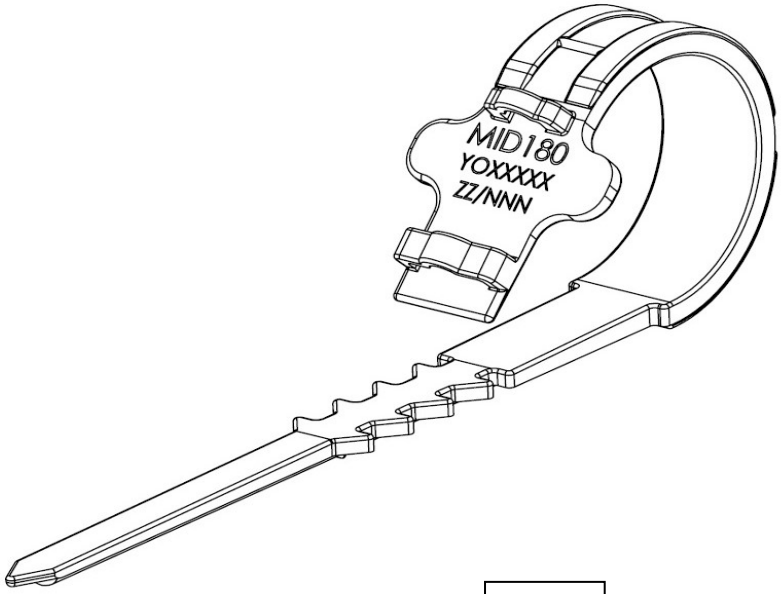
MIDCAL™



REF **MID 180**

CONTENTS

FOREWORD

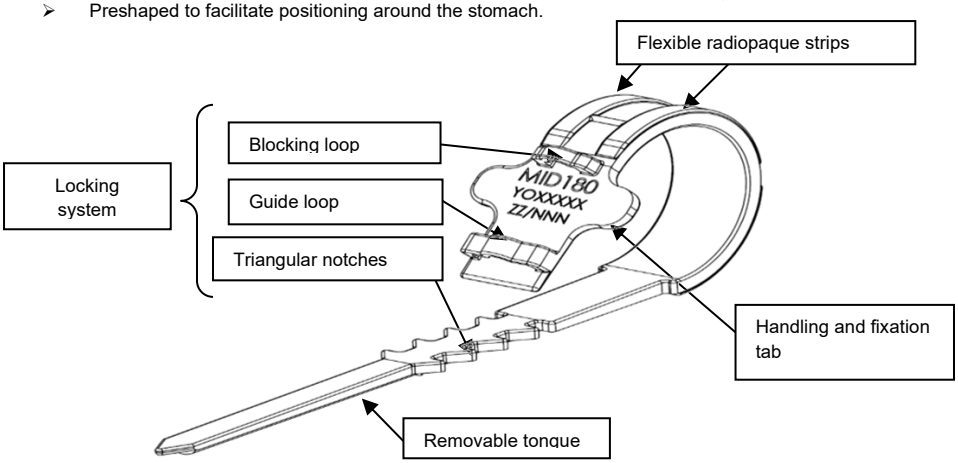
<u>Warning:</u> This sterile device intended for implantation in the human body, must be handled only by a surgeon or a qualified member of the surgical team.
<u>Warning:</u> Only practitioners experienced in obesity surgery can implant this medical device. Before any use, the practitioners must fully familiarise themselves with these instructions.
<u>Warning:</u> This medical device must be used in accordance with the current legislation in the country concerned.

The MIDCAL™ calibrated gastric ring is an implantable device for use in bariatric (weight loss) surgery to calibrate a gastric pouch, in order to reduce its size and/or avoid its expansion, particularly in the technique known as "banded bypass."

FEATURES OF THE MIDCAL™ CALIBRATED BAND

The main features of the MIDCAL™ are as follows:

- Made from medical grade silicone, suitable for long-term implantation,
- Radiopaque, partially due to strips impregnated with barium sulfate ($BaSO_4$),
- Features a removable tab designed to facilitate placement around the stomach,
- Adjustable, but non-inflatable, with the help of a closing mechanism that allows four (4) closed positions, corresponding to a respective band circumference of 65, 70, 75 and 80 mm, and holds the band to prevent it from twisting,
- Consisting of a flexible band especially designed to provide a surface with the most continuous contact possible with the stomach, and a band of almost constant thickness when closed due to the varying thickness of its profile,
- Designed so that it can be laparoscopically placed, it can be implanted through a 12 mm trocar,
- Preshaped to facilitate positioning around the stomach.



PRE-OPERATIVE ASSESSMENT

The multidisciplinary team caring for the patient is responsible for implementing the measures required by the current recommendations, and for performing the preoperative investigations required for the detection of any contraindications.

1. INDICATIONS:

The indication must be determined in accordance with current recommendations regarding the surgical management of obesity. Recommendations can vary slightly from one country to another, and are regularly

updated. In principle, only adult patients with a BMI > 40 (or > 35 if there is significant comorbidity likely to be improved by the surgery), who have received appropriate care, should undergo this type of procedure, following multidisciplinary assessment and discussion. For further information, consult the website of the *International Federation for the Surgery of Obesity and Metabolic Disorders*[(1)], *or the French National Authority for Health* (HAS) [(2)];

For every patient, the surgeon is responsible for evaluating the benefit/risk ratio of implanting the MIDCAL™. It is recommended that the evaluation be carried out at a multidisciplinary consultative meeting. The patient must be informed of other available treatments. Clear and detailed information on the device, particularly on how it works, and its complications and constraints, should be provided. MID makes communication materials available to physicians. It is recommended to have the patient sign a consent form.

Finally, before carrying out the procedure it is important to ensure that the patient will be able to modify his/her dietary habits and comply with regular and prolonged follow-up.

Placement of the MIDCAL™ gastric calibration ring is indicated as a first-line treatment, to be carried out at the same time as gastric bypass.

2. CONTRAINDICATIONS:

In addition to the usual contraindications to bariatric surgery, according to current recommendations [(1,2)], it should be borne in mind that the gastric ring must not be implanted in the following circumstances:

- intraperitoneal infection (peritonitis), either generalised or localised
- gastric wall of uncertain viability (ischaemic or inflammatory appearance)
- concomitant opening of a septic segment of the digestive tract
- suspected immuno-allergic reaction to silicone

For further information, consult the website of the *International Federation for the Surgery of Obesity and Metabolic Disorders*[(1)], *or the French National Authority for Health* (HAS) [(2)]

PRECAUTIONS

For optimal results, placement of the MIDCAL™ gastric calibration ring requires scrupulous compliance with the present instructions, and the patient must receive multidisciplinary care in accordance with recommendations. For further information, consult the website of the *International Federation for the Surgery of Obesity and Metabolic Disorders* (IFSO) [(1)], *or the French National Authority for Health* (HAS) [(2)]

1. QUALIFICATION OF THE SURGEON:

The surgeon must have training and experience in laparoscopic and bariatric surgery. In accordance with recommendations, she/he must have access to the resources needed for the selection and monitoring of patients, and for the diagnostic and therapeutic management of complications and adverse effects, in a multidisciplinary environment.

2. AUTO-IMMUNE DISEASE ASSOCIATED WITH SILICONE:

Observations of connective tissue diseases (scleroderma, lupus, polyarthritis, thyroiditis), or general manifestations suggestive of an autoimmune origin have been reported in patients with silicone implants (breast implants). Although there is no scientific evidence to support a cause-and-effect relationship between these manifestations and the presence of a silicone implant, the implantation of the MIDCAL™ device should be considered contraindicated for patients with this type of history. Similarly, the occurrence of symptoms suggestive of connective tissue disease or an autoimmune infection should lead to removal of the device as a precaution.

3. PATIENT PREPARATION:

Antibiotic prophylaxis to eliminate the cutaneous and digestive flora is recommended.

Antithrombotic prophylaxis, carried out according to current recommendations for obese patients, is recommended.

4. STORAGE AND HANDLING CONDITIONS:

Store the products in their original packaging in a dry, cool place, away from light, and avoid impacts when handling.

5. STERILISATION:

The MIDCAL™ is supplied sterile in double packaging. The double packaging should be checked to make sure it is intact before using the product, and the product should not be used if the packaging is damaged.

This product is single use, and must not be re-sterilised. Re-sterilisation would generate a risk of infection, and might affect the device, with no guarantee of sterility.

6. BECOMING OF EXPLANTED DEVICES:

Life time: the life tie of the device is 15 years (Shelf life: 5 years - Implant time: 10 years).
Available data has led to a recommendation to implant the device for 10 years. No scientific arguments justify the removal of the device after 10 years.
This should be confirmed in the follow-up care usually recommended for the patient.
Explanted devices should be returned to the distributor for expert analysis, in accordance with MID returned goods policy, with a brief summary of the observation, as part of the manufacturer's quality assurance policy. Please contact MID before returning any medical device.
Disposal of this device should not compromise the safety or health of patients, users or any other person until it has been completely destroyed. Disposal and destruction must be done in accordance with the current legislation in the country concerned.

7. COMPATABILITY WITH MODERN MEDICAL IMAGING METHODS:

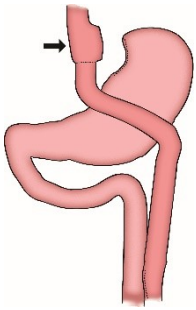
Modern medical imaging methods, including MRI, may be used for patients with a MIDCAL™. The radiologist should, however, be informed of its presence.

OPERATING TECHNIQUE

This chapter is not intended as a surgical technique manual. It is intended solely to describe the procedure for placing the MIDCAL™ calibrated band.

1. PREPARATION OF THE IMPLANTATION SITE:

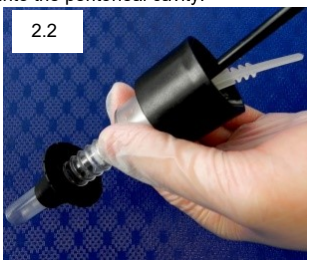
In the banded bypass technique, the calibratedring is generally positioned 1 to 2 cm above the gastrojejunal anastomosis, through a small window created in the lesser omentumat the level of the lesser curvature.
When this omental window is being made, care should be taken not to compromise the vasculature of the gastric pouch.



2. INTRODUCTION INTO THE ABDOMINAL CAVITY:

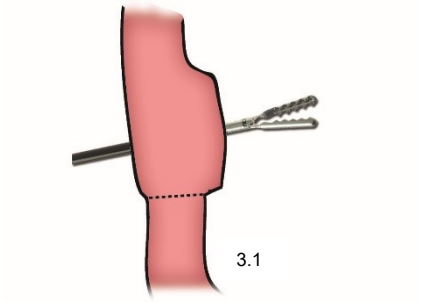
The wide end of the band, prelubricated by soaking in physiological saline, is grasped obliquely with an atraumatic grasper (figure 2.1).

The graspers and band are then introduced into a 12 mm trocar (figures 2.2. and 2.3), and the band is then released into the peritoneal cavity.

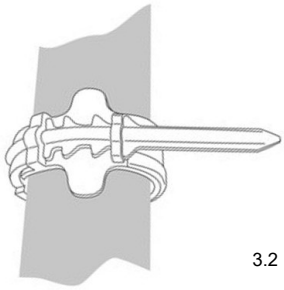


3. PLACEMENT OF THE MIDCAL™ AROUND THE GASTRIC POUCH:

The end of the removing tab is grasped with a grasper previously introduced through the window in the lesser omentum and positioned behind the gastric pouch (figure 3.1). Pulling on the graspers makes it possible to slide the band behind the stomach until the four triangular notches of the closing mechanism appear. The preformed band automatically positions itself in front of the gastric pouch (figure 3.2).



3.1



3.2

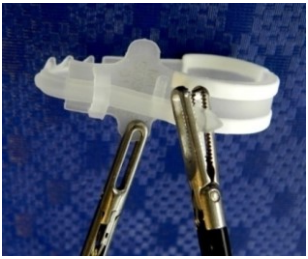
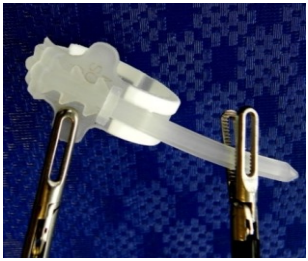
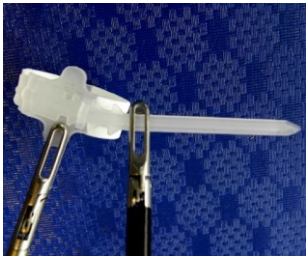
4. CLOSING AND LOCKING THE MIDCAL™:

The band is closed as shown in the figures below.

A gastric calibration tube must be used during the adjustment of the MIDCAL™

Throughout the closing procedure, the band must be held firmly with a grasper by one of the two handling and fixing tab provided for this purpose (figure 4.1).

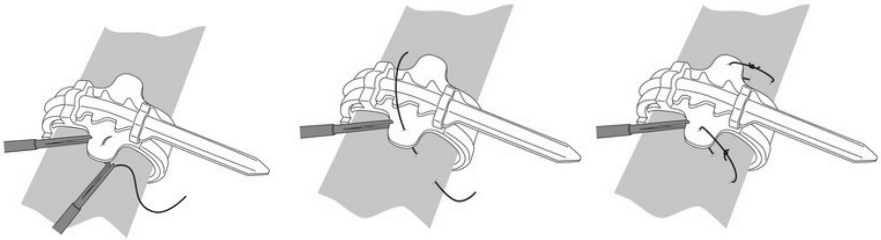
Introduce the removing tongue into the loops: guide loop followed by blocking loop (figure 4.1).

Pull on the removing tongue until the four triangular notches pass through the guide loop (photo 4.2).
Then lock the band by passing the first triangular notche through the blocking loop to obtain a 80 mm calibration.
By passing the second triangular notche through the blocking loop, a 75 mm calibration is obtained (photo 4.3).
By passing the third one through the blocking loop, a 70 mm calibration is obtained. And the last one, 65mm.

MIDCAL™ Ring should be loose around the pouch at time of banding.

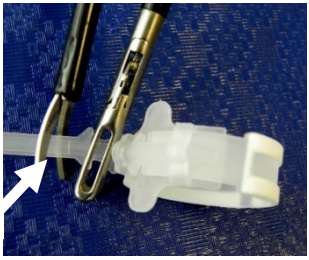
5. <u>SUTURING THE MIDCAL:</u> ONE STITCHING POINT ON EACH LATERAL TONGUES



6. REMOVING THE REMOVABLE TAB:

The removal tongue is cut off 10 mm beyond the first triangular notche, and is then withdrawn from the abdominal cavity through the 12 mm trocar.

CUT HERE



<u>CAUTION: The removable tongue must be withdrawn from the abdomen after cutting.</u>

INTRAOPERATIVE COMPLICATIONS

Intraoperative accidents are very rare, but must be known and kept in mind. They essentially involve perforation of the gastric wall as the band is being passed behind the pouch, especially when the banding is being carried out on a gastric pouch created in an earlier procedure. If there is any doubt, perforation should be checked for by

introducing coloured saline with the help of a gastric probe. Other surgical complications are rare and non-specific (injury to the viscera, especially the spleen and liver), but can be serious (haemorrhage, peritonitis), or even fatal.

POST-OPERATIVE CARE

Post-operative care and length of hospital stay should be appropriate for the context.
It is recommended to check that the patient can eat before authorising his/her return home. The need for a radiopaque transit check before the patient resumes eating is left to the surgeon's discretion.
Before returning home, the patient must again be instructed in the need to comply closely with the dietary rules, to be monitored regularly and to return for a consultation at the least problem, especially in the event of disabling dysphagia or regurgitation.
The results of procedure, in terms of weight loss and quality of life, substantially depend on the quality of monitoring. The patient must be regularly monitored to assess the progress of weight loss and digestive comfort, and to look for possible complications or adverse effects. It is recommended that the patient be seen at least four times in the first year, and then once or twice a year.
For further information, consult the website of the *International Federation for the Surgery of Obesity and Metabolic Disorders* (IFSO) *or the French National Authority for Health* (HAS).

POST-OPERATIVE COMPLICATIONS

Along with the usual complications following laparoscopic abdominal surgery, more specific complications can occur, and should be known to practitioners and patients.

1. GASTRIC EROSION AND INTRAGASTRIC MIGRATION:

A calibrated band, a foreign body surrounding a segment of the digestive tract and in close contact with its wall, can erode the latter until it migrates more or less completely to the inside. In a systematic review cited below (3), the overall prevalence of this complication was 2.3%. Intragastric migration can be manifested clinically by food intolerance, insufficient weight loss (or weight regain), abdominal pain or digestive haemorrhage, or may be discovered fortuitously. Diagnosis is based on gastro-oesophageal endoscopy.

Intragastric migration necessitates removal of the band, which may, in principle, be carried out endoscopically by a trained surgeon. However, referral to an expert centre is recommended.

2. SLIPPAGE OF THE BAND:

The risk of slippage of the calibration ring seems very low. In the systematic review cited above, it is estimated at 1.5% (3). As in gastroplasty by adjustable band, slippage of the calibrated band results in symptoms of upper gastric obstruction: regurgitation, reflux, and dysphagia, bordering on total food intolerance. It generates swelling of the pouch which can lead to ischaemic pain in the gastric wall. It is often necessary to resort to surgery to reposition or remove the ring.

3. OBSTRUCTIVE STENOSIS:

Obstructive stenosis due to narrowing at the band was found in 2.4% of patients recorded in a systematic review (3). Stenosis due to narrowing is manifested as symptoms of food intolerance (dysphagia, regurgitation, vomiting). It may require removal of the band where there is failure of endoscopic dilatation.

4. FOOD INTOLERANCE IN THE ABSENCE OF STENOSIS

Symptoms of food intolerance (dysphagia, regurgitation, vomiting) may appear in the absence of stenosis as detected by imaging and endoscopy, due solely to the presence of the ring.
Its prevalence, which is 2.8% overall in the systematic review cited above (3), is in fact highly variable depending on the diagnostic criteria, as well as the diameter of the ring and its constituent materials.
The medical and surgical teams responsible for monitoring patients must, however, remain extremely vigilant, and request radiological and endoscopic examinations, since these symptoms often indicate a complication.

5. INFECTIONS:

Other than intragastric migration, infection of the calibrated band, which is extremely rare and usually avoidable, might be associated with bacterial contamination, regardless of the source. It results in chronic suppuration, requiring removal of the device.

REFERENCES

(1) www.ifso.com , and more precisely:
- Candidate for weight loss surgery: http://www.ifso.com/Index.aspx?id=Areyouacandidate
- Patient information for gastric banding: http://www.ifso.com/index.aspx?id=gastric_banding

(2) http://www.has-sante.fr/portail/jcms/c_1002538/obesity-surgery-in-adults.

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

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