Calibration System
*Single Patient Use*
*www.boehringerlabs.com/our-patents*

## 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 gastric or bariatric surgical procedures.

## Description

ViSiGi 3D® 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 proximal end of ViSiGi 3D® 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 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 (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.

ViSiGi 3D® is not indicated for the removal of solid materials such as food. Do not use ViSiGi 3D® if solid materials such as food are present in the stomach.

Do not attempt to move ViSiGi 3D® while suction is applied. Make sure the valve is switched to CLOSED prior to removal of ViSiGi 3D®. The valve of ViSiGi 3D® has a large bore vent to rapidly remove suction, do not rely on the On/Off switch of the suction source.

NON STERILE — 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.

LATEX — This product is not made with natural rubber latex.

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*Innovation, Quality and Service*

ViSiGi 3D®

# Calibration System

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## System Components

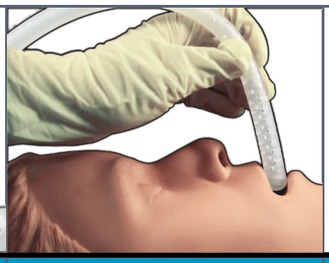
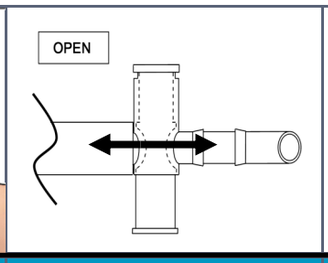
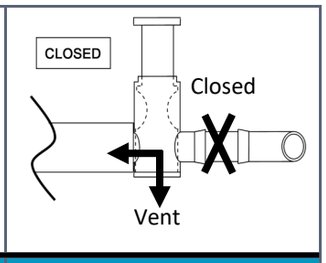
***Tubing -*** The tubing is approximately 104 cm long. Models 5240, 5240B, 5240S, and 5240SB have a tube diameter of 40 French. Models 5236, 5236B, 5236S, and 5236SB have a tube diameter of 36 French. Models 5232, 5232B, 5232S, and 5232SB have a tube diameter of 32 French. (3 French = 1 mm diameter)

***Holes -*** Models 5240, 5240B, 5236, 5236B, 5232, and 5232B include apertures that extend to a distance of approximately 13 cm from the distal end. Models 5240S, 5240SB, 5236S, 5236SB, 5232S, and 5232SB include apertures that extend to a distance of approximately 6 cm from the distal end.

***Slide Valve -*** The slide 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 -*** (Models 5240B, 5240SB, 5236B, 5236SB, 5232B, 5236SB) The bulb is a hand pump with an integral pressure gauge.

|  |  |   |   |
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| ***Step 1*** | ***Step 2*** | ***Step 3*** | ***Step 4*** |
| 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. | Advance ViSiGi 3D® under direct visualization by surgeon's direction, or insert the same way as an OG tube. STOP once gastric contents are visible. There are blue markings at 30, 40, and 50 cm. Do not pass the third marking (50 cm) without laparoscopic visualization. | For sizing, position ViSiGi 3D® within the stomach as desired and connect ViSiGi 3D® to suction.<br><br>To remove fluid, enable irrigation, or to apply suction, place the slide valve in the OPEN position. | When moving or removing ViSiGi 3D®, stop the suction, and vent ViSiGi 3D®, by placing the slide valve in the CLOSED position. |

**NOTE:** While exposing the apertured portion of ViSiGi 3D® 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 3D®.
**NOTE:** The distal end of the ViSiGi 3D® 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, Boehringer Laboratories offers a full line of suction regulators that are compatible with ViSiGi 3D and allow the user to set the level of suction applied. (https://www.boehringerlabs.com/medical-devices/suction-regulators/)
**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:*** Approx. 104 cm

***Diameter:*** 32 Fr (appr. 10.7mm), 36 Fr (Approx. 12.0 mm), 40 Fr (Approx. 13.3 mm)

***Material:*** Thermoplastic Elastomer

***Packaging:*** Poly bag

***Shelf Life:*** 2 years

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| 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. |


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5232009 Rev L ViSiGi 3D® IFU 34074 Released February 2019