RefluxStop®

Instructions for Use

⚠ IMPORTANT

Please read carefully all instructions contained within this packet before use.

⚠ ***CAUTION:* Federal law (U.S.) restricts this device to sale by or on the order of a physician.**

Implantica CE Reflux Ltd only accepts responsibility for the device's safety, usability and performance if:

- *the device is used in accordance with its intended use; and*
- *the device is used in accordance with the product labels and instructions for use. This includes the instructions for both the RefluxStop® device and the RefluxStop® Deployment Tool.*

Electronic Labelling

The Instructions for Use can be accessed online by visiting the website provided on the label (https://ifu.implantica.com) and selecting the relevant device. Additional translations are also available in electronic format for download. A paper copy is available free of charge within 7 calendar days. Please contact customer support at: customersupport@implantica.com or by clicking "Request a document" via the link provided on the website (https://ifu.implantica.com).

Product name:	**RefluxStop®**
Product catalogue number:	**RS-A1**
Instructions for use catalogue number:	**IFU-0003234 rev Draft v7.0**
Date of issue:	**2026-08**
Manufacturer:	**Implantica CE Reflux Ltd**
Contact:	Sir Temi Zammit Buildings Malta Life Sciences Park San Gwann SGN 3000 Malta Tel: +356 2144 3532
Customer support:	customersupport@implantica.com www.implantica.com https://ifu.implantica.com/

Contents

1 Instructions for Use

These instructions for use describe use of the implantable RefluxStop® device (RS-A1). Product specific training needs to be received from an Implantica representative prior to initial use.

Users must read these instructions for use and the instructions for use for the RefluxStop® Deployment Tool carefully prior to using the devices so that the features are thoroughly understood. Failure to follow these instructions may endanger the patient and/or the operator.

⚠ ***WARNING:** Always read the IFU for the RefluxStop® Deployment Tool and the RefluxStop® device prior to use. Failure to follow these instructions may endanger the patient and/or the operator.*

2 Abbreviations

Term	Definition
ADE	Adverse Device Effects
AE	Adverse Events
ARB	Anti-Reflux Barrier
GERD	Gastroesophageal Reflux Disease
GERD-HRQL	GERD Health-Related Quality of Life
GEJ	Gastroesophageal Junction
IFU	Instructions for Use
LES	Lower Esophageal Sphincter
PPI	Proton Pump Inhibitor
RS-A1	RefluxStop implantable device
RS-300	RefluxStop Deployment Tool
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event

3 Device Overview

3.1 Design Thesis & Clinical Benefit

3.1.1 Design Thesis

RefluxStop® is an implantable sterile medical device intended to treat acid and non-acid reflux in patients diagnosed with gastroesophageal reflux disease (GERD).

Acid reflux is caused by the lower esophageal sphincter (LES) temporarily or permanently entering into the chest or being positioned too close to the hiatus opening. The pressure in the abdomen typically supports the LES to close; however, if the LES is in an abnormal position or has a weaker supporting pressure, the closing function of the LES may not work sufficiently, thereby resulting in acid reflux. In addition, during the breathing process, pressure variations leak out through the hiatus opening in the diaphragm, negatively affecting the LES.

The RefluxStop® Forsell procedure reconstructs the angle of His and reinforces the top part of the stomach (fundus) by invagination of the RefluxStop® device in the fundus wall. The RefluxStop® device maintains the LES in its original physiological anatomic position, avoiding acid reflux. The RefluxStop® device dynamically interacts with the diaphragm parallel to the LES and the hiatus opening in the diaphragm, leaving the food passageway unaffected, especially advantageous in patients with weak peristalsis, with the goal of reducing side effects, such as dysphagia.

3.1.2 Clinical Benefit

RefluxStop® surgery restores and maintains the gastro-esophageal junction in its normal physiological position in the abdomen and eliminates or reduces gastroesophageal reflux disease (GERD) /acid reflux symptoms, e.g., heartburn, regular daily PPI usage and swallowing problems. By avoiding encircling and putting pressure on the food passageway, the functionality of which is often damaged over time by repeated acid exposure, a normal sphincter function is restored and results in a reduction of side-effects typically seen in standard of care anti-reflux procedures, e.g., dysphagia, swallowing pain, inability to belch and vomit, and gas bloating.

3.2 Intended Use

The RefluxStop® device is an implantable, single-use sterile device that is implanted into the abdominal cavity at a predetermined place at the fundus of the stomach during a laparoscopic procedure. Based on its placement outside the stomach fundus wall fixated only by the created pouch, the RefluxStop® device ensures maintenance of the gastro esophageal junction (GEJ) in an intra-abdominal position, allowing a normal function of the LES thereby reducing or eliminating acid and weak acid gastric reflux.

The RefluxStop® Deployment Tool (RS-300) is a reusable, invasive surgical instrument that is designed exclusively to facilitate the introduction of the implantable RefluxStop® device (RS-A1) into the abdominal cavity at a predetermined place at the fundus of the stomach during a laparoscopic surgical procedure. See the separate IFU for the RefluxStop® Deployment Tool (RS-300).

3.3 Device Description

The RefluxStop® device consists of an assembly of five components, supplied sterile, that engage to form a rounded cuboid. Each of the five components contain recesses and protrusions that are designed to fit with each other [***Figure 1***]. The components are to be pre-mounted with a resorbable suture (2-0 Vicryl Plus, 70cm) holding the pieces together, as described in Section 13.1 [***Figure 2***].

The RefluxStop® device is manufactured from an **MR Safe** material consisting of a mixture of medical grade silicone (90-95% NusilMED-4860) and barium sulphate (5-10% $BaSO_4$ powder). The barium sulphate contained is a manufacturing additive to enable visibility of the device under x-ray imaging.

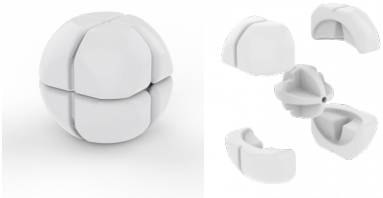


Figure 1. RefluxStop® Device Assembled (left) and in an Exploded View (right)

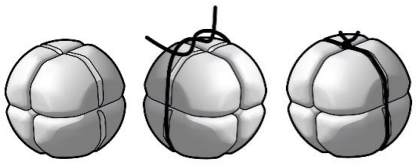


Figure 2. Assembly of the RefluxStop® Device with the Resorbable Suture

3.4 Duration of Use

The RefluxStop® device is intended for long-term use (> 30 days).

3.5 Expiry Dating

Expiration dating for RefluxStop® System has been established and approved at five (5) years for the RefluxStop® device implant and up to 200 cleaning and sterilization cycles of the metal components of the RefluxStop® Deployment Tool and 50 cleaning and sterilization cycles of the silicone component of the RefluxStop® Deployment Tool.

4 Indications for Use

4.1 Indications for Use

RefluxStop® is an implantable sterile medical device intended to treat acid and non-acid reflux in patients diagnosed with gastroesophageal reflux disease (GERD). The device ensures maintenance of a normal physiological situation for the gastroesophageal junction (GEJ) in a defined intra-abdominal position, allowing a natural physiological function of the lower esophageal sphincter (LES), thereby reducing or eliminating acid and non-acid reflux.

The RefluxStop® Deployment Tool is indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD), defined by abnormal impedance pH and/or pH testing, and indicated for RefluxStop® implantation.

4.2 Intended Patient Population

The RefluxStop® System is indicated for patients diagnosed with acid or non-acid Gastroesophageal Reflux Disease (GERD), adults ≥ 18 years old that are indicated for RefluxStop® implantation and meet the following criteria:

- Documented GERD present for > 6 months;
- Patient has endoscopy verified esophagitis, and/or a 24-hour pH monitoring proven GERD defined as pathologic number of impedance pH reflux episodes of acid or weakly acid and/or pathologic pH <4 for >4.5% of the total time, off PPI therapy for at least 7 days prior to testing.

NOTE: The RefluxStop System is not intended to be used with a Collis gastroplasty.

5 Contraindications

The RefluxStop® System is contraindicated in patients with:

- Known sensitivities or allergies to the device materials (medical grade silicone [NusilMED-4860] and barium sulphate [$BaSO_4$ powder]);
- Intraoperative findings determined by the operating surgeon that may result in unfavorable conduct of the procedure.
- Known sensitivities or allergies to the device materials (Stainless Steel AISI 316L and medical-grade silicone ML-154).

6 Warnings and Precautions

6.1 General

⚠ ***CAUTION:*** ***Federal law (U.S.) restricts this device to sale by or on the order of a physician.***

⚠ ***CAUTION:*** ***Only use the RefluxStop® System for its intended use.***

⚠ ***WARNING:*** ***Always read the IFU for the RefluxStop® Deployment Tool and the RefluxStop® device prior to use. Failure to follow these instructions may endanger the patient and/or the operator.***

6.2 Device-Specific

⚠ ***CAUTION:*** ***The safety and effectiveness of the RefluxStop® System has not been evaluated in the Study used for PMA filing in the following patient populations or conditions with precaution diagnosis:***

- ***Do not use the RefluxStop® system in patients with a body mass index (BMI) > 35 kg/m^2;***
- ***Do not use the RefluxStop® system in patients with para-esophageal or hiatal hernia >3 centimeters;***
- ***Known presence of delayed gastric emptying if no other valid reason for acid reflux;***
- ***History or suspicion of esophageal or gastric cancer;***
- ***Known presence of esophageal or gastric varices;***
- ***History of anti-reflux or bariatric procedure with extirpated fundus;***
- ***Stricture or stenosis of the lower esophagus;***
- ***Presence of esophagitis grade D according to the Los Angeles classification, which requires more time for esophagus dissection;***
- ***Female patients who are pregnant at the time of the procedure.***
- ***Patients with achalasia, scleroderma, and nutcracker esophagus.***
- ***Co-morbidity profile that creates an unfavorable risk-benefit balance for the patient.***

⚠ ***WARNING:*** ***The RefluxStop® device is designed for single patient use only. Do not reuse or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure, which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.***

⚠ ***CAUTION:*** ***The RefluxStop® System should only be used by physicians and teams trained in laparoscopic anti-reflux procedures and who have received product specific training by an Implantica representative.***

⚠ ***WARNING:*** ***Do not use the RefluxStop® device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product, and return to Implantica.***

⚠ ***WARNING:*** ***Do not use after the "USE BY" (EXPIRATION) date printed on the label. Store at room temperature.***

⚠ ***WARNING:*** ***Do not use the RefluxStop® device if it has been removed from the sterile field.***

⚠ ***CAUTION:*** ***Do not proceed with the surgical procedure before all specified accessories for the RefluxStop® device and RefluxStop® Deployment Tool are checked and in place.***

6.3 Operational (Surgical) Safety

⚠ ***CAUTION:*** ***The assembly of the RefluxStop® device shall only be performed by a healthcare professional who has received product specific training.***

⚠ ***CAUTION:*** ***Do not place patients in standing positions above 35° as this may lead to surgical difficulties with the fundoplication (i.e. the fundus may fall down more than the esophagus).***

⚠ ***WARNING:*** ***Do not cut the vagus nerves during dissection of esophagus. Prior to applying slight downward traction on the esophagus, take extra care to identify the dorsal vagus nerve since it may have a bend away from esophagus, which may increase risk of damaging the vagus nerve. Normally, this bend straightens out after slight tension is applied on esophagus.***

⚠ ***WARNING:*** ***Care should be taken to not damage or perforate the esophagus during dissection or fundoplication. Do not use instruments to grasp and move the esophagus. Additionally, do not pass instruments blindly behind the esophagus. Such actions may lead to accidental damage of the esophagus. Some surgeons introduce a large gastro-esophageal tube to help identify the esophagus during dissection, however, due to perforation risk such tubes are not encouraged.***

⚠ ***WARNING:*** ***Patient may have a shortened esophagus due to irreversible scarring from chronic esophageal reflux. Do not compensate for a short esophagus by pulling the esophagus down to lengthen it more than maximum 1.0 cm, instead use slight tension in steps to prolong the esophagus while free dissecting. Free dissecting with careful stepwise tension limits the risk of the anatomy being pulled up into the thorax post-operatively causing re-herniation, however, some tension is necessary for a successful dissection.***

⚠ ***CAUTION:*** ***Care should be taken to not enter the pleural space during esophagus dissection. Use blunt dissection to move the pleura and pericardium away from esophagus. If the pleural space is inadvertently entered, close the opening with 1-2 clips.***

⚠ ***CAUTION:*** ***Care should be taken to ensure the esophagus dissection is high enough up in the mediastinum to ensure a proper platform for the RefluxStop® placement targeting 5 cm (4–5.5cm) of total free dissected abdominal esophagus. Even if less free dissected esophagus can be achieved, the RefluxStop procedure normally provides a well-treated patient, however, patients often have some lighter symptoms remaining. If it is possible to achieve 3 cm of esophageal length only, use 1-2 cm fundus from its posterior side, which will increase the height of the invaginated device.***

⚠ ***CAUTION:*** ***The total prolongation of the esophagus caused by stretching should be minimized, instead prolonging esophagus by dissection using slight stepwise traction, as stretching to pull esophagus down centimeters may increase the risk of re-herniation.***

⚠ ***WARNING:*** ***Care should be taken to not damage or perforate the stomach wall. Care during dissection of the greater curvature including the short gastric vessels and posterior down to angle of His.***

⚠ ***WARNING:*** ***Care should be taken to not damage the gastric serosa during the dissection. Gastric serosa damage at the invagination site may cause an early erosion of the device into the stomach or abdominal cavity.***

⚠ ***WARNING:*** ***Bleeding is the leading complication from anti-reflux surgery. Ensure proper ultrasound coagulation tools are used long enough to properly coagulate the short gastric vessels, wherein vascular clips or suture ligatures may be added additionally to avoid bleeding.***

⚠ ***WARNING:*** ***Ensure any fibrotic connections to the spleen are removed and avoid forceful traction on the greater curvature of the stomach to reduce the risk of splenic capsular tear.***

⚠ ***WARNING:*** ***Care should be taken when introducing instruments through the left lateral port as off-vision injury may occur to the spleen or nearby tissue.***

⚠ ***CAUTION:*** ***Normally divide three to four of the short gastric vessels during dissection of the greater curvature and dissect slightly posterior down on fundus to mobilize enough fundus around to angle of His. Avoid dividing the splenic artery and the posterior gastric artery. Care should be taken when dissecting down posterior on the stomach close to the esophagus, where the posterior gastric artery is located.***

⚠ ***CAUTION:*** ***During hiatus repair, care should be taken to ensure that the surgical knots are tight but that the crus muscles are not squeezed or strangulated.***

⚠ ***CAUTION:*** ***Care should be taken to ensure the hiatus opening is not too small as this may lead to dysphagia. Additionally, care should be taken to ensure the hiatus opening is not too large as this may prevent the principal function of the device. To create a relevant size of the hiatal opening, leave a V-shape opening on the side of esophagus for a peanut placed on a 10 mm instrument to easily pass through the hiatus opening. If a bougie is used: If size 35 is used, allow space for a 5 mm instrument with a peanut attached to easily pass through the hiatus opening, and if size 54 is used, no additional space is needed around esophagus if loosely surrounded. Bougie use is generally not encouraged due to perforation risk.***

⚠ ***CAUTION:*** ***During hiatus closure, the sutures should capture the entire crus muscle; care should be taken to not suture through the crus muscles as this increases the risk of the sutures tearing through the muscles in the event of post-operative retching, heaving, or vomiting.***

⚠ ***CAUTION:*** ***Hiatus should be closed enough to prevent the fundal package including the device to re-herniate, passing through the diaphragm.***

⚠ ***WARNING: Do not create a connection between the diaphragm and the fundus pouch for example by suturing between the fundus and the diaphragm. This should be avoided under all circumstances due to long-term safety considerations.***

⚠ ***CAUTION: Avoid stretching esophagus during fundoplication due to increased risk of re-herniation. Mild tension to straighten esophagus, not exceeding 1.0 cm from its relaxed position, is generally acceptable provided only limited stepwise traction has occurred during esophageal dissection.***

⚠ ***CAUTION: The total prolongation of the esophagus caused by stretching, rather than by adequate free dissection, should be minimized, as tension also applied during fundoplication may increase the risk of re-herniation. Because the diaphragm is typically dome-shaped, the esophagus with its attached fundal package, including the device, usually glides up 1 cm after finalizing the procedure. Accordingly, up to 1 cm of traction during fundoplication is generally acceptable, provided the esophagus has been mobilized primarily through careful stepwise dissection using only mild traction. However, if esophageal elongation has mainly been achieved through stretching during dissection, additional traction or straightening of the esophagus during fundoplication should be avoided.***

⚠ ***WARNING:*** ***Substantially incorrect off label suturing of the esophagus or stomach combined with much too close and too tight sutures may theoretically result in erosion of the device into esophagus.***

⚠ ***CAUTION: Suture fundus to esophagus with about 1cm or more between each suture and do not simultaneously use forceful strangulation of esophageal tissue, which may lead to reduced tissue elasticity and dysphagia or reduce blood supply.***

⚠ ***WARNING:*** ***Care should be taken to ensure the sutures do not cut through the muscular tissue or that the esophagus is damaged by an instrument during dissection or fundoplication. If the esophagus muscle wall is damaged or cut through, immediately repair it with a separate suture for that purpose only (even if the entire wall thickness has not been cut through), as later perforation may occur.***

⚠ ***WARNING:*** ***During fundoplication stomach fundus to esophagus, do not include the vagus in any suture loop, especially the anterior vagus needs attention. May cause intensive retching post-op.***

⚠ ***CAUTION:** Severe retching, heaving, or vomiting immediately post-op could result in surgical failure with the crus sutures cutting through the crus muscles and subsequently causing a large hiatal opening and re-herniation. Care should be taken to discuss this matter with the anesthesiologist beforehand to take necessary precautions and medications preventing post-op retching.*

⚠ ***CAUTION:** Care should be taken to ensure the appropriate amount of sutures are used when suturing the fundus to the esophagus. Not leaving enough fundus to allow a soft invagination of the RefluxStop® device may lead to failure.*

⚠ ***CAUTION:** Positive long-term results are dependent on a stable platform of esophagus to stomach adherence close to the diaphragm and high-up on the esophagus near the LES. The most cranial part of the sutures are the most important to hold the foundation of the device.*

⚠ ***WARNING:** Place the fundus holding the device on the left side of esophagus within the two vagus nerves (trunks) and not at the back or front of the esophagus (off label procedure), which potentially may cause problems related to nervus vagus.*

⚠ ***CAUTION:** The pouch is preferably positioned dorsally in the left posterior quadrant of the esophagus. The first suture row between the stomach and the esophagus should therefore be placed approximately 60° posterior to the body midline on the esophagus on the patient's left side, carefully preserving the dorsal vagal trunk.*

⚠ ***CAUTION:** When suturing the fundoplication, ensure the esophagus bite distances are not substantially larger than the stomach bite distances. Such suturing technique may lead to bending and narrowing of the esophagus, resulting in dysphagia.*

⚠ ***CAUTION:** Do not suture substantially larger bites in the stomach compared to esophagus.*

⚠ ***CAUTION:** Avoid forceful suturing which may rupture the esophagus leading to fundus not being secured to or later separating from esophagus. Especially if knots are made extra corporally, avoid tension on any esophagus bite that could cut through.*

⚠ ***CAUTION:** Avoid fat in the suture line attachments.*

⚠ ***CAUTION:** Ensure the sutures in the esophagus are not too superficial or are placed with too tiny bites in esophagus during fundoplication. Such suturing technique could increase the risk of surgical failure if the patient coughs or vomits post-op.*

⚠ ***CAUTION: S**uture fundus to esophagus ensuring the fundoplication procedure is performed by leaving enough fundus to allow a soft invagination.*

⚠ ***CAUTION**: Only use resorbable suture to assemble the RefluxStop® device. Required to use Vicryl Plus due to its specific absorption time properties.*

⚠ ***CAUTION:** Only add lubricant to the RefluxStop® device and compress it into the RefluxStop® Deployment Tool immediately prior to introducing the implant into the abdomen. Leaving the lubricated device within the tool for an extended period of time may lead to difficulty in releasing the device. Filling the deployment tool pipe with too much lubricant may hinder the compression of the device.*

⚠ ***WARNING:** Ensure free passage for the Trocar of the RefluxStop Deployment Tool and the RefluxStop® device into the abdomen, through visual clearance using Laparoscope. Failure to ensure appropriate clearance may lead to damage of tissues or organs.*

⚠ ***CAUTION:** Incorrect device placement will prevent the intended treatment effect.*

⚠ ***CAUTION:** The lower esophageal sphincter may move cranial long-term after surgery due to tissue consolidation. Therefore, headroom in placement height is needed for an optimal long-term result.*

⚠ ***CAUTION:** As the diaphragm is slightly dome-shaped, it is important that the device is placed not only high-up but also close to the hiatus/esophagus, otherwise 1.0 - 2.0 cm of height is lost when the device acts as a mechanical stop against the diaphragm. Therefore, it is important that the device is not only placed high-up, but it should also be placed close to the hiatus/esophagus.*

⚠ ***CAUTION:** Ensure the invagination suturing is performed loosely without tension in the stomach wall. Suturing too tightly may obstruct blood supply to the stomach pouch wall and could increase the risk of device erosion into the stomach cavity.*

⚠ ***CAUTION: A bleeding in the stomach pouch wall may also restrict the pouch space with similar effect as above, increasing the risk of erosion of the device into the stomach cavity.*

⚠ ***CAUTION:** Too tight of an invagination could theoretically cause a mucosal stomach ulcer at the site of the device due to the reduced blood supply to the stomach wall.*

⚠ ***CAUTION:** Care should be taken to ensure that fundus wall is properly mobilised to be used for the invagination of the device by placing a top hat suture above the device 2 cm posterior of sail of the greater curvature to mobilise fundus wall also from behind/posterior of fundus.*

⚠ ***CAUTION**: Ensure the invagination pouch isn't too large which can lead to a lowering of the implant position. If the device moves away from esophagus, the fundus package may move cranial.*

⚠ ***WARNING:** Ensure the RefluxStop® device is completely covered by sutured stomach wall. Indirect risk only relevant if the patient experiences infection post-op.*

⚠ ***CAUTION:*** ***While holding the device with the deployment tool ensure that the position of the RefluxStop® device is secured by a distal locking non-resorbable suture, a purse string single non-barbed suture below the device.***

⚠ ***WARNING:*** ***Much too tight of an invagination could cause the device to erode into the abdominal cavity (although it's highly unlikely since the device hangs like a teardrop into the stomach cavity with a row of sutures above) due to the reduced blood supply to the stomach wall.***

⚠ ***CAUTION:*** ***Ensure to have closed enough of the loosely sutured invagination of the RefluxStop® device before releasing the device from the RefluxStop® Deployment Tool.***

⚠ ***CAUTION:*** ***If the RefluxStop® device is inadvertently released from the RefluxStop® Deployment Tool inside the abdominal cavity, re-mount the RefluxStop® device to the RefluxStop® Deployment Tool. This can be accomplished by inserting an additional and suitable instrument (e.g. a Babcock) inside the abdomen and pushing the top of the Wire of the RefluxStop® Deployment Tool into the center hole of the implant.***

⚠ ***CAUTION:*** ***In the event the RefluxStop® device components fall apart during introduction into or when inside the abdominal cavity, all parts of the RefluxStop® device shall be removed and re-sutured / re-mounted outside of the body.***

⚠ ***CAUTION:*** ***If an early erosion occurs into the stomach cavity, the device exits spontaneously through the digestive tract and no further action is needed. If seen at an early stage in one piece, it is possible to cut the suture holding the device together by EG endoscopy allowing the individual pieces to pass more quickly through the digestive tract.***

⚠ ***WARNING:*** ***A device eroded into the stomach cavity can cause ileus if the suture remains around the device early after operation or if a non-resorbable suture has been used around the device. In an undamaged digestive tract, the full device should be able to pass, however, previous abdominal surgery may cause narrowing of the intestines due to adherences.***

7 Adverse Events

7.1 Observed Adverse Events

A 50-patient European Union, multicenter, prospective study was conducted to support approval of the RefluxStop® System. Results from this study, including major adverse events related to the RefluxStop® device (RS-A1), are outlined in Section 8. Adverse events related to the RefluxStop® Deployment Tool are outlined in the RefluxStop® Deployment Tool (RS-300) instructions for use.

7.2 Potential Adverse Events

Adverse events that may be related to the use of the RefluxStop® device include, but are not limited to, those that are commonly associated with general anesthesia, abdominal laparoscopic surgery, and those that are associated with the RefluxStop® device. These may be serious and even cause death. Potential adverse events related to general anesthesia and abdominal surgery in general comprise of, but are not limited to: Abdominal abscess, abdominal pain, adverse reactions to anesthesia (dizziness, headache, nausea, sore throat, teeth damage, visual complications), allergic shock, anaphylactic shock, atrial arrhythmia or fibrillation, cardiac arrhythmia or arrest, fever, hemorrhage, heart attack, hypotension, hypoxemia, ileus, incisional herniation, infection (related risks which could also occur separately or in any combination include: perforation, esophageal stenting, fistulation, peritonitis, mediastinitis), pneumonia, pneumothorax, pulmonary embolism, respiratory distress, sepsis, septic shock, septicemia, stroke, thrombophlebitis, thrombosis, urinary retention, urinary tract infection, visceral adhesions, weight loss and wound dehiscence.

Possible risks related to anti-reflux surgery in general, which may apply to the RefluxStop® surgical procedure, may include, but are not limited to: Intraoperative complications, reinterventions, respiratory complications also comprising atelectasis, pleurisy and pneumothorax, flatulence, retching, vomiting, bloating, hiccups, reherniation also comprising fundus including the device, bleeding especially hemorrhage from the short gastrics, the spleen including spleen extirpation, gastric or esophageal perforation, dysphagia including need for esophagus dilatation, odynophagia, recurrence of GERD symptoms such as heartburn, regurgitation, crus sutures damaging/cutting through the crus muscles due to retching/heaving/vomiting, sutures damaging the esophagus with retching, pain, ileus, esophageal widening, esophageal obstruction or reconstruction, narrowing or stenosis, or infection including peritonitis and abscess, gas bloating, inability to belch or vomit, diarrhea, vomiting and delayed gastric emptying, and hiatal repair performed too tightly causing dysphagia.

Finally, there are also possible adverse events directly related to the RefluxStop® device. Potential adverse events comprise of but are not limited to: lack of treatment effect or regain of reflux symptoms, device removal or re-operation, device erosion long-term and short-term. Short-term erosion could occur due to surgery-related hampered blood supply to the stomach wall or surgically induced damage on the stomach wall serosa. Blood supply may also be affected due to too tight of an invagination, causing too much pressure on the stomach wall. Too tight of an invagination not causing erosion may instead theoretically cause a mucosal ulcer to form at the device position due to a reduced blood supply (not verified). Fundoplication sutures may also come loose, causing relapse of reflux symptoms. Not closing the pouch may cause device slippage and infection may reach the device if occurring. Re-herniation may occur, but often the re-herniated fundus could be restored with the device intact in its fundal pouch. This risk is greater in patients with larger hernia before surgery.

The device hangs in a teardrop shape into the stomach cavity surrounded by single stomach wall, with double stomach wall sutured together most cranial of the pouch. This surgical technique of placing the device in a pouch, and the design of the device in smaller pieces, are performed to reduce the risk erosion of the device, which normally occurs without any action needed. This said, an eroded device could theoretically end up anywhere.

7.3 Device-Related Adverse Event Reporting

Any adverse event (clinical incident) involving the RefluxStop® System should be reported to Implantica immediately. To report an incident, notify Implantica Customer Support.

Please observe that RefluxStop® treats reflux of stomach content into the esophagus, which often causes pain and tissue damage, however, RefluxStop® does not treat gastritis and does not treat SIBO, a bacterial inflammation in the small intestine. The lack of acid in the stomach resulting from PPI usage, allows bacteria to pass through the stomach into the small intestine with undigested food.

8 Summary of Clinical Data

Implantica has completed a clinical study of the RefluxStop® System for the treatment of acid and non-acid reflux in patients diagnosed with gastroesophageal reflux disease (GERD).

The RXI001 CE-Mark Study was a prospective, open-label, multi-center, single-arm, treatment-only study conducted at four (4) investigational sites in Europe. It was designed to evaluate the performance of the RefluxStop® device in adult subjects between 18 and 75 years of age with documented typical GERD symptoms for >6 months, daily use of proton pump inhibitor (PPIs) as anti-GERD medication, and proven GERD as determined by 24-hour pH monitoring. A total of 50 test subjects were enrolled between December 2016 and September 2017. Clinical follow-up and diagnostic test evaluations were scheduled at baseline, pre-discharge, 6-weeks, 3-months, 6-months, 1-year, and annually thereafter through five years. The study primary endpoints were established to assess the incidence of serious adverse device effects (SADEs), procedure-related serious adverse events (SAEs), adverse device effects (ADEs), and procedure-related adverse events (AEs). Additional secondary endpoints were also established to investigate the effects of the device implant on GERD symptoms, PPI usage, lower esophageal acid exposure (via pH monitoring), and health-related quality of life (HRQL).

The final, 5-year follow-up results confirm that the positive performance of the RefluxStop device is stable and sustained in the long term. GERD-HRQL scores demonstrated 90% median improvement from baseline and 24-hour pH total time improved with 90.4% reduction in acid exposure. Furthermore, regular daily PPI usage occurred in only one subject at Year 5 (1/44), a further indicator of sustained treatment success. There were no cases of esophageal dilatation, explantation, device erosion or migration, or device-related AEs (no device related AE occurred during the entire study period). Overall, only two (2) AEs occurred during Years 1-5 of the study (i.e., dyspepsia moderate and recovered mild dysphagia). This low rate of AEs is likely attributable to RefluxStop's loose fundus invagination and dynamic physiological interaction that avoids encircling or exerting pressure on the food passageway. Considering these results, the RefluxStop procedure is safe and effective long-term when used as indicated.

8.1 Safety Endpoint Results

Per the study protocol, the safety endpoints of RXI001 were as follows:

- *Primary Safety Endpoint:* The incidence of serious adverse device effects (SADEs) and procedure-related serious adverse events (SAEs) at 6 months.
- *Secondary Safety Endpoint:* The incidence of SADEs and procedure-related SAEs at 6 weeks, 3 months, and during years 1–5. The incidence of adverse device effects (ADEs) and procedure-related adverse events (AEs) during the entire 5 years after device implantation and recorded at 6 weeks, 3 months, 6 months, and at follow-up during years 1–5.

All SAEs and procedure-related SADEs for both the primary and secondary endpoints are detailed in **Table 1** below. All ADEs and procedure-related AEs reported as part of the secondary endpoint are detailed in **Table 2** below. The safety results throughout the entire 5-year study are summarized as follows:

- Two procedure-related severe SAEs were observed: one case of infection with abscess and one case of hematoma drainage due to bleeding from short gastric vessels. Both subjects recovered fully following appropriate treatment, fully treated.
- One re-operation occurred (Moderate SAE) during the entire study period due to a loose fundoplication suture that was subsequently re-sutured with the device remaining intact in its pouch. The suturing was performed as an elective surgery in the same way as the original procedure.
- One broken needle (Mild SAE) was removed subcutaneously.
- There were six (6) procedure-related adverse events (AEs) reported across five (5) patients during the 5-year study period. Only two (2) procedure-related AEs (i.e., moderate dyspepsia and mild dysphagia) occurred between Year 1-5.

In total, five (5) subjects had seven (7) SAEs assessed as related to the study procedure, i.e., surgery. All procedure-related SAEs occurred prior to the Year 1 visit (all but one in the first 30 days following surgery), had a duration between 1-52 days, and all were resolved. Four (4) SAEs that occurred in two (2) subjects were reported as severe. These are discussed below:

- One (1) subject was diagnosed and treated for a bleeding with drainage of hematoma (PT Intra-abdominal hemorrhage), wherein the bleeding had stopped spontaneously. The most probable cause of the hemorrhage is that the coagulation of the short gastric vessels was insufficient. The event was judged to be related to standard of care

fundoplication reflux surgery and not related to the device. The patient recovered successfully. Such bleeding occurs in 1% of Nissen fundoplication cases as per a published literature review[1].

- One (1) subject was diagnosed with a severe infection including an Abdominal abscess, Mediastinal abscess, and Empyema four days after implantation. The events were judged to be related to abdominal surgery in general, and the infection did not affect the device in its enclosed pouch. The patient recovered successfully. Infection is a known complication in all abdominal surgeries. No damage could be seen or any leakage from the esophagus or stomach could be verified with methylene blue (a substance used for identifying any such leakage).

The remaining three (3) SAEs were moderate or mild and included:

- One (1) subject had a part of a subcutaneously placed broken surgical needle (PT Foreign body) removed one day after device implantation. The subject completely recovered.
- One (1) subject was diagnosed with loose fundoplication sutures (PT Suture rupture). The subject was re-sutured and completely recovered. The most cranial fundoplication suture had come loose and caused fundus with the implanted device intact to move slightly away from the esophagus and thus also downwards. After free dissection, the fundus was repositioned and resutured to the esophagus in the same way as the original procedure, with successful result and a GERD-HRQL score 0 (zero) after the procedure. One (1) subject was diagnosed with a postoperative pleuritis (PT Pleurisy). The subject recovered successfully. This event could possibly be related to anesthesia as well as to the general surgical procedure.

Notably, all procedure related SAEs occurred prior to the 6-month follow-up visit. Together, these results underscore the overall safety profile of the device as no AEs were linked to the device itself, and the few procedure-related complications were effectively managed without long-term consequences. This highlights the low risk of serious complications associated with the device throughout the 5-year study period.

Table 1. RXI001 Procedure-Related Serious Adverse Events, Safety Analysis Set (n=50)

System Organ Class/Preferred Term	Related to Device or Procedure	Outcome	Time to Onset	Duration	Severity	n (%)	m
Any adverse event						**5(10.0%)**	**7**
Injury, poisoning and procedural complications						**2 (4.0%)**	**2**
Foreign body (broken needle)	Procedure	RESOLVED	0 to ≤30 days	1 days	Mild	1 (2.0%)	1
Suture rupture	Procedure	RESOLVED	>4.5 to ≤9 months	1 days	Moderate	1 (2.0%)	1
Infections and infestations						**1 (2.0%)**	**3**
One infection causing: Abdominal abscess Empyema Mediastinal abscess	Procedure	RECOVERED	0 to ≤30 days	52 days	Severe	1 (2.0%)	1
Gastrointestinal disorders						**1 (2.0%)**	**1**
Drainage of intra-abdominal haemorrhage	Procedure	RECOVERED	0 to ≤30 days	1 days	Severe	1 (2.0%)	1
Respiratory, thoracic and mediastinal disorders						**1 (2.0%)**	**1**
Pleurisy	Procedure	RECOVERED	0 to ≤30 days	11 days	Moderate	1 (2.0%)	1

n = number of subjects, m = number of events.
Adverse events are coded according to MedDRA 20.0E.
Percentages are based on the total number of subjects.

Table 2. RXI001 Procedure-Related Non-Serious Adverse Events, Safety Analysis Set (n=50)

System Organ Class/Preferred Term	Procedure or device related	Outcome	Time to Onset	Dura-tion	Severity	n (%)	m
Any adverse event						**7 (14.0%)**	**9**
Gastrointestinal disorders						**3 (6.0%)**	**3**
Abdominal pain	Procedure	UNKNOWN	>4.5 to ≤9 months		Moderate	1 (2.0%)	1
Dyspepsia	Procedure	NOT RECOVERED	>1.5 to ≤2.5 years		Moderate	1 (2.0%)	1
Dysphagia	Procedure	RECOVERED	>2.5 to ≤3.5 years	3.3 years	Mild	1 (2.0%)	1
Injury, poisoning and procedural complications						**3 (6.0%)**	**3**
Gastroparesis/intestinal paralysis directly postsurgery (known side effect to anesthesia for abdominal surgery)	Procedure	RECOVERED	0 to ≤30 days	2-4 days	Mild	1 (2.0%)	1
Incisional hernia	Procedure	UNKNOWN	>4.5 to ≤9 months		Moderate	1 (2.0%)	1
Procedural pneumothorax	Procedure	RECOVERED	0 to ≤30 days	1 days	Mild	1 (2.0%)	1
Hepatobiliary disorders	Procedure					**1 (2.0%)**	**1**
Hepatic lesion (during surgery)	Procedure	RECOVERED	0 to ≤30 days	1 days	Mild	1 (2.0%)	1
Surgical and medical procedures						**1 (2.0%)**	**1**
Adhesiolysis (during surgery)	Procedure	RECOVERED	0 to ≤30 days	1 days	Mild	1 (2.0%)	1

[1] Raue W, Ordemann J, Jacobi CA, Menenakos C, Buchholz A, Hartmann J. Nissen versus Dor fundoplication for treatment of gastroesophageal reflux disease: a blinded randomized clinical trial. Dig Surg. 2011;28(1):80-6.

Table 2. RXI001 Procedure-Related Non-Serious Adverse Events, Safety Analysis Set (n=50)

System Organ Class/Preferred Term	Procedure or device related	Outcome	Time to Onset	Dura-tion	Severity	n (%)	m
Vascular disorders						**1 (2.0%)**	**1**
Haemorrhage (related to surgery)	Procedure	RECOVERED	0 to ≤30 days	1 days	Mild	1 (2.0%)	1

n = number of subjects, m = number of events.
Adverse events are coded according to MedDRA 20.0E.
Percentages are based on the total number of subjects.

Further safety data relating to the adverse event dysphagia presented in **Table 3**.

Table 3. RXI001 Dysphagia Adverse Events, Full Analysis Set (FAS, n=50)

Dysphagia (FAS)	As per GERD-HRQL daily symptoms at baseline* (n=50)		Reported AEs 0-1 year (n=50)†		Recovered /Resolved	Reported AEs 1-5 years (n=50)†		Recovered /Resolved
None	39	78%	49	98%	-	49	98%	-
Mild	6	22%	1‡	2%	Yes	1¥	2%	Yes
Moderate	3		0		-	0		-
Severe	2		0		-	0		-

**Baseline figures represent GERD-HRQL-relevant individual question score >2 (symptoms everyday).*
† *Three (3) subjects terminated the study: two (2) at 6 months and one (1) at 3 months; data at the time of that visit have been carried forward to use in the FAS.*
‡ *One (1) subject had early onset symptoms of dysphagia immediately following surgery, lasting ~2 weeks. This indicates treatment success as opposed to AE.*
¥ *One (1) subject had severe dysphagia before surgery with a GERD-HRQL question dysphagia score of 5.0 with subsequent decrease to 2.0 at 3-year follow-up, indicating treatment success as opposed to AE.*

8.2 Effectiveness Endpoint Results

Per the study protocol, the effectiveness endpoints of RXI001 can be summarized as follows:

- *Primary Effectiveness Endpoint:* The percent reduction from Baseline of GERD symptoms, based on the GERD HRQL score (questions 1–10), was measured at 6 months. These data were also presented as the number of subjects obtaining at least 50% improvement from baseline figures, with success defined as 60% of the subjects reaching such score improvement. Thus, the aim of this analysis was to show that the lower limit of the confidence interval (CI) exceeded 60%.
- *Secondary Effectiveness Endpoint:* Reduction from baseline in GERD symptoms (GERD-HRQL Questionnaire), total acid exposure time (24-hour pH monitoring), PPI Usage, regurgitation and inability to belch/vomit (Foregut questionnaire). Additionally, the endpoint was to assess improvement in esophagitis and confirm location/function of the device (Reherniation or Device Dislocation/Migration).

8.2.1 GERD-HRQL Quality of Life Questionnaire

A validated questionnaire called the GERD-HRQL questionnaire was one method used to assess improvement in GERD-related symptoms. The data collected in the RXI001 study shows that, at 6 months (primary endpoint), 95.7% of subjects had >50% improvement in GERD-HRQL score from baseline, providing study success (≥60%), with the average GERD-HRQL total score at 6 months reduction of 89.1% from baseline with confidence interval (-94.3, -83.8). Reference **Figure 3**.

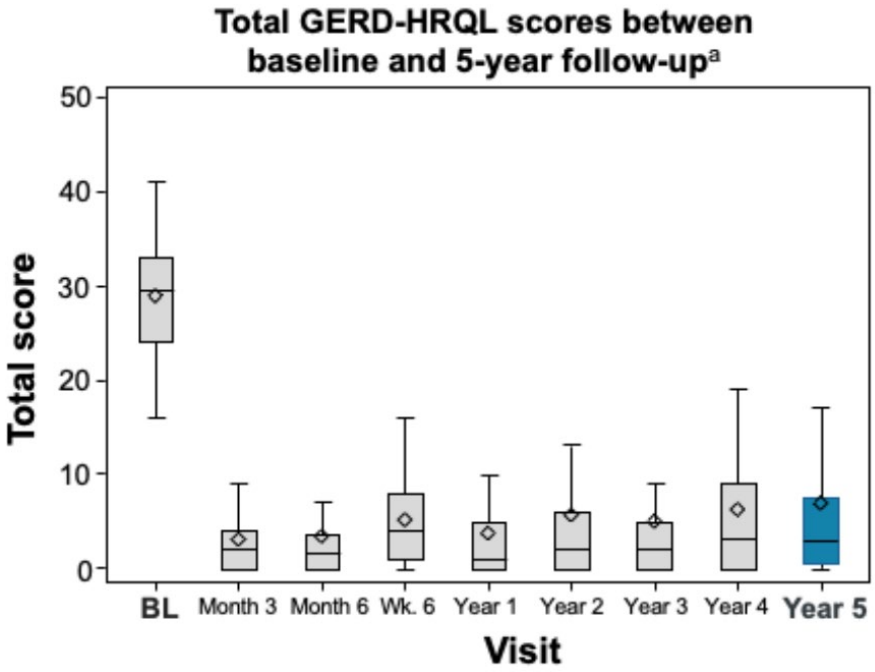


Figure 3. GERD_HRQL score over time. Eight subjects were diagnosed with gastritis which is the main reason for GERD-HRQL outliers. Only one subject was dissatisfied and had pathologic 24-hour pH monitoring results at year 5

Table 4. RXI001 Effectiveness results at Year 5, Full Analysis Set

Time (months)	Group	GERD-HRQL median score at baseline (50)	GERD-HRQL median score at follow-up	Improvement of GERD median scores	Number of subjects at follow-up (n)
60.0	FAS	29.5	3.0	90%	**5 years follow-up n=44**
60.0	FAS	29.5	3.0	90%	**End of Study[†] n=47** Including 5yr (n=44) 4yr (n=2) & 3yr (n=1)
Study success when including subjects with <50% improvement of GERD-HRQL score as successfully treated subjects, when 24-h pH monitoring is normal (%) (eliminating subjects with gastritis and SIBO affecting GERD-HRQL scores for reasons other than GERD)					
60.0	FAS	**97.9%[‡] TOTAL STUDY SUCCESS at Year 5**			**End of study[†] n=47** (Including subjects lost to COVID at 4yr n=2 & 3yr n=1)

[†] *The end of study results include imputation carried-forward for the three affected by COVID-19, totaling 47 subjects, of which two include results from year 4 and one subject from year 3.*

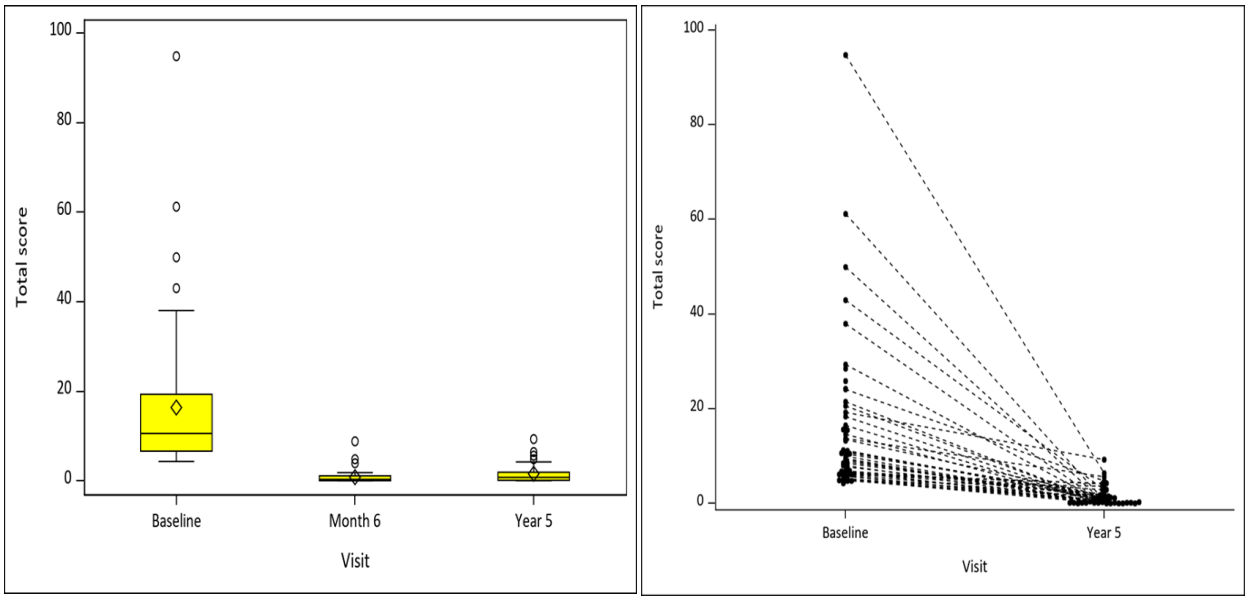
[‡] *When including subjects with <50% improvement in GERD-HRQL score from baseline with normal 24-hour pH monitoring results as successful subjects, study success reaches 97.9%.*

Additionally, a significant improvement in gas bloating was observed, with the average score decreasing from 3.5 at baseline to 1.5 at the 5-year follow-up. Moreover, 95.5% of subjects (42/44) reported either no gas bloating, an improvement, or equal to baseline in their scores at the 5-year mark, whereof 6.8% were unchanged compared to before surgery.

8.2.2 pH Monitoring

The total esophageal acid exposure time (pH<4 using Bravo™ capsules) at baseline, 6 months, and 5 years post-treatment across all FAS subjects that underwent pH testing at any timepoint following surgery is presented below. A significant reduction in duration was observed at 6 months and 5 years compared to baseline. Specifically:

- At 6 months 90% of all subjects performed 24-hour pH monitoring. From baseline to the first follow-up assessment at 6 months, the mean duration dropped from 16.35% to 0.80%, reflecting a mean change of 15.79 percentage points and notable reduction in the proportion of time spent at a pH <4.
- At 5 years 91% of subjects remaining in the study (40/44) performed the 24-hour pH monitoring. Results remained consistent up to 5 years post-treatment at which point the proportion of time spent at pH <4 was 1.57% (compared to 16.35% at baseline). On average, a 90.4% reduction of 24-hour monitoring results based on total time pH <4 was appreciated. All the individual subject's successful reduction of acid in lower esophagus is visualized below.



8.2.3 PPI Usage

At the 5-year follow-up visit, 97.7% of subjects (43/44) were not taking daily PPIs. When including the three (n=3) COVID-affected subjects with available 3- (n=1) and 4-year (n=2) data, 97.9% of subjects (46/47) were not using any PPIs.

Table 5. RXI001 PPI Usage, Full Analysis Set

	Months / n(%)						
Daily, regular PPI intake	**0**	**6**	**12**	**24**	**36**	**48**	**60**
No	**0 (0)**	**47 (97.9)**	**43 (93.5)**	**44 (93.6)**	**47 (100)**	**44 (95.7)**	**43 (97.7)**
Yes, due to GERD with pathologic 24-h pH	49 (98)	0 (0)	0 (0)	1 (2.1)	0 (0)	0 (0)	0 (0)
Yes, not due to acid reflux – normal 24-h pH	1 (2)*	1 (2)	2(4.3)	2 (4.2)	0 (0)	2(4.3)	0 (0)
Yes, 24-h pH is missing	0	0	1 (2.2)†	0	0	0	1 (2.3)
(Total, n)	50	48	46	47	47	46	44

** 24-h pH total time 4.3% and esophagitis grade B*
† Normal pH at 5 years

8.2.4 Regurgitation

Including the three COVID-affected subjects with available data at year 3 (n=1) and year 4 (n=2), 93.6% of subjects (44/47) reported no or minimal regurgitation at the 5-year follow-up visit. In total, 95.5% (42/44) of subjects had improved or no regurgitation compared to baseline.

8.2.5 Esophagitis

Endoscopy results at 6 months showed that 46 out 48 subjects had no esophagitis.

8.3 Additional Study Outcome Data

8.3.1 Subject Accountability

Subject status and accountability from the time of enrollment through final follow-up are presented in **Table 6** below.

Table 6. RXI001 Subject Status & Accountability

	Pre-op	**6 wks**	**3 mo**	**6 mo**	**12 mo**	**24 mo**	**36 mo**	**48 mo**	**60 mo**
Time Window		±7 days	±10 days	-15/+45 days	-30d/ +3mos	-30d/ +3mos	-30d/ +3mos	-30d/ +3mos	±9 mos
	I	I	I	I	I	I	I	I	I
Theoretical	50	50	50	50	50	50	50	50	50
COVID Deaths	0	0	0	0	0	0	0	1	1
Cumulative COVID Deaths	0	0	0	0	0	0	0	1[3]	2[4]
Long-COVID	-	0	0	0	0	0	0	0	1[4]
Expected	50	50	50	50	50	50	50	49	47
Terminated study		0	1[1]	2[2]	0	0	0	0	0
Cumulative terminated		0	1	3	3	3	3	3	3
Total subjects available	**50**	**50**	**49**	**48 24-h pH 45**	**46**	**47**	**47**	**46**	**44 24-h pH 40[5]**

I = investigational group

[1] One subject terminated the study at 3 months well-treated

[2] Two subjects terminated the study at 6 months, no-one took PPI at 6 months

[3] One subject died from COVID before the 4-year follow-up, one subject died from COVID before the 5-year follow-up: Neither were taking PPIs at their final study visit and both were satisfied with their condition and had >50% improvement of GERD-HRQL questionnaire score from baseline.

[4] One subject was bedbound by long-COVID, at year 5, prior to illness: satisfied, no PPI and well-treated.

[5] Of available subjects 100% performed follow-up at year 5 and 91% of those performed 24-hour pH monitoring at year 5.

8.3.2 Baseline Demographics and Clinical Parameters

As evidenced in the peri-operative assessments and medical history in **Table 7** and **Table 8** below, it can be concluded that the baseline demographic characteristics of the subjects in the study are comparable to those of the U.S. GERD patient population and, therefore, the results of this study can be generalized.

Table 7. RXI001 Demographics Before Surgery, Safety Analysis Set (n=50)

Variable	Min	Q25	Median	Q75	Max	Mean	SD	N (%)	Missing (%)
Age (years)	26	-	53.0	-	76	51.5	11.8	50 (100)	0 (0)
Height (cm)	148	-	170.0	-	200	170.8	11.3	50 (100)	0 (0)
Weight (kg)	53	66.0	80.0	88.0	118	78.2	14.7	50 (100)	0 (0)
BMI (kg/m²)	18.7	23.4	26.55	29.7	35.8	26.81	4.41	50 (100)	0 (0)
Sex, male	-	-	-	-	-	-	-	28 (56)	0 (0)
Sex, female	-	-	-	-	-	-	-	22 (44)	0 (0)
Hiatal hernia	1	-	2.5	-	3.2	2.51	0.58	37 (74)	0 (0)
GERD-HRQL (0-50)	9	24	29.5	33	49	28.8	7.3	50 (100)	0 (0)
Esophageal pH <4 (%)	4.3	6.6	10.55	19.3	94.8	16.35	16.6	50 (100)	0 (0)
Esophagitis Grade A	-	-	-	-	-	-	-	13 (26)	0 (0)
Grade B								9 (18)	0 (0)
Grade C or D								-	-
Dissatisfied	-	-	-	-	-	-	-	45 (90)	0 (0)
Neutral	-	-	-	-	-	-	-	4 (8)	0 (0)
Satisfied	-	-	-	-	-	-	-	1 (2)	0 (0)
Gastric emptying test	No severe delayed gastric emptying observed							50 (100)	0 (0)

Definitions: "Min" = Minimum; "Q25" = First Quartile; "Q75" = Third Quartile; "Max" = Maximum; "SD" Standard Deviation; "CI" = Confidence Interval

Table 8. RXI001 Prior GERD Medications, Intention-to-Treat Analysis Set (n=53)

Therapeutic subgroup/Chemical substance	Total (N=53)	
	n (%)	m
Any prior GERD medication	**50 (94.3%)**	**89**
DRUGS FOR ACID RELATED DISORDERS	**50 (94.3%)**	**89**
pantoprazole	40 (75.5%)	50
esomeprazole	16 (30.2%)	19
rabeprazole	4 (7.5%)	5
sucralfate	4 (7.5%)	4
famotidine	3 (5.7%)	3
lansoprazole	3 (5.7%)	3
omeprazole	3 (5.7%)	3
ranitidine	2 (3.8%)	2

n = number of subjects, m = number of events.
Medications are coded according to ATC 2016.
Percentages are based on the total number of subjects.

NOTE: Per protocol, GERD medications were to be discontinued for at least 7 days prior to performing 24-hour pH monitoring and completion of the GERD-HRQL questionnaire, with the exception of antacids, which could be taken for up to 24 hours before the visit.

9 Patient Selection and Treatment

9.1 Individualization of Treatment

The RefluxStop® device is only available in one size; therefore, there are no considerations related to device size selection as part of pre-operative case planning. Physicians should, however, take into account the patient's unique anatomy during pre-operative case planning as well as the specifics during surgery in order to determine the right operative strategy.

9.2 Benefit/Risk

The risks and benefits, previously described in Section 7, should be carefully considered for each patient before use of the RefluxStop® device. Additional considerations for patient selection include but are not limited to:

- Patient's age and life expectancy
- Co-morbidities
- Patient's suitability for laparoscopic surgery
- Patient's anatomical suitability for RefluxStop® repair
- Ability to tolerate general, regional, or local anesthesia

9.3 Untested Patient Populations

A 50-patient European Union, multicenter, prospective study (CE Study) was conducted to support approval of the RefluxStop® System. This safety and effectiveness data set includes data out to 5-years with the demographics specified in the CAUTION statement below. During its commercialization in Europe, the RefluxStop® System has been implanted and studied in additional patient populations. Implantica intends to revisit these untested patient population demographics as soon as more journal publications are made publicly available.

(See Section 6 Warnings and Precautions)

⚠ ***CAUTION:*** ***The safety and effectiveness of the RefluxStop® System has not been evaluated in the main prospective study in the following patient populations or conditions with precaution diagnosis:***

- ***Do not use the RefluxStop® system in patients with a body mass index (BMI) > 35 kg/m²;***
- ***Do not use the RefluxStop® system in patients with para-esophageal or hiatal hernia >3 centimeters;***
- ***Known presence of delayed gastric emptying if no other reason for acid reflux;***
- ***History or suspicion of esophageal or gastric cancer;***
- ***Known presence of esophageal or gastric varices;***
- ***History of anti-reflux or bariatric procedure with extirpated fundus;***
- ***Stricture or stenosis of the lower esophagus;***
- ***Presence of esophagitis grade D according to the Los Angeles classification, which requires more time for esophagus dissection;***
- ***Female patients who are pregnant at the time of the procedure;***
- ***Patients with achalasia, scleroderma, and nutcracker esophagus;***
- ***Co-morbidity profile that creates an unfavorable risk-benefit balance for the patient.***

NOTE: ***The RefluxStop® System has been used in the real-world setting in >1500 patients with published and/or provided results from multiple hospitals including many different patient profiles.***

10 Patient Counseling Information

The physician should review the risks and benefits when counseling the patient (and/or family members) about this device and procedure. In addition to the risks and benefits of the procedure, the physician should assess the patient's commitment and compliance to post-operative follow-up, as necessary, to ensure continuing safe and effective results.

Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter through 5 years. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of this procedure. At a minimum, annual assessments are required and should be considered a long-term commitment to the patient's health and well-being.

Physicians should refer the patient to the Patient Brochure regarding risks occurring during or after implantation of the device. Procedure and device-related risks are detailed in Section 7.

The physician should complete the Patient Implant Card and give it to the patient so that he/she can carry it with them at all times. The patient should refer to the card anytime they visit additional health practitioners, particularly for any additional diagnostic procedures.

11 How Supplied

The RefluxStop® device is supplied disassembled and sterile (gamma irradiated). The five components of the device are enclosed in two thermally-welded pouches, one sealed inside the other, creating a double sterile barrier system.

⚠ ***WARNING:*** ***The RefluxStop® device is designed for single patient use only. Do not reuse or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure, which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.***

The device packaging includes a label with peel-away stickers containing the model number, lot number, and UDI. These stickers are intended to be used with the enclosed Patient Implant Card.

12 Clinical Use Information

12.1 Intended User

The RefluxStop® device shall only be used by health care professionals who have received product specific training by an Implantica representative. The RefluxStop® device shall only be used together with the RefluxStop® Deployment Tool. The surgical procedure for the RefluxStop® device shall be performed by a surgeon experienced in laparoscopic anti-reflux procedures, who has received product specific training by an Implantica representative.

⚠ ***CAUTION:*** ***The RefluxStop® System should only be used by physicians and teams trained in laparoscopic anti-reflux procedures and who have received product specific training by an Implantica representative.***

12.2 Inspection Prior to Use

1. Inspect the device and packaging to verify that no damage has occurred as a result of shipping or storage. Do not use the device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, return device to Implantica.
2. Verify that the "USE BY" (EXPIRATION) date printed on the label is valid and has not elapsed.
3. Prior to use, verify that all components of the RefluxStop® device (totaling 5 silicone components) are included in the packaging and are not broken or damaged. Reference ***Figure 1***].
4. The device packaging includes a label with peel-away stickers containing the model number, lot number, and UDI. These stickers are intended to be used with the enclosed Patient Implant Card and any other patient records, as needed. Verify that these labels are available and retained in the patient record as there is no labelling or marking on the device.
5. Verify that all specified accessories for the RefluxStop® device and RefluxStop® Deployment Tool are checked and in place. Reference Section 12.4.

⚠ ***WARNING:*** ***Do not use the RefluxStop® device*** **if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product, and return to Implantica.**

⚠ ***WARNING:*** ***Do not use after the "USE BY" (EXPIRATION) date printed on the label. Store at room temperature.***

⚠ ***WARNING:*** ***Do not use the RefluxStop® device if it has been removed from the sterile field.***

12.3 Storage

The RefluxStop® device is to be stored in its sealed packaging, at room temperature.

⚠ ***WARNING:*** ***Do not use after the "USE BY" (EXPIRATION) date printed on the label. Store at room temperature.***

12.4 Materials Required

- RefluxStop® device (RS-A1)
- RefluxStop® Deployment Tool (RS-300)
- Absorbable Suture 2-0 Vicryl Plus, 70 cm (Ethicon), this suture is selected for its specific absorption profile and should not be replaced
- Isotonic Saline
- Water-based Lubricant, Surgilube® or Cathejell® mixed with pure Lidocaine 2%, to enable easy compression and ejection of the RefluxStop® device.
    - Lidocaine gel 2% has been used successfully in the pivotal study as well as in real-world evidence of >1500 cases. The lidocaine provides the advantage of reducing pain combined with a known bacteriostatic effect, thereby facilitating the postoperative phase.
- General laparoscopic accessories including:
    - Non-Absorbable Suture 2-0 (polyester or polypropylene) to suture the esophagus and fundus

⚠ ***CAUTION:*** ***Do not proceed with the surgical procedure before all specified accessories for the RefluxStop® device and RefluxStop® Deployment Tool are checked and in place.***

13 Assembly

The RefluxStop® device must be assembled in a sterile field prior to use. Assembly of the RefluxStop® device shall only be performed by a healthcare professional who has received product specific training.

⚠ ***CAUTION:*** ***The assembly of the RefluxStop® device shall only be performed by a healthcare professional who has received product specific training.***

13.1 Device Assembly

As shown in ***Figure 1*** above, the RefluxStop® device consists of five components: 1 core component, which serves as the center of the cuboid, and 4 identical outer piece components. The components are to be pre-mounted with a resorbable suture (2-0 Vicryl Plus, 70cm) holding the pieces together, as described below. After implantation, the suture is resorbed in a couple of months and the device is held together by fibrotic encapsulation and the invagination.

1. Assemble the five components of the RefluxStop® device to form a rounded cuboid, with the core component positioned in the center. Ensure the outer parts are assembled onto the core component according to the recesses and protrusions of the components [***Figure 1***].
2. Place the assembled cuboid on a sterile surface or on the Insert Device of the RefluxStop® Deployment Tool.
3. Use an absorbable suture **2-0 Vicryl Plus** to make a surgeon's knot 2x1 around the cuboid and [**Figure 2**]. **Do not replace this Vicryl suture since it has unique absorption properties.**
4. Verify that the knot is tight by lightly pulling the outer segments apart. The segments should remain connected but not fall apart.
5. Trim the suture ends to a maximum length of 4.0 mm.

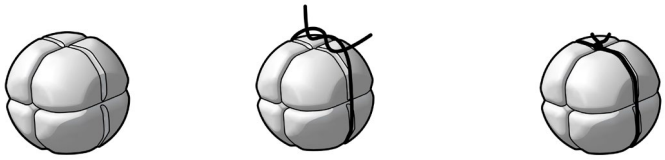


Figure 4. Assembly and Placing the Suture on the RefluxStop®

14 Surgical Procedure

14.1 Patient Preparation

The following instructions are to be followed:

1. Insert five (5) trocars into the patient's abdomen per ***Figure 5***. These trocar placements are similar to a semi-fundoplication surgery where five (5) trocars are used. As detailed in the RefluxStop® Deployment Tool instructions for use and in Section 0, the Deployment Tool trocar will be inserted at the lower left quadrant in the left axillary line of the patient or, depending on patient and trocar approach, not more than 5.0 cm medial of the axillary line. This trocar placement is important as it will assist in dissecting the fundus to introduce the device.

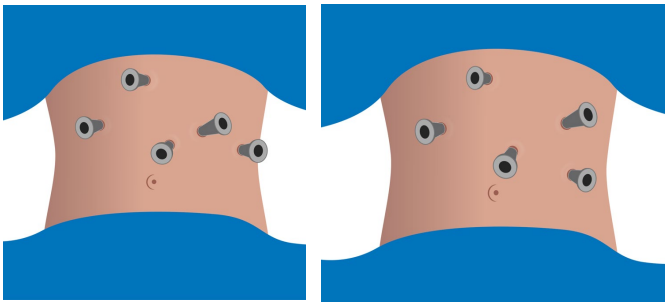


Figure 5. Normal Trocar Placement for RefluxStop® Surgery (left) and Improved Alternative Trocar Placement (right)

NOTE: In both placement images, the most left trocar is intended to be replaced by the RefluxStop® Deployment Tool. Most surgeons prefer the Alternative Trocar Placement (right) as it positions the RefluxStop trocar slightly more medial.

2. Following trocar placement, ensure the patient is placed in a semi-Fowler and reverse Trendelenburg position.

⚠ ***CAUTION:*** ***Do not place patients in standing positions above 35° as this may lead to surgical difficulties with the fundoplication (i.e. the fundus may fall down more than the esophagus).***

NOTE: Refer to the RefluxStop® Deployment Tool instructions for use for assembly instructions and final device preparation activities.

14.2 Fundoplication Preparation

14.2.1 Esophagus Dissection

3. Perform dissection of the esophagus applying light tension targeting 5.0 cm (4-5.5cm) in abdominal length. The total prolongation of the esophagus caused by stretching should be minimized, instead prolonging esophagus by dissection using slight stepwise traction, as stretching to pull esophagus down centimeters may increase the risk of re-herniation. Often required to apply a light downward traction on the esophagus to ensure a good dissection high up into the mediastinum. It is recommended to initiate the dissection close to the esophagus combining a blunt dissection technique (i.e. a peanut to subsequently move away low-placed pleura) and utilizing ultrasound coagulation. Maintain control of the anterior and posterior nervus Vagus trunks. The goal is to dissect all the way to venae pulmonalis. A plexus from the anterior vagal trunk is commonly located ventral to the esophagus, therefore, extra careful blunt dissection is recommended before applying limited coagulation high on the ventral aspect of the esophagus. Thorough high dissection is important for achieving optimal outcomes and should not be compromised. Spending additional time on meticulous dissection is considered beneficial.

   Be careful with the dorsal vagus since it may bend away from esophagus in a laying down u-shape before slight downward traction on esophagus is applied (as standard for anti-reflux surgeries, a band/elastic tube placed around esophagus at angle of His is used to apply traction). Light downward traction on the esophagus is allowed but stretching the esophagus to gain centimeters of length must be avoided since later re-herniation may occur; ensure that slight traction is only applied to ensure a good dissection high up in mediastinum. Experience to date indicates that enough length can be achieved in most patients. Perform a methodical dissection, close to esophagus combining blunt dissection moving pleura or pericard away bluntly and ultrasound coagulation on remaining blood vessels, keeping control of the anterior and posterior nervus Vagus trunks. The suture line should as far as possible be fat free. This includes free dissection of the part of the fatty pad close to the angle of His, not the entire fatty pad, as well as medial fundus along the greater curvature without burning the serosa.

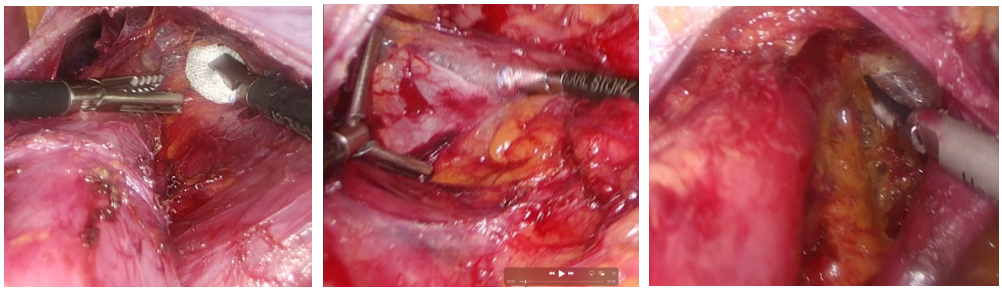


Figure 6. Free Dissection of Esophagus high-up in mediastinum close to esophagus, repeatedly combining Blunt Dissection and Ultrasound Coagulation

⚠ ***WARNING:** Do not cut the vagus nerves during dissection of esophagus. Prior to applying slight downward traction on the esophagus, take extra care to identify the dorsal vagus nerve since it may have a bend away from esophagus, which may increase risk of damaging the vagus nerve. Normally, this bend straightens out after slight tension is applied on esophagus.*

⚠ ***WARNING:** Care should be taken to not damage or perforate the esophagus during dissection or fundoplication. Do not use instruments to grasp or move the esophagus. Additionally, do not pass instruments blindly behind the esophagus. Such actions may lead to accidental damage of the esophagus. Some surgeons introduce a large gastro-esophageal tube to help identify the esophagus during dissection, however, due to perforation risk, such tubes are not encouraged.*

⚠ ***WARNING:** Patient may have a shortened esophagus due to irreversible scarring from chronic esophageal reflux. Do not compensate for a short esophagus by pulling the esophagus down to lengthen it more than maximum 1.0 cm, instead use slight tension in steps to prolong the esophagus while free dissecting. Free dissecting with careful stepwise tension limits the risk of the anatomy being pulled up into the thorax post-operatively causing reherniation, however, some tension is necessary for a successful dissection.*

⚠ ***CAUTION:** Care should be taken to not enter the pleural space during esophagus dissection. Use blunt dissection to move the pleura and pericardium away from esophagus. If the pleural space is inadvertently entered, close the opening with 1-2 clips.*

4. The targeted esophageal length in the abdomen is important; however, since patients' anatomies are different, these numbers are goals rather than minimum values. If the free-dissected esophagus is too short, the dissection around the esophagus should preferably continue as far up as possible, the extra time spent is beneficial for the outcome. Even if 3 cm of free dissected esophagus can be achieved, the RefluxStop procedure normally provides a well-treated patient, however, patients often have some lighter symptoms remaining. It is also possible to use at least 1-2 cm fundus from its posterior side, which will increase the height of the invaginated device. Please note that the dorsal vagus trunk often bends in a U-shape away from the esophagus when no tension is applied, therefore, dissection should initially be performed under slight tension until the nerve has been identified.

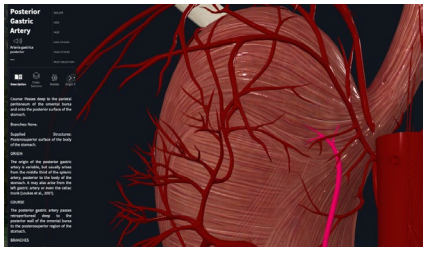
⚠ ***CAUTION:*** ***Care should be taken to ensure the esophagus dissection is high enough up in the mediastinum to ensure a proper platform for the RefluxStop® placement targeting 5 cm (4–5.5cm) of total free dissected abdominal esophagus. Even if less free dissected esophagus can be achieved, the RefluxStop procedure normally provides a well-treated patient, however, patients often have some lighter symptoms remaining. If it is possible to achieve 3 cm of esophageal length only, use 1-2 cm fundus from its posterior side, which will increase the height of the invaginated device.***

⚠ ***CAUTION:*** ***The total prolongation of the esophagus caused by stretching should be minimized, instead prolonging esophagus by dissection using slight stepwise traction, as stretching to pull esophagus down centimeters may increase the risk of re-herniation.***

14.2.2 Fundus Dissection

5. Fundus needs to be free dissected to match the esophageal length to achieve a tension-free floppy invagination. Free dissect the greater curvature (angle of His, fundus, and any fibrotic connection to the spleen). This includes dividing three to four short gastric vessels and continuing the free dissection until the angle of His. Importantly, free dissect slightly behind/posterior of fundus downwards all the way around to the angle of His. However, do not divide the posterior gastric vessel coming up close to esophagus (1-3cm) down posterior on fundus, see **Figure 7**. Divide the fibrotic and fat tissue, avoiding the posterior gastric artery and splenic artery. Divide any fibrotic connection to the spleen, if needed, in layers. Ensure to take away any fatty tissue overflowing from the fatty pad into the angle of His and, if necessary, upwards on the patient left side of the esophagus. Do not interfere with the anterior vagus. Ensure that the fundus is floppy and can move freely without tension to achieve a tension-free invagination.

   NOTE: Normally, three to four of the short gastric vessels should be divided to ensure a proper dissection that allows the fundus to move freely to achieve tension-free invagination. Start along the greater curvature during this phase of the dissection and progress cephalad. This approach permits superior exposure of individual vessels and allows use of instruments in a natural manner. NOTE: To minimize the dissection length and still achieve a floppy, tension-free fundus, the dissection may be performed from above; however, this will increase the operative time.



NOTE: In some cases, the fundus may still be too short to achieve tension-free invagination 5.0 cm up on the esophagus. In such cases, first free dissect additional tissue behind/dorsal of fundus all the way to the angle of His as mentioned above; however, do not ligate the posterior gastric artery (see anatomical picture on the left). Secondly, dissect further down at the greater curvature to divide one more short gastric vessel, if necessary, to achieve a tension free floppy fundus. An additional supply of fundus to reach the 4-5 cm is possible by moving 1-2 cm of posterior fundus into the pouch, lifting it up from posterior by the top hat suture described further below.

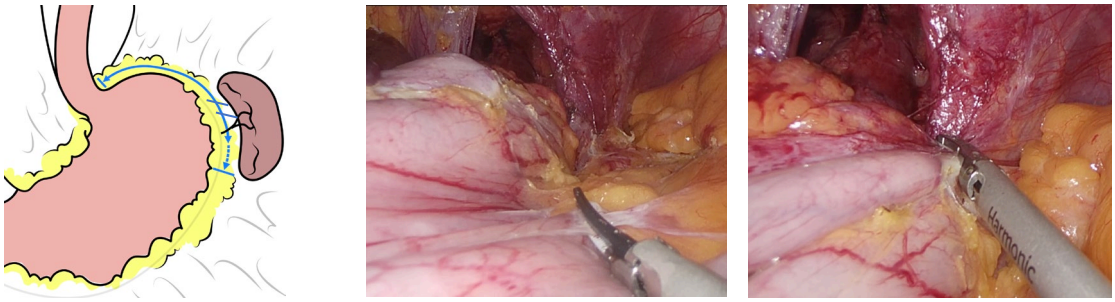


Figure 7. Dissection of Short Gastric Vessels and Down Posteriorly of Fundus

⚠ ***WARNING:*** ***Care should be taken to not damage or perforate the stomach wall. Care during dissection of the greater curvature including the short gastric vessels and posterior down to angle of His.***

⚠ ***WARNING:*** ***Care should be taken to not damage the gastric serosa during the dissection. Gastric serosa damage at the investigational site may cause an early erosion of the device into the stomach or abdominal cavity.***

⚠ ***WARNING:*** ***Bleeding is the leading complication from anti-reflux surgery. Ensure proper ultrasound coagulation tools are used long enough to properly coagulate the short gastric vessels, wherein vascular clips or suture ligatures may be added additionally to avoid bleeding.***

⚠ ***WARNING:*** ***Ensure any fibrotic connections to the spleen are removed and avoid forceful traction on the greater curvature of the stomach to reduce the risk of splenic capsular tear.***

⚠ ***WARNING:*** ***Care should be taken when introducing instruments through the left lateral port as off-vision injury may occur to the spleen or nearby tissue.***

⚠ ***CAUTION:*** ***Normally divide three to four of the short gastric vessels during dissection of the greater curvature and dissect slightly posterior down on fundus to mobilize enough fundus around to angle of His. Avoid dividing the splenic artery and the posterior gastric artery. Care should be taken when dissecting down posterior on the stomach close to the esophagus, where the posterior gastric artery is located.***

14.2.3 Hiatus Closure

6. In the RefluxStop® procedure, it is not necessary to close the hiatus without space around the esophagus. Suture the crus muscles with a slightly larger opening than performed in Nissen Fundoplication without squeezing the crus muscles. Preferably, utilize a few double loop permanent non-resorbable sutures (polyester, polypropolene, or Gore-TEX).
7. Use of a bougie is preferably avoided because of perforation risk. Confirm the size of the hiatal opening, leaving a V-shaped opening adjacent to the esophagus large enough to allow introduction of a 10 mm instrument with a peanut.
8. If a bougie is anyhow used, also here confirm the hiatus opening is neither too small nor too large. Specifically, when using a large-sized esophageal tube, the visible clearance around the esophagus should be slightly less than without a bougie. If a bougie is used: If size 35 is used, allow space for a 5 mm instrument with a peanut attached to pass through the hiatus opening, and if size 54 is used, no additional space is needed around esophagus, provided the esophagus is not stretched by the bougie.

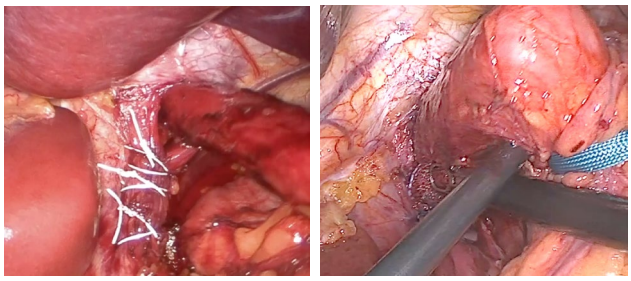


Figure 8. Hiatus Closure
NOTE: Allow more space than in a Nissen Fundoplication

NOTE: Do not create a connection between the diaphragm and the fundus pouch for example by suturing between the fundus and the diaphragm.

⚠ ***CAUTION: During hiatus repair, care should be taken to ensure that the surgical knots are tight but that the crus muscles are not squeezed or strangulated.***

⚠ ***CAUTION: Care should be taken to ensure the hiatus opening is not too small as this may lead to dysphagia. Additionally, care should be taken to ensure the hiatus opening is not too large as this may prevent the principal function of the device. To create a relevant size of the hiatal opening, leave a V-shape opening on the side of esophagus for a peanut placed on a 10 mm instrument to easily pass through the hiatus opening. If a bougie is used: If size 35 is used, allow space for a 5 mm instrument with a peanut attached to easily pass through the hiatus opening, and if size 54 is used, no additional space is needed around esophagus if loosely surrounded. Bougie use is generally not encouraged due to perforation risk***

⚠ ***CAUTION: During hiatus closure, the sutures should capture the entire crus muscles; care should be taken to not suture through the crus muscles as this increases the risk of the sutures tearing through the muscles in the event of post-operative retching, heaving, or vomiting.***

⚠ ***CAUTION: Hiatus should be closed enough to prevent the fundal package including the device to re-herniate, passing through the diaphragm.***

⚠ ***CAUTION:*** **Do not create a connection between the diaphragm and the fundus pouch for example by suturing between the fundus and the diaphragm.** ***This should be avoided under all circumstances due to long-term safety considerations.***

14.3 Fundoplication

14.3.1 Fundoplication of Esophagus to Fundus (Left Side of Esophagus)

1. Carefully move the dissected fundus to the lower part of the esophagus. Perform a partial fundoplication technique, with at least 90°- 120° fundoplication suturing in the space between the dorsal and anterior vagus trunks, with the first row, 45-60° posterior left on esophagus and on fundus placed posterior of the greater curvature or sail leading to and holding the short gastric vessels. It is recommended to not wrap or encircle the fundus more than 120° around the esophagus.

   NOTE: If the esophagus is 2.5 cm in diameter, then the circumference of the esophagus is 7.8 cm. A fundoplication using at least 2.0 cm of the curved circumference of the esophagus is in this case comparable to a 92° fundoplication.
2. As emphasized: Suture in the space between the dorsal and anterior vagus. No sutures should be made to the crus or diaphragm.
   a. It is recommended to use three (3) columns of sutures in a 4+3+3 configuration. However, fundus varies in size; therefore, fewer sutures should be used for patients with smaller fundus. For these cases, the middle suture line could be reduced to include only one (1) suture, which should be placed on top, most cranial, closest to the diaphragm. This would result in a 4+1+4 configuration with or without continuous suture. Regardless of method, the first column should start 0.5 cm above the angle of His, and both column 2 and column 3 should start above the functional part of the LES with its upper edge normally 1.5 cm above the angle of His. Sutures should be placed at least approximately 1.0 cm from each other.

b. Because the diaphragm is typically dome-shaped, the esophagus with its attached fundal package, including the device, usually glides up 1 cm after finalizing the fundoplication procedure. Accordingly, up to 1 cm of traction to straighten esophagus during fundoplication is generally acceptable, provided the esophagus has been mobilized primarily through careful stepwise dissection using mild traction only. However, if esophageal elongation has been achieved through stretching during dissection, additional traction or straightening of the esophagus during fundoplication should be avoided.

NOTE: The goal is to place the invaginated pouch more posterior, in the dorsal left quadrant of esophagus circumference. Preferably suture in the stomach 1–1.5 cm behind the sail leading to the short gastric vessels and 60° dorsal of the mid-coronal plane of esophagus. The most ventral fundoplication suture column line should normally be placed 1.0cm ventral of the sail at the greater curvature and 45° left dorsal on esophagus (max 60°). The greater curvature with the sail leading to the short gastric vessels must be free dissected to avoid fat in the fundoplication line, without damaging or burning the serosa of the stomach wall.

⚠ ***CAUTION: Avoid stretching esophagus during fundoplication due to increased risk of re-herniation. Mild tension to straighten esophagus, not exceeding 1.0 cm from its relaxed position, is generally acceptable provided limited stepwise traction has been used during esophageal dissection.***

⚠ ***CAUTION: The total prolongation of the esophagus caused by stretching, rather than by adequate free dissection, should be minimized, as tension also applied during fundoplication, may increase the risk of re-herniation. Because the diaphragm is typically dome-shaped, the esophagus with its attached fundal package, including the device, usually glides up 1 cm after finalizing the procedure. Accordingly, up to 1 cm of traction during fundoplication is generally acceptable, provided the esophagus has been mobilized primarily through careful stepwise dissection using mild traction only. However, if esophageal elongation has mainly been achieved through stretching during dissection, additional traction or straightening of the esophagus during fundoplication should be avoided.***

⚠ ***WARNING: Substantially incorrect, off-label suturing of the esophagus or stomach combined with much too close and too tight sutures may theoretically result in erosion of the device into esophagus.***

⚠ ***CAUTION: Suture fundus to esophagus with about 1cm or more between each suture and do not simultaneously use forceful strangulation of esophageal tissue, which may lead to reduced tissue elasticity and dysphagia or reduce blood supply.***

⚠ ***WARNING: During fundoplication stomach fundus to esophagus, do not include the vagus in any suture loop, especially the anterior vagus needs attention. May cause intensive retching post-op.***

⚠ ***WARNING: Care should be taken to ensure the sutures do not cut through the muscular tissue or that the esophagus is damaged by an instrument during dissection or fundoplication. If the esophagus muscle wall is damaged or cut through, immediately repair it with a separate suture for that purpose only (even if the entire wall thickness has not been cut through), as later perforation may occur.***

⚠ ***CAUTION: Severe retching, heaving, or vomiting immediately post-op could result in surgical failure with the crus sutures cutting through the crus muscles and subsequently causing a large hiatal opening and re-herniation. Care should be taken to discuss this matter with the anesthesiologist beforehand to take necessary precautions and medications preventing post-op retching.***

NOTE: The top end of the anterior suture normally does not interfere with the nerve when placed between +45° anterior from the coronal plane; however, patients' anatomies can vary. Normally it is possible to suture even more anterior to +60° ventral; however, as mentioned do not include the nerve in any suture loop. Please note that the anterior vagus following the esophagus often has a hepatic branch towards the liver in the lower cardia region.

NOTE: The posterior suture line normally does not interfere with the anterior nor posterior vagus trunk with this suture line placed approximately between -45° to -60° posterior from the coronal plane; however, patients' anatomies can vary (although more unlikely at this location). Please note that the posterior trunk following the esophagus often deviates (or a branch thereof) towards the liver in the crus muscles distal conjunction.

Ensure the sutures do not inadvertently cut through the esophagus muscle wall. If this were to occur, immediately repair it with a separate suture for that purpose only (even if the entire wall thickness has not been cut through), as later perforation may occur.

NOTE: For a smaller sized esophagus/fundus, fewer sutures may be required to complete the fundoplication. Specifically, reduce the middle column to one single suture on top closest to the diaphragm and use two (2) full columns of sutures in a 4+1+4 configuration using single or continuous sutures. Similar to the technique described above, the first column should start 0.5 cm above the angle of His, and the second full column should start above the functional part of the LES with its upper edge normally 1.5 cm above the angle of His. Sutures should be placed at least about 1.0 cm from each other.

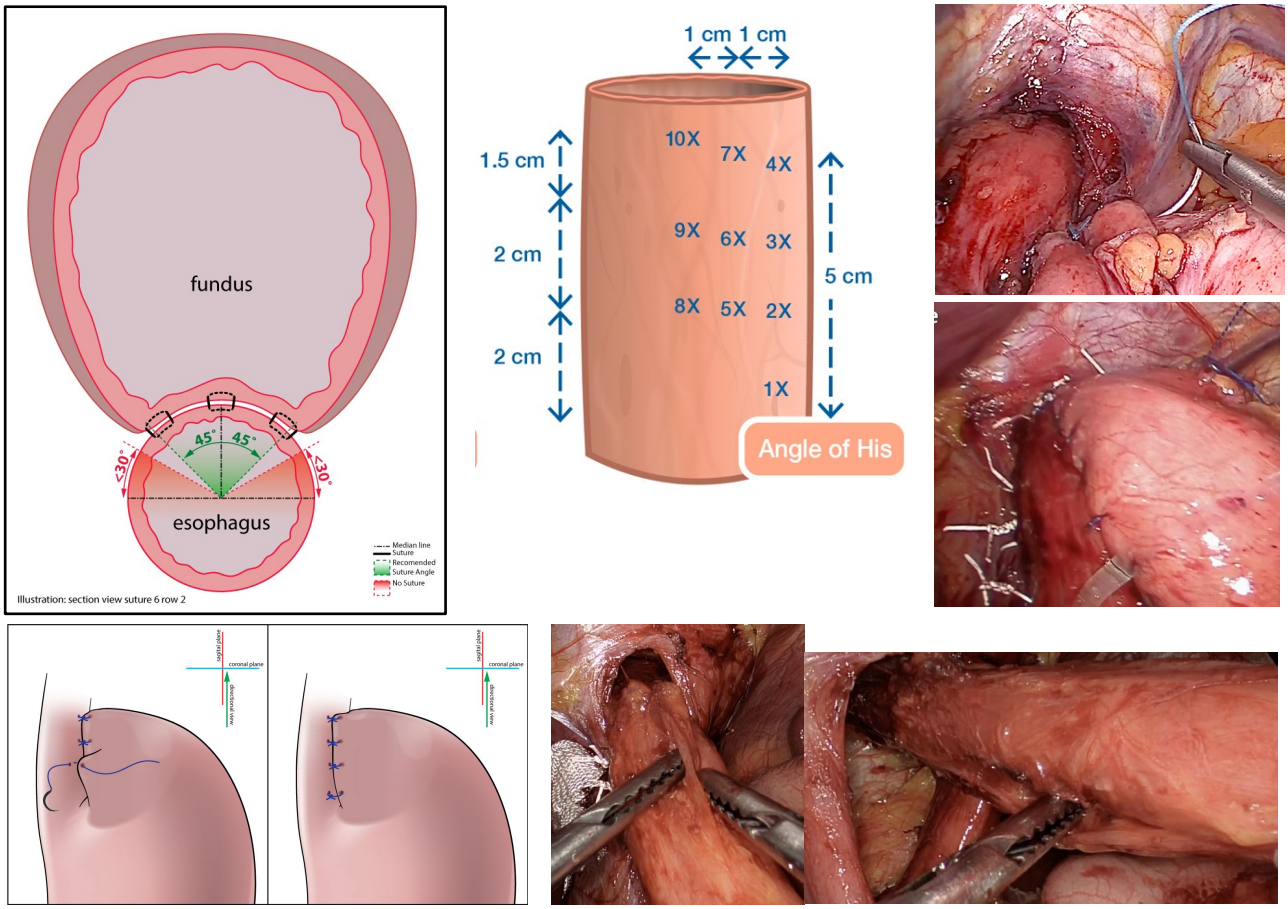


Figure 9. Fundoplication with three rows of sutures 90-120° suturing between the nervus vagus trunks on patient's left side (visualized on photos)

NOTE: Suture the first row behind the sail leading to the short gastric vessels. This will provide more fundus for a tension free invagination.

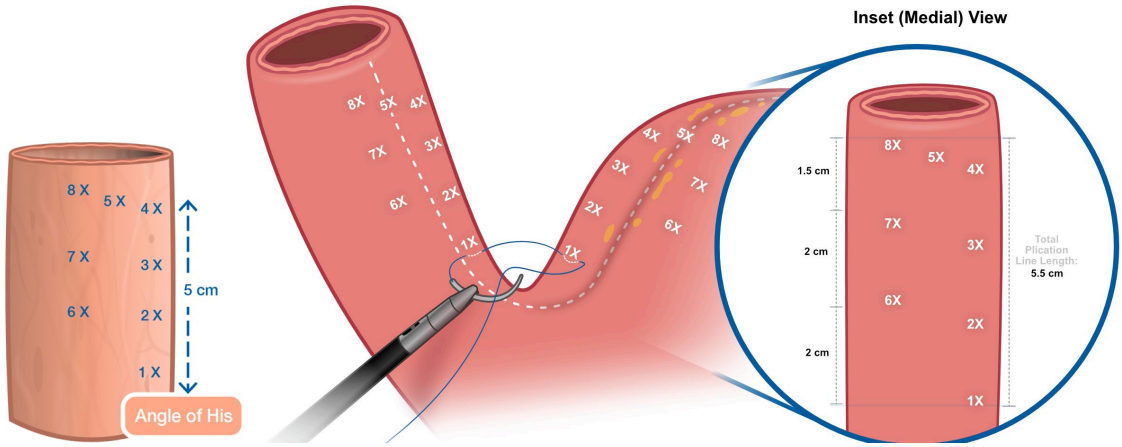


Figure 10. Fundoplication with three rows of sutures for smaller to midsize Fundus with only one suture in the middle line

NOTE: Keep cranial suture line intact.

3. Ensure the fundoplication is approximately 90° or slightly more of the circumference of the esophagus with the sutured columns placed with about 1.0 cm distance between each sutured column.

   NOTE: Fibrosis around the sutures will ensure a stronger hold in the long-term; therefore, the more suture material that is used, the better the long-term result. However, ensure that the sutures are not closer than about 1.0 cm apart as this may hamper blood supply.

Throughout suturing, ensure the following:

a. Place the most cranial top end of the sutured column as high up as possible, suturing the esophagus to the fundus close to the hiatus/diaphragm. Do not suture in the crus or diaphragm.

b. Avoid suturing more than necessary in the LES. The first column suture should be 0.5 cm above the angle of His and the other column(s) should be 1.5 cm or slightly more above the angle of His.

c. Ensure the sutures in the esophagus are not superficial.

d. Continuous sutures may increase adhesion between the fundus and esophagus if sutured with light hand. If the third and last suture row is made with a continuous suture: after the last stich from fundus over to esophagus, bring the suture back to fundus again, where the serosa provides stronger support. Finish by performing two bites in the fundus and close the continuous suture in between these bites.

e. Avoid suturing with too large suture bites involving the mucosa.

f. If esophagus bite distances are substantially larger than the stomach bites distance, the esophagus may become bent and narrowed resulting in dysphagia. If the stomach bites distances are substantially larger than the esophagus bites, the remaining fundus where the device will be invaginated, may become too small.

g. Avoid fat in the suture line attachments as much as possible. Therefore, always free dissect the angle of His by taking away any fatty tissue often overflowing from the fatty pad and upwards on the esophagus patient left side.

h. Do not suture the most cranial-ventral bites without being aware of where the anterior vagus trunk is located to avoid suturing the vagus.

i. Perform the adherence between the stomach and esophagus in between the vagus trunks. Do not include the vagus trunks in any suture loop. If needed, move the anterior vagus in a package of tissue slightly to the patient's right side for the most top-ventral suture.

⚠ ***CAUTION:** Care should be taken to ensure the appropriate amount of sutures are used when suturing the fundus to the esophagus. Not leaving enough fundus to allow a soft invagination of the RefluxStop® device may lead to failure.*

⚠ ***CAUTION:** Positive long-term results are dependent on a stable platform of esophagus to stomach adherence close to the diaphragm and high-up on the esophagus near the LES. The most cranial part of the sutures is the most important to hold the foundation of the device.*

⚠ ***WARNING:** Place the fundus holding of the device on the left side of esophagus within the two vagus nerves (trunks) and not at the back or front of the esophagus (off label procedure), which potentially may cause problems related to nervus vagus.*

⚠ ***CAUTION:** The pouch is preferably positioned dorsally in the left posterior quadrant of the esophagus. The first suture row between the stomach and the esophagus should therefore be placed approximately 60° posterior to the body midline on the esophagus on the patient's left side, carefully preserving the dorsal vagal trunk.*

⚠ ***CAUTION:** When suturing the fundoplication, ensure the esophagus bite distances are not substantially larger than the stomach bite distances. Such suturing technique may lead to bending and narrowing of the esophagus, resulting in dysphagia.*

⚠ ***CAUTION:** Do not suture substantially larger bites in the stomach compared to esophagus.*

⚠ ***CAUTION:** Avoid forceful suturing which may rupture the esophagus leading to fundus not being secured to or later separating from esophagus. Especially if knots are made extra corporally, avoid tension on any esophagus bite that could cut through.*

⚠ ***CAUTION:** Avoid fat in the suture line attachments.*

⚠ ***CAUTION:** Ensure the sutures in the esophagus are not too superficial or are placed with too tiny bites in esophagus during fundoplication. Such suturing technique could increase the risk of surgical failure if the patient coughs or vomits post-op.*

⚠ ***CAUTION:** Suture fundus to esophagus ensuring the fundoplication procedure is performed by leaving enough fundus to allow a soft invagination.*

14.4 RefluxStop® Implantation

14.4.1 RefluxStop® Deployment Tool Entry and Advancement

1. Place the Trocar of the assembled Deployment Tool at the lower left quadrant in the left axillary line of the patient or maximum 5.0 cm medial thereof. This replaces the existing fifth trocar. This trocar placement is important as it will assist in dissecting the fundus to introduce the device. For trocar entry and advancement instructions, refer to the RefluxStop® Deployment Tool instructions for use.
2. With the Deployment Tool Trocar correctly in place, remove the Deployment Tool Obturator following the instructions in the RefluxStop® Deployment Tool instructions for use.

14.4.2 Insert RefluxStop® Device

3. With the implant loaded into the Insertion Tool (per the RefluxStop® Deployment Tool instructions for use), place the Insertion Tool into the Cannula. Advance the Insertion Tool through the fifth trocar and into the abdomen per the RefluxStop® Deployment Tool instructions for use.

⚠ ***CAUTION: Only use resorbable suture to assemble the RefluxStop® device. Required to use Vicryl Plus due to its specific absorption time properties.***

⚠ ***CAUTION: Only add lubricant to the RefluxStop® device and compress it into the RefluxStop® Deployment Tool immediately prior to introducing the implant into the abdomen. Leaving the lubricated device within the tool for an extended period of time may lead to difficulty in releasing the device. Filling the deployment tool pipe with too much lubricant may hinder the compression of the device.***

⚠ ***WARNING: Ensure free passage for the Trocar of the RefluxStop Deployment Tool and the RefluxStop® device into the abdomen, through visual clearance using Laparoscope. Failure to ensure appropriate clearance may lead to damage of tissues or organs.***

14.4.3 Positioning of Implant

4. Place the RefluxStop® device against the stomach fundus, as close to the left side of the esophagus as possible. To ensure uppermost placement of the device, lift the device upwards with the stomach tissue towards the diaphragm and close to the esophagus

NOTE: It is an advantage if the invagination top-cap sutures include sections of fundus wall from downwards/ behind/posterior the fundus (just behind the greater curvature sail which, in its prolongation, includes the short gastric vessels). If this technique (to use fundus from posterior) is performed, the device will likely be placed at least 1.0 cm higher than if placed only ventral on the fundus.

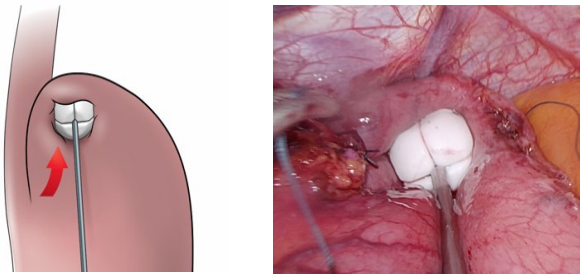


Figure 11. Position RefluxStop® Device Against Stomach Fundus

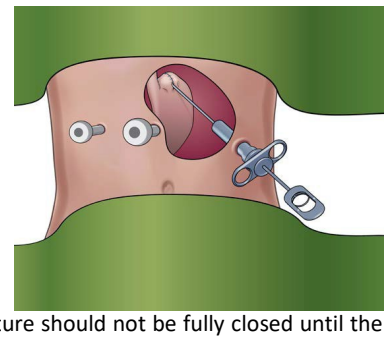
⚠ ***CAUTION: Incorrect device placement will prevent the intended treatment effect.***

⚠ ***CAUTION: The lower esophageal sphincter may move cranial long-term after surgery due to tissue consolidation. Therefore, headroom in placement height is needed for an optimal long-term result.***

⚠ ***CAUTION: As the diaphragm is slightly dome-shaped, it is important that the device is placed not only high-up but also close to the hiatus/esophagus, otherwise 1.0-2.0 cm of height is lost when the device acts as a mechanical stop against the diaphragm. Therefore, it is important that the device is not only placed high-up, but it should also be placed close to the hiatus/esophagus.***

14.4.4 Fundus Invagination

5. Using the RefluxStop® Deployment Tool, hold the RefluxStop® device in place in the intended fundus region. This placement is to be maintained throughout the fundus invagination, **Figure 12**. The invagination of the RefluxStop® device should be tension free to avoid too high pressure on the stomach fundus wall that may hamper blood supply.
6. With the RefluxStop® device in position, fixate the device in place with two single sutures: one suture above the device (top-cap/proximal suture) and one suture below the device (bottom/distal suture). As shown below, the bottom invaginating suture is to be comprised of multiple bites around the device's circumference and sutured above the RefluxStop® Deployment Tool. This will ensure stomach-to-stomach contact with the instrument in the suture loop.



a. ***Top-Cap/Proximal Suture:*** The top-cap/proximal suture should be placed from 1.0 to 4.0 cm away from the anterior fundoplication column on the esophagus (3.0 cm long) with 3-4 bites, placed 2.0 cm behind the sail of the greater curvature (most left 2.0 cm behind and reduced to 1 cm behind close to esophagus) which in its prolongation includes the short gastric vessels. The suture should not be fully closed until the bottom/distal suture has been placed and closed, as shown in **Figure 12** below. Leave the suture loop 2 cm too long and unlocked in a gliding self-locking knot or close 2 cm too long and hold/lift with an instrument.

b. ***Bottom/Distal Suture:*** The bottom/distal invaginating suture (sometimes two such sutures) should comprise multiple bites in/around two-thirds of the circumference of the device as a purse string / tobacco pouch (using non-resorbable and non-degradable suture between (2-)3 o'clock and 9(-10) o'clock, at an 0.5 cm distance from the device at 6 o'clock and 1.5 cm away at 3 o'clock and 9 o'clock) below and around the device (see ***Figure 14*** **and** ***Figure 13*****).** The suture should contain 3 bites on each side of the insertion tool and 1 bite underneath it. This will secure the device in the intended position. If the suture cannot be properly closed with a good stomach-to-stomach contact above the insertion tool, cut the suture, remove it and redo the suture again.

NOTE: When performing the bottom purse string/tobacco-type suturing, let the needle go in and out from the stomach wall close to each other to avoid any channel performed by dilating stomach, which could expand substantially.

NOTE: It is preferable to hold and lift this suture concurrently as the Deployment Tool is moved upwards together with fundus tissue to create a cap over the cranial part of the device.

NOTE: The placement of the top-cap/proximal suture should be identified by temporarily holding the Deployment Tool in place. The Deployment Tool can then be removed to place the top-cap/proximal suture. Once sutured, return the Deployment Tool to the correct position.

NOTE: If this suture includes fundus wall from 2.0 cm behind/posterior the fundus (behind the greater curvature sail), the device can be placed at least 1.0 cm higher up than if placed only ventral on the fundus.

c. ***Lock the Top-Cap/Proximal suture:*** after locking the bottom/distal suture, lock or knot the top-cap/proximal suture with a light hand.

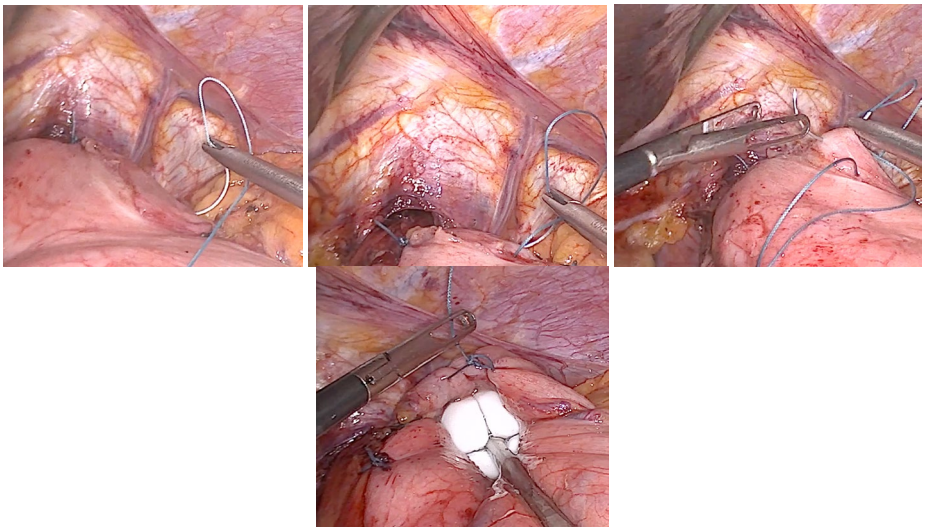


Figure 12. Suture the Top-Hat Suture 2.0 cm Behind the Sail of the Short Gastric Vessels

NOTE: The loop of the top hat suture should not be fully closed initially with 2 cm too long suture loop to leave the top part of fundus loose and floppy until the bottom suture has been placed and knotted. Then the top of fundus should be closed with very light force applied to avoid too much tension between the top and bottom sutures. The top hat suture could either be performed as a gliding self-locking knot or simply use a single suture to be knotted with a too large suture

loop. Alternatively, a polypropylene or polyester suture could be folded and knotted at the end to create a loop, through which the needle could pass after the suture has been placed. This provides a loose loop to be held by an instrument.

NOTE: The top hat suture should be left with a 2.0 cm too large loop while the bottom suture is being placed. Once the bottom suture is placed and closed, the top of the fundus and the top suture could be closed loosely. If the methodology with a loop has been used, a second double bite suture is to be made before closing the top/hat suture.

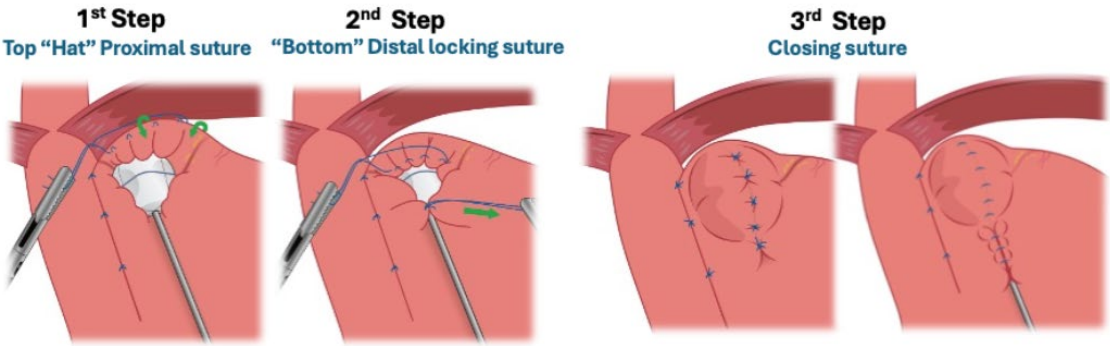


Figure 13. Suture Placement: Purse String Top-Hat, Bottom Locking (Device Securing) and Closing Suture

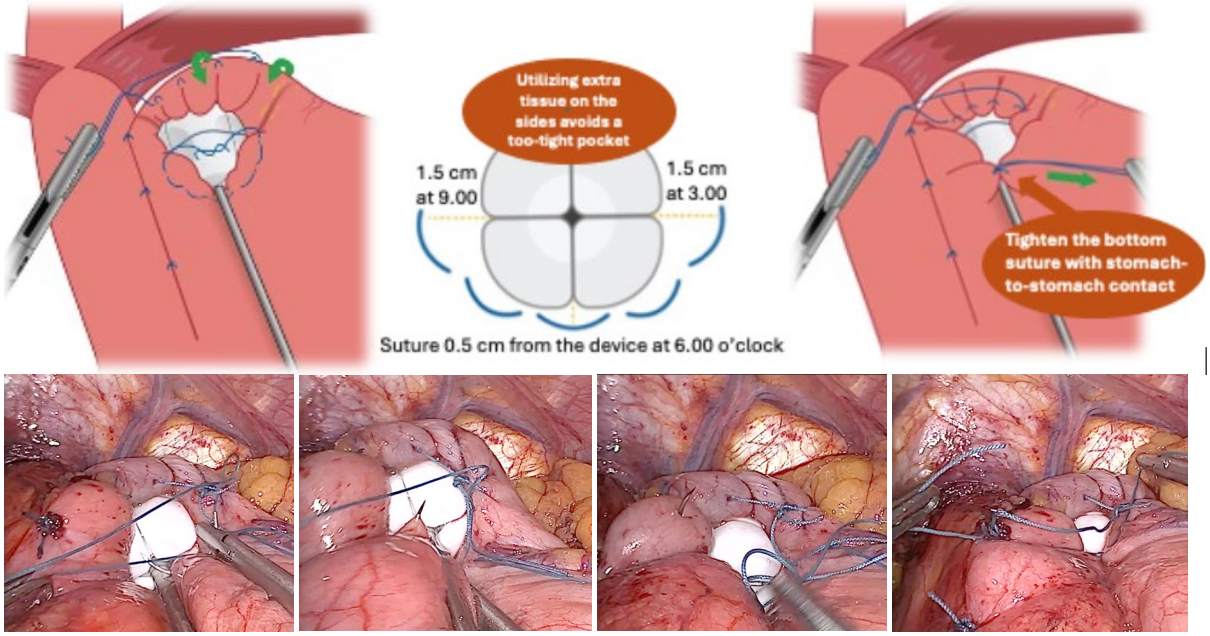


Figure 14. Suture Placement: Bottom Locking Suture

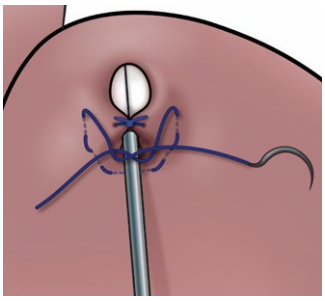
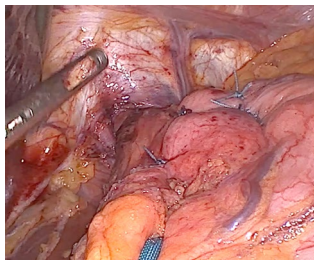


Figure 15. Close Additional Purse String Suture around the hole after the RefluxStop® Deployment Tool



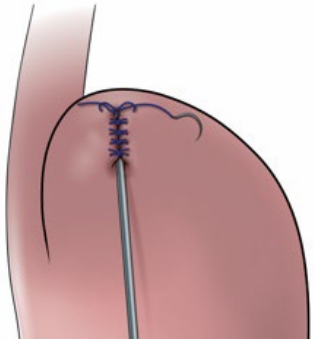


Figure 16. Suture from Bottom to Top Until RefluxStop® Device is Covered Completely by Stomach Wall

⚠ ***<u>CAUTION:</u> Ensure the invagination suturing is performed loosely without tension in the stomach wall. Suturing too tightly may obstruct blood supply to the stomach pouch wall and could increase the risk of device erosion into the stomach cavity.***

⚠ ***CAUTION:** A bleeding in the stomach pouch wall may also restrict the pouch space with similar effect as above, increasing the risk of erosion of the device into the stomach cavity.*

⚠ ***CAUTION:** Too tight of an invagination could theoretically cause a mucosal stomach ulcer at the site of the device due to the reduced blood supply to the stomach wall.*

⚠ ***CAUTION:** Care should be taken to ensure that fundus wall is properly mobilized to be used for the invagination of the device by placing a top hat suture above the device 2 cm posterior of sail of the greater curvature to mobilize fundus wall also from behind/posterior of fundus.*

⚠ ***CAUTION:** Ensure the invagination pouch isn't too large which can lead to a lowering of the implant position. If the device moves away from esophagus, the fundus package may move cranial.*

⚠ ***WARNNG:** Ensure the RefluxStop® device is completely covered by sutured stomach wall. Indirect risk only relevant if the patient experiences infection post-op.*

⚠ ***CAUTION:** While holding the device with the deployment tool ensure that the position of the RefluxStop® device is secured by a distal locking non-resorbable suture, a purse string single non-barbed suture below the device.*

⚠ ***WARNING:** Much too tight of an invagination could cause the device to erode into the abdominal cavity (although it's highly unlikely since the device hangs like a teardrop into the stomach cavity with a row of sutures above) due to the reduced blood supply to the stomach wall.*

14.4.5 Implant Release and Removal of RefluxStop® Deployment Tool

7. When the device is safely held in place by the top-cap/proximal and bottom/distal sutures, release the RefluxStop® device by pulling the looped end of the RefluxStop® Deployment Tool Wire until it stops (***Figure 17***). Retract the RefluxStop® Deployment Tool's Insertion Tool to completely remove the Insertion Tool.
8. Complete the fundus invagination by continuing to suture cranially with interrupted sutures to close the pouch completely. Ensure that the invagination is made loosely and that the sutures reach the top-cap/proximal suture.
9. Close the hole after the Deployment Tool is removed before finishing the surgery.

   NOTE: Start below the bottom/distal suture and suture from the bottom to the top of the pouch, stopping when the suture reaches the top-cap/proximal suture.

   NOTE: It is common that the closing bites may need to be taken more to the patient left or even dorsal to the sail of the greater curvature on the left side of fundus to ensure enough stomach wall tissue is available for a loose invagination. Ensure no fat in the suture line.

   NOTE: Once the invagination has been completed, examine the opening left by the Insertion Tool by stretching the stomach wall distal to the device. The device should not be visible. If visible, close the opening with additional suture(s) (e.g., a purse string suture).

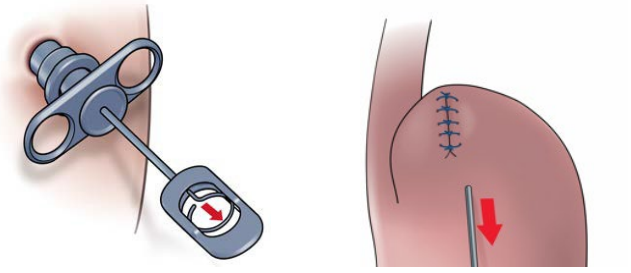


Figure 17. Removal of RefluxStop® Deployment Tool

⚠ ***CAUTION:** Ensure to have closed enough of the loosely sutured invagination of the RefluxStop® device befo releasing the device from the RefluxStop® Deployment Tool.*

⚠ ***CAUTION:** If the RefluxStop® device is inadvertently released from the RefluxStop® Deployment Tool inside t abdominal cavity, re-mount the RefluxStop® device to the RefluxStop® Deployment Tool. This can be accomplish by inserting an additional and suitable instrument (e.g. a Babcock) inside the abdomen and pushing the top of t Wire of the RefluxStop® Deployment Tool into the center hole of the implant.*

⚠ ***CAUTION:** In the event the RefluxStop® device components fall apart during introduction into or when inside t abdominal cavity, all parts of the RefluxStop® device shall be removed and re-sutured / re-mounted outside of boa*

⚠ ***CAUTION:** If an early erosion occurs into the stomach cavity, the device exits spontaneously through the digesti tract and no further action is needed. If seen at an early stage in one piece, it is possible to cut the suture holding t device together by EG endoscopy allowing the individual pieces to pass out more quickly through the digestive tra*

⚠ ***WARNING:** A device eroded into the stomach cavity can cause ileus if the suture remains around the device ea after operation or if a non-resorbable suture has been used around the device. In an undamaged digestive tract, t full device will be able to pass, however, previous abdominal surgery may cause narrowing of the intestines due adherences.*

15 Post-Operative Care

15.1 Post-Operative Retching and Coughing must be Avoided at All Times

Before adequate healing has occurred in the immediate post-operative period, re-herniation and operative failure may occur. It is therefore important that the anesthesia team is aware of measures intended to minimize post-operative retching and coughing. An example of a post-operative management program used at one of our centers is provided below for informational purposes only and does not constitute medical advice or a recommendation from Implantica. Each center is responsible for establishing its own protocols and procedures for post-operative care.

15.1.1 Anesthesia – In the operating theatre

- Extubation whilst the patient is deeply sedated or fully awake (to avoid stimulation)
- Anti-emetic regimen:
- Dexamethasone 4–8 mg at induction
- Ondansetron 4 mg IV + Droperidol 0.625 mg IV prior to skin closure
- Avoid gastric distension; remove nasogastric tube prior to extubation
- Opioid-sparing analgesia

15.1.2 Post-anesthesia care unit (PACU)

- Initially NPO (except for small sips of water)
- Ondansetron 4 mg IV every 8 hours for 24 hours
- IV PPI (Pantoprazole 40 mg)
- No straws, no carbonated drinks

15.1.3 Dietary plan

- 0–4 hours: NPO
- 4–24 hours: Clear liquids
- Days 1–3: Liquid diet (soup, yoghurt, protein-rich drinks)
- Days 3–14: Soft foods (mashed potatoes, fish, soft pasta)
- Weeks 2–6: Gradual return to a normal diet
- If swallowing difficulties occur, take a step back in the dietary progression

15.1.4 Important warnings

- Vomiting or gagging ® immediate antiemetics
- Inability to swallow liquids
- Severe chest pain ® possible complication (wrap/hiatus)

15.2 Post-Operative Diet and Discharge

After surgery, patients can drink as soon as tolerated or otherwise advised by the implanting surgeon. Once liquids are tolerated, a well-tolerated light post-operative diet can commence. Thereafter, patients should be stimulated to eat in accordance with the hospital's standard clinical procedure following similar types of anti-reflux surgery.

According to the best knowledge of Implantica, patients can be considered dismissible when they can drink, eat lighter food, and are mobile. Typically, less than 24 hours.

15.3 Contrast Swallow X-Ray

Prior to discharge, patients must undergo a simplified gastrographin contrast swallow x-ray to ensure lack of leakage due to surgical injury, lack of stenosis in the crura closure, and to categorize the RefluxStop® device position. The post-op contrast swallow x-ray should be strictly focused on the area of the lower esophageal sphincter (LES) only. To minimize radiation exposure, it is not recommended to perform unnecessary x-rays of the neck, full pulmonary region, or the complete stomach. In order to properly assess device positioning, it is important that both the RefluxStop® device and the detection of the LES area can be seen on the same x-ray during the first build-up of contrast in this area.

While viewing the contrast descending down the esophagus, a first constriction of the esophagus will be seen at the diaphragm muscle due to the narrowing sutures in the crus muscles. A second constriction usually 1.5 cm long will then be seen at the LES contracting muscle. To visualize the upper edge of the LES, it is necessary to follow the build-up and release of contrast in the LES region. While viewing and recording the transillumination x-ray, the first contrast build-up at the constriction areas will capture the upper edge of the LES visualized together with the RefluxStop® device. Pictures could be taken from the recording to visualize the upper edge of the LES in relation to the device. **NOTE:** If the transillumination x-ray equipment is capable of taking pictures with very short delay during the swallowing process, it may be possible to take pictures instead of recording.

15.3.1 Categorization

The postoperative categorization must be performed by the radiologist (preferred) or a surgeon with adequate radiology experience by viewing the x-ray recording with the contrast swallow taken during the hospital stay post-op. Based on the recording still images should be taken to document the assessment of the device positioning relative to the LES **Figure 19.**

NOTE: The size of the sphere of the device is 25 mm and can be used as a scale reference for determining the position of the

device in relation to the upper edge of the LES. The placement of two small blood vessel clips onto a suture placed at the angle of His and at the top suture close to the diaphragm will greatly assist the visualization of the angle of His on X-ray.

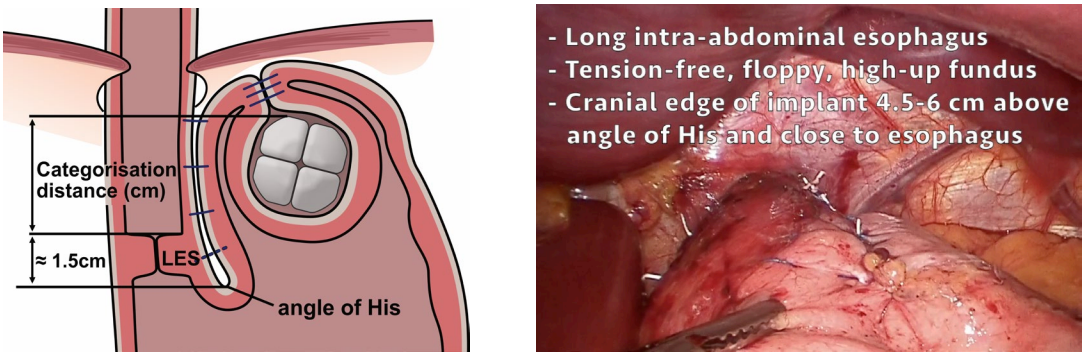


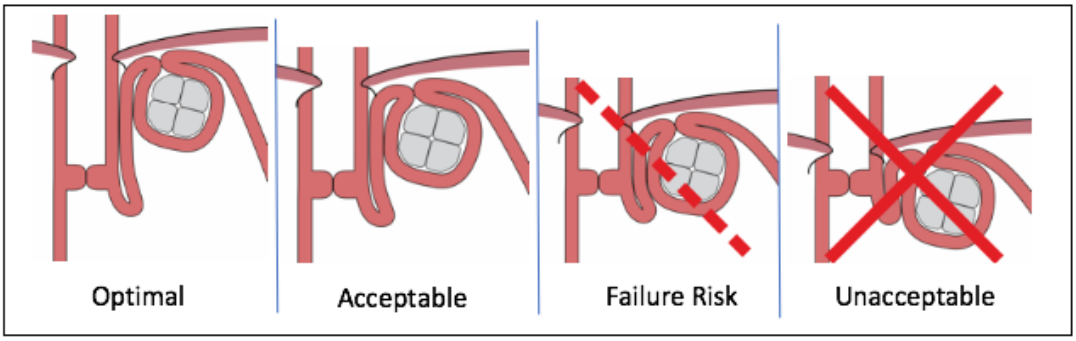
Figure 18. RefluxStop® Device Placement Measurement during X-Ray.

NOTE: Positioning during surgery refers to the height of the top edge of the device in relation to the angle of His

Once the measurements are calculated, categorize the device positioning based on the scale outlined in ***Figure 19*** below. The categorization must be noted by the surgeon and it must be kept in the patient file together with the corresponding x-ray pictures. These images and categorization will be requested as part of any complaint handling investigation related to the patient.

- "Optimal" and "Acceptable" device positioning indicate a technically accurate procedure and will ensure positive long-term results.
- "Failure Risk" device positioning indicates a non-ideal procedural placement that will likely lead to failure in the mid- to long-term as the distance between the LES and the hiatus will become smaller over time due to tissue consolidation and degeneration caused by immobilization of the fundus.

  NOTE: If reflux symptoms recur at a later stage, re-operation to place the device in a more cranial position has shown to be successful in commercial practice.
- "Unacceptable" device positioning indicates poor procedural placement that may cause immediate failure.



Optimal	Acceptable	Failure Risk	Unacceptable
X-Ray: Device top placed more than 1.5x the device size above the upper edge of the LES *Surgery: Device top placed >5.0 cm above angle of His*	*X-Ray: Device top placed 1 – 1.5x the device size above the upper edge of the LES* *Surgery: Device top placed 4.0-5.0 cm above angle of His*	*X-Ray: Device top placed 0.5 – 1x the device size above the upper edge of the LES* *Surgery: Device top placed 2.5-4.0 cm above angle of His*	*X-Ray: Device top placed <0.5x the device size above the upper edge of the LES* *Surgery: Device top placed <2.5 cm above angle of His*

Figure 19. RefluxStop® Device Placement Categorization

16 Routine Assessment Guidelines and Post-Operative Follow-Up

16.1 Pre-Operative Assessments

As part of pre-operative planning, the following standard-of-care assessments are to be completed:

- Completion of Patient Questionnaires provided by Implantica (when off medication for 1 week) including:
  - GERD-HRQL 10 Q
  - Patient Dissatisfaction
  - Regurgitation (episodes per day or per week)
  - Regular/Daily PPI Usage
  - Ability to belch and vomit
- Simplified Gastrographin Contrast Swallow X-Ray for assessment of Hernia Diagnosis
- Upper GI Endoscopy / EGD (esophago-gastro-duodenoscopy) Endoscopy with biopsies including:
  - CNM Classification
  - Los Angeles (LA) Classification for Esophagitis
  - Categorization of Barrett's Esophagus, Paris and Prague classification
  - Gastritis Diagnosis

NOTE: Patients presenting precancerous change with low- and high-grade dysplasia at the EGD endoscopy with biopsies shall follow standard clinical procedures with annual endoscopy to follow the development of the precancerous status.

- 24-hour pH monitoring

NOTE: While 24-hour pH monitoring is the preferred method of monitoring pH, many patients may consider this burdensome and endoscopy showing esophagitis is also sufficient for diagnosis.

16.2 Post-Operative Assessments

Directly after surgery, ensure that the patient is not retching, heaving, or vomiting. If a patient presents with these symptoms immediately post-operatively, then sutures could have cut through the crus muscles with reherniation as a result.

NOTE: Crus muscle sutures could completely cut through the crus muscles causing a large hiatus opening and intact fundus/device package re-herniated into the thorax which would need to be surgically restored again. Restore fundus with the device intact in its pouch and repair hiatus again.

Video recordings of the first 5 patients operated by each surgeon should be provided to the Proctor for evaluation and feedback on surgical technique. Proctor has the right to request another 10 video recordings which often is recommended as a service to the operating surgeon to align with a perfect procedure, to secure optimal results.

The following additional post-operative assessments are often completed prior to discharge and/or at each follow-up visit as detailed in Follow-up Patient Questionnaires proposed (provided by Implantica) including:

- GERD-HRQL
- Patient Dissatisfaction
- Regurgitation (episodes per day or per week)
- Regular/Daily PPI Usage
- Ability to belch and vomit (when off medication for 1 week)

NOTE: A failed GERD-HRQL questionnaire (<50% improvement of the total GERD-HRQL score compared to baseline) or regular daily PPI usage could be caused by issues other than acid reflux. Gastritis is the most common reason and often an endoscopy with visual or biopsy confirmed gastritis is a good first step if symptoms indicate gastritis. In such a case, it is recommended that the three (3) most common causes of gastritis should be evaluated and treated. A couple of weeks with PPI or Alginates is one treatment option. Due to long-term PPI use, dysbacteriosis often occurs and probiotic treatment such as Normaflore could be tested. Helicobacter pylori is an alternative treatable option, and a diagnostic test should be performed if other treatments do not work as intended.

- Simplified Gastrographin Contrast Swallow X-Ray to ensure lack of leakage due to surgical injury, lack of stenosis in the crura closure, and to categorize the device position post-surgery at Hospital stay. Alternative of complementary X-Rays may be used. Barium may also be used at other time points.
  NOTE: To ensure the correct surgical quality control and device position during post-op assessment, ensure identification of the vascular clips placed on a suture at the angle of His and at the top fundoplication suture closest to the diaphragm during surgery.
- 24-hour pH monitoring once after surgery (1 year) is recommended when starting a new procedure as quality control.
- Monitor and report any adverse events as described in Section 7.3.

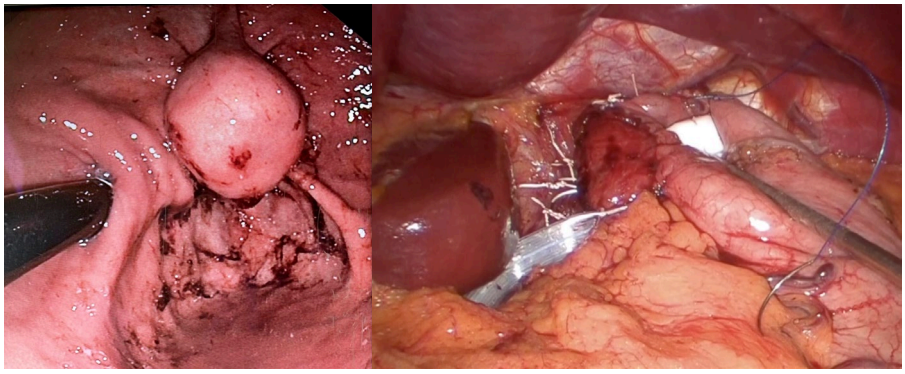


Figure 20. Invaginated RefluxStop® Device – **Inside the Stomach (Left) and Prior to Invagination (Right)**

16.3 Assessment Schedule

Table 9. Assessment Schedule for the RefluxStop® Device

Assessment	Pre-op	Hospital Stay	3-month visit*	1-year or (6- month)[1] visit	Annual Follow-Up (up to 5 years)
Completion of Patient Questionnaire	X	-	X	X	X
Contrast Swallow X-Ray (Use Gastrographin at least at Hospital stay)	X	X	-	X	
EGD Endoscopy	X	-	-	-	
24-hour pH Monitoring	X	-	-	X	
Manometry	X	-	-	-	
Reporting of Adverse Events	-	X	X	X	X

[1] ***If performed at 6 months, it is advised to re-commence the annual follow-up at 2 years.***

17 RefluxStop® Device Removal

17.1 Natural Removal

The RefluxStop® device, when completely invaginated into the outside of the stomach wall, will protrude into the stomach cavity due to the teardrop shape formed by the encapsulated device **Figure 20**. The most cranial part of the device is covered by a double layer of stomach reinforced by sutures, meanwhile the device mainly is covered by single wall-thickness of stomach as viewed in **Figure 18**. If an erosion of the device were to occur over time, the device would naturally enter into the stomach cavity. Based on the invagination technique and the device construction (5 singular pieces with a resorbable suture), the device pieces will normally naturally pass through the digestive tract and out through the anus. The effect of this complication is therefore substantially reduced and re-operative measures could normally be avoided. Erosion goes unnoticed, at least in the short-term, and is typically only reported by return of acid reflux symptoms by the patient.

17.2 Surgical Removal

If a patient experiences a complication that requires surgical intervention, the device can be explanted. To properly explant the device, the following steps should be followed:

1. Enter the abdomen, normally, via laparoscopic approach.
2. Cut through the stomach-to-stomach sutures that may still hold the pouch together, in which the RefluxStop® device is embedded.
3. A thin, fibrotic white capsule usually surrounds the implant. Cut open the capsule.
4. Cut the resorbable thread that holds the implant together, if the thread is still in place.
   NOTE: The thread on the implant is absorbable and therefore would only remain if the explant were to occur acutely (only approximately 2 months after surgery).
5. Separate the RefluxStop® device into its five (5) segments and remove them from the patient one at a time.
   NOTE: In case one or several of the segments have penetrated into the lumen of the stomach, these segments will pass naturally or will have already passed through the digestive tract and may not be in the patient anymore.
6. The RefluxStop® device parts shall be handled as hospital contaminated waste and be returned to Implantica CE Reflux Ltd.

18 Symbols Legend

Label Symbol	Description	Label Symbol	Description
REF	Catalogue Number	STERILE R	Sterilized Using Irradiation
MD	Medical Device		Double sterile barrier system
LOT	Batch Code		Do Not Resterilize
	Use-By Date		Do Not Re-Use
UDI	Unique Device Identifier		Do Not Use If Package Is Damaged
(01)	UDI Device Identifier		Caution / Warning
(10)	UDI Production Identifier (Batch Code)		Consult Instructions for Use
(11)	UDI Production Identifier (Manufacturing Date)	**Rx only**	Caution: Federal law restricts this device to sale by or on the order of a physician.
(17)	UDI Production Identifier (Use-By Date)		Date of Manufacture
MR	MR Safe		Manufacturer

19 Return Goods

In the event an unused device must be returned for any reason, please place the RefluxStop® device into its original package and shipping box. Notify Implantica Customer Support to receive a return goods authorization number and ship the device to the address provided by customer service.

20 Responsibilities

- Implantica CE Reflux Ltd only accepts responsibility for the devices' safety, usability, and performance if the device is used in accordance with its intended use and with information supplied with the device.
- It is the responsibility of the surgeon to advise the patient of the known risks and complications associated with the surgical procedure and implant when obtaining the patient's consent with the procedure.
- It is the responsibility of the surgeon to advise the patient that the RefluxStop® device is a long-term implant. Explant (removal) and replacement surgery may be indicated at any time. Medical management of adverse reactions may include explantation and/or device replacement.
- It is the responsibility of the surgeon to request the patient to contact his/her local doctor upon any complications or relapse of symptoms.
- As with other surgical decisions, it is the responsibility of the surgeon to use his or her own judgment in utilizing the procedures best suited to the needs of the patient and the skill and experience of the surgeon.
- It is the responsibility of the surgeon to contact Implantica CE Reflux Ltd if any serious events might be dependent on or related to the RefluxStop® device.

RefluxStop® Deployment Tool

Instructions for Use (Surgical)

⚠ IMPORTANT

Please read carefully all instructions contained within this packet before use.

⚠ ***CAUTION:* Federal law (U.S.) restricts this device to sale by or on the order of a physician.**

Implantica CE Reflux Ltd only accepts responsibility for the device's safety, usability and performance if:

- *the device is used in accordance with its intended use; and*
- *the device is used in accordance with the product labels and instructions for use. This includes the instructions for both the RefluxStop® device and the RefluxStop® Deployment Tool.*

Electronic Labelling

The Instructions for Use can be accessed online by visiting the website provided on the label (https://ifu.implantica.com) and selecting the relevant device. Additional translations are also available in electronic format for download. A paper copy is available free of charge within 7 calendar days. Please contact customer support at: customersupport@implantica.com or by clicking "Request a document" via the link provided on the website (https://ifu.implantica.com).

Product name:	**RefluxStop® Deployment Tool**
Product catalogue number:	**RS-300**
IFU catalogue number:	**IFU-0003235 rev Draft v6.0**
Date of issue:	**2026-08**
Manufacturer:	**Implantica CE Reflux Ltd** Sir Temi Zammit Buildings Malta Life Sciences Park San Gwann SGN 3000 Malta Tel: +35 621 443 532
Customer support:	customersupport@implantica.com www.implantica.com

Contents

1 Instructions for Use

These instructions for use describe use of the RefluxStop® Deployment Tool (RS-300). Product specific training needs to be received from an Implantica representative prior to initial use.

Users must read these instructions for use and the instructions for use for the RefluxStop® device carefully prior to using the devices so that the features are thoroughly understood. Failure to follow these instructions may endanger the patient and/or the operator.

2 Device Overview

2.1 Intended Use

The RefluxStop® Deployment Tool (RS-300) is a reusable, invasive surgical instrument that is designed exclusively to facilitate the introduction of the implantable RefluxStop® device (RS-A1) into the abdominal cavity at a predetermined place at the fundus of the stomach during a laparoscopic surgical procedure.

2.2 Device Description

The RefluxStop® Deployment Tool consists of four subassemblies: the Trocar, Insertion Tool, Compression Parts, and Ejector Device [***Figure 1***].

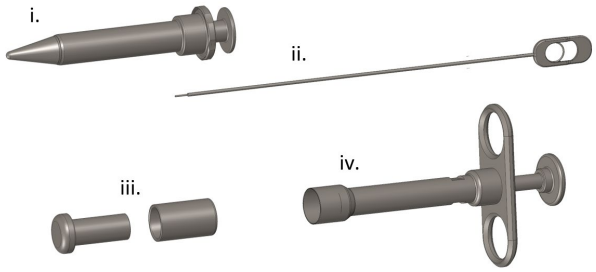


Figure 1. Subassemblies of the RefluxStop® Deployment Tool

i. **Trocar**: Obturator, Cannula, Cross Slit Valve, Lid Nut
ii. **Insertion Tool**: Tube, Wire, Insertion Handle
iii. **Compression Parts**: Insert Device and Funnel
iv. **Ejector Device**: Pipe, Handle, Ejector Tube

2.2.1 Trocar [Figure 1 (i)]

The Trocar is used to create a port into the abdominal cavity. It consists of the Obturator (RS-904), Cannula (RS-905), and Lid Nut (RS-877), which are manufactured from Stainless Steel AISI 316L and the Cross Slit Valve (RS-881), which is manufactured from medical-grade silicone ML-154.

When advanced into the abdominal cavity, the Obturator (RS-904) is removed to allow entry of the RefluxStop® device. The Cross Slit Valve (RS-881) and Lid Nut (RS-877) are mounted into the Cannula (RS-905) to create seal and maintain the abdominal pressure during the various steps of the laparoscopic procedure.

2.2.1 Insertion Tool [Figure 1 (ii)]

The Insertion Tool holds the assembled RefluxStop® device during advancement into the abdominal cavity. Upon reaching its predetermined position at the fundus of the stomach, the implant is released from the device by retracting the Wire (RS-806). It consists of the Tube (RS-807), Wire (RS-806), and Insertion Handle (RS-805), which are all manufactured from Stainless Steel AISI 316L.

2.2.2 Compression Parts [Figure 1 (iii)]

The Compression Parts allow the RefluxStop® device to be inserted into the Pipe (RS-802) of the Ejector Device. It consists of the Insert Device (RS-901) and Funnel (RS-903) , which are both manufactured from Stainless Steel AISI 316L.

2.2.3 Ejector Device [Figure 1 (iv)]

The Pipe (RS-902) of the Ejector Device, consisting of the Ejector Tube (RS-870), Handle (RS-872), and Pipe (RS-902) will house the RefluxStop® device in a compressed state while inserted into the abdominal cavity. The Ejector Device will allow the RefluxStop® device to be ejected out from the Pipe (RS-902) when in the abdominal cavity.

In total there are twelve (12) parts included in the RefluxStop® Deployment Tool, RS-300.

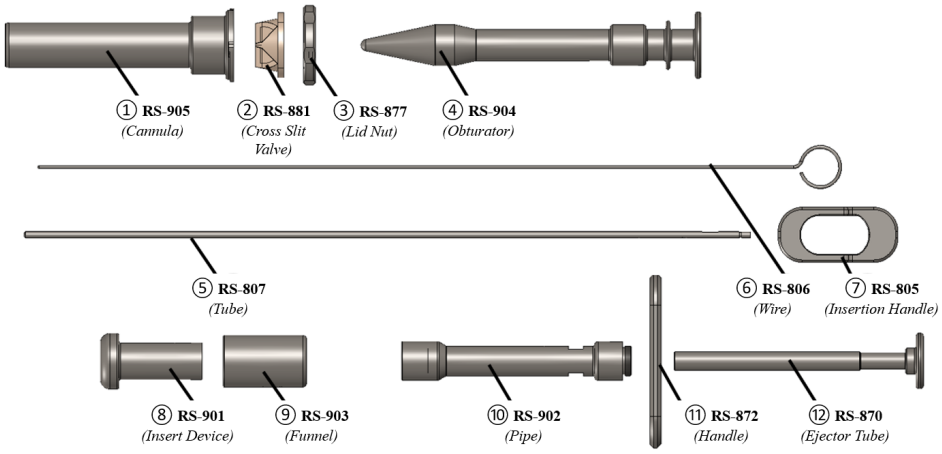


Figure 2. Components of the RefluxStop® Deployment Tool

Table 1. Components of the RefluxStop® Deployment Tool				
Figure 2 #	**Component #**	**Name**	**Qty**	**Part of**
1	RS-905	Cannula	1	**Trocar**
2	RS-881	Cross Slit Valve	1	
3	RS-877	Lid nut	1	
4	RS-904	Obturator	1	
5	RS-807	Tube	1	**Insertion Tool**
6	RS-806	Wire	1	
7	RS-805	Insertion Handle	1	
8	RS-901	Insert Device	1	**Compression Parts**
9	RS-903	Funnel	1	
10	RS-902	Pipe	1	**Ejector Device**
11	RS-872	Handle	1	
12	RS-870	Ejector Tube	1	

2.3 Duration of Use

The RefluxStop® Deployment Tool is intended for transient use (less than 60 minutes).

2.4 Expiry Dating

Expiration dating for RefluxStop® System has been established and approved at five (5) years for the RefluxStop® device implant and up to 200 cleaning and sterilization cycles of the metal components of the RefluxStop® Deployment Tool and 50 cleaning and sterilization cycles of the silicone component of the RefluxStop® Deployment Tool.

3 Indications for Use

3.1 Indications for Use

RefluxStop® is an implantable sterile medical device intended to treat acid and non-acid reflux in patients diagnosed with gastroesophageal reflux disease (GERD). The device ensures maintenance of a normal physiological situation for the gastroesophageal junction (GEJ) in a defined intra-abdominal position, allowing a natural physiological function of the lower esophageal sphincter (LES), thereby reducing or eliminating acid and non-acid reflux.

The RefluxStop® Deployment Tool is indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD), defined by abnormal impedance pH and/or pH testing, and indicated for RefluxStop® implantation.

3.2 Intended Patient Population

The RefluxStop® System is indicated for patients diagnosed with acid or non-acid Gastroesophageal Reflux Disease (GERD), adults ≥ 18 years old that are indicated for RefluxStop® implantation and meet the following criteria:

- Documented GERD present for > 6 months;
- Patient has endoscopy verified esophagitis, and/or a 24-hour pH monitoring proven GERD defined as pathologic number of impedance pH reflux episodes of acid or weakly acid and/or pathologic pH <4 for >4.5% of the total time, off PPI therapy for at least 7 days prior to testing.

NOTE: The RefluxStop System is not intended to be used with a Collis gastroplasty.

4 Contraindications

The RefluxStop® System is contraindicated in patients with:

- Known sensitivities or allergies to the device materials (medical grade silicone [NusilMED-4860] and barium sulphate [$BaSO_4$ powder]);
- Intraoperative findings determined by the operating surgeon that may result in unfavorable conduct of the procedure.
- Known sensitivities or allergies to the device materials (Stainless Steel AISI 316L and medical-grade silicone ML-154).

5 Warnings and Precautions

5.1 General

⚠ ***CAUTION:** Federal law (U.S.) restricts this device to sale by or on the order of a physician.*

⚠ ***CAUTION:** Only use the RefluxStop® System for its intended use.*

⚠ ***WARNING:** Always read the IFU for the RefluxStop® Deployment Tool and the RefluxStop® device prior to use. Failure to follow these instructions may endanger the patient and/or the operator.*

5.2 Operational (Surgical) Safety

⚠ ***WARNING:** The RefluxStop® Deployment Tool is supplied NON-STERILE and shall be cleaned, packaged, and sterilized before first time use and after each re-use. Failure to properly clean and sterilize the device may create a risk of contamination to the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.*

⚠ ***CAUTION:** The RefluxStop® System should only be used by physicians and teams trained in laparoscopic anti-reflux procedures and who have received product specific training by an Implantica representative.*

⚠ ***CAUTION:** Do not use the RefluxStop® Deployment Tool if the device is damaged or the sterile barrier is compromised.*

⚠ ***CAUTION:** Do not use the RefluxStop® Deployment Tool if it has been removed from the sterile field.*

⚠ ***CAUTION:** Do not proceed with the surgical procedure before all specified accessories for the RefluxStop® device and RefluxStop® Deployment Tool are checked and in place.*

⚠ ***CAUTION:** The assembly of the RefluxStop® Deployment Tool shall only be performed by a healthcare professional who has received product specific training.*

⚠ ***CAUTION:** Check that looped end of Wire is in extended position and RefluxStop® device is in contact with Tube.*

⚠ ***CAUTION:** Carefully compress the RefluxStop® device partially into the Funnel before compressing it using the Insert device.*

⚠ ***WARNING:** Ensure free passage for the Trocar of the RefluxStop® Deployment Tool into the abdomen, through visual clearance using Laparoscope. Failure to ensure appropriate clearance may lead to damage of tissues or organs.*

⚠ ***CAUTION:** Do not hold or apply force on the Insertion Tool or Ejector Tube when advancing the device into the Cannula. Such force may lead to accidental release of the RefluxStop® device.*

⚠ ***CAUTION:** Do not hold or apply force on the Insertion Tool when advancing the Ejector Tube. Such force may lead to accidental release of the RefluxStop® device.*

⚠ ***WARNING:** Ensure free passage for the RefluxStop® device into the abdomen, through visual clearance using Laparoscope. Failure to ensure appropriate clearance may lead to damage of tissues or organs.*

⚠ ***CAUTION:** After ejection of the RefluxStop® device from the Pipe, do not retract the Insertion Tool too far as this could lead to accidental release of the RefluxStop® device.*

⚠ **CAUTION:** To avoid loss of abdominal pressure after removal of the Insertion Tool, seal off the Ejector Tube using a thumb, or similar, to avoid loss of abdominal pressure.

⚠ ***CAUTION:** After removing the Cannula, inspect the surgical site for hemostasis and take appropriate actions to achieve hemostasis.*

⚠ ***CAUTION:** Close the wound from the Trocar opening by suturing the underlaying fascia. This will reduce the risk for incisional herniation.*

6 Adverse Events

6.1 Observed Adverse Events

A 50-patient European Union, multicenter, prospective study was conducted to support approval of the RefluxStop® System. Results from this study, including major adverse events related to the RefluxStop® device (RS-A1), are outlined in the RefluxStop® device (RS-A1) instructions for use.

6.2 Potential Adverse Events

Adverse events that may be related to the use of the RefluxStop® Deployment Tool include, but are not limited to, those that are commonly associated with general anaesthesia, abdominal laparoscopic surgery, and those that are associated with the RefluxStop® Deployment Tool. These may be serious and even cause death. Potential adverse events comprise of, but are not limited to: Abdominal abscess, abdominal pain, adverse reactions to anaesthesia (dizziness, headache, nausea, sore throat, teeth damage, visual complications), allergic shock, anaphylactic shock, atrial arrhythmia or fibrillation, cardiac arrhythmia or arrest, hemorrhage, heart attack, hypotension, ileus, incisional herniation, infection, perforation, peritonitis, pneumonia, pneumothorax, thrombosis, pulmonary embolism, septic shock, septicemia, stroke, urinary retention, urinary tract infection, visceral adhesions, wound dehiscence.

Possible risks related to anti-reflux surgery in general, which may apply to the RefluxStop® surgical procedure, may include, but are not limited to: Intraoperative complications, reinterventions, respiratory complications also comprising atelectasis, pleurisy and pneumothorax, flatulence, retching, vomiting, bloating, hiccups, reherniation also comprising fundus including the device, bleeding especially hemorrhage from the short gastrics, the spleen including spleen extirpation, gastric or esophageal perforation, dysphagia including need for esophagus dilatation, odynophagia, recurrence of GERD symptoms such as heartburn, regurgitation, crus sutures damaging/cutting through the crus muscles due to retching/heaving/vomiting, sutures damaging the esophagus with retching, pain, ileus, esophageal widening, esophageal obstruction or reconstruction, narrowing or stenosis, or infection including peritonitis and abscess, gas bloating, inability to belch or vomit, diarrhea, vomiting and delayed gastric emptying, and hiatal repair performed too tightly causing dysphagia.

Additionally, similar to other laparoscopic procedures, there are foreseeable adverse events related to careless handling of an instrument in this case especially the RefluxStop® Deployment Tool that could result in damage to tissue or organs, especially the spleen. An accidental impact or unintentional displacement of the tool could have severe consequences.

6.3 Device-Related Adverse Event Reporting

Any adverse event (clinical incident) involving the RefluxStop® System should be reported to Implantica immediately. To report an incident, notify Implantica Customer Support.

7 How Supplied

The RefluxStop® Deployment Tool is supplied disassembled and non-sterile. Before first time use and after each re-use, the device shall be cleaned, packaged, and sterilized by the user using autoclave sterilization. Before each surgery, the device shall be unpacked and assembled.

⚠ ***WARNING:*** ***The RefluxStop® Deployment Tool is supplied NON-STERILE and shall be cleaned, packaged, and sterilized before first time use and after each re-use. Failure to properly clean and sterilize the device may create a risk of contamination to the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.***

8 Clinical Use Information

8.1 Intended User

The RefluxStop® Deployment Tool shall only be used by health care professionals who have received product specific training by an Implantica representative. The RefluxStop® Deployment Tool shall only be used together with the RefluxStop® device. The surgical procedure for the RefluxStop® device shall be performed by a surgeon experienced in laparoscopic anti-reflux procedures, who has received product specific training by an Implantica representative.

⚠ ***CAUTION:*** ***The RefluxStop® System should only be used by physicians and teams trained in laparoscopic anti-reflux procedures and who have received product specific training by an Implantica representative.***

8.2 Inspection Prior to Use

Inspect the device and packaging to verify that no damage has occurred as a result of shipping or storage. Do not use the device if damage has occurred or if the sterilization barrier (from the user's packaging post-autoclave) has been damaged or broken. If damage has occurred, return device to Implantica.

Prior to use, verify that all components of the RefluxStop® Deployment Tool are included in the packaging and are not broken or damaged. Reference ***Figure 2*** and ***Table 1***.

⚠ ***WARNING:*** ***Do not use the RefluxStop® Deployment Tool if the device is damaged or the sterile barrier is compromised.***

⚠ ***WARNING:*** ***Do not use the RefluxStop® Deployment Tool if it has been removed from the sterile field.***

8.3 Storage

The RefluxStop® Deployment Tool is to be stored in packaging, at room temperature according to hospital procedures for storage of reusable surgical instruments.

8.4 Materials Required

- RefluxStop® device (RS-A1)
- RefluxStop® Deployment Tool (RS-300)
- Absorbable Suture 2-0 Vicryl Plus, 70 cm (Ethicon)
- Isotonic Saline
- Water-based Lubricant, Surgilube® or Cathejell® mixed with pure Lidocaine 2%, to enable easy compression and ejection of the RefluxStop® device.
    - Lidocaine gel 2% has been used successfully in the pivotal study as well as in real-world evidence of >1500 cases. The lidocaine provides the advantage of reducing pain combined with a bacteriostatic effect, thereby facilitating the postoperative phase.
- General laparoscopic accessories including:
    - Non-Absorbable Suture 2-0 (polyester or polypropylene) to suture the esophagus and fundus

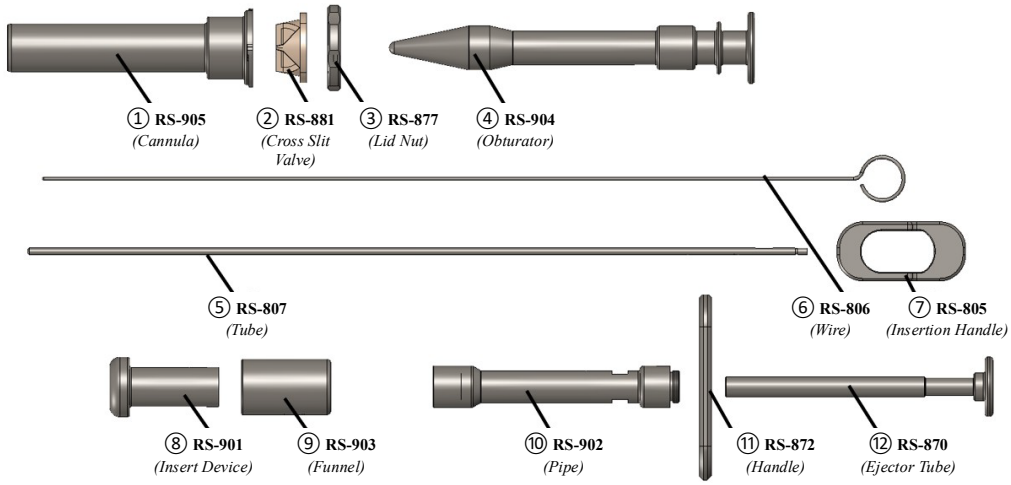
⚠ ***CAUTION:* Do not proceed with the surgical procedure before all specified accessories for the RefluxStop® device and RefluxStop® Deployment Tool are checked and in place.**

9 Assembly

The RefluxStop® Deployment Tool must be assembled in a sterile field prior to use. Assembly of the RefluxStop® Deployment Tool shall only be performed by a healthcare professional who has received product specific training.

⚠ ***CAUTION:* The assembly of the RefluxStop® Deployment Tool shall only be performed by a healthcare professional who has received product specific training.**

For identification and nomenclature of the RefluxStop® Deployment Tool components, reference the image below:



9.1 Trocar Assembly

1. Prior to assembly of the Trocar, submerge the Cross Slit Valve (RS-881) in isotonic saline.
2. Mount the silicone Cross Slit Valve (RS-881) into the large opening of the Cannula (RS-905) [***Figure 3*** (i)].
3. Place the Lid Nut (RS-877) onto the top of the Cannula (RS-905) and orient according to the fittings. Close the Lid Nut (RS-877) by turning it clockwise until it stops [***Figure 3*** (ii) and (iii)]. NOTE: The silicone Cross Slit Valve (RS-881) shall not be visible above the Lid Nut (RS-877).

Figure 3. Trocar Assembly

4. With gloved fingers, apply isotone saline onto the silicone Cross Slit Valve (RS-881). Ensure to apply on all surfaces of the valve and assemble the Trocar by inserting the Obturator (RS-904) into the Cannula (RS-905) [***Figure 4***].

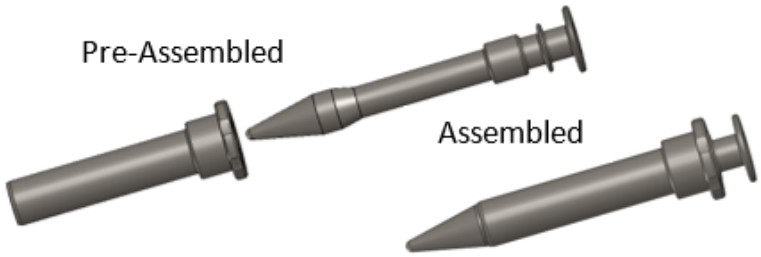


Figure 4. Assembled Trocar

9.2 Insertion Tool Assembly

5. Screw the Insertion Handle (RS-805) onto the Tube (RS-807) by turning it clockwise until it stops [***Figure 5***]. Check that no threads are visible from the Tube (RS-807).

Figure 5. Screw Insertion Handle and Tube Assembly

6. Insert the Wire (RS-806) into the Tube (RS-807) through the opening in the Insertion Handle (RS-805), ensuring proper curvature of the Wire (RS-806) as shown in ***Figure 6*** (i).

   NOTE: The curvature of the Wire (RS-806) is exaggerated in the illustration.

   Insert the Wire (RS-806) from the side of the Insertion Handle (RS-805) with the corresponding channel [***Figure 6*** (ii)].

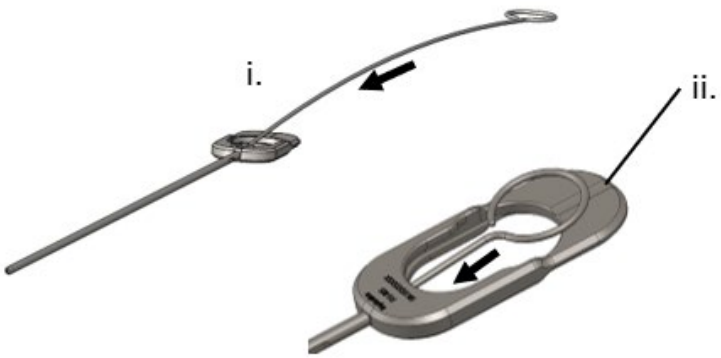


Figure 6. Wire and Insertion Handle Assembly

7. Slide the Wire (RS-806) completely into the Tube (RS-807) and guide the looped end of the Wire (RS-806) into the Insertion Handle (RS-805) groove [***Figure 7***].

Figure 7. Wire and Insertion Handle Groove Assembly

8. Check the functionality of the Wire (RS-806) by moving the looped end in the Insertion Handle (RS-805) between end positions. Confirm that the Wire (RS-806) end extends from and retracts into the Tube (RS-807).

9.3 Ejector Device Assembly

9. Insert the Ejector Tube (RS-870) through the small, centered hole of the Handle (RS-872) [***Figure 8*** (i)]. Ensure that the center hole threads of the Handle (RS-872) are oriented away from the large outer diameter of the Ejector Tube (RS-870).
10. Slide the threaded end of the Pipe (RS-902) over the Ejector Tube (RS-870) [***Figure 8*** (ii)]. Twist the Pipe (RS-902) clockwise into the threads of the Handle (RS-872) until there is no space remaining between the Pipe (RS-902) and the Handle (RS-872) [***Figure 8*** (iii)]. The Ejector Tube (RS-870) shall be trapped into the Handle/Pipe assembly with the possibility to slide back and forth approximately 20 mm.

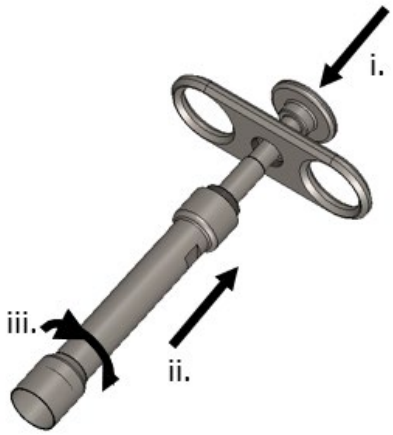


Figure 8. Ejector Device Assembly

9.4 RefluxStop® Deployment Tool Assembly

11. Slide the Insertion Tool through the Ejector Device [***Figure 9*** (i)].
12. Slide the Funnel (RS-903) over the Insertion Tool and then onto the Pipe (RS-902) of the Ejector Device until it stops [***Figure 9*** (ii)]. The coned side of the Funnel (RS-903) shall face away from the Pipe (RS-902).

Figure 9. Deployment Tool Assembly

9.5 Mounting the RefluxStop® Device

13. Assemble the RefluxStop® device according to the RefluxStop® Instructions for Use.
14. Ensure the looped end of the Wire (RS-806), within the Handle (RS-872), is in the position closest to the Tube (RS-807) and that the Wire (RS-806) is extended through the Tube (RS-807) [***Figure 10*** (i)].
15. While holding the looped end of the Wire (RS-806)in the extended position (in relation to the Tube, RS-807), push the RefluxStop® device onto the Wire (RS-806) [Figure 10 (ii)]. The Wire (RS-806) shall enter the centre hole in the RefluxStop® device, until the implant is in in contact with the Tube (RS-807).

Figure 10. Mounting the Implant onto the Wire

16. Check that the looped end of the Wire (RS-806) is in the extended position [***Figure 11*** (i)]. Then verify that the Ejector Tube is in the retracted position [***Figure 11*** (ii)]. Finally, confirm that the RefluxStop® device is in contact with Tube (RS-807) [***Figure 11*** (iii)].

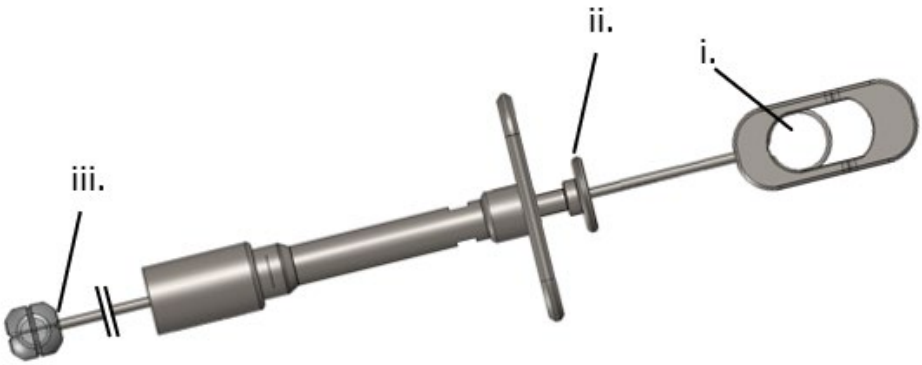


Figure 11. Final Deployment Tool and Implant Assembly

⚠ ***CAUTION:*** ***Check that looped end of Wire is in extended position and RefluxStop® device is in contact with Tube.***

9.6 Compressing the RefluxStop® Device

17. Immediately prior to introducing the implant into the body, put isotonoic saline or lubricant on the RefluxStop® device [***Figure 12*** (i)]. Make sure that the entire surface of the implant is covered with isotonoic saline or a thin layer of the lubricant. Additionally, place isotonoic saline or lubricant on the inside surface of the Funnel (RS-903) and the Pipe (RS-902).
18. Pull the Insertion Handle (RS-805) of the Insertion Tool gently to move the RefluxStop® device close to the Funnel (RS-903) edge. Use gloved hands to help advance the RefluxStop® device slightly into the Funnel (RS-903) [***Figure 12*** (ii)].

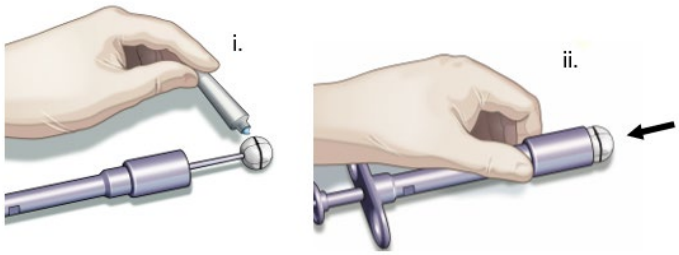


Figure 12. Compress Implant into Deployment Tool

⚠ ***CAUTION:*** ***Carefully compress the RefluxStop® device partially into the Funnel before compressing it using the Insert device.***

19. Place the concave end of the Insert Device (RS-901) against the RefluxStop® device [***Figure 13*** (i)].
20. Using the Insert Device (RS-901), push the RefluxStop® device into the Funnel (RS-903) while holding the Handle (RS-872) with a firm grip as support [***Figure 13*** (ii) and (iii)]. Make sure to only grab the Handle (RS-872) to avoid blocking the Ejector Tube (RS-870) [***Figure 13*** (iv)].
21. Keep pushing the RefluxStop® device through the Funnel (RS-903) into the Pipe (RS-902) until it stops. There shall be an approximately 10 mm gap between the flange of the Insert Device (RS-901) and the Funnel (RS-903).

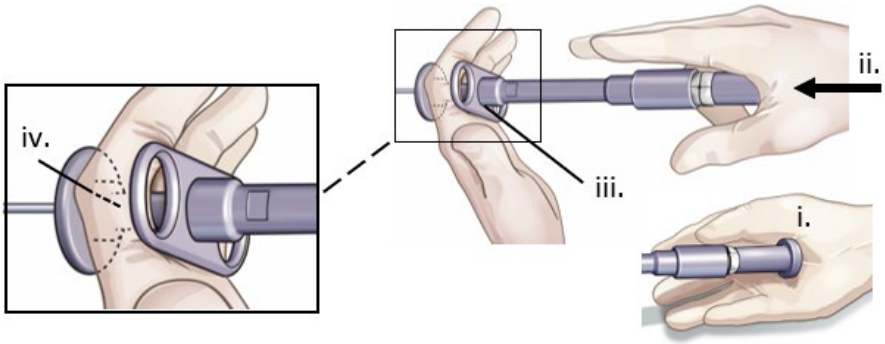


Figure 13. Final Loading of the Implant into the Deployment Tool

22. Remove the Insert device (RS-901) and the Funnel (RS-903).
23. Confirm that the RefluxStop® device protrudes approximately 5 mm from the Pipe (RS-902). Also, confirm that the Ejector Tube (RS-870) is in a retracted position and ready to push the implant out from the Pipe (RS-902) [***Figure 14***].

Figure 14. Final Loading Configuration

10 Surgical Procedure

10.1 Patient Preparation

Refer to the RefluxStop® device instructions for use for general patient and implant preparation instructions.

For the RefluxStop® Deployment Tool, the following instructions are to be followed:

1. Place the assembled Trocar [***Figure 4***] at the lower left quadrant in the left axillary line of the patient.
2. To commence the procedure, place the pointed tip of the assembled Trocar at the entry of the opening from the fifth and assisting trocar. Push the Trocar through the hole, thus expanding the abdominal wall tissue. Advance the Trocar sufficiently until the Cannula (RS-905) end is entirely entered into the abdomen of the patient. Confirm the Cannula (RS-905) is aligned towards the fundus.

   NOTE: During Trocar entry and advancement, ensure appropriate visibility and free passage via laparoscope.

   Appropriate visibility will help avoid damage to tissue or organs in the abdomen.

⚠ ***WARNING: Ensure free passage for the Trocar of the RefluxStop® Deployment Tool into the abdomen, through visual clearance using Laparoscope. Failure to ensure appropriate clearance may lead to damage of tissues or organs.***

3. Remove the Obturator (RS-904) from the Trocar with a twisting motion. The silicone Cross Slit Valve (RS-881) in the Cannula (RS-905) will close following removal and maintain the abdominal pressure.

10.2 Insert RefluxStop® Device

4. With the implant loaded into the Insertion Tool [***Figure 14***], place the Insertion Tool into the Cannula (RS-905) [***Figure 15*** (i)].
5. To facilitate smooth passage through the silicone Cross Slit Valve (RS-881), advance the Insertion Tool with a twisting motion. Continue to push on the Handle (RS-805) until it is in contact with the Cannula (RS-905) [***Figure 15*** (ii)].

   NOTE: When applying force to enter through the Cannula (RS-905), push on the Handle (RS-872) only. Do not apply force on the Insertion Tool or the Ejector Tube (RS-870) as this may lead to accidental release of the RefluxStop® device.

⚠ ***CAUTION: Do not hold or apply force on the Insertion Tool or Ejector Tube when advancing the device into the Cannula. Such force may lead to accidental release of the RefluxStop® device.***

6. With the Handle (RS-872) in contact with the Cannula (RS-905), verify full entry of the Cannula (RS-905) and clearance for the RefluxStop® device via laparoscope.
7. To eject the RefluxStop® device out from the Pipe/Cannula (RS-902/RS-905), apply force on the Ejector Tube (RS-870) with support from the Handle (RS-872) [***Figure 15*** (iii)]. Ensure that the Insertion Tool is not blocked and can move freely.

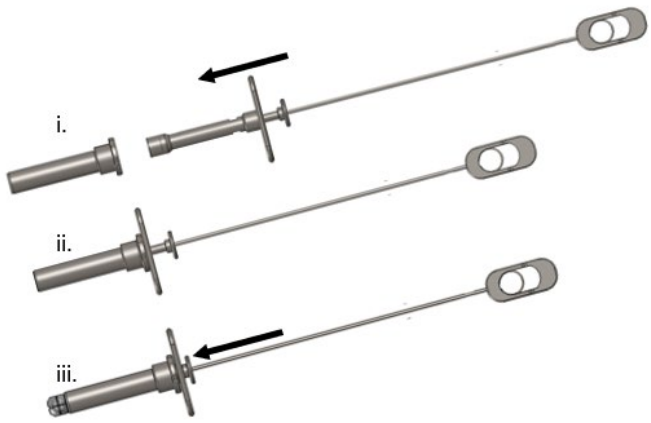


Figure 15. Insertion of the RefluxStop® Device

⚠ ***CAUTION: Do not hold or apply force on the Insertion Tool when advancing the Ejector Tube. Such force may lead to accidental release of the RefluxStop® device.***

⚠ ***WARNING: Ensure free passage for the RefluxStop® device into the abdomen, through visual clearance using Laparoscope. Failure to ensure appropriate clearance may lead to damage of tissues or organs.***

10.3 Positioning of Implant and Release

8. Position the RefluxStop® device at the intended location of the stomach. Ensure the RefluxStop® device is not retracted too far as this could lead to accidental release. Hold the implant using the Insertion Tool while performing the sutures of the invagination pouch (Refer to the RefluxStop® device instructions for use).

⚠ ***CAUTION: After ejection of the RefluxStop® device from the Pipe, do not retract the Insertion Tool too far as this could lead to accidental release of the RefluxStop® device.***

9. When the invagination of RefluxStop® device is finalized, release the RefluxStop® device from the Insertion Tool by pulling the looped end of the Wire (RS-806) and retracting the Wire (RS-806) from the Tube (RS-807) [***Figure 16***].

Figure 16. Release of RefluxStop® device

10. After finalizing the invagination pouch and the release of the RefluxStop® device, retract the Insertion Tool from the Ejector Device [***Figure 17*** (i)].

    NOTE: Following removal of the Insertion Tool, there is no closure in the Ejector Tube (RS-870). To maintain abdominal pressure, place a thumb or similar over the open hole of the Ejector Tube (RS-870).

⚠ **CAUTION: To avoid loss of abdominal pressure after removal of the Insertion Tool, seal off the Ejector Tube using a thumb, or similar, to avoid loss of abdominal pressure.**

11. Remove the Ejector Device from the Cannula (RS-905) [***Figure 17*** (ii)]. Use a twisting motion to facilitate passage through the silicone Cross Slit Valve (RS-881). The silicone Cross Slit Valve (RS-881) in the Cannula (RS-905) will close following removal and maintain the abdominal pressure.
12. When the procedure is finalized, remove the Cannula (RS-905) [***Figure 17*** (iii)]. Inspect the surgical site for haemostasis and take appropriate steps to achieve haemostasis, as needed.

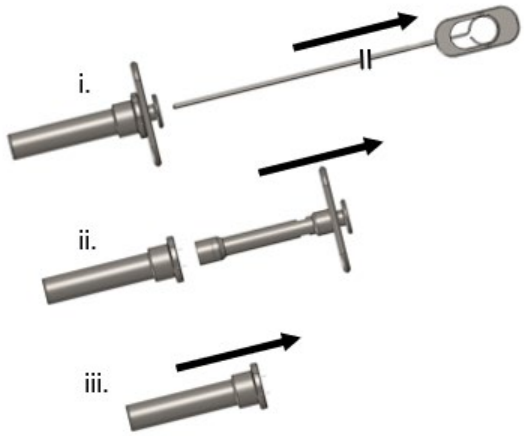


Figure 17. RefluxStop® Deployment Tool Removal

13. When closing the wound, suture the underlying fascia at the surgical site to reduce the risk for incisional herniation.

⚠ ***CAUTION: After removing the Cannula, inspect the surgical site for hemostasis and take appropriate actions to achieve hemostasis.***

⚠ ***CAUTION: Close the wound from the Trocar opening by suturing the underlaying fascia. This will reduce the risk for incisional herniation.***

10.4 Storage

- Carefully inspect every sterile device package prior to opening to ensure that package integrity has not been compromised. This includes inspection for tears, perforations, signs of moisture, or signs of tampering.

⚠ ***CAUTION:*** ***Do not use the RefluxStop® Deployment Tool if the device is damaged or the sterile barrier is compromised.*** **If the sterile barrier shows any signs of being compromised, the content is considered non-sterile and should be re-processed through cleaning, packaging and sterilization.**

10.5 Disposal

If the RefluxStop® Deployment Tool or its components require discard, dispose of the device according to facility recommendations. The RefluxStop® Deployment Tool materials of construction are Stainless Steel AISI 316L and medical-grade silicone ML-154.

11 Symbols Legend

Label Symbol	Description
REF	Catalogue Number
MD	Medical Device
LOT	Batch Code
#	Model Number (of parent device, if applicable)
UDI	Unique Device Identifier
(01)	UDI Device Identifier
(10)	UDI Production Identifier (Batch Code)
(11)	UDI Production Identifier (Manufacturing Date)
(30)	UDI Production Identifier (Quantity)
NON STERILE	Non-Sterile*
	Do Not Use If Package Is Damaged*
	Caution / Warning
	Consult Instructions for Use
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician
	Date of Manufacture
	Manufacturer

** Since the RefluxStop® Deployment Tool is supplied non-sterile, the meaning of this symbol is applicable at arrival for the first cleaning and sterilization at the hospital.*

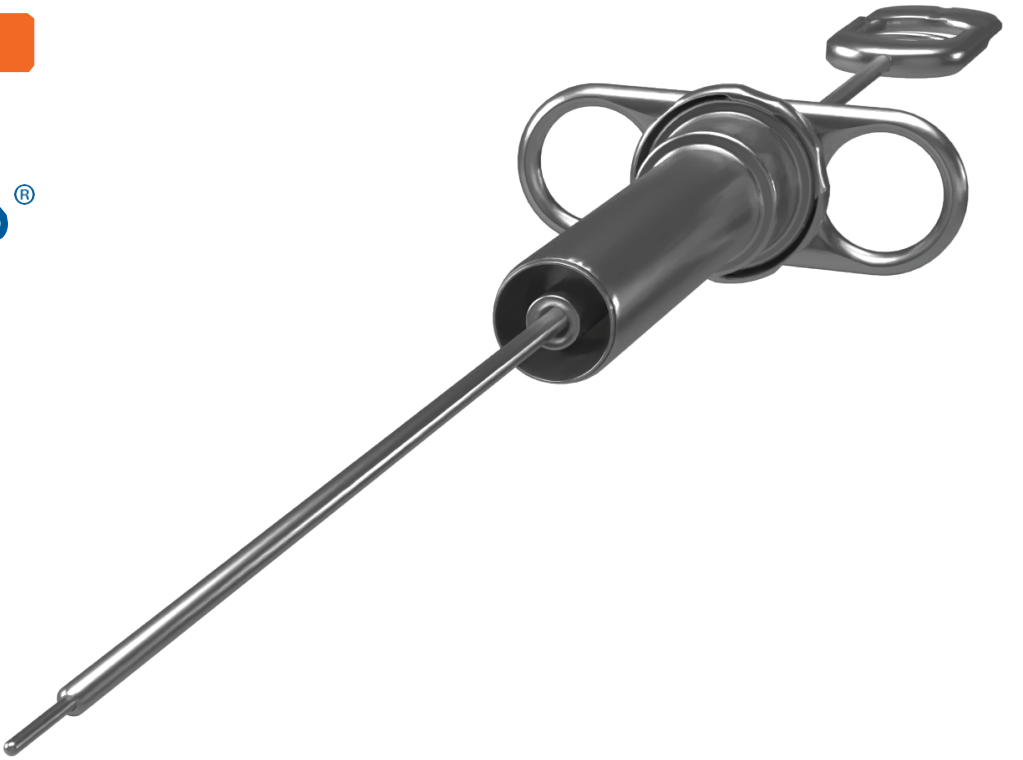
12 Return Goods

In the event an unused device must be returned for any reason, please place the RefluxStop® Deployment Tool into its original package and shipping box. Notify Implantica Customer Support to receive a return goods authorization number and ship the device to the address provided by customer service.

13 Responsibilities

- Implantica CE Reflux Ltd only accepts responsibility for the devices' safety, usability, and performance if the device is used in accordance with its intended use and with information supplied with the device.
- It is the responsibility of the surgeon to advise the patient of the known risks and complications associated with the surgical procedure and implant when obtaining the patient's consent with the procedure.
- As with other surgical decisions, it is the responsibility of the surgeon to use his or her own judgment in utilizing the procedures best suited to the needs of the patient and the skill and experience of the surgeon.
- It is the responsibility of the surgeon to contact Implantica CE Reflux Ltd if any serious events might be dependent on or related to the RefluxStop® Deployment Tool.

RefluxStop®
BY Implantica



Reprocessing Instructions

1 Intended Use

The RefluxStop® Deployment Tool (RS-300) is a reusable, invasive surgical instrument that is designed exclusively to facilitate the introduction of the implantable RefluxStop® device (RS-A1) into the abdominal cavity at a predetermined place at the fundus of the stomach during a laparoscopic surgical procedure.

2 Indications for Use

Indications for Use

RefluxStop® is an implantable sterile medical device intended to treat acid and non-acid reflux in patients diagnosed with gastroesophageal reflux disease (GERD). The device ensures maintenance of a normal physiological situation for the gastroesophageal junction (GEJ) in a defined intra-abdominal position, allowing a natural physiological function of the lower esophageal sphincter (LES), thereby reducing or eliminating acid and non-acid reflux.

The RefluxStop® Deployment Tool is indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD), defined by abnormal impedance pH and/or pH testing, and indicated for RefluxStop® implantation.

Intended Patient Population

The RefluxStop® System is indicated for patients diagnosed with acid or non-acid Gastroesophageal Reflux Disease (GERD), adults ≥ 18 years old that are indicated for RefluxStop® implantation and meet the following criteria:

- Documented GERD present for > 6 months;
- Patient has endoscopy verified esophagitis, and/or a 24-hour pH monitoring proven GERD defined as pathologic number of impedance pH reflux episodes of acid or weakly acid and/or pathologic pH <4 for >4.5% of the total time, off PPI therapy for at least 7 days prior to testing.

NOTE: The RefluxStop System is not intended to be used with a Collis gastroplasty.

3 Contraindications

The RefluxStop® System is contraindicated in patients with:

- Known sensitivities or allergies to the device materials (medical grade silicone [NusilMED-4860] and barium sulphate [BaSO4 powder]);
- Intraoperative findings determined by the operating surgeon that may result in unfavorable conduct of the procedure.
- Known sensitivities or allergies to the device materials (Stainless Steel AISI 316L and medical-grade silicone ML-154).

4 Expiry Dating

Expiration dating for RefluxStop® System has been established and approved at five (5) years for the RefluxStop® device implant and up to 200 cleaning and sterilization cycles of the metal components of the RefluxStop® Deployment Tool and 50 cleaning and sterilization cycles of the silicone component of the RefluxStop® Deployment Tool.

5 Reprocessing Instructions

- These instructions are in accordance with EN ISO 17664-1 and apply to the care, cleaning, and sterilization of the RefluxStop® Deployment Tool, RS-300.
- The RefluxStop® Deployment Tool, RS-300 may be safely and effectively reprocessed using the manual or automated cleaning instructions coupled with the sterilization parameters provided in this document.
- **The RefluxStop® Deployment Tool is reusable and shall be sterilized at the hospital prior to first time use and after each re-use.**

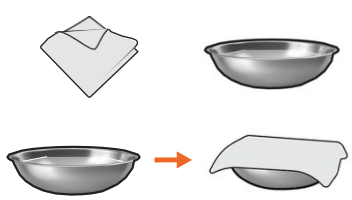
5.1 Reprocessing Limitations

- The RefluxStop® Deployment Tool has been validated for up to 200 cleaning and sterilization cycles (metal components) and 50 cycles (silicone component).
- Implantica sells additional units of the RS-300 components under their component part numbers.
- Enzymatic or alkaline (pH ≤12) cleaning agents are recommended and preferred for cleaning the RefluxStop® Deployment Tool.
- Steam/moist heat sterilization is the validated method for reprocessing the RefluxStop® Deployment Tool.
- Before each use, the RefluxStop® Deployment Tool shall pass all pre-sterilization inspection steps described below. If any part of the device fails to pass the pre-sterilization inspection, it shall be disposed of.

5.2 Post Use

- Immediately after use, remove excess soil from the device with a disposable, non-shedding cloth/paper wipe.
- Place the device in a container of **distilled water** or cover with damp towels to prevent drying of contaminants.

NOTE: Do not use tap water; the chloride in tap water may damage the anti-corrosion layer of stainless steel.



- Transport the device to a decontamination area as soon as possible.

5.3 Cleaning Timeline

- If the device cannot be kept moist, it must be cleaned within 60 minutes after use to prevent soil and contaminant drying. If the device cannot be made visibly clean, it shall be removed from service and discarded.

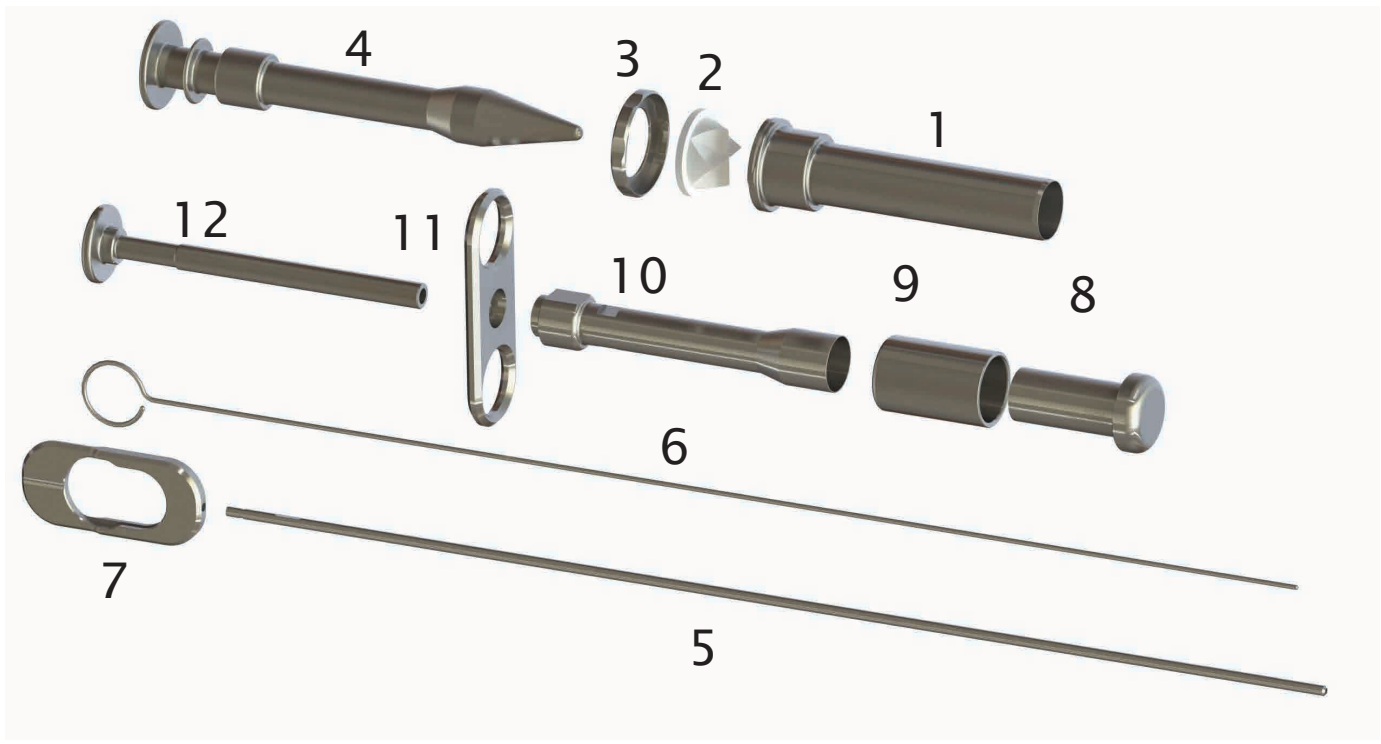
5.3.1 Cleaning Preparation / Device Disassembly

- The RefluxStop® Deployment Tool shall be disassembled before cleaning by a healthcare professional, who has read these instructions.
- **Do not clean or sterilize the device in the assembled configuration.**
- All components of the device shall be cleaned before sterilization.
- The RefluxStop® Deployment Tool consists of twelve (12) components, as depicted in the following **Table 1** and **Figure 1**.

TABLE 1

	NAME	COMPONENT #	QTY	PART OF
1	CANNULA	RS-905	1	TROCAR
2	CROSS SLIT VALVE	RS-881	1	
3	LID NUT	RS-877	1	
4	OBTURATOR	RS-904	1	
5	TUBE	RS-807	1	INSERTION TOOL
6	WIRE	RS-806	1	
7	INSERTION HANDLE	RS-805	1	
8	INSERT DEVICE	RS-901	1	COMPRESSION PARTS
9	FUNNEL	RS-903	1	
10	PIPE	RS-902	1	EJECTOR DEVICE
11	HANDLE	RS-872	1	
12	EJECTOR TUBE	RS-870	1	

FIGURE 1

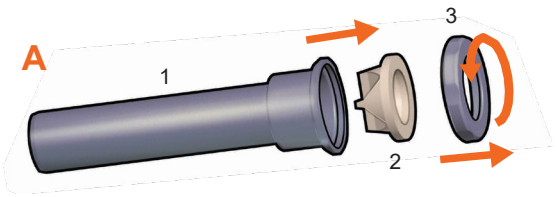


5.3.2 Device Disassembly

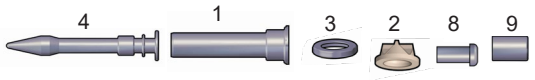
TROCAR

A Unlock the LID NUT (3) by turning it counterclockwise until it is free. Remove the LID NUT (3) and CROSS SLIT VALVE (2) from the CANNULA (1).

Set aside CANNULA (1), LID NUT (3) and CROSS SLIT VALVE (2).



Parts now set aside and ready for cleaning: OBTURATOR (4), CANNULA (1), LID NUT (3), CROSS SLIT VALVE (2), INSERT DEVICE (8), FUNNEL (9).



INSERTION TOOL

B Holding onto the EJECTOR DEVICE, slide out and remove the INSERTION TOOL.

Set aside EJECTOR DEVICE for further disassembly.

NOTE: Pay extra attention not to deform the Tube (RS-807) and Wire (RS-806). Note that the Wire (RS-806) is designed with a slight curvature for smooth movement with slight resistance in the Tube (RS-807).

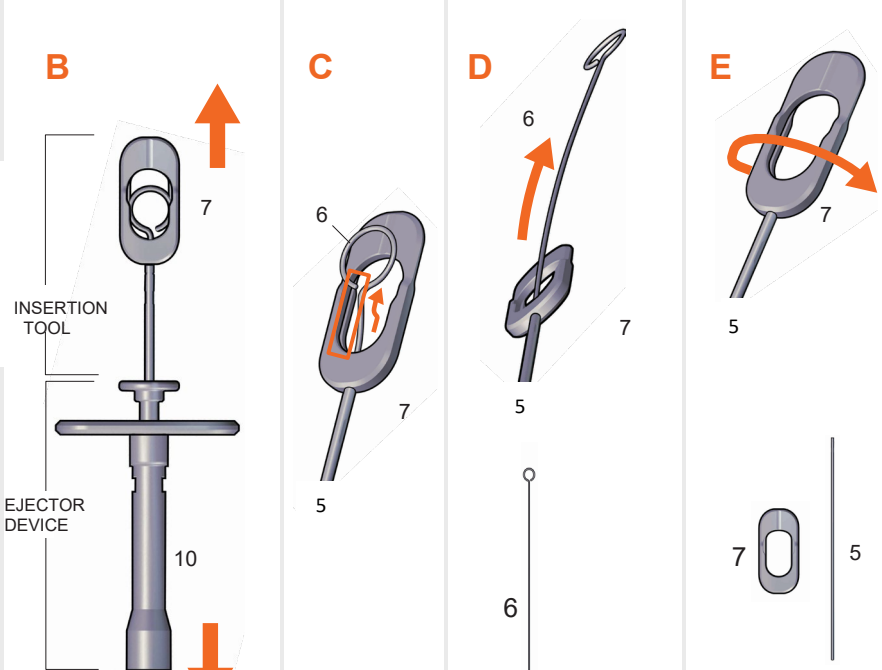
C Pull the looped end of the WIRE (6) so the loop is no longer in the groove of the INSERTION HANDLE (7).

D Once the looped end is free of the groove and no longer in the INSERTION HANDLE (7), pull and remove the WIRE (6) completely from the TUBE (5).

Set aside WIRE (6).

E Unscrew the INSERTION HANDLE (7) from the TUBE (5) counterclockwise and separate.

Set aside INSERTION HANDLE (7), TUBE (5).



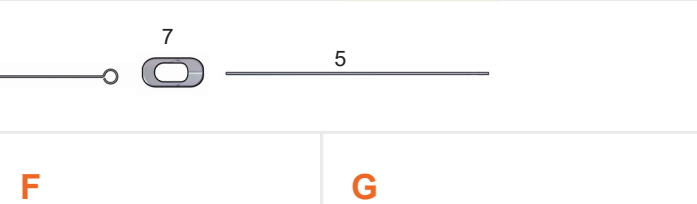
Parts now set aside and ready for cleaning: WIRE (6), INSERTION HANDLE (7), TUBE (5).

EJECTOR DEVICE

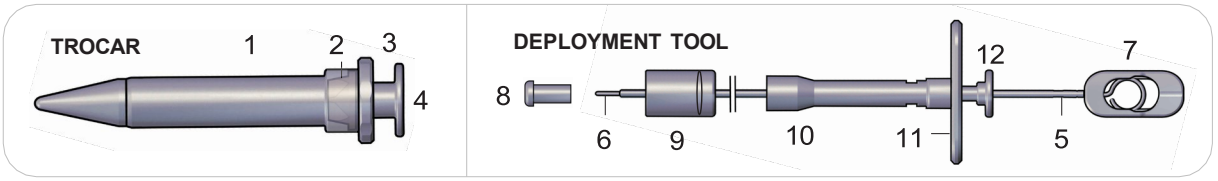
F Unscrew the HANDLE (11) from the threaded end of the PIPE (10).

G Slide the EJECTOR TUBE (12) out of the PIPE (10), and then slide off the HANDLE (11).

Set aside EJECTOR TUBE (12), PIPE (10) and HANDLE (11).



Parts now set aside and ready for cleaning: EJECTOR TUBE (12), HANDLE (11), PIPE (10).



1 CANNULA	4 OBTURATOR	7 INSERTION HANDLE	10 PIPE
2 CROSS SLIT VALVE	5 TUBE	8 INSERT DEVICE	11 HANDLE
3 LID NUT	6 WIRE	9 FUNNEL	12 EJECTOR TUBE

Following disassembly, confirm that there are twelve components of the device and inspect all components for any visual damage.

- **NOTE:** During visual inspection, pay extra attention to components including blind holes, lumens and cannulations: CANNULA (RS-905), OBTURATOR (RS-904), TUBE (RS-807). FUNNEL (RS-903), PIPE (RS-902), and EJECTOR TUBE (RS-870).

5.3.3 Preparation of Cleaning Agents

- All cleaning agents should be prepared at the dilution, time, and temperature recommended by the manufacturer.
- Enzymatic or alkaline cleaning agents with low foaming surfactants are recommended. Excess foam may inhibit the cleaning agents from reaching all surfaces of the device.
- If an automated cleaning program is applied, ensure that the detergent used in the washer/disinfector is compatible with the cleaning agent used in previous cleaning steps.
- If an ultrasonic cleaning bath is used, it is recommended to use the same cleaning agent for the ultrasonic bath as for the manual cleaning steps for soaking and brushing
- Always use distilled water; tap water could adversely affect the stainless steel.

NOTE: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

WARNING: The device must be fully disassembled prior to any cleaning or sterilization steps.

5.3.4 Cleaning: Automated

EQUIPMENT:		
DETERGENT	M16 BRUSH FOR SCRUBBING DEVICE SURFACES	FDA-CLEARED WASHER/DISINFECTOR
LUMEN BRUSH (FOR BRUSHING INSIDE THE 2 MM TUBE)	RUNNING WATER	

The device should be cleaned as follows:

1. Prepare the enzymatic or alkaline cleaning solution according to the manufacturer's instructions.

2. Completely submerge the device components in the cleaning solution and gently shake them to remove trapped bubbles. The inside of the TUBE (RS-807) should be flushed with a minimum of 30ml of cleaning solution through a 30 ml syringe to remove bubbles and ensure contact of the solution with all surfaces.

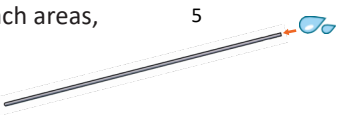
3. Soak the components for a minimum of 10 minutes. While soaking, scrub all external surfaces using a soft -bristled brush (M16) until all visible soil has been removed. The TUBE (RS-807) should be cleaned using a lumen brush (~4 mm OD with a minimum length of 230mm). Insert the brush into the TUBE (RS-807) with a twisting motion while pushing in and out at least X times from each direction, or scrub the inside of TUBE (RS-807) for a minimum of 30 seconds to ensure contact with all internal surfaces.

Soft Nylon bristle Brush

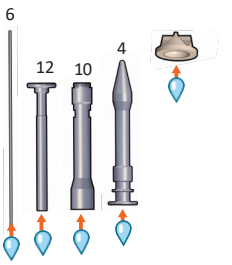
Snug Bristle Brush

NOTE: Cleaning brushes (A soft-bristled brush M16) should be used. The TUBE (RS-807) should be cleaned using a round lumen brush (~4 mm OD with a minimum length of 230mm). Brushes should, if not disposable, be cleaned and high level disinfected or steam sterilized after each use.

4. Remove the components from the cleaning solution and rinse in purified water for a minimum of three (3) minutes. Thoroughly and aggressively flush with a minimum of X ml of purified water difficult-to-reach areas, particularly the inside of the TUBE (RS-807).



5. Place the components in a suitable FDA cleared washer/ disinfector. Follow the washer/disinfector manufacturer's instructions for loading instruments. Make sure to load the TUBE (RS-807), EJECTOR TUBE (RS-870), PIPE (RS-902), AND OBTURATOR (RS-904) in such a way so that water can flow through the lumen (for instance, by placing them individually in irrigation sleeves connected to a module for cleaning of pipes/tubes). Place the silicone CROSS SLIT VALVE (RS-881) in a cleaning cage and make sure that it is fixed with the bottom facing upwards so that no liquid may gather in the cavity of the CROSS SLIT VALVE (RS-881).



6. The wash cycle parameters provided in Table 2 have been validated by Implantica and shall be used for cleaning.

7. Inspect the device to be sufficiently dry after it has completed its wash cycle. In particular, ensure components with difficult-to-reach areas and cavities are completely dry. If moisture is observed, remove the components from the washer/disinfector and dry them for a minimum of 30 minutes in a drying cabinet, or until all components are completely dry.

Table 2. Validated Wash Cycle Parameters for Cleaning

Cycle	Time (min)	Water type/Temp	Type of Detergent
Prewash	1	Cold water < 30-35 °C	NA
Wash 1	5	Water 40-55 °C	Enzymatic/ Alkaline detergent
Running water Rinse 1	1	Warm water 40 °C	NA
Running water Rinse 2	1	AD	NA
Final Rinse	5	AD > 90 °C	NA
Drying	30	90-110 °C	NA

AD = *Aqua Destillata, demineralized water*

NOTE: Dry time is dependent upon the load size placed in to the washer/disinfector. Thus, if many instruments are loaded at the same time, a longer drying time may be required.

5.3.5 Cleaning: Manual

Equipment: Detergent, brush (M-16) for scrubbing of device surfaces, lumen brush (~4 mm OD with a minimum length of 230mm) for brushing inside the 2 mm Tube, FDA-cleared ultrasonic cleaning bath, running water, 70% Ethanol.

EQUIPMENT:		
DETERGENT	FDA-CLEARED WASHER/DISINFECTOR	M16 BRUSH FOR SCRUBBING DEVICE SURFACES
LUMEN BRUSH (FOR BRUSHING INSIDE THE 2 MM TUBE)	RUNNING WATER	ULTRASONIC CLEANING BATH
		70% ETHANOL

The device should be cleaned as follows:

1. Prepare the enzymatic or alkaline cleaning solution according to the cleaning agent manufacturer's instructions.

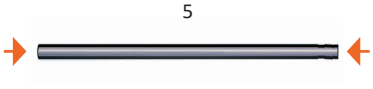
NOTE: Use the same cleaning agent for the manual cleaning as for the ultrasonic cleaning bath.

2. Completely submerge the device components in the cleaning solution and gently shake them to remove trapped bubbles. The inside of the TUBE (RS-807) should be flushed with a syringe (30 ml) to remove bubbles and ensure contact of the solution with all surfaces.

3. Soak the components for a minimum of ten (10) minutes. While soaking, scrub surfaces using a soft-bristled brush (M-16) until all visible soil has been removed. TUBE (RS-807) should be cleaned using a lumen brush (~4 mm OD with a minimum length of 230mm). Insert the brush into the TUBE (RS-807) with a twisting motion while pushing in and out at least X times from each direction, or scrub the inside of TUBE (RS-807) for a minimum of 30 seconds to ensure contact with all internal surfaces. Following brushing, visually inspect all components for residual soil.

NOTE: Cleaning brushes should, if not disposable, be cleaned and high-level disinfected or steam sterilized after each use.

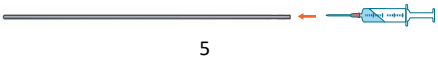
4. Remove the components from the cleaning solution and rinse in purified water for a minimum of three (3) minutes. Thoroughly and aggressively flush difficult-to-reach areas, particularly the inside of the TUBE (RS-807). A minimum flush volume of X mL of purified water shall be applied through the lumen. Following rinsing, visually inspect the components to confirm that no visible soil or detergent residues remain.



5. Prepare an ultrasonic cleaning bath with detergent according to the detergent manufacturer's recommendations. Completely submerge the components in the cleaning solution and gently shake them to remove any trapped bubbles. Lumens, blind holes, and cannulations should be flushed with a syringe (30 ml) to remove bubbles and ensure contact of the solution with all surfaces.

6. Sonically clean the device at for minimum 15 minutes using cold water (<40°C) at 37 kHz.

7. Remove the components from the ultrasonic bath and rinse in purified water for a minimum of three (3) minutes or until there is no sign of residue detergent or biologic soil. Thoroughly and aggressively flush difficult-to-reach areas, particularly the inside of the TUBE (RS-807) with a minimum of X mL of purified water. Following rinsing, visually inspect all components to confirm that no visible residue remains before proceeding to the next reprocessing step.



8. If needed, repeat the sonication and rinse steps on the previous page.

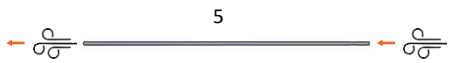
9. Remove excess moisture from the device with a clean, absorbent, and non-shedding cloth.

10. Soak the device in ethanol for 5 minutes. Flush the inside of the TUBE (RS-807) with 70% Ethanol for 30 seconds, with a minimum flush volume of 30 mL, using a 30 ml syringe.

11. Rinse the device with purified water for a minimum of one (1) minute. Ensuring to flush lumens, holes, and difficult to reach areas.

12. Dry the device on a dry cloth overnight at room temperature or in 70-80 °C (158-176°F) or 3-4 hours or at 70-80 °C (158-176°F) drying chamber for 3-4 hours.

13. Ensure that there is no moisture left in any cavity. If needed, remove moisture from inside the TUBE (RS-807) by blowing clean, filtered, compressed air.



5.4 Pre-sterilization Inspection

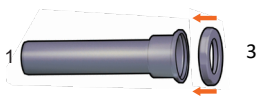
Do not proceed to packaging, or sterilization until all components are confirmed to be visibly clean. Pay extra attention to mating surfaces, shafts, and lumens.

NOTE: If contamination is noted, repeat the cleaning process.

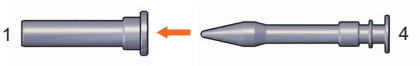
The device must pass all of the following pre-sterilization inspection to ensure proper safety and performance. If damage to any component has been detected, or if the pre-sterilization inspection indicates reduced function of any component, the component shall be disposed of.

- Visually inspect for damage, and/or excessive wear, such as: brittleness or cracks in the CROSS SLIT VALVE, metal scratching that could affect the sterilization, sharp edges that could harm the patient or user, rust, pitting or incomplete (faded) markings.

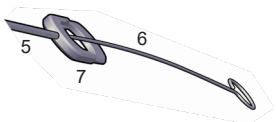
- Check the assembly of the CANNULA (RS-905) by confirming that the LID NUT (RS-877) rotates fully onto the CANNULA (RS-905).



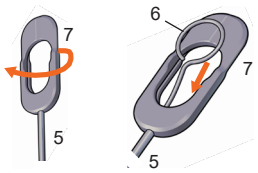
- Check that the OBTURATOR (RS-904) enters all the way in to CANNULA (RS-905), with the LID NUT (RS-877) assembled.



- Verify resistance and check for unintentional movements of the WIRE (RS-806) in the INSERTION TOOL. The WIRE (RS-806) shall have a slightly bent shape so as to not slide freely in the TUBE (RS-807).

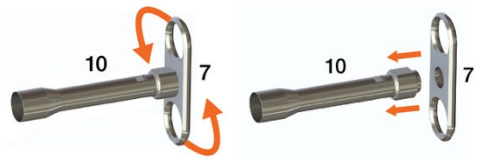


- Check the assembly of the INSERTION TOOL. Screw the INSERTION HANDLE (RS-805) onto the TUBE (RS-807) and insert the WIRE (RS-806). This is done by entering the WIRE (RS-806) from the channel side of the INSERTION HANDLE (RS-805), through the opening, and into the TUBE (RS-807). Confirm that it is possible to position the WIRE (RS-806) into the INSERTION HANDLE (RS-805) without using excessive force.

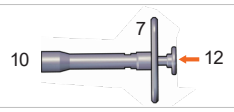


- Check the fit of the TUBE (RS-807) into the EJECTOR TUBE (RS-870). Insert the TUBE (RS-807) of the assembled INSERTION TOOL into the EJECTOR TUBE (RS-870). Confirm that the TUBE (RS-807) fits all the way into the EJECTOR TUBE (RS-870).

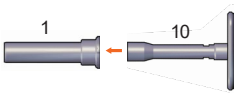
- Check the assembly of the PIPE (RS-902) onto the HANDLE (RS-872) by screwing and unscrewing the PIPE (RS-902) onto the HANDLE (RS-872). Confirm that it is possible to turn the PIPE (RS-902) all the way to the HANDLE (RS-872) and that it is possible to properly disassemble the PIPE (RS-902) from the HANDLE (RS-872).



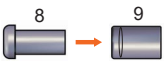
- Check that the EJECTOR TUBE (RS-870) fits into the Pipe (RS-902). Confirm that it fits all the way in to the PIPE (RS-902).



- Check that the PIPE (RS-902, attached to the HANDLE, RS-872) fits into the CANNULA (RS-905). Confirm that it fits all the way in to CANNULA (RS-905).



- Check that the INSERT DEVICE (RS-901) fits all the way into the conical opening of the FUNNEL (RS-903).



- Check that the PIPE (RS-902) fits all the way into the straight opening of the Funnel (RS-903).

- Disassemble all parts for packaging and sterilization per the instructions above.

⚠ ***CAUTION:*** Ensure that all cleaning and drying instructions are properly followed in order to minimize risk of wear of and prevent occurrence of rust on the components of the RefluxStop® Deployment Tool.

⚠ ***CAUTION:*** Before packaging and sterilization, carefully inspect all components of the RefluxStop® Deployment Tool to ensure cleanliness. Pay extra attention to mating surfaces, shafts and lumens. If contamination is noted, repeat the cleaning process.

⚠ ***CAUTION:*** If damage to any component has been detected or if the pre-sterilization inspection indicates reduced function to any component of the RefluxStop® Deployment Tool, the component shall be disposed of and the components/unit replaced.

NOTE: If at any point above the device is deemed not to be visually clean, the user should repeat the relevant previous cleaning steps or safely dispose of the device, so that a visibly soiled device is not used again. Removal of residual soil ensures the effectiveness of sterilization and disinfection processes and reduces the risk of infection to patients.

5.5 Packaging

- Package the device in a medical grade sterilization pouch that complies with ISO 11607 Ensure that the pouch is not damaged during packaging. Do not use damaged packaging.

NOTE: Packaging shall be chosen so that it will be possible to store the device for at least two months after sterilization.

5.6 Sterilization

- The RefluxStop® Deployment Tool, RS-300, has been validated to provide a 10^{-6} sterility assurance level (SAL) for Steam / Moist Heat Sterilization using a pre-vacuum sterilization process per the parameters in ***Table 3***. It has been assigned to Product Family 26 per ISO 17665-3 [***Table 4***].

Table 3. Validated Steam / Moist Heat Sterilization Parameters

Pre vacuum pulses	Temperature	Minimum exposure time
3	132 °C	4 minutes

MD	Attribute				
Product family	Design (a)	Material (b)	Weight (c)	Packaging system	**Steam penetration resistance (estimated) (e)**
26	6	2	3	2	6

Table 4. RefluxStop® Deployment Tool Product Family per ISO 17665-3

- Always follow the steriliser manufacturer instructions for load configuration and equipment operation.
- Time for drying is recommended for a minimum of 20 minutes. Extended dry times may be needed for larger loads under certain conditions, or if otherwise recommended by the sterilizer manufacturer. For large loads, verification of dry times by the health care provider is recommended.
- Time for cooling is recommended for a minimum of 30 minutes. Longer times may be necessary because of load, ambient temperature and humidity, and packaging used.

5.7 Storage

- The sterile packaged device shall be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
- Carefully inspect every sterile device package prior to opening to ensure that package integrity has not been compromised. This includes inspection for tears, perforations, signs of moisture, or signs of tampering. Reassembly of the device is performed by the user according to the assembly instructions provided in the Instructions for Use RefluxStop® Deployment Tool.

⚠ ***CAUTION:*** Do not use the RefluxStop® Deployment Tool if the device is damaged or the sterile barrier is compromised.

If the sterile barrier shows any signs of being compromised, the content is considered non-sterile and should be re-processed through cleaning, packaging and sterilization.

5.8 Disposal

- If the RefluxStop® Deployment Tool or its components require discard, dispose of the device according to facility recommendations. The RefluxStop® Deployment Tool materials of construction are Stainless Steel AISI 316L and medical-grade silicone ML-154.

5.9 Disclaimer

- The reprocessing instructions provided above have been validated by Implantica to demonstrate that, when followed as specified, they are capable of preparing the RefluxStop® Deployment Tool for reuse. It remains the responsibility of the reprocessing facility to ensure that the reprocessing, as actually performed using equipment, materials and personnel in the processing facility achieves the desired result. This requires routine monitoring and control of the process and its equipment.

5.10 Reprocessing Limitations

- ***WARNING:*** The RefluxStop® Deployment Tool is supplied NON-STERILE and shall be cleaned, packaged, and sterilized according to these instructions before first time use and after each re-use. Failure to properly clean and sterilize the device may create a risk of contamination to the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
- ***WARNING:*** The RefluxStop® Deployment Tool has been validated for up to 200 cleaning and sterilization cycles (metal components) and 50 cycles (silicone components). Reprocessing the device components beyond the stated validation cycles may lead to device failure or patient harm.
- ***WARNING:*** Do not use tap water or chloride-containing solutions, including hydrochloric acid-based cleaning agents and hypochlorite bleaches when processing the RefluxStop® Deployment Tool. Use of tap water or these cleaning agents could cause damage to the stainless steel components of the device.

5.11 Pre-sterilization Inspection

- ***CAUTION:*** Ensure that all cleaning and drying instructions are properly followed in order to minimize risk of wear of and prevent occurrence of rust on the components of the RefluxStop® Deployment Tool.
- ***CAUTION:*** Before packaging and sterilization, carefully inspect all components of the RefluxStop® Deployment Tool to ensure cleanliness. Pay extra attention to mating surfaces, shafts and lumens. If contamination is noted, repeat the cleaning process.
- ***CAUTION:*** If damage to any component has been detected or if the pre-sterilization inspection indicates reduced function to any component of the RefluxStop® Deployment Tool, the component shall be disposed of and the components/unit replaced.

5.12 Storage

- ***CAUTION:*** Do not use the RefluxStop® Deployment Tool if the device is damaged or the sterile barrier is compromised. If the sterile barrier shows any signs of being compromised, the content is considered non-sterile and should be re-processed through cleaning, packaging and sterilization.

5.13 Preparation of Cleaning Agents

- ***WARNING:*** The device must be fully disassembled prior to any cleaning or sterilization steps.

Rx only Caution: Federal law restricts this device to sale by or on the order of a physician.

Refer to Section 11 in the RefluxStop® Deployment Tool Surgical Instruction for Use for applicable symbols.

Product name:	**RefluxStop® Deployment Tool**
Product catalogue number:	**RS-300**
IFU catalogue number:	**IFU-0003236 rev Draft v3.0**
Date of issue:	**2026-08**
Manufacturer:	**Implantica CE Reflux Ltd** Sir Temi Zammit Buildings Malta Life Sciences Park San Gwann SGN 3000 Malta Tel: +35 621 443 532
Customer support:	customersupport@implantica.com www.implantica.com