

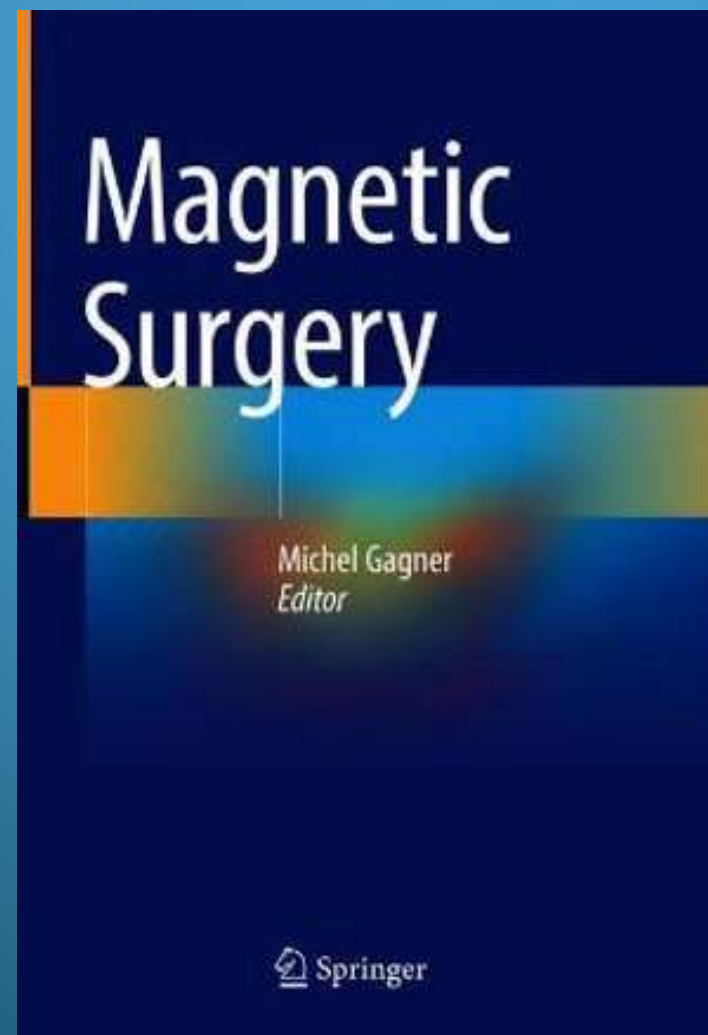
Magnetic Duodenal Bipartition

Michel Gagner, MD, FRCSC, FACS, FASMBS, FASSO

Westmount Square Surgical Center, Westmount,
QC, Canada;

Disclosures

- Consultant: NovoNordisk, Lexington Medical
- Stock ownership: 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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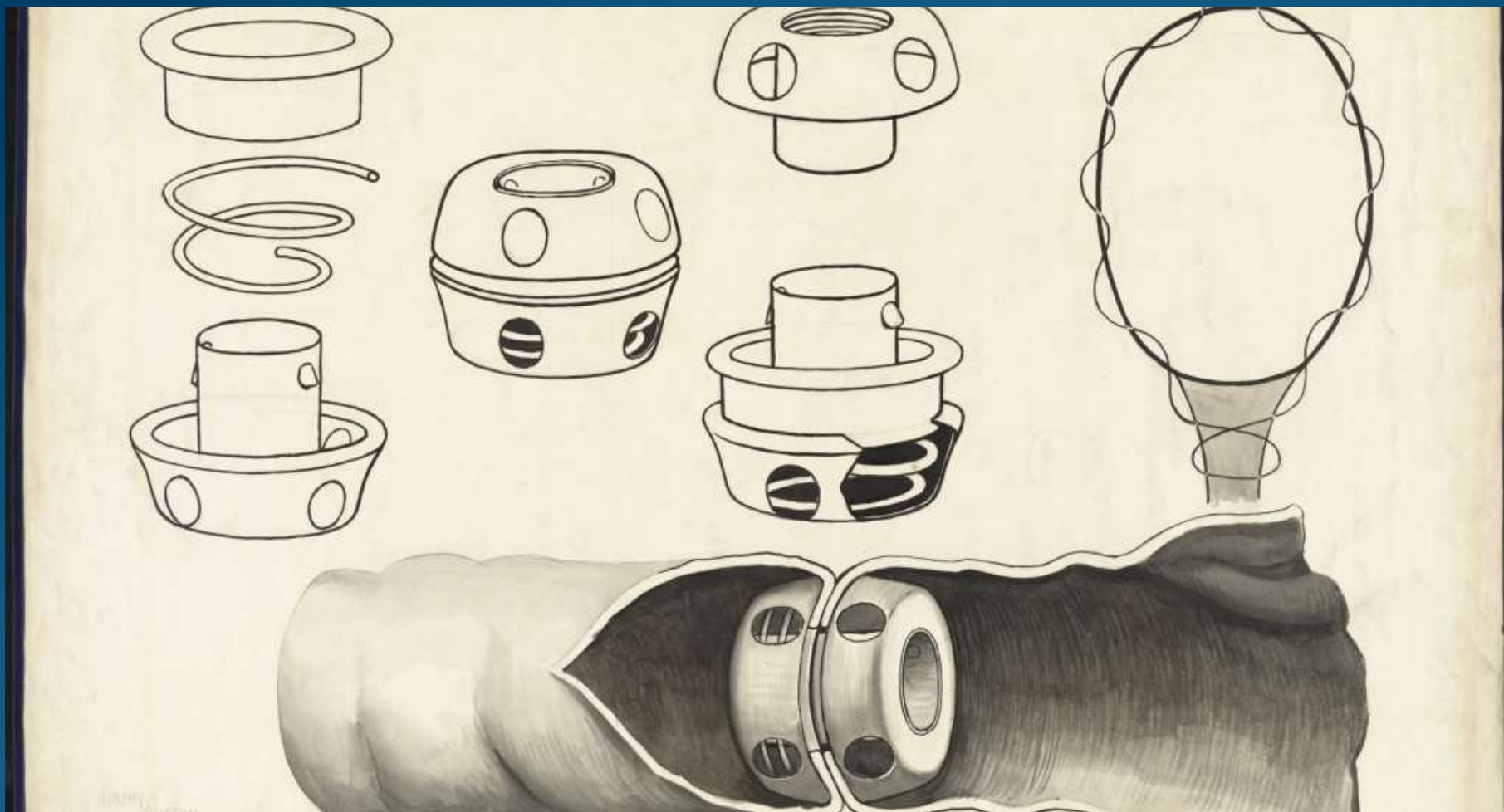
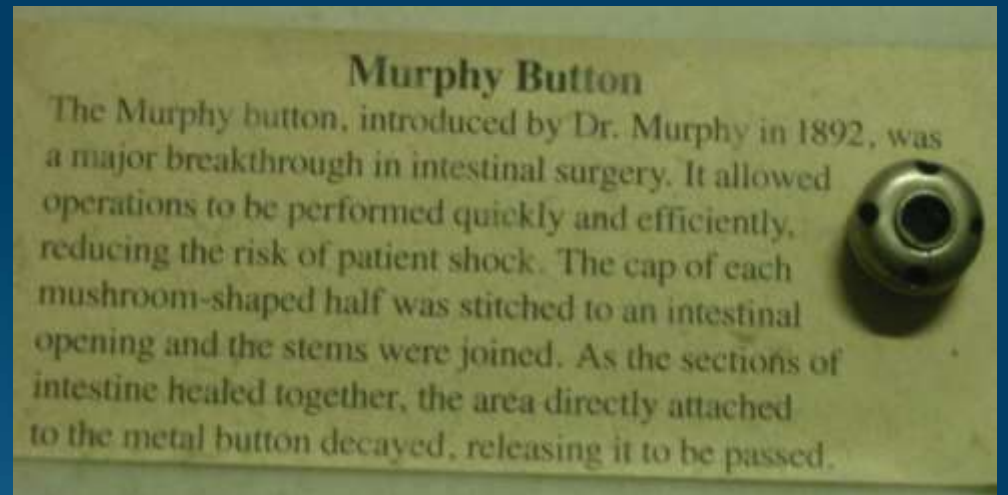
⁴Innova Medical Center, Tbilisi, Georgia
Magnetics in bariatric surgery: the future is today?

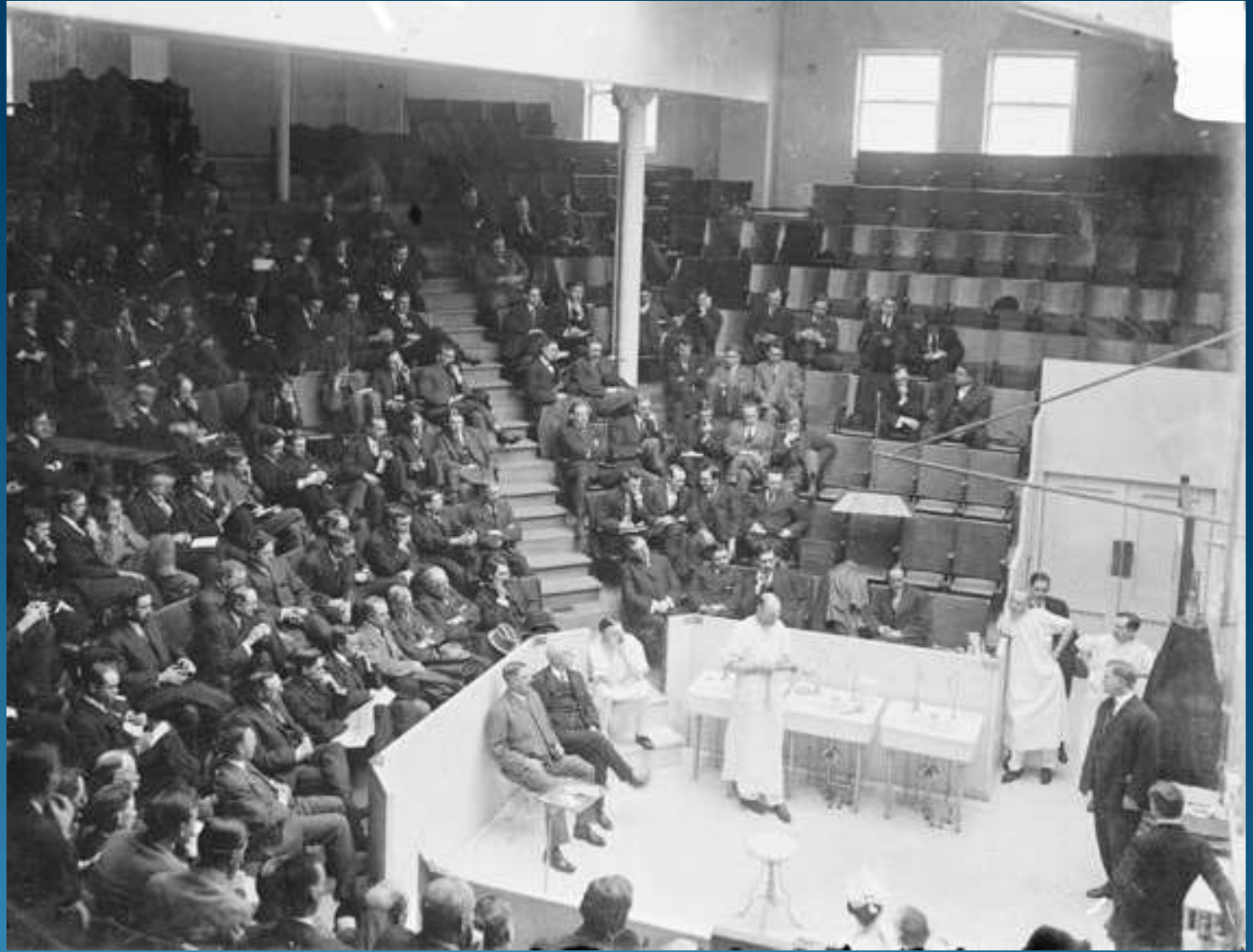
16th World Congress of Endoscopic Surgery
April 2018, Seattle
Magnets In Surgery: What's The Attraction?



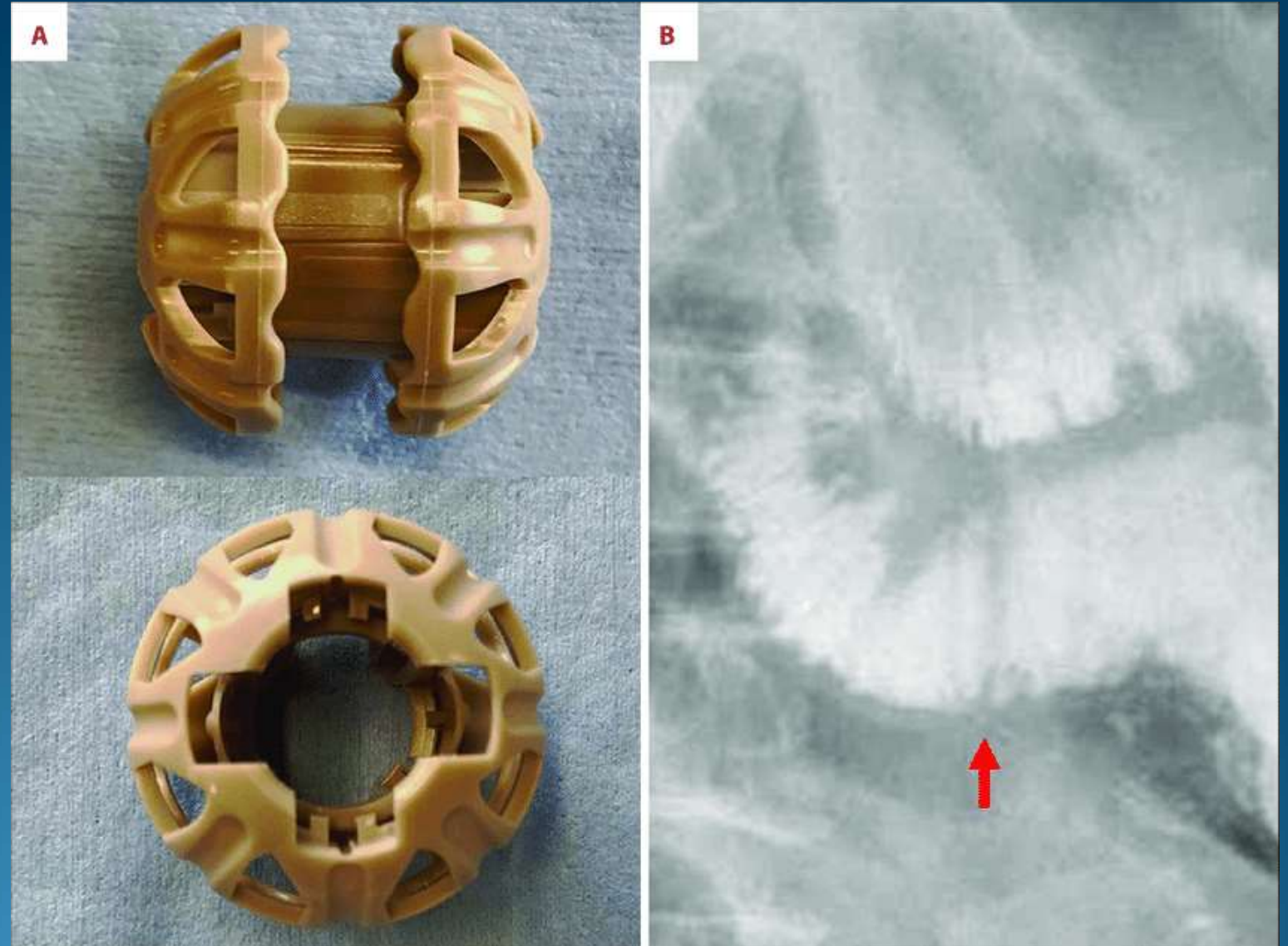
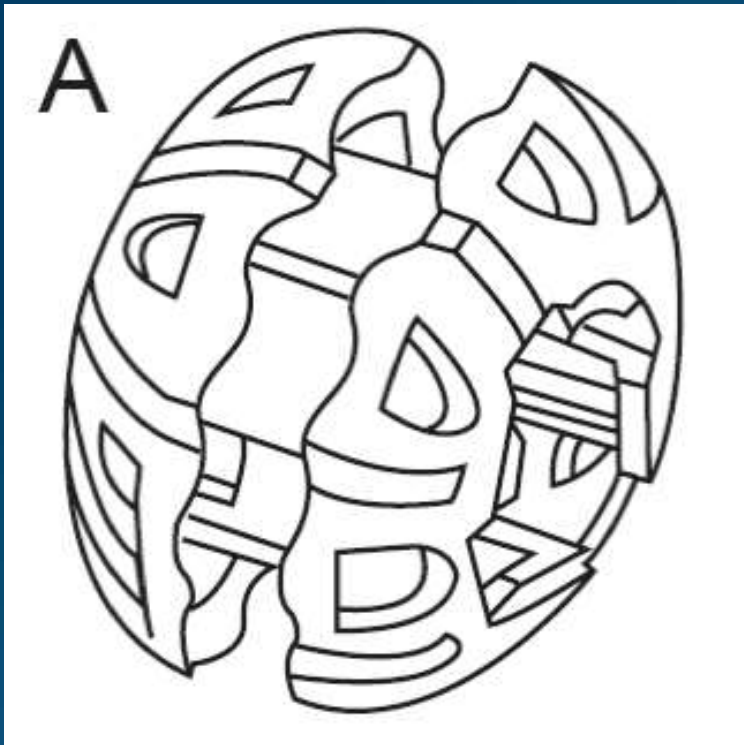
Compression Anastomosis

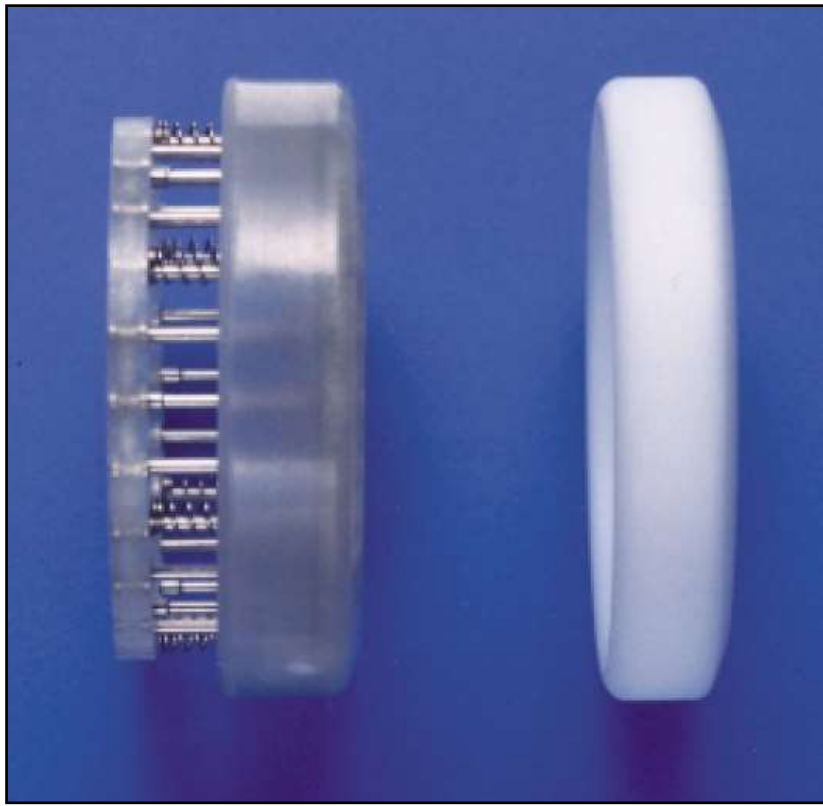
Murphy Button, 1892



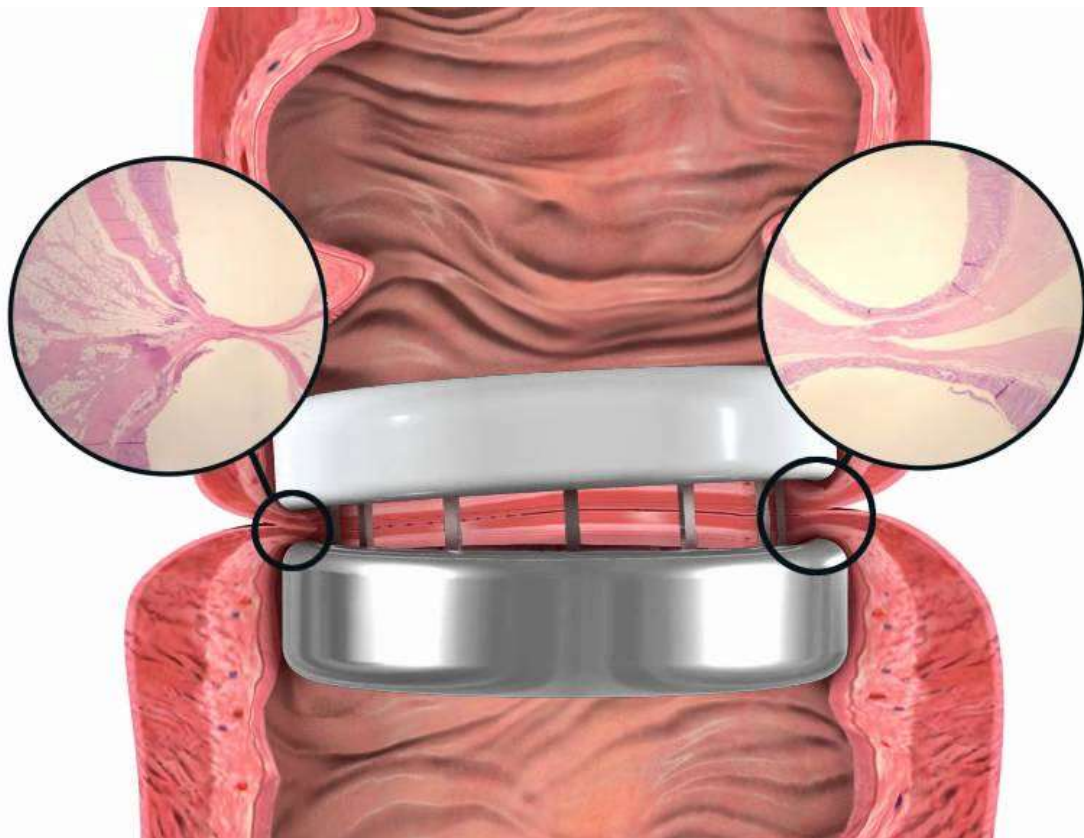
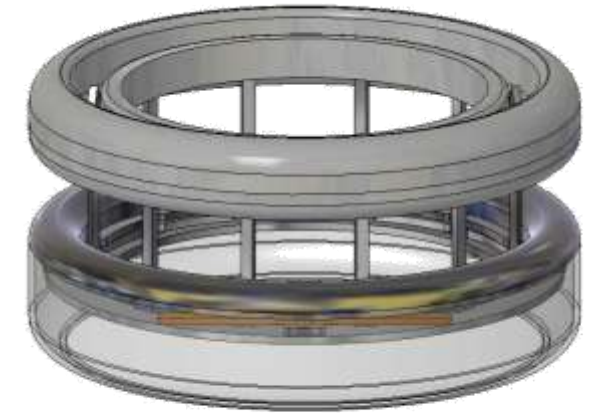


Valtrac , 1984





1989-NITI Surgical



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*Has received an application for a patent for
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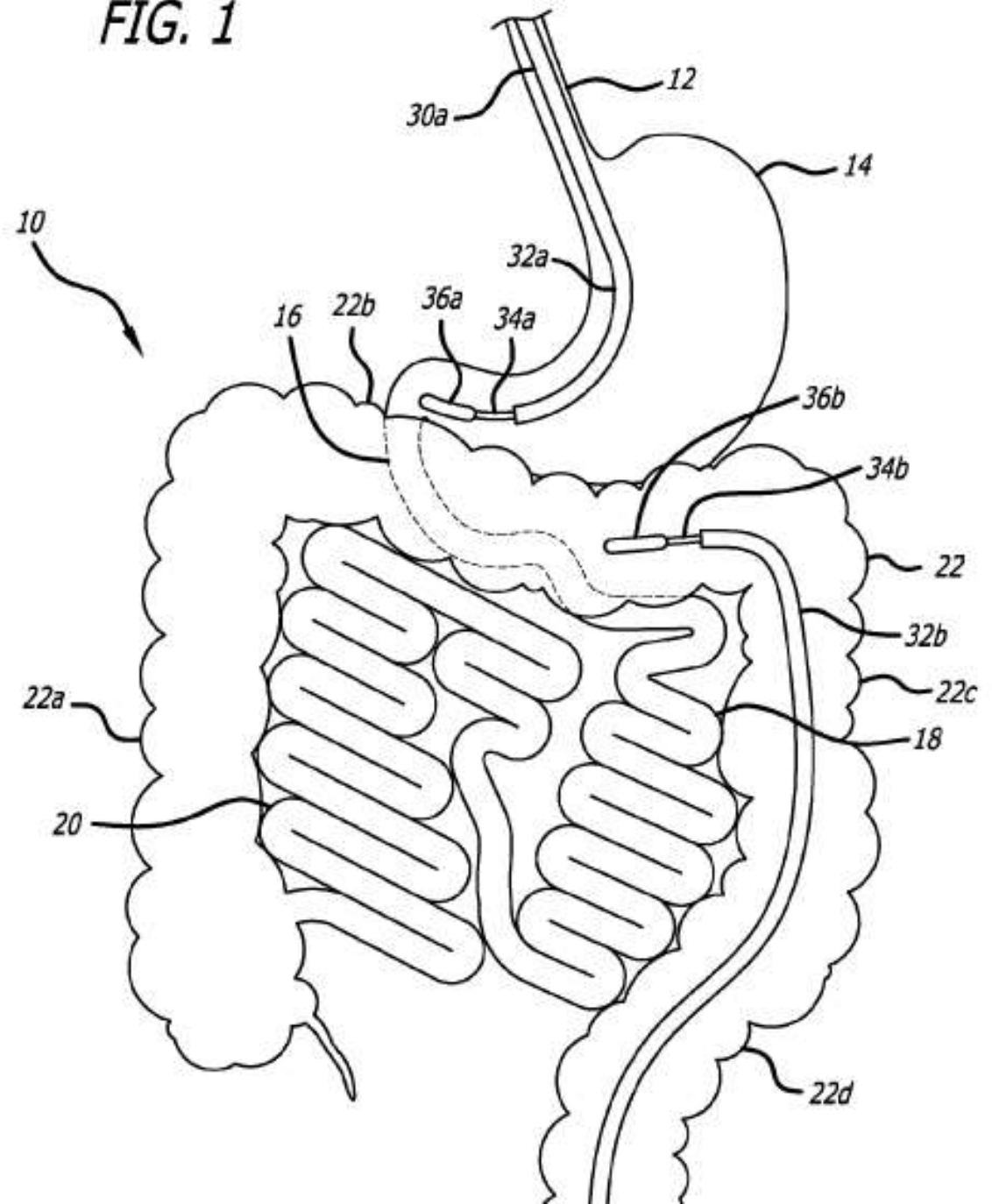
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FIG. 1



(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

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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*

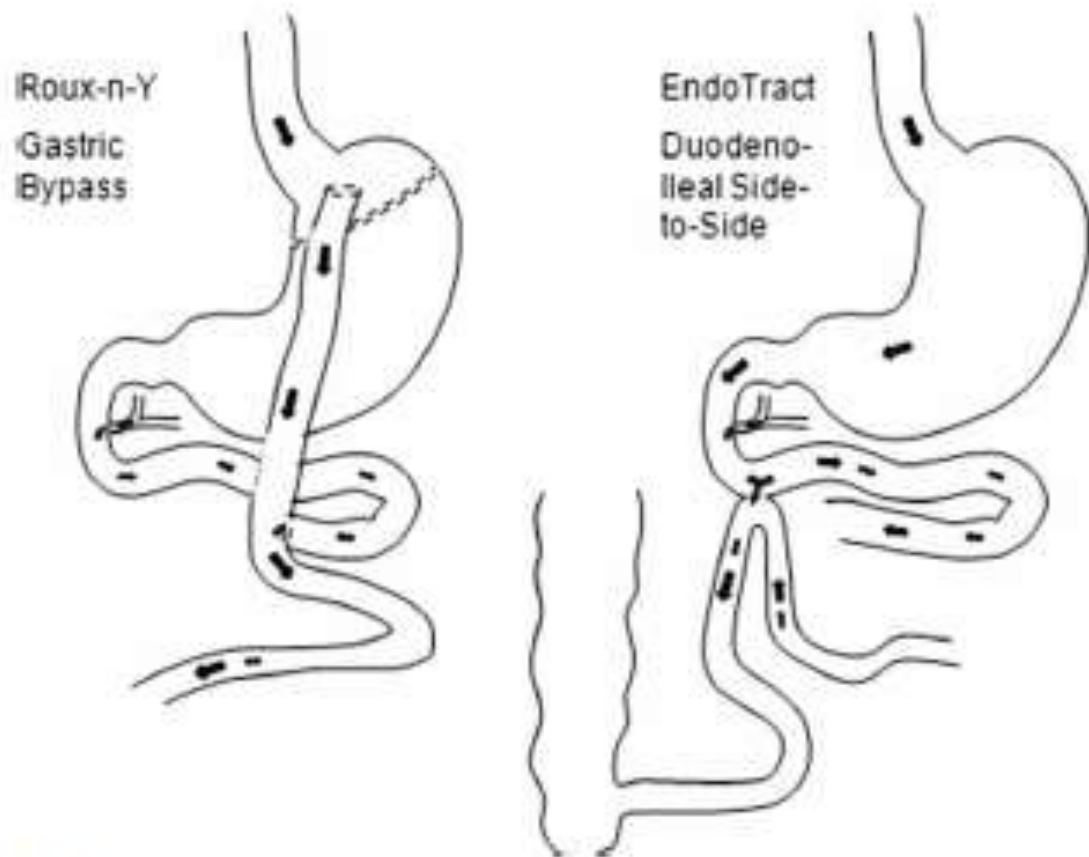


Fig. 4 Comparison of digestive flow between a gastric bypass and a side-to-side duodeno-ileal anastomosis. Alimentary flow and biliopancreatic secretions are mixing in a Y channel (100–150 cm in mid jejunum) in a gastric bypass, while in a side-to-side duodeno-ileal anastomosis, the alimentary flow is divided between a regular jejuno-ileal channel and a distal ileal channel, and biliopancreatic secretions are mixing in the proximal duodenum

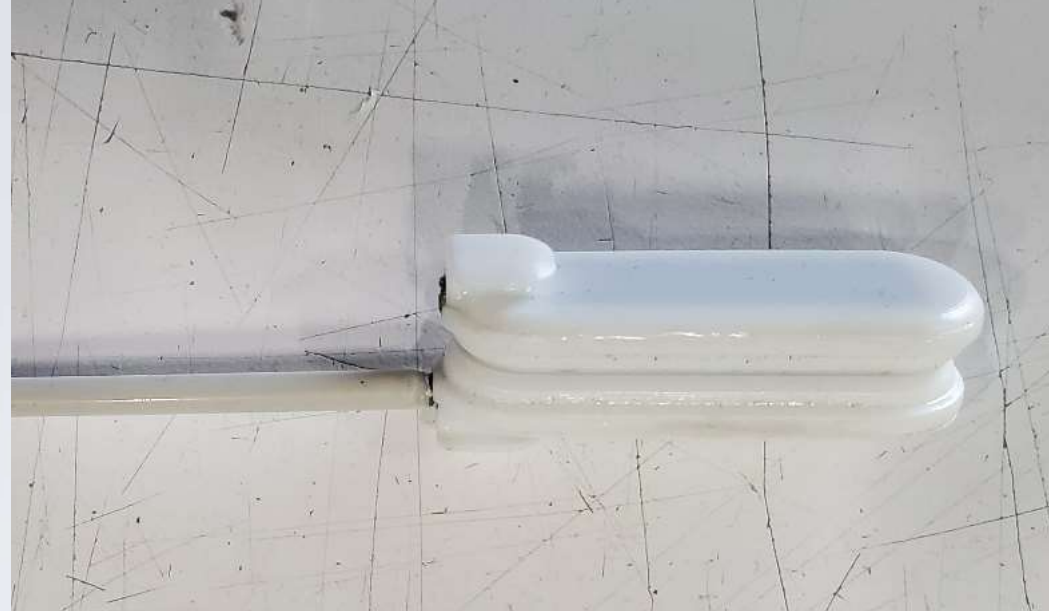


Fig. 5 a Duodenoscopy of the 3rd portion of the duodenum, showing a healed side-to-side duodeno-ileal anastomosis, with proximal ileum on the *right* and distal ileum on the *left* of the figure. **b** Duodenoscopy of the 3rd portion of the duodenum from a different animal, showing a healed side-to-side duodeno-ileal anastomosis, with distal duodenum on the far *right* of the figure



Fig. 6 Graph of % of weight change in animals that had a side-to-side duodeno-ileal anastomosis (study group) versus sham controls, over time in days. At 56 days, control animals had gained 33.2 % of weight, while study animals had lost 6.8 % of weight

Linear Magnets



Endoscopic catheter delivery system

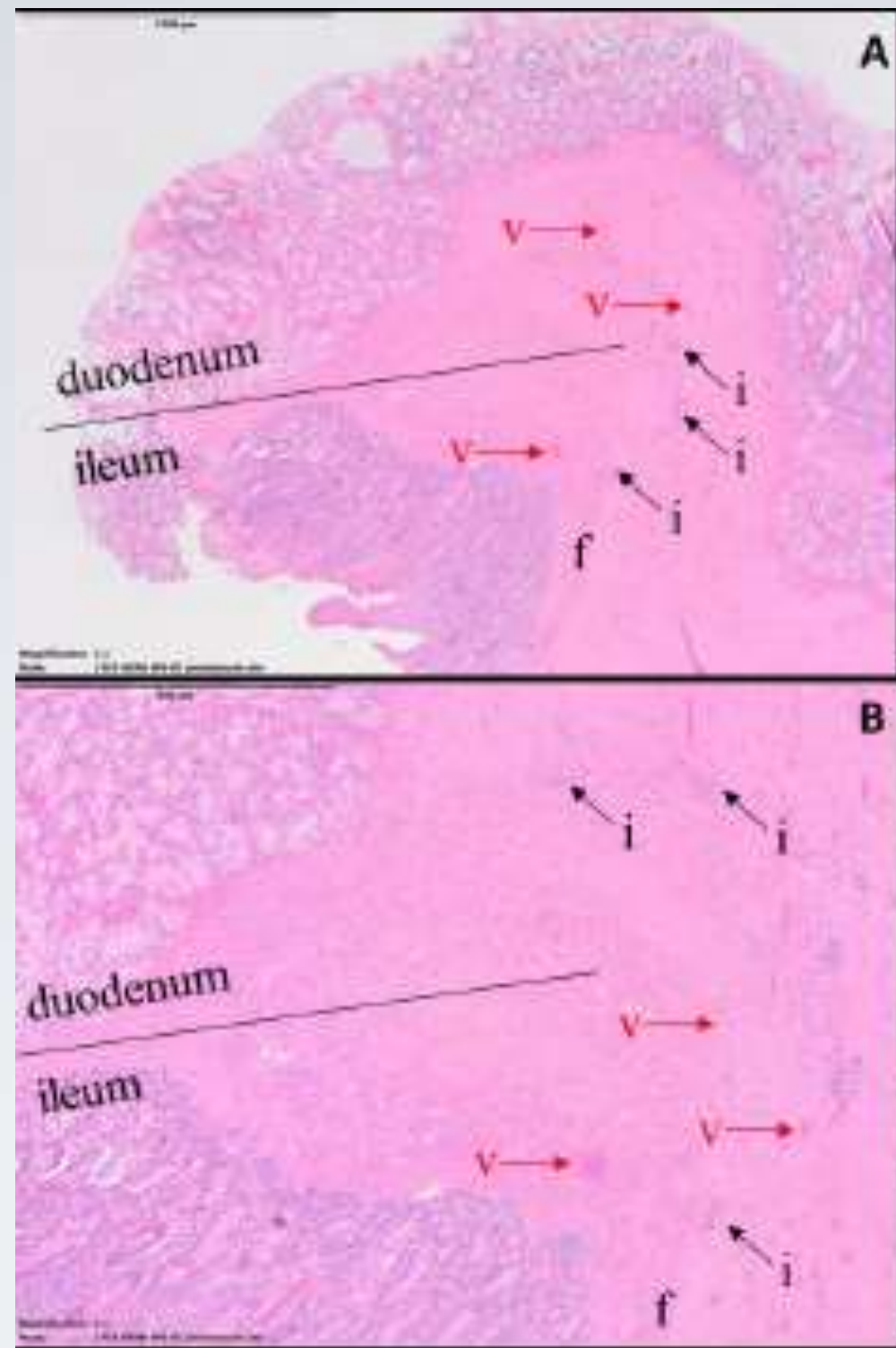


Duodeno-ileostomy

Macroscopic aspect, duodeno-ileostomy



Endoscopic view, anastomosis,
and normal duodenal pathway

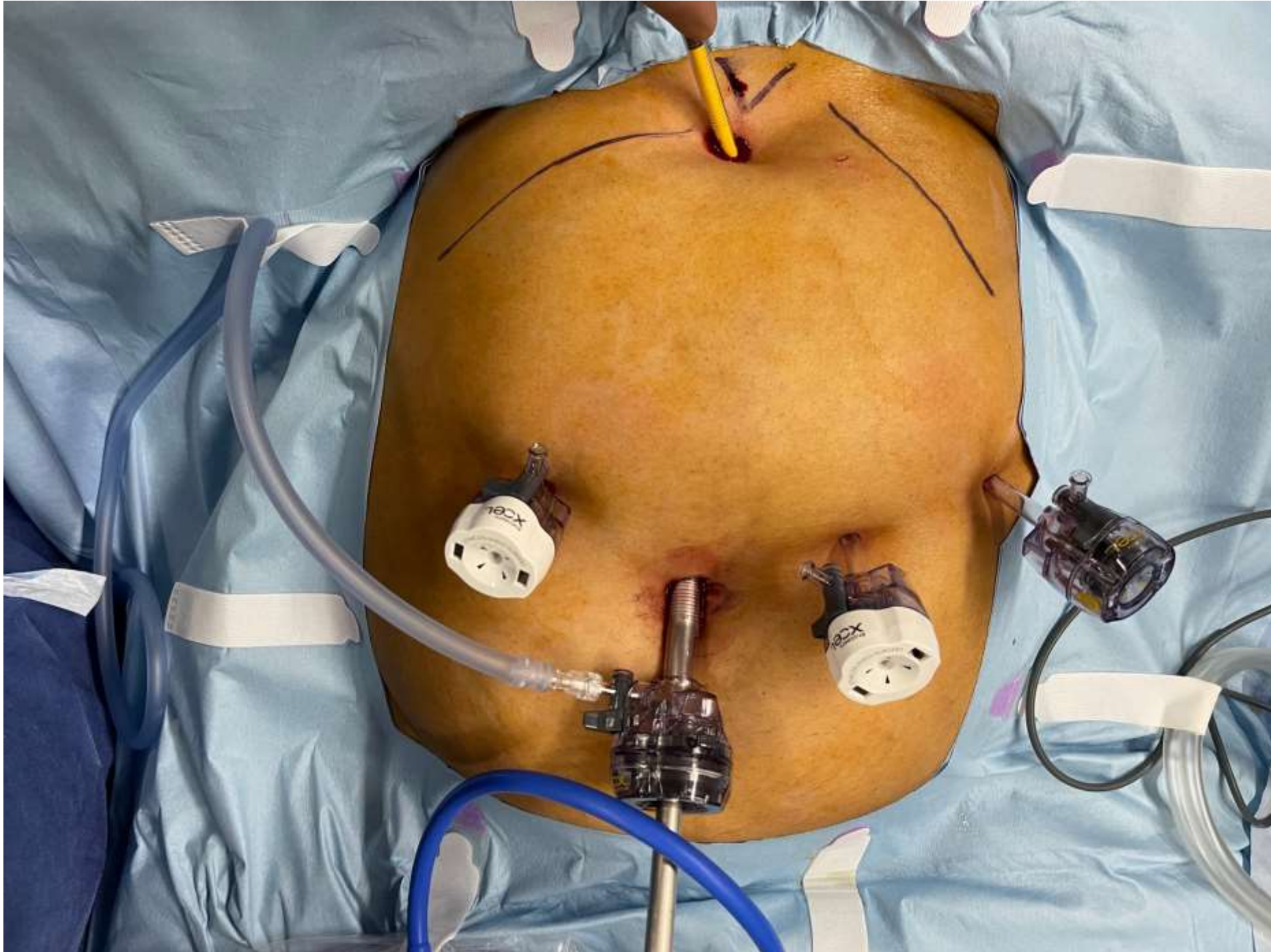


Microscopic alignment and view, no inflammation

Inclusion Criteria

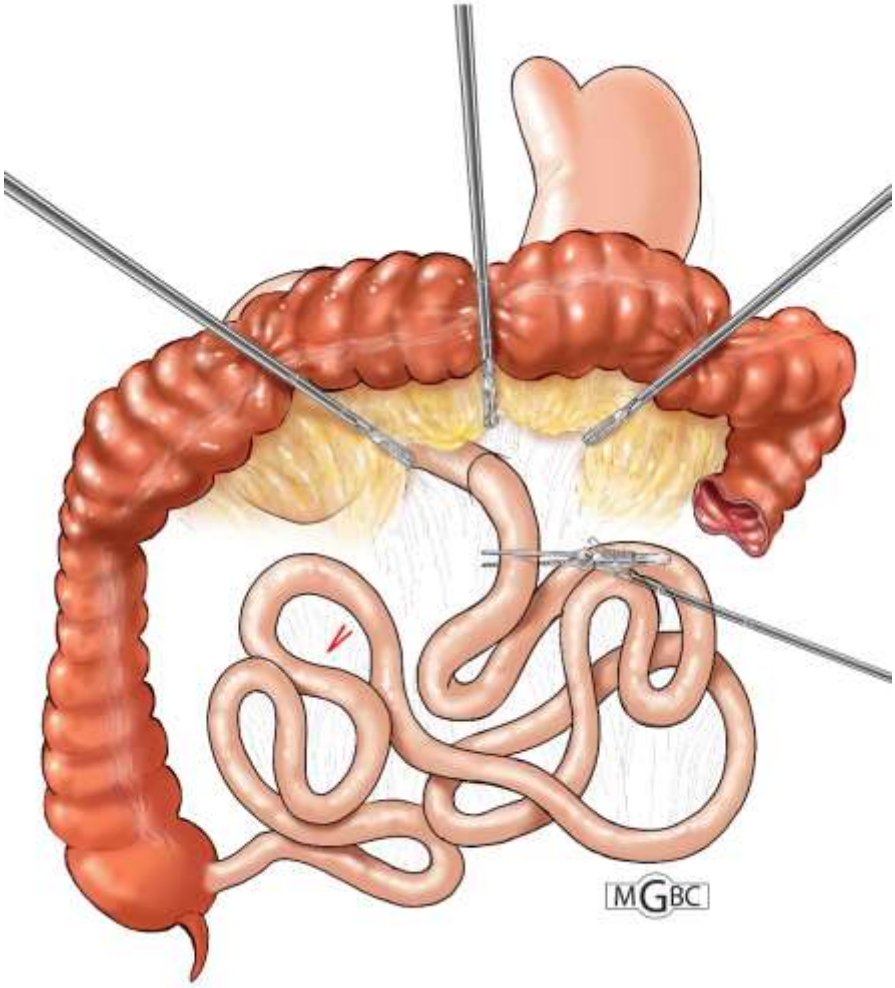
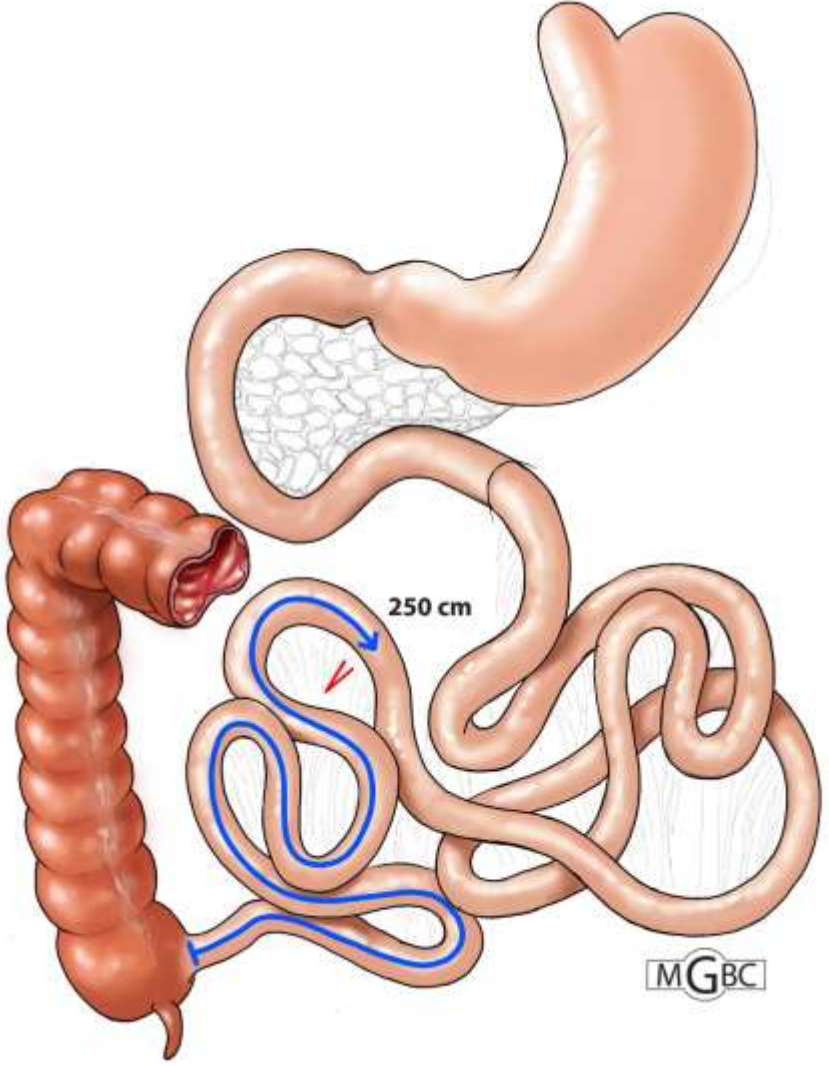
1. 18-65 years of age, inclusive, at the time of informed consent
2. BMI 30-50, inclusive with either:
 - Previous-sleeve gastrectomy (≥ 12 months) with either T2DM (defined as HbA1c $\geq 6.5\%$) or weight regain; or
 - T2DM without previous gastrectomy; or
 - Undergoing Laparoscopic Single Anastomosis 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



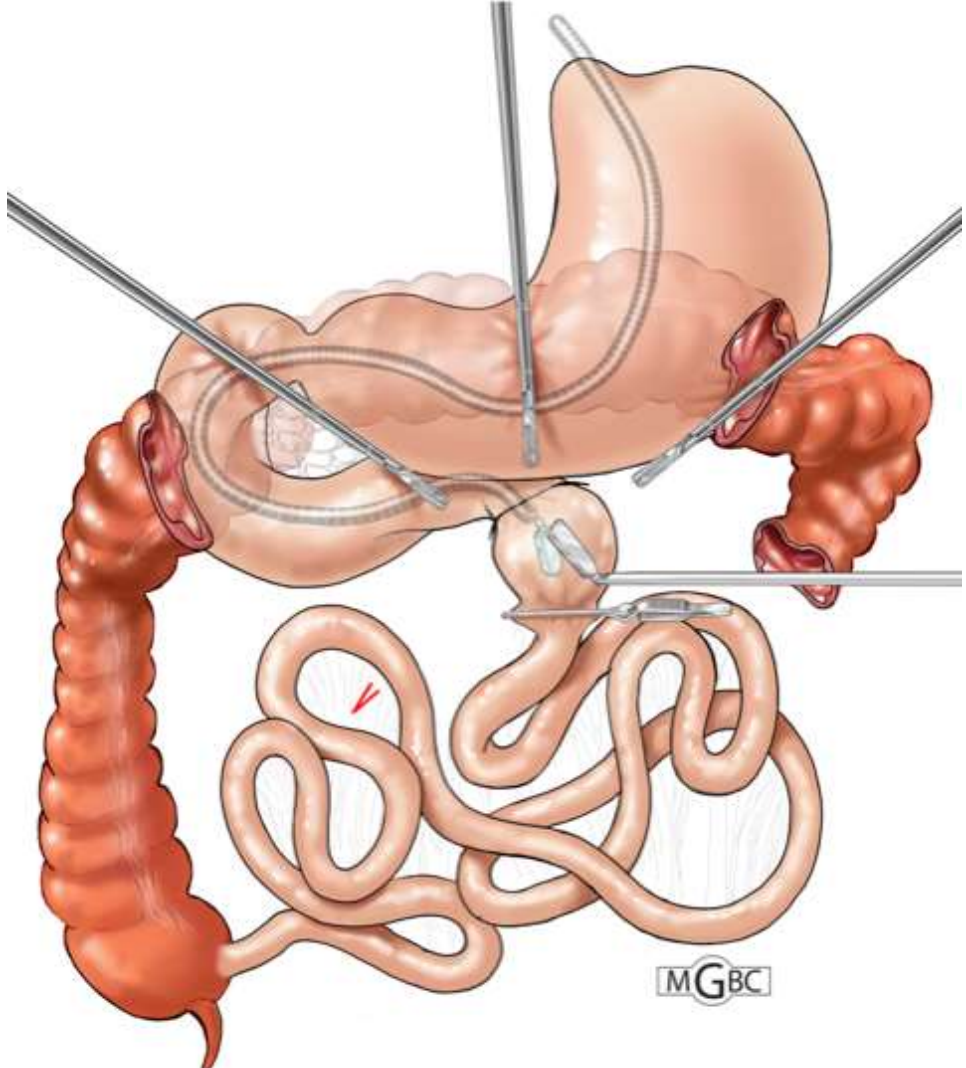
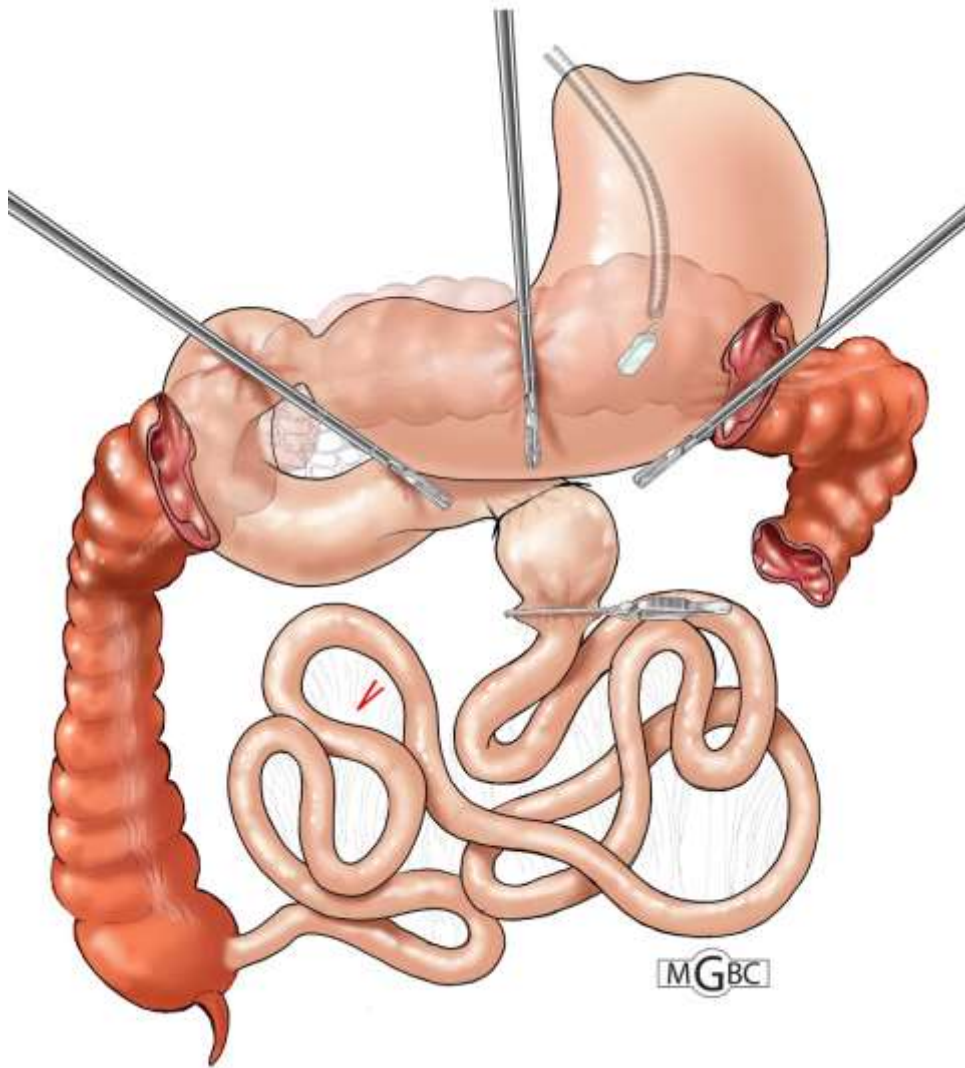
The MAGNET System

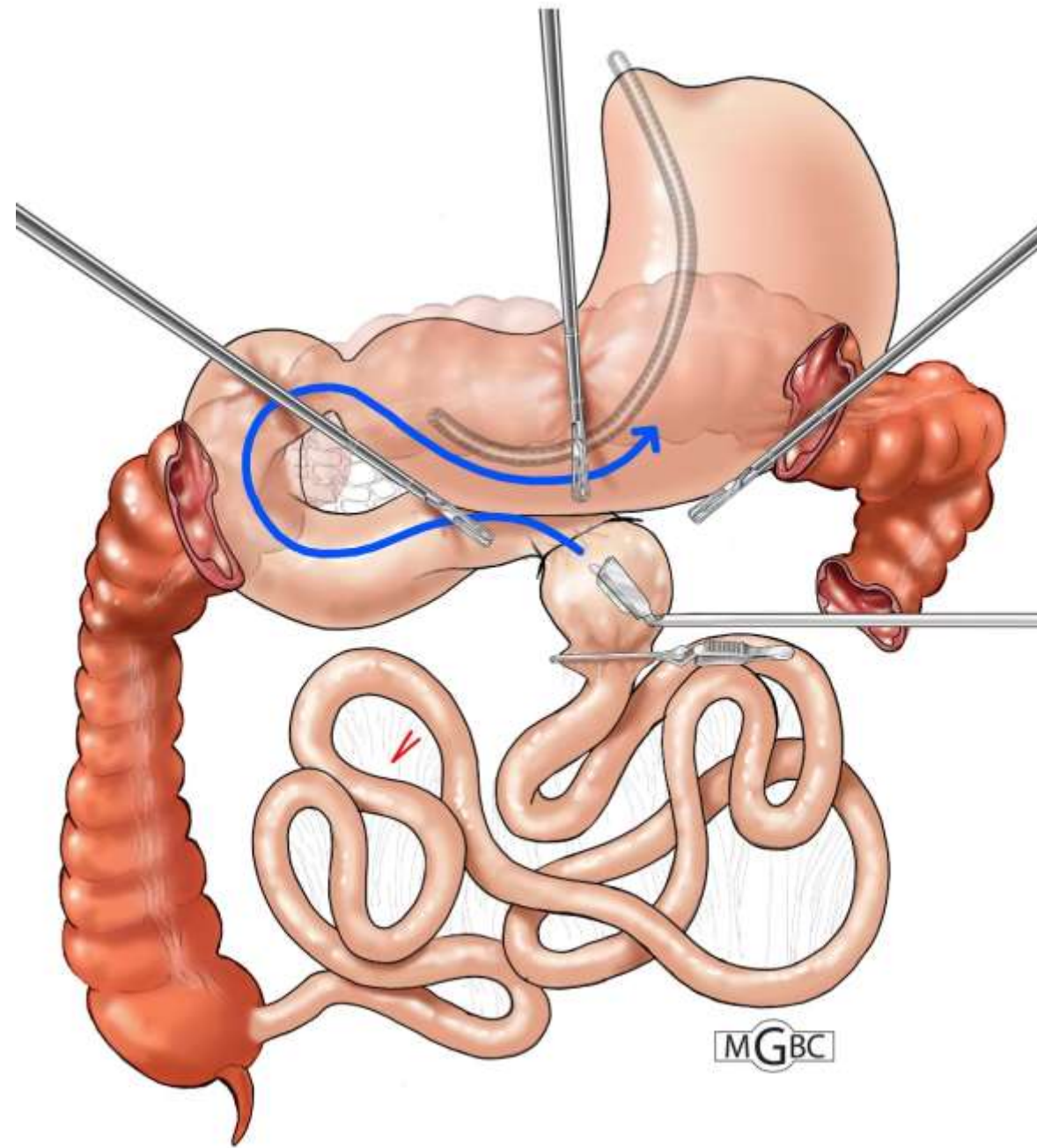
Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy



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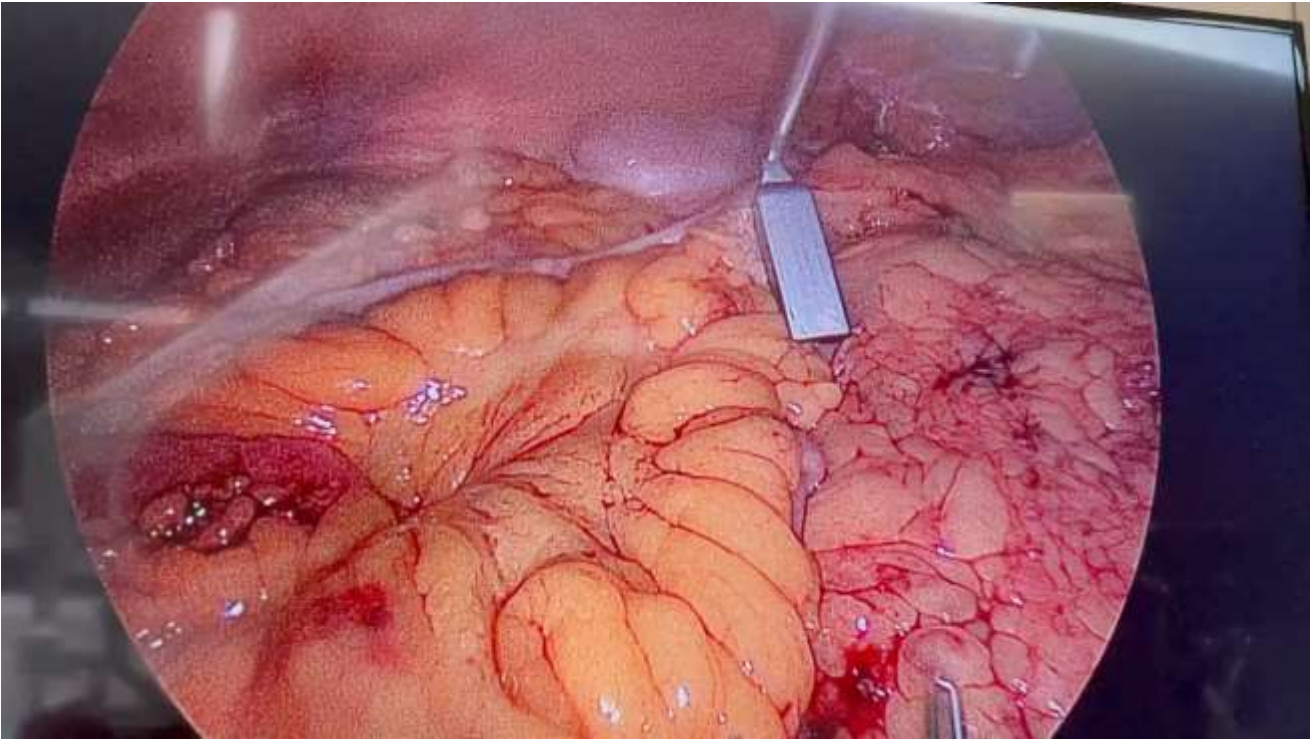
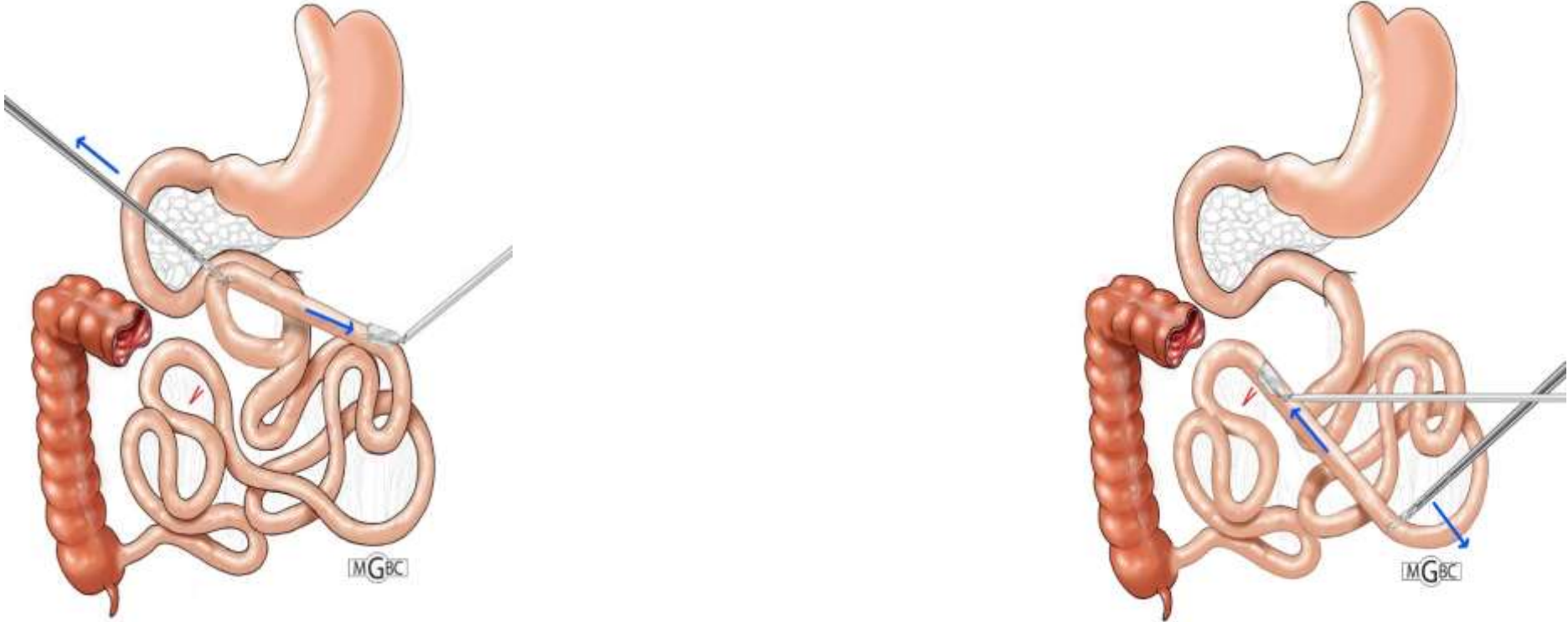
Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy





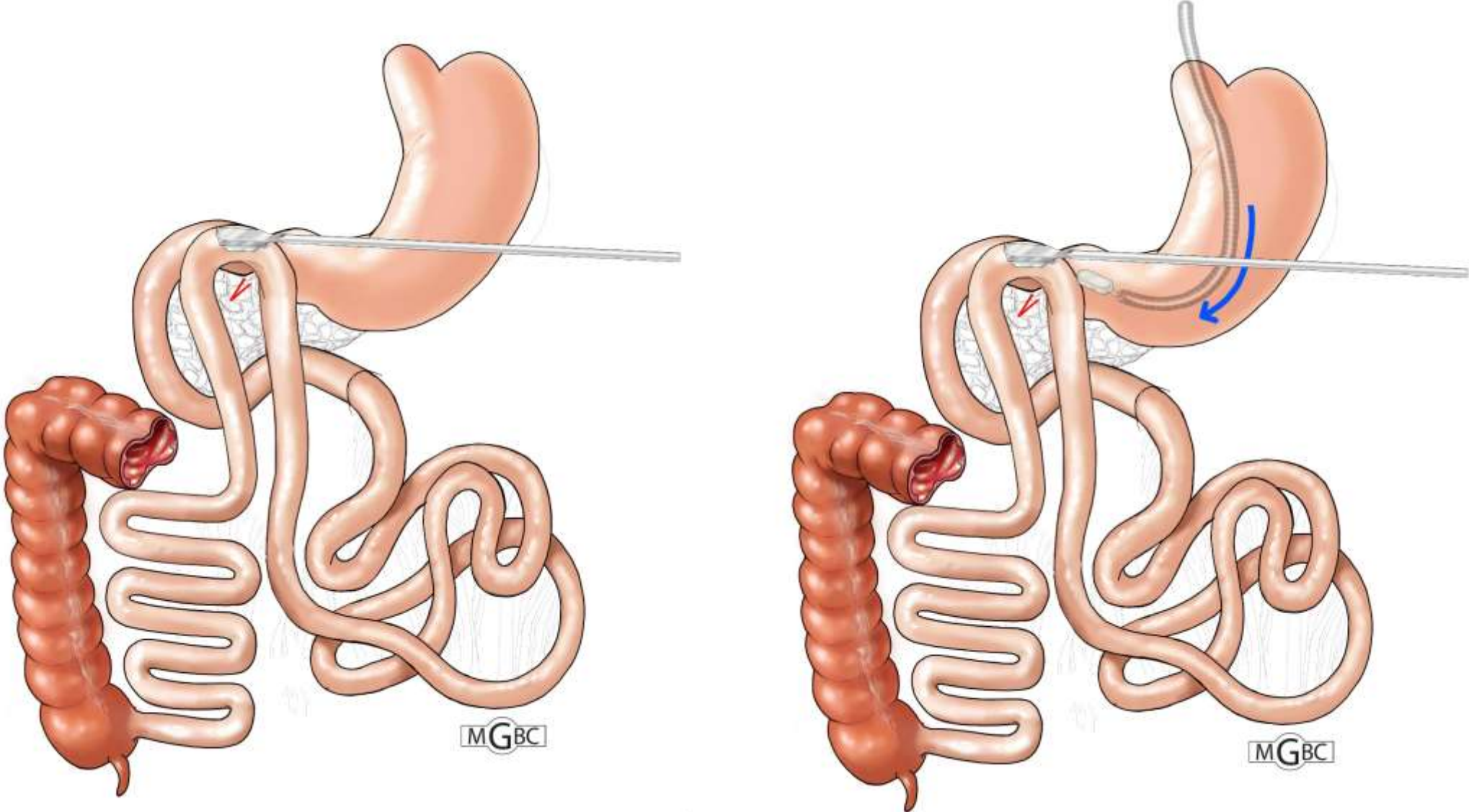
The MAGNET System

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



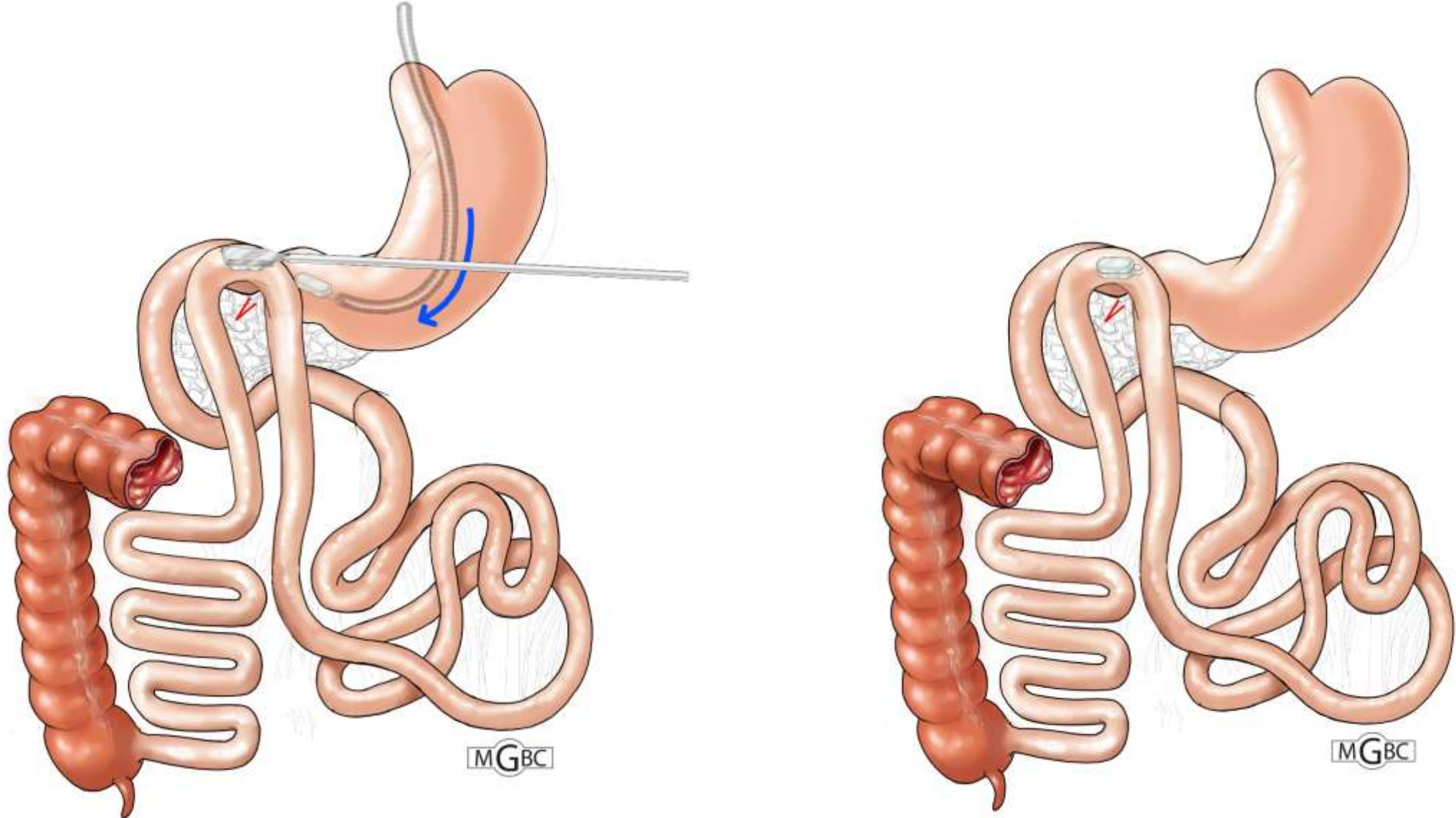
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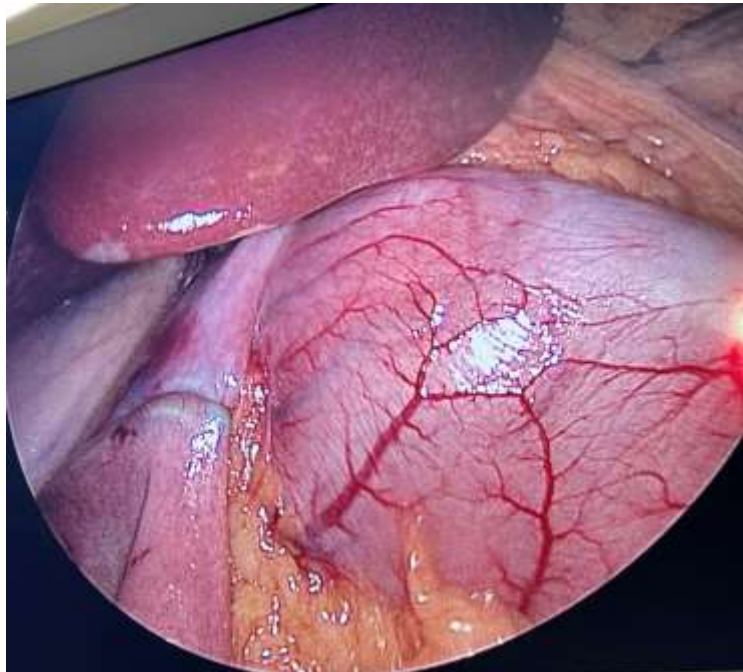
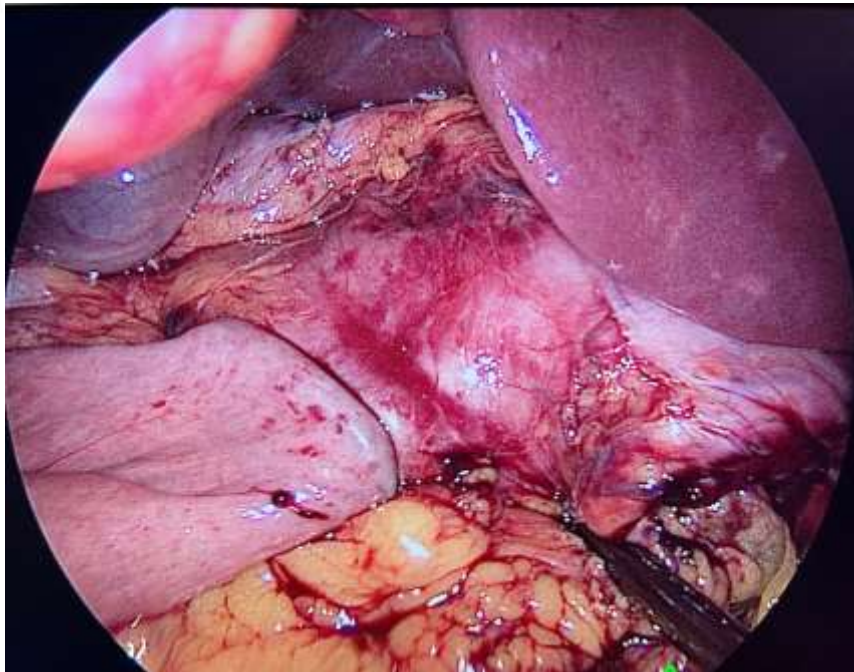
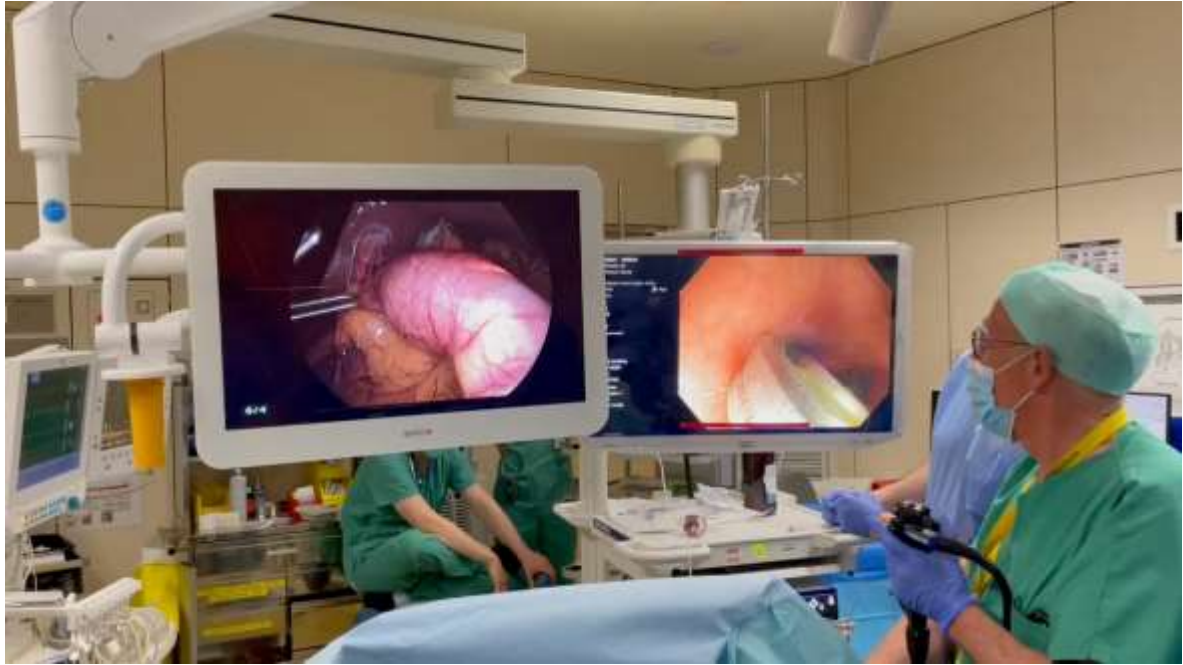
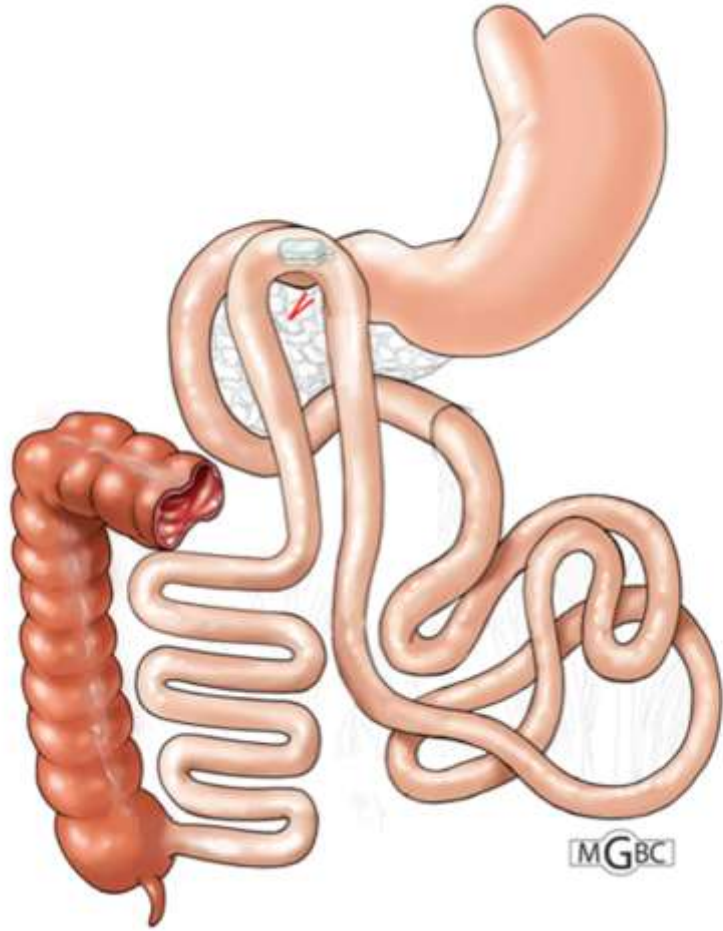


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Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy

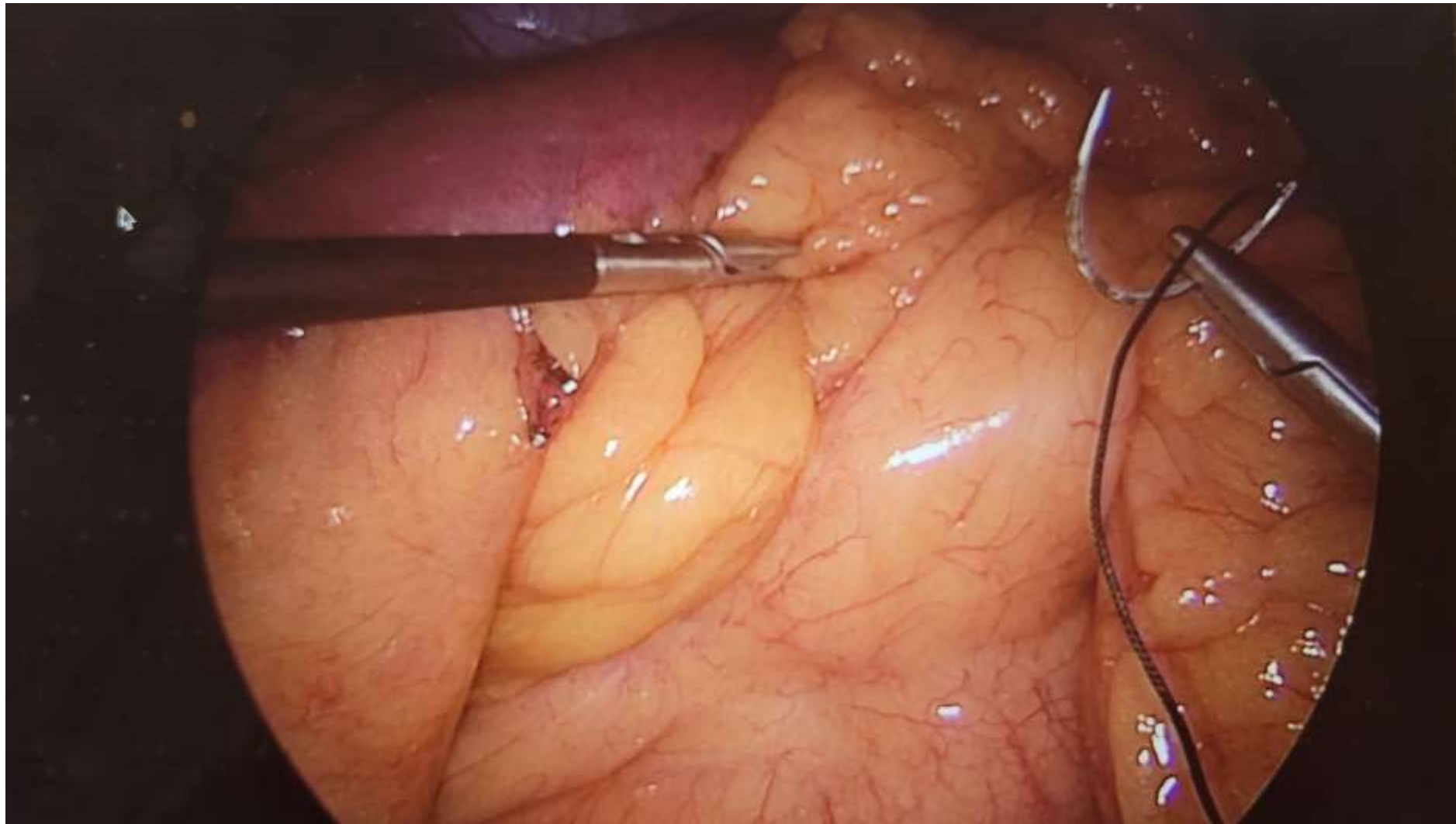


The MAGNET System Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy

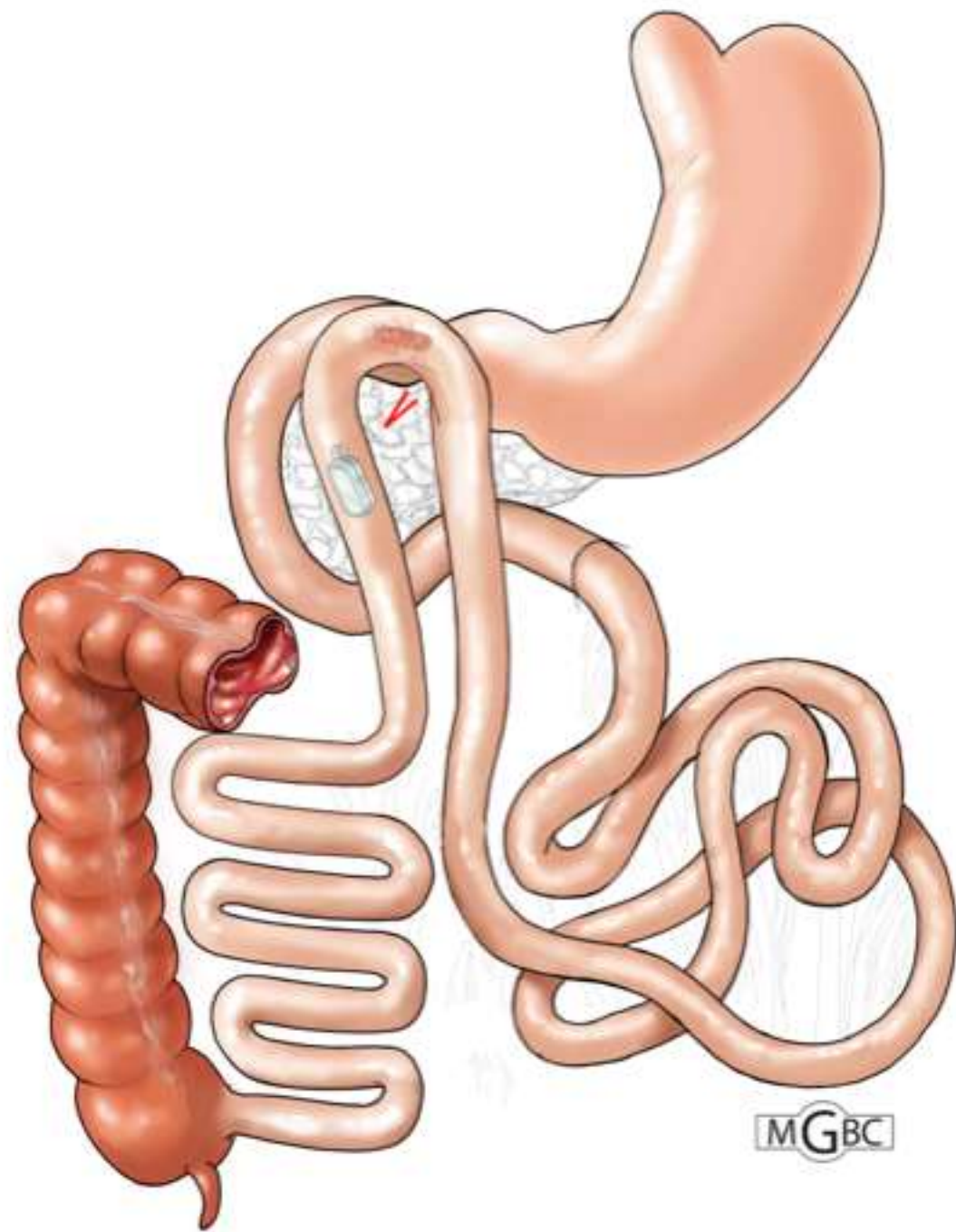
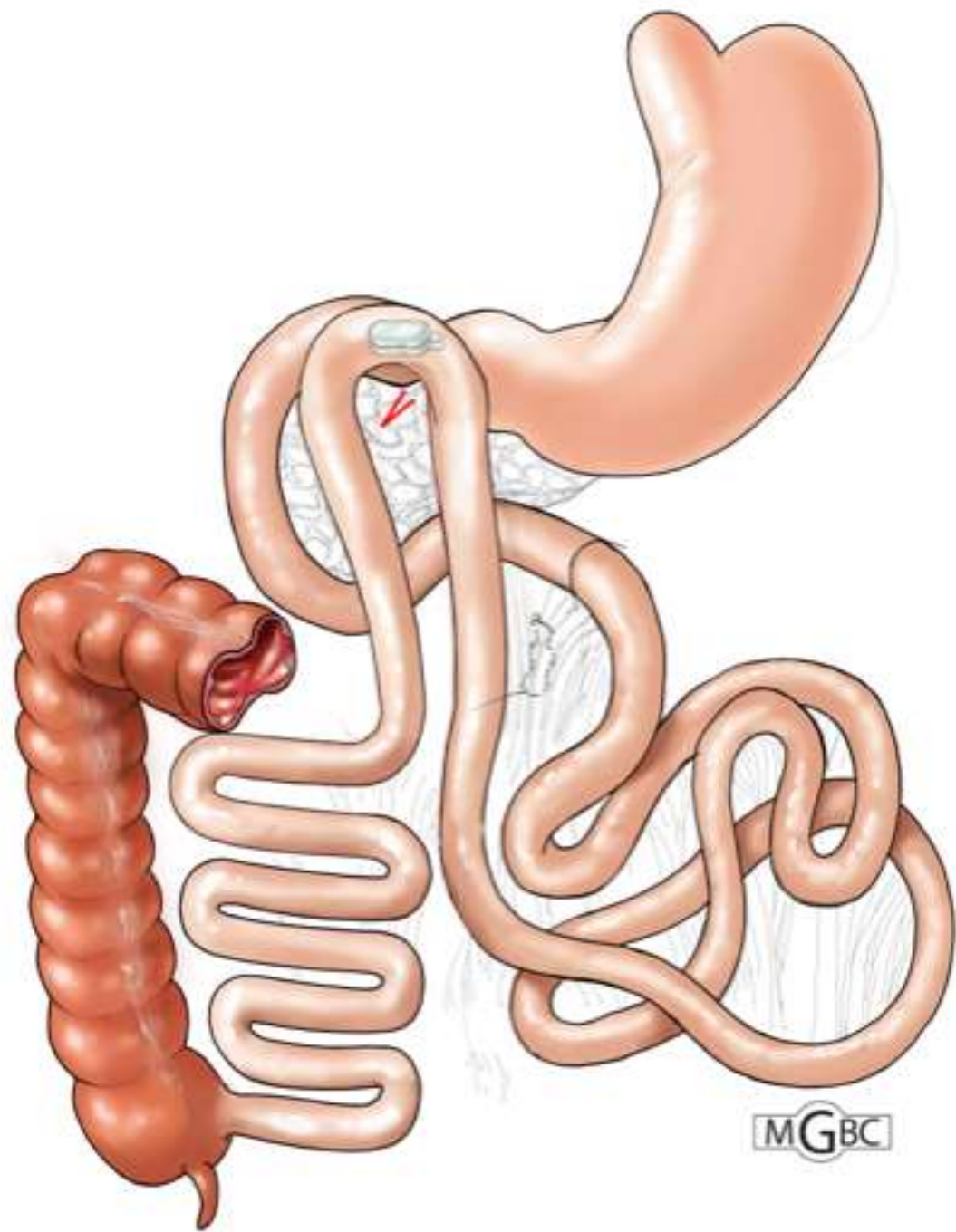


The MAGNET System

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

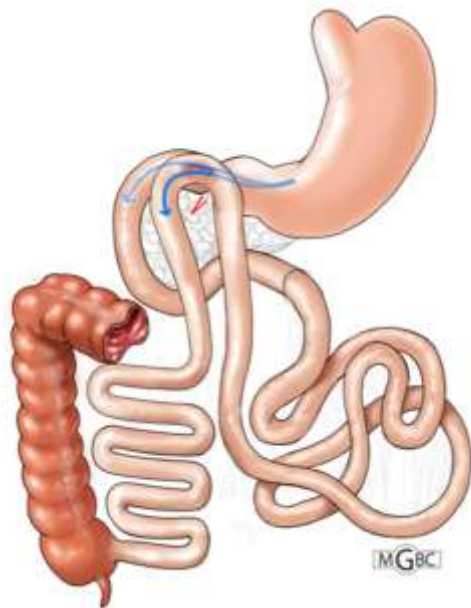
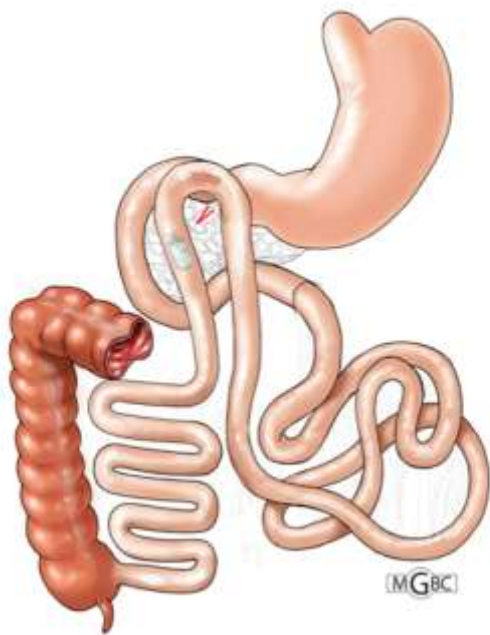
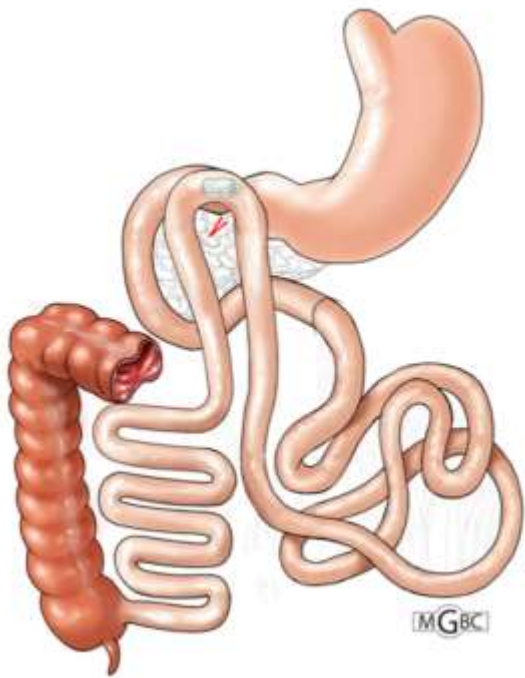
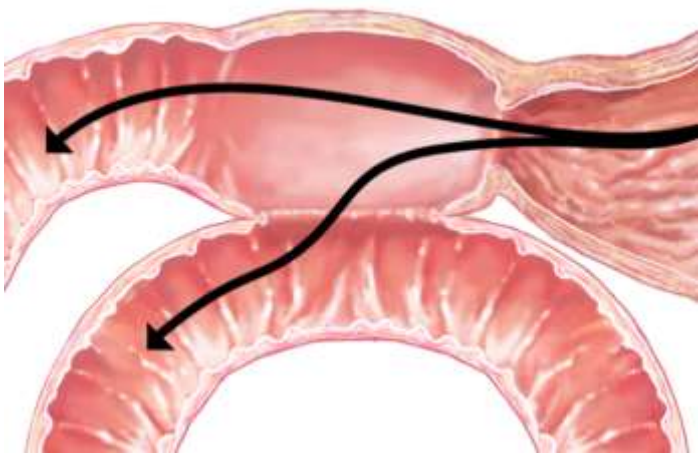
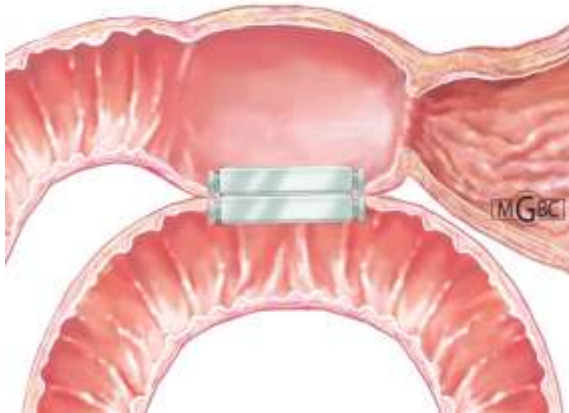


Closure of mesenteric defect
(Petersen's) on the left side



The MAGNET System

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



The MAGNET System

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

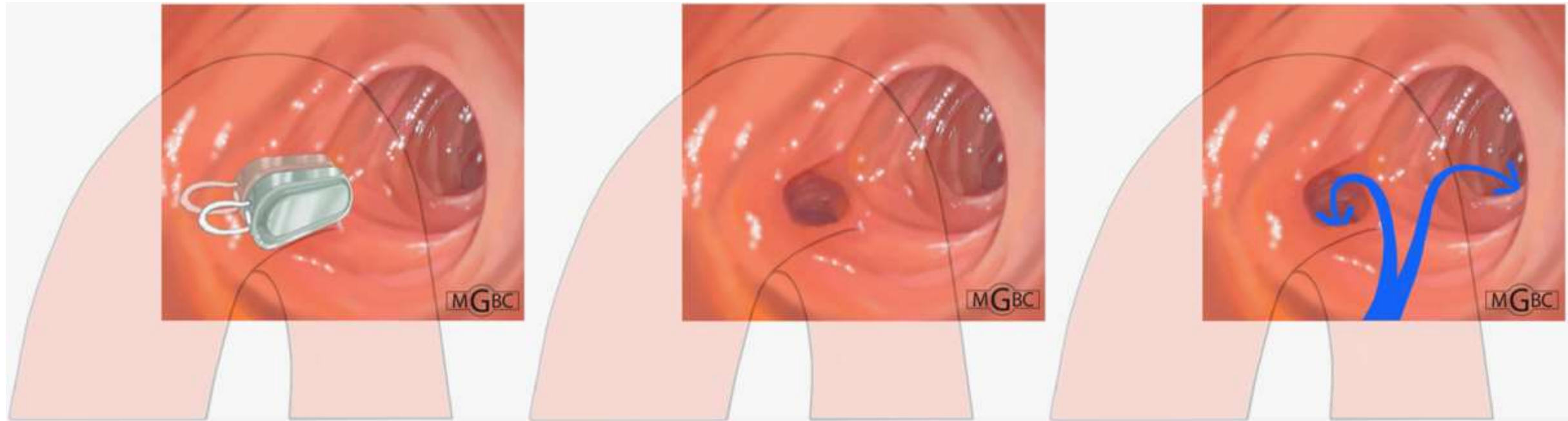
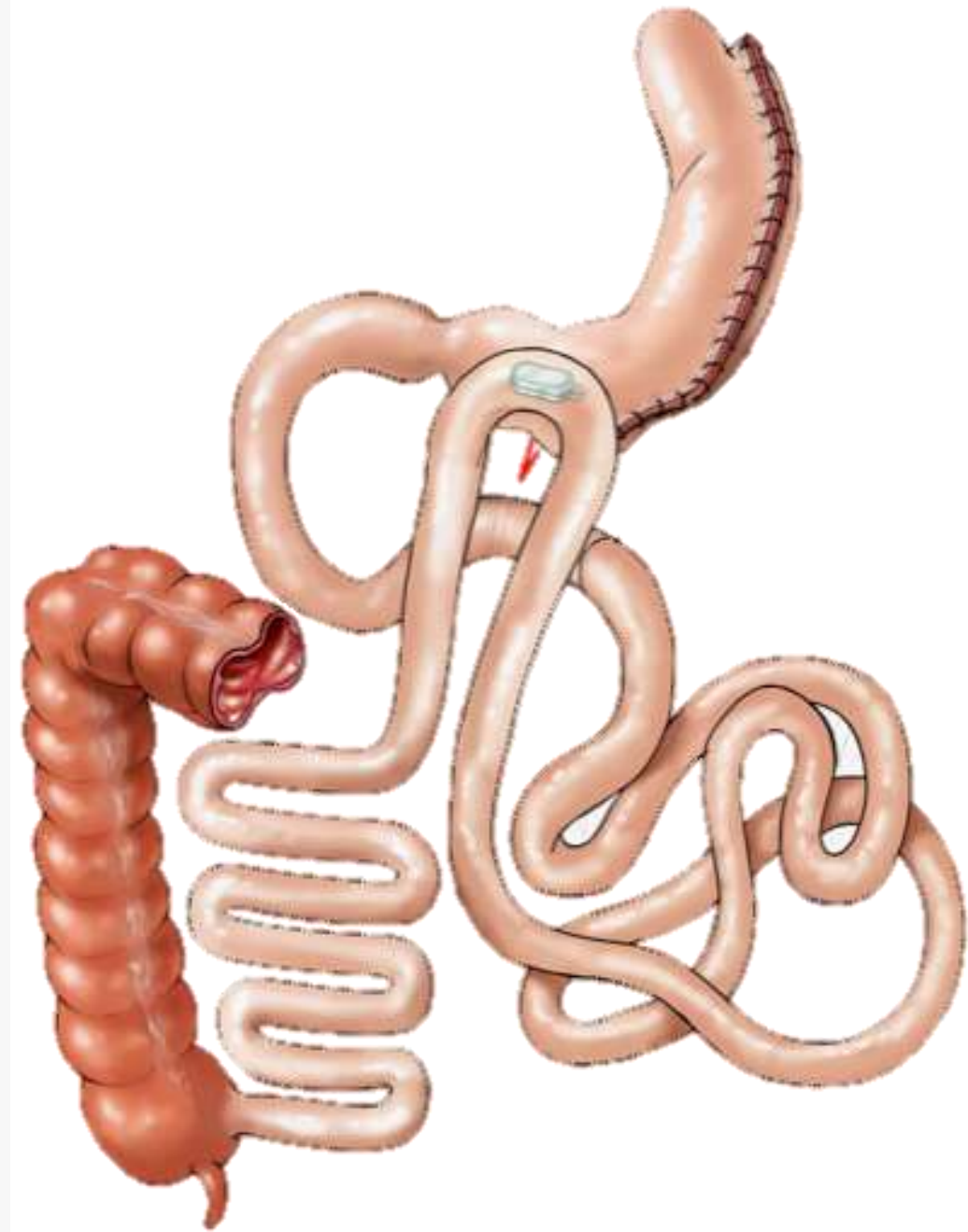
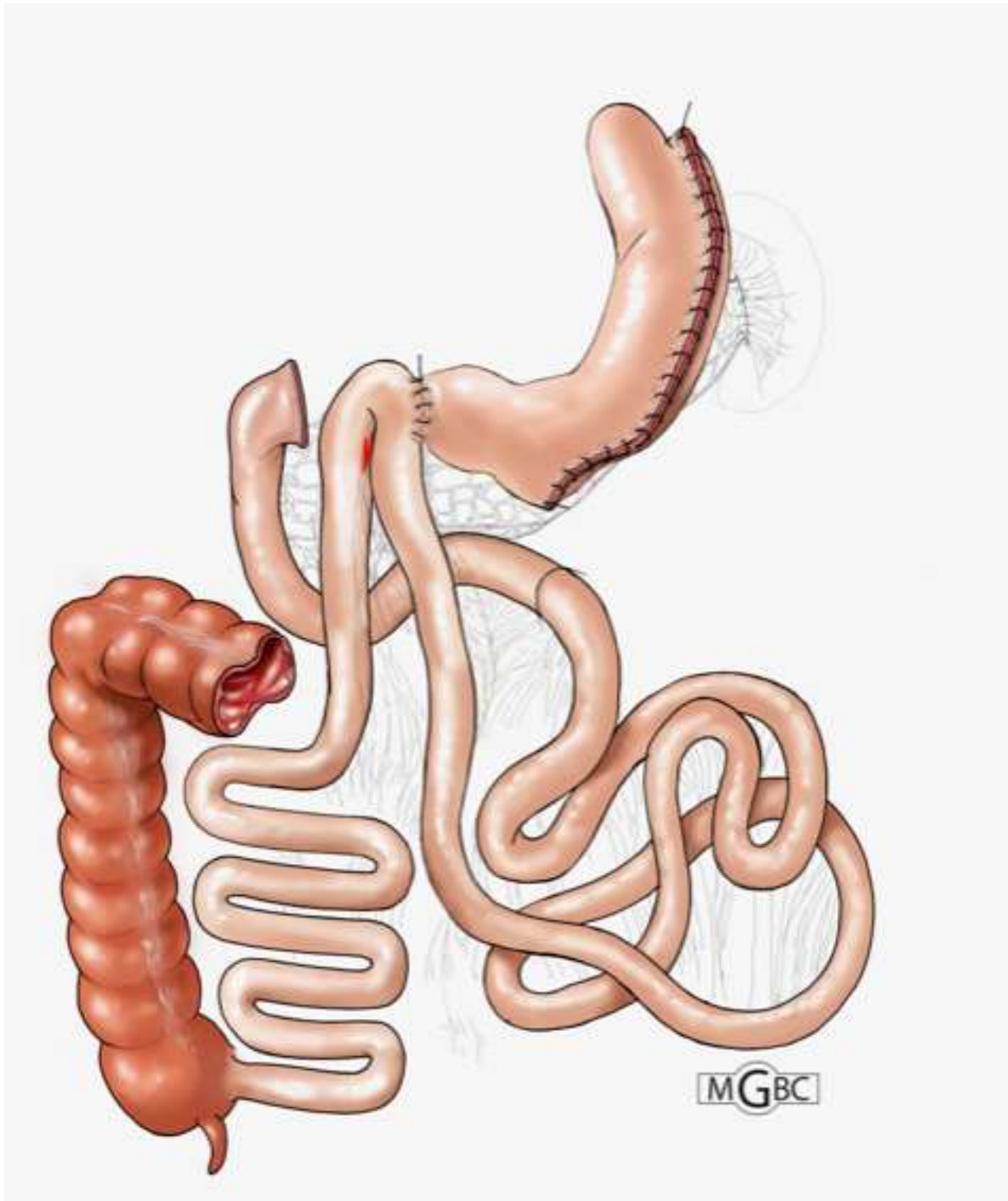
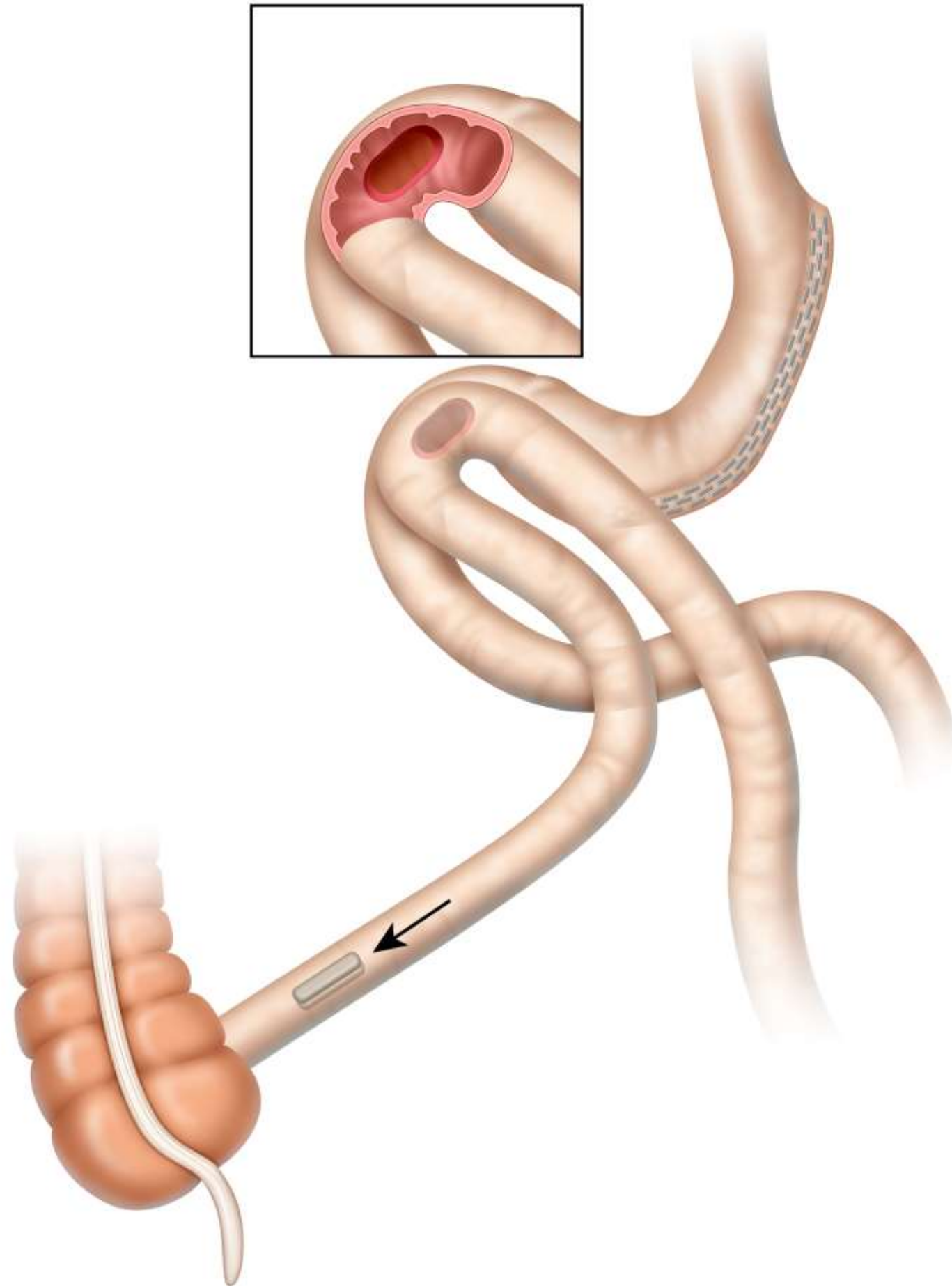
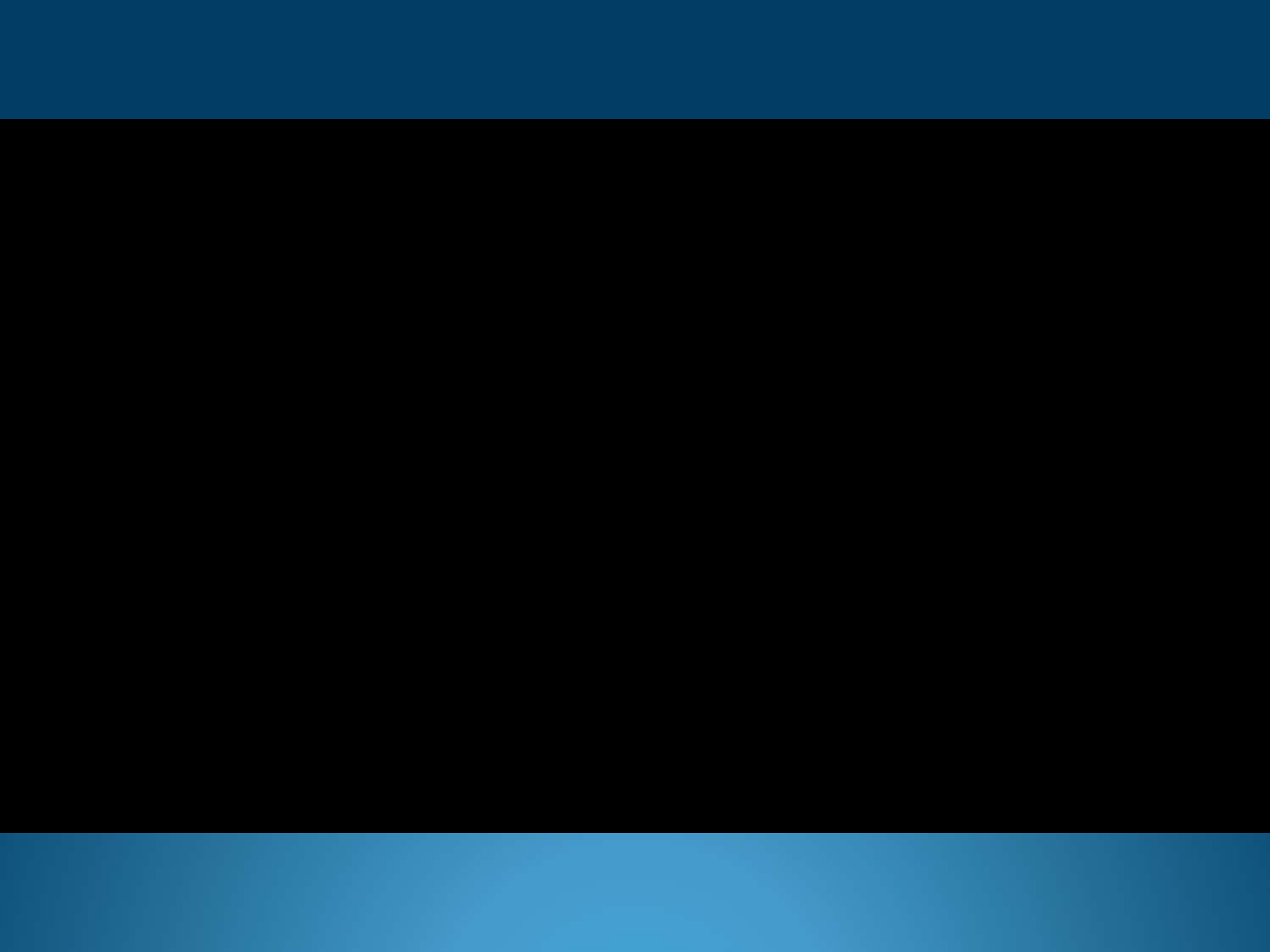


Figure 17, 18 & 19: Expulsion of the magnets and creation of patent anastomosis.

SADI-S vs. Side-to-Side Magnetic Duodeno-ileostomy







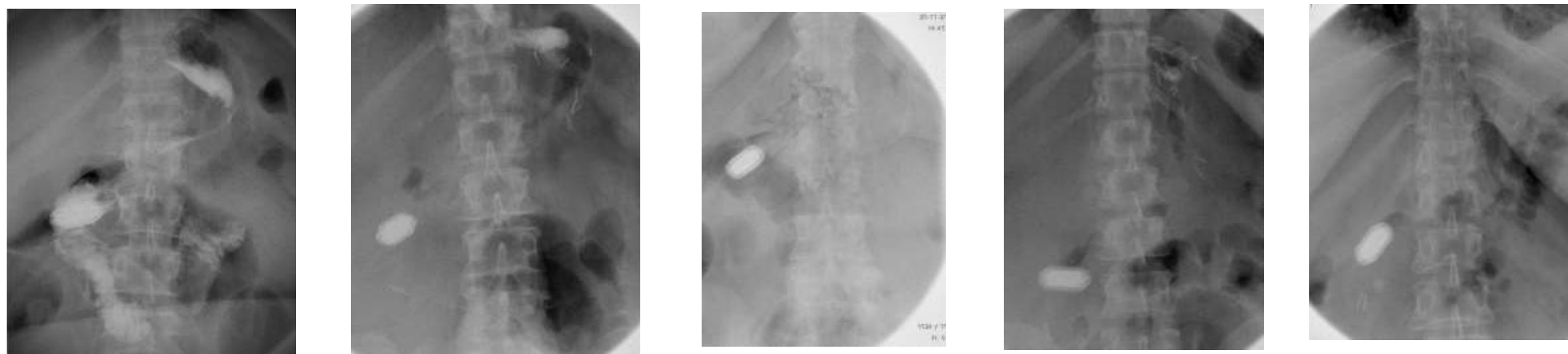
Dr. Gagner and Dr. David Abuladze started the DI Clinical Trial



Phase 1 Clinical Trial

- N=5
- Innovative Medical Center in Tbilisi, Georgia
- PI: David Abuladze, MD
- Enrollment: NOV 2021

The MAGNET System - Stage 1- Primary endpoint Device Delivery Success- Safety Population

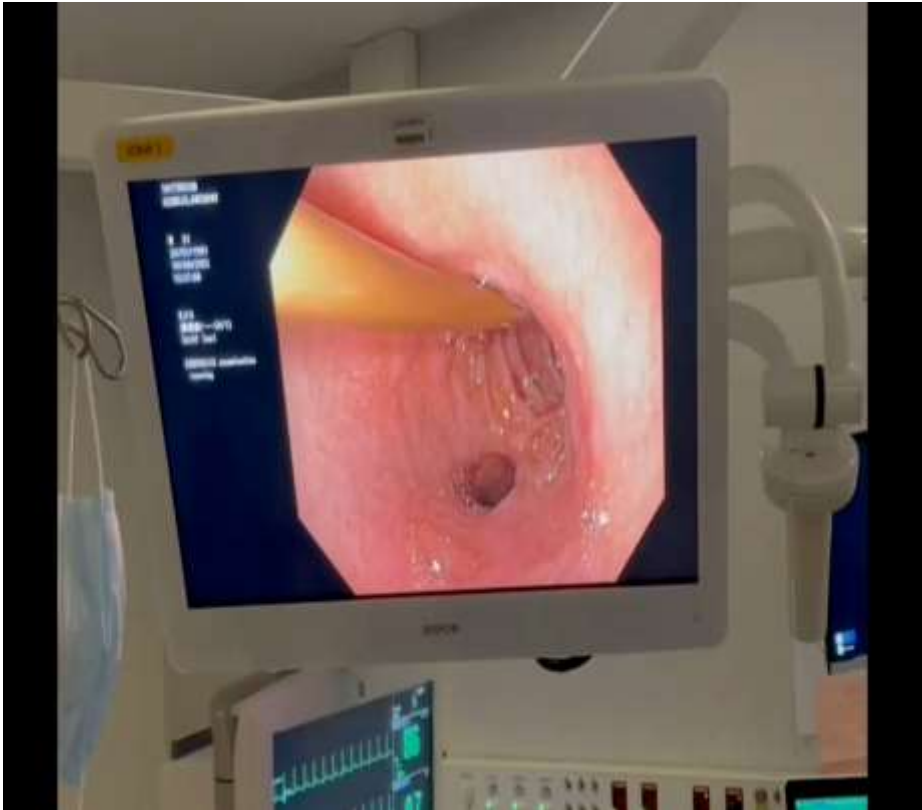


Procedure date	Duration of procedure mean in min (SD)	Placement of the magnet
22, 24, 25 and 26 November 2021	154 (24.48)	100%



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Results-Gastroscopy











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

Michel Gagner^{1,8}  · Guy-Bernard Cadierne² · Andres Sanchez-Pernaute³ · David Abuladze⁴ · Todd Krinke⁵ · J. N. Buchwald⁶ · Nathalie Van Sante⁷ · Marc Van Gossum² · Jana Dziakova³ · Levan Koiava⁴ · Maja Odovic³ · Mathilde Poras² · Lamees Almutlaq¹ · Antonio J. Torres³

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 gastroscopy; first (distal) Magnet placed at the ligament of Treitz, and second (proximal) Magnet into the proximal duodenum. Magnets re-positioned using Laparoscopic Positioning Devices:



- 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 separation and none (0%) required invasive re-intervention
- 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 followed immediately by sleeve gastrectomy (non-study):
 - **(4) cases of serosal tissue tears due to the use of laparoscopic bowel forceps** during grasp and pull maneuver to move the distal Magnet; all repaired as a precaution with no additional sequelae
 - **(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 ± SEM	Mean ± SEM	Mean change ± SEM (95%CI)	P-value	Mean ± SEM	Mean change ± SEM (95%CI)	P-value
Weight							
Absolute wt, kg	121.9 ± 3.3	87.8 ± 2.8	34.2 ± 1.6 (30.9, 37.4)	<0.001	77.6 ± 4.7	40.0 ± 3.1 (31.4, 48.6)	<0.001
BMI, kg/m ²	44.4 ± 0.8	32.0 ± 0.8	12.4 ± 0.5 (11.5, 13.3)	<0.001	29.3 ± 1.5	15.1 ± 1.0 (12.2, 18.0)	<0.001
TWL, %	–	28.1 ± 1.0	–	–	34.0 ± 1.4	–	–
EWL, %	–	66.2 ± 3.4	–	–	80.2 ± 6.6	–	–
Clinical							
HbA _{1c} , %*	6.2 ± 0.3	5.1 ± 0.2	1.1 ± 0.4 (0.2, 1.9)	<0.05	4.8 ± 0.2	2.0 ± 1.1 _††	0.173
Glucose, mg/dL [†]	111.3 ± 6.1	86.5 ± 3.5	24.8 ± 6.6 (11.0, 38.6)	<0.001	87.3 ± 6.3	53.8 ± 6.3 _††	0.113

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

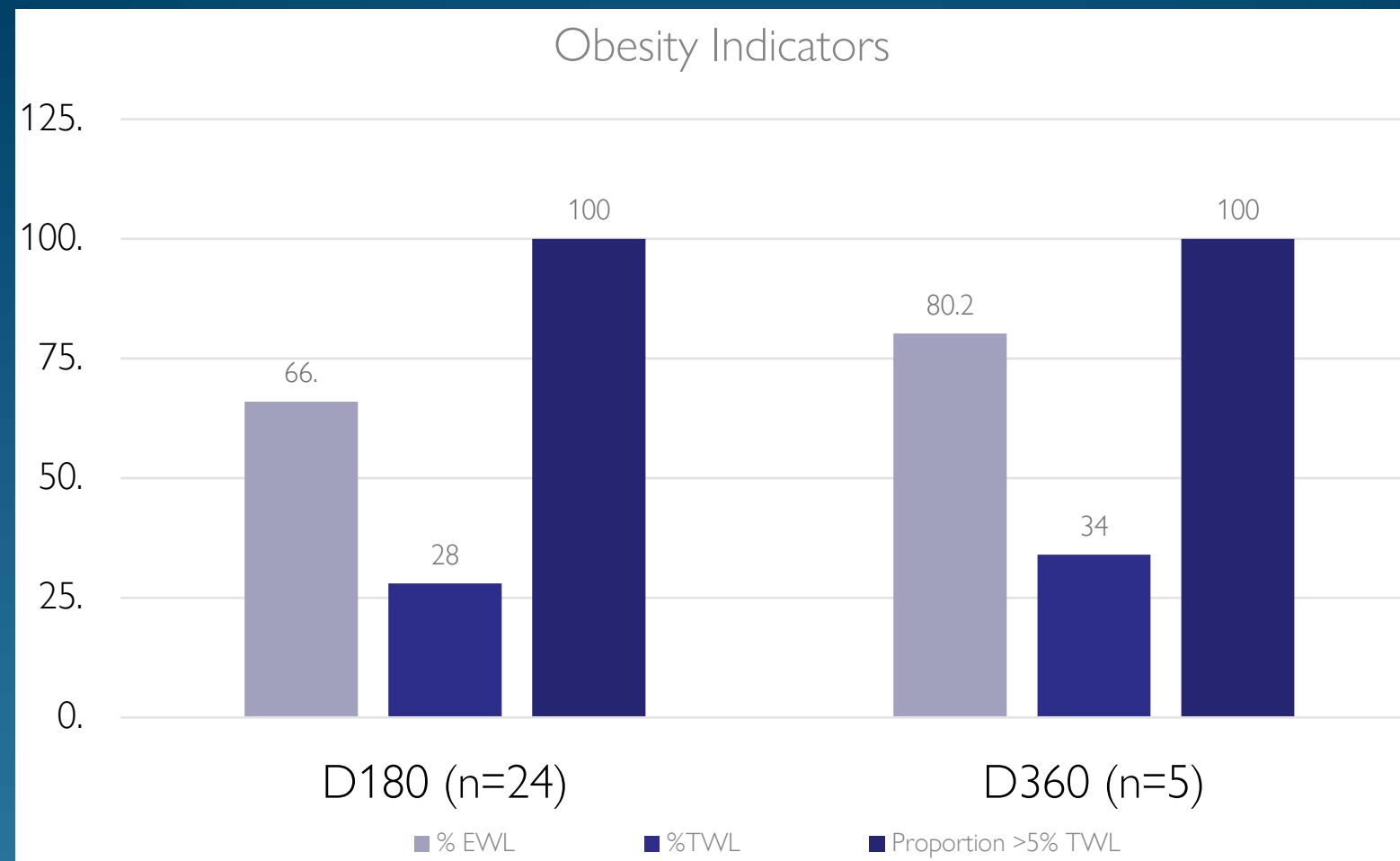
*HbA_{1c} baseline n=20; 6-month n=19; 12-month n=4

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

††Not applicable due to small sample size

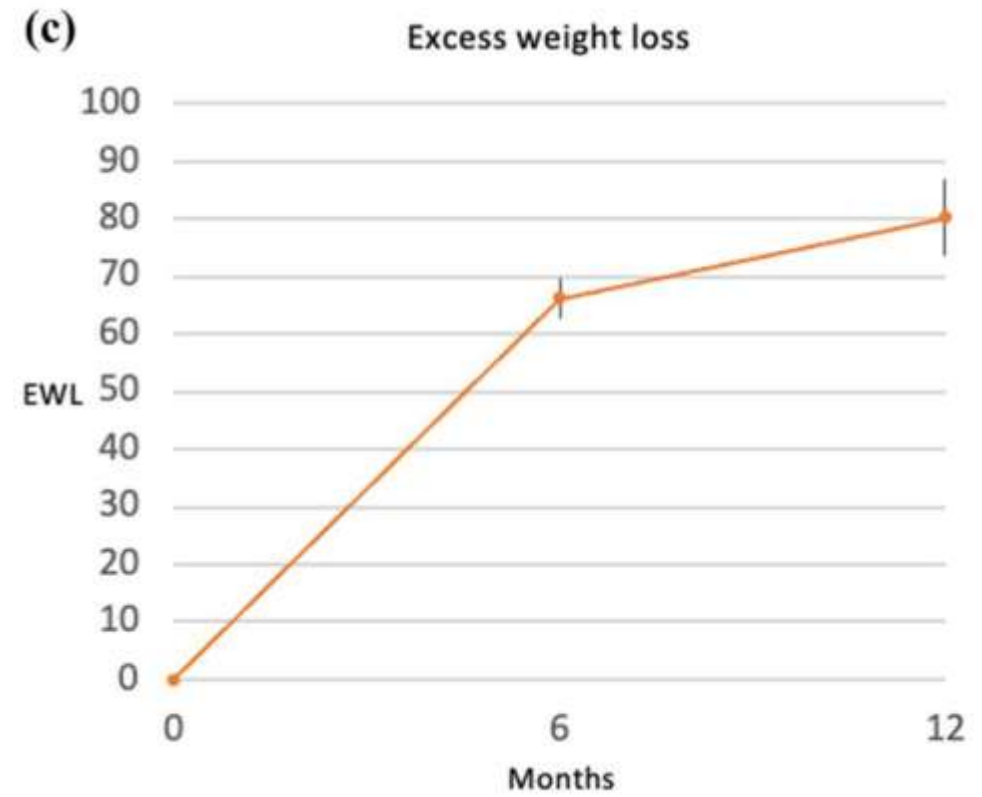
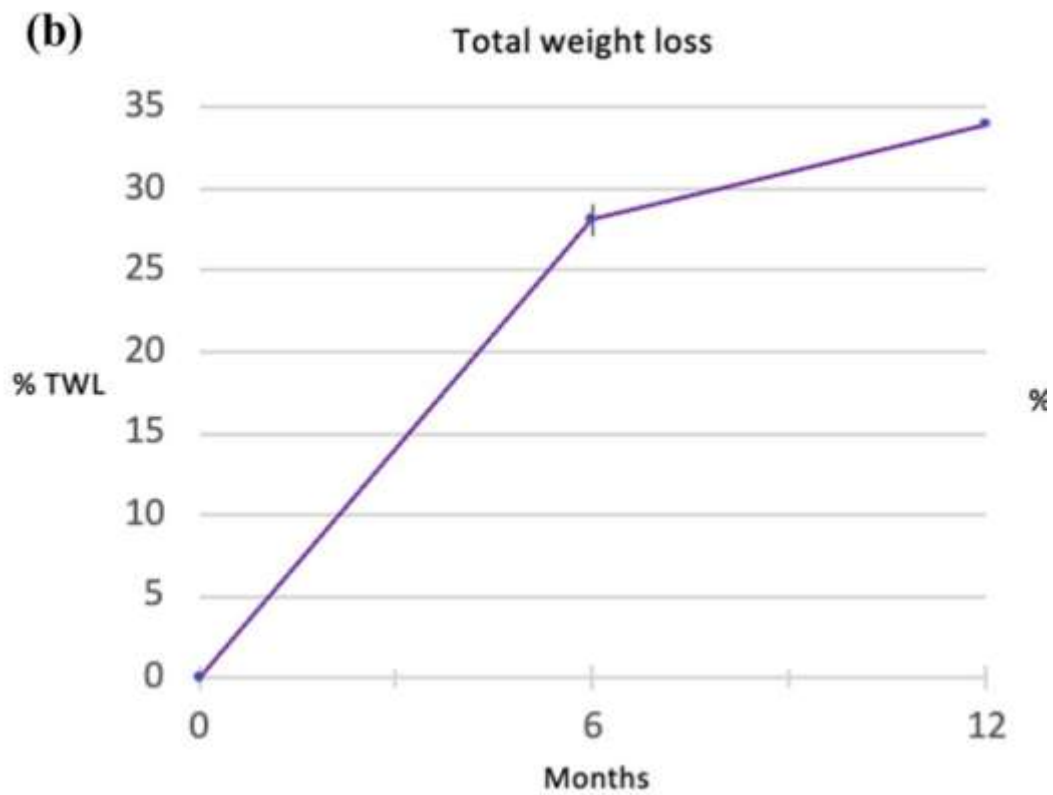
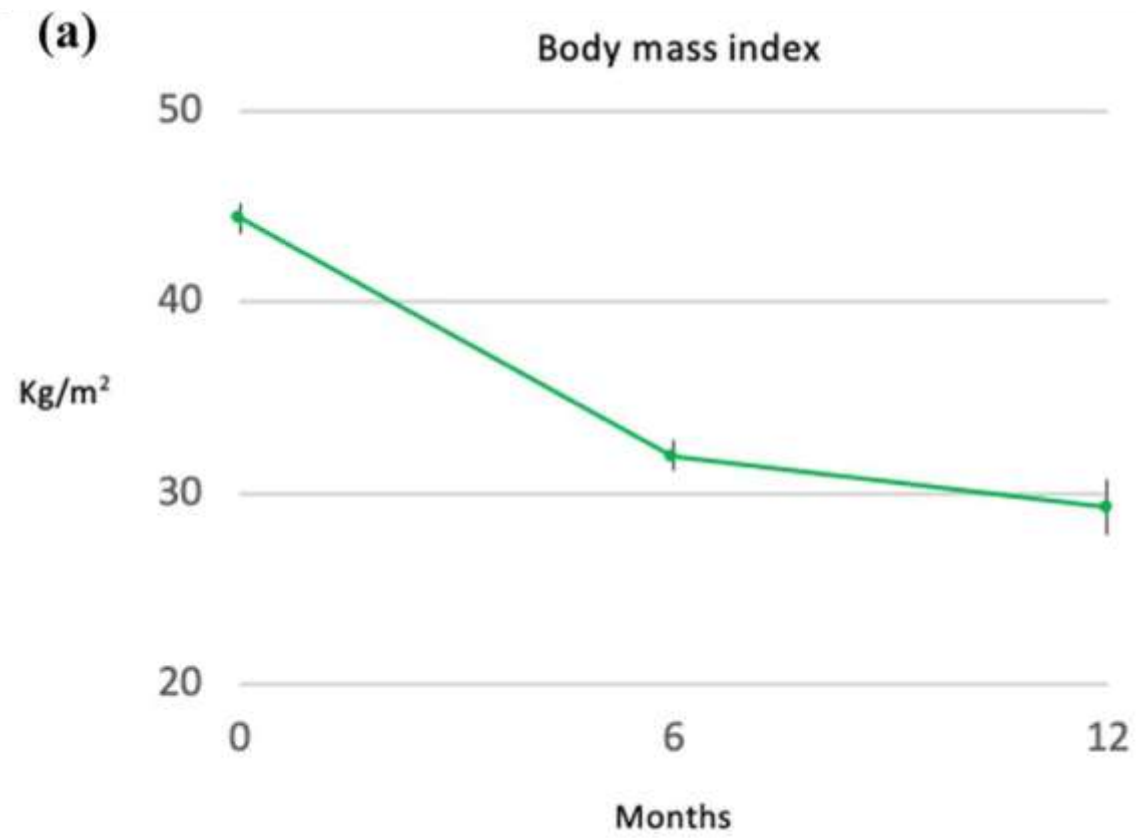
Secondary Outcomes Collected for Early Signals

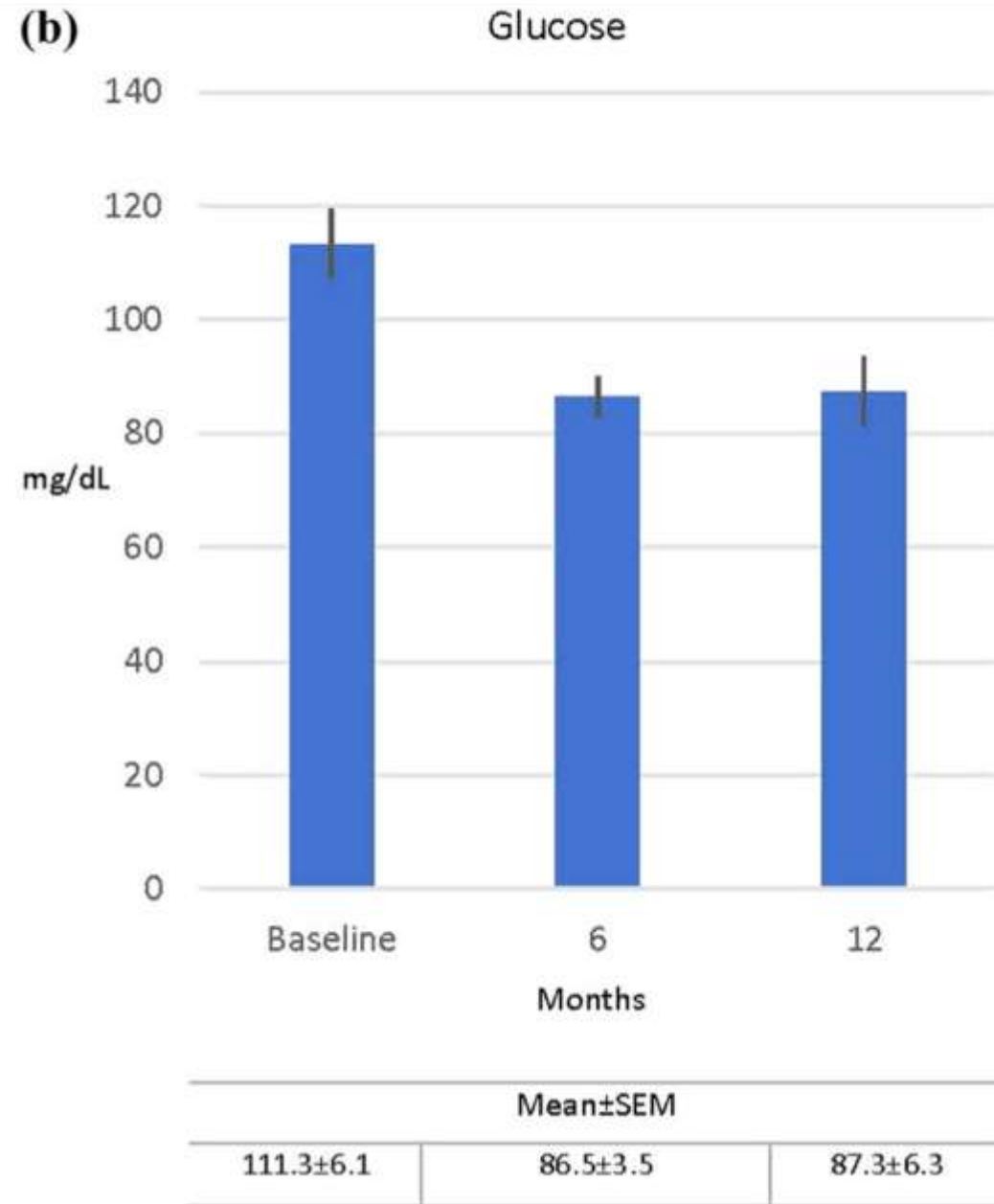
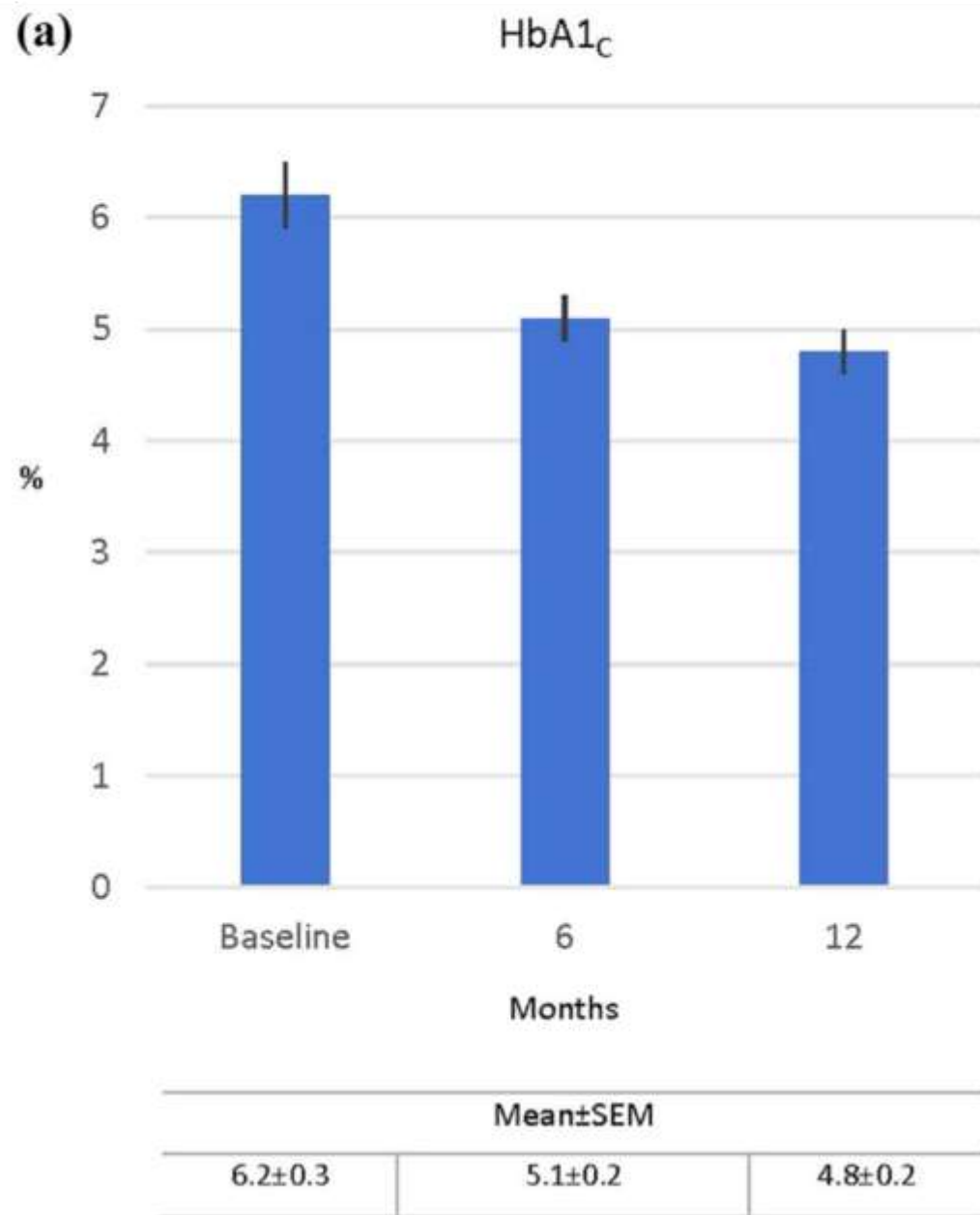
- Obesity indicators in this cohort (n=24) are very promising at six months
- Impressive results continue for the subset of 5 subjects followed to one year



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) on oral diabetes medications:
 - 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

Secondary Outcomes Collected for Early Signals

- For the subset of subjects (n=5) followed to one year, subjects demonstrated HbA1c% and glucose levels remained stable
- Four of the subjects entered on oral diabetes medications;
 - Three stopped at enrollment and remained off through one year; the fourth was on medication for a few months and stopped prior to D180

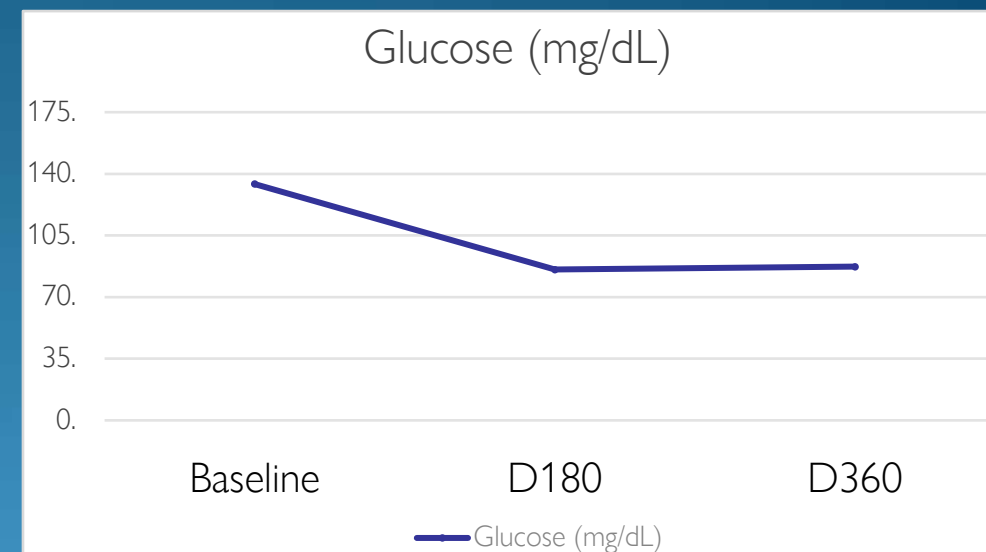
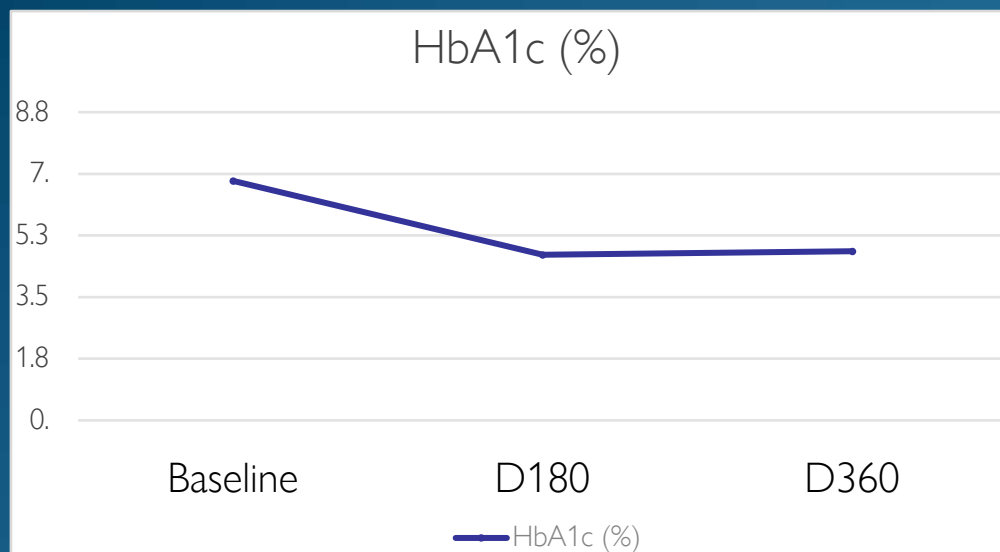
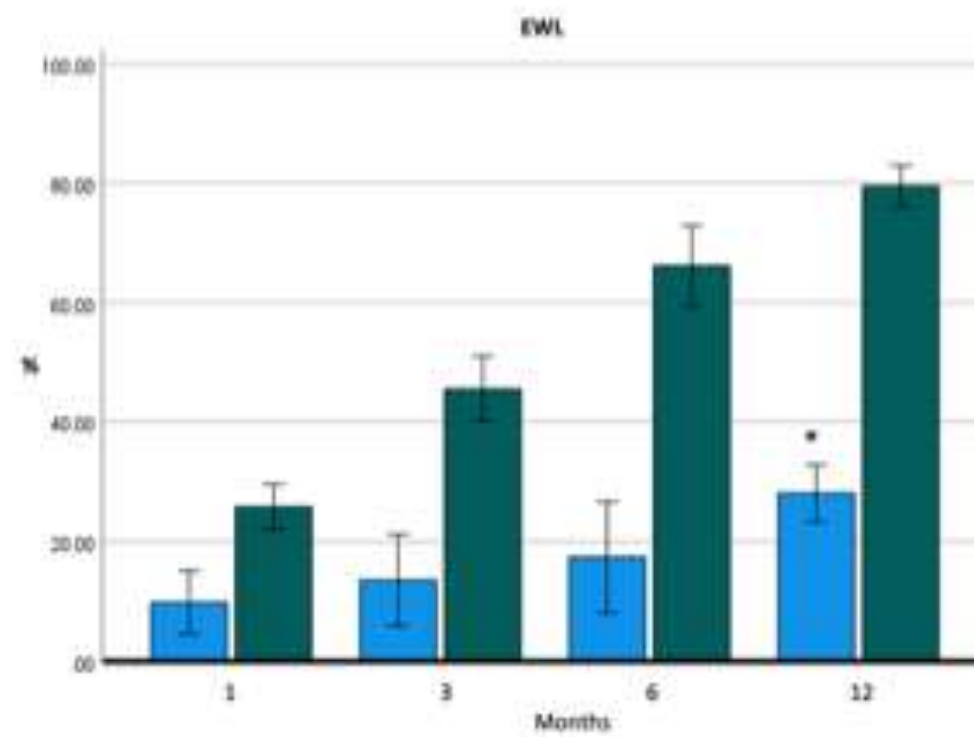
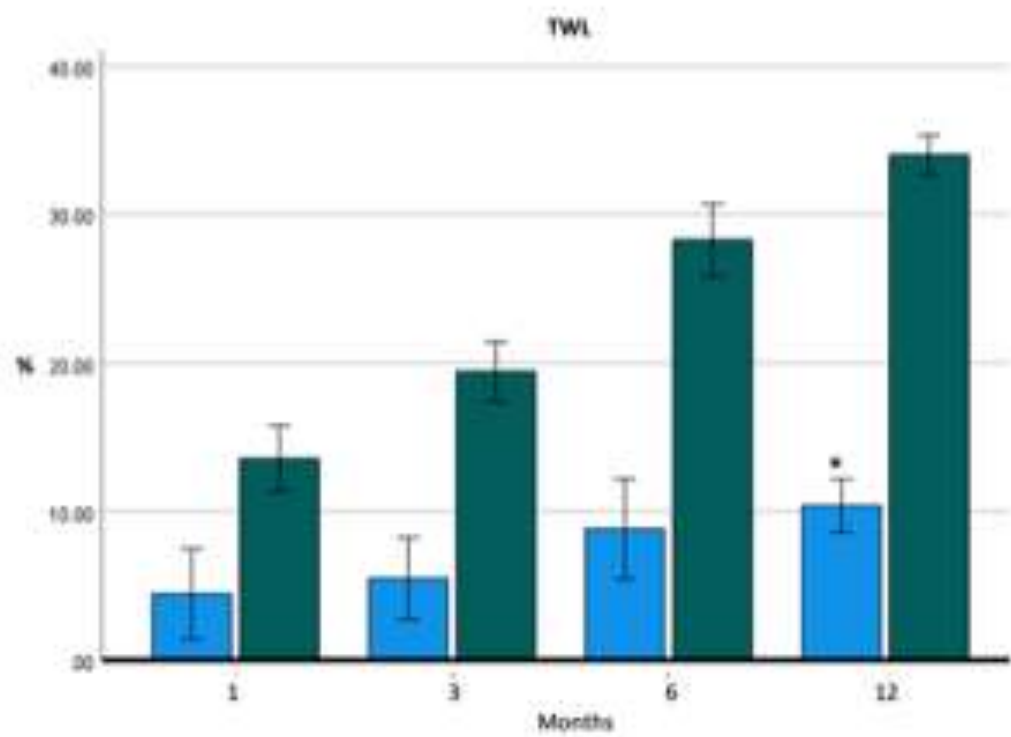
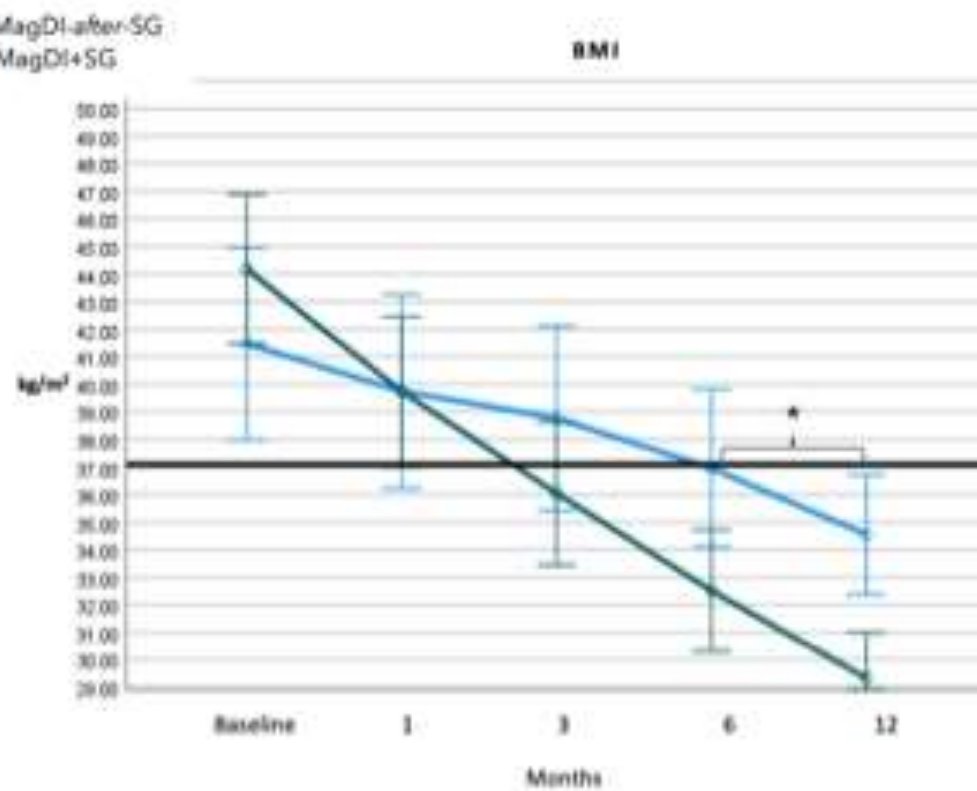
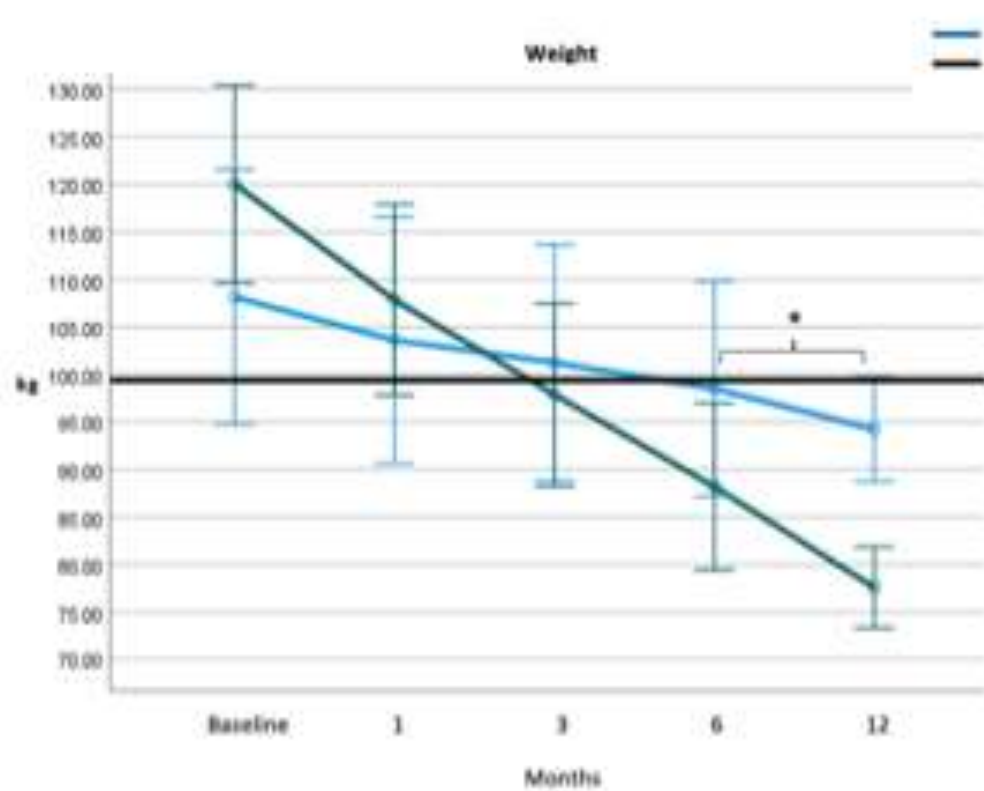


Table 1. Patient characteristics and perioperative outcomes

Characteristics	Side-to-side MagDI- <i>after</i>-SG (revision) n=19	Side-to-side MagDI+SG (concurrent; primary) n=24	P-value
Perioperative			
Operative time, min, mean±SEM (range)	67.0±4.7 (33.0-120.0)	175.1±8.6 (99.0-250.0)	< 0.001
Hospital stay, days, mean±SEM (range)	1.1±0.1 (1.0-2.0)	6.0±1.7 (2.0-40.0)*	< 0.01
Expulsion of magnets, days, mean±SEM (median)	39.0±4.6 (35.0)	48.2±4.7 (48.5)	< 0.05



80%

28%

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.