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(54) Title: METHODS AND DEVICES FOR REPAIRING DAMAGED OR DISEASED TISSUE USING A SCANNING BEAM ASSEMBLY

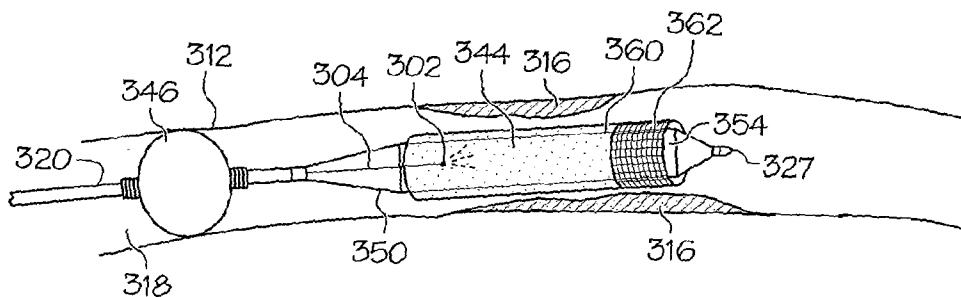


FIG. 18

(57) Abstract: A method for repairing or modifying an area of a patient's anatomy that comprises directing at least a portion of a scanning beam assembly to an area of a patient's anatomy, applying a radiation-responsive agent to portion of the anatomy, and exposing the radiation-responsive agent to radiation directed onto the agent by the reflector to cause the agent to therapeutically interact with the site. The scanning beam assembly including a radiation source capable of emitting radiation, a reflector that receives the radiation from the radiation source to direct the radiation onto the anatomy, wherein the reflector oscillates in at least two directions to create a scan of the anatomy, a detector to detect radiation returned from the anatomy, and a controller to convert the detected radiation into a displayable anatomy image.

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## METHODS AND DEVICES FOR REPAIRING DAMAGED OR DISEASED TISSUE USING A SCANNING BEAM ASSEMBLY

### Field of the Invention

**[0001]** The present invention is related generally to repairing or modifying damaged tissue within a body using a scanning beam unit.

### Background

**[0002]** The human body is complex and is often difficult for clinicians to examine internally to diagnose and treat a patient's illness. Cameras play an important part in modern medicine as a tool to aide clinicians in looking within a patient's body. Usually medical cameras are part of larger medical device, such as endoscopes, thermo-vision cameras, or laparoscopes. The cameras are usually digital, fiber optic, or pixelated sensor arrays. The cameras made with a pixelated sensor array may contain a single charge coupled assembly (CCD) or complimentary metal oxide semiconductor (CMOS) chip, or they may have multiple chips. The number of chips affects the size and resolution of the camera, and as a result limits where the camera can be used within the patient's body. There are therapeutic applications where smaller cameras or assemblies would be advantageous.

**[0003]** Recently, an assembly that can reach more remote areas within the body has been developed. This assembly is disclosed in United States Published Patent Application 2005/0020926. This assembly can be adapted to treat as well as to produce images of diseased or damaged tissue.

### Brief Summary

**[0004]** The present invention provides a method for repairing or modifying an area of a patient's anatomy that comprises directing at least a portion of a scanning beam assembly to an area of a patient's anatomy, applying a radiation-responsive agent to portion of the anatomy, and exposing the radiation-responsive agent to radiation directed onto the agent by the reflector to cause the agent to therapeutically interact with the site. The scanning beam assembly including a radiation source capable of emitting radiation, a reflector that receives the radiation from the radiation source to direct the radiation onto the anatomy, wherein the reflector oscillates in at least two directions to create a scan of

the anatomy, a detector to detect radiation returned from the anatomy, and a controller to convert the detected radiation into a displayable anatomy image.

**[0005]** In one embodiment, the present invention provides a method for repairing an area of a patient's anatomy that comprises directing at least a portion of a scanning beam assembly to an area of a patient's anatomy, displaying an image of the anatomy, identifying a portion of the anatomy for the placement of a radiation-responsive agent, applying the radiation-responsive agent to the identified portion of the anatomy, and exposing the agent to radiation directed onto the agent to cause the agent to therapeutically interact with the anatomy. The scanning beam assembly including a radiation source capable of emitting radiation, a reflector that receives the radiation from the radiation source to direct the radiation onto the anatomy, wherein the reflector oscillates in at least two directions to create a scan of the anatomy, a detector to detect radiation returned from the area of the anatomy, and a controller to convert the detected radiation into a displayable anatomy image.

**[0006]** In another embodiment, the present invention provides a balloon catheter that comprises an expandable balloon, a catheter body having a plurality of lumens, wherein at least one lumen opens into the interior of the expandable balloon, and at least a portion of a scanning beam assembly. The scanning beam assembly including a radiation source capable of emitting radiation, a reflector that receives the radiation from the radiation source to direct the radiation onto the a patient's anatomy, wherein the reflector oscillates in at least two directions to create a scan of the anatomy, a detector to detect radiation returned from the anatomy, and a controller to convert the detected radiation into a displayable anatomy image.

**[0007]** In another embodiment, the present invention provides a method for repairing or modifying an area of a patient's anatomy that comprises directing at least a portion of a scanning beam assembly to an area of a patient's anatomy, displaying an image of the anatomy, identifying a portion of the anatomy where the radiation is to make a channel into the anatomy, and emitting the radiation to make the channel. The scanning beam assembly including a radiation source capable of emitting radiation, a reflector that receives the radiation from the radiation source to direct the radiation onto the a patient's anatomy, wherein the reflector oscillates in at least two directions to create a scan of the

anatomy, a detector to detect radiation returned from the anatomy, and a controller to convert the detected radiation into a displayable anatomy image.

#### Brief Description of the Several Views of the Drawings

[0008] **FIG. 1** is a block diagram of an embodiment of a medical device system including a scanner assembly;

[0009] **FIG. 2** is a block diagram of an embodiment of a source assembly including multiple sources for generating imaging, therapeutic and aiming beams;

[0010] **FIG. 3** is a block diagram illustrating radiation paths;

[0011] **FIG. 4** is a block diagram of an embodiment of a detector assembly;

[0012] **FIG. 5** is a block diagram of an embodiment of a controller for a medical device including a scanner assembly;

[0013] **FIG. 6** is a perspective view of an embodiment of a scanner assembly;

[0014] **FIG. 7** is a side, section view of the scanner assembly of **FIG. 6** along line 7-7;

[0015] **FIG. 8** is a perspective view of an embodiment of a radiation collector;

[0016] **FIG. 9** is a perspective view of an endoscopic configuration of a medical device including a scanner assembly;

[0017] **FIG. 10** is an illustration of a bi-sinusoidal scan pattern and a rectangular coordinate pattern plotted together;

[0018] **FIG. 11** is a flowchart illustrating a method for repairing or modifying an area of the anatomy.

[0019] **FIG. 12** is a flowchart illustrating another method for repairing or modifying an area of the anatomy.

[0020] **FIG. 13** is a side elevation view of a balloon catheter for use with a scan beam assembly.

[0021] **FIG. 14** is a transverse cross-section view of the catheter body of **FIG. 13** taken along lines 14-14.

[0022] **FIG. 15** is a perspective view of the balloon catheter of **FIG. 13** shown with a scanning module inside the second balloon.

[0023] **FIG. 16** is a perspective view of the balloon catheter of **FIG. 13** shown with the scanning module external to the first and second balloon.

[0024] FIG. 17 is a perspective view of a balloon catheter shown with an radiation-responsive agent pre-applied to the second balloon.

[0025] FIG. 18 is a perspective view of a balloon catheter shown with an annular sleeve of radiation-responsive agent on its surface.

[0026] FIG. 19 is a perspective view of a balloon catheter including a cover.

[0027] FIG. 20 is a perspective view of a stent formed by the method of FIGS. 11,12.

[0028] FIG. 21 illustrates an application of a tissue solder to be activated by the scanning module.

[0029] FIG. 22 illustrates an application of radiation-responsive tissue solder to bond inner surfaces of adjacent tissues.

[0030] FIG. 23 is an elevational plan view wherein the stent is to be activated by the scan beam assembly.

[0031] FIGS. 24A to 24D are views showing steps for implantation of a stent into a lumen, where the stent will be activated by a scan beam assembly.

#### Detailed Description of the Invention

[0032] Before explaining the several embodiments of the present invention in detail, it should be noted that each embodiment is not limited in its application or use to the details of construction and arrangement of parts and steps illustrated in the accompanying drawings and description. The illustrative embodiments of the invention may be implemented or incorporated in other embodiments, variations and modifications, and may be practiced or carried out in various ways. Furthermore, unless otherwise indicated, the terms and expressions employed herein have been chosen for the purpose of describing the illustrative embodiments of the present invention for the convenience of the reader and are not for the purpose of limiting the invention. It is further understood that any one or more of the following-described embodiments, examples, etc. can be combined with any one or more of the other following-described embodiments, examples, etc.

[0033] Referring to FIG. 1, an embodiment of a scanning beam assembly 1, which may be part of a medical device, includes a scanner assembly 2, a collector 3, a radiation source assembly 4, a detector assembly 5, a controller 6 and a user interface 7. The

radiation source assembly **4**, detector assembly **5**, controller **6** and user interface **7** make up functional element **8** that is known herein as a "console." The radiation source assembly **4**, as selected by the user via the user interface **7**, and acting through the controller **6**, generates at least two wavelengths of radiation (e.g., in the visible wavelength range and/or otherwise). This radiation is conveyed in a beam to the scanner assembly **2**, which causes the beam to be swept across a tissue surface. The extent of this swept area is generally known as the "field of view" (FOV). Radiation reflected from the scene within the FOV may be intercepted by the collector **3** and passed to the detector assembly **5**. The detector assembly converts the received radiation to electrical signals that are then configured by the controller to form an image on a display assembly in the user interface **7**.

**[0034]** **FIG. 2** is a block diagram of one implementation of the source assembly **4**. Source assembly **4** includes multiple sources, each capable of generating radiation at a selected wavelength. Five sources are shown here, numbered **11** thru **15**. The outputs of the radiation sources **11-15** may, in some embodiments, be brought together in combiner element **16** to yield an output beam **17**. Combiner **16** may also include beam-shaping optics such as one or more collimating lenses and/or apertures. The sources may be of various types such as, for instance, light emitting diodes (LEDs), lasers, thermal sources, arc sources, fluorescent sources, gas discharge sources, or others. Signals **42** may be provided by controller **6** (**FIG. 1**) to one or more of the sources and optionally the combiner **16**. Signals **42** may optionally control wavelength, power, modulation or other beam properties.

**[0035]** The wavelength of radiation, for example, may be selected for imaging, therapy, or aiming. As used herein, an "imaging beam" refers to radiation selected for use in creating an image of a surface or region, a "therapeutic beam" refers to radiation selected to provide treatment of a condition such as diseased or damaged tissue, and an "aiming beam" refers to radiation selected to accentuate a portion of the FOV. The uses and application of such beams is disclosed in commonly assigned U.S. Patent Application Serial No. 11/716,806 **MEDICAL DEVICE INCLUDING SCANNED BEAM UNIT FOR IMAGING, THERAPY, AND/OR DIAGNOSIS** as well as the operation of treatment mapping or selecting a treatment path. This reference is herein

incorporated by reference in its entirety. In this example, sources **11**, **12** and **13** emit red, green and blue radiation; source **14** emits an aiming beam at a wavelength selected to yield a distinct contrast to the typical target material; and source **15** emits a therapeutic beam at a wavelength that is highly absorbed and moreover can be efficiently generated at high power to treat diseased or damaged tissue. In some embodiments, the aiming beam may be provided by source separate from the therapeutic beam source **15**. As an alternative, an aiming beam may be provided by source **15** as a reduced power therapeutic beam. In some embodiments, the aiming beam could be a virtual beam (i.e., a region in which one or more of the imaging sources is caused to increase (or decrease) significantly to create a bright (or dark) region in the displayed image.

**[0036]** In some embodiments, a source (not shown) provides a diagnostic beam. A "diagnostic beam" as used herein refers to radiation selected for analysis or detection of a disease or other medical condition including, for example, to visualize the presence of (or to activate) a diagnostic marker. The diagnostic marker could be naturally occurring (e.g., auto or self fluorescence) or introduced as part of the diagnostic procedure (e.g., fluorescent dyes).

**[0037]** Use of an aiming beam may be preferred in some circumstances. As will be seen later, while the treatment beam may follow the same path as the imaging beam, it is not constrained to follow the same timing. An aiming beam, managed in the same way as the therapeutic beam though at lower power and in a visible wavelength, may help ensure that the treatment is applied where the user intends. Furthermore, it may be a requirement of certain industry or regulatory standards such as AAMI or IEC that where higher power lasers are employed, an aiming beam be provided.

**[0038]** It should be noted that while five sources are illustrated, there may be more or fewer emitters depending, for example, on the end use. In some embodiments, sources may be combined or capable of providing various types of energy. In some cases, filters may be used to filter the radiation. In some embodiments, sources **11**, **12** and **13** comprise three lasers; a red diode laser, a green diode-pumped solid state (DPSS) laser, and a blue DPSS laser at approximately 635 nm, 532 nm, and 473 nm, respectively. While laser diodes may be directly modulated, DPSS lasers generally require external modulation such as an acousto-optic modulator (AOM) for instance. In the case where



an external modulator is used, it is considered part of the radiation source assembly and not shown separately.

[0039] **FIG. 3** illustrates the operation of an assembly **1** incorporating a scanner assembly **2**. Reflector **27** receives a beam of radiation **17** from source assembly **4** and directs the beam onto the surface **20**, for example, for one or more of imaging, therapy, or aiming purposes. At one point in time, the beam deflected by the reflector **27** is in direction shown as **21**, and impinges upon the surface to illuminate a point **23**. Reflector **27** oscillates in at least one axis (two axes in some embodiments), as indicated by the nearby arrowed arc, so that at some other point in time the deflected beam is in the direction indicated as **22** where, it illuminates point **24**. Radiation is, in general, reflected, absorbed, scattered, refracted or otherwise affected by the properties of the surface. Radiation may leave the surface in many directions. The collector **3**, however, may only capture that fraction of radiation which falls into the area subtended by its aperture. Regions **25** and **26** show the reflected radiation that is captured by the collector **3** when the beam is illuminating points **23** and **24** respectively. Directions **21** and **22** are not intended to represent any special part of the scan as the beam may be scanned using reflector **27** beyond them, and scans all points between them as well. Furthermore, a simplified two-dimensional view is represented by **FIG. 3**, and in general reflector **27** and collector **3** are adapted to illuminate and capture from surfaces occupying space in three dimensions.

[0040] Some embodiments use a micro-electromechanical (MEMS) scanner reflector to direct the imaging, aiming and therapeutic beams onto the surface. MEMS scanner reflectors are described in, for example, U.S. Patent No. 6,140,979, entitled SCANNED DISPLAY WITH PINCH, TIMING, AND DISTORTION CORRECTION; U.S. Patent No. 6,245,590, entitled FREQUENCY TUNABLE RESONANT SCANNER AND METHOD OF MAKING; U.S. Patent No. 6,285,489, entitled FREQUENCY TUNABLE RESONANT SCANNER WITH AUXILIARY ARMS; U.S. Patent No. 6,331,909, entitled FREQUENCY TUNABLE RESONANT SCANNER; U.S. Patent No. 6,362,912, entitled SCANNED IMAGING APPARATUS WITH SWITCHED FEEDS; U.S. Patent No. 6,384,406, entitled ACTIVE TUNING OF A TORSIONAL RESONANT STRUCTURE; U.S. Patent No. 6,433,907, entitled SCANNED DISPLAY WITH

PLURALITY OF SCANNING ASSEMBLIES; U.S. Patent No. 6,512,622, entitled ACTIVE TUNING OF A TORSIONAL RESONANT STRUCTURE; U.S. Patent No. 6,515,278, entitled FREQUENCY TUNABLE RESONANT SCANNER AND METHOD OF MAKING; U.S. Patent No. 6,515,781, entitled SCANNED IMAGING APPARATUS WITH SWITCHED FEEDS; U.S. Patent No. 6,525,310, entitled FREQUENCY TUNABLE RESONANT SCANNER; and U.S. Patent Application Serial No. 10/873,540, entitled SCANNING ENDOSCOPE; all of which are hereby incorporated by reference in their entirety as if fully set forth herein.

[0041] **FIG. 4** is a block diagram of the exemplary detector assembly **5**. Radiation **29** that is intercepted by the collector **3** is passed to the detector assembly **5**. This radiation includes energy at several wavelengths, corresponding to those emitted by the source assembly **4**, and possibly also including other wavelengths as may result from nonlinear processes (such as fluorescence). In some embodiments, wavelength separator **35** separates the incoming radiation **29** into pathways **36**. Such separation may be performed by filters, gratings, or other devices. In an alternate configuration, wavelength separation may be incorporated in the collector **3**, and separated wavelengths brought to the detectors **37**, each in its own fiber or fiber bundle. Each separated wavelength of radiation is then sent to detectors **37** in the detector assembly **5**. Such detectors may be physically separate, or parts of a common detector such as a CCD or CMOS device. Multiple detectors **37** may be incorporated for each wavelength. The detectors output electrical signals **38** corresponding the power, amplitude, or other characteristic of each wavelength of radiation detected. The signals can be used by a controller **6** (**FIG. 6**) to generate a digital image, e.g., for processing, decoding, archiving, printing, display, etc.

[0042] In some embodiments, X represents an input to the detectors **37** capable of modifying the transfer function from radiation to electric signals. Exemplary modifications may include adjustment of gain or offset or both. Y may represent an input to the wavelength separator **35** capable of modifying the transfer function therethrough. The modifying elements X and Y may be disposed to operate on the input to the respective detectors **37** and wavelength separator **35**, acting on all or a subset of wavelengths received, at the outputs of the respective detectors **37** and wavelength separator **35** or at both inputs and outputs.

[0043] FIG. 5 is a block diagram of the exemplary controller 6. An interface management component 43, among other tasks, accepts operating mode commands from the user, illustrated as part of path 47. Such commands may include imaging and treatment modes, FOV and/or aspect ratio of the image, image storage, etc. Specifications related to the FOV and aspect ratio result in parameters sent via path 44 to a scanner driver 45, which generates requisite drive signals 46 to the reflector 27 (FIG. 3). The user may also specify treatment parameters, such as the location, shape and size of a region to be treated, the wavelength to be used, and duration of exposure. These result in parameters being sent to a coordinate converter 40, which converts the specifications into selection and modulation commands 30 to a source control block 41. This source control and modulation block 41 drives the source assembly 4 to provide the requisite radiation outputs 42. Signals 38 from the detector assembly 5 are converted from their scan coordinate system to a Cartesian form 49 at block 48 for display and sent to the interface management block 43 for user viewing.

[0044] In some embodiments, motion sensing is incorporated within the system via target feature motion detection, element T. For example, element P may include a number of sensors attached or connected to the scanner assembly 2. The sensors may sense location, orientation or both. The sensors may be, for example, accelerometers, magnetometers, rate gyros, electromagnetic position sensors, etc. Element Q represents the location and orientation signals generated by the sensors and element R represents a mathematic operation capable of converting the signals Q into a stationary reference frame. Element S represents output of element R which is used to modify the relationship of a displayed image to the scanned data 49 to compensate for sensed movement.

[0045] Element R operates on the scanned data 49 to detect the relative movement and provides signals U indicating magnitude and direction of the movement. This image tracking functionality may provide reliable treatment of the body which might be moving due to, for example, respiration, circulation or other biological activity.

[0046] FIG. 6 is an external view of one embodiment of the scanner assembly 2. Scanner assembly 2 includes a housing 50 that encloses the reflector 27 and other components. A source fiber 51 is used to deliver energy from the source assembly 4 to

the scanner assembly 2. Source fiber 51 may be a single mode optical fiber. In some embodiments, one or more fibers may be used to deliver imaging beams and one or more other fibers may be used to deliver a therapeutic beam (e.g., therapeutic beams having longer wavelengths, e.g., greater than 1700 nm and/or higher power). In certain embodiments, a different type of fiber, such as a holey fiber, may be used to transmit energy from the source assembly 4. In some embodiments, the same optical fiber 51 is used to deliver both the imaging beams and the therapeutic beams to the reflector, the optical fiber defining a common path for both types of beams.

[0047] Electrical wires 52 convey drive signals for the reflector 27 and other signals (position feedback, temperature, etc.) to and from the scanner driver 45 (FIG. 5). Wires 52 may also provide control and feedback connections for controlling focus characteristics of the beam shaping optic 56. The distal end of the scanner assembly 2 is fitted with an optical element 53 which allows the scanned beam to pass out and illuminate the scene. This element 53 is generally referred to and illustrated as a dome; however, its curvature, contour, and surface treatments may depend on the application and optical properties required. In some embodiments, dome 53 provides a hermetic seal with the housing 50 to protect the internal elements from the environment.

[0048] FIG. 7 shows internal components of an embodiment of the scanner assembly 2. Source fiber 51 is affixed to the housing 50 using a ferrule 54. The end of the source fiber 51 may be polished to create a beam 55 of known divergence. The beam 55 is shaped by a beam shaping optic or lens 56 to create a beam shape appropriate for transmission through the system. After shaping, shaped beam 57 is fed through an aperture in the center of reflector 27, then reflected off a first reflecting surface 58. First reflecting surface 58 may have a beam shaping function. Beam 57 is then directed onto reflector 27 and then out of the scanner assembly 2, the details of which (in the case of an imaging beam) are described in U.S. Patent Application Serial No. 10/873,540, entitled SCANNING ENDOSCOPE, the details of which are hereby incorporated by reference as if fully set forth herein. Any suitable materials can be used to form the reflector 27. In some embodiments, the reflective surface of the reflector 27 may be formed of gold or other suitable material for directing each of the beams including relative high energy therapeutic radiation. In other embodiments, a multilayer dielectric configuration may be

used in forming reflector 27. In one embodiment, collecting fibers 63 may be included within housing 50.

[0049] In another embodiment, as shown in FIG. 8, collector 3 may be configured to be installed coaxially with the scanner assembly 2. Radiation reflected from a scene impinges on the face 60 of the collector 3, which constitutes the receiving aperture. Face 60 is actually made up of the polished ends of a large number of small diameter, multimode collecting fibers 63 which conduct the radiation to the detector assembly 5. Scanner assembly 2 may be inserted into a central void 61. The collector 3 is enclosed by a housing 62. The fiber ends making up face 60 may be formed in a plane, or into other geometries to control the pattern of receiving sensitivity. They may be coated with diffusing or other materials to improve their angle of acceptance, to provide wavelength conversion, or wavelength selectivity. In some embodiments, the detector assembly 5 may be configured to form the receiving aperture and mounted in position to receive the reflected radiation directly, without the need for a separate collector 3.

[0050] FIG. 9 shows diagrammatically various elements previously described as incorporated into an exemplary endoscope 69 for medical use. Endoscope 69 generally includes an elongate, rigid or flexible shaft 73 having a distal end 75 and a proximal end 74 opposite the distal end. There is typically a handle 76 which includes a number of controls, often both mechanical and electrical. In one embodiment, endoscope 69 includes scanning assembly 2 and collector 3. Endoscope 69 may be connected to console 8 by source fibers 70, collection fibers 71, and electrical wiring 72. As used herein, an endoscope refers to an instrument for use in examining, diagnosing and/or treating tissue comprising a patient's body, either percutaneously or through a natural orifice or lumen. As used herein, the term "proximal" refers to a location on the medical device nearer to a user, and the term "distal" refers to a location that is nearer the patient. Typically, the console 8 of the medical device is located outside a patient's body and the distal end of the medical device is insertable into the patient's body. However, other configurations are possible. Furthermore, while an endoscope is referred to, any suitable type of medical device may be employed such as gastroscopes, enteroscopes, sigmoidoscopes, colonoscopes, laryngoscopes, rhinolaryoscopes, bronchoscopes,

duodenoscopes, choledochoscopes, nephroscopes, cystoscopes, hysteroscopes, laparoscopes, arthroscopes, etc.

[0051] Referring now to **FIG. 10**, as mentioned above, the reflector **27** scans the beam of radiation in a pattern. **FIG. 10** shows an idealized bi-resonant or bi-sinusoidal scan pattern. High-speed MEMS reflectors and other resonant deflectors as described herein are configured and driven to execute sinusoidal angular deflections in two orthogonal axes, yielding the classical Lissajous pattern. Most current display devices are configured to address display data in a Cartesian form, for example as row and column, or a particular pixel along a nearly-horizontal scan line. The bi-resonant or Lissajous scan path **80** is shown overlaid with the Cartesian or rectilinear grid **81**. In the illustrated instance, the intersections between the vertical and horizontal lines of the Cartesian grid **80** represent display pixel positions while the Lissajous trace **81** represents the actual path taken by the scanned spot. As the actual scan path does not align perfectly with all the rectilinear pixel positions, these image values may be determined through interpolation. In some embodiments, registration of the Lissajous trace **80** to the Cartesian grid **81** is based on a marker that links a reference point in the scan to a point in the rectilinear matrix.

[0052] In one embodiment, a user defines a treatment zone, border, or path by identifying the places within the image of the FOV where treatment is to be administered. The user may also select the parameters for the treatment such as the treatment beam wavelength, the power of the beam, and the duration of the exposure. The power of the beam may be modulated by a modulator to achieve the power selected by the user, as taught in commonly assigned U.S. Patent Application No. 11/716911, titled POWER MODULATION OF A SCANNING BEAM FOR IMAGING, THERAPY, AND/OR DIAGNOSIS

[0053] While the discussion below refers to radiation-responsive agents, such as adhesives or medical drugs, those skilled in the art will recognize that the techniques described herein can be used to activate any photo or radiation responsive agent useful in medical applications. Referring now to **FIG. 11**, the method comprises the steps of applying a radiation-responsive agent to a site within an area of a patient's anatomy **91**, directing at least a portion of a scanning beam assembly to the anatomy **92**, and exposing

the agent to radiation directed onto the agent by the reflector to cause the agent to therapeutically interact with the anatomy **93**. The step of applying a radiation-responsive agent **91** may occur before directing the scanning beam assembly to the anatomy **92**, or after the scanning beam assembly has been directed to the anatomy. The scanning beam assembly may first be used to visualize and diagnose the area to be treated. The scanning beam assembly may include a radiation source capable of emitting one or more wavelengths of radiation, a reflector that receives the radiation from the radiation source to direct the radiation onto the anatomy, wherein the reflector oscillates in at least two directions to create a scan of the anatomy, at least one detector to detect radiation returned from the anatomy, and a controller to convert the detected radiation into a displayable image of the anatomy, as explained in greater detail above. The portion of the scanning beam assembly that is directed toward a portion of a patient's anatomy may include a medical guidewire to direct the assembly through the body. In another embodiment the scanning beam assembly may be part of a medical instrument.

**[0054]** The step of applying a radiation-responsive agent to the site **91** may be performed by any medical procedure or assembly that can successfully deliver the radiation-responsive agent to the site to be treated using the scanning beam assembly. In one embodiment, an applicator (i.e., a tube, sprayer, or the like) may be threaded down the working channel of endoscope or a laparoscope. In another embodiment, the applicator may be inserted through a trocar to apply the radiation-responsive agent. In yet another embodiment the radiation-responsive agent may be applied through a working channel or lumen within a catheter, balloon catheter, or the like. In one embodiment, the scanning beam assembly **1** is capable of curing all or selectively curing only a pre-determined portion of the agent the clinician indicates needs to be cured. The tool, assembly, or process chosen to apply the radiation-responsive agent will vary with the location within the body that needs to be reached for treatment, the radiation-responsive agent chosen, the form of the chosen radiation-responsive agent, and the size of the site to be treated.

**[0055]** The radiation-responsive agent may be any molecule, composition, or mixture capable of forming a biological, biocompatible, or biodegradable agent that does not cause adverse reaction in the tissue undergoing treatment. In another embodiment,

the radiation responsive agent include a biocompatible coating that allows them to be safely placed within the patient's anatomy. The radiation-responsive agent may be a radiation curable molecule, compound, or composition. The radiation used to cure the radiation-responsive agent may be ultraviolet radiation, infrared, near infrared, or any other electromagnetic radiation. In one embodiment the radiation-responsive agent may be a medical adhesive that is capable of cross-linking when exposed to electromagnetic radiation. In another embodiment, the agent may be a medical drug that is activated by radiation. In another embodiment, the radiation-responsive agent is a shape-memory alloy. In another embodiment the radiation responsive agent may be a material that acts to promotes tissue welding or sealing, in the same manner as solder flux does with two pieces of metal.

**[0056]** The medical adhesive may be a gelatin or esterified gelatin as taught in United States Patent No. 7,033,348, un-polymerized and polymerized type I and/or type III collagen compositions as taught in United States Published Application US2003/0032143, a composition of poly(L-lactic-co-glycolic acid), glycolic co-polymer, and bovine serum albumin as taught in United States Published Application US2004/0236371, a moiety containing a photosensitizing species and a protein or peptide as taught in United States Patent No. 5,552,452, or any combination or mixture thereof. In another embodiment, to ensure that the medical adhesive cures when exposed to the radiation from the scanning beam assembly other molecules, compounds, or mixtures may be added to the agent.

**[0057]** In another embodiment the medical adhesive may be a proteinaceous biomolecule or a biological, biodegradable polypeptides as taught in United States Patents 6,583, 117 and 7,078,378. A proteinaceous biomolecule agent is a protein, which may be any protein or mixture of proteins. Examples of suitable proteins includes but is not limited to albumins, collagen, fibrinogen, tropoelastin, and elastin. Suitable proteins are typically those which can be cross-linked to form a matrix and which can be absorbed by the body. A biological, biodegradable polypeptides includes synthetic polypeptides incorporate light-absorbing material, such as a dye, into the agent, to improve energy absorption and cure. Examples of a suitable dyes include but are not limited to indocyanine green, methylene blue and fluorescein isothiocyanate. It will be



understood that the light-absorbing material is chosen to be appropriate to the energy source that is used in forming tissue repairs involving the use of the medical adhesive.

**[0058]** The radiation-responsive agent may be a paste, gel, liquid, solid, pliable solid, powder, ribbon, mesh, film, metal or polymer scaffold or graft material. In one embodiment, a pliable radiation-responsive agent may be embedded into the spaces within a mesh or it may be applied as a covering to all or part of the mesh, stiffener or graft material. The pliable radiation-responsive agent may be shaped into various forms, such as tubular forms tapered or of uniform cross section. The tubular forms may be round or of ovoid profile, square crenulated, or any other geometric form. The radiation-responsive agent may be prepared in other shapes as required for the particular application to the treatment site including strips, patches, solid rods and hollow cubes with or without a flanged end. In another embodiment, the radiation-responsive agent composition may include medicinal drugs that aide in healing or treatment of the treatment site. The radiation-responsive agent referenced throughout the paragraphs below may be applied in any of the forms and may be any type of agent described above or combinations thereof.

**[0059]** The step of exposing the radiation-responsive agent with radiation emitted from the scanning beam assembly **93** may be carried out by selecting a desired wavelength, or plurality of wavelengths of radiation to be directed at the site where the radiation-responsive agent is applied. The scanning beam assembly **1** may have multiple lasers, light emitting diodes, thermal sources, arc sources, or fluorescent sources as source assembly **4**. Any of sources **11-15** may also function as a therapeutic beam to cure the radiation-responsive agent. If sources **11-15** are not effective to cure the agent, then another source emitting the necessary cure radiation may be added to the assembly or substituted for one of these sources. As used herein, therapeutically interact includes, but is not limited thereto, when the agent bonds or adheres to the anatomy where the agent was applied, the agent cures or is cross-linked into a more rigid structure by the radiation, the agent expands to fill a void, the agent kills diseased tissue, the agent applies a medicine to promote healing, the agent forms a graft to the anatomy, the agent forms a stent within the anatomy, or the like.

**[0060]** The scanning beam assembly **1** may be connected to or configured with a display system that works in conjunction with a computer to plan and identify the site to be treated. A clinician may view the displayed image and then confirm and/or select a treatment path using the display, computer keyboard, or mouse. The treatment path corresponds to the tissue in need of treatment found within the site of visualization. For more details on selecting the treatment path see commonly assigned U.S. Patent Application No. 11/716,806 MEDICAL DEVICE INCLUDING SCANNED BEAM UNIT FOR IMAGING, THERAPY, AND/OR DIAGNOSIS, incorporated by reference above.

**[0061]** In another embodiment, it is possible that the computer can pre-determine the type of treatment based on optical information collected from the scene. For example, a dye may be used to stain particular tissue, then the computer may analyze the stains and suggest treatment options. In another embodiment, the computer can be programmed to automatically recognize certain tissue types, for example cancerous tissue, either via autofluorescence, impregnated dye fluorescence, or color-based analysis, and automatically select the zones in the scene that correlate to the targeted tissue. The computer would indicate to the physician the identified targets for confirmation. Once the clinician is satisfied with the treatment, they can move the scope to the next area to be treated.

**[0062]** The therapeutic beam or laser then cures the radiation-responsive agent along the treatment path, which enables the clinician to selectively treat only a portion of the radiation-responsive agent. A bioabsorbable radiation-responsive agent may be useful when the agent is cured selectively, in that any uncured agent may be absorbed by the body and not require the clinician to remove the excess. In one embodiment the laser treatment path may be followed continuously without visualization. In another embodiment, the laser treatment path may be interspersed with the visualization to allow the clinician to monitor the treatment progress. In yet another embodiment the scanning beam assembly **1** may be capable of treating and visualizing simultaneously. Additionally, the clinician may select whether the treatment is itself continuous or pulsed.

[0063] The method as described above for repairing a site within a body may be useful in closing gastric incisions, bonding two tissues together, soft tissue attachment, reconnecting tubular vessels, placing stents within body passageways, killing cancer cells or tumors, treating diseased tissue, or placing grafts within the body (such as intraluminal grafts). The reflector 27 of the scanning beam assembly 1 may vary in size, but are capable of being made smaller than the typical cameras. Reflector 27 may be held within a housing that is as small as about 3 to about 4 millimeters by about 4 millimeters to about 10 millimeters. This small size enables the scanning beam assembly to be carried on or in a catheter and threadedly delivered to visualize areas inside the lumen of the body or other hard to reach places, including but not limited to large veins and arteries. In some embodiments, scanner assembly 2, which includes reflector 27, may be included within the central void 61 of housing 62 shown in FIG. 8, to form a scanning module.

[0064] In another embodiment, as illustrated in FIG. 12, a method for repairing an area of a patient's anatomy comprises the steps of directing at least a portion of a scanning beam assembly 1 to an area of a patient's anatomy 101, displaying an image of the anatomy 102, identifying a site within the anatomy for the placement a radiation-responsive agent 103, applying the radiation-responsive agent to the identified site using the display image 104, and exposing the agent to radiation directed onto the agent by a reflector 27, which is part of the scanning beam assembly 1 to cause the agent to therapeutically interact with the site 105. In another embodiment, the method further comprises the steps of directing a balloon catheter to the site, where a portion of the scanning beam assembly 1 is part of the balloon catheter, dispensing a radiation-responsive agent onto the balloon catheter, and expanding the balloon to apply the agent to the site.

[0065] In one embodiment, the balloon may be similar to the balloon catheter taught in United States Patent No. 6,056,721, as shown in FIG. 13 and designated by the reference numeral 300. The balloon catheter may be adapted for use with the scanning beam assembly 1. The balloon catheter 300 may include an elongate catheter body 320. This catheter body 320 may be a flexible or rigid, or semi-rigid tubular shaft having a proximal end 324 and a distal end 326. A plurality of longitudinally aligned interior passageways or lumens 328a, 328b, 328c, and 328d, as shown in FIG. 14, extend along

the catheter body **320** from the proximal end **324**. An outer surface or wall **330** surrounds the plurality of lumens **328a**, **328b**, **328c**, and **328d** and generally defines the elongate catheter body **320**.

[0066] The distal end **326** preferably terminates at a distal tip **327**. A hub **332** having a plurality of extension tubes **334** may be coupled to the proximal end **324** of the catheter body **320**. The hub **332** may be adapted to be a hand piece when the balloon catheter **300** is used with the scanning beam assembly **1**. Each of the extension tubes **334** may be connected with a respective one of the plurality of lumens **328a-328d** such that each lumen **328a-328d** is fluidly coupled or otherwise in open communication with an extension tube **334**. A connector **336**, such as a luer lock, may be provided at a proximal end **338** of each extension tube **334**. The detector may be a multi-mode optical fiber or an optical to electrical converter (i.e. a photodiode) that transmits the reflected signal.

[0067] In one embodiment, the balloon catheter **300** may have a first balloon **346**. The first balloon **346** may be a round or semi-round balloon. The balloon **346** is preferably made from a flexible and bio-compatible material. These materials may include a rubber such as a medical grade latex, a silicone, polyurethane, polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as Surlyn, manufactured by the Polymer Products Division of the Du Pont Company. The first balloon **346** may act as a seal around a passageway or act as an anchor within the passageway.

[0068] In another embodiment, the balloon catheter **300** may have a second inflatable and deflatable angioplasty balloon **350**. This second balloon **350** may have a central portion **354**. The second balloon **350** may be made of any of the materials mentioned above, or any other material capable of being inflated and deflated by a fluid or gas. In one embodiment, the material may be any material capable of allowing radiation to pass through the material to activate a radiation-responsive agent contained on the outside of the second balloon **350**. In one embodiment both the first and second balloon, **346** and **350** respectively, may be present as shown in **FIG. 13**, or in another embodiment their relative positions on the catheter body **320** may be reversed. In yet another embodiment, only the first balloon **346** may be present, or only the second balloon **350** may be present.

Both the first balloon **346** and/or the second balloon **350** may have a variable inter-diameter.

[0069] In one embodiment, balloon catheter **300** contains connecting cable **304** and a scanning module **302**. Scanning module **302** is a portion of scanning beam assembly **1**, which in some embodiments includes scanning assembly **2** within the central void **61** of housing **62** including collectors **3** (shown in **FIG. 8**). Connecting cable **304** connects the scanning module **302** to the other portions of scanning beam assembly **1**, shown in **FIG. 1**. In one embodiment, the scanning module **302** is inside the second balloon **350**.

[0070] Scanning beam assembly **1** may include a display system on which a clinician may see the anatomy and determine how to treat a site within that area. To see an image when scanning module **302** is within the second balloon **350**, second balloon **350** may be made of a material that allows the imaging wavelengths from the source assembly **4** to pass through the balloon material and likewise the returned radiation from the field of view pass back through the balloon material. In one embodiment, the scanning module **302** may be moved or directed while inside the second balloon **350** using the a hand piece or steering control that may be included as part of scanning beam assembly **1**.

[0071] In another embodiment, scanning module **302** and connecting cable **304** may be external to the balloon catheter **300** in any location that will allow the radiation emitted from the scanning module **302** to reach the radiation-responsive agent to cure it or cause it to therapeutically interact with the tissue site. In one embodiment, the scanning module **302** may be near the distal tip **327** directing the scanning beam back at the second balloon **350**, or in another embodiment the scanning module **302** may be between the first balloon **346** and the second balloon **350** directing the emitted radiation toward the second balloon **350**. In another embodiment, mirrors may be used in conjunction with the scanning module **302** to direct the radiation around the second balloon.

[0072] The step of dispensing a radiation-responsive agent onto the balloon catheter **320** may be carried out using an infusion port **340** in the catheter body **320** as shown in **FIG. 15**. The balloon catheter **300** may be inserted within a body passageway **312**, which may include almost any body passageway, including a vascular conduit such as an

artery, a vessel or a vein. An obstructing material **316** is shown constricting or otherwise obstructing a flow passageway **318**.

[0073] In one embodiment, the infusion port **340** may be used to disperse a radiation-responsive agent **344** into the flow passageway **318** to cover the external surface of the second balloon **350**. The infusion port **340** may be fluidly coupled to an infusion lumen **328a**, as shown in **FIG. 14**. The infusion port **340** and infusion lumen **328a** may be used to pass a medicine or drug, such as a radiation-responsive agent **344**, from a supply pump attached to one of the balloon catheter's connectors **336** connected to the scanning beam assembly **1**.

[0074] In one embodiment, the infusion port **340** may be a single oval, circular, or any other shaped port. In another embodiment, the infusion port **340** may be a plurality of openings or ports spaced uniformly or non-uniformly circumferentially around the catheter body **320**. The spacing and placement of the plurality of infusion ports **340** may be such that the radiation-responsive agent when pumped through a lumen **328a** will efficiently and effectively flow to cover the central portion **354** of the second balloon **350**. The infusion lumen **328a** may be connected in fluid communication with a working channel on a hand piece or a hose included as part of the scanning beam assembly **1**. The working channel and/or hose may be used to force or pump the radiation-responsive agent toward the distal end **327** of the balloon catheter **300** such that the radiation-responsive agent **344** is pushed through the infusion port **340**. The infusion lumen **328a** should comprise a sufficiently large cross sectional area along the catheter body **320** to allow for passage of a large volume of the radiation-responsive agent. The infusion lumen **328a** may also be configured with a circular, oval, square, trapezoidal, rhomboidal, or any other shaped cross section.

[0075] A second lumen **328b** of the plurality of lumens **328a-328d** extends from the proximal end **324** of the catheter body **320** and is fluidly connected to an opening or openings in the outer wall **330** of the catheter body **320** within the first balloon **346**. The third lumen **328c** of the plurality of lumens **328a-328d** extends from the proximal end **324** of the catheter body **320** and is fluidly connected to an opening or openings in the outer wall **330** of the catheter body **320** within the second balloon **350**. The fourth lumen

**328d**, may be configured for movably supporting a connecting cable **304** and scanning module **302**.

[0076] In one embodiment, the radiation-responsive agent **344** may be passed through infusion lumen **328a**, exiting from infusion port **340** disposed between the first balloon **346** and the second balloon **350**. The radiation-responsive agent **344** may be infused at a pressure greater than the pressure within the angioplasty balloon **350** but less than the pressure within the first balloon **346**. This allows the radiation-responsive agent **344** to exit the infusion port **340** into the sealed space between the first balloon **346** and the second balloon **350**. The radiation-responsive agent **344** may then seep around the inflated central portion **354** of the second balloon **350**. In one embodiment, the second balloon **350** may be completely deflated when the radiation-responsive agent **344** is applied. In another embodiment, the second balloon **350** may be partially inflated when the radiation-responsive agent **344** is applied.

[0077] In another embodiment, as shown in **FIG. 17**, the second balloon **350** may have a film or layer of agent radiation-responsive agent **344** film coating the outer surface of the central portion **354** prior to insertion of the balloon catheter **300** into a body passageway **312**. The radiation-responsive agent film may be evenly circumferentially distributed around the second balloon **350**. In another embodiment, the film or layer of radiation-responsive agent on the second balloon **350** may be a paste, mesh, graft, or gel on the outer surface of the central portion **354** of the balloon.

[0078] In one embodiment, as shown in **FIG. 18**, the radiation-responsive agent **344** may comprise a continuous or substantially continuous annular sleeve **360**. The annular sleeve **360** may be formed from a rectangular strip of radiation-responsive agent film that is rolled around the second balloon's **350** central portion **354** through one complete revolution, or two or more revolutions to provide multiple layers. The number of layers depends upon the thickness of the film and the desired amount of agent and the amount of radiation to be emitted at the site. In another embodiment, the annular sleeve **360** may be formed from a mesh **362** backing that is coated with a radiation-responsive agent **344**.

[0079] The balloon catheters of the embodiment shown in **FIGS. 17,18** may further include cover **366** illustrated in **FIG. 19**. Cover **366** protects the radiation-responsive

agent **344** contained in the coating or annular sleeve **360** while the catheter **300** is being inserted into the body. Once the catheter **300** has been reached its destination within the body, cover **366** is either pulled back away from balloon or catheter **300** is advanced out of the cover **366**.

[0080] The second balloon **350** is then expanded to apply the radiation-responsive agent **344** to the site to be treated within body passageway **312**. In this configuration, the radiation-responsive agent **344** is uniformly applied at a uniform pressure to the interior surface of the body passageway **312**. Some of the radiation-responsive agent **344** may flow into any cracks, depressions, or tears within the body passageway **312** or obstructing material **316**. The radiation-responsive agent **344** therapeutically interacts with the body passageway to bond to the tissue to stay in place, to treat diseased tissue, or to cure into a thin walled tubular member, known as a stent **368**. Stent **368** is shown in **FIG.20** within body passageway **312** at the site of obstructing material **316**, such that stent **368** is opening body passageway **312** where it was formerly constricted by obstructing material **316**. Stent **368** may be made from any of the radiation-responsive agents described above. In some embodiments, stent **368** may be a bioabsorbable radiation-responsive agent so that no separate procedure is needed to remove stent **368**. The radiation-responsive agent may be applied to the second balloon **350** such that stent **368** may have tubular walls of uniform thickness.

[0081] Then the radiation-responsive agent **344** is exposed to radiation emitted from the scan beam assembly's scanning module **302** to cure or cross-link the agent, as explained above. In one embodiment, the radiation-responsive agent **344** may be cured selectively such that the resulting stent **368** is a scaffold of cured agent similar to a metal self-expanding stent as shown in United States Patent No. 5,545,211. In another embodiment the radiation-responsive agent **344** may be gradually cured or "grown" to a custom length by scanning the agent repeatedly using the method above while gradually moving the catheter along the anatomy. In one embodiment, the radiation-responsive agent of stent **368** is selectively cured to form a stent with slots throughout. The slots may be substantially parallel to a long axis of stent **368**, perpendicular to the long axis, or a combination thereof.



[0082] In one embodiment, the radiation-responsive agent **344** is a bioabsorbable composition such that the resulting agent cured stent is a temporary stent that will be absorbed slowly by the body, which eliminates a second procedure to remove the stent. In another embodiment, the radiation-responsive agent **344** is a composition that is not bioabsorbable such that the resulting agent cured stent is a more permanent stent.

#### Bonding Separated Tissues

[0083] FIGS. 21,22 illustrate different embodiments for bonding separated tissues together by the application of a gel, film, mesh, paste, powder, ribbon, or solid radiation-responsive agent **430** and the curing due to exposure to radiation from scanning beam assembly **1**. In one embodiment, scanning module **402**, which is connected to scanning beam assembly **1** by connecting cable **404** is inserted within the area of the body to be exposed to radiation or is aligned with the area of the body to be exposed. The radiation-responsive agent **430** may be any of the agents listed above, or combinations thereof. In one embodiment, the radiation-responsive agent may include a catalyst to aid in absorbing the radiation and/or a glue to hold the agent into place prior to curing. First and second tissues **410** and **420** to be joined together are brought within close proximity with one another. The separation of the first and second tissues **410** and **420** may be a surgical incision, an accidental cut, a tear, or a separation of tissue interior to or exterior to the body.

[0084] In one embodiment, as shown in FIG. 21, a layer of gelatinized radiation-responsive agent **430** is provided overlaying the location where the tissues are to be joined. The radiation-responsive agent is overlaid using a balloon catheter as described, a sprayer, or any other method. The radiation-responsive agent **430** is then exposed to selected wavelengths of radiation **440** from the scanning module **402**, which in one embodiment may be infrared light generated by a laser depending upon the chosen radiation-responsive agent **430**. Upon activation by the radiation, the radiation-responsive agent **430** becomes less viscous and therefore flows, for example, into region **450** at the junction of the two tissues **410** and **420**. The solder penetrates the interstices of tissues **410** and **420** and fills voids located in region **450**. With further application of radiation, the radiation-responsive agent **430** cross-links to itself as well as cross-linking to the underlying tissues.

[0085] In another embodiment, as shown in **FIG. 22**, the radiation-responsive agent **430** may be applied to the inner surface of tissues **420** and **410**, respectively as a first agent layer **431** and a second agent layer **432**. Then the first and second agent layers **431** and **432** may be exposed to radiation from the laser **440** at the interface between tissues **410** and **420** to complete the bonding process.

[0086] In one embodiment, the laser light **440** emitted from the scanning module **402** is scanned across the tissue interface **450** from the first tissue **410** to the second tissue **420** then back to the first tissue **410** repeatedly along the length of the tissue interface **450**. Scanning module **402** is a portion of scanning beam assembly **1**, which in some embodiments includes scanning assembly **2** within the central void **61** of housing **62** including collectors **3** (shown in **FIG. 8**). In another embodiment the laser light **440** emitted starts at the second tissue **420** and scans across the tissue interface **450** to the first tissue **410** and back to the second tissue **420** repeatedly along the length of the tissue interface **450**. In another embodiment, the tissue interface **450** is scanned along the length of the tissue interface **450** between the first and second tissues **410** and **420**. In yet another embodiment, the laser light **440** scans across the tissue interface **450** as described above and is additionally scanned along the length of the tissue interface **450**. The scanning laser light **440** cures the radiation-responsive agent **430** slowly and evenly. Multiple passes of the laser light **440** may be needed for complete curing.

[0087] In one embodiment, the laser light **440** may be a high power infrared laser. In another embodiment, the clinician may set a scanning treatment plan using a touch-screen input or computer as part of the scanning beam assembly **1**. The scanning treatment plan may encompass any pattern of scanning, including those described above to cure all or a selected portion of the agent. The clinician may select the laser light **440** to be emitted as a continuous stream or as a pulse stream.

#### Shape Memory Alloy Stents

[0088] **FIG. 23** shows a delivery catheter **500** onto which stent **510** may be mounted as taught in United States Patent No. 5,649,952. In one embodiment, the delivery catheter **500** may be a conventional balloon dilatation catheter for angioplasty procedures. In another embodiment, the delivery catheter **500** may be a stent introducer

as shown in **FIG. 24A** and taught in United States Patent No. 5,545,211. The delivery catheter **500** may include connecting cable **504** and scanning module **502**, as shown in **FIG. 23** and **FIG. 24B-24C**. Scanning module **502** is a portion of scanning beam assembly **1**, which in some embodiments includes scanning assembly **2** within the central void **61** of housing **62** including collectors **3** (shown in **FIG. 8**). These example embodiments allow a clinician to see or visualize the site where the stent is to be placed. Once visually determined that the stent is in the desired position, the clinician may activate the stent using a therapeutic beam, laser, or one or more wavelengths of radiation that emits from scanning module **502**.

[0089] Stent **510** may be an angioplasty stent for use in the coronary artery, femoral artery, renal artery, or carotid artery, or a renal stent for use in the ureter, or a biliary tree stent for use in the biliary duct, or a prostatic stent for use in the urethra, or a transjugular intrahepatic portosystemic shunt for use in the hepatic portal veins, or any other stent for treating a tubular passageway within the body.

[0090] In **FIG. 23**, balloon **514** may be attached to one end of a catheter body **520**. The balloon **514** may be formed of suitable materials as described above for the first and second balloons **346** and **350** of **FIG. 13**. In order for the stent **510** to remain in place on the balloon **514** during delivery to the site of the damage within a body passageway **515**, the stent **510** may be compressed onto the balloon **514**, or protected by an annular sleeve, secured using a collar or ridges, or any other securing means. The delivery catheter **500** is advanced within the body passageway **515** until the stent **510** is directly under the detached lining or obstructing material **516**.

[0091] In **FIGS. 24A-24C**, the introducer comprises an inner tube **530** and a guide **532**. The inner tube **530** helps the whole delivery catheter **500** to pass through the body passageway **515** smoothly. A stent **510** may be positioned between the guide **532** and the inner tube **530**. The inner tube **530** is pulled out from the guide **532**, and the stent **510** in its compressed shape is pushed toward the opening of the guide **532** by a pusher **534** until the stent **510** is directly under the detached lining, obstructing material **516**, or desired position within the body passageway **515**.

[0092] Stent **510** may be constructed as taught in United States Patent No. 5,649,952, United States Patent No. 5,545,211, United States Patent No. 6,976,994, United States Patent No. 6,974,472, or United States Patent No. 7,035,777. In one embodiment the stent may be made of shape memory alloy, which may be manufactured by the methods taught in United States Patent No. 7,112,302.

[0093] As used herein, the term "shape memory alloy" or SMA is broadly defined as a metal-based alloy having a reversible solid-state transformation typically known as a martensitic transformation. Such materials typically exhibit the shape-memory effect and superelasticity distinct from conventional metals and alloys. These materials may be ferrous or non-ferrous martensites. Such materials include, but are not limited to, iron-based alloys, copper-based alloys, and nickel-titanium alloys. Ferrous systems include, but are not limited, iron and at least one of manganese, silicon, chromium and nickel, such as iron-manganese-silicon alloys and iron-chromium-nickel alloys. Copper-based systems are typically derived from copper-zinc, copper-aluminum, and copper-tin systems. Copper systems include, but are not limited to, copper and at least one of zinc, aluminum and nickel, such as copper-zinc-aluminum alloys, copper-nickel-aluminum alloys, and copper-beryllium-aluminum alloys. Nickel based systems include, but are not limited to nickel and at least one of titanium, copper, niobium, palladium, zirconium, and hafnium.

[0094] Stent **510** made of any of the above SMAs may have two distinct geometries that are temperature dependent. The metal may be configured in a first geometry **510a**, as shown in **FIGS. 24B,24C**, at low temperatures, but will transition to a second geometry **510b** at higher temperatures, as shown in **FIG. 24D**. The first geometry **510a** may be a compressed state of small diameter, which is convenient for delivering the stent using the delivery catheter. The second geometry **510b** may be an expanded state that conforms to the body passageway **515** as shown in **FIG. 24D**.

[0095] The transition from the compressed first geometry **510a**, a low temperature state, to an expanded second geometry **510b**, a higher temperature state, may occur after heating the SMA by exposing the SMA stent **510** to radiation emitting from the scanning module **302**. Since stents are heat sensitive, a therapeutic beam or other radiation that may supply a safe amount of heat may be used to transition the stent **510** from the

compressed first geometry **510a** to the expanded second geometry **510b**. In one embodiment the laser light may be emitted from the scanning module **302** of the scanning beam assembly **1**. In one embodiment as shown in **FIG. 23** the scanning module **302** may be inside the balloon **514**. In another embodiment the scanning module **302** may be external to the balloon as similarly illustrated in **FIG. 16**.

[0096] In another embodiment, like those shown in **FIGS. 24A-24D**, the connecting cable **504** may extend through the pusher **534**, thus placing the scanning module **502** inside the guide **532**. The scanning module **502** may be moved forward such that the scanning module **502** is inside the first compressed geometry **510a** of the stent **510**. While inside the stent **510** the scanning module **502** may be set to selectively scan the SMA to activate the expansion thereof. The selective scan may be set by the clinician using the scanning beam assembly **1** as described above. In yet another embodiment, as shown in **FIG. 24C**, the scanning module **502** and the connecting cable are within the pusher **534**. The end of the pusher **534** closest to the stent **510** may be made of a material that will allow the radiation from the laser light to pass through, or the material may have an opening or plurality of openings that allow the laser light to pass through to activate the SMA stent **510**.

[0097] In another embodiment the SMA stent **510** may be wrapped in a mesh as taught in United States Patent No. 5,545,211. The mesh may contain or be made of a radiation-responsive agent, a medical healing aide, or other treatment drug. The radiation-responsive agent may be radiation curable. The radiation curable radiation-responsive agent may be cured by exposure to the radiation emitted from the scanning module **502** as described above.

[0098] In another embodiment, the present invention includes a method for repairing or modifying an area of a patient's anatomy includes the steps of directing at least a portion of a scanning beam assembly to an area of a patient's anatomy, displaying an image of the anatomy, identifying a portion of the anatomy where radiation can be used to open a channel within a portion of the anatomy, and emitting the radiation to make the channel. The area of the anatomy may be the heart. Channels may be made into the heart (e.g., the wall of the heart) to isolate electrical signals. These channels may be used to treat arrhythmia or cause revascularization. In one embodiment, the scanning beam

assembly may be simply used to visualize or image the making of the channel. In another embodiment, the scanning beam assembly may emit radiation that is capable of removing or making a channel opening through an occlusion within a lumen or organ of the body.

**[0099]** In one embodiment, the scanning beam assembly may be used to visualize or image a patient's anatomy. The scanning beam assembly may be used to image any medical procedure. In one embodiment, the assembly may be used to image the placement of stents or grafts within the body.

**[00100]** While the present invention has been illustrated by description of several embodiments, it is not the intention of the applicant to restrict or limit the spirit and scope of the appended claims to such detail. Numerous other variations, changes, and substitutions will occur to those skilled in the art without departing from the scope of the invention. For instance, the assembly and method of the present invention has been illustrated in relation to repairing a site with a body using a scanning beam assembly, but it will be understood the present invention has applicability to other uses of a scanning beam assembly. Moreover, the structure of each element associated with the present invention can be alternatively described as a means for providing the function performed by the element. It will be understood that the foregoing description is provided by way of example, and that other modifications may occur to those skilled in the art without departing from the scope and spirit of the appended claims.

What is claimed is:

1. A method for repairing or modifying an area of a patient's anatomy comprising the steps of:
  - (a) directing at least a portion of a scanning beam assembly to an area of a patient's anatomy, the scanning beam assembly comprising:
    - a radiation source capable of emitting radiation;
    - a reflector that receives the radiation from the radiation source to direct the radiation onto the anatomy, wherein the reflector oscillates in at least two directions to create a scan of the anatomy;
    - a detector to detect radiation returned from the anatomy; and
    - a controller to convert the detected radiation into a displayable anatomy image;
  - (b) applying a radiation-responsive agent to portion of the anatomy, and
  - (c) exposing the radiation-responsive agent to radiation directed onto the agent by the reflector to cause the agent to therapeutically interact with the site.
2. The method of claim 1 wherein the method includes the additional steps of:
  - (d) imaging the anatomy using the scanning beam assembly, and
  - (e) displaying an image of the anatomy including the agent.
3. The method of claim 2 wherein the method includes the additional steps of:
  - (f) using the displayed image of the anatomy to plan the placement of the radiation-responsive agent, and
  - (g) selecting a treatment path where the reflector will direct therapeutic radiation for exposing the radiation-responsive agent.
4. The method of claim 1 wherein the area of the anatomy is selected from the group consisting of the stomach, colon, large or small intestine, ureter, urethra, biliary duct,

artery, vein, abdominal cavity, esophagus, trachea, bronchial tubes, external tissue, internal tissue, and lumen.

5. The method of claim 1 wherein the portion of the anatomy is a tissue separation.
6. The method of claim 5 wherein the tissue separation is a surgical incision.
7. The method of claim 5 wherein the agent therapeutically interacts with the site to bond the tissue on each side of the incision together.
8. The method of claim 5 wherein the agent includes at least one of albumin, collagen, gelatin, curing aides, medicines, and healing aides to crosslink the tissue at the tissue separation.
9. The method of claim 1 wherein the agent is at least one of a paste, a gelatin, a liquid, a solid, a ribbon, a mesh, a film, a graft, a stent and a powder.
10. The method of claim 1 wherein the agent is a layer on a film, tape mesh, graft, or annular sleeve.
11. The method of claim 1 wherein the agent is cured by the radiation.
12. The method of claim 1 wherein the agent is bioabsorbable.
13. The method of claim 1 wherein the agent is a medical adhesive.
14. The method of claim 1 wherein the agent is a medical drug.
15. The method of claim 13 wherein the medical adhesive includes at least one of albumin, collagen, gelatin, curing aides, medicines, and healing aides.
16. The method of claim 1 wherein applying the radiation-responsive agent comprises directing an applicator through a channel of a medical instrument to the selected area of the anatomy.



17. The method of claim 1 wherein exposing the agent with radiation is done to selectively cure a portion of the applied agent.
18. The method of claim 1 wherein the portion of the scanning beam assembly being directed to the anatomy includes a medical guidewire.
19. A stent made according to the method of claim 1.
20. The stent of claim 19 wherein the stent includes slots made by selectively curing the radiation-responsive agent.
21. A method for repairing or modifying an area of a patient's anatomy comprising the steps of:
  - (a) directing at least a portion of a scanning beam assembly to an area of a patient's anatomy, the scanning beam assembly comprising:
    - a radiation source capable of emitting radiation;
    - a reflector that receives the radiation from the radiation source to direct the radiation onto the anatomy, wherein the reflector oscillates in at least two directions to create a scan of the anatomy;
    - a detector to detect radiation returned from the anatomy; and
    - a controller to convert the detected radiation into a displayable image of the anatomy;
  - (b) displaying an image of the anatomy;
  - (c) identifying a portion of the anatomy for the placement of a radiation-responsive agent;
  - (d) applying the radiation-responsive agent to the identified site within the anatomy; and
  - (e) exposing the agent to radiation directed onto the agent by the reflector to cause the agent to therapeutically interact with the anatomy.

22. An intraluminal vascular graft made according to the method of claim 21.
23. The method of claim 21 wherein the portion of the scanning beam assembly is directed to the area of the body as part of a balloon catheter, wherein a quantity of the radiation-responsive agent is applied onto the balloon, and the balloon is expanded to apply the agent to the site.
24. A stent made according to the method of claim 21.
25. The stent of claim 24 wherein the radiation-responsive agent is bioabsorbable.
26. The stent of claim 24 wherein the stent has tubular walls of uniform thickness.
27. The stent of claim 24 wherein the stent includes slots made by selectively curing the radiation-responsive agent.
28. The stent of claim 24 wherein the stent is made to a custom length by repeating the method as the catheter is moved along the area of the body.
29. The method of claim 23 wherein the radiation-responsive agent is dispensed onto the balloon from an infusion port within the balloon catheter.
30. The method of claim 23 wherein the radiation-responsive agent is applied to the balloon before the catheter is directed to the portion of the anatomy.
31. The method of claim 30 wherein the radiation-responsive agent is applied to the balloon as at least one of a coating, a film, and an annular sleeve.
32. The method of claim 31 wherein the annular sleeve is a mesh with a coating of a medical adhesive.
33. The method of claim 31 wherein the balloon has a cover to protect the radiation-responsive agent while the catheter is directed toward the portion of the anatomy.

34. The method of claim 21 wherein the radiation-responsive agent is a shape memory alloy.
35. The method of claim 34 wherein the shape memory alloy is a stent assembly.
36. The method of claim 35 wherein the stent is applied by a catheter.
37. The method of claim 34 wherein the shape memory alloy is at least one of a nickel based alloy, a nickel titanium alloy, and a copper based alloy.
38. A balloon catheter comprising:
- (a) an expandable balloon;
  - (b) a catheter body having a plurality of lumens, wherein at least one lumen opens into the interior of the expandable balloon; and
  - (c) at least a portion of a scanning beam assembly, the scanning beam assembly comprising:
    - a radiation source capable of emitting radiation;
    - a reflector that receives the radiation from the radiation source to direct the radiation onto a patient's anatomy, wherein the reflector oscillates in at least two directions to create a scan of the anatomy;
    - a detector to detect radiation returned from the anatomy; and
    - a controller to convert the detected radiation into a displayable image of the anatomy.
39. The balloon catheter of claim 38 wherein the portion of the scanning beam assembly is fed through the lumen that opens into the interior of the expandable balloon.
40. The balloon catheter of claim 38 further comprising:
- (d) an infusion port for dispensing a radiation-responsive agent, the infusion port connected to at least one lumen within the catheter body.

41. The balloon catheter of claim 38 wherein the expandable balloon is made of a material that can transmit the radiation from the reflector through the balloon.
42. The balloon catheter of claim 38 wherein at least one lumen exits the catheter body near the proximal end of the expandable balloon.
43. The balloon catheter of claim 42 wherein the scanning beam portion of the scanning beam assembly is fed through the lumen that exits the catheter body near the proximal end of the expandable balloon.
44. A method for repairing or modifying an area of a patient's anatomy comprising the steps of:
- (a) directing at least a portion of a scanning beam assembly to an area of a patient's anatomy, the scanning beam assembly comprising:
    - a radiation source capable of emitting radiation;
    - a reflector that receives the radiation from the radiation source to direct the radiation onto the anatomy, wherein the reflector oscillates in at least two directions to create a scan of the anatomy;
    - a detector to detect radiation returned from the anatomy; and
    - a controller to convert the detected radiation into a displayable image of the anatomy;
  - (b) displaying an image of the anatomy;
  - (c) identifying a portion of the anatomy where the radiation is open a channel within a portion of the anatomy; and
  - (d) emitting the radiation to make the channel.
45. The method of claim 43 wherein the portion of the anatomy is the heart.

46. The method of claim 43 wherein the portion of the anatomy is a lumen having an occlusion.

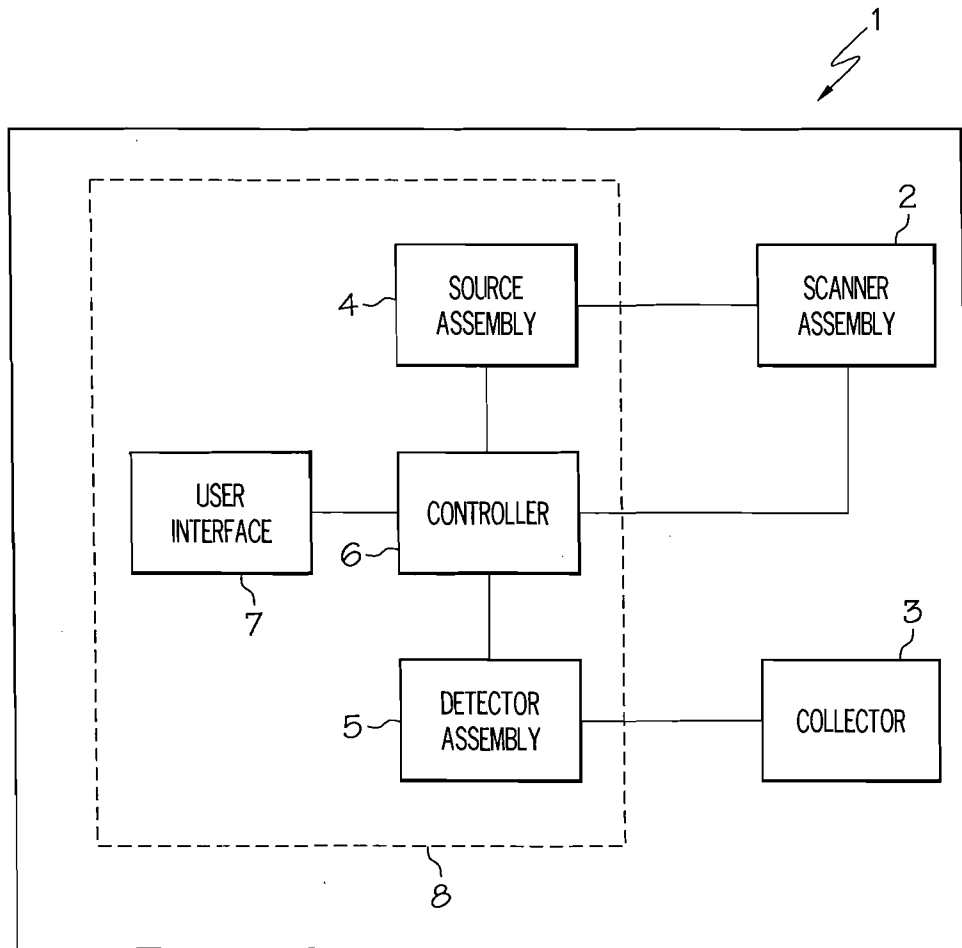


FIG. 1

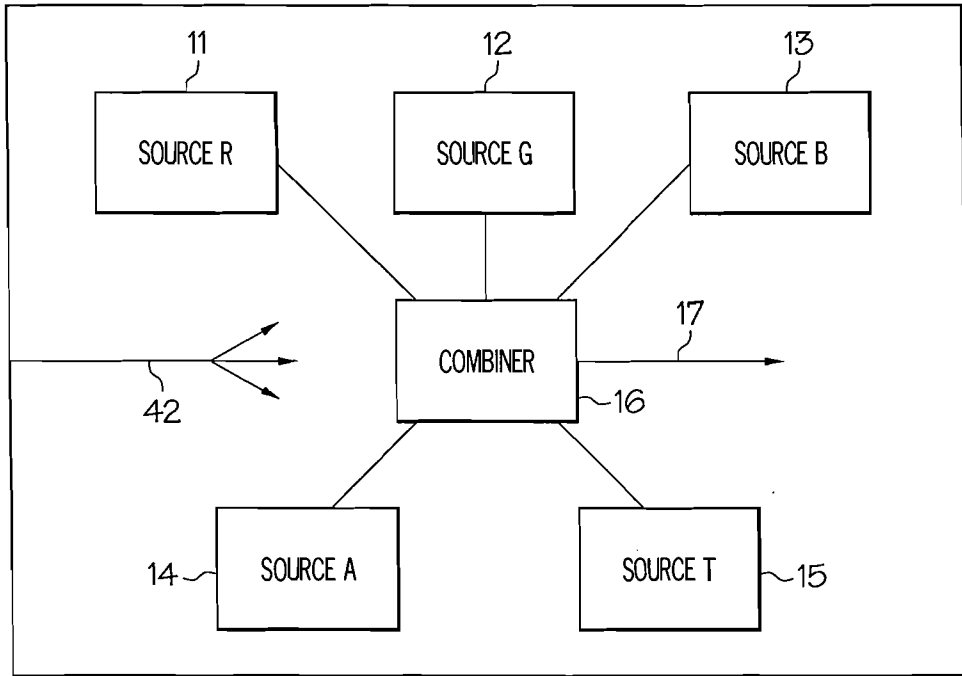
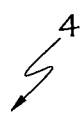


FIG. 2

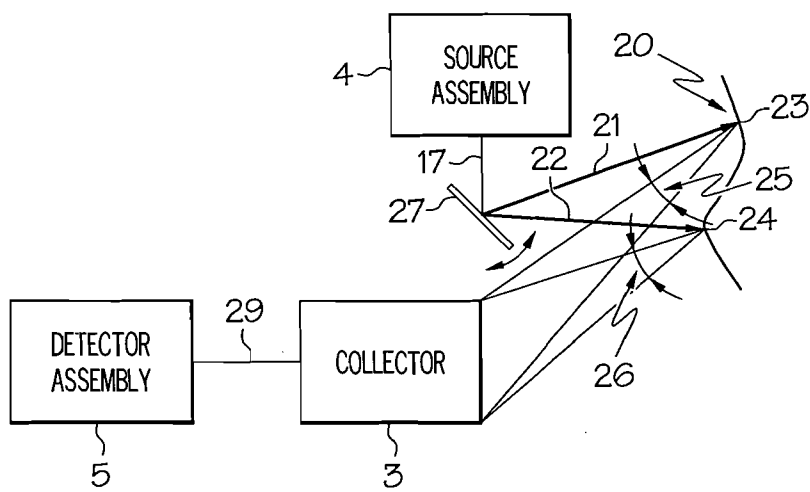


FIG. 3

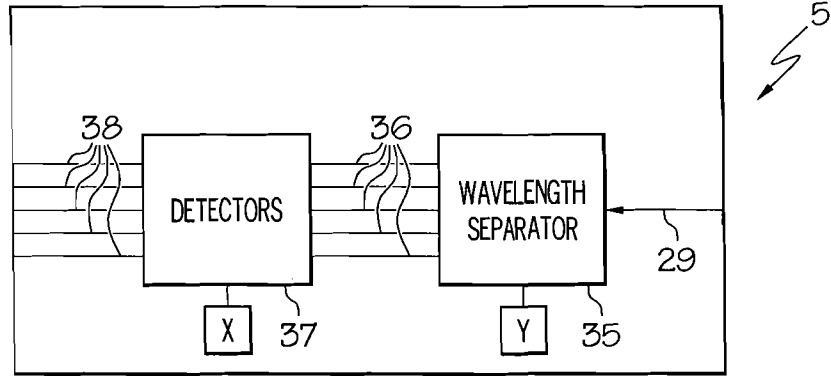


FIG. 4

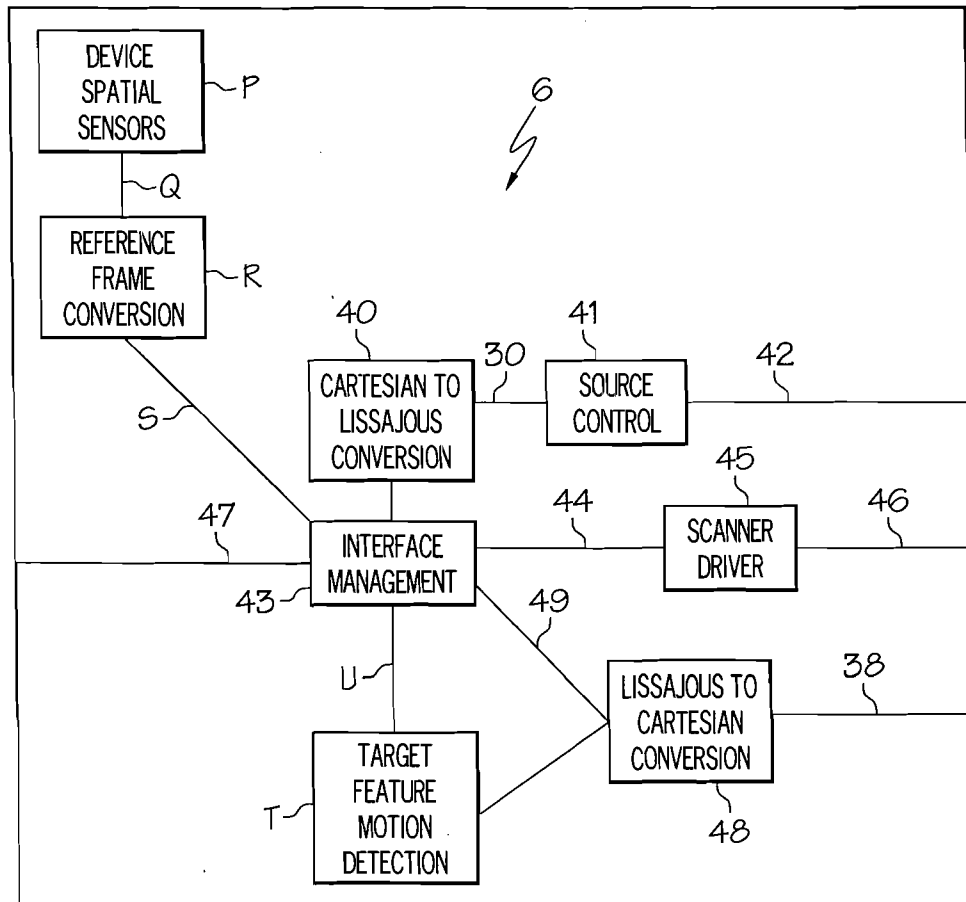


FIG. 5



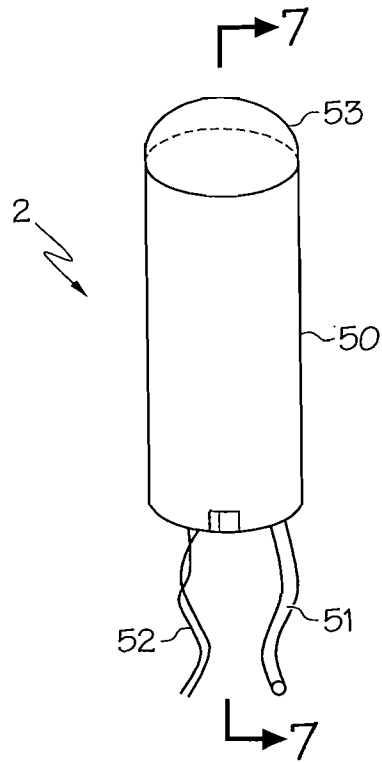


FIG. 6

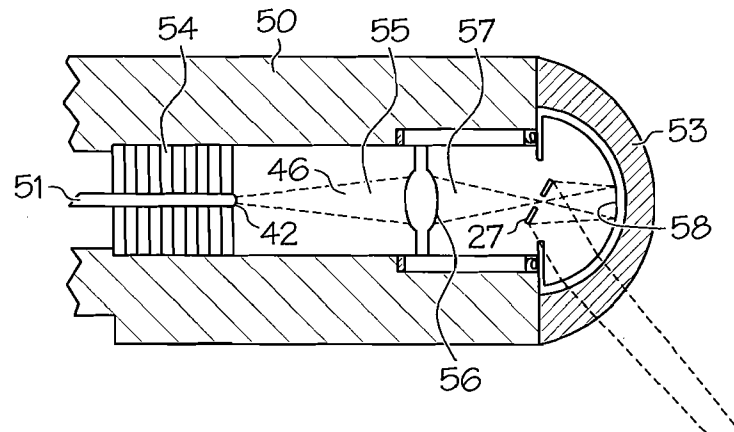


FIG. 7

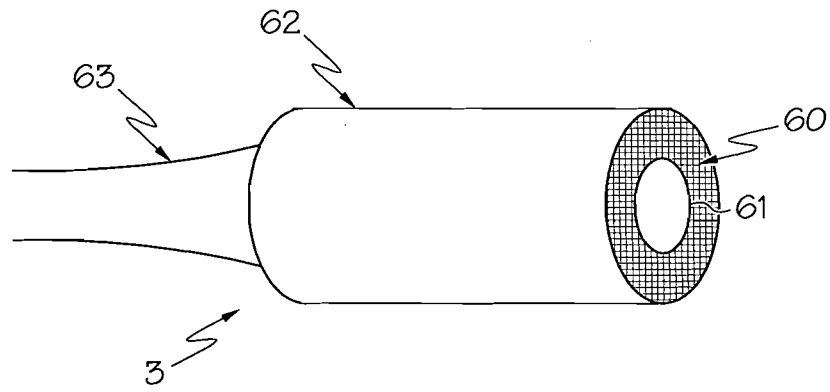


FIG. 8

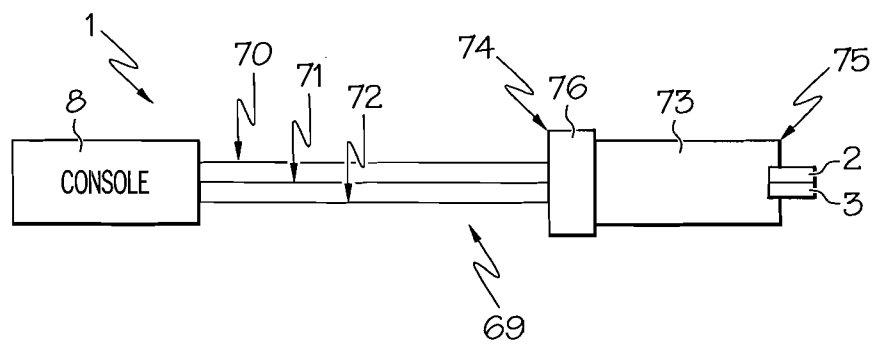


FIG. 9

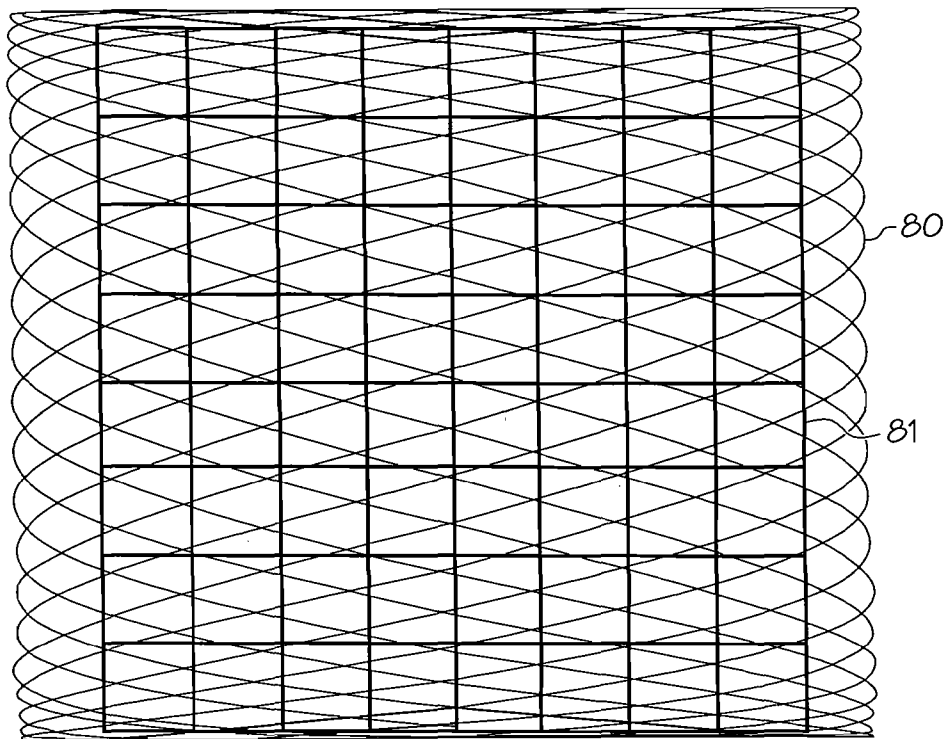


FIG. 10

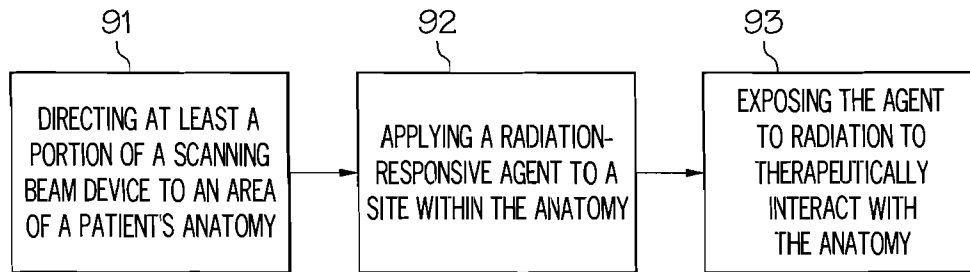


FIG. 11

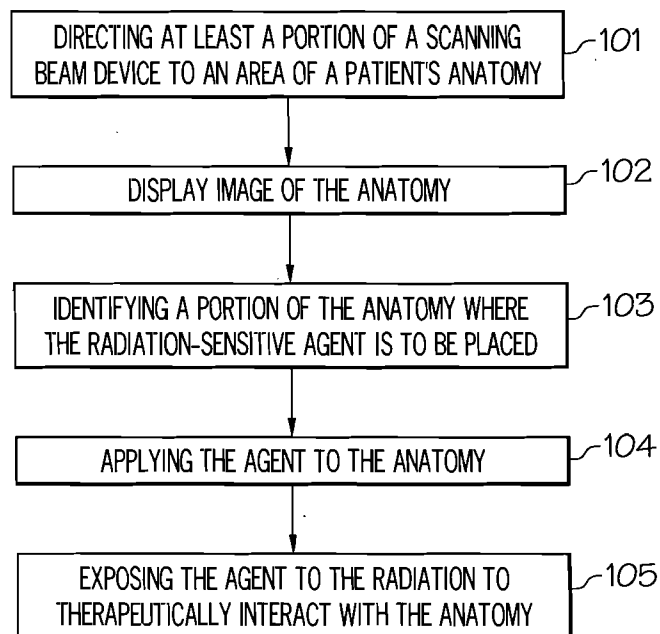


FIG. 12

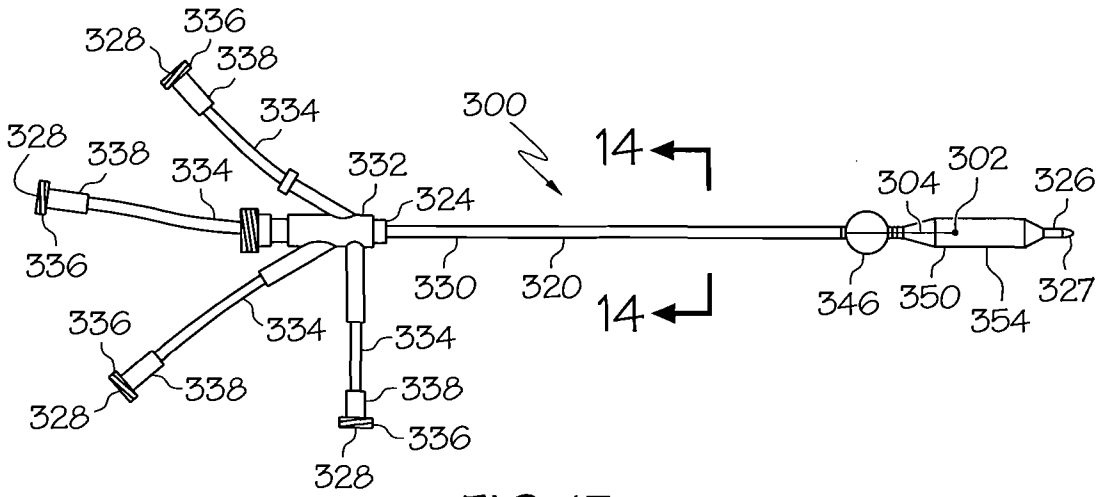


FIG. 13

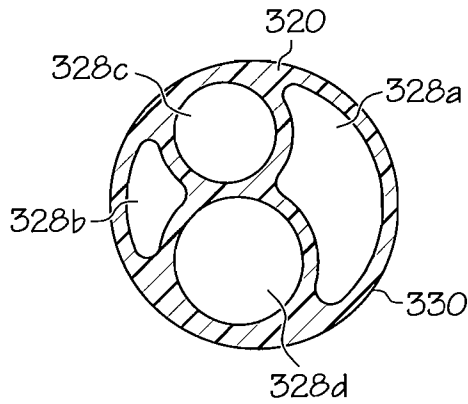


FIG. 14

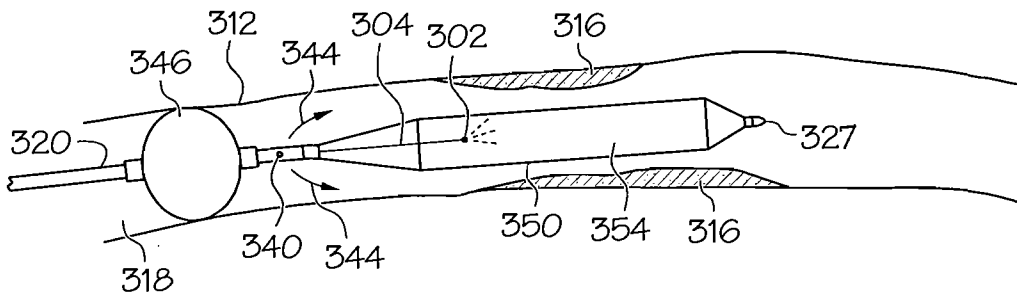


FIG. 15

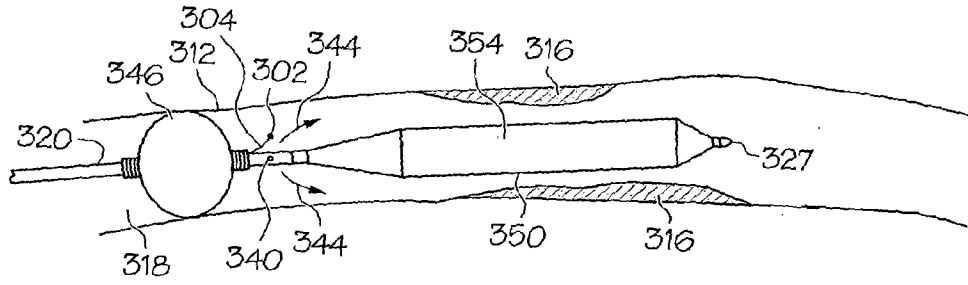


FIG. 16

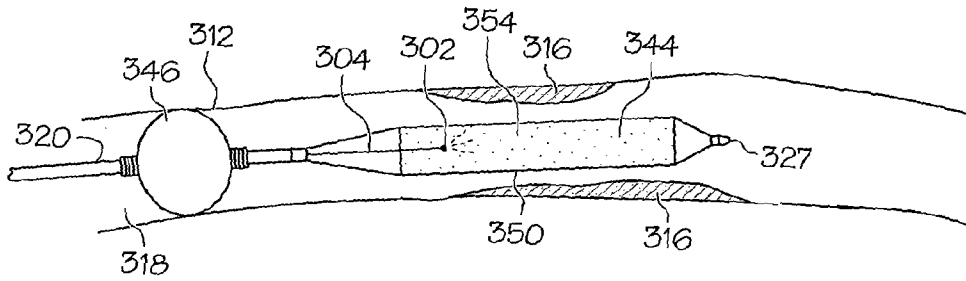


FIG. 17

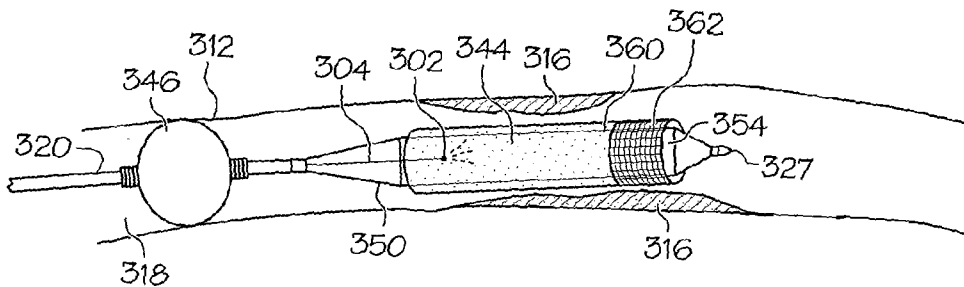


FIG. 18

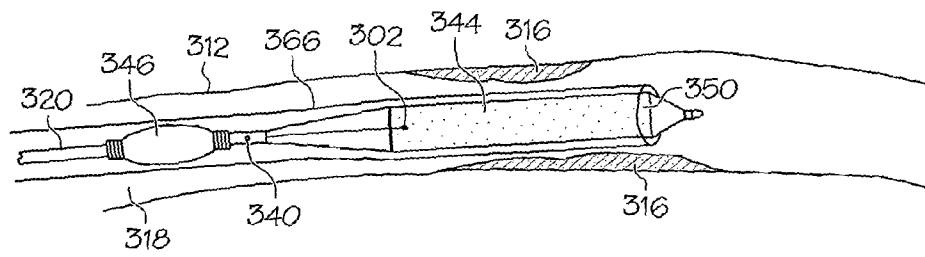


FIG. 19

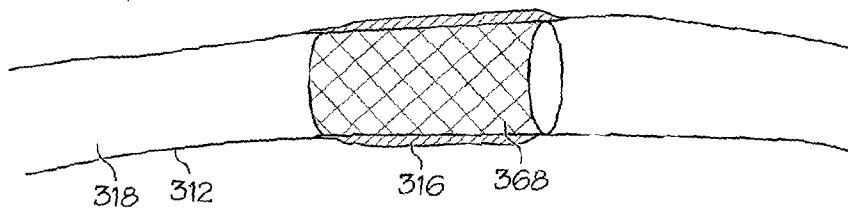


FIG. 20

FIG. 21

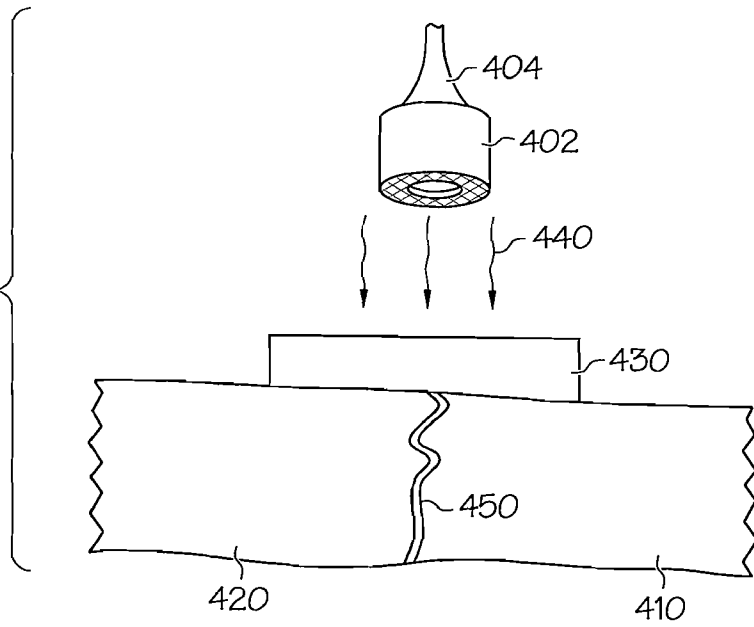
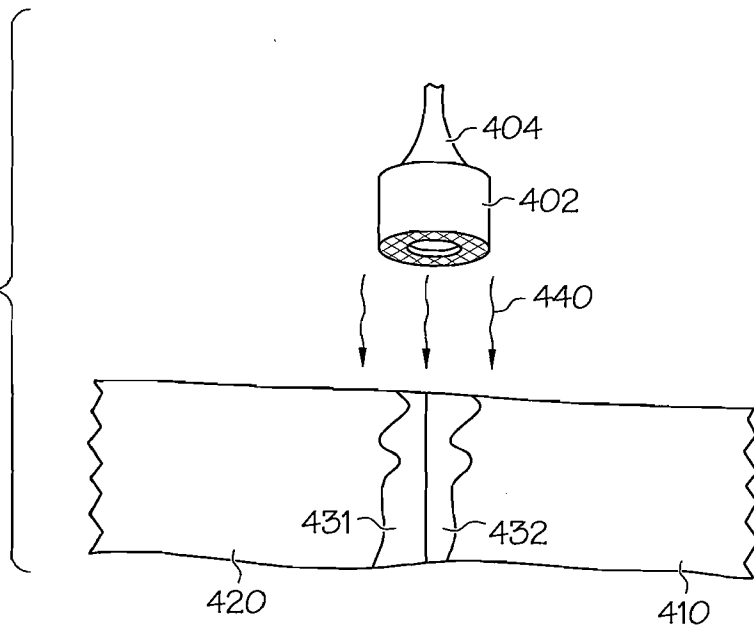


FIG. 22





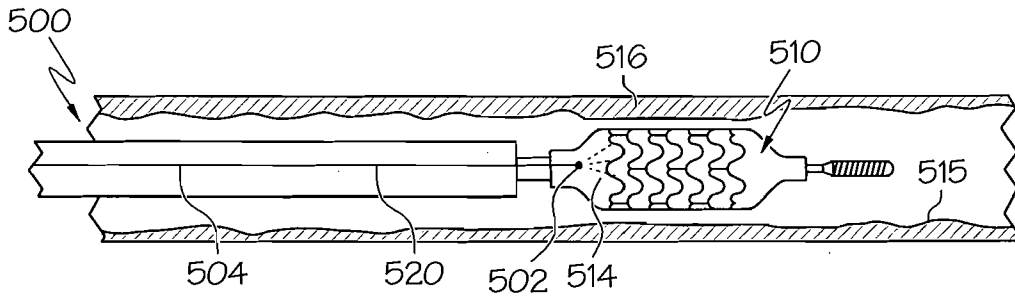


FIG. 23

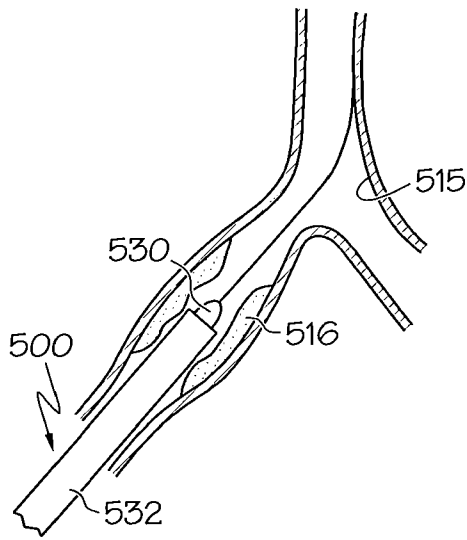


FIG. 24A

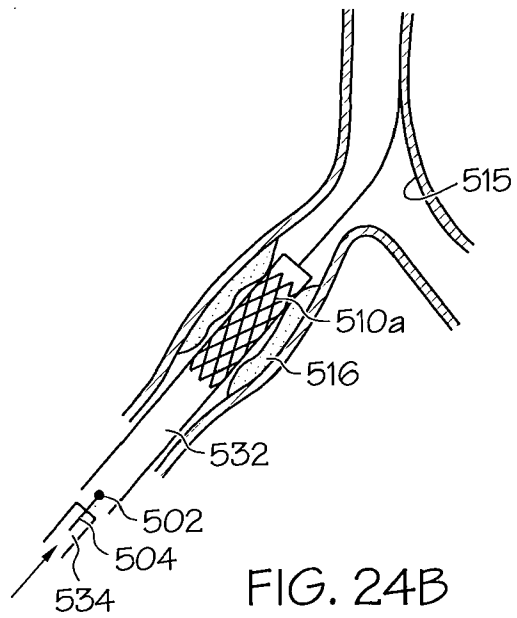
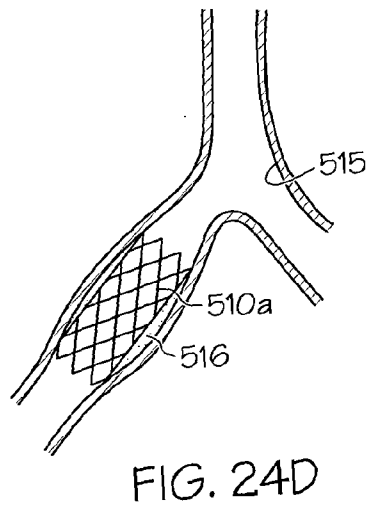
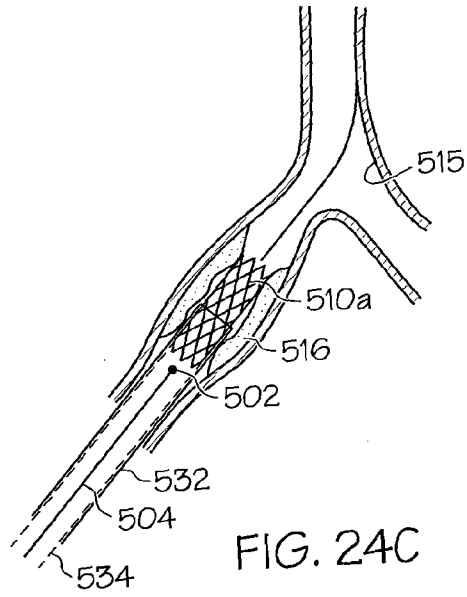


FIG. 24B



<b>A. CLASSIFICATION OF SUBJECT MATTER</b> INV. A61B1/00 ADD. A61M25/10		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) A61B A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 03/101287 A (UNIV LELAND STANFORD JUNIOR [US]) 11 December 2003 (2003-12-11) page 8, lines 5-26 page 10, lines 3-21 page 11, line 30 - page 14, line 22; figures 1A-1C	38-43
Y	US 2005/020926 A1 (WIKLOF CHRISTOPHER A [US] ET AL) 27 January 2005 (2005-01-27) cited in the application paragraphs [0009], [0127]; figures 1,12	38, 39, 41
Y	US 6 741 884 B1 (FREEMAN JENNY E [US] ET AL) 25 May 2004 (2004-05-25) column 8, lines 20-65; figure 2	40, 42, 43
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents :		
<ul style="list-style-type: none"> <li>*A* document defining the general state of the art which is not considered to be of particular relevance</li> <li>*E* earlier document but published on or after the international filing date</li> <li>*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</li> <li>*O* document referring to an oral disclosure, use, exhibition or other means</li> <li>*P* document published prior to the international filing date but later than the priority date claimed</li> <li>*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</li> <li>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</li> <li>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</li> <li>* &amp; * document member of the same patent family</li> </ul>		
Date of the actual completion of the international search 10 October 2008		Date of mailing of the international search report 23/10/2008
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Kempin, H

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 02/062239 A (OMNISONICS MEDICAL TECH [US]; RABINER ROBERT [US]; HARE BRADLEY A [US]) 15 August 2002 (2002-08-15) page 14, line 13 - page 15, line 7 -----	38
A	WO 2007/041542 A (CORNOVA INC [US]; RYAN ERIC S [US]; TANG JING [US]) 12 April 2007 (2007-04-12) page 3, line 21 - page 4, line 13; figures 1A, 1B page 22, line 25 - page 23, line 30 -----	38
A	US 6 056 721 A (SHULZE JOHN E [US]) 2 May 2000 (2000-05-02) cited in the application the whole document -----	38, 40, 42, 43

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 1-18,21-23,29-37 and 44-46

Claims 1-18, 21-23, 29-37 and 44-46 define a method for treatment of the human or animal body by therapy since they comprise the step of causing the agent to therapeutically interact with the site, or emit radiation to make a channel. The therapeutic treatment is performed during a surgical intervention. Therefore, a search is not required for these claims according to Rule 39.1(iv) PCT.

-----  
Continuation of Box II.2

Claims Nos.: 19,20,24-28

Claims 19, 20 and 24-28 define stents by a method of manufacture which is carried out in a patient during a surgical intervention. The stents remain in the patient. Consequently, the structural features of the stents are obscure since it is not clear which structure is imposed on the stents by the method of manufacture, and because the structure of the stent depends on the anatomy of the patient (lack of clarity, Art.6 PCT). Hence, a meaningful search is not possible.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2)PCT declaration be overcome.

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

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

1.  Claims Nos.: 1-18, 21-23, 29-37 and 44-46  
because they relate to subject matter not required to be searched by this Authority, namely:  
see FURTHER INFORMATION sheet PCT/ISA/210
  
2.  Claims Nos.: 19, 20, 24-28  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1.  As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
  
2.  As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
  
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 03101287	A	11-12-2003	AU 2003240831	A1 19-12-2003
			EP 1513440	A2 16-03-2005
			EP 1870018	A2 26-12-2007
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