



Instructions for Use

GT Metabolic Magnet System

Component Devices

GT Metabolic Magnet

GT Metabolic Delivery System

GT Metabolic Laparoscopic Positioning Device



GT Metabolic Magnet:

- MAG-04 (60mm)
- MAG-05 (70mm)

GT Metabolic Delivery System: DS-01

GT Metabolic Laparoscopic Positioning Device: PD-12, PD-18, PD-21, PD-24, PD-27

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Limited Warranty

GT Metabolic represents and warrants that reasonable care has been used in the manufacturing of the GT Metabolic Magnet System and component devices (GT Metabolic Magnet, GT Metabolic Delivery System, and GT Metabolic Laparoscopic Positioning Devices). These devices conform to GT Metabolic’s specifications and comply with all applicable standards, as such standards may be amended from time to time. The company makes no other express or implied warranties regarding the devices.



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1. OVERVIEW

The GT Metabolic Magnet System devices are designed for creation of oval anastomoses between the sides of the gastric and intestinal segments (side-to-side) in the gastrointestinal (GI) tract.

The GT Metabolic Magnet System enables approximation of tissue through compression between two (2) Magnet housings (a set of two (2) devices). The devices are either a set of 60mm (part number MAG-04) or 70mm (part number MAG-05) linear titanium housings each containing a central core magnet. The polar attraction between the two intraluminally placed devices creates mechanical pressure and gradual necrosis of the tissue between the housings. The devices remain magnetically engaged (docked) as the tissue around the devices heals and remodels to create a robust anastomosis.

Once wound strength is sufficient to maintain the anastomosis, the docked devices containing the necrosed central tissue drops into the intestine and pass with the patient's natural bowel movements.



Caution

Medical device is restricted to sale, distribution and use by or on the order of a physician.

2. DEVICE DESCRIPTION

The GT Metabolic Magnet System is comprised of the following devices:

- Individually packaged **GT Metabolic Magnet** (“Magnet”) devices designed to be used as a set of two (2), either a set of 60mm (MAG-04) or 70mm (MAG-05) devices;
- **GT Metabolic Delivery System** (“Delivery System”): a flexible orogastric catheter used to endoscopically deliver a GT Metabolic Magnet; and
- **GT Metabolic Laparoscopic Positioning Device** (“Laparoscopic Positioning Device”) as an accessory: five (5) models of various magnetic strengths: 12N, 18N, 21N, 24N, 27N; used to laparoscopically move and position each GT Metabolic Magnet at the desired anastomosis site in the gastrointestinal tract.

3. INTENDED USE / INDICATIONS FOR USE

The GT Metabolic Magnet System is intended for use in the creation of side-to-side gastrointestinal anastomoses of the stomach and small bowel in minimally invasive and laparoscopic surgery. Once wound strength is sufficient to maintain the anastomosis, the device is passed from the body. The effects of this device on weight loss were not studied.

The GT Metabolic Magnet System is intended for use in adult patient > 21 years.

4. IMPORTANT



Warning

This IFU provides instructions for using the GT Metabolic Magnet System devices together as a surgical tool for creation of side-to-side gastrointestinal anastomoses of the stomach and small bowel. Do not use the GT Metabolic Magnet System until you have carefully reviewed and fully understand the information presented in the IFU.

This IFU is not a reference to surgical techniques or procedures. Endoscopy and laparoscopy should be performed only by person's having adequate training and familiarity with these invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performing these procedures.

5. CONTRAINDICATIONS

- Do not use the devices if the patient is not indicated for a side-to-side gastrointestinal anastomosis of the stomach and small bowel.
- Do not use the devices if an immediate lumen patency is required while the anastomosis is formed.
- Do not use the devices if the patient has unhealed ulcers, bleeding lesions, or a tumor or any other lesion at the target Magnet sites in the stomach or small bowel.
- Do not use the devices if the patient has an expected need for magnetic resonance imaging (MRI) within 30 days after placement of the Magnets or until passage of the devices out of the body. The Magnets are MRI unsafe.
- Do not use the devices if the patient has known allergies to the Magnet materials (Titanium alloy (ASTM F136), Parylene C, stainless steel, neodymium-iron-boron (ASTM A1101)) or the flange materials (polyglycolic-co-lactic acid (PGLA)) or similar polymers, or barium sulfate).
- Do not use the devices if the patient has an implanted pacemaker and/or defibrillator.
- Do not use the devices if the patient has any other implanted electrical devices (e.g., neurological) or non-electrical implants or metal that may attract the Magnet devices.
- Do not use the devices if the patient is pregnant or plans to become pregnant.
- Do not use the devices if the patient has any conditions for which endoscopy or laparoscopic surgery would be contraindicated, and any significant congenital or acquired anomalies of the gastrointestinal tract at or distal to the placement of the Magnets.

6. WARNINGS AND PRECAUTIONS

Warning: A warning statement indicates a situation which, if not avoided, could result in a serious injury or death to the user or patient.

Caution: A caution statement indicates a situation which, if not avoided, could result in minor or moderate injury to the user or patient or damage to the devices.

6.1 WARNINGS

- The Magnets and Delivery System are provided sterile for single use only.
- Do not re-sterilize or re-use these devices, even if the package has been opened but not used. Re-sterilization may compromise the structural integrity of the devices and/or lead to device failure that may result in patient injury or death.
- Only use two (2) Magnets as provided by GT Metabolic. Do not attempt to use other manufacturers' magnets or a single Magnet. The GT Metabolic Magnet System is designed to use two (2) Magnets to create each side-to-side gastrointestinal anastomosis.
- Only use two GT Metabolic Magnet devices of the same length to create a magnetic compression anastomosis (either two 60mm (MAG-04) or two 70mm (MAG-05) devices) to support proper magnet device alignment and compression and mitigate risk of device migration.
- Do not use the GT Metabolic Magnet System if any component is cracked, broken, chipped, or otherwise appears damaged.
- The Laparoscopic Positioning Devices are provided non-sterile and must be sterilized prior to use according to the IFU section titled CLEANING INSTRUCTIONS FOR LAPAROSCOPIC POSITIONING DEVICE.
- Post-operative care assessing for potential risk of anastomotic stricture or stenosis is warranted, including educating patients on signs and symptoms and when to seek medical care.

6.2 PRECAUTIONS

- As with all anastomotic devices and techniques, there should be healthy tissue at the target sites to allow for healing of tissue in creation of the anastomosis.
- Do not use the GT Metabolic Magnet System in case of narrowing, obstruction, or other abnormalities distal to the anastomosis which may prevent expulsion of the Magnets.
- The devices should only be used by physicians who have experience in performing gastrointestinal anastomosis procedures and are experienced with endoscopic and laparoscopic surgery.
- The Magnets and Delivery System are provided sterile. Each package should be inspected to ensure package integrity prior to use. Do not use the device if sterility or integrity of the device or any component is suspect.

- Inspect Magnets, Delivery System, and Laparoscopic Positioning Devices prior to use for possible damage or defects. Any damaged or defective component should not be used and should be returned to the manufacturer.
- Use care in handling of the Magnets. Store the devices away from magnetically attractive items and surfaces when opened according to the IFU section titled HOW SUPPLIED AND STORAGE REQUIREMENTS.
- Use of disposable and non-metallic/non-magnetic commercially available trocars should be used in the laparoscopic surgery to minimize attraction of the Magnets and Laparoscopic Positioning Devices.
- Intra-operative care should be exercised to avoid damage to internal organs, including mesenteric tissues, during laparoscopic manipulations. Damage to internal organs and/or mesentery (either pre-existing or procedurally induced) should be repaired before surgical closure.
- Care should be exercised to avoid tissue damage (e.g., serosal tear) during the use of laparoscopic instruments and the Laparoscopic Positioning Device when sliding the intraluminal Magnet to the desired anastomosis site. The bowel should be inspected for any damage and required suture repair at the physician's discretion.
- Recovery of the Magnets may be required at the physician's discretion, and it is recommended the surgical suite include the GT Metabolic Magnetic Retrieval Device (MRD-02) as this device is designed specifically to attract and capture a GT Metabolic Magnet to facilitate its endoscopic retrieval from the gastrointestinal tract. Other commercially available endoscopic recovery devices (e.g., Steris Healthcare Roth Net[®] Retriever, Olympus EndoJaw Biopsy Forceps #FB-210U) may also be used.
- Conversion to gastrotomy or intestinal enterotomy for placement or retrieval of Magnet(s) may be required at the physician's discretion. It is recommended that the surgical suite include commercially available stapling or suture devices per institution's standard practice as back-up.
- Interoperative care should be taken to assure no twists of the proximal bowel with the distal are present, as the biliopancreatic limb should be on the left and the common limb on the right side and no malrotation near the anastomosis site following placement and docking together the intraluminal Magnets.
- Closure of the mesenteric defect is recommended following placement of the devices according to the institution's standard practices to decrease the likelihood of an internal hernia with associated intestinal obstruction. As with any gastrointestinal and abdominal surgery, the potential for internal hernia and intestinal obstruction following surgery is not zero even with closure of the mesenteric defect and the patient should be educated on signs and symptoms of when to seek medical care.
- Patients are not to be prescribed or take non-steroidal anti-inflammatory drugs (NSAIDs) or aspirin within 14 days prior to the procedure and remain off these medications through 14 days post-procedure.

- Caution should be taken in patients with a body mass index (BMI) > 50 kg/m² due to potential for surgical adverse events.
- If the patient is indicated for a gastric surgical procedure (e.g., sleeve gastrectomy) at the same time as the side-to-side gastrointestinal anastomosis procedure, it is recommended that the Magnets be placed first followed by the gastric procedure to reduce potential stress that could arise from putting the Delivery System through the stomach following the gastric surgical procedure.
- Patients should be monitored, including use of X-rays at the physician's discretion, to assess for potential risk of device separation leading to migration, and following anastomosis creation, to ensure appropriate movement of Magnets through the intestinal system towards natural expulsion and no need for surgical re-intervention, to assure no foreign body is left behind, and a patent anastomosis. At a minimum, weekly X-rays are recommended if the Magnets have not been passed within 50 days of the device placement procedure.
- The device may move more slowly in some patients. In the absence of need for surgical re-intervention, the physician should consider manual retrieval (e.g., colonoscopy) of the device at 90 days if natural expulsion has not occurred.

7. UNDESIREABLE SIDE EFFECTS / RESIDUAL RISKS

Undesirable side effects and risks associated with performing a side-to-side gastrointestinal anastomosis with the GT Metabolic Magnet System may include, but not be limited to: anastomotic leaking, bleeding, obstruction, or infection; anastomotic stricture or stenosis; internal hernia; bowel obstruction; ileus; pain; infection; intestinal laceration (e.g., serosal tear) or perforation; adverse tissue reaction or damage; duodenitis; intestinal ulceration and/or scarring; device migration; abdominal distention; diarrhea; constipation; nausea; vomiting; Dumping Syndrome; vitamin or mineral deficiencies; need for surgical re-intervention (e.g., failure to expel); or death.

8. CLINICAL PERFORMANCE TESTING

The GT Metabolic Magnet System with 60mm and 70mm Magnets were designed for use in side-to-side stomach to small bowel anastomosis (i.e., gastro-ileal and gastro-jejunal). These Magnets are of the same materials and design (except for length) as the 40mm and 50mm DI Magnets intended for side-to-side duodeno-ileal anastomosis (U.S. FDA 510(k) cleared under K242086 and K243359 as part of the GT Metabolic Magnet System).

The GT Metabolic Magnet System with the 40mm and 50mm DI Magnets (also called the GT Metabolic MagDI™ System) were determined substantially equivalent to the first GT Metabolic Magnet System with the 32mm DI Magnet with a titanium flange, authorized U.S. FDA De Novo as a Class II medical device (DEN240013). The 32mm MagDI System performed safely and as intended to create patent side-to-side duodeno-ileal anastomoses in 100% of 49 subjects. There were no reports (0%) of anastomotic bleeding, leakage, or infection, and no mortality. These clinical data, with over half of the subjects followed to one year, demonstrates an adverse event profile as safe as conventional anastomosis techniques with no reports of the most common anastomotic risks seen with enterotomy and sutures or staples.

40mm Magnets in Side-to-Side Duodeno-Ileal Anastomosis

Additional clinical testing was performed with the GT Metabolic MagDI System using the 40mm Magnets with a biofragmentable flange (poly glycolic co-lactic acid (PGLA) and 12% barium sulfate) (K242086, October 2024). The Clinical Study included 27 subjects from a similar population, using the same protocol design and endpoints as study of the first MagDI System (32mm Magnet; DEN240013, July 2024). However, the first study allowed subjects to receive a non-study sleeve gastrectomy (SG; performed according to the site's standard practices) performed immediately following the study procedure, while the protocol testing of the 40mm Magnet did not allow for a concurrent SG. The side-to-side duodeno-ileal magnetic compression anastomosis study procedure was the same in both studies.

The MagDI System was successfully placed and created patent anastomoses in all cases. The overall safety profile of the second Magnet device (K242086) was similar to the first Magnet device (DEN240013). The adverse event profile across the two studies (and by procedure cohort with or without a concurrent non-study SG) is presented below.

Three adverse events (6.5%, 3/46) met protocol criteria to be reported as a serious adverse event (SAE). One event was confirmed food poisoning with associated symptoms. The second event was a series of symptoms and signs (diarrhea, vomiting, hypovolemia, hypokalemia) following Magnet expulsion, with negative *C. difficile* fecal tests. The third SAE was a case of duodenitis at day 20 following study procedure and the day after the Magnet device was naturally expelled (day 19). The patient presented with epigastrium pain and one episode of vomiting and was hospitalized. CT revealed swelling of the pylorus and moderate delayed gastric emptying, with no abnormalities at the anastomosis or adjacent fluid or free gas. The patient was empirically treated with antibiotics, but no specific infection was found at or near the anastomosis site. The subject recovered without sequelae. Compression anastomosis with healing and remodeling of

tissue around devices following necrosis of central tissue is well described in the literature.¹ Additionally, inflammation with creation/healing of anastomosis and symptoms are commonly experienced, regardless of the anastomosis technique used (i.e., compression or incision and sutures or staples). This event was conservatively assigned as related to both the Magnet device and study procedure. An independent data safety monitoring board (DSMB) reviewed the event and determined no safety concerns. This patient was followed to one year for study completion with a patent anastomosis. Nonetheless, the potential risk of duodenitis has been added to the label in **Section 7**.

The clinical testing on subjects treated with the MagDI System (40mm Magnet, K242086) demonstrates a profile at least as safe as the first Magnet System (32mm Magnet, DEN240013) with most adverse events Clavien-Dindo Grade I and II, and no cases of anastomotic bleeding, leakage, infection, or obstruction and no deaths. The MagDI System performed safely and as intended to create patent side-to-side duodeno-ileal anastomoses with natural expulsion from the body, leaving no foreign material behind.

50mm Magnets in Side-to-Side Duodeno-Ileal Anastomosis

Additional clinical testing was performed on the MagDI System with the 50mm Magnet device (K243359, February 2025) demonstrating successful placement in all (100%, 13/13) procedures with alignment and creation of patent anastomoses confirmed by imaging.

The device was expelled naturally in most (88.9%, 8/9) of the subjects reaching one month follow up as a paired set of docked Magnets and confirmed by imaging. Expulsion based on subject self-report (or worst-case X-ray confirmation of device absence) averaged 32 days. One device, after creating a patent anastomosis and naturally advancing slowly through the small bowel, was removed by colonoscopy on day 93 without issues or signs of blockage or bowel abnormalities. At the time of report, this was the only case across the MagDI System devices (32mm, 40mm, 50mm) resulting in a clinical decision to extract the device or failure to expel.

A total of 23 adverse events were reported in 11 unique subjects. This included 11 grade I (47.8%), eight (8) grade II (34.8%), and four (4) grade III (17.4%) events on the Clavien-Dindo Classification grading system with no events (0%) reaching grades IV or V (life-threatening complication or death).

The MagDI System performed as intended and the data on 13 subjects treated with the 50mm Magnet (MAG-02) demonstrates a profile at least as safe as the 510(k) cleared 40mm Magnet (MAG-01) for the same intended use and with the majority of adverse events Clavien-Dindo grade I and II, and no cases of anastomotic bleeding, leakage, infection, or obstruction and no deaths.

¹ Musana K, Yale S H. John Benjamin Murphy (1857 – 1916). *Clinical Medicine & Research* 2005; 3(2)110-112.

The variation in Magnet length across the MagDI System family of surgical instruments (32mm (DEN240013), 40mm (K242086), 50mm (K243359)) provides surgeons with options based and individual patient anatomy and underlying clinical characteristics to safely create patent side-to-side duodeno-ileal anastomoses.

MagDI System (32mm, 40mm, 50mm Magnets) Adverse Event Summary

Clavien-Dindo Classification	MagDI System (32mm Magnet)			MagDI System (40mm Magnet) (n=27)	MagDI System (50mm Magnet) (n=13)
	MagDI System Procedure Only (n=25)	MagDI System Procedure + SG (n=24)	All Subjects (n=49)		
Grade I: (n (%)) Deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Antiemetics, antipyretics, analgesics, diuretics and electrolytes, and physiotherapy allowed.	5 (35.7%)	29 (39.7%)	34 (39.1%)	24 (52.2%)	11 (47.8%)
Grade II: (n (%)) Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition included.	3 (21.4%)	33 (45.2%)	36 (41.4%)	16 (34.8%)	8 (34.8%)
Grade III: (n (%)) Requiring surgical, endoscopic, or radiological intervention.	6 (42.8%)	11 (15.1%)	17 (19.5%)	6 (13.0%)	4 (17.4%)
Grade IV: (n (%)) Life-threatening complication (including certain CNS complications) requiring Intermediate Care/Intensive Care Unit-management.	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade V: (n (%)) Death of a patient.	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
TOTAL Adverse Events	14 (100%)	73 (100%)	87 (100%)	46 (100%)	23 (100%)

60mm and 70mm Magnets in Side-to-Side Gastric–Small Bowel Anastomosis

The GT Metabolic Magnet System (60mm, 70mm Magnets) was commercially authorized in Chile in December 2025 for use in creation of side-to-side gastro-ileal or gastro-jejunal anastomosis, as a line extension based on the 510(k)-cleared Magnet System (40mm, 50mm DI Magnets) intended for side-to-side duodeno-ileal anastomosis (K242086, K243359). A Clinical Study using the gastric magnetic devices (60mm and 70mm Magnets) is ongoing, enrolling obese subjects with and without type 2 diabetes (T2D) indicated for a gastro-ileal or gastro-jejunal diversion at centers in Canada, Chile, Europe, and the Middle East (ClinicalTrials.gov NCT06073457).

9. DIRECTIONS FOR USE

9.1 PLACEMENT AND ENGAGEMENT OF THE MAGNETS

1. Prepare the operating room and patient for endoscopy and laparoscopy per standard procedures at the institution. This includes placement of a commercially available retrievable bowel clamp and establishment of pneumoperitoneum for endoscopy.

NOTE: Use of disposable and non-metallic/non-magnetic commercially available trocars should be used in the laparoscopic surgery to minimize attraction of the Magnets and Laparoscopic Positioning Devices.

2. Insert the Delivery System through the working channel of the endoscope until the tip exits the distal tip of the endoscope. Engage the first (distal) Magnet with the Delivery System.
3. Align the flats on the distal tip of the Delivery System catheter with the corresponding flats on the attachment slot of the Magnet. Push the distal tip of the Delivery System catheter into the attachment slot of the Magnet until it stops. A light click will be felt. Confirm the Magnet is captured.
4. Advance the distal Magnet endoscopically to the ligament of Treitz.
5. Bring the tip of the Laparoscopic Positioning Device into proximity of the distal Magnet until the tip engages (magnetic attraction) with the Magnet through the intestinal wall.
6. Remove the retrievable bulldog clamp from the peritoneal cavity.
7. After the distal Magnet is engaged with the Laparoscopic Positioning Device, detach the distal Magnet from the Delivery System by retracting the blue collar.
8. Withdraw the Delivery System catheter.
9. Use a commercially available laparoscopic grasper to stabilize the intestinal wall immediately proximal to the Magnet and simultaneously slide the intraluminal device distally using the engaged Laparoscopic Positioning Device. Repeat this “grasp and slide” maneuver until the Magnet is advanced to the intended distal site in the ileum or jejunum.
10. Attach the second (proximal) Magnet to the Delivery System, as previously described, and advance endoscopically to the desired location in the stomach.
11. Refine the position of the stomach (proximal) Magnet using the endoscope and Delivery System combination. Do not disengage the Magnet from the Delivery System at this time.
12. Once the stomach (proximal) Magnet is in the desired position, bring the intestinal loop containing the distal intraluminal Magnet to the proximity of the proximal Magnet. The two Magnets will connect through the gastrointestinal walls and align with greater than 95% overlap due to the polarity force exerted by each device.

13. Assure that no twists of the proximal bowel with the distal are present, as the biliopancreatic limb should be on the left and the common limb on the right side and no malrotation near the anastomosis site.
14. Verify positioning of the connected Magnets at the intended anastomosis site. Positioning may be micro-adjusted using the endoscope and Delivery System combination in concert with laparoscopic manipulation with a Laparoscopic Positioning Device and bowel grasper.
15. Assure no tissue or material is interposed between the intraluminal devices (e.g., fat omentum, pancreatic tissue, colon, gallbladder, other bowel walls, metal clips) other than the target gastrointestinal walls.
16. Disengage the Delivery System from the proximal Magnet by retracting the blue collar.
17. Withdraw the Delivery System and endoscope combination.
18. Disengage the Laparoscopic Positioning Device from the distal Magnet.

Note: Rotate the magnetic tip of the Laparoscopic Positioning Device perpendicular (90°) to the Magnet to slide off or detach from the intraluminal Magnet when applicable to remove or change the laparoscopic device.

9.2 POST-OPERATIVE GUIDANCE

- Instruct the patient to not receive any MRI procedure until the Magnet devices are confirmed by X-ray to be out of the body.
- The Magnets will drop (as a docked pair of devices) from the anastomosis site into the intestine and are expected to naturally pass in less than 30 days but may be longer in some patients.
- Abdominal X-rays may be obtained at the discretion of the physician to monitor the location of the Magnets to ensure progression through the intestinal system for natural expulsion.
- Laxatives may be administered at the discretion of the physician to facilitate passage of the Magnets.

10. HOW SUPPLIED AND STORAGE REQUIREMENTS

10.1 GT Metabolic Magnet

- **Sterile:** GT Metabolic Magnets are sterilized with gamma irradiation. Do not use if package is opened or damaged. Use standard aseptic technique when handling the device. These devices are intended for single use only. Do not re-sterilize.
- **Contents:** One (1) GT Metabolic Magnet per package.
- **Storage:** Do not store the Magnets near magnetically attractive items or surface. Otherwise, no special storage conditions.

10.2 GT Metabolic Delivery System

- **Sterile:** GT Metabolic Delivery System is sterilized with gamma irradiation. Do not use if package is opened or damaged. Use standard aseptic technique when handling the device. This device is intended for single use only. Do not re-sterilize.
- **Contents:** One (1) GT Metabolic Delivery System per package.
- **Storage:** No special storage conditions.

10.3 GT Metabolic Laparoscopic Positioning Device (accessory)

- **Non-sterile:** The GT Metabolic Laparoscopic Positioning Devices are reusable and provided non-sterile. Instructions for the healthcare facility to perform cleaning and sterilization of these devices are provided in the IFU section titled CLEANING INSTRUCTIONS FOR LAPAROSCOPIC POSITIONING DEVICE.
- **Contents:** The GT Metabolic Laparoscopic Positioning Devices may be provided individually or in an optional Laparoscopic Instrument Set.
- **Storage:** No special storage conditions.

11. CLEANING INSTRUCTIONS FOR LAPAROSCOPIC POSITIONING DEVICE

11.1 INSTRUMENT PREPARATION

Remove any obvious soil or unwanted material in the operating room prior to cleaning and re-sterilization. It is preferable to use a dry non-linting wipe. If contaminants are removed using a wet method, place the instruments in a prepared solution directly after use. The instruments must be open as far as possible and completely submerged.



Caution

Cleaning or disinfecting using improper methods or using non-approved cleaning and disinfecting solutions may damage the devices or result in non-sterile devices.

Do not use metal brushes or scouring pads during the cleaning process.

NOTE: Use cleaning agents with low foaming surfactants for manual cleaning to enable visualization of the instruments in the cleaning solution. The cleaning agents selected must be easily rinsed from the instrument. Steris Prolystica® HP Enzymatic Manual Cleaner solution (i.e., Enzymatic-neutral pH cleaning solutions) is recommended for cleaning reusable instruments.

11.2 INSTRUMENT CLEANING

1. Rinse each instrument under running water for two (2) minutes to remove visible soil. Scrub each instrument, including the lumen of the shaft, with an appropriately sized soft-bristled brush while rinsing. Actuate the device at the pivot point and scrub with a soft-bristled brush while rinsing.
2. Fill the internal lumen of the shaft (blind end) with water at the open side near the articulating pivot point. Ensure that blind ends are repeatedly filled and emptied for the two (2) minutes.
3. Prepare a fresh Steris Prolystica® HP Enzymatic Manual Cleaner solution (i.e., enzymatic-neutral pH cleaning solutions) per the cleaner's manufacturer's recommendations.
4. Immerse the instrument in the detergent solution for a minimum of 5 minutes. While soaking, scrub the instrument, including shaft lumen with a soft-bristled brush to remove any remaining debris.
5. Immerse the instrument in detergent solution and sonicate for twenty (20) minutes. Leave the instrument in an open configuration.
6. Rinse the instrument with distilled or reverse osmosis (purified) water for two (2) minutes. Actuate the instrument at the pivot point and flush all surfaces during rinse.

7. Fill the shaft lumen (blind end) with distilled or reverse osmosis (purified) water. Repeatedly fill and empty for two (2) minutes.
8. Dry the instrument with a clean, dry non-linting wipe.
9. Examine the instrument under normal lighting for visible soil. If present, repeat cleaning.
10. Visually inspect under normal lighting for corrosion, damage, and function. Discard if corroded, damaged, or does not function as intended.

11.3 INSTRUMENT STERILIZATION INSTRUCTIONS

The instruments should be inspected to ensure they were thoroughly cleaned prior to sterilization. If any soil is present, it should be re-cleaned.

The sterilization parameters (table below) were validated to fifty (50) total cleaning/sterilization cycles by GT Metabolic Solutions, Inc. using an Aesculap® rigid sterilization container (Model JN445). Do not stack trays during sterilization.

Sterilization Parameters

Cycle	Minimum Temperature	Minimum Exposure Time	Minimum Drying Time
Pre-vacuum (4 pulse) Conditioning Autoclave	132 °C	4 Minutes	30 Minutes

Other configurations and sterilization parameters may also be suitable, but the user must validate any deviation from these instructions provided by GT Metabolic Solutions, Inc.

12. MRI SAFETY INFORMATION

The Magnets are MRI unsafe. Patients are not to receive MRI procedures while the Magnets are within the body. Expulsion of the devices should be confirmed by X-ray prior to the patient receiving an MRI.

13. SYMBOLS GLOSSARY

Symbol	Title of Symbol	Description of Symbol
	Medical Device	Indicates that the item is a medical device.
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Use By Date	Indicates the date after which the medical device is not to be used.
	Quantity	Indicates the number of medical devices that the package contains.
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use
	Translation	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information.
	Do Not Use if package damaged.	Indicates a medical device that should not be used if the package has been damaged or opened.
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Sterilized using irradiation.	Indicates a medical device that has been sterilized using irradiation.
	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside.

Symbol	Title of Symbol	Description of Symbol
	Contents are non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.
	MR Unsafe	A medical device which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	Manufacturer	Indicates the medical device manufacturer.
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.
	Unique Device Identifier	Indicates a carrier that contains a unique device identifier information.

14. FURTHER INFORMATION

For further information, please contact:

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