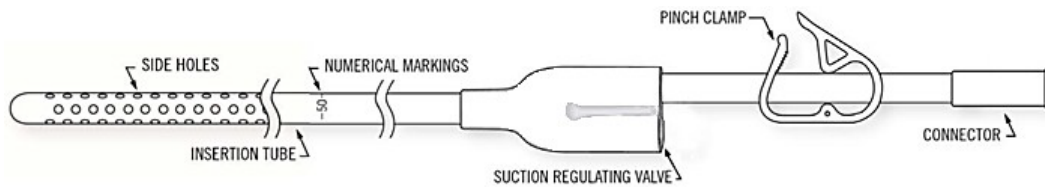


SIREN SGT™ Orogastric Tube

Catalog No. SGT-36



DESCRIPTION:

The SIREN SGT™ is a non-sterile, flexible, suction-regulating gastric tube for single patient use. The proximal portion includes a CONNECTOR, PINCH CLAMP and SUCKION REGULATING VALVE. The distal portion comprises a 104 cm long INSERTION TUBE with multiple side holes extending 13 cm from its distal end, and NUMERICAL MARKINGS to indicate depth of insertion. The device is available with an INSERTION TUBE diameter of 36 Fr (12 mm).

INDICATIONS:

The SIREN SGT™ is indicated for use in gastric and bariatric surgical procedures for gastric aspiration and lavage, and to assist in gastric sleeve formation by decompressing the stomach and serving as a sizing guide.

CONTRAINDICATIONS:

Esophageal strictures that do not allow passage of the SIREN SGT™.

WARNINGS AND PRECAUTIONS:

- Clinical literature, the patient's physiology and anatomy, and the surgeon's training and experience instruct and influence the correct sizing of a gastric sleeve or pouch. It is the responsibility of the clinician to correctly size the stomach. The SIREN SGT™ should not be used as a sizing guide if it is not of a size deemed suitable by the clinician.
- Do not use this product in patients with Zenker's diverticulum unless certain that entry into the diverticulum can be avoided.
- Use of this product in patients with esophageal varices may result in bleeding.
- **Do not staple or sew the SIREN SGT™ to the stomach.**
- Use of a powered surgical stapler may diminish haptic feedback and increase the chance of stapling across devices such as bougies, gastric tubes, and temperature probes.
- Do not attempt to remove the SIREN SGT™ while suction is applied.
- The SIREN SGT™ is provided clean but not sterile. Do not use in applications requiring sterility.

INSTRUCTIONS FOR USE:

1. Apply surgical lubricant liberally to the tip and distal end of the SIREN SGT™.
2. Insert the SIREN SGT™ into the mouth and advance through the esophagus under the surgeon's direction. There are NUMERICAL MARKINGS at 30, 40 and 50 cm.
3. Position the SIREN SGT™ within the stomach as preferred.
4. To apply suction and remove gastric fluid, set the vacuum source suction regulator to 125 mmHg (or lower, if preferred by the surgeon and anesthesia care provider), attach the CONNECTOR to the tubing from the vacuum source, and open the PINCH CLAMP. The integral SUCKION REGULATING VALVE produces an audible signal when the suction pressure in the INSERTION TUBE exceeds ≈ 160 mmHg. If the audible signal is heard, adjust the vacuum source suction regulator to 125 mmHg or lower. The SUCKION REGULATING VALVE will limit the negative pressure in the stomach to less than 170 mmHg even when full vacuum is applied.
5. The distal end of the SIREN SGT™ adheres to the stomach when suction is applied. Do not pull excessively on the SIREN SGT™ when suction is applied. Before repositioning or removing the SIREN SGT™, stop the suction and vent the SIREN SGT™ by disconnecting the tubing to the vacuum source and opening the PINCH CLAMP.

Rx only

Clean, non-sterile

Not made with natural rubber latex



U.S. Patent No. 11006957

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