GT Metabolic

Summary of Safety and Clinical Performance (SSCP)

GT Metabolic™ Magnet System

Component Devices:

GT Metabolic Magnet

GT Metabolic Delivery System

GT Metabolic Laparoscopic Positioning Device

Accessory Device: GT Metabolic Magnetic Retrieval Device

REF

GT Metabolic Magnets:

MAG-01 (40mm), MAG-02 (50mm), MAG-04 (60mm), MAG-05 (70mm)

GT Metabolic Delivery System:

DS-01

GT Metabolic Laparoscopic Positioning Devices:

PD-12, PD-18, PD-21, PD-24, PD-27

GT Metabolic Magnetic Retrieval Device

MRD-02

Table of Contents

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to the intended users or patients.

Following this information in Appendix A. there is a summary intended for the patient.

Device Identification and General Information

Device Trade Name

GT Metabolic™ Magnet System

GT Metabolic™ Magnet System Component Devices	
GT Metabolic™ Magnet System Component Device	Model Number
GT Metabolic Magnet, 40mm	MAG-01
GT Metabolic Magnet, 50mm	MAG-02
GT Metabolic Magnet, 60mm	MAG-04
GT Metabolic Magnet, 70mm	MAG-05
GT Metabolic Delivery System	DS-01
GT Metabolic Laparoscopic Positioning Device, 12	PD-12
GT Metabolic Laparoscopic Positioning Device, 18	PD-18
GT Metabolic Laparoscopic Positioning Device, 21	PD-21
GT Metabolic Laparoscopic Positioning Device, 24	PD-24
GT Metabolic Laparoscopic Positioning Device, 27	PD-27
Accessory Device:	
GT Metabolic Magnetic Retrieval Device	MRD-02

Manufacturer's Name and Address

GT Metabolic Solutions, Inc. ("GT Metabolic") with manufacturing location at:
5450 Quam Ave NE, Suite 100
St. Michael, MN 55376 USA

Manufacturer's Single Registration Number (SRN)

SRN: US-MF-000032479

Basic UDI-DI

GT Metabolic™ Magnet System Component Device	Model Number	Basic UDI-DI
GT Metabolic Magnet, 40mm	MAG-01	0850054216MAGXW
GT Metabolic Magnet, 50mm	MAG-02	
GT Metabolic Magnet, 60mm	MAG-04	
GT Metabolic Magnet, 70mm	MAG-05	
GT Metabolic Delivery System	DS-01	0850054216DS8N

GT Metabolic™ Magnet System Component Device	Model Number	Basic UDI-DI
GT Metabolic Laparoscopic Positioning Device, 12	PD-12	
GT Metabolic Laparoscopic Positioning Device, 18	PD-18	
GT Metabolic Laparoscopic Positioning Device, 21	PD-21	0850054216PD8U
GT Metabolic Laparoscopic Positioning Device, 24	PD-24	
GT Metabolic Laparoscopic Positioning Device, 27	PD-27	
Accessory Device:		
GT Metabolic Magnetic Retrieval Device	MRD-02	00850054216MRDZB

Global Medical Device Nomenclature (GMDN)

GT Metabolic™ Magnet System Component Device	GMDN Code and Description
GT Metabolic Magnets	H0299: Mechanical Surgical Staplers - Other
GT Metabolic Delivery System	G030899: Instruments for Gastro-Intestinal Endoscopy and Eco-Endoscopy, Single-Use- Other
GT Metabolic Laparoscopic Positioning Device	L1299: Laparoscopic and Thoracoscopic Surgery Instruments, Reusable – Other
Accessory Device:	
GT Metabolic Magnetic Retrieval Device	G030899: Instruments for Gastro-Intestinal Endoscopy and Eco-Endoscopy, Single-Use - Other

Device Classification

The GT Metabolic™ Magnet System is a Class IIb device.

GT Metabolic™ Magnet System Component Device	Class	Rule
GT Metabolic Magnets	IIb	8
GT Metabolic Delivery System	Is	5
GT Metabolic Laparoscopic Positioning Device	Ir	6
Accessory Device:		
GT Metabolic Magnetic Retrieval Device	Is	5

Year of First Certificate (CE) Issued

2025 – GT Metabolic Delivery System, GT Metabolic Laparoscopic Positioning Device
2026 – GT Metabolic™ Magnet System, GT Metabolic Magnetic Retrieval Device

Authorized Representative (Name and SRN)

MedEnvoy Global B.V.
Prinses Margrietplantsoen 33
Suite 123, 2595 AM
The Hague, The Netherlands
SRN: NL-AR-000024028

Notified Body (NB) Name and Single Identification Number (SRN)

BSI Group The Netherlands B.V. (Registration Number: 33264284)
Say Building, John M. Keynesplein 9
1066 EP Amsterdam, The Netherlands

INTENDED USE OF THE DEVICE

Intended Purpose

The GT Metabolic Magnet System is intended for use in the creation of side-to-side gastrointestinal anastomoses (enteroenterostomy (40mm, 50mm) and gastroenterostomy (60mm, 70mm)) in minimally invasive and laparoscopic surgery. Once wound strength is sufficient to maintain the anastomosis, the device is passed from the body.

Indications for Use and Intended Patient Population

The GT Metabolic Magnet System is intended for use in the creation of side-to-side gastrointestinal compression anastomosis (enteroenterostomy (40mm, 50mm) and gastroenterostomy (60mm, 70mm) in minimally invasive and laparoscopic surgery. The device is a surgical tool with application in metabolic and bariatric surgical procedures.

Intended Patient Population

The GT Metabolic Magnet System is intended for use in adult patients indicated for a side-to-side enteroenterostomy or gastroenterostomy with delayed patency as determined by the treating surgeon.

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 (entero-enterostomy) and/or stomach (gastro-enterostomy) with delayed patency.
- Do not use the devices if the intended segments of the small bowel and/or stomach 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 (poly glycolic-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.

DEVICE DESCRIPTION

General Description

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

- Individually packaged GT Metabolic Magnet ("Magnet") devices designed to be used as a set of two (2) of the same size (40mm (MAG-01), 50mm (MAG-02), 60mm (MAG-04), and 70mm (MAG-05)). The 40mm and 50mm Magnet variations are intended for use in the small bowel (i.e., entero-enterostomy, including the duodenum, jejunum, and/or ileum segments). The 60mm and 70mm Magnet variations are intended for use in the stomach and small bowel (i.e., gastro-enterostomy).
- The Magnets are single use. Each GT Metabolic Magnet, across variations, is composed of the following materials, listed by percentage:

Component	Percent of Material (Volume)
Titanium Housing	46.7%
Magnet Core	35.9%
PGLA Flange	17.2%
SS Spring	0.2%

- GT Metabolic Delivery System ("Delivery System"): a flexible orogastric catheter used to endoscopically deliver a Magnet. The Delivery System is single use.
- GT Metabolic Laparoscopic Positioning Device ("Laparoscopic Positioning Device"): 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 small bowel. The Laparoscopic Positioning Devices are reusable and are provided non-sterile. For cleaning and sterilizing instructions prior to use, refer to section 13. CLEANING INSTRUCTIONS FOR LAPAROSCOPIC POSITIONING DEVICE.

Reference to Previous Generations of the Device

The first-generation GT Metabolic Magnet System for side-to-side duodeno-ileal compression anastomosis was commercially authorized by the USA Food and Drug Administration (FDA) in July 2024 (DEN240013). This first-generation Magnet System has not been marketed and is not available in any geography.

Description of Accessories

The GT Metabolic Magnet System may be used with the GT Metabolic Magnetic Retrieval Device (MRD) accessory.

Device Name	Model Number	Instructions for Use
GT Metabolic Magnetic Retrieval Device	MRD-02	3117-1

MRD Accessory Description

The GT Metabolic Magnetic Retrieval Device (MRD) is an endoscopic tool used for the retrieval of a GT Metabolic Magnet within the gastrointestinal (GI) tract. The MRD consists of a long, flexible shaft with a magnetic distal tip that is introduced through the working channel of an endoscope. Once advanced to the target location, the MRD utilizes magnetic attraction to capture the Magnet, facilitating its retrieval from the body.

MRD Accessory Intended Use

The GT Metabolic Magnetic Retrieval Device (MRD) is intended for endoscopic use to magnetically attract, capture, and retrieve a GT Metabolic Magnet from the gastrointestinal (GI) tract.

MRD Accessory Endoscope Compatibility

The GT Metabolic Magnetic Retrieval Device (MRD) is compatible with endoscopes featuring a working channel diameter of 2.8mm or larger and a working length less than 200cm. Do not attempt to use the device with endoscopes that have smaller working channel diameters, as this may result in device malfunction or damage.

Description of Other Devices Intended to be Used in Combination

The GT Metabolic Magnet System is system of device components - the GT Metabolic Magnet, the GT Metabolic Delivery System, and the GT Metabolic Laparoscopic Positioning Devices. The GT Metabolic Magnet System is not intended or designed to physically or wirelessly connect with any other devices or equipment outside of the system to achieve its intended use. However, as endoscopic/laparoscopic devices:

- The GT Metabolic Delivery System is compatible with endoscopes featuring a working channel diameter of 2.8mm or larger and a working length less than 200cm.
- The GT Metabolic Laparoscopic Positioning Devices are compatible with 10mm laparoscopic trocars or larger.

Risks and Warnings

Residual Risks and Undesirable Effects

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

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.

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 Magnet System is designed to use two (2) Magnets to create each side-to-side anastomosis.
- Only use two GT Metabolic Magnet devices of the same length to create a magnetic compression anastomosis (either two 40mm (MAG-01), two 50mm (MAG-02), two 60mm (MAG-04), or two 70mm

(MAG-05) devices) to support proper device alignment and compression and mitigate risk of device migration.

- The Magnet System with two 40mm or two 50mm Magnets is intended to be used for entero-enterostomy in the small bowel; these devices have not been clinically tested in gastric tissue.
- The Magnet System with two 60mm or two 70mm Magnets has been clinically tested and are intended for use in the stomach and small bowel (i.e., gastro-enterostomy).
- Do not use the Magnet System if any component is cracked, broken, chipped, or otherwise appears damaged.
- The Laparoscopic Positioning Devices are provided non-sterile and must be sterilized prior to use according to the Instructions for Use (IFU) section 13. CLEANING INSTRUCTIONS FOR LAPAROSCOPIC POSITIONING DEVICE.
- 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.
- When a Magnet is placed in the duodenum for the 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).
- Warning is indicated to not dilate the magnetic compression anastomosis to mitigate risks of perforation (or other defects) and bleeding.
- Do not remove the Magnets prior to 14 days, unless medically required, to allow sufficient tissue remodeling for anastomosis stability and mitigate risks of bleeds or leaks.
- To minimize the risk of unintended interference, other medical electronic devices (e.g., hormone infusion pumps) should be kept at least 2.5 inches away from a single Magnet (any size) and 3.0 inches away from paired (docked) Magnets per International Commission on Non-Ionizing Radiation Protection (ICNIPR) guidelines. At this distance, the static magnetic field strength is at or below 5 Gauss (0.5mT) and is not expected to adversely affect the operation of other medical devices. Use of Magnets in a person with an implanted pacemaker, defibrillator, and/or other implantable electrical devices is contraindicated.
- 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.

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 Magnet System in case of narrowing, obstruction, or other abnormalities distal to the anastomosis which may prevent expulsion of the Magnets.
- The devices should only be used by physicians who have experience in performing gastrointestinal anastomosis procedures and are experienced with endoscopic and laparoscopic surgery.
- The Magnets and Delivery System are provided sterile. Each package should be inspected to ensure package integrity prior to use. Do not use the device if sterility or integrity of the device or any component is suspect.
- Inspect Magnets, Delivery System, and Laparoscopic Positioning Devices prior to use for possible damage or defects. Any damaged or defective component should not be used and should be returned to the manufacturer.
- Use care in handling of the Magnets. Store the devices away from magnetically attractive items and surfaces when opened according to section 12. 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 in the small bowel. 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.
- 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., GT Metabolic Magnetic Retrieval Device (MRD-02), Steris Healthcare Roth Net® Retriever, Olympus EndoJaw Biopsy Forceps #FB-210U).
- Intestinal enterotomy and/or gastrotomy 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.
- 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 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 an additional gastric surgical procedure at the same time as the side-to-side anastomosis procedure, it is recommended that the Magnets be placed first followed by the gastric procedure to reduce potential stress that could arise from putting the Delivery System through the stomach following the gastric surgical procedure.
- Patients should be monitored, including use of X-rays at the physician's discretion, 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.

Other Relevant Safety Aspects (Including any Field Safety Corrective Action)

Not applicable.

SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

Summary of Clinical Data Related to Equivalent Device

Not applicable.

Summary of Clinical Data from Conducted Investigations Pre CE-marking

The GT Metabolic Magnet System is intended for use in the creation of side-to-side gastrointestinal anastomoses (entero-enterostomy (40mm, 50mm) and gastro-enterostomy (60mm, 70mm)) 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 performance of the devices for the intended use.

GT Metabolic Magnet System (40mm, 50mm)

A clinical study was performed with the GT Metabolic Magnet 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 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 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):
    - 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.
    - 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 Cohort AEs)	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 mean hospital stay was 1.3 days, given a minimally invasive approach with no incision made to bowel.

GT Metabolic Magnet System (60mm, 70mm, 80mm)

A clinical study was performed with the GT Metabolic Magnet System [Magnet (60mm, MAG-04), Magnet (70mm, MAG-05), Magnet (80mm, MAG-03), 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.

[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.

The outline of the study is as follows:

Study Title	Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic Magnet System, GJ Biofragmentable to achieve Gastro-Ileal or Gastro-Jejunal Diversion in Adults with Obesity "Clinical Study"
Study Design	Prospective, single arm, multi-center study across four regions (Canada, Portugal, United Arab Emirates, and Chile) and followed to one year. (ClinicalTrials.gov: NCT06073457)
Study Population	Adults (18 to 65 years of age, inclusive) with obesity (BMI 30-50 kg/m^2) and are candidates for a gastro-enterostomy (gastro-ileal or gastro-jejunal anastomosis) for intestinal diversion. Note: all subjects received a gastro-ileostomy.
Primary Performance and Safety Endpoints	• Primary Performance Endpoint. The side-to-side anastomosis gastro-enterostomy 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.

The primary endpoint in this Clinical Study was defined the same as the in the clinical testing of the Magnet System using the 40mm and 50mm Magnets for enteroenterostomy. Clinical 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=46 treated subjects. Forty-four (44) individual subjects met all three criteria (95.6%, 44/46) resulting in primary endpoint performance success for the GT Metabolic Magnet System.

Magnet System (80mm, 70mm, 60mm Magnet) Performance Criteria

Performance Criteria	80mm Magnet n=7	70mm Magnet n=16	60mm Magnet n=23	TOTAL N=46
Placement of the device with ≥90% alignment of Magnets	7 (100%)	16 (100%)	23 (100%)	46 (100%)
Passage of the device without invasive re-intervention	7 (100%)	15 (93.8%)[a]	22 (95.6%)[b]	44 (95.6%)[a,b]
Creation of a patent anastomosis	7 (100%)	16 (100%)	23 (100%)	46 (100%)
SUCCESS: Meets ALL Performance Criteria	**7 (100%)**	**15 (93.8%)**	**22 (95.6%)**	**44 (95.6%)**

[a] In one case (70mm Magnets), the Magnets created a patent anastomosis, but the connect devices remained at the site. The patient experienced no clinical adverse effects. The set of connected devices was retrieved endoscopically without issue at day 168; no anastomosis or significant clinical issues were identified through one-year follow up.

[b] In the second case (60mm Magnets), the Magnets dropped and were visible on X-ray to have progressed approximately to the cecum. The patient experienced no clinical adverse effects. The connected devices were

removed successfully by colonoscopy on day 92 without clinical issues; follow-up endoscopy revealed a patent anastomosis of good size (approx. 15mm).

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. Approximately forty percent (39.1%, 18/46) 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=18) 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 (All Magnets -80mm, 70mm, 60mm) Expulsion Time

Expulsion Time (days)	All Magnets Self-report n=18[a]	All Magnets Self-report or Imaging Confirmation n=44[a]
Median	34 days	36 days
Mean (SEM)	37.7 days	44.2 (1.3) days
Range Min, Max	14, 71 days	14, 99 days

[a]Two subjects had Magnets retrieved versus natural expulsion, as previously described.

A total of 110 adverse events for all follow up were reported in 38 unique subjects (82.6% incidence, 38/46) with 14 events classified as serious (23.9% SAE incidence, 11/46). Only event, an SAE at day 9 post study procedure, was assessed as related to the Magnet device (2.2% incidence, 1/46). In the 30-day post-operative period, a total of 43 adverse events were reported in 29 unique subjects (63.0% incidence, 29/46) with four (4) events classified as an SAE (8.7% incidence, 4/46).

Three events (6.5% incidence, 3/46) were assessed as related to the Magnet device as described below with only one event qualifying as serious (SAE). The other two events were non-serious cases of non-expulsion. In both cases, the subjects had no clinical events, and the devices were retrieved successfully with minimally invasive techniques (endoscopy and colonoscopy) and no sequelae.

Thirty-six (36) 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, infection or obstruction and no mortality in all (n=46) follow up with 17 of the subjects (37.0%, 17/46) followed to one year. There was one report of a tear at the anastomosis that resulted in a leak and peritonitis (2.2% incidence, 1/46).

Magnet System (80mm, 70mm, 60mm Magnet) Adverse Event Summary

Adverse Event (AE) Category	80mm Magnet (n=7) All follow	70mm Magnet (n=16) All follow	60mm Magnet (n=23) All follow	Total Magnets (N=46) All follow	Total Magnets (N=46) 30-days Post operative
Unique subjects with AEs – n (% of Total Cohort Subjects)	7 (100%)	11 (68.8%)	23 (100%)	38 (82.6%)	29 (63.0%)
Total AEs – n (% of Total Cohort AEs)	31 (100%)	28 (100%)	51 (100%)	110 (100%)	43 (39.1%)
AEs Related to the Magnet n (Incidence (n, %))	0 (0, 0%)	2 (2, 12.5%)	1 1, 4.3%)	3 (3, 6.5%)	1 (1, 2.2%)
AEs Related to Procedure* n (Incidence (n, %))	4 (2, 28.6%)	9 (7, 43.8%)	22 (14, 60.9%)	35 (23, 50.0%)	20 (18, 39.1%)
Total SAEs – n (Incidence (n, %))	6 (4, 57.1%)	6 (6, 37.5%)	2 (1, 4.3%)	14 (11, 23.9%)	4 (4, 8.7%)
SAEs Related to the Magnet n (Incidence (n, %))	0 (0, 0%)	1 (1, 6.2%)	0 (0, 0%)	1 (1, 2.2%)	1 (1, 2.2%)
SAEs Related to Procedure n (Incidence (n, %))	3 (2, 28.6%)	3 (3, 18.8%)	2 (1, 4.3%)	8 (6, 13.0%)	4 (4, 8.7)
SAEs Related to Magnet and/or Procedure (Complications)* n (Incidence (n, %))	4 (2, 28.6%)	3 (3, 18.8%)	2 (1, 4.3%)	8 (6, 13.0%)	4 (4, 8.7%)

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

Magnet System (80mm, 70mm, 60mm Magnet) Adverse Events by Clavien-Dindo Classification Grading

Clavien-Dindo Classification	80mm Magnet (n=7) All follow	70mm Magnet (n=16) All follow	60mm Magnet (n=23) All follow	Total Magnets (N=46) All follow	Total Magnets (N=46) 30-days Post operative
Grade I (n (% of Cohort AEs))	13 (41.9%)	9 (32.1%)	18 (35.3%)	40 (36.4%)	24 (55.8%)
Grade II n (% of Cohort Aes))	14 (45.2%)	10 (35.7%)	28 (54.9%)	52 (47.3%)	13 (30.2%)
Grade III (n (% of Cohort Aes))	3 (9.7%)	6 (21.4%)	5 (9.8%)	14 (12.7%)	4 (9.3%)
Grade IV (n (% of Cohort Aes))	1 (3.2%)	3 (10.7%)	0 (0%)	4 (3.6%)	2 (4.6%)
Grade V: (n (% of Cohort Aes))	0 (0%)	0 (0%)	0 (0%)	0	0
TOTAL Cohort Adverse Events (Aes) n (% of all Aes)	**31 (28.2%)**	**28 (25.4%)**	**51 (46.4%)**	**110 (100%)**	**43 (39.1%)**

Most adverse events (83.6%, 92/110) throughout all follow up were classified as low grade Clavien-Dindo (grade I and II).

Fourteen adverse events (14) in 11 unique patients (23.9% incidence, 11/46) met criteria to be reported as a serious adverse event (SAE) during all follow up. Only one of the SAEs was assessed as related to the Magnet device (2.2% incidence, 1/46). Eight of the events were determined related to the study procedure (13.0% incidence, 6/46)) across all follow up time. Four SAEs in four patients occurred in the 30-day post-operative period (8.7%, 4/46).

Three adverse events were assessed as related to the Magnet device throughout the study, including all follow up (6.5% incidence, 3/46).

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

The Sponsor assessed the tear may have resulted from tension at the anastomosis site. The literature supports "tension-free anastomosis" as a foundational principle in surgery.[2] Surgeons are trained to investigate for and eliminate tension at the anastomosis site (e.g., clear adhesions, split the omentum sufficiently, apply intestinal stay sutures to reduce pull of bowel loop), regardless of anastomotic instrument or technique, to minimize the risk of bleeds and leaks. The Sponsor includes a precaution statement in the Instructions for Use (IFU) to eliminate tension, and this is included in the training of new investigators and surgeon users.

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

This Clinical Study for the Magnet System (80mm (MAG-03), 70mm (MAG-05), and 60mm (MAG-04) Magnets) met the primary endpoint for creating patent side-to-side gastroenterostomies with a robust safety profile. There were no anastomotic bleeds, infection, or obstruction and no mortality. The one leak was attributed to a tear at the anastomosis. The tear was laparoscopically sutured, and the Magnets were left in place, expelled naturally, created a wide anastomosis that remained patent through the one-year follow up. The case emphasizes the importance of reviewing and eliminating tension at the site, regardless of the anastomotic technique.

Summary of Clinical Data on the Device from Other Sources

Please refer to the summary above on the clinical testing to demonstrate performance and safety.

Overall Summary of the Clinical Performance and Safety

The GT Metabolic Magnet System provides a suite of compression anastomosis surgical tools of different sizes (40mm (MAG-01), 50mm (MAG-02) intended for enteroenterostomy; 60mm (MAG-04), 70mm (MAG-05), 80mm (MAG-03; not in commercial distribution) intended for gstroenterostomy) for surgeons to choose based on the

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

specific patient clinical characteristics and underlying clinical procedure, similar to gastrointestinal staplers. Conventional anastomosis techniques have well documented risks of bleeds, leaks, obstruction, and mortality.[3] Compression anastomosis is not a novel concept and given no incision or resection to the bowel, of similar or lower risk compared to state of the art, surgical staplers or sutures. Compression anastomosis devices date back to the 19th century with goals to create patent anastomoses and reduce potential for major complications by eliminating incisions and maximizing tissue approximation with contiguous healing.[4,5,6,7]

The Clinical Studies for performance testing of the GT Metabolic Magnet System met the primary endpoint (n=164 total) with a robust safety profile. The same definitions and criteria were used in the study for the 40mm and 50mm Magnets (n=118) and study for the 60mm, 70mm, and 80 (n=46) Magnets). There were no anastomotic bleeds, infection, or obstruction and no mortality. There was one leak attributed to a tear at the anastomosis (70mm; total incidence 0.6%, 1/164). The tear was laparoscopically sutured, and the Magnets were left in place, expelled naturally, created a wide anastomosis that remained patent through the one-year follow up. The case emphasizes the importance of reviewing and eliminating tension at the site, regardless of the anastomotic technique.

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

[3] Steger J, Jell A, Ficht S, et al. Systematic Review and Meta-Analysis on Colorectal Anastomotic Techniques. Therapeutics and Clinical Risk Management. 2022; 18: 523-539. https://doi.org/10.2147/TCRM.S335102.

[4] Lu A, Peng J, Li C, et al. Efficacy and Safety of a NiTi CAR 27 Compression Ring for End-to-End Anastomosis Compared with Conventional Staplers: A Real-World Analysis in Chinese Colorectal Cancer Patients. Clincs (Sao Paulo). 2016; 71(5):264-270. https://doi.org/10.6061/clinics/2016(05)04.

[5] Corman ML, Prager ED, Hardy Jr TG, Bubrick MP. Comparison of the Valtrac Biofragmentable Anastomosis Ring with Conventional Suture and Stapled Anastomosis in Colon Surgery. Results of a Prospective, Randomized Clinical Trial. Dis Colon Rectum. 1989; 32(3):183-187. https://doi.org/10.1007/BF02554523.

[6] Olavarria OA, Chhabra KR, Levi ST, et al. Small Bowel Magnetic Compression Creation for Bypass Procedures in a Porcine Model. Surg Endosc. 2025; 39(3): 2155-2163. https://doi.org/10.1007/s00464-025-11575-x.

[7] Eisenberg D. Comment on: Magnetic Single-Anastomosis Side-to-Side Duodeno-Ileostomy for Revision of Sleeve Gastrectomy in Adults with Severe Obesity: 1-Year Outcomes. World Journal of Surgery. 48: 2349-2350. https://www.doi.org/10.1002/wjs.12341.

Ongoing or Planned Post-Market Clinical Follow-Up

#	PMCF Method	Description of activity	Aim of the activity and summary of endpoints	Rationale and known limitations of the activity	Timelines of the activity
Specific PMCF					
Clinical Investigations Underway					
1	☐ General ☒ Specific	Clinical Investigation (GTM-001): Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic Solutions Magnetic Anastomosis System System (MAGNET System) to Achieve Duodeno-Ileostomy Diversion in Adults with Obesity and with or without Type 2 Diabetes Mellitus: The MAGNET Study	The objective of this study is to assess anastomosis feasibility, performance, and safety of the MagDI system (MAG-00 and DS-00)	The limitations include: • No comparison group • Small number of patients (n=49) This initial clinical investigation is a feasibility study with no comparison group. The number of patients will increase with real-world evidence from additional studies and clinical use in the market (when applicable) of the product. However, the clinical investigation is warranted based on the devices intended use and a limited amount of clinical evidence.	The study has been completed and the database is in final review for additional evidence publication and closure.
2	☐ General ☒ Specific	Clinical Investigation (GTM-005): 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 Type 2 Diabetes Mellitus: DI Biofragmentable MAGNET Study.	The objective of this study is to evaluate the feasibility, performance, safety, and initial efficacy of the MagDI system (MAG-01, and DS-01) to create side-to-side anastomosis to achieve duodeno-ileal diversion.	The limitations include: • No comparison group This initial clinical investigation is a performance study. . The study is part of a cohort of cross-geography performance and safety studies with the same study design, intended for data to be collated for a larger sample size for analysis, reaching power on the primary endpoint. The number of patients will increase with real-world evidence from additional studies of the Magnets and clinical use in the market (when applicable) of the product.	The study has enrolled n=15; all subjects have been followed to the primary endpoint. The follow-up for the clinical investigation is 1 year and has been completed for data collection. It will also take several months to analyze the data and prepare for submission.

#	PMCF Method	Description of activity	Aim of the activity and summary of endpoints	Rationale and known limitations of the activity	Timelines of the activity
				However, the clinical investigation is warranted based on the devices intended use and a limited amount of clinical evidence.	
3	☐ General ☒ Specific	Clinical Investigation (GTM-003): Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic Solutions DI Biofragmentable Magnetic Anastomosis System (MAGNET System, DI Biofragmentable) to Achieve Gastro-Ileostomy or Gastro-jejunostomy Diversion in Adults with Obesity: (MagGJ Study)	The objective of this clinical research study is to evaluate the feasibility, performance, safety, and initial efficacy of the GJ System (MAG-03, MAG-04, MAG-05 and DS-01) for creation of a side-to-side gastro-ileal or gastro-jejunal magnetic compression anastomosis.	The limitations include: • No comparison group This clinical investigation is a performance and safetystudy reaching power on the primary endpoint. The number of patients will increase with real-world evidence from additional studies of the Magnets and clinical use in the market (when applicable) of the product. However, the clinical investigation is warranted based on the devices intended use of Magnets in the gastric tissue and a limited amount of clinical evidence.	The study has completed enrollment for n=46 and completed follow up for primary endpoint analysis. The follow-up for the clinical investigation is 1 year for all subjects. It will also take several months to analyze the data and prepare for submission.
4	☐ General ☒ Specific	Clinical Investigation (GTM-002): 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 Type 2 Diabetes Mellitus: MAGNET 2 Study (Mexico)	The objective of this clinical research study is to evaluate the feasibility, performance, safety, and initial efficacy of the MagDI System (MAG-01 and DS-00) for creation of a side-to-side duodeno-ileal magnetic compression anastomosis.	The limitations include: • No comparison group The study is part of a cohort of cross-geography performance and safety studies with the same study design, intended for data to be collated for a larger sample size for analysis, reaching power on the primary endpoint.The number of patients will increase with real-world evidence from additional studies of the Magnets and clinical use in the market (when applicable) of the product. However, the clinical investigation is warranted based on the devices intended use and a limited amount of clinical evidence.	The study has enrolled n=10 subjects, all reaching follow up for the primary endpoint. The study is ongoing with closed enrollment. Then a follow-up of 1 year for the clinical investigation, plus time to analyze the data and prepare a final report.

#	PMCF Method	Description of activity	Aim of the activity and summary of endpoints	Rationale and known limitations of the activity	Timelines of the activity
5	☐ General ☒ Specific	Clinical Investigation (GTM-006): Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic MagDI System in Canada to Achieve Duodeno-Ileal Diversion in Adults with Obesity and with or without Type 2 Diabetes Mellitus (MagDI Canada Study)	The purpose of this clinical research study is to evaluate the feasibility/performance, safety, and initial efficacy of the MagDI System (MAG-01, MAG-02, and DS-01) for creation of a side-to-side duodeno-ileal magnetic compression anastomosis.	The limitations include: • No comparison group The study is part of a cohort of cross-geography performance and safety studies with the same study design, intended for data to be collated for a larger sample size for analysis, reaching power on the primary endpoint.The number of patients will increase with real-world evidence from additional studies of the Magnets and clinical use in the market (when applicable) of the product. However, the clinical investigation is warranted based on the devices intended use and a limited amount of clinical evidence.	The study has enrolled n=31 subjects, all reaching follow up for the primary endpoint. The study is ongoing with closed enrollment Then a follow-up of 1 year for the clinical investigation, plus time to analyze the data and prepare a final report.
6	☐ General ☒ Specific	Clinical Investigation (GTM-009): Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic MagDI System in Australia to Achieve Duodeno-Ileal Diversion in Adults with Obesity and with or without Type 2 Diabetes Mellitus (MagDI Australia Study)	The purpose of this clinical research study is to evaluate the feasibility/performance, safety, and initial efficacy of the MagDI System (MAG-01 and DS-01) for creation of a side-to-side duodeno-ileal magnetic compression anastomosis.	The limitations include: • No comparison group The study is part of a cohort of cross-geography performance and safety studies with the same study design, intended for data to be collated for a larger sample size for analysis, reaching power on the primary endpointThe number of patients will increase with real-world evidence from additional studies of the Magnets and clinical use in the market (when applicable) of the product. However, the clinical investigation is warranted based on the devices intended use and a limited amount of clinical evidence.	The study has enrolled 25 subjects; all have reached follow up for the primary endpoint.The study is ongoing with closed enrollment. Then a follow-up of 1 year for the clinical investigation, plus time to analyze the data and prepare a final report.
7	☐ General ☒ Specific	Clinical Investigation (GTM-010): Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic MagDI System in Italy to Achieve	The purpose of this clinical research study is to evaluate the feasibility/performance, safety, and initial efficacy of the MagDI System (MAG-01	The limitations include: • No comparison group The study is part of a cohort of cross-geography performance and safety studies with the same	The study has enrolled n=27 subjects. All have reached follow up for the primary endpoint.The study is ongoing with closed

#	PMCF Method	Description of activity	Aim of the activity and summary of endpoints	Rationale and known limitations of the activity	Timelines of the activity
		Duodeno-Ileal Diversion in Adults with Obesity and with or without Type 2 Diabetes Mellitus (MagDI Italy Study)	and DS-01) for creation of a side-to-side duodeno-ileal magnetic compression anastomosis.	study design, intended for data to be collated for a larger sample size for analysis, reaching power on the primary endpointThe number of patients will increase with real-world evidence from additional studies of the Magnets and clinical use in the market (when applicable) of the product. However, the clinical investigation is warranted based on the devices intended use and a limited amount of clinical evidence.	enrollment. Then a follow-up of 1 year for the clinical investigation, plus time to analyze the data and prepare a final report.
8	☐ General ☒ Specific	Clinical Investigation (GTM-012): Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic MagDI System in Chile to Achieve Duodeno-Ileal Diversion in Adults with Obesity and with or without Type 2 Diabetes Mellitus (MagDI Chile Study)	The purpose of this clinical research study is to evaluate the feasibility/performance, safety, and initial efficacy of the MagDI System (MAG-01, MAG-02, and DS-01) for creation of a side-to-side duodeno-ileal magnetic compression anastomosis.	The limitations include: • No comparison group The study is part of a cohort of cross-geography performance and safety studies with the same study design, intended for data to be collated for a larger sample size for analysis, reaching power on the primary endpointThe number of patients will increase with real-world evidence from additional studies of the Magnets and clinical use in the market (when applicable) of the product. However, the clinical investigation is warranted based on the devices intended use and a limited amount of clinical evidence.	The study has enrolled n=10 with subjects followed to the primary endpoint. Enrollment is closed and the study is ongoing. Then a follow-up of 1 year for the clinical investigation, plus time to analyze the data and prepare a final report.
9	☐ General ☒ Specific	Clinical Investigation (GTM-014): Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic Magnet System as either the Primary or the First Stage of Colorectal Surgery (MagCR Study)	The purpose of this clinical research study is to assess the performance of side-to-side anastomosis using the Magnet System (50mm, 60mm Magnets) in patients indicated for colorectal surgery.	The limitations include: • No comparison group This initial clinical investigation is a 2-stage study with first-in-human (FIH, n=5), a pause for D30 safety data by an external data safety monitoring board (DSMB), and at performance stage 2 (n=45 additional).	The study was initiated with n=5 FIH subjects enrolled. Enrollment is paused pending data follow and DSMB safety review. Then a follow-up of 1 year for the clinical investigation, plus time to analyze the data and prepare a final report.

#	PMCF Method	Description of activity	Aim of the activity and summary of endpoints	Rationale and known limitations of the activity	Timelines of the activity
				The number of patients will increase with real-world evidence from additional studies of the Magnets and clinical use in the market (when applicable) of the product. However, the clinical investigation is warranted based on the devices intended use to expand the clinical evidence in the large bowel for regulatory authorizations.	
10	☐ General ☒ Specific	GTM-020: Compression Anastomosis Using the GT Metabolic Magnet System in Adults with Gastrointestinal Disorders (GT Metabolic Magnet System Study)	This purpose of the study is to expand evidence in the use of the Magnet System (40mm, 50mm, 60mm, 70mm Magnets) for side-to-side gastrointestinal anastomosis in subjects with Gastric Outlet Obstruction (GOO), partial bowel obstruction, or Superior mesenteric artery syndrome (SMAS).	The limitations include: • No comparison group • Single center This study will enroll n=35 in Canada. The number of patients will increase with real-world evidence from additional studies of the Magnets and clinical use in the market (when applicable) of the product. However, the clinical investigation is warranted to expand the clinical evidence in different underlying conditions.	The study is ongoing with n=6 subjects enrolled. Then a follow-up of 90 days for the clinical investigation, plus time to analyze the data and prepare a final report.
11	☐ General ☒ Specific	GTM-018: Creation of Magnetic Compression Gastroenterostomy Using the GT Metabolic Solutions Magnet System in Adults with Gastric Outlet Obstruction (GOO): Magnet System GOO Study	This purpose of the study is to expand evidence in the use of the Magnet System (60mm, 70mm Magnets) for side-to-side gastrointestinal anastomosis in subjects with Gastric Outlet Obstruction (GOO).	The limitations include: • No comparison group • Single center This study will enroll n=10 in the Czech Republic. The number of patients will increase with real-world evidence from additional studies of the Magnets and clinical use in the market (when applicable) of the product.	The study is in the active study start-up/initiation phase. Then a follow-up of 90 days for the clinical investigation, plus time to analyze the data and prepare a final report.

#	PMCF Method	Description of activity	Aim of the activity and summary of endpoints	Rationale and known limitations of the activity	Timelines of the activity
				However, the clinical investigation is warranted to expand the clinical evidence in different underlying conditions.	
General Activities					
12	☒ General ☐ Specific	Post market surveillance & vigilance database collection	Confirm the safety and performance of the subject devices, identify any previously unknown side-effects or risks, monitor identified side-effects and contraindications based on emerging factual evidence and identify and analyze emergent risks, ensure the acceptability of the clinical benefit-risk determination, and identify possible systematic misuse or off-label use of the subject devices.	The limitations include: • The activity is reactive. • complaints/ vigilance data are self-reported. Further data collection during post-market surveillance and vigilance database collection is warranted for the subject devices as they are used in the market and based on the intended use.	This is an on-going activity.
13	☒ General ☐ Specific	Clinical literature data collection for subject and similar devices	Confirm the safety and performance of the subject devices, identify any previously unknown side-effects or risks, identify and analyze emergent risks, and identify possible systematic misuse or off-label use of the devices.	The limitations include: • The activity is reactive. • There are longer time frames from data acquisition to publication. Clinical data collection for the subject device and similar devices is warranted based on subject device intended use.	The clinical literature will be updated along with the CER update, unless there are new emergent risks, side effects, change in labeling, field safety corrective action and/or recall.

Possible Diagnostic or Therapeutic Alternatives

The GT Metabolic Magnet System is a surgical tool provided as an alternative technique to available surgical anastomosis methods (incision plus sutures or staples (e.g., gastrointestinal staplers) or other compression anastomosis devices) for the intended purpose and indications for use.

Suggested Profile and Training of Users

- **User Profile:** The user groups are surgeons treating adult patients indicated for a side-to-side enteroenterostomy or gastroenterostomy with delayed patency as determined by the treating surgeon.

- **User Training:** The instructions for use (IFU, document 1419-1) provided with the GT Metabolic Magnet System provides users with the information required to safety use the device for the intended purpose. Additionally, GT Metabolic requires new users to receive training from the company and be proctored for initial cases to support safe and appropriate use.

Reference to Harmonized or Clinical Standards / Guidance Applied

- MDCG 2019-9 Rev 1 – Summary of Safety and Clinical Performance, A Guide for Manufacturers and Notified Bodies, March 2022 was followed in the development of this SSCP.
- EN ISO 14155:2011 – Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice
- EN ISO 14971:2012 – Medical Devices – Application of Risk Management to Medical Devices
- MEDDEV 2.7/1 Rev. 4, June 2016 – Guidelines on Medical Devices, Clinical Evaluation: A Guide for Manufacturer's and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
- MEDDEV 2.12/2 Rev. 2, January 2012 – Guidelines on Medical Devices, Post-Market Clinical Follow-up Studies: A Guide for Manufacturer's and Notified Bodies
- GHTF SG5/N2R8:2007 Global Harmonization Task Force, Clinical Evaluation
- GHTF SG5 N2R8:2007: Clinical Evaluation
- GHTF SG5 N41R9:2005: Essential Principles of Safety and Performance

Revision History

SSCP Revision #	Date Issued	Change Description	Revision Language(s) Validated by the Notified Body
A	13Apr2026	• DRAFT	English
B	07May2026	• Updated to add General Activities to the PMCF Plan table. Added Appendix A. Patient-Facing Summary. Administrative and formatting corrections. • Updated Indications for Use to change from "application in gastrointestinal, metabolic, and bariatric surgical procedures" to "application in metabolic and bariatric surgical procedures". • Removed precaution "Swallow of a 70mm Magnet was not clinical testing and is not advised." Two subjects swallowed the first 70mm Magnet in clinical testing.	English
1	20May2026	• Released • Administrative and formatting corrections.	English

GT Metabolic

Appendix A: Summary of Safety and Clinical Performance for Patients

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of safety and clinical performance prepared for healthcare professionals is found in the first part of this document. The SSCP is not intended to give general advice on the treatment of a medical condition. This SSCP is not intended to replace a medical device implant card or the Instructions for Use (IFU) to provide information on the safe use of the device.

Please contact your healthcare professional (for example, your doctor) in case you have questions about your medical condition or about the use or risks of this device.

Device Identification and General Information

Device Name: GT Metabolic™ Magnet System made up of the following devices:

GT Metabolic™ Magnet System Component Device	Model Number	Basic UDI-DI
GT Metabolic Magnet, 40mm	MAG-01	0850054216MAGXW
GT Metabolic Magnet, 50mm	MAG-02	
GT Metabolic Magnet, 60mm	MAG-04	
GT Metabolic Magnet, 70mm	MAG-05	
GT Metabolic Delivery System	DS-01	0850054216DS8N
GT Metabolic Laparoscopic Positioning Device, 12	PD-12	0850054216PD8U
GT Metabolic Laparoscopic Positioning Device, 18	PD-18	
GT Metabolic Laparoscopic Positioning Device, 21	PD-21	
GT Metabolic Laparoscopic Positioning Device, 24	PD-24	
GT Metabolic Laparoscopic Positioning Device, 27	PD-27	
Accessory Device:		
GT Metabolic Magnetic Retrieval Device	MRD-02	00850054216MRDZB

Manufacturer:
GT Metabolic Solutions, Inc. (“GT Metabolic”) with manufacturing location at:
5450 Quam Ave NE, Suite 100
St. Michael, MN 55376 USA

Year when the device was first CE-marked:
2025 – GT Metabolic Delivery System, GT Metabolic Laparoscopic Positioning Device
2026 – GT Metabolic™ Magnet System, GT Metabolic Magnetic Retrieval Device

Intended Use of the Device

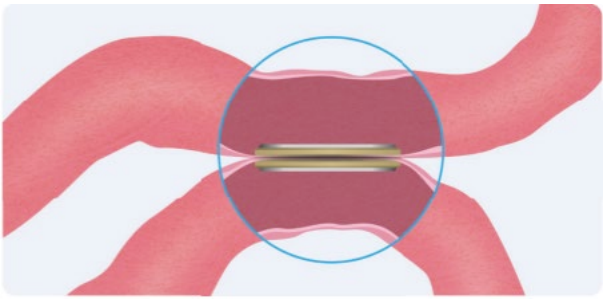
Intended Purpose

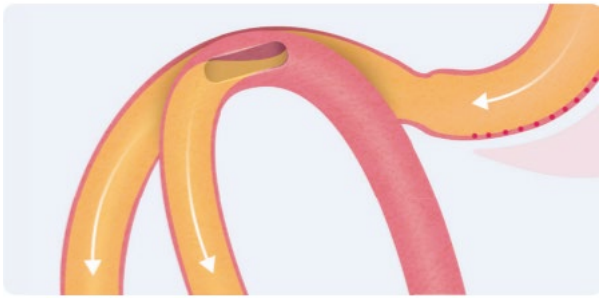
The GT Metabolic Magnet System is used to create a new connection in the small intestines and/or the stomach and small intestine (also called magnetic compression anastomosis).

The procedure uses two magnetic devices (“Magnets”) to connect two parts of the small intestine or the stomach to the small intestine, creating a new connection. The Magnets are placed using endoscopy (a scope placed through your mouth and stomach to deliver a Magnet). Your doctor may also discuss the ability to swallow one of the Magnets, but that will be your decision. The two Magnets are positioned and connected in laparoscopy surgery, using surgical instruments through small (keyhole size) cuts in your abdomen (stomach or belly area) to gently lift the intestines and/or stomach.

You will be sent home with the Magnets in place. Once the connection is made using the natural healing of your body, the two Magnets together will pass through your system, just like food, and out with your stool.

The pictures below provide an example of creating a new connection in two parts of the small intestine for passage of food and liquids. The approach is the same when making a new connection between the stomach and small intestine.





Indications for Use and Intended Patient Population

The GT Metabolic Magnet System is only to be used by doctors in treating patients that need a new connection in the small intestine and/or the stomach.

Contraindications

Your doctor will review your medical history to determine if the device may be right for you. The following lists the contraindications, where the device is not the right instrument for your case.

- A new gastrointestinal connection is not needed or a new connection (anastomosis) that happens over time (when you go home) is not the right approach for the clinical case.
- The sections of the small intestine and/or stomach do not have enough opening (for example, there is a blockage) to allow for adequate flow of foods, liquids, and stool until the anastomosis is formed.
- Unhealed ulcers, bleeding lesions, or a tumor or any other lesion at the target Magnet sites.
- 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 until your doctor determines (for example by X-ray) the devices are out of your body.
- 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 (poly glycolic-co-lactic acid (PGLA), barium sulfate).
- The patient has an implanted pacemaker and/or defibrillator.
- The patient has any implanted electrical devices (e.g., neurological) or non-electrical implants or metal that may attract the Magnet devices.
- The patient is pregnant or plans to become pregnant.
- The patient has any conditions for which endoscopy (a scope placed through your mouth and stomach to deliver a Magnet) or laparoscopic surgery would be contraindicated.
- Any significant abnormalities of the gastrointestinal system at the placement of the Magnets or farther down through the lower portion of the intestines to the rectum.

Device Description

Device Description and Materials/Substances in Contact with Patient Tissues

The GT Metabolic System is made up of:

1. GT Metabolic Magnet ("Magnet"):
    - Two Magnets of the same size (40mm, 50mm, 60mm, and 70mm Magnets). Your doctor will determine the size Magnets right for your case.
    - Each Magnet includes an outer titanium housing containing an outer ring (flange) made up of PGLA (poly glycolic-co-lactic acid), a material designed to break apart in your body. This material has been tested to confirm it is biocompatible or safe to be used in your body. The housing includes a stainless-steel spring in the connection for the Delivery System. An example picture is provide below.

2. GT Metabolic Delivery System: a flexible catheter that can be used to deliver the Magnet through an endoscope.

3. GT Metabolic Laparoscopic Positioning Device (LPD): a laparoscopic instrument or tool with a magnetic tip used to position and connect the two Magnets in your body. There are five LPD models of different magnetic strengths available to your doctor. An example picture is provided below:

Information About Medicinal Substances in the Device

The device does not include any medicinal substances (medicines or drugs).

Information of How the Device Achieves the Intended Mode of Action (Purpose)

The GT Metabolic Magnet System is a tool for magnetic compression anastomosis. Two Magnets of the same size are used to create a new gastrointestinal connection using magnetic compression. The two Magnets placed within the intestines and/or stomach are connected to

each other through polar attraction (like magnets used on your refrigerator) and create pressure on the tissue between the two devices. This pressure is intended to necrose (kill) the central tissue while the tissue around the two devices heals to create the new natural passageway. This natural healing process is the same as when your body heals after a cut or incision. Once the healing is done, the connected Magnets pass naturally in the stool. Many patients are not aware the Magnets have passed.

Description of Accessories

The GT Metabolic Magnetic Retrieval Device is a tool available to your surgeon if needed to retrieve a Magnet. This device is a flexible catheter with a magnetic tip that attracts the Magnet.

Risks and Warnings

Contact your doctor if you believe that you are experiencing side-effects related to the device or if you are concerned about risks. This document is not intended to replace a meeting or discussion with your doctor.

How Potential Risks Have Been Controlled or Managed

The GT Metabolic Magnet System is only available for use by doctors. Only doctors who are experienced in anastomosis procedures and on the use of the GT Metabolic Magnet System should use the device. GT Metabolic provides new users with the Instruction for Use (IFU) and proctoring (training by another surgeon already trained on use of the device). The doctor is informed of remaining (potential) risks and undesirable side effects in the IFU, which is available on the GT Metabolic company website (www.gtmetabolic.com).

Remaining Risks and Undesirable Effects

The remaining risks and undesirable side effects associated with performing an anastomosis procedure with the GT Metabolic Magnet System may include the following:

- anastomosis leak, bleeding, obstruction, or infection
- anastomosis stricture or stenosis (narrowing or closure)
- internal hernia
- bowel obstruction or ileus (problems with the normal contraction of the intestines)
- pain
- intestinal laceration (e.g., serosal tear) or perforation: tears or cuts to the stomach or intestinal tissue during the surgery that may need to be sutured
- adverse tissue reaction or damage
- intestinal ulceration and/or scarring

- abdominal issues: distention (bloating), diarrhea, constipation, nausea, vomiting, Dumping Syndrome (a condition where food moves quickly and causes abdominal issues)
- choking or aspiration if Magnet is swallowed
- vitamin or mineral deficiencies (low levels)
- need for surgical re-intervention (e.g., failure to expel); or
- death.

If you have any questions, please discuss these risks and effects that may happen with your doctor.

Warnings and Precautions

All Warnings and Precautions associated with the GT Metabolic Magnet System are provided to the doctor using the device. These are provided in the Instructions for Use (IFU) and during the training provided to new users.

Those issues specific to you as the patient following a procedure include:

- While the Magnets are in your body, it not safe to receive magnetic resonance imaging (MRI) procedures. MRI uses magnets in the technique that may attract to the devices.
- Do not receive MRI procedures until your doctor confirms the Magnets are out of your body (for example, by X-ray).
- Do not take non-steroidal anti-inflammatory drugs (NSAIDS) or aspirin with 14 days prior to the procedure and remain off these medications for 14 days after the procedures. These medications may increase to potential for bleeding.

Summary of Any Field Safety Corrective Action (FSCA)

No safety actions or recalls (needing to call back devices because of safety issues) have been conducted for the GT Metabolic Magnet System.

Summary of Clinical Evaluation and Post-Market Clinical Follow-Up

Clinical Background of the Device Before CE-Marking

The GT Metabolic Magnet System for anastomosis in two parts of the small intestine (40mm and 50mm Magnets) was first available in the U.S.A. in November 2024 and has been sold and used in other non-Europe geographies. The Magnet System intended for use in connections between the stomach and small intestine (60mm and 70mm Magnets) was first available for clinical use in Chile in December 2025. The post-market data from these regions support the GT Metabolic Magnet System has performed safely and as intended.

The Clinical Evidence for CE-Marking

The GT Metabolic Magnet System, including all Magnet sizes (40mm, 50mm, 60mm, 70mm), has been tested in clinical studies.

Safety and Performance

The table below provides a summary the safety and performance of the device in the clinical studies. Ask your doctor to discuss information on the the clinical testing if you have questions.

Intended Purpose	The GT Metabolic Magnet System is intended for use in the creation of side-to-side gastrointestinal anastomoses (enteroenterostomy (40mm, 50mm) and gastroenterostomy (60mm, 70mm) in minimally invasive and laparoscopic surgery. Once wound strength is sufficient to maintain the anastomosis, the device is passed from the body. Note: "enteroenterostomy" means a connection between two parts of the small intestine and "gastroenterostomy" means a connection between the stomach and small intestine.
Performance	▪ A total of 164 patients were included in the studies ▪ The Magnet System met the study outcomes for success in creating gastrointestinal anastomoses ▪ The Magnets passed naturally in the stool in most patients (98%, 160/164)
Safety	▪ Most of the adverse events (86%, 310/361) required no treatment or minimal treatment such as medication. Many of these events were gastrointestinal symptoms such as vomiting, nausea, diarrhea, stomach pain, and bloating. ▪ There was 1 case (1/164 (<1%)) of a tissue tear at the anastomosis site resulting in a leak of intestinal fluids in the abdomen. This tear was related to the Magnets (70mm) creating tension (weight or pulling) at the site. The tissue tear was sutured and leak treated during laparoscopy without issue. The Magnets were left in place and went created an open anastomosis and passed naturally in the stool.
Conclusion	This clinical testing provided evidence the device safely created gastrointestinal anastomosis as intended in the study population.

Possible Alternatives Your Doctor May Use for Anastomosis

The device is a tool providing doctors with another technique for creating anastomosis. Other techniques the doctor may choose from include other compression devices or use of staplers or suturing.

Suggested Training for Users

Only doctors who have experience with anastomosis procedures and are trained on use of the GT Metabolic Magnet System should use the device.