NOW APPROVED!

Axonics R20®

Sacral Neuromodulation System

The **Axonics R20® System** provides a best-in-class patient and physician experience.

Offer your patients the confidence of a long-lasting therapy.

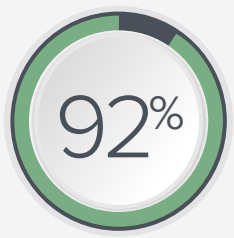
- Battery that only needs recharging every 6 to 10 months*
- Designed to last 20+ years
- Miniaturised device, only 5 cc in volume
- Pocket-sized Patient Remote Control that doesn't require recharging
- Expanded MRI access
- Dual program capability

Fuss-Free Patient and Provider Experience

Axonics R20 features **two programming options** supported by our proprietary Smart programming algorithm:

- Accurately predicts effective programming at implant, with minimal need for reprogramming[1]
- Minimises the need for patients to adjust their programs[1]

In the ARTISTRY Registry study,



of patients were on one of their top two recommended programs after one year.[1]

Expanded MRI Access

The Axonics R20 System is approved for a broader set of MRI specifications and labeling. Axonics R20 is MRI conditionally safe for:

- 1.5T and 3T Full-Body Coil - expanded conditions NEW
- 1.5T and 3T Head Coil
- 1.5T and 3T Upper and Lower Extremity Coils NEW

* Typical therapy settings: 1200 Ohms, 14 Hz, 210 µS

1. ARTISTRY Registry data on file. October 2023

Axonics

IMPORTANT SAFETY INFORMATION:

Indications: The Axonics R15 System for urinary control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence (leakage) and significant symptoms of urgency-frequency, either alone or in combination, in patients who have failed or could not tolerate more conservative treatments. The Axonics R15 System for bowel control is indicated for the treatment of chronic faecal incontinence in patients who have failed or are not candidates for more conservative treatments.

The Axonics R20 System for urinary control is indicated for the treatment of the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

Contraindications: The Axonics SNM System is contraindicated for patients who have not demonstrated an appropriate response to test stimulation or patients who are unable to operate the Axonics SNM System.

Warnings: Implantation and use of the Axonics System incurs risk beyond those normally associated with surgery, some of which may necessitate surgical intervention. These risks include but are not limited to adverse change in voiding, infection, pain, or irritation at the implant site, lead or device migration, electrical shock, change in sensation or magnitude of stimulation which has been described as uncomfortable (jolting or shocking) by some patients, and heating or burns at the device site.

For more information about safety and potential risks, refer to **Information for Prescribers and Patients** at www.axonics.com/eIFU.

Precautions: The safety and effectiveness of the Axonics R15 System has not been established for use in women who are pregnant or in delivery; for pediatric patients (under the age of 18 years for faecal incontinence and under the age of 16 years for overactive bladder and urinary retention); for patients with neurological disease origins, such as multiple sclerosis or diabetes; or for bilateral stimulation.

The safety and effectiveness of the Axonics R20 System has not been established for use in women who are pregnant or in delivery; for pediatric patients under the age of 16 years; for patients with neurological disease origins, such as multiple sclerosis or diabetes; or for bilateral stimulation.

For a complete listing of indications, contraindications, warnings and precautions, go to www.axonics.com/isi

For Summary of Safety and Clinical Performance (SSCP), refer to https://ec.europa.eu/tools/eudamed/#/screen/home.

Adverse Event Reporting: In case of any serious incident related to the product, please report to Axonics (+1-877-929-6642) as well as the competent authority of your state.

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℞ ONLY

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