MIDSLEEVE™

REF **MID160**

USER PRECAUTIONS

1. **QUALIFICATION OF PRACTITIONERS**

MIDSLEEVE™ must be handled only by practitioners (surgeons, anaesthesiologists, registered anaesthetic nurses, etc.) with experience of bariatric surgery.

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.

Warning: There is a potential risk of misconnections with connectors from others healthcare applications

⚠The introduction of a MIDSLEEVE calibration tube into the esophagus can create a risk of esophageal perforation. This can only be realized by an experienced user, aware of the MIDSLEEVE 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 in a dry, cool location, sheltered from light and impact.

Sterility:

- MIDSLEEVE® is delivered in a package that ensures a sterile probe (ethylene oxide sterilisation). Check the integrity of the packaging before use. Do not use a product from a damaged package.
- **Do not use the product after the expiry date shown on the package.**
- 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 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.**
- **The maximum volume to insufflate into the balloon is 75 ml (75 cc).**
- **Do not inflate MIDSLEEVE® before the balloon has reached the stomach.** This could cause serious complications.
- **Ensure that the balloon is deflated before withdrawing the probe.** If the ballon cannot be deflated, cut the catheter before the Luer Lock and wait until the balloon is completely deflated.
- **Remove MIDSLEEVE® before starting a dissection in its vicinity.**
- **The suction system must be disconnected from MIDSLEEVE® before any dissection.**
- When handling MIDSLEEVE®, do not bring it into contact with any instrument that could damage the device.
- The **inflation valve** is a fragile component, to be handled with care.
- It is essential to keep **at least one spare device** available in the event of malfunction or other incidents.
- The balloon must be inflated progressively under visual inspection of the user.

- **Always inflate the MIDSLEEVE™ balloon BEFORE POSITIONING THE TWEEZERS DURING THE FIRST STAPLE.**
- **Always MOBILISE THE PROBE BEFORE STAPLING.**

This is to determine the exact position of the balloon and probe, and thereby avoid accidentally stapling them.

CHARACTERISTICS / INDICATIONS / CONTRAINDICATIONS

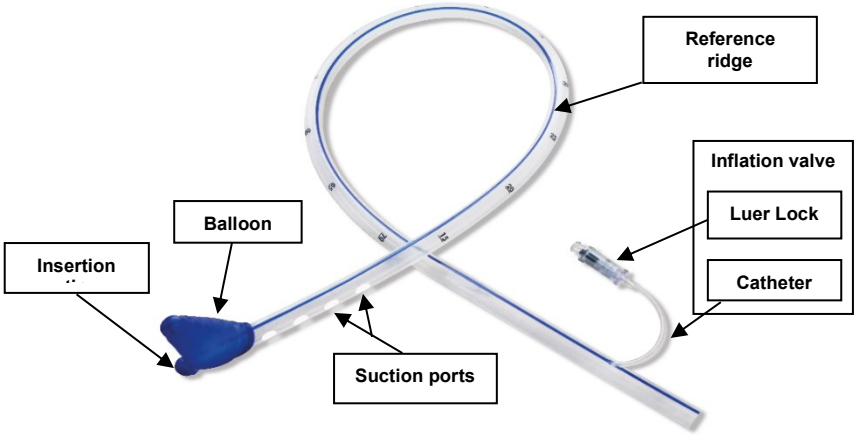
1. PRODUCT CONCERNED BY THIS GUIDE:

MIDSLEEVE®, Calibration tube for Sleeve Gastrectomy, Cat. No. MID160.

2. MIDSLEEVE® CHARACTERISTICS

Materials used:	Medical silicone
Tube length:	894 +/- 5 mm
Tube outer diameter:	12.5 +/-0.5 mm; about 38 French
Tube inner diameter:	8 +/- 0.4 mm
Maximum balloon volume:	75 ml or 75 cc
Valve fitting type:	Luer

MIDSLEEVE® probe with balloon inflated



3. INDICATIONS

MIDSLEEVE™ Calibration Tube for Sleeve Gastrectomy is indicated for use in the bariatric procedure known as Longitudinal Sleeve Gastrectomy (LSG), to drain and remove gastric fluid and to provide a calibration of the gastric pouch.

MIDSLEEVE® is designed and adapted for the bariatric surgery technique known as 'sleeve gastrectomy'. It's strictly dedicated to this use.

For more information on the technique of sleeve gastrectomy, consult the website of the *International Federation for the Surgery of Morbid Obesity and Metabolic Disorder* (IFSO) *(1),* or *la Haute Autorité De Santé (HAS) (2)*

The shape of the MIDSLEEVE™ balloon after inflation has been specially designed to be positioned in the gastric antrum. This balloon allows for more precise and reproducible calibration of the residual gastric volume.

The MIDSLEEVE™ can be connected to a suction system to remove any air or fluid present in the patient's stomach (leak test).

4. CONTRAINDICATIONS

The use of MIDSLEEVE® is most notably contraindicated in the following cases:

- Patients with a risk of allergy to the constituent material of the product, i.e. solid silicone.
- Disorders or pathologies of the oesophagus: Oesophageal varices, oesophageal diverticula, oesophageal tumours, oesophageal strictures.
- Coagulation disorders.
- The user must remain mindful to all possible incidents that coud be reported during congresses or specialized magazines and that could constitute new contraindications
- The MIDSLEEVE must be introduced with special attention in case of large hiatal hernia

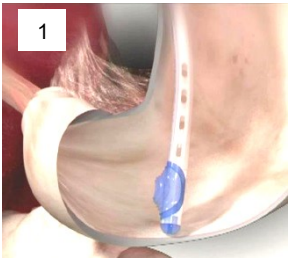
POSITIONNING MIDSLEEVE™ FOR GASTRIC CALIBRATION

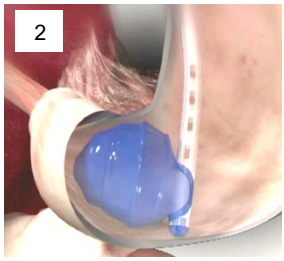
1. PRECAUTIONS TO APPLY BEFORE INSERTION

- Before inserting MIDSLEEVE®, check the operation of the balloon using a syringe, via the inflation valve.
- ⚠ **Completely deflate the balloon.**
- Lubricate the probe.

2. POSITIONING THE PROBE

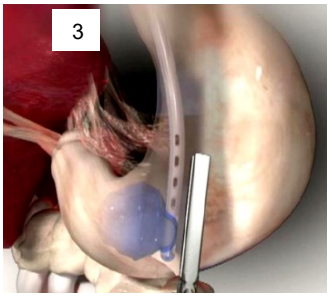
- Introduce the probe via the oral route, insertion tip first. The blue ridge must be placed so that it will be in contact with the small curvature of the stomach when the probe is in position, i.e. at three o'clock, where twelve o'clock is in line with the patient's lower incisors (opposite the right labial commissure).
- Lower the probe into the stomach.
- If necessary, connect the probe to a suction system to exsufflate the stomach.
- Disconnect the suction system.
- Withdraw the probe to the oesophageal position (20 to 30 cm from the dental arches) whilst the gastric dissection is taking place.
- When the dissection is finished, push the probe back down into the stomach under visual monitoring,

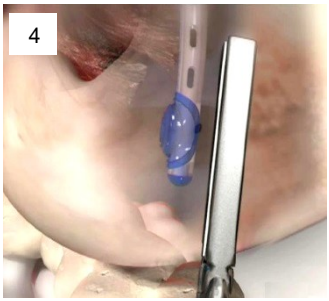


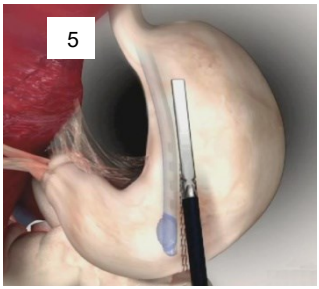


- Place the insertion tip of the probe in contact with the large curvature of the stomach (1).
- Check that the blue ridge is correctly positioned.
- Using a syringe filled with air or saline only, inflate the balloon to the volume chosen by the surgeon (typically between 10 cc and 50 cc). **It should inflate in the gastric antrum, towards the pylorus (2).**
- ⚠ **Never connect the valve of the MIDSLEEVE to anything other than a syringe filled with air or saline.**
- Inflate the probe balloon with either saline or air.
- **Never exceed 75 ml in the balloon.**
- If the balloon does not inflate in the right direction, deflate it, move the probe (ANESTHETIST AND/OR SURGEON using tweezers). Re-inflate the balloon

3. STAPLING







- Using the stapler but **without stapling**, identify the points defining the start of the stapling line (3).
- Deflate the balloon (4). If the balloon cannot deflate, perform a transgastric puncture of the balloon.
- ⚠ **Move the probe up by at least 3 to 4 cm before the first stapling** to ensure that the balloon or probe body is not caught in the stapler (4).
- **Replace the probe in the initial position, tip of the introducer up against the greater curvature.**
- Begin stapling.
- ⚠ **Move the probe 3 to 4 cm before each time you staple**, to avoid stapling the body or balloon of the probe and **replace the probe in the initial position, tip of the introducer up against the greater curvature (5)**.
- Use the body of the probe to determine the portion of stomach to be preserved. The exact volume and dimensions of the preserved portion are subject to the surgeon's judgement.
- 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 MIDSLEEVE™. If gastric mucosa is sucked into the drainage holes of the MIDSLEEVE, please immediately disconnect the MIDSLEEVE from the suction source to reposition the MIDSLEEVE 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.

4. LEAK TEST

- For suction to be applied, the probe must be deployed and its distal part must be placed in the gastric antrum, without being pressed against the stomach walls.
- At the end of the procedure, withdraw the probe.

REFERENCES:

(1) www.ifso.com, and more specifically:
- Candidate of obesity surgery: http://www.ifso.com/Index.aspx?id=Areyouacandidate
- Patient information for sleeve gastrectomy: http://www.ifso.com/sleeve-gastrectomy/

(2) https://www.has-sante.fr/portail/jcms/c_765529/en/obesity-surgery-in-adults

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 – Uden latex – Utan latex – Lateks içermez-本品不含有乳胶

لا يحتوي هذا المنتج على مادة اللاتكس – **عارى از لاتكس**

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Marquage CE depuis 2011
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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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