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Medtronic Presents New Nocturia Data for the Altaviva™ Device, Announces National Principal Investigator for the ENDURANCE Study

At 47th AUGS Annual Scientific Meeting, Medtronic advances Altaviva™ clinical program with 24-month exploratory findings from TITAN 2 showing sustained reductions in nightly nocturia episodes and announces partnership to advance patient awareness of pelvic floor disorders

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Medtronic the global leader in healthcare technology today announced new updates, including clinical evidence, for the Altaviva™ implantable tibial neuromodulation device at AUGS 2026, reinforcing continued momentum in the first year following FDA approval.

Key takeaways

- New 24-month exploratory analysis from the TITAN 2 pivotal clinical trial showed sustained reductions in nocturia episodes.
- Ariana L. Smith, MD, of Penn Medicine named national principal investigator (NPI) of the ENDURANCE post-approval study.
- Medtronic has joined the American Urogynecologic Society (AUGS) as a presenting partner for efforts to raise awareness of pelvic floor disorders.

The Medtronic Altaviva™ device was approved in September 2025 by the FDA for the treatment of urge urinary incontinence (UUI). The latest updates reflect continued focus by Medtronic on expanding clinical evidence, advancing patient education, and improving awareness of treatment options for patients with UUI.

24-Month TITAN 2 Analysis Shows Durable Nocturia Reduction

Nocturia, or waking during the night to urinate, is a common symptom among patients with overactive bladder, including those with UUI, and can adversely affect sleep and quality of life (QoL).¹⁻³

A new exploratory analysis from the TITAN 2 pivotal clinical trial showed sustained reductions in nocturia through 24 months among participants with baseline nocturia, and may inform future prospective investigation. Findings were shared as an oral presentation at the 47th AUGS Annual Scientific Meeting.

Participants treated with the Altaviva™ device experienced statistically significant reductions in nocturia episodes at every follow-up through 24 months. Sleep-related quality of life also improved, with two-thirds of participants in both groups achieving clinically meaningful improvement in sleep domains⁵. The analysis included participants with at least one nocturia episode during the 3-day baseline diary and a subset with at least two nocturia episodes on at least one day during the baseline diary.

“For people who regularly wake up during the night to urinate, those disruptions can have a meaningful impact on sleep and day-to-day life, and put them at greater risk for falls,” said Jerome Yaklic, MD, MBA, professor and chair of the Department of Obstetrics and Gynecology at UTMB and lead investigator of the nocturia analysis. “These findings reinforce the need for effective treatment options that can help patients manage their urge urinary incontinence symptoms while supporting meaningful improvements in everyday life, including better sleep.”

Ariana L. Smith, MD, Named National Principal Investigator of ENDURANCE Study

Medtronic also announced Ariana L. Smith, MD, director of Pelvic Medicine and Reconstructive Surgery at Penn Medicine, as national principal investigator of the ENDURANCE post-approval study evaluating the Altaviva™ device for the treatment of UUI.

ENDURANCE is a prospective, multicenter study designed to evaluate real-world outcomes of the Altaviva™ device in a broad patient population. The study will follow 170 implanted patients at up to 30 U.S. centers over five years.

“I look forward to leading this next phase of research for the Altaviva™ device,” said Smith. “Generating long-term evidence in real-world clinical practice will be important to deepen our understanding and help clinicians make informed treatment decisions for people living with urge urinary incontinence.”

Medtronic and the American Urogynecologic Society Announce Patient Awareness Partnership

Medtronic has joined the American Urogynecologic Society (AUGS) in a collaboration to highlight a shared commitment to patient education and expanding access to care for women living with pelvic floor disorders. Through the partnership, Medtronic and AUGS aim to help more women recognize symptoms, understand treatment options are available, and have informed conversations with their healthcare providers, particularly pelvic floor specialists, as many patients live with symptoms for years before seeking treatment.

“Rather than accepting symptoms as an inevitable part of aging, we want more people to recognize that while these conditions are common, they are not normal,” said Emily Elswick, president of Pelvic Health at Medtronic. “Through partnerships like this one with AUGS, alongside continued clinical research, patient education and innovation, we can help more people recognize that there are therapy options and feel empowered to seek the care that’s right for them.”

About the Altaviva™ device for urge urinary incontinence

The Altaviva™ device was approved by the U.S. Food and Drug Administration (FDA) in September 2025, for the treatment of urge urinary incontinence (UUI) – a condition that impacts 16 million adults in the U.S.⁶ The Altaviva™ device is indicated for treatment of UUI in patients who failed or could not tolerate more conservative treatments. The device is approximately half the length of a stick of chewing gum and is placed under the skin near the ankle in a minimally invasive procedure.⁷ under the skin near the ankle. The device delivers stimulation to the tibial nerve to help restore communication between the bladder and brain to improve bladder leakage symptoms.⁸⁻⁹ The Altaviva™ device does not require imaging for implantation, requires only local anesthesia and can be activated the same day as the procedure. The device is designed to provide a long-lasting treatment experience, including automatic therapy delivery and an expected 15 years of therapy under expected therapy settings. The Altaviva™ device is also MRI-compatible¹⁰, offering patients peace of mind for future medical imaging needs.

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, visit www.Medtronic.com and follow 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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