Public Summary

Summary for ARTG Entry: 351635

Johnson & Johnson Medical Pty Ltd - GYNECARE TVT™ Device Tension Free Vaginal Tape - Female stress urinary incontinence surgical mesh

ARTG entry for Medical Device Included Class III

Sponsor Johnson & Johnson Medical Pty Ltd

Postal Address PO Box 134, NORTH RYDE BC, NSW, 1670 Australia

ARTG Start Date 11/12/2020

Product Category Medical Device Class III

Status Active

Approval Area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name Ethicon SARL

Address Puits Godet 20 . Neuchatel, CH-2000 Switzerland

Products

1. GYNECARE TVT™ Device Tension Free Vaginal Tape - Female stress urinary incontinence surgical mesh

Product Type Single Device Product

Effective Date 11/12/2020

GMDN 47986 Female stress urinary incontinence surgical mesh

Functional Description Device is a sterile, single-use device, consisting of one piece of blue (Phthalocyanine blue, colour 74160) PROLENE™ Polypropylene Mesh (tape) approx 1.1 x 45 cm, covered by a plastic sheath cut & overlapping in the middle, held between two stainless steel needles bonded to mesh & sheath with plastic collars. The Sheath, needles, collars are cut & removed after mesh is placed. Reusable accessories(supplied separately),facilitate placement of device during procedure.

Intended Purpose The GYNECARE TVT Device is intended to be used as a pubo-urethral sling for treatment of Stress Urinary Incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Variant Information Nil variant (as 1 device) 810041B

Specific Conditions

1. The person in relation to whom the kind of medical device is included in the ARTG (the sponsor) must provide to the Therapeutic Goods Administration, Department of Health (the TGA) consecutive annual reports. Reports should be for the period 1 July to 30 June. The first report must be provided by no later than 1 October 2021 and include information from when the device was included as a Class IIb device, being ARTG entry 99193, to cover the entire 12 month period. The annual report must include records of all complaints and adverse events relating to problems with the use of the device that have been received by the manufacturer and/or sponsor over the year. Note: The reports must clearly identify each device of the kind (e.g. by the unique product identifier, model name or catalogue number) to which the complaints and adverse events relate. The first report is due 1 October 2021. This condition applies for the entire period that the ARTG entry remains current.

2. The sponsor also, as required under s41FN (3)(d), must report to the TGA all adverse events that occur in Australia. However, reporting exemption rules in the Australian Regulatory Guidance for Medical Devices do not apply to this ARTG entry. These adverse event reports should be submitted in accordance with the timeframes specified in the Therapeutic Goods (Medical Devices) Regulations (2002) (Regulation 5.7). Adverse event rates in each report should include confirmed and unconfirmed events and be based on the event description, and not whether the event has been confirmed or the cause has been identified. Please: All these conditions apply for the entire period that the ARTG entry remains current. The imposition of the conditions takes effect when the Device is included in the ARTG. These conditions imposed on the kind of device are in addition to any other conditions imposed on the ARTG entry and conditions applying automatically under the Therapeutic Goods Act 1989. How to provide the information requested You are required to provide documents and information in response to this notification through the TGA Business Services (TBS) portal, which can be found at https://www.tga.gov.au/tga-business-services Please quote the above FILE REFERENCE number on all correspondence relating to this post-market review. This information is essential for the TGA to track and identify all pieces of data relevant to the post market review.