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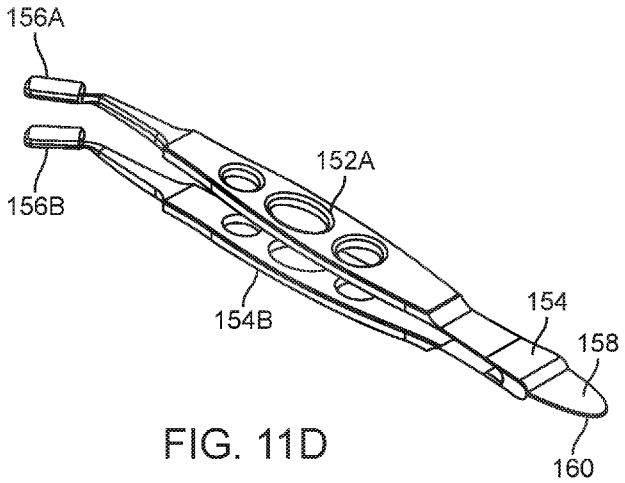


FIG. 11D

(57) Abstract: Forceps treatment systems are described in which a forceps apparatus may generally comprise a first handle and a second handle coupled to one another near or at respective proximal ends. A first paddle may be coupled to the first handle and define a first inner surface, a second paddle may be coupled to the second handle and define a second inner surface which is positioned in apposition to the first inner surface. Furthermore, a debriding member may extend proximally from the first and second handles and reduce and curve gently to define a debriding edge for debriding tissue in proximity to one or more meibomian glands. The forceps apparatus may be used in combination with a heat treatment for treating one or more meibomian glands in a subject.

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# FORCEPS TREATMENT SYSTEMS

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application is a continuation of U.S. Patent Application No. 16/127,870 filed September 11, 2018, which is incorporated herein by reference in its entirety.

## FIELD OF THE INVENTION

**[0002]** The present invention relates to methods and apparatus for treatment of dry eye syndrome and other related conditions. More particularly, the present invention relates to methods and apparatus for the treatment of various eye-related conditions such as dry eye syndrome using forceps embodiments configured for meibomian gland expression and for debriding obstructions as well as adhesive strips which are specifically contoured or shaped to adhere to selected regions around a patient's eyes or peri-orbital region.

## BACKGROUND OF THE INVENTION

**[0003]** Tears are a complex mixture of water, lipids, mucus, proteins and electrolytes and this mixture helps to maintain a smooth, lubricious, and optically clear optical surface and also helps to protect the eyes from infection. The tear film has three basic layers: oil, water, and mucus and problems or disturbances in any of these layers can cause ocular surface problems including dry eye symptoms.

**[0004]** The outermost layer of the tear film is typically comprised of an oil layer containing fatty acids and lipids (meibum), which are produced primarily by sebaceous glands called the meibomian glands located along the eyelid margin. The oil layer smoothes the tear surface and retards evaporation of the aqueous or watery middle layer. However, if the meibomian glands fail to produce enough oil, produce suboptimal fatty acid mixtures, or if the glands become obstructed or clogged, the watery layer typically evaporates too quickly causing dry eyes. A blockage or inflammation of the meibomian glands can, among many things, lead to enlarged glands or infections, inspissated secretions, styes, chalazia, hordeolum, or preseptal cellulitis . Dry eyes are thus common in people whose meibomian glands are obstructed or functioning improperly. The aforementioned are some examples of meibomian gland dysfunction which is also sometimes referred to as evaporative dry eye.

**[0005]** The middle watery layer of tears is composed primarily of an aqueous solution, which is produced by the lacrimal glands and accessory glands (tear glands). The

middle layer cleanses the eyes and washes away foreign particles or irritants, maintains a clear optical medium, and keeps the ocular surface moist. The innermost layer of the tear film is composed primarily of mucus, which helps to spread the tears evenly over the surface of the eyes. A lack of mucus in the tear film is also associated with dry eye syndrome.

**[0006]** As discussed above, the meibomian glands are oil-secreting glands located within both the upper and lower eyelids. There are approximately 30 to 40 glands along the upper eyelid and approximately 20 to 30 glands along the lower eyelid with the ducts for each of the glands opening along the inner edge of the free margin of the respective lids by minute foramina through which their secretion is released to prevent the lids adhering to each other or to the ocular surfaces. An example of the location of the meibomian glands is illustrated in the cross-sectional view of the upper eyelid **UL** shown in Fig. 1A which illustrates the relative positioning of a single meibomian gland **MG**. Other glands and anatomical features are illustrated for reference, e.g., the glands of Wolfring **GW**, tarsus **TR**, gland of Moll **GM**, gland of Zeis **GZ**, gland of Krause **GK**, upper fornix **UF**, conjunctiva **CN** and cornea **CR** of the eye which is partially covered by the upper eyelid **UL**. As illustrated, the meibomian gland **MG** is positioned along a length of the upper eyelid **UL** (and lower eyelid **LL**) with the duct opening along the inner edge of the eyelid **UL** in proximity to a surface of the underlying eye.

**[0007]** Fig. 1B illustrates a front view of a patient's eye having the upper eyelid **UL** and lower eyelid **LL** in a closed position, such as when the patient blinks. As shown, the meibomian glands **MG** may be seen aligned adjacent to one another over both the upper **UL** and lower eyelids **LL**. Fig. 1C also shows a perspective view of a patient's eye in the open position to illustrate how the meibomian glands are typically aligned relative to one another when the patient's eye is opened.

**[0008]** Blinking is thought to be the primary mechanism to open the orifice of the meibomian glands and to generate compressive force to allow for the release of oily secretions from the glands. The natural blinking motion and blinking force causes the upper lid to pull or drag a sheet of the lipids secreted by the meibomian glands over the two underlying layers of the tear film thus forming the protective coating which limits the rate at which the underlying layers evaporate. It is estimated that at least 65% of meibomian gland disease or dry eye results from a defective lipid layer or an insufficient quantity of such lipids that results in accelerated evaporation of the aqueous layer. Hence, eyelid

closure or blinking disorders, or other disorders that affect proper tear distribution, may also cause or exacerbate meibomian gland dysfunction or dry eye.

**[0009]** As the eyelids close in a total blink, the superior and inferior fornices, which hold a reservoir of tears, are compressed by the force of the preseptal muscles and the eyelids move toward one another. The upper eyelid, for instance, moves over the eye while exerting upon the eye surface a force which helps to clear the front of the eye of debris, insoluble mucin, and also expresses the oil secretions from the meibomian glands. The lower lid moves horizontally in the nasal direction and pushes debris toward both punctae, the openings that ultimately drain into the nasal cavities.

**[0010]** As the eyelids open the tear film is redistributed where the upper lid pulls the aqueous phase via capillary action and the lipid layer spreads as quickly as the eyelids move. Hence, eyelid movement is accordingly important in tear-film renewal, distribution, turnover, and drainage.

**[0011]** For a variety of reasons, the meibomian glands can become blocked, plugged, inflamed, or occluded resulting in meibomian gland dysfunction and dry eye disease. The obstruction that triggers the disease can occur anywhere within the meibomian gland, for instance, at the gland's surface or orifice preventing normal lipid secretions from flowing; in the main channel of the gland which may be narrowed or blocked; or in other locations deeper within the gland that lead to the main channel.

**[0012]** Treatments for blocked meibomian glands may include a number of conventional treatments. One course of treatment includes the application of soap and cleaning agents, eyelid scrubs, antiseptics, or antibiotics to reduce eyelid inflammation. Antibiotics such as tetracycline, doxycycline, minocycline, metronidazole, azithromycin, bacitracin, or erythromycin can be administered orally or topically to help regulate or improve meibomian gland lipid production. Inflammation on the surface of the eye may also be controlled with topical drugs such as corticosteroids or cyclosporine (RESTASIS®, Allergan, Inc., CA), or other anti-inflammatory compounds or immune-suppressants. Evidence suggests that ocular surface inflammation is not only associated with meibomian gland dysfunction but also with dry eye syndrome.

**[0013]** Other examples of dry eye treatments may include the application of prescription eye inserts for people with moderate to severe dry eyes symptoms who are unable to use artificial tears. An eye insert, e.g., hydroxypropyl cellulose (LACRISERT®, Merck & Co., Inc., NJ), may be inserted between the lower eyelid and eye. The insert dissolves slowly to release a substance which lubricates the eye. Alternatively, special

contact lenses or amniotic membrane transplants may be used to shield the surface of the eye to trap moisture.

**[0014]** In other treatments, the patient's tear ducts may be closed to prevent the tear film from draining away from the surface of the eye too quickly by procedures such as insertion of punctal plugs into the tear ducts or cauterizing the tissues of the drainage area. Aside from implants or cauterizing treatments, dry eye syndrome may be treated using pharmaceutical agents such as eyedrops, ointments which coat the eyes, etc. Artificial tears, gels, ointments, autologous serum tears, or albumin drops have all been employed in the treatment of dry eye.

**[0015]** Additionally, warm compresses are also typically placed over the eyes and are used to restore function to the meibomian glands by melting any lipid plugs as well as incorporating massaging of the lids which may further reduce meibomian gland obstruction and express meibomian gland contents. However, application of warm compresses often can require their application two to three times daily during which time patients may incorrectly target only one of the affected lids and are also prevented from seeing out of the treated eye because of the compresses. Warm compresses pose multiple issues such as noncompliance, poor persistence, or high variability. Compresses may be too hot, further exacerbating inflammation, or they may cool too quickly preventing adequate therapeutic effect.

**[0016]** Other treatment devices have also been developed which cover the entire affected eye to apply heat and a massaging force directly to the affected eyelids. However, such devices, like the compresses, require that the patient's eyes be temporarily but completely obstructed during the treatment resulting in discomfort, lost productivity, and potentially lower compliance among patients. Additionally, these treatments require visits to a physician or healthcare provider, and thus are labor intensive, inconvenient, expensive, and consequently are not as well-suited for widespread consumer adoption.

**[0017]** There are also forceps that are used for expressing meibomian glands but these forceps are not customized or optimized for meibomain gland expression. Expression of the meibomian glands typically involves application of compressive force to the glands to express the secretions of the gland, also known as meibum, from the gland orifice. For instance, such forceps are neither heated nor dimensionally customized for directional expression of meibum.

**[0018]** Accordingly, there exists a need for methods and apparatus which are relatively simple to routinely use for the patient or physician to use and which also allow

for the patient to continue their normal activities, is non-obtrusive and non-disruptive, and which also take advantage of the patient's natural physiological activities to facilitate treatment and which facilitates meibomian gland expression.

## SUMMARY OF THE INVENTION

**[0019]** In treating conditions such as meibomian gland dysfunction (MGD), which is commonly associated with the evaporative form of dry eye syndrome (DES), the meibomian glands may be mechanically pressed or squeezed to express solidified meibum from the glands in order to help treat MGD. Forceps are typically used to apply pressure upon the meibomian glands in combination with a heat treatment. The forceps may also be used to debride the tissue along the upper and/or lower eyelid margins to facilitate the clearing of any internal or external obstructions, keratinization, or "capping" at or near the orifices or openings of the meibomian glands. The methods of treatment described may also be used for other procedures as well, e.g., improved vision, contact lens comfort improvement, tear quality improvement, surgical outcome improvement due to accurate measurements from an improved tear quality or optical surface, etc.

**[0020]** With respect to the assembly for the treatment strip or strips, the assembly may generally comprise one or more strips configured to adhere to an underlying region of skin in proximity to one or both eyes of a subject such that the one or more strips allow for the subject to blink naturally without restriction from the one or more patches. Moreover, the one or more strips may be configured to emit energy or therapy to the underlying region of skin and where the one or more strips are shaped to follow a location of one or more meibomian glands contained within the underlying region of skin.

**[0021]** A programmable controller having a controller board and a processor may be in communication with the one or more strips, where the controller may induce, and monitor a programmable temperature of the one or more heater strips and to provide a treatment therapy. The therapy may be programmed to maintain a set point, within a known accuracy, (e.g., 42°C +/- 1°C) above a threshold temperature of, e.g., 39°C, and below a maximum temperature of, e.g., 48°C, over a treatment period of, e.g., 15 minutes. Other treatment times may be implemented in other variations; for instance, the treatment time may extend from 1 minute to 60 minutes in other treatment variations.

**[0022]** In use, the one or more strips may be adhered to a region of skin in proximity to one or both eyes of a subject such that the one or more strips allow for the subject to blink naturally without restriction from the one or more patches. While adhered,

the strips may treat or emit energy to the region of skin, where the one or more strips are shaped to follow a location of one or more meibomian glands contained within the region of skin. Alternatively, while the strip may not directly overly a meibomian or other ocular or orbital gland, it may deliver energy or absorb energy from underlying neighboring tissue or vasculature, which ultimately diffuses, or supplies said glands, respectively. In other words, heating or cooling the blood supply to the eyelids, meibomian glands, and/or lacrimal glands using these strips may affect their function and metabolism while not necessarily needing to directly overlay them in particular variations. For instance, the strips may effect the heating or cooling via any heat transfer modality, e.g., radiation, conduction, convection, or any combination thereof, without directly overlaying upon the tissue.

**[0023]** The upper strip may thus have an upper curved or arcuate periphery which is shaped to extend and follow the upper (or superior) border of the meibomian glands (such as along or up to the upper eyelid crease) while the straightened periphery of the lower edge may be shaped to extend and follow the lower (or inferior) border of the meibomian glands such as along the free margin of the upper eyelid. Although straightened, the lower edge may be gently curved or arcuate in alternative variations. The lower strip may similarly have an upper straightened periphery to extend and follow the upper (or superior) border of the meibomian glands along the free margin of the lower eyelid and a lower curved or arcuate periphery to extend and follow the lower (or inferior) border of the meibomian glands along the lower eyelid (such as along or up to the lower eyelid crease). Alternatively, the upper periphery of the lower strip may also be gently curved or arcuate in alternative variations as well.

**[0024]** In other words, with the tarsal plate containing the meibomian glands, which span from proximal to distal, the peripheral edges of the treatment strips may correspond to the distal eyelid margin and proximal peripheral edge and the treatment strips can assume multiple configurations. Generally, the peripheral distal edge of the treatment strip may be relatively straight or assume a gentle curve either of which can follow the underlying distal eyelid margin and tarsal plate while having a proximal peripheral edge that is relatively curved to assume the more curved proximal edge of the underlying tarsal plate.

**[0025]** The strips may be used individually for placement upon only the upper eyelid or only the lower eyelid depending upon the desired treatment. Moreover, the lengths of the treatment strips may also be varied to target individual meibomian glands for providing a targeted treatment, if desired, and as described in further detail herein.

Additionally, while the treatment strips may be sized generally, they may also be custom made or sized for a specific individual's eyelid dimensions.

**[0026]** Because of the specific contoured sizes and flexibility of the treatment strips the treatment strips may be placed upon the patient to apply therapy to the underlying meibomian glands allowing the patient's eyes to be opened and closed normally without interference from one or both treatment strips. Accordingly, the treatment strips contoured size, shape, thickness, and flexibility allow for treatment to occur while also allowing for the patient to have one or both eyes remain opened such that normal, physiologic blinking can proceed during the course of treatment. To further reduce the forces on the eyelids, heaters may be decoupled from the forces acting on their connections (such as wires) by the addition of multiple turns (e.g., non-linear regions) in their connection paths that destabilize loads that would otherwise be communicated from power supply cabling to the eyelid(s). Rather than relying on an application of any type of external force, the treatment strips take advantage of the eye's natural mechanism for clearing oil from the meibomian glands via blinking. Hence, the treatment strips may be adhered in place for treatment without any further intervention by the patient or healthcare provider such that the treatment strips may apply, e.g., heat energy, to melt or liquefy any waxy or solid meibomian gland obstructions while the eyes remain unobstructed and are allowed to blink naturally. The treatment strips thus allow for the natural blinking force to clear the glands of the heat-treated softened obstructions before they have re-solidified unlike other treatments which require that the patient keep their eyes closed or obstructed during the course of a treatment and prevent or inhibit the patient from blinking.

**[0027]** The forceps may be used before, after, and/or during a heat treatment in combination with the heating strips as described herein. Alternatively, the forceps may be used to first apply a heat treatment to melt the meibum plugs contained within the glands and then the forceps may be used to mechanically express the liquefied meibum before it re-solidifies. The two apposed handles of the forceps may each terminate at their distal ends in respective paddles and a proximal end of the forceps may comprise a debriding member extending proximally and which defines a curved or arcuate debriding edge around a periphery of the member. To facilitate positioning of the paddles relative to the tissue region of the eye to be mechanically expressed, the paddles may be angled along their lengths to define an angle relative to a longitudinal axis of the forceps.

**[0028]** The debriding member may extend from a proximal end of the forceps define an edge which is relatively thin with respect to the rest of the forceps. In one

variation, the debriding member may have a length which reduces and curves gently into, e.g., an elliptical shape. In use, while the paddles may be used to mechanically express the meibomian glands directly and/or to apply pressure to the tissue region in proximity to the meibomian glands, the debridement edge may be used before, during, and/or after the mechanical expression to scrape along the upper lid and/or lower lid margin to remove any obstructions, keratiniztion, membrane, film, debris, or capping from or overlying the meibomian glands and meibomian gland orifices. Moreover, mechanical expression and/or debridement using forceps may be performed at any time during a heat treatment with the one or more heat strips and in any order of treatment. For example, the upper and/or lower lids may be thermally treated with the one or more heat strips for a specified period of time after which the upper and/or lower lids may then be mechanically expressed with the forceps and may then undergo debridement with the debriding edge after, during, and/or even before the heat treatment. Alternatively, the tissue may undergo debridement with the debriding edge before, during, and/or after a heat treatment with or without mechanical expression or the tissue may undergo mechanical expression alone without use of the debriding edge. In another variation, the tissue may first undergo debridement with the debriding edge and then a thermal treatment may be performed with the treatment strips. The debriding procedure may be performed with the patient either wearing the treatment strips or before the treatment strips are applied. The forceps may then be used to mechanically express the meibomian glands. The mechanical expression may be done with the patient either wearing the treatment strips or after they have been removed. The combination of procedures may be varied depending upon the desired results.

**[0029]** In one variation, a forceps apparatus may generally comprise a first handle and a second handle coupled to one another near or at respective proximal ends, a first paddle coupled to the first handle and defining a first inner surface, a second paddle coupled to the second handle and defining a second inner surface which is positioned in apposition to the first inner surface, and a debriding member extending proximally from the first and second handles and which reduces and curves gently to define a debriding edge for debriding tissue in proximity to one or more meibomian glands. In other variations, the forceps may have the first and/or second paddles configured with one or more of its edges modified to not only provide the mechanical expression but to also function as a debriding edge.

**[0030]** In another variation, a forceps apparatus may generally comprise a first handle and a second handle coupled to one another near or at respective proximal ends, a

first paddle coupled to the first handle and defining a first inner surface, and a second paddle coupled to the second handle and defining a second inner surface which is positioned in apposition to the first inner surface, wherein the first paddle and/or second paddle defines a debriding edge along a distal terminal edge or a proximal side edge for debriding tissue in proximity to one or more meibomian glands.

**[0031]** In one method of treating a subject, the method may generally comprise debriding tissue or debris in proximity to one or more meibomian glands within a tissue region of a subject via a debriding member extending proximally from a forceps having a first handle and a second handle coupled to one another near or at respective proximal ends, applying a thermal treatment to the one or more meibomian glands, and mechanically expressing the one or more meibomian glands via a first paddle coupled to the first handle and defining a first inner surface, and a second paddle coupled to the second handle and defining a second inner surface which is positioned in apposition to the first inner surface.

**[0032]** Furthermore, any of the forceps variations and combinations described herein may be used alone for treating a patient or they may be used in combination with any of the treatment apparatus and methods described in further detail in U.S. Pats. 9,724,230; 9,510,972; 9,844,459; 9,642,743; and U.S. Pat. Pubs. 2016/0106576; 2017/0165106; 2017/0304110; and 2017/0087009, each of which is incorporated herein by reference in its entirety and for any purpose herein, particularly for treatment of MGD and dry eye syndrome.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0033]** Fig. 1A shows a cross-sectional side view of an upper eyelid and an example of the location of a meibomian gland.

**[0034]** Fig. 1B shows a front view diagram of meibomian gland distribution in human eyelids having the upper eyelid and lower eyelid in a closed position, such as when the patient blinks, and the alignment of the meibomian glands over both the upper and lower eyelids.

**[0035]** Fig. 1C shows a perspective view of a patient's eye in the open position to illustrate how the meibomian glands are typically aligned relative to one another when the patient's eye is opened.

**[0036]** Fig. 2A shows a front view of a patient's eye in a closed position with an example of treatment strips which adhere onto the upper or lower eyelids (or both) and

where the strips are sized or contoured for placement directly over the meibomian glands located in the underlying eyelids.

**[0037]** Fig. 2B shows the treatment strips of Fig. 2A illustrating how the strips may remain adhered to the patient skin while allowing for the eyelids to retract and allow for the patient to continue blinking while viewing normally out of the eye. While the strips may be applied from eyelid margin to eyelid crease, they may alternatively flex or accordion and/or compress during blinks to prevent impairment of normal blinking and maximize comfort.

**[0038]** Fig. 3 shows yet another variation of an eyelid treatment system which may be coupled to a portable remote controller such as a smartphone or tablet.

**[0039]** Fig. 4 shows a perspective view of a controller which is specifically designed and programmed for use with the treatment strip assemblies.

**[0040]** Figs. 5A and 5B show perspective views of the controller having connectors for respective treatment strip assemblies coupled to the controller.

**[0041]** Fig 6 shows the mating connection of a treatment strip assembly to a re-usable cable assembly.

**[0042]** Fig. 7A shows a perspective view of treatment strip assembly coupled via respective connectors to a common junction for attachment to a cable.

**[0043]** Fig. 7B shows a perspective view of a treatment strip with a sensing layer exposed, illustrating the positions of various sensors.

**[0044]** Fig. 8 shows a perspective view of one variation of the forceps which are sized and angled for expressing the meibomian glands.

**[0045]** Fig. 9 shows an example of a treatment kit which includes forceps and optionally included additional treatments.

**[0046]** Fig. 10A shows another example of a treatment kit which includes forceps and one or more heating strips.

**[0047]** Fig. 10B shows another example of a treatment kit which includes forceps, one or more heating strips, and optionally a controller.

**[0048]** Fig. 10C shows yet another example of a treatment kit which includes forceps, and optionally includes one or more heating strips, controller, and/or additional treatments.

**[0049]** Figs. 11A to 11D show respective top, side, end, and perspective views of another variation of the forceps having a debridement feature.

**[0050]** Fig. 12A shows a detail side view of the paddles of the forceps.

**[0051]** Fig. 12B shows a detail side view of another variation of the paddles having one or more debriding edges.

**[0052]** Figs. 13A and 13B show respective side and end views of the debridement feature.

**[0053]** Fig. 14 shows a perspective view of the debridement feature used to remove obstructions from the meibomian glands.

**[0054]** Figs. 15A to 15C show detail side views of different variations for a debriding feature defined along a notched portion.

## DETAILED DESCRIPTION OF THE INVENTION

**[0055]** In treating conditions such as meibomian gland dysfunction (MGD), which is commonly associated with the evaporative form of dry eye syndrome (DES), the meibomian glands may be mechanically pressed or squeezed to express solidified meibum from the glands in order to help treat MGD. Forceps are typically used to apply pressure upon the meibomian glands. The forceps may be modified to create a pressure gradient upon the meibomian glands to direct meibum and any other meibomian gland secretions towards the meibomian gland orifices. The forceps may be configured to further provide for debridement of the tissue along the upper and/or lower lids to facilitate the clearing of any obstructions such as inspissated oil and meibum plugs from the main ducts and orifice openings of the meibomian glands, meibomian gland channel, and meibomian gland orifices. Additionally and/or alternatively, the forceps may be configured to also provide a thermal treatment, e.g., to the eyelid surfaces to simultaneously melt, soften, or liquefy and express meibum to increase its therapeutic efficacy.

**[0056]** The forceps may be used before, during, and/or after a heat treatment in combination with the heating strips as described herein. Alternatively, the forceps may be used to first apply a heat treatment to melt the meibum plugs contained within the glands and then the forceps may be used to mechanically express the liquefied meibum before it re-solidifies. In another alternative, the forceps may be used to apply a thermal treatment and mechanical expression simultaneously to effectively express the meibum. In treating the meibomian glands, the forceps may also be used to apply heat to other regions, e.g., inner eyelids, outer eyelids, or both. However, when the heating strips are used to apply a heat treatment to a patient, the forceps used for mechanically expressing the glands may be configured to separately heat the glands and/or they may include any number of mechanical features, as described herein, to facilitate mechanical expression.

**[0057]** In treating conditions such as meibomian gland dysfunction (MGD), which is commonly associated with the evaporative form of dry eye syndrome (DES), a patch, strip or thin adhesive device can be affixed to the skin of the upper and/or lower eyelids to deliver or absorb heat or other forms of energy, pressure, drugs, moisture, etc. (alone or in combination) to the one or more meibomian glands contained within the underlying skin. In particular, the treatment strip or strips may be configured and sized specifically for placement over one or more targeted meibomian glands contained within the skin of the upper and/or lower eyelids. The application of thermal therapy, e.g., heating or cooling, can cross the eyelids quite easily as the eyelids are generally the thinnest skin found on the human body and the tissue is highly vascularized. With the root of the eyelid located proximally and the eyelid margin located distally, the net arterial flow of blood flows from proximal to distal. So wherever these treatment strips are placed, the heating or cooling therapy may easily be carried throughout the eyelid and any structures contained therein, e.g., meibomian glands **MG**, lacrimal glands **LG**, gland of Zeis **GZ**, gland of Moll **GM**, gland of Wolfring **GW**, gland of Kraus **GK**, etc.

**[0058]** Moreover, because the eyelid is so thin, the heating or cooling therapy can be transmitted to the ocular surface and the eye itself (described in further detail below). Thus, the therapy can impart energy to the conjunctiva, goblet cells, episcleral vasculature, cornea, aqueous humor, iris, ciliary body, and possibly the retina, choroid, optic nerve, anterior vitreous, and lens. Thus, any thermal therapy by the treatment strips may also impact and be used to treat ocular surface disorders and anterior segment diseases, e.g., conjunctivitis, keratitis, keratopathy, iritis, cyclitis, glaucoma, cataract, etc. Also, there may be use in the postoperative state-like after LASIK, PRK, or cataract or corneal surgery or other ocular, peri-ocular, intraocular, or eyelid surgery, as described in further detail below.

**[0059]** As shown in the front view of Fig. 2A and Fig. 2B, one variation of such treatment strips may be seen as being adhered temporarily upon the upper eyelid **UL** and lower eyelid **LL** over an eye of a patient **P** when closed for illustrative purposes. The contoured upper strip **10** may be sized for adherence directly upon the skin of the upper eyelid **UL** such that the strip **10** has a configuration and shape which follows the location of the one or more meibomian glands contained within the underlying skin of the upper eyelid **UL**. Likewise, the contoured lower strip **12** may also have a configuration and shape which follows the location of the one or more meibomian glands contained within

the underlying skin of the lower eyelid **LL**. In other variations, the contoured strip may stop at the eyelid crease or cross over it as described in other variations below.

**[0060]** The upper strip **10** may thus have an upper curved or arcuate periphery **14** which is shaped to extend and follow the upper (or superior) border of the meibomian glands (such as along or up to the upper eyelid crease) while the straightened periphery **16** of the lower edge may be shaped to extend and follow the lower (or inferior) border of the meibomian glands such as along the free margin of the upper eyelid **UL**. The lower strip **12** may similarly have an upper straightened periphery **20** to extend and follow the upper (or superior) border of the meibomian glands along the free margin of the lower eyelid **LL** and a lower curved or arcuate periphery **18** to extend and follow the lower (or inferior) border of the meibomian glands along the lower eyelid **LL** (such as along or up to the lower eyelid crease). The use of the terms lower and upper herein refer to the periphery of the treatment strips when placed upon the patient **P** (human or animal) and are used herein for descriptive purposes.

**[0061]** While the treatment strips **10**, **12** are both shown adhered upon the respective upper eyelid **UL** and lower eyelid **LL**, the strips **10**, **12** may be used individually for placement upon only the upper eyelid **UL** or only the lower eyelid **LL** depending upon the desired treatment. Moreover, the lengths of the treatment strips **10**, **12** may also be varied to target individual meibomian glands for providing a targeted treatment, if desired, and as described in further detail herein.

**[0062]** While the treatment strips **10**, **12** are shown placed upon the closed eyelids of the patient **P**, the strips **10**, **12** are arc-shaped or flexible enough to assume the curvature of the patient's eyelid margin and may be long enough to cover some or all of the underlying meibomian glands in the tarsal plate. While the treatment strips **10**, **12** may be sized generally, they may also be custom made or sized for a specific individual's eyelid dimensions or shaped to optimize adhesion and/or comfort and/or stability. Generally, the treatment strips **10**, **12** may have a length anywhere from about 1 mm to 50 mm depending upon the desired treatment length as well as the anatomical considerations of the patient since the typical palpebral fissure length in an adult is about 27 mm to 30 mm. Thus, to cover as many as all of the meibomian glands, the treatment strips **10**, **12** may be sized to have length of, e.g., 25 mm to 30 mm, or if sized to cover just beyond all the meibomian glands, a length of, e.g., 30 mm to 50 mm (or more if needed to optimize coverage / adhesion / comfort / stability). Moreover, one or both treatment strips **10**, **12** can have a width ranging anywhere from about 1 mm to 25 mm since the typical eyelid crease in a

Caucasian male is about 8 mm to 9 mm above the eyelid margin while in Caucasian females it is about 9 mm to 11 mm above the eyelid margin (or more if needed for adhesion/comfort and potentially increased efficacy from heating or cooling the inbound blood flow). Customization enables it to fit any particular anatomy, race, ethnicity, etc. Moreover, the treatment strips may be manufactured with varying levels of flexibility to accommodate the ergonomics of the eyelid and eyelid blink for optimal comfort and minimal obtrusiveness or movement.

**[0063]** Because of the specific contoured sizes and flexibility of the treatment strips **10**, **12**, the treatment strips may be placed upon the patient **P** by the patient himself/herself for consumer use or by a healthcare provider to apply therapy to the underlying meibomian glands allowing the patient's eyes to be opened and closed normally, as shown in Fig. 2B, without interference from one or both treatment strips. While the strips may be applied from eyelid margin to eyelid crease, they may alternatively flex or accordion and/or compress during blinks to prevent impairment of normal blinking and maximize comfort.

**[0064]** Typical treatment patches, such as for application of a warm compress, are generally sized for placement over the entire eye or eyes such that the patient is unable to open their eyes or blink during a treatment session. Yet, because of the strong association between DES and MGD (for instance, MGD includes the spectrum of MGD, meibomitis, blepharitis, and ocular rosacea), natural blinking by an individual is the mechanism by which meibomian gland secretions are normally released onto the eyelid margin and over the tear. In the absence of blinking, the oil contained within the meibomian glands remain unexpressed within the glands' terminal ducts and fail to contribute to distribution of the oily layer upon the tears.

**[0065]** Accordingly, the treatment strips **10**, **12** contoured size, shape, and flexibility allow for treatment to occur while also allowing for the patient to have one or both eyes remain opened such that normal, physiologic blinking can proceed during the course of treatment. Rather than relying on an application of any type of external force to express the oil or obstruction from the glands, the treatment strips **10**, **12** take advantage of the eye's natural mechanism for clearing oil from the meibomian glands via blinking. Hence, the treatment strips **10**, **12** may be adhered in place for treatment without any further intervention by the patient or healthcare provider such that the treatment strips **10**, **12** may apply, e.g., heat energy, to melt or liquefy any waxy or solid meibomian gland obstructions while the eyes remain unobstructed and are allowed to blink naturally. The treatment strips **10**, **12** thus allow for the natural blinking to help clear the glands of the

heat-treated softened obstructions before they have re-solidified unlike other treatments which require that the patient keep their eyes closed or obstructed during the course of a treatment and prevent or inhibit the patient from blinking. Delivery of heat may also increase blood flow by promoting vasodilation as increased delivery of blood can affect metabolism, temperature of other tissues, may have effects on inflammation, and can thereby improve tissue function or recovery.

**[0066]** Because some patients have obstructions or occlusions in their meibomian glands that may not sufficiently melt, loosen, or soften without attaining heightened temperatures at the meibomian glands, the treatment strips **10**, **12** may apply heat or other treatments to the surface of the eyelids for a significant period of time for relatively longer treatment times and at higher treatment temperatures because of the ability of the treatment strips **10**, **12** to remain attached to the patient during any given period throughout the day. Treatment strips may be relatively transparent or skin toned, and thereby inconspicuous, to allow for normal functioning throughout the treatment ranges. Patients can assume their daily activities with their eyes open and eyes blinking and with the comfort of a strip-based treatment. Moreover, patients can affix the treatment strips as many times as needed throughout the day, week, month, etc. until dry eye symptoms subside. This increases the frequency of treatment, convenience of treatment, and thus efficacy of treatment.

**[0067]** Because of the prolonged treatment times, the application of a separate force beyond the application of the strips may not be needed so long as the patient is able to continue blinking during the course of treatment. Moreover, the treatment frequency may be adjusted or varied depending upon the severity of the condition to be treated. One example for potential treatment frequency may include application of one or both strips, e.g., up to six times per day for ten minutes or up to an hour or more for each treatment. Moreover, because the treatment strips are positioned over the meibomian glands which overlie the ocular surfaces, the application of the heating therapy may also indirectly heat the ocular surface as well and may further reduce any chronic ocular surface inflammation, chronic conjunctival inflammation, or corneal neovascularization.

**[0068]** Aside from heating of the ocular surface, heat therapy may also optionally be used to potentially provide for indirect heating through the ocular surface as well for heating of the retina to provide a thermal therapy to limit inflammation and neovascularization which are underlying conditions for diseases such as age-related macular degeneration (AMD), retinal vascular occlusions, retinal neovascularization, glaucoma, retinal degenerations and dystrophies, and Diabetic Retinopathy.

**[0069]** While the treatment strips **10**, **12** may be used throughout the day to take advantage of the patient's physiologic blinking, the treatment strips **10**, **12** may also be used while the patient is resting or sleeping or while the patient simply maintains their eyes closed. The treatment strips **10**, **12** may be applied as a single-use treatment or they may be configured to be robust enough as a re-usable device. In a re-usable embodiment, the adhesive component might be easily replaced while the thermal mechanism, circuitry, and sensors of the treatment strips are re-used.

**[0070]** The treatment strips **10**, **12** are desirably flexible enough to accommodate movement of the upper eyelid **UL** and/or lower eyelid **LL** which may move as much as about 15 mm or more. Thus, the treatment strips **10**, **12** may be fabricated from various materials.

**[0071]** Fig. 3 shows another variation where the eyelid treatment system **30** may be formed into a coupled dual-strip design, e.g., a "wishbone" design, where the dual-strip heating strips may have two heating elements which follow the location of the meibomian glands the upper **UL** and lower **LL** eyelid of a single eye. Depending upon whether both eyes or a single eye and/or both upper and lower eyelids are treated, the system **30** may comprise a first heating strip assembly **32** and a second heating strip assembly **34** for each respective eye. Each of the assemblies **32**, **34** may accordingly utilize an upper and a lower lid treatment heater, e.g., upper lid treatment strip **32A** and lower lid treatment strip **32B**, where each of the upper and lower elements may be coupled to one another via wires **36** (e.g., flexible circuit). Moreover, each of the assemblies **32**, **34** may be coupled via a connecting cable **38** to controller **40** which may be coupled (e.g., through an input/output port such as a headphone jack, USB port, micro HDMI, or other connection port) to a portable electronic device **42** (e.g., smartphone having a touch screen interface, tablet, PDA, laptop computer, etc.) as shown.

**[0072]** In other variations, the number of connecting cables may range anywhere from 1-4 connector cables rather than utilizing a single cable **38**. For instance, one cable may be used to provide power and communication to a few or all four heating elements in each of the assemblies **32**, **34**. Alternatively, four connecting cables may provide power and communication to each of the heating elements in assemblies **32**, **34**. Yet in other alternatives, two connecting cables may provide power and communication to each of the assemblies **32**, **34**.

**[0073]** In other additional variations, any of the treatment strips described may be used in combination with the controller **42** described herein, as practicable. Yet in a further

variation, oval or circular shaped heating elements may cover the eye and both eyelids where an outer border of the heating elements or strips may follow the path of the upper and lower meibomian glands. In this case, one treatment strip may cover both eyelids and both sets of meibomian glands and the user may use a total of two (rather than four) round, circular, or oval shaped treatment strips to cover both eyes. Such a variation may be used, e.g., for a night time therapy in bed prior to or during sleep when the eyes need not necessarily be open.

**[0074]** The assemblies **32**, **34** may generally comprise strips, as previously described, which follow the location of the meibomian glands while still allowing patients to blink easily and proceed in comfort with daily activity. An example of such heaters which may be configured for use with the treatment system **30** may include thin, flexible heaters which are commercially available through companies such as Minco Products, Inc. (Minneapolis, MN) or can be custom designed and manufactured independently or through third party manufacturing. Each individual treatment strip, e.g., treatment strips **32A**, **32B**, may each be sized for a single eyelid, e.g., 28 mm x 7 mm x 0.15 mm, having a bottom chord length of, e.g., 28 mm, with a radius of curvature of, e.g., 75 mm, and having a general configuration of an arcuate rectangle having blunted corners where the nasal or temporal edges may coincide with the radii of the arc. However, these size limitations are intended to be exemplary and not limiting since the treatment strips **32A**, **32B** may be sized to be smaller or larger to accommodate different eye anatomies.

**[0075]** Moreover, the individual treatment strips **32A**, **32B** may be formed as thin, flexible transparent polymers containing the heating elements while the contact surface of the strips may be affixed to the respective eyelids with, e.g., a disposable adhesive. Other variations may utilize opaque or colored strips, e.g., skin-tone colors. Moreover, one or more temperature sensors may also be integrated into the treatment strips where the heating elements and sensors may be routed through the connecting cable **38** to a power source and/or controller **40** and/or portable electronic device **42**, as shown.

**[0076]** Controller **40** may generally comprise a hardware/software platform or unit which may be programmed for controlling the therapy treatments. Accordingly, the controller **40** may include a processor as well as a power supply such as a battery (rechargeable or disposable) for providing power to the assemblies **32**, **34**. The power supply within controller **40** may be optionally rechargeable separate from the portable electronic device **42** or the power supply may draw power for the assemblies **32**, **34** and processor directly from the portable electronic device **42** as well.

**[0077]** In the case where the controller **40** is programmed to provide the therapy treatment protocols, one or several controls for controlling the treatments may be built directly into controller **40**. The portable electronic device **42** may interface with the controller **40** to display, in one variation, part of the controls on a screen (e.g., touchscreen) of the electronic device **42** such as controls for starting and/or stopping a treatment. The controller may also have facilities for detecting when leads are not properly connected, measuring power levels, and measuring temperature levels. Accordingly, there will be the capability to notify or alert a user should any of these values fall out of range or the ability to prevent initiation of treatment or cease treatment until these scenarios are explicitly acknowledged or corrected. Alternatively, all of the controls may reside on the controller **40** while a display on the electronic device **42** may serve primarily to show or track various results or treatment parameters, and or treatment status. A separate display and controller combination may also be used.

**[0078]** In yet another alternative, the all of the controls may reside on the display of the electronic device **42** for controlling the various treatment options and parameters rather than on the controller **40**. In this variation, the electronic device **42**, in this example a smartphone, may also provide the power to the treatment strip assemblies **32**, **34** and may also control the various treatment temperatures and times as well as receive and display temperature feedback or other physiological parameters which may be measured. In this case, the treatment strips **32**, **34** and connecting cable **38** may be plugged directly into the mobile or portable consumer electronic device **42**. For instance, the electronic device **42** may be used to display treatment parameters and controls such as an icon or button for initiating therapy. In one example, therapy may be initiated by the user through electronic device **42** to heat one or more of the strips of one or both of the treatment strip assemblies **32**, **34**. In any of the variations, the electronic device **42**, particularly in the case of a smartphone or tablet, may have an optional program or application downloaded onto the device which facilitates the various control and/or display parameters on the electronic device **42** depending upon how the electronic device **42** is used with the controller **40** and assemblies **32**, **34**. Depending on the variation, the display and control display may reside on the controller **40** itself or on another device separate from the controller **40**.

**[0079]** Additionally, the electronic device **42** may also provide a diagnostic function to allow the user to test for dry eye and/or to determine how treatment is progressing either before, during, or after treatment. Accordingly, the electronic device **42** or controller **40** may leverage, e.g., an integrated camera and/or flash/light source, for

purposes of imaging the user's ocular tear film or ocular surface and evaluating commonly used tear assessment criteria such as total tear film layer thickness, and/or tear film mucin layer thickness, and/or tear film lipid layer thickness, and/or tear film aqueous layer thickness, or any combination thereof. Such a camera may also display or "mirror" strip placement for evaluation or adjustment by the user or remotely, either synchronously or asynchronously. In addition to imaging of the user's tear film and/or ocular surface conditions, the mobile application may include other common methods for diagnosing dry eye such as user questionnaires related to the user patient's symptoms, discomfort, and/or improvement or worsening of symptoms that can be completed using the electronic device's touch screen interface, results stored on the electronic device **42** or web application or manufacturer's servers, tracked over time for trend evaluation, and possibly shared with the user's physician.

**[0080]** Moreover, in any of the variations, the controller **40** and/or electronic device **42** may be programmed or initiated to heat up the assemblies **32**, **34** to, e.g., 42.5° C +/- 1° to 2° C. Treatment time may be set to, e.g., 1 to 30 minutes or more such as 60 minutes, and the controller **40** and/or electronic device **42** may further be programmed to shut down when the allotted treatment time has passed or if the measured temperature rises above a predetermined level, e.g., 45° C. Additionally, the controller **40** and/or electronic device **42** may also be programmed or set to indicate various treatment parameters (e.g., the initiation of treatment, warming of the heating elements, completion of treatment, errors, battery life, etc.) through any number of visual, auditory, or haptic indicators.

**[0081]** Additionally, the controller **40** and/or electronic device **42** may be used to store and/or transmit various data such as historical treatment data, usage time, total treatment time, temperature data, etc. Furthermore, the controller **40** and/or electronic device **42** may communicate wirelessly with a remote server or additional controller, allowing the controller **40** and/or electronic device **42** to also be programmed remotely, e.g., by a physician or other party. In yet other variations, audio and/or visual information (e.g., advertisements, educational media, social media connectivity, or other media) may also be displayed upon the controller **40** and/or electronic device **42** which may be received from remote servers or various other data may be transmitted to and/or from the controller **40** and/or electronic device **42** as well.

**[0082]** In yet other variations, although controller **40** is illustrated as being coupled to assemblies **32**, **34** via a wired connecting cable **38**, other variations may have controller

**40** wirelessly connected with assemblies **32**, **34**. Such a connection may be through any number of wireless protocols such as Bluetooth®, RF, etc.

**[0083]** This "precision temperature control" mobile heating therapy system may be used for heating other parts of the body as well, where the system remains nearly the same, but the heating element dimensions may be varied and power requirements may also be changed depending on the total surface area being treated, temperature goals, patient comfort, or other situational specifics.

**[0084]** With the incorporation of a processor into the treatment strips, treatment times or other parameters such as temperature of the strips may be programmed and optionally shut on or off selectively by the patient or automatically. Moreover, other parameters such as the frequency of the heat delivery or other stimulation may also be programmed by the processor to provide further flexibility in treatment.

**[0085]** In yet another variation, the treatment strip assemblies may be used with a controller **50** which is specifically designed and programmed for use with the treatment strip assemblies. An example of such a controller **50** is shown in the perspective view of Fig. 4 which illustrates the controller **50** which may comprise a housing **52**, e.g., a circularly-shaped housing which may weigh less (or more) than 8 ounces, which encloses the power supply and controller board having a programmable processor contained within. The controller housing **52** may incorporate two ports **54** for plugging two heater assemblies, i.e., a first port for connecting a first treatment assembly for the first eye and a second port for connecting a second treatment assembly for the second eye, although in other variations, a single port may be used for treating a single eye. In cases where the tissues around only the first eye are treated, a single port may be utilized. Connector indicators **58** may be included to provide a visual indicator (and/or auditory indicator) to indicate to the user whether the first and/or second ports **54** have heaters properly connected. A charging port **56** for connecting to a power supply for charging the controller **50** may also be incorporated into the housing **52**. Ports for heater assemblies **54** on the controller may be oriented relative to the charging port **56** such that charging is not possible with any number of heaters connected to the controller.

**[0086]** A power button **60** may be provided to allow the user to activate the controller **50** on/off and a power indicator **62** may also be provided to show the power level of controller **50**. In addition to the power indicator **62**, a temperature controller **64** may also be provided to allow for the user to adjust the temperature of the strip assemblies during treatment, e.g., by pressing the "+" or "-" as appropriate. Additionally, a timer **66**

may also be provided to give feedback like a visual (and/or auditory) countdown of the treatment time. For instance, when a 15 minute timer has been initiated, each indicator bar of the timer **66** may pulse for 1 min then turn off until the entire 15 minute treatment time has elapsed.

**[0087]** As shown in the perspective views of Figs. 5A and 5B, the controller **50** may provide a visual indication, as indicated by the connector indicators **58**, of when the first connector **70A** for the first treatment strip assembly has been inserted into the first port **54A** and likewise when the second connector **70B** for the second treatment strip assembly has been inserted into the second port **54B**.

**[0088]** With respect to the treatment strip assemblies, another variation is shown in the perspective view of Fig. 6 which illustrates heating strips **80A**, **80B** (which may be applied to the upper lid **UL** and lower lid **LL**) which are coupled via respective connectors **82A**, **82B** (e.g., flexible connectors to accommodate the positioning of the heating strips **80A**, **80B** to the patient) to a common junction **84** coupling the heating strips **80A**, **80B**. The junction **84** may be connected to a coupler **90** having a receiving port **92** which is sized to removably receive the junction **84**. The coupler **90** may be connected to a cable **94** (e.g., which may be several feet in length to reach from patient's eyes to the controller **350** when located on the wrist) which is then coupled to the port **54A** or **54B**.

**[0089]** Because the treatment strip assemblies may be designed for single use, the treatment strips may be marked or otherwise electronically tagged (such as via junction **84** or some other indicator) to prevent their re-use by the controller board when previously used treatment strips are connected to the controller **350**. In one variation, the junction **84** may incorporate a usage tracking mechanism **88** such as a memory chip that may be programmed to have a "0" or "1" memory which may indicate to the controller board that the particular treatment strip assembly has previously been used, as shown in the detail perspective view of Fig. 7A. In another variation, the usage tracking mechanism **88** may comprise a sacrificial fuse located on the junction **84**. A short burst of high energy may be delivered by the controller to the mechanism **88** to blow the fuse. Then the energy for treatment may be lowered by the controller to deliver the proper temperature therapy. Optionally, once the treatment strip assembly has been used, the junction **84** may be removed from receiving port **92** and another junction for a new treatment strip assembly may be inserted for another treatment or for another patient.

**[0090]** In other variations, rather than having a wired connection, the treatment strips may incorporate an antenna and transmitter and/or receiver for communicating wirelessly with the controller board.

**[0091]** Each of the heating strips **80A**, **80B** may include one or more respective sensors **86A**, **86B**, e.g., thermistors or thermocouples, which may be coupled to a common wire connector or separate wires and positioned upon the strips to provide treatment feedback to the controller board **382** for each eyelid strip, as also shown in Fig. 7A. Each of the heating strips **80A**, **80B**, for instance, may incorporate anywhere from 1-4 temperature sensors on each strip, e.g., one sensor positioned on a first end, a second sensor positioned on the middle, and a third sensor positioned on a second end of the strip. Fig. 7B shows a top view of the heating strips **80A**, **80B** illustrating how each strip may incorporate one or more sensors. As shown, the first strip **80A** may have a first sensor **100A** positioned near or at a first end such as a distal end of the strip, a second sensor **100A'** positioned mid-way along the strip, and a third sensor **100A''** positioned near or at a second end such as the proximal end of the strip. Likewise with the second strip **80B**, a first sensor **100B** may be positioned near or at a first end such as a distal end of the strip, a second sensor **100B'** may be positioned mid-way along the strip, and a third sensor **100B''** may be positioned near or at a second end such as the proximal end of the strip.

**[0092]** An additional temperature sensor may also be placed upon or in proximity to the patient body, e.g., near the patient's temple, upon an additional treatment strip and away from the treatment strips placed upon the patient's eyelids to measure and monitor an ambient temperature where the patient is being treated. This separate ambient temperature data may help to ensure that the treatment strips themselves are working properly and delivering the targeted temperature therapy. Sensors may be used in a comparative mode to determine if any portion of the treatment strip is not in contact with the patient or is malfunctioning.

**[0093]** As described above, the meibomian glands may be mechanically pressed or squeezed to express solidified meibum from the glands in order to help treat MGD. Forceps are typically used to apply pressure upon the meibomian glands. Aside from treating MGD, the forceps may also be used to treat other conditions such as acne, arthralgia, myalgia, hordeolum, styes, chalazion, abcesses, other dermatological conditions, etc. The forceps may also be used for dental applications such as curing adhesives, fillings, etc. Additionally, the forceps may be used for other medical purposes such as tissue

ablation, maintaining hemostasis, etc. as well as non-medical purposes such as welding-type applications.

**[0094]** One variation of the forceps is shown in the perspective view of Fig. 8 which illustrates forceps **110** which has a first handle **110A** and second handle **110B** coupled at a proximal end and optionally positioned to extend in parallel such that a respective first bridge **114A** and second bridge **114B** project and optionally curve relative to the handles **110A**, **110B** such that a first jaw or paddle **112A** is aligned in apposition to a second jaw or paddle **112B**. The first paddle **112A** and second paddle **112B** may also be aligned such that a respective first inner surface **116A** and second inner surface **116B** are angled relative to one another to impart a directional pressure gradient, e.g., in a direction perpendicular to the direction of the force applied, upon the contacted tissue for facilitating meibomian gland expression, as described in further detail below. Alternatively, the angled surfaces of the paddle may articulate relative to one another, creating a progressive pinching motion or progressive apposition of paddle surfaces from one paddle edge to the other. The first and second paddles **112A**, **112B** may be sized for positioning in proximity to the eyes and directly upon the eyelids of a patient and the paddles **112A**, **112B** may also be spaced apart from one another to allow for the positioning of the tissue (e.g., eyelid tissue containing the meibomian glands) in-between. In other variations, the first and second handles **110A**, **110B** may be curved or arcuate provided that the paddles **112A**, **112B** are spaced apart from one another.

**[0095]** The forceps **110** may be disposable after a single use or it may be configured to be fully reusable. Alternatively, it may be configured to be partially disposable, e.g., having reusable handles **110A**, **110B** with removably disposable first and second paddles **112A**, **112B** or other portion. Hence, the forceps **110** may be fabricated in part or in whole from any number of various materials, e.g., polymers, metals, composites, ceramics, etc. One or both of the paddles may be suitably sized for application to various regions of the body but when configured for treating the meibomian glands, the paddles may have a height **H** ranging anywhere, e.g., between 1 mm to 20 mm with a length **L** ranging anywhere, e.g., between 1 mm to 50 mm. In one variation, one or both paddles may have a height **H** and length **L** of, e.g., respectively, 5 mm by 25 mm.

**[0096]** Additionally, one or both paddles **112A**, **112B** may optionally incorporate an insulating or reflective layer **120** which may be used to protect the contacted tissues as well as to increase the efficiency and efficacy of a treatment therapy. The insulating or reflective layer **120** may be integrated on a single or both inner surfaces and they may also

be configured to cover a partial surface or the entire surface of the paddle, as needed or desired.

**[0097]** In treating the meibomian glands, one or both paddles **112A**, **112B** may be configured to heat up to a predetermined temperature range and optionally for a predetermined period of time. In one variation, the forceps **110** may have heating strips or sleeves which may be attached or secured or otherwise applied as separate elements onto their respective paddles.

**[0098]** While any of the forceps or forceps combinations described herein may be packaged and distributed individually, they may also be packaged into kits **130**, as shown in Fig. 9, to include not only the forceps **110** but also various combinations of additional devices or treatments. In one example, a pharmaceutical treatment **132** (e.g., eyedrops, ointments, medications, etc.) may be included as well as optional heating strips **134** which may be applied to the skin surface of the patient's eyelids (or in proximity to the eyelids) for heating and/or pre-heating the meibomian glands prior to or during gland expression with the forceps **110**. Such a kit **130** may provide a complete treatment solution. Moreover, while pharmaceutical treatment **132** and optional heating strips **134** are shown included in the kit **130** along with the forceps **110**, any combination of these may be included within the kit **130** as well as various other treatments or devices.

**[0099]** Another example of a kit **140** is shown in Fig. 10A which illustrates one or more heating strips **124** provided in combination with forceps **142**. In this variation, the forceps **142** may be configured with paddles **124** which define grooves **126** extending over the inner surface(s) between the lower and upper edges of one or both paddles **122** to facilitate mechanical expression after (or before) the heat treatment. Optionally, the heating strips **524** may be single-use and disposable, if so desired.

**[00100]** Fig. 10B shows yet another example of a kit which includes the one or more heating strips **134** and forceps **142**, as described above, but which also optionally includes a controller **50** for controlling the heat treatment of the one or more heating strips **134**. The controller **50** may be a re-usable unit while the heating strips **134** and/or forceps **142** may be optionally configured as single-use and disposable, if so desired.

**[0100]** Fig. 10C shows yet another example of a kit **144** which also includes forceps **150** which are configured to facilitate mechanical expression as well as tissue debridement, and which may also optionally include a controller **50**, a pharmaceutical treatment **132**, and/or one or more heating strips **134** in various combinations. For example, the kit **144** may include a combination of the forceps **150** and one or more

heating strips **134** while in other variations, the kit **144** may include a combination of the forceps **150**, one or more heating strips **134**, and controller **50**. In yet other variations, the kit **144** may incorporate one or more eyelid wipes **136** for cleaning or wiping a surface of the eyelids off to remove oil, make-up, etc. so that the heat treatment strips **134** adhere to the eyelids consistently. The eyelid wipes **136** may be included along with the forceps **150**, one or more heating strips **134**, and/or controller **50**.

**[0101]** Another variation of the forceps **150** is illustrated in further detail in Figs. 11A to 11D which show respective side, top, end, and perspective views. This variation of the forceps **150** has two apposed handles **152A**, **152B** extending from a common pivoting connection **154**. The two apposed handles **152A**, **152B** may each terminate at their distal ends in respective paddles **156A**, **156B** and a proximal end of the forceps **150** may comprise a debriding member **158** extending proximally and which defines a curved or arcuate debriding edge **160** around a periphery of the member **158**. As the gap **G** defined between the paddles **156A**, **156B** may vary to accommodate a range of anatomies, the resting open gap **G** may range from, e.g., 5.72 mm to 9.09 mm.

**[0102]** Fig. 12A shows a detailed side view of the paddle **156B** which may have a length **L** of, e.g., 7.37 mm to 8.26 mm, with a width of about, e.g., 4.00 mm. The paddles **156A**, **156B** may be configured to have a square or rectangular shape, as shown, but in other variations, the paddles may be configured into various other shapes, e.g., elliptical. To facilitate positioning of the paddles **156A**, **156B** relative to the tissue region of the eye to be mechanically expressed, the paddles **156A**, **156B** may be angled along their lengths **L** to define an angle **172** relative to a longitudinal axis **170** of the forceps **150**. In one variation, the angle **172** may be define an angle of, e.g., 35°, although this angle **172** may range from, e.g., 0° to 90°, depending upon the desired application for use.

**[0103]** While the debriding edge **160** may be defined about the debriding member **158**, other variations of the forceps may have a debriding edge defined along the edges of the paddles. An example is shown in the side view of Fig. 12B which illustrates paddle **156B** having one or more debriding edges. For instance, the distal side edge **162A** of the paddle **156B** may be configured as the debriding edge while other variations may have either the distal terminal edge **162B** or proximal side edge **162C** of one or both paddles configured as debriding edges. Other variations may also have one or both paddles with one or more debriding edges, as desired.

**[0104]** The debriding member **158** which extends from a proximal end of the forceps **150** may define an edge **160** which is relatively thin with respect to the rest of the

forceps **150**. In one variation, the debriding member **158** may have a length of, e.g., between 10.00 mm to 11.00 mm or 10.67 mm, and a width of, e.g., 8.00 mm to 9.00 mm such as 8.13 mm, which reduces and curves gently into, e.g., an elliptical or semi-elliptical shape, along a proximal direction as shown in the detail view of Fig. 13A. In other variations, the shape of periphery of the debriding member **158** may approximate other shapes such as semi-circles, parabolic, rectangular, triangular, etc. provided that a debriding edge **160** is presented for use. Fig. 13B shows a detail edge view of the debriding member **158** and further illustrates the debriding edge **160** having a thickness **TH**. The edge **160**, shown in the detail view of Fig. 13B, may further define a radiused edge which may range from, e.g., 0.05 mm to 0.13 mm. The thickness **TH** may range from, e.g., between 0.40 mm to 0.55 mm such as 0.46 mm +/- 0.05 mm, however, this thickness **TH** may be varied up to, e.g., 0.92 mm, provided that the edge **160** is materially thinner from the handles **152A**, **152B** of the forceps **150** to provide an effective scraping edge.

**[0105]** The debriding member **158** may define a plane which is coplanar or parallel with a plane defined by the paddles **156A**, **156B** when compressed against one another. In other variations, the plane of the debriding member **158** may be transverse or may form other angles relative to the plane defined by the paddles **156A**, **156B**.

**[0106]** In use, while the paddles **156A**, **156B** may be used to mechanically express the meibomian glands directly and/or to apply pressure to the tissue region in proximity to the meibomian glands, the debridement edge **160** may be used before, during, and/or after the mechanical expression to scrape along the upper lid **UL** margin and/or lower lid **LL** margin, e.g., along the direction of debridement **180** shown in Fig. 14, to remove any obstructions from the meibomian glands. Moreover, mechanical expression and/or debridement using forceps **150** may be performed at any time during a heat treatment with the one or more heat strips **134** and in any order of treatment. For example, the upper **UL** and/or lower lids **LL** may be thermally treated with the one or more heat strips **134** for a specified period of time after which the upper and/or lower lids may then be mechanically expressed with the forceps **150** and may then undergo debridement with the debriding edge **160** after, during, and/or even before the heat treatment.

**[0107]** Alternatively, the tissue may undergo debridement with the debriding edge **160** before, during, and/or after a heat treatment with or without mechanical expression or the tissue may undergo mechanical expression alone without use of the debriding edge **160**. In another variation, the tissue may first undergo debridement with the debriding edge and

then a thermal treatment may be performed with the treatment strips. The debriding procedure may be performed with the patient either wearing the treatment strips or before the treatment strips are applied. The forceps may then be used to mechanically express the meibomian glands. The mechanical expression may be done with the patient either wearing the treatment strips or after they have been removed. The combination of procedures may be varied depending upon the desired results.

**[0108]** Alternative variations for debriding embodiments are illustrated in the detail side views of Figs. 15A to 15C which illustrate debriding elements that define a notch or groove where a cross-section of the lid may be received or positioned such that debriding can be accomplished, e.g., via a side-to-side sweeping motion, while the lid margin is maintained within the notch. Such a feature may enhance the safety of the instrument as the debriding element is restrained from inadvertently intruding upon the eye while moving the instrument side-to-side.

**[0109]** One variation is shown in Fig. 15A which shows the debriding member **158** previously described but with a notch or groove **192** defined along a side portion of the member **158** in proximity to the proximal end of the debriding member **158**. The debriding edge **160** may also be replaced with a smooth, atraumatic proximal edge **190** and the recessed edge **194** of the notch or groove **192** may define a debriding edge. The side edges **196** within the notch or groove **192** on either side of the recessed edge **194** may be smooth and atraumatic so as to prevent any trauma to the front and the back of the eyelid during a sweeping, side-to-side debridement.

**[0110]** Because the very end of the debriding member **158** may come into contact against the surface of the eye during use, the member **158** may be rounded or smoothed to present a blunt and atraumatic surface to avoid damage, such as scratches, to the eye surface. Fig. 15B shows another variation where the proximal edge **198** may be further blunted and Fig. 15C shows yet another variation where the proximal edge **200** is rounded to present a gently curved edge or surface. In any of these variations, a layer or separate edge made of a material different from the forceps may be positioned over or upon or otherwise attached to the proximal edge where this material is a relatively softer material, e.g., silicone, rubber, foam, etc., to provide an additional feature for preventing any injury to the surface of the eye.

**[0111]** The applications of the devices and methods discussed above are not limited to the treatment of dry eye syndrome but may include any number of further treatment applications. Moreover, such devices and methods may be applied to other treatment sites

within the body where acute or chronic inflammation causes a disease or condition. The treatment strips can be accordingly custom-designed to follow the path of the underlying physiology, e.g. custom designed and contoured cooling or heating treatment strips to treat the sinuses and acute or chronic sinusitis, respectively, rhinitis and allergic rhinitis, joint aches and inflammation, arthritis, muscle aches, back pain, headaches, wounds, sports injuries, etc. Modification of the above-described assemblies and methods for carrying out the invention, combinations between different variations as practicable, and variations of aspects of the invention that are obvious to those of skill in the art are intended to be within the scope of the claims.

# CLAIMS

What is claimed is:

1. A forceps apparatus, comprising:

a first handle and a second handle coupled to one another near or at respective proximal ends;

a first paddle coupled to the first handle and defining a first inner surface;

a second paddle coupled to the second handle and defining a second inner surface which is positioned in apposition to the first inner surface; and

a debriding member extending proximally from the first and second handles and which reduces and curves gently to define a debriding edge for debriding tissue in proximity to one or more meibomian glands.

2. The apparatus of claim 1 wherein the debriding member has a length between 10.00 mm to 11.00 mm.

3. The apparatus of claim 1 wherein the debriding member has a width between 8.00 mm to 9.00 mm.

4. The apparatus of claim 1 wherein the debriding member has a thickness of between 0.40 mm to 0.55 mm.

5. The apparatus of claim 1 wherein the debriding edge has a radius of between 0.05 mm to 0.13 mm.

6. The apparatus of claim 1 wherein the debriding member reduces and curves gently into an elliptical shape.

7. The apparatus of claim 1 wherein the debriding member defines a plane which is coplanar or parallel with a plane defined by the first and second paddles when compressed against one another.

8. The apparatus of claim 1 wherein the debriding member defines a plane which is transverse relative to a plane defined by the first and second paddles when compressed against one another.

9. The apparatus of claim 1 wherein a length of the first and second paddles defines an angle of 35° relative to a longitudinal axis of the forceps.

10. The apparatus of claim 1 further comprising one or more strips configured to adhere to an underlying region of skin in proximity to one or both eyes of a subject such that the one or more strips allow for the subject to blink naturally with minimal, or no restriction from the one or more strips.

11. The apparatus of claim 10 wherein the one or more strips are configured to emit thermal energy to the underlying region of skin, and wherein the one or more strips are shaped to follow a location of one or more meibomian glands contained within the underlying region of skin.

12. The apparatus of claim 10 further comprising a controller in communication with the one or more strips, wherein the controller is programmable to monitor and induce a temperature in the one or more strips to provide a therapy.

13. A forceps apparatus, comprising:

a first handle and a second handle coupled to one another near or at respective proximal ends;

a first paddle coupled to the first handle and defining a first inner surface; and

a second paddle coupled to the second handle and defining a second inner surface which is positioned in apposition to the first inner surface,

wherein the first paddle and/or second paddle defines a debriding edge along a distal terminal edge or a proximal side edge for debriding tissue in proximity to one or more meibomian glands.

14. The apparatus of claim 13 wherein the debriding edge has a radius of between 0.05 mm to 0.13 mm.

15. The apparatus of claim 13 wherein a length of the first and second paddles defines an angle of 35° relative to a longitudinal axis of the forceps.

16. The apparatus of claim 13 further comprising one or more strips configured to adhere to an underlying region of skin in proximity to one or both eyes of a subject such that the one or more strips allow for the subject to blink naturally with minimal, or no restriction from the one or more strips.

17. The apparatus of claim 16 wherein the one or more strips are configured to emit thermal energy to the underlying region of skin, and wherein the one or more strips are shaped to follow a location of one or more meibomian glands contained within the underlying region of skin.

18. The apparatus of claim 16 further comprising a controller in communication with the one or more strips, wherein the controller is programmable to monitor and induce a temperature in the one or more strips to provide a therapy.

19. A method of treating a subject, comprising:

debriding tissue or debris in proximity to one or more meibomian glands within a tissue region of a subject via a debriding member extending proximally from a forceps having a first handle and a second handle coupled to one another near or at respective proximal ends;

applying a thermal treatment to the one or more meibomian glands; and

mechanically expressing the one or more meibomian glands via a first paddle coupled to the first handle and defining a first inner surface, and a second paddle coupled to the second handle and defining a second inner surface which is positioned in apposition to the first inner surface.

20. The method of claim 19 wherein applying a thermal treatment comprises:

adhering an upper strip to an upper eyelid of a subject such that the upper strip has a flexibility sufficient to accommodate movement of the upper eyelid to allow for the subject to blink naturally without restriction from the upper strip while covering one or more meibomian glands contained within the upper eyelid with the upper strip, wherein the upper strip has a first curved or arcuate periphery which is shaped to extend and follow a border of the one or more meibomian glands contained within the upper eyelid and a second curved or arcuate periphery which is shaped to extend and follow a free margin of the upper eyelid;

initiating a treatment with the upper strip via a controller transmitting electrical energy to the upper strip via a connecting cable; and

emitting thermal energy from the upper strip to the upper eyelid.

21. The method of claim 20 further comprising adhering a lower strip to a lower eyelid of the subject such that one or more meibomian glands contained within the lower eyelid are covered by the lower strip.

22. The method of claim 21 wherein the lower strip has a first curved or arcuate periphery which is shaped to extend and follow a border of the one or more meibomian glands contained within the lower eyelid and a second curved or arcuate periphery which is shaped to extend and follow a free margin of the lower eyelid.

23. The method of claim 21 wherein the upper strip and lower strip are electrically coupled to one another.

24. The method of claim 20 wherein emitting thermal energy comprises applying thermal energy from a heating layer in the upper strip.

25. The method of claim 19 wherein the method of treating comprises treating one or more conditions selected from the group consisting of dry eye, evaporative dry eye, meibomian gland dysfunction, improved vision, contact lens comfort improvement, tear quality improvement, and surgical outcome improvement due to accurate measurements from an improved tear quality.

26. The method of claim 19 wherein mechanically expressing comprises urging the first paddle and second paddle towards one another such that the tissue region is compressed between the first inner surface and second inner surface.

27. The method of claim 19 wherein debriding tissue or debris comprises debriding the tissue or debris via a debriding edge defined along a periphery of the debriding member along an eyelid margin.

28. The method of claim 19 further comprising cleaning a surface of the tissue region with a wipe prior to applying a thermal treatment.

29. A forceps apparatus, comprising:

a first handle and a second handle coupled to one another near or at respective proximal ends;

a first paddle coupled to the first handle and defining a first inner surface;

a second paddle coupled to the second handle and defining a second inner surface which is positioned in apposition to the first inner surface; and

a member extending proximally from the first and second handles and which reduces and curves gently to present an atraumatic proximal edge, the member defining a notch having a recessed debriding edge in proximity to the proximal edge.

30. The apparatus of claim 29 wherein the notch further defines atraumatic side edges on either side of the recessed debriding edge.

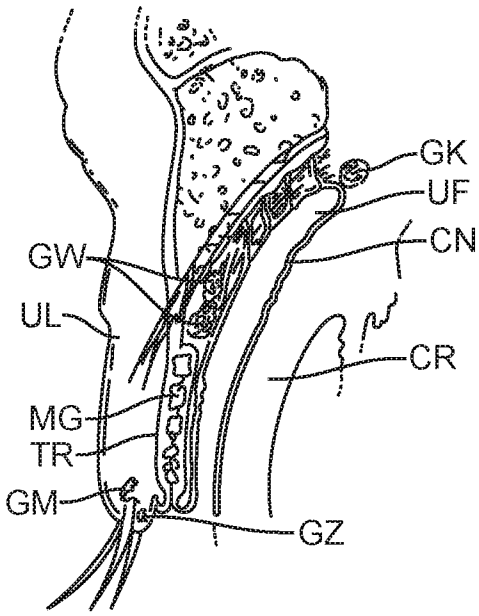


FIG. 1A

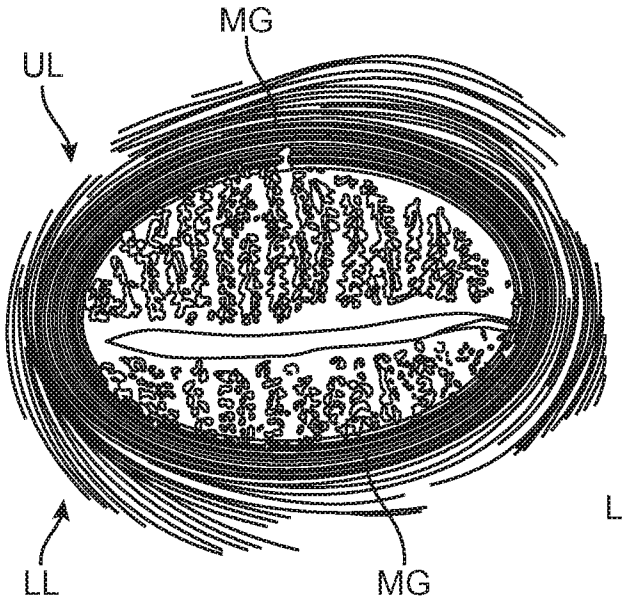


FIG. 1B

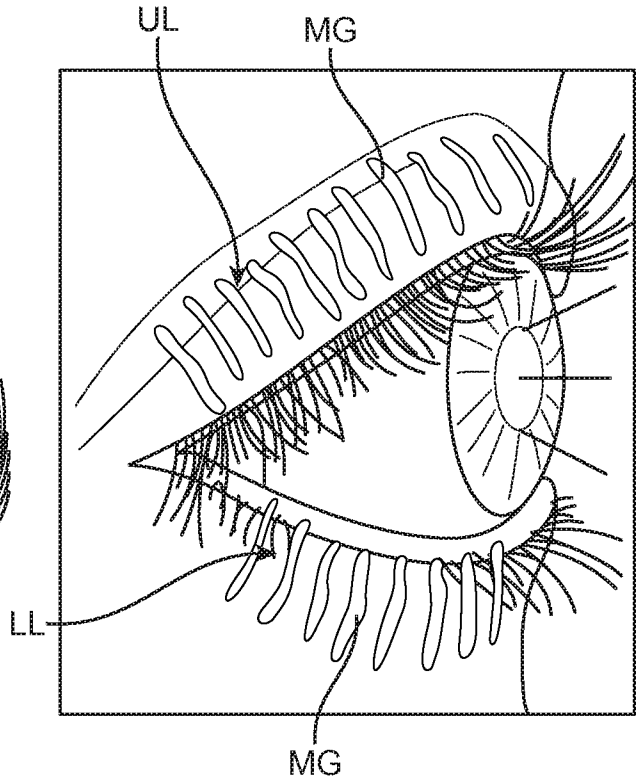


FIG. 1C

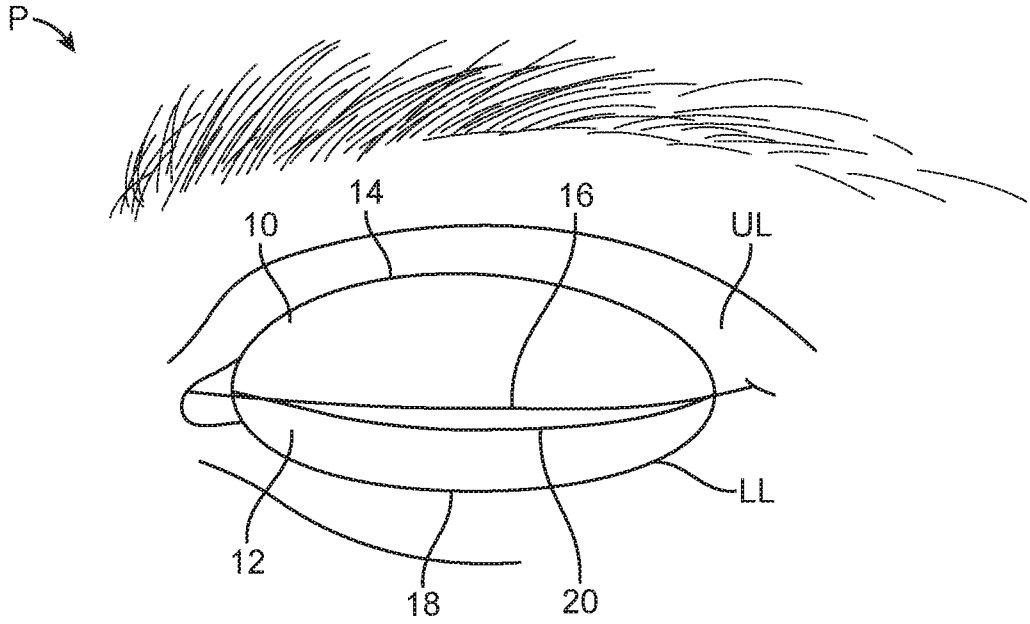


FIG. 2A

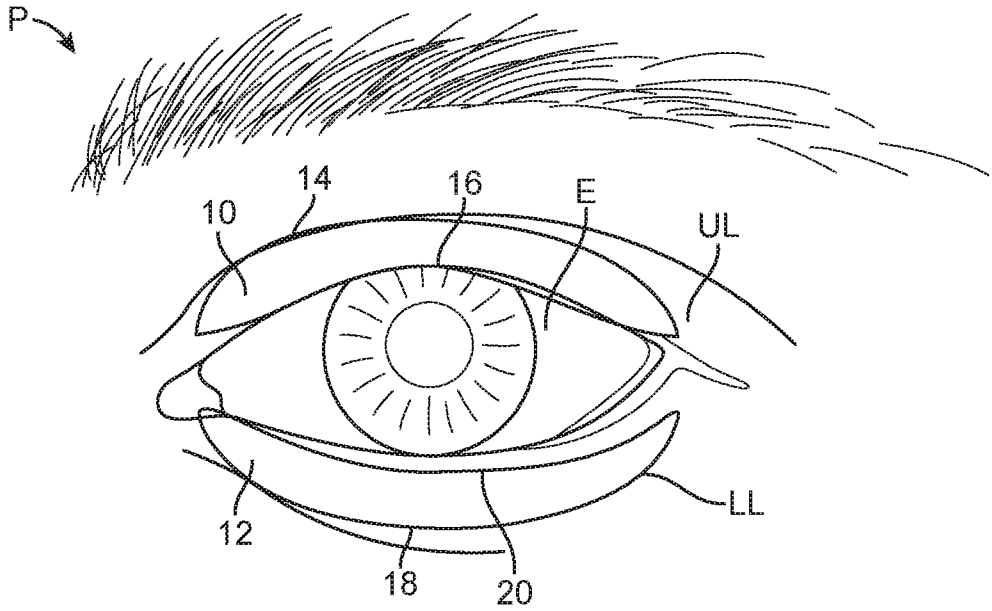


FIG. 2B

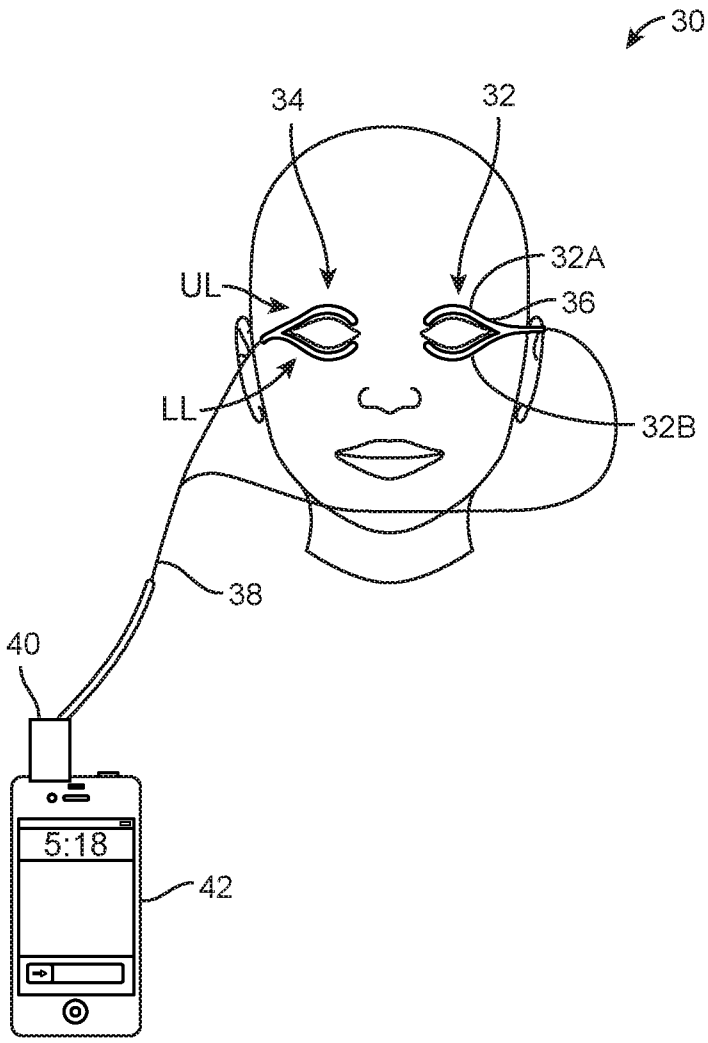


FIG. 3

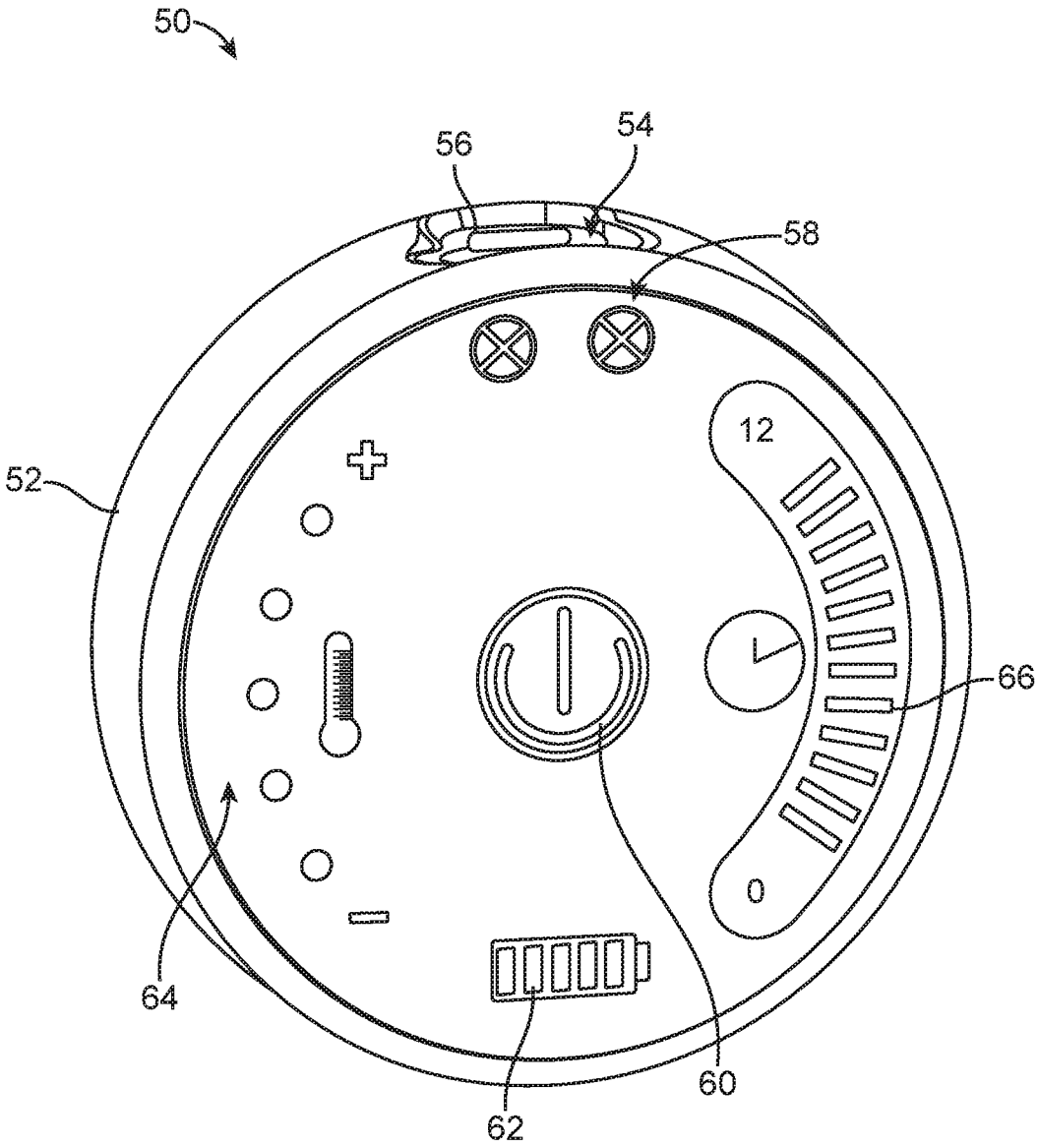


FIG. 4

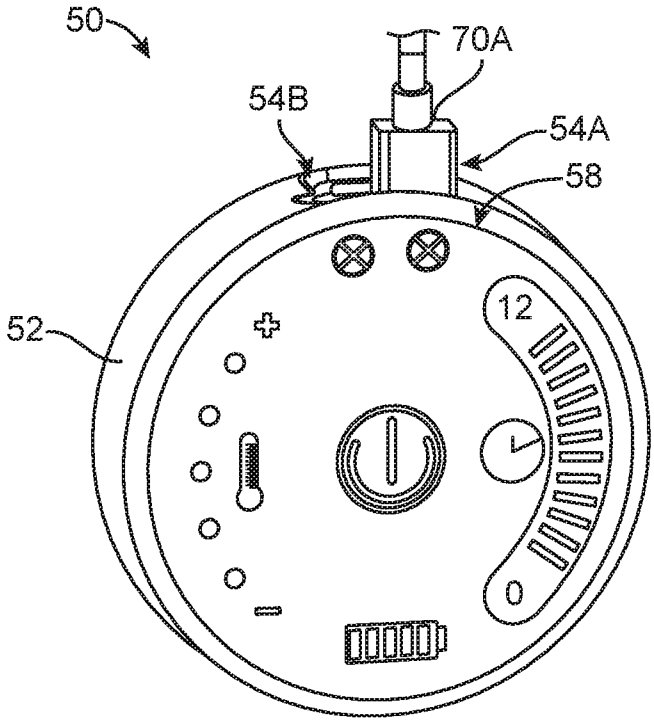


FIG. 5A

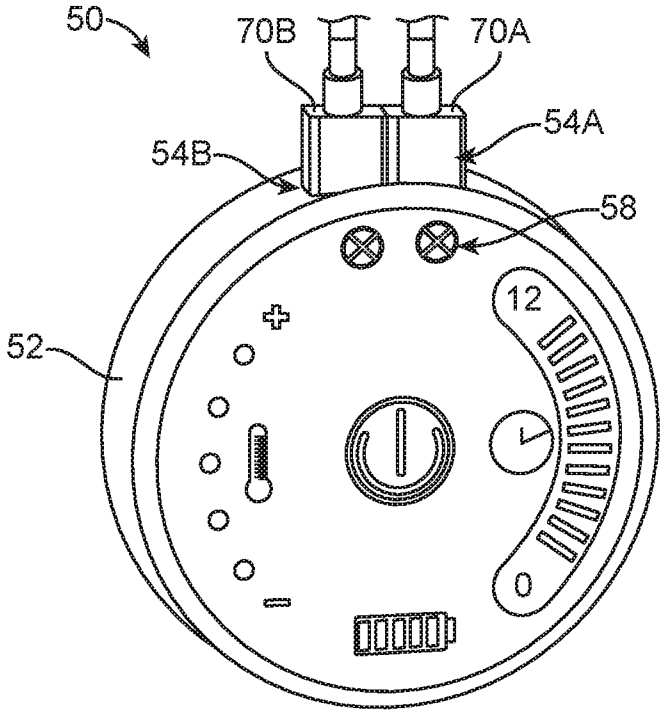


FIG. 5B

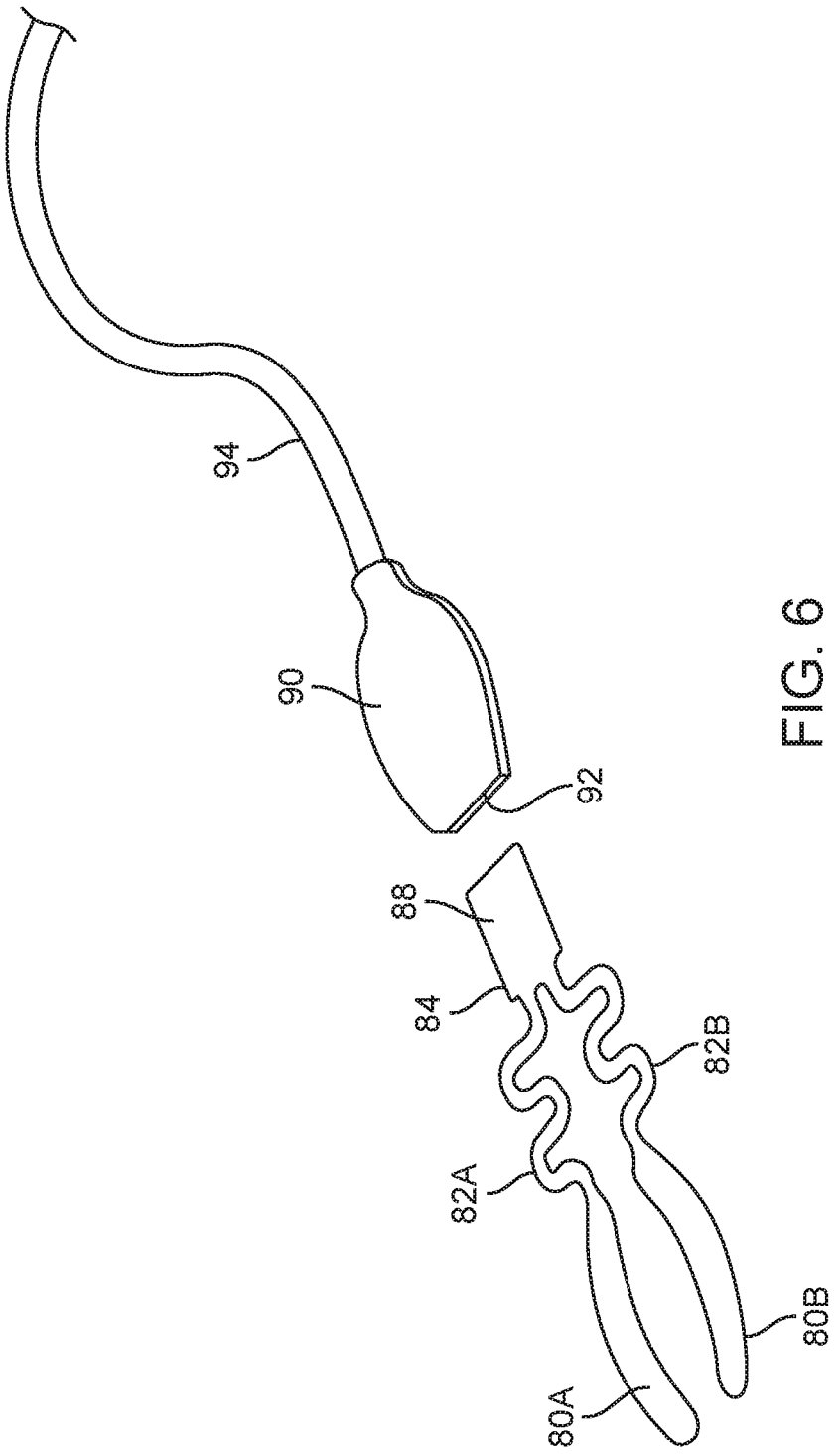


FIG. 6

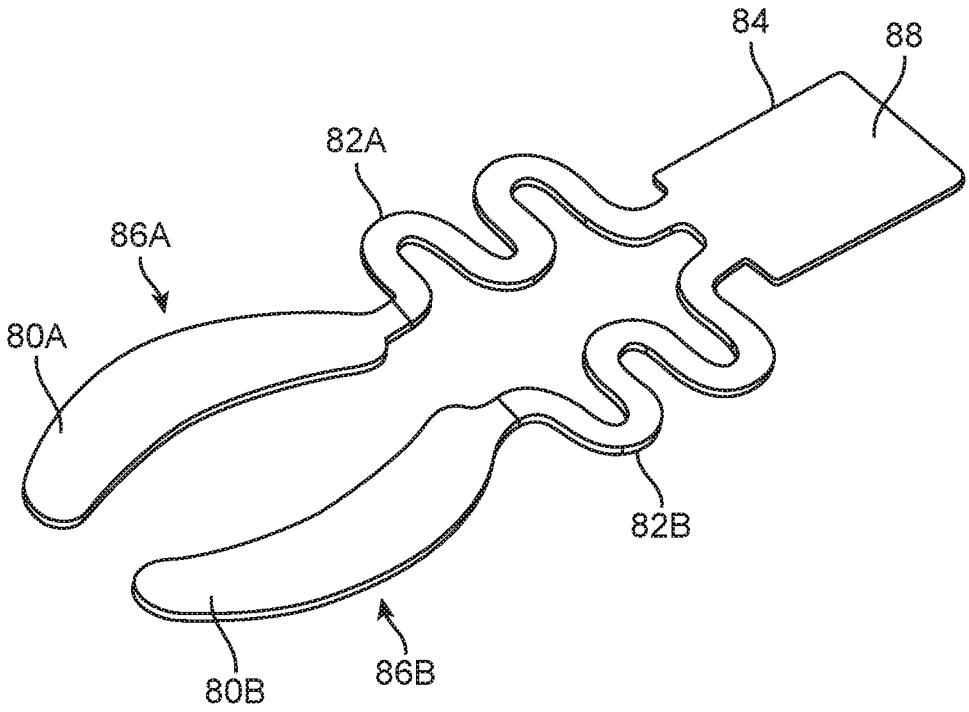
84
88
82A
86A
80A
82B
80B
86B

FIG. 7A

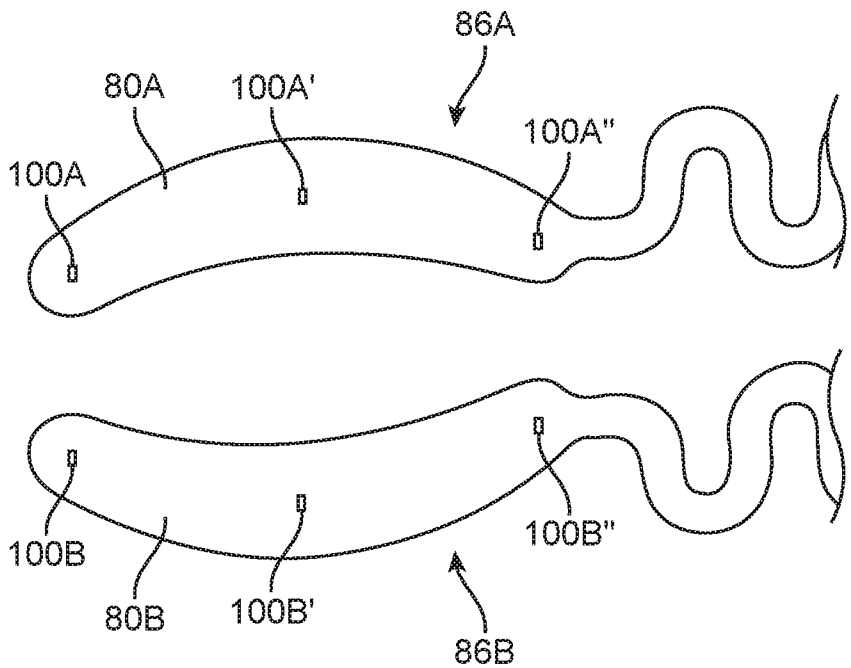
86A
80A
100A'
100A"
100A
100B
100B"
80B
100B'
86B

FIG. 7B

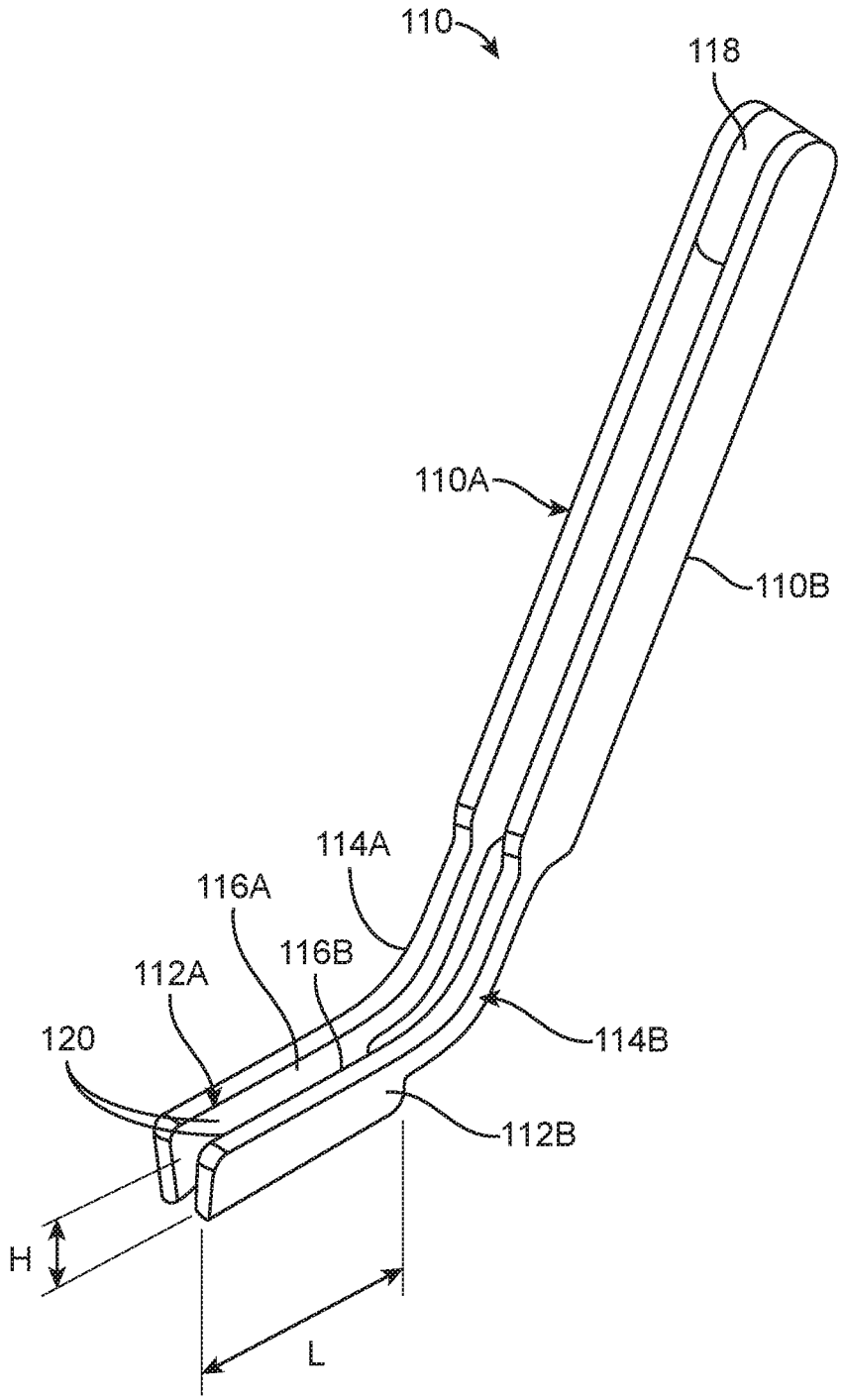


FIG. 8

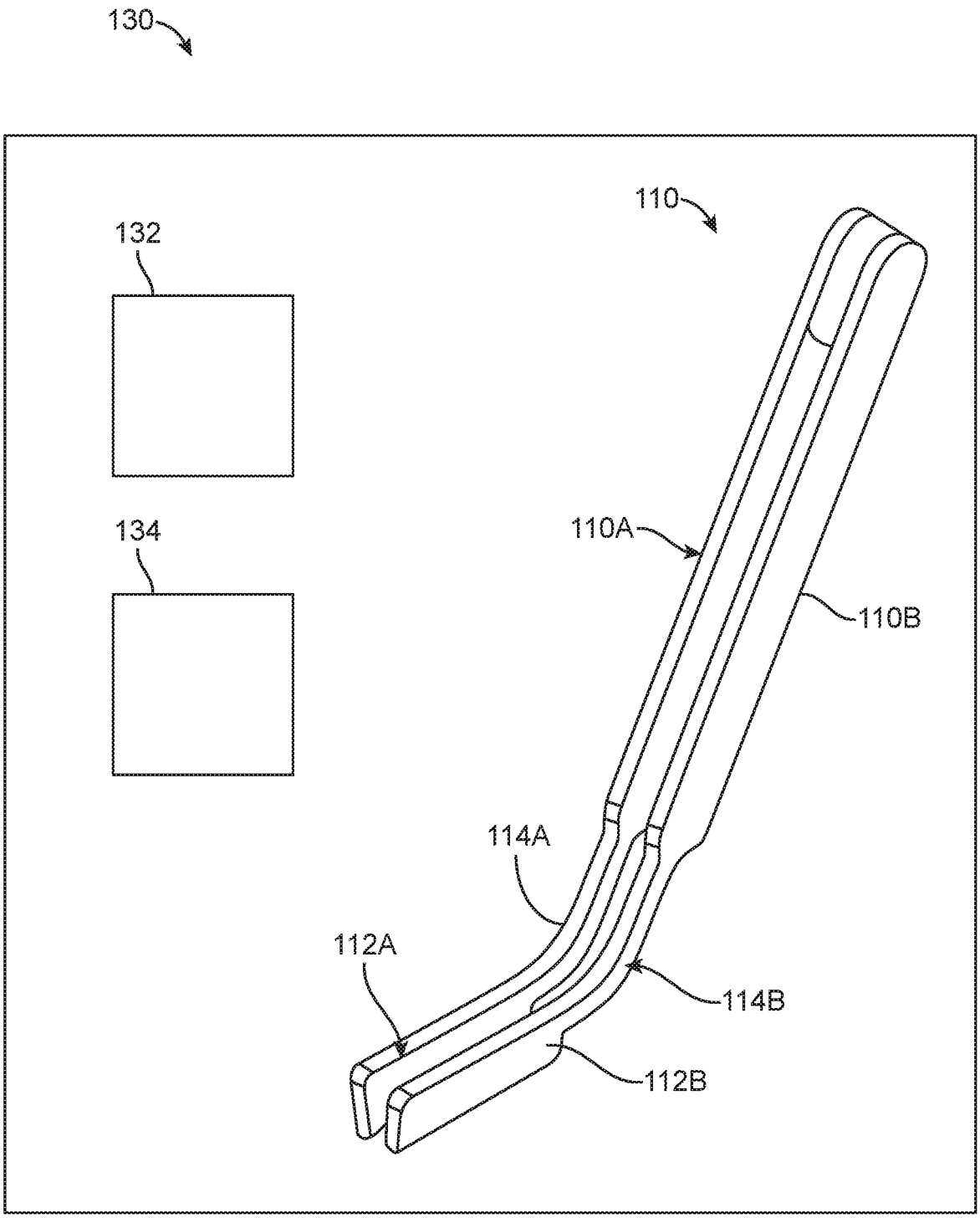


FIG. 9

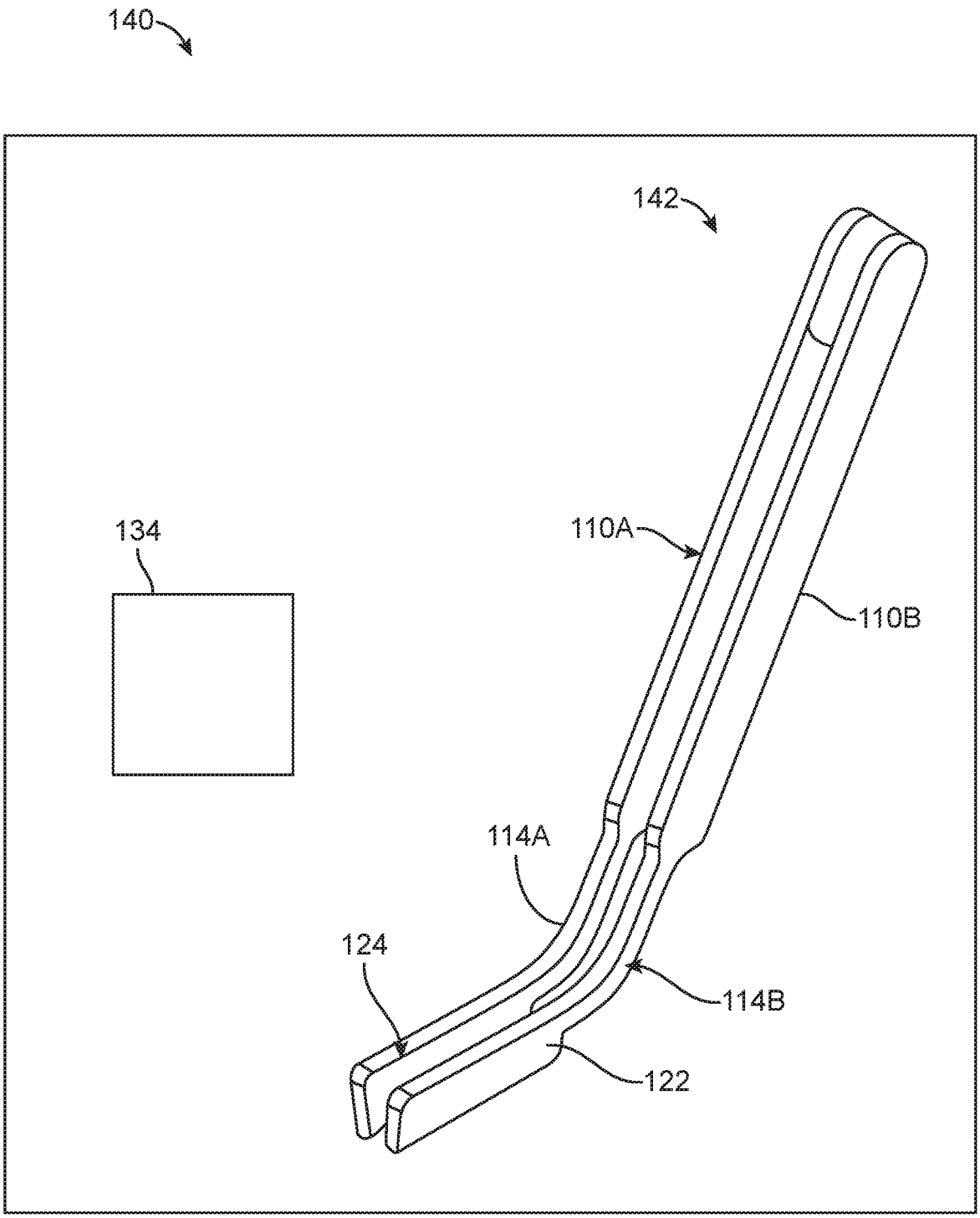


FIG. 10A

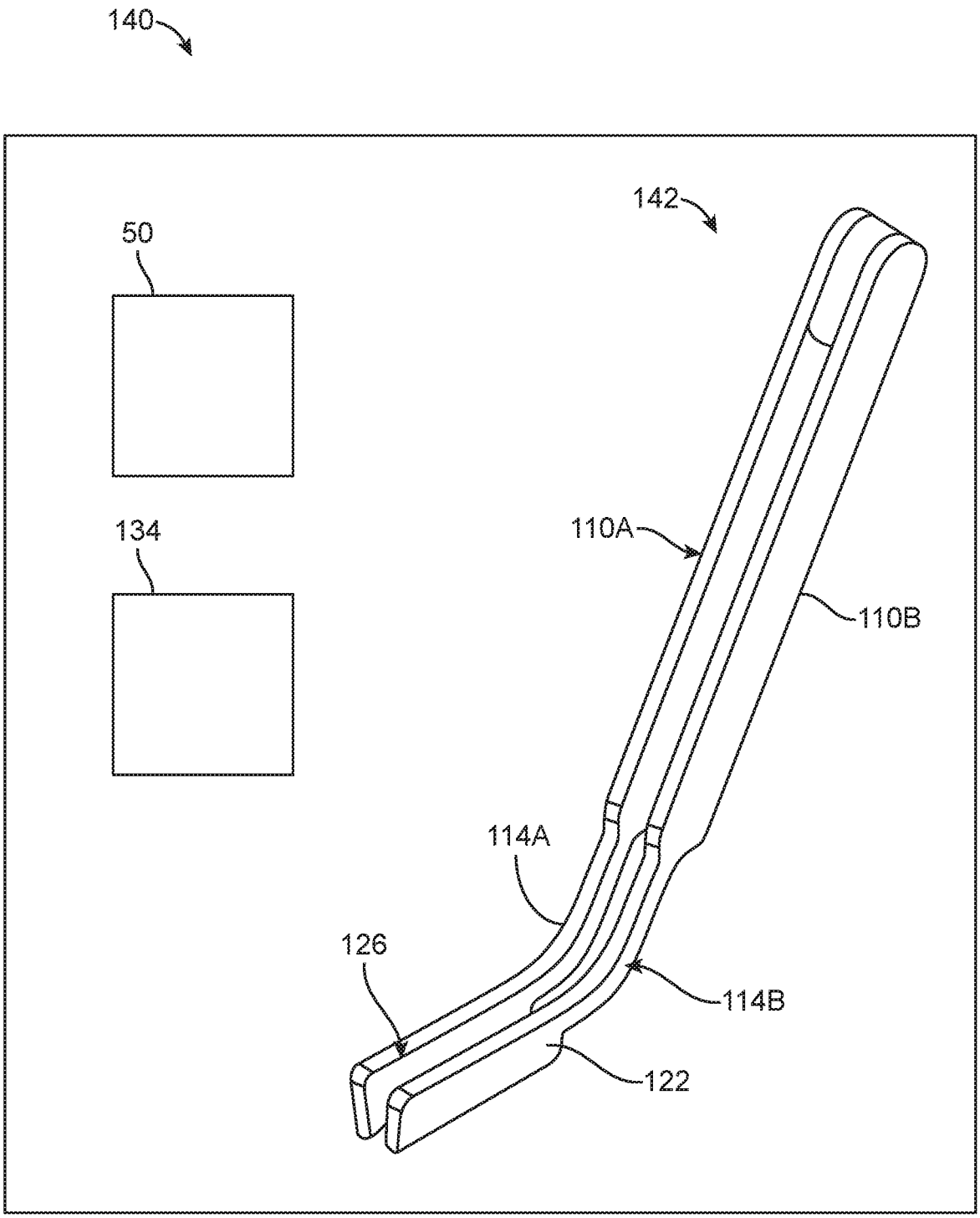


FIG. 10B

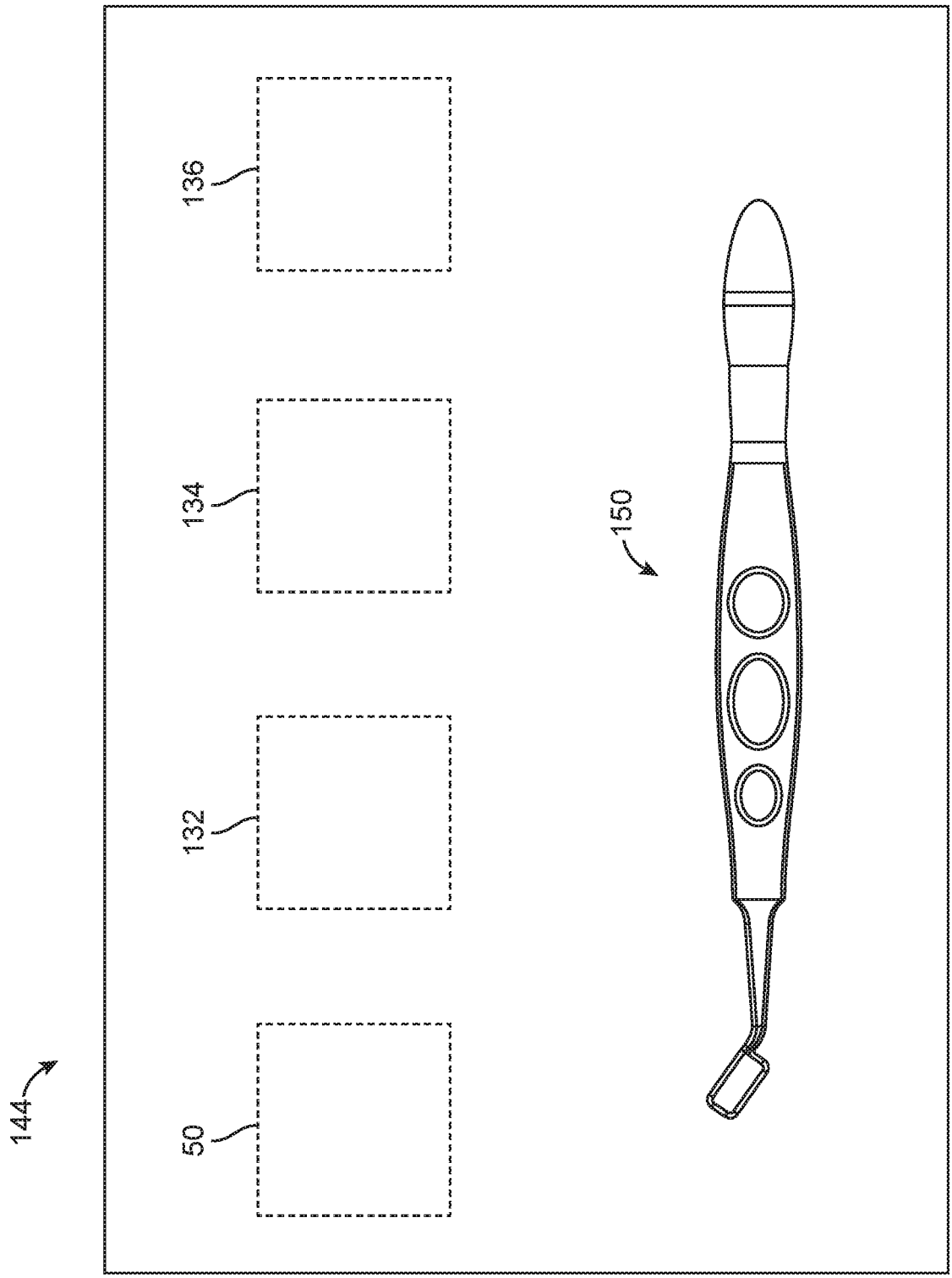


FIG. 10C

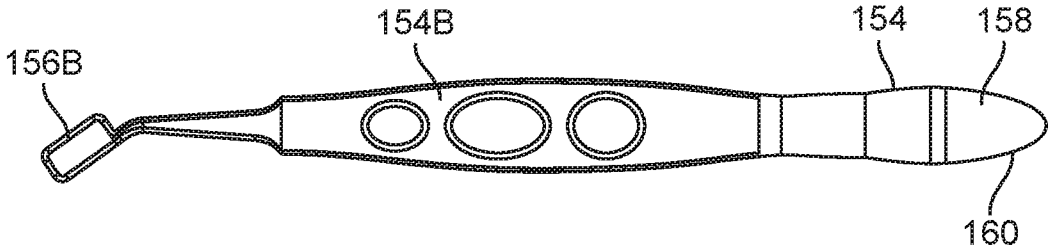


FIG. 11A

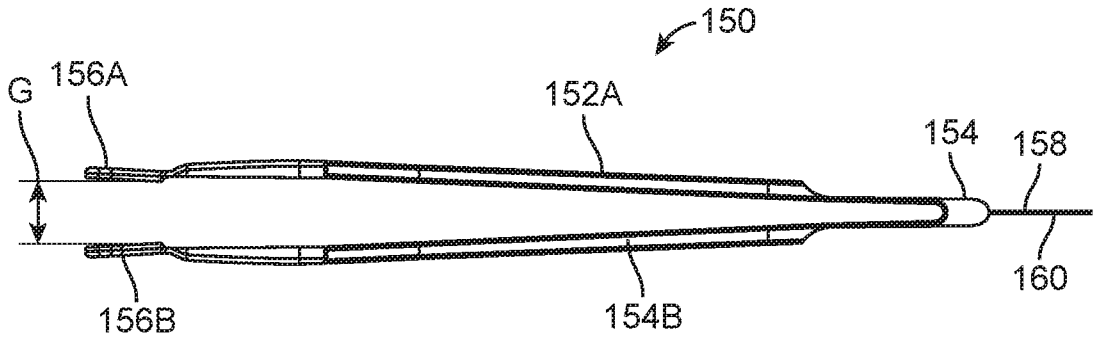


FIG. 11B

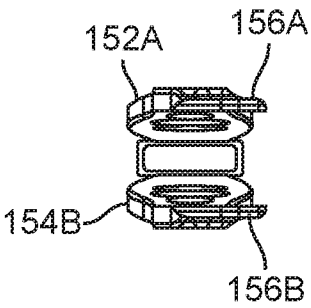


FIG. 11C

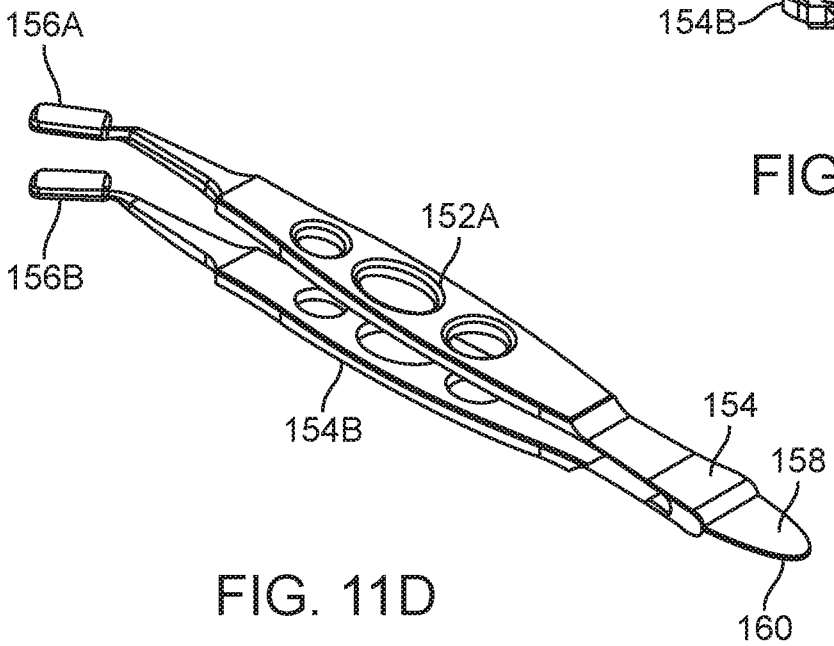


FIG. 11D

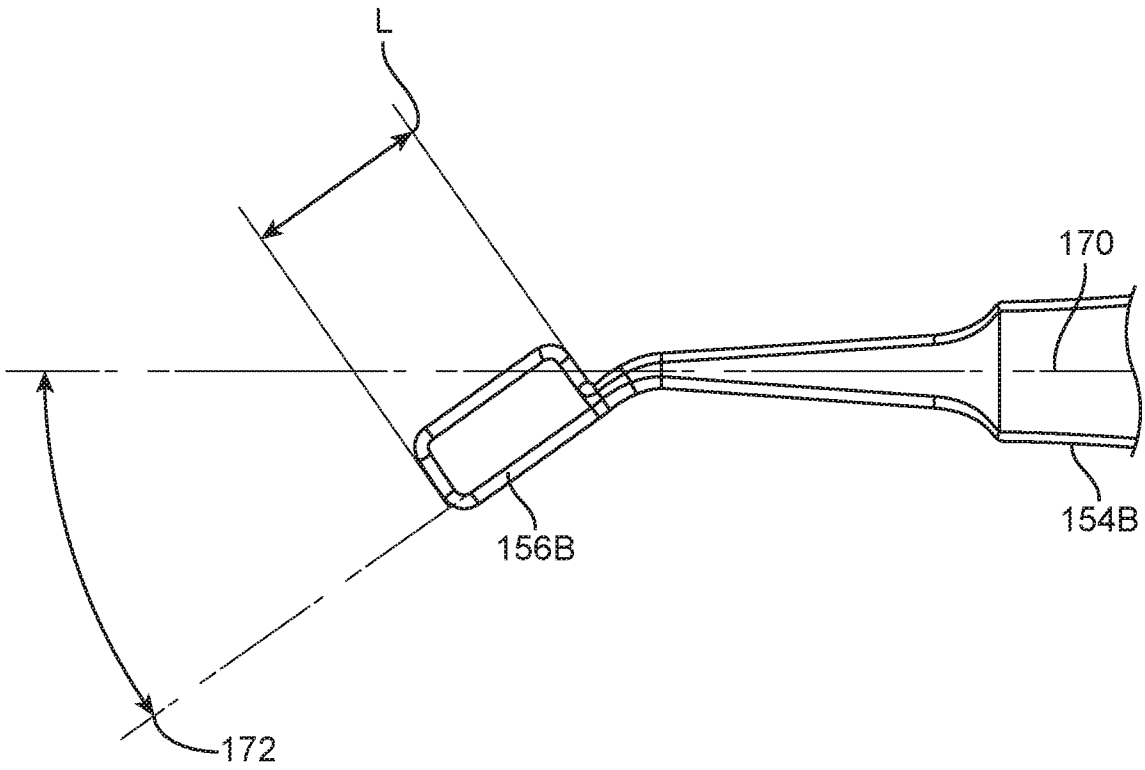


FIG. 12A

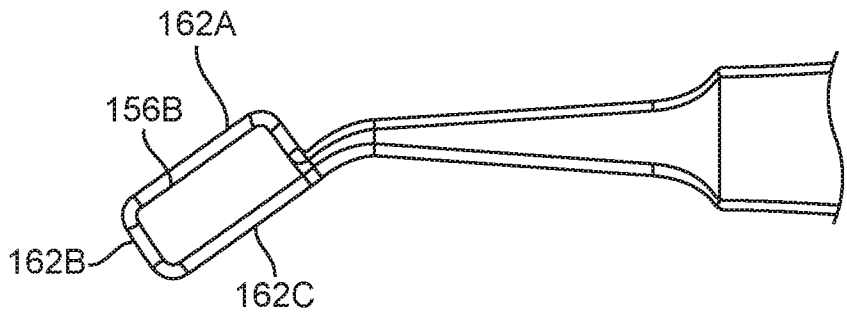


FIG. 12B

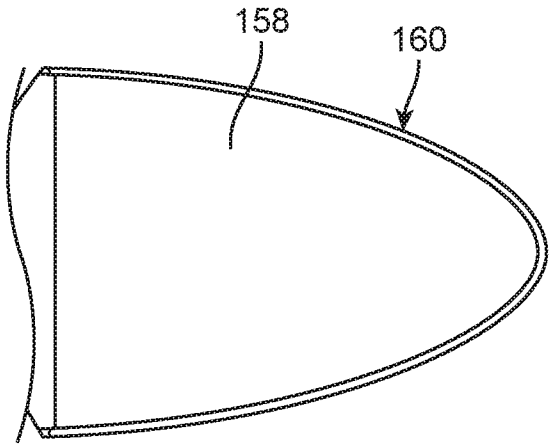


FIG. 13A

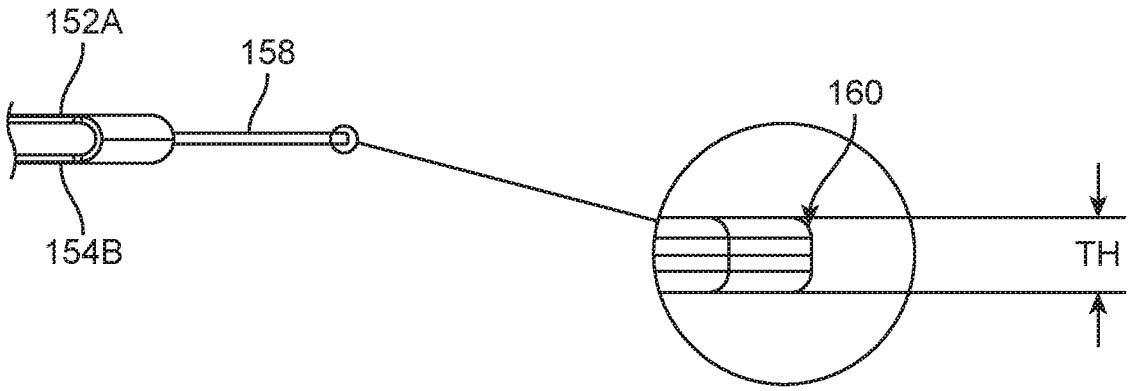


FIG. 13B

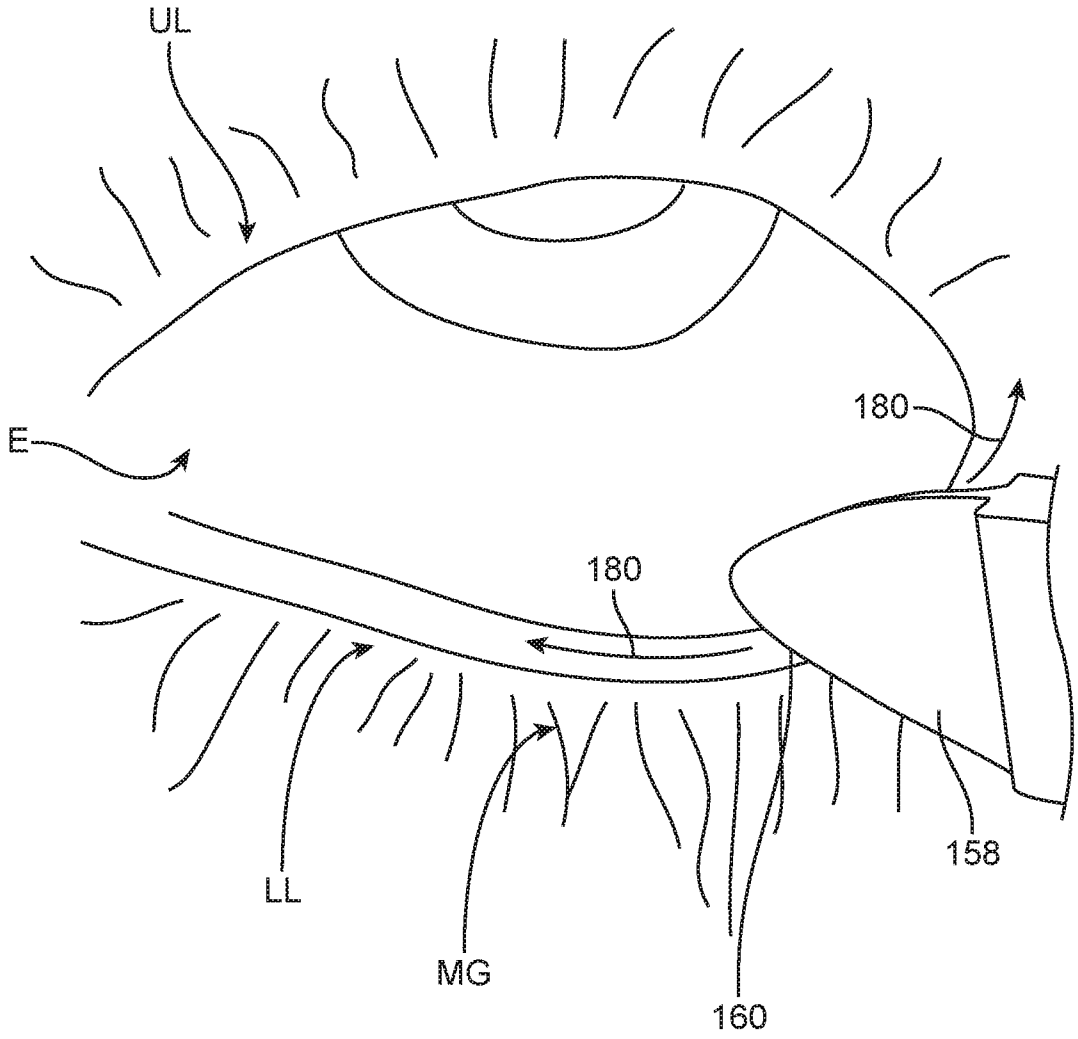


FIG. 14

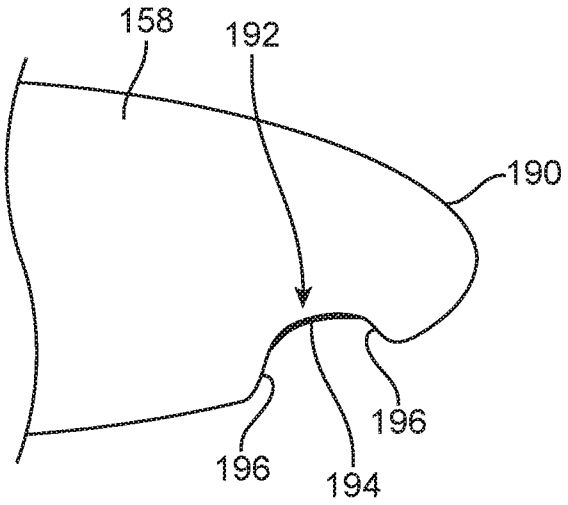


FIG. 15A

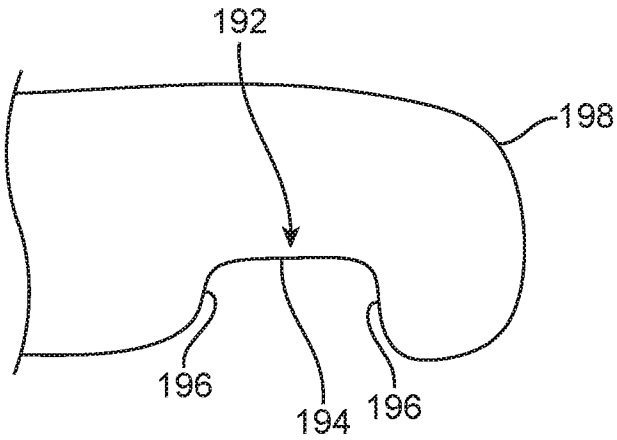


FIG. 15B

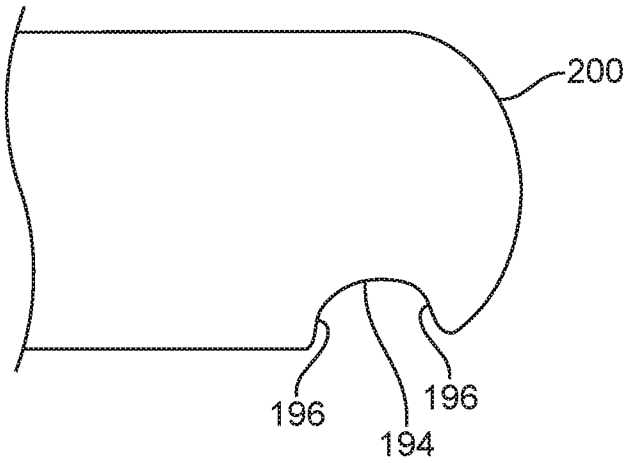


FIG. 15C

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/049440

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 7/02; A61B 5/01; A61B 17/02; A61B 18/04; A61B 18/08; A61F 7/03; A61F 7/08 (2019.01)
CPC - A61B 17/02; A61B 5/01; A61B 17/0483; A61B 18/04; A61B 18/08; A61F 7/02; A61F 7/08; A61F 9/00772; A61F 9/04; A61F 2007/0004 (2019.08)

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

B. FIELDS SEARCHED

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

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 607/96; 607/108; 601/18; 606/5 (keyword delimited)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 2017/0087009 A1 (SIGHT SCIENCES INC) 30 March 2017 (30.03.2017) entire document | 1-18 |
| A | CN 103417306 A (WU) 04 December 2013 (04.12.2013) see original and machine translation | 1-30 |
| A | CN 202313590 U (LI) 11 July 2012 (11.07.2012) see original and machine translation | 1-30 |
| A | US 2015/0025545 A1 (TEARSCIENCE INC) 22 January 2015 (22.01.2015) entire document | 1-30 |
| A | US 2016/0317379 A1 (MOSADDEGH) 03 November 2016 (03.11.2016) entire document | 1-30 |

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

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"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 |
|---|---|
| 04 October 2019 | 24 OCT 2019 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, VA 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Blaine R. Copenheaver<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |