



For Gastric Bypass

Model 5232B

Single Patient Use

Patent Pending

Indications

ViSiGi 3D™ is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and to serve as a sizing guide.

Contraindications

Esophageal stricture that does not allow passage of ViSiGi 3D™.

Conditions which would preclude a gastric bypass.



Warnings and Precautions

RxOnly 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 3D™ 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 3D™ to the stomach. Before firing any staple loads in the stomach, always confirm placement of ViSiGi 3D™ by either visual or tactile cues.

Laparoscopic stapling techniques rely upon visual and tactile feedback to preclude stapling across devices in the field (including ViSiGi 3D™). Use of a powered stapler may affect normal tactile feel making it possible to staple across items such as a weighted bougie or ViSiGi 3D™.

Any instrument passed blindly through the esophagus presents the risk of esophageal perforation. ViSiGi 3D™ 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 3D™.

Stapling indwelling tubes is a risk when performing a sleeve gastrectomy. To limit this risk, ViSiGi 3D™ 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.

Do not attempt to remove ViSiGi 3D™ while suction is applied. Make sure the valve is switched to CLOSED prior to removal of ViSiGi 3D™.



ViSiGi 3D™ is provided clean but not sterile. Do not use in applications requiring sterility.



Single patient use. Do not reuse, reprocess or autoclave ViSiGi 3D™, as this action may compromise the safety, function and integrity of the device.

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



This product is not made with natural rubber latex.

Description

ViSiGi 3D™ is a flexible gastric tube for use in gastric and bariatric surgery. It may be used for the following: to decompress the stomach, remove gastric fluids with suction, for irrigation, and as a sizing guide during surgery.

ViSiGi 3D™ is a non-sterile, single patient use device. The tube is 107 cm long, and is available in 32 French diameter. It has a closed, rounded tip and small side holes at the distal end. The proximal end includes an integral suction regulator and slide valve. An additional squeeze bulb with pressure gauge may be attached to the end of the valve.

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Innovation, Quality and Service



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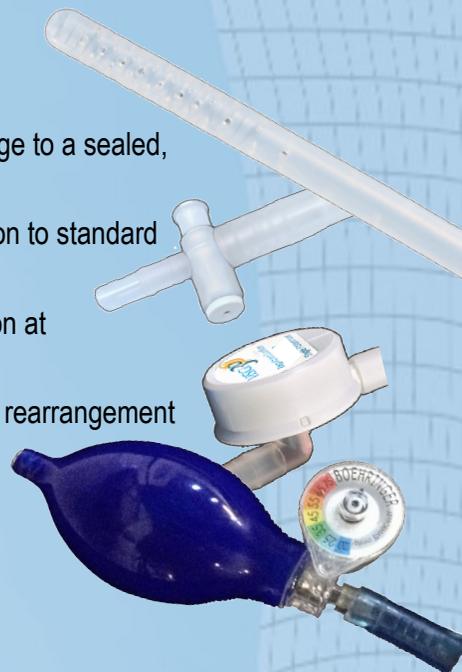
System Components

Tubing - The tubing is a 107 cm long, (32French). Small holes around one end of the tube merge to a sealed, rounded tip. The other end of the tubing is attached to the slide valve.

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

Suction Regulator - The integral suction regulator is factory calibrated to deliver normal suction at approximately 125 mmHg.

Squeeze Bulb - The bulb is a hand pump with an integral pressure gauge to enable controlled rearrangement of the gastric folds/rugae of the stomach.



Instructions



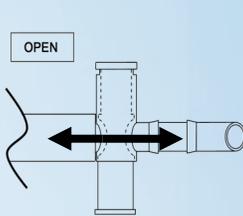
Step 1

Remove ViSiGi 3D™ from the clear packaging, ensure the valve is set to OPEN, and apply surgical lubricant generously onto the tip of ViSiGi 3D™ before inserting into patient.



Step 2

Advance ViSiGi 3D™ under direct visualization by surgeon's direction, or insert the same way as an OG tube. STOP once gastric content is visible. There are blue markings at 30, 40, and 50 cm. Do not pass the third marking (50 cm).



Step 3

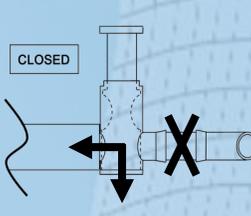
For sizing, position ViSiGi 3D™ within the stomach as desired and connect ViSiGi 3D™ to suction.

To remove fluid, enable irrigation, or to apply suction, place the slide valve in the OPEN position.



Step 4

Any time ViSiGi 3D™ enters the peritoneal cavity or is exposed in the peritoneal cavity, clamp ViSiGi 3D™ just below the regulator.



Step 5

When moving or removing ViSiGi 3D™, stop the suction, and vent ViSiGi 3D™, by placing the slide valve in the CLOSED position.

NOTE: If using the ViSiGi 3D™ as a sizing guide, select the appropriate diameter device.

NOTE: If using suction, place the slide valve in the CLOSED position prior to removing the ViSiGi 3D™.

NOTE: The distal end of the ViSiGi 3D™ adheres to the lumen of the stomach when suction is applied. Do not pull excessively on the device when suction is applied.

NOTE: When using the ViSiGi 3D™ 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 3D™ 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 3D™ into the esophagus.

Specifications

Supplied: Clean, Non Sterile

Length: 107 cm

Diameter: 32 Fr (approx. 10.7 mm)

Material: Thermoplastic Elastomer

Packaging: Poly bag

Shelf Life: 2 years

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	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.



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