Magnetic Anastomosis: Clinical Evidence, Outcomes, and Future Directions

Real world data

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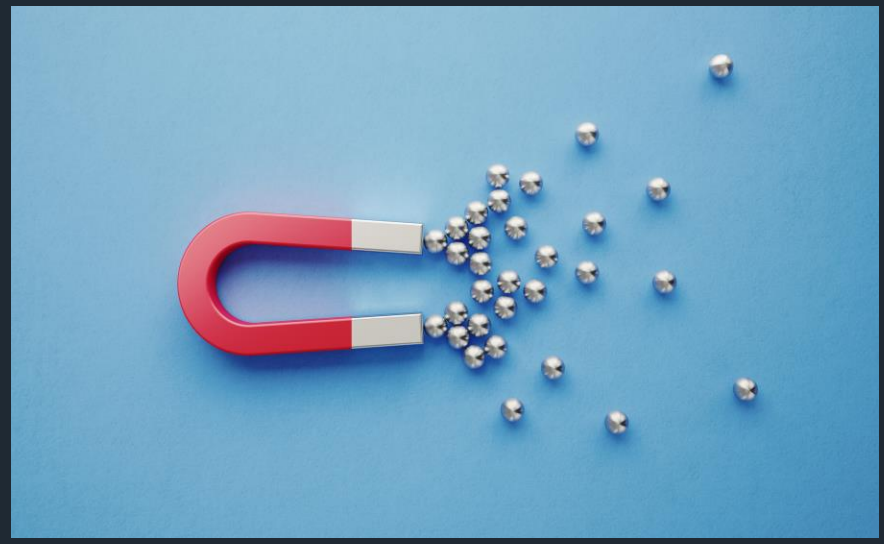


Disclosures

Johnson & Johnson: Educational Speaking and Consulting

RATIONALE

The anastomosis is a technical risk

0.7–1.0%

GJ/DJ leak rate

Higher

After revisional surgery

Magnetic technology is not exclusive to bariatric surgery

Ore, Surg Endosc 2022 · Olavarria, Surg Endosc 2025 · Gumustop, iGIE 2022 · Gagner, Surg Endosc 2023

Beyond bariatrics and real-world outcomes

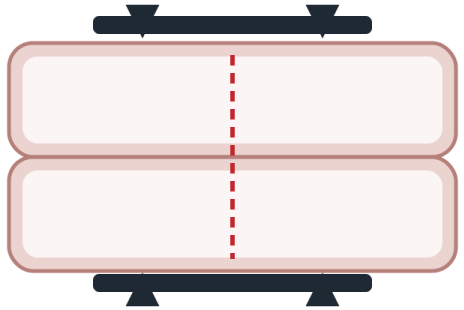
- Esophageal atresia for lengthening and anastomosis
- Vascular anastomosis
- Biliary strictures after bile duct reconstruction
- Colonic anastomosis
- DJ bypass for SMA syndrome
- GJ bypass for palliation in oncology

TWO MECHANISMS OF ANASTOMOTIC HEALING

Stapled fixation versus magnetic compression

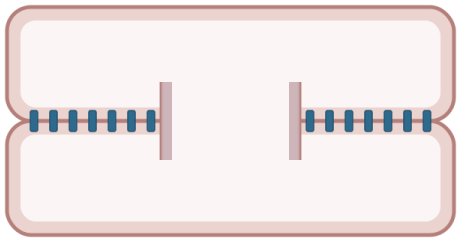
STAPLED — compression applied in under one second

The instant of firing
compression under one second



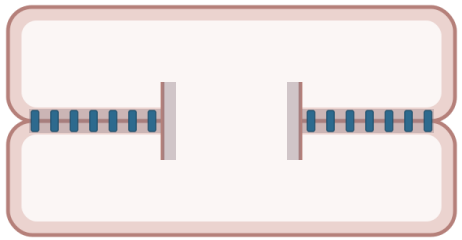
knife cuts as the staples form

Immediately after
lumen open, seal untested



crushed, devascularised staple line

Weeks later
titanium stays in the wall



permanent foreign body and fibrosis

seconds → *weeks*

The order is reversed

Stapled

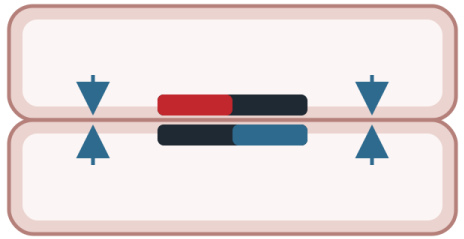
The lumen is created first. The seal must hold immediately, under full load, across crushed and devascularised tissue.

Magnetic

The seal forms first. The lumen opens only after a mature serosa-to-serosa ring has already formed around it.

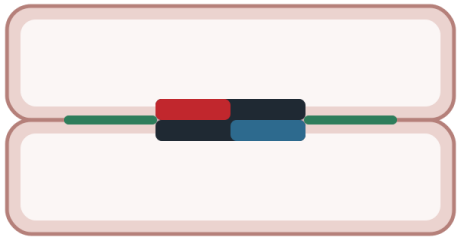
MAGNETIC COMPRESSION — compression applied over 7 to 21 days

Day 0 — couple
no enterotomy, no lumen



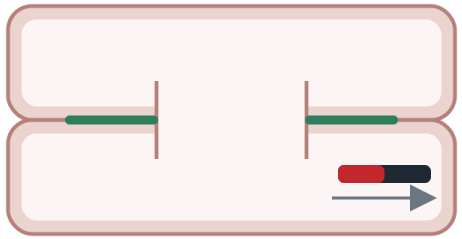
walls apposed, bowel never opened

Days 1–7 — the seal forms first
serosa fuses around the magnets



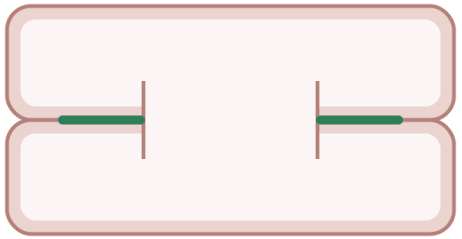
green = serosa-to-serosa seal
captured core turning ischaemic

Days 7–21 — the lumen opens
into an already-sealed ring



necrosed core sloughs, magnets detach

After expulsion
nothing left behind

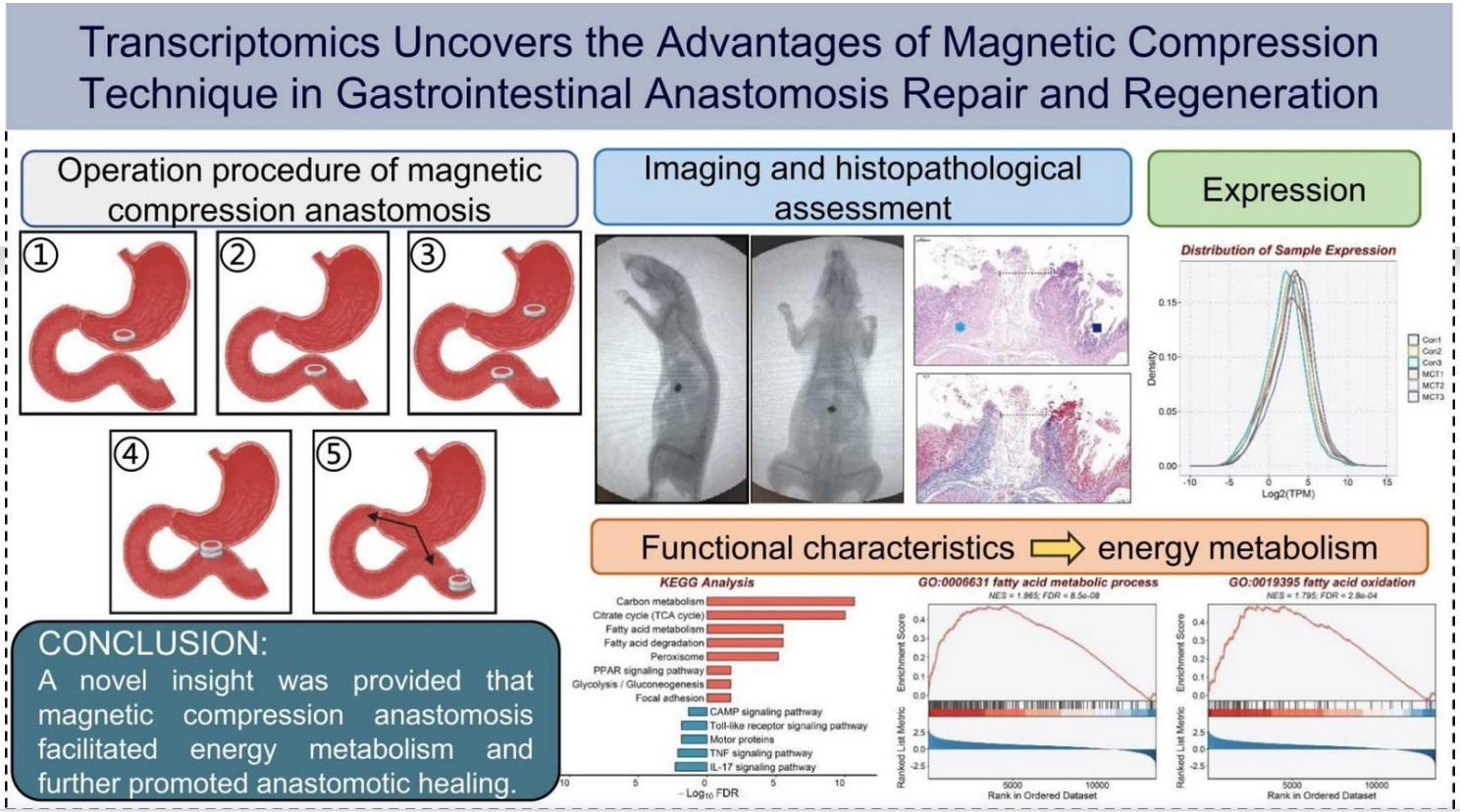


no staples · no suture · no retained material
smooth, wide, remodelled anastomosis

day 0 → *day 21 onward*

Magnetic compression over days rather than seconds with stapling/suturing is a fundamentally different mechanistic process.

Preclinical physiology



Preclinical work: magnetic anastomoses show less fibrosis, less tissue distortion, less bacterial ingress, and burst pressures approaching native tissue — with no retained foreign material.

DEVICES

Two platforms, two design philosophies

Linear Magnet System (LMAS)

Form	Paired linear magnets, 30 / 40 / 50 mm
Lumen	Delayed — matures over 7–21 days
Access	Endoscopic delivery + laparoscopic alignment; no enterotomy a potential
Status	FDA cleared Oct 2024 (40 mm), Feb 2025 (50 mm); De Novo DEN240013
Use case	Duodeno-ileal bipartition, primary and revisional

Self-Forming Magnets (SFM)

Form	Chain of eight nitinol-clad magnet segments, 25 mm formed
Lumen	Immediate — 8–10 mm via silicone implant
Access	Requires enterotomy; laparoscopic deployment
Status	IDE pivotal trial completed 2026
Use case	Any small-bowel anastomosis — JJ, DI, ileo-ileal

FDA K242086, K243359 · Teixeira, Surg Endosc 2026 · Gagner, Obes Surg 2023

TRAJECTORY

First-in-human to commercial use: Adoption ahead of data?

2021 First-in-human side-to-side magnetic DI (Tbilisi), n = 5

2023 Early multicentre MagDI + sleeve

2024 One-year single-centre data from Madrid and Brussels; SNAP-S multicentre trial; FDA clearance of MagDI (Oct)

2025 First US commercial cases; 50 mm magnet cleared; swallowable biofragmentable system first-in-human

2026 FLOWS North American pivotal trial published; randomized MagDI vs semaglutide trial recruiting

Roughly 200 patients have been reported in the peer-reviewed literature across all magnetic bariatric applications combined.

EVIDENCE MAP

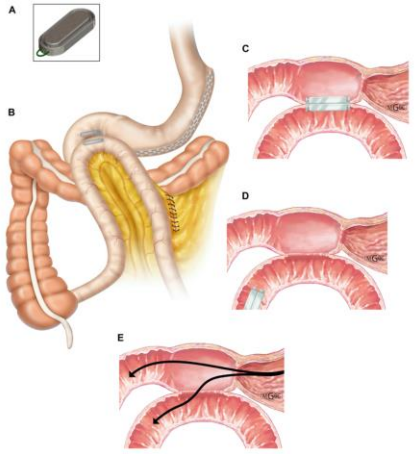
The published evidence base

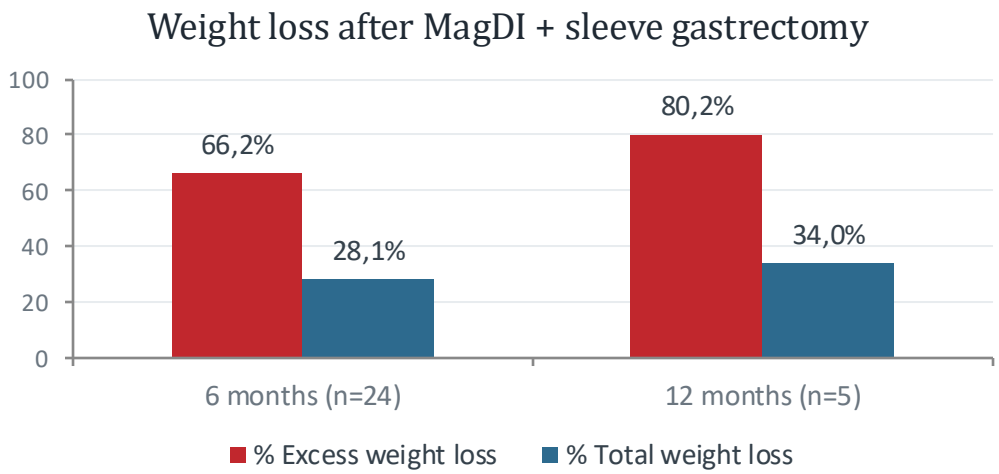
Study	Design	n	Procedure	Follow-up
Gagner, Obes Surg 2023	First-in-human	5	MagDI	6 mo
Gagner, Surg Endosc 2023	Multicentre, 3 sites	24	MagDI + SG	6 mo
Gagner, SOARD 2024	Multicentre prospective	**43**	MagDI ± SG	6–12 mo
Cadiere, JOGS 2024	Single centre (Brussels)	10	MagDI + SG	12 mo
Dziakova, Obes Surg 2024	Single centre (Madrid)	10	MagDI + SG	12 mo
Gagner, World J Surg 2024	Single centre, revisional	24	MagDI after SG	12 mo
Biertho, SOARD 2025	Multicentre prospective	19	SNAP-S (SFM)	12 mo
Gagner, JACS 2025	First-in-human	15	Swallowable LMAS	12 mo
Teixeira/Shah, Surg Endosc 2026	IDE pivotal, 6 US centres	**79**	SFM, mixed anastomoses	60 d

No study is randomized. No study has a concurrent stapled or sutured control arm. Median cohort size is under 25 patients.

TRIAL DATA

MagDI with concurrent sleeve: primary procedure





100%
Technical feasibility and radiologic patency

0
Device-related leaks, bleeds, or infections

48.5 d
Median time to magnet expulsion

Clinical trial done under IRB with safety board
Caution: the 12-month weight loss is for five patients.

Gagner et al., Surg Obes Relat Dis 2024;20:341–352 · Gagner et al., Surg Endosc 2023;37:6452–6463

Primary and Revisional Weight Loss

MagDI performed as a second-stage procedure after prior sleeve gastrectomy produced markedly less weight loss than when done with a concurrent sleeve.

MagDI + concurrent sleeve

66.2%

% excess weight loss

28.1% TWL

n = 24, 6 months

MagDI after prior sleeve

17.4%

% excess weight loss

8.0 kg TWL

n = 19, 6 months

Revisional at 12 months

16.4%

% excess weight loss

5.3% TWL

n = 24, single centre

Initial data suggests low weight loss at 12 months with 3 cm linear magnet.

Gagner et al., SOARD 2024;20:341–352 · Gagner et al., World J Surg 2024;48:2337–2348

REAL-WORLD SERIES

Single-centre European experience

Madrid — Hospital Clínico San Carlos

n = 10 · 12 months

Total weight loss	**38.7 ± 8.5%**
Excess weight loss	**82.5 ± 18.4%**
Complication rate	**30%**
Anastomosis diameter	**13.8 × 11.4 mm**
Magnet expulsion	**mean 42 days**

Brussels — CHU Saint-Pierre (MAGDi after SG)

n = 10 · 12 months

Patency after expulsion	**10 / 10**
Patency at 12 months	**9 / 10**
Magnet expulsion	**43 d (IQR 21–87)**
Median hospital stay	**3 days**
Conversions	**none**

Caution: Both cohorts are ten patients drawn from the same multicentre protocol
The 30% complication rate in Madrid reflects mostly sleeve-attributable events

Dziakova et al., Obes Surg 2024;34:3569–3575 · Cadière et al., J Gastrointest Surg 2024;28:640–650

TRIAL DATA

Swallowable biofragmentable system: lower BMI, diabetes

A first-in-human study deliberately targeted patients outside conventional MBS criteria — BMI 30–35 with poorly controlled type 2 diabetes.

15
Patients enrolled

33.0
Mean baseline BMI (kg/m²)

8.2%
Mean baseline HbA1c

100%
Anastomoses patent at 1 year

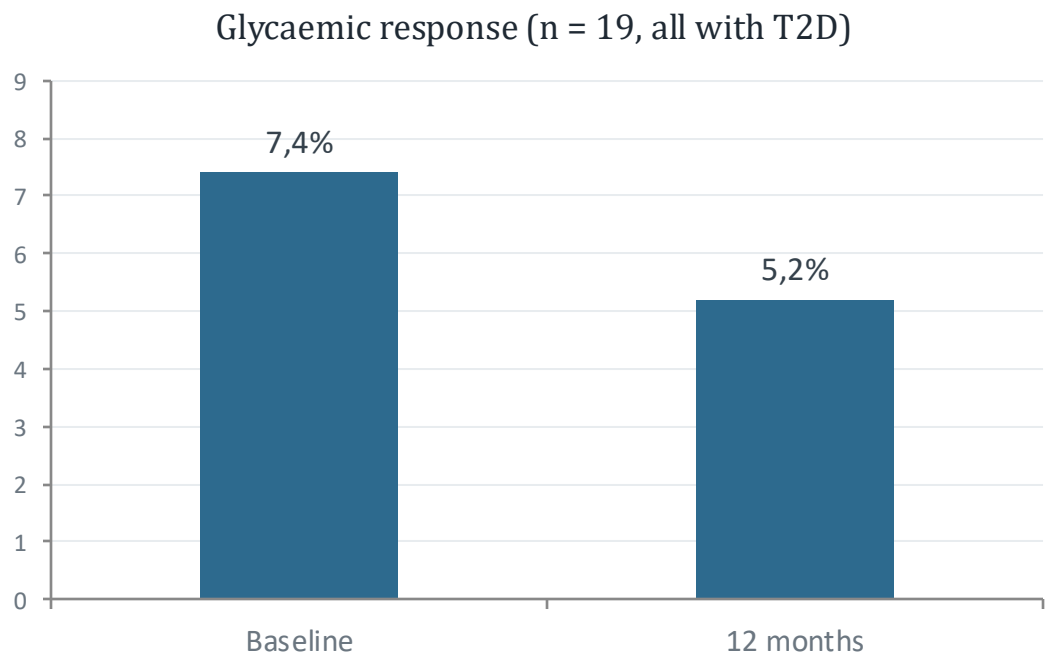
What was reported

- Feasibility confirmed at 90 days in all patients; sub-one-hour operative time
- No leak, bleeding, infection, stricture, or mortality reported
- Magnet delivered by swallowing or endoscopy, guided laparoscopically to the distal ileum
- BMI 30, EWL% 38.8, A1C 6.6% (n=8)

Gagner et al., J Am Coll Surg 2025;241:146–159

TRIAL DATA

SNAP-S: self-forming magnets with sleeve, one year



31% Mean total weight loss at 12 months

78% Complete type 2 diabetes resolution

100% Patients achieving ≥10% total weight loss

2.2 → 0.2 Mean number of diabetes medications

Three of nineteen developed protein malnutrition requiring readmission and nasoenteric feeding within six months. No adverse event was attributable to the anastomosis itself. 300 cm common channel

Biertho et al., Surg Obes Relat Dis 2025;21:166–174

DURABILITY

The only medium-term durability data we have

A fourteen-patient cohort followed to four years is currently the longest published follow-up for any magnetic bariatric anastomosis.

Table 2 Metabolic and weight outcomes at baseline and at 12, 24, 36, and 48 months following SNAP. Data are presented as mean±SD or n (%). *Indicates statistically significant differences compared with baseline values

Outcomes	Baseline	Month 12	Month 24	Month 36	Month 48
HbA1c (%)	8.3±1.3	6.4±0.6*	6.6±1.2*	6.4±1.5*	6.9±1.8*
Number of T2DM medications	2±1	1.1±1	1.1±1	1±1	1±1
Weight (kg)	113±22	98±26*	96±27*	96±31*	102±29
BMI (kg/m^2)	40.3±3.7	35.0±5.5*	34.5±6.7*	33.8±8.0*	35.4±7.3*
Total weight loss (%)	N/A	13.4±8.6*	14.2±11.5*	15.6±13.6*	13.5±12.9*

What do we know:

- Weight loss was maintained— durability of the anastomosis at 4 years
- 13.4% total weight loss from DI bipartition (below sleeve or bypass benchmarks)
- Glycemic benefit attenuated modestly between years one and four
- Fourteen patients; technical success 100%

Jirapinyo P, et al. Obesity Surgery 2026; 36:3155-3160.

PIVOTAL TRIAL

FLOWS: the first pivotal trial for self-forming magnets with an immediately function lumen

A six-centre US IDE pivotal study, and the largest magnetic anastomosis cohort published.

79
Patients across 6 centres

100%
Primary endpoint achieved

0
Leaks, bleeds, obstructions, reoperations, deaths

13 min
Median anastomosis creation time

What was done

- Most common: jejunojejunostomy during Roux-en-Y gastric bypass
- Also duodeno-ileostomy during SADI and ileo-ileal anastomoses
- Learning curve short — 18 down to 12 minutes across the cohort

Negative results

- Four serious adverse events total; none device-related
- Two intraoperative small bowel perforations during magnet placement — both recognised and repaired immediately
- Five device malfunctions, all in delivery components, none causing harm

Teixeira, Seger, Shah et al., Surg Endosc 2026 (published online 31 July 2026)

The FLOWS Study (Functional Lumen Opening With Self-forming magnetic anastomosis): Results from the North American Pivotal Trial

A Prospective, Multicenter, Single-arm Pivotal Clinical Study

BACKGROUND

Anastomotic complications remain a major challenge.

Magnetic compression anastomosis (MCA) may allow gradual tissue compression and healing with less trauma.

The Flexagon SFM with OTOLoc provides an immediately functional lumen (IFL) enabling immediate enteral flow.

STUDY DESIGN

- Prospective, multicenter, single-arm pivotal trial
- 6 North American centers
- Adults (>22 years) undergoing laparoscopic surgery requiring a small bowel anastomosis
- Follow-up: 60 days

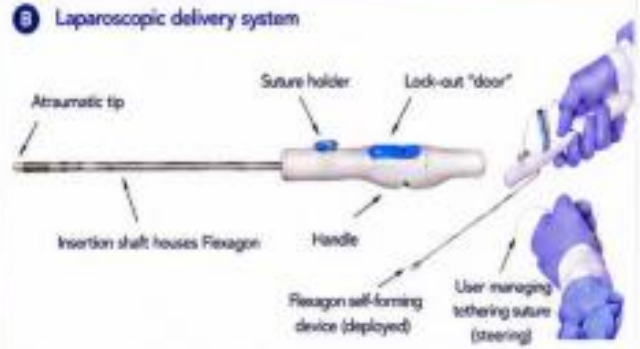
Primary endpoint:
Successful anastomosis with SFM with IFL without procedure, device, or target anastomosis-related reoperation through 30 days.

THE FLEXAGON SFM SYSTEM WITH OTOLOC

A Flexagon SFM

Self-forming magnet assembly (8 magnet segments connected by stainless-steel rollers, coated with parylene).

B Laparoscopic delivery system



C OTOLoc provides immediate functional lumen (IFL)

Two deployed Flexagon SFMs (through OTOLocs) | Flexagons are coupled together | Immediate fluidic flow

Compression over 8–14 days

Magnets pass naturally and are excreted

No residual foreign body

TYPICAL PROCEDURES (mITT COHORT, n=71)

Jejunojejunostomy (Roux-en-Y gastric bypass)	Duodenoileostomy (Single anastomosis duodeno-ileal bypass)	Ileoileostomy (other indications)
55 (77.5%)	8 (11.3%)	8 (11.3%)

KEY RESULTS (mITT COHORT, n=71)

Primary endpoint achieved (success without related reoperation through 30 days)	71/71 (100%)
No anastomotic leak, bleed, obstruction, re-intervention, or death	0
Procedure Metrics	
• Median (IQR) procedure time	92 (76, 116) min
• Median (IQR) anastomosis creation time	13 (9, 17) min
• Mean (SD) distance from anastomosis to staple line	2.5 ± 1.2 cm
Adverse Events	
• Serious AE (Clavien-Dindo ≥3b)	4 (5.6%)
• Device-related SAE	0

CLINICAL TAKEAWAY

The Flexagon SFM with OTOLoc enables safe and technically successful creation of small bowel anastomosis with an **immediately functional lumen** using a minimally invasive approach, with no anastomotic complications and an excellent **short-term safety profile.**

CONCLUSION: This pivotal trial demonstrates the feasibility, technical success, and short-term safety of magnetic compression anastomosis with immediate functional lumen for small bowel anastomosis. These results support further comparative and registry studies to define its role in gastrointestinal surgery.

ClinicalTrials.gov NCT06454916

SYNTHESIS

Magnetic data synthesis: Safety across the whole literature

Consistent findings

Anastomotic leak
Not reported in any published magnetic bariatric series

Anastomotic bleeding
Not reported in any published series

Stricture
Rare; final lumen 13–25 mm depending on platform

Device retention
No retained magnets requiring retrieval in the pivotal cohort

What still needs watching

Protein malnutrition
3 of 19 in SNAP-S required readmission — a hypoabsorption effect, not a device effect

Intraoperative injury
Two small bowel perforations in 79 patients during magnet introduction

Adverse event counting
Long-term follow-up

Delayed expulsion
Awareness and need for extended follow-up beyond 30 days

CRITICAL APPRAISAL

What "real-world outcomes" does not yet mean

No comparator

Not one study includes a concurrent stapled or sutured control. Every safety claim is a single-arm observation against historical benchmarks.

Small and overlapping

Roughly 200 patients total, with several "single-centre" papers reporting subsets of the same multicentre protocol.

Industry-sponsored throughout

Device manufacturers funded, and in several cases co-authored, essentially the entire published literature.

Confounded efficacy

Weight loss is reported for magnet-plus-sleeve. Isolating the bipartition gives 5–13% total weight loss.

Short follow-up

Almost all data is 12 months

No registry data

No MBSAQIP or IFSO registry capture, so real-world adoption outcomes are currently invisible.

None of this means the technology does not work.

IMPLEMENTATION

Practical considerations and what is coming

If you are adopting this now

- Patients cannot undergo MRI until magnets have passed — screen for anticipated imaging needs
- No contraindication with pacemakers or defibrillators for abdominal procedures
- Counsel on expulsion timing: median six weeks, occasionally longer
- Only one anastomosis per case can currently be magnetic
- Device cost is additive up front; the long-term offset?
- Learning curve appears short for experienced minimally invasive surgeons

Trials to watch

MAGvMED

Randomized crossover: magnetic duodeno-ileostomy versus semaglutide in BMI 30–40 with T2D.

MagCR

Magnetic compression anastomosis in colorectal surgery — extension beyond bariatric indications.

MagGJ / MagGI

Gastrojejunal and gastroileal diversion feasibility studies.

International cohorts

MagDI studies recruiting in Italy, Australia, Chile, and Mexico.

GOVERNANCE

Is duodeno-ileal bipartition an approved operation?

FDA device clearance and procedure endorsement are two separate things

ASMBS endorsed procedures

- Sleeve gastrectomy
- Roux-en-Y gastric bypass
- BPD with duodenal switch
- SADI-S
- One anastomosis gastric bypass
- Bariatric re-operative procedures
- Adjustable gastric banding
- ESG

Bipartition is not on that list

- Any non-endorsed procedure requires IRB review and approval before use as a primary treatment for MBSAQIP
- Approval must cover the procedure itself — not merely data collection
- If the IRB deems a protocol unnecessary, a letter of exemption is required for MBSAQIP compliance
- Re-operative procedures are exempt, though this still should align with endorsed operations

My practical advice: bipartition (not magnetic compression anastomosis) currently requires an IRB given lack of randomized data and follow-up
- Off-label magnetic compression use should be thoughtful and cautious

ASMBS Endorsed Procedures and FDA-Approved Devices, updated 15 December 2025

Conclusions

The safety seems real but still underpowered

Zero anastomotic leaks and zero anastomotic bleeds across every published series, now including a 79-patient pivotal trial.

The efficacy

The magnetic anastomosis is durable. What procedure it is used in drives the efficacy question.

The immediate-lumen generation likely brings more options

Clinical footprint to be determined

Ethical obligation to our patients to study new procedures and not apply as primetime with unknown long-term outcomes

No randomized comparison against stapling, no registry capture, no data beyond one year in more than fourteen patients.

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