



Australian Government

Department of Health, Disability and Ageing Therapeutic Goods Administration

Smith & Nephew Pty Ltd – REGENETEN Bioinductive Implant with Arthroscopic Delivery System - Multi-purpose surgical mesh, collagen (ARTG 384118)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Smith & Nephew Pty Ltd

I, Michael Shum, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from Smith & Nephew 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 product 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: In a clinical study of patients with partial thickness tears of the rotator cuff undergoing keyhole surgery, the patients that had REGENETEN® implanted had a faster return to daily living, office work and higher-intensity household activities than those that received standard rotator cuff repair.
- Representations to the effect that Regeneten may require less sling time than conventional surgical repair of rotator cuff tears.
- Representations to the effect that having your rotator cuff tear repaired (with Regeneten or standard surgical repair) can help relieve shoulder pain

(B)

- REGENETEN Bioinductive Implant with Arthroscopic Delivery System - Multi-purpose surgical mesh, collagen (ARTG 384118).

(C)

- Speak to your doctor about whether Regeneten may be suitable for you.

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

- Your orthopaedic surgeon/doctor will decide whether Regeneten is suitable for you, based on your situation, including the nature of your rotator cuff injury/tear.
- Surgery is required to use this product. Any surgical procedure carries risk.
 - Where the representation referred to in paragraph 2 is used, the advertisement will include (in addition to the advisory statements identified in paragraphs 5-7):
 - a footnote with the citation for the clinical study.
 - b) an advisory statement to the effect that individual results may vary depending on the patient and the nature of the rotator cuff tear.
- Where the representation referred to in paragraph 3 is used, the advertisement will include (in addition to the advisory statements identified in paragraphs 5-7) advisory statements to the effect that:
 - Your doctor will advise you on sling use and the timing of sling removal, which may vary depending on your personal circumstances.
 - Patients will still need to undergo rehabilitation, including a regular supervised exercise regime.
- Where the representation referred to in paragraph 4 is used, the advertisement will include (in addition to the advisory statements identified in paragraphs 5-7) an advisory statement to the effect that patients will still need to undergo rehabilitation, including a regular, supervised exercise regime.

Dated this 2nd day of October 2026

Signed electronically

Michael Shum

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

Education Policy and Guidance Section

Regulatory Compliance Branch