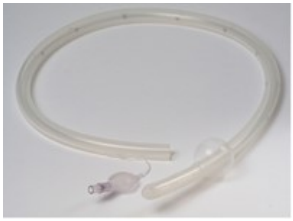
CHARACTERISTICS / INDICATIONS / CONTRAINDICATIONS

1. PRODUCTS AFFECTED BY THESE INSTRUCTIONS:



MIDSOND - Gastric Calibration Tube - ref. MID012.
The MIDSOND is a gastric calibration tube designed to assist the surgeon in an adjustable gastric banding or eventually another bariatric surgical procedure where the use of a calibration tube is useful.

2. CHARACTERISTICS OF THE MIDSOND

Material used :	Medical silicones
Tube length :	730 +/- 4mm
Tube diameter :	12.5 +/- 0.5mm (about 38 french)
Maximum volume of the balloon :	25mL ou 25cc
Valve tip type :	Luer

3. INDICATIONS

Gastric banding procedure:
The MIDSOND has been designed and adapted to assist with the insertion of the MIDBAND™ adjustable gastric band, which are indicated for the treatment of obesity.
Please refer to the MIDBAND™ operating instructions delivered with the product and also available upon request from MID.
The catheter is fitted with a balloon located 6 cm from the distal tip, which can be inflated up to 25 mL.
The balloon is inflated between the band and the cardia during surgical intervention in order to determine the dimension of the gastric pouch to be created by the MIDBAND™.

Other bariatric procedures:
The MIDSOND can also be used in other bariatric surgical procedures such as sleeve gastrectomy, gastric by-pass…
When the balloon is NOT inflated, the MIDSOND facilitates calibration of the vertical portion of the stomach by using only the body of the catheter (tube).

4. CONTRAINDICATIONS

Use of the MIDSOND is CONTRAINDICATED in the following cases:
- Patients presenting with a risk of allergy to the product material - solid silicone.
- Disorders or pathologies of the oesophagus: Oesophageal varices, oesophageal diverticula, oesophageal tumours, oesophageal strictures.
- More generally, all other contraindications that have been the subject of a scientific paper or have been identified by the practitioner or practitioners.
- The MIDSOND should be introduced with special attention in case of large hiatal hernia

USE OF THE MIDSOND FOR THE MIDBAND™ PROCEDURE

⚠ **BEFORE INSERTION , test the inflation capacity of the balloon by injecting 20 mL (or cc) of air – Completely deflate the balloon and lubricate the probe.**
- Insert the catheter orally with the guide tip first.
- Pass the catheter down into the stomach.
- Inflate the balloon to 25 mL (or cc) maximum to distend the gastric wall in order to create a proximal gastric pouch.
- Move the catheter back until the balloon is blocked by the oesogastric junction.
- The band must be placed under this pouch.
- Deflate the balloon before suturing in position and remove the tube.
- If suturing with the balloon inflated, it is important to ensure that all sutures avoid the gastric mucosa and the wall of the balloon and only involve the seromuscular tunic of the stomach.

USE OF THE MIDSOND FOR OTHER BARIATRIC SURGERY

Do not inflate the balloon for this type of procedure.
- Insert the catheter orally with the guide tip first. Pass the catheter down into the stomach.
- Use the body of the MIDSOND (tube) without inflated balloon 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 balloon or tube body is not caught in the stapler.
- Remove the tube.

PRECAUTIONS FOR USE

1. QUALIFICATION OF THE PRACTITIONER

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

⚠ The introduction of a MIDSOND calibration tube into the esophagus can create a risk of esophageal perforation. This can only be realized by an experienced user, aware of the MIDSOND 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

2. STORAGE CONDITIONS AND STERILITY

Storage:
Keep products in their original packaging. Store in a cool, dry place, away from light and damage.

Sterility:
- **The MIDSOND 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.

3. IMPORTANT POINTS

- **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.**
- **The probe must not be used for longer than one hour.**
- **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.**
- **The balloon must be inflated progressively under visual inspection of the user.**
- **The maximum volume of the balloon is 25 mL (or cc).**
- **DO NOT inflate the MIDSOND when the balloon is in the esophagus**
- **ALWAYS ensure that the balloon is deflated before removing the catheter.**
- **REMOVE the MIDSOND from the stomach before starting any localized dissection.**
- **DO NOT allow any instrument that could damage the MIDSOND to come into contact with it.**
- **HANDLE the inflation valve with care as this is fragile.**
- **ALWAYS have at least one spare device in case of any failure or incident.**

CE 0459

CE mark since 2006

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