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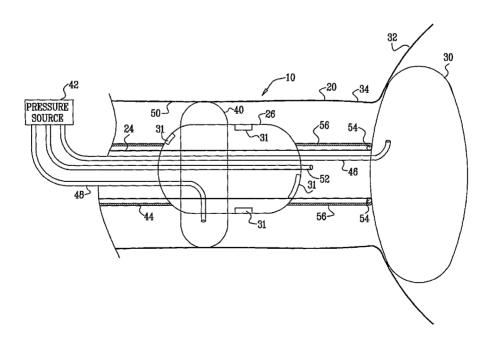
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(54) Title: TOOLS FOR USE IN ESOPHAGUS



(57) Abstract: Apparatus (10) is provided, including an elongate carrier (24), configured to be advanced through an esophagus (20) of a subject. An anchor member (30) is coupled to a distal end of the carrier, and configured to be mounted in a stomach (32) of the subject in a vicinity of a lower esophageal sphincter (LES) (34) of the subject. An imaging capsule (26) is configured to move with respect to the carrier when the anchor member is in the vicinity of the LES. Other embodiments are also described.



TOOLS FOR USE IN ESOPHAGUS

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application claims the benefit of US Provisional Patent Application 60/704,656 to Goldwasser et al., filed August 1, 2005, which is assigned to the assignee of the present patent application and is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to a 10 pressure-propelled system, suitable for imaging body lumens, such as the esophagus.

BACKGROUND OF THE INVENTION

Many imaging devices are known for producing medical images of body lumens, such as the gastrointestinal (GI) tract. For example, endoscopy is widely used for observing, photographing tissue, and taking specimens from lesions and the like.

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US Patent Application Publication 2005/0154355 to Gross et al., which is assigned to the assignee of the present application and is incorporated herein by reference, describes apparatus for use with a fluid pressure source. The apparatus includes an elongate carrier, adapted to be inserted through a proximal opening of a body lumen, and a distal piston head coupled to a distal portion of the carrier. The piston head is adapted to be in direct contact with a wall of the lumen when the carrier is inserted into the lumen, and to be advanced distally through the body lumen in response to pressure from the fluid pressure source.

The following references, which are incorporated herein by reference, may be of interest:

US Patent Application Publication 2004/0102681 to Gross

- US Patent Application Publication 2005/0036059 to Goldwasser
- 5 US Patent Application Publications 2005/0038318 and 2005/0038319 to Goldwasser
 - US Patent Application Publication 2005/0038335 to Gross et al.
- US Patent Application Publication 2005/0154278 to 10 Cabiri et al.
 - PCT Publication WO 05/065044 to Cabiri et al.
 - US Patent 5,984,860 to Shan
 - US Patent 6,866,626 to Long et al.
 - US Patent 5,571,114 to Devanaboyina
- US Patent 6,682,479 to Takahashi et al.
 - US Patent Application Publication 2004/0260150 to Bernstein
 - US Patent 6,709,388 to Mosse et al.
- US Patent Application Publication 2005/0095200 to 20 Schwarzberg
 - US Patent Application Publication 2005/0038317 to Ratnakar
 - US Patent 6,869,393 to Butler
 - US Patent 5,941,815 to Chang
- US Patent 5,879,325 to Lindstrom et al.
 - US Patent 5,337,732 to Grundfest et al.
 - US Patent Application Publication 2003/0168068 to Poole and Young

US Patent Application Publication 2003/0105386 and US Patent 6,485,409 to Voloshin et al.

US Patent Application Publication 2002/0107478 to Wendlandt

- 5 US Patent 6,702,735 to Kelly
 - US Patent 5,259,364 to Bob, et al.
 - US Patent 4,403,985 to Boretos
 - US Patent 4,176,662 to Frazer
 - US Patent 4,148,307 to Utsugi
- 10 US Patent 5,906,591 to Dario et al.
 - US Patent 6,007,482 to Madni et al.
 - US Patent 5,662,587 to Grundfest et al.
 - US Patent 4,690,131 to Lyddy, Jr. et al.
 - US Patent 4,040,413 to Ohshiro
- 15 US Patent 6,503,192 to Ouchi
 - US Patent 6,814,728 to Ouchi
 - US Patent 6,911,005 to Ouchi et al.
 - US Patent Application Publication 2003/0083547 to Hamilton et al.
- 20 PCT Publication WO 04/069057 to Gobel
 - US Patent Application Publication 2003/0000526 to Gobel
 - PCT Publication WO 03/045487 to Gobel
 - US Patent 4,561,427 to Takada
- 25 US Patent 6,071,234 to Takada
 - US Patent 6,332,865 to Borody et al.

SUMMARY OF THE INVENTION

In some embodiments of the present invention, an imaging system is provided for examining an esophagus of a subject. The system comprises an elongate carrier coupled at a distal end thereof to an inflatable anchoring member. The anchoring member is inserted via the esophagus to a site in the stomach in a vicinity of a lower esophageal sphincter (LES), and inflated so as to anchor the distal end of the carrier. The system further comprises an imaging capsule configured to travel along the carrier distally and proximally in the esophagus (i.e., towards the stomach and towards the mouth, respectively). The imaging capsule comprises at least one imaging element, which is configured to image the esophagus.

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In some embodiments of the present invention, the imaging capsule comprises a piston head, which is configured to form a pressure seal with a wall of the esophagus. Pressure from a fluid pressure source is applied to the area of the esophagus between the piston head and the anchoring member. The pressure causes the imaging capsule to travel proximally through the esophagus. Alternatively, the imaging capsule is withdrawn proximally using a wire.

25 There is therefore provided, in accordance with an embodiment of the invention, apparatus, including:

an elongate carrier, configured to be advanced through an esophagus of a subject;

an anchor member, coupled to a distal end of the 30 carrier, and configured to be mounted in a stomach of the subject in a vicinity of a lower esophageal sphincter (LES) of the subject; and

an imaging capsule, configured to move with respect to the carrier when the anchor member is in the vicinity of the LES.

In an embodiment, the capsule includes a sample collection unit, configured to sample fluid or tissue of the esophagus.

In an embodiment, the apparatus includes a sample collection unit coupled to the carrier and not an integral portion of the imaging capsule, wherein the collection unit is configured to sample fluid or tissue of the esophagus.

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In an embodiment, the imaging capsule is shaped to define a bore thereof, and wherein the carrier is configured to pass through the bore to allow the imaging capsule to move with respect to the carrier.

In an embodiment, the anchor member includes an inflatable anchor member.

In an embodiment, the anchor member includes a non-inflatable anchor member.

There is further provided, in accordance with an embodiment of the invention, apparatus for use with a biologically-compatible-fluid pressure source, including:

an elongate carrier, configured to be advanced through an esophagus of a subject;

an inflatable anchor member, coupled to a distal end of the carrier, and configured to be mounted in a stomach of the subject in a vicinity of a lower esophageal sphincter (LES) of the subject, and to form a pressure seal upon inflation; and

an imaging capsule, configured to travel along the carrier, the imaging capsule including:

an imaging element; and

a piston head configured to:

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form a pressure seal with a wall of the esophagus, and

be advanced proximally through the esophagus in response to pressure from the fluid pressure source.

In an embodiment, the capsule includes a sample collection unit, configured to sample fluid or tissue of the esophagus.

In an embodiment, the apparatus includes a sample collection unit coupled to the carrier and not an integral portion of the imaging capsule, wherein the collection unit is configured to sample fluid or tissue of the esophagus.

There is still further provided, in accordance with an embodiment of the invention, a method, including:

advancing an elongate carrier through an esophagus of a subject;

mounting in a stomach of the subject in a vicinity
of a lower esophageal sphincter (LES) of the subject an
anchor member that is coupled to a distal end of the
carrier; and

moving a capsule with respect to the carrier when the anchor member is in the vicinity of the LES.

In an embodiment, moving the capsule includes moving an imaging capsule.

In an embodiment, moving the capsule includes moving a capsule that applies a treatment to the esophagus.

In an embodiment, the method includes sampling fluid or tissue of the esophagus by the capsule.

In an embodiment, the capsule is shaped to define a bore thereof, and including placing the carrier within the bore.

In an embodiment, mounting the anchor member includes inflating the anchor member when it is in the stomach.

In an embodiment, mounting the anchor member includes expanding the anchor member when it is in the stomach.

The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1 and 2 are schematic illustrations of an imaging system configured to be inserted into an esophagus of a subject, in accordance with an embodiment of the present invention; and

Fig. 3 is a schematic illustration of the imaging system of Fig. 1, in accordance with another embodiment of the present invention.

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DETAILED DESCRIPTION OF EMBODIMENTS

Figs. 1 and 2 are schematic illustrations of an imaging system 10 configured to be inserted into an esophagus 20 of a subject, in accordance with an embodiment of the present invention. System 10 comprises an elongate carrier 24, an imaging capsule 26 configured to travel along the carrier, and an inflatable anchoring member 30 coupled to a distal end of carrier 24. Imaging capsule 26 comprises at least one imaging element 31, which is configured to image esophagus 20. Anchoring member 30 is inserted via esophagus 20 to a site in a

stomach 32 in a vicinity of a lower esophageal sphincter (LES) 34, and inflated so as to anchor the distal end of carrier 24.

Imaging capsule 26 and anchoring member 30 are typically advanced distally through esophagus 20 by positioning the imaging capsule at a distal end of carrier 24 near the anchoring member, and pushing on carrier 24 until anchoring member 30 reaches stomach 32. Alternatively, carrier 24 and anchoring member 30 are first advanced through esophagus 20, and a tube 44 is used to push imaging capsule 26 over the inserted carrier. (Tube 44 may be larger than as shown in Fig. 1, and, for some applications, may surround carrier 24.)

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In an embodiment of the present invention, elongate carrier 24 comprises a plurality of tubes and communication wires. An interior of anchoring member 30 is, in an embodiment, in fluid communication with a pressure source 42 via an anchoring member fluid supply tube 46. Pressure source 42 provides a pressurized biologically-compatible fluid, such as but not limited to, a source of pressurized air, CO2, or water, in order to inflate anchoring member 30.

In an embodiment of the present invention, imaging capsule 26 comprises an inflatable piston head 40. The piston head is configured to be inflated in response to pressure from fluid pressure source 42 delivered via a piston fluid supply tube 48. Once inflated, piston head 40 forms a pressure seal with a wall 50 of esophagus 20. Piston head 40 comprises a medically-safe elastomeric material, such as polyurethane or silicone rubber. Piston head 40 is configured to travel proximally (i.e., towards the mouth) through esophagus 20 in response to pressure from fluid pressure source 42 delivered, via an

advancement fluid supply tube 52, to a volume of esophagus 20 between piston head 40 and anchoring member 30. Alternatively, imaging capsule 26 is withdrawn proximally using tube 44.

Imaging element 31 comprises a camera (e.g., CCD or 5 CMOS), or an x-ray, ultrasonic, MRI, infrared, microwave imaging device, or another sensor configured to perform For the esophagus. optical biopsy of applications, imaging element 31 comprises one or more lenses configured to enable forward and omnidirectional 10 viewing, and/or means for illuminating the esophagus. For example, techniques may be used that are described in US Provisional Patent Application 60/571,438, filed May and/or International Patent Application 2004, PCT/IL2005/000500, filed May 11, 2005, both of which are 15 assigned to the assignee of the present application and are incorporated herein by reference. Alternatively or additionally, imaging element 31 is positioned to enable viewing in a proximal direction.

In an embodiment of the present invention, system 10 comprises one or more pulleys 54, which enable imaging capsule 26 to be pulled distally via wires 56. This embodiment may be practiced in addition to the use of a piston head, as described, or, alternatively, without the use of a piston head.

In an embodiment of the present invention, carrier 24 comprises a plurality of markers 60 that enable an operator of system 10 to visually determine a depth of imaging capsule 26 in the esophagus from the patient's teeth. Alternatively or additionally, the operator may view the markers using imaging element 31.

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Although piston head 40 has been described in embodiments of the present invention as being in direct

contact with wall 50 of esophagus 20, the scope of the invention includes establishing contact between the piston head and the wall of the esophagus through an intermediary, such as a sheath surrounding the piston head.

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Fig. 3 is a schematic illustration of imaging system 10 in accordance with an embodiment of the present invention. In the embodiment shown in Fig. 3, piston head 40 (Fig. 2) is not utilized. Instead, imaging capsule 26 is attached to a tube 70 that typically surrounds carrier 24. Tube 70 is free to advance and withdraw capsule 26. Capsule 26, in turn, is free to move proximally or distally with respect to carrier 24. In this manner, carrier 24 serves as a monorail, which is inserted into the esophagus at the beginning of a procedure, and maintained in place by anchoring member 30.

While anchoring member 30 is inflatable in accordance with some embodiments of the present invention, for some applications other techniques known in the art for stabilizing a tool in the gastrointestinal tract are used in order to maintain the position of member 30 near the lower esophageal sphincter.

In an embodiment, system 10 comprises a sample collection unit, which is configured to collect a tissue or fluid sample from the esophagus. For example, the collection unit may use suction to pull tissue into a collection compartment, whereupon the tissue is excised by a cutting instrument. The excised tissue is maintained within the collection unit, and, typically, a portion of the collection unit closes in order to maintain separation of the excised tissue from the surrounding environment. The closure of the collection

unit and excision of the tissue may, for some applications, be accomplished by the cutting instrument, which is typically activated by an actuator under physician control. Alternatively, a suitably-instrumented mechanical arm extends from the collection unit and retrieves a sample for biopsy.

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Upon completion of the procedure, the collection unit is typically withdrawn proximally. For some applications, the collection unit performs analysis (e.g., chemical or optical analysis) of collected samples in situ, such as using techniques known in the art, and, typically, transmits information to a site outside of the patient's body. For example, the information may include raw data or results of analysis, and may be transmitted over wires or wirelessly.

In an embodiment, system 10 applies a drug to a site of the esophagus, in response to or independently of data retrieved or samples collected by system 10.

The scope of the present invention includes embodiments described in the following applications, all of which are assigned to the assignee of the present application and are incorporated herein by reference. In an embodiment, techniques and apparatus described in one or more of the following applications are combined with techniques and apparatus described herein.

US Patent Application Publication 2005/0154355 to Gross et al.

US Patent Application Publication 2004/0102681 to Gross

30 US Patent Application Publication 2005/0036059 to Goldwasser

US Patent Application Publications 2005/0038318 and 2005/0038319 to Goldwasser

US Patent Application Publication 2005/0038335 to Gross et al.

5 US Patent Application Publication 2005/0154278 to Cabiri et al.

PCT Publication WO 05/065044 to Cabiri et al.

US Patent Application 10/967,922 to Cabiri et al., filed October 18, 2004, entitled, "Pressure-propelled system for body lumen"

US Patent Application 10/523,578 to Gross et al., filed January 28, 2005, entitled, "Self-propelled imaging system"

US Provisional Patent Application 60/571,438 to
15 Dotan et al., filed May 14, 2004, entitled,
"Omnidirectional and forward-looking imaging device"

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US Provisional Patent Application 60/607,986 to Cabiri et al., filed September 8, 2004, entitled, "Mechanical aspects of pressure-propelled system for body lumen"

US Provisional Patent Application 60/642,245, filed January 6, 2005, entitled, "Gastrointestinal tool over guidewire"

International Patent Application PCT/IL2005/000178

25 to Goldwasser et al., filed February 10, 2005, entitled,

"Gastrointestinal tool over guidewire"

US Provisional Patent Application 60/652,049 to Goldwasser et al., filed February 10, 2005, entitled "Advanced techniques for gastrointestinal tool with guiding element"

US Provisional Patent Application 60/680,074 to Degtiar et al., filed May 11, 2005, entitled, "Disposable endoscope connector"

an international patent application to Dotan et al., 5 filed May 11, 2005, entitled, "Omnidirectional and forward-looking imaging device"

US Patent Application 10/753,424 to Gross et al., entitled, "Pressure-propelled system for body lumen," filed January 9, 2004

10 US Provisional Patent Application 60/704,656 to Goldwasser et al., entitled, "Tools for use in esophagus," filed August 1, 2005

a PCT patent application to Degtiar et al., entitled, "Disposable endoscope connector," filed May 11, 2006

a PCT patent application to Cabiri et al., entitled, "Endoscopic measurement techniques," filed May 11, 2006

a PCT patent application to Goldwasser et al., 20 entitled, "Tools for use in small intestine," filed on even date herewith.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art,

30 reading the foregoing description.

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which would occur to persons skilled in the art upon

CLAIMS

1. Apparatus, comprising:

an elongate carrier, configured to be advanced through an esophagus of a subject;

an anchor member, coupled to a distal end of the carrier, and configured to be mounted in a stomach of the subject in a vicinity of a lower esophageal sphincter (LES) of the subject; and

an imaging capsule, configured to move with respect to the carrier when the anchor member is in the vicinity of the LES.

- 2. The apparatus according to claim 1, wherein the capsule comprises a sample collection unit, configured to sample fluid or tissue of the esophagus.
- 3. The apparatus according to claim 1, wherein the apparatus comprises a sample collection unit coupled to the carrier and not an integral portion of the imaging capsule, wherein the collection unit is configured to sample fluid or tissue of the esophagus.
- 4. The apparatus according to claim 1, wherein the imaging capsule is shaped to define a bore thereof, and wherein the carrier is configured to pass through the bore to allow the imaging capsule to move with respect to the carrier.
- 25 5. The apparatus according to any one of claims 1-4, wherein the anchor member comprises an inflatable anchor member.

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6. The apparatus according to any one of claims 1-4, wherein the anchor member comprises a non-inflatable anchor member.

7. Apparatus for use with a biologically-compatible-fluid pressure source, comprising:

an elongate carrier, configured to be advanced through an esophagus of a subject;

an inflatable anchor member, coupled to a distal end of the carrier, and configured to be mounted in a stomach of the subject in a vicinity of a lower esophageal sphincter (LES) of the subject, and to form a pressure seal upon inflation; and

an imaging capsule, configured to travel along the carrier, the imaging capsule comprising:

an imaging element; and a piston head configured to:

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form a pressure seal with a wall of the esophagus, and

be advanced proximally through the esophagus in response to pressure from the fluid pressure source.

- 20 8. The apparatus according to claim 7, wherein the capsule comprises a sample collection unit, configured to sample fluid or tissue of the esophagus.
- 9. The apparatus according to claim 7, wherein the apparatus comprises a sample collection unit coupled to the carrier and not an integral portion of the imaging capsule, wherein the collection unit is configured to sample fluid or tissue of the esophagus.
 - 10. A method, comprising:

advancing an elongate carrier through an esophagus 30 of a subject;

mounting in a stomach of the subject in a vicinity of a lower esophageal sphincter (LES) of the subject an

anchor member that is coupled to a distal end of the carrier; and

moving a capsule with respect to the carrier when the anchor member is in the vicinity of the LES.

- 5 11. The method according to claim 10, wherein moving the capsule comprises moving an imaging capsule.
 - 12. The method according to claim 10, wherein moving the capsule comprises moving a capsule that applies a treatment to the esophagus.
- 10 13. The method according to claim 10, comprising sampling fluid or tissue of the esophagus by the capsule.
 - 14. The method according to claim 10, wherein the capsule is shaped to define a bore thereof, and comprising placing the carrier within the bore.
- 15 15. The method according to any one of claims 10-14, wherein mounting the anchor member comprises inflating the anchor member when it is in the stomach.
 - 16. The method according to any one of claims 10-14, wherein mounting the anchor member comprises expanding
- 20 the anchor member when it is in the stomach.

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