The balloon has been clinically tested by:

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OPERATION MANUAL

for medical use of a set of silicone devices for gastric restriction

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Description: A collapsed silicone balloon in a sheath with a check valve connected with a fill tube and a metal guide wire for increased rigidity.

The balloon is supplied nonsterile complete a placement catheter and a filling system and is intended for single use only.

Effect:

The balloon is deigned to assist weight loss by partially filling the stomach and inducing satiety.

Composition:

All the components of the device are produced from biologically inert silicone resistant to the aggressive stomach environment.

Indications for use:

The decision to use the balloon is made by a physician on the basis of the data obtained as a result of the total examination of a patient suffering from obesity. The balloon can be placed into the stomach of patients whose body mass index (BMI) is 30-40 kg/m^2.

Patients whose BMI is more than 40 kg/m^2 can be treated with the balloon for the purpose of surgery preparation.

Contraindications:

- Use of the balloon is contraindicated for weight loss in patients with a BMI less than 30, unless accompanied by comorbidities associated with obesity that would be expected to improve with weight loss.
- Any inflammatory disease of the gastrointestinal tract including esophagitis, gastric ulceration, duodenal ulceration, Crohn's disease.
- Gastrointestinal tract cancer
- Esophageal or gastric varices, telangiectasis.
- Congenital anomalies of the gastrointestinal tract such as atresias or stenoses
- A stricture or diverticulum of the esophagus or pharynx
- Prior gastric or intestinal surgery
- A large hiatal hernia
- Psychological disorder, alcoholism or drug addiction
- Pregnancy or breast-feeding (if pregnancy is confirmed at any time during the course of balloon treatment, the device should be removed)
- Patients receiving aspirin, anti-inflammatory agents, anticoagulants or other gastric irritants
- Allergic reaction to silicone
- Any other medical condition which would not permit endoscopy
- It is not recommended to use the balloon for patients with low discipline unwilling to participate in an established diet and behavior modification program, with medical follow-up at least once every two weeks.

Possible complications:

- An insufficiently inflated balloon or a leaking balloon may be able to pass from the stomach into the small bowel. It may pass all the way through into the colon and be passed with stool. However, if there should be a narrow area in the bowel, as might occur after prior surgery on the bowel or neoformation the balloon may not pass and then may cause a bowel obstruction. If this occurs, surgery or endoscopic removal could be required.
- Injury to the lining of the digestive tract as a result of direct contact with the balloon, grasping forceps.
- Ulcer formation, bleeding or perforation as a result of increased acid production by the stomach.
- The erosion of the wall of the balloon by aggressive stomach environment in case of ill-time balloon removal (if the balloon is left in place longer than 6 months).
- The erosion of the wall of the balloon as a result of strain (pressure or blow) in the anterior abdomen.

ATTENTION: The change of urine color is the basic symptom of the balloon leakage

By-effects:

- Gastric discomfort
- A feeling of nausea
- Vomiting
- Hypersalivation
- Gastroesophageal reflux

WARNING: Each patient must be monitored closely during the entire term of treatment in order to detect the development of possible complications. Each patient should be instructed regarding symptoms of deflation, gastrointestinal obstruction, ulceration and other complications which might occur, and should be advised to contact his/her physician immediately upon the onset of such symptoms.

Placement method:

The balloon placement should be performed in an operating room or specially equipped room for endoscopy. Gastroscope, 0,9-% NaCl solution colored with 2 ml methylene blue, a grasping forceps, 50-ml syringe are required for the balloon placement procedure.

It is recommended that the balloon should be placed under a general anaesthetic.

The placement procedure:

1. Perform diagnostic gastroscopic inspection to of esophagus and stomach to eliminate diseases which contradict the balloon placement. After esophagus, stomach and duodenal bulb inspection remove the gastroscope.
2. Treat the balloon with lubricant, introduce 1,0 ml of lubricant under the sheath (Glycerine may be used as lubricant, hydrocarbonic oilings should not be used) and introduce the device into the lumen of stomach as a stomach pump
3. Reinsert the endoscope to define precisely the balloon position. The balloon must be below the lower esophageal sphincter and well within the stomach cavity.
4. Remove the metal guide-wire.
5. Fill the balloon with the liquid (500-700 0,9-% NaCl solution colored with methylene blue). Warning The balloon is to be filled under total visual gastroscopic control. 50-ml syringe is used for the balloon filling. 500-700 ml of liquid is introduced by degrees into the balloon lumen through the silicone tube. To prevent liquid refluence from the silicone tube it is necessary to shut off the tube with the grasping forceps while the syringe is disconnected. While the balloon is being inflated the thin silicone sheath covering the balloon should blow out and release the balloon.
6. Make sure that the balloon is in the proper position and leak-proof.
7. Remove the silicone tube by pulling it until the balloon is detached.
8. Check the valve for leak-proofness by controlling the color of the valve after detachment.
9. Remove the gastroscope.

The balloon is composed of silicone and is easily damaged by instruments or sharp objects.

Do not treat the balloon with disinfectants because silicone may absorb some of the solution which could subsequently leach out and cause gastric mucosa reaction).

Rapid fill rates will generate high pressure which can damage the balloon valve or cause premature detachment (always use a 50-ml syringe only).

A kink in the area of the balloon attachment to the tube while filling may cause premature detachment.

The balloon removal:

The maximum placement period for balloon is 6 months, and it must be removed at that time or earlier.

The removal procedure is performed under a general anaesthetic.

1. Insert a gastroscope with an instrument channel into the stomach (the instrument channel should provide the introduction of additional flexible instruments).
2. Introduce an aspiration irrigation needle into the working channel of the gastroscope and puncture the balloon.
3. Push the needle through the shell inside the balloon.
4. Remove the needle from the instrument sleeve.
5. Apply suction to the tube until all fluid is evacuated from the balloon.
6. Remove the tubing from the balloon and out of the working channel of the gastroscope.
7. Insert 2-pronged wire grasper through the working channel of the gastrscope. Grab the balloon with the hooked grasper (ideally at the opposite end of valve if possible) and slowly withdraw the balloon together with the gastroscope.

The repeated course of treatment using the balloon can be done only after at least 1 month since the balloon removal.

Warning: Throughout the period of the balloon's stay in the stomach drugs reducing gastric acid secretion are recommended.

Warning: Within a few days after balloon placement dysphagia (nausea and vomiting) may be observed. If the symptoms of dysphagia remain for 3 or more days the balloon has to be removed!

Warning: The effectiveness of weight loss when using the balloon varies depending on the individual body peculiarities. For some patients weight loss may be inconsiderable.

Warning: In the long-term outlook a patient may regain weight after balloon removal (unless another balloon is placed instead).