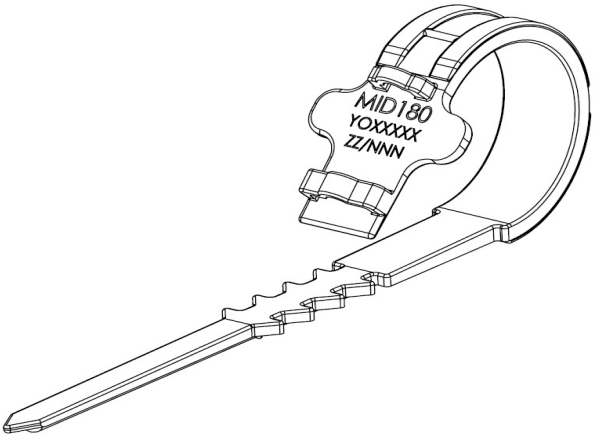
MIDCAL™

REF **MID180**



Patient leaflet (EN) : MIDCAL™ Gastric Calibration Ring

1. THE MEDICAL DEVICE

The surgical procedure that you are going to undergo or have undergone entails putting in place a MIDCAL™ implantable medical device, used in obesity surgery to calibrate a gastric pouch so it does not dilate, particularly with the so-called “banded by-pass” technique.

This document contains useful information for you. You should read this document and keep it in a safe place. You can also find it on the manufacturer's website, MID. If you have any questions, please ask your surgeon.

2. THE DEVICE AND ITS PURPOSE

The MIDCAL™ is a wide, flexible, pre-formed medical silicone ring that is inserted and closed around the gastric pouch to keep its size at a specified value (4 possible settings).

The references required to trace the device are shown on the card you have been given. If you have not been given this card, ask your surgeon.

3. WHO IS THE DEVICE INTENDED FOR?

The MIDCAL™ device is intended for use in bariatric surgery (obesity surgery) to calibrate a gastric pouch.
The target population consists of patients eligible for bariatric surgery in accordance with current recommendations.

Usually, only adult patients with a BMI of over 40 (or over 35 if there are significant comorbidities likely to be improved by the surgery), who have received appropriate medical care, may undergo this type of procedure, following a multidisciplinary assessment.

4. EXPECTED RESULTS / CLINICAL PERFORMANCE

Many publications have documented the effectiveness of the “banded by-pass” in terms of long-term weight loss. A recent meta-analysis of randomised studies comparing the banded by-pass with the non-banded by-pass showed a 5% gain in weight loss at the cost of a slight increase in upper digestive tract disorders (vomiting, reflux, a “blocked” feeling when eating), but no significant increase in complications (1).

5. ADVERSE EFFECTS

As well as classic post-operative complications of laparoscopy for obesity, as advised by your surgeon, adverse effects more specific to wrapping a silicone ring around the assembly may occur. Practitioners and patients should be aware of these.

- **Gastric erosion and intragastric migration:**

A calibration ring, a foreign body enclosing a segment of the digestive tract as close as possible to its wall, can erode the latter until it migrates more or less completely inside. The frequency of this complication is around 2% (2). Intra-gastric migration may manifest as food intolerance, insufficient weight loss (or weight regain), abdominal pain, digestive haemorrhage, or be discovered during endoscopy. The implanted device should be removed, preferably at a specialist centre.

- **Ring sliding:**

The risk of the calibration ring sliding appears very low. In a systematic review, it was assessed at 1.5% (2). If the calibration ring slides, it can cause symptoms of upper gastric obstruction: (vomiting, reflux, a “blocked” feeling when eating) which can lead to more or less total food intolerance. There may also be dilation of the pouch which may alter the gastric wall. Surgery is often required to reposition or remove the ring.

- **Obstructive stenosis:**

Stricture stenosis of the ring was found in fewer than 3% of the procedures identified in a systematic review (2). Stricture stenosis is manifested by a clinical picture of food intolerance (vomiting, reflux, “blocked” feeling when eating). It may require endoscopic dilation or even removal of the ring.

- **Infections:**

Apart from intra-gastric migration, infection of the calibration ring – which is rare and usually preventable – could be related to bacterial contamination, whatever the origin. This maintains chronic suppuration, which requires the device to be removed.

- **Upper digestive tract disorders:**

Upper digestive tract problems (vomiting, fluid or food build-up, a blocked feeling when eating) may occur without one of the complications mentioned above. These functional disorders are generally not very serious, usually episodic and often avoidable by strict compliance with dietary rules. However, in less than 3% of cases (2), the disorders may be more serious, leading to actual food intolerance, which may require the device to be removed. These disorders must be further investigated in a specialised setting to ensure that the patient is not suffering from one of the aforementioned complications.

- **Autoimmune diseases related to silicone:**

Although there is no scientific evidence to support a causal relationship between the manifestation of an autoimmune disease and the presence of a silicone implant, implantation of the MIDCAL™ device should be considered contraindicated in patients for whom the manifestation of an autoimmune disease event is suspected or proven. Similarly, the occurrence of symptoms suggestive of an autoimmune condition should lead, as a precaution, to the removal of the device.

6. SPECIAL WARNINGS AND PRECAUTIONS

If you are to undergo general anaesthesia or an upper endoscopy (gastroscopy), you must inform the anaesthetist and/or the endoscopist.
Modern medical imaging methods, including MRI, can be used in patients with MIDCAL™. However, the radiologist must be informed that the patient has this implant.

7. DEVICE LIFETIME

In view of certain regulatory constraints, the available data indicates a life span of 15 years (5 years of storage and 10 years implanted in the patient). However, the silicone it is made with has been implanted in another form around the stomach in patients for more than 20 years without any manifestations of intolerance or damage to the device. However, if any adverse effects occur after 10 years of implantation or there is a change to the therapeutic strategy, the ring may have to be removed by your surgeon. The removed devices must be returned to the manufacturer, MID, for investigation.
Non-compliance with dietary constraints and excessive tightening may increase the likelihood of certain adverse events and may affect its lifespan.

8. MONITORING AND FOLLOW-UP

All obesity surgery procedures require multidisciplinary care and regular follow-up in accordance with the recommendations of the competent authorities and/or learned societies in your place of residence. The result in terms of weight loss and digestive comfort depends to a large extent on compliance with dietary constraints and the quality of this monitoring, which is also intended to detect any complications or adverse effects inherent to the procedure or the implanted device.

More information on recommendations for the management of obesity can be consulted on the sites of international or national learned societies as well as on the site of national health authorities,
some examples of which are cited below:

- *HAS (French National Health Authority)*
- *ANZMOSS (Australian & New Zealand Metabolic and Obesity Surgery Society)*

9. BIOLOGICAL ASSESSMENT

a. Materials and substances included in the device

The MIDCAL™ implantable device is made of silicone loaded with barium sulphate. These components do not present any biological risks.
This product does not contain latex or phthalates.

b. Manufacturing residue that may present a risk for the patient

No health risks related to manufacturing residue has been identified by MID, which manufactures MIDCAL™.

⚠ Any serious incident with the MIDCAL™ must be communicated to MID and to the national competent authority TGA website: www.tga.gov.au.

References:

(1) *Shoar S, Khorgami Z, Brethauer SA, Aminian A. Banded versus non-banded Roux-en-Y gastric bypass: a systematic review and meta-analysis of randomized controlled trials. Surg Obes Relat Dis. 2019;15: 688-695.*

(2) *Buchwald H, Buchwald J. N. , McGlennon T. W. Systematic Review and Meta-analysis of Medium-Term Outcomes After Banded Roux-en-Y Gastric Bypass. Obes Surg 2014.*

CE 0459

Made in FRANCE

MEDICAL INNOVATION DEVELOPPEMENT SAS (MID SAS)
9, chemin du Jubin – 69570 Dardilly - FRANCE

Tel.: +33 (0)4 78 17 48 04 - Fax: +33 (0)4 72 82 91 23

E-mail: mid@mid-med.com
Patient leaflet website: www.mid-ifu.com