



Instructions for Use

Magnet System

Component Devices:

GT Metabolic Magnet

GT Metabolic Delivery System

GT Metabolic Laparoscopic Positioning Device



GT Metabolic Magnets:

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

GT Metabolic Delivery System: DS-01

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

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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, GT Metabolic Laparoscopic Positioning Devices, and GT Metabolic Magnetic Retrieval Device). 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.



Manufacturer

GT Metabolic Solutions, Inc.

5450 Quam Ave NE, Suite 100

St. Michael, MN 55376 USA

Website: <https://www.gtmetabolic.com>

Customer Service: +1-800-906-4948

Technical Support

Website: <https://www.gtmetabolic.com>

Email: cs@gtmetabolic.com

Phone: +1-800-906-4948

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1. OVERVIEW

The GT Metabolic Magnet System devices are designed for creation of oval anastomoses between the stomach and ileal or jejunal intestinal segments (side-to-side gastroileostomy or gastrojejunostomy) using two (2) 60mm (MAG-04) or 70mm (MAG-05) GT Metabolic Magnets.

The GT Metabolic Magnet System enables approximation of tissue through compression between two 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

Federal law (United States) restricts this device 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 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 Magnet at the desired anastomosis sites in the stomach and ileum or jejunum.

The GT Metabolic Magnetic Retrieval Device ("MRD" (MRD-02)) is an optional accessory device intended for endoscopic use to magnetically attract, capture, and retrieve a GT Metabolic Magnet if required at the discretion of the surgeon. Refer to the GT Metabolic Magnetic Retrieval Device Instructions For Use (document 2764; product listed on FDA's Unified Registration and Listing System (FURLS) #D568263).

3. INTENDED USE / INDICATIONS FOR USE

3.1 60mm and 70mm GT Metabolic Magnet System

The GT Metabolic Magnet System (60mm, 70mm) is intended for use in the creation of side-to-side gastroileostomy or gastrojejunostomy 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 patients > 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 gastro-ileal or gastro-jejunal anastomoses.
- 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 gastroileostomy or gastrojejunostomy.
- 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, ileum, or jejunum.
- 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 (GI) 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 resterilize or re-use these devices, even if the package has been opened but not used. Resterilization 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 gastroileostomy or gastrojejunostomy.
- Only use two GT Metabolic Magnet devices of the same length to create a magnetic compression anastomosis to support proper Magnet device alignment and compression and mitigate risk of device migration. Only use two 60mm (MAG-04) OR two 70mm (MAG-05) devices for gastroileostomy or gastrojejunostomy.
- 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 CLEANING INSTRUCTIONS FOR LAPAROSCOPIC POSITIONING DEVICE section of this IFU.
- 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 instructions in the HOW SUPPLIED AND STORAGE REQUIREMENTS section of this IFU.
- 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.

- As with any anastomotic technique or device and according to the surgeon's standard practices, eliminate tension at the anastomosis site to minimize risks of bleeding or leaking. For example, clear adhesions from the abdominal wall, intestines, or stomach where warranted; consider splitting the greater omentum if applicable; and consider utilizing stay sutures.
- 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 device (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 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 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.
- Users, healthcare professionals, and patients and their caregivers should be cautioned to minimize the risk of unintended interference, other medical electronic devices (e.g., hormone infusion pumps) should be kept at least 2.5 inches away from a single Magnet (any size) and 3.0 inches away from paired (docked) Magnets per International

Commission on Non-Ionizing Radiation Protection (ICNIPR) guidelines. At this distance, the static magnetic field strength is at or below 5 Gauss (0.5mT) and is not expected to adversely affect the operation of other medical devices.

- 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. UNDESIRABLE 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; tissue inflammation; 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

8.1 60mm and 70mm GT Metabolic Magnet Systems

The following clinical study was performed with the GT Metabolic Magnet System (using 60mm (MAG-04) and 70mm (MAG-05) Magnets to create a side-to-side gastro-ileal or gastro-jejunal magnetic compression anastomosis. The 60mm Magnet (MAG-04) and 70mm Magnet (MAG-05) are magnetic compression anastomosis devices.

Table 1. Outline of the Clinical Study

Study Title	Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic Magnet System, GJ Biofragmentable to achieve Gastro-Ileal or Gastro-Jejunal Diversion in Adults with Obesity ○ (“MGI/MGJ Study” or “Clinical Study”)
Protocol Number / NCT Number: GTM-003 /NCT06073457	
Study Design	This is an operationally seamless, 2-stage, open-label, multi-center study enrolling up to 45 subjects at 4 study centers across Canada, Chile, Portugal, and Middle East as follows: • Stage 1 first-in-human (FIH) and proof-of-concept with 5 subjects; and • Stage 2 feasibility with 4 up to 40 subjects • All subjects in Stage 1 and 2 are followed for 12 months.
Study Population	Adults (all enrolled > 21 years of age) with: • obesity (BMI 30-50) with one of the following criteria: (1) have type 2 diabetes mellitus (T2DM) or (2) experienced weight regain following previous sleeve gastrectomy - OR; • obesity (BMI 35-50) without previous sleeve gastrectomy with one of the following criteria: (1) gastro-jejunal is indicated as the first stage of a 2-stage one anastomosis gastric bypass (OAGB) or (2) single anastomosis gastric bypass (SAGB) where the second stage gastric pouch stapling will be conducted >12 months after the gastric-ileal diversion (not part of the study)
Primary and Safety Endpoints	Primary: Feasibility/performance. The side-to-side anastomosis will be considered feasible if results are successful at three months: • Placement of the MAGNET System ($\geq 90\%$ alignment of magnets); and • Passage of magnets without surgical re-intervention; and • Creation of a patent anastomosis confirmed radiologically. ○ Safety: Incidence of treatment emergent AEs.

A multi-center study as outlined in **Table 1** was conducted to evaluate the feasibility/performance and safety of the GT Metabolic Magnet System for the intended use in patients indicated for a side-to-side gastroenterostomy. Thirty-nine (39) subjects were treated across four (4) centers in Canada, Portugal, United Arab Emirates, Chile.

Thirty-five (35) subjects (89.7%, 35/39) received the study treatment following prior sleeve gastrectomy (SG) ≥ 12 months with weight regain or development of T2DM. All subjects (100%) have been followed to day 90 for primary endpoint, and 10 of the subjects (25.6%) to one year for study completion as of the date of data closure for the report (March 31, 2026).

Tables 2 and **Table 3** show the subject demographics and clinical characteristics respectively.

Table 2. Demographic Characteristics

Baseline Characteristics (Consented)	All Treated N=39
Age (years) Mean (SEM)	44.6 (1.5) years
Age (years) Min, Max	25, 65 years
Female: n (%)	33 (84.6%)
Male: n (%)	6 (15.4%)

Table 3. Baseline Clinical Characteristics

Baseline Characteristics (Consented)	All Treated N=39
Body Weight: Mean (SEM)	104.8 (2.8) kg
Body Mass Index (BMI, kg/m²): Mean (SEM)	38.3 (0.8) kg/m ²
Type 2 Diabetes Mellitus (T2DM): n (%)	6 (15.4%)
HbA1c (%): Mean (SEM)	5.8 (0.2) %
Glucose (mg/dL): Mean (SEM)	94.8 (4.4) mg/dL
Prior Sleeve Gastrectomy (SG) ≥ 12 months with weight gain or development of T2DM: n (%)	35 (89.7%)

Study Procedure

A side-to-side magnetic compression anastomosis with the Magnet System (using two 70mm or 60mm Magnets) was performed for all subjects to establish a gastro-ileal or gastro-jejunal anastomosis (study procedure). The underlying clinical procedures require a gastro-ileal or gastro-jejunal anastomosis (at the discretion of the treating investigator) for intestinal diversion for weight loss in an obese population. The underlying clinical procedure was standardized solely as a control for evaluating performance of the investigational device for creation of a safe and patent anastomosis, the primary study endpoint at 90 days. The device is not intended for any clinical claims of weight loss.

Subjects were provided the option, at the discretion of the investigator, of swallowing (orogastric delivery) the first Magnet or endoscopic delivery of both Magnets with the Delivery System. The first Magnet (becomes distal, 1 of 2 Magnets) intended for placement in the small bowel is swallowed and patients are radiographically monitored for position of the device as it naturally moves through the intestinal system with peristalsis. Subjects are then moved to the operating room to start the laparoscopic procedure approximately 2 – 3 hours after swallowing the first Magnet when the device is estimated to be near or past the ligament of Treitz.

Laparoscopic Positioning Devices and standard laparoscopic instruments (e.g., bowel graspers) are used to move the distal Magnet to the intended position in the small bowel and manipulate the proximal Magnet to the desired position in the stomach. This specific measurement for the anastomosis location for the underlying clinical procedure is based on the clinical literature and at the discretion of the surgeon.

Under general anesthesia, the second Magnet (becomes proximal, 2 of 2 Magnets) is placed using the Delivery System through a flexible endoscope into the stomach. Laparoscopic instruments are used to gently lift the small bowel loop with the intraluminal distal Magnet to meet the proximal Magnet in the stomach enabling the Magnets to connect (or “dock”) via polar attraction of the devices through the gastric and intestinal walls. The study protocol also includes closure of the mesentery defect to standardize the surgical procedure and mitigate potential risk of internal hernia and intestinal obstruction at the mesentery, known risks for many laparoscopic and open abdominal surgeries.

Primary Performance Endpoint

The GT Metabolic Magnet System was successfully placed in all 39/39 (100%) study procedures with alignment (docking of the Magnets together). Creation of a patent anastomosis was confirmed radiographically or by endoscopy in all 39/39 (100%) of the subjects. The device passed successfully in natural bowel movements for 37/39 (94.9%) subjects. In one case, the 70mm Magnets created a patent anastomosis, but the connected devices remained at the site. The patient experienced no clinical adverse effects. The set of

connected devices was retrieved endoscopically without issue at day 168; no anastomosis or significant clinical issues were identified through one-year follow up. In the other case, the 60mm the Magnets dropped and were visible on X-ray to have progressed approximately to the cecum. The patient experienced no clinical adverse effects. The connected devices were removed successfully by colonoscopy on day 92 without clinical issues; follow-up endoscopy revealed a patent anastomosis of good size (approx. 15mm).

The GT Metabolic Magnet System met the primary performance endpoint for success as pre-defined in the protocol ($\geq 80\%$ of the subjects meet all three performance criteria) and as shown in **Table 4**.

Table 4. Feasibility/Performance Criteria

Protocol Feasibility/Performance Criteria	n (%)
Placement of the device with $\geq 90\%$ alignment of Magnets	39 (100%)
Passage of the device without invasive re-intervention	37 (94.9%)
Creation of a patent anastomosis confirmed radiologically	39 (100%)

Safety

A total of 82 adverse events for all follow up were reported in 31 unique subjects (79.5% incidence, 31/39) with 8 events classified as serious (17.9% SAE incidence, 7/39). Most adverse events (82.9%, 68/82) throughout all follow up were classified as low grade Clavien-Dindo (grade I and II; see **Table 6**).

Three events (7.7% incidence, 3/39) were assessed as related to the Magnet device with only one event qualifying as serious (SAE). The other two events were non-serious cases of non-expulsion as described above under **Table 4. Performance Criteria**. In both cases, the subjects had no clinical events, and the devices were retrieved successfully with minimally invasive techniques (endoscopy and colonoscopy) and no sequelae.

Thirty-two (32) of the total events were assessed as related to the study procedure, with none associated with the Delivery System or Laparoscopic Positioning Device.

Table 5. Adverse Event Summary

Adverse Event (AE) Category	70mm Magnet (n=16) All follow	60mm Magnet (n=23) All follow	Total Magnets (N=39) All follow	Total Magnets (N=39) 30-days Post operative
Unique subjects with AEs – n (% of Total Cohort Subjects)	11 (68.8%)	20 (87.0%)	31 (79.5%)	24 (61.5%)
Total AEs – n (% of Total Cohort AEs)	28 (100%)	54 (100%)	82 (100%)	35 (100%)
AEs Related to the Magnet n (Incidence (n, %))	2 (2, 12.5%)	1 (1, 4.3%)	3 (3, 7.7%)	1 (1, 2.6%)
AEs Related to Procedure* n (Incidence (n, %))	9 (7, 43.8%)	23 (15, 65.2%)	32 (22, 56.4%)	20 (18, 46.2%)
Total SAEs – n (Incidence (n, %))	6 (6, 37.5%)	2 (1, 4.3%)	8 (7, 17.9%)	4 (4, 10.2%)
SAEs Related to the Magnet n (Incidence (n, %))	1 (1, 6.2%)	0 (0, 0%)	1 (1, 2.6%)	1 (1, 2.6%)
SAEs Related to Procedure n (Incidence (n, %))	3 (3, 18.8%)	2 (1, 4.3%)	5 (4, 12.8%)	4 (4, 10.2%)
SAEs Related to Magnet and/or Procedure (Complications)* n (Incidence (n, %))	3 (3, 18.8%)	2 (1, 4.3%)	5 (4, 12.8%)	4 (4, 10.2%)

*None were determined related to the Delivery System or Laparoscopic Positioning Device (Magnet System components)

Table 6. Adverse Events by Clavien-Dindo Classification Grading

Clavien-Dindo Classification	Total Magnets (N=39) All follow up	Total Magnets (N=39) 30-days Post operative
Grade I: (n (% of Cohort AEs)) 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.	29 (35.4%)	17 (48.6%)
Grade II: (n (% of Cohort AEs)) Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition included.	39 (47.6%)	12 (34.3%)
Grade III: (n (% of Cohort AEs)) Requiring surgical, endoscopic, or radiological intervention.	11 (13.4%)	4 (11.4%)
Grade IV: (n (% of Cohort AEs)) Life-threatening complication (including certain CNS complications) requiring Intermediate Care/Intensive Care Unit-management.	3 (3.6%)	2 (5.7%)
Grade V: (n (% of Cohort AEs)) Death of a patient.	0	0
TOTAL Cohort Adverse Events (AEs) n (% of all AEs)	82 (100%)	35 (100%)

Serious Adverse Events

One serious adverse event (SAE), an anastomosis tear leading to a leak and peritonitis, was assessed as related to the Magnet device and the study procedure (2.6%, 1/39). The Magnets were placed successfully with the subject developing intense abdominal pain at day 9. An abdominal CT scan showed a leak at the distal end of the paired Magnets (70mm) with fluid collection in the abdomen. Laparoscopic surgery identified a tear at the distal end of the anastomosis, on the intestine side at the gastric side of the antrum (where tissue is quite thick). The tear was laparoscopically sutured, the Magnets were left in place, and drains were placed for fluid drainage. The Magnets dropped from the site, creating a patent anastomosis, and were naturally expelled at day 36. The endoscopy at the day 90 study visit confirmed a wide and patent anastomosis with easy passage of the scope.

The Sponsor assessed the tear may have resulted from tension at the anastomosis site. The literature supports “tension-free anastomosis” as a foundational principle in surgery.¹

¹ Khalid MU, Ali D, Wu JY, et al. Impact and Measurement of Mechanical Tension in Bowel Anastomosis: A Scoping Review of the Current Literature. Journal of Surgical Research. 2025; 308: 161-173. <https://doi.org/10.1016/j.jss.2025.02.011>

Surgeons are trained to investigate for and eliminate tension at the anastomosis site (e.g., clear adhesions, split the omentum sufficiently, apply intestinal stay sutures to reduce pull of bowel loop), regardless of anastomotic instrument or technique, to minimize the risk of bleeds and leaks. There were two cases of iatrogenic tissue tears (one to the small bowel tissue and one to the anastomosis tissue) caused by the physician with laparoscopic bowel forceps (commercial, not investigational). In both cases, the tears were sutured and the events resolved. Additionally, in both cases, the paired Magnets were left in place and created patent anastomoses followed by natural expulsion.

There was one laparoscopic reversal of the study gastroileostomy (60mm Magnets). The patient experienced repeated episodes of constipation, diarrhea, vomiting, food intolerance, malaise, and dehydration over the first month post procedure. The Magnets expelled naturally at day 30 with a patent, large and regular anastomosis formed, with good flow to the bowel. However, the symptoms continued and the subject was assessed by the investigator to have excessive incretinic (metabolic gut hormones) stimulation which can occur with any anastomosis diversion, regardless of the anastomosis technique. Given continued intolerance of the diversion, a laparoscopic reversal of the anastomosis was performed with an intestinal stapler at day 143 with no clinical issues and the subject completed follow up through one year without sequelae.

Conclusion

This Clinical Study for the Magnet System (70mm (MAG-05) and 60mm (MAG-04) Magnets) met the primary endpoint for creating patent side-to-side gastroileostomy or gastrojejunostomy with a robust safety profile. There were no anastomotic bleeds, infection, or obstruction and no mortality. The one leak was attributed to a tear at the anastomosis. The tear was laparoscopically sutured, and the Magnets were left in place, expelled naturally, created a wide anastomosis that remained patent through the one-year follow up. The case emphasizes the importance of reviewing and eliminating tension at the site, regardless of the anastomotic technique.

The Magnet System (60mm, 70mm Magnets) has benefits of requiring no incision or resection of the intestine and leaving no foreign material behind (e.g., staples). Additionally, the ability to easily reverse an anastomosis if clinically indicated is a unique benefit, providing surgeons and patients with options for addressing individual clinical scenarios.

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 (1 of 2 devices) 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 bowel clamp from the peritoneal cavity at this time.
7. After the distal Magnet is engaged with the Laparoscopic Positioning Device, detach the distal Magnet from the Delivery System by retracting the collar.
8. Withdraw the Delivery System from the endoscope.
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 (jejunum or ileum). It is recommended to start with the middle-strength LPD (PD-21) and change to an LPD of higher or lower strength based on the individual patient case and quality of the bowel.
10. Attach the second (proximal) Magnet (2 of 2 devices) to the Delivery System, as previously described, and advance endoscopically to the desired location in the stomach.
11. Refine the position of the proximal Magnet using the endoscope and Delivery System combination.

12. Once the proximal Magnet is in the desired position, change to the lowest strength LPD (PD-12) on the distal Magnet. Bring the intestinal loop containing the distal intraluminal device into the proximity of the proximal intraluminal device slowly. The two (2) Magnets will connect through the stomach and intestinal walls (“dock”) 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 and no malrotation near the anastomosis site.
14. Verify positioning of the docked Magnets at the intended anastomosis site. Positioning may be micro-adjusted using the Delivery System if it is still attached to the proximal Magnet in concert with laparoscopic manipulation with a Laparoscopic Positioning Device. Assure no tissue or material is interposed between the intraluminal devices (e.g., fat omentum, other bowel walls, metal clips) other than the target intestinal walls.

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.
15. Disengage the Delivery System from the proximal Magnet by retracting the collar.
16. Withdraw the Delivery System from the endoscope.

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 CLEANING INSTRUCTIONS FOR LAPAROSCOPIC POSITIONING DEVICE section of this IFU.
- **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 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 (refer to **Table 8**) 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.

Table 8. Sterilization Parameters

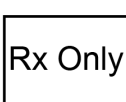
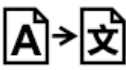
Cycle	Minimum Temperature	Minimum Exposure Time	Minimum Drying Time
Pre-vacuum (4 pulse) Conditioning Autoclave	132 °C	4 Minutes	30 Minutes

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. SYMBOL 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.
	Caution: Federal law (United States) restricts this device to sale, distribution and use by or on the order of a physician.	US law restricts this medical device to be sold only with a prescription from a licensed healthcare provider.
	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.

Symbol	Title of Symbol	Description of Symbol
	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside.
	Contents are non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Do not resterilize	Indicates a medical device that is not to be resterilized.
	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:

GT Metabolic Solutions, Inc.
5450 Quam Ave NE, Suite 100
St. Michael, MN 55376 USA

Customer Service: +1-800-906-4948

IFU Website: <https://www.gtmetabolic.com>

Email: cs@gtmetabolic.com