LABORATOIRE endalis

end-ball

Intragastric Balloon System
Medical Device

ENDT110

INSTRUCTIONS FOR USE – INS30 v10- 2022-06-30

BEFORE USING THE PRODUCT
PLEASE READ THE INFORMATION IN THESE INSTRUCTIONS FOR USE CAREFULLY

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Unique registration number (SRN): FR-MF-000009349 (manufacturer) and FR-PR-000009350 (assembler)

MADE FR

CE 0459

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1 IMPORTANT

- The information below is generalised. Each patient must be assessed individually for treatment with the end-ball® intragastric balloon on the basis of a medical opinion issued by a qualified bariatric medical team.
- Each doctor and patient should assess the risks associated with endoscopy and intragastric balloons and the possible advantage of temporary treatment for weight loss before the use of end-ball®.
- The placement and extraction of an intragastric balloon requires specific training in these techniques.
- The practitioner must be experienced in endoscopic techniques.
- The anaesthesia and the endoscopy must be compliant with the procedure applied in the health establishment.
- The preparation of the patient for the endoscopy must be compliant with the procedure applied in the health establishment.
- The intragastric balloon must be filled with a minimum of 400 ml (air and isotonic saline solution (= physiological saline)) to allow complete deployment. The total recommended volume is 150 ml air plus 500 ml saline solution with methylene blue (balloon deflation marker, used in accordance with good hospital practice), i.e. a total volume of 650 ml. In accordance with our clinical data, the balloon may be inflated with a minimum total volume of 400 ml and a maximum total volume of 700 ml.
- The balloon must be removed after 6 months.
- Any balloon damaged (deterioration, leak or contamination) before placement must be returned to ENDALIS® with a note explaining the problem.

Any serious incident which occurs related to the device must be notified to the legal manufacturer, ENDALIS, and the local Competent Authority of the state in which the user and/or the patient is established.

You can contact ENDALIS at the following address: **contact@endalis.com**

CE **0459** Endalis declares that the device complies with Directive 93/42/EC. CE marking has been approved by a Notified Body, GMED, and the device has been marketed since 2010.

2 INFORMATION TO BE GIVEN TO THE PATIENT

The insertion of an intragastic balloon is an optional procedure; the patient must be completely informed of the benefit/risk ratio. It is incumbent upon the doctor to inform the patient of the warnings, precautions and adverse events listed in this document. The doctor should also warn the patient that serious adverse reactions may require an early withdrawal of the balloon. The doctor should inform the patient that any serious incident which occurs relating to the device must be notified to the legal manufacturer, ENDALIS, and the local Competent Authority of the state in which the user and/or patient is established. The doctor must give the patient a “patient card” when the intragastric balloon is inserted.

3 PRESENTATION OF THE MEDICAL DEVICE

end-ball® is a Class IIb medical device in compliance with Directive 93/42/EC, and CE marked since 2010.
end-ball® is a temporary, non-surgical intragastric balloon system for the treatment of obesity in adults.

Our device presents a suitable solution at the service of experienced gastroenterologists, who wish to offer a solution to obese patients. The purpose of the technical innovations of this device is to improve the patients’ quality of life while reducing the risks linked to this type of device.
The operation involves filling a balloon in the stomach with air and isotonic saline solution (= physiological saline). The volume taken up encourages the feeling of satiety and weight loss. After inflation, this balloon acts as a dead space.

4 DESTINATION OF THE MEDICAL DEVICE

4.1 Indications

The intragastric balloon is intended for adults. It is a temporary, non-surgical device, the duration of use for which is less than or equal to 6 months. It is intended to allow weight loss when a monitored slimming programme has not been sufficient.

The indications are:
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/m^2 :

- With or without comorbidity factors (HBP, SAS, diabetes, etc.)
- Before bariatric surgery
- In subjects presenting a contraindication to bariatric surgery
- In the context of orthopaedic surgery.

4.2 Target population

The end-ball® intragastric balloon is intended to be used in adult patients presenting with a failure of conservative treatment (procedures linked to lifestyle, including nutrition, exercise and behavioural changes) and a drug treatment, with a BMI ≥ 28 kg/m$^{2.}$

4.3 Users

The end-ball® intragastric balloon is intended to be used by health professionals who are competent in gastroenterology and experienced in endoscopy techniques.

4.4 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, unstabilised 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.

4.5 Duration of implantation

The end-ball® intragastric balloon is intended to be implanted for 6 months. It MUST be removed at the end of this period or before.

4.6 Removal of the intragastric balloon

Balloon removal is generally indicated due to:

- Reaching the end of its recommended placement period (6 months) The studies performed on the end-ball® intragastric balloon support its safety and efficacy solely for a period of 6 months.
- The occurrence of a complication: gastric perforation, erosion of a gastric ulcer, intestinal obstruction, deflation and migration of the balloon.
- Intolerance to the balloon, particularly due to vomiting or persistent abdominal pains.
- Incorrect positioning of the balloon in the stomach (balloon blocked in the antrum).
- Abnormal appearance of the balloon (bag not under tension, balloon withered, etc.)

5 CLINICAL BENEFIT/PERFORMANCE

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. Currently there are no studies on weight loss maintenance after the balloon has been extracted.

The end-ball® medical device aims to cause weight loss and improve comorbidities and the quality of life of patients who are overweight and obese, whilst reducing the risks linked to the device.

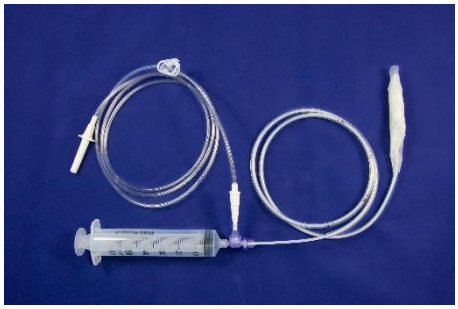
The rate of early removal is between 4 and 6%.

6 PREREQUISITE BEFORE USE AND INSTRUCTIONS FOR USE

For the **preparation**, **placement** and **extraction** of the end-ball® intragastric balloon, referring to the **User manual** attached to these Instructions for use is recommended.

7 TECHNICAL CHARACTERISTICS

7.1 Technical description



This **NON-STERILE, SINGLE USE** device includes:

1. An ENDT110 intra-gastric balloon system:
   - An intragastric balloon (radiopaque), a single polyurethane pouch connected to an introduction system.
   - An introduction system

2. Accessories (packaged separately):
   - 1 **STERILE, SINGLE USE** 50 ml syringe
   - A **SINGLE USE** ENDAC01 filling system
   - 1 **SINGLE USE** ENDAC03[1] extraction kit composed of:
     - ❖ 1 **STERILE** hollow drainage needle (sclerosis type), Reference AS264106
     - ❖ 1 **NON-STERILE** universal double taper connector for the connection between the aspiration and the ENDAC02 drainage needle
     - ❖ 1 pair of **STERILE** extraction forceps (with hooks), VIPER- Reference AS2290718

The balloon and its accessories are **SINGLE USE ONLY**:

[1] 50 ml syringe instructions: no associated instructions from the regulatory manufacturer
Instructions for hollow drainage needle, Reference AS264106 and extraction forceps, and Reference AS2290718: instructions from the regulatory manufacturer (PRINCE MEDICAL)

- To reduce the risks of cross-contamination, infection, etc.
- To achieve its performances safely and efficiently (insertion of the balloon);
- To simplify its use for users (no cleaning, disinfection and sterilisation procedures to be implemented by users);
- The balloon is pierced during the extraction.

ENDALIS® has not demonstrated the conformity of its device in the case of re-use with or without decontamination of the device with the basic requirements of Directive 93/42/EEC and its amendment 2007/47/EEC. Consequently, the user exposes himself to serious risks if he re-uses this single use device or tries to decontaminate this device (risk of contamination, deflation of the balloon, risk of intestinal obstruction, surgical operation, deterioration of the balloon, etc.).

Components not supplied:

- Endoscope
- Lubricating gel
- STERILE isotonic saline solution
- Methylene blue

7.2 Characteristics

7.2.1 ENDT110 Balloon

Polyurethane balloon, single pouch.
Size of the empty balloon: 110 mm flat disc.
The balloon can withstand a minimum total volume of 400 ml and a maximum total volume of 700 ml of isotonic saline solution (= physiological saline) and air.

7.2.2 Biocompatibility

The materials in the composition of this device (see Table 1) have been tested in compliance with the international standard, ISO 10993, concerning the biological evaluation of medical devices. The end-ball® intragastric balloon is biocompatible with the human body in accordance with the standard, ISO 10993. The risk associated with substances that could be released by the intragastric balloon and its introduction system has been assessed and is considered to be low following the toxicological assessment performed on the device.
The intragastric balloon is free from latex, phthalate and substances said to be CMR (carcinogenic, mutagenic, reprotoxic).

Table 1 - Materials in the end-ball® intragastric balloon system

Gastric balloon		Polyurethane
Balloon valve		Silicone elastomer
		Polyurethane
Introduction system	**Positioner**	Silicone
	PVC sheath	Polyvinyl chloride
	Tube	High density polyethylene (97%) Low density polyethylene (3%)

7.2.3 Packaging

The ENDT110 intragastric balloon is supplied clean and NON-STERILE, packaged in a heat-sealed peelable sachet and packed in a cardboard case.
The accessories are packaged in a heat-sealed peelable pouch or a plastic sachet.
The balloon and its accessories are accompanied by the following documents:

- Instructions for use
- User manual
- Patient identification card
- Identification labels for the records

The manufacturing conditions in a controlled atmosphere room (monitored by microbiological analyses for each production batch) and a preventive ETO treatment ensure the microbiological cleanliness status.

The accessories such as the syringe, drainage needle and the extraction forceps are SINGLE USE and are delivered STERILE (they are CE marked by a different manufacturer to **ENDALIS®**).

8 CAUTIONS, PRECAUTIONS FOR USE, WARNING

8.1 Recommendations

a) Before the procedure

- Treatment of patients with a view to the placement of a balloon should be global. It should be performed within multi-disciplinary teams liaising with the attending physician. As a minimum these teams are made up of a gastroenterologist, a doctor specialising in obesity (nutritionist, endocrinologist or internal medicine specialist), a dietician, a psychiatrist or psychologist and an intensive care anaesthetist. These teams make take the advice of other health professionals whenever necessary (surgeon, diabetologist, radiologist, cardiologist, lung specialist, rheumatologist, rehabilitation doctor, dental surgeon, masseur-physiotherapist, etc.)
- The patient should be informed of the advantages and disadvantages of the balloon (including the failure rate and complications), the obligation to extract the balloon after 6 months, 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.
- Before the procedure, routinely checking women for pregnancy is recommended by performing a plasma b-HCG assay
- Looking for and treating a *Helicobacter pylori* infection should be routine
- Patients receiving serotonergic drugs and other prescription and over-the counter medications should be warned of the possibility of developing serotonergic syndrome due to the combination of these drugs and the release of methylene blue (if the balloon should rupture). Patients should consult a doctor immediately if they develop symptoms of confusion, headache, nausea and vomiting, rapid heart rate or severe sweating. Serotonergic syndrome has been notified in patients receiving serotonergic psychiatric drugs and methylene blue by intravenous administration in doses from 1 mg/kg to 8 mg/kg.

b) During the performance of the procedure

- **Cleaning:** No cleaning is necessary. In no circumstances should the product be sterilised because no procedure has been validated on the product. Do not soak the product in disinfectant. The material may absorb part of the solution and cause a tissue reaction.

- **Anaesthesia**: The placement of the balloon must be performed under general anaesthetic with or without tracheal intubation, with endoscopic control in the endoscopy theatre, with equipment for monitoring vital functions and a respirator, by professionals who have received specific training, in a referral centre which already practices this activity

  Insertion
  - ❖ General anaesthetic using Propofol, a short-term anaesthetic (e.g. Diprivan or generic)
  - ❖ Continuous positive airway pressure
  - ❖ Duration: ~15 min

  Extraction
  - ❖ General anaesthetic using Propofol, a short-term anaesthetic (e.g. Diprivan or generic)
  - ❖ Patient intubated and ventilated
  - ❖ Duration: ~15 min

- **Placement: The end-ball® intragastric balloon system must be positioned under endoscopic control.** The practitioner must ensure they have the appropriate equipment available for removing the balloon in case of complication during insertion (needle locked in the balloon during release, balloon leakage, for example):
  - ❖ Alligator clamp
  - ❖ ENDAC03 extraction kit

When carrying out the procedure, it is important to check the following points:

- ❖ The integrity of the oesophagus, cardia and stomach;
- ❖ The correct placement of the balloon in the stomach before inflation and release;
- ❖ Photographs of all these anatomical parts must be taken and entered in the patient's file.

Placement of the intragastric balloon must be performed using an aseptic technique (use of clean or sterile gloves, sterile endoscope, etc.), as there is a risk of spontaneous hyperinflation of the intragastric balloon if the isotonic saline solution (= physiological saline) is contaminated.

c) After the procedure

- After releasing the balloon, under endoscopic control, check that the balloon is properly inflated (tight bag, smooth appearance, etc.), the correct positioning and freedom of movement of the balloon in the stomach and the integrity of the balloon. This ensures that the introducer needle is disconnected from the balloon and there is no leakage. If the introducer needle remains locked in the balloon after delivery or if a leak in the balloon is detected, the balloon should be removed immediately using suitable equipment (e.g. Alligator clamp for removing the locked needle, ENDAC03 extraction kit in the event of a leak);
- A visual inspection of the introduction system must be carried out after its removal (in particular, the presence of the inflation needle);
- Advice on progressive restarting of food intake must be provided;
- Serum electrolytes and creatinaemia testing are recommended on about the 3rd day
- A check of the patient's state of health (pain, inflammation, etc.) must be carried out one week after installation;
- Consultation with a member of the multi-disciplinary team is recommended every 4 to 6 weeks
- Prescription of medicines: This is the responsibility of the practitioner.

  - ❖ Short-term (the first 8 days)
    - Anti-emetic of the controlled release metaclopramide type taken twice daily
    - On request, digestive anti-spasmodic of the Tiemonium Methylsulphate 50 mg type

  - ❖ Long-term (for the 6 months)
    - Gastric anti-secretory agent proton pump inhibitor (PPI), full dose taken daily (e.g. Lansoprazole 30 mg/d)

Important: Do not prescribe food supplements or equivalents which include biological enzymes.

- Restriction of activity**:** It is strictly forbidden for the patient to go scuba diving or fly in an unpressurised aircraft (if the balloon is filled with air). Practising combat or extreme sports is highly unadvisable.

- Patients are recommended to contact their doctor immediately if their urine is green-blue, which may be a sign of balloon leakage. The clinical resources to evaluate possible deflation include abdominal ultrasound and endoscopy.

d) Removal of the balloon

Removal is a technically difficult procedure which should be performed:

- under general anaesthetic with tracheal intubation
- under endoscopic control, using the first intention kits supplied by the manufacturers
- in the endoscopy theatre, with equipment for monitoring vital and respiratory function
- by professional who have received specific training in a referral centre already practising this activity

Fasting for 6 hours is recommended for the removal of the intragastric balloon. A short period of a liquid diet is often necessary before a 6-hour fast.

After the removal procedure:

- it is necessary to check endoscopically that there are no gastric or oesophageal lesions

- the patient is reviewed at a consultation on about the 15th day by a member of the multi-disciplinary team. After this the follow-up should be multi-disciplinary according to the methods defined in the recommendations for treatment of the obese adult.

8.2 Warning

ENDALIS® has no control over the conditions of use, the choice of patient, the procedures used for implantation and extraction, the pressures produced in the device and handling of the device after sale.
ENDALIS® cannot be held responsible for any accidental or indirect damage, or losses or expenses resulting directly or indirectly from the use of this product.
Any product explanted for reasons of intolerance by the patient will not be reimbursed.
The balloon explantation procedure requires specialist equipment. The gastroenterologist must use the equipment recommended by **ENDALIS®**. Any use of different equipment will in no way render **ENDALIS®** liable.
The intragastric balloon is implanted for a maximum duration of 6 months. Any use for a longer duration than that recommended will relieve **ENDALIS®** of any responsibility.

Should the balloon rupture, the methylene blue will be released into the stomach and absorbed into the circulation. Methylene blue is a medicine with many pharmacological indications. Methylene blue is also a DNA-binding agent which has proved positive for mutagenicity and for damage to DNA in bacteria, yeasts, mammal cells and human tissues obtained after clinical exposure. The internal release of methylene blue would cause a local concentration higher than that delivered by normal IV injection. The consequences of an acute transient exposure to methylene blue after the rupture of the balloon are not known.

9 ADVERSE EVENTS/SIDE EFFECTGS

Risk of death by intestinal obstruction, oesophageal perforation and gastric perforation

Adverse events that could result from the use of the end-ball® intragastric balloon includes the risks linked to the drugs and methods used during an endoscopy procedure, the risks linked to any endoscopy procedure, the risks linked specifically to the intragastric balloon and the risks linked to the patient's intolerance threshold to a foreign body introduced into his/her stomach.

Complications linked to the placement or extraction of the balloon
Apart from complications from upper digestive endoscopy (digestive perforation or haemorrhage, bronchial inhalation by gastric reflux, heart rhythm disorders) or anaesthesia, a certain number of complications specific to the insertion or extraction of the balloon are possible:

- Pharyngo-oesophageal injuries
- Injuries to the gastric wall
- Perforation of the oesophagus, duodenum, cardia or the stomach wall if the balloon is incorrectly positioned during inflation.

Mechanical complications due to the balloon:

- Ulceration of the stomach wall that could result in perforation due to the weight of the balloon filled with liquid, requiring an urgent surgical procedure with a risk to life
- Obstructions in the digestive tract are possible in the case of migration, which is observed if the balloon is insufficiently filled or partially deflated. It may be a stomach obstruction if the balloon is impacted in the gastric antrum or an intestinal obstruction sometimes requiring an operation.

The risk of these complications is greatly increased if the maximum duration of six months has not been respected.

- A risk of spontaneous hyperinflation of the balloon due to the production of gas in the balloon has been described in the literature
- Acute pancreatitis is possible following mechanical pressure exerted on the pancreas by the balloon through the stomach wall.

Functional complications (side effects)
The placement of an intragastric balloon is sometimes accompanied in the early days by:

- 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

They result from uncontrolled or neglected vomiting, which may cause dehydration, metabolic alkalosis, hypokalaemia, and functional kidney failure. The hypokalaemia can be responsible for life-threatening serious heart rhythm problems.

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

10 STORAGE/DISPOSAL

10.1 Storage

To be stored in a cool, dry place.

10.2 Disposal

After use, all our products should be considered to be infectious clinical waste (DASRI in French).
It is ESSENTIAL to follow the sorting and disposal procedure described for the user health establishment.

11 SYMBOLS

The following symbols are found on the labelling of the end-ball® ENDT110 intragastric balloon medical device

Table 2 – Meaning of the symbols on the labelling of the end-ball® medical device

Symbol	Description	Symbol	Description
	Legal manufacturer		Do not use if the packaging is damaged
 YYYY-MM-DD	Expiry date: • YYYY: year • MM: month • DD: day		Consult the instructions for use
LOT YY-XXXX	Batch number: • AA: year • XXXX: Incremental No.		Caution: Refer to the instructions for use
REF	Product reference		Keep dry
CE 0459	Conformity with Directive 93/42/EEC and its amendment 2007/47/ECC for which CE marking has been issued by the Notified Body, GMED, referenced by No.0459		Device for single use only Do not re-use

MADE FR	Made in France	MD	Medical Device
UDI	Unique identification number		

Barcode using GS1/EAN128. It includes the Company code, batch number and expiry date