The present invention is drawn to methods for ablating tissue within an organ, e.g., a heart, using a catheter. The catheter includes a tubular catheter having a proximal end, a distal end and a lumen therebetween, a plurality of independent flexible guide members, and an energy emitter. The method includes introducing the catheter into an organ, e.g., a heart, and performing ablation of tissue, e.g., diseased tissue. The energy emitter is slidably positioned within one or more of the flexible guide members so that the energy emitter is located proximate to the tissue site. Energy is emitted through the emitter, thereby treating, e.g., phototherapeutically, e.g., ablating, the tissue with minimal or no harm to the surrounding healthy tissue. A method may be used for therapeutic or prophylactic treatment of tissue.
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
OPTICAL FIBER BASKET DEVICE FOR CARDIAC PHOTOABLATION

FIELD OF THE INVENTION

The present invention is directed to systems and methods for ablating interior regions of the heart for treatment of cardiac abnormalities.

BACKGROUND OF THE INVENTION

Treatment of tissues generally requires direct contact of the target tissue with a medical instrument, usually by a surgical procedure which exposes both the target and intervening tissue to substantial trauma, e.g. bleeding and/or infection. Often, precise placement of a treatment probe is difficult due to the location of a target tissue in the body or proximity of the target tissue to easily damaged critical body organs, nerves, or other physiological components.

Destruction of cellular tissues in situ has been used in the treatment of diseases and medical conditions alone or as an adjunct to surgical removal procedures. These methods are often less traumatic than surgical procedures and may be the only alternative where surgical procedures are unfeasible. Phototherapeutic treatment devices, e.g., lasers, have the advantage of using intense light energy which is rapidly attenuated to a non-destructive level outside of the target region.

For example, microwave, radio frequency, acoustical (ultrasound) and light energy (laser) devices and tissue destructive substances have been used to destroy malignant, benign and other types of aberrant cells in tissues from a wide variety of anatomical sites and organs. Tissues sought to be treated include isolated carcinoma masses and, more specifically, organs such as the prostate, bronchial passage ways, passage ways to the bladder, passage ways to the urethra, and various passage ways into the thoracic area, e.g., the heart.

Devices useful for the treatment of such disease states or conditions typically include a catheter or an cannula which can be used to carry an energy source or waveguide through a lumen to the zone of treatment. The energy is then emitted from the
catheter into the surrounding tissue thereby destroying the diseased tissue, and sometimes surrounding tissue.

Steerable catheters are known for use in a variety of medical procedures. See, for example, U.S. Patent Nos. 4,998,916 to Hammerslag, 4,960,134 to Webster, Jr., 4,753,223 to Bremer, 4,685,457 to Donenfeld, 3,605,725 to Bentov, 3,470,876 to Barchilon, 4,944,727 to McCoy and 4,838,859 to Strassman. These catheters employ a plurality of steering wires which extend from a steering mechanism at the proximal end of the catheter to an anchor point at the distal end of the catheter. By manipulating the individual steering wires using the control mechanism, the tip of the catheter can be manipulated in a desired direction. In addition to being steerable in the lateral direction, further positioning of known catheters is accomplished by rotating the catheter as a whole about its longitudinal axis, typically by turning or twisting the proximal end of the catheter. This action exerts a torque along the length of the catheter which is translated into a rotational motion at the distal end which allows a laterally deflected distal tip to be rotated.

For example, careful and precise control over the catheter is required during critical procedures which ablate tissue within the heart. Such procedures are termed "electrophysiological" therapy and are becoming widespread for treatment of cardiac rhythm disturbances. During these procedures, an operator guides a catheter through a main artery or vein into the interior of the heart which is to be treated. The operator manipulates a mechanism to cause an electrode which is carried on the distal tip of the catheter or along the outer surface to have direct contact with the tissue area to be treated. Energy is applied from the electrode into the tissue and through an indifferent electrode (in a uni-polar electrode system) or to an adjacent electrode (in a bi-polar electrode system) to ablate the tissue and form a lesion.

Cardiac mapping can be used prior to ablation to locate aberrant conductive pathways within the heart. The aberrant conductive pathways are called arrhythmias. Mapping of the heart identifies regions along these pathways, termed "foci", which are then ablated to treat the arrhythmia.
There are drawbacks with many of the currently available catheters. Oftentimes it is difficult, if not impossible, to maneuver the instrument into small passage ways, such as a ventricle, without damaging the surrounding tissue. Positioning and maintaining contact between an apparatus and a beating heart is also problematic. Additionally, directing the ablative energy onto the tissue site to be treated can be problematic, especially when vital organs surround the diseased tissue. Current devices often suffer from the inability of the device to be manipulated to conform to the tissue site area, e.g., a ventricular or atrial wall. Therefore, it would be desirable to direct ablative energy onto a specific treatment area wherein surrounding tissue is minimally degraded.

**SUMMARY OF THE INVENTION**

The present invention circumvents the problems described above by delivering energy, e.g., laser light or other ablating energy, in a linear lesion thereby avoiding damage to surrounding tissues, e.g., healthy tissue(s). In one embodiment, the apparatus of the invention includes a positionable energy transparent member which can slidably guide an energy emitter to a specific target site. Optionally, a shape controller, such as a wire, can be slidably attached to the distal portion of the positionable, e.g., retractable, energy transparent member, such that manipulating the wire attenuates the degree which the positionable energy transparent member bends.

In another embodiment, the apparatus of the invention includes a plurality of independently positionable energy transparent members, any of which can slidably guide an energy emitter to a specific target site. Optionally, a shape controller, such as a wire, can be slidably attached to the distal portions of the positionable energy transparent members, such that manipulating the wire attenuates the flexure of the positionable energy transparent members. The present invention thus provides instruments and methods for percutaneous catheter phototherapy of diseased, necrotic, or aberrant tissue cells with minimal or no degradation of tissue surrounding these target sites. Patients may therefore not require pharmacological or surgical therapy, thus reducing the morbidity and expense of therapy.
The invention provides a device and method for tissue treatment of body tissues by delivering therapeutic energy directly into a target tissue while minimizing effects on the surrounding tissue. In a preferred embodiment, the therapeutic energy is phototherapeutic radiation.

This invention is directed to a unique device and method for penetrating body tissues for medical purposes such as forming lesions, preferably linear lesions, in a body cavity. The present device limits the energy delivered to a precise preselected site, thereby minimizing trauma to adjacent surrounding tissue and achieving an enhanced medical benefit. The present invention is a catheter-like device for positioning a treatment assembly in the area or organ selected for medical treatment. In one embodiment, the device includes one or more prestressed flexible guide members which, upon exiting the catheter, bow outwardly to form a three-dimensional array.

The present invention is based, at least in part, on the discovery that manipulation of flexible guide members, independent from each other, provides the ability to tailor a catheter device to any body cavity or organ. Optionally, a shape controller, such as a wire, can be slidably attached to the distal portions of the positionable energy transparent members, such that manipulating the wire attenuates the flexure of the positionable energy transparent members. In one embodiment, the flexible guide members are hollow or act as a guide, e.g., a track, and provide a means for positioning an energy emitter. As a consequence of the three-dimensional maneuverability and tailoring of each flexible guide member to the preselected site, the energy emitter can be positioned proximate to the tissue site which requires phototherapeutic radiation, e.g. hyperthermia, coagulation and/or phototherapeutic processes in tissue.

The present invention is drawn to a catheter for treating tissue by inducing hyperthermia, coagulation and/or phototherapeutic processes in tissue, preferably by phototherapeutic radiation. In one embodiment, the catheter includes a tubular catheter, a flexible guide member and an energy emitter. The tubular catheter and the flexible guide member have a proximal end, a distal end and a lumen therebetween. The distal end of the flexible guide member can be connected to a distal end fitting and, optionally, to a shape controller.
Upon extension from the tubular catheter, the flexible guide member, which can be prestressed, bows outwardly in a three-dimensional array. The flexible guide member can be flexed, e.g., expanded outwardly or withdrawn inwardly, when sufficient force or pressure is applied to the proximal end of the flexible guide member. Optionally, a shape controller is attached to the distal end of the flexible guide member or distal end fitting. The shape controller can be manipulated such that the wire attenuates the degree which the positionable energy transparent member bends.

In another embodiment, the catheter includes a tubular catheter, a plurality of flexible guide members and an energy emitter. The tubular catheter and each flexible guide member has a proximal end, a distal end and a lumen therebetween. In one embodiment, the distal ends of the flexible guide members are connected by a distal end fitting. Optionally, a shape controller can be slidably attached to the distal portions of the positionable energy transparent members, such that manipulating the wire attenuates the flexure of the positionable energy transparent members.

Upon extension from the tubular catheter, each independent flexible guide member, each of which can be prestressed, bows outwardly, thereby forming a three-dimensional array. Each of the flexible guide members can be expanded flexed or withdrawn inwardly, independently, from each other flexible guide member when sufficient force or pressure is applied to the proximal end of the particular flexible guide member.

In one embodiment, the flexible guide members are expandable and positionable. That is, the flexible guide members are pretended, e.g., prestressed, and are initially compressed within the tubular catheter until sufficient force is applied to the proximate ends of each member, such that the members are forced out of the tubular catheter and expand into a three-dimensional array. Each flexible guide member can thereafter be retracted into the tubular catheter by application of pressure in an opposing direction. Each flexible guide member, independently, can be a hollow tube or a tracking guide. In a preferred embodiment, at least one of the plurality of flexible guide members is transparent, e.g., energy transparent.
In an alternative embodiment, the flexible guide member(s) are not prestressed. Manipulation of each flexible guide member, individually, causes the flexible guide members to form a two or three-dimensional array. Optionally, a shape controller can be attached to the end cap, which connects the flexible guide members, to facilitate in the expansion and positioning of the flexible guide members. Alternatively, where the flexible guide members are connected to each other at their respective distal ends, the shape controller can be attached to one of the flexible guide members to effect maneuverability.

The emitter, having a proximal end and a distal end, is for transmitting energy to a preselected tissue site and is slidably disposed within one of the flexible guide members. In a preferred embodiment, the emitter is in communication with an energy source. Suitable emitters are those known in the art and include those which conduct heat, cryogenic temperatures, microwave radiation, ultrasound, ultraviolet light, infrared light, and coherent light, e.g., laser light. In one embodiment, the energy emitter is an optical fiber. In a preferred embodiment, the emitter can be manipulated by an operator in such a manner that the emitter can be repositioned sequentially into as many of the flexible guide members as required to treat, e.g., ablate, a selected tissue site.

The present invention is also drawn to methods for delivering energy emitters to form anatomically guided lesions within an organ, e.g., a heart, using a catheter. The catheter includes a tubular catheter having a proximal end, a distal end and a lumen therebetween, a plurality of hollow independent flexible guide members, and an energy emitter. The method includes introducing the catheter into an organ, e.g., a heart, and contacting the tissue with a two or three-dimensional array with an expandable member(s). The energy emitter is slidably positioned within one or more of the flexible guide members so that the energy emitter is located proximate to the diseased tissue site. Energy is emitted through the emitter, thereby treating, e.g., phototherapeutically, e.g., ablating, the diseased tissue with minimal or no harm to the surrounding healthy tissue.

The present invention is particularly well-adapted for the treatment of trabecular (atrial) tissue using a catheter. In one embodiment, the catheter includes a tubular catheter having a proximal end, a distal end, a lumen therebetween, a positionable energy
transparent flexible guide member having a distal end and proximal end and an energy emitter. Optionally, a shape controller is attached to the distal portion or an end cap attached to the flexible guide member. The catheter is introduced proximate to trabecular tissue and the flexible guide member is expanded outwardly from the catheter body to contact the trabecular tissue. Optionally, the shape controller is maneuvered in conjunction with the flexible guide member to provide optimum contact with the trabecular tissue. The energy emitter is positioned within the energy transparent flexible guide member so that the energy emitter is proximate to a trabecular treatment site which is treated with energy emitted by the energy emitter. The trabecular tissue is treated, e.g., ablated, coagulated, and/or phototherapeutically modulated, or otherwise altered by emitted energy without damaging surrounding tissue.

In another embodiment, the catheter includes a tubular catheter having a proximal end, a distal end, a lumen therebetween, a plurality of independent positionable transparent flexible guide members each member having a distal end and proximal end and an energy emitter. Optionally, a shape controller is attached to the distal portion or to an end cap of attached to the flexible guide members. The catheter is introduced proximate to trabecular tissue and the flexible guide members are independently expanded to so that at least one of the flexible guide members contacts a portion of the trabecular tissue. The energy emitter is positioned within a flexible guide member so that the energy emitter is proximate to a trabecular treatment site which is treated with energy emitted by the energy emitter. Optionally, the shape controller is maneuvered in conjunction with the flexible guide members to provide optimum contact with the trabecular tissue. The trabecular tissue is treated, e.g., ablated, coagulated, and/or phototherapeutically modulated, or otherwise altered by emitted energy without damaging surrounding tissue. In one aspect, each of the flexible guide members is independently flexed from each other member when a force is applied to said proximal end of any of said flexible guide members. The methods can be used prophylactically or therapeutically.

The present invention is also drawn to methods for treating or preventing atrial fibrillation by ablation, coagulation and/or phototherapeutic processes using a catheter. In
one embodiment, the catheter includes a tubular catheter having a proximal end, a distal end, a lumen therebetween, a positionable energy transparent flexible guide member having a distal end and proximal end and an energy emitter. Optionally, a shape controller is attached to the distal portion or an end cap of the flexible guide member.

The catheter is introduced proximate to atrial tissue and the flexible guide member is expanded outwardly from the catheter body to contact the atrial tissue. Optionally, the shape controller is maneuvered in conjunction with the flexible guide member to provide optimum contact with the atrial tissue. The energy emitter is positioned within the energy transparent flexible guide member so that the energy emitter is proximate to an atrial treatment site which is treated with energy emitted by the energy emitter. The atrial tissue is treated, e.g., ablated, coagulated, and/or phototherapeutically modulated, or otherwise altered by emitted energy without damaging surrounding tissue.

In another embodiment, the catheter includes a tubular catheter having a proximal end, a distal end, a lumen therebetween, a plurality of independent positionable transparent flexible guide members each member having a distal end and proximal end and an energy emitter. Optionally, a shape controller is attached to the distal portion or to the end cap of the flexible guide members. The catheter is introduced proximately to atrial tissue and the flexible guide members are independently expanded to so that at least one of the flexible guide members contacts a portion of the atrial tissue. Optionally, the shape controller is maneuvered in conjunction with the flexible guide members to provide optimum contact with the atrial tissue. The energy emitter is positioned within a flexible guide member so that the energy emitter is proximate to an atrial treatment site which is treated with energy emitted by the energy emitter, such that the atrial tissue is ablated, coagulated, and/or phototherapeutically modulated or otherwise altered by emitted energy without damaging surrounding tissue. In one aspect, each of the flexible guide members is independently flexed from each other member when a force is applied to said proximal end of any of said flexible guide members. The methods can be used prophylactically or therapeutically.
BRIEF DESCRIPTION OF THE DRAWINGS

Other objects, advantages and features of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

FIG. 1 is a perspective view of an endocardial ablation system that embodies the features of the invention;

FIG. 2 is a perspective view, with portions broken away, of one embodiment of an intraventricular ablation probe of the present invention;

FIG. 3 is a perspective view of the probe shown in FIG 2 which depicts a distal end portion of four flexible guide member assemblies of the probe extended from the distal open end of the catheter;

FIG. 4 is a sectional view through the distal end portion of four extended flexible guide member assemblies;

FIG. 5 is a sectional view through the distal end portion of four extended flexible guide member assemblies where one flexible guide member is more fully extended in relation to the remaining three flexible guide members;

FIG. 6 is a cross section view of a flexible guide member and an energy emitter slidably contained within the flexible guide member;

FIG. 7 is a cross section view of flexible guide member taken along the lines 7-7 of FIG. 6;

FIG. 8 is a cross section view of a flexible guide member guiding track and an energy emitter which is slidably retained by the tracking guide;

FIG. 9 is a cross section view of flexible guide member taken along lines 9-9 of FIG. 8;

FIG. 10 is a perspective view of a single flexible guide member and a shape controller extended outwardly from a catheter body;

FIG. 11 is a schematic block diagram of a laser tissue treatment system according to the present invention; and
FIG. 12 is a detailed schematic diagram of a reflectance monitor for use in the present invention.

**DETAILED DESCRIPTION OF THE INVENTION**

The features and other details of the invention will now be more particularly described and pointed out in the claims. It will be understood that the particular embodiments of the invention are shown by way of illustration and not as limitations of the invention. The principle features of this invention can be employed in various embodiments without departing from the scope of the invention.

The present invention is based, at least in part, on the discovery that the present invention can be used for inducing hyperthermia, coagulation and/or phototherapeutic processes in tissue, e.g., alteration, ablation, degradation, or destruction of tissue, at a specified site in tissue without harming the surrounding tissue. A particular advantage of the apparatus and methods of the invention is the ability to form long continuous lesions on a target site without the need to repeatedly position/reposition the delivery catheter.

The ability to target a specific tissue site is a result of an operator's ability to position an energy emitter proximate to the tissue site to be treated. One or more hollow or track-like flexible guide members can be guided through the distal end of a flexible elongate member, e.g., a tubular catheter, to ultimately provide means for positioning the energy emitter. Where more than one member is included in the apparatus, each individual flexible guide member can be independently controlled in relation to the other flexible guide members. As a consequence of this maneuverability, a linear energy pattern can be illuminated onto/into a specific target site for treatment by slidably positioning an energy emitter(s) through one or more of the flexible guide member(s) proximate to the site of interest to form a linear lesion.

The present invention is drawn to a catheter for treating tissue *in vivo* by inducing hyperthermia, coagulation and/or phototherapeutic processes in tissue, preferably by phototherapeutic radiation. In one embodiment, the catheter includes a tubular catheter, a flexible guide member and an energy emitter. The tubular catheter and the flexible guide
member have a proximal end, a distal end and a lumen therebetween. The distal end of the flexible guide member can be connected to a distal end fitting and, optionally, to a shape controller.

Upon extension from the tubular catheter, the flexible guide member, which can be prestressed, bows outwardly in a three-dimensional array. The flexible guide member can be flexed when sufficient force or pressure is applied to the proximal end of the flexible guide member. Optionally, a shape controller, capable of independent transitory axial motion can be attached to the distal end of the flexible guide member or distal end fitting. The shape controller or guide wire can be manipulated such that it the degree which the positionable energy transparent member bends.

In another embodiment, the catheter includes a tubular catheter, a plurality of flexible guide members and an energy emitter. The tubular catheter and each flexible guide member has a proximal end, a distal end and a lumen therebetween. In one embodiment, the distal ends of the flexible guide members are connected by a distal end fitting.

Upon extension from the tubular catheter, each independent flexible guide member, which can be prestressed, bow outwardly, thereby forming a three-dimensional array. Each of the flexible guide members can be flexed, independently, from each other flexible guide member when sufficient force or pressure is applied to the proximal end of the particular flexible guide member. Optionally, a shape controller or guide wire is attached to the distal ends of the flexible guide members or distal end fitting. The shape controller can be manipulated such that it controls the degree which the positionable energy transparent members bend.

In one embodiment, the flexible guide members are expandable and positionable. That is, the flexible guide members are pretensed, e.g., prestressed, and are initially compressed within the tubular catheter until sufficient force is applied to the proximate ends of each member, such that the members are forced out of the tubular catheter and expand into a three-dimensional array. Each flexible guide member can thereafter be retracted into the tubular catheter by application of pressure in an opposing direction.

Each flexible guide member, independently, can be a hollow tube or a tracking guide. In
a preferred embodiment, at least one of the plurality of flexible guide members is transparent, e.g., energy transparent.

In an alternative embodiment, the flexible guide member(s) are not prestressed. Manipulation of each flexible guide member, individually, causes the flexible guide members to form a two or three-dimensional array. Optionally, a shape controller can be attached to the end cap, which connects the flexible guide members, to facilitate in the expansion and positioning of the flexible guide members. Alternatively, where the flexible guide members are connected to each other at their respective distal ends, the shape controller can be attached to one of the flexible guide members to effect maneuverability.

The emitter, having a proximal end and a distal end, is for transmitting energy to a preselected tissue site and is slidably disposed within one of the flexible guide members. In a preferred embodiment, the emitter is in communication with an energy source. Suitable emitters are those known in the art and include those which conduct heat, microwave radiation, ultraviolet light, infrared light, and coherent light, e.g., laser light. In one embodiment, the energy emitter is an optical fiber. In a preferred embodiment, the emitter can be manipulated by an operator in such a manner that the emitter can be repositioned sequentially into as many of the flexible guide members as required to treat, e.g., ablate, a selected tissue site.

The term "phototherapeutic" is intended to include photochemical, photoablative and photothermal processes which are therapeutic and/or prophylactic in a subject.

The terms "treat", "treatment" or "treating" are intended to include both prophylactic and/or therapeutic applications. The methods of the invention can be used to protect a subject from damage or injury caused by a disease, or can be used therapeutically or prophylactically treat the subject after the onset of the disease or condition. Such treatment includes treatment with sufficient energy such that the tissue treated no longer exhibits the previous disease or condition. Typically, energy is emitted from the device of the invention into the diseased tissue until the diseased tissue does not require further treatment. The tissue can be ablated, coagulated, phototherapeutically modulated or otherwise altered by the emitted energy.
The terms "ablate" or "ablation" or "photothermal" are well recognized in the art and are intended include to thermal coagulation and/or removal of tissues which are necrotic, damaged, or are aberrant in nature. Ablation also includes the desiccation of tissue by the application of heat. For example, an ablating energy, such as those described above, would be one that would cause the tissue to reach a temperature of between about 60-90° C. Ablation increases the physiological temperature of a tissue by energetic stimulation to a temperature which degrades or eradicates tissue, thereby removing diseased tissue from a localized area. Ablation can be used as a therapeutic treatment, where diseased or otherwise unwanted tissue or cells exist, or as a preventative treatment to inhibit growth of undesirable tissue or cells in a specific region of an organ or viscera. In order to obtain destruction of tissue exclusively by thermal effects, it is necessary for the energy to be able to reach a threshold of destruction referred to as the "thermal dose". This threshold is a function of temperature reached and of the duration of the application. Therefore, ablation, to some degree, is based on the rise of the local temperature of tissue.

The term "coagulation" is well recognized in the art and is intended to mean the action whereby cells and/or body fluids within a treated tissue site are caused to become necrosed, thickened and/or lose the ability to conduct electrical activity, thereby resulting in a coherent mass by the methods of the invention. The method and apparatus of the invention permit selective, coagulation of a targeted tissue area and not blood or other body fluids which are found external, e.g., surrounding, to the target site.

The term "photochemical" is well recognized in the art and includes various energetic processes, including chemical reactions initiated by photons generated by an energy source. Typically photochemical processes are associated with laser, ultraviolet light, visible light or infrared light. Photochemical processes include the generation of radicals by photons colliding with tissue. The radical species are generated within cell tissue, often times causing oxidation of the cell contents; degradation or eradication occurs after the radical species are generated.

Photochemical processes cause injury to cells and tissue either by mechanical lysis or by the generation of by products such as free radicals, e.g., such as HO₂•, OH•
•, HO• and H₂O•, which damage the cell membrane. These reactive by products can interact with the localized surrounding tissue area such that the tissue is cleansed of unwanted material. Photochemical processes can involve oxidation or radical polymerization of, for example, cell walls, extracellular matrix components, cell nuclei, etc. Such photochemical processes are induced by ultraviolet, laser and far infrared energy.

The terms "into" and "onto" are used interchangeably and are intended to include treatment of tissue by directing energy toward the afflicted area. In some instances the energy penetrates the tissue and in other instances the energy only superficially treats the surface of the tissue. An ordinary skilled artisan would understand what depths of penetration are required and are dependent upon the application, tissue type, area to be treated and severity of condition. Accordingly, the amount of energy used to treat the afflicted area would be attenuated based upon the disease or condition being treated.

The term "flexible elongate member" is well recognized in the art and is intended to refer to a hollow tube having at least one lumen. In general, a flexible elongate member is often termed a "catheter", a term which is well known in the art. The flexible elongate member has proximal and distal ends with at least one longitudinal lumen extending therebetween. The distal end can be open or closed as is known in the art. In one embodiment, the distal end of the flexible elongate member is open, thereby allowing a emitter, described infra, to protrude beyond the elongate member. In another embodiment, the distal portion of the elongate member is closed, thereby preventing a emitter from passing beyond the distal end of the elongate member.

Flexible elongate members, e.g., tubular catheters, can be formed from biocompatible materials known in the art such as cellulosic ethers, cellulosic esters, fluorinated polyethylene, phenolics, poly-4-methylpentene, polyacrylonitrile, polyamides, polyamideimides, polyacrylates, polymethacrylates, polybenzoxazole, polycarbonates, polycycanoarylethers, polyesters, polyestercarbonates, polyethers (PEBAX, polyether block amide), polyetherketones, polyetherimide, polyetheretherketones,
polyethersulfones, polyethylene, polypropylene, polyfluoroolefins, polyimides, polyolefins, polyoxadizoles, polyphenylene oxides, polyphenylene sulfides, polysulfones, polytetrafluoroethylene, polythioethers, polytriazoles, polyurethanes, polyvinyls, polyvinylidene fluoride, silicones, urea-formaldehyde polymers, or copolymers or physical blends thereof.

Preferably, the materials used to construct the flexible elongate member or the catheter end portion can be “transparent” materials, such as fluoropolymers. Suitable transparent materials include polyethylene, nylon, polyurethanes and silicone containing polymers, e.g., silastic. Suitable fluoropolymers include, for example, fluorinated ethylene propylene (FEP), perfluoroalkoxy resin (PFA), polytetrafluoroethylene (PTFE), and ethylene-tetrafluoroethylene (ETFE). Typically the diameter of the flexible elongate member is between about 0.5 millimeters and about 2.5 millimeters, preferably between about 0.75 millimeters and about 2.0 millimeters. The diameter of at least one inner lumen of the flexible elongate member is between about 0.25 millimeters and about 1.5 millimeters, preferably between about 0.5 millimeters and about 1.0 millimeters. The length of the flexible elongate member varies with the intended application and in generally between about 1 meter and about 3 meters in length. For cardiac applications the flexible elongate member is between about 2 meters and about 3 meters long.

The term “catheter” as used herein is intended to encompass any hollow instrument capable of penetrating body tissue or interstitial cavities and providing a conduit for selectively injecting a solution or gas, including without limitation, venous and arterial conduits of various sizes and shapes, bronchoscopes, endoscopes, cystoscopes, culpascope, colonoscopes, trocars, laparoscopes and the like. Catheters of the present invention can be constructed with biocompatible materials known to those skilled in the art such as those listed supra, e.g., silastic, polyethylene, Teflon, polyurethanes, etc.

The term "biocompatible" is well recognized in the art and as used herein, means exhibition of essentially no cytotoxicity while in contact with body fluids or tissues. "Biocompatibility" also includes essentially no interactions with recognition proteins,
e.g., naturally occurring antibodies, cell proteins, cells and other components of biological systems.

The term "transparent" is well recognized in the art and is intended to include those materials which allow transmission of energy through, for example, the flexible guide members. Preferred transparent materials do not significantly impede (e.g., result in losses of over 20 percent of energy transmitted) the energy being transferred from an energy emitter to the tissue or cell site. Suitable transparent materials include fluoropolymers, for example, fluorinated ethylene propylene (FEP), perfluoroalkoxy resin (PFA), polytetrafluoroethylene (PTFE), and ethylene-tetrafluoroethylene (ETFE).

The terms "prestressed" or "pretensed" are used in connection with those materials which are useful as flexible guide members. Such materials have "memory", a term which is well recognized in the art. The material with "memory" has a preformed configuration, typically a bowed configuration, so that it will extend radially outwardly from a central axis extending from the proximal and distal ends of the flexible guide member. Typically the flexible guide member will have a shape, e.g., bowed, preformed into the base material. However, other configurations are contemplated by the invention. The degree of extension from the central axis is controlled by the amount of stress applied to the material prior to use as a flexible guide member. The degree of extension from the central axis is also controlled by the length of the flexible guide member and how far the flexible guide member is pushed through the tubal catheter. Maximum displacement from the central axis is achieved by fully extending the flexible guide member from the tubal catheter.

The term "flexible guide member" is intended to include those materials which can be used as catheters and have a lumen or a portion of a lumen. In one embodiment, the flexible guide member is a tubular catheter. In another embodiment, the flexible guide member is a track or a guide mechanism. Typically, the distal end of a flexible guide member is closed. Optionally, the distal end of a flexible guide member can be open, so that an energy emitter can extend beyond the distal end of the flexible guide member. Preferably, flexible guide members are transparent as described above.
The term "shape controller" refers to a mechanism which is used to position and to flex a flexible guide member. The shape controller is generally attached to the distal portion of a flexible guide member(s) or an end cap attached to the distal portion of the flexible guide member(s). The shape controller extends the distance between the point of attachment and to the proximal portion of the catheter body so that the shape controller can be manipulated. Tensing or pulling the shape controller proximally causes the flexible guide member(s) to contract and flex toward the applied force. Pushing the shape controller proximally causes the flexible guide member(s) to extend away from the applied force. Shape controllers can be utilized with pretensed flexible guide members as well as those flexible guide members which are not pretensed. Shape controllers can be formed from polymeric materials, such as polyethylene, polypropylene, urethanes, etc. or can be metallic. In certain embodiments, the shape controller is radioopaque.

A track or guide mechanism is intended to include those members which form a channel for which an energy emitter can slide through and be retained by the member; however, a portion of the member is removed along the longitudinal axis. A suitable example of a track or guide mechanism includes a U-shaped trough having open distal portions bend inwardly. Another example is an elliptically shaped tube which has one portion large enough to accommodate an energy emitter without it slidably disconnecting from the tubular structure. Any cylindrical tube can function as a tracking mechanism, where up to 49% of the tube is removed along the longitudinal axis.

In one embodiment, the catheter of the invention includes a distal end fitting. A plurality of flexible positionable members can be fixedly attached to the distal fitting, e.g., glued, sealed, welded, e.g., ultrasonically welded, or tightly fitted into the distal fitting such that the fitting does not disengage during a procedure. Optionally, a shape controller is attached to the distal end of the flexible guide member or distal end fitting. The shape controller can be manipulated such that the wire attenuates the degree which the positionable energy transparent member bends. Where the invention provides a single flexible positionable member, the shape controller can also be attached to a distal end fitting. The distal end fitting can further be connected to an activation and recording device, e.g., a computer for visualizing the position of the catheter and points of contact
with(in) tissue. The distal end fitting can facilitate in placement of the device into an
anatomic feature or orifice of a subject, e.g., the superior vena cava.

The terms "outwardly" and "inwardly" are relative to an axis or centerline of the
three-dimensional array, e.g., a basket or cage, which is formed by the plurality of
flexible guide members.

The term "independent" is well recognized in the art and is intended to mean that
each flexible guide member, for example, functions without any interaction from any
other flexible guide member. Each flexible guide member can, therefore, have a different
degree of "pretension", and/or maneuverability, thereby providing varying amounts of
curvature to the basket. Each flexible guide member can also have a twist about the
longitudinal axis of the member. Each flexible guide member can be controlled
separately from each other flexible guide member, e.g., shortened, twisted, or lengthened
relative to other flexible guide members or the tubular catheter. This functions as a
means to tailor the apparatus to unique body cavities, no two which are alike.

The term "control handle" is are recognized and is intended to include various
means to manipulate the apparatus of the invention, including at least the tubular
catheter elongate member, the flexible guide members and the emitter, described infra.
Various control handles useful with the present invention are commercially available,
such as those manufactured by Cordis Webster, Inc., 4750 Littlejohn St, Baldwin
Park, CA, 91706. When used, the control handle applies tension, e.g., stress, to the
flexible guide member(s), thereby causing the distal end of the flexible guide member(s)
to pass through the tubular catheter, e.g., extend, or retract into the catheter. As a
consequence of this action, the plurality of flexible guide members form a three-
dimensional array such as a basket or cage within the targeted site, e.g., a heart.

The terms "emitter" and "energy emitter" are intended to include those
apparatus which emit energy to facilitate non-contact heating by radiation. In a
preferred embodiment, the emitter is an optical fiber that serves as a waveguide for
light transmission. Typically, the energy transmitted is in the range between about 200
nanometers and about 10.5 micrometers. A preferred energy is coherent light, e.g.,
laser light, in the range between about 200 nm to about 2.4 μm, preferably between
about 400 to about 3,000 nm, more preferably between about 805 and 1600 nm. Suitable lasers include diode lasers, YAG: Nd lasers, YAG: Ho lasers, and diode pumped solid state lasers. A particularly preferred AlGaAs diode array, manufactured by Optopower, Tucson, Arizona, produces a wavelength of 915 nm. Typically the emitter emits between about 2 to about 10 watts/cm of length, preferably between about 4 to about 6 watts/cm, most preferably about 4 watts/cm. Alternatively, the energy emitter can be an ultrasound emitter and an acoustic waveguide. In one embodiment, the emitter can extend beyond the distal end of the flexible elongate member.

The emitter transmits the energy from an energy source which is in communication with the proximal end of the emitter. Suitable energy sources are known in the art and produce the above-mentioned types of energy. The emitter is positioned within lumen formed by a tubular catheter and especially those lumen of the flexible guide member(s). The emitter can be slidably controlled within the lumen such that positioning of the emitter at a distal end of a particular flexible guide member is readily achieved.

The emitter can have many forms known to those skilled in the art and can include a light diffuser other appropriate configurations. Exemplary tips are described in U.S. Patents 5,042,980, 5,207,669, 5,253,312, 5,269,777, and those diffusion tips described in "Phototherapeutic Apparatus" by Edward L. Sinofsky, Lincoln S. Baxter and Norman Farr and PCT Application No. PCT/US95/11246, International Publication No. WO 96/07451, published March 14, 1996, the teachings of all are incorporated herein by reference. A preferred tip is the diffusing laser tip available from Cardiofocus, Inc., West Yarmouth, MA 02673. The end of the tip can also be coated or coupled with an energy or light reflecting or deflecting material in order to prevent forward propagation of ablating energy.

For example, the end of the tip can be a diffusive tip assembly for use with various devices of the present invention. Tip assemblies suitable for use with the present invention include those disclosed in U.S. Patent Application No. 08/992,930, filed December 17, 1997, entitled "Non-occluding Phototherapy Probe Stabilizers" by Norman Farr, et al., the contents of which, are incorporated herein by reference. The
tip assembly includes an energy transmissive, e.g., light, tubular housing alignable with, and adapted to receive, the distal end of the fiber. The tip assembly serves as a waveguide for light propagating through the fiber. Furthermore, the tubular housing can contain radiation-scattering particles and the tip assembly can include a reflective end. Thus, as radiation propagates through the diffusive tip assembly, the radiation is scattered. When radiation impinges on the side walls of the tubular housing at an angle that exceeds the critical angle for internal reflection, the radiation exits the tip.

Radiation which is not emitted during this initial pass through the tip is reflected by at least one end surface or end cap and returned through the tip. During this second pass, the remaining radiation (or at least a major portion of this returning radiation) again encounters the scatterers which provide further radial diffusion of the radiation.

The term subject is intended to include mammals susceptible to diseases, including one or more disease related symptoms. Examples of such subjects include humans, dogs, cats, pigs, cows, horses, rats and mice.

The term "tissue" is well recognized in the art and is intended to include extracorporeal materials, such as organs, e.g., mesentery, liver, kidney, heart, lung, brain, tendon, muscle etc., and corporeal materials, such as blood cells, e.g., red and white blood cells and extracellular components.

The term "disease" is associated with an increase of a pathogen within a subject such that the subject often experiences physiological symptoms which include, but are not limited to, release of toxins, gastritis, inflammation, coma, water retention, weight gain or loss, ischemia and immunodeficiency. The effects often associated with such symptoms include, but are not limited to fever, nausea, diarrhea, weakness, headache and even death. Examples of diseases which can be treated by the present invention include undesirable cell proliferation, bacterial infection, cancer, e.g., bladder, urethral, mammalian, ovarian cancer, or, ischemia, and benign prostatic hypertrophy or hyperplasia (BPH).

The language "undesirable cell proliferation" is intended to include abnormal growth of cells which can be detrimental to a subject's physiological well being.

Effects of undesirable cell proliferation can include the release of toxins into the
subject, fever, gastritis, inflammation, nausea, weakness, coma, headache, water retention, weight gain or loss, immunodeficiency, death, etc. The undesired cells which proliferate can include cells which are either benign or malignant. Examples of undesirable cell proliferation include bacterial cell proliferation and aberrant cell division and/or proliferation of foreign cells, such as in cancer cells.

The terms "aberrant cell" or "aberrant tissues" as used herein, is well recognized in the art and is intended to include aberrant cell division and/or proliferation where cells are generated in excess of what is considered typical in physiologically similar environment, such as in cancers.

The language "control of undesirable cell proliferation" or "controlling undesirable cell proliferation" is intended to include changes in growth or replication of undesired cells or eradication of undesired cells, such as bacteria, cancer, or those cells associated with abnormal physiological activity. The language includes preventing survival or inhibiting continued growth and replication of an undesired cell. In one preferred embodiment, the control of the undesired cell is such that an undesired cell is eradicated. In another preferred embodiment, the control is selective such that a particular targeted undesired cell is controlled while other cells which are not detrimental to the mammal are allowed to remain substantially uncontrolled or substantially unaffected, e.g., lymphocytes, red blood cells, white blood cells, platelets, growth factors, etc.

The term "cancer" is well recognized in the art and is intended to include undesirable cell proliferation and/or aberrant cell growth, e.g., proliferation.

The term "modulate" includes effect(s) targeted tissue(s) that prevent or inhibit growth of diseased tissue, which may ultimately affect the physiological well being of the subject, e.g., in the context of the therapeutic methods of the invention.

FIG. 1 depicts an ablation system 10 which embodies the features of the invention. The system includes a hand held probe 12, a control handle 14 and an attached flexible tubular catheter 16. Catheter 16 slidably carries within an interior lumen 18, flexible basket assembly 20 that is extendable out of the distal end of catheter 18.
Flexible basket assembly 20 includes a plurality of flexible guide members 22 and optionally distal end cap 24 which, when deployed, are bowed outwardly to establish a three-dimensional array. In use, the flexible basket assembly 20 is positioned within a body lumen and opened. Each of flexible guide members 22 can be individually maneuvered to provide maximum contact with targeted tissue within the lumen. A emitter 26 is positioned within one or more of flexible guide members 22 proximate to the targeted tissue site. Ablative energy is transmitted through emitter 26 and focused onto the site to effect treatment.

In one aspect of the invention, the physician positions flexible basket assembly 20 by maneuvering catheter 16 through a main vein or artery into a selected heart chamber. For example, atrial therapies can be performed by inserting catheter 16 into the femoral vein, guiding catheter 16 through the inferior vena cava, and into the right atrium, and if required, is guided into the left atrium via atrial septal puncture. Left ventricular treatment can be performed by inserting catheter 16 into the femoral artery and guiding catheter 16 through the iliac artery, the aorta, through the aortic valve and into the left ventricle. Alternatively, an approach can be used entering the left atrium transeptally. During the procedure, flexible basket assembly 20 can be carried within lumen 18 of catheter 16. Progress of catheter 16 through the femoral artery or view can be observed by use of a fluoroscope, e.g., x-rays, ultrasound imaging, or the like.

It should be appreciated that additional radio-opaque markers can be provided about the assembly if necessary to provide adequate visualization with x-rays.

Once the distal end of catheter 16 is positioned in the desired endocardial location, catheter 16 is manipulated via control handle 14 of probe 12 to deploy and open flexible basket assembly 20 into a desired three-dimensional array. Energy is transmitted through emitter 26 from energy source 28 to modify, e.g. ablate, coagulate, abnormal foci in the tissue that disrupt normal heart rhythm leading to cardiac arrhythmia. Once the site(s) is located, each individual flexible guide member 22 can be attenuated via control handle 14 to optimally position flexible array 20. Emitter 26 can be slidably positioned within any one of flexible guide member lumen 30 which is (are) most proximate to the preselected site for tissue ablation. Emitter 26 is connected
to energy source 28 which provides ablative energy to emitter 26.

Energy source 28 can be one of many well known apparatus that provide energy for use at remote site. Energy source is in communication with the proximal end of the conductor and is effective to transmit energy through the conductor. A typical energy source provides a source of energy such as light energy. Preferred sources of energy include, for example, microwave, laser, or ultrasonic energy. In a preferred embodiment, the energy supplied by the energy source is laser energy.

The present invention is further drawn to methods for treating trabecular tissue using a catheter. In one embodiment, the catheter includes a tubular catheter having a proximal end, a distal end, a lumen therebetween, a positionable energy transparent flexible guide member having a distal end and proximal end and an energy emitter. Optionally, a shape controller is attached to the distal portion or an end cap attached to the flexible guide member. The catheter is introduced proximate to trabecular tissue and the flexible guide member is expanded outwardly from the catheter body to contact the trabecular tissue. Optionally, the shape controller is maneuvered in conjunction with the flexible guide member to provide optimum contact with the trabecular tissue. The energy emitter is positioned within the energy transparent flexible guide member so that the energy emitter is proximate to a trabecular treatment site which is treated with energy emitted by the energy emitter. The trabecular tissue is treated, e.g., ablated, coagulated, photochemically modulated, or otherwise altered by emitted energy without damaging surrounding tissue.

In another embodiment, the catheter includes a tubular catheter having a proximal end, a distal end, a lumen therebetween, a plurality of independent positionable transparent flexible guide members each member having a distal end and proximal end and an energy emitter. Optionally, a shape controller is attached to the distal portion or to an end cap attached to the flexible guide members. The catheter is introduced proximate to trabecular tissue and the flexible guide members are independently expanded to so that at least one of the flexible guide members contacts a portion of the trabecular tissue. The energy emitter is positioned within a flexible guide member so that the energy emitter is proximate to a trabecular treatment site which is treated with energy emitted by the
energy emitter. Optionally, the shape controller is maneuvered in conjunction with the flexible guide members to provide optimum contact with the trabecular tissue. The trabecular tissue is treated, e.g., ablated, coagulated, and/or phototherapeutically modulated, or otherwise altered by emitted energy without damaging surrounding tissue. In one aspect, each of the flexible guide members is independently flexed from each other member when a force is applied to said proximal end of any of said flexible guide members. The methods can be used prophylactically or therapeutically.

The term “trabecular” is well recognized in the art and is intended to include tissue, e.g., cardiac tissue, which is a spongy tissue often formed of bands and cords called trabeculae consisting of fibrous tissue, elastic fibers and muscle fibers.

The present invention is also drawn to methods for treating or preventing atrial fibrillation by ablation, coagulation and/or phototherapeutic processes using a catheter. In one embodiment, the catheter includes a tubular catheter having a proximal end, a distal end, a lumen therebetween, a positionable energy transparent flexible guide member having a distal end and proximal end and an energy emitter. Optionally, a shape controller is attached to the distal portion or an end cap attached to the flexible guide member. The catheter is introduced proximate to atrial tissue and the flexible guide member is expanded outwardly from the catheter body to contact the atrial tissue.

Optionally, the shape controller is maneuvered in conjunction with the flexible guide member to provide optimum contact with the atrial tissue. The energy emitter is positioned within the energy transparent flexible guide member so that the energy emitter is proximate to an atrial treatment site which is treated with energy emitted by the energy emitter. The atrial tissue is treated, e.g., ablated, coagulated, and/or phototherapeutically modulated, or otherwise altered by emitted energy without damaging surrounding tissue.

In another embodiment, the catheter includes a tubular catheter having a proximal end, a distal end, a lumen therebetween, a plurality of independent positionable transparent flexible guide members each member having a distal end and proximal end and an energy emitter. Optionally, a shape controller is attached to the distal portion or to an end cap attached to the flexible guide members. The catheter is introduced
proximately to atrial tissue and the flexible guide members are independently expanded to so that at least one of the flexible guide members contacts a portion of the atrial tissue. Optionally, the shape controller is maneuvered in conjunction with the flexible guide members to provide optimum contact with the atrial tissue. The energy emitter is positioned within a flexible guide member so that the energy emitter is proximate to an atrial treatment site which is treated with energy emitted by the energy emitter, such that the atrial tissue is ablated, coagulated, and/or phototherapeutically modulated or otherwise altered by emitted energy without damaging surrounding tissue. In one aspect, each of the flexible guide members is independently flexed from each other member when a force is applied to said proximal end of any of said flexible guide members. The methods can be used prophylactically or therapeutically.

Atrial fibrillation and atrial flutter are abnormalities in the rhythm or rate of the heart beat. For an adult at rest, the heart normally beats between 60 and 80 beats per minute, but when atrial fibrillation occurs, the atria may beat irregularly and very rapidly between 350 and 600 times per minute. This causes the ventricles to beat irregularly in response as they try to keep up with the atria. Atrial flutter is similar to atrial fibrillation. The atrial contractions are less rapid, however, usually between 200 to 400 beats per minute, and are regular. Atrial flutter is often associated with a heart attack or may occur after heart or lung surgery. Atrial fibrillation often results from a myriad of heart conditions such as angina, tachycardia, heart attack, heart valve problems, and even high blood pressure. All of these conditions can cause stretching and scarring of the atria that interfere with the heart conduction system. The heart muscle can be weakened if episodes lasting several months or longer (with rapid heart rates) occur. Briefer episodes only cause problems if the heart rate is very fast or if the patient has a serious heart problem in addition to the atrial fibrillation.

FIG. 2 depicts flexible basket assembly 20, including flexible guide members 22 constricted by catheter 16 prior to deployment from the distal end of catheter 16. Energy emitter 26 is located within a flexible guide member lumen 30. Flexible guide members 22 are slidably extended from catheter 16 into a tissue area of interest. Subsequently, energy emitter 26 can be slidably positioned within any one of flexible
guide members as shown in FIG 3. FIG. 3 depicts flexible basket assembly, including flexible guide members 22 extended from the distal end of catheter 16 with energy emitter 26 positioned in an extended flexible guide member 22.

FIG. 4 and FIG. 5 demonstrate that flexible guide members 22 can be deformed independently upon extension from catheter 16 to conform to the tissue environment surrounding assembly 20 in x, y and z coordinates. For example, FIG. 4 shows that individual flexible guide members 22 of mapping assembly 20 can all be attenuated to the same degree, thereby placing flexible basket assembly 20 in a spherical like three-dimensional array for mapping. FIG. 4 further includes, optional shape controller 32 attached to optional end cap 24. FIG. 5 shows that at least one flexible guide member 22 can be independently elongated relative to remaining flexible guide members, thereby demonstrating that flexible basket assembly 20 can be fitted to unique physical constraints presented by a patient. Optional shape controller 32, attached to optional end cap 24, can be used to further attenuate the degree of flexure and positioning of flexible guide members 22.

FIG. 6 and FIG. 7 depict an enlarged view of energy emitter 26, reflectance fiber 36 and reflective material 38 located within lumen 30 of a flexible guide member 22. Energy emitter 26 is slidably positioned within lumen 30 of a flexible guide member 22 proximate to a target tissue. Emission of energy through flexible guide member 22 from energy emitter 26 into the target tissue is accomplished with minimal, if any, harm to surrounding tissues. Preferably, energy emitter 26 is equipped with a diffusive tip assembly as described above. In one embodiment, reflective material 38 encircles approximately one half of the energy emitter and diffusive tip to reflect and concentrate the energy toward the treatment site. Typically the reflective material is configured into a 180 degree tube which can be slidably positioned with the energy emitter 26 or fixedly attached to flexible guide member 22. Reflectance fiber 36, described infra, is used to monitor the degree of treatment by the methods described herein.

The term “reflective material” is intended to encompass those materials which reflect energy, such as light, e.g., laser, ultraviolet, visible, or infrared light. Suitable
materials are known in the art and include metal foils useful in the art, preferably gold. Typically the reflective material has a thickness between about 0.05 mm and about 0.1 mm, inclusive.

FIG. 8 and FIG. 9 depict an enlarged view of another embodiment of the present invention where energy emitter 26, reflectance fiber 36 and reflective material 38 are slidably retained within the track or guide of U-shaped flexible guide member 22. Energy emitter 26 is slidably positioned within the tracking lumen 30 of U-shaped flexible guide member 22 proximate to a target tissue. As depicted in FIG. 9, a portion of flexible guide member 22 is removed, however, still retains energy emitter 26 within flexible guide member lumen 30. Emission of energy through flexible guide member 22 from energy emitter 26 into the target tissue is accomplished with minimal, if any, harm to surrounding tissues. Preferably, energy emitter 26 is equipped with a diffusive tip assembly as described above. In one embodiment, reflective material 38 encircles approximately one half of the energy emitter and diffusive tip to reflect and concentrate the energy toward the treatment site. Typically the reflective material is configured into a 180 degree tube which can be slidably positioned with the energy emitter 26 or fixedly attached to flexible guide member 22.

FIG. 10 depicts flexible assembly 34, including a flexible guide member 22 and optional shape controller 32. Energy emitter 26 is located within flexible guide member lumen 30 of flexible guide member 22. Flexible guide member 22 is slidably extended from catheter 16 into a tissue area of interest. Subsequently, energy emitter 26 can be slidably positioned within extended flexible guide member 22.

In the present invention, reflective feedback is used to monitor the state of coagulation, ablation and/or phototherapeutic processes of the treatment site so as to allow an optimal dose by either manipulation of the energy level or exposure time, or by controlling the sweep of energy across an exposure path.

Reflectance changes can also be employed by a control means in the present invention to adjust or terminate laser operation.

In another aspect of the invention, a real-time display means can be incorporated into a surgical microscope or goggles worn by a clinician during the procedure to provide
a visual display of the state of tissue coagulation simultaneously with the viewing of the surgical site. The display can reveal reflectance values at one or more specific wavelengths (preferably, chosen for their sensitivity to the onset and optimal state of tissue modification), as well as display a warning of the onset of tissue carbonization.

In one method, according to the invention, application of laser to a biological structure(s) while the reflectance of light from the irradiated site is monitored. Changes in scattering due to coagulation, ablation, phototherapeutic effects or crosslinking of the tissue will cause a reflectance change. In addition, dehydration due to laser exposure also affects the site's reflection. The reflectance can be monitored in real-time to determine the optimal exposure duration or aid as visual feedback in the timing used in sweeping the energy across the treatment site during the procedure.

In FIG. 11, a schematic block diagram of a laser tissue treatment system 40 is shown, including a laser 42, power supply 44, controller 46 and reflectance monitor 48. The system further includes flexible basket assembly 20, and, optionally, illumination source 50, display 52 and/or tuner 54. In use, the output of laser 42 is delivered, preferably via flexible basket assembly 20 (e.g., through flexible member(s) 22 via energy emitter 26), to treatment site 56 to phototherapeutically treat selected tissue. As the laser beam irradiates treatment 56 the biological tissue of the site is coagulated, ablated and/or phototherapeutically treated. The degree of treatment is determined by the reflectance monitor 48, which provides electrical signals to controller 46 in order to control the procedure. The reflectance monitor 48 receives light reflected by the site from a broadband or white light illumination source 50 via fiber 51 and/or from laser 42. In addition to controlling the laser operation automatically, the reflectance monitor 48 and/or controller 46 can also provide signals to a display 52 to provide visual and/or audio feedback to the clinical user. Optional, tuner 54 can also be employed by the user (or automatically controlled by controller 46) to adjust the wavelength of the annealing radiation beam.

FIG. 12 is a more detailed schematic diagram of a reflectance monitor 48, including a coupling port 58 for coupling with one or more fibers 60 to receive reflectance signals. A preferred reflectance fiber is a 100 micron diameter silica pyrocoat
fiber from Spectran (Spectran, Connecticut, part number CF04406-11). The reflectance monitor 48 can further include a focusing lens 62 and first and second beam splitting elements 64 and 66, which serve to divide the reflected light into 3 (or more) different beams for processing. As shown in FIG. 12, a first beam is transmitted to a first optical filter 68 to detector 70 (providing, for example, measurement of reflected light at wavelengths shorter than 0.7 micrometers). A second portion of the reflected light signal is transmitted by beam splitter 66 through a second optical filter 72 to detector 74 (e.g., providing measurement of light at wavelengths shorter than 1.1 micrometers). Finally, a third portion of the reflected light is transmitted to photodetector 76 (e.g., for measurement of reflected light at wavelengths greater than 1.6 micrometers). Each of the detector elements 70, 74 and 76 generate electrical signals in response to the intensity of light at particular wavelengths.

The detector elements 70, 74 and 76 preferably include synchronous demodulation circuitry and are used in conjunction with a modulated illumination source to suppress any artifacts caused by stray light or the ambient environment. (It should be apparent that other optical arrangements can be employed to obtain multiple wavelength analysis, including the use, for example, of dichroic elements, either as beam splitters or in conjunction with such beam splitters, to effectively pass particular wavelengths to specific detector elements. It should also be apparent that more than three discreet wavelengths can be measured, depending upon the particular application.) The signals from the detector elements can then be transmitted to a controller and/or a display element (as shown in FIG. 11).

In the controller, signals from the reflectance monitor are analyzed to determine the degree of coagulation, ablation and/or phototherapeutic effect(s) which is occurring in the biological tissue exposed to the laser radiation. Typically, such treatment is performed for 100 seconds or less. Such analysis can generate control signals which will progressively reduce the laser output energy over time as a particular site experiences cumulative exposure. The control signals can further provide for an automatic shut-off of the laser when the optimal state of treatment has been exceeded and/or the onset of carbonization is occurring.
In use, the apparatus of the present invention can be employed to analyze the degree of treatment by comparing the reflectance ratios of a site at two or more wavelengths. Preferably, intensity readings for three or more wavelength ranges are employed in order to accurately assess the degree of treatment and to ensure that the optimal state is not exceeded. The particular wavelengths to be monitored will, of course, vary with the particular tissue undergoing treatment. Although the tissue type (e.g., blood-containing tissue or that which is relatively blood-free) will vary, the general principles of the invention, as disclosed herein, can be readily applied by those skilled in the art to diverse procedures in which the phototherapeutic treatment of biological materials is desired.

One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:
1. An apparatus for treating tissue \textit{in vivo}, comprising:
   a tubular catheter having a proximal end, a distal end and a lumen therebetween;
   at least one flexible guide member having a proximal end, a distal end and a lumen therebetween, wherein said flexible guide member can be flexed when a force is applied to said proximal end of said flexible guide member; and
   an energy emitter for transmitting energy, slidably coupled to said flexible guide member, said emitter having a proximal end and a distal end.

2. The apparatus of claim 1, further comprising a shape controller attached to a distal portion of said flexible guide member.

3. The apparatus of claim 1, wherein said flexible guide member comprises a fluoropolymer.

4. The apparatus of claim 3, wherein said fluoropolymer is ethylene-tetrafluoroethylene, tetrafluoroethylene, or a perfluoroalkoxy resin.

5. The apparatus of claim 1, further comprising an energy source in communication with said proximal end of said energy emitter effective to transmit energy through said energy emitter.

6. The apparatus of claim 5, wherein said energy source is a laser.

7. An apparatus for treating tissue \textit{in vivo}, comprising:
   a tubular catheter having a proximal end, a distal end and a lumen therebetween;
   a plurality of independent transparent flexible guide members which, upon extension from said catheter, bow outwardly to form a three-dimensional array, each member having a distal end and proximal end, wherein each of said flexible guide members can be independently flexed when a force is applied to said proximal end of one or more flexible guide members; and
an emitter for transmitting energy, slidably positioned within one or more of said flexible guide members, said emitter having a proximal end and a distal end.

8. The apparatus of claim 7 further comprising a distal end fitting connecting said distal ends of said flexible guide members together.

9. The apparatus of claim 7, wherein each flexible guide member is tubular, having a distal end, a proximal end and a lumen therebetween.

10. The apparatus of claim 9, wherein said flexible guide member comprises a fluoropolymer.

11. The apparatus of claim 10, wherein said fluoropolymer is ethylene-tetrafluoroethylene, tetrafluoroethylene, or a perfluoroalkoxy resin.

12. The apparatus of claim 7, wherein each flexible guide member is tracking member.

13. The apparatus of claim 12, wherein said tracking member comprises a fluoropolymer.

14. The apparatus of claim 13, wherein said fluoropolymer is ethylene-tetrafluoroethylene, tetrafluoroethylene, or a perfluoroalkoxy resin.

15. The catheter of claim 7, further comprising an energy source in communication with said proximal end of said emitter effective to transmit energy through said emitter.

16. The catheter of claim 15, wherein said energy source is a laser.

17. The catheter of claim 15, wherein said energy source is ultrasound.
18. The catheter of claim 7, further comprising a control handle connected to said proximal ends of said flexible guide members and said catheter.

19. The catheter of claim 18, wherein said control handle applies a proximally directed force to at least one of said flexible guide members.

20. The catheter of claim 18, wherein said control handle applies a distally directed force to at least one of said flexible guide members.

21. A method for phototherapeutically treating tissue within an organ using a catheter, said catheter comprising a tubular catheter having a proximal end, a distal end and a lumen therebetween, a plurality of independently positionable transparent flexible guide members, each member having a distal end and proximal end, and an energy emitter, comprising the steps of

22. The method of claim 21, wherein at least one of said flexible guide members is flexed.

23. The method of claim 21, wherein said energy emitter is positioned within a plurality of said flexible guide members, thereby ablating a plurality of tissue sites.

24. A method for phototherapeutically treating tissue within a heart using a catheter, said catheter comprising a tubular catheter having a proximal end, a distal end and a lumen therebetween, a plurality of independently positionable transparent flexible
guide members each member having a distal end and proximal end and an energy emitter, comprising the steps of

a) introducing said catheter into a chamber of a heart;

b) independently positioning at least one of said flexible guide members to contact a heart wall;

c) positioning said energy emitter within a flexible guide member so that said energy emitter is proximate to a treatment site; and

d) treating said treatment site with energy emitted from said energy emitter.

25. The method of claim 24, wherein at least one of said flexible guide members is flexed.

26. The method of claim 24, wherein said energy emitter is positioned within a plurality of said flexible guide members, thereby ablating a plurality of tissue sites.

27. A method for treating trabecular tissue using a catheter, said catheter comprising a tubular catheter having a proximal end, a distal end and a lumen therebetween, a plurality of independently positionable transparent flexible guide members each member having a distal end and proximal end and an energy emitter, comprising the steps of

a) introducing said catheter proximate to trabecular tissue;

b) independently positioning at least one of said flexible guide members to contact said trabecular tissue;

c) positioning said energy emitter within a flexible guide member so that said energy emitter is proximate to a trabecular treatment site; and

d) treating said trabecular treatment site with energy emitted from said energy emitter.

28. The method of claim 27, wherein at least one of said flexible guide
members is flexed relative to said other flexible guide members.

29. A method for treating or preventing atrial fibrillation by phototherapeutic treatment using a catheter, said catheter comprising a tubular catheter having a proximal end, a distal end and a lumen therebetween, a plurality of independently positionable transparent flexible guide members each member having a distal end and proximal end and an energy emitter, comprising the steps of

a) introducing said catheter into a chamber of a heart;

b) independently positioning at least one of said flexible guide members to contact a portion of heart wall;

c) positioning said energy emitter within a flexible guide member so that said energy emitter is proximate to a treatment site; and

d) treating said treatment site with energy emitted from said energy emitter, such that said atrial target tissue is modified without damaging surrounding tissue, thereby treating or preventing atrial fibrillation.

30. The method of claim 20, wherein at least one of said flexible guide members is flexed.

31. An apparatus for treating tissue in vivo, comprising:

a tubular catheter having a proximal end, a distal end and a lumen therebetween;

at least one flexible guide member having a proximal end, a distal end and a lumen therebetween, wherein said flexible guide member can be flexed when a force is applied to said proximal end of said flexible guide member;

an energy emitter for transmitting energy, slidably coupled to said flexible guide member, said emitter having a proximal end and a distal end;

an energy source in communication with said proximal end of said emitter effective to transmit laser energy through said conductor;

a reflectance sensor for measuring intensity of light reflected from said tissue
while illuminating said tissue;

a monitor connected to said reflectance sensor for monitoring changes in the intensity of light reflected from said tissue;

an analyzer connected to said monitor for determining the degree of therapeutic treatment based upon said monitored changes in said tissue; and

a controller connected to said analyzer and laser for controlling the output of said laser in response to said reflected light from said treated tissue.

32. A method for treating or preventing atrial fibrillation by phototherapeutic treatment using a catheter, said catheter comprising a tubular catheter having a proximal end, a distal end and a lumen therebetween, a plurality of independently positionable transparent flexible guide members each member having a distal end and proximal end and an energy emitter, comprising the steps of

a) introducing said catheter into a chamber of a heart;

b) independently positioning at least one of said flexible guide members to contact a portion of wall;

c) positioning said energy emitter within a flexible guide member so that said energy emitter is proximate to a treatment site;

d) transmitting laser energy to said distal end of said elongate member through said emitter;

e) measuring the intensity of light reflected from said target tissue; and

f) controlling the energy applied to said site in response to monitored changes in the intensity of said light reflected from said target tissue, thereby treating or preventing atrial fibrillation.