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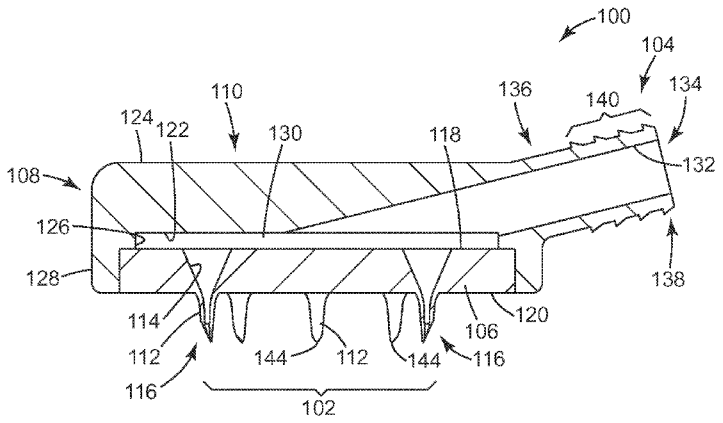

Fig. 1B

(57) Abstract: The present disclosure provides for a micro-needle device (100, 200, 300, 400) that includes a micro-needle array (102, 202, 302, 402) and a liquid connection port (104, 204, 304, 404). The micro-needle array includes a base (106, 206, 306, 406), a sidewall (108, 208, 308, 408) and a top (110, 210, 310, 410), where the base includes two or more of an elongate micro-needle (112, 212, 312, 412) having an interior surface (114, 214, 314, 414) defining an opening 8116, 216, 316, 416) through the elongate micro-needle. The base has a first major surface (118, 218, 318, 418) and a second major surface (120, 220, 320, 420) through which the opening of the elongate micro-needle passes to provide a passage across the base. The top has an interior surface (122, 222, 322, 422) and the sidewall has an interior surface (126, 226, 326, 426), where the interior surface of the side wall, the interior surface of the top and the first major surface of the base define a volume (130, 230, 330, 430). The liquid connection port has a fluid connection with the volume of the micro-needle array such that dental local anesthetic fed through the connection port can exit through the opening of the elongate micro-needle.

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MICRO-NEEDLE DEVICE

Field of the Disclosure

The disclosure relates to a medical device and in particular to a medical device having micro-needles.

Background Art

Needles sometimes need to be used for injections during medical procedures. The sight, thought and/or feeling of a needle can cause fear in the patient. This fear, or phobia, of needles is known as needle phobia.

Depending upon the degree of needle phobia, a patient can display a wide variety of symptoms. For example, a patient with needle phobia can have anxiety, a panic attack, an elevated blood pressure and/or an elevated heart rate knowing that a needle may or will be used in their medical procedure. In extreme cases the patient can faint due to a vasovagal reflex reaction. This leads to an unsafe situation for both the patient and the medical personnel. Other reactions of patients with needle phobia can include avoiding medical treatment if they know or believe a needle will be used. In extreme cases, some patients will avoid all medical care. This fear of needles can also be associated with the sight of a syringe.

In dentistry, a syringe fitted with a needle is often times used to deliver an anesthetic to the patient. The needle and syringe are inserted at least partially into the patient's mouth, where the needle is inserted into the gingiva and/or other tissues (e.g., oral mucosa) in order to deliver a local anesthetic. Using a local anesthetic can help to decrease intraoperative and postoperative pain, decrease the amount of general anesthetics used in the operating room, increase the patient cooperation during the procedure. Often times the injection is more painful and traumatic than the actual procedure.

Therefore, there is a need in the art for a suitable device for injecting a local anesthetic that does not use a traditional needle and syringe configuration, which configurations are well known to cause issues with many patients.

Summary of the Disclosure

The present disclosure provides a device for delivering a dental local anesthetic that does not use a traditional needle and syringe configuration. For example, the micro-needle device of the present disclosure does not include a plunger.

The present disclosure provides a micro-needle device for delivering a dental local anesthetic that includes a micro-needle array having a base, a sidewall and a top. The base includes two or more of an elongate micro-needle, the elongate micro-needle having an interior surface defining an opening through the elongate micro-needle and the base having a first major surface and a second major surface through which the opening of the elongate micro-needle passes to provide a passage across the base. The top has an interior surface and the sidewall has an interior surface, where the interior surface of the side wall, the interior surface of the top and the first major surface of the base define a volume.

The liquid connection port provides a fluid connection with the volume of the micro-needle array such that dental local anesthetic fed through the connection port can exit through the opening of the elongate micro-needle. The liquid connection port extends from the sidewall of the micro-needle array. The micro-needle device can further include a catheter that extends from the liquid connection port to a first end, where the catheter provides a fluid connection from the first end to the volume of the micro-needle array. A syringe can be releasably coupled to the first end of the catheter to provide the fluid connection with the volume of the micro-needle array.

The micro-needle array can further include a spring that connects the micro-needle array and a button positioned over the top of the micro-needle array, where the spring compresses under pressure applied through the button and against the micro-needle array when the micro-needle device is positioned in a mouth of a patient. The top can include an exterior surface opposite the second major surface of the base, the exterior surface of the top having a protrusion that extends towards the button positioned over the top of the micro-needle array. The micro-needle array can further include a finger ring that extends from the spring, where the finger ring holds a finger against the button. The finger ring can have a first arm and a second arm that form a hoop of the finger ring.

The button can have a surface defining an opening through the button, where the protrusion passes at least partially through the opening in the button when the spring is compressed under pressure applied through the button and against the micro-needle array

when the micro-needle device is positioned in a mouth of a patient. The top of the micro-needle device includes an exterior surface opposite the second major surface of the base, the exterior surface of the top having a pressure sensitive adhesive for retaining the micro-needle device on a user's finger.

Brief Description of the Figures

The Figures may not be to scale.

Fig. 1A is a perspective view of a micro-needle device according to an embodiment of the present disclosure.

Fig. 1B is a cross sectional view of the micro-needle device taken along lines 1B in Fig. 1A.

Fig. 1C is a plane view of the micro-needle device of Fig. 1A, a catheter and a syringe according to an embodiment of the present disclosure.

Fig. 2 is a perspective view of a micro-needle device according to an embodiment of the present disclosure.

Fig. 3 is a perspective view of a micro-needle device according to an embodiment of the present disclosure.

Fig. 4 is a cross-sectional view of a micro-needle device according to an embodiment of the present disclosure.

Detailed Description of the Disclosure

The micro-needle device of the present disclosure may be used to inject a local anesthetic without using a traditional needle and syringe configuration. As disclosed herein, the micro-needle device has a non-medical device appearance, but yet enables the delivery of a dental local anesthetic to the oral tissues of a patient. The micro-needle device of the present disclosure provides a micro-needle array having a low profile that allows for discrete handling and insertion into the patients mouth. As such, a patient having needle phobia may be less likely to react negatively and/or be more willing to undergo a dental procedure because the traditional needle and syringe configuration will not be used.

The micro-needle device also includes a liquid connection port associated with the micro-needle array. The liquid connection port allows for a liquid (e.g., dental local

anesthetic) to be injected through the micro-needle array. It is also possible to use a catheter with the liquid connection port, where a free end of the catheter can include a fluid fitting to allow a syringe to be releasably attached to the micro-needle device. Given an appropriated length of the catheter the syringe can be located out of sight of the patient. This option of locating the syringe out of sight of the patient along with the low profile nature of the micro-needle device of the present disclosure will potentially help those patients who have needle phobia.

As used herein, "a," "an," "the," "at least one," and "one or more" are used interchangeably. The term "and/or" means one, one or more, or all of the listed items. The recitations of numerical ranges by endpoints include all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, 5, etc.).

As recited herein, all numbers can be considered to be modified by the term "about."

The figures herein follow a numbering convention in which the first digit or digits correspond to the drawing figure number and the remaining digits identify an element or component in the drawing. Similar elements or components between different figures may be identified by the use of similar digits. For example, 214 may reference element “14” in Figure 2, and a similar element may be referenced as 314 in Figure 3. Elements shown in the various figures herein can be added, exchanged, and/or eliminated so as to provide a number of additional examples of the present disclosure. In addition, the proportion and the relative scale of the elements provided in the figures are intended to illustrate the examples of the present disclosure, and should not be taken in a limiting sense.

Referring now to Figs. 1A-1C, there is shown an embodiment of a micro-needle device **100** for delivering a dental local anesthetic. The micro-needle device **100** includes a micro-needle array **102** and a liquid connection port **104**. The micro-needle array **102** includes a base **106**, a sidewall **108** and a top **110**. The base **106** includes two or more of an elongate micro-needle **112**. The elongate micro-needle **112** has an interior surface **114** defining an opening **116** through the elongate micro-needle **112**. The base **106** has a first major surface **118** and a second major surface **120** through which the opening **116** of the elongate micro-needle **112** passes to provide a passage across the base **106**. The top **110** has an interior surface **122** and an exterior surface **124**.

The sidewall **108** has an interior surface **126** and an exterior surface **128**. The interior surface **126** of the sidewall **108**, the interior surface **122** of the top **110** and the first major surface **118** of the base **106** define a volume **130**.

The liquid connection port **104** includes a lumenal surface **132** defining a lumen **134** that is in fluid connection with the volume **130** of the micro-needle array **102**. This allows dental local anesthetic fed through the liquid connection port **104** to pass through the lumen **134**, into the volume **130** and exit through the opening **116** of the elongate micro-needle **112**.

A problem with traditional needle structures is that the connector of the needle (e.g., a Luer connector) is aligned with the needle along the direction through which the force is applied to insert the needle into the patient. In order to apply this force and inject the substance into the patient a syringe is joined to the needle. Once the syringe is joined to the needle the structure is so long that the patient could not help noticing it. The sight of this very long structure with its needle can be of great concern for those people with needle phobia.

In contrast to traditional needle and syringe structure, the micro-needle array **102** of the present disclosure has a disk-shape. As illustrated, the exterior surface **128** of the sidewall **108**, the exterior surface **124** of the top **110** and the second major surface **120** of the base **106** give the micro-needle array **102** this disk-shape. The disk-shape provides a relatively large surface on which the doctor can both hold the micro-needle device **100** (via the exterior surface **128** of the sidewall **108**) and apply force (via the exterior surface **128** of the top **110**) to insert the micro-needles **112** in the oral tissue of the patient. One advantage of this disk-shape is that the doctor can discretely hold the micro-needle array **102** in a position that also allows them to use the micro-needle device **100.**

Another advantageous feature of the micro-needle device **100** is that the liquid connection port **104** does not extend in the direction along which the force is applied to insert the micro-needles **112** into the tissue of the patient. In other words, the liquid connection port **104** is outside the exterior surface **124** of the top **110** (e.g., the pressure area of the micro-needle device **100**). For example, as illustrated in Figs. 1A and 1B the liquid connection port **104** extends not from the top **110** of the micro-needle array **102**, but from the sidewall **108** of the micro-needle array **102**. This allows for almost the entire exterior surface **124** of the top **110** to be available to the doctor. An additional advantage

is also that the doctor can apply force via the exterior surface **124** of the top **110** to insert the micro-needles **112** into the tissue of the patient without having to simultaneously dispense the substance, as is the case with other micro-needle devices.

It is appreciated that other flat thin shapes may also be used instead of a disk-shape for the micro-needle array **102**. For example, the micro-needle array **102** may have, as viewed perpendicular to the exterior surface **124** of the top **110**, an oval shape, an elliptical shape, a polygon shape such as a rectangular shape or a square shape. The exact shape of the micro-needle array **102** can be determined based on the desired use and location of the use for the micro-needle device **100**.

The exterior surface **124** can also have a variety of shapes. For example, the exterior surface **124** can have a planar shape. Alternatively, the exterior surface **124** can have a concave shape. The concave shape can help to better center a finger (e.g., an index finger) that is used to press on the micro-needle array **102**. Other geometrical shapes can be used for the exterior surface **124** that would help as a finger guide.

As illustrated, the liquid connection port **104** extends away from the micro-needle array **102** in a manner that allows the liquid connection port **104** to connect to a fluid source (e.g., a catheter and syringe as discussed herein) without having the components of the fluid source extend, relative the top **110**, beyond the second major surface **120** of the base **106**. So, for example, the liquid connection port **104** can include an elbow **136** that helps to project a distal end **138** of the liquid connection port **104** away from the base **106**. As illustrated, the liquid connection port **104** near the distal end **138** can include a fluid fitting **140** to receive and retain a catheter (seen in Fig. 1C). Figs. 1A-1C illustrate the fluid fitting **140** as a series of circular barbs. It is also appreciated the outer diameter of the liquid connection port **104** can taper to present a distal end **138** having a diameter that is smaller than a portion of the port **104** that meets with the sidewall **108**. Other fluid fittings **140** are possible, such as a female part or male part of a Luer Taper connector (either a "Luer-Lok" or "Luer-Slip" configuration).

The base **106** and the top **110** of the micro-needle array **102**, in the disk- shape can, have a diameter of 4 millimeters (mm) to 15 mm, where the sidewall **108** can have a height of 0.5 mm to 8 mm. Preferably, the base **106** and the top **110** of the micro-needle array **102**, in the disk- shape can, have a diameter of 5 mm to 10 mm, where the sidewall **108** can have a height of 1 mm to 6 mm. Most preferably, the base **106** and the top **110** of

the micro-needle array **102**, in the disk- shape can, have a diameter of 6 mm to 8 mm, where the sidewall **108** can have a height of 2 mm to 4 mm.

The base **106** of the micro-needle array **102** has 6 to 18 micro-needles **112**. The second major surface **120** of the base **106** includes an outer boundary **142** (shown with a broken line in Fig. 1C) that along with the exterior surface **128** of the sidewall **108** define an infiltration area **146** (the area that extends from the outer boundary **142** to the exterior surface **128** of the sidewall **108**). As discussed herein, the exterior surface **124** of the top **110** is opposite the second major surface **120** of the base **106**. The exterior surface **124** of the top **110** provides a continuous surface which can receive pressure from a finger and also where the exterior surface **124** opposite of the second major surface **120** and the infiltration area **146** overlap each other by at least 75%. So, for example, when the exterior surface **124** of the top **110** has the same size and shape of the second major surface **120** of the base **106** and the sidewall **108** is perpendicular to both the exterior surface **124** and the second major surface **120** there is an overlap of 100%. If one of either the exterior surface **124** of the top **110** or the second major surface **120** of the base **106** has a different size and/or shape then the overlap of these areas should be at least 75%.

The micro-needles **112** of the micro-needle array **102** can have variety of patterns. For example, the micro-needles **112** can be uniformly arranged in a circular pattern to help define the infiltration area **146**, as illustrated in Fig. 1C. In this embodiment, the circular pattern is centric relative the geometric center of the second major surface **120** of the base **106**. If desired, the pattern of the micro-needles **112** can be either centric or eccentric relative the geometric center of the second major surface **120** of the base **106**. Other patterns for the micro-needles **112** include, but are not limited to, elliptical, oval or polygonal, where the patterns can be eccentric or centric relative the geometric center of the second major surface **120** of the base **106**.

The width of the infiltration area **146** defined by the pattern of the micro-needles **112** can be from 2 mm to 10 mm. So, when the micro-needles **106** are arranged in a circular pattern the infiltration area can be from 3.14 mm^2 to 78.5 mm^2. Preferably, the pattern of the micro-needles **106** provides a width (e.g., a diameter) of the infiltration area of 6 mm. Micro-needles **106** can be spaced, on center of their longitudinal axis from each other, in a range from 1 mm to 5 mm. Preferably, the micro-needles **106** can be spaced, on center of their longitudinal axis from each other, in a range from 1.5 mm to 2 mm.

As for the micro-needles **112**, they can have a tip **144** spaced from the exterior surface **120** of the base **106**, where the tip **144** has a bevel. Examples of such bevels include, but are not limited to, a true short bevel, a short bevel or a standard bevel as are known. The elongate micro-needles **112** also have an outer diameter in a range of 100 micrometer (μm) to 400 μm. The micro-needles **112** also have a length in a range from 500 μm to 1500 μm. The micro-needles **112** of the micro-needle array **102** can all have the same approximate length so that the tip **144** of micro-needles **112** are all approximately on a common plane. Alternatively, micro-needles **112** of the micro-needle array **102** can have different lengths so that the tips **144** of micro-needles **112** are not all approximately on a common plane.

The different components of the micro-needle array **102** can be formed from a polymeric material. For example, the micro-needle array **102** can be made of a polymer selected from the group consisting of aromatic polyester polymers or polycarbonate polymers. Examples of aromatic polyester polymers include liquid crystal polymers (partially crystalline aromatic polyesters based on p-hydroxybenzoic acid and related monomers), such as those sold under the trade designator "Siveras LX" (Toray), "Sumikasuper" (Sumitomo), "Titan" (DuPont), "Vectra" (Celanese), "Xydar" (Solvay Specialty Polymer) or "Zenite" (Celanese). Suitable examples of polycarbonate polymers include those of medical grade that comply with ISO 10993-1 and/or USP Class VI standards.

Examples of suitable polymers for the liquid connection port **104**, the sidewall **108** and the top **110** include polymers selected from the group consisting of high density polyethylene, low density polyethylene, polypropylene, polyethylene terephthalate, aromatic polyester polymers (as provided herein), brominated butyl rubber or acrylonitrile-methyl acrylate copolymer. An example of the acrylonitrile-methyl acrylate copolymer includes BAREX®. The different components of the micro-needle array **102** can be formed as separate structures or different combinations of the components can be formed from a single piece of the polymeric material. For example, the base **106** and the micro-needles **122** can be formed as a first piece of the micro-needle array **102** in an injection molding process, where the openings **116** can directly be injection molded or a laser can be used to form (e.g., drill) the openings **116** of the micro-needles **122**. Other

techniques for forming the openings **116** are possible, including using a water jet or a plasma cutting operation to form the openings **116**.

Similarly, the liquid connection port **104**, the sidewall **108** and top **110** can be formed as a second piece of the micro-needle array **102** in an injection molding process. The two pieces of the micro-needle array **102** can then be joined together using a variety of techniques. For example, the two pieces of the micro-needle array **102** can be joined using ultrasonic welding. Alternatively, a medical grade chemical adhesive can be used to join the two pieces of the micro-needle array **102**. Examples of such medical grade chemical adhesives include, but are not limited to, cyanoacrylates, epoxies, polyurethanes and silicones, as are known.

The two pieces of the micro-needle array **102** can also be joined using a mechanical interaction. For example, the base **106** and the sidewall **108** can include a screw thread that allows the two pieces to be joined. In this embodiment, the base **106** can include an external thread and the sidewall **108** includes an internal thread that allows the two pieces to be joined together by rotating the two pieces along the threads. If desired, ultrasonic welding and/or a medical grade chemical adhesive can also be used.

In an additional embodiment, the micro-needle device **100** can also include a medical grade pressure sensitive adhesive located at least partially across the exterior surface **124** of the top **110**. For example, the medical grade pressure sensitive adhesive can be located across the entirety of the exterior surface **124** of the top **110**. The medical grade pressure sensitive adhesive can help to retain the micro-needle device **100** on a user's finger. Examples of suitable medical grade pressure sensitive adhesive include, but are not limited to, rubber or Acrylic ester copolymers, zinc oxide rubber adhesives and polyacrylate adhesives

The micro-needle device **100** of the present disclosure can also include a catheter **150**, as seen in Fig. 1C. The catheter **150** can be formed of medical grade silicon rubber, nylon, polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyurethane or polyethylene terephthalate, among other elastomers useful in the medical arts.

The catheter **150** includes a first end **152**, at which the lumen of the catheter **150** can receive the liquid to be injected through the micro-needles **112**. The catheter **150** can extend from the liquid connection port **104** to the first end **152**, where the catheter **150**

provides a fluid connection from the first end **152** to the volume **130** and the micro-needles **112** of the micro-needle array **102**.

The catheter **150** further includes a second end **154** of the catheter **150**, distal from the first end **152**. The second end **154** can be positioned relative the liquid connection port **104** to engage the fluid fitting **140** in a fluid tight manner. For example, the second end **154** of the catheter **150** can be slid over the barbs of the fluid fitting **140** to retain the catheter **150** in a fluid tight manner on the micro-needle device **100**. Alternatively, the fluid fitting **140** of the liquid connection port **104** and the second end **154** of the catheter **150** can be configured to engage in a fluid tight manner to allow a liquid to flow through the lumen of the catheter **150** through the opening **116** of the micro-needles **112**. An example of such a fluid fitting **140** of the liquid connection port **104** and the second end **154** of the catheter **150** can include the female part and the male part of a Luer Taper connector (either a "Luer-Lok" or "Luer-Slip" configuration) as discussed herein.

A syringe **156** can be used to provide a liquid, such as the dental local anesthetic, through the catheter **150**, where the syringe **156** releasably couples to the first end **152** of the catheter **150** to provide the fluid connection with the volume **150** of the micro-needle array **102**. The syringe **156** can be releasably joined to the first end **152** of the catheter **150** using a fluid fitting such as a Luer Taper connector (either a "Luer-Lok" or "Luer-Slip" configuration) as discussed herein. The syringe **156** can include the dental local anesthetic. Air can be removed from the syringe **156**, the catheter **150** and the micro-needle device **100** by positioning the micro-needles **112** at the highest relative point for these structures and driving any air from the assembly using the syringe **156**.

Referring now to Fig. 2, there is shown an embodiment of the micro-needle device **200** according to the present disclosure. The micro-needle array **202** includes, as previously discussed, the micro-needle array **202** and the liquid connection port **204**. The micro-needle array **202** includes the base **206**, the sidewall **208** and the top **210**. The base **206** includes two or more of the elongate micro-needle **212** having the interior surface defining the opening through the elongate micro-needle **212**. The elongate micro-needle **212** passes across the base **206**, and the interior surface of the sidewall **208**, the interior surface of the top **210** and the first major surface of the base **206** define a volume, as discussed herein. The liquid connection port **204** includes the lumenal surface **232** defining a lumen **234** that is in fluid connection with the volume of the micro-needle array

202. This allows dental local anesthetic fed through the liquid connection port **204** to pass through the lumen **234**, into the volume and exit through the opening of the elongate micro-needle **212**. The micro-needle array **202** of the present disclosure has a disk-shape, as previously discussed.

In addition to the structures and advantages discussed for the micro-needle device of the present disclosure, the micro-needle array **202** further includes a spring **260**. The spring **260** compresses under pressure applied through a user's finger and against the micro-needle array **202** when the micro-needle device **200** is positioned in a mouth of a patient. As illustrated, the spring **260** is a flat spring having a first leaf **262** and a second leaf **264**. The first leaf **262** extends from a first side **266** of the micro-needle array **202** and the second leaf **264** extends from a second side **268** of the micro-needle array **202** opposite of the first leaf **262**. Each of the first leaf **262** and the second leaf **264** has an arc-shape that extends from their respective sides in opposite directions. The first leaf **262** and the second leaf **264** arch back over to join a button **269** that is located over the top **210** and the base **206** of the micro-needle array **202**. As illustrated, the button **269** is located at a relative low point in the spring **260**, which provides both a non-visual guide for the user's finger and allows for greater lateral stability when pressing on the button **269**

When the micro-needle device **200** is positioned in a mouth of a patient the user presses on the button **269**, which causes the first leaf **262** and the second leaf **264** to bend (the spring 260 compresses). As force is applied to the button **269** the first leaf **262** and the second leaf **264** bend until the button **269** contacts a protrusion **272** on the top **210** of the micro-needle array **202**. The protrusion **272** provides the user tactile feedback that the button **269** is in contact with the top **210** of the micro-needle array **202**. Contact between the button **269** and protrusion **272** also signals the user that they should not apply any additional pressure to the button **269** as the first leaf **262** and the second leaf **264** have reached the force limit and will not compress any further by applying force to the button **269**.

In an alternative embodiment, the button 269 can further include a surface defining an opening through the button **269**, where the protrusion **272** can pass at least partially through the opening in the button **269** when the spring **260** is compressed under pressure applied through the button **269** and against the micro-needle array **202** when the micro-needle device **200** is positioned in a mouth of a patient. Fig. 3, and the accompanying

discussion, provide a further illustration of this embodiment for the micro-needle device **200**.

The amount of force required to bend the first leaf **262** and the second leaf **264** to the point that the button **269** touches the protrusion **272** can be adjusted, as desired, to ensure that the micro-needles **212** of the micro-needle device **200** fully insert into the gingiva and/or other tissues (e.g., oral mucosa) in order to deliver a local anesthetic. This amount of force can also be adjusted to allow the dental professional to better gauge when to stop applying force when using the micro-needle device **200**. The height of the protrusion 272 can be designed to set the force threshold for force limitation before the tactile feedback signal is sent. Such adjustments to the required force can be made by changes in any one of the cross-sectional size and/or shape of the first leaf **262** and the second leaf **264**. As illustrated, the first leaf **262** and the second leaf **264** each have a rectangular cross-section. It is appreciated that other cross-sectional shapes for the first leaf **262** and the second leaf **264** are possible. Examples include, but are not limited to circular, oval or polygonal, among others.

Additionally, the material from which the first leaf **262** and the second leaf **264** are formed can also be used to adjust the amount of force required to bend the first leaf **262** and the second leaf **264**. The shape and size of each of the first leaf **262** and the second leaf **264** can also be used to adjust the amount of force required to bend the first leaf **262** and the second leaf **264**. Preferably, the amount of force required for bending the first leaf **262** and the second leaf **264** is from 2 to 20 Newtons.

The first leaf **262**, the second leaf **264**, the button **269** and the protrusion **272** can each be formed from the same polymeric material during the same process used to form the top **210** of the micro-needle array **202**. In an additional embodiment, the button **269** can also include a medical grade pressure sensitive adhesive, as discussed herein, located at least partially across an exterior surface **274** of the button **269**. The medical grade pressure sensitive adhesive can help to retain the micro-needle device **200** on a user's finger. Examples of medical grade pressure sensitive adhesives include rubber or Acrylic ester copolymers, zinc oxide rubber adhesives and polyacrylate adhesives.

Referring now to Fig. 3, there is shown an embodiment of the micro-needle device **300** according to the present disclosure. The micro-needle array **302** includes, as previously discussed, the micro-needle array **302** and the liquid connection port **304**. The

micro-needle array **302** includes the base **306**, the sidewall **308** and the top **310**. The base **306** includes two or more of the elongate micro-needle **312** having the interior surface defining the opening through the elongate micro-needle **312**. The elongate micro-needle **312** passes across the base **306**, and the interior surface of the sidewall **308**, the interior surface of the top **310** and the first major surface of the base **306** define a volume, as discussed herein. The liquid connection port **304** includes the lumenal surface **332** defining a lumen **334** that is in fluid connection with the volume of the micro-needle array **302**. This allows dental local anesthetic fed through the liquid connection port **304** to pass through the lumen **334**, into the volume and exit through the opening of the elongate micro-needle **312**. The micro-needle array **302** of the present disclosure has a disk-shape, as previously discussed. The micro-needle array **302** further includes the spring **360**, as previously discussed.

The micro-needle device **300** further includes a finger ring **374** that extends from the spring **360**. The finger ring **374** can, among other things, hold a user's finger against the button **369**. As illustrated, the finger ring **374** includes a first arm **376** and a second arm **378** that form a hoop **380** of the finger ring **374**. The first arm **376** and the second arm **378** each include an end **382**, where the end **382** of each of the first arm **376** and the second arm **378** are free so as to allow the hoop **380** of the finger ring **374** to have an adjustable diameter.

Fig. 3 also illustrates an embodiment in which the button **369** has a surface **384** defining an opening **386** through the button **369**. The protrusion **372** can pass at least partially through the opening **386** in the button **369** when the spring **360** is compressed under pressure applied through the button **369** and against the micro-needle array **302** when the micro-needle device **300** is positioned in a mouth of a patient. So, for example, the protrusion **372** can have a diameter and a height that allows it to pass through the opening **386** so the user can first feel the protrusion **372** before the button **369** touches the top **310**. Allowing this to happen provides the user tactile feedback that the button 3**69** is almost in contact with the top 3**10** of the micro-needle array 3**02**.

In an additional embodiment, the button **369** can also include a medical grade pressure sensitive adhesive, as discussed herein, located at least partially across an exterior surface **374** of the button **369**. The medical grade pressure sensitive adhesive can help to retain the micro-needle device **300** on a user's finger.

Referring now to **Fig. 4**, there is shown an additional embodiment of the micro-needle device **400** according to the present disclosure. The micro-needle array **402** includes, as previously discussed, the micro-needle array **402** and the liquid connection port **404**. The micro-needle array **402** includes the base **406**, the sidewall **408** and the top **410**. The base **406** includes two or more of the elongate micro-needle **412** having the interior surface defining the opening through the elongate micro-needle **412**. The elongate micro-needle **412** passes across the base **406**, and the interior surface of the sidewall **408**, the interior surface of the top **410** and the first major surface of the base **406** define a volume, as discussed herein. The liquid connection port **404** includes the lumenal surface **432** defining a lumen **434** that is in fluid connection with the volume of the micro-needle array **402**. This allows dental local anesthetic fed through the liquid connection port **404** to pass through the lumen **434**, into the volume and exit through the opening of the elongate micro-needle **412**. The micro-needle array **402** of the present disclosure has a disk-shape, as previously discussed. The micro-needle array **402** further includes the spring **460** and the finger ring **474**, as previously discussed.

As illustrated in Fig. 4, the second major surface **420** of the base **406** can further include a compressible coat **490** that surrounds the micro-needles **412**. The compressible coat **490** is formed from a foamed elastic material that is compressible. Examples of such a foamed elastic material include viscoelastic polyurethane foams and low-resilience polyurethane foams. The compressible coat can also be formed from foams of polystyrene, polypropylene, polyethylene or polymers of other vinyl monomers as are known.

The compressible coat **490** has an outer surface **492**. As illustrated in Fig. 4, each tip of the micro-needle **412** does not extend above the outer surface **492** of the compressible coat **490**. The compressible coat **490** can change shape under a compressive force, allowing the micro-needles **412** to extend beyond the outer surface **492** of the compressible coat **490**.

Claims

We claim:

1. A micro-needle device for delivering a dental local anesthetic, comprising:
a micro-needle array having a base, a sidewall and a top, where:
the base includes two or more of an elongate micro-needle, the elongate micro-needle having an interior surface defining an opening through the elongate micro-needle and the base having a first major surface and a second major surface through which the opening of the elongate micro-needle passes to provide a passage across the base;
the top having an interior surface; and
the sidewall having an interior surface, where the interior surface of the side wall, the interior surface of the top and the first major surface of the base define a volume; and
a liquid connection port in fluid connection with the volume of the micro-needle array such that dental local anesthetic fed through the connection port can exit through the opening of the elongate micro-needle.

2. The micro-needle device of claim 1, where the liquid connection port extends from the sidewall of the micro-needle array.

3. The micro-needle device of any one of claims 1-2, where the micro-needle array further includes a spring that connects the micro-needle array and a button positioned over the top of the micro-needle array, where the spring compresses under pressure applied through the button and against the micro-needle array when the micro-needle device is positioned in a mouth of a patient.

4. The micro-needle device of claim 3, where the top includes an exterior surface opposite the second major surface of the base, the exterior surface of the top having a

protrusion that extends towards the button positioned over the top of the micro-needle array.

5. The micro-needle device of any one of claims 3-4, where the micro-needle array includes a finger ring that extends from the spring, where the finger ring holds a finger against the button.

6. The micro-needle device of claim 5, where the finger ring includes a first arm and a second arm that form a hoop of the finger ring.

7. The micro-needle device of claim 6, where the first arm and the second arm each include an end, where the end of each of the first arm and the second arm are free so as to allow the hoop of the finger ring to have an adjustable diameter.

8. The micro-needle device of any one of claims 3-7, where the button has a surface defining an opening through the button, where the protrusion passes at least partially through the opening in the button when the spring is compressed under pressure applied through the button and against the micro-needle array when the micro-needle device is positioned in a mouth of a patient.

9. The micro-needle device of any one of claims 3-8, where the spring is a flat spring having a first leaf and a second leaf, where the first leaf extends from a first side of the micro-needle array to the finger ring and the second leaf extends from a second side of the micro-needle array opposite of the first leaf.

10. The micro-needle device of any one of the proceeding claims, where the second major surface of the base includes an outer boundary that extends radially from the two or more of the elongate micro-needle to define an infiltration area, and where the top includes an exterior surface opposite the second major surface of the base, the exterior surface of the top providing a continuous surface on which can received pressure from a finger and where the exterior surface opposite of the second major surface and the infiltration area overlap each other by at least 75%.

11. The micro-needle device of claim 1, where the top includes an exterior surface opposite the second major surface of the base, the exterior surface of the top having a pressure sensitive adhesive for retaining the micro-needle device on a user's finger.

12. The micro-needle device of any one of the preceding claims, where the base, the sidewall and the top of the micro-needle array have a disk-shape.

13. The micro-needle device of claim 12, where the base and the top of the micro-needle array in the disk-shape have a diameter of 4 millimeters (mm) to 15 mm and the sidewall has a height of 0.5 mm to 8 mm.

14. The micro-needle device of claim 12, where the base of the micro-needle array has 6 to 18 micro-needles.

15. The micro-needle device claim 14, where the micro-needles are uniformly arranged in a circular pattern to define the infiltration area.

16. The micro-needle device of any one of the preceding claims, where the second major surface of the base further includes a compressible coat surrounding the micro-needles, the compressible coat formed from a foamed elastic material and having an outer surface, where the compressible coat changes shape under a compressive force to allow the micro-needles to extend beyond the outer surface of the compressible coat.

17. The micro-needle device of claim 16, where each micro-needle includes a tip that does not extend above the outer surface of the compressible coat.

18. The micro-needle device of any one of the preceding claims, where the micro-needle device includes a catheter that extends from the liquid connection port to a first end, where the catheter provides a fluid connection from the first end to the volume of the micro-needle array.

19. The micro-needle device of claim 18, further including a syringe that releasably couples to the first end of the catheter to provide the fluid connection with the volume of the micro-needle array.

20. The micro-needle device of claim 19, where the syringe includes the dental local anesthetic.

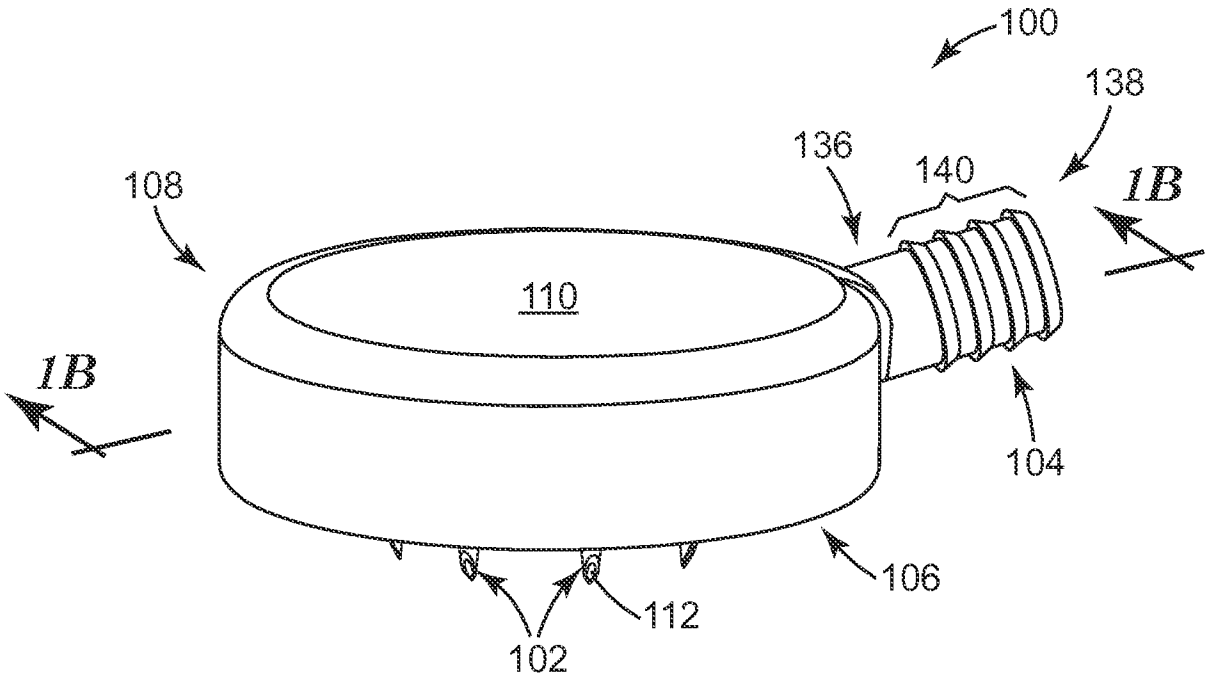
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Fig. 1A

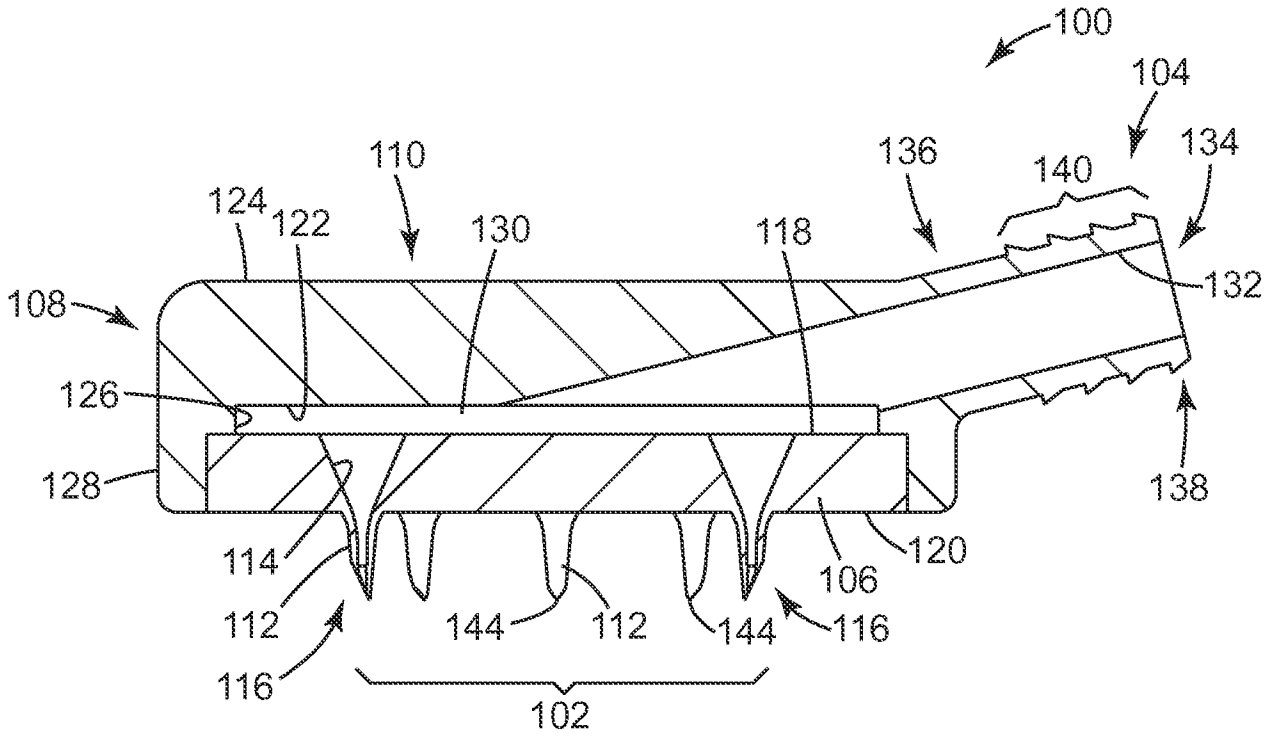
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Fig. 1B

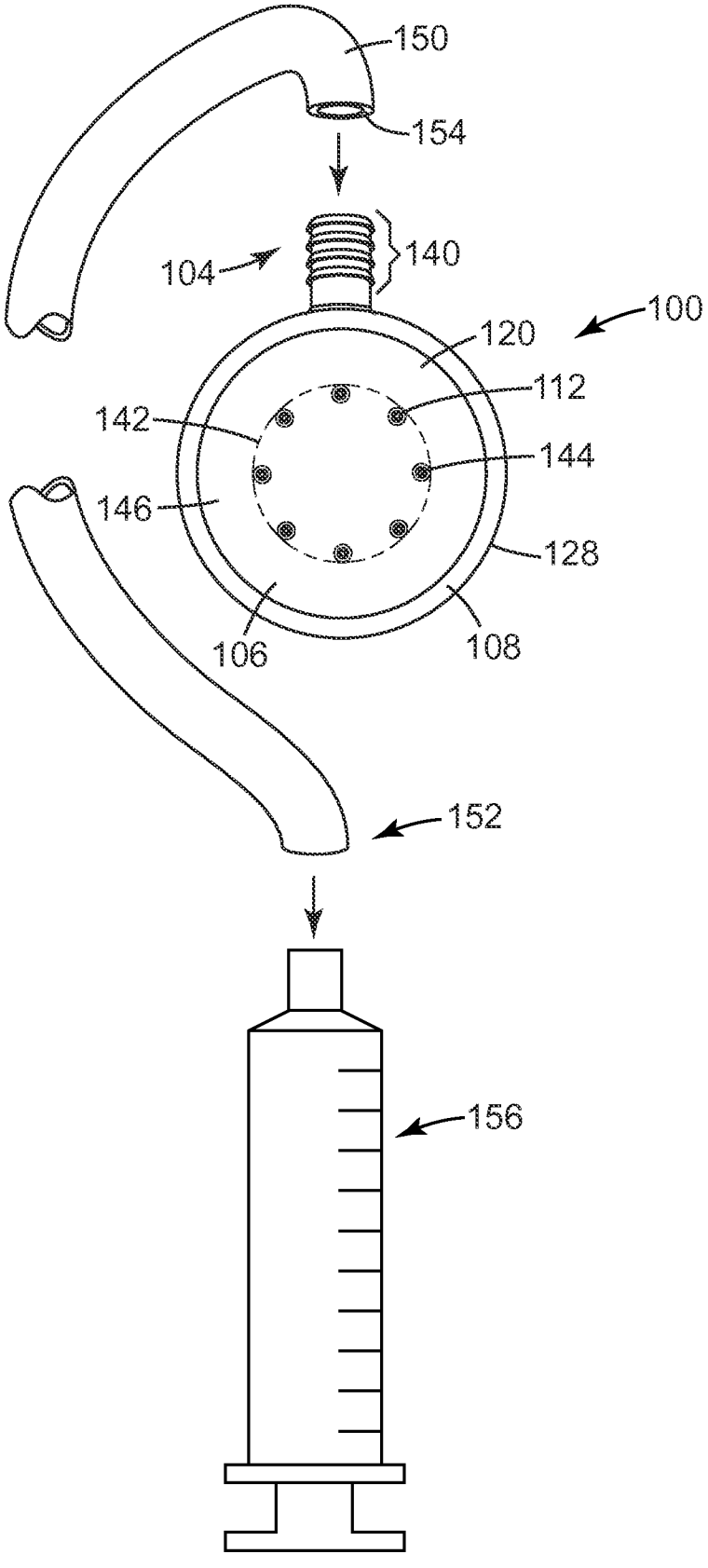

Fig. 1C

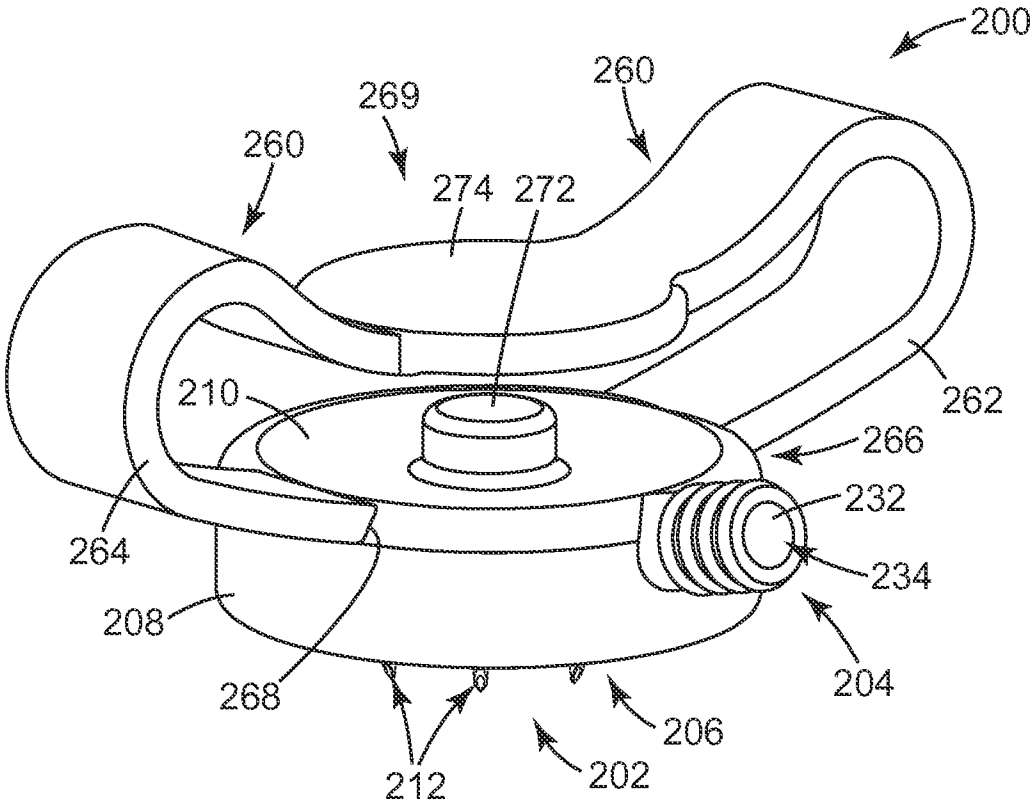
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Fig. 2

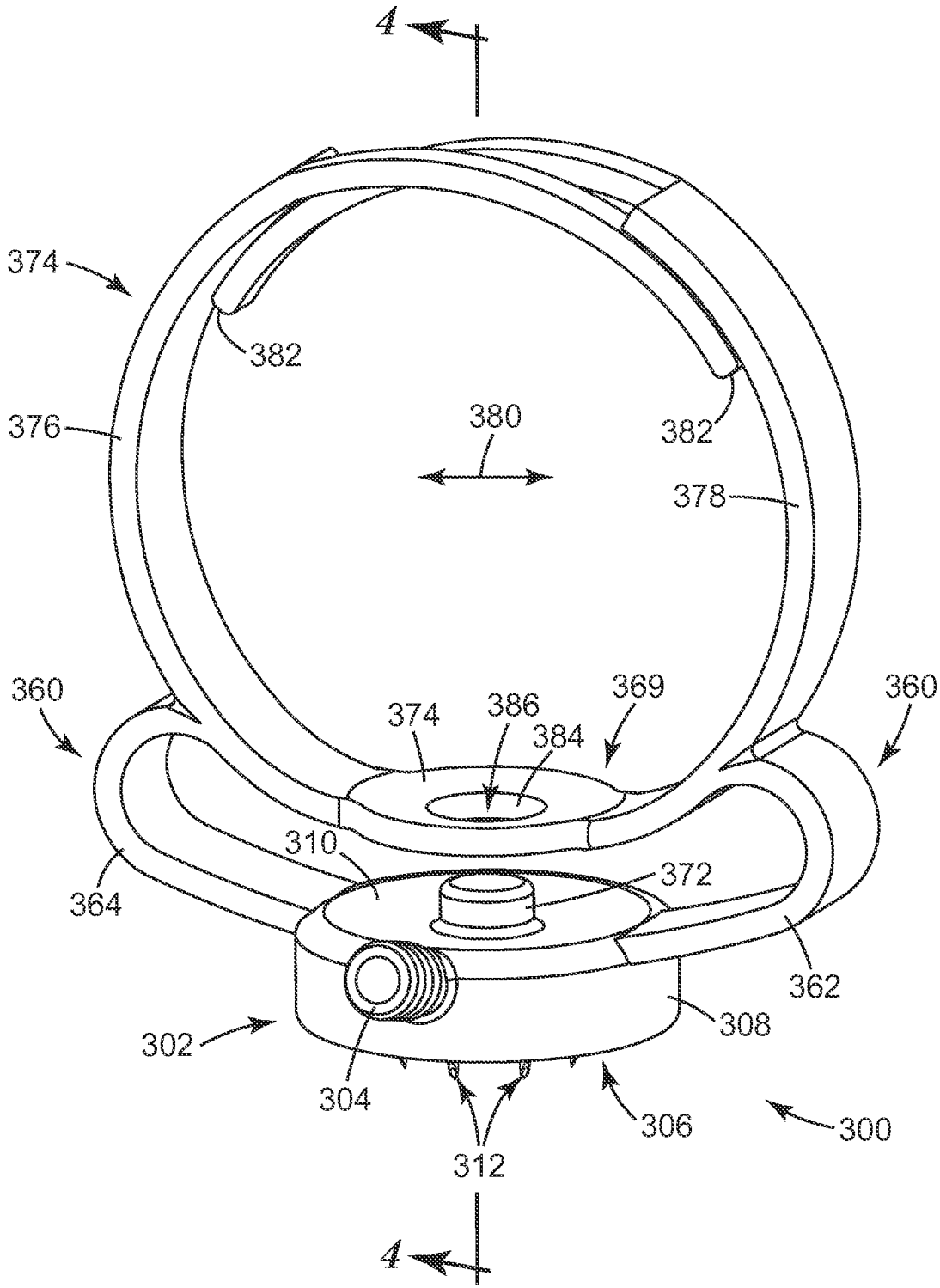
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Fig. 3

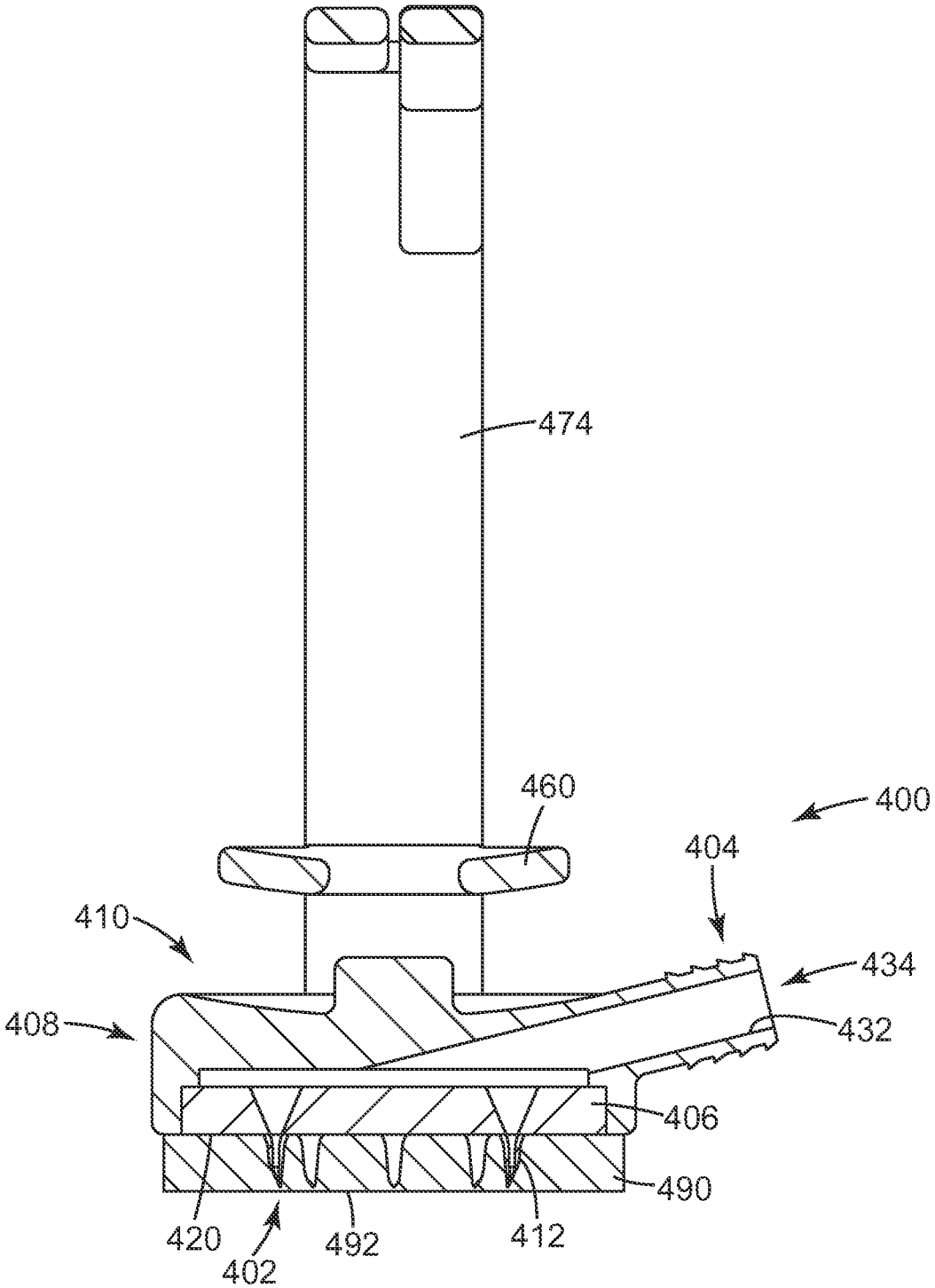

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/018899

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M37/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/110525 A2 (ALLERGAN INC [US]; KIMMELL STEVEN D [US]; GERONDALE SCOTT J [US]) 24 November 2005 (2005-11-24) the whole document	1-4, 10-15, 18-20
X	WO 02/05890 A2 (BECTON DICKINSON CO [US]; LASTOVICH ALEXANDER G [US]; EVANS JOHN D [US]) 24 January 2002 (2002-01-24) the whole document	1,3,4, 10-15, 18-20
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A	WO 2012/088154 A1 (VALERITAS INC [US]; MCALLISTER DEVIN V [US]) 28 June 2012 (2012-06-28) the whole document	3,4

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 May 2015	08/06/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Rodrigues, Elodie

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/018899

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KR 2012 0024102 A (MITI SYSTEMS INC [KR]) 14 March 2012 (2012-03-14) the whole document -----	5

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/018899

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

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

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

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

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

see additional sheet

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-20

   Microneedle device comprising a microneedle array and a liquid connection port in fluid connection with the volume of the micro-needle array.

1.1. claims: 2, 10-15, 18-20

   General constructional details of a micro-needle device

1.2. claims: 3-9

   Manual delivery trigger mechanism of a micro-needle device.

1.3. claims: 16, 17

   Compressible coat covering the micro-needles of a micro-needle device prior to application.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2015/018899

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