

MID BANDTM

REF

MID100-M



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FOREWORD

Warning: This sterile device intended for implantation in the human body must only be handled by a surgeon or qualified operating theatre staff.

Warning: only experienced practitioners in obesity surgery can implant this medical device. Practitioners must fully familiarise themselves with these instructions before use.

Warning: Medical devices described in this instruction of use have to be used in accordance with local regulations.

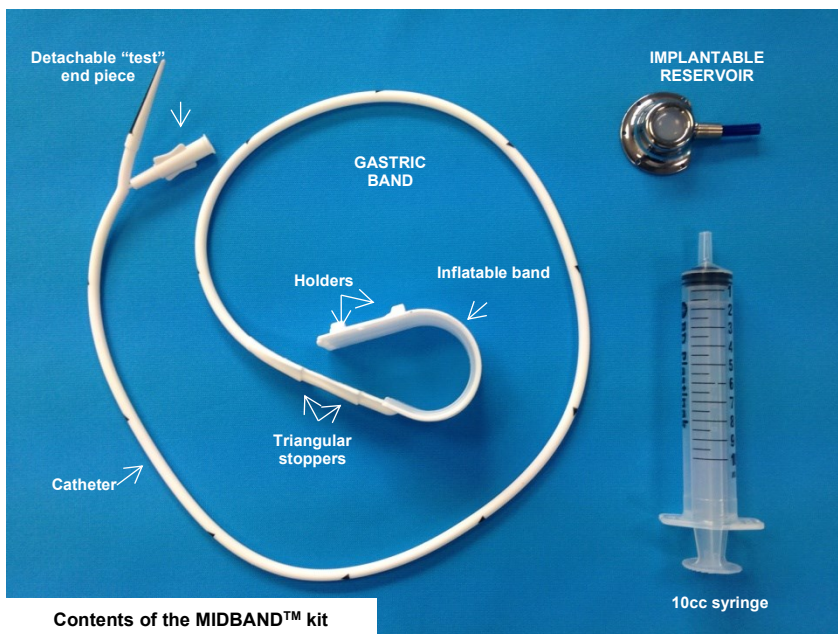
The MIDBAND™ adjustable gastric band is an implantable device intended to permit significant weight loss in the case of morbid obesity, by restricting the quantity of food ingested. The device features a flexible, low pressure ring that can easily be positioned by laparoscopy. It is specially designed to ensure efficient gastric restriction with high comfort and minimum complications and secondary effects.

1. CONTENT OF MIDBAND™ KIT

The kit contains the following elements (see images below):

- the adjustable band itself, comprising a balloon connected to a catheter
- an implantable reservoir
- a syringe

Note that the detachable “test” end piece connected to the catheter and the disposable tube connected to the implantable reservoir are to be removed before the device is implanted



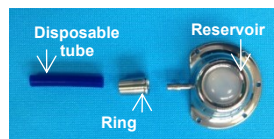
Contents of the MIDBAND™ kit



Holders: details



Triangular stoppers: details



Implantable reservoir: details

2. **MORBID OBESITY**

Morbid obesity is defined by a body mass index (BMI = weight / (size)²) in excess of 40 Kg/m² (or over 35 when combined with conditions associated to obesity). Morbid obesity alters quality of life, reduces life expectancy and is associated with many pathologies (comorbidities), including:

- Arterial hypertension
- Dyslipemia
- Sleep apnoea syndrome
- Articular pathologies
- Reactive depression
- Respiratory disorders
- Cardiac and cardio-vascular pathologies

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

3. **TREATING MORBID OBESITY**

Medical treatment of morbid obesity (dieting, physical exercise, other therapies, etc.) does not always produce satisfactory results over the long term. Correctly conducted surgical treatment can result in sustainable weight loss and the improvement – and often the disappearance – of comorbidities.

The main surgical methods used are gastroplasty using an adjustable band, gastric bypass, sleeve gastrectomy and biliopancreatic diversion.

The MIDBAND™ is used to perform gastroplasty with an adjustable band. This simple, fully reversible operation does not require digestive suture and is one of the most frequently performed in the world. It can produce a loss of excess weight in the region of 50-60%, recovery from or improvement in comorbidities and improved quality of life for the patient. Perioperative mortality is very low. Complications are rare and generally benign.

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

4. **FEATURES OF THE MIDBAND™ GASTRIC BAND**

The implantable device is made of silicone and titanium, with a small amount of barium sulphate. The product does not contain latex.

The MIDBAND™ is a band that:

- is highly flexible but inextensible,
- has no sharp edges,
- operates at low pressure,
- features a closure method that locks the band without additional sutures being required.

These features make it a band suitable for laparoscopy and the *pars flaccida* approach. They most certainly explain its excellent results in terms of weight loss and complications ⁽³⁾

The interior diameter of the band can be adjusted. Adjustment is done by adding or removing physiological saline via a subcutaneous implantable site, connected to the MIDBAND™ by the catheter.

Positioned on the upper part of the stomach, the MIDBAND™ causes a sensation of satiation very rapidly, after a few mouthfuls. It does not affect the absorption of food by the digestive system. Weight loss is brought about simply by reducing the amount of food eaten.

A recent multi-centric prospective study in France showed that the MIDBAND™ gastric band could produce a loss of excess weight up to 61%, a significant reduction of comorbidities and a significant improvement in patient quality of life ⁽³⁾

PRE-OPERATIVE EVALUATION

It is incumbent on the multi-disciplinary team responsible for the patient to take all measures imposed by applicable recommendations and to perform the necessary investigations to identify contraindications prior to the operation.

1. **INDICATIONS**

All indications must be stated in accordance with applicable recommendations concerning surgical intervention

on an obese patient. The recommendations may vary from one country to another and are regularly updated. In principle only adult patients with a BMI > 40 (or 35 if combined with significant comorbidities likely to improve with the surgical intervention), who have been treated under suitable medical supervision and after a multi-disciplinary evaluation, should be treated with this type of surgery. For more information, consult the website of the International Federation for the Surgery of Morbid Obesity and Metabolic Disorder (IFSO) ⁽¹⁾, or the website of the French Haute Autorité De Santé (HAS) ⁽²⁾

The surgeon is responsible for assessing the benefits and risks of the implantation of the MIDBAND™ gastric band for each patient.

The patient must be informed of other possible treatments. Clear and detailed information about the device, notably about how it functions, any complications and limitations, must be provided to the patient. To assist medical practitioners in communicating this information, MID provides informative brochures. It is recommended that the patient signs a consent form.

Lastly, prior to surgery, it is important to ensure that the patient will be capable of modifying their eating habits and to undergo regular, long term monitoring.

2. CONTRAINDICATIONS

The most common contraindications, possibly temporary, identified by the applicable recommendations are the following:

1. Patient not satisfying the specified conditions, in particular concerning the BMI, comorbidities, prior medical care, age, multi-disciplinary assessment,
2. Patients suffering from an unbalanced psychiatric disorder (reactive depression is not a contraindication),
3. Patients with alcohol-abuse or substance-abuse problems,
4. Cirrhosis with or without portal hypertension,
5. Pregnancy,
6. Patients incapable of limiting themselves to the dietary restrictions resulting from the intervention. This concerns patients presenting serious dietary behavioural problems (bulimia, compulsive eating),
7. Allergies (or supposed allergies) to the product materials,
8. Patients presenting a progressive or chronic infection that may represent a risk of bacterial contamination of the device,
9. Patients with a progressive or chronic serious condition (cancer, inflammatory illness, cardio or pulmonary disorders),
10. Patients whose condition requires a long term corticosteroid treatment,
11. Patients presenting an imbalanced endocrinal disorder,
12. Patients with emotional troubles or psychological characteristics that may make it impossible for them to respect the dietary constraints and monitoring,
13. Patients with a recognised diagnosis or pre-existent symptoms of an auto-immune disorder of conjunctive tissue such as lupus erythematosus or dermatosclerosis,
14. Patients presenting a congenital or acquired anomaly or pathology of the digestive tract, particularly of the stomach or the oesogastric junction (hiatal hernia, oesophageal or gastric varicose veins, ulcers, tumours, etc.),
15. Patients with a specific or non-specific inflammatory disorder of the gastro-intestinal tract, such as Crohn's disease.
16. An accidental perforation during oesogastric dissection must result in the abandonment of the implantation of the band.
17. Patients presenting contraindications for general anaesthetic.

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

PRECAUTIONS

To achieve optimal results, the implantation of the MIDBAND™ is conditional on the strict respect of the indications in this manual and the patient must be rigorously monitored in accordance with the recommendations. For more information, consult the website of the International Federation for the Surgery of Morbid Obesity and Metabolic Disorder (IFSO), or the website of the French Haute Autorité De Santé (HAS).^{1,2}

1. QUALIFICATION OF SURGEON

The surgeon must be trained and experienced in laparoscopic and bariatric surgery. He/she must have received specific training in implanting the MIDBAND™ gastric band before performing their first implantation alone. In accordance with official recommendations, the surgeon must have at their disposal, in a multi-disciplinary environment, the resources required to select and monitor patients and to handle the diagnosis and treatment of complications and undesirable side-effects.

2. AUTO-IMMUNE DISORDERS RELATED TO SILICONE

Cases of connective tissue diseases (dermatosclerosis, lupus, polyarthritis, thyroiditis) or general symptoms suggesting an auto-immune origin, have been reported for patients carrying a silicone implant (breast implants). Although no scientific proof exists to ascertain a cause and effect relationship between such symptoms and the presence of a silicone implant, the insertion of the MIDBAND™ device should be considered as contraindicated for patients with a history of such symptoms. Similarly, the occurrence of symptoms evoking connective tissue disease or auto-immune infection must result in the removal of the device for precautionary reasons.

3. USE OF THE MIDBAND™ SUBSEQUENT TO BARIATRIC SURGERY

If the MIDBAND™ is implanted subsequent to bariatric surgery, the presence of staples risks damaging the band itself. Insofar as it is possible, any staples that may come into contact with the band must be removed. As with any reworking surgery, the risks of complications, in particular of the migration of the band or infection are higher.

4. STORAGE CONDITIONS

Keep products in their original packaging in a dry, cool location, sheltered from light and impact.

5. STERILISATION

The MIDBAND™ is delivered sterile in double packaging. It is important to verify the integrity of the packaging before using the product and not to use any product if its packaging is damaged.

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

6. SUBSEQUENT USE OF DEVICES REMOVED

Life time: the life time 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

OPERATING TECHNIQUE

The MIDBAND™ has been designed to be implanted preferably by laparoscopic route, using the *pars flaccida* approach.

In this approach the band must be placed above the lesser sac of peritoneum, that is above the peritoneal reflection zone. This zone contains an adhesive fibrous tissue that prevents later slipping of the band. The dissection zone includes the arterial circle of the lesser gastric curvature and the pneumogastric nerve, which also reduces the risks of intra-gastric migration of the band.

1. PREPARATION OF THE PATIENT

A prophylactic antibiotic with a spectrum covering cutaneous and digestive germs is recommended. An anti-thrombotic prophylactic administered according to recommendations applicable to obese patients is also recommended.

2. INSTRUMENTS RECOMMENDED

The basic instrumentation is that used for hiatal region surgery. Taking into account the obesity of the patient and the characteristics of the band, it is recommended that you have at least one long atraumatic clamp and a 12 mm trocar.

A 37.5 Fr-calibration gastric probe (MIDSOND available from MID) may be useful. This probe features a balloon located 6 cm from the distal end, which can be inflated to 25 ml on the ventral side only, between the band and the cardia so as to create a pouch to hold the gastric reservoir created by the implantation of the band.

The surgeon must have an assistant and if possible an instrument operator.

3. OPERATING POSITION

The operating position is the same as for the anti-reflux procedure. The surgeon is positioned between the patient's legs, who is installed in a semi-seated position. The trocars are placed in a half circle 15 to 20 cm around the **xiphoid appendix**.

The 12 mm trocar is positioned in the right hypochondrium in the future position of the reservoir.

4. DISSECTION OF GASTROPHRENIC LIGAMENT

The greater tuberosity is moved outwards using a clamp in order to tense the gastrophrenic ligament near the angle of His. The gastrophrenic ligament is sectioned using an electric hook or scissor, just in the angle of the left pillar in contact with it. This sectioning releases the angle of His in relation to the pillar.

5. DISSECTION OF LESSER CURVATURE

The small omentum is sectioned in the middle of the *pars flaccida* distal to the gastric wall and the vascular circle of the lesser curvature in order to uncover the right pillar.

The peritoneal reflection is sectioned in front of the right pillar in its lower third, while the assistant lifts up the stomach using a clamp.

The clamp in the operator's left hand is progressively inserted into the fatty retroperitoneal tissue while under observation and exits close to the gap created earlier in front of the left pillar. The process must be done without forcing and the clamp must reappear at the angle of His covered with a thin film of avascular tissue. Even the slightest doubt at this time will require the procedure to be started again to prevent any risk of damaging the gastric wall.

6. VERIFICATION, INTRODUCTION AND POSITIONING OF THE MIDBAND™

CAUTION: You must always have a reserve device at hand in the event of an incident during the preparation or insertion of the band.

You must change gloves each time before using the MIDBAND™.

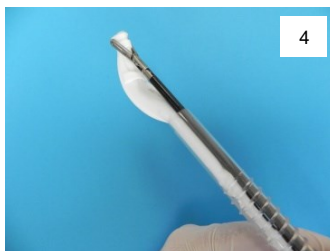
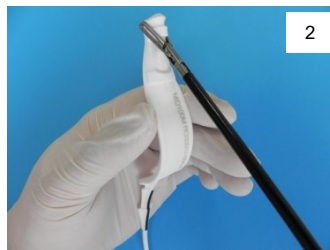
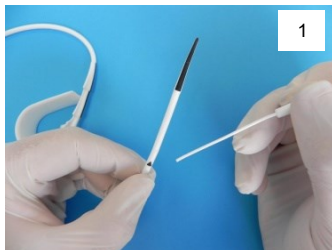
a) Leak test

The procedure for verifying the integrity of the device, in particular its leak tightness, is illustrated in figures 1 and 2.



Verify the leak tightness of the MIDBAND™ gastric band by injecting 7 cc of physiological saline. Connect the syringe to the detachable “test” end piece on the end of the catheter. No liquid should leave the band. The balloon should inflate evenly (1). Release the saline from the balloon by compressing it (2).

b) Preparing the MIDBAND™ for introduction in the abdominal cavity



Remove the detachable end piece before introducing the MIDBAND™ gastric band into the patient’s abdominal cavity (1).

Lubricate the band with physiological saline.

Using an endoscopic clamp, grasp the balloon at the end where the holders are located, in order to bend it in two. It must be clamped with the holders on the outside, so as not to damage the balloon (2).

Introduce the MIDBAND™ into the abdominal cavity using the 12 mm trocar for the instruments used by the right hand, taking care not to damage it when passing it through (3 and 4).

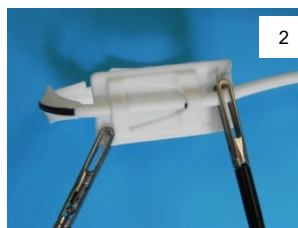
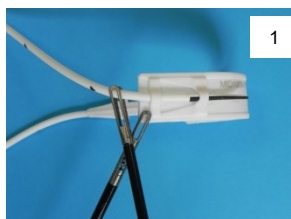
CAUTION:

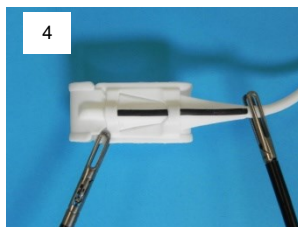
- **The detachable end piece must be removed before introducing the band into the abdominal cavity.**
- **When handling the MIDBAND™, do not use any instruments that could damage the device and never grasp the inflatable part.**

c) Closing the MIDBAND™

To position the band around the cardia, grasp the end of the catheter close to the angle of His using the clamp previously positioned in the retro-gastric area. Slide the catheter around to the rear of the stomach until the MIDBAND™ appears.

Close the band as shown in the figures below:





Insert the catheter into the holders (1). The band should be held firmly with a clamp on the rear corner throughout the closing procedure.

Pull the catheter until the first triangular stopper comes into contact with the rear holder (2).

Then pull both triangular stoppers through the rear holder (3).

Then fully close the MIDBAND™ gastric band by passing the first triangular stopper through the front holder (4).

d) Positioning the MIDBAND™

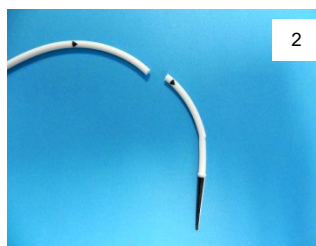
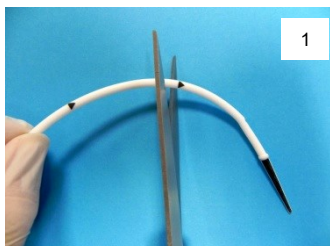
Once the MIDBAND™ is closed, the catheter must be pushed back towards the greater curvature and not be left near the lesser curvature. This manoeuvre enables easier access to the device in the event of further surgery and prevents overly-tight adhesences to the interior wall of the left hepatic lobe.

e) Suturing the MIDBAND™

It is recommended to fasten the band with a suture fixing the anterior wall of the fundus to the left pillar of the diaphragm.

f) Removal of connection catheter

Remove the end of the catheter from the abdominal cavity using the 12 mm trocar.



Once the band is in place, remove the end of the catheter from the abdominal cavity using the 12 mm trocar and cut off the end of the catheter just under the last arrow (1 and 2).

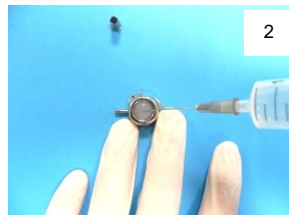
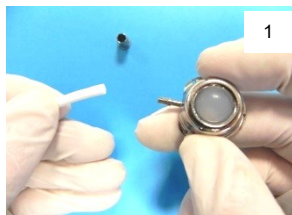
g) Connecting the catheter and positioning the implantable reservoir

Only use the implantable reservoir supplied in the MIDBAND™ kit.

Change gloves.

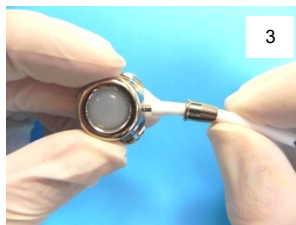
Create a subcutaneous pouch in the fatty tissue.

Connect the reservoir to the catheter as indicated in the picture.



Grasp the implantable reservoir in the blister pack and remove the ring and the disposable tube (1).

Check the reservoir functions correctly: pierce the membrane using the Huber needle and the syringe and inject a few cc of physiological saline. The liquid should escape via the connector (2).



Place the ring on the MIDBAND™ catheter. Pay attention to which way the ring is placed on the catheter: the thick end should be towards the end of the catheter. Introduce the reservoir connector into the catheter and leave 2-3 mm between the catheter and the reservoir (3).

Push the ring onto the connector. Hold and crimp the ring and catheter onto the reservoir.

Caution: The tube must be visible between the ring and the reservoir (4).

Place the reservoir in the pouch in the fatty tissue.

It is recommended to attach it, to avoid percutaneous manoeuvres in the event it turns over.

PEROPERATIVE COMPLICATIONS

Peroperative accidents are rare but must be recognised and searched for. Most accidents involve the perforation of the gastric wall when creating the retro-gastric tunnel. In the event of doubt, any perforations must be identified using an infusion of methylene blue via the gastric probe. Other surgical complications are rare and non-specific (visceral wounds, in particular splenic and hepatic) but can be serious (haemorrhage, peritonitis) even mortal.

POST-OPERATIVE CARE

Post-operative hospital care can be very short. The intervention can even be done as outpatient surgery if the regulations governing this type of treatment are respected.

Food can be eaten a few hours after the operation, in the form of a small, slowly-eaten meal that must be well-chewed and taken without liquids. It is recommended to check that the patient can feed him or herself suitably before returning home. The need for an x-ray inspection using an opaque transit before starting to take food again is left to the discretion of the surgeon.

Before returning home, the patient must once again receive instruction about the need to strictly respect the dietary rules, to be regularly monitored and to come back for a consultation at the first sign of any problems, especially in the event of dysphagia or incapacitating regurgitation.

The long term result of the intervention, in terms of weight loss and quality of life, largely depends on the quality of continued care ⁽³⁾. The patient must be regularly monitored to assess the progress in weight loss, digestive comfort and to identify any complications or undesirable side-effects. It is recommended to see the patient at least four times in the first year and then once or twice a year thereafter.

For more information, consult the website of the International Federation for the Surgery of Morbid Obesity and Metabolic Disorder (IFSO), or the website of the French Haute Autorité De Santé (HAS)

ADJUSTING THE MIDBAND™ DEVICE

Only **straight Huber-type needles** (22G) of the type must be used, connected with a 10 ml syringe. It is preferable to use physiological saline rather than an isotonic contrast solution (such as Iopamidol).

We recommend you do not make any adjustments until 2 to 3 months after the operation.

All adjustments of the device must be made in strictly aseptic conditions. The operator must wear sterile gloves after performing a surgery prep wash on their hands.

The patient's skin must be carefully disinfected.

The transcutaneous puncture is generally done easily, without systematic x-ray identification, when the reservoir has been placed in a subcutaneous pouch. Simply hold the reservoir between two fingers under the skin and puncture the centre of the membrane with the needle until the point reaches the bottom of the reservoir. Accidental puncture of the catheter close to the reservoir may cause a leak.

It is recommended to pump out all the contents of the device before each adjustment and to note the total quantity injected.

The injection is done under radiological control to ensure that the MIDBAND™ is not overly tight. The patient drinks an opaque solution showing up on the radiographic image while the operator checks the quantity of liquid injected. A passage of at least **a few millimetres** through the band is needed.

The maximum dose of liquid used to adjust the MIDBAND™ can vary between 5 and 7 ml. An optimal dose has not been defined. It depends on each patient and therefore implies rigorous monitoring. The aim is to achieve progressive weight loss with suitable digestive comfort.

You must avoid filling the band with more than 7 ml of solution so as not to create an ischemia in the gastric wall, which would increase the risk of migration.

The patient must be informed that the occurrence of dysphagia or regurgitation, in particular subsequent to an adjustment, must result in a timely consultation in order to deflate the device if necessary.

Full deflation of the device may also be necessary in certain circumstances, especially in the event of general anaesthetic or pregnancy.

POST-OPERATIVE COMPLICATIONS

Subsequent to gastroplasty using an adjustable band, complications are rare and generally not serious. They may nonetheless appear. Aside classic post-abdominal surgery complications, more specific problems may appear so practitioners and patients should be aware of them.

1. COMPLICATIONS CONCERNING THE DEVICE

In a recent multi-centric prospective study in France, after three years ⁽³⁾, complications concerning the device were observed in less than 9% of patients.

a) Complications concerning the band itself

In the study cited above, complications involving the band itself were observed in less than 5% of patients.

i. Intra-gastric migration

In the study mentioned above ⁽³⁾, the migration of the MIDBAND™ across the gastric wall was observed in less than 0.5% of cases, presumably due to its vast flexibility and its low pressure operation.³ Most migrations of the band across the gastric wall are due to the balloon being overly inflated.

Intra-gastric migration may manifest itself clinically by insufficient weight loss (or weight gain), an infection of the device or abdominal pains. The diagnosis relies on an oesogastric endoscopy.

Intra-gastric migration is a potentially serious complication that is difficult to manage. It imposes the removal of the band, which can sometimes be performed by endoscopic route by a trained operator. It is recommended that the patient uses an expert centre.

ii. Slipping of the band and dilation of pouch

The slipping of the MIDBAND™ gastric band was observed in 2% of cases in the study mentioned above. It provokes symptoms of upper gastric obstruction: regurgitation, reflux, dysphagia. It causes the pouch to dilate, which can cause ischemic suffering of the gastric wall. Treatment requires the device to be deflated rapidly. In the event this does not work or the symptoms return, surgical intervention is required to reposition or remove the band.

The risk of slipping is increased if the band is placed below the lesser sac of peritoneum and if the device is overly inflated.

iii. Oesophageal motricity problems

The presence of the band can aggravate pre-existent oesophageal motricity problems and even cause their appearance. These troubles provoke dysphasia and/or regurgitation bordering on food intolerance, with or without radiological dilation of the oesophagus. Diagnosis relies on the manometric exploration of the oesophagus. In general removal of the band causes the troubles to disappear. Such problems have only recently been observed and their frequency remains imprecise (2% in the study mentioned above).

b) Complications related to the reservoir

Complications were observed in 3.3% of cases in the study cited above ⁽³⁾.

The mobility of the reservoir may be at the origin of undesirable effects (pain, tilting, obstruction of adjustments) which may be easily corrected if needed by a small corrective intervention under local anaesthetic.

c) Other complications concerning the device

i. Infections

No cases were observed in the study cited above ⁽³⁾. The risk of infection of the reservoir exists but it can be reduced by respecting strict asepsis rules. In the event of infection, the reservoir must be withdrawn immediately

and the catheter must be abandoned in the peritoneal cavity. When removing the reservoir, the gastric band must be checked. As indicated above, an infection of the device may indicate intragastric migration, which must always be searched for.

An infection strictly localised to the reservoir will be treated with suitable antibiotic therapy. Later a new reservoir may be fitted in another site to continue the weight loss programme (replacement reservoirs are available from MID under reference MIDPORT). It is preferable to wait 2 months before fitting a new reservoir.

ii. Leaks from the MIDBAND™ device

Rare leaks may occur affecting the life of the device.

Particular attention should be paid to the MIDBAND™ balloon for which thickness is less than 1mm. Any handling with instruments risks damaging it and causing leaks. Handling must be done either by grasping the end of the catheter, or using the holders on the outside of the ring. The MIDBAND™ must be introduced into the abdomen using a 12 mm trocar to avoid any damage to the MIDBAND™. You must use **high quality trocars** to avoid damage to the MIDBAND™ when it is passed through.

A leak on the catheter end may be the result of a rupture of the catheter on the connection with the reservoir or an accidental puncture of the catheter when injecting fluid into the reservoir. Although the MIDBAND™ reservoir connection with the catheter is reinforced with a ring, misplaced movements during the puncture may perforate the catheter distal to the reservoir.

In all events the catheter should be filled under radiological inspection in order to detect the source of the leak.

A leak from the catheter entails an intervention to correct it. This intervention can be performed under local anaesthetic.

d) Other undesirable effects

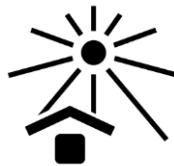
In addition to the complications mentioned above, episodic upper digestive tract troubles (regurgitation, gastro-oesophageal reflux, dysphagia) are frequently observed when systematically searched for (almost one patient out of two in the prospective series cited above)⁽³⁾. They are nonetheless not frequent in general and often avoidable by strictly respecting dietary rules. It is vital that patients learn these rules before the intervention takes place, especially to stop eating immediately when they perceive the sensation of being full. The use of a medical treatment such as proton pump inhibitors may be useful. If the troubles continue to hinder the patient it may be useful to deflate the device slightly.

2. COMPATIBILITY WITH MODERN MEDICAL IMAGING METHODS

Modern medical imaging methods including MRI scanners can be used on patients fitted with the MIDBAND™. The radiologist must nonetheless be alerted to its presence.

REFERENCES

- (1) www.ifso.com, and more specifically:
 - Candidate for obesity 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) 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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