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Description

BACKGROUND OF THE DISCLOSURE

[0001] Phototherapy has recently been recognized as having a wide range of applications in the medical, cosmetic and dental fields including surgeries, therapies, examinations and diagnosis. Phototherapeutic techniques have been applied to disinfect target sites to kill bacteria in the oral cavity and for whitening teeth. Phototherapy is also used to promote wound healing, skin rejuvenation and to treat skin conditions such as acne. These techniques typically rely on the use of laser light sources. Lasers, however, can be very dangerous, particularly in clinical settings, and are typically expensive, large, cumbersome and complicated to use. WO2006/115761 A1 teaches a device similar to the claimed one, but with a flexible connector sleeve rather than an elastic one. Accordingly, there is a need for an improved phototherapy device.

SUMMARY OF THE DISCLOSURE

[0002] The invention is defined in independent claim 1.

[0003] The present disclosure provides devices and methods useful in phototherapy including phototherapy device members and phototherapy kits that can utilize any light source, not necessarily lasers, but still provide effective treatment. The use of common clinical light sources such as LEDs or halogen bulbs may be more desirable for phototherapy than lasers due to the cost and other disadvantages associated with lasers. Thereby the phototherapy devices, device members, kits and methods of the present disclosure may simplify, complement and/or improve phototherapy regimens, such as for example periodontal treatment, wound healing, collagen modulation, anti-bactericidal treatment, anti-fungal treatment, anti-parasitic treatment, anti-viral treatment, anti-inflammatory treatment, skin condition treatment, or treatment to reduce or prevent scarring.

[0004] In certain embodiments, the present disclosure relates to a phototherapy device that can deliver light to the periodontal regions of the mouth to activate photoactive reagents that have been applied in periodontal pockets, e.g. between the gum and the tooth. The phototherapy device may comprise a fiber optic tip suitable for delivering light from a light source, such as a light emitting diode (LED), to periodontal regions of the mouth. The tip may be coupled to the light source using a sleeve that may help to maintain optical alignment. The present disclosure also relates to methods of treating and preventing periodontal disease using the phototherapy device to kill bacteria in a periodontal treatment region.

[0005] For purposes of clarity, and not by way of limitation, the devices and kits of the present disclosure are described herein in the context of providing phototherapy for treatment or prevention of periodontal disease. However, it will be appreciated that the principles described

herein may be adapted to a wide range of applications, such as for example post extractive sockets, endodontic treatment in dental root canals, teeth whitening treatment, wound healing, key hole surgery/treatment or any antimicrobial or therapeutic application in hard to reach places of the body where a fiber optic may be useful. Uses for devices, methods and kits of the present disclosure also include for collagen modulation, anti-bactericidal treatment, anti-fungal treatment, anti-parasitic treatment, anti-viral treatment, anti-inflammatory treatment, skin condition treatment, or treatment to reduce or prevent scarring. For example, the principles of this disclosure may be applied to phototherapeutic antibacterial treatment or tooth whitening between teeth. In addition, the principles may be applied to phototherapeutics in connection with orthodontics. More generally, the devices and methods described herein may be employed in any phototherapeutic treatment that requires the application of focused light, and in some cases, the application of light in generally closed and hard to reach sites of the mouth or other parts of the body. Accordingly, the devices, kits and methods disclosed herein may be performed instead of or in addition to conventional treatment methods, including subgingival debridement, supragingival debridement, scaling/root planning, wound healing, skin disorder treatment, topical and systemic treatments.

[0006] One aspect of the present disclosure provides a phototherapeutic device member. In some embodiments, the phototherapeutic device member comprises a flexible fiber optic tip member and an elastic tubular connector sleeve for mechanically coupling the flexible tip member to a light source. The flexible fiber optic tip member functions as a waveguide and transmits light along its length. The flexible fiber optic tip member may have a polymer core for transmitting light. The flexible fiber optic tip member may be made of any other suitable material which can transmit light and has appropriate optical properties, such as a glass. The flexible fiber optic tip member can include a proximal end and a distal end, wherein the diameter of the proximal end is greater than the diameter of the distal end, and wherein the proximal end is curved to cause light entering the flexible tip member through the proximal end to converge. The elastic tubular connecting sleeve may include a proximal end having an opening and a distal end having an opening, the proximal end configured to be stretched and mechanically coupled to the light source. In use, the flexible fiber optic tip may be partially disposed within the elastic tubular connecting sleeve such that the distal end of the flexible fiber optic tip member extends distally through the opening in the distal end of the sleeve, and the proximal end of the flexible fiber optic tip member is disposed within the sleeve and between the proximal and distal ends of the sleeve, thereby positioning the flexible fiber optic tip member near the light source. The sleeve is configured to receive the flexible fiber optic tip such that the distal end of the flexible fiber optic tip member extends distally through the opening in the distal end of the sleeve,

and the proximal end of the flexible fiber optic tip member is disposed within the sleeve and between the proximal and distal ends of the sleeve, thereby positioning the flexible fiber optic tip member near the light source.

[0007] The flexible fiber optic tip may be unitarily formed. The flexible fiber optic tip may be formed by moulding. Optionally, the flexible fiber optic tip is cut from a single block of material, such as a block of polymer material. In some embodiments, the flexible fiber optic tip member has a rough surface formed such as by grating. The flexible fiber optic tip member may include a rough outer surface configured to allow a portion of light transmitted through the core to diffuse out through the outer surface. In this way, light can be transmitted in many directions from the surface of the entire flexible fiber optic tip member. Alternatively, the flexible fiber optic tip member can include a coating to limit the direction and surface area for emitting light. The flexible fiber optic tip can include an optical axis extending through the center of the polymer core from the proximal end to the distal end, and wherein light passing through the tip member travels along at least a portion of the optical axis. The polymer core of the flexible fiber optic tip may comprise polycarbonate or polymethylmethacrylate. The core may also be a glass or a composite material or any other material which is not brittle and which transmit light. The flexible fiber optic tip may further comprise a photoactive agent which can absorb and emit light.

[0008] In some embodiments, an interior surface of the elastic tubular connector sleeve includes a plurality of ribs extending radially inwards (circumferentially) and configured to grip the light source or a catheter. The elastic tubular connector sleeve can be stretched around the light source or catheter and held in place by the ribs. In certain embodiments, the flexible fiber optic tip member is removable from the elastic tubular connector sleeve.

[0009] In some embodiments, a proximal region of the flexible fiber optic tip member is substantially conical having a base along the proximal end. The proximal end of the flexible fiber optic tip member may be convex shaped relative to the proximal portion of the flexible fiber optic tip member. A distal region of the tip member may be substantially cylindrical. The length from the proximal end to a distal end of the flexible fiber optic tip member can be between about 10 mm and about 30 mm. The length may be much longer than this if, for example, a catheter is used. In this case, the length of the flexible fiber optic tip member can be as long as needed, such as the length of the catheter. The diameter at the distal end of the flexible fiber optic tip member is optionally between about 500 micron and about 1500 micron. Further, the diameter can vary along the length of the flexible fiber optic tip member. The diameter of the distal end of the flexible fiber optic tip members can vary according to the use. In certain embodiments, the distal end of the flexible fiber optic tip member may comprise a plurality of bristles, e.g. like a brush. This may be useful in applications where debridement may be useful such as cleaning teeth,

cleaning wounds, cleaning skin (e.g. exfoliating) and the like.

[0010] In some embodiments, the light source to which the flexible fiber optic tip is coupled includes one or more light emitting diodes. Alternatively, the light source may include a halogen lamp. In some embodiments, the flexible fiber optic tip may be coupled to an end of a catheter.

[0011] A second aspect of the present disclosure provides a device for phototherapy. In some embodiments, the device comprises a light source, a probe member having a flexible fiber optic tip member and an elastic tubular connector sleeve for mechanically coupling the probe member to the light source. The proximal end of the flexible fiber optic tip member may be curved to cause light entering the tip member through the proximal end to converge. The proximal end of the sleeve may be configured to be stretched and mechanically coupled to the light source. Optionally, the tip member is partially disposed within the sleeve and extends distally through a distal opening of the sleeve. The device may be used for treating/preventing periodontitis, in which case a distal end of the flexible fiber optic tip member is sized and/or shaped to be received in periodontal pockets. The device may also be used for treating tissues in hard to reach

places, internal tissues and cavities such as through key-hole surgery, in which case the proximal end of the sleeve may be configured to be stretched and mechanically coupled to an end of a catheter or other suitable devices. In this case, the flexible fiber optic tip member may extend along the length of the catheter and be attached to a light source at a proximal end of the catheter. A further sleeve according to the present disclosure may be provided for attaching to the light source at the proximal end of the catheter.

[0012] The flexible fiber optic tip may be unitarily formed. The flexible fiber optic tip may be formed by moulding. Optionally, the flexible fiber optic tip is cut from a single block of material, such as a polymer material. In some embodiments, the flexible fiber optic tip member is grated to generate a rough surface. The flexible fiber optic tip member may include a rough outer surface configured to allow a portion of light transmitted through the core to diffuse out through the outer surface. The flexible fiber optic tip can include an optical axis extending

through the center of the polymer core from the proximal end to the distal end, and wherein light passing through the tip member travels along a portion of the optical axis. The polymer core of the flexible fiber optic tip may comprise polycarbonate or polymethylmethacrylate. The flexible fiber optic tip may further comprise a photoactive agent which can absorb light and emit as energy.

[0013] In some embodiments, an interior surface of the elastic tubular connector sleeve includes a plurality of ribs extending radially inwards (circumferentially) and configured to grip the light source. In certain embodiments, the flexible fiber optic tip member is removable from the sleeve.

[0014] In some embodiments, a proximal region of the

flexible fiber optic tip member is substantially conical having a base along the proximal end. A distal region of the tip member may be substantially cylindrical. The length from the proximal end to a distal end of the flexible fiber optic tip member is between about 10 mm and about 30 mm. The length may be much longer than this if a catheter is used. In which case the length of the flexible fiber optic tip member will be as long as the length of the catheter. The diameter at the distal end of the flexible fiber optic tip member is optionally between about 500 micron and about 1500 micron. Further, the diameter can vary along the length of the flexible fiber optic tip member. The proximal end of the flexible fiber optic tip member may be convex shaped relative to the proximal portion of the flexible fiber optic tip member. Further, the diameter can vary along the length of the flexible fiber optic tip member. The diameter of the distal end of the flexible fiber optic tip members can vary according to the use. In certain embodiments, the distal end of the flexible fiber optic tip member may comprise a plurality of bristles, e.g. like a brush. This may be useful in applications where debriement may be useful such as cleaning teeth, cleaning wounds, cleaning skin and the like.

[0015] In some embodiments, the device further comprises an actuating mechanism for moving at least the flexible fiber optic tip member relative to a treatment surface. For example, the actuating mechanism may further comprise a motor in communication with the flexible fiber optic tip member to move the flexible fiber optic tip member backwards and forwards across the treatment surface (substantially perpendicular to the optical axis), or to cause the flexible fiber optic tip member to vibrate.

[0016] In some embodiments, the light source to which the flexible fiber optic tip is coupled includes one or more light emitting diodes. Alternatively, the light source may include a halogen lamp. In some embodiments, the flexible fiber optic tip may be coupled to an end of a catheter. The light source may be able to emit any suitable wavelength or power density to light such as visible light (400-800nm).

[0017] Another aspect of the present disclosure provides a method of treating and/or preventing periodontal disease. In some embodiments, the method comprises attaching to a light source having one or more light-emitting diodes a periodontal probe member, which comprises a flexible fiber optic tip member with a core for transmitting light, and an elastic tubular connector sleeve for mechanically coupling the flexible tip member to a light source; introducing a composition comprising a photoactivating agent and optionally an oxygen-releasing agent into a periodontal treatment region; introducing the flexible fiber optic tip into the periodontal treatment region; and applying light through the flexible fiber optic tip member to activate the photoactivating agent in the periodontal treatment region. The core may be made of polymer or glass or any other suitable material. By "photoactivating agent" is meant a chemical compound which, when contacted by light irradiation, is capable of absorbing the

light. The photoactivating agent readily undergoes photoexcitation and can then transfer its energy to other molecules or emit it as light. The terms "photoactivating agent", "photoactive agent" and "chromophore" are used herein interchangeably herein. In some embodiments, the photoactivating agent is activated without requiring an incubation period which is differentiated from standard photodynamic therapy which does require an incubation period and which can cause sensitization problems in the patient.

[0018] Another aspect of the present disclosure provides a method for treating wounds or for promoting tissue regeneration. In some embodiments, the method comprises attaching to a light source having one or more light-emitting diodes a probe member, which comprises a flexible fiber optic tip member with a core for transmitting light, and an elastic tubular connector sleeve for mechanically coupling the flexible tip member to a light source or a catheter; introducing a composition comprising a photoactivating agent and optionally an oxygen-releasing agent into a treatment region; introducing the flexible fiber optic tip member into the treatment region; and applying light through the flexible fiber optic tip member to activate the photoactivating agent in the treatment region. The core may comprise polymer or glass or any other suitable material.

[0019] Another aspect of the present disclosure provides a method for antibacterial treatment of a tissue site. In some embodiments, the method comprises attaching to a light source having one or more light-emitting diodes a probe member, which comprises a flexible fiber optic tip member with a core for transmitting light, and an elastic tubular connector sleeve for mechanically coupling the flexible tip member to a light source or a catheter; introducing a composition comprising a photoactivating agent and optionally an oxygen-releasing agent into the tissue site; introducing the flexible fiber optic tip member into the tissue site; and applying light through the flexible fiber optic tip member to activate the photoactivating agent in the tissue site. The core may comprise polymer or glass or any other suitable material. The flexible fiber optic tip may be unitarily formed, such as by moulding. Optionally, the flexible fiber optic tip is cut from a single block of material, such as a polymer. In some embodiments, the flexible fiber optic tip member is grated to generate a rough surface. The flexible fiber optic tip member may include a rough outer surface configured to allow a portion of light transmitted through the core to diffuse out through the outer surface. The flexible fiber optic tip can include an optical axis extending through the center of the polymer core from the proximal end to the distal end, and wherein light passing through the tip member travels along a portion of the optical axis. The polymer core of the flexible fiber optic tip may comprise polycarbonate or polymethylmethacrylate.

[0020] In some embodiments, an interior surface of the elastic tubular connector sleeve includes a plurality of ribs extending radially inwards (circumferentially) and

configured to grip the light source or the catheter. In certain embodiments, the flexible fiber optic tip member is removable.

[0021] In some embodiments, a proximal region of the flexible fiber optic tip member is substantially conical having a base along the proximal end. The proximal end of the flexible fiber optic tip member may be convex shaped relative to the proximal portion of the flexible fiber optic tip member. A distal region of the tip member may be substantially cylindrical. The length from the proximal end to a distal end of the flexible fiber optic tip member is between about 10 mm and about 30 mm. The length may be much longer than this if a catheter is used. In this case the length of the flexible fiber optic tip member will be as long as the length of the catheter. The diameter at the distal end of the flexible fiber optic tip member is optionally between about 500 micron and about 1500 micron. Further, the diameter can vary along the length of the flexible fiber optic tip member. The diameter of the distal end of the flexible fiber optic tip members can vary according to the use. In certain embodiments, the distal end of the flexible fiber optic tip member may comprise a plurality of bristles, e.g. like a brush. This may be useful in applications where debridement may be useful such as cleaning teeth, cleaning wounds, cleaning skin and the like.

[0022] The periodontal treatment region can be exposed to the light for a period of less than five minutes, such as between one minute and five minutes. The periodontal treatment region can be exposed to the light for a period of less than ten minutes, such as between one minute and ten minutes. The method may comprise exposing the periodontal treatment region to light for about 1-30 minutes, about 1-25 minutes, about 1-20 minutes, about 1-15 minutes, about 1-10 minutes. The method may be performed over several distinct periodontal treatment regions within the oral cavity. In such cases, each periodontal treatment region exposed to the light for a period of less than five minutes, such as between one minute and five minutes. The light may have a wavelength between about 400 nm and about 800 nm.

[0023] The composition may be introduced on a gingiva within the oral cavity, or a portion thereon. The composition may be introduced near at least one tooth, preferably on at least one tooth. The composition may be introduced on or between a gingiva and a tooth.

[0024] The oxygen-releasing agent may be a peroxide such as hydrogen peroxide, carbamide peroxide or benzoyl peroxide. Additionally or alternatively, the oxygen-releasing agent may comprise alkali metal peroxides, alkali metal percarbonates, alkali metal perborates (e.g. sodium perborate), or combinations of these compounds.

[0025] The photoactivating agent can be xanthene derivative dye, an azo dye, a biological stain or a carotenoid. Xanthene derivative dyes may be a fluorescein dye, a fluorescein dye or a rhodole dye. Optionally, the fluorescein dye is a pyronine dye, such as pyronine Y or pyronine B, or a

rhodamine dye, such as rhodamine B, rhodamine G or rhodamine WT. In some embodiments, the fluorescein dye is fluorescein or a fluorescein derivative, such as phloxine B, rose Bengal, merbromine, eosin Y, eosin B or ethro-sine B, preferably eosin Y. Optionally, the azo dye is methyl violet, neutral red, para red, amaranth, carmoisine, allura red AC, tartrazine, orange G, ponceau 4R, methyl red or murexide-ammonium purpurate. The biological stain may be saffranin O, basic fuchsin, acid fuchsin, 3,3' dihexylocarbocyanine iodide, carminic acid or indocyanine green. In some embodiments, the carotenoid is crocetin, a-crocetin, zeaxanthine, lycopene, α -carotene, β -carotene, bixin, fucoxanthine, or a mixture of carotenoid compounds, such as saffron red powder, annatto extract or brown algae extract.

[0026] Another aspect of the present disclosure provides a method for phototherapeutic treatment, and which differs from the above method in that the flexible fiber optic tip member comprises a photoactive agent in the core. In some embodiments, the method comprises attaching to a light source having one or more light-emitting diodes a probe member, which comprises a flexible fiber optic tip member with a core for transmitting light and a photoactive agent, and an elastic tubular connector sleeve, for mechanically coupling the flexible tip member to a light source; introducing the flexible fiber optic tip member into the treatment region; and applying light through the flexible fiber optic tip member to activate the photoactive agent. When the photoactive agent is activated by the light, the flexible fiber optic tip member may fluoresce and/or activate oxygen-releasing agents, if present, in the treatment region.

[0027] From a yet further aspect, there is provided a kit for phototherapy comprising a plurality of flexible fiber optic tip members for transmitting light, the flexible tip member including a proximal end and a distal end, wherein the diameter of the proximal end is greater than the diameter of the distal end, and wherein the proximal end is curved to cause light entering the flexible tip member through the proximal end to converge; and an elastic tubular connector sleeve for receiving at least a portion of one of the plurality of flexible fiber optic tip members and for mechanically coupling the flexible tip member to a light source, wherein the sleeve includes a proximal end having a first opening and a distal end having a second opening, the proximal end configured to be stretched and mechanically coupled to the light source. The flexible fiber optic tip members may have a core made of any suitable light transmitting material such as suitable polymers or glass.

[0028] The plurality of flexible fiber optic tip members may have different size and shape distal ends suitable for different applications. The plurality of flexible fiber optic tip members may include a photoactive agent in a polymer matrix. In certain embodiments, the kit further comprises a biophotonic composition comprising a photoactive agent. The composition may optionally include an oxygen-releasing agent. The kit may also include in-

structions for use, or a tool for trimming flexible fiber optic tip members to the appropriate length.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029]

FIG. 1 depicts a phototherapeutic device, according to an illustrative embodiment of the present disclosure.

FIG. 2A depicts a flexible fiber optic tip member of the device of FIG. 1, according to an illustrative embodiment of the present disclosure.

FIG. 2B-2C depict a flexible fiber optic tip member, of the device of FIG. 1, having a ridge, according to an illustrative embodiment of the present disclosure..

FIG. 2D depicts a flexible fiber optic tip member, of the device of FIG. 1, having a rough surface portion, according to an illustrative embodiment of the present disclosure.

FIG. 3A depicts the coupling of the flexible fiber optic tip member to a light source using an elastic tubular connector sleeve, according to an illustrative embodiment of the present disclosure.

FIG. 3B depicts a zoomed-in view of an elastic tubular connector sleeve of the device of

FIG. 1, according to an illustrative embodiment of the present disclosure.

FIG. 4 is a flow chart outlining a process of treating periodontal disease using the device of FIG. 1, according to an illustrative embodiment of the present disclosure.

DETAILED DESCRIPTION

[0030] The devices, kits and methods described herein will now be described with reference to certain illustrative embodiments. However, the disclosure is not to be limited to these illustrated embodiments which are provided merely for the purpose of describing the devices, kits and methods of the disclosure and are not to be understood as limiting in anyway.

[0031] FIG. 1 depicts a phototherapeutic device in accordance with present disclosure. The phototherapeutic device comprises a flexible fiber optic tip member 100 coupled to a light source 300 with an elastic tubular connector sleeve 200. The flexible fiber optic tip member 100 will be discussed in greater detail in the descriptions of FIG. 2A-FIG. 2D. The elastic tubular connector sleeve will be discussed in greater detail in the descriptions of FIG. 3A and FIG. 3B.

[0032] The light source 300 may be any light source commonly found in a clinical setting, including, for example, light sources for photocuring. In some embodiments, the light source 300 comprises an elongated cable of a suitable length to permit a dental professional to work in a patient's mouth. Optionally, the light source 300 provides actinic light. In some embodiments, the light source 300 comprises light emitting diodes. Alternatively, the light source 300 may comprise a halogen lamp. In some embodiments, the light source 300 is configured to provide light at a wavelength that will activate a photoactivating agent. By "actinic light" is meant light energy emitted from a specific light source (e.g., lamp, LED, or laser) and capable of being absorbed by matter (e.g. the photoactivating agent). In a preferred embodiment, the actinic light is visible light. The light source 300 may provide visible light or ultraviolet light. In some embodiments, the light source 300 provides visible light having a wavelength between about 400 nm and about 800 nm. Furthermore, the light source 300 should have a suitable power density. Suitable power density for non-collimated light sources (LED, halogen or plasma lamps) are in the range from about 50 mW/cm² to about 200 mW/cm², about 30-150 mW/cm². A light beam from the light source

300 may travel from the light source to the proximal end 110 of a flexible fiber optic tip member 100 along the optical axis 190 to the distal end 120 for delivery to a periodontal treatment region. In certain embodiments, the light source 300 may emit a continuous beam of light or a pulsed beam of light.

[0033] The light source 300 may additionally include a control box attached to a flexible fiber optic waveguide to allow a dental professional to place the free end of the fiber optic waveguide in or near a patient's mouth. The control box of light source 300 may include a lamp, a transformer and a control board, which allows dental professionals to control variables such as light intensity and voltage. Light source 300 may be controlled by a foot pedal, which leaves the dental professionals hands free to operate the fiber optic waveguide in addition to any other dental tools. Light source 300 may also include a time-delay, such that the light transmitted through the fiber optic waveguide stays on after the foot pedal is released.

[0034] FIG. 2A depicts a flexible fiber optic tip member 100 in accordance with the present disclosure. The flexible fiber optic tip member 100 has a polymer core along with a proximal end 110 configured for coupling to the light source 300 and a distal end 120 configured for insertion into a periodontal treatment region. The flexible fiber optic tip member 100 is configured to have a conical portion 140 proximal to a cylindrical portion 150. The conical portion 140 may have its base at the proximal end 110. The conical portion 140 will be configured to comprise a curved structure 130 to focus the light transmitted from the light source 300 into the cylindrical portion 150. Further, the flexible fiber optic tip member 100 is configured such that light traverses through the polymer core

along the optical axis 190.

[0035] FIG. 2B depicts an additional flexible fiber optic tip member 100 in accordance with the present disclosure. The flexible fiber optic tip member 100 in FIG. 2B comprises a ridge feature 160, which may be configured to be disposed in the distal opening 250 of the elastic tubular connecting sleeve to help the flexible fiber optic tip member 100 in place near the light source 300. The flexible fiber optic tip member 100 has a polymer core along with a proximal end 110 configured for coupling to the light source 300 and a distal end 120 configured for insertion into a periodontal treatment region. The flexible fiber optic tip member 100 is configured to have a conical portion 140 proximal to a cylindrical portion 150. The cylindrical portion 150 can be configured to comprise a ridge 160 proximal to a flexible portion 170 which terminates at the distal end 120. The distal end 120 may comprise a rounded tip 121. The conical portion 140 may have its base at the proximal end 110. The conical portion 140 will be configured to comprise a curved structure 130 to focus the light transmitted from the light source 300 into the cylindrical portion 150. Further, the flexible fiber optic tip member 100 is configured such that light traverses through the polymer core along the optical axis 190.

[0036] FIG. 2C depicts a further flexible fiber optic tip member 100 in accordance with the present disclosure. The flexible fiber optic tip member 100 in FIG. 2C comprises a ridge feature 160, which may be configured to be disposed in the distal opening 250 of the elastic tubular connecting sleeve to help the flexible fiber optic tip member 100 in place near the light source 300. Further the flexible fiber optic tip member 100 in FIG. 2C comprises a narrowing region 180, along which the diameter of the cylindrical portion 150 varies along the length of the cylindrical portion 150. The flexible fiber optic tip member 100 has a polymer core along with a proximal end 110 configured for coupling to the light source 300 and a distal end 120 configured for insertion into a periodontal treatment region. The flexible fiber optic tip member 100 is configured to have a conical portion 140 proximal to a cylindrical portion 150. The cylindrical portion 150 can be configured to comprise a ridge 160 proximal to a flexible portion 170 which terminates at the distal end 120. The flexible portion 170 may contain a narrowing region 180, wherein the diameter of the proximal end of the narrowing region 180 is greater than the diameter of the distal end for the narrowing region 180. The narrowing region 180 may traverse the entire length for the flexible portion 170, running from the ridge 160 to the distal end 120. The conical portion 140 may have its base at the proximal end 110. The conical portion 140 will be configured to comprise a curved structure 130 to focus the light transmitted from the light source 300 into the cylindrical portion 150. Further, the flexible fiber optic tip member 100 is configured such that light traverses through the polymer core along the optical axis 190.

[0037] FIG. 2D depicts another flexible fiber optic tip member 100 in accordance with the present disclosure.

The flexible fiber optic tip member 100 in FIG. 2D comprises a rough outer surface 123 and a rough tip 122, which allows light traversing through the flexible fiber optic tip member 100 to diffuse. The flexible fiber optic tip member 100 has a polymer core along with a proximal end 110 configured for coupling to the light source 300 and a distal end 120 configured for insertion into a periodontal treatment region. The flexible fiber optic tip member 100 is configured to have a conical portion 140 proximal to a cylindrical portion 150. The cylindrical portion 150 can be configured to comprise a ridge 160 proximal to a flexible portion 170 which terminates at the distal end 120. The distal portion of flexible portion 170 may include a rough outer surface 123 configured to allow a portion of light transmitted through the flexible portion 170 to diffuse out through the rough outer surface 123. Similarly, the distal end 120 may comprise a rough tip 122 configured to allow a portion of light transmitted through the distal end 120 to diffuse out through the rough tip 122. The flexible fiber optic tip member 100 may be grated to generate the rough outer surface 123 or the rough tip 122. The conical portion 140 may have its base at the proximal end 110. The conical portion 140 will be configured to comprise a curved structure 130 to focus the light transmitted from the light source 300 into the cylindrical portion 150. Further, the flexible fiber optic tip member 100 is configured such that light traverses through the polymer core along the optical axis 190.

[0038] Regarding any of FIG. 2A-2D, the flexible fiber optic tip member 100 may be unitarily formed. In some embodiments, the flexible fiber optic tip member is cut from a single block of polymer material. In some embodiments, the polymer core includes polycarbonate. In some embodiments, the flexible fiber optic tip member 100 comprises polymeric materials such as, for example, any of polycarbonate, polystyrene, polyacrylate and polymethylmethacrylate materials. In some embodiments, the flexible fiber optic tip member 100 comprises glass materials such as, for example, any of quartz, silica glass, borosilicate glass, lead glass, and fluoride glass materials.

[0039] The rough outer surface 123 or rough tip 122 of the flexible fiber optic tip member 100 may be generated by any suitable method, including sandpapering and/or grating the surface of the flexible fiber optic tip member 100. The rough outer surface 123 or rough tip 122 of the flexible fiber optic tip member 100 may be generated by sandblasting techniques.

[0040] In certain embodiments, flexible fiber optic tip member 100 may be removed from phototherapeutic periodontal device and disposed of, to be replaced by a fresh flexible fiber optic tip member 100 in order to avoid cross contamination, for example, between different periodontal diseased tissues or between patients. The length of the flexible fiber optic tip member 100 may be between about 10 mm and about 30 mm. The length of the flexible fiber optic tip member 100 may be longer than about 30 mm, and be trimmed to size by the user.

[0041] Still referring to any of FIG. 2A-2D, the curved structure 130 may be convex relative to the proximal end 110. In other words, the curved structure 130 curves toward from the light source 300, which allows the flexible fiber optic tip member 100 to focus light received from the light source 300 along the optical axis 190 for traversal along the cylindrical portion 150 of the flexible fiber optic tip member 100. Any suitable degree of curvature may be used as desired so that light is allowed to propagate and focus into the optical fiber. In some embodiments, the diameter of the proximal end 100 of the flexible fiber optic tip member is the same size as the diameter of the light source 300. In some embodiments, the diameter of the proximal end 100 of the flexible fiber optic tip member is greater than the diameter of the light source 300, which allows the flexible fiber optic tip member 100 to prevent any light from escaping. In certain embodiments, the distance between the curved surface 130 and the light source 300 may be selected such that light from the light source 300 is focused into the fiber optic tip member 100. For example, the curved surface 130 may be touching or in minimal contact or in near proximity to the light source 300.

[0042] Still referring to any of FIG. 2A-2D, the cylindrical portion 150 of the flexible fiber optic tip member 100 may have a diameter of about 0.75-1.0 mm at its proximal end and a diameter of about 0.05-0.2 mm at its distal end 120. In some embodiments, the diameter at the distal end 120 of the flexible fiber optic tip member 100 is between about 500 micron and about 1500 micron. The cylindrical portion 150 and/or the flexible portion 170 of the flexible fiber optic tip member 100 may be sufficiently flexible so as to allow insertion of the distal end 120 into small spaces such as periodontal pockets, dental root canals, tooth cavities, oral lesions, ear canal, and other hard to reach or internal sites. The flexible fiber optic tip member 100 and, in particular, the distal end 120 may be configured to deliver and focus light directly to a periodontal treatment region to provide treatment, and/or to activate a photoactivating agent in a composition as will be described below. In certain embodiments, the flexible fiber optic tip member 100 and, in particular, the distal end 120 may be configured to disperse light in all directions and from both the distal end 120 and/or along a portion of the cylindrical portion 150 or the flexible portion 170 to aid in treatment. In some embodiments, the dispersal light in all directions is achieved by providing a rough end 122 or a rough outer surface 123, as shown in FIG. 2D.

[0043] Still referring to any of FIG. 2A-2D, the ridge 160 may be configured to be partially disposed within the distal opening 250 of the elastic tubular connecting sleeve 200. In some embodiments, the diameter of the proximal end of the ridge 160 is greater than the diameter of the distal opening 250 of the elastic tubular connecting sleeve 200. In some embodiments, the diameter of the distal end of the ridge 160 is less than the diameter of the distal opening 250 of the elastic tubular connecting

sleeve 200. In some embodiments, the diameter of the ridge 160 may be between 5 mm and 10 mm.

[0044] FIG. 3A depicts the assembly of a phototherapeutic device in accordance with the present disclosure.

5 The proximal end 110 of the flexible fiber optic tip member 100 is coupled to the light source 300. The distal end 120 of the flexible fiber optic tip member 100 passes through the elastic tubular connector sleeve 200 and extends beyond the distal end 220 of the elastic tubular connector sleeve 200. The proximal end 210 of the elastic tubular connector sleeve 200 will extend beyond the proximal end 110 of the flexible fiber optic tip member 100 and will couple to the light source 300. The elastic tubular connector sleeve 200 will have one or more flexible ridges 230 which will allow for attachment to the light source 300 and will firmly hold the flexible fiber optic tip member 100 in place. When fully assembled, the proximal end 110 of the flexible fiber optic tip member 100 will be disposed within the elastic tubular connector sleeve 200,

10 such that the proximal end 110 of the flexible fiber optic tip member 100 is between the proximal end 210 and the distal end 220 of the elastic tubular connector sleeve 200.

[0045] FIG. 3B depicts an elastic tubular connector sleeve 200 in accordance with the present disclosure.

15 The elastic tubular connector sleeve 200 comprises a proximal end 210, configured for coupling to a light source 300, and a distal end 220, configured to house the cylindrical portion 150 of a flexible fiber optic tip member 100. The proximal end 210 comprises a proximal opening 240 and the distal end 220 comprises a distal opening 250. A light source 300 will be coupled to the elastic tubular connector sleeve through the proximal opening 240. The cylindrical portion 150 and distal end 120 of a flexible fiber optic tip will extend through the distal opening 250.

20 The tubular connector sleeve comprises one or more flexible ridges 230 which will allow for attachment to the light source 300 and may help hold the flexible fiber optic tip member 100 firmly in place.

[0046] The proximal end 210 of the elastic tubular connector sleeve 200 is configured for coupling to a light source 300, such that the light source 300 passes through

25 the proximal opening 240 and is partially disposed within the elastic tubular connector sleeve 200. The proximal end 210 may be elastic, such that the diameter of the proximal opening 240 can be increased by mechanical stretching. Accordingly, the diameter of the proximal opening 240 may be the same or smaller than the diameter of the light source 300, such that the proximal end 210 must be stretched to dispose the light source 300 in

30 the proximal opening 240. Alternatively, the proximal end 210 may be rigid, such that the diameter of the proximal opening 240 is greater than the diameter of the light source 300. In such embodiments, the one or more flexible ridges 230 keep the light source 300 partially disposed within the elastic tubular connector sleeve 200. In some embodiments, the elastic tubular connector sleeve 200 has multiple layers, including a rigid outer layer and an

35 elastic inner layer that firmly grasps the light source 300.

[0047] The distal end 220 of the elastic tubular connector sleeve 200 is configured to allow the flexible fiber optic member 100 to extend through the distal opening 250. The distal end 220 may be configured such that the cylindrical portion 150 of the flexible fiber optic member 100 passes through the distal opening 250. Alternatively, the distal end 220 may be configured such that the conical portion 140 of the flexible fiber optic member 100 passes through the distal opening 250. In further embodiments, the distal end 220 may be configured such that the ridge 160 of the flexible fiber optic member 100 is partially disposed in the distal opening 250. In some embodiments, the distal end 220 is elastic, such that the diameter of distal opening 250 may be increased by mechanical stretching. In such embodiments, the diameter of the distal opening 250 may be the same or smaller than the diameter of the conical portion 140 or the cylindrical portion 150 of the flexible fiber optic tip member 100, such that the distal end 220 must be stretched to extend flexible fiber optic tip member 100 through the distal opening 250. Alternatively, the distal end 220 may be rigid, such that the diameter of the distal opening 250 is greater than the diameter of the conical portion 140 or the cylindrical portion 150 of the flexible fiber optic tip member 100. In such embodiments, the one or more flexible ridges 230 may keep the flexible fiber optic tip member 100 firmly disposed within the elastic tubular connector sleeve 200. Alternatively, the length of the elastic tubular connecting sleeve 200 may be short enough that when the flexible fiber optic tip member 100 is partially disposed within the connecting sleeve 200 and the connecting sleeve 200 is coupled to the light source 300, the flexible fiber optic tip 100 does not have room to move and is firmly held in place within the connecting sleeve 200. In some embodiments, the flexible fiber optic tip 100 is contacting the light source 300. In other embodiments, the flexible fiber optic tip 100 is contacting the light source 300, such as less than about 1 mm away from the light source 300.

[0048] The one or more flexible ridges 230 may be concentrically disposed within the elastic tubular connecting sleeve 200. Alternatively, the flexible ridge 230 may be a single ridge helically disposed within the elastic tubular connecting sleeve 200. The one or more flexible ridges 230 may be rigid. In such embodiments, the elastic tubular connecting sleeve 200 may be snapped onto the light source using a lip/clip method. Alternatively, the elastic tubular connecting sleeve 200 may be screwed on to the light source 300 using a threaded system. Alternatively, the one or more flexible ridges 230 may be elastic, such that the proximal end 210 of the elastic tubular connecting sleeve 200 may be mechanically stretched for coupling to the light source 300.

[0049] FIG. 4 depicts a process of treating or preventing periodontal disease 400 in accordance with the present disclosure. The process 400 comprises an attachment 401, wherein a flexible fiber optic tip 100 is attached to a periodontal light source 300 to generate a phototherapeutic device. Preferably, an elastic tubular

connecting sleeve 200 is used to attach the flexible fiber optic tip 100 to the light source 300, as shown in FIG. 1 and FIG 3A. The process 400 further comprises a composition introduction 402, wherein a composition comprising a photoactivating agent and optionally an oxygen-releasing agent is introduced into a periodontal treatment region. The process 400 further comprises a flexible tip member introduction 403, wherein the flexible fiber optic tip member 100 of the phototherapeutic device is inserted into the periodontal treatment region. The process 400 further comprises an activation step 404, wherein light from the flexible fiber optic tip member 100 activates the photoactivating agent.

[0050] In one example, upon activation with light from the flexible fiber optic tip 100, the photoactivating agent absorbs energy from the light and releases some of the absorbed light energy as a fluorescent light. Without being bound to theory, it is thought that fluorescent light emitted by photoactivated chromophores may have therapeutic properties due to its femto-second or pico-second emission properties which may be recognized by biological cells and tissues, leading to favourable bi-modulation. Furthermore, the emitted fluorescent light has a longer wavelength and hence a deeper penetration into the tissue than the activating light. Irradiating tissue with such a broad range of wavelength, including in some embodiments the activating light which passes through the composition, may have different and complementary therapeutic effects on the cells and tissues.

[0051] In another example, the composition also comprises an oxygen-releasing agent. In this case, the photoactivating agent may transfer at least some of the absorbed light energy to the oxygen-releasing agent, which in turn can produce oxygen radicals such as singlet oxygen. These are distinct applications of these agents and differ from the use of chromophores as simple stains or as a catalyst for photo-polymerization.

[0052] Suitable photoactivating agents include fluorescent dyes (or stains), biological dyes, histological dyes, food colorings, naturally occurring photoactive agents and carotenoids.

[0053] Suitable photoactivating agents include, but are not limited to, the following:

45 *Chlorophyll dyes*

[0054] Exemplary chlorophyll dyes include but are not limited to chlorophyll a; chlorophyll b; oil soluble chlorophyll; bacteriochlorophyll a; bacteriochlorophyll b; bacteriochlorophyll c; bacteriochlorophyll d; protochlorophyll; protochlorophyll a; amphiphilic chlorophyll derivative 1; amphiphilic chlorophyll derivative 2, phycobiliproteins.

Xanthene derivatives

[0055] Exemplary xanthene dyes include but are not limited to Eosin B (4',5'-dibromo,2',7'-dinitro-o-fluorescein, dianion); eosin Y; eosin Y (2',4',5',7'-tetrabromo-

fluorescein, dianion); eosin (2',4',5',7'-tetrabromo-fluorescein, dianion); eosin (2',4',5',7'-tetrabromo-fluorescein, dianion) methyl ester; eosin (2',4',5',7'-tetrabromo-fluorescein, monoanion) p-isopropylbenzyl ester; eosin derivative (2',7'-dibromo-fluorescein, dianion); eosin derivative (4',5'-dibromo-fluorescein, dianion); eosin derivative (2',7'-dichloro-fluorescein, dianion); eosin derivative (4',5'-dichloro-fluorescein, dianion); eosin derivative (2',7'-diiodo-fluorescein, dianion); eosin derivative (4',5'-diiodo-fluorescein, dianion); eosin derivative (tribromo-fluorescein, dianion); eosin derivative (2',4',5',7'-tetrachloro-*o*-fluorescein, dianion); eosin; eosin dicetylpyridinium chloride ion pair; erythrosin B (2',4',5',7'-tetrailodo-fluorescein, dianion); erythrosin; erythrosin dianion; erythrosin B; fluorescein; fluorescein dianion; phloxin B (2',4',5',7'-tetrabromo-3,4,5,6-tetrachloro-fluorescein, dianion); phloxin B (tetrachloro-tetrabromo-fluorescein); phloxine B; rose bengal (3,4,5,6-tetrachloro-2',4',5',7'-tetraiodofluorescein, dianion); pyronin G, pyronin J, pyronin Y; Rhodamine dyes such as rhodamines include 4,5-dibromo-rhodamine methyl ester; 4,5-dibromo-rhodamine *n*-butyl ester; rhodamine 101 methyl ester; rhodamine 123; rhodamine 6G; rhodamine 6G hexyl ester; tetrabromo-rhodamine 123; and tetramethyl-rhodamine ethyl ester.

Methylene blue dyes

[0056] Exemplary methylene blue derivatives include but are not limited to 1-methyl methylene blue; 1,9-dimethyl methylene blue; methylene blue; methylene blue (16 .mu.M); methylene blue (14 .mu.M); methylene violet; bromomethylene violet; 4-iodomethylene violet; 1,9-dimethyl-3-dimethyl-amino-7-diethyl-*a*-mino-phenothiazine; and 1,9-dimethyl-3-diethylamino-7-dibutyl-amino-phenothiazine.

Azo dyes

[0057] Exemplary azo (or diazo-) dyes include but are not limited to methyl violet, neutral red, para red (pigment red 1), amaranth (Azorubine S), Carmoisine (azorubine, food red 3, acid red 14), allura red AC (FD&C 40), tartrazine (FD&C Yellow 5), orange G (acid orange 10), Ponceau 4R (food red 7), methyl red (acid red 2), and murexide-ammonium purpurate.

[0058] In some aspects of the disclosure, the one or more photoactivating agents of the biophotonic composition disclosed herein can be independently selected from any of Acid black 1, Acid blue 22, Acid blue 93, Acid fuchsin, Acid green, Acid green 1, Acid green 5, Acid magenta, Acid orange 10, Acid red 26, Acid red 29, Acid red 44, Acid red 51, Acid red 66, Acid red 87, Acid red 91, Acid red 92, Acid red 94, Acid red 101, Acid red 103, Acid roseine, Acid rubin, Acid violet 19, Acid yellow 1, Acid yellow 9, Acid yellow 23, Acid yellow 24, Acid yellow 36, Acid yellow 73, Acid yellow S, Acridine orange, Acriflavine, Alcian blue, Alcian yellow, Alcohol soluble eosin,

Allophycocyanin (APC), Alizarin, Alizarin blue 2RC, Alizarin carmine, Alizarin cyanin BBS, Alizarol cyanin R, Alizarin red S, Alizarin purpurin, Aluminon, Amido black 10B, Amidoschwarz, Aniline blue WS, Anthracene blue SWR, Auramine O, Azocannine B, Azocarmine G, Azoic diazo 5, Azoic diazo 48, Azure A, Azure B, Azure C, Basic blue 8, Basic blue 9, Basic blue 12, Basic blue 15, Basic blue 17, Basic blue 20, Basic blue 26, Basic brown 1, Basic fuchsin, Basic green 4, Basic orange 14, Basic red 2, Basic red 5, Basic red 9, Basic violet 2, Basic violet 3, Basic violet 4, Basic violet 10, Basic violet 14, Basic yellow 1, Basic yellow 2, Biebrich scarlet, Bismarck brown Y, Brilliant crystal scarlet 6R, Calcium red, Carmine, Carminic acid, Celestine blue B, China blue, Cochineal, Coelstine blue, Chrome violet CG, Chromotrope 2R, Chromoxane cyanin R, Congo corinth, Congo red, Cotton blue, Cotton red, Croceine scarlet, Crocin, Crystalponceau 6R, Crystal violet, Dahlia, Diamond green B, Direct blue 14, Direct blue 58, Direct red, Direct red 10, Direct red 28, Direct red 80, Direct yellow 7, Eosin B, Eosin Bluish, Eosin, Eosin Y, Eosin yellowish, Eosinol, Erie garnet B, Eriochrome cyanin R, Erythrosin B, Ethyl eosin, Ethyl green, Ethyl violet, Evans blue, Fast blue B, Fast green FCF, Fast red B, Fast yellow, Fluorescein, Food green 3, Gallein, Gallamine blue, Gallocyanin, Gentian violet, Haematein, Haematine, Haematoxylin, Helio fast rubin BBL, Helvetia blue, Hematein, Hematine, Hematoxylin, Hoffman's violet, Indocyanin green, Imperial red, Ingrain blue, Ingrain blue 1, Ingrain yellow 1, INT, Kermes, Kermesic acid, Kernechtrot, Lac, Laccaic acid, Lauth's violet, Light green, Lissamine green SF, Luxol fast blue, Magenta 0, Magenta I, Magenta II, Magenta III, Malachite green, Manchester brown, Martius yellow, Merbromin, Mercurochrome, Metanil yellow, Methylene azure A, Methylene azure B, Methylene azure C, Methylene blue, Methyl blue, Methyl green, Methyl violet, Methyl violet 2B, Methyl violet 10B, Mordant blue 3, Mordant blue 10, Mordant blue 14, Mordant blue 23, Mordant blue 32, Mordant blue 45, Mordant red 3, Mordant red 11, Mordant violet 25, Mordant violet 39 Naphthol blue black, Naphthol green B, Naphthol yellow S, Natural black 1, Natural red, Natural red 3, Natural red 4, Natural red 8, Natural red 16, Natural red 25, Natural red 28, Natural yellow 6, NBT, Neutral red, New fuchsin, Niagara blue 3B, Night blue, Nile blue, Nile blue A, Nile blue oxazone, Nile blue sulphate, Nile red, Nitro BT, Nitro blue tetrazolium, Nuclear fast red, Oil red O, Orange G, Orcein, Pararosanilin, Phloxine B, Phycocyanins, Phycoerythrins, Phycoerythrin cyanin (PEC), Phthalocyanines, Picric acid, Ponceau 2R, Ponceau 6R, Ponceau B, Ponceau de Xylidine, Ponceau S, Primula, Purpurin, Pyronin B, Pyronin G, Pyronin Y, Rhodamine B, Rosanilin, Rose bengal, Saffron, Safranin O, Scarlet R, Scarlet red, Scharlach R, Shellac, Sirius red F3B, Solochrome cyanin R, Soluble blue, Solvent black 3, Solvent blue 38, Solvent red 23, Solvent red 24, Solvent red 27, Solvent red 45, Solvent yellow 94, Spirit soluble eosin, Sudan III, Sudan IV, Sudan black B, Sulfur yellow S, Swiss blue, Tartrazine, Thio-

flavine S, Thioflavine T, Thionin, Toluidine blue, Toluyline red, Tropaeolin G, Trypaflavine, Trypan blue, Uranin, Victoria blue 4R, Victoria blue B, Victoria green B, Water blue I, Water soluble eosin, Xylidine ponceau, or Yellowish eosin.

[0059] In certain embodiments, the composition of the present disclosure includes any of the chromophores listed above, or a combination thereof, so as to provide a biophotonic impact at the application site. Photoactive agent compositions may increase photo-absorption by the combined dye molecules or may enhance photo-bi-modulation selectivity. In some embodiments, the combination of photoactive agents may be synergistic. In some embodiments, the two or more photoactive agents are both xanthene dyes, for example, Eosin Y as a first chromophore and any one or more of Rose Bengal, Erythrosin, Phloxine B as a second chromophore. It is believed that these combinations have a synergistic effect as Eosin Y can transfer energy to Rose Bengal, Erythrosin or Phloxine B when activated. This transferred energy is then emitted as fluorescence or by production of reactive oxygen species. By means of synergistic effects of the chromophore combinations in the composition, chromophores which cannot normally be activated by an activating light (such as a blue light from an LED) can be activated through energy transfer from chromophores which are activated by the activating light. In this way, the different properties of photoactivated chromophores can be harnessed and tailored according to the cosmetic or the medical therapy required.

[0060] As discussed above, the photoactivating agent stimulates the oxygen-releasing agent in the composition to produce oxygen radicals. Bacteria are extremely sensitive to exposure to oxygen radicals, such that the production of oxygen radicals converts the composition into a bactericidal composition. Peroxide compounds are oxygen-releasing agents that contain the peroxy group (R-O-O-R), which is a chainlike structure containing two oxygen atoms, each of which is bonded to the other and a radical or some element. When a biophotonic composition of the present disclosure comprising an oxygen-releasing agent is illuminated with light, the chromophores are excited to a higher energy state. When the chromophores' electrons return to a lower energy state, they emit photons with a lower energy level, thus causing the emission of light of a longer wavelength (Stokes' shift). In the proper environment, some of this energy transfer is transferred to oxygen or the reactive hydrogen peroxide and causes the formation of oxygen radicals, such as singlet oxygen. The singlet oxygen and other reactive oxygen species generated by the activation of the biophotonic composition are thought to operate in a hormetic fashion. That is, a health beneficial effect that is brought about by the low exposure to a normally toxic stimuli (e.g. reactive oxygen), by stimulating and modulating stress response pathways in cells of the targeted tissues.

[0061] Endogenous response to exogenous generated free radicals (reactive oxygen species) is modulated

in increased defense capacity against the exogenous free radicals and induces acceleration of healing and regenerative processes. Furthermore, activation of the composition will also produce an antibacterial effect. The extreme sensitivity of bacteria to exposure to free radicals makes the composition of the present disclosure a de facto bactericidal composition.

[0062] Specific oxygen-releasing agents that are preferably used in the materials or methods of this disclosure include, but are not limited to, hydrogen peroxide, carbamide peroxide, or benzoyl peroxide.

[0063] Hydrogen peroxide (H_2O_2) is the starting material to prepare organic peroxides. H_2O_2 is a powerful oxidizing agent, and the unique property of hydrogen peroxide is that it breaks down into water and oxygen and does not form any persistent, toxic residual compound. Hydrogen peroxide for use in this composition can be used in a gel, for example with 6% hydrogen peroxide. A suitable range of concentration over which hydrogen peroxide can be used in the present composition is from about 0.1% to about 6%.

[0064] Urea hydrogen peroxide (also known as urea peroxide, carbamide peroxide or percarbamide) is soluble in water and contains approximately 35% hydrogen peroxide. Carbamide peroxide for use in this composition can be used as a gel, for example with 16% carbamide peroxide that represents 5.6 % hydrogen peroxide. A suitable range of concentration over which urea peroxide can be used in the present composition is from about 0.3% to about 16%. Urea peroxide breaks down to urea and hydrogen peroxide in a slow-release fashion that can be accelerated with heat or photochemical reactions. The released urea [carbamide, $(NH_2)_2CO$], is highly soluble in water and is a powerful protein denaturant. It increases solubility of some proteins and enhances rehydration of the skin and/or mucosa.

[0065] Benzoyl peroxide consists of two benzoyl groups (benzoic acid with the H of the carboxylic acid removed) joined by a peroxide group. It is found in treatments for acne, in concentrations varying from 2.5% to 10%. The released peroxide groups are effective at killing bacteria. Benzoyl peroxide also promotes skin turnover and clearing of pores, which further contributes to decreasing bacterial counts and reduce acne. Benzoyl peroxide breaks down to benzoic acid and oxygen upon contact with skin, neither of which is toxic. A suitable range of concentration over which benzoyl peroxide can be used in the present composition is from about 2.5% to about 5%.

[0066] In certain embodiments, the photoactivating agent may be incorporated in the matrix of the flexible fiber optic tip. In this way, the flexible fiber optic tip can be made to fluoresce on activation with a light. An oxygen-releasing agent may also be included within the matrix of the flexible fiber optic tip. The concentration of the photoactive agent to be used can be selected based on the desired intensity and duration of the biophotonic activity from the flexible fiber optic tip. For example, some

dyes such as xanthene dyes (e.g. Eosin Y and Fluorescein) reach a 'saturation concentration' after which further increases in concentration do not provide substantially higher emitted fluorescence. Further increasing the photoactive agent concentration above the saturation concentration can reduce the amount of activating light passing through the solid biophotonic. Therefore, if more fluorescence is required for a certain application than activating light, a high 'saturation' concentration of the photoactive agent can be used. However, if a balance is required between the emitted fluorescence and the activating light, a concentration close to or lower than the saturation concentration can be chosen.

[0067] It should be appreciated that the invention is not limited to the particular embodiments described and illustrated herein but includes all modifications and variations falling within the scope of the invention as defined in the appended claims.

Claims

1. A phototherapeutic device member, comprising:

a flexible fiber optic tip member having a core for transmitting light, the flexible tip member including a proximal end and a distal end, wherein the diameter of the proximal end is greater than the diameter of the distal end, and wherein the proximal end is curved to cause light entering the flexible tip member through the proximal end to converge; and
 an elastic tubular connector sleeve, for mechanically coupling the flexible tip member to a light source, wherein the sleeve includes a proximal end having an opening and a distal end having an opening, the proximal end configured to be stretched and mechanically coupled to the light source;
 wherein the flexible fiber optic tip member is partially disposed within the sleeve, such that the distal end of the flexible fiber optic tip member extends distally through the opening in the distal end of the sleeve, and the proximal end of the flexible fiber optic tip member is disposed within the sleeve and between the proximal and distal ends of the sleeve, thereby being configured to position the flexible fiber optic tip member near the light source.

2. The phototherapeutic device member of claim 1, wherein the flexible fiber optic tip member is unitarily formed.

3. The phototherapeutic device member of claim 2, wherein the flexible fiber optic tip member has a rough outer surface configured to allow a portion of light transmitted through the core to diffuse out

through the outer surface.

- 4. The phototherapeutic device member of any one of claims 1 to 3, wherein the flexible fiber optic tip member includes an optical axis extending through the center of the core from the proximal end to the distal end, and wherein light passing through the tip member travels along at least a portion of the optical axis.
- 5. The phototherapeutic device member of any one of claims 1 to 4, wherein the flexible fiber optic tip member core comprises a glass or a polymer.
- 10. The phototherapeutic device member of any one of claims 1 to 5, wherein a proximal region of the flexible fiber optic tip member is substantially conical having a base along the proximal end.
- 15. The phototherapeutic device member of any one of claims 1 to 6, wherein a distal region of the tip member is substantially cylindrical.
- 20. The phototherapeutic device member of any one of claims 1 to 7, wherein an interior surface of the elastic tubular connector sleeve includes a plurality of ribs extending radially inwards configured to grip the light source.
- 25. The phototherapeutic device member of any one of claims 1 to 8, wherein a length from the proximal end to a distal end of the flexible fiber optic tip member is between about 10 mm and about 30 mm and/or a diameter at the distal end of the flexible fiber optic tip member is between about 500 microns and about 1500 microns.
- 30. The phototherapeutic device member of claim 9, wherein the diameter varies along the length of the flexible fiber optic tip member.
- 35. The phototherapeutic device member of any one of claims 1 to 10, wherein the proximal end of the flexible fiber optic tip member is convex shaped relative to the proximal portion of the flexible fiber optic tip member.
- 40. The phototherapeutic device member of any one of claims 1 to 11, further comprising the light source and wherein the light source includes one or more light emitting diodes and/or includes a halogen lamp.
- 45. The phototherapeutic device member of any one of claims 1 to 12, wherein the flexible fiber optic tip member comprises a plurality of bristles at the distal end.
- 50. The phototherapeutic device member of any one of claims 1 to 13, wherein the flexible fiber optic tip

member comprises a photoactive agent.

Patentansprüche

1. Lichttherapeutisches Vorrichtungselement, das Folgendes umfasst:

ein flexibles faseroptisches Spitzenelement mit einem Kern zum Übertragen von Licht, wobei das flexible Spitzenelement ein proximales Ende und ein distales Ende einschließt, wobei der Durchmesser des proximalen Endes größer als der Durchmesser des distalen Endes ist und wobei das proximale Ende gebogen ist, um zu bewirken, dass sich Licht, das in das flexible Spitzenelement durch das proximale Ende eintritt, bündelt; und
eine elastische röhrenförmige Verbindungshülse zum mechanischen Koppeln des flexiblen Spitzenelements an eine Lichtquelle, wobei die Hülse ein proximales Ende mit einer Öffnung und ein distales Ende mit einer Öffnung einschließt, wobei das proximale Ende konfiguriert ist, um gedehnt und mechanisch an die Lichtquelle gekoppelt zu werden;
wobei das flexible faseroptische Spitzenelement teilweise innerhalb der Hülse angeordnet ist, sodass sich das distale Ende des flexiblen faseroptischen Spitzenelements distal durch die Öffnung im distalen Ende der Hülse erstreckt, und das proximale Ende des flexiblen faseroptischen Spitzenelements innerhalb der Hülse und zwischen dem proximalen und dem distalen Ende der Hülse angeordnet ist, wodurch es konfiguriert ist, um das flexible faseroptische Spitzenelement nahe der Lichtquelle zu positionieren.

2. Lichttherapeutisches Vorrichtungselement nach Anspruch 1, wobei das flexible faseroptische Spitzenelement einstückig ausgebildet ist.

3. Lichttherapeutisches Vorrichtungselement nach Anspruch 2, wobei das flexible faseroptische Spitzenelement eine rauere äußere Oberfläche aufweist, die konfiguriert ist, um einem Teil des durch den Kern übertragenen Lichts zu erlauben, durch die äußere Oberfläche auszutreten.

4. Lichttherapeutisches Vorrichtungselement nach einem der Ansprüche 1 bis 3, wobei das flexible faseroptische Spitzenelement eine optische Achse einschließt, die sich durch die Mitte des Kerns vom proximalen Ende zum distalen Ende erstreckt, und wobei Licht, das das Spitzenelement passiert, entlang mindestens eines Teils der optischen Achse wandert.

5. Lichttherapeutisches Vorrichtungselement nach einem der Ansprüche 1 bis 4, wobei der Kern des flexiblen faseroptischen Spitzenelements ein Glas oder ein Polymer umfasst.

6. Lichttherapeutisches Vorrichtungselement nach einem der Ansprüche 1 bis 5, wobei ein proximaler Bereich des flexiblen faseroptischen Spitzenelements im Wesentlichen konisch ist, wobei es eine Basis entlang des proximalen Endes aufweist.

7. Lichttherapeutisches Vorrichtungselement nach einem der Ansprüche 1 bis 6, wobei ein distaler Bereich des Spitzenelements im Wesentlichen zylindrisch ist.

8. Lichttherapeutisches Vorrichtungselement nach einem der Ansprüche 1 bis 7, wobei eine innere Oberfläche der elastischen röhrenförmigen Verbindungs hülse eine Vielzahl von sich radial nach innen erstreckenden Rippen einschließt, die konfiguriert sind, um die Lichtquelle zu ergreifen.

9. Lichttherapeutisches Vorrichtungselement nach einem der Ansprüche 1 bis 8, wobei eine Länge vom proximalen Ende zu einem distalen Ende des flexiblen faseroptischen Spitzenelements zwischen etwa 10 mm und etwa 30 mm beträgt und/oder ein Durchmesser am distalen Ende des flexiblen faseroptischen Spitzenelements zwischen etwa 500 Mikrometer und etwa 1500 Mikrometer beträgt.

10. Lichttherapeutisches Vorrichtungselement nach Anspruch 9, wobei der Durchmesser entlang der Länge des flexiblen faseroptischen Spitzenelements variiert.

11. Lichttherapeutisches Vorrichtungselement nach einem der Ansprüche 1 bis 10, wobei das proximale Ende des flexiblen faseroptischen Spitzenelements relativ zum proximalen Teil des flexiblen faseroptischen Spitzenelements konvex geformt ist.

12. Lichttherapeutisches Vorrichtungselement nach einem der Ansprüche 1 bis 11, das ferner die Lichtquelle umfasst und wobei die Lichtquelle eine oder mehrere Leuchtdioden und/oder eine Halogenleuchte einschließt.

13. Lichttherapeutisches Vorrichtungselement nach einem der Ansprüche 1 bis 12, wobei das flexible faseroptische Spitzenelement eine Vielzahl von Borten am distalen Ende umfasst.

14. Lichttherapeutisches Vorrichtungselement nach einem der Ansprüche 1 bis 13, wobei das flexible faseroptische Spitzenelement ein lichtaktives Mittel umfasst.

Revendications

1. Élément de dispositif de photothérapie, comprenant :

un élément de pointe de fibre optique flexible ayant un cœur pour transmettre de la lumière, l'élément de pointe flexible comprenant une extrémité proximale et une extrémité distale, dans lequel le diamètre de l'extrémité proximale est supérieur au diamètre de l'extrémité distale, et dans lequel l'extrémité proximale est incurvée pour converger la lumière entrant dans l'élément de pointe flexible à travers l'extrémité proximale ; et
 un manchon de connexion tubulaire élastique, pour le couplage mécanique de l'élément de pointe flexible à une source lumineuse, dans lequel le manchon comprend une extrémité proximale ayant une ouverture et une extrémité distale ayant une ouverture, l'extrémité proximale est configurée pour être étirée et mécaniquement couplée à la source lumineuse ;
 dans lequel l'élément de pointe de fibre optique flexible est partiellement placé à l'intérieur du manchon, de sorte que l'extrémité distale de l'élément de pointe de fibre optique flexible se prolonge distalement à travers l'ouverture dans l'extrémité distale du manchon, et l'extrémité proximale de l'élément de pointe de fibre optique flexible est placée à l'intérieur du manchon et entre les extrémités proximale et distale du manchon, où elle est configurée pour positionner l'élément de pointe de fibre optique flexible proche de la source lumineuse.

2. Élément de dispositif de photothérapie de la revendication 1, dans lequel l'élément de pointe de fibre optique flexible est formé de façon unitaire.

3. Élément de dispositif de photothérapie de la revendication 2, dans lequel l'élément de pointe de fibre optique flexible a une surface externe rugueuse configurée pour permettre la diffusion d'une partie de la lumière transmise à travers le cœur à travers la surface externe.

4. Élément de dispositif de photothérapie de l'une quelconque des revendications 1 à 3, dans lequel l'élément de pointe de fibre optique flexible comprend un axe optique se prolongeant à travers le centre du cœur à partir de l'extrémité proximale vers l'extrémité distale, et dans lequel la lumière passant à travers l'élément de pointe voyage le long d'au moins une partie de l'axe optique.

5. Élément de dispositif de photothérapie de l'une quelconque des revendications 1 à 4, dans lequel le

coeur de l'élément de pointe de fibre optique flexible comprend un verre ou un polymère.

6. Élément de dispositif de photothérapie de l'une quelconque des revendications 1 à 5, dans lequel une région proximale de l'élément de pointe de fibre optique flexible est sensiblement conique ayant une base le long de l'extrémité proximale.

10 7. Élément de dispositif de photothérapie de l'une quelconque des revendications 1 à 6, dans lequel une région distale de l'élément de pointe est sensiblement cylindrique.

15 8. Élément de dispositif de photothérapie de l'une quelconque des revendications 1 à 7, dans lequel la surface intérieure du manchon de connexion tubulaire élastique comprend une pluralité de nervures se prolongeant radialement vers l'intérieur et configurée pour agripper la source lumineuse.

20 9. Élément de dispositif de photothérapie de l'une quelconque des revendications 1 à 8, dans lequel une longueur de l'extrémité proximale par rapport à une extrémité distale de l'élément de pointe de fibre optique flexible se situe entre environ 10 mm et environ 30 mm et/ou un diamètre au niveau de l'extrémité distale de l'élément de pointe de fibre optique flexible se situe entre environ 500 microns et environ 1500 microns.

25 10. Élément de dispositif de photothérapie de la revendication 9, dans lequel le diamètre varie le long de la longueur de l'élément de pointe de fibre optique flexible.

30 11. Élément de dispositif de photothérapie de l'une quelconque des revendications 1 à 10, dans lequel l'extrémité proximale de l'élément de pointe de fibre optique flexible est de forme convexe par rapport à la partie proximale de l'élément de pointe de fibre optique flexible.

35 12. Élément de dispositif de photothérapie de l'une quelconque des revendications 1 à 11, comprenant également la source lumineuse et dans lequel la source lumineuse comprend une ou plusieurs diodes électroluminescentes et/ou comprend une lampe d'halogène.

40 13. Élément de dispositif de photothérapie de l'une quelconque des revendications 1 à 12, dans lequel l'élément de pointe de fibre optique flexible comprend une pluralité de soies au niveau de l'extrémité distale.

45 14. Élément de dispositif de photothérapie de l'une quelconque des revendications 1 à 13, dans lequel l'élé-

ment de pointe de fibre optique flexible comprend
un agent photoactif.

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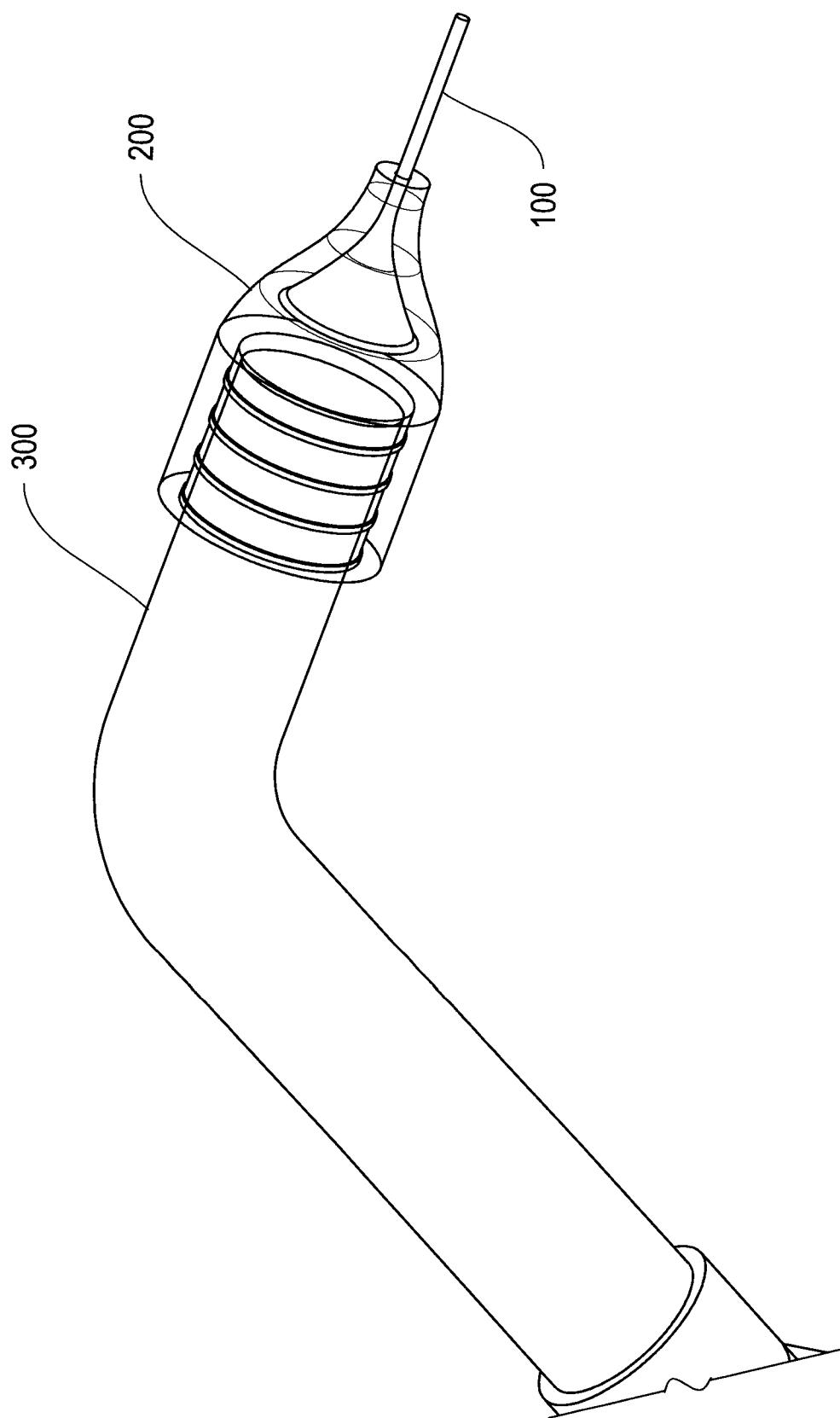


Figure 1

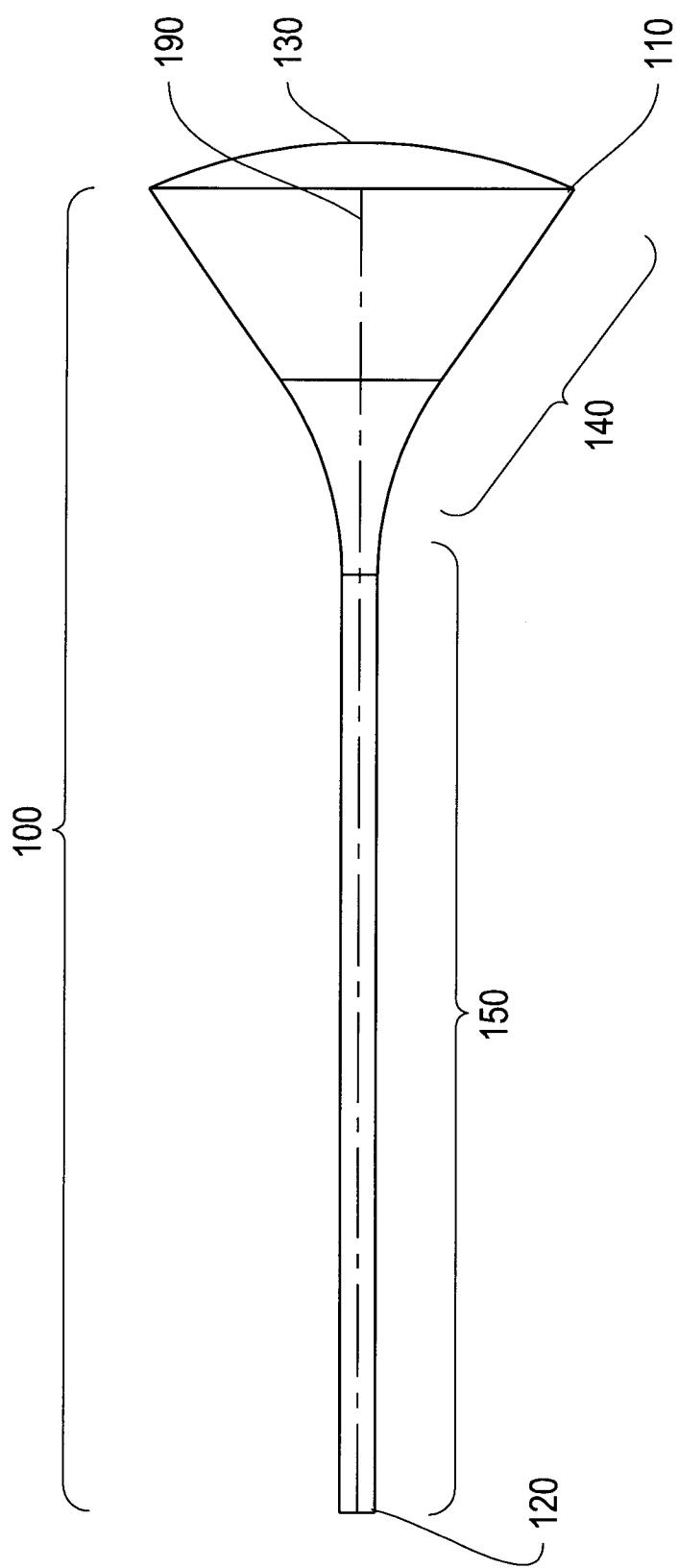
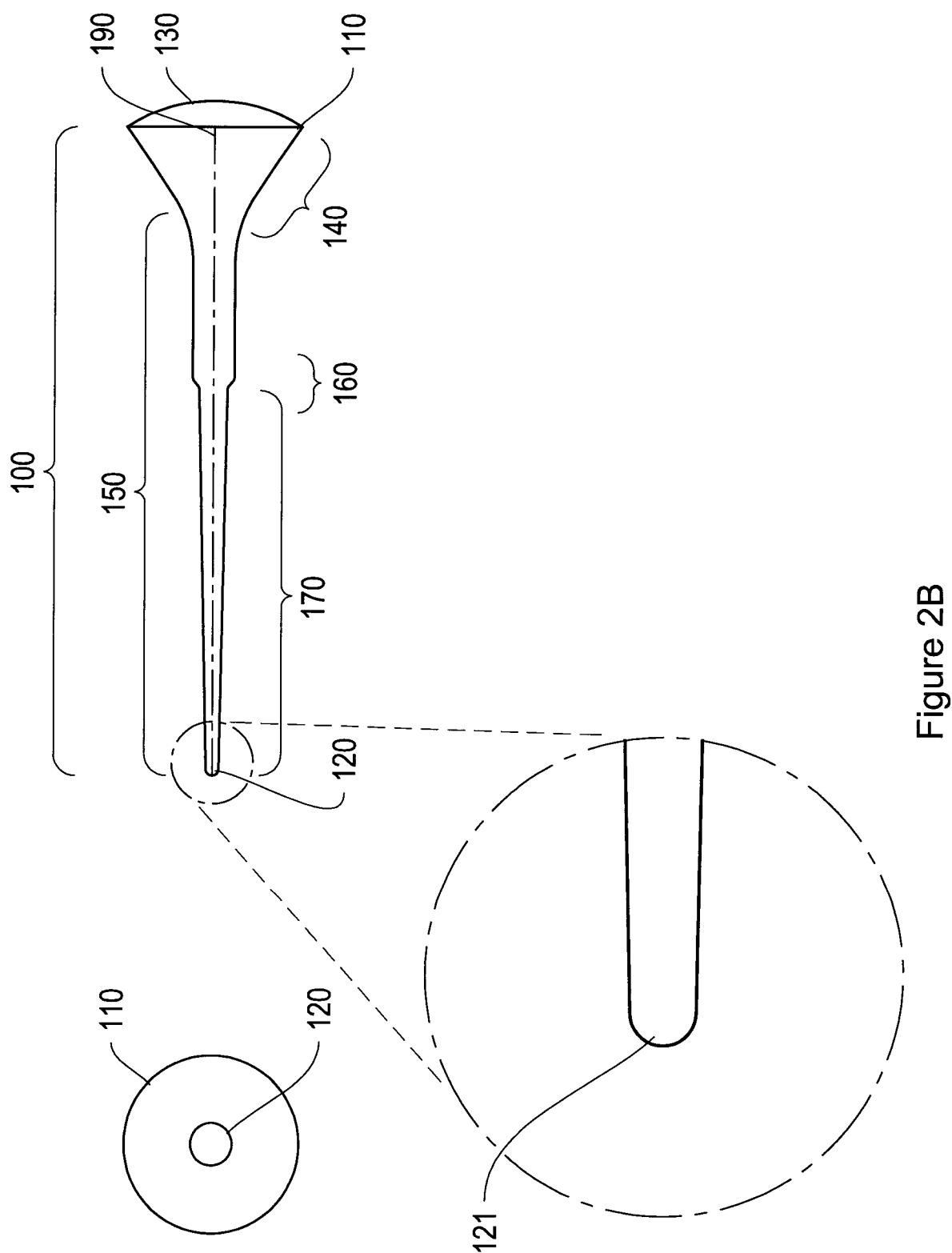


Figure 2A



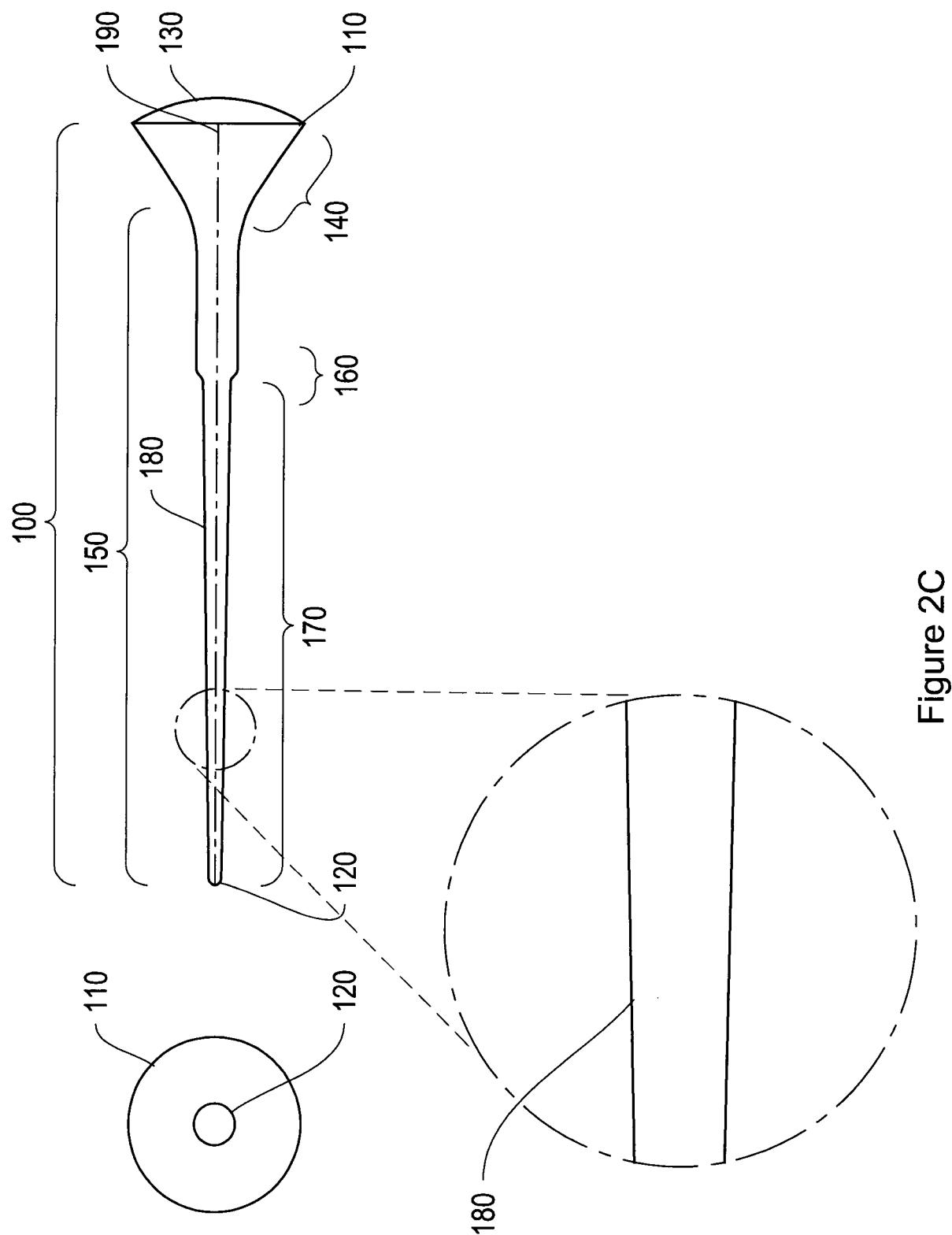
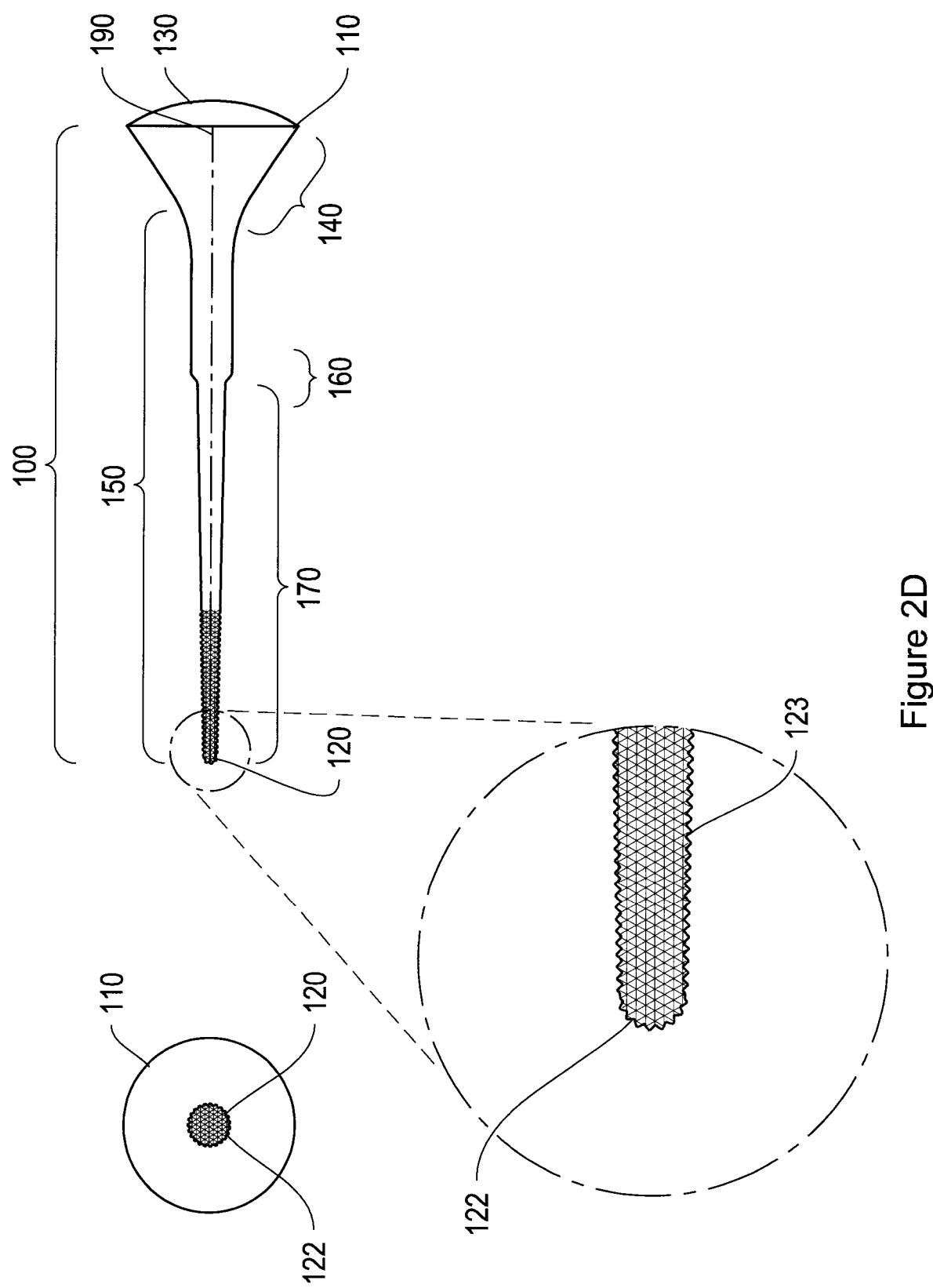


Figure 2C



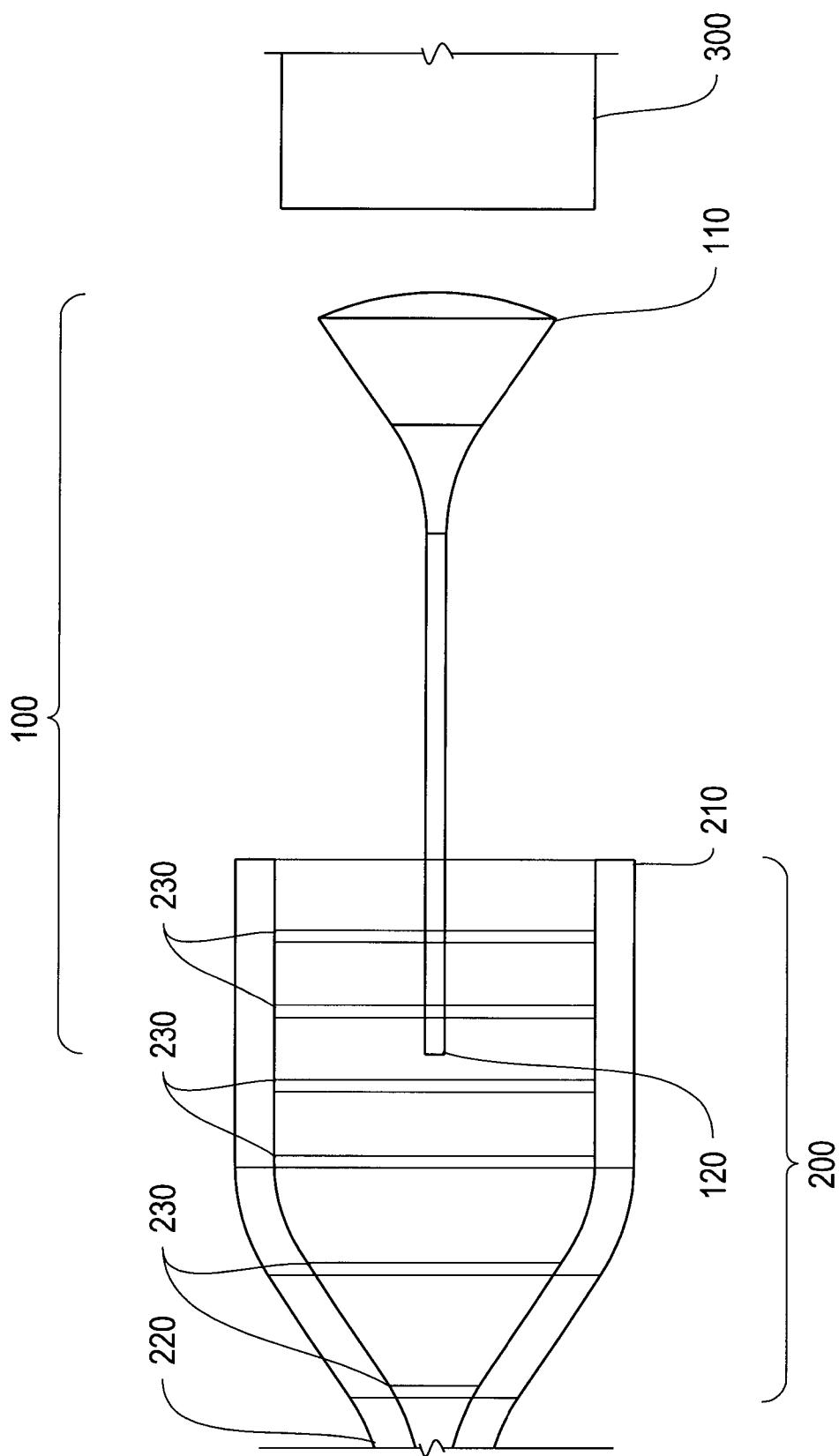


Figure 3A

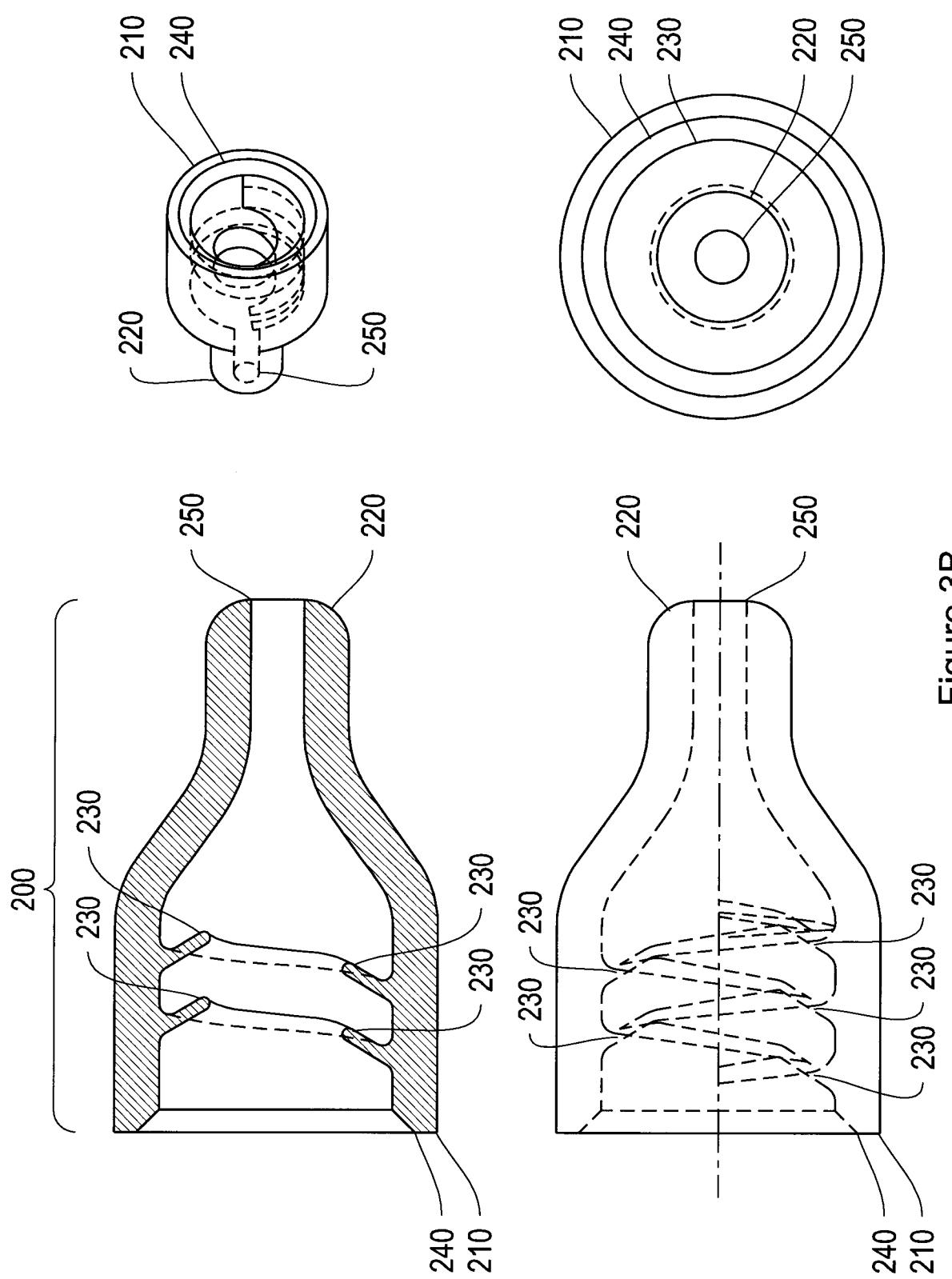


Figure 3B

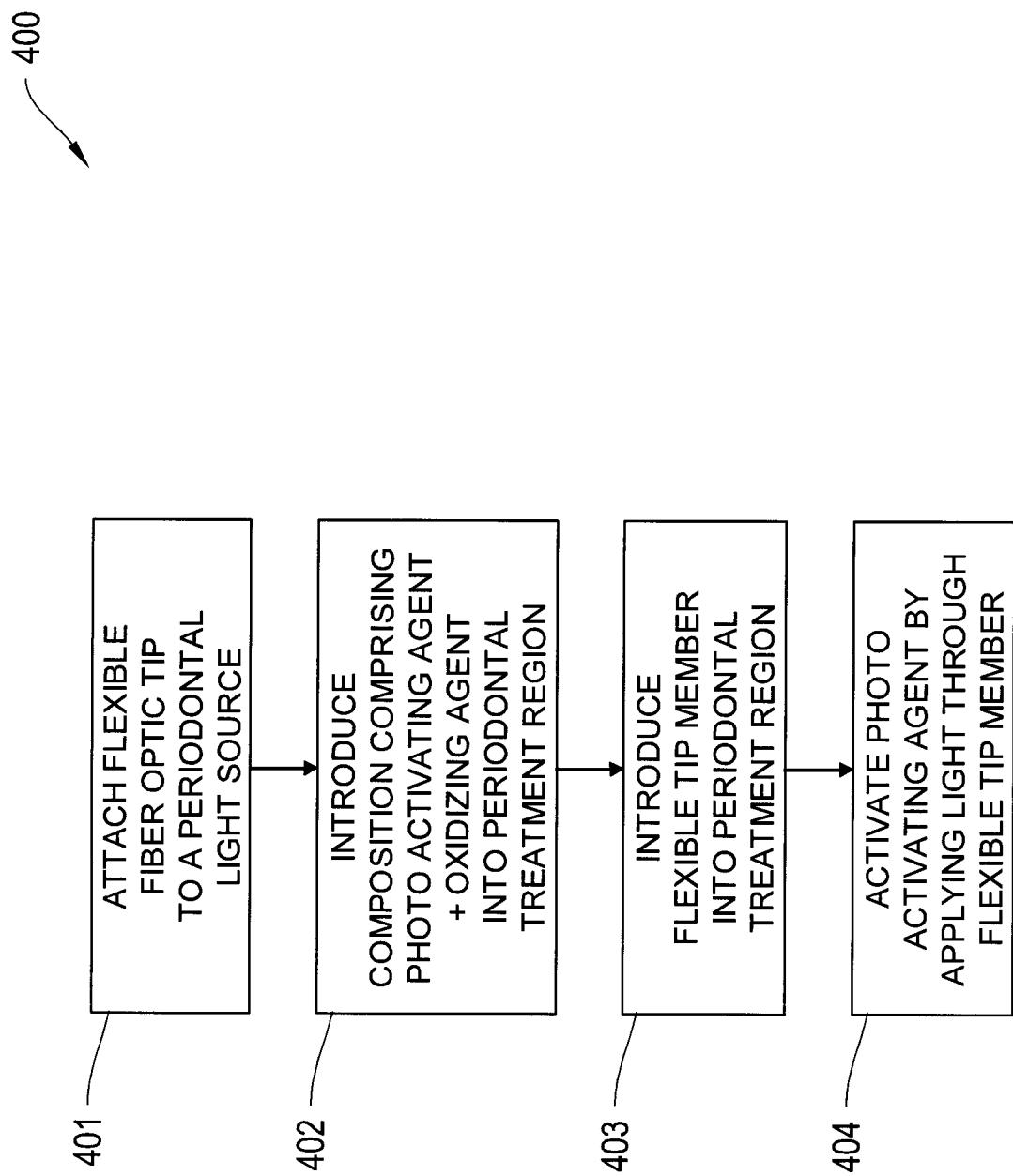


Figure 4

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO 2006115761 A1 [0001]

FÉNYGYÓGYÁSZATI KÉSZÜLKÉK

SZABADALMI IGÉNYPONTOK

1. Fénygyógyászati készülék-elem, amely tartalmaz:

egy hajlékony száloptika hegy-elemet, amelynek van egy fénytovábbításra szolgáló magja, amely hajlékony hegy-elem magában foglal egy proximális véget és egy disztális véget, a proximális vég átmérője nagyobb, mint a disztális vég átmérője, továbbá a proximális vég íveit a hajlékony hegy-elembe a proximális végen át belépő fény összetartásának előidézése céljából; valamint

egy rugalmas, csöves csatlakozó-hüvelyt a hajlékony hegy-elemnek egy fényforráshoz való mechanikus csatlakoztatására, amely hüvely magában foglal egy nyílással rendelkező proximális véget és egy nyílással rendelkező disztális véget, és a proximális vég úgy van kialakítva, hogy ki lehessen nyújtani és mechanikusan csatlakoztatni lehessen a fényforráshoz;

továbbá a hajlékony száloptika hegy-elem részben a hüvelyen belül van elhelyezve, úgyhogy a hajlékony száloptika hegy-elem disztális vége disztálisan kiterjed a hüvely disztális végében lévő nyíláson, és a hajlékony száloptika hegy-elem proximális vége a hüvelyen belül, valamint a hüvely proximális és disztális végei között van elhelyezve, miáltal úgy van kialakítva, hogy a hajlékony száloptika hegy-elemet a fényforrás közelében pozicionálja.

2. Az 1. igénypont szerinti fénygyógyászati készülék-elem, amelyben a hajlékony száloptika hegy-elem egységeként van kialakítva.

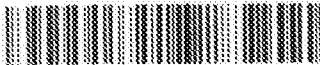
3. A 2. igénypont szerinti fénygyógyászati készülék-elem, amelyben a hajlékony száloptika hegy-elem külső felülete durva, és úgy van kialakítva, hogy lehetővé tegye a magon átbocsátott fény egy részének a külső felületen át történő diffundálását.

4. Az 1-3. igénypontok bármelyike szerinti fénygyógyászati készülék-elem, amelyben a hajlékony száloptika hegy-elem magában foglal egy, a proximális végétől a disztális végig, a mag középpontján át kiterjedő optikai tengelyt, és a hegy-elemen átmenő fény ennek az optikai tengelynek legalább egy része mentén halad.

5. Az 1-4. igénypontok bármelyike szerinti fénygyógyászati készülék-elem, amelyben a hajlékony száloptika hegy-elem magja üveget vagy polimert tartalmaz.

6. Az 1-5. igénypontok bármelyike szerinti fénygyógyászati készülék-elem, amelyben a hajlékony száloptika hegy-elem proximális régiója nagyjából kúp alakú, és a kúp alapja a proximális vég mentén van.

7. Az 1-6. igénypontok bármelyike szerinti fénygyógyászati készülék-elem,



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amelyben a hegy-elem disztális régiója nagyjából henger alakú.

8. Az 1-7. igénypontok bármelyike szerinti fénygyógyászati készülék-elem, amelyben a rugalmas, csöves csatlakozó-hüvely belső felülete magában foglal több, sugárírányban befelé kiterjedő bordát, amelyek a fényforrás befogására vannak kialakítva.

9. Az 1-8. igénypontok bármelyike szerinti fénygyógyászati készülék-elem, amelyben a hajlékony száloptika hegy-elemnek a proximális végétől a disztális végéig mért hosszúsága körülbelül 10 mm és körülbelül 30 mm között van, és/vagy a hajlékony száloptika hegy-elemnek a disztális végén mért átmérő körülbelül 500 mikron és körülbelül 1500 mikron között van.

10. A 9. igénypont szerinti fénygyógyászati készülék-elem, amelyben az átmérő a hajlékony száloptika hegy-elem hossza mentén változik.

11. Az 1-10. igénypontok bármelyike szerinti fénygyógyászati készülék-elem, amelyben a hajlékony száloptika hegy-elem proximális vége a hajlékony száloptika hegy-elem proximális részéhez képest domborúra van alakítva.

12. Az 1-11. igénypontok bármelyike szerinti fénygyógyászati készülék-elem, amely magában foglal továbbá egy fényforrást, amely fényforrás magában foglal egy vagy több fénykibocsátó diódát, és/vagy magában foglal egy halogén lámpát.

13. Az 1-12. igénypontok bármelyike szerinti fénygyógyászati készülék-elem, amelyben a hajlékony száloptika hegy-elem sörtek sokaságát tartalmazza a disztális végen.

14. Az 1-13. igénypontok bármelyike szerinti fénygyógyászati készülék-elem, amelyben a hajlékony száloptika hegy-elem fényérzékeny anyagot tartalmaz.