GT Metabolic<sup>™</sup> Solutions, Inc., opens doors to new surgical platform as FDA grants De Novo marketing authorization to its novel magnet compression anastomosis technology



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GT Metabolic Solutions →
Sep 04, 2024, 10:00 ET

MINNEAPOLIS, Sept. 4, 2024 /PRNewswire/ -- **GT Metabolic™ Solutions, Inc.,** a company dedicated to reinventing bariatric, metabolic, and digestive surgery, today announced its first-generation MagDI™ System for side-to-side duodeno-ileal anastomosis was granted De Novo marketing authorization from the U.S. Food and Drug Administration (FDA).

"Creating a secure anastomosis free of complications bleeds or leaks is the goal of any minimally invasive surgical approach," said Michel Gagner, MD, and Co-Founder of GT Metabolic.

"Magnetic compression anastomosis is designed to allow for more consistent tissue alignment, central necrosis, and circumferential healing while leaving no foreign materials behind to impede the natural tissue healing process."

Traditional anastomotic devices like staples or sutures can be difficult to apply in confined spaces during minimally invasive surgical procedures and can cause trauma by cutting or piercing the bowel tissue and leaves foreign material behind.

Magnetic compression anastomosis is designed to: mitigate the need for incision to the bowel, reduce user technical variability during a procedure, and be naturally excreted from the body.

To date, seven peer-reviewed publications have been completed, including most recently a multicenter clinical consisting of 43 patients conducted by Gagner et al. which demonstrated no anastomotic leaks, bleeds, or obstruction in duodeno-ileal side-to-side anastomosis in bariatric



and metabolic procedures. "Side-to-Side Magnetic Duodeno-lleostomy in Adults with Severe Obesity with or without Type 2 Diabetes: Early Outcomes with Prior or Concurrent Sleeve Gastrectomy in the journal Surgery for Obesity and Related Diseases" was <u>published in November 2023 in the ASMBS</u> journal for Surgery for Obesity and Related <u>Diseases (SOARD).</u>

Future planned studies may be able to broaden improvements in patient outcomes and potentially reach more patients with this less invasive anastomotic approach. Gagner said, "This technology has the potential to offer new standards of care in many procedures."

"Obtaining Medical Device De Novo Classification to market our platform in just four years following the company's inception is incredible. This was achieved due to the vision of the founders and the focus and leadership of the management team and



Michel Gagner, MD, pioneer in magnetic compression anastomosis surgery

its investors who support and share our dream to democratize anastomosis technique," said Thierry Thaure, CEO, and Co-Founder, GT Metabolic.

Thaure went on to say, "The MagDI™ System offers the concept, for the first time, to democratize the surgical approach to anastomosis, enabling surgeons to potentially achieve a more consistent outcome in a less invasive and potentially less expensive solution. We are looking forward to worldwide launch of our incisionless anastomosis system later this year."

"Surgeons are going to like this technology," said Gagner.

## **About GT Metabolic**<sup>™</sup> Solutions Inc.

GT Metabolic Solutions Inc. is leading the world with its development of magnetic compression anastomosis technologies for next-stage minimally invasive procedures. An elegant approach that uses magnets to help achieve anastomosis, the incisionless, sutureless, staple-free technique leaves behind no foreign material to impede the natural tissue healing process.

Working in tandem with renowned global experts, our team has engineered a magnetic compression solution called delayed anastomosis technology (DAT) that surgeons can use to create consistent anastomosis while helping minimize potential complications, such as leaks and bleeds, in challenging applications. Our solution democratizes the surgical approach to anastomosis. It can be used in procedure staging and is 100% reversible.

Committed to improving patients' lives and healthcare provider outcomes, GT Metabolic Solutions Inc. is disrupting the market by introducing magnetic compression anastomosis technologies to bariatric, metabolic and digestive health providers in the U.S. and abroad.

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You can learn more about GT Metabolic™ Solutions, Inc. <u>here</u>.

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