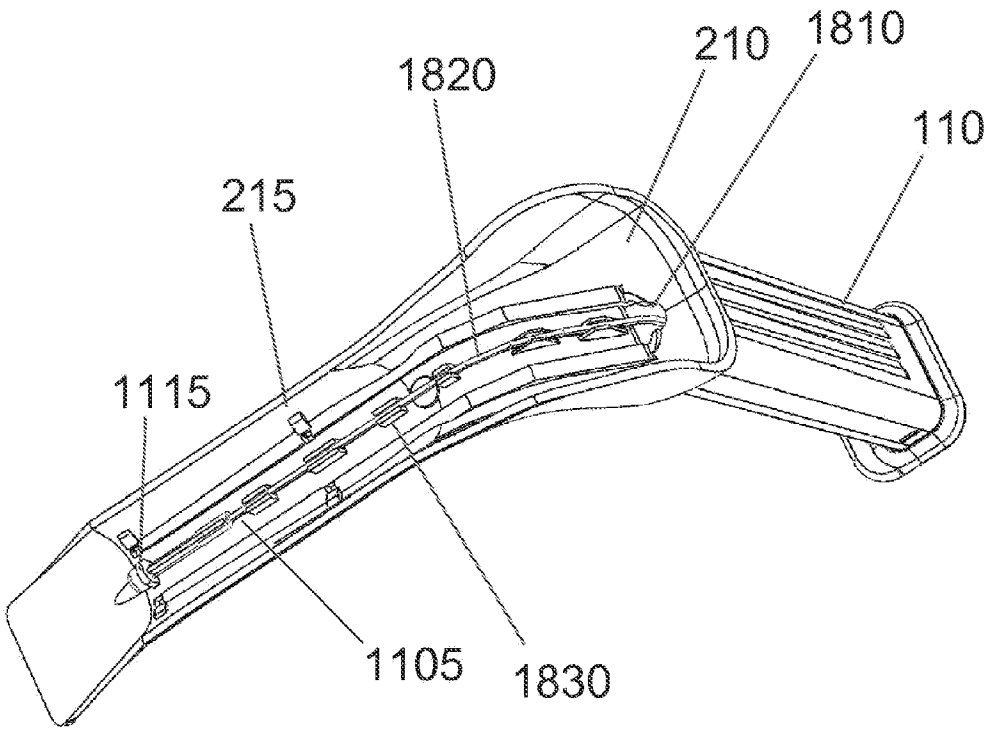



FIG. 18

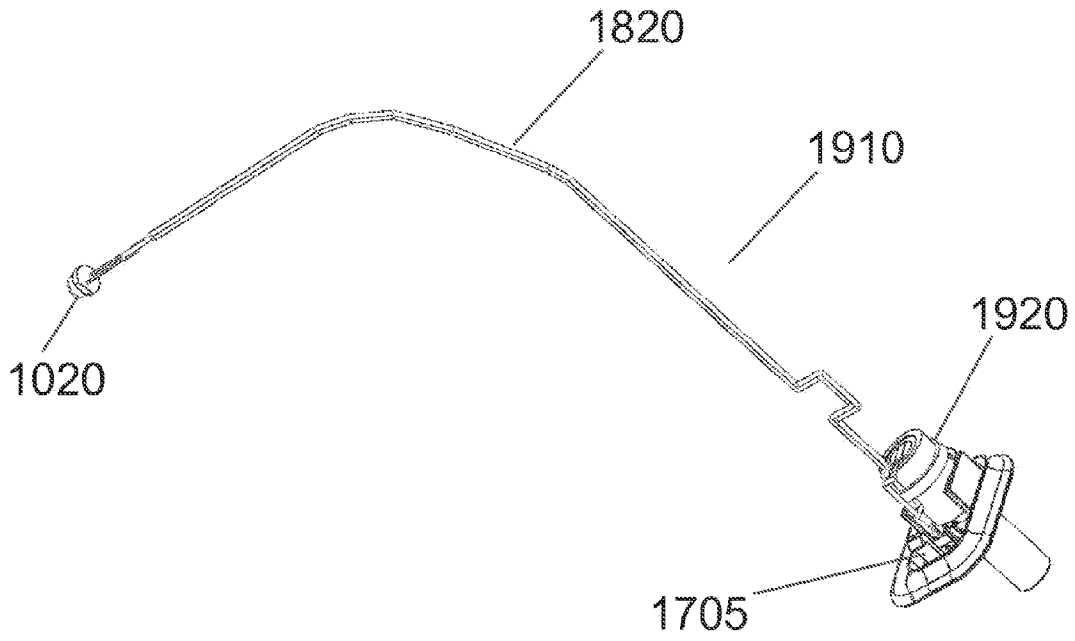



FIG. 19

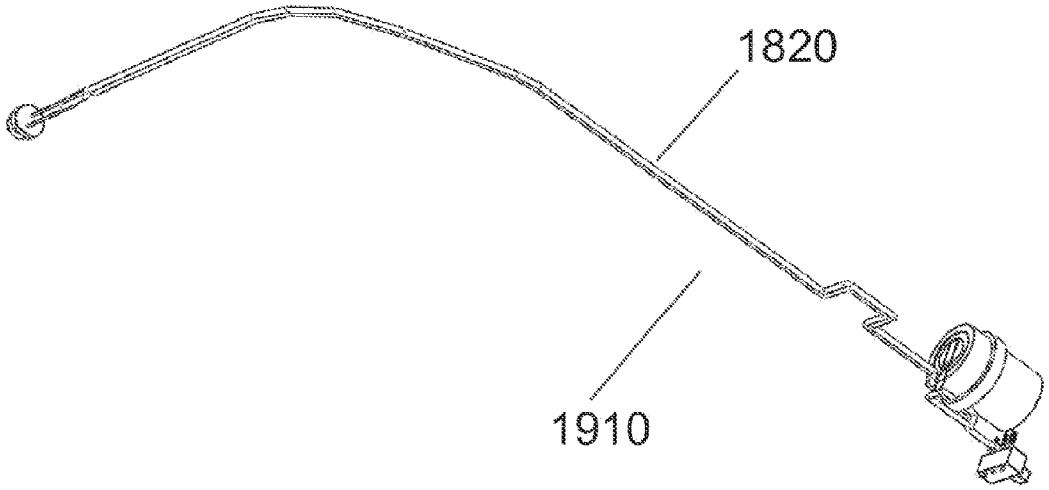



FIG. 20

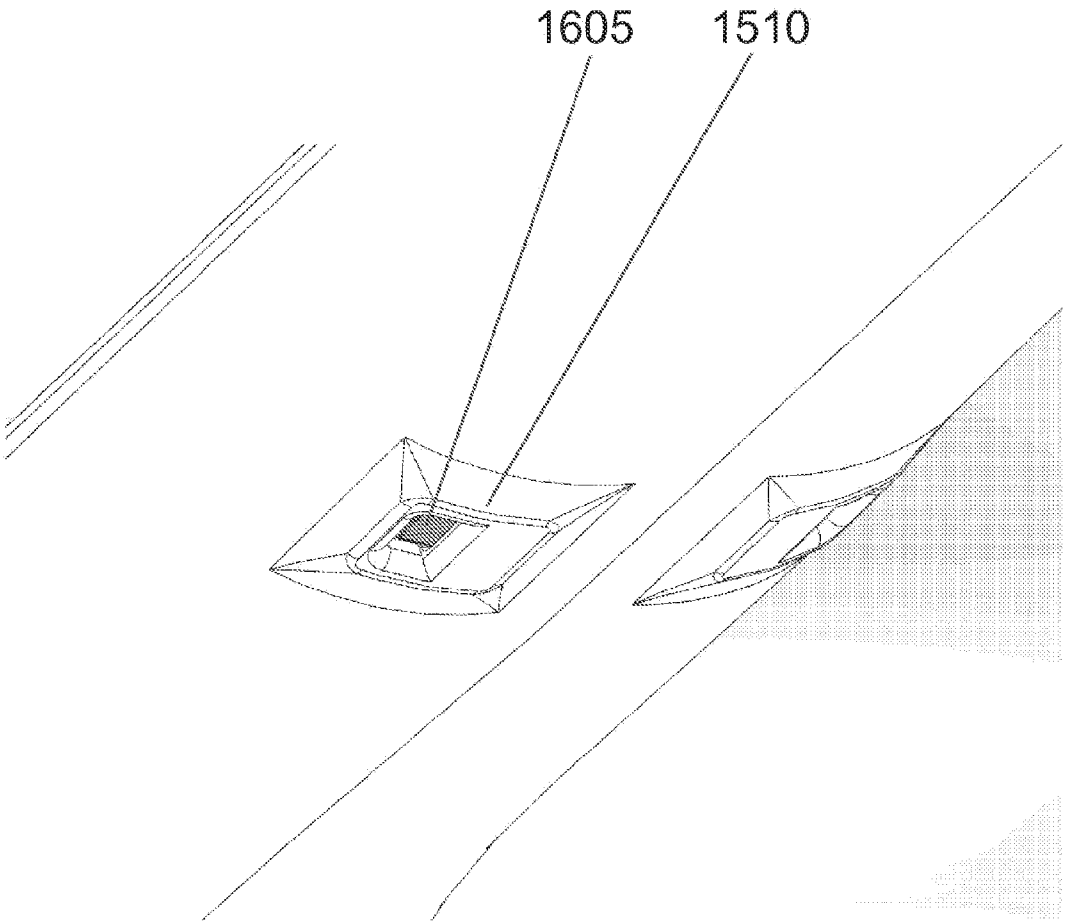



FIG. 21

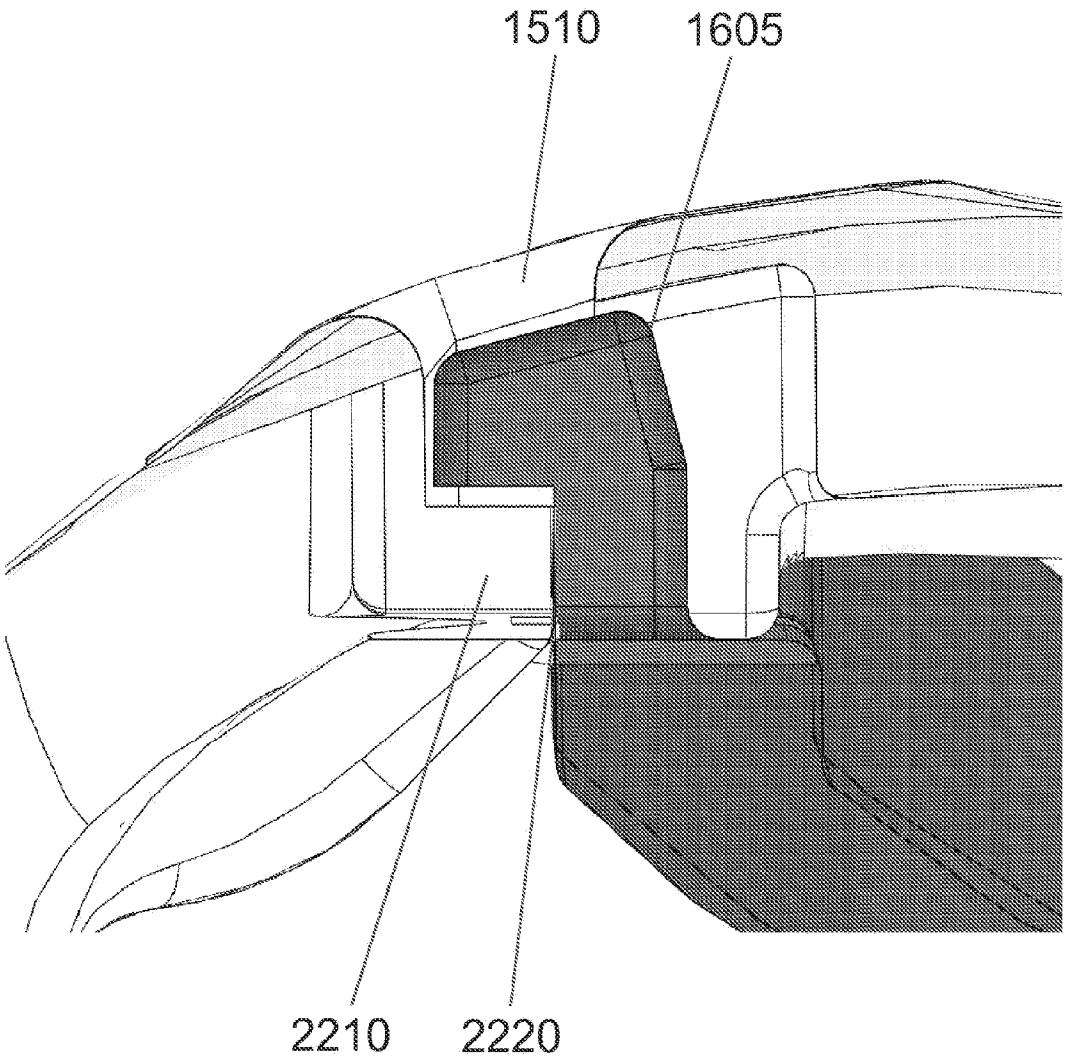



FIG. 22

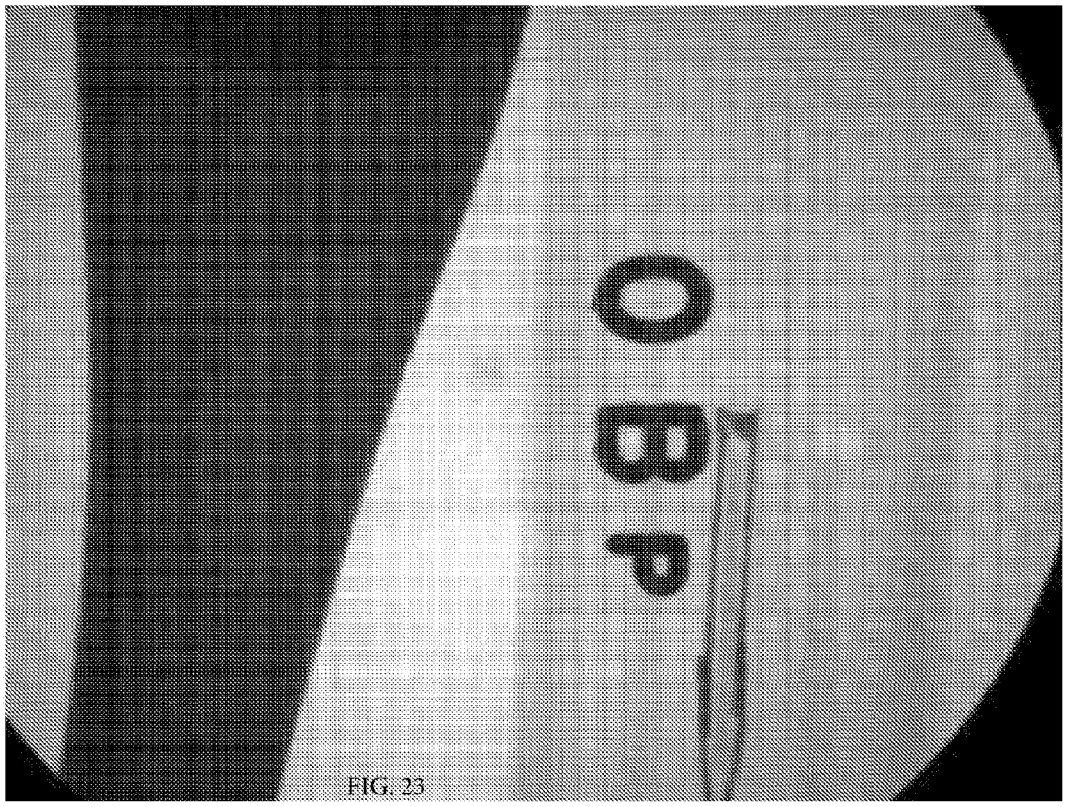
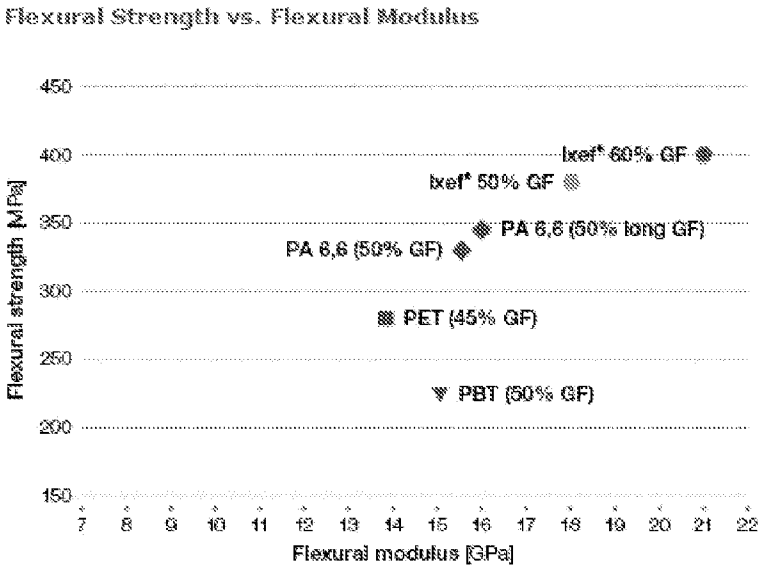



FIG. 23

# FIG. 24


Flexural Strength vs. Flexural Modulus
Flexural strength [MPa]
450
400
350
300
250
200
150
Ixef® 60% GF
Ixef® 50% GF
PA 6,6 (50% long GF)
PA 6,6 (50% GF)
PET (45% GF)
PBT (50% GF)
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
Flexural modulus [GPa]