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

Notice & Disclaimer

GT Metabolic Solutions, Inc. (GT Metabolic), shall not be liable for the errors contained herein. The information contained in this document is subject to change without notice.

Proprietary Statement

This document contains proprietary information, which is protected by copyright.

Copyright



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.

 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

**TABLE OF CONTENTS**

## 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 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 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 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.

WARNINGS, continued

- 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.

PRECAUTIONS, continued

- 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.

PRECAUTIONS, continued

- 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 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.

PRECAUTIONS, continued

- 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 following clinical study was performed with the GT Metabolic MagDI System (MAG-00(US), DS-00(US)) using 32mm Magnets to create a side-to-side duodeno-ileal magnetic compression anastomosis. The 32mm Magnet (MAG-00(US)) and 40mm Magnet (MAG-01), and 50mm Magnet (MAG-02) are all magnetic compression anastomosis devices.

### Table 1. Outline of the Clinical Study

| | |
|---|---|
| **Study Title** | Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic Solutions Magnetic Anastomosis System (MAGNET System) to Achieve Duodeno-Ileostomy Diversion in Adults with Obesity and with or without Type 2 Diabetes Mellitus: The MAGNET Study |
| **Protocol Number / NCT Number: GTM-001 / NCT05322122** | |
| **Study Design** | This is an operationally seamless, 2-stage, open-label, multicenter study enrolling up to 50 subjects at 5 study centers across Canada and Europe as follows:<br>• **Stage 1** first-in-human (FIH) and proof-of-concept with 5 subjects; and<br>• **Stage 2** feasibility with 45 subjects<br>• All subjects in Stage 1 and 2 are followed for 12 months. |
| **Study Population** | Adults (18 to 65 years of age, inclusive) with obesity (BMI 30-50) who meet one of the following criteria: (1) have type 2 diabetes mellitus (T2DM) or experienced weight regain following previous sleeve gastrectomy; (2) have T2DM without previous sleeve gastrectomy; or (3) are candidates for a laparoscopic single anastomosis duodenal-ileal bypass with sleeve (SADI-S) procedure and have BMI $\geq$ 40. |
| **Primary and Safety Endpoints** | **Primary: Feasibility/performance.** The side-to-side anastomosis duodeno-ileostomy will be considered feasible if results are successful at three months:<br>• Placement of the MAGNET System ($\geq$90% alignment of magnets); and<br>• Passage of magnets without surgical re-intervention; and<br>• Creation of a patent anastomosis confirmed radiologically.<br>**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 MagDI System for the intended use in patients indicated for a side-to-side duodeno-ileal anastomosis. Forty-nine (49) subjects were treated across four (4) centers in Belgium, Canada, Republic of Georgia, and Spain.

Twenty-five subjects (51%, 25/49) received the study treatment only and 24 subjects (49%, 24/49) received the study treatment followed by a sleeve gastrectomy (SG)

performed using standard practices at the institution (non-study procedure). Forty-two subjects (86%) have been followed to six months, 38 (78%) to nine months, and over half of the subjects (53%) to one year for study completion as of the date of data closure for the report (August 28, 2023). Tables 2 and 3 shows the subject demographics and clinical characteristics respectively.

**Table 2. Demographic Characteristics by Procedure Cohort**

| Characteristic | MagDI System Procedure Only subjects (n=25) | MagDI System Procedure + SG (n=24) | All subjects (n=49) |
|---|---|---|---|
| **Age (Years)** | | | |
| Mean (SD) | 44.2 (7.9) | 43.8 (9.0) | 44.0 (8.4) |
| Min, Max | 28 years, 57 years | 28 years, 59 years | 28 years, 59 years |
| **Gender n (%)** | | | |
| Female | 24 (96%) | 20 (83%) | 44 (90%) |
| Male | 1 (4%) | 4 (17%) | 5 (10%) |
| **Race n (%) – patient self-report** | | | |
| Caucasian | 24 (96%) | 18 (75%) | 42 (86%) |

It is notable that the study enrolled a subject cohort that consisted mostly of Caucasian and female participants. Based on this limited representation, there is moderate uncertainty of device efficacy when used in the targeted U.S. patient population.

**Table 3. Baseline Clinical Characteristics by Procedure Cohort**

| Characteristic | MagDI System Procedure Only Subjects (n=25) | MagDI System Procedure + Sleeve Gastrectomy (n=24) | All Subjects (n=49) |
|---|---|---|---|
| **Weight (kg) Mean (SD)** | 104.7 (21.1) | 122.0 (16.2) | 113.1 (20.6) |
| **Body Mass Index ($kg/m^2$) Mean (SD)** | 39.7 (6.4) | 44.4 (3.7) | 42.0 (5.7) |
| **Type II Diabetes Mellitus n (% of Cohort)** | 1 (4.0%) | 9 (37.5%) | 10 (20.4%) |

### Study Procedure

A side-to-side compression anastomosis with the MagDI System (study procedure) was performed for all 49 subjects to establish a duodeno-ileostomy for partial intestinal diversion. Under general anesthesia, two (2) Magnets were sequentially placed using the

Delivery System through a flexible endoscope; the first (distal) Magnet was placed at the ligament of Treitz, and the second (proximal) Magnet into the proximal duodenum.

Laparoscopic Positioning Devices and standard laparoscopic instruments were used to move the distal Magnet from the ligament of Treitz to the intended position in the ileum, 250 cm from the ileocecal valve, and manipulate the proximal Magnet to the correct position in the duodenum. This specific measurement for the anastomosis was based on the clinical literature and standardized to control for the underlying duodeno-ileal diversion procedure in which a side-to-side anastomosis is indicated in the small bowel. Laparoscopic instruments were used to lift the ileum loop with intraluminal distal Magnet to meet the proximal Magnet in the duodenum enabling the Magnets to connect (or dock) via polar attraction of the devices through the intestinal walls. The study protocol also included closure of the mesentery defect to standardize the surgical procedure and mitigate potential risk of internal hernia and intestinal obstruction, known risks for laparoscopic and open abdominal surgeries.

**Primary Effectiveness Endpoint**

The MagDI System was successfully placed in all 49 (100%) attempted study procedures with alignment (docking of the Magnets together). In one case, placement required an enterotomy due to intestinal malrotation, and Magnets were placed successfully. No adverse events were reported related to this placement. The protocol included instructions for such placement as risk mitigation.

Creation of a patent anastomosis was confirmed radiographically in 100% of the subjects. The device passed successfully in natural bowel movements for all (100%, 49/49) subjects, and none (0%) required invasive re-intervention.

The MagDI System successfully met feasibility/performance criteria pre-defined in the protocol for all (100%, 49/49) subjects as shown in Table 4.

**Table 4. Feasibility/Performance Criteria**

| Protocol Feasibility/Performance Criteria | n (%) |
|---|---|
| Placement of the device with ≥90% alignment of Magnets | 49 (100%) |
| Passage of the device without invasive re-intervention | 49 (100%) |
| Creation of a patent anastomosis confirmed radiologically | 49 (100%) |

The median hospital stay post procedure was 2 days (n=49; mean 3.5 days (SD 6.4 days)) for all subjects. The post-procedure stay was shorter for those subjects receiving the study procedure only, with a median of 1 day (n=25; mean 1 day (SD 0.3 days)) compared to the cohort receiving the study procedure plus a concurrent non-study sleeve gastrectomy with a median of 3.5 days (n=24; mean 6 days (SD 8.4 days)).

The time to device expulsion (days from study procedure to passage of the device (naturally in bowel movements) in all subjects ranged from 14 to 93 days with a median of 41 days (n=49; mean 46.7 days (SD 23.1 days). Subjects were trained to examine their stools for passage of the device and report the date of expulsion to the study investigator. Two of the subjects indicated they did not know the device had passed as they did not feel it, but passage was confirmed through imaging. Imaging to confirm passage of the device was conducted for all to ensure no Magnets remained in any subject.

The devices retrieved from the first-in-human cases after passing were visually inspected for signs of damage and photos taken of each device. The expelled devices had indications of usage, such as minor scratches and discoloration of the metal, but were generally in good condition. One (1) Magnet had visual evidence of approximately 2mm of the nitinol core wire sticking through the polyester fibers of the suture loop. The wire did not extend beyond the edge of the outer titanium housing. The subject passed this Magnet naturally and reported no adverse events (e.g., abrasions, bleeding, pain), indicating that no tissue was damaged in the subject. During the clinical study, the subject underwent x-ray examinations per protocol and there were no reports that the wire protruded at that time. The most likely explanation is that the suture was damaged ex vivo during one of the cleaning or shipping processes, which is beyond the life cycle

of the device. Based on this information, it appears that the device does not have unintended erosions of the material during its transit through the gastrointestinal tract.

The median expulsion time for the subjects receiving only the study procedure (no concurrent sleeve gastrectomy) was 38 days (n=25; mean 44 days (SD 24.2 days)). For those subjects receiving the study procedure followed by a sleeve gastrectomy (non-study), the median was 51.5 days (n=24; mean 49.7 days (SD 22 days)).

**Safety Endpoints**

A total of 89 adverse events were reported in 33 unique subjects, comprising 34 grade I (38.2%), 36 grade II (40.4%), and 19 grade III (21.3%) events on the standard Clavien-Dindo Classification grading system for ranking surgical complications and no events (0%) reaching grades IV or V (life-threating complication or death). Most adverse events (84.2%, 75/89) were reported in subjects receiving the study procedure followed immediately by a sleeve gastrectomy (non-study procedure). Fourteen events (15.7%, 14/89) occurred in subjects receiving only the study procedure. Table 5 presents a summary of adverse events.

**Table 5. Adverse Event Summary**

| Study Time Period (n subjects followed) | MagDI System Procedure Only (n=25) | MagDI System Procedure + SG (n=24) | All Subjects (n=49) |
|---|---|---|---|
| **Unique subjects with AEs –** (n (% of Cohort)) | 10 (40.0%) | 23 (95.8%) | 33 (67.3%) |
| **Total AEs –** (n (% of Total AEs)) | 14 (15.7%) | 75 (84.2%) | 89 (100%) |
| **AEs Related to the Magnet** (n (% of Total AEs)) | 0 (0%) | 0 (0%) | 0 (0%) |
| **AEs Related to Procedure*** (n (% of Total AEs)) | 4 (4.5%) | 32 (36%) | 36 (40.4%) |
| **SAEs –** (n (% of Total AEs)) | 4 (4.5%) | 10 (11.2%) | 14 (15.7%) |

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

All AEs are summarized in Table 7 using the Clavien-Dindo Classification grading system for ranking surgical complications based on deviation from a normal postoperative course, severity, and level of interventions required.

Nineteen adverse events (21.3%, 19/89) were grade III Clavien-Dindo, requiring surgical intervention. None were determined related to the Magnets and eleven (12.3%, 11/89) assessed as related to the study procedure. Seven (7) of these were serosal tissue tears observed prior to closing the surgical procedure with none reaching the level of a serious adverse event (SAE). These events were determined related to the use of standard laparoscopic bowel forceps to manipulate the intestines during the grasp (grasping the bowel) and slide (sliding the intraluminal Magnet with the Laparoscopic Positioning Device) maneuver to move the distal Magnet to the desired position in the ileum; all were repaired at the time of the surgical procedure with no additional sequelae. None were attributed to the Laparoscopic Positioning Device. These events were conservatively assigned as grade III given; they may have required surgical intervention to repair if they had not been repaired prior to closing the study procedure. The additional two (2) grade III events included a jejunal intestinal obstruction (at the mesenteric defect despite surgical closure as per protocol) and a pelvic collection, both qualified as SAEs and are further described in Table 6 below.

Seventy-five of all the adverse events (84.2%, 75/89) occurred in the cohort receiving the study procedure plus a concurrent sleeve gastrectomy (non-study procedure) and 95.8% (23/24) of the subjects in this group experienced at least one adverse event. The study procedure only cohort (no concurrent sleeve gastrectomy) had fewer adverse events overall (16.1%, 14/87) and 40% (10/25) experienced an adverse event.

Given the possible challenges in determining device-relatedness for a given adverse event, the Sponsor has identified the following potential risks that may be associated with the use of the subject device:

- Bowel obstruction
- Ileus
- Inability to maneuver or couple magnets
- Inability to retrieve magnets
- Inability to disconnect catheter from magnet and/or fracture of connecting elements
- Inability to visualize anatomical structures by endoscopy/laparoscopy

- Migration of the magnets
- Decoupling of the magnets
- Anastomotic leak
- Bleeding
- Peri-operative infection
- Laceration/perforation of the GI tract
- Scarring
- Stenosis
- Need for extended or additional surgery, including enterotomy
- Ulceration
- Abdominal distension
- Abdominal pain
- Internal hernia
- Constipation
- Nausea
- Vomiting
- Tissue damage
- Adverse tissue reaction
- Foreign body response
- Potential for hospitalization
- Potential for death

**Serious Adverse Events**

Fourteen of all adverse events (15.7% 14/89) met criteria to be reported as a serious adverse event (SAE) as defined by the protocol (i.e., death, life-threatening, permanent impairment, inpatient hospitalization, or prolongation of hospitalization).

None of the SAEs were determined related to the MagDI System components (Magnets, Delivery System, Laparoscopic Positioning Device). Four SAEs (4.5%, 4/89) were determined to be related to the study procedure. One event was a jejunal obstruction due to an internal hernia in the mesentery, despite the closure of the mesenteric defect by the investigator as per study protocol. Laparoscopic repair was performed, and the subject was discharged the following day without sequelae. The

second event was a case of pelvic fluid collection of unknown etiology that continued for two months. The subject recovered in good general condition following two transvaginal drainage procedures. The third and fourth together presented in a single subject as a clinically asymptomatic anastomotic stricture identified at endoscopy at the 6 month follow up. Endoscopic balloon dilatation was performed that resulted in an iatrogenic perforation. This was treated with surgical closure of the duodeno-ileal anastomosis, and the subject recovered without further sequelae.

There were no reports of bleeding, leakage, or infection at the anastomosis site and no deaths. All SAEs are presented in Table 6 by relatedness (adjudicated as definitely or probably related to Magnet / study procedure) and Clavien-Dindo Classification grade.

**Table 6. Serious Adverse Events by Relatedness, Severity, and Clavien-Dindo Grade**

| Number | Adverse Event/Diagnosis/Syndrome | Definitely /Probably Related to Device (Y/N) | Definitely /Probably Related to Procedure (Y/N) | Clavien-Dindo Grade | Percentage of total subjects |
|---|---|---|---|---|---|
| 1 | Jejunal intestinal obstruction | N | Y | III | 2% (1/49) |
| 2 | Stricture | N | Y | III | 2% (1/49) |
| 3 | Iatrogenic perforation from endoscopic stricture balloon dilatation | N | Y | III | 2% (1/49) |
| 4 | Pelvic Collection | N | Y | III | 2% (1/49) |
| 5 | Anorexia with diarrhea, nausea and vomiting | N | N | II | 2% (1/49) |
| 6 | Dehydration | N | N | II | 2% (1/49) |
| 7 | Kidney Stones | N | N | III | 2% (1/49) |
| 8-9 | Cholecystitis | N | N | III | 4% (2/49) |
| 10 | Cholecystitis with choledocholithiasis | N | N | III | 2% (1/49) |
| 11 | Menorrhagia with anemia | N | N | II | 2% (1/49) |
| 12 | Major pneumoperitoneum on gastric fistula | N | N | III | 2% (1/49) |
| 13 | Abdominal pain and nausea and vomiting | N | N | III | 2% (1/49) |
| 14 | Peri-anal abscess, gangrene | N | N | III | 2% (1/49) |

The MagDI System performed safely and as intended to create patent side-to-side duodeno-ileal anastomoses in 100% of 49 subjects. There were no reports (0%) of anastomotic bleeding, leakage, or infection, and no mortality. These clinical data, with over half of the subjects followed to one year, demonstrates an adverse event profile as safe as conventional anastomosis techniques with no reports of the most common anastomotic risks seen with enterotomy and sutures or staples.

**Additional Clinical Testing (MagDI System, 40mm Magnet)**

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

The MagDI System was successfully placed and created patent anastomose in all cases. The overall safety profile of the second Magnet device (K242086) was similar to the first Magnet device (DEN240013). The adverse event profile across the two studies (and by procedure cohort with or without a concurrent non-study SG) is presented in Table 7.

Three adverse events (6.5%, 3/46) met protocol criteria to be reported as a serious adverse event (SAE). One event was confirmed food poisoning with associated symptoms. The second event was a series of symptoms and signs (diarrhea, vomiting, hypovolemia, hypokalemia) following Magnet expulsion, with negative *C. difficile* fecal tests. The third SAE was a case of duodenitis at day 20 following study procedure and the day after the Magnet device was naturally expelled (day 19). The patient presented with epigastrium pain and one episode of vomiting and was hospitalized. CT revealed swelling of the pylorus and moderate delayed gastric emptying, with no abnormalities at the anastomosis or adjacent fluid or free gas. The patient was empirically treated with

antibiotics, but no specific infection was found at or near the anastomosis site. The subject recovered without sequelae. Compression anastomosis with healing and remodeling of tissue around devices following necrosis of central tissue is well described in the literature.[1] Additionally, inflammation with creation/healing of anastomosis and symptoms are commonly experienced, regardless of the anastomosis technique used (i.e., compression or incision and sutures or staples). This event was conservatively assigned as related to both the Magnet device and study procedure. An independent data safety monitoring board (DSMB) reviewed the event and determined no safety concerns. This patient was followed to one year for study completion with a patent anastomosis. Nonetheless, the potential risk of duodenitis has been added to the label in **Section 7**.

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

**Additional Clinical Testing (MagDI System, 50mm Magnet)**

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

The device was expelled naturally in most (88.9%, 8/9) of the subjects reaching one month follow up as a paired set of docked Magnets and confirmed by imaging. Expulsion based on subject self-report (or worst-case X-ray confirmation of device absence) averaged 32 days. The device, after creating a patent anastomosis and naturally advancing slowly through the small bowel, was removed by colonoscopy on

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

day 93 without issues or signs of blockage or bowel abnormalities. This is the only case to date across the MagDI System devices (32mm, 40mm, 50mm) resulting in a clinical decision to extract the device or failure to expel.

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

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

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

**Table 7** provides a summary of adverse events across the MagDI System family.

**Table 7. MagDI System (32mm, 40mm, 50mm Magnets) Adverse Event Summary**

| **Clavien-Dindo Classification** | **MagDI System (32mm Magnet)** | | | **MagDI System (40mm Magnet)** (n=27) | **MagDI System (50mm Magnet)** (n=13) |
|---|---|---|---|---|---|
| | **MagDI System Procedure Only** (n=25) | **MagDI System Procedure + SG** (n=24) | **All** Subjects (n=49) | | |
| **Grade I: (n (%))** Deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Antiemetics, antipyretics, analgesics, diuretics and electrolytes, and physiotherapy allowed. | 5 (35.7%) | 29 (39.7%) | 34 (39.1%) | 24 (52.2%) | 11 (47.8%) |
| **Grade II: (n (%))** Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition included. | 3 (21.4%) | 33 (45.2%) | 36 (41.4%) | 16 (34.8%) | 8 (34.8%) |
| **Grade III: (n (%))** Requiring surgical, endoscopic, or radiological intervention. | 6 (42.8%) | 11 (15.1%) | 17 (19.5%) | 6 (13.0%) | 4 (17.4%) |

| Clavien-Dindo Classification | MagDI System (32mm Magnet) | | | MagDI System (40mm Magnet) (n=27) | MagDI System (50mm Magnet) (n=13) |
|---|---|---|---|---|---|
| | MagDI System Procedure Only (n=25) | MagDI System Procedure + SG (n=24) | All Subjects (n=49) | | |
| **Grade IV: (n (%))** Life-threatening complication (including certain CNS complications) requiring Intermediate Care/Intensive Care Unit-management. | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| **Grade V: (n (%))** Death of a patient. | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| **TOTAL Adverse Events** | **14 (100%)** | **73 (100%)** | **87 (100%)** | **46 (100%)** | **23 (100%)** |

# 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. 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 (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

**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.

**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.

**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.

## 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**

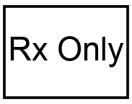
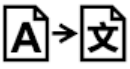
| Cycle | Minimum Temperature | Minimum Exposure Time | Minimum Drying Time |
|---|---|---|---|
| Pre-vacuum (4 pulse) Conditioning Autoclave | 132 °C | 4 Minutes | 30 Minutes |

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 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