



# Sleeve Gastrectomy Calibration System With Bulb

Models 5236B, 5240B Single Patient Use Patent Pending

## Indications

The 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 the ViSiGi 3D™.

Conditions which would preclude a sleeve gastrectomy.

## 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 the 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 the ViSiGi 3D™ to the stomach.

Laparoscopic stapling techniques rely upon visual and tactile feedback to preclude stapling across devices in the field (including the 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 the ViSiGi i3D™.

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

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



Single patient use. Do not reuse, reprocess or autoclave the 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.



Does not contain natural rubber latex.

## Description

The 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.

The ViSiGi 3D™ is a non-sterile, single patient use device. The tube is 107 cm long, and is available in 2 different diameters: 36 and 40 French. 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.





# Sleeve Gastrectomy Calibration System With Bulb

Models 5236B, 5240B Single Patient Use Patent Pending

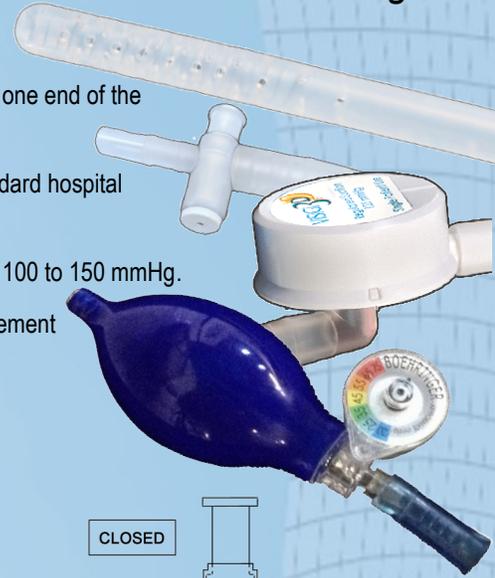
## System Components

**Tubing** - The tubing is a 107 cm long, (36 French, or 40 French sizes are available). Small holes around one end of the tube merge up 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 suction in the range of 100 to 150 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

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



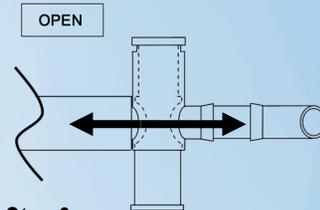
Step 1

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

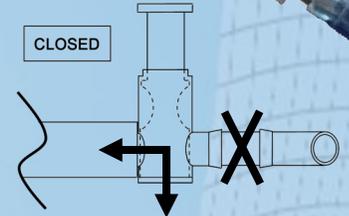
Advance ViSiGi 3D™ under direct visualization with surgeon's direction or insert it the same way an OG tube is inserted. STOP once gastric content is visible. There are blue markings are 30, 40, and 50 cm. Do not pass the third marking (50 cm).



Step 3

For sizing, position the 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

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 suction, place the slide valve in the OPEN 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:** To adjust the gastric folds/rugae of the stomach, connect the bulb to the valve and squeeze to achieve the desired effect. Use bulb only when the stomach can be directly visualized.

## Specifications

**Supplied:** Clean, Non Sterile

**Length:** 107 cm

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

**Material:** Thermoplastic Elastomer

**Packaging:** Poly bag

**Shelf Life:** 2 years

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 peel pouch. Consult instructions for use.
	Found on the IFU to indicate latex free device.
	Found on the IFU and peel pouch to indicate manufacturer.

Made in USA



© 2013 Boehringer Laboratories, Inc.  
300 Thoms Drive, Phoenixville, PA 19460  
1-800-642-4945 www.visigi.com

