Endolumik Gastric Calibration Tube
Models EGCT40, EGCT36

Single Patient Use ***Patented: www.endolumik.com/patents***

INDICATIONS

The Endolumik Gastric Calibration Tube is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation, to test for leaks, to provide visualization of the tube position, and to serve as a sizing guide. The tube is also indicated for use in esophageal surgical procedures as an esophageal bougie and visualization device.

CONTRAINDICATIONS

Esophageal stricture that does not allow passage of the Endolumik Gastric Calibration Tube.
Do not use this product in patients presenting with Zenker's diverticulum, or in conditions which would preclude a sleeve gastrectomy or gastric bypass operation.

WARNINGS AND PRECAUTIONS

Rx Only

Federal law restricts this device to sale by or on the order of a physician or licensed practitioner. Use of this device should only be performed by persons having adequate training and familiarity with minimally invasive surgical techniques, and with the use of this device. Consult medical literature relative to techniques, complications, and hazards prior to use of this device.

Please read these instructions carefully.

Correctly sizing the stomach is a clinical decision made based upon an assessment of the patient, training, clinical literature, experience, etc. It is the responsibility of the clinician to correctly size the stomach. If the Endolumik tube is not of a size deemed suitable by the clinician, it should not be used as a sizing guide.

NON STERILE

The Endolumik Gastric Calibration Tube is provided clean but not sterile. Do not use in applications requiring sterility.

Single patient use. Do not reuse, reprocess or autoclave the Endolumik Gastric Calibration Tube, as this action may compromise the safety, function and integrity of the device.Use of this product in patients presenting with esophageal varices may result in increased bleeding risk.

Do not staple or sew the Endolumik tube to the stomach.

Laparoscopic stapling techniques rely upon visual and tactile feedback to preclude stapling across devices in the field (including the Endolumik tube). Use of a powered stapler may affect normal tactile feel making it possible to staple across items such as a weighted bougie or the Endolumik Gastric Calibration Tube.

Do not attempt to remove the Endolumik Gastric Calibration Tube while suction is applied. Ensure suction has been disconnected prior to removal of the Endolumik Gastric Calibration Tube.

Do not remove while the tube is being used for suction/leak testing purposes in the stomach or esophagus as this could result in gastric and/or esophageal damage.

Dispose of per your facility's biohazardous waste disposal protocol.

LATEX

Does not contain natural rubber latex.

DESCRIPTION

The Endolumik Gastric Calibration Tube is a flexible gastric tube for use in gastric and bariatric surgery. It may be used for the following: the application of suction, stomach decompression, drainage of gastric fluids, irrigation, to test for leaks, to provide visualization of the tube position, and to serve as a sizing and measurement guide. The tube is also indicated for use in esophageal surgical procedures as an esophageal bougie and visualization device.

The Endolumik Gastric Calibration Tube is a non-sterile, single patient use device. The tube is 80 cm long, and is available in 2 different diameters: 36 and 40 French. It has a rounded tip and small side holes at the distal end. The proximal end includes a handle with an integral suction regulator. An additional squeeze bulb with pressure gauge may be attached to the end of the regulator.

SYSTEM COMPONENTS

Tubing - The tubing is 80 cm long, (36 French, or 40 French sizes are available). Small holes are located around the distal end of the tube, and it ends with a rounded tip. The other end of the tubing is attached to the handle. Markings on the distal end of the tubing begin at 5cm from the tip, and indicate 1cm lengths.

Handle & Section Regulator - The handle includes a tubing connector for connection to standard hospital suction tubing. The internal suction regulator is designed to deliver suction below a maximum of 150 mmHg.

Near Infrared (NIR) Lighting System - Once the pull tab on the bottom of the handle is removed, the lighting system emits near-infrared spectrum light along the distal length of the tubing for a minimum of 4 hours.

SYSTEM ACCESSORIES

Squeeze Bulb - The bulb is a hand pump with an integral pressure gauge to enable controlled introduction of pressure to the stomach.

INSTRUCTIONS

NOTE: If using the Endolumik Gastric Calibration Tube as a sizing guide, select the appropriate diameter device.
NOTE: The Endolumik Gastric Calibration Tube is designed to be used with a minimally-invasive laparoscopic or robotic camera with NIR or NIR overlay mode. Select the appropriate camera NIR mode to view NIR light. NIR overlay mode will allow traditional visualization with the Endolumik tube NIR light highlighted.

Step 1: Remove the Endolumik tube from the clear packaging. Do not use if packaging has been previously opened or damaged. Check the outer surfaces for any unintended rough or sharp edges and protrusions, and discard if found. Apply surgical lubricant generously onto the tip of Endolumik tube before inserting into patient.

Step 2: Remove the pull tab from the bottom of the handle to turn on the NIR light.

Step 3: Advance the Endolumik tube under direct visualization with surgeon's direction or insert it the same way an OG tube is inserted. STOP once gastric content is visible. There are markings along the tube at 30, 40, 50, 60, and 70 cm. Direct visualization of the tube is recommended when advancing the device past 30cm.

NOTE: Resistance should not be noted. If resistance is noted, please stop advancing tube and inspect for hiatal hernia or other defects.

Step 4: To remove fluid or enable irrigation, connect active suction tubing to the connector located at the proximal end of the handle. If the nasogastric tube was previously used, this step may not be necessary.

NOTE: Suction or irrigation is intended for use in the stomach only. Do not apply suction or irrigation to the esophagus.

Step 5: When removing the tube, stop the suction, and vent the Endolumik Tube by disconnecting the suction tubing.

NOTE: The distal end of the tube adheres to the lumen of the stomach when suction is applied. Do not pull excessively on the device when suction is applied.
NOTE: To apply leak testing, the stomach may be insufflated through the port of the handle of the device, and after removing the suction tubing. Connect the bulb accessory to the handle port and squeeze to achieve the desired effect. Use bulb only when the stomach can be directly visualized.

ADVERSE REACTIONS AND POTENTIAL COMPLICATIONS ASSOCIATED WITH CALIBRATION SYSTEMS
The possible complications associated with the use of the Endolumik Gastric Calibration Tube are those typically associated with calibration systems:

- Esophageal / gastric perforation
- Bleeding / hemorrhage
- Fistula
- Improper disinfection / infection
- accidental stapling of tube

Potential events associated with bariatric surgeries may include: Leaks, strictures, ischemia, gastroesophageal reflux disease, chronic pain, dysphagia, and excess weight loss.

RxOnly	Found on the IFU to indicate federal law restricts this device to sale by or on the order of a physician.
	Single patient use only, do not reuse.
	Found on the IFU to indicate proper disposal of biohazardous waste.
	Found on the IFU to indicate an important statement.
	Found on the IFU to indicate that device is not sterile.
	Found on the IFU to indicate latex free device.
	Found on the IFU and peel pouch to indicate manufacturer.

Specifications

Supplied: Clean, Not Sterile
Length: 80 cm
Diameter: 36 Fr (approx 12.0mm),
40 Fr (approx 13.3mm)
Material: PVC
Packaging: Poly bag
Shelf Life: 24 Months
Power Source: AAA battery (2)
Max Output: 3.3 V, 0.5 A
Max Ambient Operating Air Temperature: 35 °C

Product Classification Per IEC 60601-1

Degree of protection against electric shock -- Type BF applied part

CAUTION: No modification of this device is allowed

Electromagnetic Compatibility Guidance (EN/IEC 60601-1-2)

The Endolumik Gastric Calibration Tube requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these accompanying documents.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Endolumik Gastric Calibration Tube, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: This device has been tested for compatibility with other RF Emitters such as X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, and Electronic Article Surveillance devices. Caution should still be used if such emitters are present within the use environment, as not all RF Transmitters can be tested for.

WARNING: A risk of increased emissions or decreased immunity may result if any additional cables are attached.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Endolumik Gastric Calibration Tube is intended for use in the electromagnetic environment specified below. The customer or the user of the Endolumik Gastric Calibration Tube should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11 Group 1 Class A	Not Evaluated. Device does not contain any active electronic circuitry.	The Endolumik Gastric Calibration Tube does not contain any active electronic circuitry and is not likely to cause any interference in nearby electronic equipment of any environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Endolumik Gastric Calibration Tube is intended for use in the electromagnetic environment specified below. The customer or the user of the Endolumik Gastric Calibration Tube should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ± 15kV air	±8kV contact ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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Guidance and manufacturer's declaration – electromagnetic immunity			
The Endolumik Gastric Calibration Tube is intended for use in the electromagnetic environment specified below. The customer or the user of the Endolumik Gastric Calibration Tube should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communi-cations equipment should be used no closer to any part of the Endolumik Gastric Calibration Tube, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [3.5/3] √P 80 MHz to 800 MHz d = [7/3] √P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the trans-mitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3 IMMUNITY to proximity fields from RF wireless communications equipment	3 V/m 80 MHz to 2.7 GHz MHz – Modulation – Field Strength: 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m 0.1342 - 2.1kHz - 65 A/m 13.56 - 50kHz - 7.5 A/m 0.030 - CW – 8 A/m	3 V/m 80 MHz to 2.7 GHz MHz – Modulation – Field Strength: 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m 0.1342 - 2.1kHz - 65 A/m 13.56 - 50kHz - 7.5 A/m 0.030 - CW – 8 A/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Endolumik Gastric Calibration Tube is used exceeds the applicable RF compliance level above, the Endolumik Gastric Calibration Tube should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Endolumik Gastric Calibration Tube.			

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the Endolumik Gastric Calibration Tube

The Endolumik Gastric Calibration Tube is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Endolumik Gastric Calibration Tube can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Endolumik Gastric Calibration Tube as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**			
	80 to 800 MHz $d = [3.5/3] \sqrt{P}$	800 MHz to 2.7 GHz $d = [7/3] \sqrt{P}$	710, 745, 780, 5240, 5500, 5785 MHz $d = [6/9] \sqrt{P}$	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 MHz $d = [6/28] \sqrt{P}$
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.

Do not use if package is opened or damaged.

Type BF applied part

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