EN

STELLA® ENDOGASTRIC BALLOON SYSTEM

REF: 9092981

INSTRUCTIONS FOR USE

READ THE FOLLOWING INFORMATION CAREFULLY BEFORE USING THIS PRODUCT

1. INTRODUCTION

The following information is generalized. Each patient must be individually evaluated for the use of the **STELLA® ENDOGASTRIC BALLOON SYSTEM** based on the medical judgment of a medical team qualified in bariatric techniques.

Each doctor and patient should evaluate the risks associated with endoscopy and balloons, as well as the potential benefits of temporary weight loss treatment using the **STELLA® ENDOGASTRICAL BALLOON SYSTEM**. When appropriate, verify during preliminary interview that patients have not been able to achieve and maintain weight loss following a supervised weight control program.

Any doctor using the **STELLA® ENDOGASTRIC BALLOON SYSTEM** must meet the following requirements:

- Advanced skill in endoscopy and experience evidenced by possession of appropriately granted interventional endoscopy privileges as per training protocols.
- Have access to information on the specificity of the **STELLA® ENDOGASTRIC BALLOON SYSTEM.**
- Clinical use of the **STELLA® ENDOGASTRIC BALLOON SYSTEM** as a component of a multidisciplinary weight management practice providing long-term support and follow-up.
- Have a comprehensive weight management support program that includes appropriate endoscopy facilities, nutritional and exercise counseling, psychology, general medicine, and support staff.

A permanent emergency department with the availability of a doctor, endoscopist and surgeon must be arranged to diagnose and treat any potential complications early and efficiently.

2. INFORMATION TO BE PROVIDED TO THE PATIENT

The placement of the **STELLA® ENDOGASTRIC BALLOON SYSTEM** is an elective procedure, and the patient must be well advised on the risk-benefit ratio. The doctor should inform the patient of the warnings, precautions and adverse events listed in this document. The doctor should also advise the patient that early removal of the balloon may be necessary if serious adverse reactions occur, including situations in which the patient suffers from stress they cannot overcome.

The implant card document includes the patient's name and physician contact information, placement and removal date, device information, and warnings for related health care providers. Patients should be provided with the completed patient implant card and informed about specific information of procedure including precautions and warnings.

3. INTENDED PURPOSE AND PRODUCT DESCRIPTION

STELLA® ENDOGASTRIC BALLOON SYSTEM is a temporary (up to 6 months) non-surgical, non-sterile, single-use, liquid-filled expandable endogastric balloon with a double-lumen probe. It is intended to be used in a clinical setting by healthcare professionals trained in endoscopy, to treat adult patients with obesity or other health-risk factors related to being overweight, and who have failed to achieve and maintain weight loss. When deployed and inflated in the stomach, the balloon reduces stomach capacity, promoting a feeling of satiety and reducing the desire for food thereby enabling weight loss maintenance.

STELLA® ENDOGASTRIC BALLOON entirely consists of medical grade silicones coated with corn starch. **STELLA® ENDOGASTRIC BALLOON** works by partially filling the stomach, remaining freely inside and stimulating a feeling of satiety and consequently a reduction in food intake. **STELLA® ENDOGASTRIC BALLOON** is placed in the stomach and filled with sterile saline solution stained with blue dye, which causes it to assume a spherical shape and at the same time acts as an alarm system that warns of possible leaks. Its expandable design enables the filling volume to be adjusted from 400 to 700 ml.

In the **STELLA®** introducer system, the deflated endogastric balloon is folded on itself inside two silicone covers that keep it folded at an optimal diameter for its insertion. This balloon is also attached to double lumen probe through a shut-off and non-return valve.

The **STELLA®** introducer system or double-lumen probe is made up of two polyvinyl chloride tubes medical grade that are joined together and have an outer oval diameter of 4x8 mm: a transporter (or carrier tube) and a feed channel. The carrier tube runs along a guidewire that ensures the path and placement of the balloon in the stomach. The blunt end of the transporter's flexible silicone neck enables it to adapt and travel without causing injury to every anatomical structure.

The feed channel has a capillary tube of stainless steel attached to the distal end and this capillary, in turn, is attached to the balloon via the non-return valve. A Luer-Lock connector, made of medical grade PVC, can be found at the proximal end of the same channel. This will enable the filling kit to be connected when necessary.

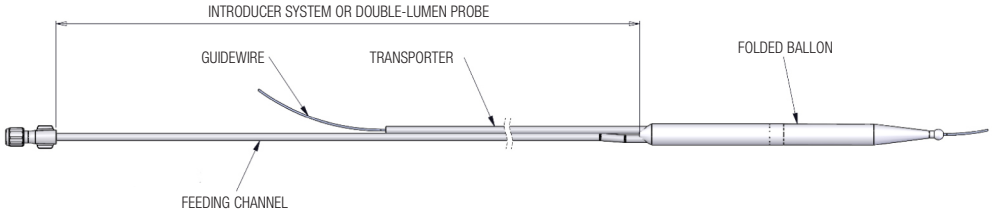

Figure 1. Parts of the STELLA® Endogastric Balloon System (guidewire not included)

	Components	Material
Introducer system	Double tube	Medical grade PVC
	Cone and tip	Medical grade Silicone
	Covers	Medical grade Silicone
	Capilar tube	Steel AISI 316
	Raccord female luer lock	Medical grade PVC
	Cap luer lock male	Medical grade LDPE
	Union -Primer	Silicone primer
	Unión - Adhesive	Silicone adhesive
Endogastric balloon	Balloon	Medical grade Silicone
	Cap	Medical grade Silicone
	Valve	Medical grade Silicone
	Union - Adhesive	Adhesive silicone

Table 1. Qualitative composition of STELLA® Endogastric balloon system

The balloon consists of 15 grams of silicone elastomer, covered by corn starch in estimated amount 2,2 g/device (balloon and introducer system) to prevent the silicone from sticking to itself during the fill process.

Stella endogastric balloon is made of medical grade silicone and it is coated with corn starch. Leachable substances have been estimated to be maximum 130 mg/device of corn starch or its hydrolysis derivatives (dextrins, maltose and glucose) and less than 1.7 mg/device of silicone, followed by trace elements consistent with siloxane oligomers.

It is necessary to use a filling kit during placement of balloon.

The filling kit is supplied packaged and sterile, together with the **STELLA® ENDOGASTRIC BALLOON SYSTEM** as a group (STELLA® KIT ENDOGASTRIC BALLOON). The filling kit consists of a tube, a plastic clip, a double non-return valve, and a spike with raccord luer lock male to fill the balloon with coloured sterile saline solution.

The **STELLA® ENDOGASTRIC BALLOON SYSTEM** is latex-free and does not contain any natural rubber materials. All the materials used for its manufacture have been evaluated according to ISO 10993, the international standard for the biological evaluation of medical devices.

STELLA® ENDOGASTRIC BALLOON SYSTEM is supplied clean, non-sterile, and packaged with the fill kit.

This device has been designed for single use only. Any contaminated device should not be used.

4. INDICATION FOR USE

Overweight or obese adults (men and women), who have failed with previous diets and who require a physical aid that increases the feeling of satiety to reduce the amount of intake and thus promote weight loss.

- Patients with BMI between 27 and 34.9 kg/m² (with at least 1 obesity-related comorbidity for Patients with BMI between 27.0 to 29.9 kg/m²).
- Patients with BMI between 35 kg/m² and 39.9 kg/m² provided they do not have more than 3 major comorbidities associated with obesity.

The **STELLA® ENDOGASTRIC BALLOON SYSTEM** should be used in conjunction with a program involving dietary supervision and changes in behaviour designed to increase the likelihood of sustained maintenance of weight loss.

CAUTION: Temporary weight loss treatments have been shown to have poor long-term success rates in obese and severely obese patients.

The maximum placement period of the **STELLA® ENDOGASTRIC BALLOON** is 6 months. It must be removed at the end of that period or before.

CAUTION: The potential for balloon deflation causing life-threatening bowel obstruction may increase over time.

5. CONTRAINDICATIONS

- Previous gastrointestinal or bariatric surgery.
- The presence of more than one endogastric balloon at the same time.
- Any inflammatory disease of the gastrointestinal tract including oesophagitis, gastric ulceration, duodenal ulceration, cancer, or specific inflammation such as Crohn's disease.
- Possible upper gastrointestinal bleeding conditions, such as esophageal or gastric varices, congenital or acquired intestinal telangiectasias, or other congenital anomalies of the gastrointestinal tract such as atresia or stenosis.
- A large hiatal hernia of > 5 cm or one of ≤ 5 cm with severe or intractable gastroesophageal reflux symptoms.

- A structural abnormality in the esophagus or pharynx, such as a stenosis or diverticulum that could prevent passage of the delivery catheter and/or endoscope.
- Achalasia, or any other severe motility disorder that may pose a safety risk during device removal.
- Gastric mass.
- Severe coagulopathy.
- Liver failure or cirrhosis.
- Chronic abdominal pain.
- Patients known to have or suspected of having an allergic reaction to any of the materials contained in the **STELLA® ENDOGASTRIC BALLOON SYSTEM.**
- Subjects with any serious health condition unrelated to their weight that would increase the risk of endoscopy.
- Any other medical condition that does not allow for elective endoscopy, such as poor general health or a history and/or symptoms of severe kidney, liver, heart, and/or lung disease.
- Serious or uncontrolled psychiatric illness or disorder that could compromise patient understanding or compliance with follow-up visits and device removal after 6 months.
- Active Alcoholism or drug addiction.
- Patients who are unable or unwilling to take prescribed proton pump inhibitor medication for the duration of device implantation.
- Patients who are unwilling to participate in a doctor-supervised diet and behaviour modification program with routine medical follow-up.
- Patients receiving treatment using aspirin, anti-inflammatory agents, anticoagulants or other gastric irritants, without medical supervision.
- Patients known to be pregnant or lactating.
- Relative contraindications in eosinophilic esophagitis and previous abdominal radiation therapy.

6. WARNINGS AND PRECAUTIONS

- Patients should be informed that the **STELLA® ENDOGASTRIC BALLOON** is intended to be placed for a maximum period of 6 months, at which point it must be removed. Longer periods of balloon placement may increase the risk of balloon deflation (a reduction in device size due to liquid loss) which can lead to intestinal obstruction and risk of urgent surgery requirement and potential death. The risk of these adverse events is also significantly higher when the balloons are inflated to larger volumes (greater than 700 ml).
- Patient should be duly informed that any change of colour urine is alarm system of possible leaks and consequently patient should immediately contact the doctor.
- The physiological response of the patient to the presence of the **STELLA® ENDOGASTRIC BALLOON** may vary depending on the patient's general condition and the level and type of activity they do. The types and frequency with which dietary medicines or supplements are administered and the patient's general diet may also affect the response.
- Each patient must be closely monitored throughout the treatment period to detect the development of possible complications. Each patient should be instructed regarding the symptoms of deflation, gastrointestinal obstruction, acute pancreatitis, spontaneous inflation, ulceration, gastric and oesophageal perforation and other complications that may occur and should be advised to contact their doctor immediately at the onset of such symptoms.
- Pregnancy or lactation contraindicates the use of this device. Patients should receive instructions to take necessary precautions to avoid pregnancy prior to balloon placement and during treatment. Similarly, if pregnancy is confirmed at any time during the course of treatment, the patient should communicate this so that the device can be removed as soon as possible according to the obstetrician.
- Patients reporting loss of satiety, increased hunger, and/or weight gain should be endoscopically/radiologically examined as this may be indicative of balloon deflation.
- Deflated devices should be removed quickly. Patients should be warned that balloon deflation can lead to serious adverse events including intestinal obstruction and the need for emergency surgery. Patients should immediately contact their doctor for instructions on preparation for balloon removal.
- If a spontaneously deflated balloon needs to be replaced, the recommended initial fill volume is the same as for the balloon that has been removed. A larger initial fill volume in the replacement balloon may cause severe nausea, vomiting, or ulcer formation.
- A patient whose deflated balloon has moved into their intestines should be closely monitored for an appropriate period of time (at least 2 weeks) to confirm that it has passed through the intestine without problems. Patients need to be evaluated and the device removed at or within 6 months of placement.
- Intestinal obstructions due to passage of deflated balloons into the intestine have been reported. These cases have been treated conservatively, by endoscopy of the small intestine to remove the deflated balloon, and sometimes required surgical removal. The risk of obstruction may be higher in patients with diabetes, a dysmotility disorder, inflammatory disease of the small intestine or who have undergone gynaecological or abdominal surgery. This should therefore be considered in the risk assessment of the procedure. Intestinal obstruction may require surgical treatment or lead to death.
- Endoscopic removal of the **STELLA® ENDOGASTRIC BALLOON** should be performed on an empty stomach (fasting). Patients must fast for a minimum of 12 hours prior to removal. If food is detected in the stomach after endoscopic examination, measures (aspiration of stomach contents, endotracheal intubation, or delay of the procedure) must be taken to protect the airways. The risk of aspiration of gastric contents into the patient's lungs represents a serious risk that can result in death. Some patients may experience clinically significant delayed gastric emptying and refractory intolerance to the balloon. In these cases, it is necessary to remove the balloon early. Failure to do so may result in other adverse events. The risk of aspiration when removing the balloon or when administering anaesthesia in these patients is higher and it is necessary to communicate it to the anaesthesia team and to the patient.

- Proper positioning of the **STELLA® ENDOGASTRIC BALLOON** within the stomach is necessary to provide for adequate inflation. Lodging of the balloon in the opening of the esophagus during inflation may cause damage to the device and/or cause it to break. Failure to confirm correct positioning may result in damage to the esophagus, duodenum, or pylorus.
- When filling the balloon during the placement procedure, avoid filling it at a fast rate as this will generate high pressure that can damage the balloon valve or cause premature dislodgement of the placement and filling tubes.
- If difficulty with the feeding channel is observed during placement (e.g., resistance to balloon fill), then the device should be removed and replaced with a new balloon. To reduce or prevent feeding channel defects, the feeding channel must remain loose during the filling process. If the feeding channel is under stress during this process, it may become detached from the balloon, preventing the balloon from unfolding further.
- Do not immerse the balloon in disinfectant. This could cause some of the solution to be absorbed by the silicone elastomer, seeping through and subsequently causing a reaction in the tissues.
- The **STELLA® ENDOGASTRIC BALLOON** is made of a soft silicone elastomer and is easily damaged by sharp instruments or objects. The balloon should only be handled with gloved hands and with the recommended instruments.
- Patients with a balloon in place who have severe abdominal pain but show no abnormalities on endoscopy and radiography may require a CT scan to definitively rule out any complication or even a perforation.
- Antiemetics, antispasmodics, and anticholinergics may be prescribed to lessen the symptoms experienced during early placement, such as nausea, vomiting, and abdominal pain. Patients will need to contact their doctor immediately regarding any serious or unusual problems. Placing the balloon inside the stomach produces an expected and predictable reaction characterized most commonly by a feeling of heaviness in the abdomen, nausea and vomiting, gastroesophageal reflux, belching, esophagitis, heartburn, diarrhea and sometimes abdominal pain, back pain, or epigastric pain and cramps. Digestion can be slowed down during this adjustment period. These symptoms can be treated with antiemetic, antispasmodic, and anticholinergic medications. Normally, the stomach acclimatizes to the presence of the device in the first 2 weeks. In order to prevent or improve the symptoms most frequently experienced during the adjustment period, it is recommended that doctors use proton pump inhibitors (PPIs), antiemetics, antispasmodics and anticholinergics prophylactically (before balloon placement). Patients should be advised to contact their doctor immediately if their symptoms worsen or are unusually severe.
- To prevent ulcers, it could be recommended that the patient be started on an oral proton pump inhibitor (PPI) program according to medical criteria prior to **STELLA® ENDOGASTRIC BALLOON** placement so that the maximum effect of gastric acid suppression is present on the day of placement. It is recommended that the PPI dose be administered sublingually after the placement of the **STELLA® ENDOGASTRIC BALLOON** if nausea and/or vomiting occurs. A regime of 20-40 mg/day of an oral PPI should be continued while the **STELLA® ENDOGASTRIC BALLOON** is in place. Other medications that are started prophylactically should be continued after placement of the **STELLA® ENDOGASTRIC BALLOON** until no longer needed. Additionally, patients will be instructed to avoid medications known to cause or exacerbate gastroduodenal mucosal damage.
- The **STELLA® ENDOGASTRIC BALLOON** is a silicone elastomer balloon that can be degraded by gastric acid. Doctors have reported that the concurrent use of medications, such as proton pump inhibitors, may reduce acid formation or reduce acidity, potentially prolonging the integrity of the **STELLA® ENDOGASTRIC BALLOON**.
- The **STELLA® ENDOGASTRIC BALLOON** has not been studied in individuals who have a pathologic pylorus, an active *H. pylori* infection, or patients with symptoms or a diagnosis of delayed gastric emptying.
- It is recommended not to use the device in case the pouch is damaged before use.
- After use, dispose of the device in accordance with local regulations.
- If the balloon becomes detached from the sleeve prior to placement, do not attempt to use or reinsert the balloon into the covers.
- Fill **STELLA® ENDOGASTRIC BALLOON** with sterile saline. Though the cause of hyperinflation is unknown, it may be caused by fungal or bacterial microbes contaminating the balloon. One recommended mitigation is to avoid contaminating the saline solution within the balloon with microorganisms that may lead to spontaneous hyperinflation. The use of sterile gloves may be helpful.
- Symptomatic hyperinflation of the intragastric balloons often warrants its early removal to prevent serious complications such as gastric outlet obstruction and contact ulceration. Because hyperinflation increases the internal pressure of the intragastric balloons (due to accumulated gas) and may increase the fragility of the intragastric balloons wall, there is an increased risk of rupture followed by the sudden forceful release of gas and fluid contents when it is punctured or endoscopically manipulated. Therefore, it is suggested that the patient's airway is protected with endotracheal intubation prior to endoscopic removal in order to prevent pulmonary aspiration of the balloon contents. Additionally, in situations in which controlled balloon aspiration is done, it is recommended that mid-stream fluid aspirated from the balloon is sent for bacterial and fungal cultures.
- During the filling process, the balloon feed channel must remain loose. If the tube is under stress it may dislodge from the balloon preventing further unfolding of the balloon.
- If the initial fill volume of the replacement balloon is greater, it may cause nausea, vomiting, or ulcer formation.

7. ADVERSE EVENTS

Any serious incident that has occurred in relation to the **STELLA® ENDOGASTRIC BALLOON SYSTEM** should be reported to the manufacturer (see contact of manufacturer data) and the competent authority of the Member State in which the user and/or patient is established.

It is important to discuss all possible complications and adverse events with your patient. Complications that may arise from the use of this product include the risks associated with the drugs and methods used in the endoscopic procedure, the risks associated with any endoscopic procedure, the risks associated specifically with the **STELLA® ENDOGASTRIC BALLOON SYSTEM**, and the risks associated with the degree of the patient's intolerance to the lodging of a foreign object in the stomach.

7.1 Possible Complications

Possible complications of using the **STELLA® ENDOGASTRIC BALLOON** include:

- Intestinal obstruction caused by the balloon. An insufficiently inflated or leaking balloon which has lost enough volume may be able to pass from the stomach to the small intestine. It can go all the way through the colon and end up with fecal matter. However, if there is a narrow area in the intestine, such as may occur after previous surgery on the intestine or from adhesion formation, or small bowel inflammatory disease, the balloon may not be able to pass, subsequently causing a bowel obstruction. If this occurs, percutaneous drainage, endoscopic removal, or surgery may be required.
- Esophageal obstruction. Once the balloon is inflated in the stomach, it could inadvertently pass into the esophagus. If this occurs, surgery or endoscopic removal may be necessary.
- Gastric outlet obstruction. A partially filled balloon (ie, <400 ml), or a leaky balloon could cause gastric outlet obstruction, requiring balloon removal. It is also possible that a fully inflated balloon (400-700 ml) could lodge in the gastric outlet causing pyloric obstruction. Obstruction that can produce a mechanical impediment to gastric emptying. Gastric outlet obstruction may require surgical removal of the balloon.
- Injury to the lining of the digestive tract as a result of direct contact with the balloon, grasping forceps, or as a result of increased acid production by the stomach. This could lead to the formation of ulcers with pain, bleeding, or even perforation. Endoscopy therapy or surgery may be required to correct this condition.
- Injury to the gastrointestinal tract during placement of the balloon in an inappropriate location such as the esophagus or duodenum. This could cause bleeding and perforation, which may require surgical correction to control.
- Injuries to the pancreas and the appearance of acute pancreatitis. Symptoms can include nausea, vomiting, and abdominal and/or back pain, either constant or cyclical. If the abdominal pain is constant, this can be a sign that pancreatitis has developed. Patients should be advised to contact their doctor immediately if they experience any of the symptoms.
- Death from complications related to intestinal obstruction and gastric or esophageal perforation is possible.
- Not enough or no weight loss or weight regain over time.
- Adverse health effects caused by weight loss.
- Gastric discomfort, feeling of nausea and vomiting after balloon placement as the digestive system adjusts to the presence of the balloon.
- Constipation, meteorism, aerophagia, headache.
- Asthenia and anxiety.
- Continuous nausea and vomiting. This may be due to direct irritation of the stomach lining, as a result of the balloon blocking the gastric outlet, or due to spontaneous inflation of the balloon. It is even theoretically possible that the balloon could prevent vomiting (but not nausea) by blocking the entrance to the stomach from the esophagus.
- Feeling of heaviness in the abdomen.
- Abdominal or back pain, constant or cyclical.
- Gastroesophageal reflux.
- Influence on digestion of food.
- Blockage of food entering the stomach. Vitamin deficiency.
- Bacterial growth in the fluid that fills the balloon. A rapid release of this fluid in the intestine could cause infection, fever, cramps, and diarrhea.
- Deflation of the balloon and subsequent replacement.
- Spontaneous inflation of the placed balloon. Symptoms include severe abdominal pain, swelling of the abdomen (abdominal distention) with or without discomfort, shortness of breath and/or vomiting. Patients should be advised to contact their doctor immediately if they experience any of the symptoms.
- Dehydration, Wernicke-Korsakoff syndrome, or acute kidney failure.
- Other non serious effect adverse (Biliary and renal colic, Dizziness, Urinary tract infection).

7.2 Possible Complications Associated with the Endoscopy and Sedation Routine

Potential risks associated with major endoscopic procedures include, but are not limited to:

- Adverse reaction to sedation or local anesthesia.
- Abdominal cramps and discomfort caused by the air used to distend the stomach.
- Sore throat.
- Injury or perforation of the digestive system including irritation, bleeding, infection, tearing of the esophagus or stomach.
- Inhalation of stomach contents into the lungs leading to aspiration pneumonia.
- Cardiac or respiratory arrest is a very rare situation, normally associated with serious patients' health problems.

8. CLINICAL DATA

The expected clinical benefit of the **STELLA® ENDOGASTRIC BALLOON SYSTEM** is a weight loss improvement at 6 months. A prospective, multicenter clinical trial of the Stella® endogastric balloon system* demonstrated:

- An average of 11.32% TBWL (percent total body weight loss) (95% CI: 10.11, 12.53) at 3 months and 15.39 % (95% CI: 13.77, 17.00) at 6 months. TBWL greater than 10 % was observed in 83.33% of patients at 6 months.
- An average of 47.03% EWL (percent excess weight loss) (95% CI: 41.20, 52.86) at 3 months and 64.71% (95% CI: 56.96, 72.46) at 6 months. EWL greater than 25% was observed in 96.88% of patients at 6 months.

** Prospective, multicentre, clinical trial to evaluate the safety of the STELLA® endogastric balloon at 7 months and the balloon insertion system performed in Spain during in year 2022-2023 (N=69).*

The Summary of Safety and Clinical Performance (SSCP) document, as required by the European Medical Device Regulation, is located at https://ec.europa.eu/tools/eudamed.

While Eudamed is not available, the SSCP can be requested to manufacturer and it will be made available to the public without undue delay.

9. INSTRUCTIONS FOR USE

STELLA® ENDOGASTRIC BALLOON SYSTEM is a part of kit which is composed by:

- One **STELLA® ENDOGASTRIC BALLOON SYSTEM** containing one balloon supplied with the double lumen probe (introducer system) in a single use non-sterile packaging.
- One filling kit in a sterile individual packaging.

The device should not be used if any damage is observed.

A backup **STELLA® ENDOGASTRIC BALLOON SYSTEM** must be available at the time of placement.

DO NOT SEPARATE THE BALLOON FROM THE DOUBLE LUMEN PROBE. Inspect the system for possible damage before use.

Other materials not included in the kit but to be used for the procedure are:

Endoscope, lubricant gel, sterile saline solution, blue dye (i.e. methylene blue), sterile syringe and other tools such as guidewire, drainage needle, extraction forceps with two sharp grippers.

CAUTION: If the balloon is detached from the sleeve prior to placement, do not attempt to use it or to reinsert the balloon into the covers.

9.1 Balloon Placement and Inflation

Prepare the patient for endoscopy. Inspect the esophagus, stomach and duodenum endoscopically. If there are no contraindications, insert the guidewire into the stomach or duodenum. Once the position of the guidewire within the stomach has been confirmed, remove the endoscope. Then introduce the balloon system by inserting/running the guidewire into the carrier tube. Introduce the endoscope to confirm the balloon is in place. Then, the guidewire can be removed. The small size of the double lumen probe allows the endoscope to be re-inserted to observe the position of the balloon and the filling process.

Once it has been confirmed that the balloon is below the lower esophageal sphincter and well inserted into the stomach cavity, the balloon can be filled with sterile saline solution stained with methylene blue. Place the spike from the filling kit into the sterile saline bag using aseptic technique. Attach a syringe to the double non-return valve on the fill kit and prime the fill system. Next, connect the Luer-Lock connector located at the end of the feed channel to the same double valve. Proceed to fill and unfold the balloon, verifying with the endoscope that it is inside the stomach (see filling recommendations below).

CAUTION: Fill the balloon with sterile saline. Though the cause of hyperinflation is unknown, it may be caused by fungal or bacterial microbes contaminating the balloon. One recommended mitigation is to avoid contaminating the saline solution within the balloon with microorganisms that may lead to spontaneous hyperinflation. The possibility of using sterile gloves should be considered.

CAUTION: During the filling process, the balloon feed channel must remain loose. If the tube is under stress it may dislodge from the balloon preventing further unfolding of the balloon.

WARNING: Fast fill rates will generate high pressure that can damage the balloon no-return shut-off valve or cause premature detachment.

9.1.1 Filling Recommendations

The expandible design of the **STELLA® ENDOGASTRIC BALLOON** provides for a filling volume range of 400 ml (minimum) up to 700 ml (maximum). The **STELLA® ENDOGASTRIC BALLOON** should not be underfilled or overfilled with volumes (less than 400 ml or more than 700 ml), as overfilling or underfilling the balloon could cause an increased risk of serious side effects, such as migration (deflated balloon) or gastric rupture/perforation (overfilled balloon). Once filled, the **STELLA® ENDOGASTRIC BALLOON** is not adjustable. A balloon volume of 400 ml or higher is enough to induce the feeling of satiation.

The following filling recommendations are provided to avoid inadvertent damage to the balloon closure valve or premature dislodgement:

- Always use the fill kit supplied along with the STELLA® System.
- With a 50 or 60 ml syringe, each fill stroke should be done slowly (minimum 10 seconds) and steadily. Slow and constant filling will avoid generating high pressure in the closing valve.
- Filling should always be performed under direct (gastroscopic) visualization. The integrity of the balloon shutoff valve should be confirmed by observing the valve's lumen when the balloon's delivery tube is withdrawn from the shutoff valve. A balloon with a leaking valve should be removed immediately. A partially inflated or deflated balloon can result in an intestinal obstruction, which can result in death. Bowel obstructions have occurred as a result of unrecognized or untreated balloon deflation.

A minimum fill volume of 400 ml is required for the balloon to completely separate from the double lumen probe. Once the balloon is filled, remove the filling kit from the feed channel by gently pulling on the double probe while the balloon is against the tip of the endoscope or the lower esophageal sphincter. Continue to pull on the probe until it comes out of the self-closing valve. Once released, the balloon should be inspected visually.

9.1.2 Balloon Placement and Inflation (Step-by-Step Procedure)

1. Prepare the patient according to the hospital protocol for sedation and endoscopy.
2. Perform endoscopic inspection of the esophagus, stomach and duodenum.
3. If there are no contraindications, insert the guidewire through the endoscope until it reaches the stomach or duodenum.
4. Confirm the guidewire position within the stomach and withdraw the endoscope.

5. Open the pouch and remove the **STELLA® ENDOGASTRIC BALLOON SYSTEM** with clean or sterile gloves to place it on the endoscopy field. Handle the product with care without excessive force.
6. Lubricate the **STELLA® ENDOGASTRIC BALLOON SYSTEM** with surgical lubricant gel and pass the guidewire along the transporter/ carrier tube starting at the end of the tip, crossing the channel from one end to the other.
7. Bring the set close to the mouth and push gently to begin inserting it through the esophagus until it reaches the stomach. In the introducer system, 3 marks can be distinguished at 40, 45 and 50 cm from the balloon to establish how far it has been introduced.
8. Insert the endoscope to observe the location of the balloon and the filling steps. The balloon should be below the lower esophageal sphincter and well within the stomach cavity.
9. Connect the 50 or 60 ml syringe or the infusion system and the Luer-Lock connector to the double non-return valve of the filling kit. Insert the spike from the filling kit into a bag of saline solution previously stained with methylene blue.
10. Slowly fill the balloon with sterile saline solution, 50 ml at a time. Repeat until the required volume is reached. The maximum recommended volume is up to 700 ml; the minimum filling volume is 400 ml.
11. Remove the guidewire, and gently pull the introducer system out so that the filled balloon detaches from the set. Check by endoscopy that the self-closing valve is not leaking and the balloon is well located into the stomach.

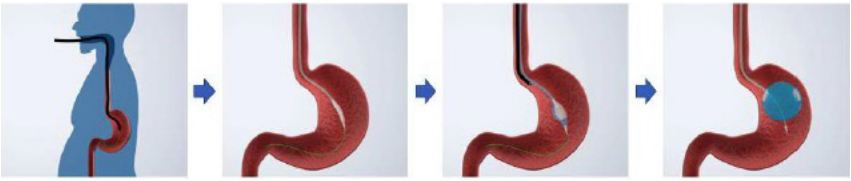

Figure 2. Diagram showing steps for the placement and inflation of the STELLA® endogastric ballon

12. Dispose the introducer system and other single-use devices in accordance with applicable requirements for its correct disposal.

The reference of the implanted balloon must be recorded in the patient's implant card and in the medical record kept by the hospital.

9.1.3 Balloon removal (Step-by-Step Procedure)

1. Make sure the patient has fasted for a minimum of 12 hours before attempting removal. If removal is urgent and conditions do not allow 12 hours of fasting prior to removal, then the airway should be secured, and general anesthesia employed, because potential for residual gastric contents in some patients, additional precautions for aspiration should be considered.
2. Prepare the patient based on the hospital protocol for sedation and endoscopy.
3. Insert the endoscope into the patient's stomach.
4. Assess whether or not food is present. If food is present in the stomach the procedure must be delayed. If the removal is an emergency, airways must be protected before proceeding.
5. Get a clear view of the filled balloon through the endoscope.
6. Insert a needle instrument into the working channel of the endoscope.
7. Use the needle instrument to pierce the balloon.
8. Push the distal end of the suction tubing through the balloon shell.
9. Remove the needle from the tubing sleeve.
10. Apply suction to the tube until all the fluid is evacuated from the balloon.
11. Remove the suction tubing from the balloon and out of the working channel of the endoscope.
12. Insert a two-pronged wire/grip forceps through the working channel of the endoscope.
13. Grasp the balloon with the two-pronged forceps (ideally at the opposite end of the valve if possible).
14. Consider administering an antispasmodic medication, such as hyoscine, to relax the muscles of the esophagus for when the balloon is extracted through the neck region.
15. With a firm grip on the balloon, slowly extract it via the esophagus.
16. When the balloon reaches the throat, hyperextend the head to allow an easier curve and extraction.
17. Remove the balloon from the mouth.
18. Reinsert the endoscope to rule out any potential injury or complications arising from the removal of the balloon.
19. After using **STELLA® ENDOGASTRIC BALLOON SYSTEM**, it should be disposed of according to local regulations for disposable surgical instruments.

10. BALLOON REPLACEMENT

In cases where the intragastric balloon needs to be replaced, the instructions for removal, placement and inflation of the **STELLA® ENDOGASTRIC BALLOON SYSTEM** must be followed. The replacement balloon may have the same volume as the extracted balloon if the latter has not lost volume at the time of withdrawal. However, if the first balloon was deflated prior to removal, it is recommended that the fill volume of the replacement balloon be the measured volume of the balloon that has been removed.

CAUTION: If the initial fill volume of the replacement balloon is greater, it may cause nausea, vomiting, or ulcer formation.

11. RISKS ASSOCIATED WITH REUSE

The **STELLA® ENDOGASTRIC BALLOON SYSTEM** is intended for single use device which is intended to be used exclusively for a single patient during a single procedure.

Do not reuse, sterilize, reprocess and /or repack the device, because it may compromise the physical, chemical and biological properties of the device that are critical to the performance and safety of the device. Reuse of the device poses a high risk of contamination and intestinal obstruction. To remove the balloon, it is necessary to puncture it. Any subsequent reuse would cause the balloon to deflate within the stomach. This could lead to a possible bowel obstruction and the need for surgery to remove it. Balloons that fail to implant cannot be reused either.

Any attempt at decontamination could cause damage causing the balloon to deflate again after filling.

12. RISKS ASSOCIATED WITH MAGNETIC RESSONANCE (MR)

STELLA® ENDOGASTRIC BALLOON SYSTEM filled with saline solution is considered as MR safe.

13. STORAGE CONDITIONS

STELLA® ENDOGASTRIC BALLOON SYSTEM is supplied in non-sterile individual unit. The intact pouch protects and maintains the device cleaned.

It should be storage in its original packaging in a cool dry and protected from direct sunlight place.

Storage temperature should be maintained between 5 ºC to 40 ºC.

STELLA® ENDOGASTRIC BALLOON SYSTEM should not be used after the expiry date (see label).

Before using the **STELLA® ENDOGASTRIC BALLOON SYSTEM**, make sure that the packaging is not damaged. If it is, it should not be used in any case.

14. LABELLING SYMBOLS DESCRIPTION

SYMBOL	DESCRIPTION
	Symbol MANUFACTURER. This symbol is accompanied by the name and the address of the manufacturer
	Symbol “DATE OF MANUFACTURE”
	Symbol “BATCH CODE”
	Symbol “CATALOGUE NUMBER”
	CE symbol with the intervention of a Notified Body
	Symbol for “CONSULT ELECTRONIC INSTRUCTIONS FOR USE”
	Symbol “STAY OUT OF SUNLIGHT”
	Symbol “KEEP DRY”
	Symbol “USE BY” (AAAA-MM-DD)

	Symbol “DO NOT USE IF PACKAGE IS DAMAGED”
	Symbol “SINGLE USE”
	Symbol “non-sterile device”
	Symbol “MR safe” (filled balloon only)
	Temperature limits
	Symbol for Unique Device identifier
	Symbol for caution
	Symbol “Medical Device”
	Device restricted to use by a physician

15. GUARANTEE

Guarantee is not valid if:

- **STELLA® ENDOGASTRIC BALLOON** stay in the stomach more than 6 months, and if it is not placed before expiry date.
- The conditions of storage or transportation are violated (including the damage of the device).
- The device is damaged during placement carried by specialists as the result of violating the requirements of the instruction of use.

16. VALIDITY

These instructions for use supersede all previous versions.

17. DECLARATION OF CONFORMITY

The **STELLA® ENDOGASTRIC BALLOON SYSTEM** device complies with the requirements of Regulation 2017/745 on medical devices. It bears the symbol CE 2797.

18. MANUFACTURER

SWAN MEDICAL S.L.
Córcega 270, 3º 2ª
08008 Barcelona – Spain
www.swanmedical.es
Phone: +34 938 325 897
Email: info@swanmedical.es

CE 2797