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 device is intended as an anastomotic tool and does not claim treatment effects for any condition, including weight loss or diabetes control.

The GT Metabolic MagDI™ System is intended for use in adult patients.

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 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 small bowel.

CONTRAINDICATIONS, continued

- Do not use the devices if the patient has an expected need for magnetic resonance imaging (MRI) within 40 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 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 10. 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.
- Warning is indicated to not dilate the magnetic compression anastomosis to mitigate risks of perforation (or other defects) and bleeding.
- The expected time of tissue necrosis and anastomosis formation is 7 – 21 days based on testing data. Do not remove the Magnets prior to 21 days, unless medically required, to allow sufficient tissue remodeling for anastomosis stability and mitigate risks of bleeds or leaks.

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.
- Use of the device in patients with conditions leading to tissue friability or necrosis has not been clinically tested and potential risks are unknown (e.g., inflammatory or diverticular disease, ischemic or edematous disease, or radiation induced small bowel disease).
- Use of the device in patients with immunodeficiency, poorly controlled diabetes, liver disease or other conditions leading to bilirubin abnormalities has not been clinically tested and potential risks are unknown.
- Evaluate patients for adhesions or excessive scarring due to previous pelvic or abdominal surgery. It is advised to release adhesions (i.e., incision, lysis) affecting the distal ileum prior to placement and connection of the Magnets to mitigate potential tension on the anastomosis and facilitate standard bowel measurement.
- 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 9. STORAGE 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.
- 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).
- Conversion to 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 21 days post-procedure.
- The effects of use in patients actively taking medications affecting gastrointestinal healing were not clinically tested and potential risks are unknown (e.g., corticosteroids, anticoagulants, or immunosuppressive or antineoplastic agents).
- Physicians are advised to alert female patients of childbearing potential of the unknown effects of the anastomosis procedure on the absorption of oral contraceptives (may reduce effectiveness) and recommend combining with or using another method.
- 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 60 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; gallbladder issues (e.g., choledocholithiasis); need for surgical re-intervention (e.g., failure to expel); or death.

8. CLINICAL PERFORMANCE TESTING

A clinical study was performed with the GT Metabolic MagDI System [510(k) cleared in USA (K242086, K243359): MAG-01 (40mm, Magnet) or MAG-02 (50mm, Magnet), 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 side-to-side small bowel anastomosis.

The underlying clinical procedure of duodeno-ileostomy diversion in patients with obesity (with or without comorbidity) was standardized and is an example procedure requiring a small bowel anastomosis.

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. "MagDI Study" or "Clinical Study"
Study Design	Prospective, single arm, multi-center study across five regions (Republic of Georgia, Canada, Australia, Italy, and Chile) and followed to one year. (ClinicalTrials.gov: NCT05692518, NCT06467955, NCT06473831, NCT06613711, NCT06613724)
Study Population	Adults (18 to 65 years of age, inclusive) with obesity (BMI 30-50 kg/m^2) with or without Type 2 Diabetes Mellitus (T2DM, HbA1c ≥ 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 MagDI 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.

The study is ongoing, and all subjects will be followed to one year.

A total of ninety-one (91) subjects enrolled in the study with 90 receiving a completed study procedure at the time data closure for this interim report.

At the time of this report, 84 (92.3%) treated subjects have been followed to one month, 64 (70.3%) to three months, 31 (34.1%) to six months, and 14 (15.4%) to one year.

Demographic Characteristics

Baseline Characteristics (Consented)	40mm Magnet n=65	50mm Magnet n=26
Age		
Mean (SEM)	45.6 (1.2) years	44.1 (1.5) years
Min, Max	22, 61 years	34, 59 years
Gender		
Female: n (%)	43 (66.2%)	19 (73.1%)
Male: n (%)	22 (33.8%)	7 (26.9%)

Clinical Characteristics

Baseline Characteristics (Consented)	40mm Magnet n=65	50mm Magnet n=26
Body Weight: Mean (SEM)	98.3 (1.8) kg	102.3 (3.7) kg
Body Mass Index (BMI): Mean (SEM)	34.9 (0.5) kg/m^2	36.0 (1.2) kg/m^2
Type 2 Diabetes Mellitus: n (%)	24 (36.9%)	5 (19.2%)
HbA1c (%): Mean (SEM)	6.3 (0.2) %	5.7 (0.2) %
Glucose (mg/dL): Mean (SEM)	187.93 (15.5)	90.2 (2.9)
Prior Sleeve Gastrectomy (SG) or Endoscopic Sleeve Gastroplasty (ESG) ≥12 months: n (%)	45 (69.2%)	22 (84.6%)

Progression of Treated Subjects by Magnet Cohort

Study Visit	40mm Magnet	50mm Magnet	Total All Treated Subjects
Study Procedure (D0) n (%)	65 (100%)	26 (100%)	91 (100%)
One month (D30) n (%)	64 (98.5%)[a,b]	20 (76.9%)	84 (92.3%)
Three months (D90) n (%)	44 (67.7%)	20 (76.9%)	64 (70.3%)
Six months (D180) n (%)	24 (36.9%)	7 (26.9)	31 (34.1%)
One year (D360) n (%)	14 (21.5%)	0 (0%)	14 (15.4%)

[a]one subject withdrew consent after incomplete procedure; swallowed first Magnet and naturally progressed to cecum; procedure was completed; Magnet passed without issue

[b]one subject withdrew consent after D30 visit with move out of country; subject reconsented prior to D360 visit for anastomosis evaluation and safety check only; patent anastomosis and no issues

Primary Endpoint

Orogastric delivery (swallow and use of endoscopic Delivery System) and placement of the MagDI System was completed in 90 of the 91 enrolled subjects. In one case, the subject swallowed the first Magnet and was found to have naturally progressed to the cecum when laparoscopy was started. The procedure was not completed and Magnet passed naturally without issues. This subject withdrew consent following passage.

Performance of MagDI System

The MagDI System performance results are shown in **Table 5**. The MagDI System met performance success (≥ 80% of subjects meeting all 3 criteria) with n=81 subjects (n=61 40mm, n=20 50mm) confirmed of Magnet passage[a,b] prior to or at D90 study visit and confirmed patent anastomoses. Nine subjects continue to be followed for Magnet expulsion (3 40mm and 6 50mm devices).

Performance Criteria

Performance Criteria	40mm Magnet n=61	50mm Magnet n=20	Total n=81
Placement of the device with ≥90% alignment of Magnets	61 (100%)	20 (100%)	**81 (100%)**
Passage of the device without invasive re-intervention	61 (100%)	18(90.0%)[a,b]	**79 (97.5%)**[a,b]
Creation of a patent anastomosis confirmed radiologically	61 (100%)	19 (95.0%)[b]	**80 (98.8%)**[b]
Meets all 3 criteria:	**61 (100%)**	**18 (90.0%)**[a,b]	**79 (97.5%)**[a,b]

[a] In one case, the Magnets were successfully placed, the device created a patent anastomosis, and the Magnets dropped into and began movement through the intestines. The device was slow to progress on radiographic monitoring, though no adverse events occurred. The investigator made a clinical decision to remove the device via colonoscopy at day 93. No clinical issues or abnormalities were noted during movement of the device through the intestinal system or on colonoscopy (e.g., no ileus, obstruction, inflammation, bleeding, or signs of tissue interference), thus relationship to the device was assessed by the investigator as indeterminate and slow progression likely due to underlying low bowel motility.

[b] In one case (50mm Magnet), the patient presented to the emergency room (day 6); peritonitis was diagnosed, patient proceeded to surgery; non-study surgeon removed Magnets from anastomosis site prior to anastomosis creation. The subject withdrew from the study following removal, given no anastomosis, and records have not been made available to the investigator, so root cause of the peritonitis cannot be ascertained.

Safety

Adverse events were categorized according to the Clavien-Dindo Classification[1] grading system, a standard scale for ranking surgical complications based on deviation from a normal post-operative course, severity, and level of intervention required. Relationship to the study device (Magnet) and/or Study Procedure (including use of the Delivery System or Laparoscopic Positioning Device) was classified as *possible*, *probable*, *definite*, or *indeterminate*. Events assessed as *probable* or *definite* are categorized as "Related" for causality in this report and per protocol definition. The protocol defined a serious adverse event (SAE) based on the definition in *ISO 14155:2020* (i.e., event resulting in death, a life-threatening illness or injury, permanent impairment of a body structure or a body function, inpatient hospitalization, or prolongation of existing hospitalization).

A summary of adverse events is presented below:

Adverse Event Summary

Adverse Event (AE) Category	40mm Magnet (n=465)	50mm Magnet (n=26)	Total Treated (n=91)
Unique subjects with AEs – (n (% of Cohort))	36 (55.4%)	22 (84.6%)	58 (63.7%)
Total AEs – (n (% of Total AEs))	111 (60.3%)	73 (39.7)	184 (100%)
AEs Related to the Magnet (n (% of Cohort AEs))	1 (0.9%)	2 (2.7%)	3 (1.6%)
AEs Related to Procedure* (n (% of Cohort AEs))	54 (48.6%)	30 (41.1)	84 (45.6%)
SAEs – (n (% of Cohort AEs))	11(9.9%)	5 (6.8%)	16 (8.7%)

*None were determined related to the Delivery System or Laparoscopic Positioning Devices (MagDI System components)

[1]Clavien PA, Barkun J, deOliveira ML, Dindo D, et al. The Clavien-Dindo Classification of Surgical Complications: Five-Year Experience. Ann Surg. 2009; 250(2):187-196. doi: 10.1097/SLA.0b013e3181b13ca2

Adverse Events by Clavien-Dindo Classification Grading

Clavien-Dindo Classification	40mm Magnet (n=65)	50mm Magnet (n=26)	Total Treated (n=91)
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.	41 (36.9%)	43 (58.9%)	84 (45.6%)
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.	56 (50.5%)	20 (27.4%)	76 (41.3%)
Grade III: (n (% of Cohort AEs)) Requiring surgical, endoscopic, or radiological intervention.	14 (12.6%)	10 (13.7%)	24 (13.0%)
Grade IV: (n (% of Cohort AEs)) Life-threatening complication (including certain CNS complications) requiring Intermediate Care/Intensive Care Unit-management.	0 (0%)	0 (0%)	0 (0%)
Grade V: (n (% of Cohort AEs)) Death of a patient.	0 (0%)	0 (0%)	0 (0%)
TOTAL Adverse Events (AEs)	**111 (60.3%)**	**73 (39.7%)**	**184 (100%)**

Most of the adverse events (87.0%, 160/184) were low grade events (Grade I and II).

Three events (1.6%, 3/184) were assessed as related to the Magnet device by the investigator. The first event (40mm Magnet) was a case of duodenitis, assessed as related to both the device and the study procedure, and described in section 3.5.3 Serious Adverse Events. The second event (50mm Magnet) was reported as a duodenal ulcer covered with fibrin at the pyloric side at anastomosis, not determined serious, and was treated with medication and resolved without sequelae. The third event (50mm Magnet) was conservatively labeled as “failure of the device to expel”. The Magnet created a patent anastomosis and dropped from the site, was slow to progress through the intestines to the cecum, and a colonoscopy retrieval was performed on day 93 without issues.

Sixty-seven (36.4%, 67/184) events were gastrointestinal symptoms typical of the underlying intestinal diversion procedure (e.g., diarrhea, nausea, vomiting, pain, distention). Additionally, there were 36 (19.6%, 36/184) cases of mineral and vitamin deficiencies or other signs of malnutrition, also known risks of intestinal diversion procedures. One case of malnutrition resulted in reversal of the DI anastomosis

procedure.

In nine of the completed study procedures (10%, 9/90), serosal tears were reported as an adverse event. None of the serosal tears reached the level of an SAE. One intestinal tissue tear reached level of perforation and was reported as an SAE. All were determined related to use of the standard laparoscopic forceps used in the “grasp and slide” maneuver used to move the intraluminal Magnet and thus attributed to the study procedure.

Sixteen adverse events (8.7%, 16/184) met protocol criteria to be reported as a serious adverse event (SAE).

There were two internal hernias (2.2%, 2/90 completed procedures; one 40mm and one 50mm case) at the Petersen’s defect with associated complications, despite closure as required per protocol. This rate is similar to the study of the first generation all-metal MagDI System (32mm Magnet; GTM-001) where one case was reported despite closure of the defect per protocol (2.0%, 1/49). The occurrence does not appear related to Magnet length given one case has been reported for each size device.

Two cases of perforation at the anastomosis were reported, not related to the MagDI System. Both were considered iatrogenic by the investigators, attributed to manipulation of the endoscope through the anastomosis. In one case, torsion of the bowel caused a deformation of the anastomosis with inflammatory narrowing. The perforation was caused by insufflation (dilatation) and challenging navigation of the endoscope through the anastomosis.

The study included gastroduodenoscopy/endoscopy for evaluation of the anastomosis at regular intervals (i.e., Day 30, 60, or 90 following Magnet release and day 180 and day 360). The study did not collect data from these evaluations, rather investigators were to report adverse events if the anastomosis was not patent or required intervention. There were no other adverse events related to these study evaluations. The first MagDI System study with the all-metal Magnet (32mm; GTM-001) included one case of anastomosis perforation due to dilatation

of a stenotic anastomosis. The sponsor has included a warning in the IFU and training to not dilate a magnetic compression anastomosis to mitigate risks of perforation (or other defects) and bleeding.

There were no reports of bleeding, leakage, infection, or obstruction at the anastomosis site attributed to the Magnet device and no deaths.

CLINICAL PERFORMANCE TESTING CONCLUSION

The MagDI System (40mm and 50mm Magnets) performed safely and as intended to create patent magnetic compression anastomoses in the small bowel without incision to the intestines and leaving no foreign material behind (e.g., sutures or staples).

MagDI System Performs as Intended: The device was successfully placed in all completed procedures (100%, 90/90) with alignment of two Magnets (either as set of 40mm or 50mm devices). Eighty-one (81) of the subjects reached the performance endpoint as of this report. 97.5% (79/81) of the devices were expelled naturally without issue or intervention and created patent anastomosis. One procedure was reversed laparoscopically without issues due to malnutrition, severe weight loss, and symptoms, with the subject returning to daily activities and nutritional autonomy.

Robust safety profile: A total of 184 adverse events were reported in 58 (63.7%) unique subjects, with many experiencing none (36.3% 33/91). The majority of events were of low grade Clavien-Dindo I – II (87.0%, 160/184). No events reached grades IV or V (life-threatening complication or death) in a high-risk obese patient population and anastomosis created in the duodenum, the most challenging location in the small bowel. Two reports of perforation at the anastomosis were iatrogenic, attributed to insufflation and endoscopy manipulation and not device performance. The two internal hernias at the mesenteric defect (one in 40mm and one 50mm devices), despite closure at the procedure, are known risk factors for many laparoscopic and abdominal surgeries and not related to the Magnet device.

The MagDI System performed safely and as intended with no cases of anastomosis leakage, obstruction, or infection, all known and serious risks with conventional

techniques of suturing and stapling, and no mortality.

The safety profile is at least as strong as the literature reports with conventional anastomosis techniques the most serious risks of anastomotic bleeding (1%) or leaks (2.9% to 15.3%) (Buchberg, et al., 2011) (Bobkiewicz, et al., 2017).[2,3] These types of complications may require further surgical interventions (8.4%), increasing morbidity and mortality (Buchberg, et al., 2011).

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.

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[2] Buchberg, B. S. et al., 2011. The Use of a Compression Device as an Alternative to Hand-Sewn and Stapled Colorectal Anastomoses: Is Three a Crowd?. *Journal of Grastrointestinal Surgery,* pp. 304-310.

[3] Bobkiewicz, A. et al., 2017. Gastrointestinal tract anastomoses with the biofragmentable anastomosis ring: is it still a valid technique for bowel anastomosis? Analysis of 203 cases and review of the literature. *Int J Colorectal Dis,* pp. 107-111.

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. 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.

    Note: Rotate the magnetic tip of the Laparoscopic Positioning Device perpendicular (90º) 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 40 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. STORAGE

- **GT Metabolic DI Magnet:** Do not store the devices near magnetically attractive items or surfaces.
- **GT Metabolic Delivery System:** Store at room temperature only.
- **GT Metabolic Laparoscopic Positioning Device** (accessory): See Section 10 CLEANING INSTRUCTIONS FOR LAPAROSCOPIC POSITIONING DEVICE for the cleaning and sterilization instructions.

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 1**) 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 1. Sterilization Parameters

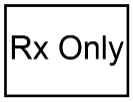
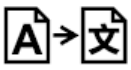
Cycle	Minimum Temperature	Minimum Exposure Time	Minimum Drying Time
Pre-vacuum (4 pulse) Conditioning Autoclave	132 °C	4 Minutes	30 Minutes

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 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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