INSTRUCTIONS FOR USE / INFORMATION ON THE PRODUCT

DESCRIPTION

GASTRIC BALLOON

It consists of a round fluorated silicone envelope, filling tube, luer-lock and metal guide. The silicone envelope has a smooth, soft surface resistant to gastric juices and an internal valve connected to the filling tube.

The silicone elastomer filling tube has a Teflon needle at the end connected to the valve. The metal guide inside it is a spiral stainless steel thread coated with Teflon to facilitate the device’s insertion.

It is supplied empty, carefully coiled inside a thin silicone wrapping, previously connected to the filling tube, so that it allows the introduction by endoscopic route.

It is presented in the size shown in the commercial catalogue, the result of the clinical experience obtained among medical professionals, and listed as follows:

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<tr>
<th>Drawing</th>
<th>Volume (mL)</th>
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<tbody>
<tr>
<td><img src="image" alt="Diagram" /></td>
<td>xxx - 350</td>
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Note: XXX = Volume. Volume with approximate value.

CONSTITUENT MATERIALS

The raw-materials used are medical–grade and biocompatible, as required by international standards. The environmental conditions of manufacture and productive techniques are rigorously controlled by a quality management system in accordance with the Good Manufacturing Practices for Medical Devices from FDA (GMP) and from ANVISA, as well as ISO 9001 and EN ISO 13485 standards.

- Envelope: Fluorated silicone elastomer;
- Valve: Polydimethyl siloxane.
- Filling tube: Silicone elastomer with Teflon needle and plastic Luer-Lock;
- Metal guide: Stainless steel wire cable in spiral coated with Teflon;
- Wrapping: Silicone elastomer.
PRESENTATION

The Gastric Balloon is supplied sterile and apyrogenic, in double packaging, within a sealed outer package containing the documents related to the product.

The label on the external package contains, among other, the following information: description of the product, reference number, amount of products per package, serial number, sterilization expiry date and dimensions.

The symbols used on this label indicate the characteristics of the product and are described in a printed sheet attached to these instructions for use.

STERILIZATION

The Gastric Balloon is sterilized using the following sterilization method:

- Ethylene Oxide

The process of sterilization to which this product was submitted, as well as the date of expiry, are shown on the labels on the packaging. The sterilization process meets the requirements of the country to which the product is destined and which granted the register for commercialization. Each sterilization lot receives individual confirmation.

It is forbidden to re-process.

INDICATIONS

The Gastric Balloon is recommended for temporary use up to 6 months in the following cases:

- Pre-surgery treatment in obese patients with Body Mass Index (BMI) over 40, to reduce weight and surgical risk, on account of serious associated disease;

- In obesity treatment for patients with Body Mass Index (BMI) between 30-40 who have been previously submitted to well-oriented clinical treatment without losing weight, with the presence or risk of associated diseases;

- In treatment for serious obesity in patients who do not accept the surgical indication or lack the clinical conditions to undergo surgery;

- For weight loss induction in patients whose obesity is not serious enough for surgical indication and who have failed to lose weight when submitted to traditional treatments.

The Gastric Balloon is a non-surgical treatment of obesity that shall be accompanied by a change in the patient’s behavior – alterations to eating habits and practicing physical exercises – to help in an efficient weight loss. Behavioral re-education reinforces weight
loss during treatment and maintains it for a prolonged period after the device has been removed.

CONTRAINDICATIONS

The use of the Gastric Balloon is contraindicated in: patients who were submitted to previous gastric surgery; patients with inflammatory ailments of the gastrointestinal tract, including acute esophagitis, gastric ulcer, duodenal ulcer or specific inflammations, such as Crohn’s disease or prone to gastrointestinal hemorrhages in the upper tract, such as esophageal or gastric varicose veins, or acquired intestinal telangiectasia; patients with serious cardio-pulmonary or organic disturbances in general; patients with congenital or acquired anomalies of the gastrointestinal tract, such as atresia or stenosis; patients with large hiatus hernia (larger than 5 cm); patients addicted to alcohol/drugs; patients who have an infection anywhere in the body; patients unable or unwilling to adopt the restrictions relating to the diet required by the procedure; patients with kidney diseases and/or serious hepatitis; and patients with AIDS.

PRECAUTIONS

The Gastric Balloon shall be used with caution in the following cases: patients previously submitted to intestinal or gynecological surgery; under therapy with the use of anticoagulants; pregnant or breast-feeding; under 18 years of age; prone (or suspected) to allergic reactions to the constituent materials of the system or who have displayed intolerance to pain with implanted devices; emotionally unstable or presenting psychological characteristics that the physician considers sufficient to advise against the placement of the device; endocrine disorders; known diagnosis of diseases related to the immune system and/or the connective tissue, such as systemic lupus erythematosus or scleroderma; under treatment with anti-inflammatory medication, aspirin, anticoagulants or other gastric irritants.

INSTRUCTIONS FOR HANDLING AND USE

Opening the Package:

1. Make sure that the outer plastic covering has not been opened;
2. Remove the double packaging from the interior of the sealed box. This shall be examined thoroughly before the device is used in the surgical center. No product shall be used whose packaging has in any way been violated;
3. Separate the documents accompanying the product;
4. Stick the adhesive labels containing the product data to the hospital and physician’s cards as well as to the dossier to be given to the patient, as indicated by the symbols;
5. Open the external blister to have access to the sterile internal blister that contains the product. Take care not to contaminate the product against the external part of the former;
6. Open the sterile internal blister in the surgical center.
This product is supplied sterile and has been submitted to careful tests which assure its biocompatibility and absence of reactions of the organism. Possible rare exceptions may occur due to specific and individual conditions, as described in the item “Adverse Effects.”

The high dielectric value of silicone can generate static charges that are responsible for attracting particles present in the environment, such as lint in general and talcum. For this reason, the precautions taken to open the packaging are very important.

Do not handle the Gastric Balloon prior to insertion in the patient without the metal guide wire being inserted in the filling tube, so as not to damage the needle. Remove the guide-wire only after positioning the Gastric Balloon inside the stomach, because it serves as protection for the needle during introduction via the esophagus.

Do not pull the filling tube while holding the Gastric Balloon, in order to avoid disconnecting the needle.

**PROCEDURE**

The techniques and procedures for placing the device are necessarily the responsibility of the physician, who shall evaluate them in accordance with his/her own training and experience, observing the latest accepted techniques in order to reduce the occurrence of adverse reactions to a minimum. Scientific bibliography is available at SILIMED. It can be requested through its representatives or directly from the main office. The physician is also responsible for making sure that his/her team is adequately trained to carry out the required medical procedures.

To insert the Gastric Balloon, SILIMED suggests prior evaluation of the patient, taking into consideration the patient’s conditions and clinical requirements. Special attention shall be given to minimize the risk of adverse effects. The surgical operation shall be planned with the complete understanding and consent of the patient.

The physician shall always have a spare product available during the procedures to place the device.

SILIMED suggests the following procedures:

- Evaluation of the patient prior to placement of the Gastric Balloon

The Gastric Balloon is a non-surgical treatment of obesity that shall be accompanied by a change in the patient’s behavior – alterations to eating habits and practicing physical exercises – to help in an efficient weight loss. Behavioral re-education reinforces weight loss during treatment and maintains it for a prolonged period after the device has been removed. The pre-procedure preparation shall be made by a multidisciplinary team.

- Procedure for placement of the Gastric Balloon
The placing of the Gastric Balloon can be done under normal sedation for diagnostic endoscopy or general anesthesia carried out and monitored by an experienced anesthetist. The patient should stay under observation and be accompanied by the physicians for at least two hours after completing the placement procedure.

- Gastric Balloon placement technique

The patient shall observe a 12-hour fast prior to the procedure for placement of the Gastric Balloon.

Prior to endoscopy, the patient shall be on the position of dorsal or left lateral decubitus. Proceed with normal sedation for diagnostic endoscopy or general anesthesia carried out and monitored by an experienced anesthetist. Apply lidocaine spray on the oropharynx.

Proceed with diagnostic esophagogastroduodenoscopy in order to define the gastric anatomy, check for the existence of any anatomical or pathological abnormality among the clinical conditions mentioned in the contraindications, and aspirate the gastric contents whenever necessary.

Remove the endoscopic apparatus.

Open the Gastric Balloon packaging (see item Instructions for Handling and Use).

Lubricate the Gastric Balloon with lidocaine gel, without twisting or pulling the Gastric Balloon from the Filling Tube;

One of the possibilities to make insertion of the Gastric Balloon easier is to anchor the end of the wrapping to the end of the endoscope using a polypectomy loop. The anchoring of the polypectomy loop unit to the tip of the endoscope shall be restricted to the end of the wrapping of the Gastric Balloon without reaching its envelope, so as not to damage it.

Carefully introduce the Gastric Balloon into the stomach by endoscopic traction and under direct visualization, releasing it by means of the polypectomy loop near the pylorus and finally positioning it in the gastric fundus by retrovision maneuver (Picture 1);

Another possibility is to introduce the Gastric Balloon by pushing it through the filling tube.

Carefully introduce the Gastric Balloon by oral route taking care when passing through the oropharynx; continue the movement down the esophagus to the gastro-esophageal transition. Reintroduce the endoscope, ensuring that the Gastric Balloon is correctly positioned in the gastric fundus, with a rear-view maneuver (Picture 1);

After positioning the Gastric Balloon in the gastric fundus, remove the guide-wire;

Connect the luer-lock supplied with the Gastric Balloon to the Filling Tube;
In the gastric fundus, the Gastric Balloon shall be filled with a 2% methylene blue solution diluted in 0.9% saline solution, with or without the addition of 200mg/mL iodopamidol in the proportion of 0.5:50:2, respectively. The filling procedure shall be continuously monitored in retrovision in order to promote a better adequacy of the Gastric Balloon volume to the capacity of the gastric fundus. The filling procedure may be carried out using only a 60 mL syringe or with the help of the Filling Kit apparatus for the Guebert TC Injector with 1 Head (not supplied).

To fill with a syringe:

Fill a 60mL syringe with the filling solution and inject into the Gastric Balloon through the luer-lock, repeating the operation until the desired volume is reached (between 350 and 700mL);

To fill with the apparatus:

Connect the apparatus to the luer lock and to the recipient containing the filling solution.

Connect a 60mL syringe to the apparatus and pump it to perform the filling. It is not necessary to disconnect the syringe to refill. Count the volume of saline solution injected so that it is at least 350mL and at most 700mL;

Remove the filling tube to which the wrapping is connected and the Teflon needle; the valve of the Gastric Balloon will close with the removal of the tube. Following the filling procedure, the Gastric Balloon shall be visually inspected to detect any leakage and to confirm the correct positioning in the gastric fundus (Picture 2). Any Gastric Balloon that presents leakage at this moment shall be promptly removed and replaced by another. Once the filling tube of the Gastric Balloon is disconnected, it can no longer be reconnected;

During the removal of the endoscope, try to visualize the final position of the Gastric Balloon.
- Procedures after the Placement of the Gastric Balloon

In the first few days after placing the Gastric Balloon, episodes of vomiting, nausea and flatulence are common until the patient has adapted to the food most suitable for the new diet to be followed. Oral or intravenous administration of antiemetics and antispasmodics for 24 to 72 hours is recommended, whenever necessary. In extreme cases it is necessary to perform endovenous hydration in the first 2 to 3 days after the procedure. A proton pump blocker shall be prescribed for all patients throughout the entire treatment with the Gastric Balloon.

- Gastric Balloon Removal Procedure

The removal of the Gastric Balloon shall be done under normal sedation for diagnostic endoscopy or general anesthesia carried out and monitored by an experienced anesthetist. The following steps shall be taken:

Apply an adequate dose of anti-spasmodic to allow the relaxation of the lower sphincter of the esophagus, facilitating the passage of the empty Gastric Balloon through the cardia.

Start the digestive endoscopy by identifying the position of the Gastric Balloon through the endoscope; a double overtube made of silicone can be used in the patient’s esophagus to facilitate removal of the Gastric Balloon;

The inner tube of the “overtube” is removed;

Under direct visualization and preferably in retrovision, maintaining the Gastric Balloon secured to the gastric fundus, a hole is made in the Gastric Balloon with a catheter on an endoscopic needle. This catheter is inserted to empty the Gastric Balloon. Then the needle
is removed and the catheter coupled to the aspirator. The Gastric Balloon shall be completely emptied;

Once completely emptied, the Gastric Balloon shall be secured by a polypectomy loop or by foreign-body pincers and exert traction until part of the Gastric Balloon is inside the “overtube”, thus enabling the simultaneous removal of the whole unit by endoscopic route.

While the Gastric Balloon is passing through the cardia, an endovenous injection of anti-spasmodic shall be applied. The Gastric Balloon is then taken up to the oral cavity, through which it is extracted.

An endoscopic view is taken, for a full evaluation of the duodenal bulb, stomach, esophagus and oropharynx.

The patient shall remain under observation for at least two hours after the removal of the Gastric Balloon.

IMPORTANT RECOMMENDATIONS / WARNINGS

The Gastric Balloon can only be purchased by physicians or under their prescription.

It is supplied sterile. To keep its aseptic conditions in surgery, asepsis and cleanliness are necessary in the conditions of its use.

The implant and its packaging shall be intact, otherwise the product shall not be used. It can only be used when complete in its original manufactured form, that is, with no alteration to its original characteristics.

The surface of the product shall not be contaminated with talc, dust or oils. The sterile surgical gloves shall be washed with a sterile saline solution before coming in contact with the Gastric Balloon.

Solutions containing iodine cannot come into contact with the Gastric Balloon.

It cannot be soaked in disinfectant solutions. The elastomer can absorb the product, which in turn can be released into the organism.

The Luer Lock valve shall be tested prior to the procedure to place the Gastric Balloon to make sure that it is compatible with the syringe used.

The use of the Luer Lock is indispensable when the Gastric Balloon is filled with a syringe. The syringe shall never be connected directly to the filling tube. Otherwise the filing solution will return and leak through the tube.
In filling the Gastric Balloon, the recommended volume is 350-700mL of saline solution, since the possibility of deflating is greater with volumes above 700mL. This procedure shall be done slowly in order not to damage its valve.

If a spontaneous deflation of the Gastric Balloon occur, the methylene blue will give a bluish coloring to the urine and feces, which is a warn to the patient to consult the physician immediately, thereby reducing considerably the possibility that the Gastric Balloon will pass to the intestine and, in the extreme situation, a process of intestinal obstruction. There is a considerable number of studies demonstrating the efficacy and safety of this dye, even in cases of deflation of the Gastric Balloon. Occasionally a person who is hypersensitive to methylene blue may report symptoms compatible with allergy to this component, in the case of deflation of the device. If spontaneous deflation occurs, the Gastric Balloon may be eliminated naturally through the feces, without the patient noticing and without causing any harm to his health.

Discoloring of the filling solution may occur due to the use of methylene blue, caused by the migration of this substance through the Gastric Balloon envelope, causing a false positive of deflation of the device (the patient detects a greenish urine). Accordingly, to reduce this risk, SILIMED recommends using another substance together with methylene blue so as to help diagnose possible deflation: the Iopamidol, which is a medium of radiological contrast. If the patient detects greenish urine, an X-ray will be taken to verify whether there was a rupture of the Gastric Balloon or only a migration of the methylene blue through the silicone envelope. The radiography procedure is not invasive and is more effective because there are no problems with false positives. If the Iopamidol contrast is not used, an endoscopy will be necessary to investigate a possible rupture of the Gastric Balloon.

The use of proton pump inhibitors, albeit necessary, causes the pH of the stomach to increase, making the medium favorable for the growth of Candida albicans, a fungus present in the microbiota of the gastro-intestinal tract. The fluorated silicone used in the Gastric Balloon is resistant to colonization by this fungus. However it is known to be able to attack silicone, thus fragilizing the envelope and facilitating occurrence of distension of the envelope, separation of layers, and rupture. SILIMED therefore warns as to the need to monitor patients, with routine visits to the physician throughout the treatment in order to detect colonization of this fungus and carry out the proper treatment early.

It shall be stressed that sedation with propofol at the moment the device is inserted can lead to the color of the urine changing to green. Although this is a rare benign effect, endoscopists and bariatric surgeons shall be aware of this possibility so as to avoid unnecessary removal of the Gastric Balloon, besides the additional stress to the patient and the medical team.

Each patient shall be thoroughly monitored, with a programmed routine of appointments to the physician throughout the whole treatment, aiming at the early detection of possible complications. The patient shall be instructed on some symptoms, which are characteristic of the implantation, and shall immediately inform the physician when they are recognized.
Any patient whose Gastric Balloon is displaced to the intestinal region shall be carefully monitored, so that, in the case of intestinal obstruction, the proper treatment can be immediately administered.

If it is necessary to make perforations with needles or the like in the region of the Gastric Balloon, the utmost care shall be taken to avoid contact with the device.

In the case of removal of the device, it is recommended that the volume to be placed in the new Gastric Balloon shall be the same used on the previous one. Inserting a greater volume in the new Gastric Balloon can result in serious episodes of nausea and vomiting and even formation of ulcers.

In the case of meteorism, it is recommended to use an antiphysetic for a period of 1-2 weeks.

Any hole, cut or even an accidental scratch on the Gastric Balloon will invalidate it for use. It is not possible to repair a damaged product. It shall be replaced by another.

The Gastric Balloon is intended for a single use. According to the legislation, it can be neither re-used nor re-sterilized, since it compromises its performance and safety.

The damaged product shall be returned to the manufacturer to be disposed of.

ADVERSE EFFECTS

Any patient submitted to surgery for introduction of an element foreign to the organism is liable to possible complications.

SILIMED transfers to the physicians the responsibility on clarifying the patients on the possibility of a new surgery to remove or replace the implant, as well as the possible occurrence of adverse reactions after its implantation. Medical professionals are invited to report any other pertinent findings.

For the Gastric Balloon, the problems reported in current medical-scientific literature, or directly to SILIMED, followed up through the process of risk management of the product – post-production phase - are as follows:

ALLERGENICITY - Allergic process generally characterized by irritation of the tissue cause by silicone. However, this is a rare adverse effect that is only mentioned in the literature.

BLOCKING THE EXIT OF THE BOLUS FROM THE STOMACH – Inadequate positioning, insufficient insufflation or deflation of the gastric balloon may lead to the temporary obstruction of the antropyloric region by the device, preventing the passage of the bolus to the intestine. This blockage may cause gastric discomfort, nausea, and vomiting, among other effects.

COLONIZATION BY FUNGI – Colonization of the Gastric Balloon envelope by fungi, in particular Candida albicans, is a possible effect, but of a low rate of occurrence.
Although patients are generally asymptomatic and there is no major damage to their health, except for some cases of halitosis, in extreme cases the effect can cause progressive fragilization of the Gastric Balloon envelope.

BIOLOGICAL CONTAMINATION – THIS ADVERSE EFFECT RARELY OCCURS provided that the recommendations as to use and asepsis, associated with placing the device, are followed. The use of infected saline solution, or its contamination during the filling process of the gastric balloon, can cause this effect. Although the presence of micro-organisms at the moment the gastric balloon is removed has been observed in some cases, no symptoms were reported associated with infection or other hazards to the patient’s health. If applicable, local culture is recommended, and the use of antibiotics if necessary. More intense cases may lead to the need to remove the device.

DEFLATION OF THE DEVICE - The deflation of the Gastric Balloon, that is, its gradual or sudden emptying, may happen as a result of mechanical failures (e.g. valve problem) or using unsuitable medical procedures during its insertion. To warn about the possibility of this occurrence, methylene blue dye is added to the Gastric Balloon filling solution. In this way, if the patient detects a bluish coloring in his urine or feces, he shall consult the physician immediately. Deflation of the Gastric Balloon may result in intestinal obstruction.

ELECTROLYTIC IMBALANCE – After the insertion of the gastric balloon, most patients feel gastric discomfort with episodes of nausea, vomiting and abdominal pains. These symptoms normally cease in the first 72 hours after the digestive system adapts to the presence of the Gastric Balloon’s. However, when the episodes persist for more than two weeks, dehydration, hypocalcemia among other effects may occur, leading to the electrolytic imbalance. In this case, hydrolytic replacement is carried out and the physician shall evaluate the need to remove and/or replace the device.

GASTRIC DILATATION – The treatment with gastric balloons generally leads to a slight gastric dilatation, which recedes after the conclusion of the treatment. However, in some cases this dilatation can be more intense, leading to episodes of gastric discomfort, pain, and removal of the Gastric Balloon, among other possible effects. Insufflating the Gastric Balloon with a volume of saline solution above specifications, and incorrect positioning of the Gastric Balloon in the gastric space, are among the causes of this adverse effect.

EPIGASTRIC PAIN – This is a consequence of gastric discomfort caused by situations of inflammation and stomach ache, principally in the first few days after inserting the Gastric Balloon. It may also be indicative of ulcers, incorrect positioning of the Gastric Balloon, intestinal obstruction and other complications. It may occur in a mild to intense form from short to long duration, and shall be immediately investigated.

GASTRIC EROSION – Is characterized by a diffuse erosion of the gastrointestinal epithelium, which may lead to pain and persistent gastric discomfort. The physician shall evaluate the need to remove the device.
ESOPHAGITIS - This can occur mainly on account of gastroesophageal reflux or damage to the esophagus during insertion of the device. Among the consequences are problems in deglutition, dysphagia and ulcer of the esophagus. Depending on the clinical status of esophagitis, removal of the device may be necessary for the proper treatment of the condition.

HEMATOMA – Extravasation of blood and its confinement in an organ or tissue (hematoma) may occur in any type of surgery. When this occurs, it shall be carefully investigated. With the risk of preceding infection and erosion, if not re-absorbed, the hematoma shall be removed.

IMPACTION OF THE ANTROPYLORIC REGION – Inadequate positioning, insufficient insufflation or deflation of the Gastric Balloon may lead to impaction of the antropyloric region by the device, preventing the passage of the bolus to the intestine. This blockage may cause gastric discomfort, nausea, and vomiting, among other effects.

INTOLERANCE TO THE DEVICE – This is the patient’s inability to adapt to the presence of the Gastric Balloon due to the resulting severe gastric discomfort, nausea and vomiting. In some cases it is necessary to remove the device.

METEORISM – The placement of Gastric Balloons may lead to the production of gases in the intestinal cavity and consequent abdominal discomfort and distension. In the case of very severe meteorism resistant to medication, it may be necessary to remove the Gastric Balloon.

ESOPHAGEAL OBSTRUCTION: Once the Gastric Balloon is inflated in the stomach, it can be pulled back to the esophagus causing an esophageal obstruction. This event is generally associated with spontaneous deflation, poor positioning in the stomach or filling the Gastric Balloon with insufficient volume of saline solution. Esophageal obstruction can cause discomfort in the digestive tract and prevent food from entering the stomach, among other effects. Procedures for the disobstruction are required, which can range from drinking water, endoscopic procedure, and even removal of the device.

INTESTINAL OBSTRUCTION - A Gastric Balloon filled to a volume lower than specified or deflated can migrate to the intestines and may be expelled in the feces or cause intestinal obstruction. Occurrence is rare, but it has the potential to lead to the death of the patient, mainly if not diagnosed and treated in the proper manner. Surgical procedures may be necessary to treat the more serious cases of intestinal obstruction. To avoid this hazard, close follow-up on the patient is recommended throughout the entire period of implantation. Furthermore, adding methylene blue dye to the saline solution of the filling lends a bluish color to feces and urine in the case of deflation or emptying of the device, thus minimizing the risk of the device passing to the intestine if the necessary measures are taken by the patient and physician after the initial alert given by the methylene blue.

LOSS OF MECHANICAL INTEGRITY / PRODUCT FAILURE – These are flaws that damage the integrity of the product, such as deformities of the device or any other difference in relation to the standard to be obtained in the productive process, and
unrelated to rupture of the envelope or problems with the valve. Generally, these kinds of failures are detected before placement. However, if they are not detected, the physician shall evaluate the need to remove and/or replace the device.

GASTRIC PERFORATION – This is rarely directly associated with the Gastric Balloon. Gastric perforation can be caused by trauma preceding the gastric surgery and is characterized by a lesion in the stomach mucosa. It might lead to peritonitis.

GASTROESOPHAGIC REFLUX – This is the returning of stomach contents to the esophagus, resulting in heartburn, malaise, esophagitis, among other effects. In case the discomfort is very severe and resistant to medication, it is necessary to remove the device.

IMMUNOLOGICAL RESPONSE – Auto-immune and conjunctive-tissue diseases may come to cause irreversible serious damage and even the death of the patient. However, in the studies carried out to date, no evidence has been found that placing silicone intragastric balloons, among other silicone devices, leads to connective or auto-immune diseases.

INFLAMMATORY RESPONSE – The presence of a foreign body in the organism may trigger an inflammatory process. The inflammation may also be the result of traumas or unsuitable procedures. It causes pain, rubor, increased local temperature, among other effects. This effect can be treated pharmacologically.

PEPTIC ULCER – This is a local injury of the gastric mucosa, generally in the stomach or duodenum, exposed to acid gastric secretion. Some of the causes may be the result of using an unsuitable technique for inserting the Gastric Balloon, lack of medical follow-up, the patient’s failure to comply with medical recommendations or placement of the gastric balloon for a period longer than six months. The main associated consequences are: pain, abdominal discomfort and the need to remove the device for effective treatment. The measure implemented to reduce the associated risk is based mainly on the recommendation of the use of an appropriate pharmacological therapy.

RUPTURE OF THE ENVELOPE – In addition to rupture due to mechanical problems of the device, the envelope can rupture if the patient fails to follow the recommendation to properly take, throughout the treatment, the proton pump inhibitor prescribed by the physician, or if there is a large colonization of the envelope by Candida albicans.

DURABILITY

The Gastric Balloon is a product recommended for treatment with a maximum duration of 6 months. The risk of deflation and intestinal obstruction is far greater if the device is maintained in the patient for a period longer than 6 months. It is recommended that a continuous follow-up of the patients is made and that they are warned on the possibility of the occasional removal or replacement of the product.

CLARIFICATION AND CONSENT OF THE PATIENT
Considering the risks inherent to any medical procedure, with or without the use of the Gastric Balloon, and the possible complications related to it, SILIMED relies on the physicians to clarify their patients on the existing risk-benefit balance, as well as to obtain their formal consent, whenever necessary, for the procedure.

**STORAGE / CONSERVATION / TRANSPORTATION**

SILIMED products and packages are resistant and if stored at room temperature and according to the guidance printed in the package, they will not be damaged. It is recommended that they are not transported or stored along with other types of materials which can cause physical or chemical damages to the product, which would render it unfit for use.

**WARRANTY**

SILIMED will replace any of its line products that presents a proven manufacturing defect, provided it is returned duly identified by the person who purchased it and after examination at the SILIMED laboratory.

The adverse effects presented herein and an inadequate placement procedure, are not considered to be defects of the product.

SILIMED maintains an accurate register, unit by unit, of raw materials, manufacturing stages, and environmental and operational conditions, assigning a single number to each product which completely identifies it at any time. In this sense, it is absolutely necessary that any complaint is sent together with the SERIAL NUMBER (SN) of the unity complained shown on the packaging.

The warranty of SILIMED products does not cover the simple decision of the patient or physician to change the product.