

Minnesota Medical Technologies Announces FDA 510(k) Clearance for its Fecal Incontinence Device

STEWARTVILLE, MN, July 24, 2025 /PRNewswire/ -- [Minnesota Medical Technologies](#), today announced that it received FDA 510(k) clearance for its fecal incontinence device ("**StaySure**TM").

The disposable, easy to use, self-inserted **StaySure**TM fecal incontinence insert is a breakthrough in the management of fecal incontinence and accidental bowel leakage. The innovation lies in its adaptability. Made from 100% silicone and filled with an encased fluid, **StaySure**TM is specially crafted to conform to your body as you move throughout the day. Its soft silicone shaft, flexible structure, and supple external retainer ensure a secure fit without compromising comfort.

David A. Jonas, CEO of Minnesota Medical Technologies, commented: "We are thrilled to have received U.S. regulatory clearance for StaySureTM, and I want to congratulate our product development and regulatory teams for their excellent work in achieving this important milestone for the company.

Fecal Incontinence (FI) and Accidental Bowel Leakage (ABL) are conditions endured by millions of people in the United States alone. StaySureTM is a true breakthrough in the management of FI and ABL—and represents the first truly practical and effective solution for many of those living with these challenging conditions. We are excited to bring this product to the people who need it most."

Our device has been available in Europe since 2021 and is clinically proven to be safe and effective in managing both FI and ABL. A recently completed clinical trial ^[1] clearly demonstrated the safety and efficacy of the device. The device significantly reduced the frequency of FI and improved quality-of-life for those patients with frequent FI. We expect the full results to be published later this year.

Anthony J. Conway, Chairman and Founder of Minnesota Medical Technologies added: "We designed StaySureTM to help people thrive in everyday life. This innovative solution is intended to help manage the symptoms of fecal incontinence and accidental bowel leakage. With StaySureTM, you can move through your day confidently—free from the stress and uncertainty that ABL can bring. While most incontinence products attempt to contain or absorb leakage, StaySureTM is different: it's designed to prevent ABL altogether. That

makes StaySure™ not only an elegant solution but also the most innovative approach to managing FI symptoms on the market today.”

Developed by the experienced team at Minnesota Medical Technologies, in collaboration with some of the world’s leading gastroenterologists, **StaySure™** is a flexible insert that provides a complete seal—preventing ABL from the rectum and eliminating associated odors. The true innovation behind **StaySure™** lies in its flexibility, allowing it to adapt and conform comfortably to the body for secure, effective protection.

About Minnesota Medical Technologies.

Minnesota Medical Technologies, headquartered in Stewartville Minnesota, was founded by four industry veterans with over 100 years of combined experience developing, manufacturing, and marketing innovative silicone incontinence devices. Our team has deep expertise in bringing medical devices from concept to market on a global scale. In Europe, our device is marketed and distributed exclusively by Wellspect Healthcare under their brand name—Navina Insert.

For more information on Minnesota Medical Technologies and its products, visit www.mnmedicaltechnologies.com.

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^[1] A Study to Assess the Effects of the Minnesota Medical Technologies Anal Insert Device in Fecal Incontinence. Conducted at the Mayo Clinic in Rochester, MN.
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