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(54) **FIBER OPTIC ENDOSCOPIC GASTROINTESTINAL PROBE**

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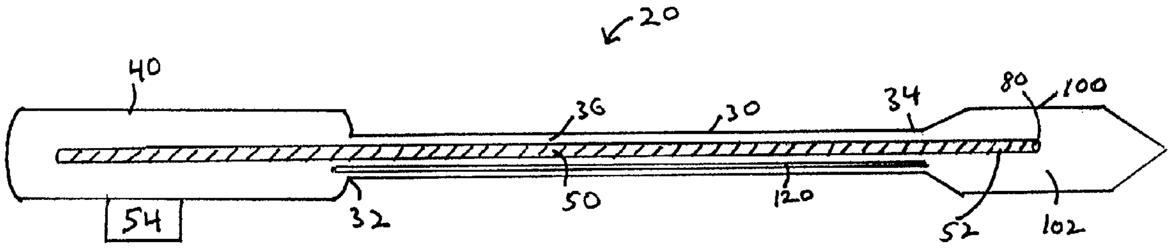
(57) **ABSTRACT**

A fiber optic probe and a balloon catheter used in conjunction with optical imaging systems, in particular with systems which deliver and collect a single spatial mode beam, such as a single photon, a multiphoton, confocal imaging and ranging systems, such as fluorescence imaging systems.



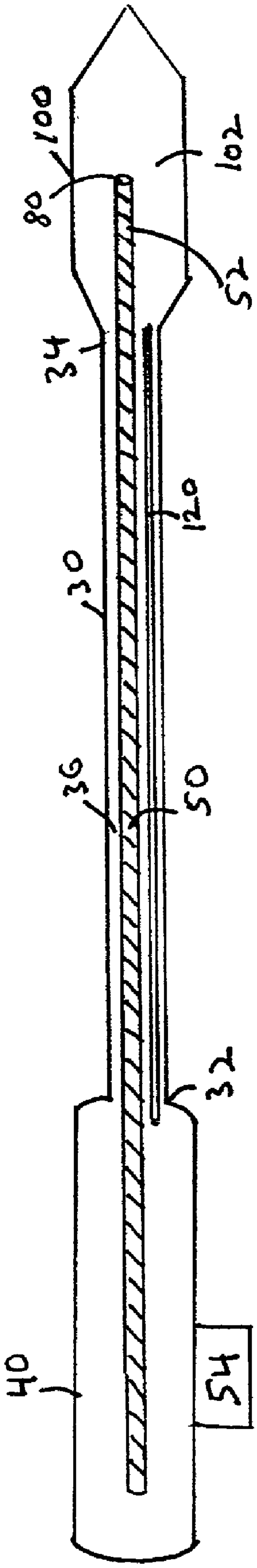


FIG. 1

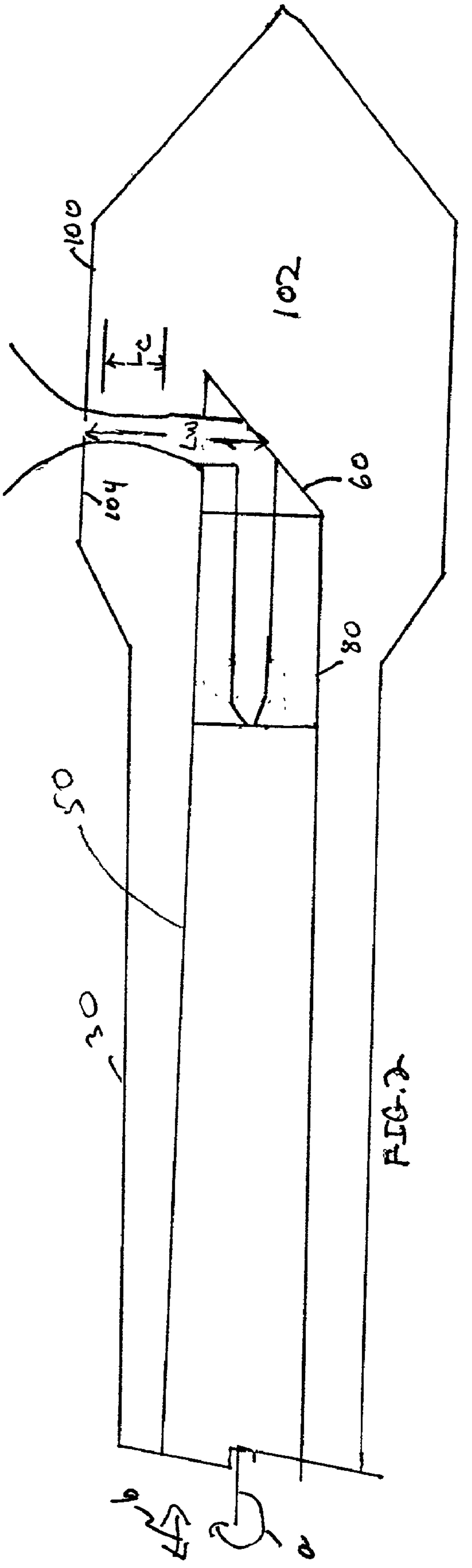


FIG. 2

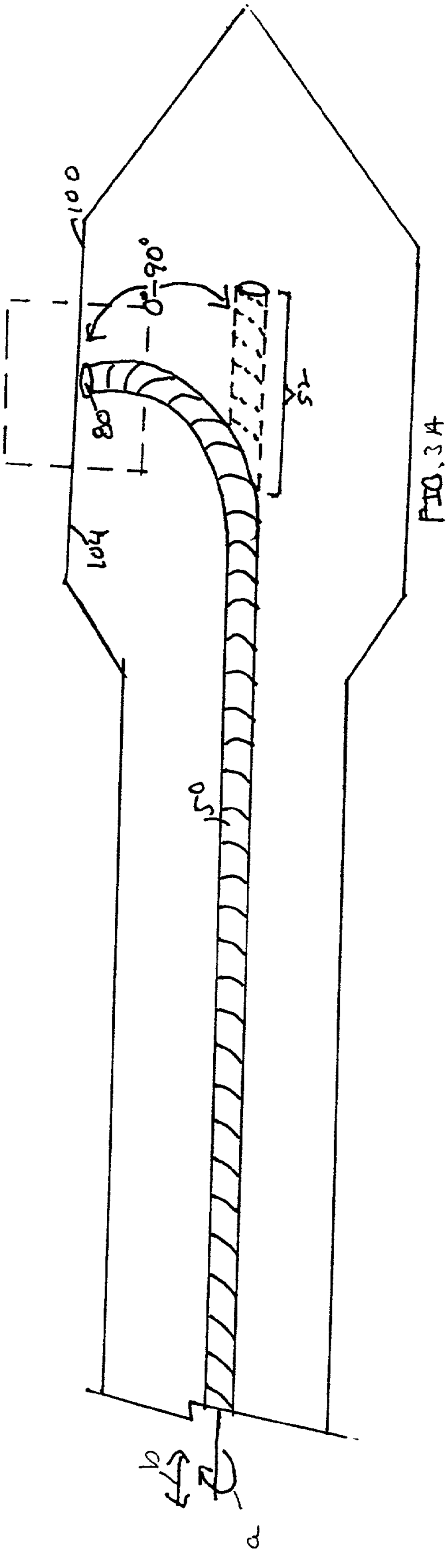


FIG. 3A

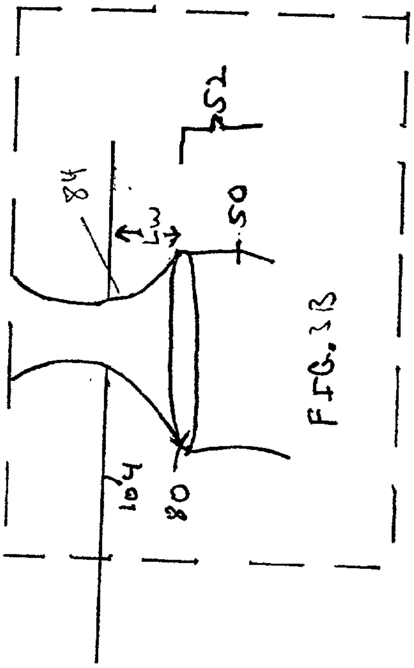


FIG. 3B

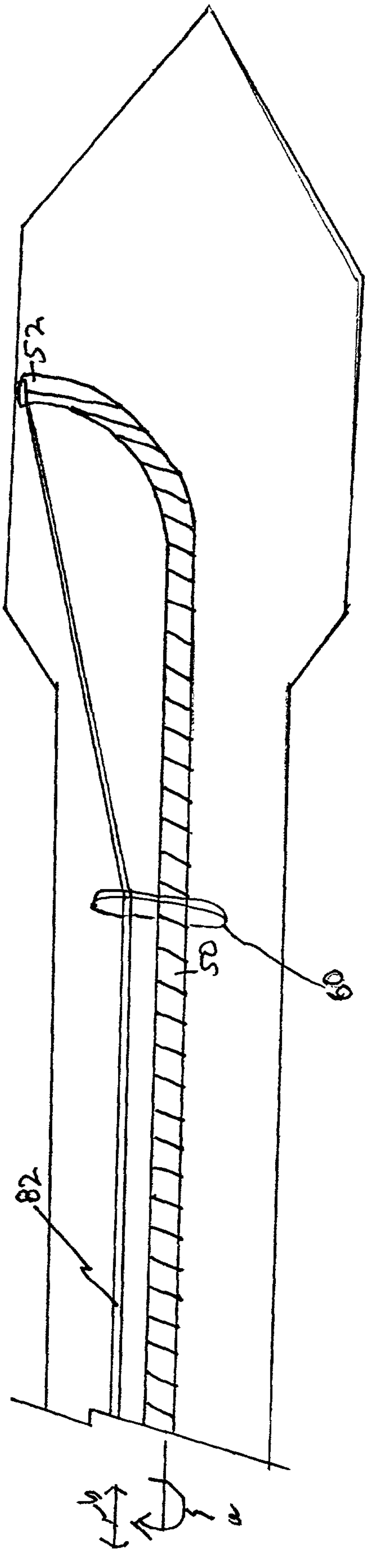


FIG. 4

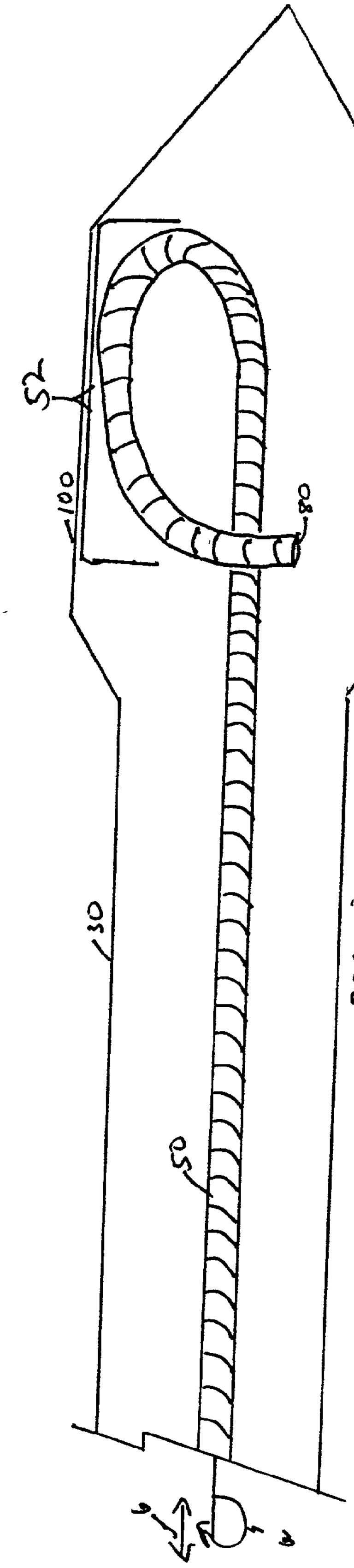


FIG. 5B

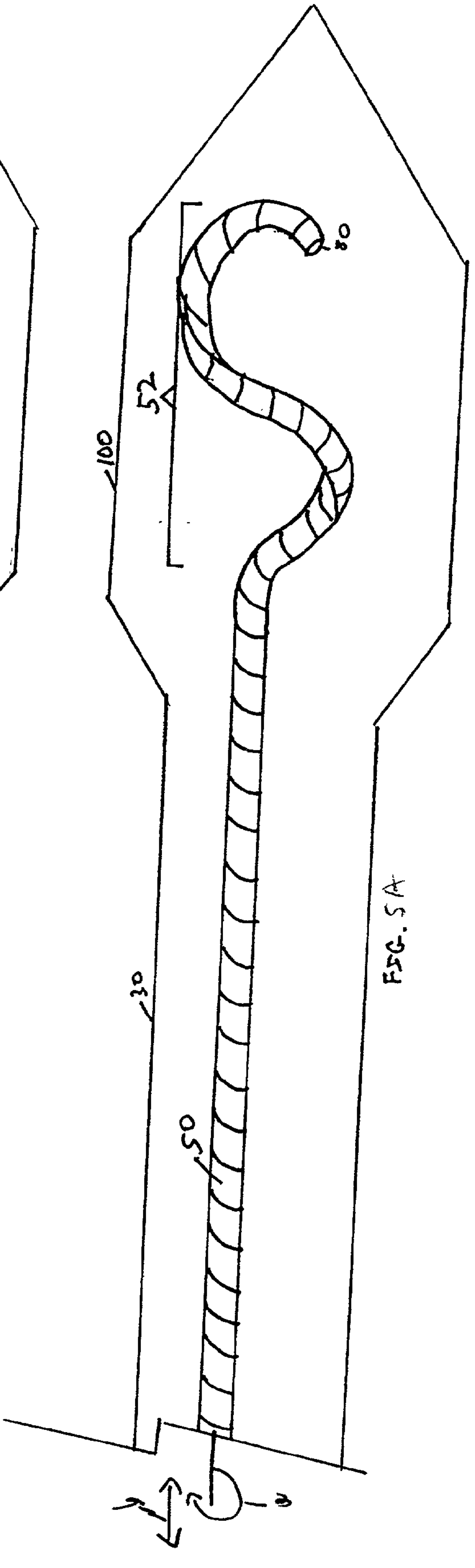


FIG. 5A

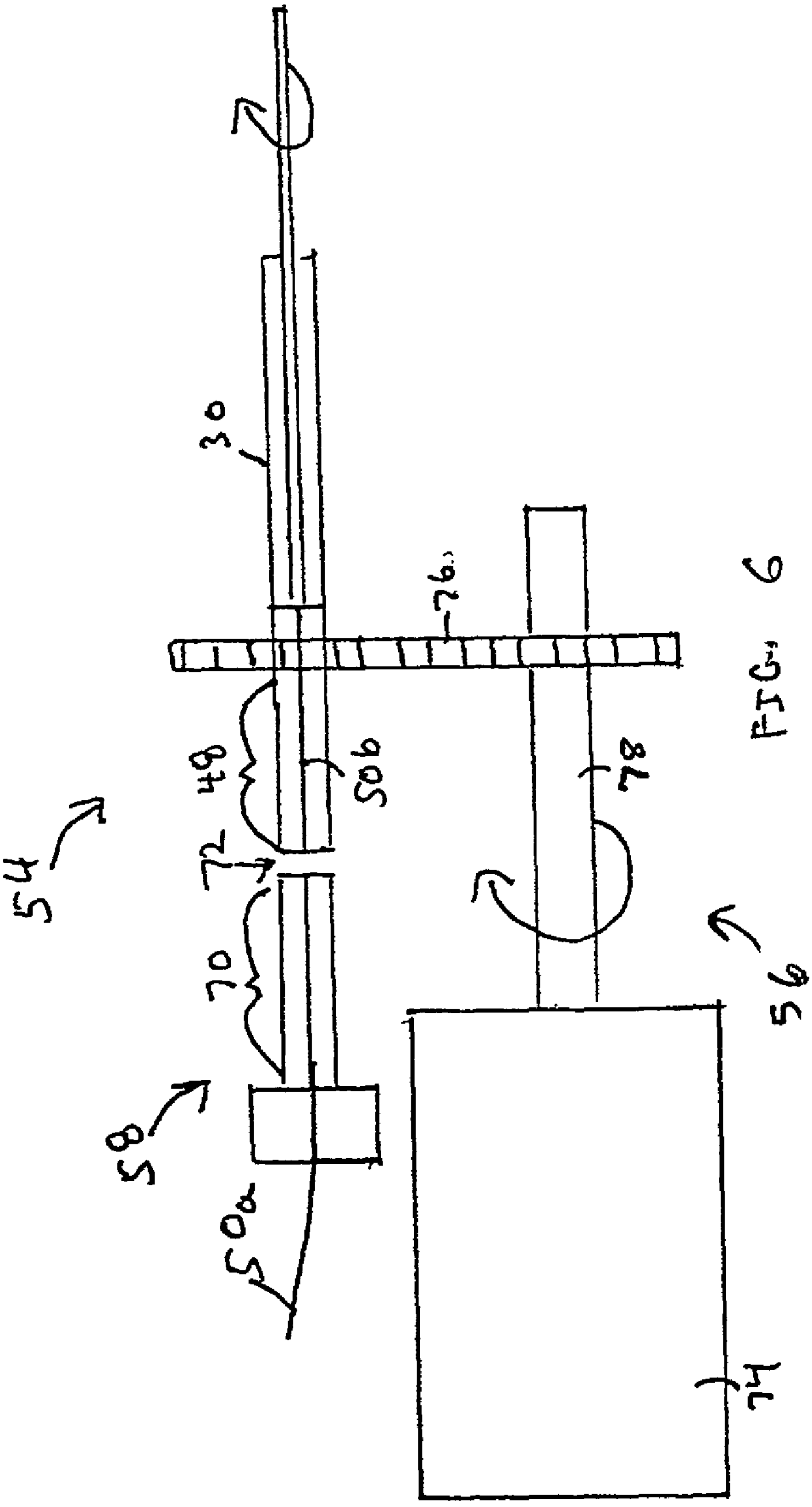


FIG. 6

FIBER OPTIC ENDOSCOPIC GASTROINTESTINAL PROBE

FIELD OF THE INVENTION

[**0001**] This invention relates to the field of optical imaging and more specifically to the field of endoscopic medical imaging of the gastrointestinal system.

BACKGROUND OF THE INVENTION

[**0002**] Optical imaging systems such as optical coherence tomography (OCT) systems generate images or measurements by measuring the intensity of light backscattered or backreflected from a specimen and providing a gray scale or false color two-dimensional representation of this light intensity in a plane or cross-section through the object image being measured. OCT enables the non-excisional, in situ, real-time imaging of microstructure of a specimen with a resolution of approximately 2-20 microns.

[**0003**] An OCT system can be separated into an imaging engine and probes. The imaging engine contains the optical light source, optical interferometer and other optical detection elements, as well as electronics, motor, control(s), and computers for image generation and display. The probes are modules which are attached to the engine and direct light to and from the specimen that is to be measured or imaged.

[**0004**] In spite of advances in probe construction and in related delivery and scanning techniques, existing probes are not suitable for examination of tissues within lumens with a wide range of diameters. Some regions of the gastrointestinal system, such as the esophagus and duodenum, may have a diameter of 18 mm or more. Although the diameters of these structures are relatively large, the probes that fit within existing endoscopes and catheters used to examine them, are comparatively small in diameter to fit within endoscopic channels. The present invention aims to overcome these limitations.

SUMMARY OF THE INVENTION

[**0005**] In an aspect of the invention, a balloon catheter includes an inflatable balloon having an inner surface and a longitudinal axis, a catheter with a bore, and an optical fiber. The catheter is in communication with the balloon. The optical fiber is extendable and retractable in the bore of the catheter.

[**0006**] The optical fiber, according to one embodiment of the invention, has a longitudinal axis and a distal end. In one embodiment, a feature of the optical fiber includes a flexible distal end. The distal end of the optical fiber may be pre-bent into an "s" shape or spiral shape. Alternatively, a pull wire may be attached to the distal end of the optical fiber for pulling the distal end of the optical fiber so that the distal end is substantially perpendicular to the inner surface of the balloon. In a particular embodiment, the distal end of the optical fiber is substantially adjacent to an inner surface of the balloon when inflated. For example, the distance between the distal end of the optical fiber and the inner surface of the inflated balloon can be in the range of 0.01 mm to 15 mm, and preferably 1.0 mm-5.0 mm. In an embodiment of the invention, the optical fiber is rotatable, translational, or rotatable and translational, such that the distal end of the optical fiber describes a path of motion about the longitudinal axis substantially along the inner surface of the circumference of the balloon. Alternatively, the distal end of the optical fiber is moved translationally to describe a path of motion along the inner surface, substantially parallel to the longitudinal axis of the optical fiber.

[**0007**] In an embodiment of this aspect of the invention, the balloon of the balloon catheter has a radius between 2.5 mm-20 mm, preferably 9 mm when the balloon is inflated. The length of the catheter is 5 cm to 200 cm, and more preferably 10-110 cm. In a particular embodiment of the invention, a guidewire is joined to the distal end of the balloon catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[**0008**] **FIG. 1** illustrates a highly schematic plan view of one embodiment of an endoscopic balloon catheter device according to the invention.

[**0009**] **FIG. 2** illustrates an embodiment of the invention including a rotating optical beam director.

[**0010**] **FIG. 3A** illustrates an embodiment of the invention including a flexible optical fiber.

[**0011**] **FIG. 3B** illustrates an enlargement of the boxed area of **FIG. 3A**.

[**0012**] **FIG. 4** illustrates an embodiment of the invention including a pull wire.

[**0013**] **FIG. 5A** illustrates another embodiment of the invention.

[**0014**] **FIG. 5B** illustrates another embodiment of the invention.

[**0015**] **FIG. 6** illustrates an embodiment of the invention including a rotational scanning mechanism.

DETAILED DESCRIPTION OF THE INVENTION

[**0016**] As described below, a fiber optic endoscopic gastrointestinal probe according to the invention, can be used in conjunction with a number of different types of optical imaging systems, in particular with systems which deliver and collect a single spatial mode beam such as a single photon, a multiphoton, confocal imaging and ranging systems such as fluorescence imaging system. OCT is the preferred imaging technology to be used in the fiber optic endoscopic gastrointestinal probe described herein.

[**0017**] In the preferred embodiment of the invention, the fiber optic endoscopic gastrointestinal probe communicates with the imaging engine of an OCT device by means of a single mode optical fiber housed within the gastrointestinal probe. Used in conjunction with an OCT imaging system, the fiber optic endoscopic gastrointestinal probe of the invention enables the tomographic imaging of the microstructure of internal organs and tissues in a living subject.

[**0018**] Referring to **FIG. 1**, shown is an embodiment of a fiber optic endoscopic gastrointestinal probe **20** of the invention. In general, the probe includes a handle **40**, a catheter **30**, an optical fiber **50**, a scanning mechanism **54**, and a balloon **100**. The catheter **30**, optical fiber **50**, and balloon **100** are dimensioned for insertion into the body. For example, the fiber optic endoscopic gastrointestinal probe **20** is sized for insertion into the gastrointestinal tract, or a duct, such as the cystic duct of a patient. The fiber optic endoscopic gastrointestinal probe **20** of the invention ranges from about 5 cm to 200 cm in length, and more preferably about 10 cm to 110 cm.

[**0019**] With continued reference to **FIG. 1, a** long, small diameter optical fiber or fiber bundle **50** extends through bore **36** of the catheter **30**. The catheter **30** has a proximal end **32** closest to the operator, and a distal end **34** which is inserted into the body of a patient. The catheter **30** is made of material that is sufficiently flexible to permit an operator to maneuver the catheter **30** into a body tract, and sufficiently rigid to prevent the catheter **30** from collapsing as the catheter **30** is moved in the body tract.

[**0020**] Still referring to **FIG. 1**, disposed on the distal end **34** of the catheter **30** is an annular balloon **100**. A guidewire (not shown) may optionally be attached to the distal end of the catheter **30**. Balloon **100** is filled via port **120** which communicates with the lumen **102** of the balloon. The lumen **102** may be filled with air, water, deuterated water or other fluid or gaseous substance that is substantially transparent to the OCT probe illumination. The diameter of the balloon ranges from about 5 to 40 mm in the expanded state, preferably about 18 mm. The materials used to construct the balloon **100** are substantially transparent to the selected wavelengths of light used to image structures in the body surrounding the balloon **100**. For example, the balloon **100** may be constructed of nylon, PET (polyethylene terephthalate), PE (polyethylene), PEBAX™ (Atochem Corp.; France) (polyethylene block amide), other thermoplastics, and more.

[**0021**] Within the bore **36** of the catheter **30** resides the optical fiber **50**, which is, in one embodiment, a flexible single mode optical fiber or a single mode fiber optic bundle, either of which may be of the type known as "polarization maintaining," depending on the specific application. The use of a single mode optical fiber, for example, is preferable for applications of OCT imaging because it will propagate and collect a single transverse spatial mode optical beam which can be focused to its minimum spot size for a desired application, and single-mode wavefronts are well suited for OCT detection.

[**0022**] In one embodiment, the catheter **30** with optical fiber **50** may be translationally or rotationally moveable, or both, within the balloon **100**. In another embodiment, the catheter **30**, optical fiber **50**, and balloon **100** comprise a single, integrated unit, moveable as one. A transparent window or a lens **80** such as a grin lens or micro lens is positioned at the distal end **36** of optical fiber **50** to permit the focusing of light onto and receiving backscatter from the structures surrounding the balloon **100**.

[**0023**] In a particular embodiment of the invention, a beam director **60**, illustrated in **FIG. 2**, is positioned within the lumen **102** of the balloon **100** in close juxtaposition to the distal end of the optical fiber **50** to direct light from the optical fiber **50** to the structure being imaged. The optical beam director **60**, in one embodiment, may be translated longitudinally, rotated, or both. Alternatively, the optical beam directing system **60** is directly coupled to the distal end of a translationally moveable or rotatable single mode optical fiber and is positioned to transmit the optical radiation from the single mode optical fiber to the structure and to transmit reflected optical radiation from the structure to the single mode optical fiber. The optical fiber may be simultaneously translationally moveable and rotatable. In one embodiment, the beam director **60** directs light from the distal end **52** of the optical fiber **50** in a direction substantially perpendicular to the inner surface **104** of the balloon **100**. The beam director **60** may include a prism, a lens, a diffraction grating, or a turning mirror and may be driven from a motor external to the device **20** via a mechanical linkage or may be driven via a micromotor.

[**0024**] Referring still to **FIG. 2**, in this embodiment, the confocal length "Lc" of the lens **80** is about 0.5 to 4 cm, preferably about 1-3 cm. In a particular embodiment, the lens **80** is a grin lens coupled to a turning prism. Alternatively, the lens is a multi-mode fiber of a length determined by the application. Alternatively, a piece of cladless fiber angle polished and attached to the lens **80** may be used as a turning mirror.

[**0025**] Referring now to **FIG. 3A**, in another embodiment of the invention, the distal end **52** of optical fiber **50** can be flexed from 0° (shown in phantom in **FIG. 3A**) to any acute angle up to about 90° from the long axis of the catheter **30**. In the flexed position, the distal end **52** of optical fiber **50** is preferably oriented perpendicular to the long axis of the inner surface **104** of the balloon **100**. The lens **80** at the distal end of the optical fiber **50** is thereby located a distance "Lw" from the balloon wall for maximal performance based on the focal length "Lc" of the lens **80**, best illustrated in **FIG. 3B**. Because of the short working distance "Lw" between the lens **80** and the inner surface **104** of balloon **100**, the diameter of the lens **80** can be small. Furthermore, little loss of signal from the media filling the balloon **100** occurs since the beam **84** being so close to the balloon wall travels only a short distance through the media. Distance "Lw" ranges from about 0.01 mm to 15 mm, and preferably 1.0 mm to 5.0 mm.

[**0026**] The optical fiber **50** in one embodiment is rotatable such that the distal end **52** of the optical fiber **50** describes a path of motion indicated by arrow (a) substantially along the inner surface **104** of the inflated balloon **100**. In another embodiment, the optical fiber **50** is translationally moveable such that the distal end **52** of the optical fiber describes a path of motion indicated by arrow (b) substantially parallel to the long axis along the inner surface **104** of the balloon **100**. In yet another embodiment, optical fiber **50** is both rotationally and translationally moveable.

[**0027**] An embodiment of the invention can also feature a pull wire **82**, illustrated in **FIG. 4**. Pull wire **82**, such as a nitinol wire, is joined at one end to the distal end **52** of the optical fiber **50**, passes through ring structure **60**, and extends to the proximal end of the device. An operator, by pulling on pull wire **82**, causes the distal end **52** of the optical fiber **50** to bend 0°-90° from the long axis of the catheter.

[**0028**] In yet another embodiment according to the invention, the distal end **52** of optical fiber **50** is "s" shaped, or spiral shaped, illustrated in **FIG. 5A**, or may turn 360° on itself, as illustrated in **FIG. 5B**. Alternatively, a turning mirror (not shown) is placed adjacent the lens. In this embodiment, the fiber could be bent less than 90°. In all of these embodiments, imaging occurs as the optical fiber **50** is rotated along its long axis or moved translationally within the bore **36** of the catheter **30**.

[**0029**] In a particular embodiment, the optical fiber **50** is rotatable. Referring to **FIG. 6**, one embodiment of a rotational scanning mechanism **54** typically includes a rotation mechanism **56** and an optical coupling system **58**. The optical fiber bundle **50** terminates within the coupling system **58**. The coupling system **58** includes a coupling member **70** which is spaced by an interface **72** from an optical connector **48**. The interface **72** is used to terminate optical radiation from the input optical fiber **50**a to the optical fiber extending within catheter **30**. The coupling member **70** can be physically coupled to the optical connector **48** or, as shown, can be separated by an air or a fluid medium formed in the interface **72**. In the event that the coupling member **70** is physically coupled to the optical connector **48**, the coupling member **70** can be removed from the optical connector **48**, thereby enabling the catheter **30** to be replaced with each patient.

[**0030**] The optical connector **48** functions as the drive shaft for the optical fiber **50** as the rotation mechanism is coupled thereto. The rotation mechanism includes a DC or AC drive motor **74** and a gear mechanism **76** having predetermined gear ratios. The gear mechanism **76** is coupled to the motor **74** via a shaft **78**. Upon activation of the drive motor **74**, the shaft **78** rotates causing gear mechanism **76** and rotatable optical fiber **50** to rotate. Alternatively, the DC motor can be a micromotor (not shown) causing rotation of optical fiber **50**.

[**0031**] While the present invention has been described in terms of certain exemplary preferred embodiments, it will be readily understood and appreciated by one of ordinary skill in the art that it is not so limited and that many additions, deletions and modifications to the preferred embodiments may be made within the scope of the invention as hereinafter claimed. Accordingly, the scope of the invention is limited only by the scope of the appended claims.

What is claimed is:

1. A balloon catheter comprising:

an inflatable balloon having a lumen, an inner surface, and a longitudinal axis;

a catheter having a bore in communication with said lumen of said balloon; and

an optical fiber having a longitudinal axis and a distal end, said distal end of said optical fiber positioned within and substantially adjacent to said inner surface of said balloon when inflated.

2. The balloon catheter of claim 1 wherein said optical fiber is rotatable such that said distal end of said optical fiber describes a path of motion about said longitudinal axis of said optical fiber substantially along the inner surface of a circumference of said balloon.

3. The balloon catheter of claim 2 wherein said optical fiber is translationally moveable.

4. The balloon catheter of claim 1 wherein said optical fiber is translationally moveable such that said distal end of said fiber describes a path of motion substantially parallel to said longitudinal axis of said optical fiber.

5. The balloon catheter of claim 1 wherein said distal end of said optical fiber is oriented substantially perpendicular to said inner surface of said inflated balloon.

6. The balloon catheter of claim 1 further comprising a grin lens.

7. The balloon catheter of claim 1 wherein said distal end of said optical fiber is about 1.0 to 5.0 mm from the inner surface of said balloon when inflated.

8. The balloon catheter of claim 1 further comprising a beam director.

9. The balloon catheter of claim 1 wherein said distal end of said optical fiber is flexible.

10. The balloon catheter of claim 9 further comprising a guidewire wherein said guidewire is operably joined to said distal end of said optical fiber.

11. A balloon catheter comprising:

an inflatable balloon having an inner surface;

a catheter having a long axis and a bore, said bore in communication with said balloon; and

an optical fiber having a distal end, said distal end positioned substantially adjacent to said inner surface of said balloon, said distal end oriented substantially at an acute angle as measured from said long axis of said catheter to said inner surface of said balloon.

12. The balloon catheter of claim 11 wherein said optical fiber is rotatable such that said distal end of said optical fiber describes a path of motion about said long axis of said catheter substantially along said inner surface of said balloon.

13. The balloon catheter of claim 11 wherein said optical fiber further comprises a moveable beam director coupled to said distal end of said optical fiber, said moveable beam director directing light emitted from said distal end of said optical fiber in a direction substantially perpendicular to said inner surface of said balloon.

14. The balloon catheter of claim 11 wherein said optical fiber is translationally moveable such that said distal end of said optical fiber describes a path of motion substantially parallel to said long axis of said catheter.

15. The balloon catheter of claim 11 wherein the balloon has a radius between 2.5 mm and 20 mm when inflated.

16. The balloon catheter of claim 11 wherein said balloon when uninflated and said optical fiber are dimensioned to fit within said catheter.

17. The balloon catheter of claim 11 wherein said distal end of said optical fiber is 1.0 ; to 5.0 mm from the inner surface of said balloon when inflated.

18. The balloon catheter of claim 11 wherein said distal end of said optical fiber is flexible.

19. The balloon catheter of claim 18 further comprising a guidewire wherein said guidewire is operably joined to said distal end of said optical fiber.

20. A balloon catheter comprising:

an inflatable balloon having an inner surface, a lumen, and a radius between about 2.5 mm and 20 mm when inflated;

a catheter having a bore in communication with said lumen of said balloon;

an optical fiber having a distal end positioned within about 1.0 mm to 5.0 mm from said inner surface of said balloon when inflated, said optical fiber being rotatably and translationally moveable relative to said catheter;

a grin lens; and

a beam director,

wherein said optical fiber, when moved translationally and rotationally, focuses light onto and receives backscatter from structures substantially adjacent to the exterior of said balloon.

* * * * *