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Endostart receives FDA 510(k) clearance for Endorail®, ushering in new era of gastrointestinal endoscopy innovation

Next-generation magnetic balloon technology optimizes colonoscopy procedural outcomes

Certaldo, Italy, March 26, 2024 - Endostart, a pioneering medical device company specializing in gastrointestinal endoscopy solutions, today announces a major breakthrough with the FDA 510(k) clearance of its flagship product, Endorail®. This milestone achievement represents a significant step forward in advancing the field of gastrointestinal endoscopy and improving patient care worldwide.

Now commercially available in the US, Endorail enhances the efficiency and safety of endoscopic procedures, offering a revolutionary solution to solve looping and facilitate the completion of prolonged colonoscopies. Designed to streamline the colonoscopy process, Endorail combines its innovative magnetic balloon solution with user-friendly features, empowering physicians to overcome procedural challenges with confidence and precision.

Colonoscopy remains a cornerstone procedure for the diagnosis, surveillance, prevention and treatment of various colon diseases, including colorectal cancer and chronic inflammatory bowel diseases. With Endorail, physicians gain access to a powerful on-demand tool that not only optimizes procedural outcomes but also reduces the healthcare costs associated with prolonged or incomplete procedures.

"We are thrilled to obtain FDA clearance for Endorail, marking a significant milestone in our journey to revolutionize gastrointestinal endoscopy," said Dr. Alessandro Tozzi, co-founder and CEO of Endostart. "This clearance underscores our commitment to innovation and our dedication to improving patient care. We look forward to introducing Endorail to endoscopic centers across the United States, empowering physicians with the tools they need to deliver exceptional care."

In 2023, Endostart conducted a multicenter clinical trial to demonstrate the high safety and efficacy profile of Endorail in the completion of difficult colonoscopies. The results of this study will be presented at the Digestive Disease Week Congress, taking place in Washington DC, (US), May 18 – 21, 2024.

"Through this study, Endostart and our research partners have established that Endorail is safe and can be used effectively on demand in patients with prolonged colonoscopies. Future studies will be carried out to identify additional benefits, including cost advantages and time-saving with our device," added Dr. Tozzi.

Since its founding in 2018, Endostart has been at the forefront of developing cutting-edge medical devices. These are tailored to meet the evolving needs of healthcare professionals and patients in a colonoscopy devices market valued at around $2.1 billion in 2023 and expected to expand at a CAGR of 5% from 2024 to 2032. Leveraging magnetic balloon technology, Endostart intends to position itself as a leader in advancing endoscopic capabilities and setting new standards for procedural excellence.

Supported by a team of seasoned industry experts and guided by an international board of directors, Endostart is poised for continued growth and success in the global medical device market. With FDA clearance secured, the company is strategically positioned to expand its

footprint in the United States and bring its innovative solutions to a broader audience of healthcare providers and patients.

Endostart remains committed to ongoing research and development initiatives aimed at further enhancing the performance and capabilities of its product portfolio. With its focus on innovation, quality and patient outcomes, Endostart is dedicated to driving positive change in gastrointestinal endoscopy and improving healthcare delivery worldwide.

About Endostart
Endostart is a pioneering medical device company specializing in gastrointestinal endoscopy solutions. Founded in 2018, the company has developed a next-generation magnetic balloon technology solution aimed at enhancing endoscope procedures and enabling endoscopists to easily achieve quality standards. Endostart is supported by private investors, led by a highly professional team and an international board of directors.
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