



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Boston Scientific Pty Ltd – Axonics SNM system

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Boston Scientific Pty Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from Boston Scientific Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph (A), for use in advertisements for the products identified in paragraph (B), when each of the statements identified in paragraph (C) is prominently displayed or communicated¹ in the advertisement in which the restricted representations are used.

(A)

- Representations to the effect that the Boston Scientific Axonics SNM system (or its components) is indicated for the treatment of urinary retention and 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.
- Representations to the effect that the Boston Scientific Axonics SNM system (or its components) is indicated for the treatment of chronic faecal incontinence in patients who have failed or are not candidates for more conservative treatments.

(B)

- AXONICS SNM SYSTEM™ Neurostimulator R20 Model 5101 - Stimulator, electrical, neuromuscular, incontinence, implantable (ARTG 462565)
- Axonics Charging System - Implant battery charger (ARTG 297956)
- AXONICS SNM SYSTEM™ Neurostimulator F15 Model 4101 - Stimulator, electrical, neuromuscular, incontinence, implantable (ARTG 448867)
- AXONICS SNM SYSTEM™ Remote Control 2301 - Incontinence-control electrical stimulation system, nonimplantable, remote control (ARTG 325941)
- Axonics Tined Lead - Stimulator, electrical, neuromuscular, incontinence, implantable (ARTG 297953)

¹ ***prominently displayed or communicated***, in relation to a statement in an advertisement, means:

(a) either:

(i) for a visual statement—easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or

(ii) for a spoken statement—able to be clearly heard and understood; and

(b) repeated as often as necessary to be noticed by a viewer or listener

- Incontinence-control electrical stimulation system, nonimplantable, percutaneous (ARTG 313220)
- Neural-tissue electrical stimulation lead adaptor (ARTG 312912).

(C)

- The Axonics SNM system is not a first-line treatment.
- Surgery is required for use of Axonics SNM system, and any surgical procedure carries risk.
- Outcomes may vary for each patient.
- Patients should consult their healthcare professional about factors that could impact response.

Dated this 5th day of August 2026

Signed electronically

Rowena Love

Delegate of the Secretary to the Department of Health, Disability and Ageing

Education Policy and Guidance Section

Regulatory Compliance Branch