



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
Smith & Nephew 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 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 advertising the product identified in paragraph **(B)**, when all of the statements identified in paragraph **(C)** are prominently displayed or communicated¹ when any of the restricted representations in paragraph **(A)** are used.

(A)

1. PIC07 is intended for patients who would benefit from a suction device (NPWT) as it may promote wound healing via removal of low to moderate levels of exudates and infectious materials for surgical closed incision sites.
2. The PIC07 System can help reduce the risk of surgical site / incision infections after caesarean section. This representation will always be accompanied with representations to the effect of Representation 3 and 4.
3. Adequate education about surgical site infections is important to ensure mothers to be aware of any potential risk factors associated with caesarean delivery, such as being obese, smoking or having high blood pressure. Representation 3 will always be accompanied with representations to the effect of Representation 4.
4. Speak to your doctor about interventions to help prevent surgical site complications.

(B)

- Negative-pressure wound therapy system, battery-powered, single-use (ARTG 185785)

(C)

- PIC07 is to be used under the direction of Healthcare Professional only.
- The device can be used in homecare setting under the training and supervision from Healthcare Professional.

¹ As defined in the applicable version of the Therapeutic Goods Advertising Code, as amended from time to time.

- PICO7 dressings should only be applied and changed by your Healthcare Professional.

Dated this 20th day of March 2024

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