Urgency incontinence: The implant option for non-refractory patients

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Urgency urinary incontinence (UUI) significantly impacts quality of life, often requiring patients to navigate a complex treatment market. While various therapies exist, many patients struggle with adherence or find current options insufficient. The field has sought less burdensome, more effective long-term solutions.
The FDA recently cleared the Revi Extend implant, a novel implantable tibial neuromodulation system, for UUI. This device, manufactured by BlueWind Medical, stands out as the first FDA-cleared implantable neuromodulation device available for patients traditionally considered nonrefractory to other treatments, according to three-year follow-up data from the OASIS Study, which was instrumental in securing regulatory approval, published in J Urol.1

KEY TAKEAWAYS

- The Pivot: Revi Extend is the first implantable neuromodulation device cleared for UUI in patients not traditionally considered refractory to other therapies.
- The Data: The OASIS Study demonstrated sustained efficacy over three years, with the system providing individually tailored stimulation.
- The Action: Clinicians now have an implantable neuromodulation option for a broader UUI patient population, potentially offering a long-term alternative to less invasive or less durable treatments.

Urgency urinary incontinence, characterized by involuntary leakage of urine accompanied by or immediately preceded by urgency, affects millions globally. Current management strategies range from lifestyle modifications and pharmacotherapy to more invasive procedures like sacral neuromodulation. But many patients find these options either ineffective, associated with intolerable side effects, or too cumbersome for long-term adherence. The need for durable, patient-friendly solutions remains substantial.
The Revi System addresses this gap with an implantable tibial neuromodulation device. This system consists of a small implant placed near the tibial nerve and an external, battery-operated wearable that delivers individually tailored stimulation. The OASIS Study, which was instrumental in securing FDA clearance, followed patients for three years. Amundsen, Sutherland, and Heesakkers led the investigation into the long-term efficacy and safety of this novel approach.1

The OASIS Study Design and Patient Cohort

The OASIS Study was a prospective, multicenter clinical trial designed to evaluate the safety and efficacy of the Revi System for UUI. The trial enrolled patients with urgency urinary incontinence, a population that, importantly, included

individuals not necessarily refractory to prior conservative treatments. This broad inclusion criterion distinguishes Revi from other implantable neuromodulation devices, which typically target patients who have failed multiple lines of therapy. The study's primary objective was to assess the reduction in UUI episodes and improvements in quality of life over an extended period.1

Patients underwent implantation of the Revi device and were then instructed on the use of the external wearable. The wearable facilitates personalized stimulation, allowing for adjustments based on individual patient response and symptom severity. This tailored approach aims to optimize therapeutic benefit while minimizing potential discomfort. The study collected data on UUI episodes, voiding diary parameters, and patient-reported outcomes at regular intervals over the three-year follow-up period.1

Sustained Efficacy Over Three Years

The three-year follow-up results from the OASIS Study demonstrated sustained efficacy of the Revi System. Patients experienced a significant reduction in UUI episodes, a key primary endpoint. The individually tailored stimulation proved effective in managing symptoms over the long term, which is a critical consideration for chronic conditions like UUI. The study authors highlighted the consistent performance of the device, indicating its potential as a durable treatment option.1

Beyond objective measures, patient-reported outcomes also showed improvements. Participants reported enhanced quality of life, reflecting the impact of reduced UUI episodes on daily activities and overall well-being. This dual benefit, encompassing both measurable symptom reduction and subjective patient improvement, reinforces the clinical utility of the Revi System. The ability to customize stimulation settings likely contributed to these positive outcomes, allowing for adaptation to individual patient needs over time.1

Safety Profile and Unique Positioning

The Revi System maintained a favorable safety profile throughout the three-year follow-up. The study reported no unexpected safety concerns or device-related serious adverse events that would preclude its use. This long-term safety data is important for an implantable device, as clinicians and patients require assurance regarding its enduring tolerability. The external wearable component also proved user-friendly, with high patient adherence to the stimulation regimen.1

The unique aspect of Revi is its clearance for use in traditionally nonrefractory patients. This broadens the treatment options significantly. Previously, implantable neuromodulation was reserved for those who had exhausted other options. Now, clinicians can consider an implantable solution earlier in the treatment pathway, potentially offering a more definitive and less burdensome alternative to repeated conservative therapies or medications with systemic side effects. This positioning could reshape treatment algorithms for UUI.1

The Catch: Long-Term Comparative Data

While the OASIS Study provides robust three-year data, the open-label design is an obvious caveat. The absence of a sham control group beyond initial phases means the observed benefits, while compelling, lack direct comparison to a placebo effect over the entire follow-up period. This is a common limitation in device trials, but it still warrants consideration when evaluating the magnitude of the treatment effect. Future studies might explore comparative effectiveness against established UUI therapies in this expanded patient population.1

The trial also did not explicitly detail the specific criteria for 'nonrefractory' patients, leaving some ambiguity regarding

the precise patient profile for whom this device is now indicated. Clinicians will need to interpret this in the context of their local guidelines and patient presentations. Still, the availability of an implantable option for a broader group of patients represents a significant step forward. For a comprehensive overview of general medical conditions, many clinicians find the Oxford Handbook of Clinical Medicine (11th ed) a valuable resource.

The next step for Revi will involve real-world implementation and further data collection on patient selection and long-term outcomes in diverse clinical settings. Understanding how this device integrates into existing UUI management pathways, particularly for patients who might otherwise be managed with less invasive but potentially less durable treatments, will be key.

CLINICAL IMPLICATIONS

The FDA clearance of the Revi Extend implant for urgency urinary incontinence marks a notable shift in the treatment paradigm. For the first time, an implantable neuromodulation device is available for patients who are not necessarily refractory to other therapies. This expands the utility of neuromodulation beyond a last-resort option, offering a potentially more definitive solution earlier in the disease course.

Clinicians now have a new tool for patients struggling with UUI, particularly those who find daily medications burdensome or ineffective, but who may not yet qualify for sacral neuromodulation. The individualized stimulation facilitated by the external wearable could lead to better patient satisfaction and adherence compared to therapies requiring constant vigilance or frequent clinic visits. This could reduce the overall burden of UUI management for both patients and healthcare systems.

But the long-term cost-effectiveness and integration into existing care pathways will need careful evaluation. While the OASIS Study demonstrated sustained efficacy and safety over three years, comparative data against established first- and second-line therapies in this nonrefractory population remains limited. This gap is important for guiding optimal patient selection and resource allocation.

BlueWind Medical will need to clearly articulate the ideal patient profile for Revi Extend to ensure appropriate uptake and maximize clinical benefit. The device's success will hinge on its ability to offer a superior balance of efficacy, safety, and patient convenience compared to less invasive options, particularly for those who have not yet failed multiple treatments.

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REFERENCES

1. 1. Amundsen CL, Sutherland SE, Heesakkers JPFA. Three-Year Efficacy and Safety of Revi Implantable Tibial Neuromodulation from the Pivotal OASIS Study. J Urol 2026;41973947.

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