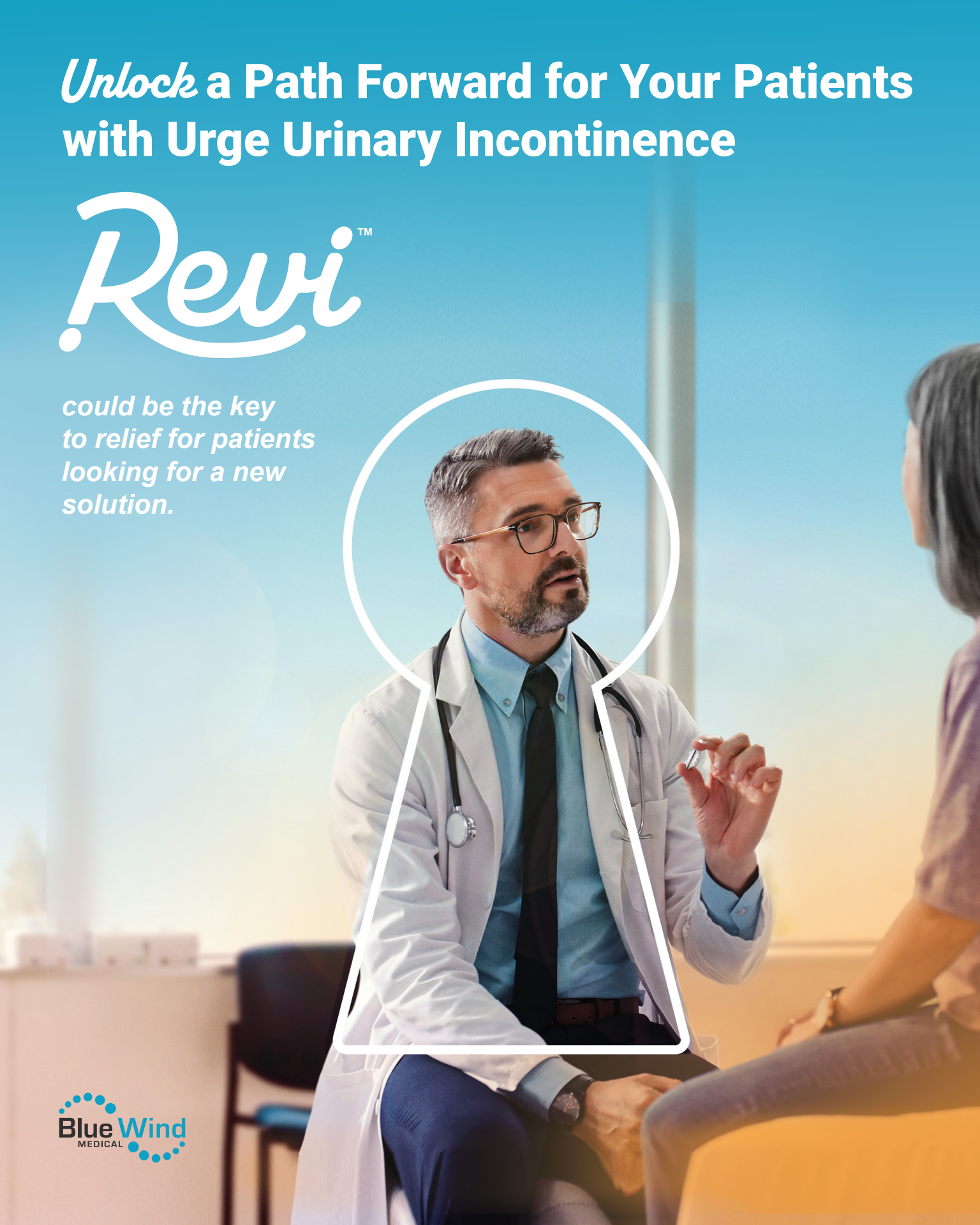
Unlock a Path Forward for Your Patients with Urge Urinary Incontinence

Revi™

could be the key to relief for patients looking for a new solution.



Blue Wind MEDICAL

Demonstrated Efficacy & Safety

The OASIS Pivotal Trial

A prospective, single-arm, open-label study with 151 patients at 23 medical centers globally was conducted to evaluate the safety and efficacy of the Revi™ System for treating patients with Urge Urinary Incontinence (UUI).

Safety

During the pivotal OASIS trial ITT analysis, Revi demonstrated a favorable safety profile at 12 months.[1]

0%
device- or procedure-related serious adverse events

0%
adverse events related to surgical revision or reintervention*

ALL
device- and procedure-related AEs were either mild or moderate

Outcomes at 12 Months

in the Completers Analysis† (N=139) Include[1]:

- **82%** of patients had **≥50% reduction** in UUI episodes
- **67%** of patients had **≥ 75% reduction** in UUI episodes
- **50%** of patients **were dry** on 3 consecutive days

Outcomes at 12 Months

in the Intent-To-Treat (ITT) Analysis Include[1]:

- **80%** **improvement** in urgency episodes and voids
- **88%** **reduction** in UUI or large volume UUI
- **85%** **≥10 point improvement** in Health-Related Quality of Life

Reference:
1. Heesakkers, J., et al. Pivotal Study of a Novel Wirelessly Powered, Patient Tailored Programmed, Tibial Neurostimulator for the Treatment of Patients with Overactive Bladder. Journal of Urology. 2023; 209(4S):e1178.

*Due to battery depletion, implant migration, or lead fracture.
†Completers analysis represents the patients with available data at 12 months. Satisfaction results are from 130 patients.

The Power of Proof[1]

In the OASIS Study Completers analysis† (N=139) at 12 months:

95%
patient satisfaction at 12 months

92%
compliance with daily therapy

How it Works

Proven Process. Single Procedure.

Revi is a patient-centric therapy with a unique implant placement and system design. It provides an alternative treatment solution that may be better suited to some of your UUI patients.

Minimally Invasive: The battery-free miniature device is implanted in the ankle region near the posterior tibial nerve in a single predictable procedure under local anesthesia.

Predictable Placement: Subfascial placement allows for direct visualization of the posterior tibial nerve. Intraoperative testing and suture fixation allow for predictable control.

Customized Therapy: Optimized treatment based on patient response. Clinician Programmer, Hub, and myRevi App allow provider visibility into device usage and status to better support and optimize patient therapy.

Convenient Therapy.

Revi is designed to be easy to use at home so it can fit into patients' lives and help them stay compliant with therapy.

Lightweight Wearable: 7.8 oz wireless Wearable is worn around the ankle to activate the implant, only during therapy.

Convenient Sessions: At the patient's convenience for about 30-60 minutes daily, based on symptoms.

Customized Programming: With preset treatment programs set for use at home.

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1. Heesakkers, J., et al. Pivotal Study of a Novel Wirelessly Powered, Patient Tailored Programmed, Tibial Neurostimulator for the Treatment of Patients with Overactive Bladder. Journal of Urology. 2023; 209(4S):e1178.

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Designed With Both Patients and the Physicians Who Treat Them in Mind

Integrated components make the procedure, treatment, and ongoing management convenient.

Revi Implant

- Advanced battery-free implant allows the device to be miniature in size without the need for replacement surgeries due to battery depletion, lead fracture, or lead migration.
- Only 3 cm in length and 3 mm in diameter, this tibial implant delivers reliable and long-lasting performance in a compact form.
- MR Conditional

Revi Wearable

- Innovative lightweight external wearable technology powers the implant, enabling programming changes without regard for energy consumption.
- A mere 7.8 oz, it is worn around the ankle for ~30-60 minutes daily based on symptoms, delivering therapy at the patient's convenience.

Revi Clinician Programmer

- Allows for customization of therapy based on a patient's response.
- Enables adjustment of frequency, pulse width, polarity, and amplitude.

Hub

- Wirelessly retrieves therapy data from the Wearable.
- Provides the clinical care team visibility into device usage and status to better support and optimize patient therapy.

myRevi App

- Online patient support center providing customized education, online chat functionality, and symptom tracking.
- Enables monitoring of symptoms to facilitate therapy optimization.

Learn About Our Comprehensive Services For:

Patient Support Program

Clinician Training

Indication
Revi is indicated for the treatment of patients with symptoms of urgency incontinence alone or in combination with urinary urgency.

Visit www.bluewindmedical.com for more details.

Caution:
Federal Law (USA) restricts this device TO sale by or on the order of a physician. Refer to product instruction manual/package insert for instructions, warning, precautions, and contraindications. For more information, please contact BlueWind Medical at 888-715-2080, and/or consult BlueWind Medical's website at **www.bluewindmedical.com.**

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