



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

**Boston Scientific Pty Ltd – Prosthesis, internal, penile, inflatable (ARTG 390412) and
AMS 700 Inflatable Penile Prosthesis including antibiotic coating - Prosthesis,
internal, penile, inflatable (ARTG 352831)**

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, 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 about the products identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed or communicated¹ in the advertisement in which the restricted representations are used (including on the label and packaging of the goods).

(A)

- Representations to the effect that the Boston Scientific AMS 700 Inflatable Penile Prosthesis is indicated for use in the treatment of chronic, organic, male erectile dysfunction (impotence).

(B)

- Prosthesis, internal, penile, inflatable (ARTG 390412)
- AMS 700 Inflatable Penile Prosthesis including antibiotic coating - Prosthesis, internal, penile, inflatable (ARTG 352831)

(C)

- The AMS 700 Inflatable Penile Prosthesis is not a first-line treatment for Erectile Dysfunction.
- Surgery is required to implant the AMS 700 IPP, and any surgical procedure carries risk.
- Outcomes may vary for each patient.

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

- Consult with your doctor to determine if AMS 700 IPP is suitable for you and any factors that could impact your response.

Dated this 21 February 2025

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