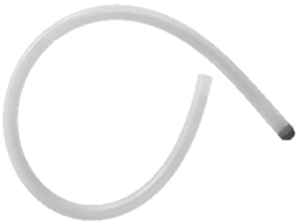
# MID-TUBE

**REF** **MID130**

**REF** **MID136**

**REF** **MID131**



## 1. INDICATIONS

MID-TUBE, orogastric calibration tube is indicated for use in gastric and bariatric surgical procedures to provide visible and tactile delineation of the stomach and with the ability to decompress the stomach, drain and remove gastric fluid.
MID-TUBE, Orogastric Calibration Tube may be used during bariatric surgeries (for example Gastric Bypass, Sleeve gastrectomy…) or gastric surgeries (for example Fundoplication, Gastrectomy…).
The product MID-TUBE is available in 3 sizes.

## 2. CHARACTERISTICS OF THE MID-TUBE

| | MID-TUBE ref. MID130 | MID-TUBE ref. MID136 | MID-TUBE ref. MID131 |
|---|---|---|---|
| Material used : | Medical silicone | Medical silicone + blue tip | Medical silicone + blue tip |
| Tube length : | 800 +/- 5mm | 800 +/- 5mm | 791 +/- 5mm |
| Tube external diameter : | 12.8 +/- 0.2mm (38 french) | 12 +/- 0.2mm (36 french) | 16 +/- 0.2mm (48 french) |
| Tube internal diameter : | 7.8 +/- 0.2mm | 7 +/- 0.2mm | 8 +/- 0.2mm |

## 3. CONTRAINDICATIONS

Use of the MID-TUBE is CONTRAINDICATED in the following cases:

- Patients presenting with a risk of allergy to the product material - solid silicone.
- Disorders or pathologies of the esophagus: Esophageal varices, esophageal diverticula, esophageal tumors, esophageal strictures.
- Coagulation disorders.
- More generally, all other contraindications that have been the subject of a scientific paper or have been identified by the practitioner or practitioners.
- The MID-TUBE should be introduced with special attention in case of large hiatal hernia.

## 4. INTENDED USE

⚠ Before insertion, lubricate the probe.

- Insert the catheter orally with the guide tip first. Pass the catheter down into the stomach.
- Use the body of the MID-TUBE to determine the size of the stomach pouch being conserved during the intervention. The precise volume and dimensions of the conserved portion depend on the surgeon's assessment.
- The intervention needs one or more staples, the user must always move the tube before each stapling to ensure that the tube body is not caught in the stapler.
- When stapling is complete, the probe can be used to inject and withdraw the coloured liquid (e.g., food colouring) used for the leak test. In this case, the suction system must be connected to the MID-TUBE. If gastric mucosa is sucked into the drainage holes of the MID-TUBE, please immediately disconnect the MID-TUBE from the suction source to reposition the MID-TUBE in the stomach prior to reconnecting to suction.
  **CAUTION: Do not move while the tube is being used for suction/irrigation purposes in the stomach or esophagus as this could result in gastric and/or esophageal damage.**
  **WARNING: For MID-TUBE ref. MID131, maximum vacuum level -500 mbar (50kPa). For MID-TUBE ref. MID130, maximum vacuum level -600 mbar (60kPa). For MID-TUBE ref. MID136, maximum vacuum level -600 bar (60kPa).**
- Remove the tube.

## 5. QUALIFICATION OF THE PRACTITIONER

Only experienced practitioners who belong to a dedicated team fully skilled in obesity surgery can use the MID-TUBE.
**Warning: Practitioners must fully familiarize themselves with these instructions before use.**

⚠ The introduction of a MID-TUBE calibration tube into the esophagus can create a risk of esophageal perforation. This can only be realized by an experienced user, aware of the MID-TUBE instructions of use and the patient's history. If the introduction is delegated to another staff (not a doctor), he must be specifically trained to this surgery and the surgery remains the surgeon's full responsibility.

## 6. STORAGE CONDITIONS AND STERILITY

**Storage:**
Keep products in their original packaging in a dry, cool location, sheltered from light and impact.

**Sterility:**

- **The MID-TUBE is delivered in sterile packaging. This is completed using ethylene oxide sterilization. Please ensure integrity of packaging before use. Do not use a product with damaged packaging.**
- **Do not use this product once the expiry date has passed**
- This is a single-use product – **DO NOT RE-STERILISE / DO NOT REUSE.** To do so would entail the following risks:
  - Sterile condition not guaranteed outside MID-approved methods.
  - Significant risk of cross-contamination or post-operative complications.
  - The expected performance characteristics of the device would not be guaranteed.

## 7. WARNING AND IMPORTANT POINTS

- **The probe must not be used for longer than two hours.**
- **The devices could be returned to the distributor for expert analysis in accordance with MID returned goods policy with a brief description of the observation, to satisfy the manufacturer's quality assurance policy. Please contact MID before returning.**
- **Removal of this device must not compromise the safety or health of patients, users or any other person. The device must be removed and destroyed in accordance with current legislation in the country concerned.**
- **DO NOT allow any instrument that could damage the MID-TUBE to come into contact with it.**
- **ALWAYS have at least one spare device in case of any failure or incident.**

For single use only

Store in a cool, dark, dry place

Do not used if package is opened or damaged

**Rx Only** "Caution : Federal Law restricts this device to sale by or on the order of a physician or a licensed practitioner"

Not made with natural rubber latex – ne contient pas de latex – kein latex– No Latex – No Lattice – não latex – Latexvrij

لا يحتوي هذا المنتج على مادة اللاتكس

STERILE EO

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**POLITIQUE de RETOURS/RETURNED Goods POLICY**

Aucun retour produit ne peut se faire sans l'autorisation préalable de MID. Afin de connaitre les modalités de retour merci de nous contacter à :

Authorization must be received from MID prior to return of the medical device. For particular return indications, please contact us:


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