GT Metabolic

Instructions for Use

MagDI™ System

Component Devices:

GT Metabolic DI Magnet

GT Metabolic Delivery System

GT Metabolic Laparoscopic Positioning Device

REF GT Metabolic Magnets: MAG-01, MAG-02
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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Limited Warranty

GT Metabolic represents and warrants that reasonable care has been used in the manufacturing of the GT Metabolic MagDI™ System and component devices (GT Metabolic DI 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 MagDI™ System devices are designed for creation of oval anastomoses between the sides of the duodenal and ileal intestinal segments (side-to-side) in the small bowel.

The MagDI™ System enables approximation of tissue through compression between two Magnet housings (a set of two (2) devices). The devices are either a set of 40mm (part number MAG-01) or 50mm (part number MAG-02) 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 MagDI™ System is comprised of the following devices:

- Individually packaged **GT Metabolic DI Magnet** ("Magnet") devices designed to be used as a set of two (2), either a set of 40mm (MAG-01) or 50mm (MAG-02) 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 site in the duodenum and ileum.

3. INTENDED USE / INDICATIONS FOR USE

The GT Metabolic MagDI™ System is intended for use in the creation of side-to-side duodeno-ileal anastomoses 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 MagDI™ System is intended for use in adult patients > 21 years.

4. IMPORTANT

Warning

- This IFU provides instructions for using the MagDI™ System devices together as a surgical tool for creation of side-to-side duodeno-ileal anastomoses. Do not use the MagDI™ 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 anastomosis of two (2) segments of the small bowel.
- Do not use the devices if the intended segments of the small bowel have insufficient patency to allow for adequate intestinal flow until the side-to-side 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.
- 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 (316LVM), neodymium-iron-boron (ASTM A1101)) or the flange materials (polyglycolic-co-lactic acid (PGLA), 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 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 MagDI™ System is designed to use two (2) Magnets to create each side-to-side duodeno-ileal anastomosis.
- Only use two GT Metabolic DI Magnet devices of the same length to create a magnetic compression anastomosis (either two 40mm (MAG-01) or two 50mm (MAG-02) devices) to support proper magnet device alignment and compression and mitigate risk of device migration.
- Do not use the MagDI™ 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 Section 11. CLEANING INSTRUCTIONS FOR LAPAROSCOPIC POSITIONING DEVICE.
- When the Magnet is placed in the duodenum for anastomosis, it must be proximal to the Sphincter of Oddi and pancreatic ducts to preserve their patency with the gall bladder and pancreas respectively and distal to the pylorus (1-2 cm).

- 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 MagDI™ 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 intestinal 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 Section 10. HOW SUPPLIED AND STORAGE REQUIREMENTS instructions below.
- 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 a commercially available endoscopic recovery device (e.g., Steris Healthcare Roth Net® Retriever, Olympus EndoJaw Biopsy Forceps #FB-210U).

- 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/m^2 due to potential for surgical adverse events.

- If the patient is indicated for a gastric surgical procedure at the same time as the side-to-side duodeno-ileal 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. UNDESIRABLE SIDE EFFECTS/RESIDUAL RISKS

Undesirable side effects and risks associated with performing a side-to-side duodeno-ileal anastomosis with the MagDI™ 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 ("GT Metabolic MagDI System") is intended for use in the creation of side-to-side small bowel anastomoses (enteroenterostomy) in minimally invasive and laparoscopic surgery. Once wound strength is sufficient to maintain the anastomosis, the device is naturally passed from the body. Clinical testing was conducted to demonstrate the safety and the performance of the devices for the intended use.

A clinical study was performed with the GT Metabolic Magnet System ("GT Metabolic MagDI System") [Magnet (40mm, MAG-01), Magnet (50mm, MAG-02), DS-01 (Delivery System), and Laparoscopic Positioning Devices (LPD: PD-12, PD-18, PD-21, PD-24, PD-27)] to support the performance of the device to safely create a patent side-to-side entero-enterostomy.

The outline of the study is as follows:

Study Title	Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic Solutions DI Biofragmentable Magnetic Anastomosis System (Magnet System, DI Biofragmentable) to Achieve Duodeno-Ileostomy Diversion in Adults with Obesity and with or without Type 2 Diabetes Mellitus. "Clinical Study"
Study Design	Prospective, single arm, multi-center study across six regions (Republic of Georgia, Canada, Australia, Italy, Chile, and Mexico) and followed to one year. (ClinicalTrials.gov: NCT05692518, NCT06467955, NCT06473831, NCT06613711, NCT06613724, NCT07085741)
Study Population	Adults (18 to 65 years of age, inclusive) with obesity (BMI 30-50 kg/m2) with or without Type 2 Diabetes Mellitus (T2DM, HbA1c $\geq$ 6.5%) and are candidates for a duodeno-ileostomy for intestinal diversion.

Primary Performance and Safety Endpoints	**Primary Performance Endpoint.** The side-to-side anastomosis duodeno-ileostomy will be considered feasible if results are successful at three months: • Placement of the MAGNET System (>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.

Performance success at 90 days for an individual subject is defined as meeting all three performance criteria (1) placement with alignment (i.e., connection of two Magnets), 2) natural passage of device without invasive re-intervention (e.g., device does not require manual or surgical retrieval), and 3) creation of a patent anastomosis confirmed radiologically. The sponsor considered success to be met if all three criteria were positive “up to and including 90 days”. Creation of a patent anastomosis following expulsion was allowed to be confirmed radiologically or by endoscopy.

The device exceeded the performance success threshold (≥ 80% of subjects meeting all criteria) with n=118 treated subjects.

One hundred and fourteen (114) individual subjects met all three criteria (96.6%, 114/118) resulting in primary endpoint performance success for the GT Metabolic Magnet System.

Magnet System (40mm, 50mm Magnet) Performance Criteria

Performance Criteria	40mm Magnet n=89	50mm Magnet n=29	TOTAL N=118
Placement of the device with ≥90% alignment of Magnets	89 (100%)	29 (100%)	118 (100%)
Passage of the device without invasive re-intervention	88 (98.9%)	27 (93.1%)	115 (97.4%)
Creation of a patent anastomosis confirmed radiologically	87 (97.8%)	28 (96.6%)	115 (97.4%)

SUCCESS: Meets ALL Performance Criteria	**87 (97.8%)**	**27 (93.1%)**	**114 (96.6%)**

Four subjects did not meet all three success criteria:

- 1 subject (40mm) withdrew consent prior to device expulsion and was assumed a worst-case failure for natural passage and creation of a patent anastomosis in the analysis.
- 1 subject had confirmed stenosis (40mm): The Magnets were naturally expelled at day 27; the day 90 endoscopy revealed gastric emptying into the duodenum, but no evidence of flow through the duodeno-ileostomy. The subject was followed through one year (day 360) with no clinical issues or adverse events.
- 2 cases resulted in device retrieval (50mm cohort):
    1) The Magnets created a patent anastomosis, dropped and proceeded with slow transit through the small bowel without clinical issues or adverse events. The investigator retrieved the Magnet set at the cecum by colonoscopy and without issues at day 93.
    2) The subject presented with peritonitis on day 6 prior to anastomosis and the Magnets were retrieved by a non-study surgeon addressing the peritonitis (event described in the adverse event section).

The median hospital stay was 1 day with a mean of 1.2 days (0.07 SEM).

Device expulsion time (measured as days from study procedure) was based on subject self-report. Subjects were trained to examine their stool for passage of the device and self-report the date of expulsion to the study investigator. X-rays were taken to monitor for device drop from the anastomosis site and movement via peristalsis (i.e., natural movement with the chyme through the intestinal tract) to ensure and eventually confirm devices were no longer present. Confirmation of device expulsion was allowed by X-ray

or endoscopy. The study protocol allowed for laxatives if the patient was experiencing constipation, given peristalsis and bowel patterns differ across patients.

Not all subjects were aware of Magnet (two devices connected) passage in the stool. Forty percent (40%, 46/115) of the subjects with naturally expelled Magnets were aware and self-reported the day of passage. The one subject who withdrew consent was censored and two subjects had their Magnets retrieved. The table below summarizes expulsion time by self-report (n=46) and where self-report was not available, confirmation of device expulsion was used as a worst-case proxy to estimate expulsion (i.e. assume expulsion on day of imaging).

Magnet System (40mm, 50mm Magnet) Expulsion Time

Expulsion Time (days)	Magnet Self-report n=46[a]	Magnet Self-report or Imaging Confirmation n=115[a]
Median	28 days	30 days
Mean (SEM)	30.7 (1.9) days	33.8 (1.3) days
Range Min, Max	15, 80 days	11, 97 days

[a]Subject who withdrew consent for reporting on expulsion was censored for this summary; two subjects had Magnets retrieved versus natural expulsion, as previously described.

A total of 251 adverse events for all follow up were reported in 76 unique subjects (64.4% incidence, 76/118) with 26 events classified as serious (15.2% SAE incidence, 18/118).

In the 30-day post-operative period, a total of 95 adverse events were reported in 58 unique subjects (49.2% incidence, 58/118) with five (5) events classified as an SAE (4.2% incidence, 5/118).

Three events (2.5% incidence, 3/118) were assessed as related to the Magnet device as described below. One-hundred and ten (110) of the total events were assessed as

related to the study procedure, with none associated with the Delivery System or Laparoscopic Positioning Device. There were no reports of anastomotic bleeding, leaks, infection, or obstruction and no mortality in all (n=118) follow up with 21 of the subjects (28.0%, 33/118) followed to one year.

Magnet System (40mm, 50mm Magnet) Adverse Event Summary

Adverse Event (AE) Category	**40mm Magnet (n=89) All follow up**	**50mm Magnet (n=29) All follow up**	**Total Magnets (N=118) All follow up**	**Total Magnets (N=118) 30-days Post operative**
Unique subjects with AEs – n (% of Total Cohort Subjects)	52 (58.4%)	24 (82.8%)	76 (64.4%)	58 (49.2%)
Total AEs – n (% of Total CohortAEs)	153 (100%)	98 (100%)	251 (100%)	95 (37.8%)
AEs Related to the Magnet n (Incidence (n, %))	1 (1, 1.1%)	2 (2, 6.9%)	3 (3, 2.5%)	2 (2, 1.7%)
AEs Related to Procedure* n (Incidence (n, %))	76 (34, 38.2%)	34 (16, 55.2%)	110 (50, 42.4%)	55 (42, 35.6%)
Total SAEs – n (Incidence (n, %))	20 (13, 14.6%)	6 (5, 17.2%)	26 (18, 15.2%)	5 (5, 4.2%)
SAEs Related to Magnet and/or Procedure (Complications)* n (Incidence (n, %))	11 (9, 10.1%)	3 (3, 10.3%)	14 (12, 10.2%)	5 (5, 4.2%)

*None were determined related to the Delivery System or Laparoscopic Positioning Device

Magnet System (40mm, 50mm Magnet) Adverse Events by Clavien-Dindo Classification Grading

Clavien-Dindo Classification	**40mm Magnet (n=89) All follow up**	**50mm Magnet (n=29) All follow up**	**Total Magnets (N=118) All follow up**	**Total Magnets (N=118) 30-days Post operative**
Grade I: (n (% of Cohort AEs))	51 (33.3%)	55 (56.1%)	106 (42.2%)	44 (46.3%)
Grade II: (n (% of Cohort AEs))	80 (52.3%)	32 (32.6%)	112 (44.6%)	33 (34.7%)
Grade III: (n (% of Cohort AEs))	21 (13.7%)	11 (11.2%)	32 (12.7%)	18 (18.9%)

Grade IV: (n (% of Cohort AEs))	1 (0.6%)	0 (0%)	1 (0.4%)	0
Grade V: (n (% of Cohort AEs))	0 (0%)	0 (0%)	0	0
TOTAL Cohort Adverse Events (% TOTAL AEs)	**153 (100%)**	**98 (100%)**	**251 (100%)**	**95 (37.8%)**

Most adverse events (86.8%, 218/251) throughout all follow up were classified as low grade Clavien-Dindo (grade I and II).

Twenty-six adverse events (26) in 18 unique patients (15.2% incidence, 18/118) met criteria to be reported as a serious adverse event (SAE) during all follow up. Eleven (11) of all SAEs were assessed as related to the device/procedure in 9 unique patients (10.1%, 9/89). Five SAEs occurred in the 30-day post-operative period, all assessed as related to the device/procedure, in four unique patients (4.2%, 5/118).

Three adverse events were assessed as related to the Magnet device throughout the study, including all follow up (2.5% incidence, 3/118). One serious adverse event (SAE), a case of duodenitis, was assessed as related to the Magnet device and the study procedure. The Magnets were placed successfully and naturally expelled on day 19 without issues. A study-required endoscopy was scheduled for the next day to assess the anastomosis (required for all subjects). The anastomosis was well formed and patent with no bleeding or leaks. Inflammation of the duodenal intestinal tissue (duodenitis) was observed between the anastomosis and the pylorus (valve between the stomach and small bowel). Additionally, edema of the pylorus and delayed gastric emptying with the edema was noted (not gastric outlet obstruction). The subject was empirically treated with antibiotics, though there were no findings of abscess of the duodenum and no underlying bacterial, viral, or fungal infection. A follow-up endoscopy with fluoroscopy was conducted at the day 30 study visit demonstrating a patent anastomosis and resolution of the adverse event.

There was only one grade IV event (0.8% incidence; 1/118) reported throughout all follow up, an adhesive bowel obstruction at day 141. The patient entered the study with significant adhesions (scar tissue) within the abdominal cavity resulting from prior

surgeries (one laparoscopic cholecystectomy and one abdominal hysterectomy). Time was required to sufficiently breakdown these adhesions and free up the small bowel prior to the Magnet procedure ensure no tension (pulling) at the anastomosis site when the two intraluminal Magnets were connected. The Magnets were placed successfully, expelled naturally on day 34, and the anastomosis was confirmed by fluoroscopy imaging to be patent and without bleeding or leaks. On day 141, the subject presented with severe abdominal pain, nausea, vomiting, and absence of bowel movements. A CT revealed intestinal obstruction at the distal jejunum (no obstruction at the study duodeno-ileal anastomosis site) caused by a band of adhesions deep in the pelvic cavity. One adhesion completely constricted the circumference of the intestine, causing ischemia and a perforation (break) through all layers of the intestinal tissue, leading to peritonitis. The affected jejunum section was surgically removed, and a mechanical (not using Magnets) side-to-side anastomosis was created to enable flow through the intestine. The study duodeno-ileal anastomosis remained intact, with no evidence of leak or perforation at the site. The subject experienced a challenging clinical course but recovered normal gastrointestinal function. An endoscopy performed at study-visit day 180 further demonstrated a wide, patent anastomosis without bleeding or leaks.

There were two cases of iatrogenic perforation of the anastomosis (small breaks through the tissue) caused by the physician performing a study-required endoscopy (iatrogenic) during routine assessment of the anastomosis (1.7%, 2/118). In both cases, the subjects had successful study procedures for placement of the Magnets followed by natural device expulsion, and creation of patent anastomoses with no defects, bleeds or leaks. In one case after assessing a well-formed anastomosis, the investigator manipulated the endoscope through the new opening and observed creation of a small tear (5mm) not present earlier in the examination. The tear was repaired by suture without complication. In the second case, the endoscopist (not the study investigator) assessed inflammatory stenosis and attempted to dilate the anastomosis with the endoscope, creating a micro perforation. The tear was also repaired by suture. In both cases, follow-up fluoroscopy imaging demonstrated anastomosis patency and resolution of the events with no sequelae.

It is usual practice for surgeons to dilate anastomoses when the connection is between the stomach and small bowel (e.g., gastro-jejunostomy in Roux-en-Y gastric bypass). Stenosis in these bariatric clinical procedures can reach 25% and endoscopy dilatation, even repeat dilatation is common. Gastric tissue is thicker than in the small bowel and more pliable, allowing stretch, though perforation is still a risk (5%). And though common practice, there is still debate in the literature on technique for dilatation to minimize risk[1]. Given the small bowel tissue is thinner and less elastic, the Sponsor does not advocate for dilatation or manipulation of the magnetic compression anastomosis in training materials. Further, a statement was added to the instructions for use (IFU), "Warning is indicated to not dilate the magnetic compression anastomosis to mitigate risks of perforation (or other defects) and bleeding."

There were two laparoscopic reversals of the study duodeno-ileostomy. In both cases, the Magnets were placed successfully, created patent anastomoses and were expelled naturally. In one case, the subject experienced recurrent elevated liver enzymes that led to the reversal decision. The duodeno-ileal anastomosis was closed on day 144 using conventional stapling without issues. The liver function tests were stable through day 180 and 270 study visits and there were no additional adverse events reported. The second subject experienced severe weight loss reducing from a BMI of 33 at baseline to 22 kg/m^2. The reversal was performed at day 163. The study endoscopy at the subject's one-year visit revealed the closed anastomosis site was completely healed without any abnormalities or signs of inflammation.

This Clinical Study for the MagDI System (40mm Magnet (MAG-01) and 50mm Magnet (MAG-02)) met the primary endpoint for creating patent anastomoses with a robust safety profile and none of the most serious risks of conventional techniques. There were no anastomotic leaks, bleeds, infection, or obstruction and no mortality. Additionally, the

[1] Garcia-Garcia ML, Martin-Lorenzo JG, Liron-Ruiz R, et al. Gastrojejunal Anastomotic Stenosis After Laparoscopic Gastric Bypass. Experience in 300 Cases in 8 Years. Cirugia Espanola. 2014; 92(10):665-669. https://www.sciencedirect.com/science/article/abs/pii/S2173507714004517?via%3Dihub.

mean hospital stay was 1.3 days, given a minimally invasive approach with no incision made to bowel.

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.

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 duodenum.

11. Refine the position of the proximal Magnet using the endoscope and Delivery System combination. Do not disengage the proximal Magnet from the Delivery System at this time, unless the target anastomosis site for the proximal intraluminal device is past the ligament of Trietz. In that case, engage the proximal Magnet with a Laparoscopic Positioning Device as described above, disengage, and withdraw the Delivery System, and move the proximal intraluminal device in the “grasp and slide” maneuver to the desired location.

12. Once the proximal Magnet is in the desired position, 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 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, 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 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.

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 intestinal walls.

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

17. Withdraw the Delivery System from the endoscope.

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

- GT Metabolic DI Magnet:
    - **Sterile:** GT Metabolic DI 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 DI Magnet per package.
    - **Storage:** Do not store the Magnets near magnetically attractive items or surface. Otherwise, no special storage conditions.
    - **Disposal:** The Magnets do not contain hazardous substances. There are no special disposal requirements for the Magnets.
- 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.
    - **Disposal:** The devices do not contain hazardous substances. However, following clinical use, it may be contaminated with biological material. Dispose of the device in accordance with institutional guidelines and local regulations for biohazardous waste.
- 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 Section 11. 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.

- **Disposal:** The instruments do not contain hazardous substances and are reusable. Dispose of the instruments when applicable in accordance with institutional guidelines

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

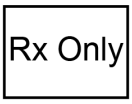
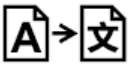
Cycle	Minimum Temperature	Minimum Exposure Time	Minimum Drying Time
Pre-vacuum (4 pulse) Conditioning Autoclave	132 °C	4 Minutes	30 Minutes

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.

Symbol	Title of Symbol	Description of Symbol
	Sterilized using irradiation.	Indicates a medical device that has been sterilized using irradiation.
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside.
	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:

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