



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Act 1989

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

I, Michael Shum, as a delegate of the Secretary to the Department of Health and Aged Care, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representation described in paragraph (A), for use in advertising the products identified in paragraph (B) to consumers, subject to the conditions identified in paragraph (C).

(A) Representations to the effect that the Boston Scientific WaveWriter Alpha Spinal Cord Stimulator System is indicated as an aid in the management of chronic intractable pain (the **Representation**).

The Representation will always be accompanied by the following statement, prominently displayed or communicated:

- i. Talk to your healthcare professional about whether this product may be suitable for you as part of your overall plan to manage chronic pain (the **Advisory Statement**).

(B)

- i. WaveWriter Alpha IMPLANTABLE PULSE GENERATOR KIT - Analgesic spinal cord electrical stimulation system pulse generator implantable (ARTG 400392)
- ii. WaveWriter Alpha 16 IMPLANTABLE PULSE GENERATOR KIT - Analgesic spinal cord electrical stimulation system pulse generator implantable (ARTG 400374)
- iii. WaveWriter Alpha Prime IMPLANTABLE PULSE GENERATOR KIT - Analgesic spinal cord electrical stimulation system pulse generator implantable (ARTG 400373)
- iv. WaveWriter Alpha Prime 16 IMPLANTABLE PULSE GENERATOR KIT - Analgesic spinal cord electrical stimulation system pulse generator implantable (ARTG 400292)
- v. Avista MRI 8 Contact Lead Kit - Stimulator, electrical, analgesic, spinal cord (ARTG 287236)
- vi. Infinion CX Lead - Stimulator, electrical, analgesic, spinal cord (ARTG 275241)
- vii. CoverEdge MRI 32 Contact Surgical Lead Kit - Electrode/lead, stimulator, implantable, neurological (ARTG 218230)
- viii. Infinion 16 Contact Lead Kit - Electrode/lead, stimulator, implantable, neurological (ARTG 197909)
- ix. Artisan 2 x 8 Surgical Lead - Electrode/lead, stimulator, implantable, neurological (ARTG 163471)
- x. PRECISION Linear 8 Contact Leads (model SC-2138-xx) (ARTG 128775)

- (C) The Representation must always be accompanied by the following statements, prominently displayed or communicated:
- i. The WaveWriter Alpha System is not a first-line treatment for chronic intractable pain.
 - ii. Surgery is required in order to use the WaveWriter Alpha System and any surgical procedure carries risk.
 - iii. Outcomes may vary for each patient.
 - iv. Patients should consult their healthcare professional about factors that could impact their response.

Dated this 1st day of August 2023

Signed electronically

Michael Shum

Delegate of the Secretary to the Department of Health and Aged Care
Advertising and Compliance Education and Policy Section
Regulatory Compliance Branch