Medtronic News

# Medtronic secures FDA approval for the Altaviva™ device, a simple experience for treating urge urinary incontinence

*The Implantable Tibial Neuromodulation (ITNM) device will expand treatment options for the 16 million people living with urinary urges and involuntary leaks*

GALWAY, Ireland, Sept. 19, 2025 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, announced today that it has received U.S. Food and Drug Administration (FDA) approval for the **Altaviva™ device.** The minimally invasive implantable tibial neuromodulation (ITNM) therapy is inserted near the ankle and designed to treat **urge urinary incontinence**.

Bladder control problems affect an estimated 43 million – or one in six – U.S. adults. Of those, nearly 16 million people have urge urinary incontinence, a common symptom of overactive bladder (OAB) characterized by a sudden, intense urge to urinate, often followed by involuntary leaks before reaching the bathroom. However, only a quarter of people with general bladder control issues have discussed their symptoms with a doctor. These conditions can affect quality of life, mental health, and sleep, while also posing a significant economic burden on both society and patients.

"The Altaviva device represents a significant advancement for patients with urge urinary incontinence who often weigh the invasiveness of a therapy and the potential side effects when considering treatment options," said Dr. Kevin Benson, Urogynecologist at Sanford Health and investigator for the Altaviva device pivotal study (TITAN 2). "I'm excited to offer my patients this simple experience and believe the Altaviva device has the potential to transform lives and bring new hope to more people."

Patients who receive an Altaviva device return home with therapy activated, a first among implantable tibial devices for urge urinary incontinence. The device is inserted near the ankle during a minimally invasive procedure that doesn't require sedation or imaging. Approximately half the length of a stick of chewing gum, the Altaviva device sits slightly below the skin and above the fascia. It sends electrical impulses to the tibial nerve, helping restore communication between the bladder and the brain to regulate bladder control.

"It's an honor to bring the Altaviva device to market," saidEmily Elswick, president of the Pelvic Health business, which is part of the Neuroscience Portfolio at Medtronic. "For too long, society has told people it is normal to eventually lose bladder control. We say, "enough". What is common does not mean it is normal. The Altaviva device is designed to provide a simple and effective experience to treat urge urinary incontinence, empowering patients with a technology that supports them in their daily lives and opens the door to renewed hope and improved quality of life."

The Altaviva device is designed to have a 15-year battery lifespan under expected therapy settings and delivers therapy automatically, requiring no daily intervention or manual adjustments from the patient. Recharging will take up to 30 minutes when using the default recharging speed, eliminating the need for daily at-home charging equipment. Designed for real-life needs, the Altaviva device is MRI-compatible, providing patients with peace of mind for planned or unexpected medical imaging.

"Too many people silently struggle with the challenges of urgency and loss of bladder control, often believing that relying on diapers or pads *is their only option*," said Brett Wall, executive vice president and president of the Medtronic Neuroscience Portfolio. "The Altaviva device represents a transformative milestone and ushers in a new bladder control therapy with advanced features. Medtronic has earned its position as the global leader in neuromodulation by consistently pushing the boundaries of innovation, and this FDA approval underscores our unwavering commitment to delivering therapies that truly change lives."

For over 30 years, Medtronic neuromodulation devices have improved the lives of people with bladder control symptoms. With the introduction of the Altaviva device, Medtronic becomes the only company with a full portfolio of neuromodulation therapies for this condition.

Medtronic will host an investor call featuring Emily Elswick, General Manager of the Pelvic Health business, to discuss the Altaviva™ device and its impact on the treatment landscape for urge urinary incontinence on October 9, 2025 at 10am CST. A live webcast of this call will be available to the public on Medtronic's Investor Relations website.

**About Medtronic**

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE: MDT), visit www.Medtronic.com and follow Medtronic on LinkedIn.

**Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.**

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