

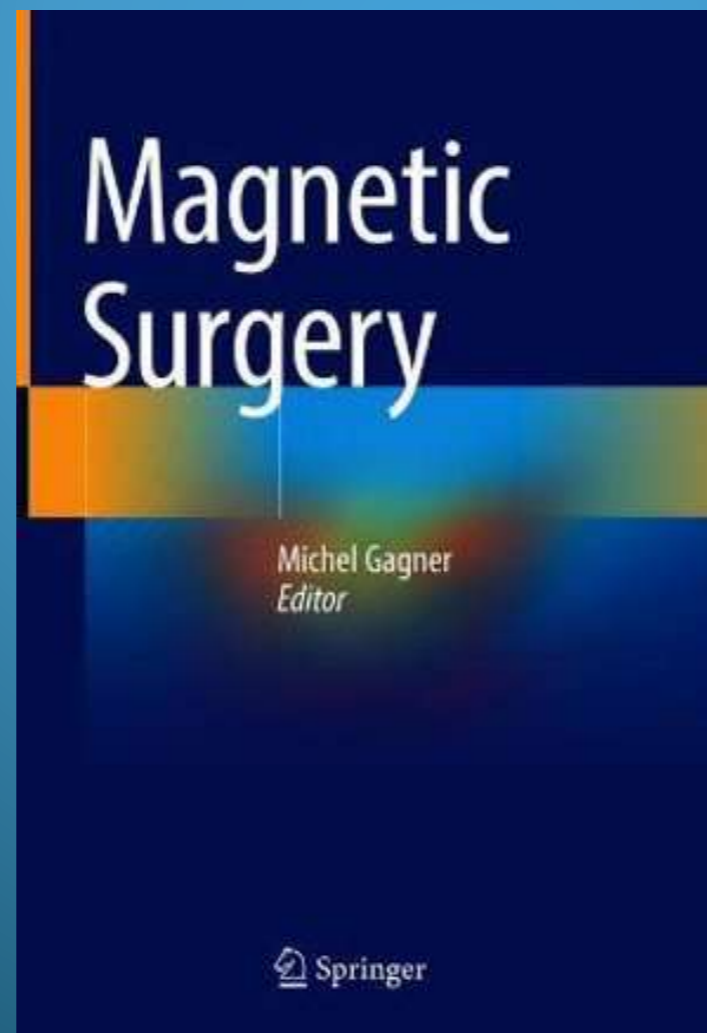
Update on Magnetic GI surgery

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Disclosures

- Stock ownership/Consultant: Lexington medical, GT Metabolic



Creation of a Side-to-Side Magnetic Compression Anastomosis to Achieve Duodeno-Ileostomy Diversion in Adults with Severe Obesity with or without Type-2 Diabetes.

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Magnetics in bariatric surgery: the future is today?

Valtrac , 1984

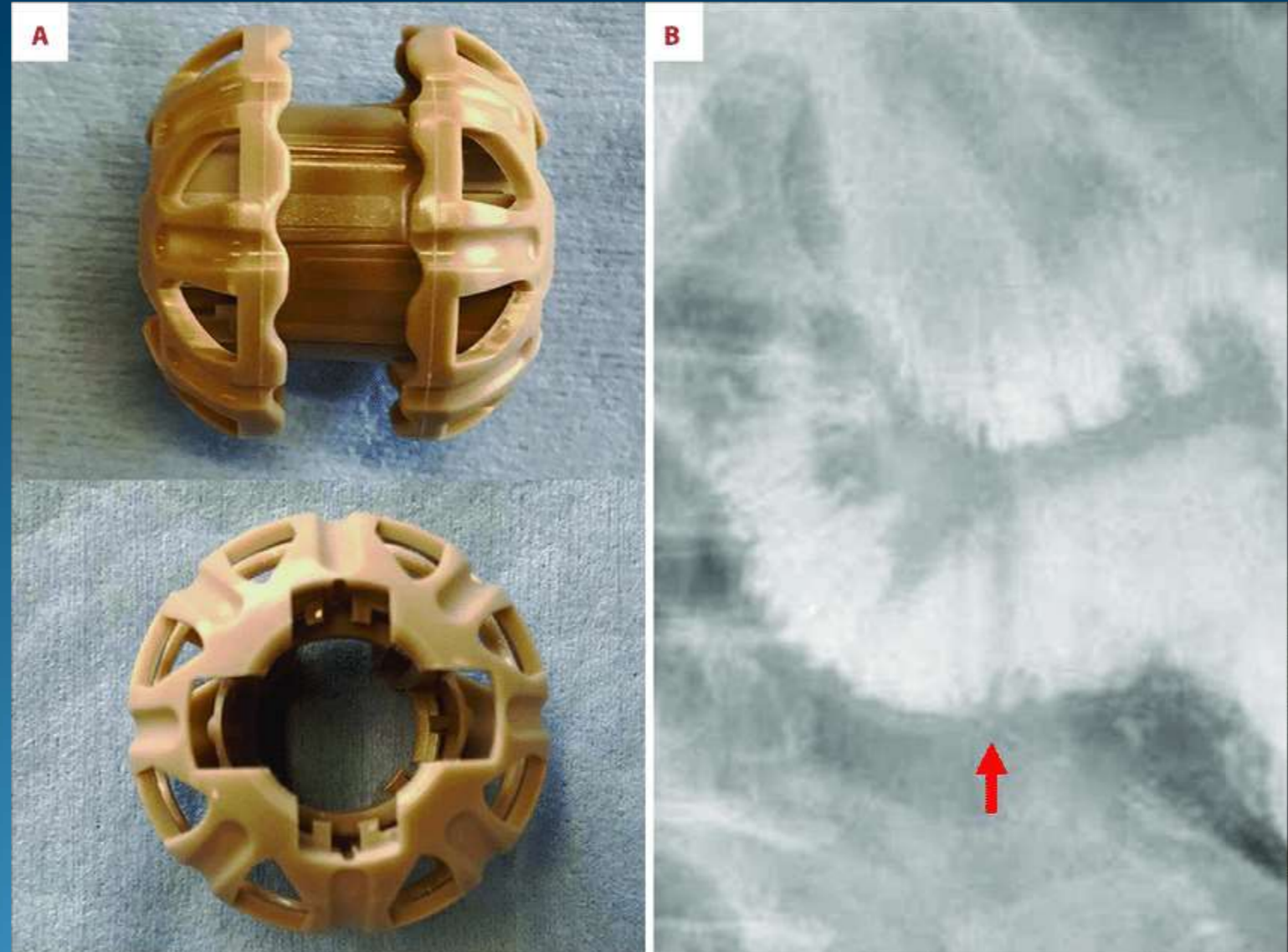
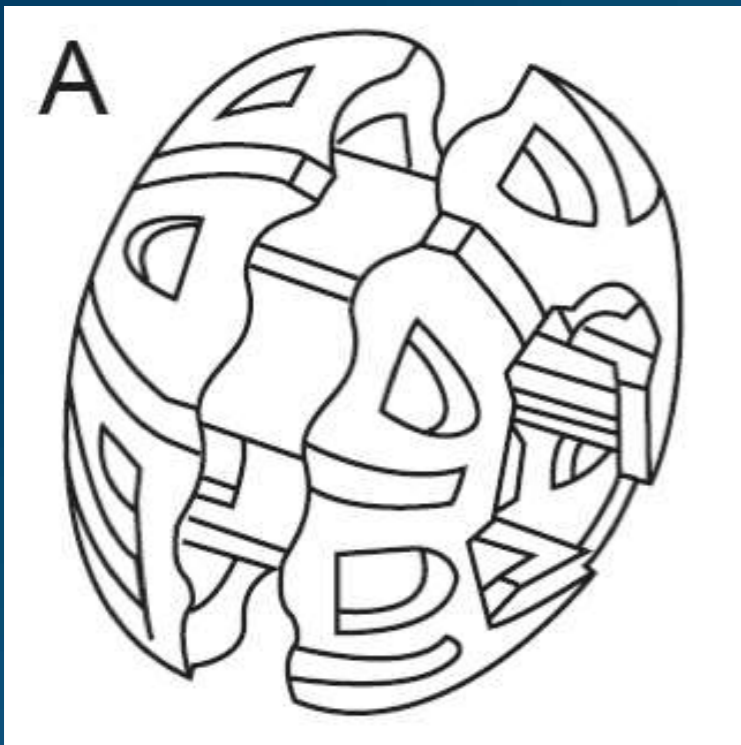
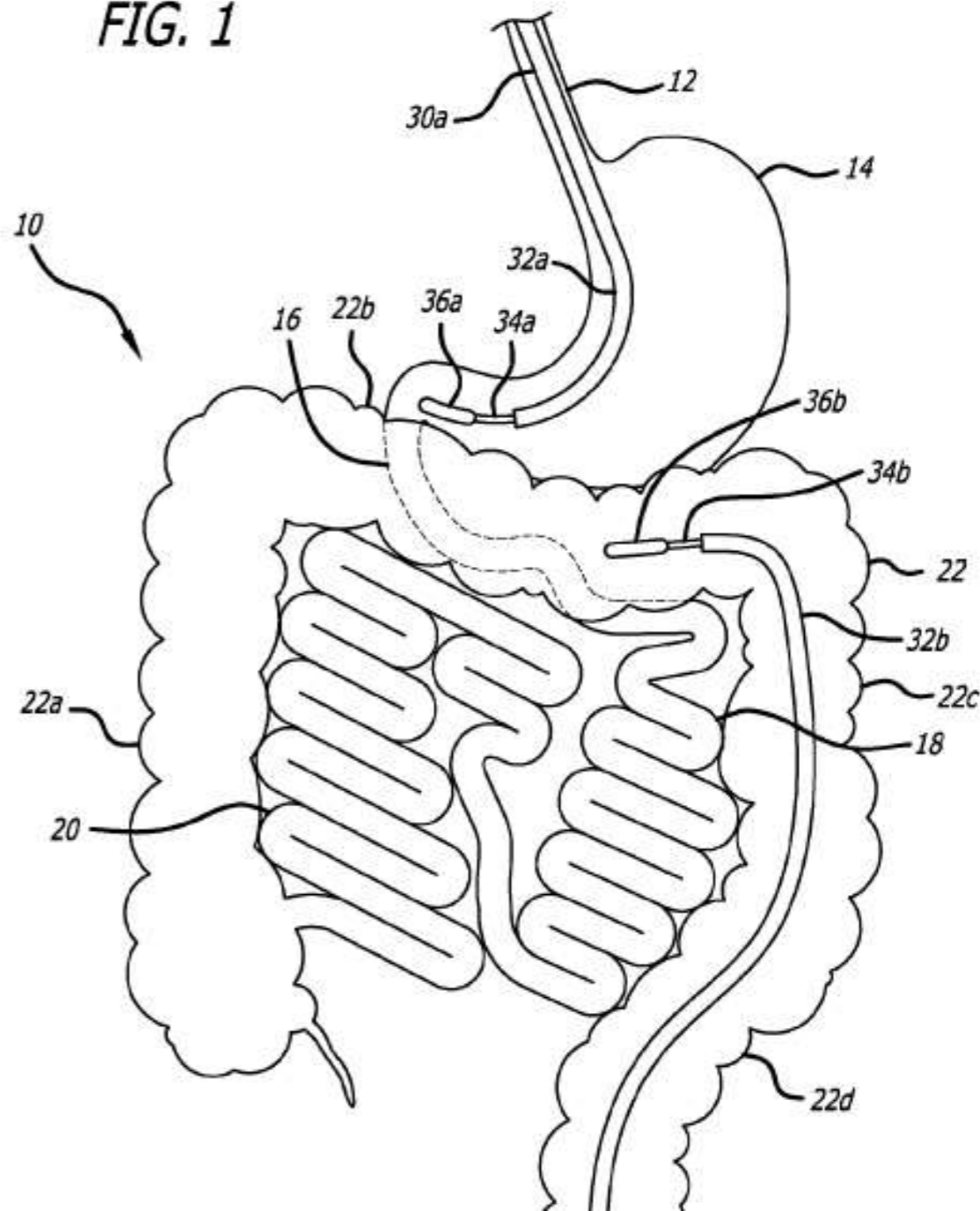


FIG. 1



The
United
States
of
America



**The Director of the United States
Patent and Trademark Office**

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America, and if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States of America, or importing into the United States of America, products made by that process, for the term set forth in 35 U.S.C. 154(a)(2) or (c)(1), subject to the payment of maintenance fees as provided by 35 U.S.C. 41(b). See the Maintenance Fee Notice on the inside of the cover.

Joseph Matof

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Director of the United States Patent and Trademark Office

(12) **United States Patent**

(10) **Patent No.:** **US 9,801,635 B2**

New Anti-diabetes operation “Duodenal Bipartition”

Gagner *Ann Surg Innov Res* (2015) 9:6
DOI 10.1186/s13022-015-0015-0



ANNALS OF SURGICAL
INNOVATION AND RESEARCH

RESEARCH ARTICLE

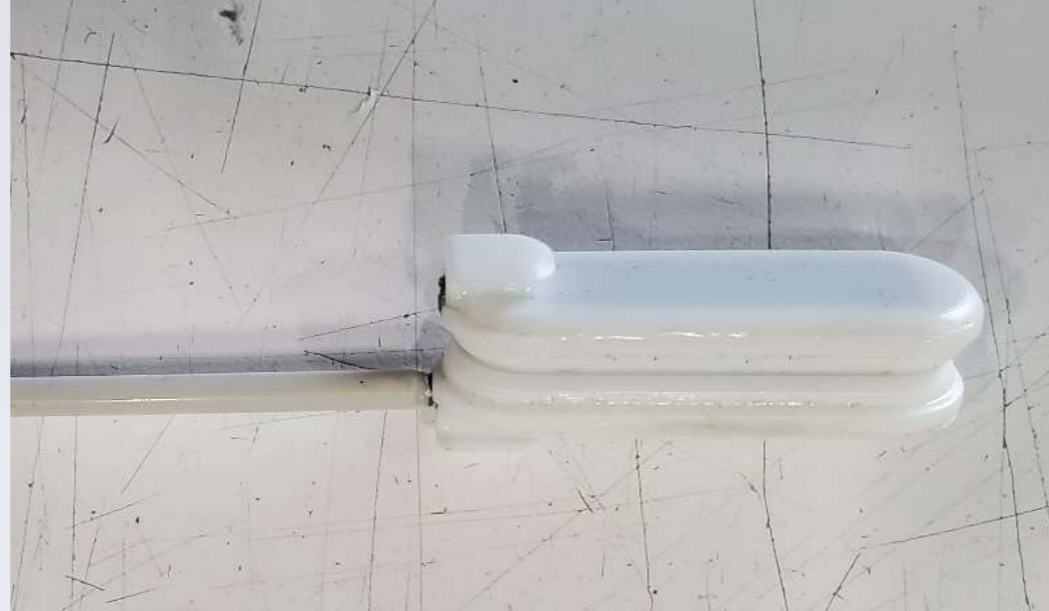
Open Access



Safety and efficacy of a side-to-side duodeno-ileal anastomosis for weight loss and type-2 diabetes: duodenal bipartition, a novel metabolic surgery procedure

Michel Gagner*

Linear Magnets



Endoscopic catheter delivery system

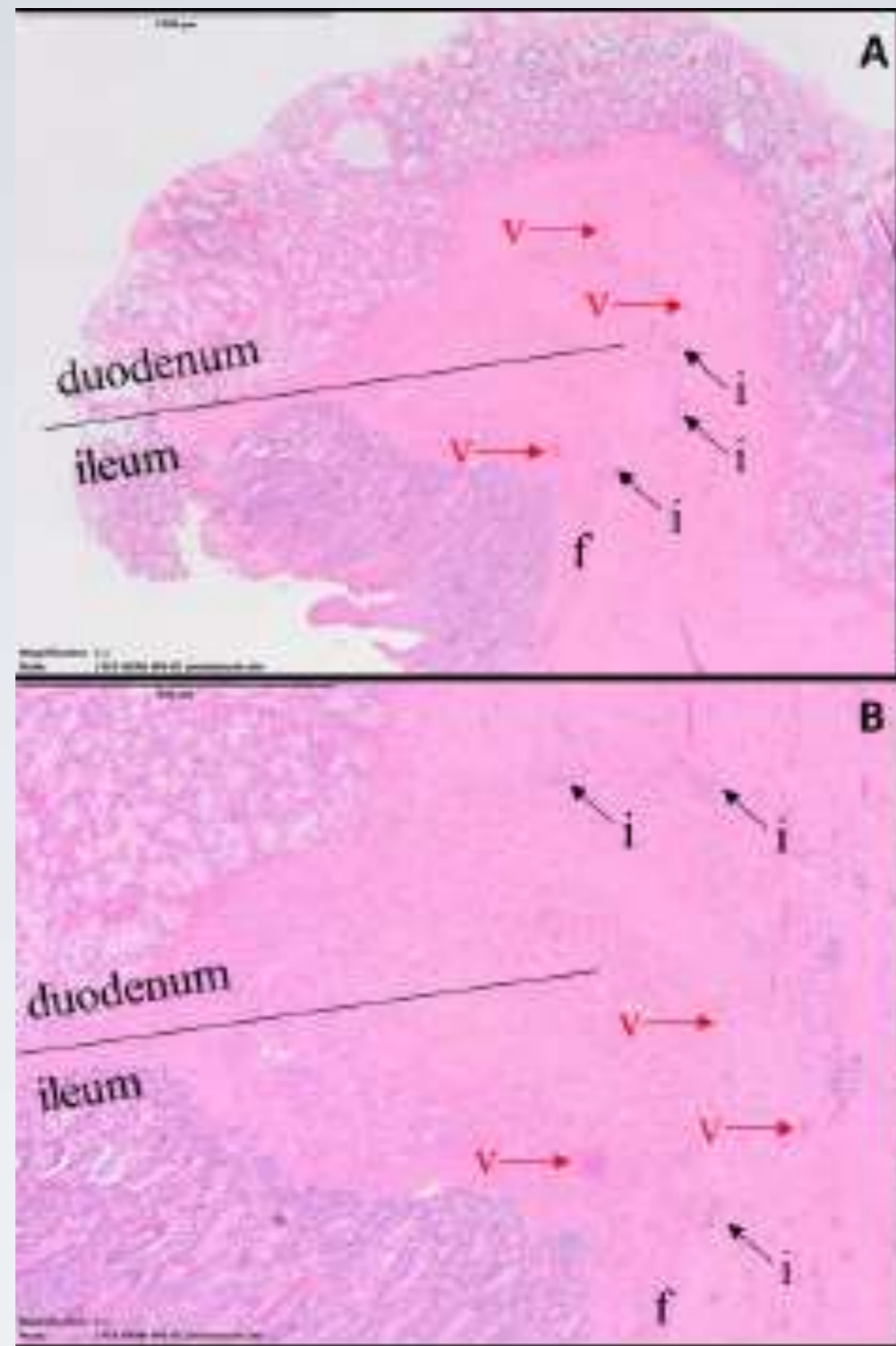


Duodeno-ileostomy

Macroscopic aspect, duodeno-ileostomy



Endoscopic view, anastomosis,
and normal duodenal pathway

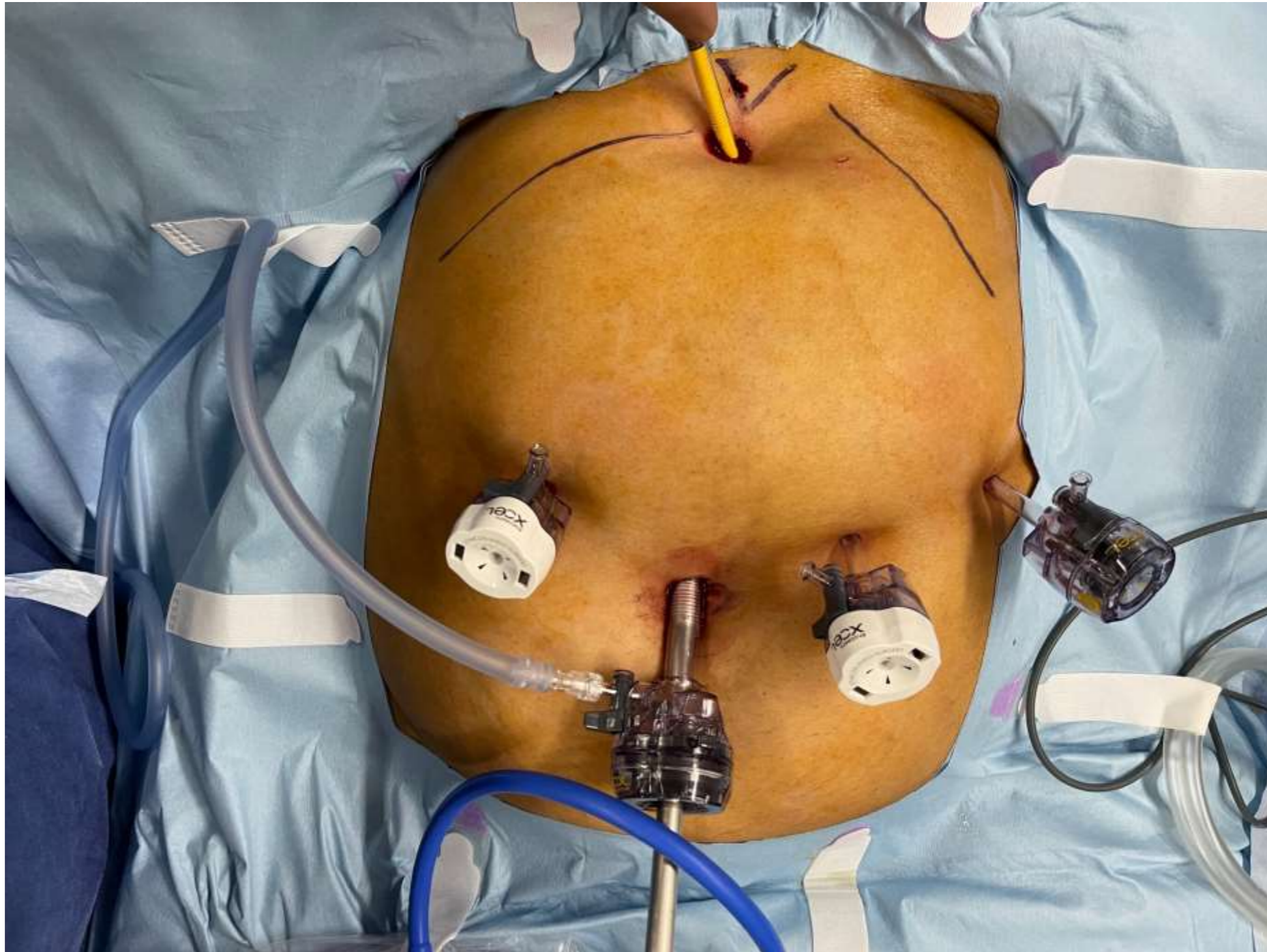


Microscopic alignment and view, no inflammation

Inclusion Criteria

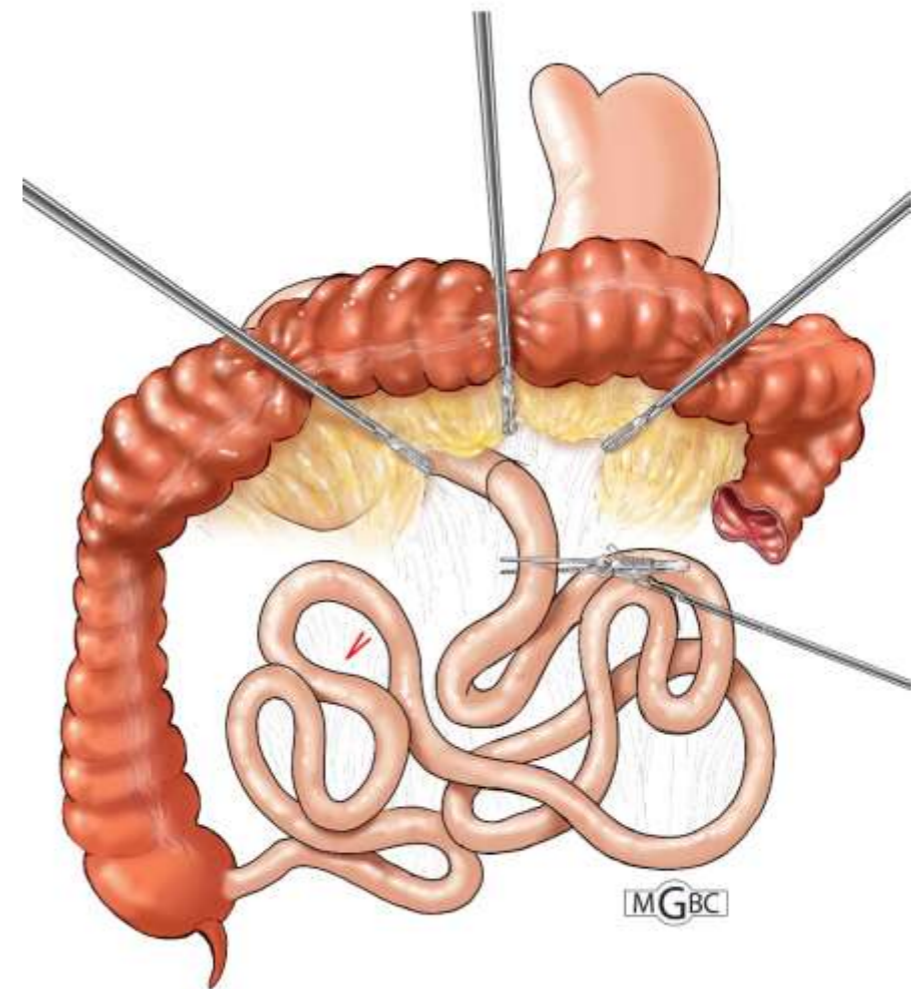
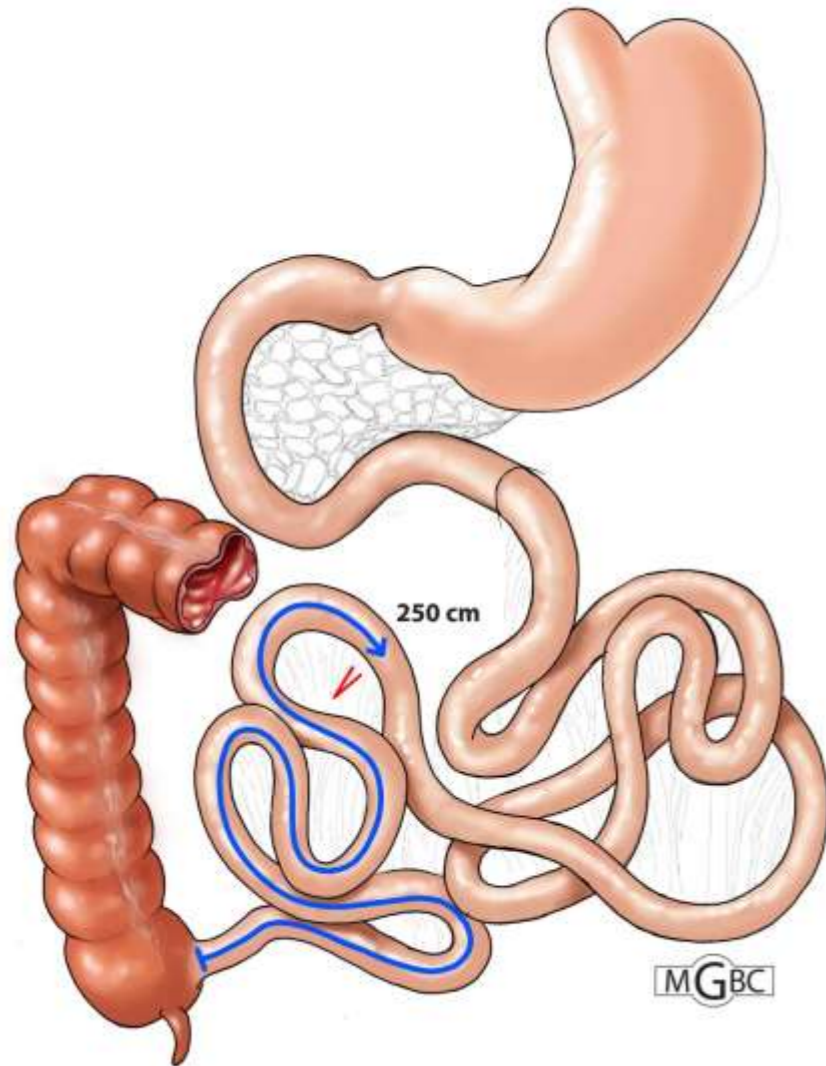
1. 18-65 years of age, inclusive, at the time of informed consent
2. BMI 30-50, inclusive with either:
 - Previous-sleeve gastrectomy (≥ 12 months) with either T2DM (defined as HbA1c $\geq 6.5\%$) or weight regain; or
 - T2DM without previous gastrectomy; or
 - Undergoing Laparoscopic Single Anastomosis Duodenal-Ileal bypass with Sleeve (SADI-S) where duodeno-ileostomy is performed side-to-side with the Magnet System and BMI ≥ 40
3. Agrees to refrain from any type of additional bariatric or reconstructive surgery that would affect body weight for 1 year
4. If a child-bearing female, subject must commit to not becoming pregnant and agree to use contraception for 1 year
5. Willing and able to comply with protocol requirements

Laparoscopic assisted procedure



The MAGNET System

Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy

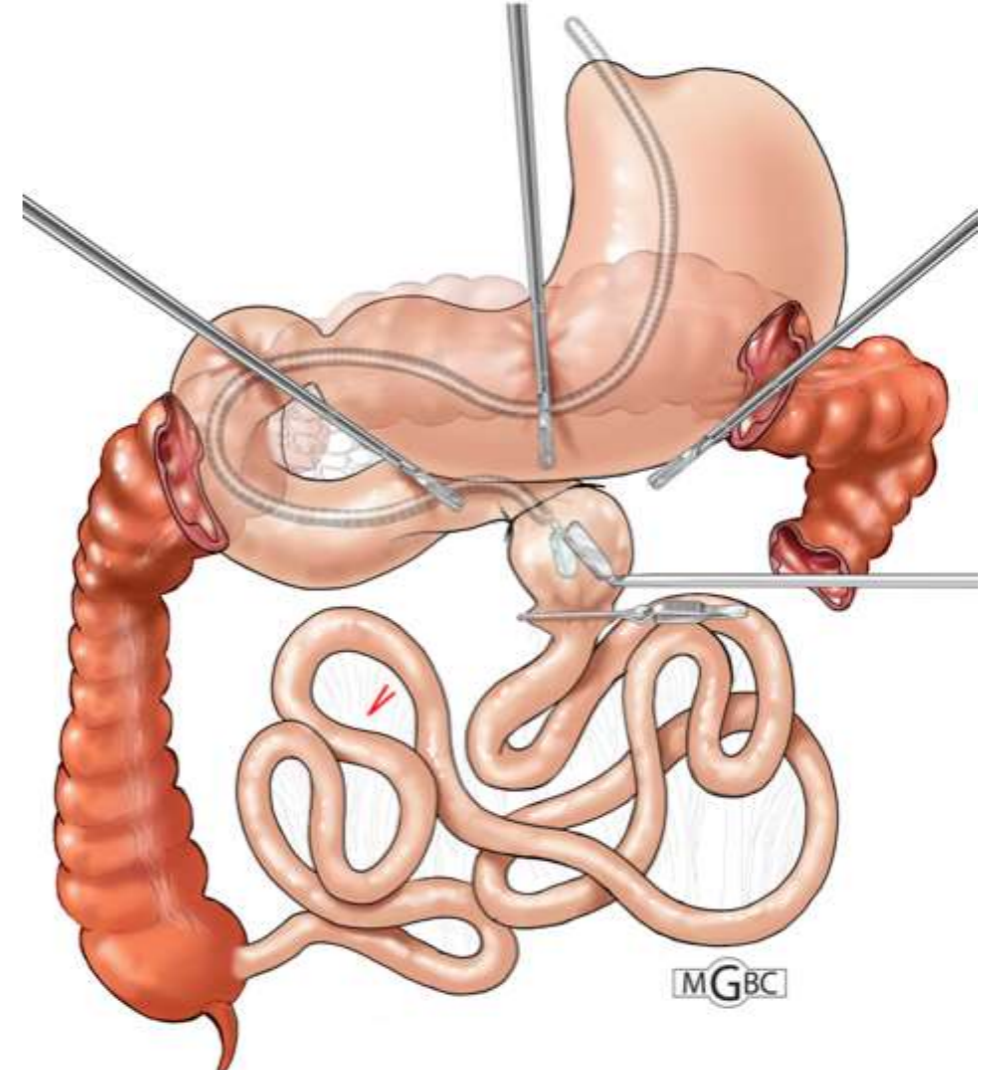
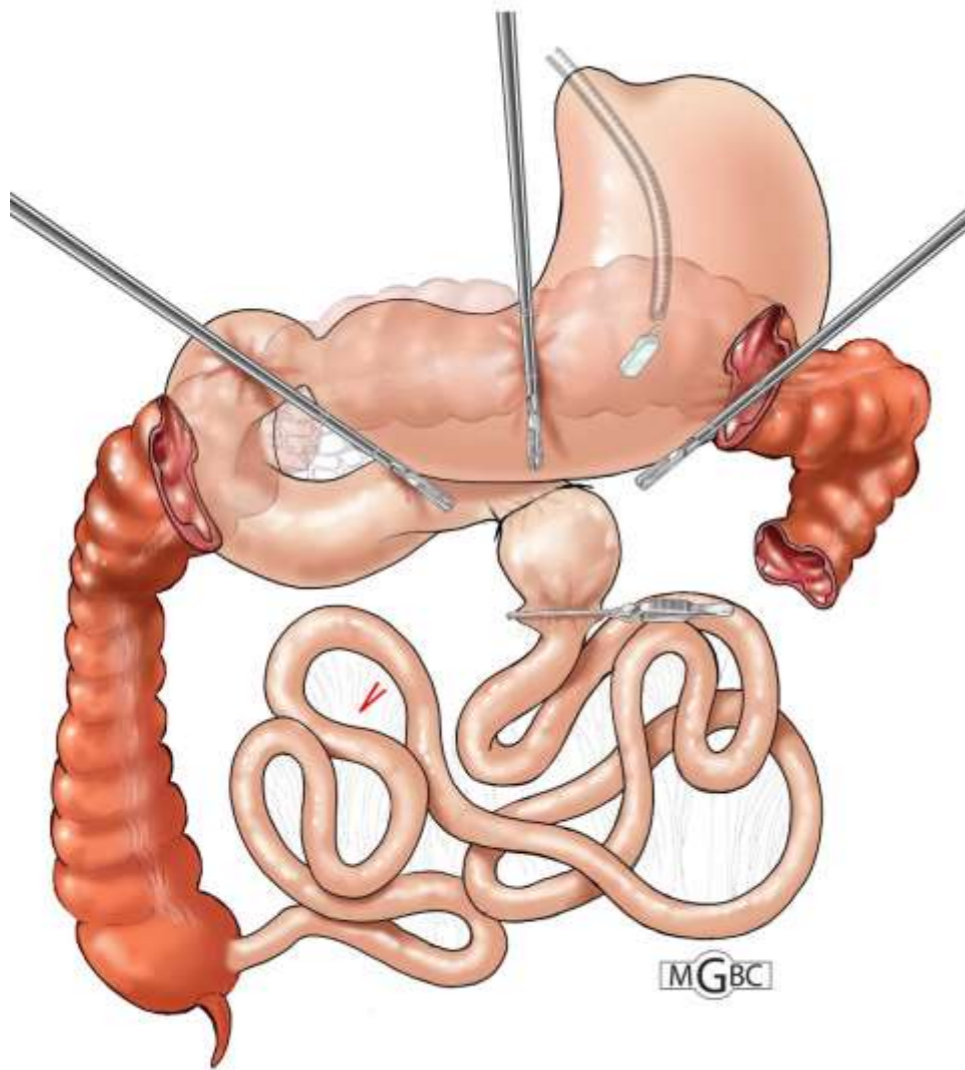


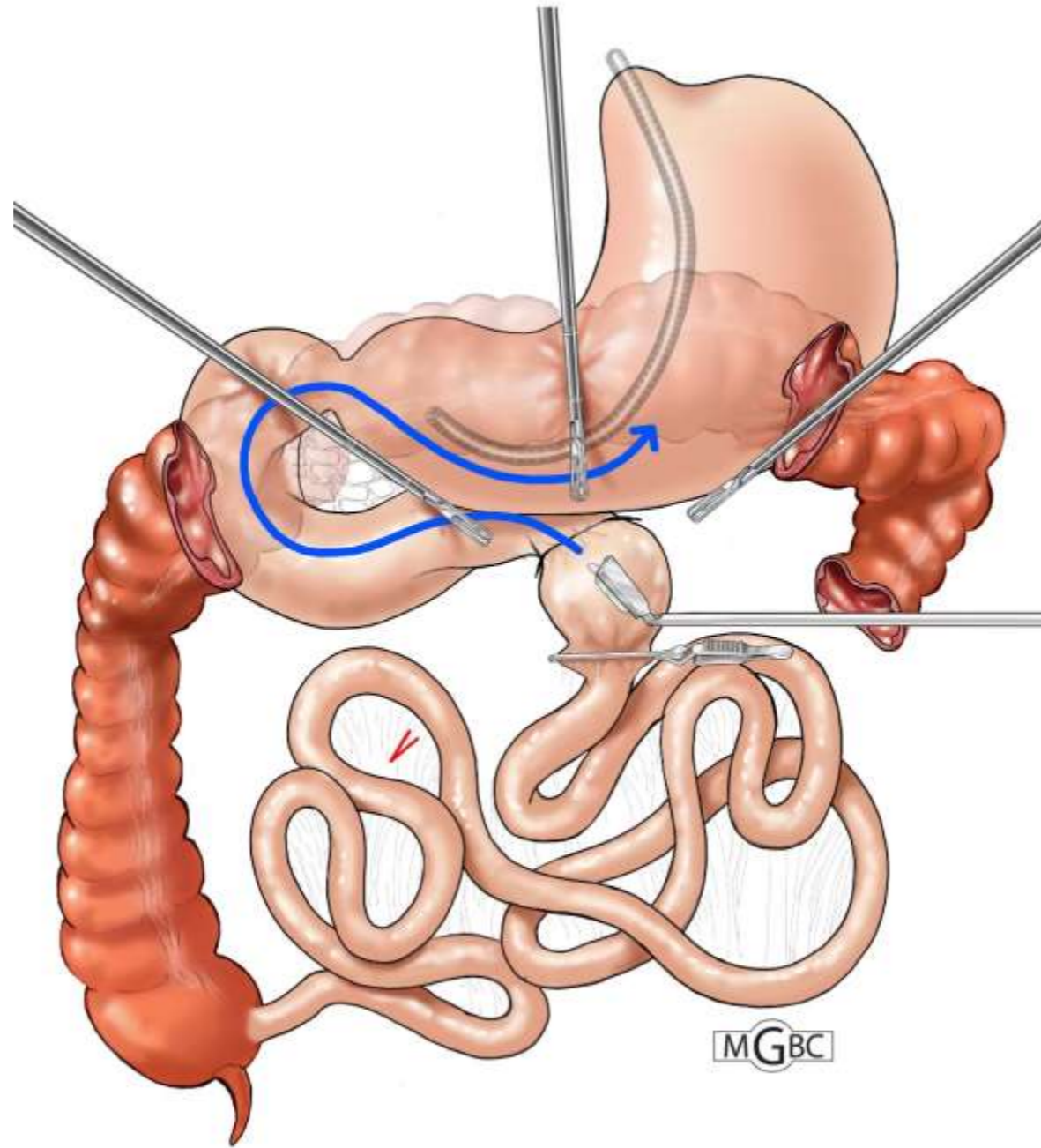
The MAGNET System Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy



The MAGNET System

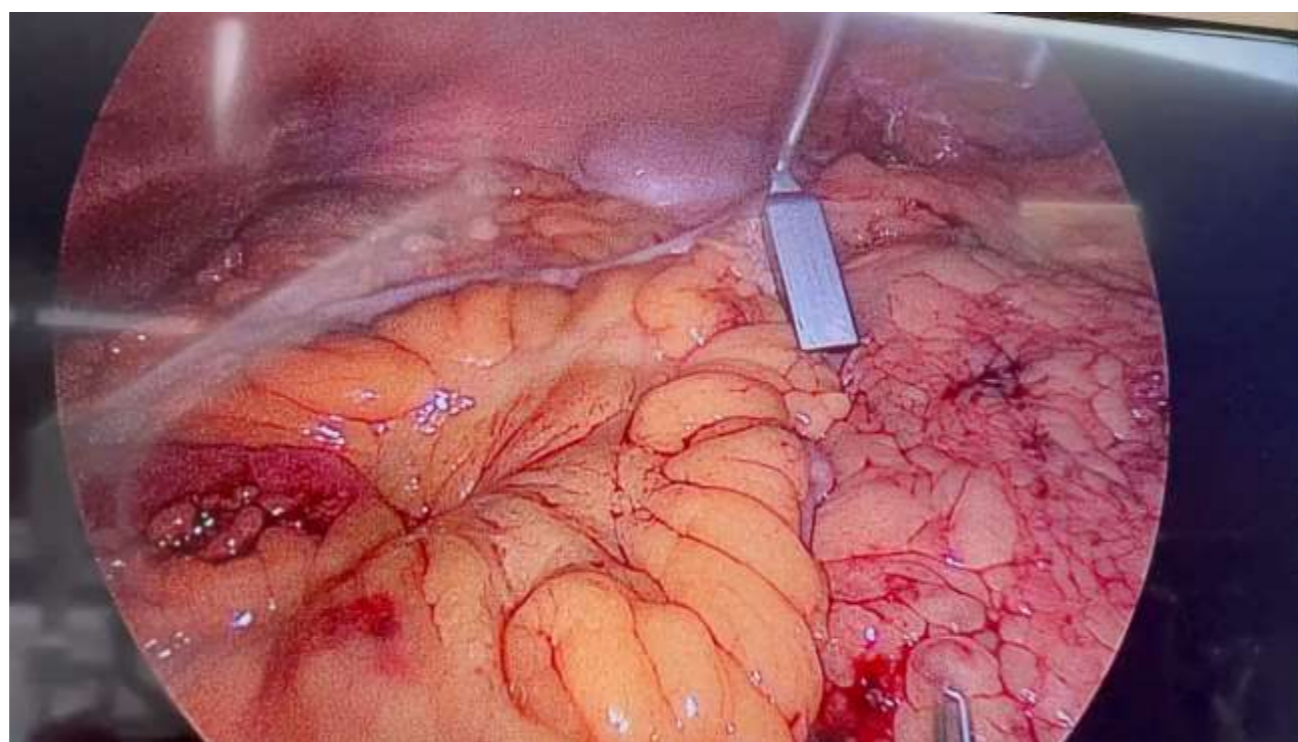
Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy





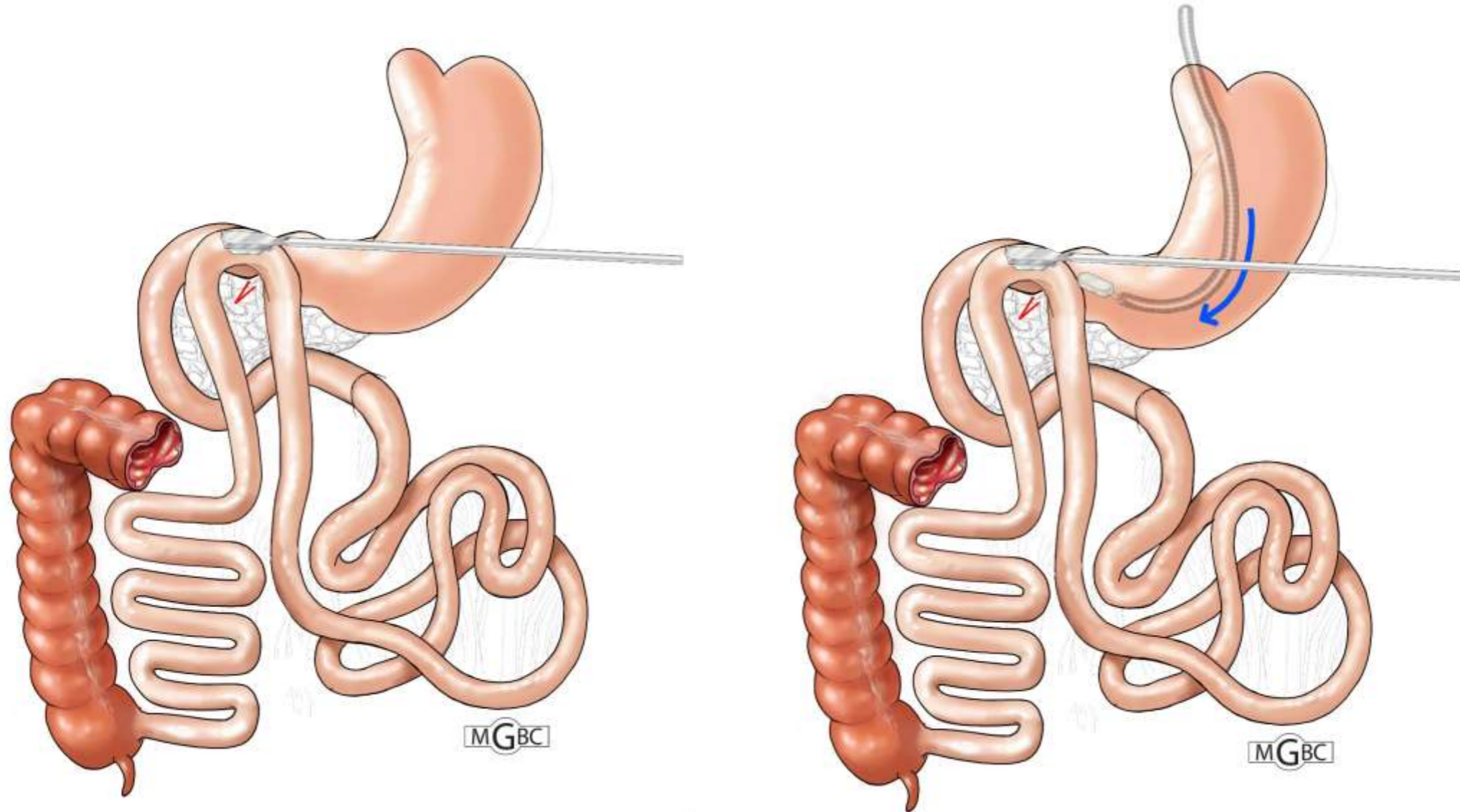
The MAGNET System

Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy



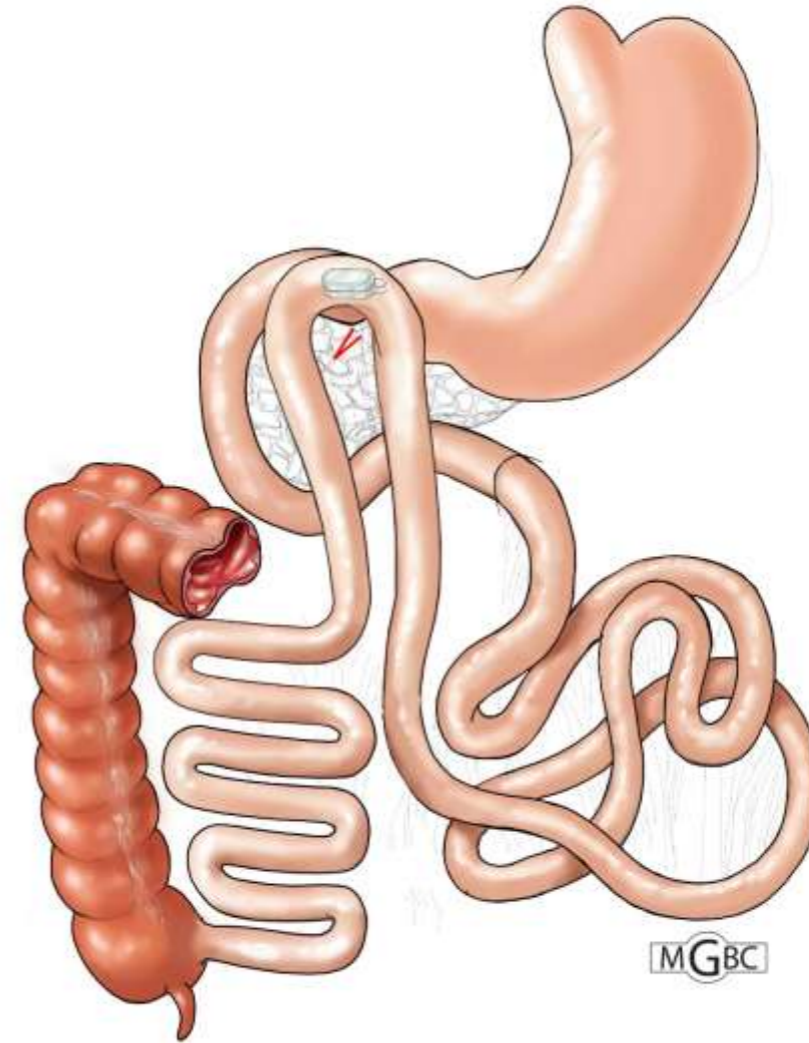
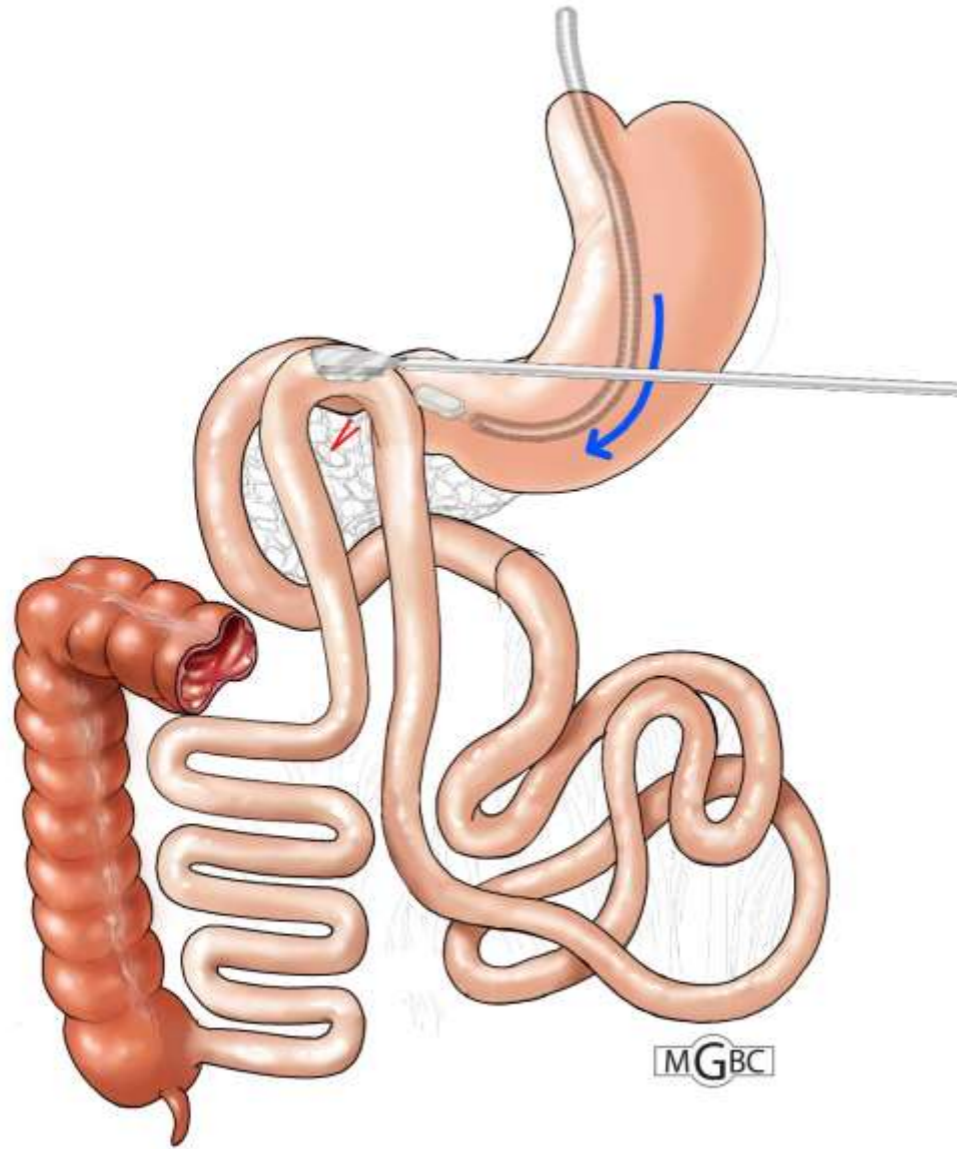
The MAGNET System

Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy



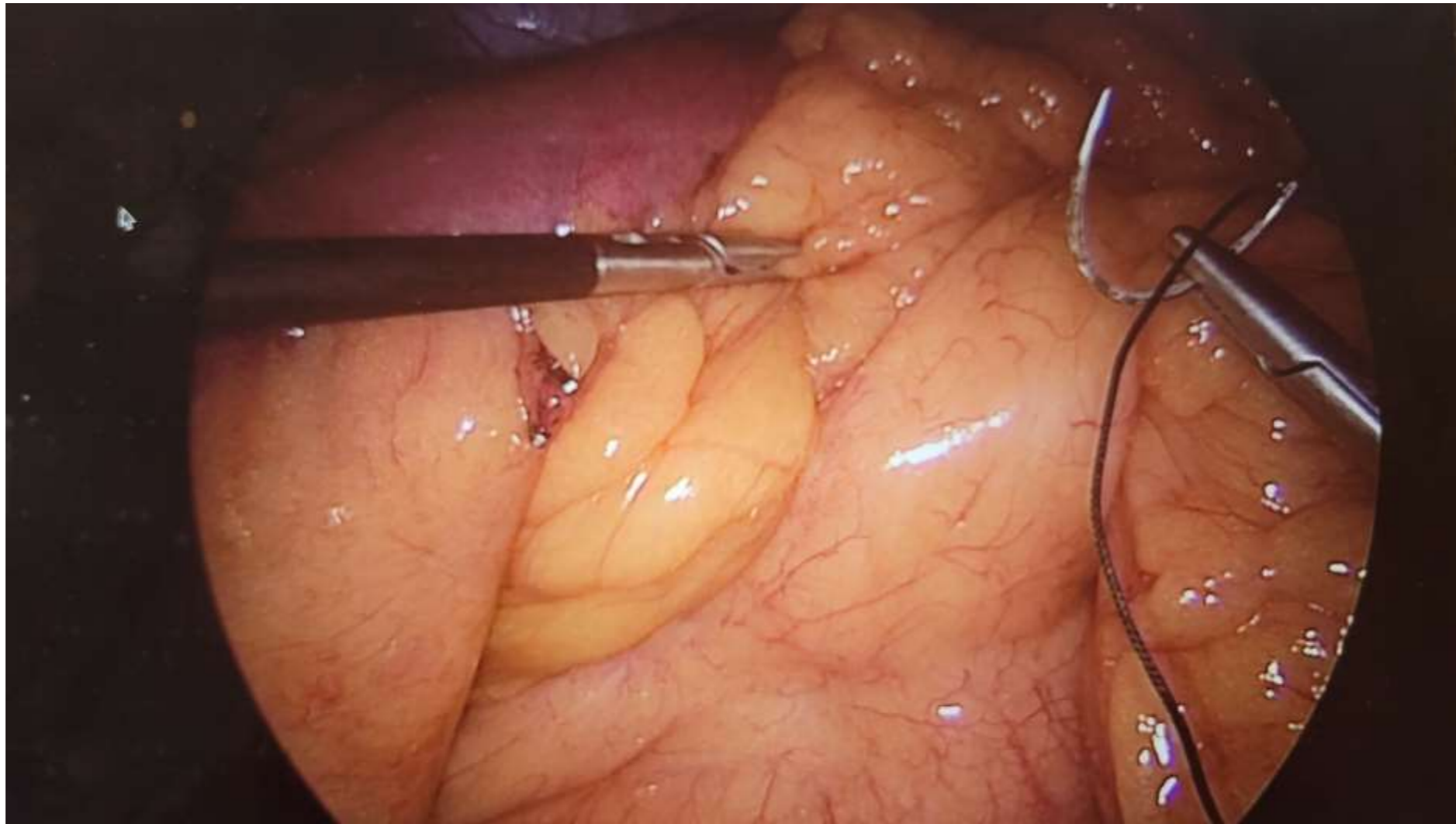
The MAGNET System

Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy

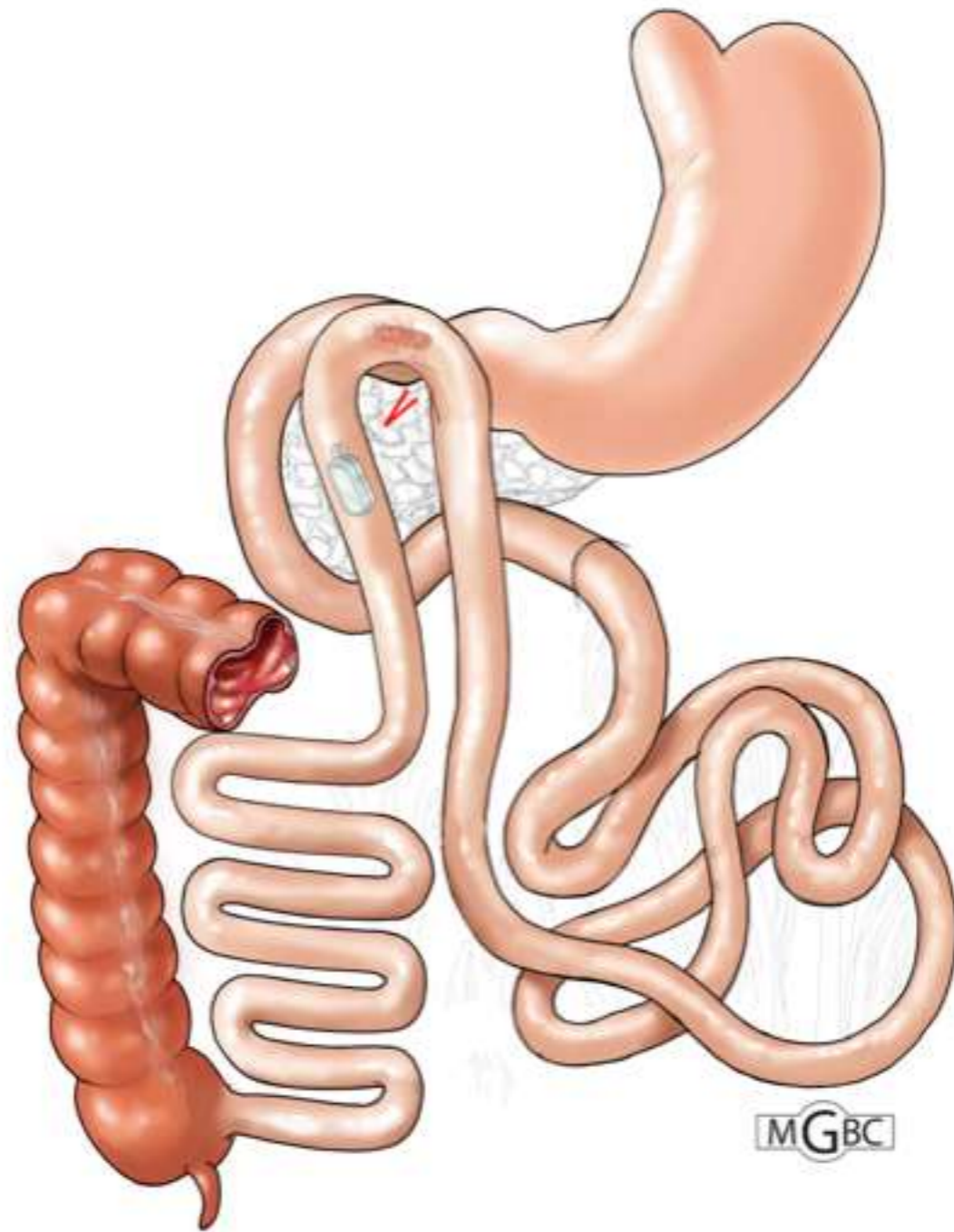
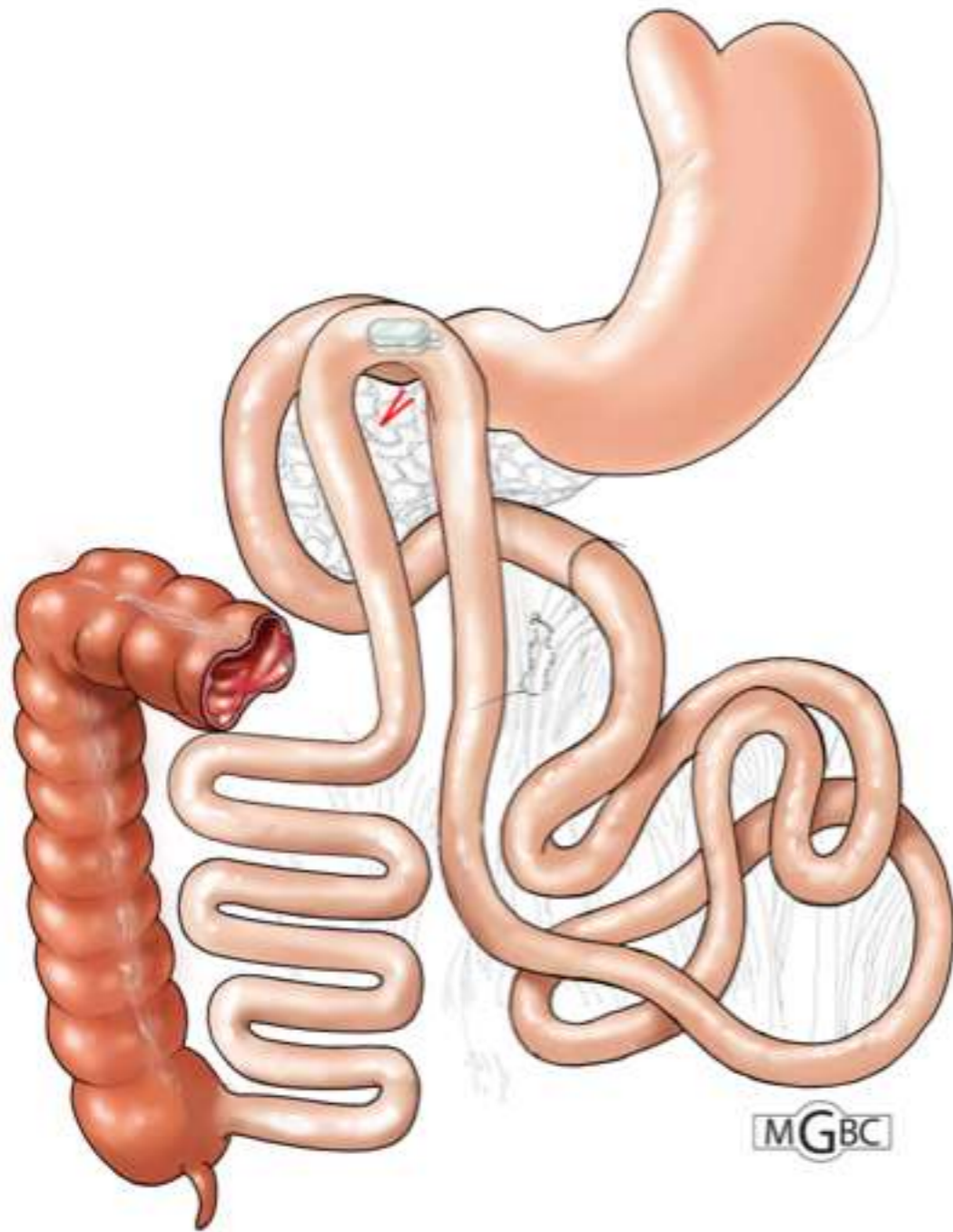


The MAGNET System

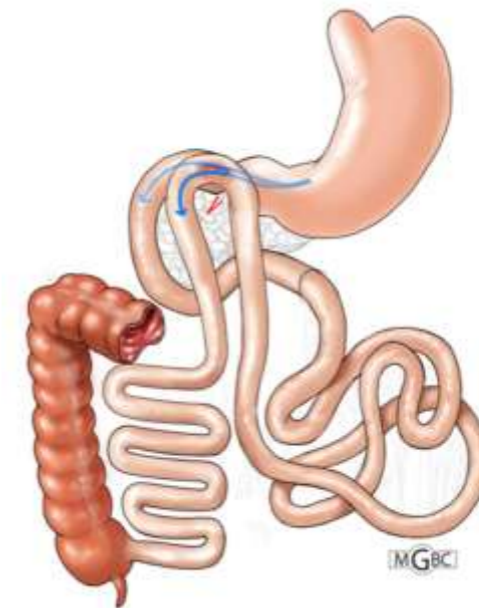
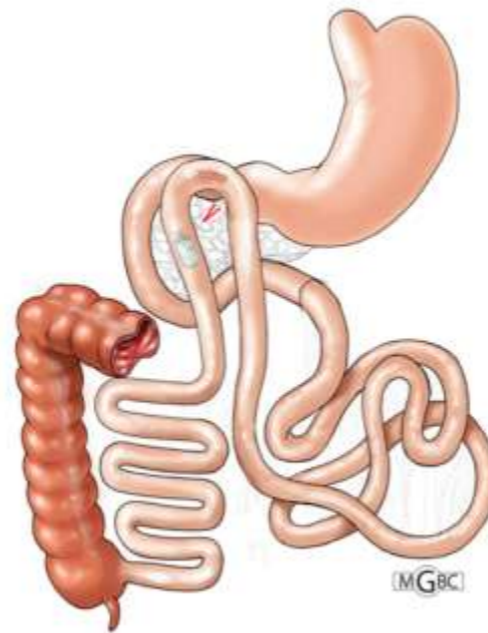
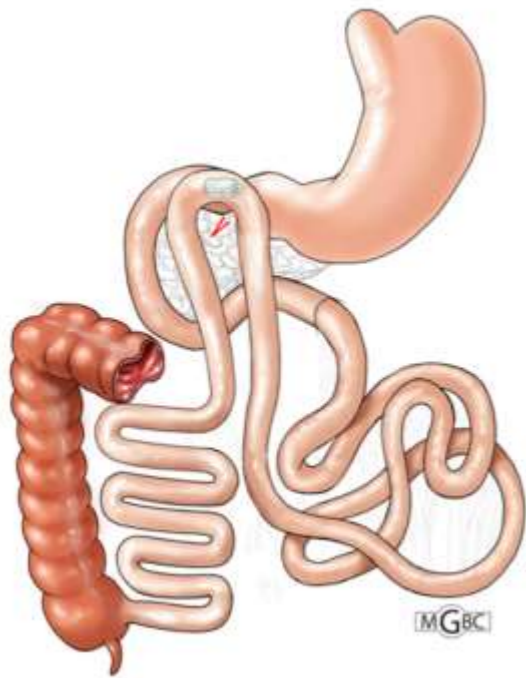
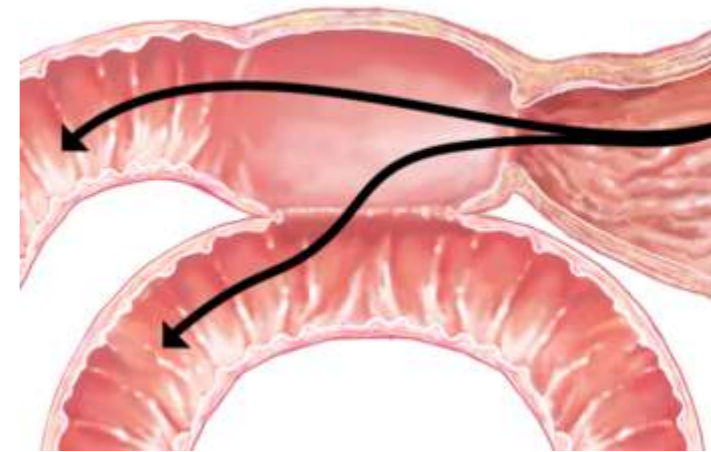
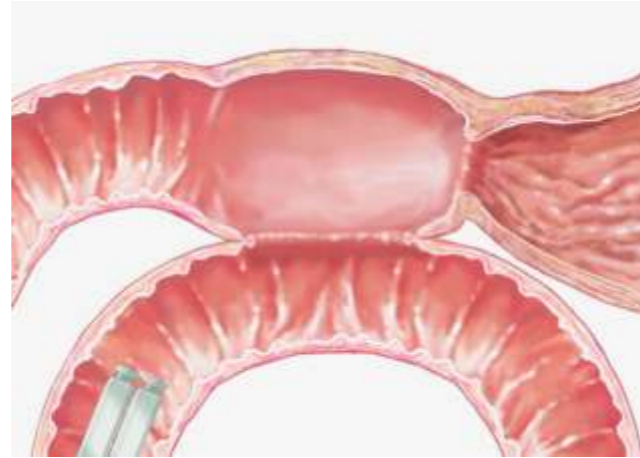
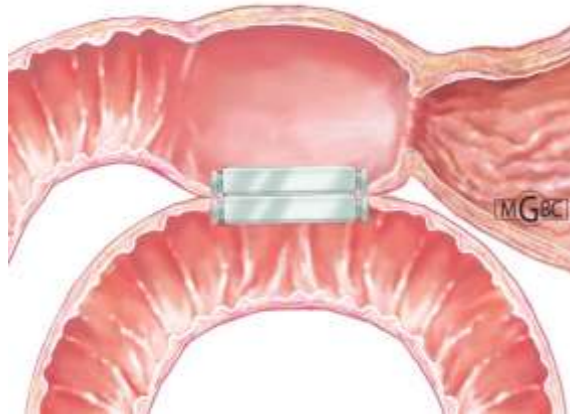
Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy

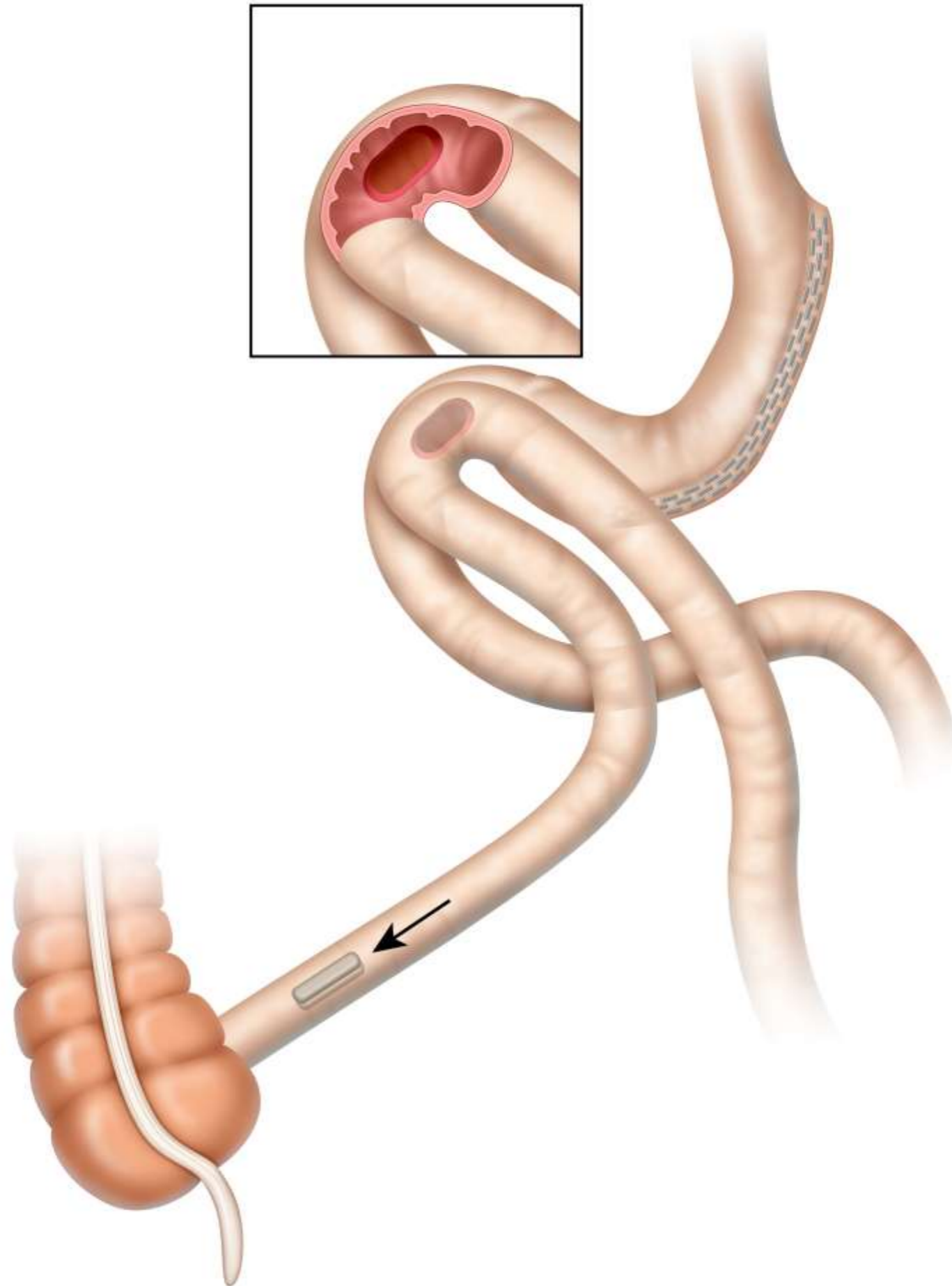


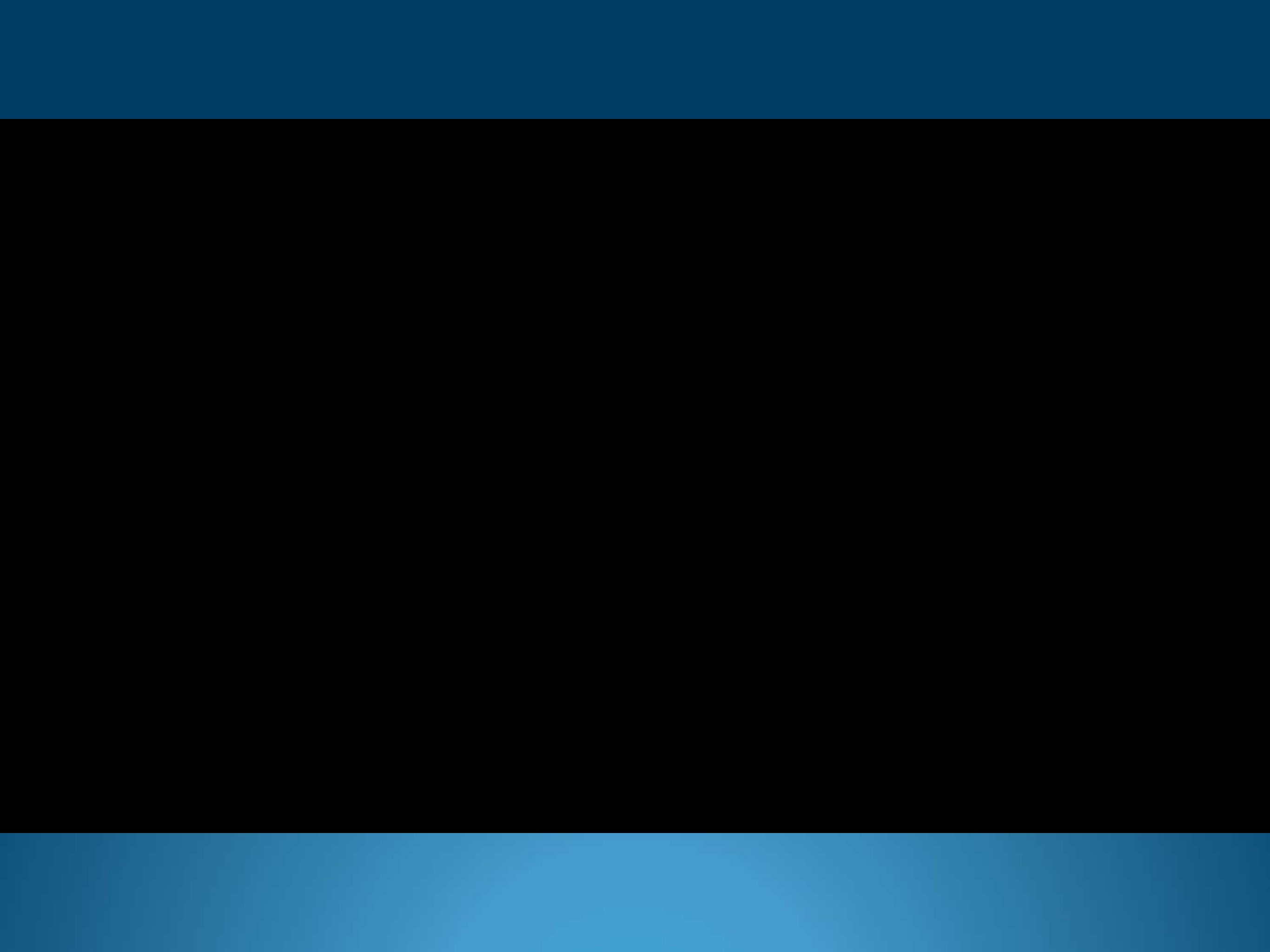
Closure of mesenteric defect
(Petersen's) on the left side



The MAGNET System Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy







Future revisions possibilities

- Reversibility
- Possible laparoscopic linear stapling at Duodeno-ileostomy
- Revision to Full SADI-S
- Possible laparoscopic duodenal stapling below the side-to-side
- Revision to Full DS

- Clinical Sites: Belgium, Republic of Georgia, Spain, Canada
- n=54 subjects enrolled between Nov 2021 and March 2023
- 24 Sleeve + DI
- 25 DI post Sleeve Gen I
- 5 DI Gen II



Side-to-side magnet anastomosis system duodeno-ileostomy with sleeve gastrectomy: early multi-center results

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Received: 1 April 2023 / Accepted: 8 May 2023

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- Clinical Sites: Belgium, Republic of Georgia, Spain
- n=24* subjects enrolled between 22 Nov 2021 and 18 Jul 2022
- All subjects completed six months of follow up (last D180 visit 16 Jan 2023)
 - A subset (n=5) completed one year follow up (last D360 visit 06 Dec 2022)

Baseline Characteristics	All subjects (n=24)
Clinical	
Undergoing SADI-S where duodeno-ileostomy is performed side-to-side with the Magnet system: n (%)	24 (100%)
Type 2 Diabetes: n (%)	9 (37.5%)
Body Mass Index (BMI): Mean (SEM)	44.4 (0.8) kg/m ²
Age	
Mean (SEM)	43.8 (1.8) years
Min, Max	28, 59 years
Gender	
Female: n (%)	20 (83.3%)
Male: n (%)	4 (16.7%)

- Side-to-side duodeno-ileal (DI) compression anastomosis performed with the Magnet System
- Magnets sequentially placed using a flexible gastroscope; first (distal) Magnet placed at the lig



- Median Procedure time: 130 minutes (Mean (SEM) = 128 (7) minutes)
- Median Hospitalization time post procedure: 3.5 days

Primary Outcome: 100% Magnet System Feasibility and Performance

- The Magnet System was successfully placed for all subjects (100%, 24/24)
- All subjects passed the device (paired set of docked Magnets) naturally without migration or s
- Patent anastomoses confirmed radiologically in all subjects at D90 primary endpoint time

Feasibility / Performance Criteria (D90)	n (%)
Placement of the device with >90% alignment of Magnets	24 (100%)
Passage of the device without invasive re-intervention	24 (100%)
Creation of a patent anastomosis confirmed radiologically	24 (100%)

- Median expulsion time: 48.5 days (Mean (SEM): 36 (4.2) days)
- D180 visits confirmed anastomoses were patent in all subjects at six months

Early Data Demonstrates Safety of the Magnet System

- A total of 57 adverse events (AEs) reported in 21 subjects
 - No adverse events were assessed as related to the Magnet device
 - Forty-seven events (83%, 47/57) were grade I-II on Clavien-Dindo Classification
 - Ten (17%, 7/57) were grade III on Clavien-Dindo Classification (*next slide*)
- No (0%) reports of anastomotic bleeds, leaks, obstruction, or infection, and no deaths

Clavien-Dindo Classification (n total AEs)	Procedure – D30 (n=57)	>D30 – D180 (n=57)	TOTAL (n=57)
Grade I	17 (30%)	8 (14%)	25 (44%)
Grade II Requiring pharmacological treatment	9 (16%)	13 (23%)	22 (39%)
Grade III Requiring surgical, endoscopic, or radiological intervention	6 (10%)	4 (7%)	10 (17%)
Grade IV Life-threatening	0 (0%)	0 (0%)	0 (0%)
Grade V Death of a patient	0 (0%)	0 (0%)	0 (0%)
TOTAL Adverse Events	32 (56%)	25 (44%)	57 (100%)

Grade III Adverse Events on Clavien-Dindo Classification

- Ten (83%, 10/57) grade III events on Clavien-Dindo Classification; all subjects had Magnet procedure
 - **(4) cases of serosal tissue tears due to the use of laparoscopic bowel forceps** during grasp and pull maneuver
 - **(1) jejunal obstruction from internal hernia at mesentery**, despite mesentery defect closure per protocol
 - **(1) major pneumoperitoneum and pneumonia** associated with a gastric fistula
 - **(1) case of pelvic fluid collection** of unknown etiology starting post-op D2, persisted over two months,
 - resolved after transvaginal draining x 2
 - **(1) benign stenosis mid gastric sleeve**
 - **(1) abdominal pain, nausea, and vomiting**
 - **(1) cholecystolithiasis with choledocholithiasis**
- None (0%) of the grade III events were determined to be related to the Magnet device

Table 2 Evolution of weight and clinical parameters after side-to-side magnetic duodeno-ileostomy with sleeve gastrectomy

	Baseline	6-month follow-up (n=24)			12-month follow-up (n=5)		
	Mean \pm SEM	Mean \pm SEM	Mean change \pm SEM (95%CI)	P-value	Mean \pm SEM	Mean change \pm SEM (95%CI)	P-value
Weight							
Absolute wt, kg	121.9 \pm 3.3	87.8 \pm 2.8	34.2 \pm 1.6 (30.9, 37.4)	<0.001	77.6 \pm 4.7	40.0 \pm 3.1 (31.4, 48.6)	<0.001
BMI, kg/m ²	44.4 \pm 0.8	32.0 \pm 0.8	12.4 \pm 0.5 (11.5, 13.3)	<0.001	29.3 \pm 1.5	15.1 \pm 1.0 (12.2, 18.0)	<0.001
TWL, %	–	28.1 \pm 1.0	–	–	34.0 \pm 1.4	–	–
EWL, %	–	66.2 \pm 3.4	–	–	80.2 \pm 6.6	–	–
Clinical							
HbA _{1c} , %*	6.2 \pm 0.3	5.1 \pm 0.2	1.1 \pm 0.4 (0.2, 1.9)	<0.05	4.8 \pm 0.2	2.0 \pm 1.1 _††	0.173
Glucose, mg/dL [†]	111.3 \pm 6.1	86.5 \pm 3.5	24.8 \pm 6.6 (11.0, 38.6)	<0.001	87.3 \pm 6.3	53.8 \pm 6.3 _††	0.113

BMI: Body mass index; *TWL*: Total weight loss; *EWL*: Excess weight loss; *HbA_{1c}*: Glycosylated hemoglobin

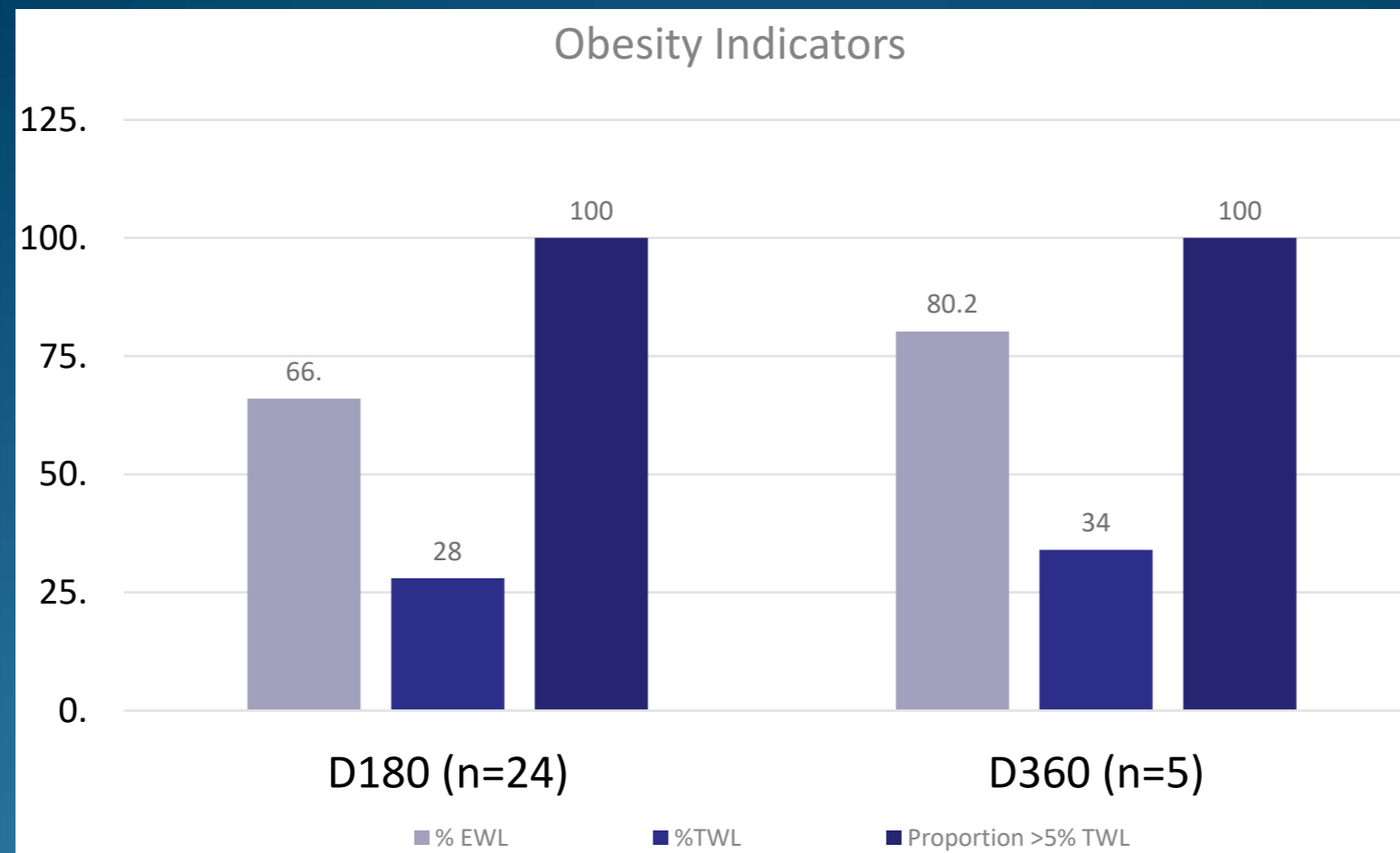
*HbA_{1c} baseline n=20; 6-month n=19; 12-month n=4

[†]Glucose baseline n=21; 6-month n=21; 12-month n=4

^{††}Not applicable due to small sample size

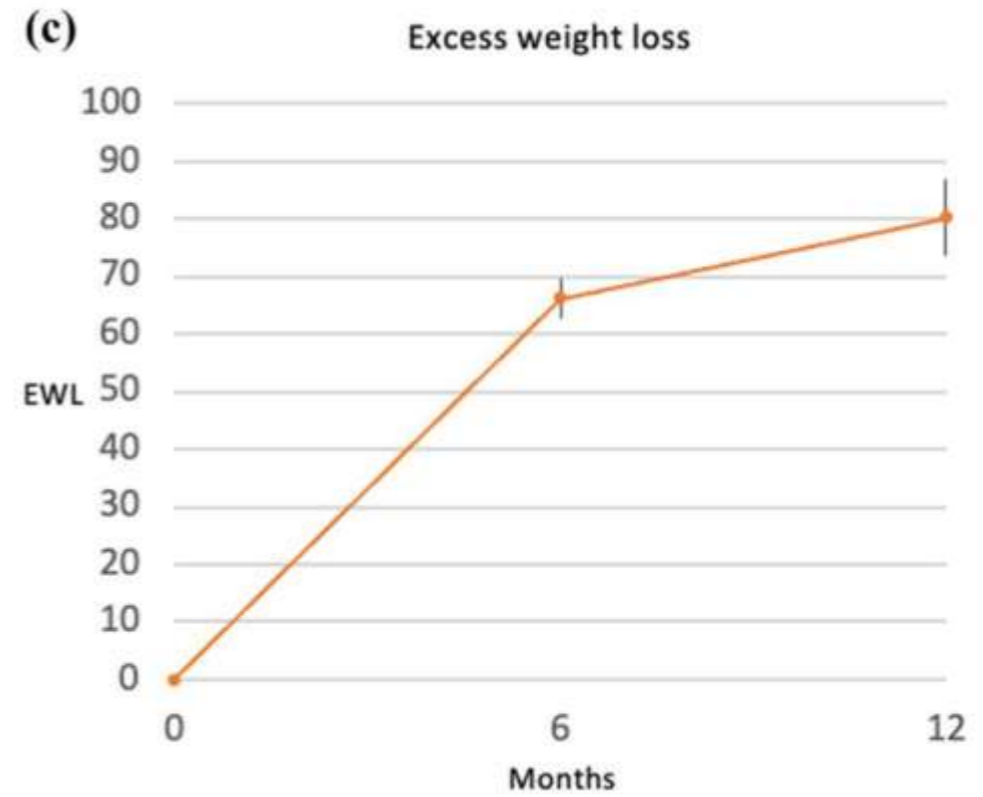
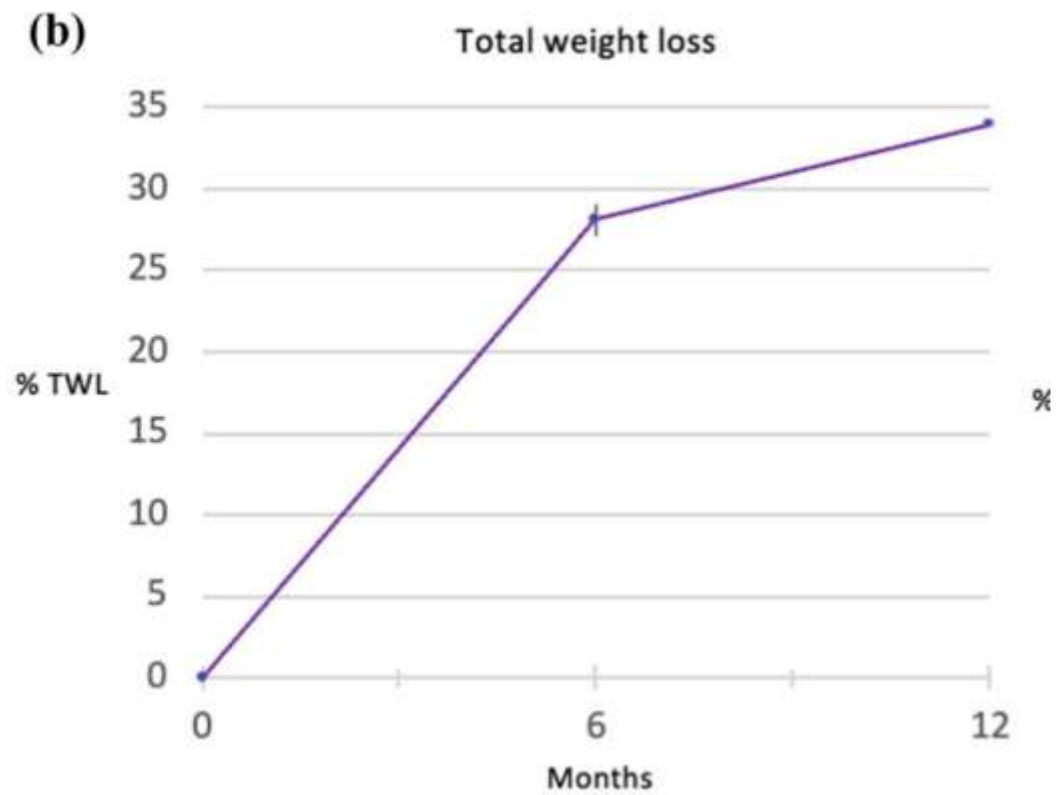
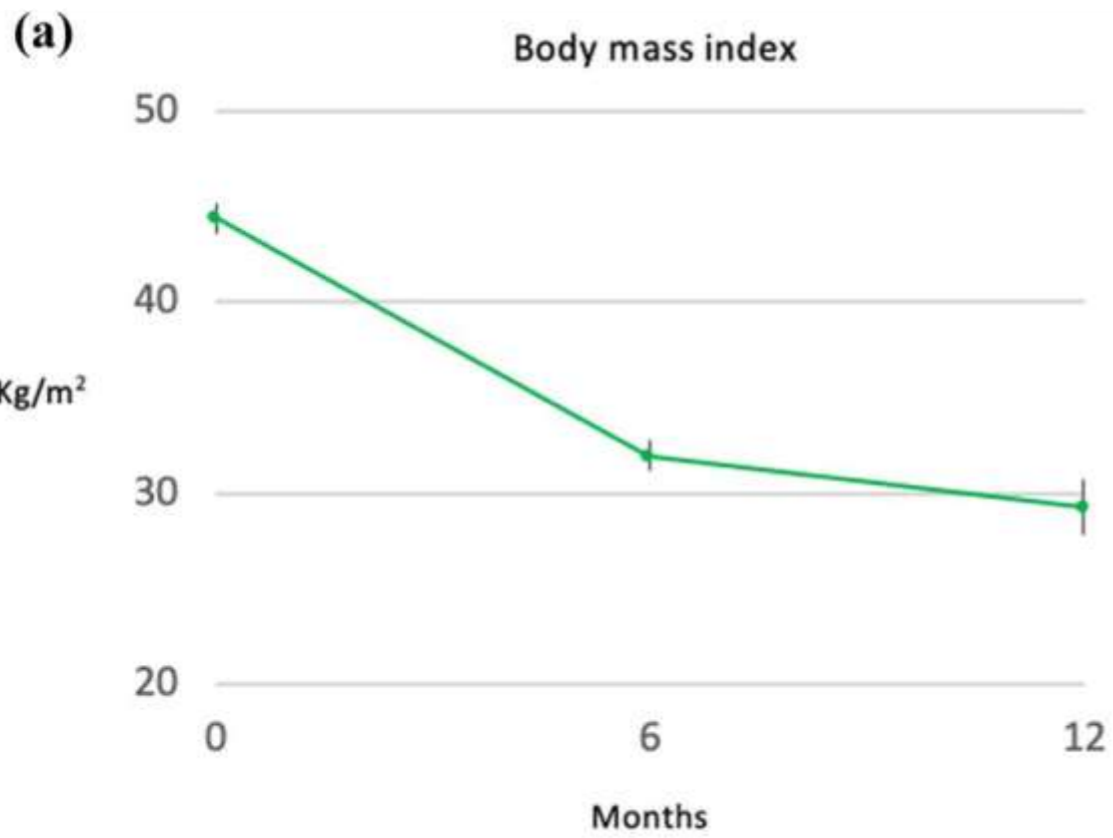
Secondary Outcomes Collected for Early Signals

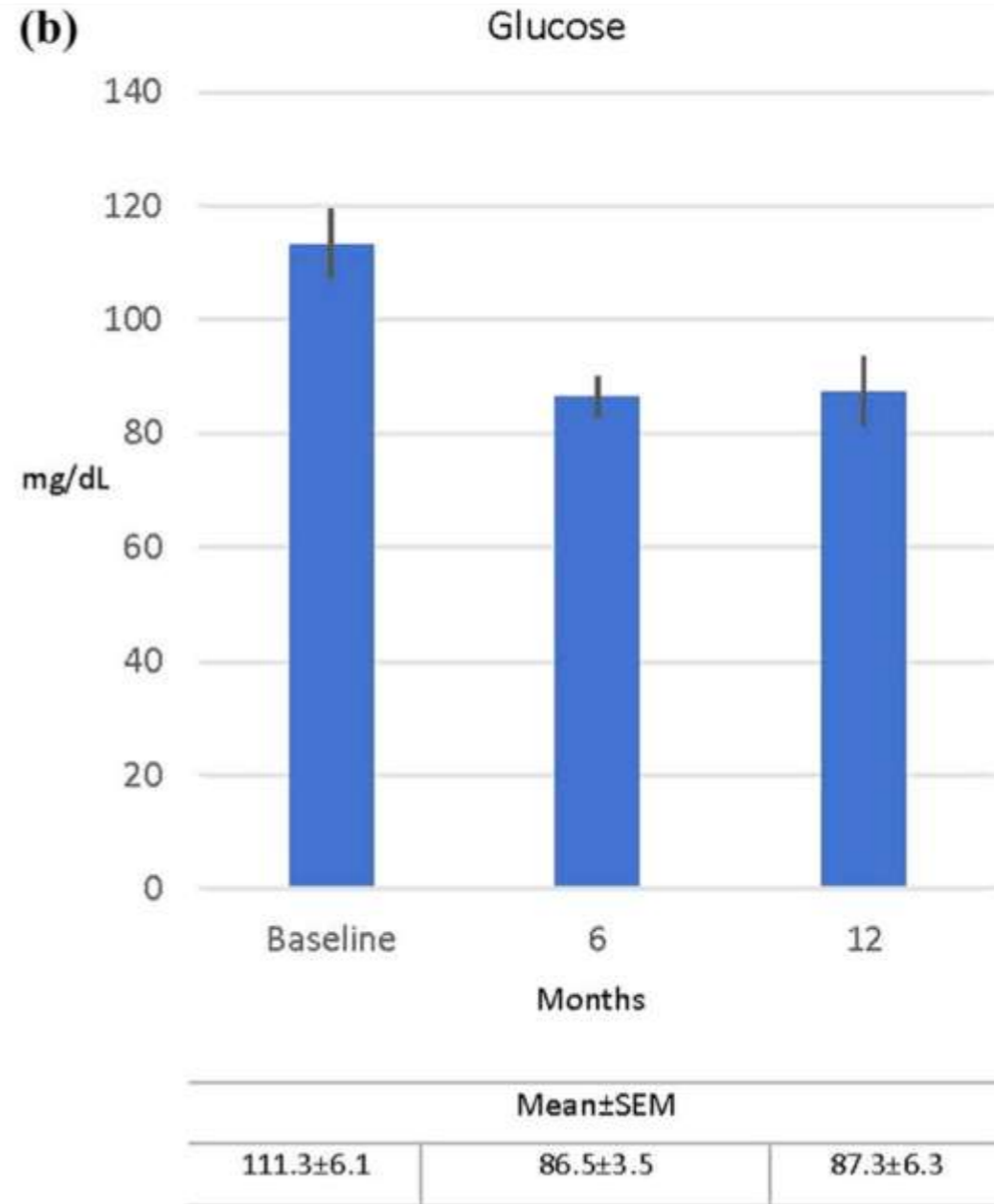
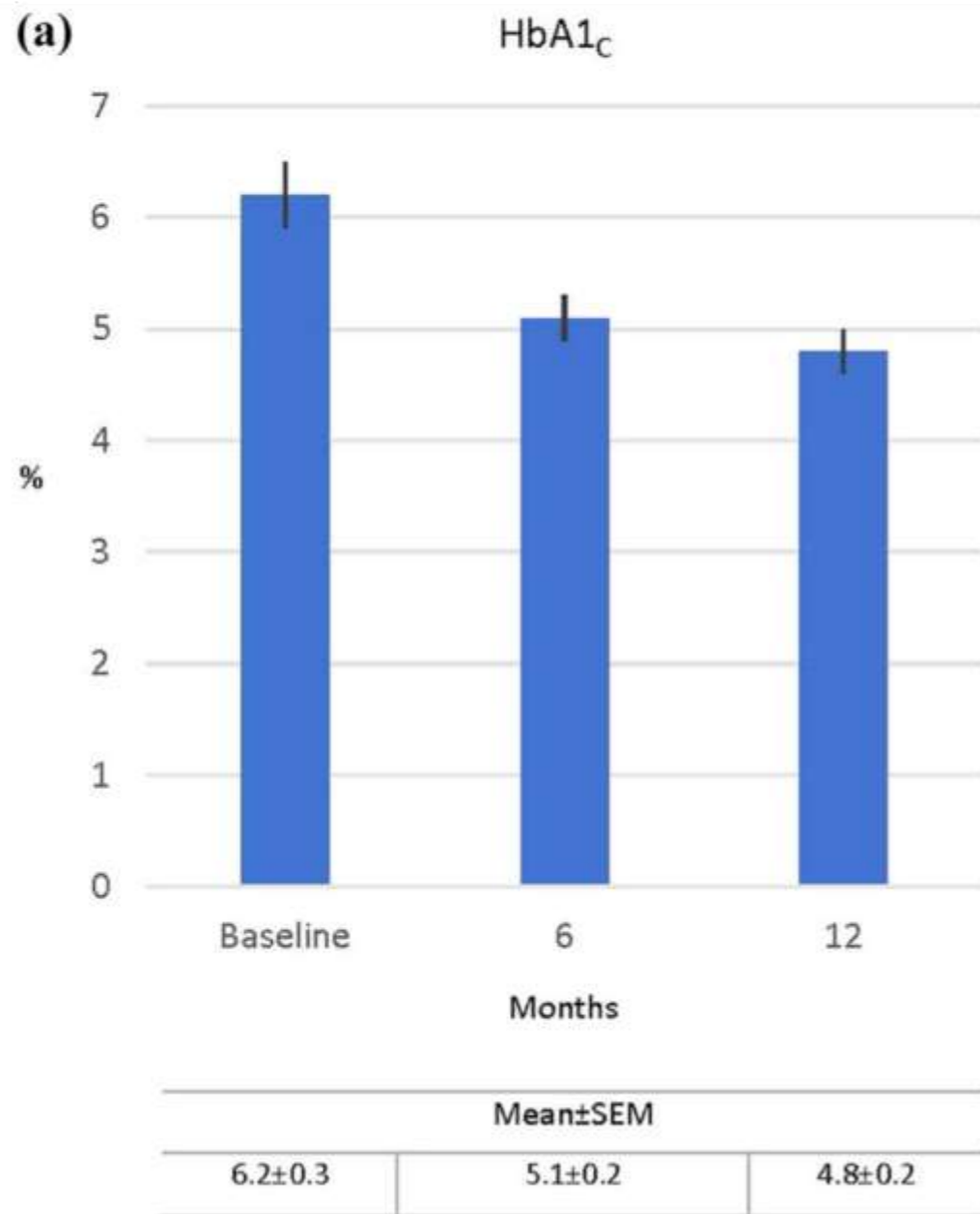
- Obesity indicators in this cohort (n=24) are very promising at six months
- Impressive results continue for the subset of 5 subjects followed to one year



Obesity Indicator	D180 n=24	D360 n=5
Proportion of Subjects >5% TWL	100% (24/24)	100% (5/5)
% TWL Mean (SEM)	28 (0)	34.0 (1.4)
% EWL Mean (SEM)	66 (3)	80.2 (6.6)







Secondary Outcomes Collected for Early Signals

- Functional improvement of metabolic indicators at six months are also quite promising (n=24):

Metabolic Indicator	Baseline	D180
HbA1c % Mean (SEM)	6.0 (0.3) (n=20)	5.1 (0.1) (n=19)
Glucose, mg/dL Mean (SEM)	112.7 (5.8) (n=21)	87.5 (3.2) (n=21)

- Nine (9) subjects entered the study with a diagnosis of Type 2 Diabetes with seven (78%, 7/9)
 - Four (4) subjects stopped medications at enrollment and remained off
 - Two (2) subjects stopped medications after enrollment (2 weeks and 4 months) and remained off
 - One (1) subject reduced the number of diabetes medications, remaining on metformin

Summary

- All 24 subjects received a side-to-side DI compression anastomosis with the Magnet System (study procedure) followed by a non-study sleeve gastrectomy
- All cases (100%, 24/24) resulted in successful alignment of the two Magnets with passage of the device naturally without migration or separation and none (0%) required invasive re-intervention
- All anastomoses were confirmed patent radiologically and remained patent through six months of follow up
- All adverse events (n=57) were of grade III or lower on the Clavien-Dindo Classi. grading system. None were determined related to the Magnet device.
- There were no reports of anastomotic bleeds, leaks, obstruction, or infection and no deaths, known risks with conventional techniques (sutures or staples)
- The secondary outcomes of weight loss and functional improvement in metabolic indicators
- are promising in this cohort (n=24) at six months and continued to be maintained for the the subset of five (5) followed to one year.

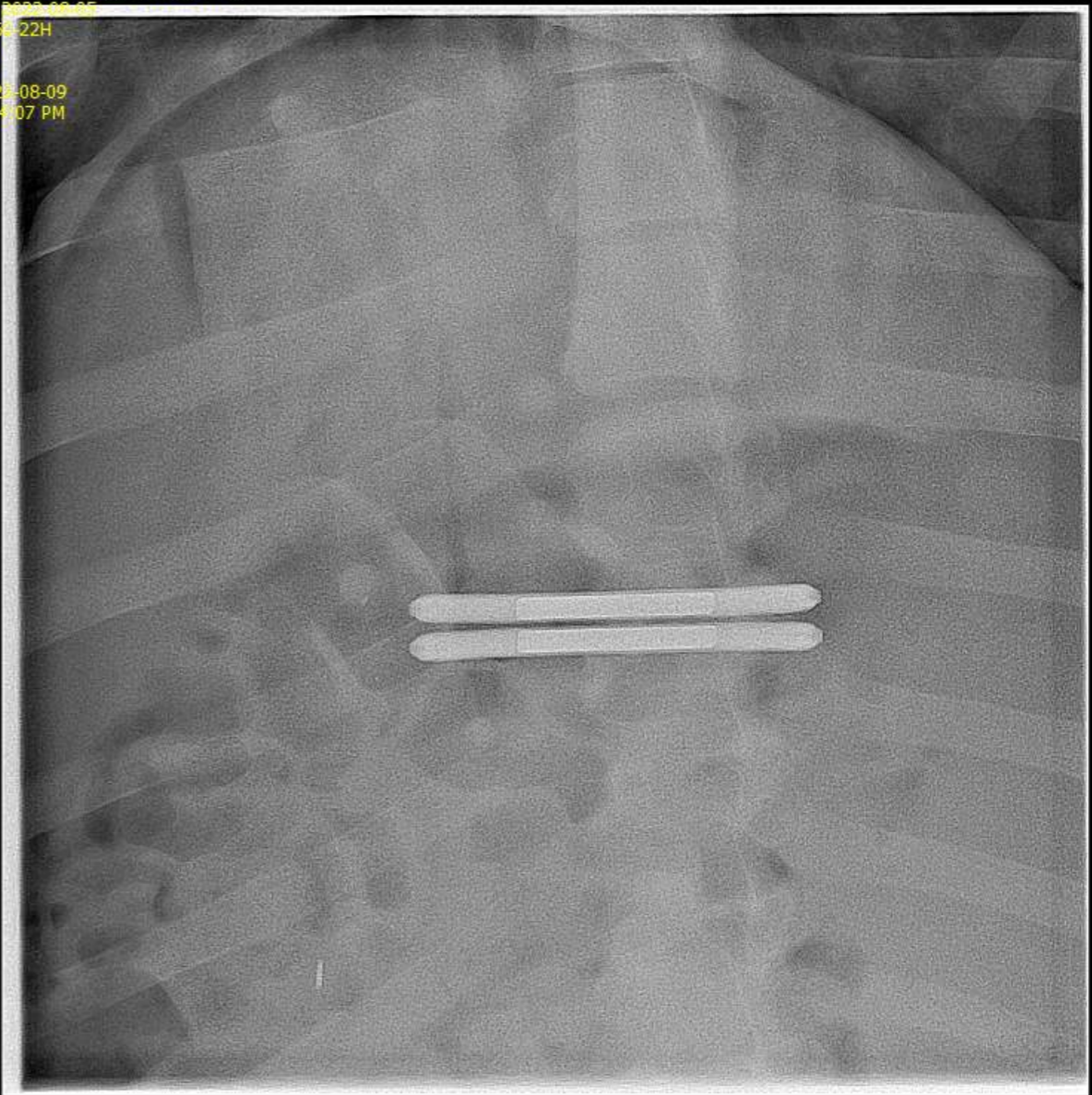


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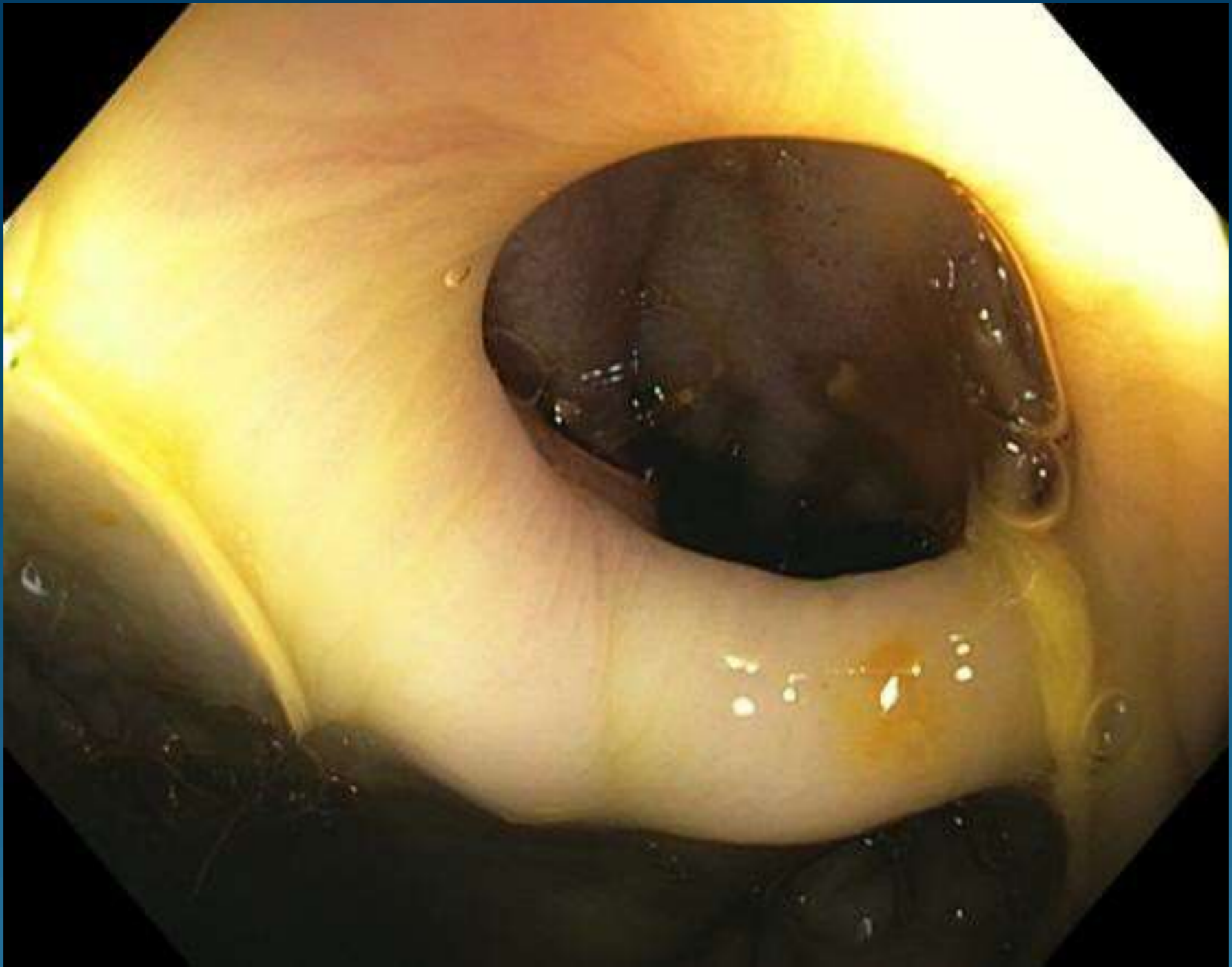


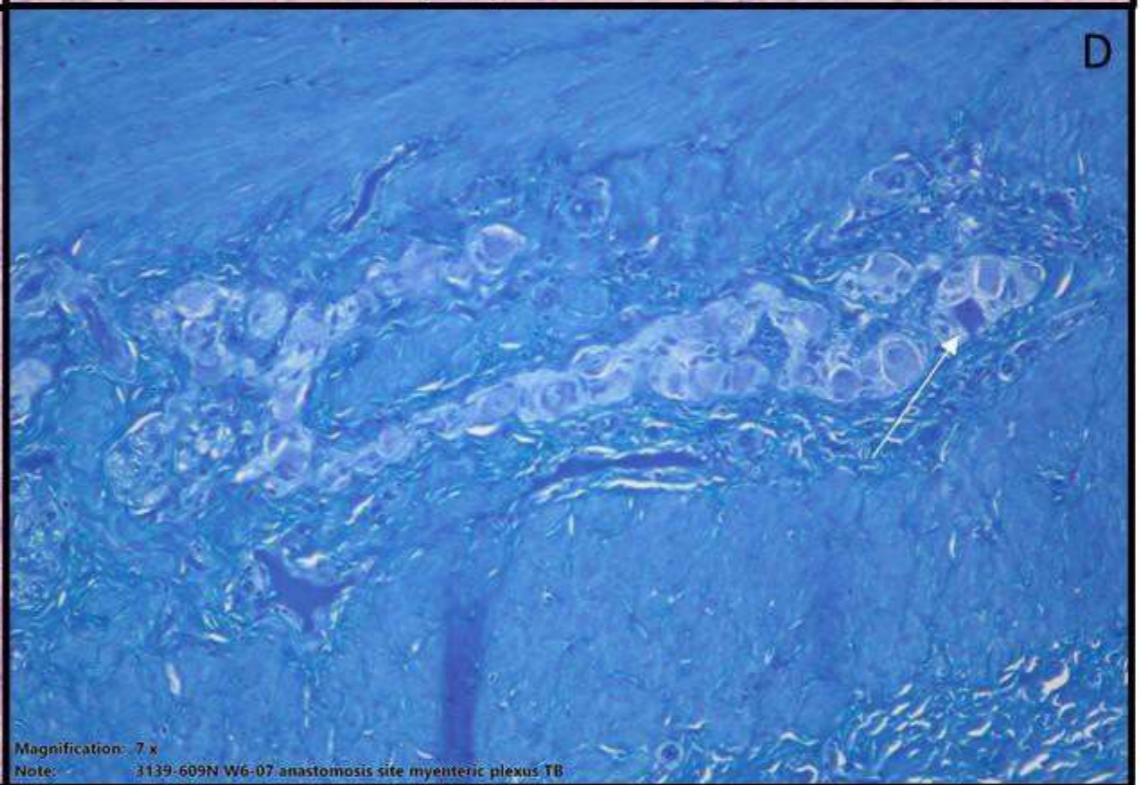
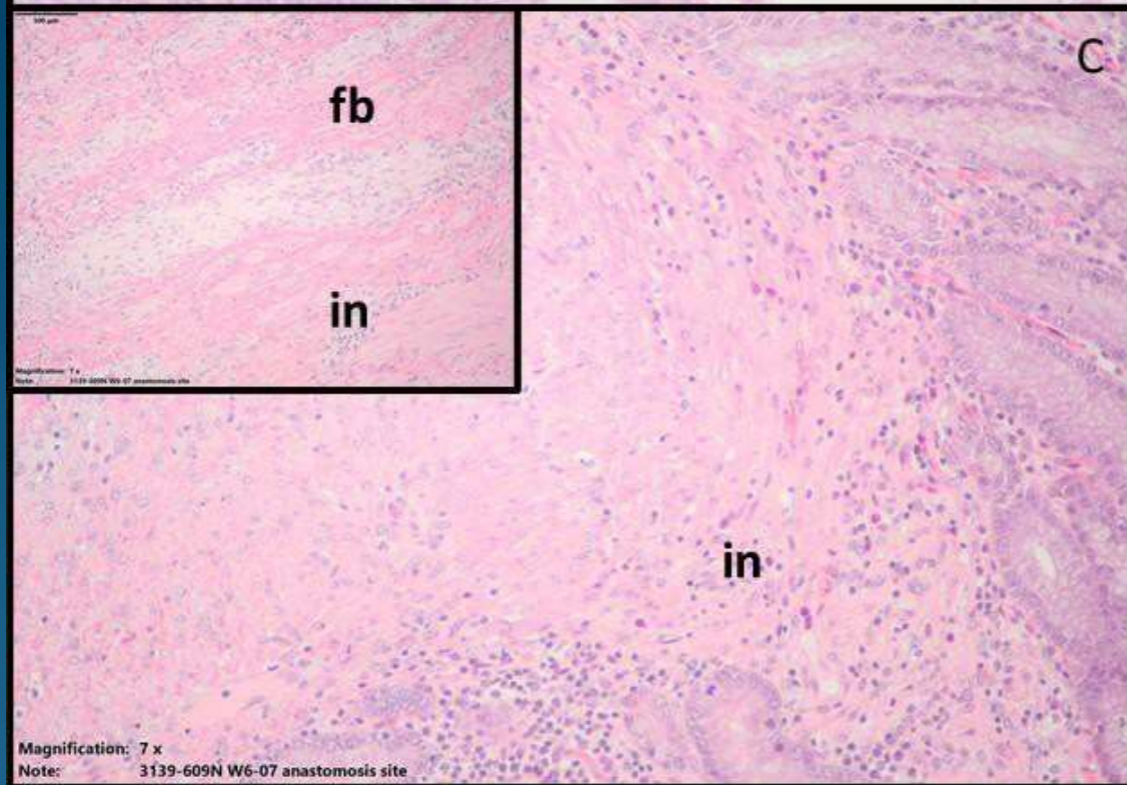
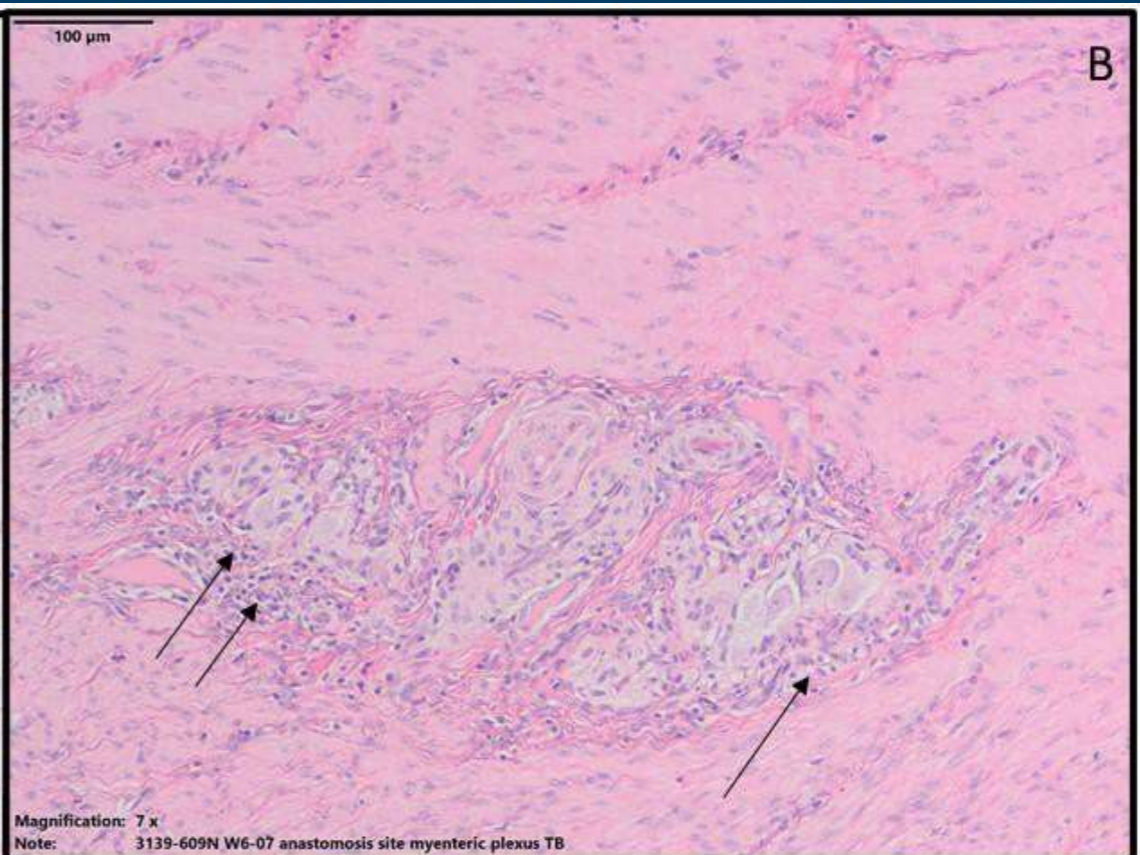
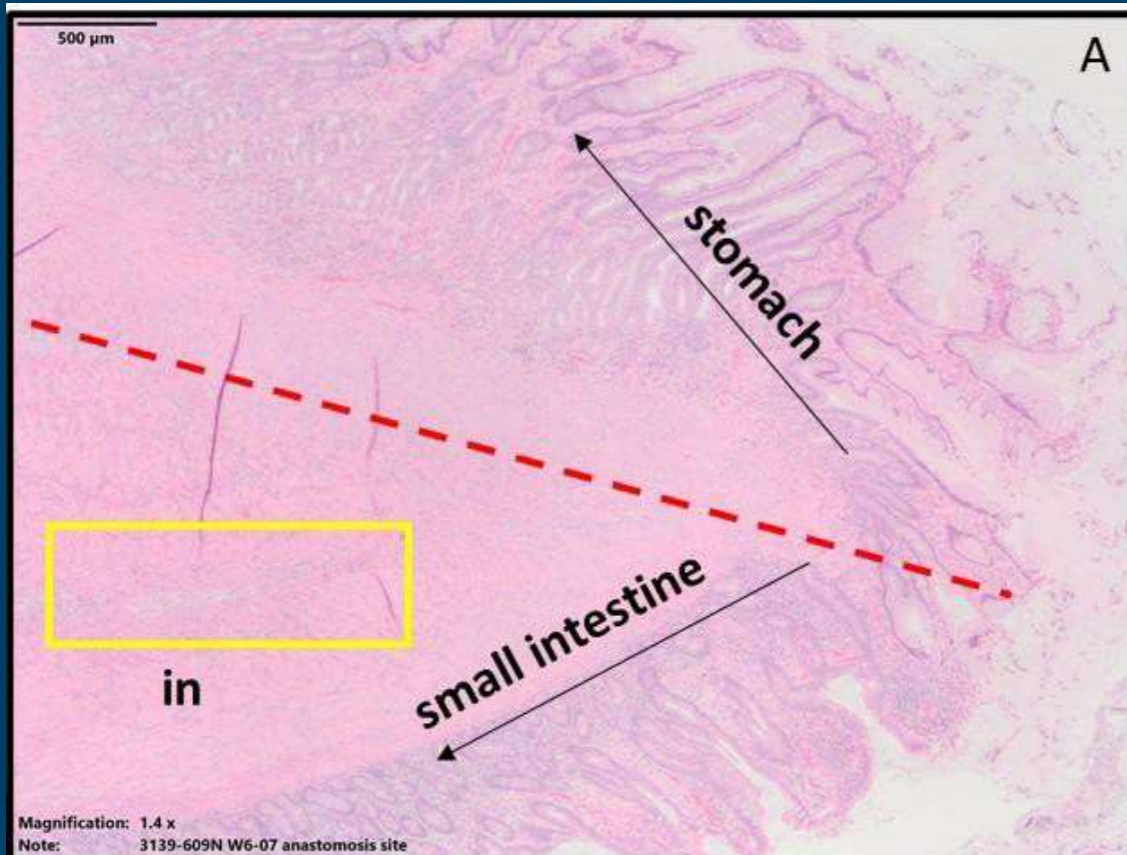
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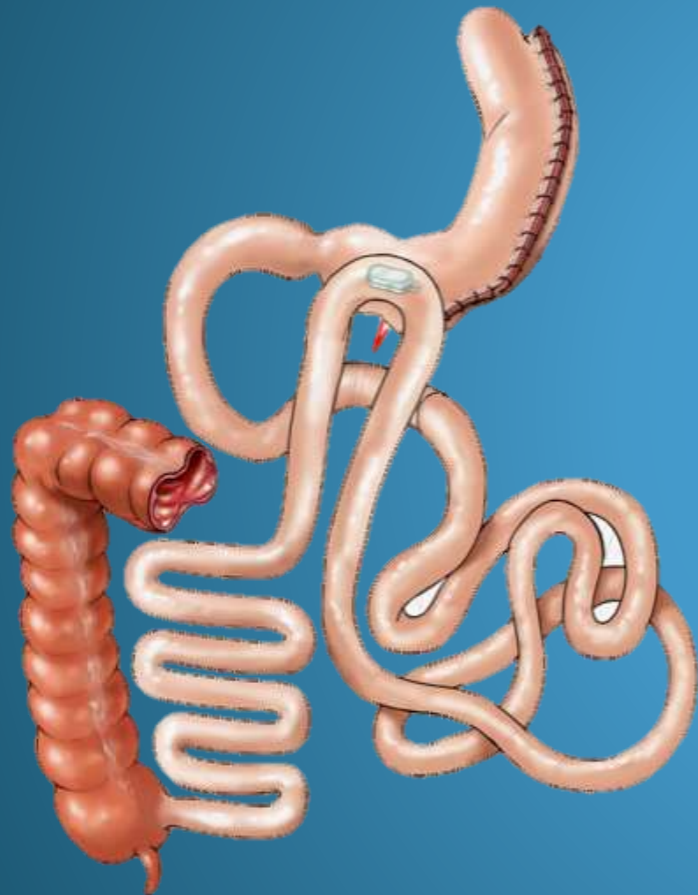


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Magnetic Gastro- Ileostomy (MGI) FIM



In patients post Sleeve Gastrectomy
weight regain or failure to lose adequate weight
Lower antrum and ileum at 250 cm (SASI)

Magnetic Surgery

Michel Gagner
Editor

 Springer

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