



# BlueWind Medical Revi™ Patient FAQ

**Have questions? We've got answers.**

Get answers to frequently asked questions and connect with informative resources.

## 1. What is Urge Urinary Incontinence (UUI)?

Urge Urinary Incontinence, sometimes called urgent bladder leaking, is a condition that causes an urgent need to empty your bladder, even when it's not full. It is a chronic condition, which means it won't go away by itself. It can be a disabling condition with physical, psychological, and social consequences that may significantly impact the quality of life of those with UUI.

## 2. What is tibial neuromodulation?

Tibial neuromodulation is a proven technique that stimulates the tibial nerve in your leg, sending signals up to your spinal cord to block abnormal signals to the bladder. Revi is implanted near the tibial nerve in your ankle so it can send a message through the nerve to your bladder, calming the urge to go.

## 3. What is Revi and how does it treat urgent bladder leaks?

Revi is a small device that is implanted near the ankle so it can deliver personalized levels of nerve stimulation through the leg to the bladder to help control bladder symptoms. A lightweight wearable is used to activate the implanted device to provide this stimulation.

## 4. What are the components of the Revi System?

- **Miniature Implant:** The Revi Implant is placed in your ankle region during a single, outpatient procedure that is performed under local anesthesia. Revi is miniature in size at only 3 cm long.
- **Lightweight Wearable:** You wear the lightweight Revi Wearable around your ankle to wirelessly activate the implant and deliver ongoing therapy—at a time and place convenient for you.
- **Hub:** The Hub wirelessly communicates therapy data from the wearable, allowing your care team to better support and optimize your therapy.
- **myRevi app:** The app helps you optimize your therapy through online chat functionality and educational content. MyRevi guides you through the treatment process and provides access to information and answers.

## 5. Who are appropriate patients for Revi?

Revi is for men and women struggling with urgent bladder leaks and looking for a new treatment because lifestyle changes haven't worked. Revi may be the key to getting back to the life you want to live. Find out if Revi is right for you by taking [this quiz](#). Then, talk to your doctor about Revi.

## 6. Who should I talk to about Revi to learn more and see if it's right for me?

Your primary care physician is typically the first person to discuss your bladder symptoms with. Often, they are the first healthcare provider to diagnose and treat people with urge urinary incontinence, but they may need to refer you to a urologist or urogynecologist for more advanced care like Revi.

If lifestyle changes haven't helped and medications aren't right for you, it may be time to speak with a urologist or urogynecologist who can work with you to decide if Revi may be the solution you're looking for.

## 7. Does insurance cover Revi?

If you and your healthcare provider agree that Revi is the best option for you, if required, they may submit for prior authorization with your insurance to better understand your coverage benefits. Since Revi is a new type of treatment, this process may take a little longer than usual. BlueWind has partnered with a prior authorization support company to assist with this process and keep you and your doctor informed of the status of your request.

## 8. What is the Revi procedure like?

The Revi Implant is placed during a single out-patient procedure. Because it is miniature in size, Revi can be implanted under local anesthesia via a small incision in your ankle region. You'll be able to walk out of the hospital or outpatient clinic after the procedure is complete. Your doctor will allow for the incision site to heal for several weeks before turning on and personalizing your Revi therapy.

## 9. Is the Revi procedure safe?

In the OASIS study, Revi demonstrated a favorable safety profile with no serious complications related to the device or procedure at 12 months.<sup>1\*</sup> An earlier study showed that Revi provides safe and effective treatment for at least 3 years.<sup>2</sup>

## 10. When can I start using Revi?

You will have stitches and a wrap covering the incision area after the procedure. Your doctor will wait several weeks to turn on your system to allow your incision to heal. Typically, you can start therapy 2 to 4 weeks after the procedure but refer to your doctor's instructions for additional steps and details on the procedure and recovery.

After healing from the procedure, a BlueWind Representative will work with your physician to personalize your treatment settings to optimize therapy-all based on your response.

## 11. What does ongoing use of Revi involve?

In the OASIS study, participants used Revi for approximately 30 minutes twice a day. Your provider will work with you to determine the frequency and length of treatments that is best for you. You can give yourself treatment sessions when and where it is most convenient for you by placing your wearable around your ankle to deliver therapy.

## 12. What does a treatment session feel like?

When you're conducting a Revi treatment, you will feel a mild tingling sensation in the sole of your foot. When you feel this, it's normal and means the therapy is working correctly.

## 13. Has Revi been studied in other patients with overactive bladder?

Yes, the OASIS study followed 151 patients who were using Revi. Of the 139 patients who completed the study, after 12 months:<sup>1</sup>

- **95%** of study participants reported they were satisfied with their therapy.\*\*
- **82%** of study participants had  $\geq 50\%$  reduction in episodes of urinary urge incontinence (a sudden, intense need to go to the bathroom that cannot be delayed, resulting in accidents).
- **50%** of study participants were dry without leaks for three consecutive days.

## 14. What happens if I need on-going support after Revi?

BlueWind Patient Support is here to answer questions and help you along your Revi treatment journey. You can reach the Patient Support team by using the myRevi app, a phone call or through an email on our website. The Patient Support Number is **1-888-715-2080**. Patient Support is offered Monday-Friday from 8:00am CST-5:00pm CST. Visit the Revi Patient Support page on [bluewindmedical.com](https://www.bluewindmedical.com).

## 15. How long does the Revi Implant last?

The Revi Implant lifespan is 10-years from implantation.<sup>3</sup>

## 16. What's the myRevi app?

MyRevi is a mobile app developed to help you track leaks and stay connected with the BlueWind Support team. Additionally, myRevi provides educational content and an online chat function for you to use. You will be provided access to myRevi once you have scheduled your Revi procedure or immediately following the procedure. A BlueWind Representative will help you download the app and show you how to use it.

\*Some women (10.6%) had mild to moderate issues, including numbness after the procedure, pain, swelling, skin rash, wound infections, and delayed healing.<sup>4</sup>

\*\*Of the 130 patients who completed the satisfaction survey.

For further information on the OASIS study and other on-going clinical studies, please visit [clinicaltrials.gov](https://clinicaltrials.gov) (**[OASIS NCT03596671](https://clinicaltrials.gov/ct2/show/study/NCT03596671)**)

### References

1. Heesakkers, J. et al. (2023, April 30). Pivotal Study of a Novel Wirelessly Powered, Patient Tailored Programmed, Tibial Neurostimulator for the Treatment of Patients with Overactive Bladder. AUA 2023.
2. Dorsthorst MJ, Digesu GA, Taylor V, Gore M, van Kerrebroeck PE, van Breda HMK, Elneil S, Heesakkers J. 3-year follow-up of a new implantable tibial nerve stimulator for the treatment of Overactive Bladder Syndrome. Juroi Vol. 204, 545-550, September 2022. <https://doi.org/10.1097/JU.0000000000001024>
3. Revi Surgical Technique Guide August 2023
4. Sutherland, S et. al. OASIS Pivotal Trial to Evaluate the Safety and Efficacy of the Renova iStim System and for the Treatment of Women with OAB. Juroi. 2022; 207(S5):e1043.

### 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](https://www.bluewindmedical.com).

