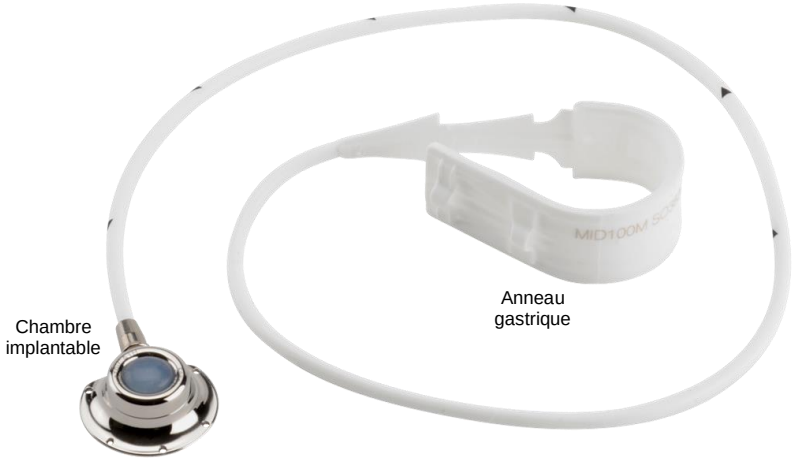
MID BAND™

REF **MID100-M**



Patient leaflet (EN) : Adjustable Gastric Band

1. THE MEDICAL DEVICE

MIDBAND™, reference MID100-M adjustable gastric band

To treat your obesity, a MIDBAND™ gastroplasty band will be or has been implanted in you.
This document provides you with useful information and should be read and kept. You can also find it on the following site: www.mid-ifu.com. If you have any questions, please ask your surgeon.

2. THE DEVICE AND ITS PURPOSE

The MIDBAND™ adjustable gastric band is an implantable device designed to induce significant weight loss in cases of morbid obesity by restricting the amount of food intake. It is a flexible, low pressure band, easily placed using laparoscopy around the upper part of the stomach. It has been specially designed to ensure that food intake is restricted effectively, while maintaining a high level of comfort and keeping complications and side effects to a minimum.

The device consists of a very flexible silicone band connected by a silicone catheter (small pipe) to a titanium housing implanted under the skin. The level of tightening can be adjusted through controlled instillation of saline solution. A little barium salt is also incorporated into the silicone.

3. WHO IS THE DEVICE FOR?

The MIBAND™ is intended for the surgical treatment of morbid obesity using an adjustable gastric band.
The target population consists of patients eligible for bariatric surgery in accordance with current recommendations. Usually only adult patients with a BMI greater than 40 (or greater than 35 if there are significant comorbidities likely to be improved by surgery), who have undergone appropriate medical treatment, may be eligible for this type of procedure after a multidisciplinary assessment.

4. EXPECTED RESULTS / CLINICAL PERFORMANCE

A prospective multi-centre French study[1] showed that the MIDBAND™ band resulted in 61% weight loss after 3 years, a significant reduction in the pathologies associated with obesity, and a significant improvement in the quality of life of patients.

In the event of insufficient weight loss and/or poor digestive comfort, multidisciplinary management is necessary to correct the cause and, if necessary, consider another type of procedure.

5. ADVERSE EFFECTS

In the above-mentioned study, complications related to the band itself were observed in less than 5% of patients.

- **Intragastric migration:**

In the study mentioned above, band migration through the gastric wall was observed in less than 0.5% of cases, probably due to its great flexibility and its low-pressure operation. Most band migrations through the gastric wall are due to excessive filling of the device.
Intragastric migration can manifest clinically as insufficient weight loss (or weight regain), device infection or abdominal pain. Referral to an expert centre is recommended.

- **Band slippage and dilation of the pouch:**

MIDBAND™ band slippage was observed in 2% of cases in the above study. It often results from excessive inflation of the device and/or a diet that does not respect the dietary constraints associated with modular band gastroplasty. If the band slides, upper gastric obstruction symptoms may be caused: vomiting, reflux of fluid or food, a sensation of blockage when eating or even when just drinking. These symptoms require a prompt medical consultation to deflate the device. In the event of failure or recurrence, surgery is usually required to reposition or remove the band.

- **Oesophageal motricity disorders:**

The presence of the band can worsen pre-existing oesophageal motricity disorders, and may even cause them. These functional disorders, observed in 2% of cases in the above-mentioned study, cause food discomfort such as blockages and/or vomiting, or even food intolerance. These symptoms require a consultation with a specialist to deflate the band and carry out additional examinations. If the diagnosis is confirmed, removing the band usually resolves the problems.

- **Mobility of the implanted chamber:**

This was seen in 3.3% of cases in the above study.
The mobility of the implanted chamber may cause discomfort (pain, toppling, difficulty in making adjustments) which can be corrected, if necessary, by a corrective procedure under local anaesthesia.

- **Infection:**

No cases were observed in the above-mentioned study. There is a risk of infection of the housing, but this can be kept down by strictly applying aseptic rules when adjusting the device. In the event of an infection, the implanted chamber should be removed and, as noted above, infection of the device may indicate intragastric migration, so an investigation should always be carried out.
Strictly localised infection of the implanted chamber will be treated with appropriate antibiotics. Subsequently, a new chamber may be moved to another site to continue the weight loss programme.

- **Leaks on the MIDBAND™ device:**

Leaks are very rare. However, they may occur, particularly on the band itself and at the connection between the catheter and the housing. Leakage may be suspected during an adjustment of the device and confirmed by a radiological control. Corrective surgery is usually required.

- **Upper gastrointestinal disorders:**

Apart from the complications mentioned above, episodic upper gastrointestinal disorders (vomiting, liquid or food reflux, a blockage sensation when eating) are frequently found if they are systematically investigated (nearly one patient in two in the prospective series mentioned above). However, they are generally not very serious and often preventable through strict compliance with dietary rules. Patients must learn these rules before the procedure is actually carried out, and must know to stop eating as soon as they feel full. These disorders must be further investigated in a specialised setting to ensure that none of the complications mentioned above has occurred. Complementary drug therapy may be useful. If the problems persist, the device should be deflated slightly.

- **Autoimmune diseases related to silicone:**

Although there is no scientific evidence to support a causal link between the manifestation of an autoimmune disease and the presence of a silicone implant, implanting a MIDBAND™ device should be considered contraindicated for patients with a suspected or proven autoimmune disease. Similarly, the occurrence of symptoms suggestive of an autoimmune disorder should lead, as a precaution, to the removal of the device.

6. SPECIAL WARNINGS AND PRECAUTIONS

As part of follow-up, if any unusual symptoms such as abdominal pain, acid reflux or vomiting, skin changes near the housing or unexpected weight gain, a surgeon should be consulted.
If the patient is to undergo general anaesthesia, you must notify the anaesthetist who may ask for the device to be deflated temporarily.
In the event of upper gastrointestinal endoscopy (gastroscopy), even without anaesthesia, the endoscopist must be warned and the device must be deflated in most cases.
However, modern medical imaging methods, including MRI, can be used in patients with MIDBAND™. However, the radiologist must be notified of the presence of the device.

7. DEVICE LIFE

In view of certain regulatory constraints, the available data leads to the conclusion that a 15-year shelf life of the device (5 years of shelf life and 10 years implanted in the patient) should be indicated. However, MIDBAND™ bands have been implanted in patients for more than 20 years without manifestations of intolerance or damage to the device. However, adverse effects or a change in therapeutic strategy may lead to the removal of the band. Removed devices should be returned to the distributor for analysis.
Non-compliance with dietary restrictions and device adjustment procedures (excessive inflation) may lead to certain adverse events and affect its lifespan. Inflation above 7 ml may cause the balloon to burst, and the device will have to be replaced.

8. MONITORING AND FOLLOW-UP

As with all obesity surgical procedures, modular band gastroplasty requires multidisciplinary management and regular follow-up according to 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 restrictions and the quality of this monitoring, which is also intended to detect any complications or adverse effects.

Adjustments to the degree of tightening must be decided on and carried out by the medical-surgical team in accordance with best practice, with the aim of using minimal inflation to achieve the desired weight loss while maintaining good digestive comfort. Inflation of the balloon must remain below 7 ml.

More information on recommendations for managing obesity can be found on the websites of international or national learned societies as well as on the website 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 EVALUATION

a. Materials and substances included in the device

The MIDBAND™ Implantable Device consists of silicone loaded with barium sulphate and titanium for the implantable chamber.
This product does not contain latex or phthalate.

b. Manufacturing residue that may pose a risk to the patient

No risk to the patient's health related to manufacturing residues has been identified by MID, which manufactures MIDBAND.

⚠ Any serious incident with the MIDBAND™ must be communicated to MID and to the competent authority in the country where the user/patient is living.

References

(1) *Gouillat C et al. – Prospective, Multicenter, 3-year Trial of Laparoscopic Adjustable Gastric Banding with the MIDBAND™ – OBES SURG (2012) 22:572-581 (Obesity Surgery)*

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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

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