



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 409977 Johnson & Johnson Medical Pty Ltd t/a DePuy Synthes - Modular CathCart Tapered Spacer 12/14 Taper - Femoral head/stem prosthesis adaptor

ARTG entry for Medical Device Included Class III
Sponsor Johnson & Johnson Medical Pty Ltd t/a DePuy Synthes
Postal Address PO Box 134, NORTH RYDE, NSW, 2113
Australia
ARTG Start Date 2/06/2023
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	Address
DePuy Ireland UC	Loughbeg Ringaskiddy , Co Cork, Ireland

Products

1 . Modular CathCart Tapered Spacer 12/14 Taper - Femoral head/stem prosthesis adaptor

Product Type	Single Device Product	Effective Date	2/06/2023
GMDN	59688 Femoral head/stem prosthesis adaptor		
Functional Description	Modular CathCart Tapered Spacers are made from CoCr and are adapter spacers that allow the use of hip stems with 12/14 tapers to be implanted with Modular Cathcart unipolar heads during hemi arthroplasty. Neck length adjustment is achieved by the use of these tapered spacers.		
Intended Purpose	The Modular Cathcart Tapered Spacer is used during Hemi-hip arthroplasty where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem. Indicated in the following conditions: 1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation. 2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation. 3. Avascular necrosis of the femoral head. 4. Non-union of femoral neck fractures. 5. Certain high subcapital and femoral neck fractures in the elderly. 6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty		
Variant information	Size (mm) -3 to +10		

Specific Conditions

No Specific Conditions included on Record

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