

(19) **DANMARK**

(10) **DK/EP 2967745 T3**



Patent- og
Varemærkestyrelsen

(12) **Oversættelse af
europæisk patentskrift**

-
- (51) Int.Cl.: **A 61 B 18/18 (2006.01)** **A 61 B 18/20 (2006.01)** **A 61 F 9/007 (2006.01)**
A 61 F 9/008 (2006.01)
- (45) Oversættelsen bekendtgjort den: **2020-11-16**
- (80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2020-09-23**
- (86) Europæisk ansøgning nr.: **14763812.6**
- (86) Europæisk indleveringsdag: **2014-03-14**
- (87) Den europæiske ansøgnings publiceringsdag: **2016-01-20**
- (86) International ansøgning nr.: **US2014029216**
- (87) Internationalt publikationsnr.: **WO2014144697**
- (30) Prioritet: **2013-03-15 US 201361798379 P**
- (84) Designerede stater: **AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR**
- (73) Patenthaver: **Hipsley, AnnMarie, 2941 Kent Road, Silver Lake, OH 44224, USA**
- (72) Opfinder: **Hipsley, AnnMarie, 2941 Kent Road, Silver Lake, OH 44224, USA**
- (74) Fuldmægtig i Danmark: **Zacco Denmark A/S, Arne Jacobsens Allé 15, 2300 København S, Danmark**
- (54) Benævnelse: **Systemer til påvirkning af de biomekaniske egenskaber af bindevæv**
- (56) Fremdragne publikationer:
EP-A2- 0 933 096
WO-A1-02/36029
WO-A1-03/041623
WO-A2-2006/099594
WO-A2-2007/134256
WO-A2-2011/163508
US-A1- 2006 133 433
US-A1- 2008 058 779
US-A1- 2012 029 489
US-A1- 2012 078 240
US-B1- 6 258 082
US-B2- 7 220 255
US-B2- 7 769 059
US-B2- 8 276 593
US-E1- R E42 998

DESCRIPTION

FIELD

[0001] The subject matter described herein relates generally to systems for affecting the biomechanical properties of connective tissue and more specifically, to systems for treating connective tissue to alter the fundamental and biomechanical properties of the connective tissue.

BACKGROUND

[0002] Connective tissue is tissue that supports and connects other tissues and parts of the body. The fundamental and biomechanical properties of connective tissue, such as scleral tissue of the eye, may change as it ages. These fundamental and biomechanical tissues have properties which include, but are not limited to, their structure, function, immunology, elasticity, shock absorption, resilience, mechanical dampening, pliability, stiffness, rigidity, configuration, alignment, deformation, mobility, volume, biochemistry and molecular genetics of connective tissue proper and newly metabolized connective tissue. The alterations of these properties may result in an accumulation of low grade stress/strain of the connective tissue. This can occur by acute injury or as a normal gradual process of aging. The alterations of these properties of connective tissue may change the overall desired properties of the connective tissue and may also undesirably affect the surrounding tissues, structures, organs, or systems related to the connective tissue. Examples of such undesirable affects are increased tension, loss of flexibility, contracture, fibrosis, or sclerosis, any of which can prevent the connective tissue or structures that are related to the connective tissue from performing their desired function.

[0003] Natural alterations in fundamental and biomechanical properties, specifically pliability and elasticity of the scleral tissue of the eye may affect the ability of the eye to focus. These alterations may be caused by disease or age-related changes to the tissue. These alterations of the scleral tissue may also contribute to an increase in intraocular pressure and to the loss of the contrast sensitivity of the eye or visual field of the eye. Biomechanical and structural alterations of the sclera may affect the refractive ability as well as the efficiency of the homeostatic functions of the eye such as intraocular pressure, aqueous production, pH, balance, vascular dynamics, metabolism and eye organ function. Furthermore, alterations of the scleral tissue may contribute to damage to the mechanoreceptors, photoreceptors, or sensory receptors in tissue layers and structures that are directly or indirectly related to the scleral tissue. Additionally, fundamental and biomechanical alterations of the scleral tissue may also be a contributing factor in the ability of the cerebral cortex to process accurate visual stimulus necessary for processing visual signals into accurate visual perception.

[0004] Presbyopia is a condition which affects focusing ability of the eye, especially in the elderly. Presbyopia is the loss of accommodation - the ability to focus through a range of near to far object. Some causes of presbyopia are considered to be a loss of elasticity in the crystalline lens and loss of strength in the ciliary muscles of the eye. Although naturally occurring, presbyopia affects a person's vision including increased eyestrain, visibility issues in low or dim lighting, and focusing problems on small objects. As such, presbyopia causes a loss of accommodation. A device for presbyopia treatments comprising an eye tracking system is described in publication US 2012/0029489 A1.

[0005] It is therefore desirable to provide improved systems and methods for altering the biomechanical properties of connective tissue having advantages not heretofore taught.

SUMMARY OF THE INVENTION

[0006] Systems for delivering ablative medical treatments to biological tissue to improve biomechanics of an eye are described herein that overcomes the limitations noted above. The invention is defined by the claims. Other described systems and methods are exemplary and do not constitute the embodiments of the invention.

[0007] In general a device for delivering medical treatments is disclosed which comprises a laser for generating a beam of laser radiation, a housing, a controller within the housing, in communication with the laser and operable to control the qualities of the beam of laser radiation in application to a target material, a lens operable to focus the beam of laser radiation onto a target material, and a power source operable to provide power to the laser and controller.

[0008] Other features and advantages of the present invention will become apparent from the following more detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the presently described invention.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[0009] Illustrated in the accompanying drawing(s) is at least one of the best mode embodiments of the present invention. In such drawing(s):

FIG. 1 illustrates an overview of a medical treatment system using a laser

FIG. 2 illustrates a laser treatment system ;

FIG. 3 illustrates a laser treatment system ;

FIG. 3A illustrates a laser treatment system ;

FIG. 3B illustrates a laser treatment system ;

FIG. 3C illustrates a camera correction system ;

FIG. 3D illustrates a flow diagram of a camera-based eye tracker process ;

FIG. 3E illustrates a flow diagram for a laser ablation procedure ;

FIG. 4 illustrates a laser treatment system ;

FIG. 4A illustrates a laser treatment system including ablation pore depth ;

FIG. 4B illustrates a flow diagram of OCT-based depth control ;

FIG. 5A illustrates a laser treatment system lens placement ;

FIG. 5B illustrates a laser treatment system lens placement ;

FIG. 5C illustrates a laser treatment system lens placement ;

FIG. 6 illustrates a laser treatment system component map showing relation of related subsystems ;

FIG. 7 illustrates a laser treatment system;

FIG. 8 illustrates an eye treatment map ;

FIG. 9 illustrates a front view of an pore matrix ;

FIG. 10 illustrates a front view of pore matrices ;

FIG. 11 illustrates a rear view of an pore matrix ;

FIG. 12 illustrates a pore matrix ;

FIG. 13 illustrates a pore matrix ;

FIG. 14 illustrates a pore matrix ;

FIG. 15 illustrates a pore matrix ;

FIG. 16 illustrates a pore matrix depth ;

FIG. 17 illustrates a pore matrix depth ;

FIG. 18 illustrates a pore matrix ;

FIG. 19 illustrates a pore matrix ;

FIG. 20 illustrates a pore matrix in spiral form according to an embodiment of the present invention;

FIG. 21 illustrates a pore matrix in spiral form according to an embodiment of the present invention;

FIG. 22 illustrates a pore matrix in concentric circular form ; and

FIG. 23 illustrates a pore matrix in interspersed circular form .

FIG. 24A illustrates an accommodated and a dis-accommodated eye in showing muscle movement of the eye.

FIG. 24B illustrates the three parts of ciliary muscle and their relation to one another in the eye.

FIG. 24C shows contraction of ciliary muscle and its effect on the eye.

FIG. 25 shows a configuration where the beam delivery system scans over the eye in a "goniometric" motion.

FIG. 26 shows an isotropic linearly elastic material subjected to tension along the x axis with a Poisson's ratio of 0.5. The cube is unstrained while the rectangle is expanded in the x direction due to tension and contracted in the y and z directions.

DETAILED DESCRIPTION

[0010] The above described figures illustrate the described invention in at least one of its preferred, best mode embodiments, which is further defined in detail in the following description. Those having ordinary skill in the art may be able to make alterations and modifications to what is described herein without departing from its scope. While this invention is susceptible to embodiment in many different forms, there is shown in the drawings and will herein be described in detail a preferred embodiment of the invention with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the broad aspect of the invention to the embodiment illustrated. Therefore, it should be understood that what is illustrated is set forth only for the purposes of example and should not be taken as a limitation on the scope of the present invention, since the scope of the present disclosure will be limited only by the appended claims.

[0011] As used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

[0012] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present disclosure is not entitled to antedate such publication by virtue of prior disclosure. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[0013] It should be noted that all features, elements, components, functions, and steps described with respect to any embodiment provided herein are intended to be freely combinable and substitutable with those from any other embodiment. If a certain feature, element, component, function, or step is described with respect to only one embodiment, then it should be understood that that feature, element, component, function, or step can be used with every other embodiment described herein unless explicitly stated otherwise. This paragraph therefore serves as antecedent basis and written support for the introduction of claims, at any time, that combine features, elements, components, functions, and steps from different embodiments, or that substitute features, elements, components, functions, and steps from one embodiment with those of another, even if the following description does not explicitly state, in a particular instance, that such combinations or substitutions are possible. It is explicitly acknowledged that express recitation of every possible combination and substitution is overly burdensome, especially given that the permissibility of each and every such combination and substitution will be readily recognized by those of ordinary skill in the art.

[0014] In general, as discussed above, the fundamental and biomechanical properties of connective tissue, such as scleral tissue of the eye, may change over time. These fundamental and biomechanical tissues have properties which include, but are not limited to, their structure, function, immunology, elasticity, shock absorption, resilience, mechanical dampening, pliability, stiffness, rigidity, resilience, configuration, alignment, deformation, mobility, volume, biochemistry and molecular genetics of connective tissue proper and newly metabolized connective tissue. The alterations of these properties may result in an accumulation of low grade stress/strain of the connective tissue. This can occur by acute injury or as a normal gradual process of aging. The alterations of these properties of connective tissue may change the overall desired properties of the connective tissue and may also undesirably affect the surrounding tissues, structures, organs, or systems related to the connective tissue. Examples of such undesirable affects are increased tension, loss of flexibility or resilience, along with contracture, fibrosis, or sclerosis, any of which can prevent the connective tissue or structures that are related to the connective tissue from performing their desired function.

[0015] For example, in the human eye, natural alterations in fundamental and biomechanical properties, specifically resilience, pliability and elasticity of the scleral tissue of the eye may affect the ability of the eye to focus. The sclera is the outer layer of the eye and contains collagen and elastic fiber. It is commonly referred to as the "white of the eye" and is opaque and protects the eye. These alterations may affect the ability of the ciliary muscles and complexes to exert forces on the crystalline lens to affect central optical power (COP). These alterations of the scleral tissue may also contribute to an increase in intraocular pressure and to the loss of the contrast sensitivity of the eye or visual field of the eye. Biomechanical and structural alterations of the sclera may affect the refractive ability as well as the efficiency of the homeostatic functions of the eye such as intraocular pressure, aqueous production, pH, balance, vascular dynamics, metabolism and eye organ function. Furthermore, alterations of the scleral tissue may contribute to damage to the mechanoreceptors, photoreceptors, or sensory receptors in tissue layers and structures that are directly or indirectly related to the scleral tissue. Additionally, fundamental and biomechanical alterations of the scleral tissue may

also be a contributing factor in the ability of the cerebral cortex to process accurate visual stimulus necessary for processing visual signals into accurate visual perception.

[0016] The connective tissue may be any desired connective tissue. For example, in the eye, the pore matrix may be applied to the conjunctiva; the cornea (including all its layers and membranes); the iris; the ciliary body; the ciliary muscles; the anterior chamber; the zonula ciliaris; the subchoroidal lamina; the zonular ligaments, the lens capsule, the extraocular muscles and their associated connective tissues, membranes, and fascia; the posterior chamber; the lens and all of its associated layers, tissues, capsules, and membranes; the canal of schlemm, the trabecular meshwork and all of its associated layers, tissues, capsules, and membranes; the ora serrata; the vitreous body; the papilla nervi optici; the optic nerve; the lamina cribrosa; the choroid; the sclera; the vitreous and associated membranes; the retina; all epithelial cell layers in the eye; the vascular structures in the eye; the accessory organs of the eye; and the lymph vessels of the eye and even the lamina cribrosa bony structure surrounding the optic nerve head of the eye.

[0017] The present disclosure described herein relates to the creation of one or more matrices of pores in the aged connective tissue so as to restore the lost biomechanical properties of the connective tissue. Such restorations include but are not limited to increase in elasticity, resilience, shock absorption, pliability, structural integrity and/or mobility, optimal organ or system function. The pores (or perforations) may be formed via laser ablation or other similar means, and may be maintained in the connective tissue via the use of a healing inhibitor. Preferably, the matrices are formed in the scleral tissue of the eye. However, it will be appreciated that the present disclosure may be applied to other connective or non-connective tissue as the case may be where application of the one or more matrices restores lost biomechanical properties to the tissue. In at least some embodiments, as will be explained further herein, the one or more matrices may form a tessellated pattern of pores in the connective tissue. In at least one embodiment, the at least one matrices comprises at least one of: anisotropic patterns, fractal patterns, random nano-patterns, or any other patterns now known or hereinafter developed that may alter the properties of the connective tissue to improve the biomechanics thereof.

[0018] The relationship between the plurality of matrices to one another in a plurality of planes which creates a change in biomechanical properties affecting the tissue resilience, pliability and preferably the viscoelastic properties of the aged connective tissue and creates "negative stiffness". More physically explained, the connective tissue biomechanical properties are changed in a specific and unique manner by the matrices which create tissue resilience. A second biomechanical effect of the application of these plurality of matrices is that the tissue properties has have a specific effect on the Poisson ratio - i.e. are changed to a value of negative Poisson ratio. The Poisson ratio (PR) is a fundamental mechanical parameter that approximates the ratio of relative change in cross sectional area to tensile elongation. A third biomechanical effect of the application of these plurality of matrices is that the physical and biomechanical changes have a remodeling effect on the connective tissue. A fourth biomechanical effect of the application of the plurality of matrices is that the physical and

biomechanical property changes have a negative Poisson's ratio structure with mechanical isotropy in a minimum of two dimensions. When subjected to positive strain in a longitudinal axis, the transverse strain in the material may actually be positive (i.e. it would increase the cross sectional area).

Laser Surgery System

[0019] A surgical laser system 102 for treating connective tissue according to at least one preferred embodiment will now be discussed with particular reference to Figures 1-15.

[0020] As illustrated for example in Figure 1, the laser system 102 may be used to remove scleral tissue by ablating the scleral tissue to form perforations therein. Normal tissue healing may be at least partially affected to maintain the perforations or pores in the scleral tissue. In other words, forming the perforations may inhibit, disrupt, restrict, or otherwise cause the tissue to deviate from healing, repairing, or regenerating in a manner conforming to the usual or ordinary course of nature, producing observable deficiencies therein.

[0021] The surgical laser system 102 includes a laser head 106 coupled to one end of a connector such as a laser delivery fiber 120, the opposite end of which is connected to a delivery apparatus such as a hand piece 130.

[0022] The laser delivery fiber 120 delivers laser energy from the laser emitter to the hand piece 130. The laser delivery fiber may be of any desired construction that transfers laser energy from the laser to the hand piece 130. In some embodiments the laser delivery fiber 120 may be a fiber optic assembly. In other embodiments a collimated arm system or an atomized particle beam may be used in lieu of delivery fiber 120, as known in the art. The connector may deliver energy through an optical pumped assembly or a fiber to fiber assembly.

[0023] Laser 202 may be any desired laser. For example, the laser may be a gas type laser (e.g. argon, krypton, CO₂, HeNe, Nitrogen, etc.), an excimer type laser (e.g. ArF, KF, KCl, etc.), a solid state type laser (e.g. glass (e.g. fiber optic) crystal (e.g. ruby, YAG, YLF, GSSG, etc.), dopant (e.g.. neodymium, erbium, holmium ytterbium, thulium, chromium, etc.)), a diode type laser, a metal vapor type laser (e.g. Cu, Ag, etc.), or a dye type laser. Preferred wavelengths may range from 193 nanometers to 10,600 nanometers. The laser may also be a continuous wave, long pulse, q-switched, or mode locked laser.

[0024] In a preferred embodiment, laser 202 has a wavelength of about 2.94 μm . In some embodiments a CO₂ laser with a 10.6 micron wavelength may be used. In some embodiments a Ho:YAG laser with a 2.1 micron wavelength may be used.

[0025] In at least one embodiment, the pulse width of laser 202 may be approximately 250 μs . In some embodiments "Long Pulse" lasers are used with pulse widths in the hundreds of microseconds range. In some embodiments Q-switched lasers with pulse widths in the ten to

one hundred nanosecond range are used. In some embodiments Mode-locked lasers with pulse widths in the tens to hundreds of picoseconds are used. In some embodiments ultrafast lasers with pulse widths in the tens to hundreds of femtoseconds are used. In at least one embodiment, the repetition rate may range from 3 to 50 pps, preferably selected from 3, 10, 15, 20, 25, 30, 40 and 50 pps. In some embodiments, the repetition rate may range from hundreds of hertz to tens of kilohertz. Exemplary lasers are described in the materials appended hereto.

[0026] Spatial mode structure in embodiments of the invention herein may be varied. In some embodiments single mode Gaussian spatial mode may be used. In other embodiments multi-spatial mode lasers may be used.

[0027] Energy distribution from lasers according to embodiments of the invention may in some embodiments be Gaussian and in some embodiments flat-top.

[0028] As shown for example in Figure 2, the delivery system may be configured to direct the laser energy along a path from a beam input location 204 to a beam output location 216. This may be accomplished, inter alia, via a series of mirrors and/or lenses 204, 208, 210, 212, 214, 216 configured to direct the laser energy. The series of mirrors and/or lenses may be adjustable either manually, or automatically so as to direct the laser energy to one or more desired locations.

[0029] The delivery system may further be configured to focus the laser energy onto the scleral tissue 140. This may be accomplished, inter alia, via a series of mirrors and/or lenses 204, 208, 210, 212, 214, 216 configured to focus the laser energy. The series of mirrors and/or lenses 204, 208, 210, 212, 214, 216 may be adjustable either manually, or automatically so as to focus the laser energy to one or more desired locations.

[0030] The delivery system may also include an image platform, a viewing platform, a slit lamp, a microscope, or a viewscope 150.

[0031] The delivery system 200 may further be configured to cause the laser energy to form the pore matrix in the scleral tissue.

[0032] In at least one embodiment, the delivery system comprises a hand piece 130 configured to apply the laser energy in the pore matrix over the tissue. Such application is automatic.

[0033] In some embodiments, the delivery system comprises a scanning mechanism or system (such as eye tracker 304 in FIG. 4) configured to move the laser energy in the pore matrix over the tissue. This is an automated process. For example, in at least one embodiment, the delivery system comprises a 2D or 3D galvano-scanning system configured to move the laser energy in a desired pattern over the tissue. The scanning system may also include a reverse imagery device and software platform. As discussed further herein, the

scanning mechanism or system directs the laser ablation beam from pore to pore during formation of the pore matrix. Conversely, as also discussed herein, the tracking mechanism maintains the relative positioning of the scanning system and the target tissue stable. The tracking system is communicatively coupled to the scanning system for at least that reason.

[0034] In at least one embodiment, the delivery system comprises a mask configured to apply the laser energy in the pore matrix over the tissue. For example, the mask may selectively permit laser energy to reach the scleral tissue.

[0035] In some embodiments a mask or film may incorporate a biological, chemical, electrical, ion, or other sensor in order to control numerous parameters of laser beam function and homogenization. In some embodiments a sensor can be incorporated into a mask, film or galvo-optic assembly to control the gain medium and bandwidth function of the laser beam. In other words, in some embodiments, the scanning system includes a biofeedback control loop. The biofeedback loop provides real-time feedback about the characteristics of the irradiated tissue, such as thickness, topography, focus, hydration, etc. In at least one embodiment, the laser beam used to irradiate the tissue is measured to give this feedback and is adjusted based on the real-time tissue characteristics.

[0036] In at least one embodiment, the laser and delivery system is an Ytterbium Fiber to Fiber system (such as in FIG. 1, element 120) that does not require a crystal. In at least one embodiment, laser 202 has an amplifier that is either in the body piece, the head piece, or remote hand piece 130.

[0037] It is important to note, that none of the aforementioned features or embodiments are intended as being mutually exclusive and all combinations thereof are specifically contemplated. For example, the delivery system may comprise hand piece 130 having a scanning mechanism therein to be used in conjunction with a mask.

[0038] Turning to FIG. 1, a medical treatment system 100 using a laser system 102 is shown that may be used in performing the methods later described

[0039] In the example embodiment, medical treatment system 100 broadly requires the use of laser system 102 which delivers a laser beam via laser delivery fiber 120 to hand piece 130 and then to patient (also referred to herein as patient's eye) 140. Operator 160 controls laser system 102 via foot pedal 114 and laser beam via hand piece 130 and monitors progress of a medical procedure via surgical microscope 150.

[0040] In the example embodiment laser system 102 is comprised of various components including system control electronics 104, laser head 106, laser cooling system 108, HV power supply 110, and system power supplies 112.

[0041] In some embodiments laser cooling system 108 is a water cooling system. In some embodiments laser cooling system 108 may be an air or chemical substrate. Also included may

be a user interface button and LED panel including status indicators such as on, off, standby, or others. An interface exists between laser system 102 and delivery fiber 120.

[0042] In the example embodiment laser system 102 creates a laser beam that has an operational wavelength of 2.94 microns and typical pulse repetition frequency of 10-50Hz. The laser pulsewidth is typically 250 microseconds.

[0043] Laser system 102 is coupled to hand piece 130 held by operator 160 via a fiber optic cable. To transmit mid-infrared light, the fiber material is a chalcogenide glass. It could be made from germanium or ZBLAN. Alternatively, the fiber could be a hollow core fiber, a photonic crystal fiber, or a double- or multi-clad fiber. Fiber core diameter is about 400 microns, but could range from single mode to 600 microns diameter.

[0044] Hand piece 130 interfaces at the proximal end to the fiber cable and couples the light via focusing optics to a waveguide tip. This tip can be composed of amorphous glass or crystalline material, such as quartz or sapphire. The diameter of the tip may range from 100 to 600 microns and may be straight or bent at an angle. The end of the tip may be polished or cleaved flat or may be angled or rounded. The tip of hand piece 130 is positioned in close proximity to the tissue to be treated.

[0045] Hand piece 130 may be passive or active. An active hand piece 130 may communicate in some way with laser control system 102 to activate/deactivate the laser beam, or to change other laser parameters (e.g. pulsewidth, repetition frequency, or pulse energy).

[0046] An alternative configuration for hand piece 130 is to contain the actual laser crystal and cavity. Semiconductor diodes are used rather than flashlamps to pump the laser crystal and the diode optical energy is delivered to the laser crystal in handpiece 130 via fiber optics as disclosed in associated reference patent Shen, US 6,458,120.

[0047] In some embodiments a hands-free system may be used in place of hand piece 130. In some embodiments a slit lamp interface may be used to monitor or perform procedures. In some embodiments a supine interface may be used as is common in some laser eye surgery procedures.

[0048] In the example embodiment surgical microscope 150 is used to provide magnification of the treatment area for operator 160 to guide treatment. In other embodiments surgical microscope 150 may be another viewing apparatus that provides magnification or other vision of the treatment area.

[0049] Physician or operator 160 may interface with the system in numerous manners in the various embodiments of the invention. Some embodiments include a touchscreen video monitor. Other embodiments include a video monitor without touchscreen capabilities. Some embodiments allow for the use of a keyboard and mouse, hand activated switch, additional foot pedals, virtual reality or three-dimensional goggles, remote interaction capabilities, stereo

surgical microscopes, or other related equipment.

[0050] In some embodiments a laser crystal is disposed between two reflective surfaces and these help form a laser beam. In some embodiments the laser crystal is a rod crystal or a thin disk crystal. An aperture member may be positioned between the laser crystal and one of the reflective surfaces may include a substantially circular aperture for passing the laser beam. In many embodiments the size of the aperture is selectively adjustable. The aperture member may have a plurality of apertures of various different sizes and is rotatable about an axis of rotation. The axis of rotation may be parallel to the longitudinal axis of the laser crystal. By appropriately rotating the aperture member, a selected one of the apertures may be positioned to pass the laser beam. In some embodiments, an aperture is used to adjust the laser beam size. The aperture is located outside the laser cavity. The aperture is located relatively close to irradiation surface. In such embodiments, the laser is preferably a handheld probe diode laser pump crystal.

[0051] In some embodiments a stepper motor and flexible shaft are utilized for rotating the aperture member. At least one of the apertures may be surrounded by a beveled portion of the rotatable member.

[0052] In some embodiments, two lasers with different size fixed apertures may be utilized and directed to a common surface. According to an aspect of the invention, an articulated arm is provided in some embodiments along with one or more refocussing optics for refocussing the laser beam as it travels through the arm.

[0053] In some embodiments, the laser source is provided along with a galvanometer for directing each of two laser beams to a surface to be treated. Such an arrangement may provide additional versatility and control.

[0054] In some embodiments, the laser source is provided along a fiberoptic along with a hand piece and one or more focusing optics or tips. According to another aspect, a fourth laser source is provided with a semiconductor disk.

[0055] For broad wavelength tuning and for ultrashort pulse generation, other ytterbium-doped gain media may offer a wider gain bandwidth. Examples are tungstate crystals (Yb:KGW, Yb:KYW, Yb:KLuW), Yb:LaSc₃(BO₃)₄ (Yb:LSB), Yb:CaGdAlO₄ (Yb:CALGO) and Yb:YVO₄. Particularly promising are novel sesquioxide materials such as Yb:Sc₂O₃, Yb:Lu₂O₃ and Yb:Y₂O₃, having excellent thermo-mechanical properties and a potential for very high output powers and high efficiencies. A slope efficiency of 80% has been demonstrated with Yb:Lu₂O₃.

[0056] Nd:YAG or Nd:YVO₄ may also be used in thin-disk lasers, e.g. when a wavelength of 1064 nm is required, or when the much smaller saturation energy of Nd:YV₀4 is relevant. Generally, a high doping concentration is desirable for thin-disk gain media. This allows one to use a rather thin disk (and thus to minimize thermal effects) without arranging for too many passes of the pump radiation. Most ytterbium doped gain media are quite favorable in this

respect.

[0057] According to another aspect a fifth laser source is provided with an apparatus wherein said apparatus is part of a stand-alone semiconductor wafer edge-processing system or is a fiberoptic assembly is integrated into a module for use in a semiconductor wafer edge-processing system. A unique light amplifier platform to be adapted for laser marking and engraving is found in Ytterbium fiber amplifiers.

[0058] In some embodiments the fiber to fiber laser system (such as shown in FIG. 1) comprising of a clad fiber pumping technique creates coherence in the beam structure that closely approaches a Gaussian beam intensity profile. A method of ablating biological tissue with a laser system comprising of a Ytterbium fiber-to-fiber solid state laser wherein the optical fiber itself is the lasing medium and which contains no laser crystal or intra-cavity optics near the galvo assembly and the entire beam steering/galvo mount assembly is reduced to a compact module.

[0059] In some embodiments the assembly is a true solid-state design and comprises of a pumping chamber optics which is grown into the active fiber assembly including a built-in ability of the system to automatically monitor the output power of the laser source through a self-calibrating feature which constantly provides minute feedback, keeping the output power constant regardless of variations in incoming voltage or any possible slight degradation of the individual diodes.

[0060] In some embodiments, the small package size of the fiber-to-fiber laser allows positioning of the beam in almost any angle, giving an almost unlimited angle spatial treatment area.

[0061] In some embodiments, the preferred wavelength of the near-infrared frequency of Ytterbium fiber at 1060 nm which can be doubled, tripled or quadrupled. Preferably in this invention the 2940nm wavelength parameter is presented.

[0062] In some embodiments, the laser system comprises a built-in power monitoring feedback circuits as is known in the art.

[0063] In some embodiments the basic laser system is an all fiber format that allows adjustment of pulse energy and/or change pulse repetition rate without affecting any of the output beam parameters.

[0064] In some embodiments the basic laser system features a single mode M-squared of <1.2 . M-squared is a beam quality metric indicating how close the laser beam is to a true Gaussian beam.

[0065] Provided herein is a method of ablating biological tissue in which the laser source is a single-frequency, broadly-tunable mid-IR laser.

[0066] In some embodiments the laser beam may be positioned with sub-nanometer accuracy. This may be accomplished with an automated, high resolution, resonant probe AFM instrument that can be connected to a closed loop nano-positioning system. In some embodiments three axis nano-positioning systems with 100, 200, and 300 micron ranges of motion are provided in all three axes.

[0067] Other components may be provided in some embodiments including laser components such as a sensor preamplifier, an Akiyama probe, a mounting board, and/or a closed loop nano servo controller.

[0068] Turning to FIG. 2, an embodiment of a medical treatment system is shown using a laser treatment system 200 according to an embodiment of the present invention.

[0069] In the example embodiment, a hands-free laser treatment system 200 consists of a treatment laser 202 emitting a laser beam which travels through relay lens 204 to dichroic or flip-in 208. Treatment laser 202 is coupled to the system either via a fiber optic, a hollow waveguide, or free space propagation. For free space propagation, the laser beam may be manipulated with fixed mirrors or prisms, or mirrors or prisms on an articulating arm. One or more lenses are used to collimate and/or change the size of and/or image the laser beam. Additional transport optics may be used to control the beam as it is brought to the focusing optics.

[0070] In some embodiments active steering elements change the angle of the beam into the focusing subsystem to scan the focus spot over an area of tissue. These active elements can be galvo, voice coil, DC motor, stepper motor, piezo-driven or MEMS mirrors. Alternatively, the steering elements could be refractive or diffractive elements, such as Risley prisms or an electro-, magneto-, or acousto-optic modulators. These are alternatively referred to herein as a scanning system.

[0071] In the example embodiment, the beam or beams leave dichroic or flip-in 208 and travels to Galvo 1 210. Galvo 1 210 may consist of a mirror which rotates through a galvanometer set-up in order to move a laser beam. The beam or beams leave Galvo 1 210 and travel to Galvo2 212 which may be a similar setup to Galvo 1 210. The beam or beams leave Galvo2 212 and travel to dichroic (visible/IR) 214. Operator 160 may monitor the beam or beams at dichroic (visible/IR) 214 by using a surgical microscope 150. The beam or beams travel from dichroic (visible/IR) 214 through focusing optics 216 to patient eye 140.

[0072] In some embodiments the tracking system further includes a 3D image stabilization system for microscopy is provided, capable of controlling temperature gradients, sample drift, and microscope drift.

[0073] In some embodiments focusing optics 216 may include a focusing subsystem focuses the beam onto the tissue to be treated, creating a focus spot with desired spot size, energy

profile, and focus depth. The focusing subsystem can consist of refractive, reflective, or diffractive elements.

[0074] In some embodiments visual spotting laser 206 may be a low power laser employed as a spotting beam to aid visualization of the focus spot location on tissue. Visual spotting laser 206 may be a gas, solid state or semiconductor laser. The preferred embodiment would be a visible wavelength laser that can be seen with the naked eye or with a silicon CCD or CMOS camera.

[0075] Visual spotting laser 206 is injected into the optical system via a beam-splitter dichroic or flip in 208 optic and is preferably collinear to the line of sight of treatment laser 202. Alternatively, an element that selectively blocks some of the treatment or spotting laser beam and allows a portion of the other beam to pass could be used so that the spotting and treatment beams are incident on the tissue simultaneously. Alternatively, a rotating or oscillating reflective element that alternates between the treatment and spotting lasers could be used. In other embodiments the beams may reach dichroic or flip-in 208 at staggered times.

[0076] It is also possible to have the visible spotting beam integral to the treatment laser. An example would be to propagate a visible laser beam through the intra-cavity mirrors or a solid state laser. The intra-cavity mirrors could be coated to transmit the spotting laser wavelength while reflecting the treatment laser wavelength.

[0077] Alternatively, multiple spotting laser beams may be used and aligned such that they are coincident at the focal plane of the focusing optics. If the tissue is not in the focus plane, multiple visible beams will be apparent, indicating the need to adjust focus.

[0078] A line of sight for operator 160 to view the area of tissue being treatment is injected after the steering elements and before the focusing subsystem. A beam-splitter dichroic 208 is used so that the tissue may be viewed concurrently with the spotting and/or treatment lasers 206. It is also possible to employ a reflective element to combine the treatment/spotting laser lines of sight with the visible line of sight. This reflective element may create a central obscuration in the laser beam or visible line of sight. Shown in the figure is a surgical, binocular microscope head 150. Instead of a direct visual system to the operator's eye, a CCD or CMOS camera with imaging optics could be employed. This preferably includes a controller for adjusting for parallax error.

[0079] Alternatively, the line of sight could be located after focusing optics 216. A similar aperture sharing element as described above could be used to combine the lines of sight. In this case, separate focusing optics 216 would be required for operator 160 to focus on the surface of the tissue such as patient's eye 140.

[0080] Turning to FIG. 3, a laser treatment system 300 according to an embodiment of the present invention is shown. FIG. 3 shows the optical system of Figure 2, with additional

subsystems added for monitoring and controlling the depth of tissue ablation and for tracking eye movement.

[0081] Similar to the embodiment depicted in FIG. 2, in the example embodiment, laser treatment system 300 consists of a treatment laser 202 emitting a laser beam which travels through relay lens 204 to dichroic or flip-in 208. Visible spotting laser 206 emits a laser beam which also travels to dichroic or flip-in 208. In some embodiments the beams from treatment laser 202 and visible spotting laser 206 may meet simultaneously at dichroic or flip-in 208. In other embodiments the beams may reach dichroic or flip-in 208 at staggered times.

[0082] The beam or beams leave dichroic or flip-in 208 and travels to Galvo1 210. Galvo1 210 may consist of a mirror which rotates through a galvanometer set-up in order to move a laser beam. The beam or beams leave Galvo1 210 and travel to Galvo2 212 which may be a similar setup to Galvo1 210. The beam or beams leave Galvo2 212 and travel to dichroic (visible/IR) 214. Operator 160 may monitor the beam or beams at dichroic (visible/IR) 214 by using a surgical microscope 150. The beam or beams travel from dichroic (visible/IR) 214 through focusing optics 216 to patient eye 140.

[0083] In FIG. 3, additional monitoring elements are provided for use by operator 160 to aid in medical procedures. Depth control subsystem 302 is coupled to surgical microscope to assist in controlling the depth of ablation procedures in accordance with the present invention. Similarly, eye tracker 304 is coupled to surgical microscope to assist in tracking landmarks on patient eye 140 during medical procedures in accordance with the present invention.

[0084] Depth control may be achieved by viewing the ablation region and visually detecting a change in structure or color in the image. A CCD camera and passive or active illumination may be employed to visualize the ablation region of patient's eye 140. Image data may be processed and algorithms used to segment the image to determine characteristics of the image within a region of interest. These characteristics may be compared to known, stored, or computed values that may be used to determine when to stop the treatment laser exposure. Alternatively, a measure of ablation depth may be made and compared to known or stored maximum depth desired for ablation. Alternatively, the subsurface tissue may be imaged using, for example, ultrasound or optical coherence tomography. The depth of ablation may be viewed in reference to imaged landmarks or layers to provide indicators when desired ablation depth has been achieved.

[0085] The region of tissue to be treated must remain positionally stable during treatment. In the case of the eye, whole body or head movement, as well as ocular movements such as saccades, smooth motion pursuit, vergence, and vestibular-ocular movements must be detected and compensated. One method of accomplishing this is via imaging of the eye with a camera, such as a CCD or CMOS camera. Image data can be processed in a variety of ways. One method is to extract features in the image field and track changes in position relative to the fixed position of the camera pixels. A feedback loop to the steering elements is employed to compensate the line of sight of the treatment beam to maintain its relative position on the

eye. The imaging camera may be in front of or behind the steering elements. If it is in front, then the compensation will run open-loop, in that there is no error signal between the commanded and resultant position of compensation. If the camera is behind the steering elements, then the image field of the camera can generate a continuous error signal to feedback to the steering elements. If the system has one set of steering elements, then they will be used both for scanning the treatment laser beam over tissue and compensating for eye motion. Alternatively, two sets of steering elements could be employed to separate these functions.

[0086] Turning to FIG. 3A, a laser treatment system 301 according to an embodiment of the present invention is shown.

[0087] In this embodiment, a treatment laser beam travels to dichroic 208. At dichroic 208 the laser beam travels to Galvo Setup 320 which consists of Galvo1 210 and Galvo2 212. The beam then passes from Galvo Setup 320 to focusing optics 216 and ultimately to patient eye 140.

[0088] Also provided for in this embodiment is a control and monitoring system which broadly consists of a computer 310, video monitor 312, and camera 308. Camera 308 provides monitoring of the laser beam at dichroic 208 via lens 306. Camera 308 transmits its feed to computer 310. Computer 310 is also operable monitor and control Galvo Setup 320. Computer 310 is also coupled to video monitor 312 to provide a user or operator a live feed from camera 308.

[0089] In some embodiments of the invention a dual axis closed loop galvanometer optics assembly is used.

[0090] Since multiple lasers systems may be used for treatment in some embodiments, additional laser systems will now be described.

[0091] The laser system may include a cage mount galvanometer containing a servo controller, intelligent sensor, feedback system and mount assembly with an optical camera. Some embodiments may include use of a cage mount galvanometer optics assembly. Some embodiments may include ultra-high resolution nano-positioners to achieve sub-nanometer resolution.

[0092] To expand, FIG. 3A shows more detail of a CCD (or CMOS) camera-based eye tracker subsystem. Dichroic 208 beamsplitter is used to pick off visible light, while allowing the IR treatment beam to transmit. The beamsplitter 208 is located in front of the steering elements, shown here as galvo mirrors 320. Lens 306 images the tissue plane (eye) onto the camera. Features in the image field (e.g. blood vessels, edge of the iris, etc.) are identified by image processing and their coordinates in the camera pixel field computed. If the eye moves within the pixel field frame-to-frame, the change in position of the reference features can be computed. An error function is computed from the change in reference feature position and

commands issued to the galvo mirrors 320 to minimize the error function. In this configuration, the optical line of sight is always centered on the treatment spot, which is at a fixed coordinate in the camera pixel field. The apparent motion from repositioning the galvos 320 will be to move the eye image relative to the fixed treatment spot.

[0093] Turning to FIG. 3B, another embodiment of a laser treatment system 303 according to an embodiment of the present invention is shown. FIG. 3B is similar to FIG. 3A, except that the eye tracking subsystem is located after galvo mirrors 320.

[0094] In this embodiment, a treatment laser beam travels to Galvo Setup 320 which consists of Galvo1 210 and Galvo2 212. The beam then passes from Galvo Setup 320 to dichroic 208. At dichroic 208 the laser beam travels to focusing optics 216 and ultimately to patient eye 140.

[0095] Also provided for in this embodiment is a control and monitoring system which broadly consists of a computer 310, video monitor 312, and camera 308. Camera 308 provides monitoring of the laser beam at dichroic 208 via lens 306. Camera 308 transmits its feed to computer 310. Computer 310 is also operable monitor and control Galvo Setup 320. Computer 310 is also coupled to video monitor 312 to provide a user or operator a live feed from camera 308.

[0096] Here, the eye image is shown centered in the pixel field. When eye motion is detected within the pixel field, the galvos 320 are repositioned to move the treatment spot to a new position within the pixel field corresponding to the movement of the eye, and to a desired fixed position relative to the eye reference features.

[0097] With reference to the aforementioned biofeedback look, eye tracking includes in some embodiments includes use of light source producing an infrared illumination beam projected onto an artificial reference affixed to an eye. The infrared illumination beam is projected near the visual axis of the eye and has a spot size on the eye greater than the reference and covering an area when the reference moves with the eye.

[0098] In some embodiments the reference has a retro-reflective surface that produces backward scattering orders of magnitude stronger than backward scattering from the eye would. An optical collector may be configured and positioned a distance from the eye to collect this backward scattered infrared light in order to form a bright image spot of the reference at a selected image location.

[0099] The bright image spot appears over a dark background with a single element positioning detector positioned at the selected image location to receive the bright image spot and configured to measure a two-dimensional position of the bright image spot of the reference on the positioning detector. An electric circuit may be coupled to the positioning detector to produce positioning signals indicative of a position of the reference according to a centroid of the bright image spot based on the measured two-dimensional position of the bright image spot on the positioning detector.

[0100] FIG. 3C illustrates a camera correction system according to an embodiment of the present invention.

[0101] In the example embodiment the top row illustrates the camera focus location after galvos have been used and the bottom row illustrates the camera focus location before galvos. Various landmarks 392 may be seen in the example embodiments including capillaries, iris, pupil, etc. Treatment spot 394 may also be seen in each embodiment.

[0102] As is shown in the example embodiment the top row of focus before the galvos each show the pupil of as the center pixel of each image. Compensation after galvos in the bottom row allows the treatment spot 394 to remain the focus of the camera's attention in each image and thereby allow the system to remain in position for the associated procedure.

[0103] Turning to FIG. 3D, a camera-based eye tracker flow diagram 330 is depicted showing a process according to an embodiment of the present invention.

[0104] Broadly put, the diagram represents the use of a CCD or CMOS camera to capture an image of eye. Image data is transmitted to a computer, where key features are segmented/extracted (e.g. blood vessels, iris features, edge of pupil). The image is stored as a reference frame. Subsequent images are then compared to reference frame. A shift is computed after comparing reference features in pixel coordinates. Conversion of pixel coordinates to scanning system coordinates then occurs before commanding the scanning system to deviate treatment beam line of site to restore relationship relative to reference features. If the shift is too large or out of range of scanning system, halt procedure and take steps to reacquire the target image field.

[0105] As a more detailed explanation referencing each step, an initialization or starting sequence according to some embodiments requires capture image frame in step 332 before processing the captured image frame in order to extract features in step 334. This captured frame with extracted features is then used to set a reference frame in step 336.

[0106] After a reference frame is set, step 338 consists of capturing an additional image frame, called a current frame. This image or current frame is processed in step 340 in order to extract features. Step 342 consists of comparing the current frame to the reference frame which was set in step 336. An image shift is computed between the current frame and the reference frame in order to determine the difference between the frames. A comparison to a pre-set threshold allows the system to determine if the image shift exceeds the pre-set threshold and stops the procedure at this point by going to step 352.

[0107] If an image shift does not exceed the pre-set threshold and therefore is not too large, the system computes a compensation level in step 346 in order to compensate for the change or shift between the current frame and the reference frame. This compensation level is computed into physical coordinates used by a scanner in step 348. The scanner is then

commanded to compensate using the coordinates in step 350. After this compensation step 338 occurs and another current image frame is captured and the cycle continues.

[0108] Turning to FIG. 3E, a flow diagram for a laser ablation procedure 360 embodiment is shown in accordance with the present invention.

[0109] Generally put, the procedure flow represents a procedure for stepping through, one quadrant at a time, one pore at a time, an ablation pattern. The procedure starts with a patient focused on an off-axis fixation target. A position scanning system locates pore 1 coordinates. Eye tracking is initiated, starting with reference frame. Pore 1 is ablated while tracking. The procedure is halted if eye movement is out of range to prevent harm or other negative consequences. Upon completion of pore 1, the position scanning system locates pore 2 coordinates and repeats the eye tracking and ablation process. These steps are repeated until quadrant 1 pattern complete. The fixation target is then moved and patient focuses on new position and repeat application of ablation pattern on a new quadrant.

[0110] As a more detailed explanation referencing each step, in the example embodiment a patient is positioned in step 362 in order to receive the treatment. The patient is then instructed to fixate their gaze for a first quadrant procedure in step 364.

[0111] The line of sight of the laser beam is positioned to a first pore position in step 366 before a tracker reference is set for the first pore position in step 368. The user or operator then initiates the ablation in step 370 and the first pore is ablated.

[0112] The user or operator then moves to step 372 and positions the line of sight of the laser beam for the second pore position before tracker reference is set for the second pore position in step 374. The user or operator then initiates the ablation in step 376 and the second pore is ablated.

[0113] The several steps described in the above paragraph which are similar to those in the paragraph above it are repeated in step 378 until ablation in the quadrant is complete.

[0114] After the quadrant is complete, the patient is instructed to fixate their gaze for a second quadrant in step 380 and the process repeats for each successive quadrant until the procedure as a whole is complete.

[0115] Also provided for in the diagram is eye tracking 382 that represents the steps required and repeated in tracking the position of the eye concurrently with the steps of laser ablation procedure flow 360 in the embodiment.

[0116] Also provided for in the diagram is eye tracking 384 that represents the steps required and repeated in tracking the position of the eye concurrently with the steps of laser ablation procedure flow 360 in the embodiment.

[0117] In some embodiments an eye tracking subsystem may be a camera based imaging system. This camera based imaging system may be used for image feature identification and to assist in tracking position of a laser beam during a procedure. Feedback from the eye tracking subsystem is provided to the scanning system to maintain correct position during procedures.

[0118] In some embodiments the eye tracking subsystem is used for registration of previously created pores (also referred to as voids) for retreatment or additional treatment as necessary.

[0119] Also provided for in the diagram is depth control 386 that represents the steps required and repeated in controlling the depth of the laser beam on the eye concurrently with the steps of laser ablation procedure flow 360 in the embodiment.

[0120] Depth control subsystem in some embodiments includes an imaging system and/or Optical Coherence Tomography. The imaging system may include detection of a pigmented layer or layers in order to ensure proper depth is reached without exceeding a particular limit.

[0121] FIG. 4 illustrates a laser treatment system 400 according to an embodiment of the present invention. In the example embodiment, laser treatment system 400 consists of a treatment laser 202 emitting a laser beam which travels through relay lens 204 to dichroic or flip-in 208. Visible spotting laser 206 emits a laser beam which also travels to dichroic or flip-in 208. In some embodiments the beams from treatment laser 202 and visible spotting laser 206 may meet simultaneously at first dichroic or flip-in 208. In other embodiments the beams may reach first dichroic or flip-in 208 at staggered times.

[0122] The beam or beams leave first dichroic or flip-in 208 and travels to a second dichroic 208. The beam or beams leave second dichroic 208 and travel to Galvo1 210. Galvo1 210 may consist of a mirror which rotates through a galvanometer set-up in order to move a laser beam. The beam or beams leave Galvo1 210 and travel to Galvo2 212 which may be a similar setup to Galvo1 210. The beam or beams leave Galvo2 212 and travel to dichroic (visible/IR) 214. Operator 160 may monitor the beam or beams at dichroic (visible/IR) 214 by using a surgical microscope 150. The beam or beams travel from dichroic (visible/IR) 214 through focusing optics 216 to patient eye 140.

[0123] In FIG. 4, additional monitoring elements are provided for use by operator 160 to aid in medical procedures. Depth control subsystem 302 assists in controlling the depth of ablation procedures in accordance with the present invention and receives input from second dichroic 208. Similarly, eye tracker 304 assists in tracking landmarks on patient eye 140 during medical procedures in accordance with the present invention and also receives input from second dichroic 208. Another dichroic 208 is shown in the example embodiment splitting the beam with outputs to eye tracker 304 and depth control subsystem 302.

[0124] FIG. 4A illustrates a laser treatment system including ablation pore depth according to an embodiment of the present invention.

[0125] FIG. 4A generally shows a treatment laser beam traveling to dichroic 208 before travelling to Galvo1 210, then to Galvo2 212, through focusing optics 216, and to patient eye 140.

[0126] An OCT system 404 is an Optical Coherence Tomography system used to obtain subsurface images of the eye. As such, when coupled to computer 310 which is coupled to video monitor 312, OCT system 404 provides a user or operator the ability to see subsurface images of the tissue ablation.

[0127] In at least some embodiments OCT provides a real-time, intraoperative view of depth levels in the tissue. OCT may provide for image segmentation in order to identify sclera interior boundary to help better control depth.

[0128] OCT system 404 uses an OCT measurement beam, injected into the treatment beam line of sight via a dichroic beam splitter 208, located before the scanning system. In this way, the OCT system line of sight is always centered on the pore being ablated. The OCT system is connected to a computer 310 for processing the images and for control of the laser.

[0129] In some embodiments of the invention an anatomy avoidance subsystem is provided to identify critical biological obstacles or locations during procedures (e.g. blood vessels and others). As such, subsurface visualization may be provided to identify obstacles such as blood vessels intraoperatively.

[0130] Also shown in FIG. 4A is a simple diagram of an ablation pore in the sclera showing an example of the depth of an ablation in relation to the inner boundary of the sclera.

[0131] Turning to FIG. 4B, a flow diagram of OCT-based depth control 410 is shown according to an embodiment of the present invention.

[0132] In general, The OCT system executes a repetitive B-scan, synchronized with the laser. The B-scan shows the top surface of the conjunctiva and/or sclera, the boundaries of the pore being ablated, and the bottom interface between the sclera and the choroid or ciliary body. Automatic image segmentation algorithms are employed to identify the top and bottom surfaces of the sclera (typically 400 - 1000 microns thick) and the boundaries of the ablated pore. The distance from the top surface of the sclera to the bottom surface of the pore is automatically computed and compared to the local thickness of the sclera. In some embodiments this occurs in real time. When the pore depth reaches a predefined number or fraction of sclera thickness, ablation is halted and the scanning system indexed to the next target ablation location. In some embodiments images may be segmented to identify interior sclera boundaries.

[0133] With reference to the steps in the figure, in the example embodiment a starting or initialization set of steps occurs first. This starting set of steps begins with positioning to a pore

coordinate in step 412. A B-scan of the target region occurs in step 414. This scan creates an image which is processed in step 416 in order to segment and identify the sclera boundary. A distance is then computed in step 418 between the conjunctive surface and the sclera boundary.

[0134] After completion of this starting set of steps ablation is initiated in step 420. A laser beam pulse is fired in step 422 followed by a B-scan in step 424. This B-scan creates an image that is then segmented in step 426 and pore depth and ablation rate are computed from the image. This pore depth and ablation rate are compared to the target depth in step 430. If the target depth has not been reached then the process loops back to step 422 and repeats. Upon reaching a target depth step 432 stops the ablation process and the starting process begins again at step 434 with positioning to a next pore coordinates.

[0135] FIG. 5A- FIG. 5C show various means of coupling the treatment laser into the optical system.

[0136] Turning to FIG. 5A, a laser treatment system lens placement is shown according to an embodiment of the present invention. In the example embodiment the laser beam emitted from treatment laser 202 travels through a waveguide, either hollow or fiber. These were described above in depth in FIG. 1.

[0137] Turning to FIG. 5B, a laser treatment system lens placement is shown according to an embodiment of the present invention. In the example embodiment free space propagation is shown. A multi-lens collimating telescope can serve to change the size of the beam (expand or reduce) as well as image the beam waist or output aperture of the laser beam to some location in the optical system. Shown here is a so-called Keplarian configuration, where a real focus is formed inside the telescope.

[0138] Turning to FIG. 5C, a laser treatment system lens placement is shown according to an embodiment of the present invention. In the example embodiment, an aperture is used similar to the embodiment in FIG. 5B except that this embodiment uses a Galilean configuration telescope with a negative and a positive element rather than a Keplarian configuration. This configuration does not form a real image within the telescope. This optical configuration is also known as a telephoto or reverse telephoto configuration (depending on orientation), which can be important when considering the desired position of the beam waist or laser beam output aperture in the system.

[0139] FIG. 6 illustrates a laser treatment system component map 600 showing relation of related subsystems according to an embodiment of the present invention.

[0140] In general laser treatment system component map 600 shows a laser 602, a laser delivery fiber 120, laser control system 604, monitoring system 608, and beam control system 606.

[0141] Laser 602 is generally made up of several subsystems. In the example embodiment these subsystems include system control electronics 104, Er:YAG laser head 612, laser cooling system 108, HV power supply 110, and system power supplies 112. Foot pedal 114 provides some control for the system user. Laser 602 transmits a laser beam via laser delivery fiber 120 to beam control system 606.

[0142] Beam control system 606 is generally made up of beam transport optics 624, red spotting laser 626, galvo mirrors 628, beam delivery optics 630, and active focus 632.

[0143] Laser control system 604 maintains a link to laser 602 via a laser sync and to beam control system 606 via power control position status. Laser control system 604 is generally made up of a user interface 614, power supply 616, galvo controller 618, galvo controller 620, and microcontroller 622. Laser control system 604 is also manipulable via joystick 610.

[0144] Monitoring system 608 is generally made up of CCD camera 634 and visual microscope 636.

[0145] In some embodiments a fiber laser is used which is composed of an undoped cladding and a doped core of higher refraction. The laser beam travels through the fiber guided within the fiber core and experiences a high amplification due to the length of interaction. Fiber lasers are considered advantageous to other laser systems because, among other qualities, they have simple thermal management properties, high beam quality, high electrical efficiency, high optical efficiency, high peak energy, in addition to being low cost, requiring low maintenance, having superior reliability, a lack of mirror or beam path alignment, and they are lightweight and generally compact.

[0146] In some embodiments of the invention spot arrays may be used in order to ablate multiple pores at once. These spot arrays may, in some cases, be created using microlenses and also be affected by the properties of the laser. A larger wavelength may lead to a smaller number of spots with increased spot diameter.

[0147] Turning to FIG. 7, a laser treatment system 700 is shown according to an embodiment of the present invention.

[0148] Laser treatment system 700 is generally made up of control system 702, optics and beam controls.

[0149] Control system 702 includes monitor1 704 and monitor2 706 as well as keyboard 708 and mouse 710 to provide a user the ability to interact and control with a host computer 724 running computer programs. In many embodiments the computer programs running on host computer 724 include control programs for controlling visible spotting laser 712, laser head 714, laser cooling system 716, system power supplies 718, laser power supply 720, and beam transport optics 722.

[0150] Also provided for in this embodiment are depth control subsystem 726, galvo mirrors 728, CCD Camera 730, visual microscope 732, focus subsystem 734, and beam delivery optics 736.

[0151] Preoperative measurement of ocular properties and customization of treatment to an individual patient's needs is beneficial in many embodiments. Preoperative measurement of ocular properties may include measuring intraocular pressure (IOP), scleral thickness, scleral stress/strain, anterior vasculature, accommodative response, and refractive error. Measurement of scleral thickness may include use of optical coherence tomography (OCT). Measurement of scleral stress/strain may include using Brillouin scattering, OCT elastography, photoacoustics (light plus ultrasound). Measurement of anterior vasculature may include using OCT or Doppler OCT. Measurement of refractive error may include using the products such as the iTrace trademarked product from Tracey Technologies Corp.

[0152] Intraoperative biofeedback loops may be important during the procedure in order to keep the physician informed on the progress of the procedure. Such feedback loops may include use of topographical measurements and monitoring "keep away" zones such as anterior ciliary arteries.

[0153] Biofeedback loops may include a closed-loop sensor to correct for nonlinearity in the piezo scanning mechanism. The sensor in some embodiments may offer real-time position feedback in a few milliseconds and utilizing capacitive sensors for real-time position feedback. Sensor/feedback apparatus may also perform biological or chemical "smart sensing" to allow ablation of target tissue and protect or avoid surrounding tissue. In some instances this smart sensing may be accomplished by using a biochip incorporation in a mask which is activated by light irradiation and senses location, depth, size, shape, or other parameters of an ablation profile. Galvo-optic assemblies are also contemplated in some embodiments and may be used to gage numerous parameters of laser steering and special function.

[0154] FIG. 8 illustrates an eye treatment map 800 according to an embodiment of the present invention.

[0155] In the example embodiment sclera 802 is shown broken into four quadrants. Limbus 804 is located aside from ablative pore locations 806. As procedures in many embodiments of this invention are completed by quadrants, only a first quadrant is shown however each additional quadrant will have similar mapping.

[0156] FIGS. 9-11 illustrates exemplary pore matrices according to preferred embodiments of the present invention. Patient eye 900 has pupil 902, iris 904, and sclera 906. The pore matrices comprise a plurality of pores 912 formed in first ablation pattern location 908 and second ablation pattern location 910.

[0157] In at least one embodiment, the connective tissue is the sclera of the eye, and the delivery system comprises a spacer/fixator configured to fix the delivery system relative to the

eye, and a corneal shield configured to be placed over the cornea so as to block laser energy from being applied thereto. In some embodiments the spacer/fixator may be detachable and/or disposable. The delivery system may then form the pore matrix in the sclera of the eye.

[0158] In at least one embodiment, the fixator includes a track along which the delivery system can move relative to the eye. The laser energy is selectively delivered to the scleral tissue therethrough to form one or more matrices of the pore matrix at a first location of the scleral tissue. Then, the delivery system is relocated so that the laser energy may be selectively delivered to the scleral tissue at a second location of the scleral tissue. In this way, tessellated matrices may be formed.

[0159] The eye spacer/fixator is an adjustable dual cylinder shaped apparatus that accommodates the anterior globe of the sclera where a central cylinder excludes the cornea from a treatment zone and where a periphery cylinder includes a scleral treatment zone up to a 6-7mm radius.

[0160] A scleral fixator may be attached to the inferior surface of the dual cylinder assembly and may have four fixator prongs at 1:30 - 4:30 - 7:30 - 10:30 and the fixator may be detachable and disposable from a treatment spacer bar.

[0161] In some embodiments there may be a corneal shield or plate which can be tinted to protect associated portions of the eye.

[0162] In at least one embodiment, the delivery system contains a sensor with a feedback configured to control depth, spot size and dynamic control of the delivery system, and energy parameters of the laser beam delivery.

[0163] In at least one embodiment, the delivery system contains a transmitter communicatively coupled to a satellite unit that communicates with the base unit - preferably by Radio frequency or blue tooth or WIFI - regarding the tissue parameters and has a dynamic control which communicates with the laser. Such communication may include delivery parameters and shut off features.

[0164] In some embodiments accessories may be provided for use with the main system and device disclosed herein. These accessories may include, in addition to the detachable and/or disposable eye spacer/fixator described above, a disposable eye suction ring for use with an eye module. The eye suction ring may be used in a complementary or supplementary role with the eye spacer/fixator or, in some embodiments, as a replacement.

[0165] In some embodiments a sterile "docking station" may be provided for slit lamp-type configuration of the procedure.

Ablation Patterns

[0166] A method of use of the invention will now be discussed with reference to the figures. As mentioned previously, the main purpose of the method is to modify the biomechanical properties of the tissue, particularly the sclera. This modification allows the pars plicata of the ciliary body to move upward and inward on contraction of the ciliary muscle, compensating for an increase in choroidal and/or scleral stiffness with age and also potentially enables corneal accommodation.

[0167] As shown in FIGS. 9 to 23, ablation patterns are formed in various configurations on a patient's eye in accordance with the invention.

[0168] Ablation patterns are formed by the laser beam during the procedure. These are also referred to herein as pore matrices.

[0169] A pore matrix is formed of a plurality of perforations scleral tissue of a patient. By being located in the scleral tissue according to the pore matrix, the perforations interact with and affect the fundamental mechanisms involved in the immunology, biochemistry and molecular genetics of scleral tissue metabolism. Indeed, tension or resilience in the scleral tissue is modified in such a way that reduces natural degradation of physiological, biomechanical, and biologic function of the tissues and organ. This in turn helps restore mechanical efficiency of the natural accommodative mechanism in optical focus and improves biomechanical mobility to achieve this accommodative power.

[0170] The perforations may be formed by any means now known or later developed. Such means may, for example, ablate, excise, incise, vaporize, remodel or puncture the scleral tissue to create the perforations. Although the pores or perforations in the scleral tissue are generally described herein as being formed by ablating the tissue using laser energy, it is contemplated that the perforations could be formed using any desired surgical tool, such as a diamond knife, ruby knife, or a radio frequency device, or a nano device, robotics, a chemical application, electrical application or a substrate wafer application.

[0171] In many embodiments the increase in pliability, resilience, and restoration of viscoelastic properties caused by successful ablation by the methods disclosed herein induces a "negative stiffness" or Poisson's effect in the tissue. Poisson's effect is described as the negative ratio of transverse to axial strain in a material. That is to say, that when a material is compressed in one three-dimensional direction that the material tends to expand in the other two three-dimensional directions. Conversely, if a material is stretched in one three-dimensional direction then the material compresses in the other two three dimensional directions. This is beneficial in the case where tissue has become stiff because an increase in its ability to stretch or compress allows for a greater range of movement and greater biomechanical adaptability.

[0172] Ablation by the methods disclosed herein may be considered to have a remodeling effect on the tissue being ablated since it is inherently changing the properties of the tissue. This remodeling effect creates mechanical isotropy in a minimum of two dimensions. That is to

say mechanical properties are identical in at least two dimensions as a result of successful ablation.

[0173] In some cases, additional positive results may be observed as a result of successful ablation. These may include improved physiological interaction between pores including improved ion exchange, separation catalysis, as well as improved biological, chemical, and molecular purification and processing.

[0174] FIG. 12- FIG. 19 will now be described in detail. For each of FIG. 12- FIG. 19, the region shown varies from Limbus to Ora Serrata in one quadrant of the eye. The edge of the treatment zone is 0.5mm from the limbus and nominally extends down 5.5mm towards the Ora Serrata. Eye dimensions vary with race, patient to patient and with orientation around the globe (Temporal, Superior, Nasal, Inferior).

[0175] The treatment region is divided radially into zones correlating to anatomy. Zone 1: Ciliary body Pars Plicata; Zone 2: Ciliary body Pars Plana; Zone 3: Transition of ciliary body to Ora Serrata. This is described in further detail below in FIGS. 24A-C.

[0176] Aside from the exterior boundaries of the patterns, the main differences in the patterns are regular grids (e.g. FIG. 12) versus an "interspersed" grid (e.g. FIG. 14). In the regular grid, 4 pores form the vertices of a square, whereas in the interspersed grid, 3 pores form the vertices of an equilateral triangle.

[0177] Turning to FIG. 12, a pore matrix map according to an embodiment of the present invention is shown.

[0178] FIG. 12 generally shows distance map 1200 including excision locations 1202. In some embodiments excision locations 1202 include nine locations per oblique quadrant of the eye in a mathematical diamond matrix pattern. Excision locations are set to six-hundred micrometer sizes and are ablated using an Er:YAG laser. The process is completed until each oblique quadrant has been completed. In some embodiments the quadrants need not be oblique.

[0179] FIG. 13 illustrates a pore matrix according to an embodiment of the present In some embodiments excision locations 1302 include nine locations per quadrant of the eye in a mathematical angle matrix pattern. Excision locations are set to six-hundred micrometer sizes and are ablated using an Er:YAG laser. The process is completed until each quadrant has been completed.

[0180] FIG. 14 illustrates an exemplary pore matrix. In some embodiments excision locations 1402 include nine locations per quadrant of the eye in a mathematical chevron matrix pattern. Excision locations are set to six-hundred micrometer sizes and are ablated using an Er:YAG laser. The process is completed until each quadrant has been completed.

[0181] FIG. 15 illustrates an exemplary pore matrix. In some embodiments excision locations

1502 include ten locations per quadrant of the eye in a mathematical horizontal hexagonal matrix pattern. Excision locations are set to six-hundred micrometer sizes and are ablated using an Er:YAG laser. The process is completed until each quadrant has been completed.

[0182] FIG. 16 illustrates an exemplary pore matrix. In some embodiments excision locations 1602 include ten locations per quadrant of the eye in a mathematical vertical hexagonal matrix pattern. Excision locations are set to six-hundred micrometer sizes and are ablated using an Er:YAG laser. The process is completed until each quadrant has been completed.

[0183] FIG. 17 illustrates an exemplary pore matrix. In some embodiments excision locations 1702 include fifteen locations per quadrant of the eye in a mathematical triangular matrix pattern. Excision locations are set to six-hundred micrometer sizes and are ablated using an Er:YAG laser. The process is completed until each quadrant has been completed.

[0184] FIG. 18 illustrates an exemplary pore matrix. In some embodiments excision locations 1802 include fifteen locations per quadrant of the eye in a mathematical wave matrix pattern. Excision locations are set to six-hundred micrometer sizes and are ablated using an Er:YAG laser. The process is completed until each quadrant has been completed.

[0185] FIG. 19 illustrates an exemplary pore matrix. In some embodiments excision locations 1902 include locations per quadrant of the eye in a mathematical decagon matrix pattern. Excision locations are set to six-hundred micrometer sizes and are ablated using an Er:YAG laser. The process is completed until each quadrant has been completed.

[0186] Turning to FIG. 20- FIG. 21, examples of pores tracing out "golden" spirals - clockwise, counterclockwise and combined are shown. A golden spiral is a logarithmic spiral that grows by a factor of ϕ (the golden number; $\phi = 1.618$) for each quarter turn of the spiral. This is a form of spiral commonly found in nature. This "golden" spiral pore matrix is the preferred embodiment. In other exemplary embodiments other types of spirals could be used as well.

[0187] Spiral and circle patterns in accordance with the invention generally demonstrate a transition from quadrant-based treatment to complete circumferential treatment.

[0188] FIG. 20 illustrates pore matrices in spiral form according to embodiments of the present invention. According to the example embodiment patterns 2000 are made of pores 2002.

[0189] FIG. 21 illustrates a pore matrix in spiral form according to an embodiment of the present invention. According to the example embodiment patterns 2100 are made of spirals 2102. Spirals 2102 are in turn made of pores (not shown in the current embodiment).

[0190] FIG. 22 illustrates an exemplary pore matrix in concentric circular form According to the example embodiment patterns 2200 are made of pores 2202.

[0191] These concentric circles are shown emanating from limbus to ora serrata. Each circle

shown here has pores with equal angular spacing. In some embodiments patterns may also be created with equal pore to pore lateral spacing. In some embodiments every other circle shifted by one half of the pore spacing rotationally to produce an "interspersed" pattern.

[0192] FIG. 23 illustrates an exemplary pore matrix in interspersed circular form . According to the example embodiment patterns 2300 are made of pores 2302.

[0193] The pore matrix is such that the fundamental biomechanical properties of the scleral tissue may be improved by formation of the pore matrix therein. The pore matrix may consist of one or more regularly spaced arrays of perforations. The pore matrix may also comprise one or more matrices, each matrix comprising one or more regularly spaced arrays of perforations. That is, the pore matrix is comprised of one or more matrices, which is comprised of one or more regularly spaced arrays of perforations in the scleral tissue. Various pore matrices are contemplated, some non-limiting examples of which are described above. Other exemplary pore matrices are described in the materials appended hereto .

[0194] The pore matrix may be a tessellated pore matrix. That is, the pore matrix may comprise a plurality of matrices repeating with no gaps and no overlap. Although patterns shown in the drawings are discretized, showing a specific number of ablations in specific patterns, the drawings are not exhaustive. As such, numerous other regular or interspersed grid patterns are contemplated and different spirals, concentric circles, three dimensional, and even other irregular or perturbed patterns are contemplated.

[0195] In some embodiments, the pores or perforations may extend through the entire depth or thickness of the scleral tissue, or substantially therethrough. Accordingly, the tissue may be ablated through an infinite number of planes of the tissue. Alternatively, the pore matrix may be formed in multiple discrete planes of the scleral tissue. Indeed, it subsurface pore matrices are specifically contemplated. Thus, for example, pore matrices of $n \times m \times 1$ matrices may be formed.

[0196] Additionally, the perforations may be formed according to different sizes and shapes. These may include cylindrical, cone-shaped, square, rectangular, pyramidal, and others.

[0197] Turning to FIG. 24A, an illustration of an accommodated eye 2401 and a disaccommodated eye 2402 and associated muscle movement of the eye is shown. FIG. 24A generally shows ciliary muscle 2404, lens 2406, pars plicata portion 2408 of ciliary body, cornea 2410, zonules 2412, and sclera 2414. In FIG. 24A, accommodated eye 2401 and disaccommodated eye 2402 are shown, the changes between the two described below.

[0198] The relaxed, or disaccommodated eye 2402 is shown on the right. The ciliary muscle 2402 is relaxed and the zonules 2412 are pulled taut, flattening (thinning) the lens 2406 for distance vision and lower power.

[0199] The accommodated eye 2401 is shown on the left. Here, the ciliary muscle 2404 is

contracted, relaxing the tension on the zonules 2412 and allowing the crystalline lens 2406 to take its more natural, curved shape for near vision. Lens 2406 in this configuration may also be referred to as steeper or thicker. Also, the pars plicata 2408 of the ciliary body moves inward.

[0200] Zonules 2412 are variously known as suspensory ligaments, zonules of Zinn, and zonular apparatus. Zonular fibers that attach to the lens are anterior, central, and posterior. Ciliary muscle 2402 is contained within the ciliary body.

[0201] FIG. 24B illustrates the three parts of ciliary muscle and their relation to one another in the eye. Ciliary body 2414 contains ciliary muscle. Ciliary muscle includes Circular Ciliary Muscle Fibers 2416, Radial (Oblique) Ciliary Muscle Fibers 2418, Longitudinal (Meridional) Ciliary Muscle Fibers (aka Bruke's Muscle) 2420, and "Epichoroidal Star" attachment 2422. Also shown is sclera spur 2424 of sclera 2414.

[0202] These muscles are generally grouped into three types, circular, radial and longitudinal. The radial and longitudinal muscle fibers terminate in the scleral spur 2424. The longitudinal muscle fibers terminate in "epichoroidal stars" 2422 for attachment to the choroid layer 2426 at the ora serrata 2428.

[0203] FIG. 24C is corneo-scleral shell with the ciliary body 2414 showing contraction of ciliary muscle and its effect on the eye. Shown in FIG. 24C is the increase in the bundle cross section of Circular Ciliary Muscle Fibers 2416 as the contraction of ciliary muscles stretches choroid 2426 and causes inward/upward movement of pars plicata 2408, relaxing zonules 2412. More particularly, when the ciliary muscle contracts, the longitudinal fibers stretch the choroid and pull ora serrata 2428 up. The end of the ciliary body 2414 close to the scleral spur 2424 is called the pars plicata 2408. As the ciliary muscle contracts, the pars plicata 2408 moves inward and upward. This relaxes the tension on the zonules 2412 attached to the crystalline lens 2406, allowing lens 2406 to take a steeper shape for near vision. As discussed above, aging generally impairs the biomechanical properties of the scleral tissue and so impedes the above described functionality of the sclera with respect to accommodation. Formation of the aforementioned pore matrices in the scleral tissue in accordance with the embodiments described herein restore the biomechanical properties of the scleral tissue that were impaired by age.

[0204] Ablation creates pliable matrix zones in the sclera and in the example embodiment micro-excisions are created in three critical zones over the ciliary complex. However, matrix zones are not limited to two dimensional matrices. In many embodiments of the invention the matrix zones are three dimensional. Also provided are treatments wherein locations may be reached within the tissue without ablating regions above the tissue. That is, a location with x, y, z coordinates in the tissue may be reached without ablating any or all tissue in the three dimensional space to get to the x, y, z coordinate location.

[0205] In some embodiments the living tissue matrix creates a hyperbolic plane of tissue having a differential tissue plane within a plurality of pore matrices being anisotropic,

tessellated and within a mathematical array exists. Additionally, particular matrices chosen may effect biological or biomechanical reactions.

[0206] In some embodiments pores may be nanopores which are less than two nanometers in diameter, neopores which are between two and fifty nanometers, or macropores which are greater than fifty nanometers in diameter. Pores may generally be between one and one hundred nanometers.

[0207] Some embodiments of the invention provide for a high surface to volume ratio ordered uniform pore structure throughout a plurality of planes. In general there is a specificity of pore size, shape and distribution in the matrix used in an embodiment and pores are specifically and mathematically arranged in a matrix.

[0208] In some embodiments the specificity of a pore pattern may be a fractal. In some embodiments the specificity of a pore wall morphology is integral. Pore walls contain an inner wall, an outer wall, and interstitial space which may occur at a plurality of depths, angles, and planes through several layers of tissue.

[0209] Some pre configurations have a three dimensional architecture of particle aggregates. The biomechanical properties of a tissue cross section where matrices are placed may be effected by porosity such as the equation $f=V_f/V_t$ or $F=V_a+V_u/V_s+V_a+V_w$ where there is a surface volume ratio diameter and depth distribution of the pore relationship within the plurality of matrices of $F_v = -(dV/dD)$ where V = pore Volume and D = pore Diameter.

[0210] As another example, in the ear, the surgical laser system may be used to treat the tympanic membrane, the crista ampullaris, the cochlear, the cochlear duct, and hair cells. As another example, the surgical laser system may be used to treat tissue of the kidneys or tissue of the ovaries. As another example, the surgical laser system may be used to treat large aponeuroses, such as lumbosacral fascia, abdominal raphe, and neural sheath in the spinal cord. As yet another example, the surgical laser system may be used to treat bones, cartilage, ligaments, and tendons. As still another example, the surgical laser system may be used to treat the brain, such as dura matter of the brain and the bony surroundings of the brain. As another example, the surgical laser system may be used to treat lymph node CT or spleen CT. As another example, the surgical laser system may be used to treat vascular vessels and/or the heart as well as the surrounding tissue such as the pericardium. As a further example, the surgical laser system may be used to treat muscles.

[0211] FIG. 25 shows a configuration where the beam delivery system scans over the eye in a "goniometric" motion - that is the beam delivery system traces an arc with an offset center of curvature. In this case, the center of curvature is at the center of the treated eye. This allows the nominal line of sight from the beam delivery system to maintain perpendicularity to the surface of the sclera. The motion of the beam delivery system can be along either or both of two axes, labeled with the alpha and beta angles in the drawing. The galvo scanners can be used to scan locally within an angular neighborhood of theta, to place spots in the (annular)

treatment zone while maintaining perpendicularity of the line of sight to the scleral surface.

[0212] The effects of ablation may be seen in many of the structures of the eye. For instance, the ciliary muscle is a ring of striated smooth muscle that controls accommodation for viewing objects at varying distances. In simpler terms, it helps in focusing of the eye. Some of the mechanisms used include regulating flow of aqueous humour into Schlemm's canal and changing the shape of the lens within the eye (but not the pupil size which is affected by a different muscle). Ablation of scleral tissue as performed in numerous embodiments in this description causes a decrease in scleral resistive forces. This decrease in scleral resistive forces in turn increases ciliary muscle resultant forces and allows for improved focusing and restoration of dynamic accommodation within the eye.

[0213] In some instances near and intermediate vision and both uncorrected and distance corrected vision improves as a result of the methods described herein.

Healing Inhibition

[0214] The perforations may have inner walls that are spaced from each other a distance that alters the fundamental mechanisms involved in the immunology, biochemistry and molecular genetics of scleral tissue metabolism in such a way as to inhibit normal tissue healing, repair, or regeneration to prevent total healing of the perforations in the scleral tissue. The inner walls of the perforations may be spaced from each other by a distance greater than 400 μm . It is also contemplated that the inner walls of the perforations may be spaced from each other by a distance greater than 600 μm . It is also contemplated that the inner walls of the perforations may be spaced from each other by a distance greater than 200 μm . It is also contemplated that the size of the perforations can range from .001 to 1 μm . Preferably, the perforation size is determined by the proportion of removed tissue to remaining tissue in the target tissue. For the perforations of the pore matrix, there may be a positive correlation of the perforation area to the residual interstitial tissue - in other words, the perforation may comprise a complete negative space. Additionally, for the perforations of the pore matrix, the perforation may comprise a negative, or reverse pattern, where the perforation may comprise a negative space encapsulating a positive space - in other words, the perforation may comprise an outline of remaining interstitial tissue. Preferably, such reverse perforations comprise rings surrounding interstitial tissue.

[0215] The perforations may be filled with a scarring inhibitor substance such as a porous collagen-glycosaminoglycan scaffold. An example of such a porous collagen-glycosaminoglycan scaffold is made by Mediking under the trade name OccuusGen. Alternatively, the perforations may be filled with a biological glycoprotein or a synthetic glycoprotein. As another alternative, the perforations may be filled via the application of a biologically compatible product, which can be in the form of a liquid, a gel, or a porous solid. The perforations may also be treated with a sealant. An example of such a sealant is made by Johnson and Johnson under the tradename Band-Aid® brand liquid bandage; and a similar product is made by Spenco under the

tradename 2nd Skin® and OcuSeal™ Liquid Ocular BandageAs a further alternative, the perforations may be filled via application or treatment to facilitate an ionic reaction, chemical reaction, photonic reaction, organic reaction, inorganic reaction, electronic reaction, or a combination of these reactions to disrupt normal tissue healing. One such preferred embodiment would be to utilize anti fibrotic or other wound healing prevention agent in the form of a collagenous contact lens or biodegradable material. Another such preferred embodiment would be to utilize a biochemical to inhibit wound healing or a biological synthetic to inhibit wound healing.

REFERENCES CITED IN THE DESCRIPTION

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

Patent documents cited in the description

- [US20120029489A1 \[0004\]](#)
- [US6458120B \[0046\]](#)

Patentkrav

1. Indretning til tilvejebringelse af ablativ medicinske behandlinger på biologisk væv til forbedring af et øjes biomekanik, omfattende:
- 5 en laser (202) til generering af en stråle af laserstråling, til anvendelse ved ablativ medicinske behandlinger af et måløjenvæv til frembringelse af en matrice af porer, der forbedrer øjets biomekanik;
- en styreenhed, der er i forbindelse med laseren og kan anvendes til at styre dosimetrien af strålen af laserstråling;
- 10 en linse, der kan anvendes til at fokusere strålen af laserstråling på måløjenvævet;
- et øjensporingsundersystem (304) til sporing af øjets referencepunkter og bevægelser;
- et dybdekontrolundersystem (302) til styring af en dybde af ablation på måløjenvævet;
- 15 et scanningssystem, der er kommunikativt koblet til øjensporingsundersystemet og dybdekontrolundersystemet til scanning af en fokusplet over et område af måløjenvævet;
- et undgåelsesundersystem til identificering af kritiske biologiske forhindringer eller lokationer af øjet;
- 20 en strømkilde, der kan anvendes til at levere strøm til indretningen; og
- hvor scanningssystemet indbefatter en biofeedback-reguleringskreds, der er konfigureret til at tilvejebringe realtidsfeedback om egenskaberne af det bestrålede måløjenvæv, herunder tykkelse, topografi, fokus, hydrering under de
- 25 ablativ medicinske behandlinger; og
- hvor scanningssystemet er konfigureret til at tilvejebringe de medicinske behandlinger omfattende en fuldstændig cirkumferentiel behandling under anvendelse af et gylden spiral-mønster, hvor mønsteret har en af en retning med uret, en retning mod uret eller en kombination deraf, hvor den gyldne spiral er
- 30 en logaritmisk spiral, der vokser med en faktor $\phi = 1,618$ for hver kvarte omdrejning af spiralen.
2. Indretning til tilvejebringelse af ablativ medicinske behandlinger på biologisk væv til forbedring af et øjes biomekanik ifølge krav 1, hvor: indretningen

5 endvidere kan anvendes til at rekonfigurere positionen af laserstrålen, hvis de sporede øjenbevægelser har bevæget sig en strækning, der er mindre end en på forhånd valgt tærskelstrækning, og at stoppe den medicinske behandling, hvis de sporede øjenbevægelser har bevæget sig en strækning, der er større end den på forhånd valgte tærskelstrækning.

10 **3.** Indretning til tilvejebringelse af ablativ medicinske behandlinger på biologisk væv til forbedring af et øjes biomekanik ifølge krav 1, hvor: indretningen endvidere kan anvendes til at tillade fortsættelse af den medicinske behandling, hvis en behandlingsdybde ikke har nået en tærskel; og indretningen endvidere kan anvendes til at stoppe den medicinske behandling, hvis behandlingsdybden har nået eller overskredet tærsklen.

15 **4.** Indretning til tilvejebringelse af ablativ medicinske behandlinger på biologisk væv til forbedring af et øjes biomekanik ifølge et hvilket som helst af de foregående krav, hvor laseren endvidere omfatter enten en optisk pumpe med blitzlampe eller en optisk pumpe med højeffektsdiode.

20 **5.** Indretning til tilvejebringelse af ablativ medicinske behandlinger på biologisk væv til forbedring af et øjes biomekanik ifølge krav 1, hvor dybdekontrolundersystemet endvidere omfatter: mindst en optisk kohærenstomografi OCT-indretning til overvågning af ablationsproceduren.

25 **6.** Indretning til tilvejebringelse af ablativ medicinske behandlinger på biologisk væv til forbedring af et øjes biomekanik ifølge krav 5, hvor OCT-indretningen er indrettet til at opnå billeder af øjet under overfladen og er koblet til en videomonitor til visning af billederne under overfladen.

30 **7.** Indretning til tilvejebringelse af ablativ medicinske behandlinger på biologisk væv til forbedring af et øjes biomekanik ifølge krav 1, hvor det biologiske målvæv omfatter scleravæv.

DRAWINGS

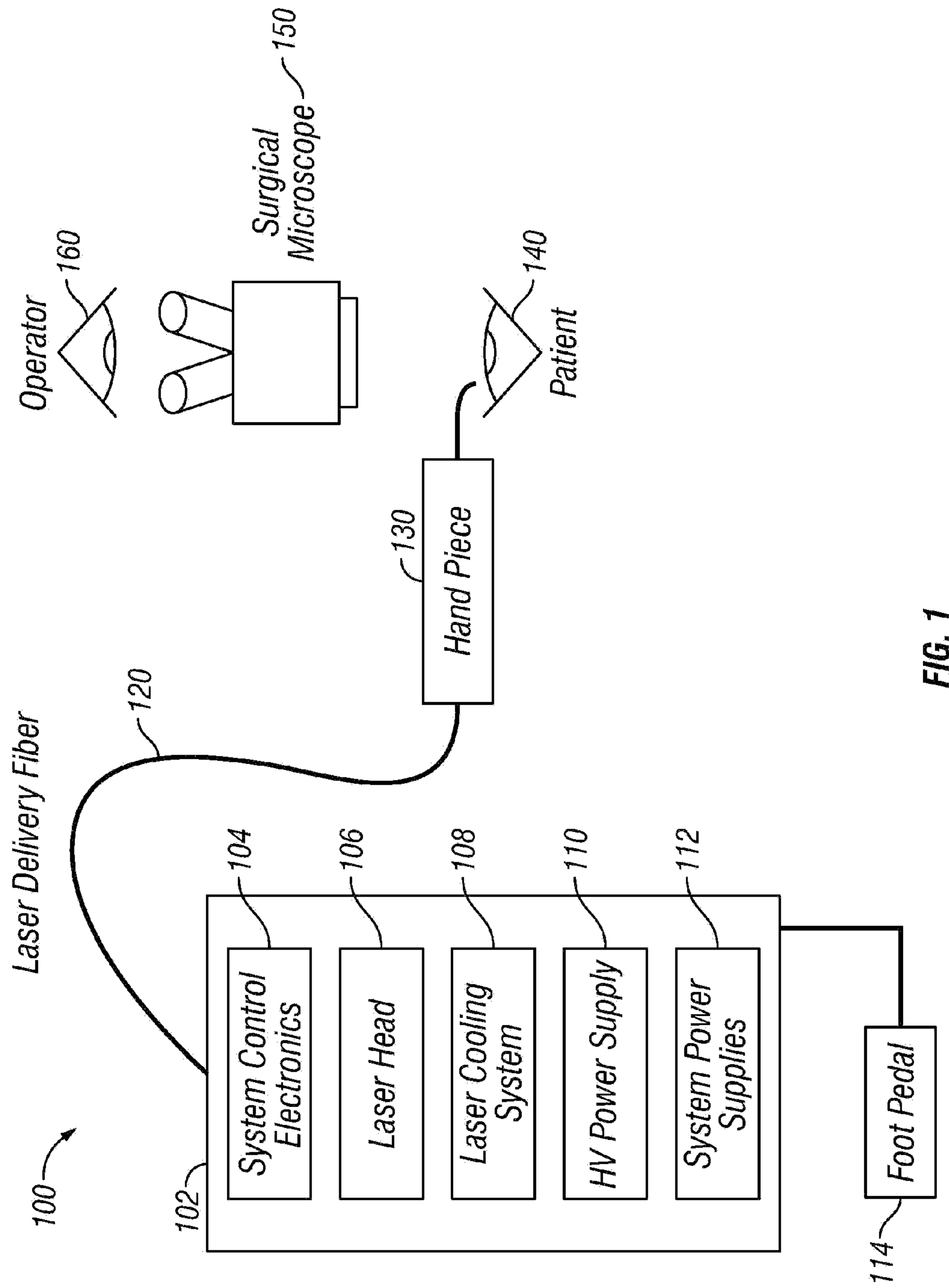


FIG. 1

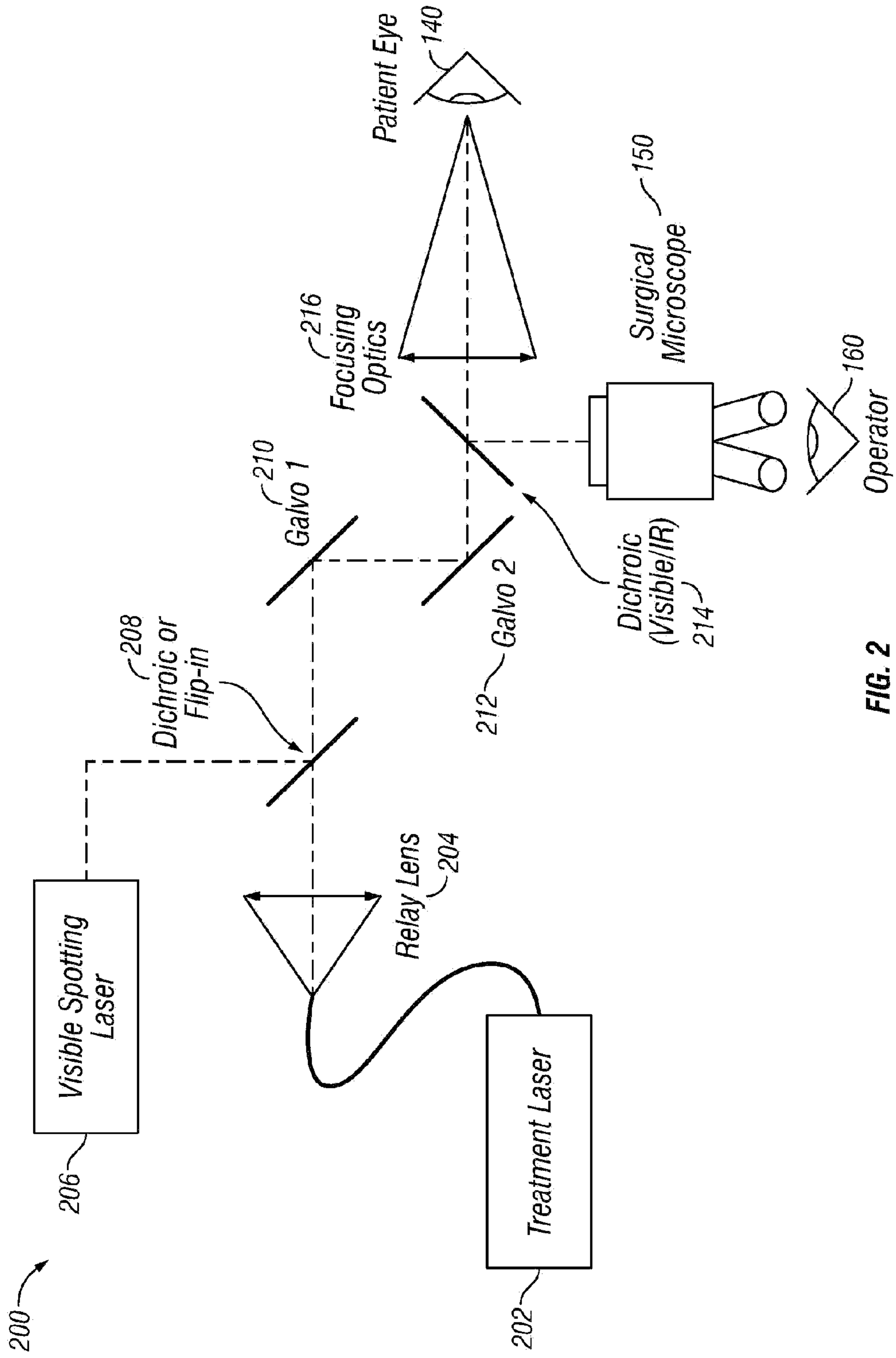


FIG. 2

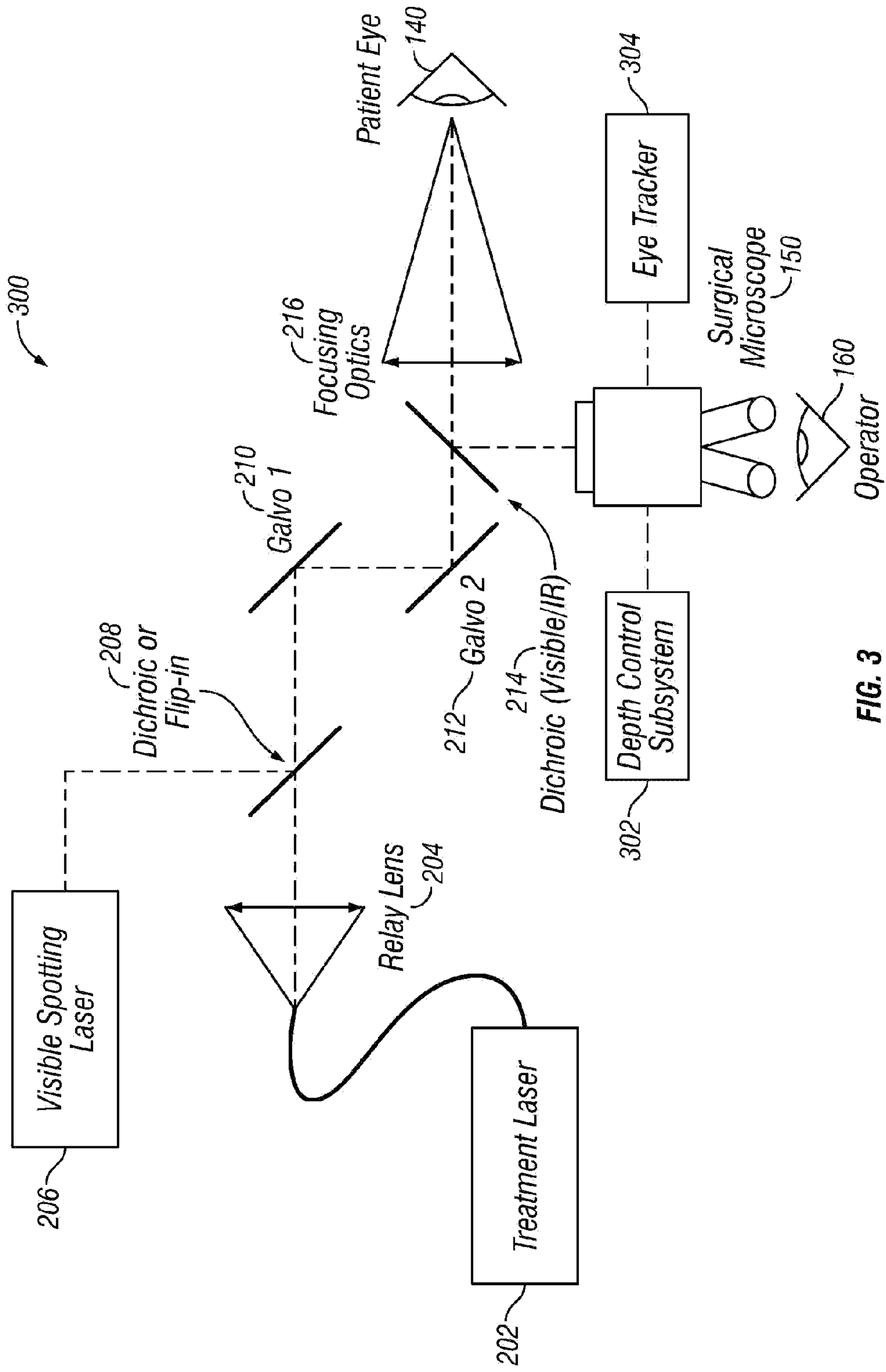


FIG. 3

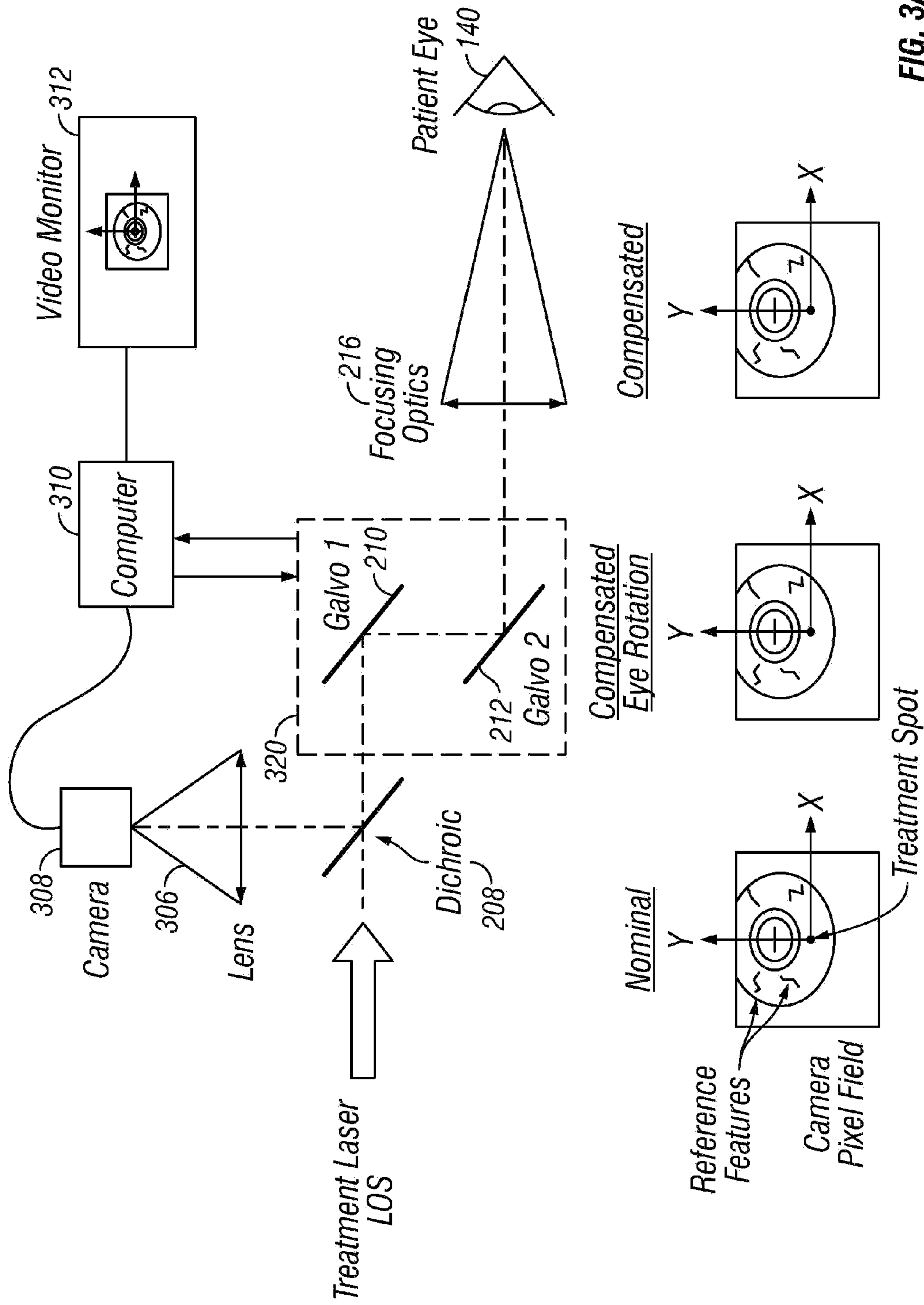


FIG. 3A

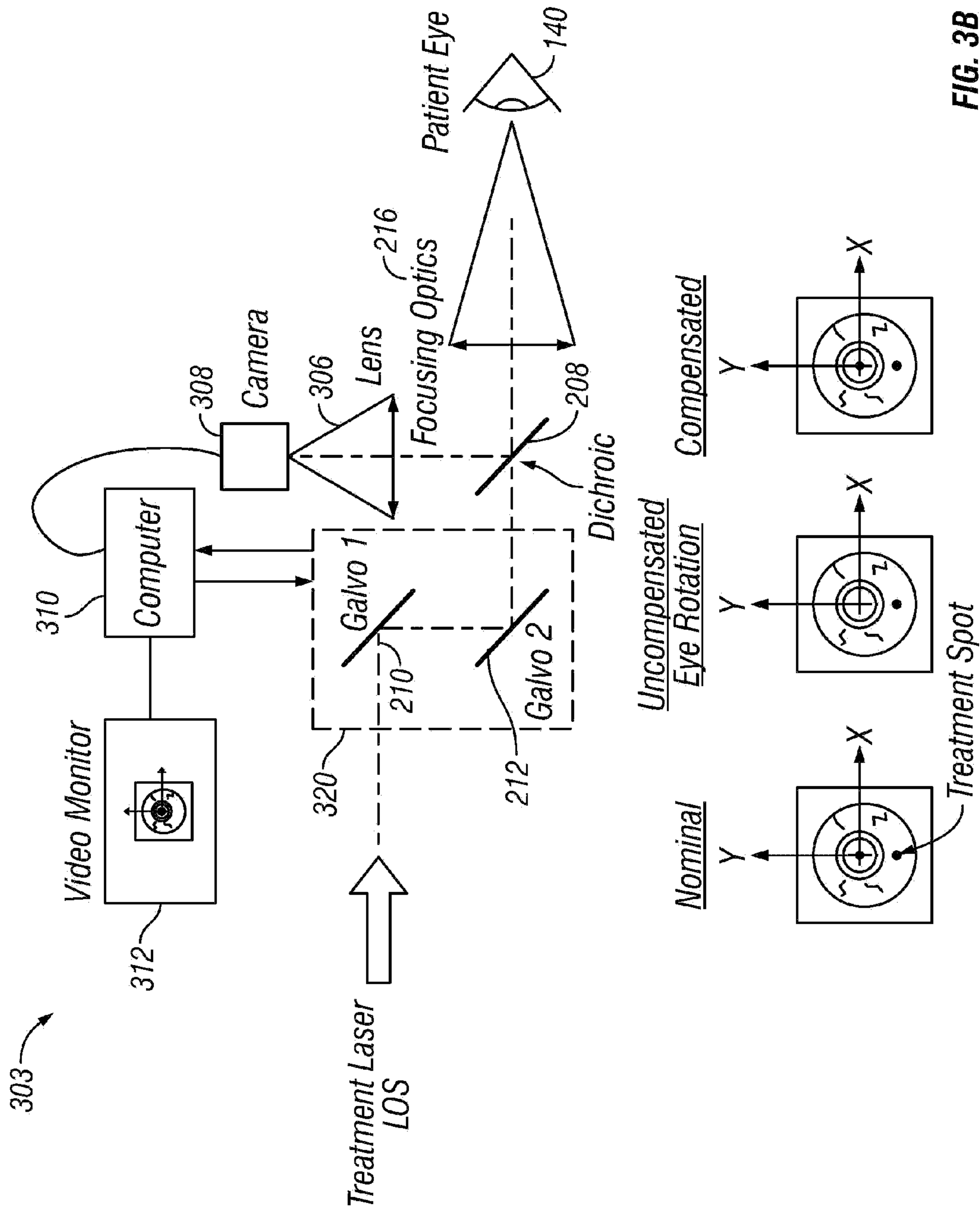


FIG. 3B

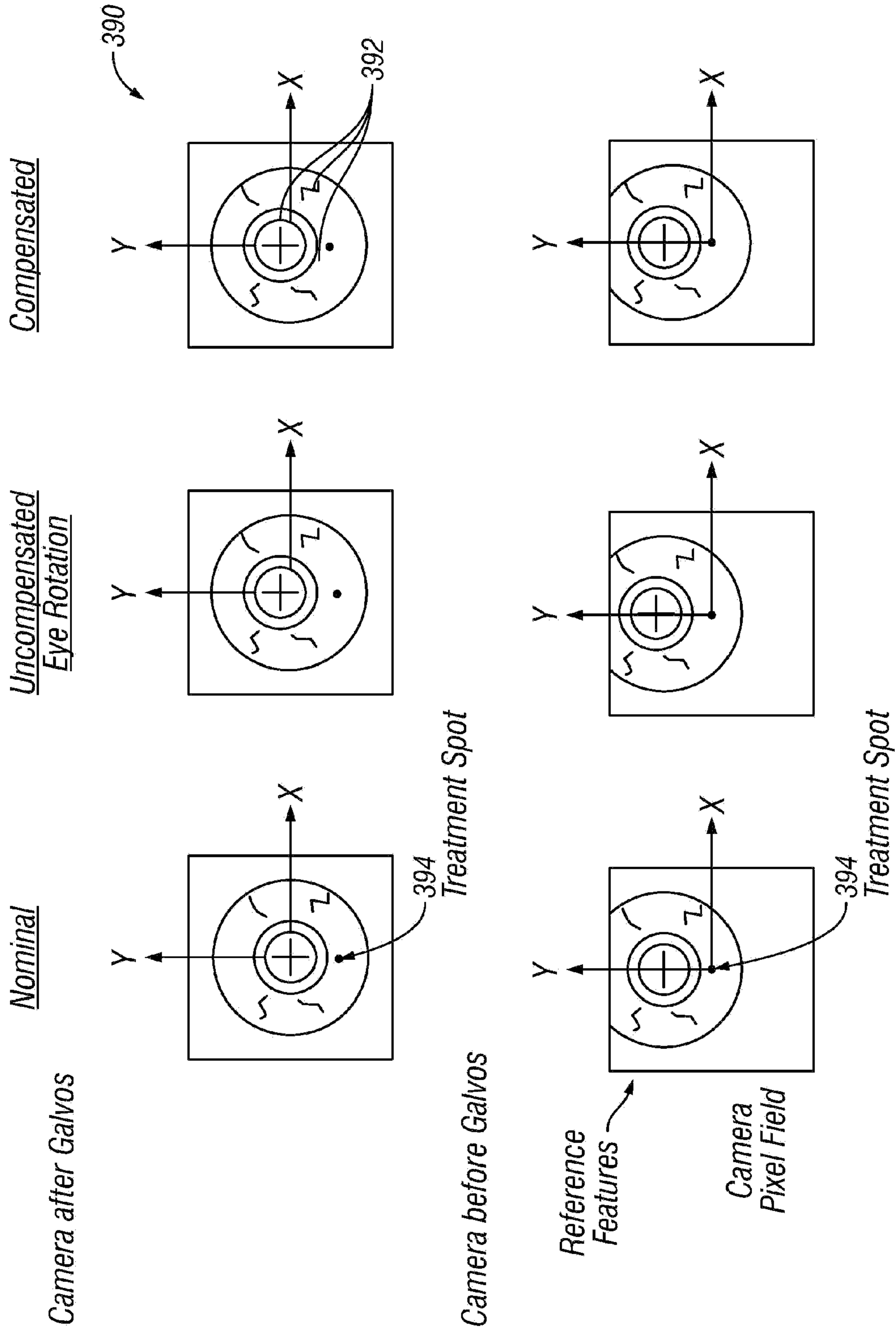


FIG. 3C

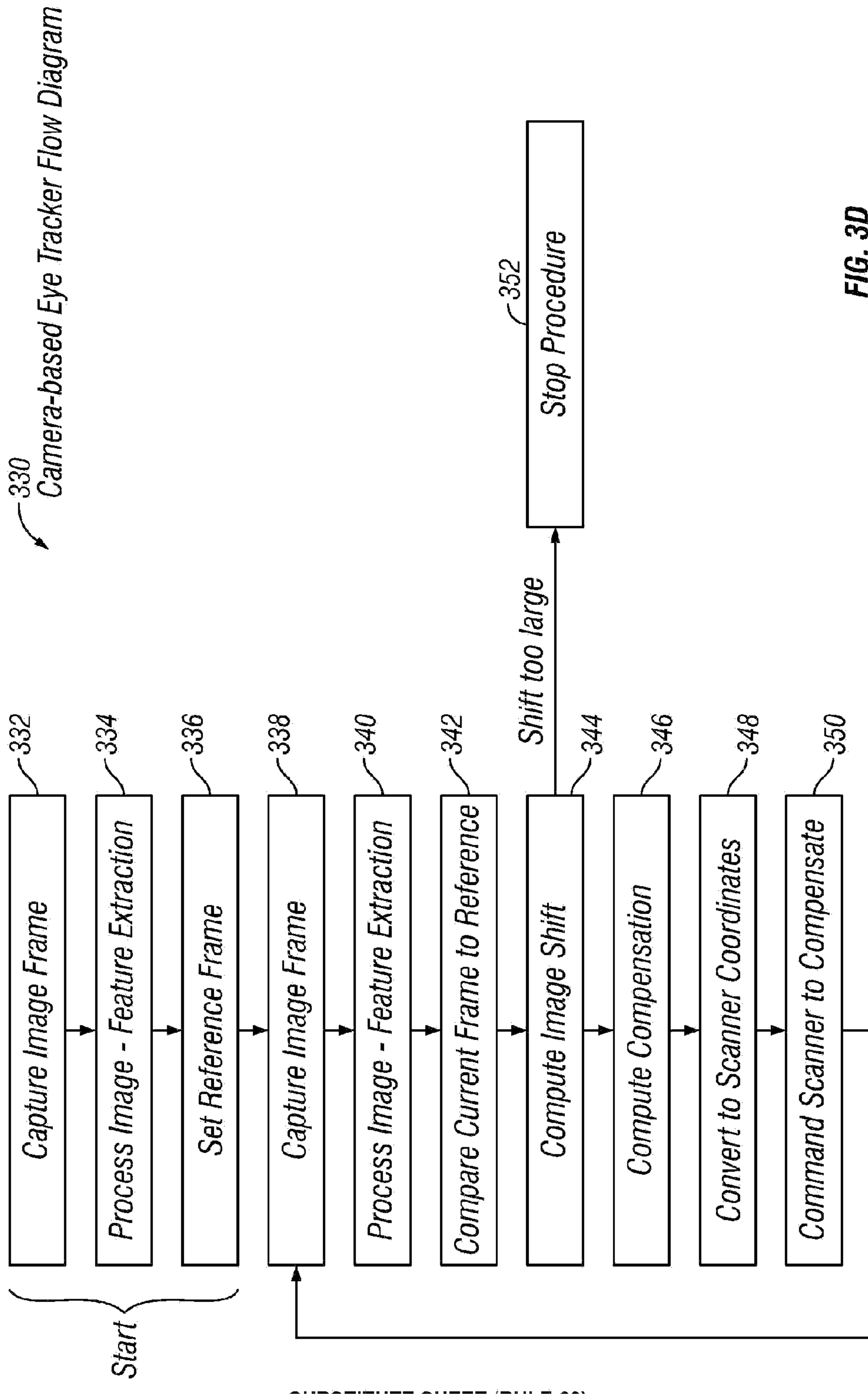


FIG. 3D

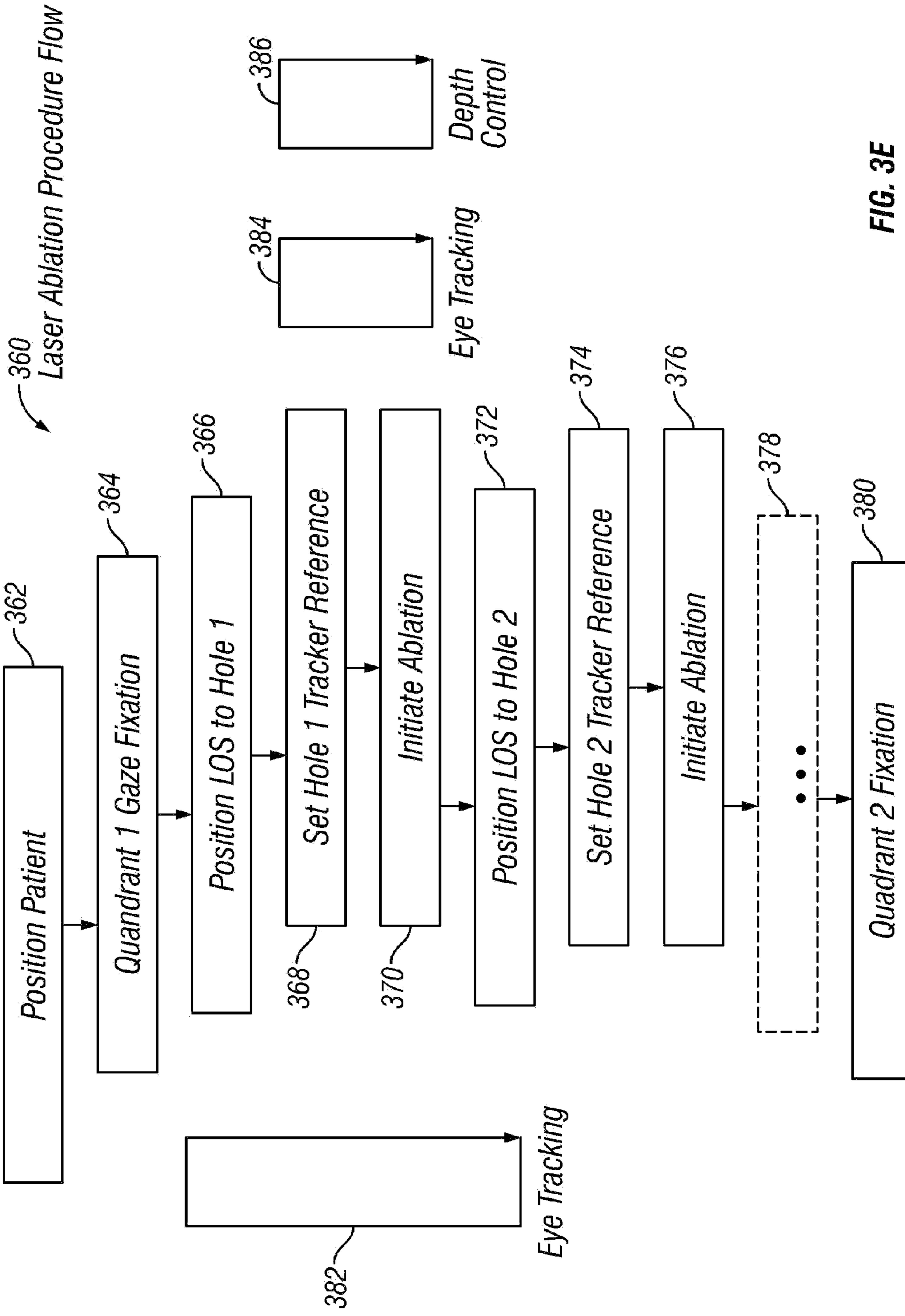


FIG. 3E

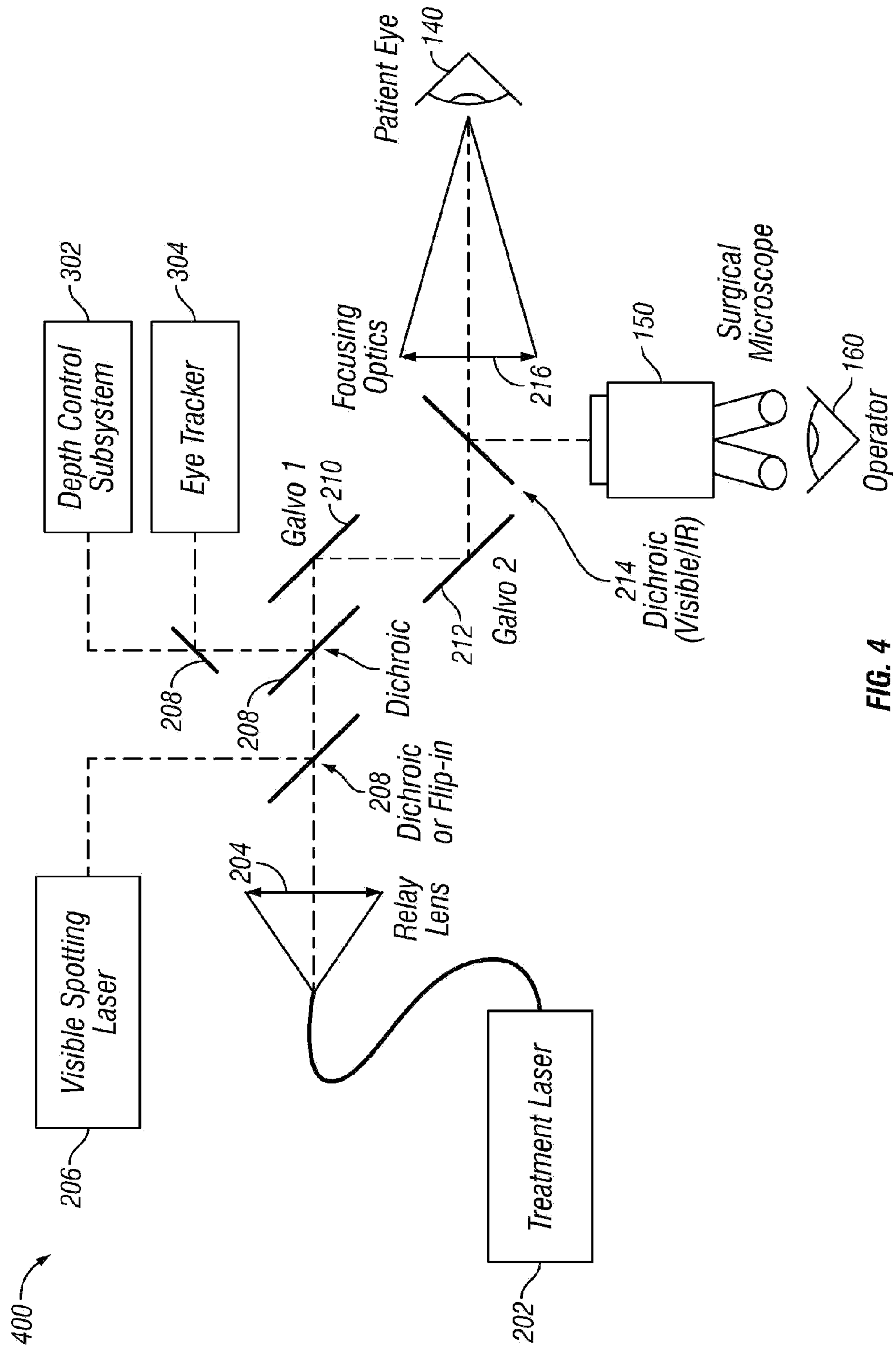


FIG. 4

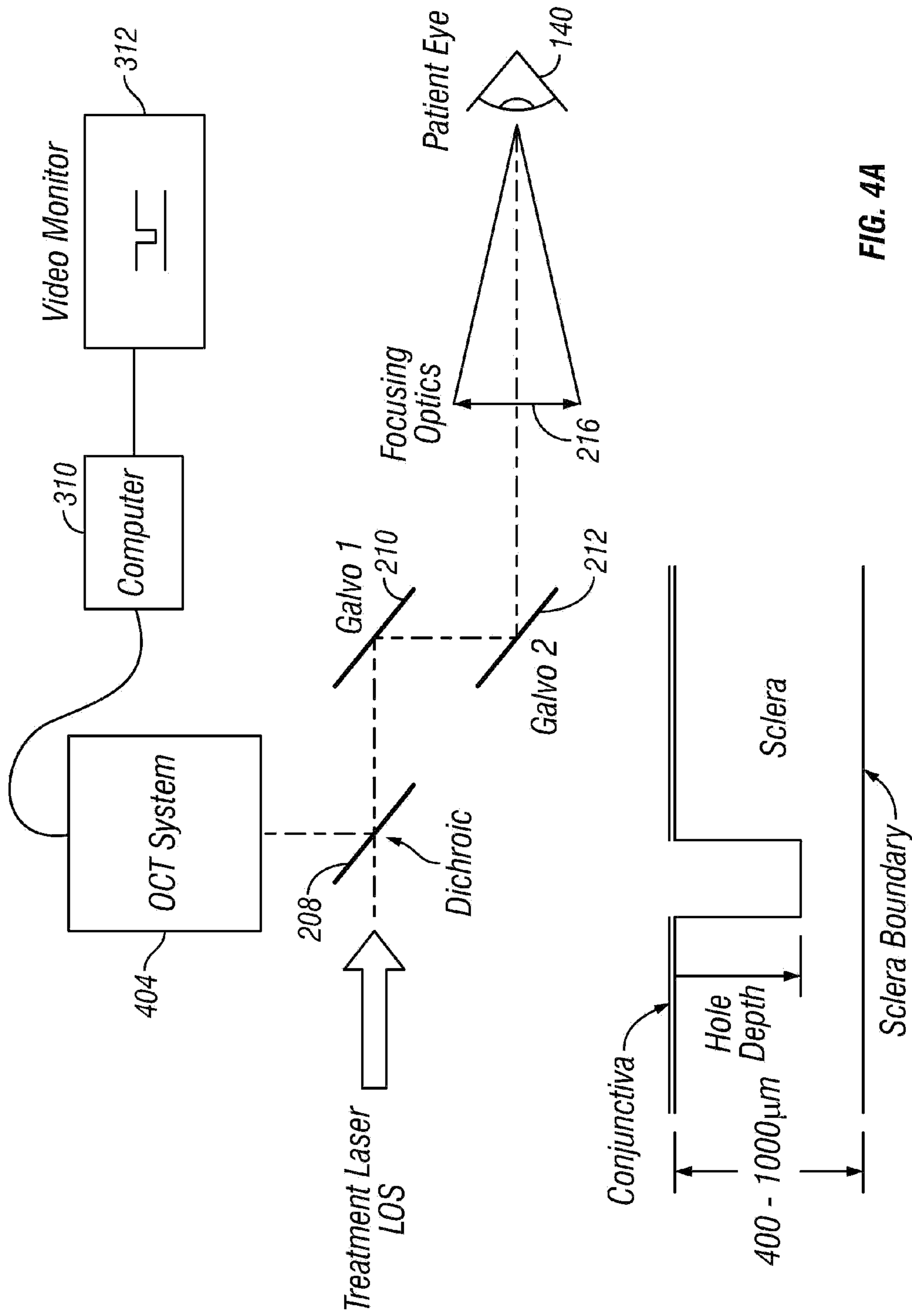


FIG. 4A

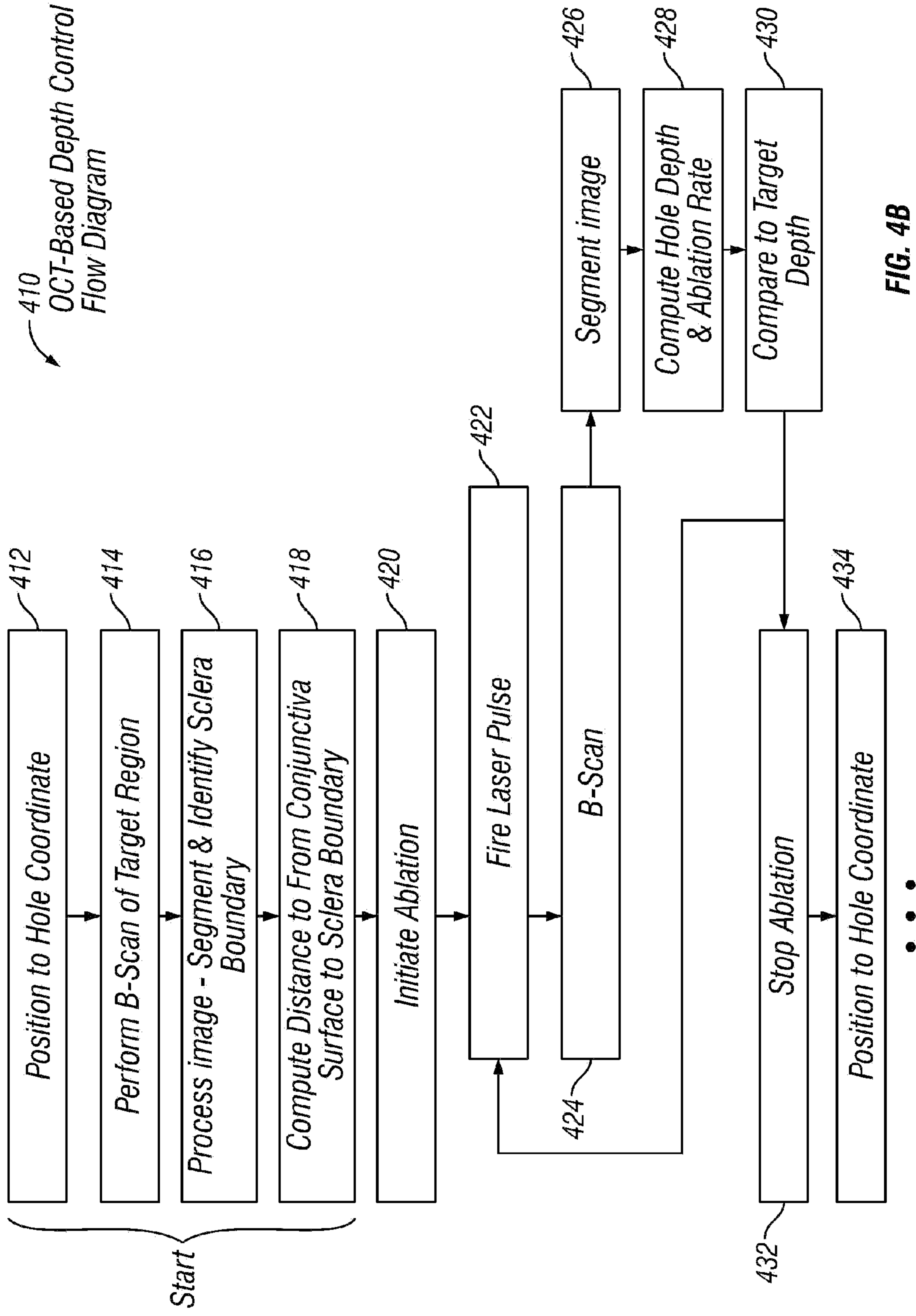


FIG. 4B

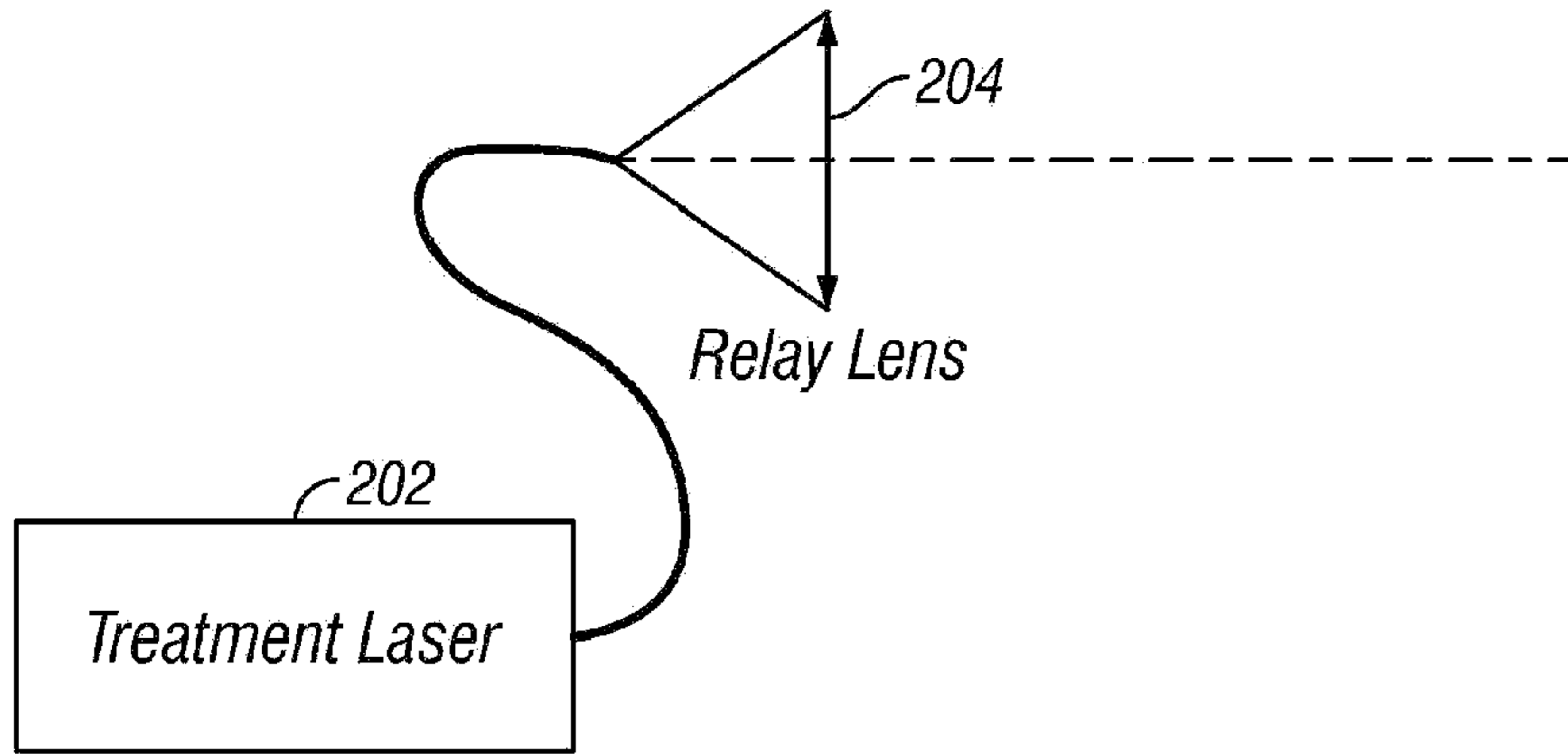


FIG. 5A

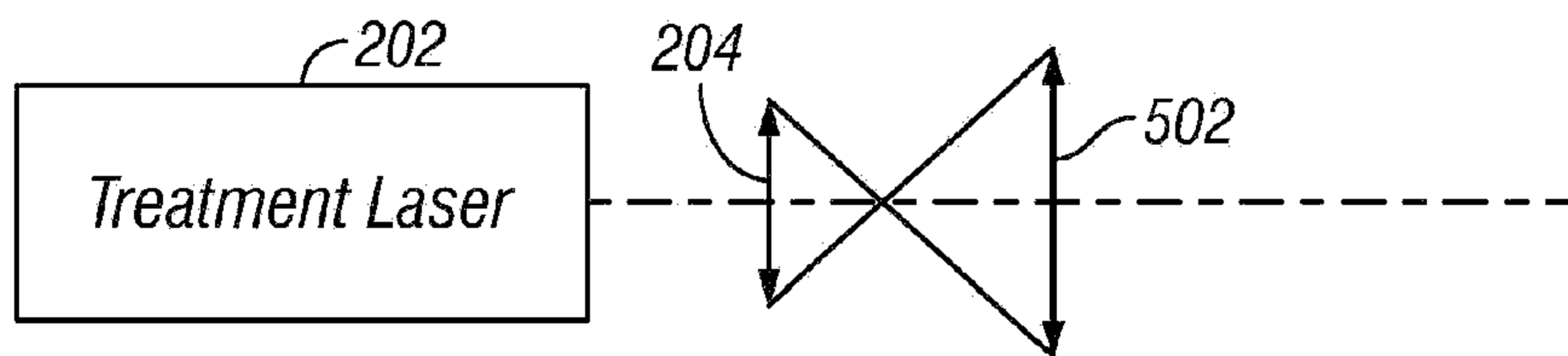


FIG. 5B

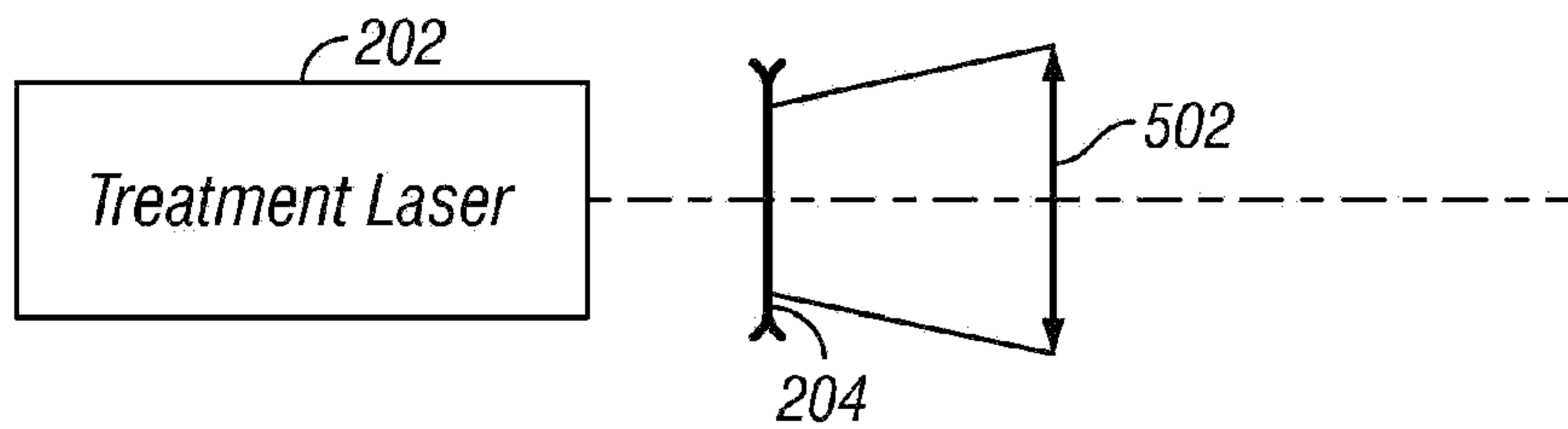


FIG. 5C

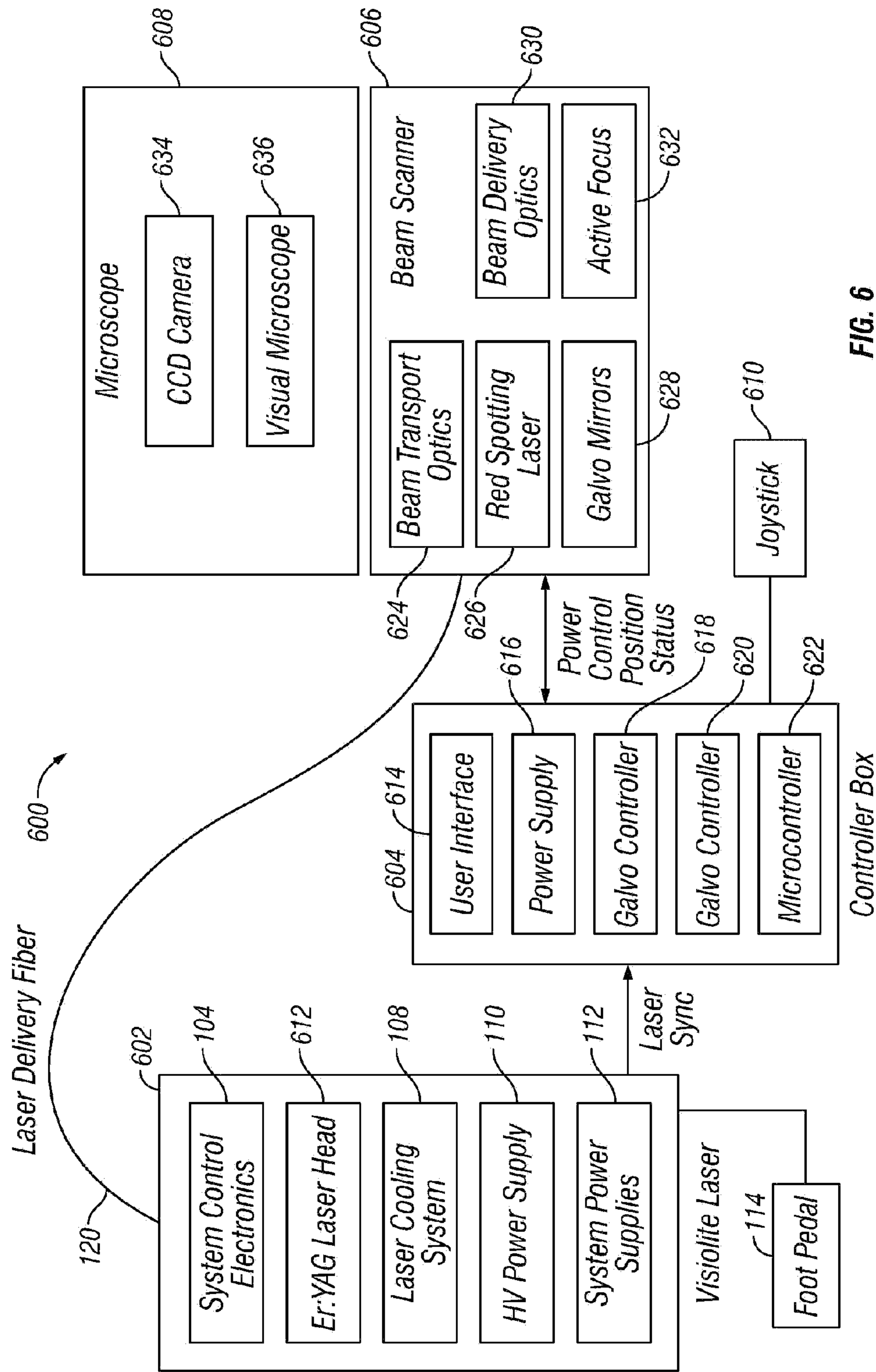


FIG. 6

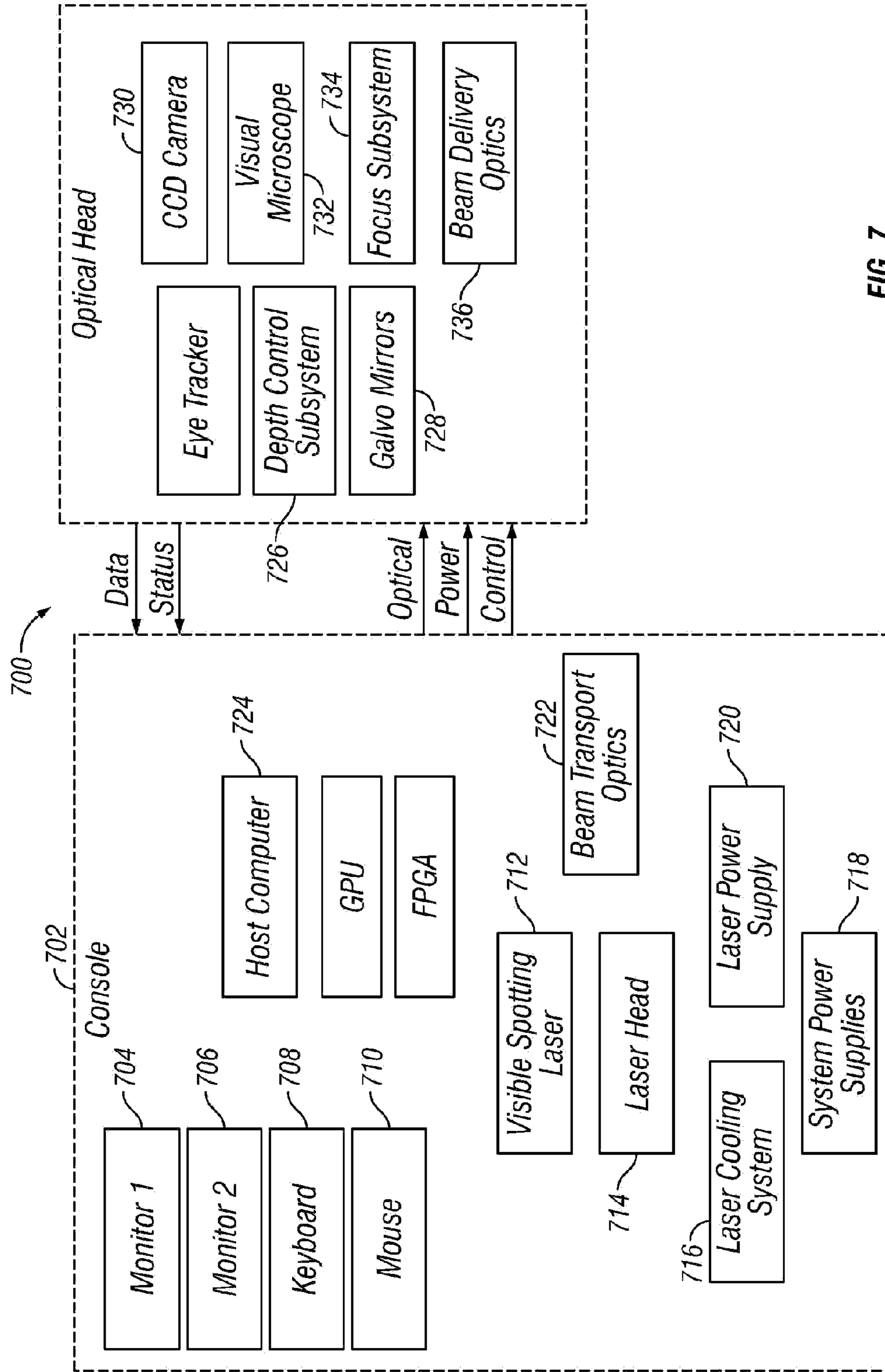


FIG. 7

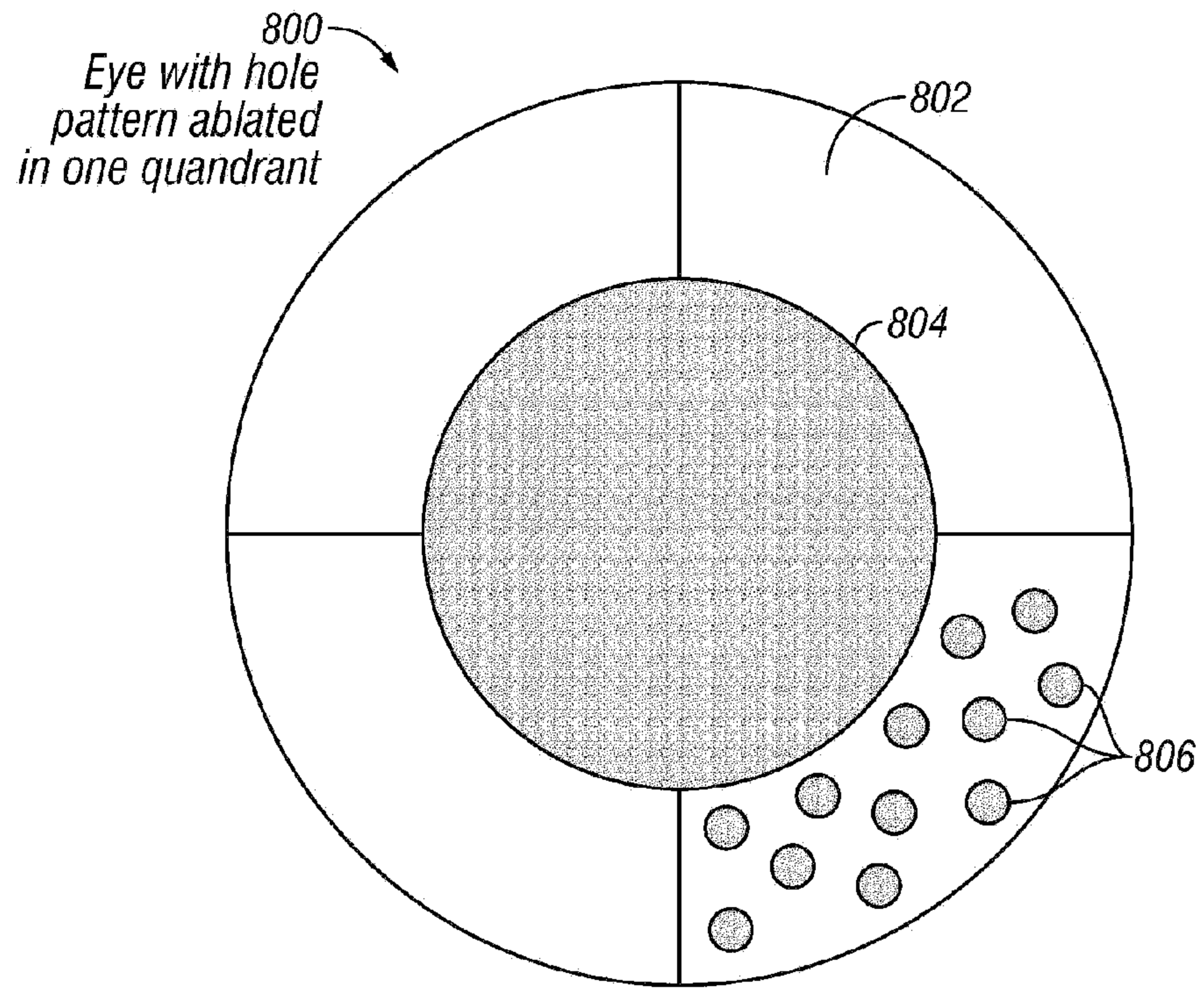


FIG. 8

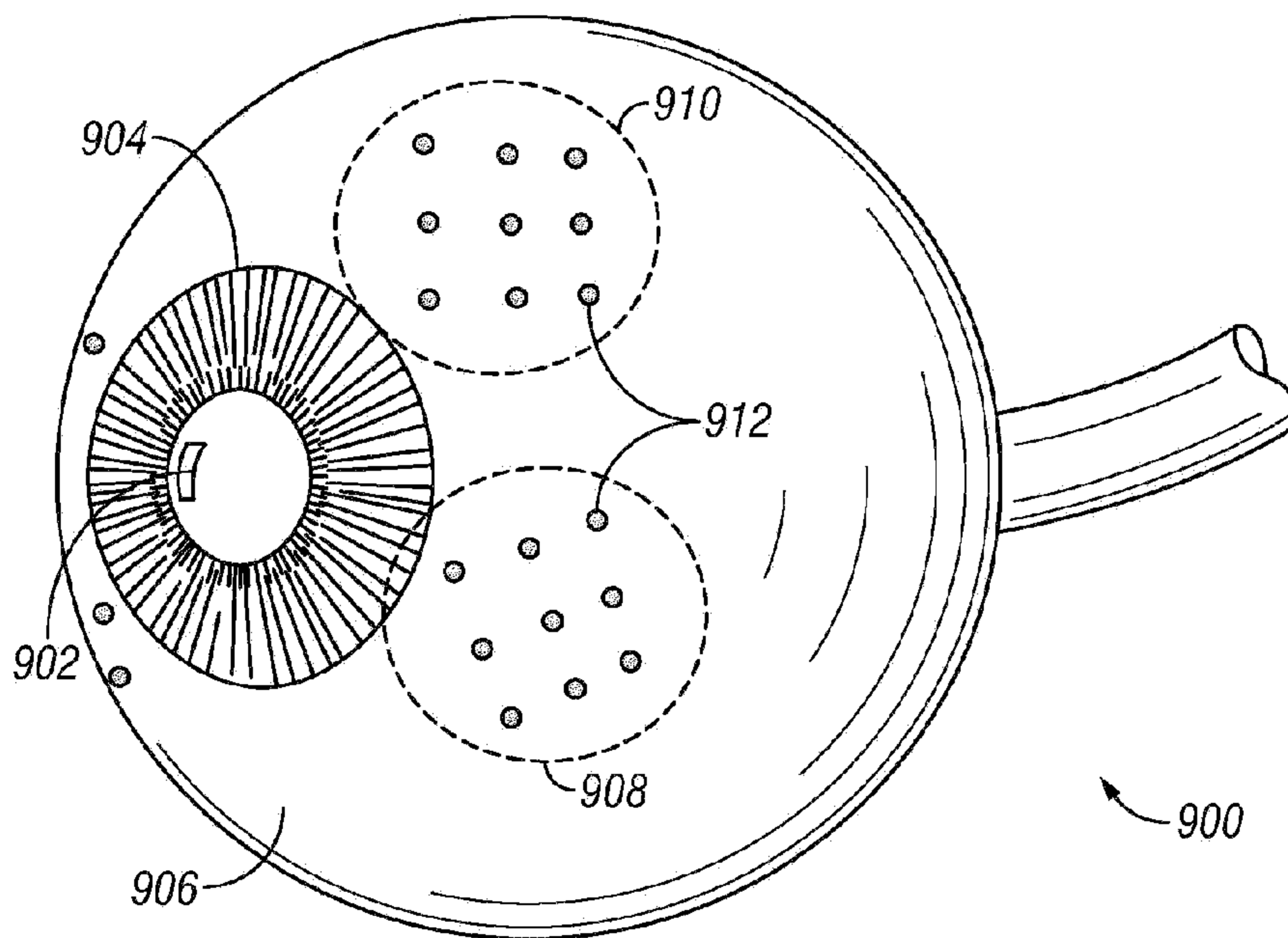


FIG. 9

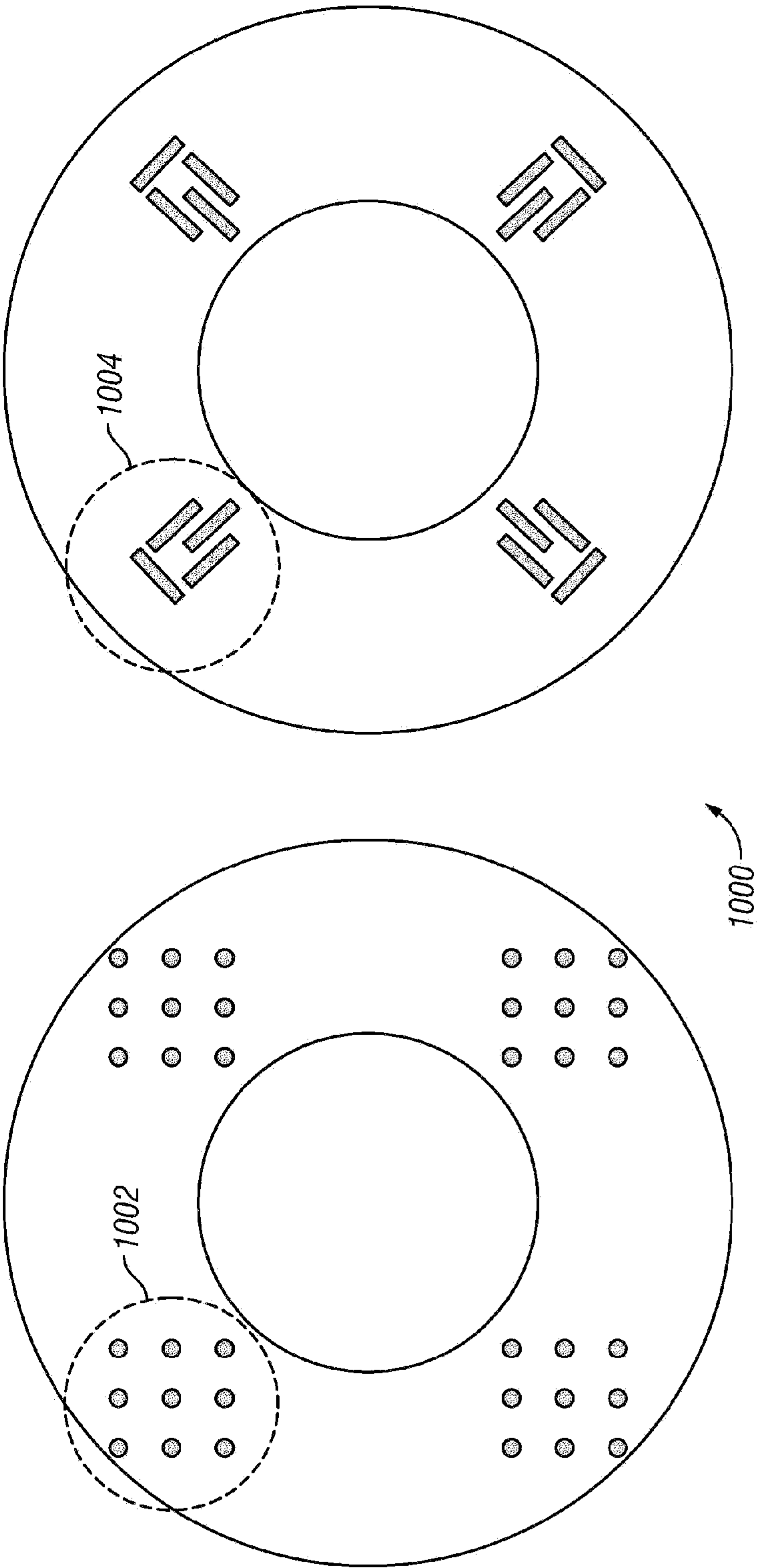


FIG. 10

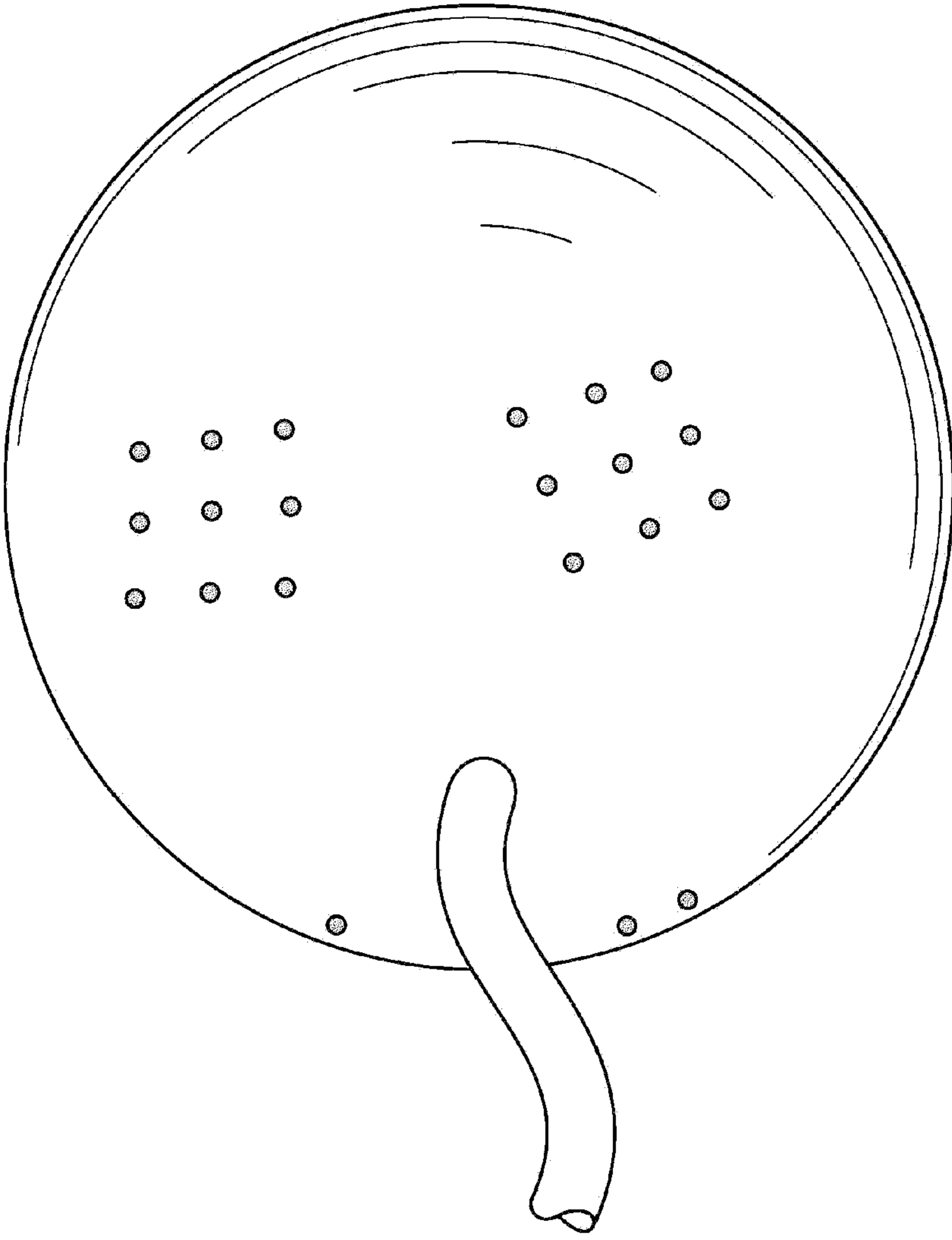


FIG. 11

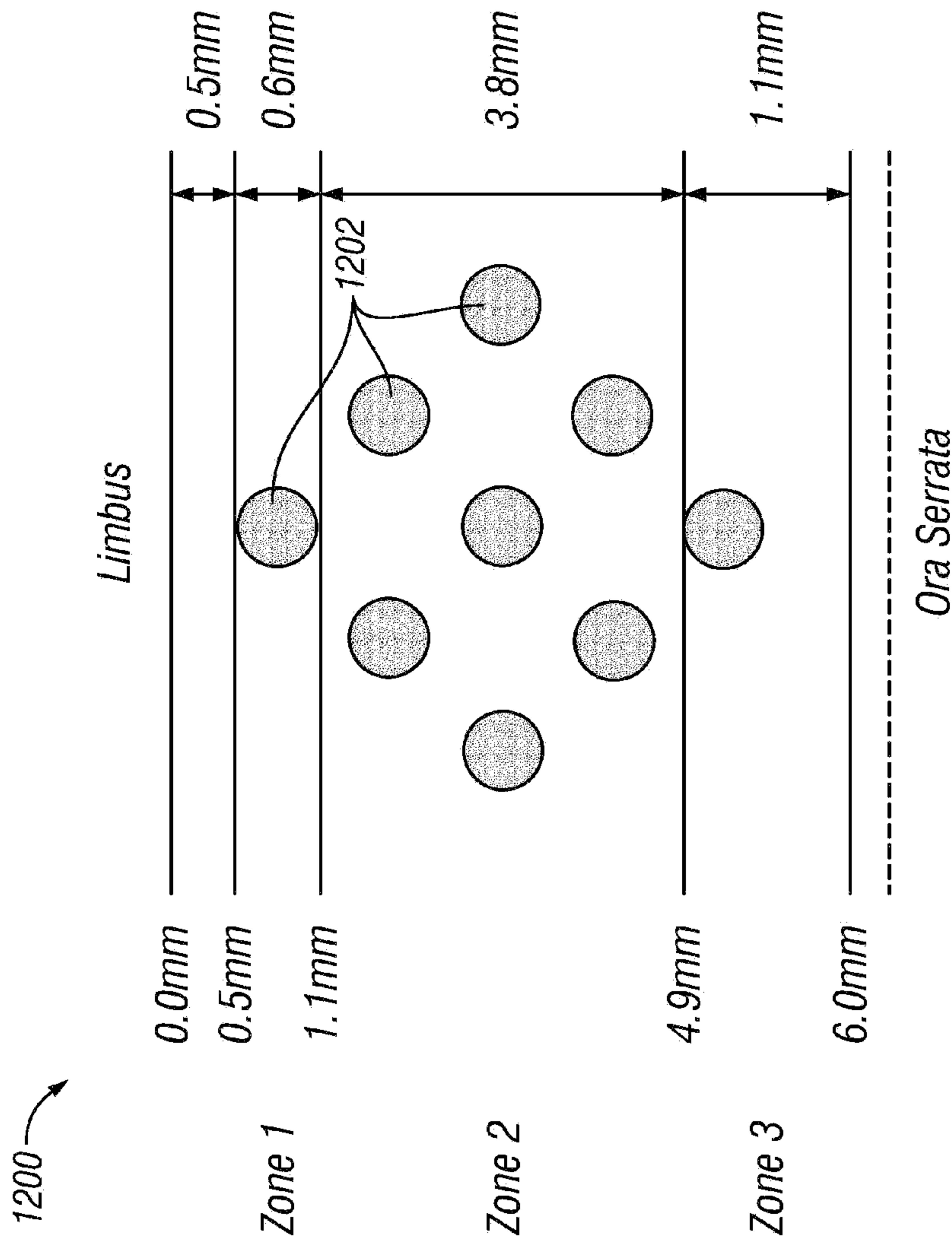


FIG. 12

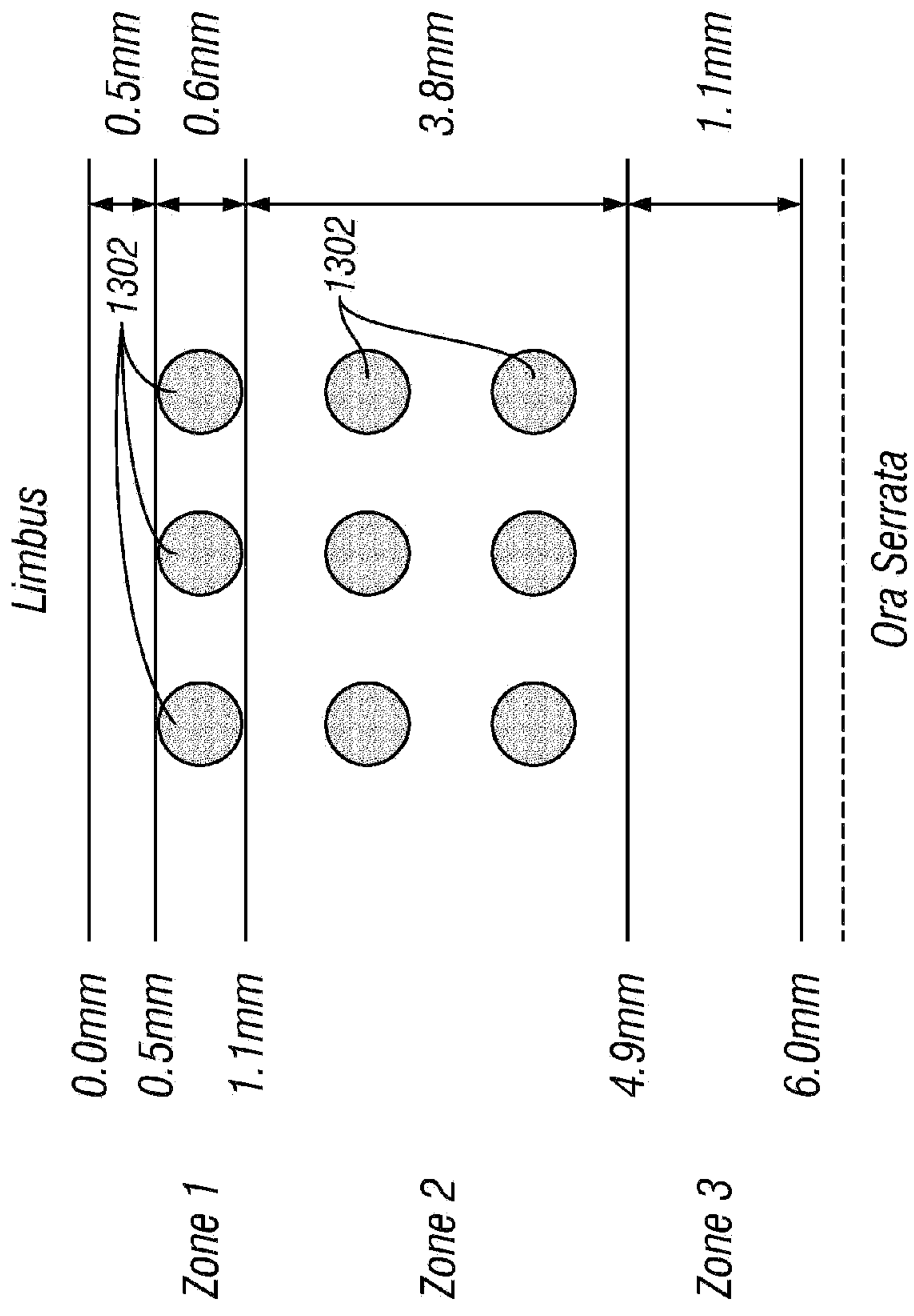


FIG. 13

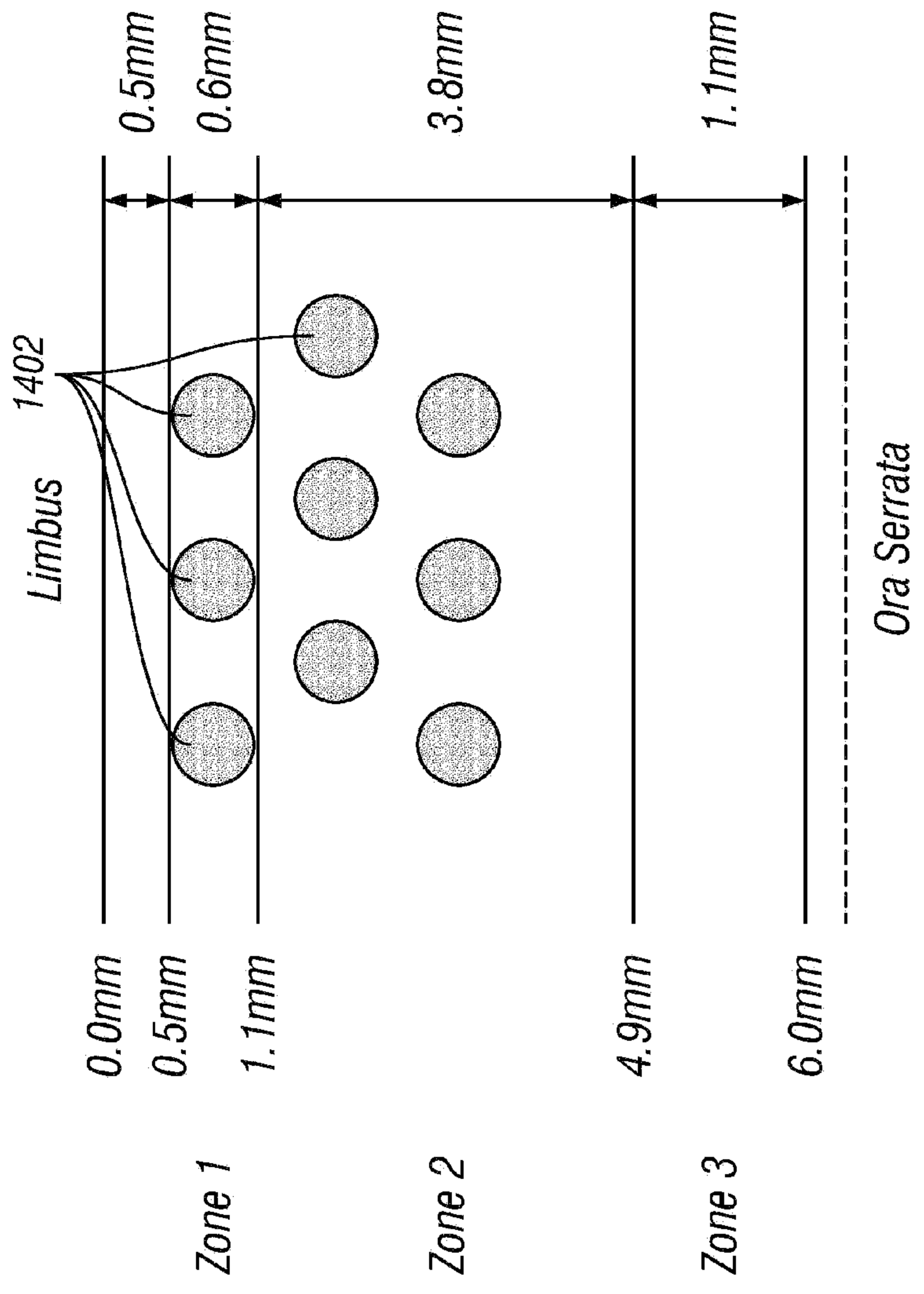


FIG. 14

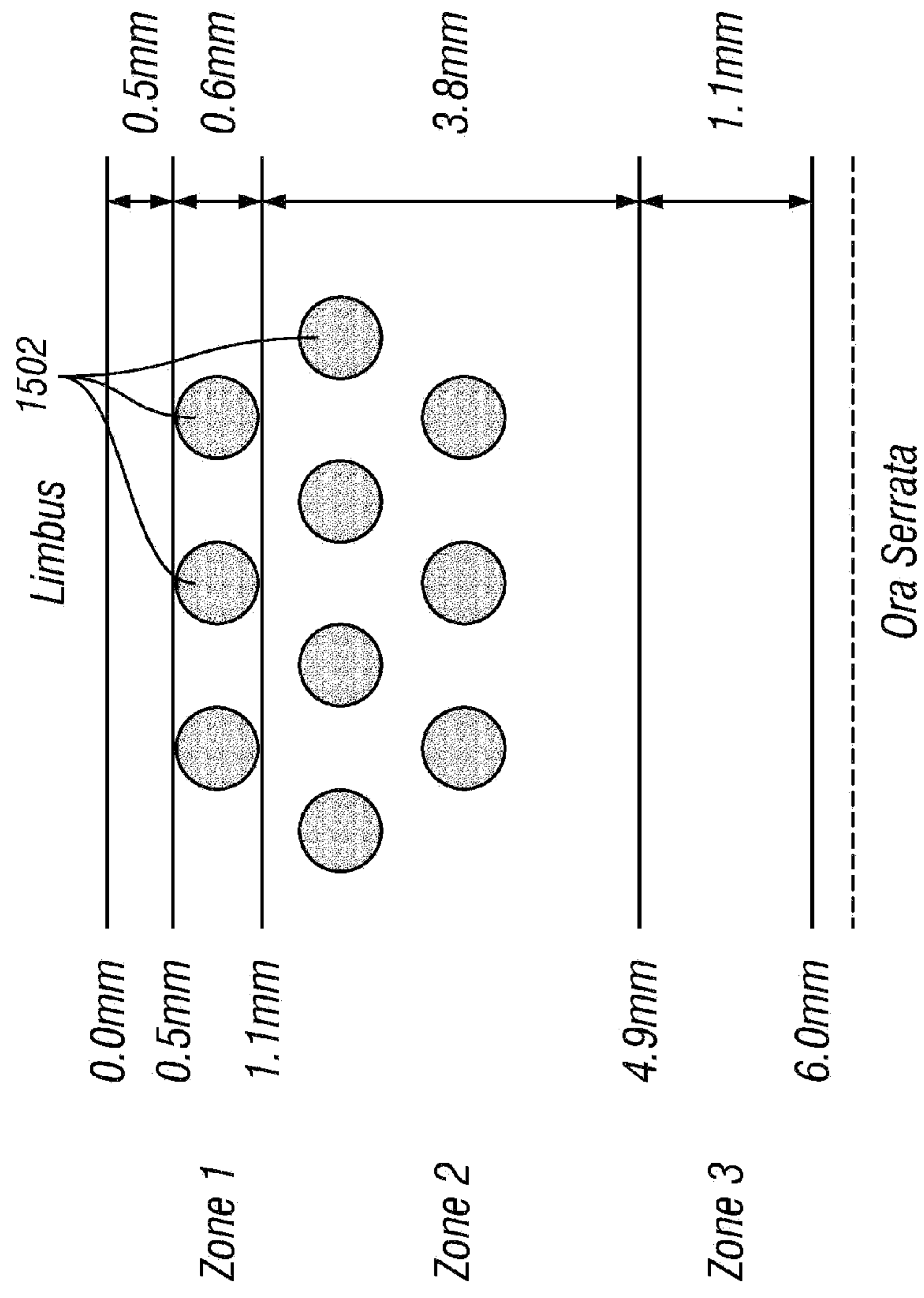


FIG. 15

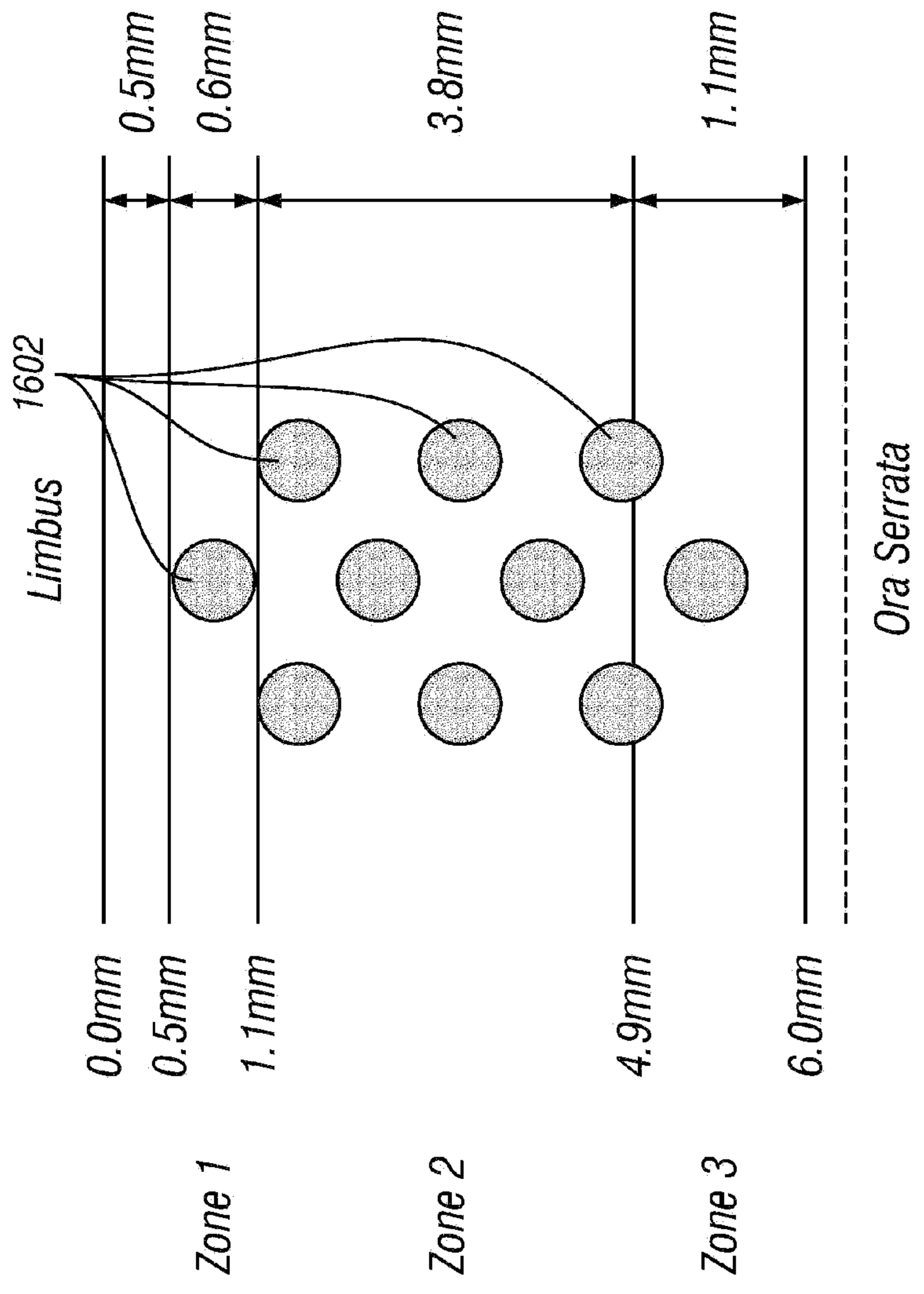


FIG. 16

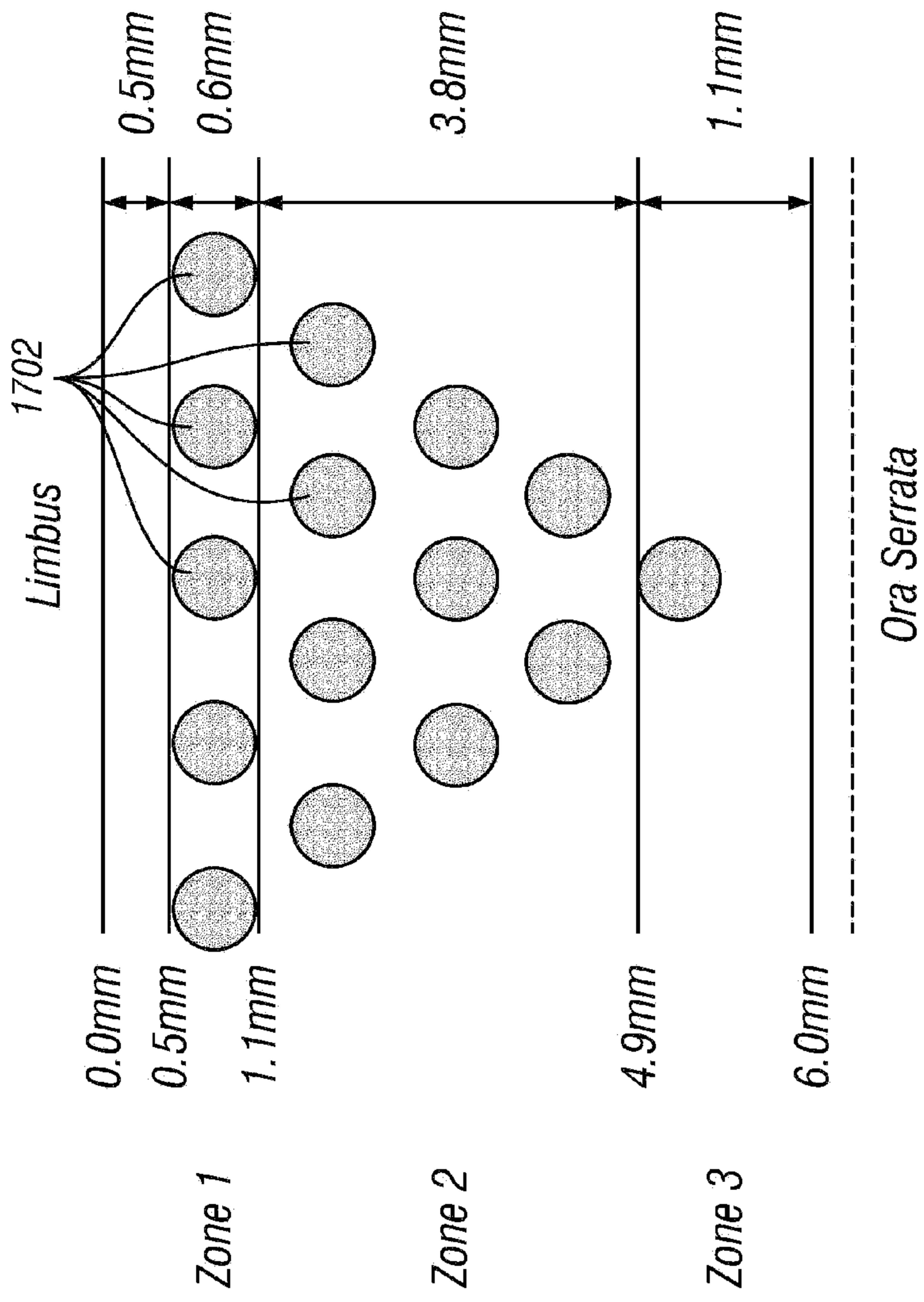


FIG. 17

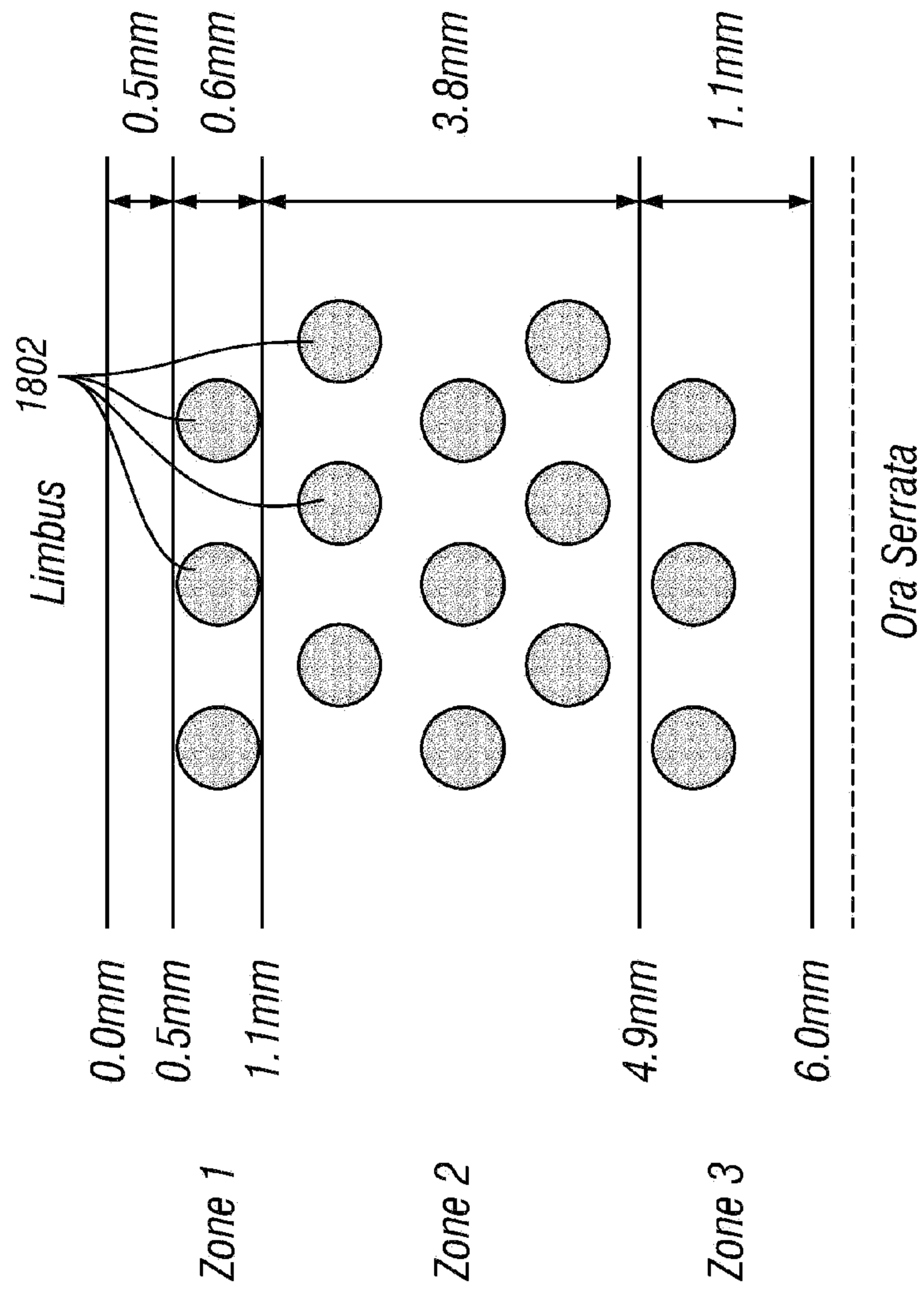


FIG. 18

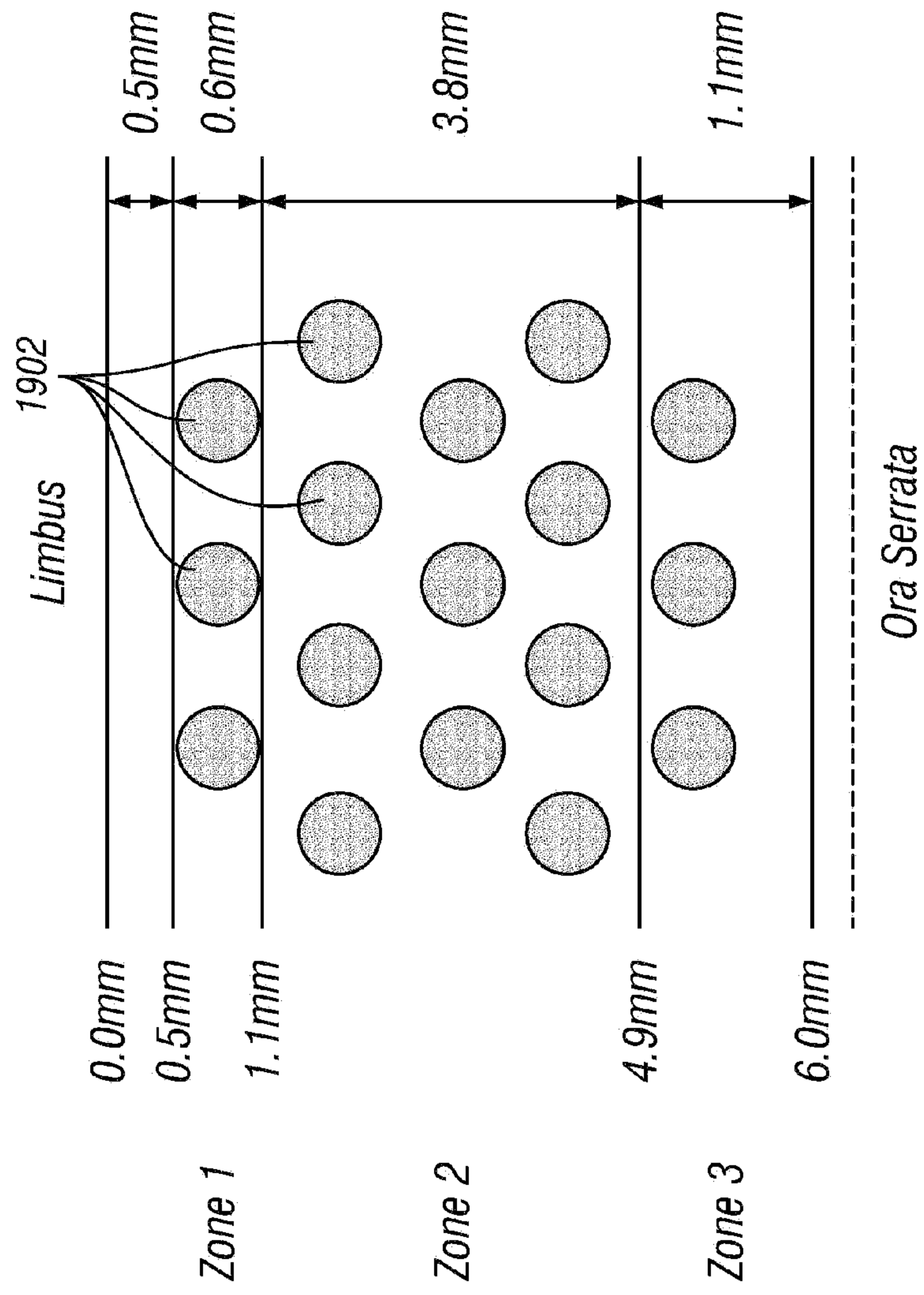


FIG. 19

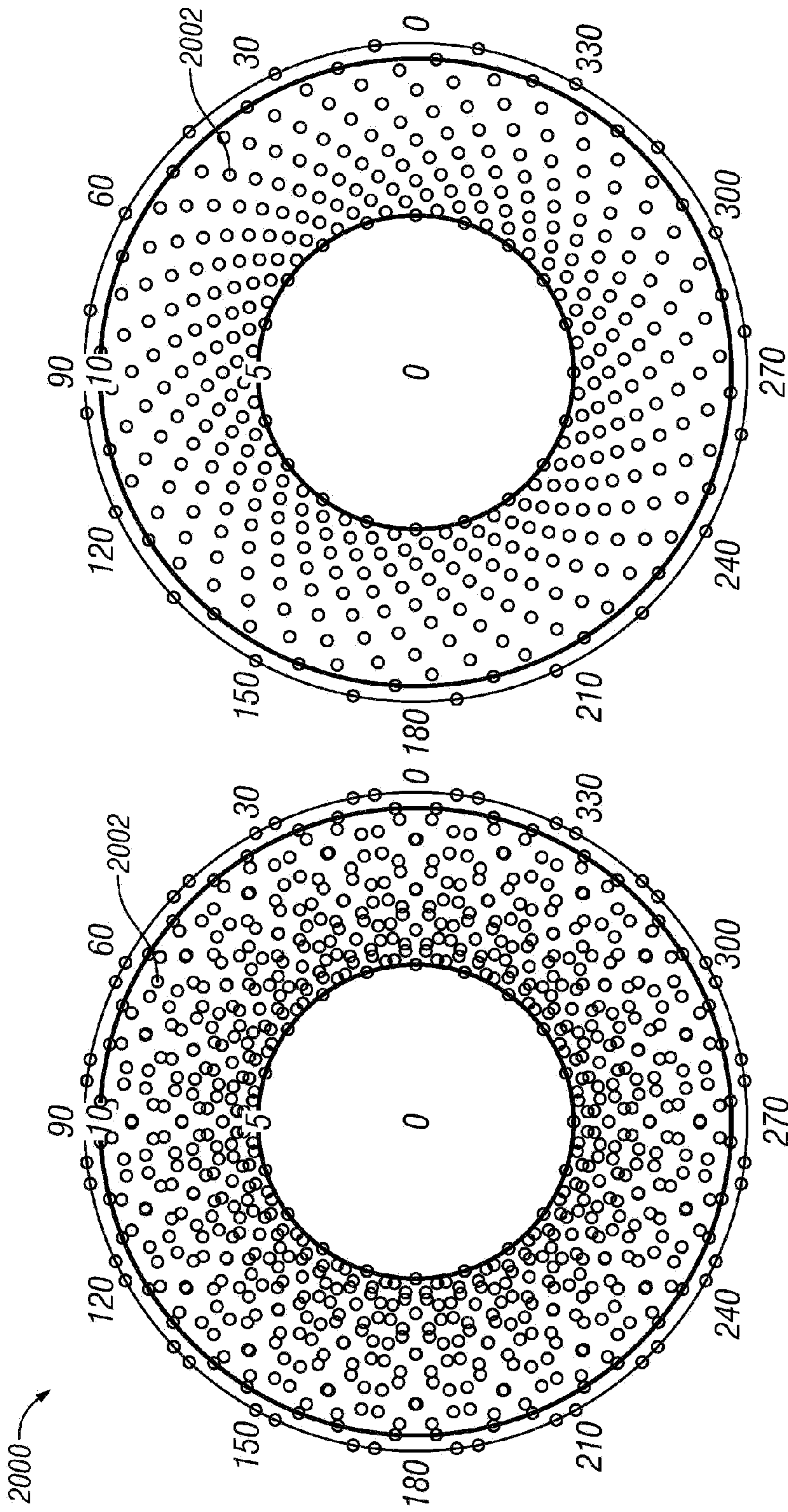


FIG. 20

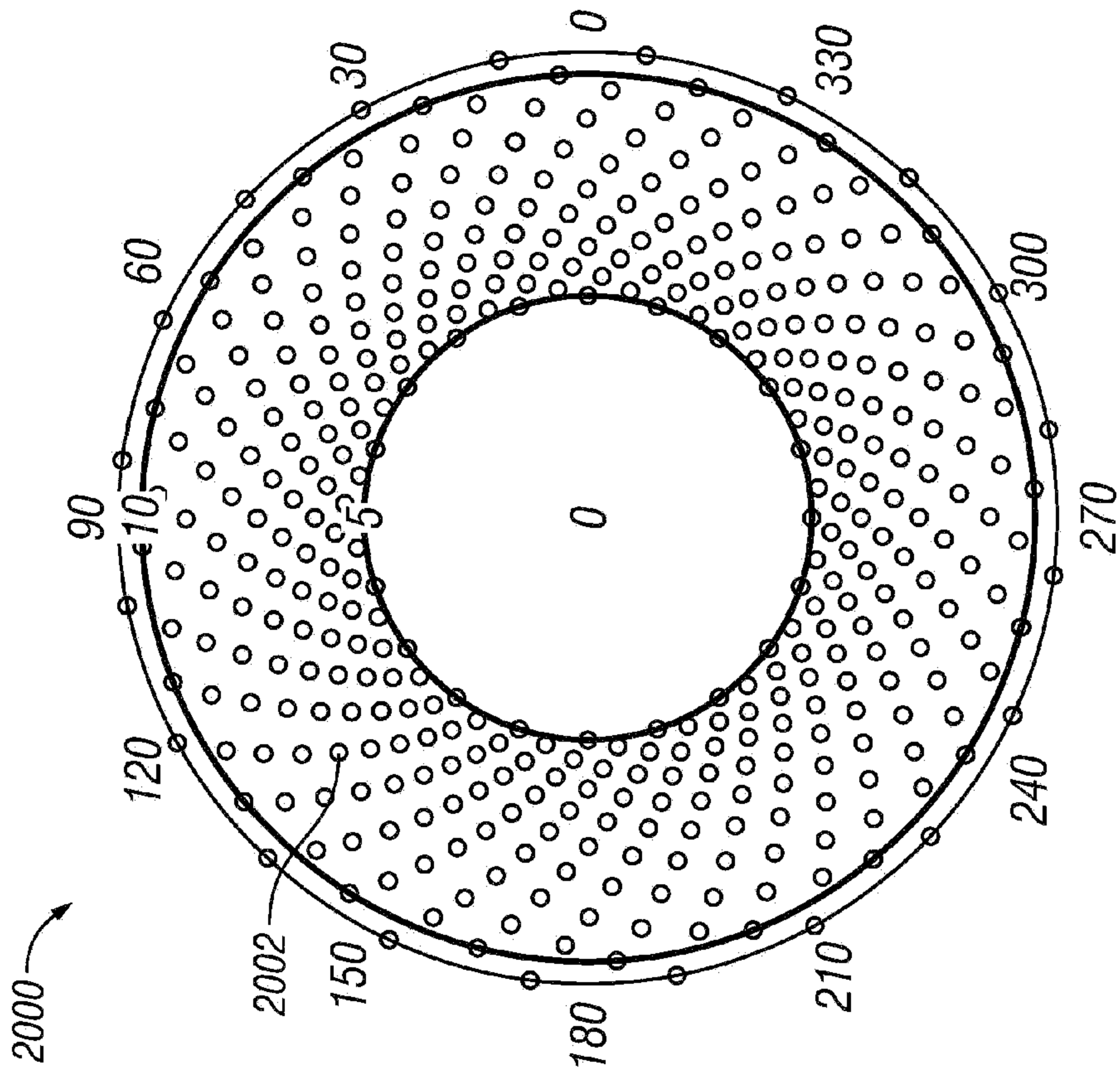


FIG. 20
(Cont'd)

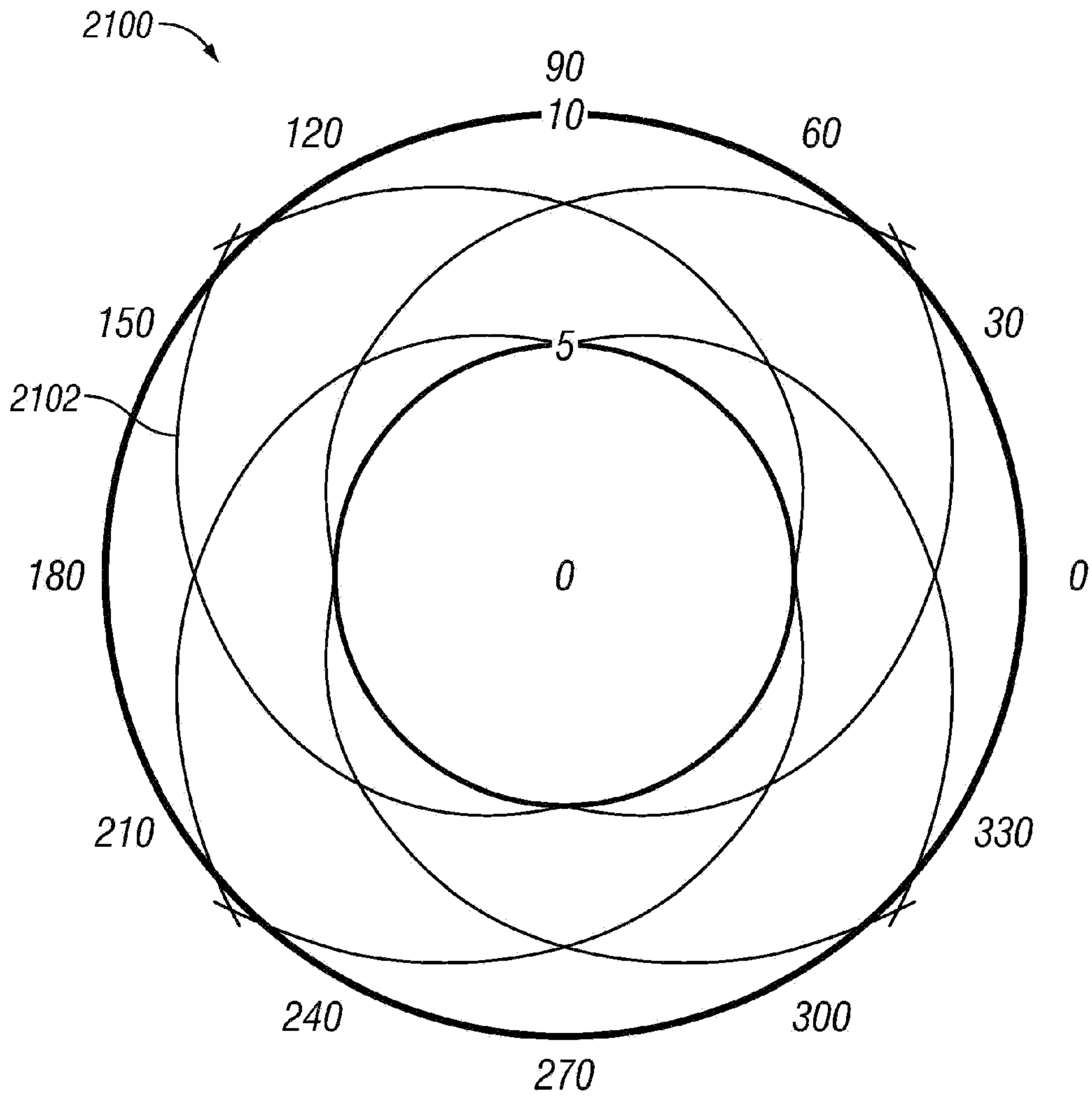


FIG. 21

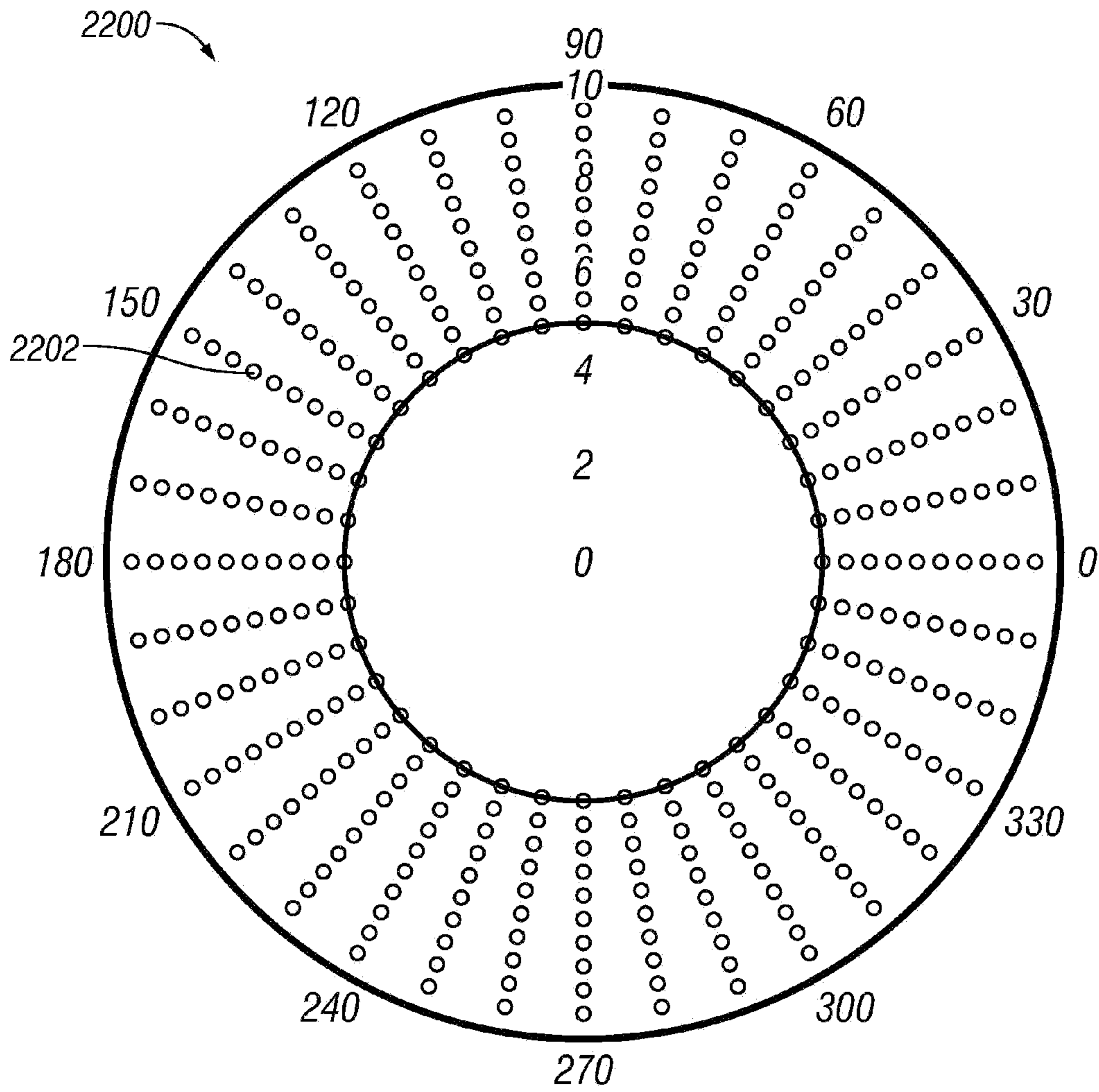


FIG. 22

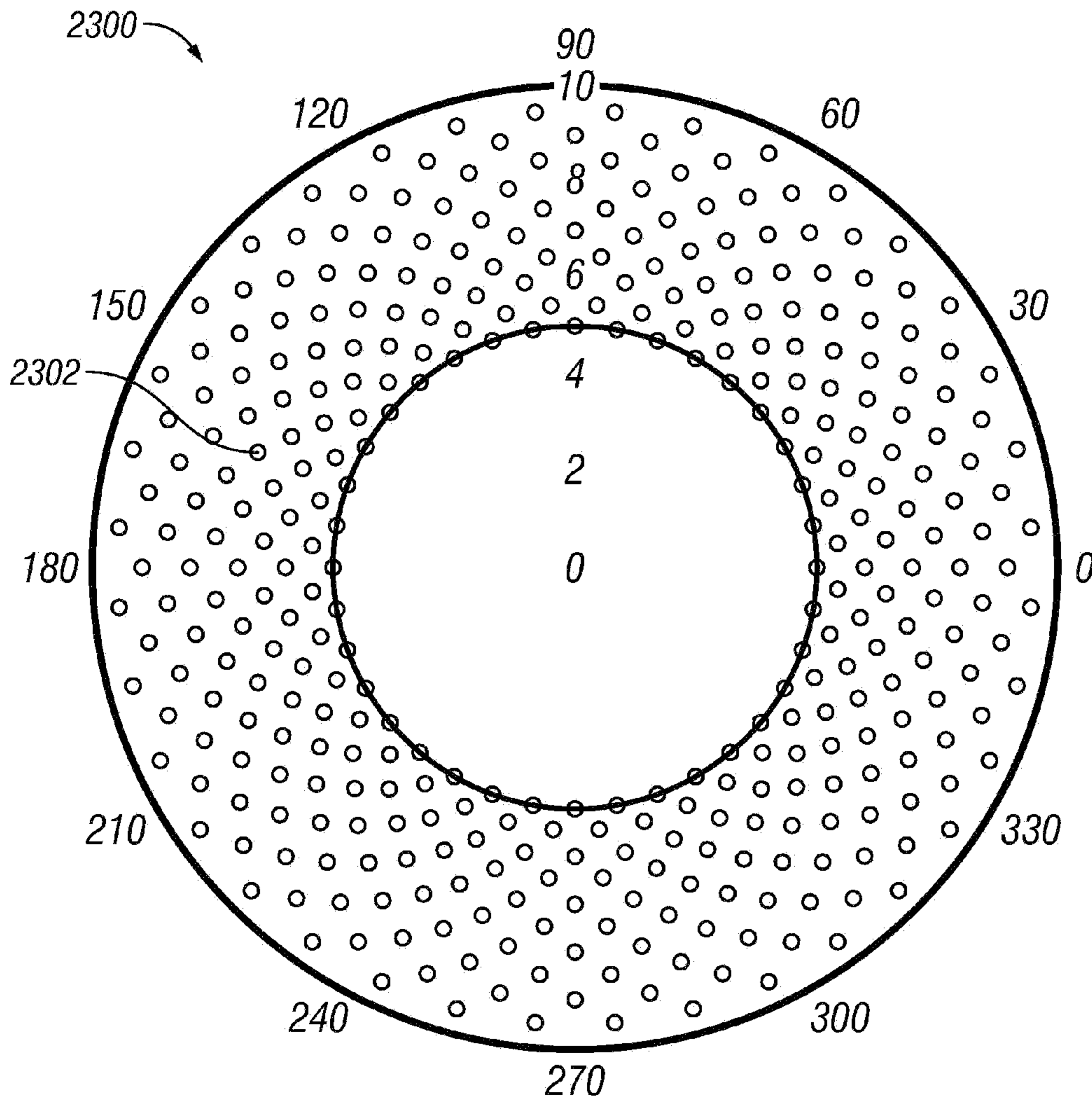


FIG. 23

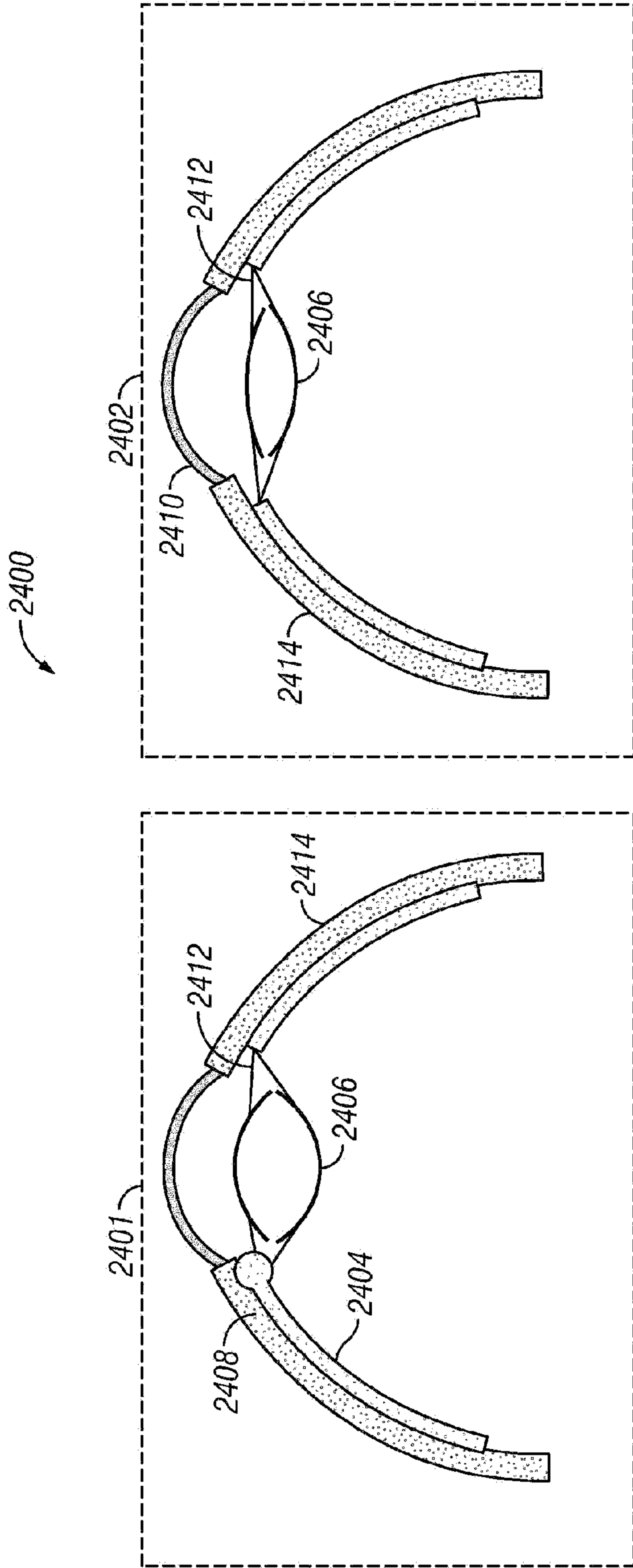


FIG. 24A

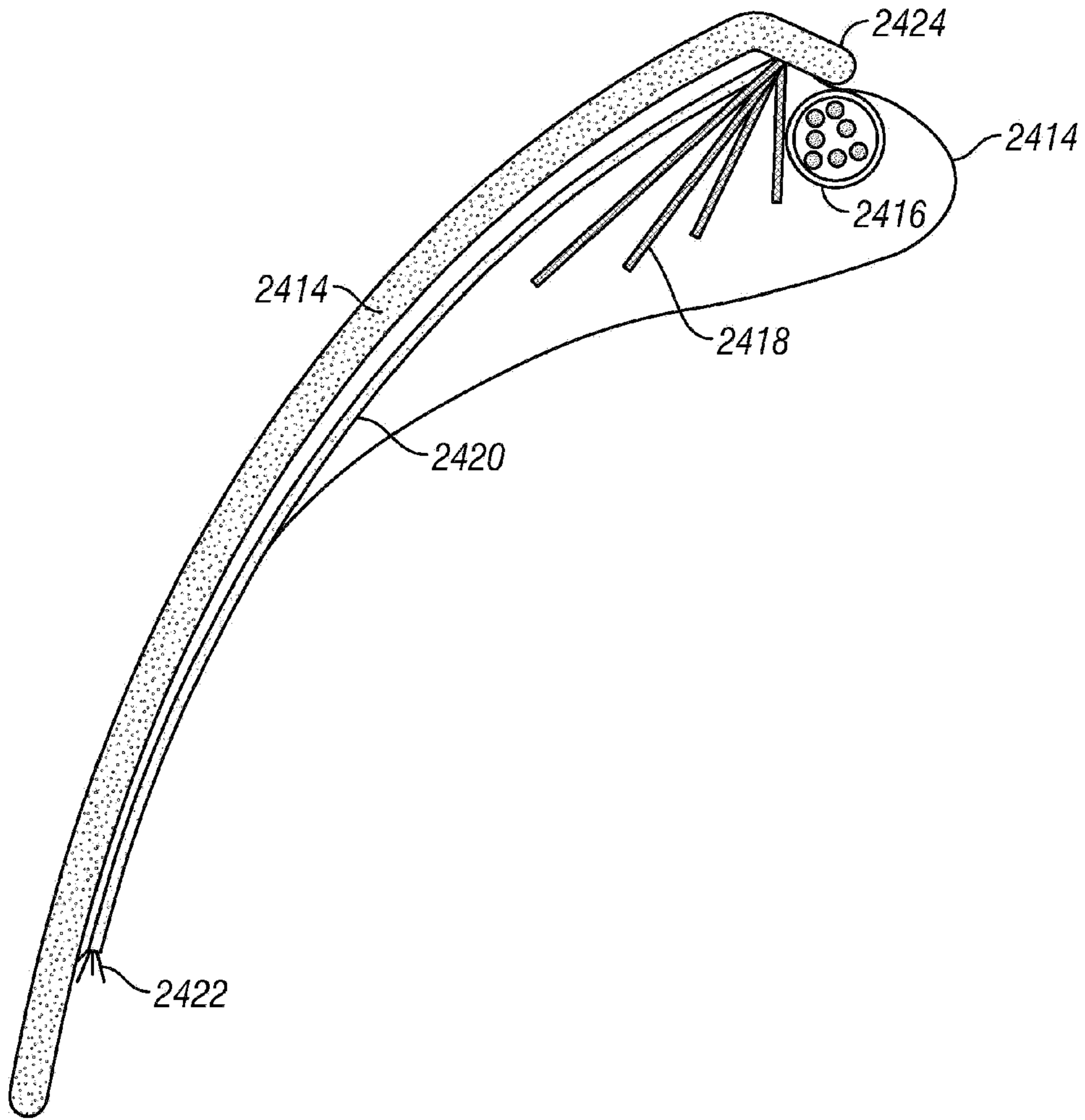


FIG. 24B

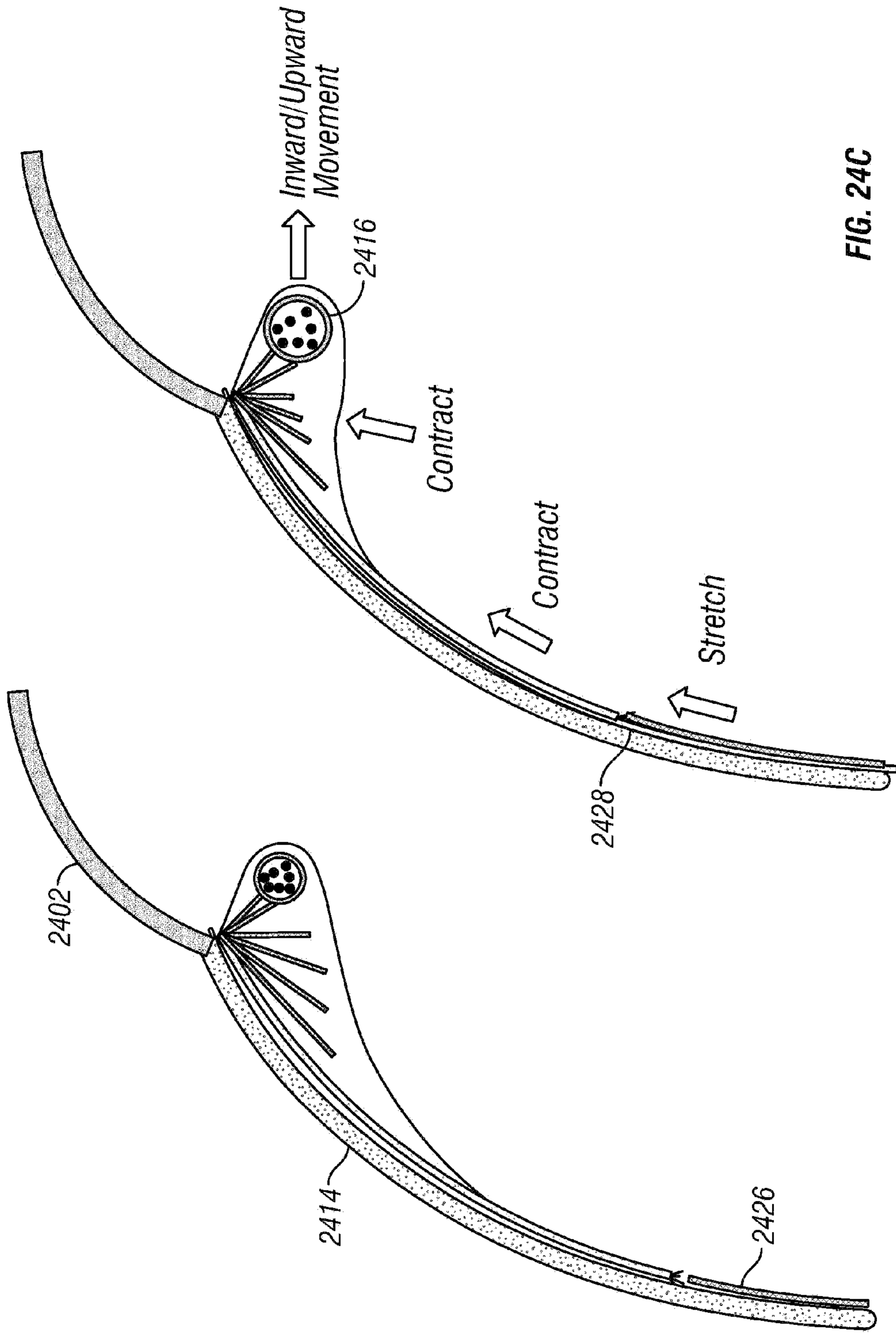


FIG. 24C

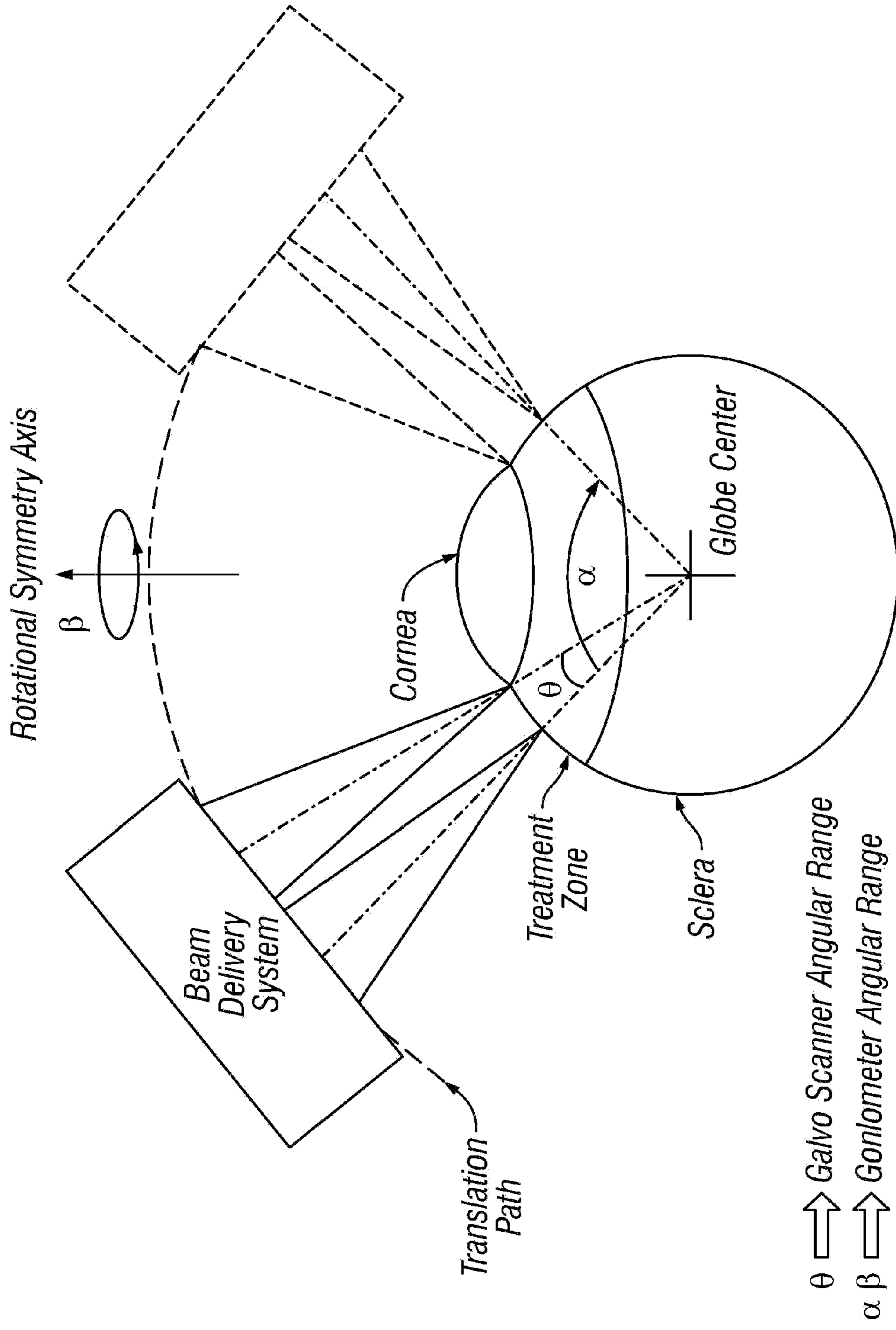


FIG. 25

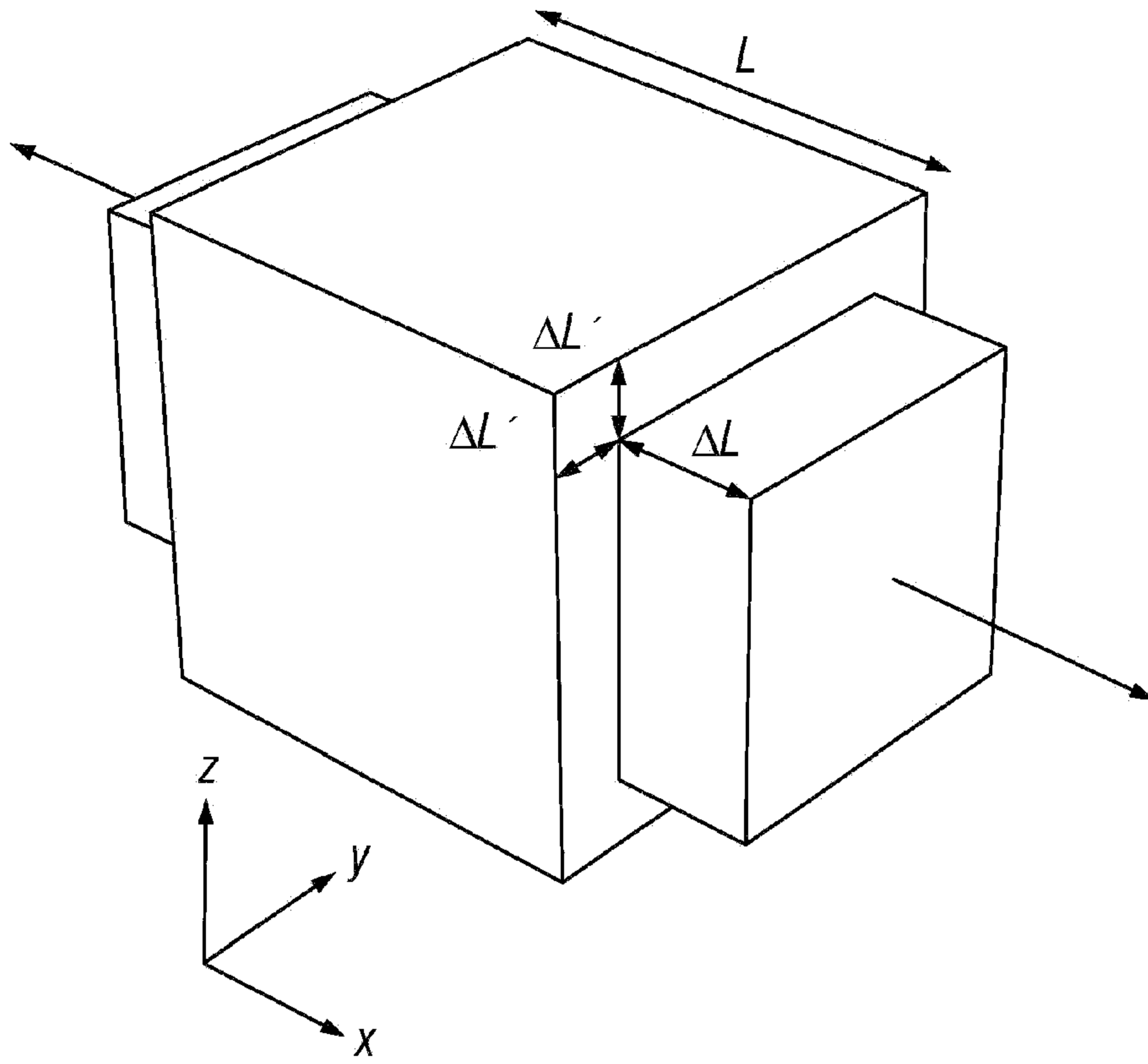


FIG. 26