ViSiGi LUX™

Calibration System
Single Patient Use

Indications	Contraindications
ViSiGi LUX™ is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and to test for leaks, and to serve as a sizing guide.	Esophageal stricture that does not allow passage of ViSiGi LUX™. Conditions which would preclude gastric or bariatric surgical procedures.

Description

ViSiGi LUX™ is a non-sterile, single patient use device. The device comprises a tube with a closed, rounded tip, and holes at the distal end. The distal end of the device is equipped with an array of LEDs that emit near-infra red and visible red light. The proximal end of ViSiGi LUX™ includes an integral suction regulator and vented On/Off valve.

Warnings and Precautions

℞ 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 ViSiGi LUX™ is not of a size deemed suitable by the clinician, it should not be used as a sizing guide.

Do not use this product in patients presenting with Zenker's diverticulum unless certain that entry into the diverticulum can be avoided.

Use of this product in patients presenting with esophageal varices may result in increased bleeding risk.

Do not staple or sew ViSiGi LUX™ to the stomach. Before firing any staple loads in the stomach, always confirm placement of ViSiGi LUX™ by either visual or tactile cues. Laparoscopic stapling techniques rely upon visual and tactile feedback to preclude stapling across devices (including ViSiGi LUX™). Use of a powered stapler may affect normal tactile feel making it possible to staple across items such as a weighted bougie or ViSiGi LUX™.

Any instrument passed blindly through the esophagus presents the risk of esophageal perforation. ViSiGi LUX™ is designed to be flexible, with a blunt tip to limit this risk. If at any point undue resistance is felt, do not continue to advance ViSiGi LUX™.

Stapling indwelling tubes is a risk when performing a sleeve gastrectomy. To limit this risk, ViSiGi LUX™ is designed and indicated for stomach decompression, negating the need of an OG/NG tube for initial decompression of the gastric space.

Stapling indwelling temperature probes is a risk when performing a sleeve gastrectomy. If temperature monitoring is warranted for these shorter, elective procedures, consider the use of a forehead probe rather than an indwelling temperature probe. If an indwelling temperature probe is required, note the depth of placement, and externally tape the probe in place. Before any staple loads are fired, ensure the placement of the probe has not changed.

ViSiGi LUX™ is not indicated for the removal or solid materials such as food. Do not use ViSiGi LUX™ if solid materials such as food are present in the stomach.

Do not attempt to move ViSiGi LUX™ while suction is applied. Make sure the valve is switched to CLOSED prior to removal of ViSiGi LUX™. The valve of ViSiGi LUX™ has a large bore vent to rapidly remove suction, do not rely on the On/Off switch of the suction source.

NON STERILE

ViSiGi LUX™ is provided clean but not sterile. Do not use in applications requiring sterility.

Single patient use. Do not reuse, reprocess or autoclave ViSiGi LUX™, as this action may compromise the safety, function and integrity of the device.

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

LATEX

This product is not made with natural rubber latex.

Type BF Applied Part

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System Components

Tubing - The tubing is approximately 98 cm long. Model 5340SB has a tube diameter of 40 French. Model 5336SB has a tube diameter of 36 French. Model 5332SB has a tube diameter of 32 French. (3 French = 1 mm diameter)

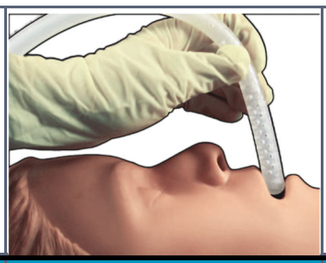
Holes - The tubes include apertures that extend to a distance of approximately 6.2 cm from the distal end.

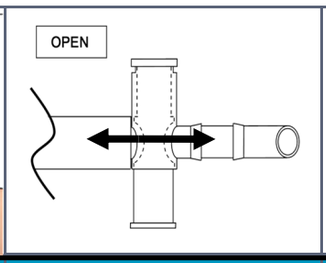
Slide Valve - The valve is a vented 2-position valve that includes a tubing connector for connection to standard hospital suction tubing.

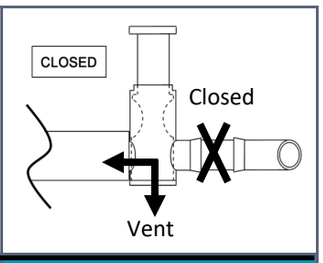
Suction Regulator - The integral suction regulator delivers regulated suction.

Squeeze Bulb - The bulb is the hand pump with an integral pressure gauge.

Visible/Near Infrared (NIR) Lighting System - Visible/NIR lights within the distal tip of the device are activated by removing the battery insulator pull tab. Additionally, an ON/OFF toggle switch can turn off the lights if desired by toggling the switch to the "OFF" position.







Step 1	Step 2	Step 3	Step 4
Remove ViSiGi LUX™ from the packaging. Remove the battery insulator pull tab and ensure the switch is on. Red light at the distal end of the tube indicates the device is energized. Ensure the valve is set to OPEN, and apply surgical lubricant generously onto the tip before inserting into patient. If using with a laparoscopic or robotic camera with NIR mode, select the appropriate camera mode to enable NIR-assisted visualization of device.	Advance ViSiGi LUX™ under direct visualization by surgeon's direction, or insert the same way as an OG tube. STOP once gastric contents are visible. There are length markings at 30, 40, and 50 cm. Do not pass the third marking (50 cm) without laparoscopic visualization.	For sizing, position ViSiGi LUX™ within the stomach as desired and connect ViSiGi LUX™ to suction. To remove fluid, enable irrigation, or to apply suction, place the slide valve in the OPEN position.	When moving or removing ViSiGi LUX™, stop the suction, and vent ViSiGi LUX™, by placing the slide valve in the CLOSED position.

NOTE: If exposing the apertured portion of ViSiGi LUX™ directly to the peritoneal space, suction should not be applied.
NOTE: If using suction, place the slide valve in the CLOSED position prior to removing the ViSiGi LUX™.
NOTE: The distal end of the ViSiGi LUX™ adheres to the lumen of the stomach when suction is applied. Do not pull on the device when suction is applied.
NOTE: The integral suction regulator limits suction levels to approximately 125 mm Hg. If it is desired to limit suction to lower levels, attach to a standard hospital wall suction regulator and adjust suction level accordingly.
NOTE: When using the ViSiGi LUX™ in the Roux-en-Y or similar procedure, prior to stapling, such as when creating the pouch, make sure that the exact location of the ViSiGi LUX™ is known and that it is not in the path of the stapler. One way to ensure that it is not in the path of the stapler is to withdraw the tip of the ViSiGi LUX™ into the esophagus.
NOTE: If performing leak testing, the stomach may be inflated by connecting the squeeze bulb to the slide valve tubing connector. Set the slide valve to OPEN position and squeeze the bulb to achieve the desired effect. Use squeeze bulb only when the stomach can be directly visualized.

Specifications

Supplied: Clean, Non Sterile

Length: Approx. 98 cm

Diameter: 36 Fr (Approx. 12.0 mm), 40 Fr (Approx. 13.3 mm)

Material: Thermoplastic Elastomer

Packaging: Poly bag

Shelf Life: 2 years

Storage: 5-30°C, 0-65% rel. humidity, 50-106 kPa

Power Source: AAA battery (2)

Max Output: 3.3 V, 0.1 A

Product Classification Per IEC 60601-1: Type BF applied part

CAUTION: No modification of this device is allowed

RxOnly	Found on IFU and packaging labels. Definition: Federal law restricts this device to sale by or on the order of a physician.
NON STERILE	Found on IFU and packaging labels. Definition: Non-sterile.
	Found on IFU and packaging labels. Definition: Do not re-use.
LATEX	Found on IFU and packaging labels. Definition: This product is not made with natural rubber latex.
	Found on the IFU and packaging labels. Definition: Manufacturer.
	Found on packaging labels. Definition: Do not use if package is damaged.
	Found on packaging labels. Definition: Consult instructions for use.
REF	Found on packaging labels. Definition: Reorder number.
LOT	Found on packaging labels. Definition: Lot number.
	Found on packaging labels. Definition: Use-by-date.
	Found on IFU and packaging labels. Definition: Type BF applied part
	Found on packaging labels. Definition: Third Party certification.

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Electromagnetic Compatibility Guidance

The Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB require special precautions regarding EMC and need 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 Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

WARNING: This device has been tested for compatibility with other potential RF Emitters such as X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveillance (EAS) devices. However, caution should be used if such emitters are present within the use environment, as not all RF Emitters can be tested for.

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 Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB are intended for use in the electromagnetic environment specified below. The customer or the user of the Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB are suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB or shielding the location.

Guidance and manufacturer's declaration – electromagnetic immunity

The Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB are intended for use in the electromagnetic environment specified below. The customer or the user of the Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB 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.

NOTE: U_T is the A.C. mains voltage prior to application of the test level.

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Guidance and manufacturer's declaration – electromagnetic immunity

The Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB are intended for use in the electromagnetic environment specified below. The customer or the user of the Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB 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	3 Vrms 0,15 MHz – 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Boehringer Laboratories LLC ViSiGi LUX™, models 5332SB, 5336SB and 5340SB, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 3 V/m 80 MHz to 2.7 GHz	6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 3 V/m 80 MHz to 2.7 GHz	Recommended separation distance: d = [3.5/10] √P 80 MHz to 800 MHz d = [7/10] √P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recom-mended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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 Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB are used exceeds the applicable RF compliance level above, the Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB.

Guidance and manufacturer's declaration – electromagnetic immunity

The Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB are intended for use in the electromagnetic environment specified below. The customer or the user of the Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB should assure that it is used in such an environment.

Immunity test	IEC 60601 test level			Compliance level			Electromagnetic environment - guidance
	MHz	Modulation	Field Strength	MHz	Modulation	Field Strength	
IMMUNITY to proximity fields from RF wireless communications equipment	385 450 710 745 780 810 870 930 1720 1845 1970 2450 5240 5500 5785	18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 18 Hz 18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz	27 V/m 28 V/m 9 V/m 9 V/m 9 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 9 V/m 9 V/m 9 V/m	385 450 710 745 780 810 870 930 1720 1845 1970 2450 5240 5500 5785	18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 18 Hz 18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz	27 V/m 28 V/m 9 V/m 9 V/m 9 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 9 V/m 9 V/m 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: E = [6/d] √P d = [6/E] √P where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/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: 
IMMUNITY to proximity magnetic fields IEC 61000-4-39	0.1342 13.56 0.030	2.1kHz 50kHz CW	65 A/m 7.5 A/m 8 A/m	0.1342 13.56 0.030	2.1kHz 50kHz CW	65 A/m 7.5 A/m 8 A/m	

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB.

The Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Boehringer Laboratories, LLC ViSiGi LUX™ models 5332SB, 5336SB and 5340SB 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.

FCC statements

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.