

LABORATOIRE

endolis

end-ball



Intra-gastric Balloon System

Moving towards a healthier life!

INFORMATION AND PATIENT FOLLOW-UP

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INTRODUCTION

The “END BALL” intra-gastric balloon enables you to take advantage of a non-drug, non-surgical approach to losing weight. It is a “starter” which will give you a feeling of satiety.



By combining it with your motivation and a nutritional treatment you will enjoy greater weight loss and you will learn the principles of long-lasting success.



DESCRIPTION

end-ball

Principle: The intra-gastric balloon occupies a volume of the stomach causing a feeling of satiety and a reduction in food intake. The treatment must be combined with dietary and behavioural management.



- **Non chirurgical** : Insertion by an endoscopic procedure
- **Characteristics** : Non-sterile, single use only, biocompatible, radio-opaque filled with air and water
- **Expected weight loss** : The expected weight loss at 6 months is in the order of 34% of the excess weight, which corresponds to a weight loss of about 16 kg. There are currently no studies on the maintenance of weight loss over time after extraction of the balloon
- **Duration of treatment** : 6 months maximum
- **Average duration of the operation** :
 - Insertion 15 minutes (under general anaesthetic with or without intubation)
 - Extraction 15 minutes (under general anaesthetic with intubation)
- **Average duration of the hospitalisation** : As a day case or short hospitalisation for the insertion. As a day case for the extraction.

Indications: In adult patients presenting with a failure of conservative treatment (procedures linked to lifestyle, including diet, exercise and behavioural changes) and a drug treatment, with a BMI ≥ 28 kg / m²

- with or not the comorbid factors ((HT, Sleep apnea, diabetes, ...)
- before bariatric surgery
- in patients with a contraindication to bariatric surgery
- in the context of orthopedic surgery

- **Contraindications :**

The presence of one of the following conditions contraindicates the insertion of a balloon :

- Presence of several gastric balloons at the same time
- History of gastric surgery
- Digestive diseases or any inflammatory disease of the digestive tract: large hiatus hernias (> 5 cm) or hiatus hernias of ≤ 5 cm associated the symptoms of serious or chronic gastro-oesophageal reflux, active gastric and duodenal ulcers, severe oesophagitis of Grade III or IV (Savary-Miller classification) or Grade C or D (Los Angeles classification), cancer, Crohn's disease or any other digestive tract lesion which could bleed, pyloric stenosis and abnormalities in the structure of the digestive tract, particularly of the oesophagus or pharynx likely to obstruct the passage of a catheter and/or an endoscope.
- Diseases that are life-threatening in the short and medium term
- Severe cognitive or mental disorders likely to disturb the patient's comprehension or prevent him/her from attending visits for follow-up and withdrawal of the device after 6 months
- Severe, un stabilised eating disorders
- Alcoholism, drug addiction
- Treatment with antiplatelet drugs or non-steroidal anti-inflammatories in the absence of treatment with antisecretory drugs
- Anticoagulants
- Foreseeable inability of the patient to participate in a prolonged medical follow-up
- Absence of previously identified medical treatment
- Pregnancy, desire to be pregnant during treatment with the balloon, breastfeeding
- Severe liver disease (liver failure or cirrhosis)
- Haemostasis disorder
- Infection with *Helicobacter pylori*.
- Treatment by serotonergic drugs
- Patients presenting with a known or suspected allergic reaction to the materials making up the gastric balloon.
- Any other illness which would not allow an elective endoscopy such as precarious general state of health or history and/or symptoms of serious kidney, liver, heart and/or lung disease.

Some of these contraindications may be temporary

COMPLICATIONS

Principal complications:

Complications related to balloon deployment or removal:

Above and beyond complications due to the upper digestive tract endoscopy (perforation or bleeding, bronchial inhalation as a result of gastric reflux, arrhythmia) or the anaesthetic, other complications are specifically associated with deployment and extraction of the balloon:

- Damage to the pharynx or oesophagus,
- Damage to the stomach wall,
- Perforation of the oesophagus, duodenum, ostium cardiacum or stomach wall if the balloon is in the wrong place when it is inflated.

Mechanical complications caused by the balloon:

- The weight of the liquid-filled balloon can act on ulcers in the stomach wall to cause frank perforation, a life-threatening situation that requires emergency surgery.
- The digestive tract can become obstructed as a result of migration of an insufficiently inflated or partially deflated balloon; obstruction of the gut is possible as is gastric obstruction if the balloon gets lodged in the pyloric antrum: this will sometimes require surgical repair.

Such complications are far more likely if the maximum time frame of six months is exceeded.

- The literature reports a risk of spontaneous hyperinflation due to the generation of gas inside the balloon.
- Acute pancreatitis is possible if the balloon exerts mechanical pressure on the organ across the stomach wall.

COMPLICATIONS

Functional complications (side effects):

Insertion of an intra-gastric balloon is sometimes accompanied in the early days by gastric:

- Heaviness/weight in the stomach, fatigue, pain, gastric pain, abdominal pain, nausea and vomiting which normally improves in 2 to 7 days
- Symptoms of gastro-oesophageal reflux
- Gastroparesis which could be accompanied by abdominal pains and vomiting
- Gastro-duodenitis

These disorders may be corrected by suitable drug treatment (anti-secretory agents, anti-emetics, antacids). Sometimes vomiting persists necessitating premature removal of the balloon.

Metabolic complications:

These result from uncontrolled or neglected vomiting which can be the cause of dehydration, metabolic alkalosis, hypokalemia, and functional renal failure. Hypokalemia can be responsible for serious cardiac rhythm disorders with a risk to life.

Failures:

The absence or refusal of dietary treatment concomitant with the placement of an intragastric balloon will compromise the result in terms of weight loss. Similarly, the risk of regaining weight some time after the removal of the intragastric balloon becomes higher if the obesity is of long date and severe.

In addition, adverse events linked to weight loss can occur, with harmful consequences for health.

There is a risk of premature expulsion of the balloon by vomiting

- **Restriction of activity** : It is strictly forbidden for the patient to go scuba diving or fly in an unpressurised aircraft. Practising combat or extreme sports is also not recommended.

THE PROGRAMME

Before the procedure :

Overall management within a multi-disciplinary team liaising with the attending physician. This team is made up of :

- A gastroenterologist: He inserts and extracts the balloon and supports you throughout the treatment
- A nutritionist, endocrinologist or dietician: They recommend a formula suitable for your situation after considering your eating habits
- A psychiatrist or psychologist: They assess and treat eating disorders
- And an intensive care anaesthetist: He monitors all the body functions throughout the balloon insertion and extraction procedures.



You should be informed of the advantages and disadvantages of the balloon, of the obligation to extract the balloon after 6 months, of the necessity of a multi-disciplinary treatment and a long-term follow-up.

Patients must be advised to use contraception.

The decision to insert the balloon must be taken after discussion and deliberation by the multi-disciplinary team.

THE PROGRAMME

Insertion :

- under general anaesthetic with or without tracheal intubation
- under endoscopic control
- in the endoscopy theatre
- with equipment for monitoring vital and respiratory functions
- by professionals who have received specific training

After insertion :

- you will receive advice on suitable progressive nutritional management
- you will be prescribed anti-secretory agents, anti-emetics, anti-spasmodics and/or analgesics
- a serum electrolyte and a creatinaemia test (3rd day) will be performed
- consultation with a member of the multi-disciplinary team every 4 to 6 weeks
- therapeutic education programme implemented with the multi-disciplinary team before the procedure and continued afterwards
- you should be informed of the alarm signals, complications, the follow-up methods, the dietary and behavioural treatment

INSTRUCTIONS TO BE OBSERVED AFTER INSERTION OF THE BALLOON



Eat slowly in a calm atmosphere chewing the food.

Reduce food intake by using small plates

If you experience acid liquid reflux or bloating stop eating

Fraction food into three meals and 1 snack

Avoid nibbling

Drink at least a liter and a half of water daily

Do not drink and eat at the same time. A glass of water half an hour before a meal and one to two glasses of water half an hour after the meal are useful for the purpose of rehydrating yourself and particularly cleaning the balloon. This avoids disagreeable burping which is linked to the stagnation of food around the balloon.

Avoid fizzy drinks. Very strong tea and coffee are also not recommended

Do not smoke

Do not have your evening meal too late. Wait at least two hours before going to bed.

Intensify physical activity. Walk for at least 15 minutes a day

PHYSICAL ACTIVITY



Restarting physical activity is very important because this enables you to stabilize weight loss.

This restart should be progressive.

The more weight you lose, the easier this will seem.

Profit from this to increase the duration of your physical activity.

The first month : progressive restarting of physical activity. As the simplest activity is walking : get off public transport one station before your destination, or park several hundred metres from your work place to start with, and then increase the distance progressively.

Recommendation: Buy a pedometer in a sports shop and try to take 10,000 to 12,000 steps a day.

After the first month : you can restart any sport.

FOOD HYGIENE RECOMMENDATION



- drink 1,5 l of water a day
- to preserve the vitamins and minerals preferably cook using steam
- use a list of equivalents and a table of food calorie values to vary your meals
- use spices and seasonings to season your preparations and avoid using salt (lemon juice, cumin, pepper, curry powder, paprika, chives, parsley, etc.)

Do not miss a meal: breakfast, lunch and dinner are necessary
However, you can add 1 snack in the afternoon
Avoid nibbling!



QUESTIONS / ANSWERS



How many kg will I lose with the balloon?

The balloon makes it possible to lose between 10 kg and 25 kg in 6 months if the nutritional and behavioural treatments are combined. Continuation of this treatment makes it possible to continue to lose weight after the balloon is extracted

Will I regain the weight after the balloon is extracted?

Continuation of the nutritional and behavioural follow-up makes it possible to avoid regaining weight after the balloon is extracted. You do not change your eating habits in 6 months. Stopping treatment after extraction exposes you to the yo-yo effect.

Why must the balloon be extracted after 6 months?

Because the stomach adapts to the balloon after 6 months and it no longer causes a feeling of satiety.

Can a second balloon be inserted if you have not lost the desired weight during the 6 months?

Yes, after a minimum of 6 weeks so that the stomach is once again sensitive to the effect of the balloon.

How will I eat with the balloon?

Diet is normal several days after insertion of a balloon. The feeling of rapid satiety makes it possible to reduce the quantity ingested and to follow the dietary changes recommended by the nutritionist.

Will I be ill after insertion of the balloon?

Spasms, vomiting, and acid reflux are frequent in the 3 days following insertion of the balloon. A drug treatment will be prescribed by your doctor to reduce these side effects. It is possible you will have sick leave prescribed. Sometimes the symptoms may last a week and are sometimes treated by a short hospitalisation. In rare cases the balloon has to be extracted for intolerance.

Is it possible to be pregnant with a gastric balloon?

Pregnancy is contraindicated with the treatment. So contraception is prescribed for sexually active women.

Will I feel the balloon in my stomach?

You will feel discomfort in the early days. After that the main feeling created by the balloon will be satiety.

How long does it take to recover after insertion of the balloon?

Plan at least 3 days' rest to recover after the operation. Going back to work depends on the ability of your body to adapt to the balloon.

What are the differences in weight loss compared with other slimming programmes?

You can expect to lose more weight with the intra-gastric balloon. Given that the balloon provides a feeling of satiety you will be more able to control what you eat.

Does the balloon limit activities?

You must not plan any significant activity in the first week. Once your body has adapted to the balloon you can restart your usual activities. Starting a programme of physical activity is strongly recommended to improve your chances of success.

What happens if the balloon leaks?

You will observe a change in the colour of your urine (blue/green). Although rare this situation can be serious. If you notice a change in the colour of your urine you must ring your doctor immediately. He can then extract it easily by endoscopy. Conversely, if you delay informing your doctor, there is a risk of the completely deflated balloon migrating into the intestine and being evacuated by the natural route. In the worst case the balloon will cause an intestinal obstruction requiring surgery if extraction is impossible by an endoscopic approach.

Do I need to take part in follow-up visits to succeed?

The intra-gastric balloon is not a magic pill but a tool intended to help you change your lifestyle. By taking part in the programme you will have the advantage of the necessary training and support to change your habits and increase your chance of long-term success.

Are there dietary restrictions?

There are no dietary restrictions but you won't want to eat as much as you usually do.

How is the intra-gastric balloon extracted?

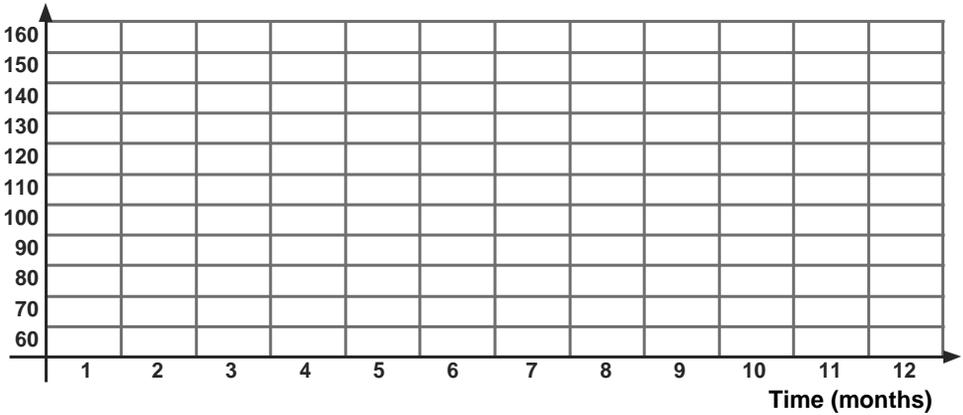
The intra-gastric balloon is extracted in the same way as it was introduced, i.e. via the mouth. This 15-minute procedure is carried out under anaesthetic.

FOLLOW-UP

Weight monitoring curve :

(Put the exact value in the box)

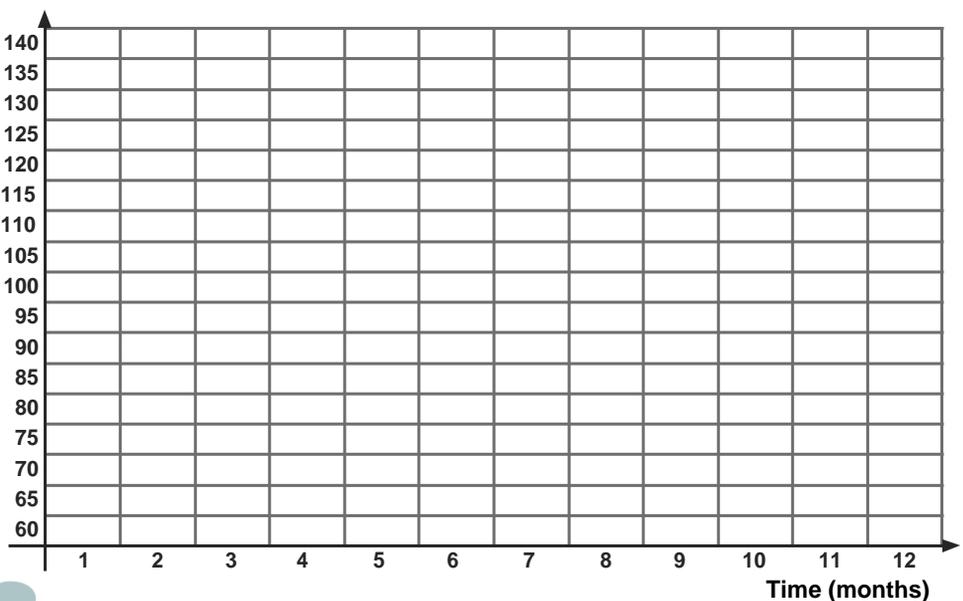
Weight (kg)



Waist measurement monitoring curve :

(Put the exact value in the box)

Waist measurement (cm)

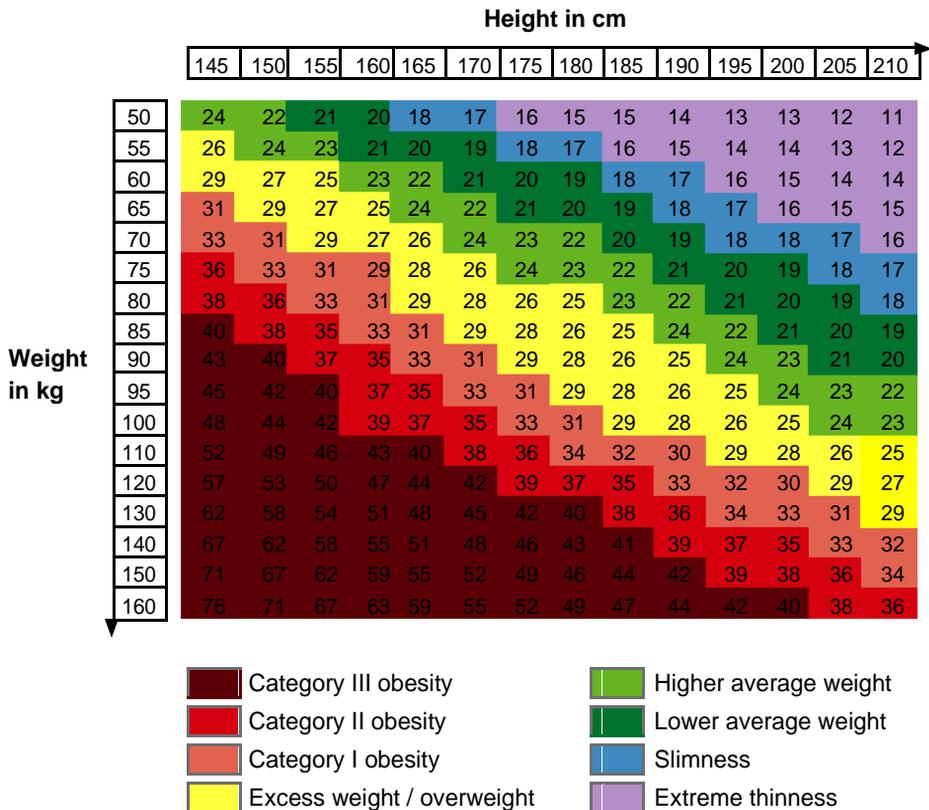


BODY MASS INDEX (BMI)

TABLE

The Body Mass Index (**BMI**) makes it possible to estimate the excess fat in the body and define corpulence.

The more the BMI increases the greater the risks linked to obesity.



LABORATOIRE
endalis

1 Allée des Tilleuls
69530 Brignais - France
Tel +33 (0)4 37 57 57 00
www.endalis.com
contact@endalis.com