Medtronic

Altaviva™ implant media talking points

This is being provided as a quick reference to ensure consistent, accurate, and compliant messaging when discussing Altaviva™ therapy with media, helping you confidently address key points and questions. If you use the talking points to discuss product benefits, it is required that any associated risk information is also presented to ensure balanced and accurate communication in accordance with regulatory guidelines.

Risk information: In addition to risks related to surgery, complications can include pain at the implant site, lower leg pain, infection, and/or technical or device problems. Results vary. Talk to your doctor to see if the Altaviva™ system is right for you.

- Nearly 16 million adults in the United States experience urge urinary incontinence (UUI).[1,2]
- Living with UUI can be challenging and it's important to know you're not alone.[1]
- One study reported that on average, people with bladder control symptoms wait for 3.5 years before initiating treatment.[3]
- For those who move forward with treatment, many become unsatisfied with the options they are given due to intolerable side effects,[4] or lack of efficacy[5] which may have a significant impact on the patient's quality of life.[6]
- Many patients report feeling frustrated[7] and may be living restricted lives, a recent study found that 71% of patients with bladder control symptoms said they stayed close to a bathroom.[7] For these patients Medtronic offers another option which may:
  - Reignite hope
  - Inspire them with a new, simple treatment they didn't know existed
  - Drive confidence that the Altaviva™ implant is a possibility that they may consider exploring
- Developed by Medtronic, the trusted leader in neuromodulation for bladder control, the Altaviva™ tibial implant not only addresses UUI,[8] it may also improve a patient's quality of life.[8]
- Reaching out to a healthcare professional can be a positive step towards finding the relief patients deserve.
- With the introduction of the Altaviva™ implant for UUI, an additional (treatment) option is available that can help patients improve their quality of life.[8]
- Altaviva™ therapy works by placing a small device under the skin near the ankle. This device sends pulses that stimulate the nerves that control the bladder.[9,10] These pulses help to restore the communication pathway between the brain and bladder,[9,10] which may reduce urgency with leaks.[8] This treatment is called tibial neuromodulation, a proven therapy for reducing bladder control symptoms.[8, 11-15]
- It's a single procedure, which may free up time for what matters most to patients.
- The Altaviva™ device can be placed in a single procedure that does not require sedation or radiology.[16]
- The experience is simple with no sedation required,[16] same-day therapy activation,[17] and MRI compatibility from the outset.[18]

- The Altaviva™ therapy offers convenience with a single implant procedure that lets you walk out the same day with your therapy activated.
- Patients can expect 15 years of battery life from the device with expected therapy settings.[17*]

*Based on clinical and bench testing for expected therapy settings

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2. US Census Bureau 2020. US adult and under-age-18 populations: 2020 census. https://www.census.gov/library/visualizations/interactive/adult-and-under-the-age-of-18-populations-2020-census.html. Accessed January 31, 2025.
3. Filipetto FA, et al. The patient perspective on overactive bladder: a mixed-methods needs assessment. BMC Family Prac. 2014;15:96.
4. MacDiarmid SA. Concomitant medications and possible side effects of antimuscarinic agents. Rev Urol. 2008;10(2):92-98.
5. Benner JS, Nichol MB, Rovner ES, et al. Patient-reported reasons for discontinuing overactive bladder medication. BJU Int. 2010;105(9):1276-1282.
6. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU guideline on the diagnosis and treatment of idiopathic overactive bladder (2024). J Urol. 2024;212:11-20.
7. National Association for Continence, Leede Research. Views on overactive bladder: a study for NAFC. Final report: December 16, 2015.
8. Medtronic Altaviva Clinical Summary 2025.
9. Li X, Li X, Liao L. Mechanism of action of tibial nerve stimulation in the treatment of lower urinary tract dysfunction. Neuromod. 2023;27:256-266.
10. Bhide AA, Tailor V, Fernando R, Vik K, Digesu GA. Posterior tibial nerve stimulation for overactive bladder - techniques and efficacy. Int Urogynecol J. 2020;31:865–70.
11. Peters KM, Carrico DJ, et al. Randomized trial of percutaneous tibial nerve stimulation versus sham efficacy in the treatment of overactive bladder syndrome: results from the SUmiT trial. J Urol. 2010;183:1438-1443.
12. Peters KM, MacDiarmid SA, Wooldridge LS, et al. Randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the overactive bladder innovative therapy trial. J Urol. 2009;182(3):1055-1061.
13. Kobashi K, Nitti V, Margolis E, et al. A prospective study to evaluate efficacy using the NURO percutaneous tibial neuromodulation system in drug-naïve patients with overactive bladder syndrome. J Urol. 2019;131:77-82.
14. Rogers A, Bragg S, Ferrante K, et al. Pivotal study of leadless tibial nerve stimulation with eCoin for urgency urinary incontinence: an open-label, single arm trial. J Urol. 2021;206:399-408.
15. Heesakkers JPFA, Toozs-Hobson P, Sutherland SE, et al. A prospective study to assess the effectiveness and safety of the BlueWind system in the treatment of patients diagnosed with urgency urinary incontinence. Neurourol Urodyn. 2024;43:1491-1503.
16. M028930C001RevB - Altaviva™ Model P7850N Neurostimulator Implant Manual
17. M028929C001RevB - Clinician Therapy and Programming Guide Altaviva™ Model P7850N
18. M028949C001 MRI Guidelines for Altaviva™ Neurostimulator

Tibial Neuromodulation delivered by the Altaviva™ system is indicated for treatment of urge urinary incontinence (UUI) in patients who failed or could not tolerate more conservative treatments.

Contraindications: Poor surgical candidates including patients with skin lesions or compromised skin integrity; current or recent history of venous insufficiency and/or venous stasis ulcers in the lower leg; anatomical defects or previous surgeries at the implant site which preclude use of the device. Patients who are not able to operate or receive assistance in operating the system.

Warnings: This therapy is not intended for patients who are considered poor candidates for surgery or are at risk for poor wound healing including, but not limited to, severe uncontrolled diabetes, clinically significant edema in the lower leg, clinically significant peripheral neuropathy, nerve damage, or a neurological condition affecting the lower leg. Do not implant the neurostimulator within 5 cm of another metal implant. This therapy is also not intended for patients with current or unresolved mechanical obstruction such as caused by benign prostatic hypertrophy, cancer, or urethral strictures, or patients with known allergies to any of the materials in the Altaviva™ neurostimulator. Continuous stimulation should not be used as safety and effectiveness have not been established. Safety and effectiveness have also not been established for pregnant women; patients under the age of 18; patients with progressive, systemic neurologic disease; patients with history of urinary retention; bilateral leg stimulation. Diathermy (shortwave and microwave) should not be used on patients with a neurostimulator, as it can cause tissue damage or device damage. The Altaviva™ system may affect the operation of other implanted or

external systems. The Altaviva™ system may interfere with the operation of other implanted cardiac devices such as pacemakers and defibrillators. Recharging the neurostimulator within 5 cm of a metal implant may cause recharge heating leading to tissue damage. Do not use the recharger or ankle band in direct contact with an unhealed wound.

MRI Warnings: Prior to an MRI scan, determine if the patient has multiple active or abandoned medical device implants. The most restrictive MRI exposure requirement must be used. MRI scans with another metal implant less than 3 cm away from the Altaviva™ neurostimulator have not been tested, and scanning may cause excessive tissue heating surrounding the device resulting in tissue damage and possible need for surgical intervention.

Adverse Events: In addition to the risks normally associated with surgery, adverse events may include pain at the implant site, infection, reaction to local anesthesia, wound complications, lower leg pain, nerve injury, movement of the implant, adverse change in bowel or urinary function, uncomfortable or unintended stimulation sensations or an inappropriate shock sensation, loss of therapeutic effect, discomfort during recharge, or technical or device problems.

For full prescribing information, refer to the product manuals at www.medtronic.com. Product manuals must be reviewed prior to use for detailed disclosure.

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