# Post Approval Effectiveness and Durability Evaluation of the Altaviva™ Tibial Device

NCT07456865

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| **Status** | RECRUITING |
| **Phase** | Not Applicable |
| **Sponsor** | MedtronicNeuro |
| **Enrollment** | 256 participants |

## Key Eligibility Criteria

### Inclusion (5)

- Candidate for Altaviva™ therapy per Altaviva™ labeling
- Have a diagnosis of UUI as demonstrated on a 3-day voiding diary by having a minimum of 3 episodes of urinary urge incontinence in 72 hours
- If taking OAB medications, subjects should be on a stable dose for at least 3 months prior to baseline and willing to remain on stable treatment through completion of the 12-month voiding diary
- Patient must be willing and able to accurately complete study questionnaires, attend visits, operate the system, and comply with the study protocol
- Willing and able to provide signed and dated informed consent

### Exclusion (12)

- Patient who is not a candidate for Altaviva™ therapy per Altaviva™ labeling, including:
- Patients who are considered to be poor surgical candidates or who are at risk for poor wound healing per Altaviva™ labeling
- Have progressive, systemic neurological disease
- Have clinically significant peripheral neuropathy in the lower leg
- Severe, uncontrolled diabetes

... and 7 more (see full listing online)

## Locations (1 total)

Institute for Female Pelvic Medicine and Reconstructive Surgery, Allentown, Pennsylvania, United States



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