Altaviva™
implant for bladder control
by Medtronic

Welcome to the Altaviva™ implant

Improved bladder control from urge urinary incontinence (UUI) symptoms may be within reach.

What you'll find inside

Living with urge urinary incontinence (UUI)

Understanding UUI

Urge urinary incontinence (UUI) is a condition where individuals experience a sudden and uncontrollable urge to urinate, often leading to unintended leakage of urine.[1] This occurs when the bladder muscles contract unexpectedly, signaling the need to empty the bladder even when it may not be full. For those living with UUI, this condition can be disruptive and unpredictable, impacting their quality of life.[2]

How UUI affects patients

The effects of UUI go beyond physical inconvenience—it can negatively impact your social interactions, mental health, and sleep.[2] Despite the prevalence of the condition,[2,3] many patients don't talk to their doctor about symptoms.[4] Additionally, adherence to bladder control medications is often low,[5] and advanced therapies remain underutilized - it's estimated that less than 4% of patients with UUI receive advanced treatments.[6,7]

Nearly

16 million

adults in the United States experience UUI symptoms.[2,3]

One study reported above

66%

of people have never discussed their condition with a doctor.[4]

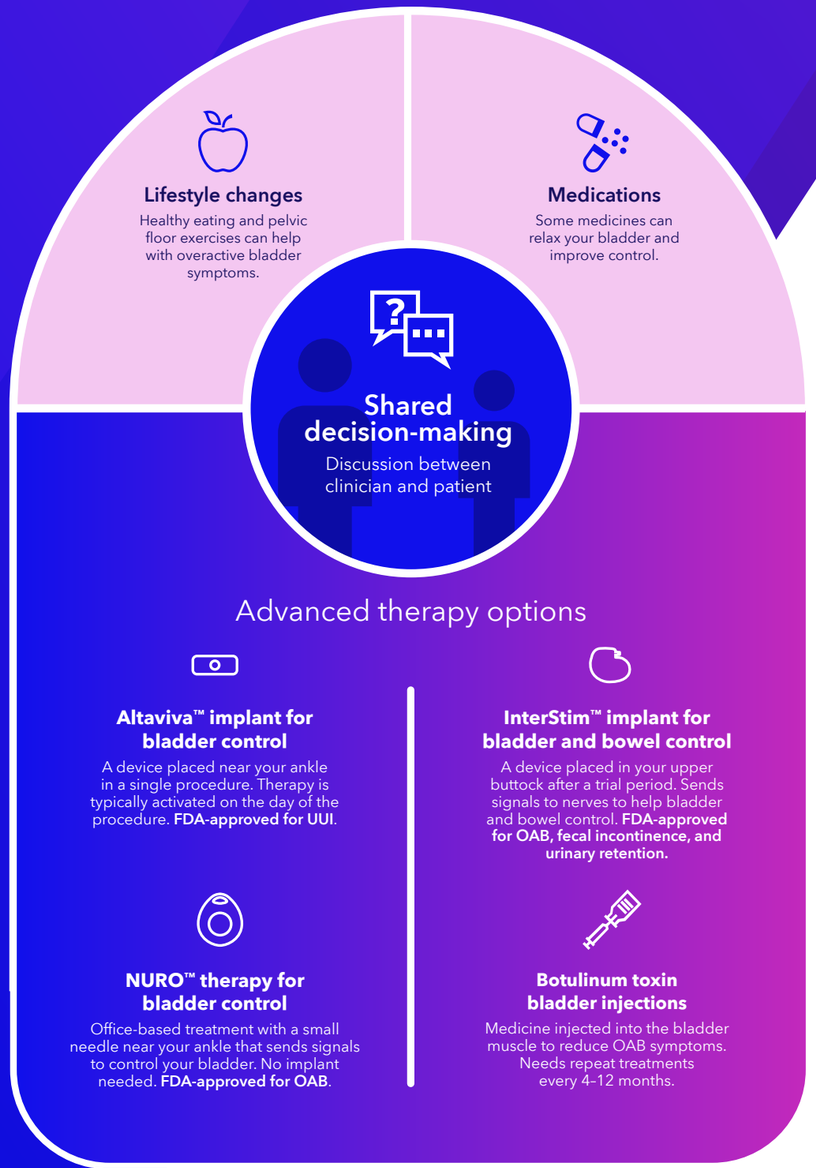
A new option: The Altaviva™ implant for UUI

When other treatments fall short, the Altaviva™ implant may offer hope for those living with UUI. This advanced therapy is designed to help relieve UUI symptoms,[8] giving patients time to focus on the things that matter most. By addressing UUI with the Altaviva™ system, patients may find improved quality of life.[8]

The Altaviva™ implant provides an opportunity for individuals to move beyond the limitations of UUI, offering relief[8] and a chance to live life on their own terms.

Your path to relief

Everyone's experience with UUI is different, but most people follow a similar journey toward relief. Here's how the Altaviva™ implant fits in:



For stimulation devices, common risks may include surgical infection, pain, and undesirable changes in urinary or bowel function and uncomfortable stimulation (sometimes described as a jolting or shocking feeling). These treatments must be prescribed by a doctor who should review all potential risks and benefits with you. Please see Important Safety information.

Why choose Medtronic?

Medtronic is a trusted leader in neuromodulation for bladder control.

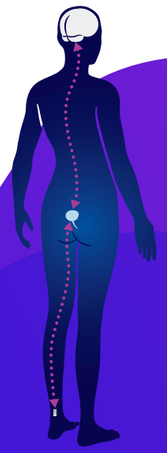
25+
years of experience

450,000+
people treated for bladder and bowel control symptoms worldwide

When you choose the Altaviva™ implant, you receive more than just an advanced device—you get support at every step:

- A dedicated patient support team to answer your questions
- Ongoing educational and technical support whenever you need it

With Medtronic, you're choosing a partner committed to improving your quality of life and supporting your journey toward better bladder control.



How the Altaviva™ implant works

The Altaviva™ implant is a small device placed just under the skin near your ankle. The procedure is minimally invasive[9] and doesn't require general anesthesia or sedation.[10]

Once in place, the implant sends pulses to the tibial nerve. This may help restore the communication pathway between your bladder and brain,[11,12] reducing urgency with leaks and giving you more control.[8] This therapy is called tibial neuromodulation, and it's a proven therapy for achieving bladder control.[8,13-17]

Altaviva™ therapy offers convenience with a single implant procedure[10] that lets you walk out the same day with your therapy activated.[18] This allows you more time for the things in life that matter to you most.†

Altaviva™ therapy benefits:

- FDA-approved therapy for UUI
- Minimally invasive procedure[9]
- No general anesthesia or sedation required[10]
- Same-day therapy activation[18]
- Long-lasting battery expected to deliver 15 years of therapy[18]
- MRI-ready from the start‡,[18]

In addition to risks related to surgery, complications can include pain at the implant site, lower leg pain, infection, wound complications, nerve injury, movement of the implant, undesirable change in bowel or bladder function, uncomfortable or unintended stimulation sensations, loss of therapeutic effect, discomfort when recharging, or technical or device problems. Please see Important Safety Information for more details. Talk with your doctor about ways to minimize these risks.

†See labeling for activity restrictions.
‡MRI compatibility is subject to certain conditions. See approved labeling for details.

Therapy outcomes

Altaviva™ therapy may help improve your quality of life by reducing urgency with leaks.[8] In the pivotal clinical trial, after 12 months of therapy:

80%

of patients **reported their condition had improved**† compared to before their implant.[8]

70%

of patients experienced a **clinically meaningful‡ improvement in health-related quality of life.**[8]

61%

of patients had **a 50% or greater reduction in UUI episodes** after 12 months of therapy.[8]

Adverse events related to the device, procedure, and/or therapy occurred in 20% of implanted subjects through 12-month follow-up. The most common types of related AEs were implant-related infections at the implant site (7%) and implant site pain (3%).

†As assessed by the Patient Global Impression of Improvement (PGI-I).
‡Minimally Important Difference (MID) = 10 points.

Imagine the places you'll go when you don't have to "GO"

As you take the next step, know that you're choosing a therapy that may improve your quality of life.[8]

Perspectives from real users

"It's a boost of confidence... I'm not worried about embarrassing myself somewhere, or always having to carry pads with me."

Frances, living with UUI

"I used to feel trapped. I couldn't go anywhere without worrying about accidents. Now I can go to the grocery store, travel, and enjoy life again."

Adeana, living with UUI

Individual results may vary. Talk to your doctor to see if this therapy is right for you.

Note: These patients participated in the TITAN 2 clinical trial that studies the investigational tibial neuromodulation device and its use. For more information, visit clinicaltrials.gov: NCT0522686

Ambassador program

Want to hear from someone who's using the Altaviva™ implant? The Medtronic Ambassador Program connects you with real patients who have received bladder control therapy and are willing to share their experience.

You can learn what the procedure felt like, how therapy changed their routines, and ask the questions that matter to you most.

Ambassadors do not provide medical advice or technical support, but can help you understand what life with the Altaviva™ implant is really like.

How to request a call:

1. Scan the QR code or call 800-503-4110.
2. Answer a few questions about your symptoms.
3. An ambassador will contact you at a scheduled time. Calls usually last about 20 minutes.

Frequently asked questions

What is the Altaviva™ implant for bladder control?

The Altaviva™ implant for UUI involves placing a small device under the skin near your ankle, which sends electrical pulses to the tibial nerve that helps maintain normal bladder function.[11,12] These pulses help restore the communication pathway between your brain and bladder, which may help urgency with leaks.[11,12] This treatment is called tibial neuromodulation and is a proven therapy for reducing bladder control symptoms.[8,13-17]

Why does the Altaviva™ implant target the tibial nerve?

Bladder control issues may stem from miscommunication between the brain and the nerves controlling bladder function.[11,12] By targeting the tibial nerve, the therapy may help restore normal bladder function.[8]

Does the Altaviva™ device need to be recharged?

The device needs to be charged 1–2 times per year under standard therapy settings and charging takes about 30 minutes with proper placement and default recharge speed.

What are the risks of the Altaviva™ implant for UUI?

In addition to risks related to surgery, complications can include pain at the implant site, lower leg pain, infection, technical or device problems, movement of the implant, undesirable change in bowel or bladder function, or uncomfortable or unintended stimulation sensations. Please see Important Safety Information for more details. Talk with your doctor about ways to minimize these risks.

Will this therapy cure my condition?

UUI is a chronic condition. Altaviva™ therapy can help manage the symptoms but does not cure the condition.

How long does the device last?

The implant has a long-lasting battery expected to deliver 15 years of therapy.[18]

Is the procedure invasive?

The procedure is minimally invasive,[9] requiring a 2 cm incision.[10]

Will I be able to get an MRI with the implantable device?

You can have a full body MRI scan if certain conditions are met. Your clinician can provide more details about these conditions, as well as safety information.

Will insurance cover costs related to the Altaviva™ implant?

Talk to your doctor and your insurance provider to learn more about your coverage.

I have more questions. How can I contact Medtronic?

- Prospective patients can reach an authorized specialist at 800-664-5111.
- Existing patients can reach a service specialist at 800-510-6735.

Track your symptoms

MyFuture™ App
Digital Diary

Patient Name: _____

UUI Events

Date	Time	Did it wake you up?	How urgent did it feel? (0–4)*	Did you experience a leak? (Yes = 1–3* or No)	Did you need to change your protective pad or underwear?
6/1	3:23 AM (PM)	No	2	Yes - 2	Yes
	AM PM				
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*Urgency: 0 = not urgent, 1 = somewhat urgent, 2 = urgent, 3 = very urgent, 4 = extremely urgent or an accident without warning
*Leak amount: 1 = slight, 2 = moderate, 3 = heavy

Patient Name: _____

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Important Safety Information

Medtronic Altaviva™ tibial neuromodulation system treats urge urinary incontinence (leakage). It should be used after you have tried other treatments such as medications and behavioral therapy, and they have not worked or you could not tolerate them.

This therapy is not for everyone. The Altaviva™ system is contraindicated (not allowed) for patients who are poor surgical candidates including patients with open wounds, sores, or damaged skin near the treatment area; current or recent history of poor blood circulation in the legs or open sores on the legs from circulation problems; physical changes or previous surgeries where the Altaviva™ device is placed. You must be able to operate or receive assistance in operating the system to be a candidate. This therapy is not intended for patients who: are not good candidates for surgery or have conditions that make it hard to heal from wounds (such as uncontrolled diabetes, swelling in the lower leg, or nerve problems in the leg); have metal implanted within 5 cm of where the Altaviva™ device would be placed; have a current or unresolved blockage in the urinary tract caused by things like an enlarged prostate, cancer, or urethral narrowing; are allergic to any materials in the Altaviva™ device. The Altaviva™ system may affect or be affected by other implanted medical devices, including pacemakers and defibrillators. Talk to your doctor if you have a pacemaker or other implanted devices. You cannot have diathermy (deep heat treatment using shortwave or microwave electromagnetic energy) if you have an Altaviva™ device. Do not place the charger or ankle band on broken or unhealed skin. Safety and effectiveness have not been established for pregnancy; patients under the age of 18; patients with progressive, systemic neurologic disease; patients with history of urinary retention, or bilateral stimulation. In addition to risks related to surgery, complications can include pain at the implant site or lower leg pain, infection, wound complications, nerve injury, movement of the implant, undesirable change in bowel or bladder function, uncomfortable or unintended stimulation sensations, unexpected shocking sensation, loss of therapeutic effect, discomfort when recharging, or technical or device problems. This therapy is not for everyone. This treatment is prescribed by your doctor. Please talk to your doctor to decide whether this therapy is right for you. Your doctor should discuss all potential benefits and risks with you. Although many patients may benefit from the use of this treatment, results may vary.

For complete safety information about this treatment, please visit the Medtronic website at www.medtronic.com. USA Rx Only. Rev 0925

Medtronic Bladder Control Therapy delivered by the InterStim™ system treats urinary retention (inability to completely empty the bladder) and the symptoms of overactive bladder, including urinary urge incontinence (leakage) and significant symptoms of urgency-frequency. It should be used after you have tried other treatments such as medications and behavioral therapy and they have not worked, or you could not tolerate them. You must demonstrate an appropriate response to the evaluation to be a candidate. You cannot have diathermy (deep heat treatment from electromagnetic energy) if you have an InterStim™ device. This therapy is not intended for patients with a urinary blockage. Safety and effectiveness have not been established for pregnancy and delivery; patients under the age of 16; or for patients with neurological disease origins.

In addition to risks related to surgery, complications can include pain at the implant sites, new pain, infection, lead (thin wire) movement/migration, device problems, interactions with certain other devices or diagnostic equipment such as MRI, undesirable changes in urinary or bowel function, and uncomfortable stimulation (sometimes described as a jolting or shocking feeling).

Medtronic Bladder Control Therapy delivered by the NURO™ system treats overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence. This therapy is not intended for patients with pacemakers or implantable defibrillators, patients prone to excessive bleeding, patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function, or on patients who are pregnant or planning pregnancy. Do not use if the skin in the area of use is compromised.

Exercise caution for patients with heart problems. Adverse events are typically temporary, and include mild pain, minor inflammation and bleeding near treatment site.

These therapies are not for everyone. These treatments are prescribed by your doctor. Please talk to your doctor to decide whether these therapies are right for you. Your doctor should discuss all potential benefits and risks with you. Although many patients may benefit from the use of these treatments, results may vary. For further information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com. USA Rx Only. Rev 0517

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