



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 409976 Johnson & Johnson Medical Pty Ltd t/a DePuy Synthes - Self Centering Bi-Polar Head - Femoral head bipolar component

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 . Self Centering Bi-Polar Head - Femoral head bipolar component

Product Type	Single Device Product	Effective Date	2/06/2023
GMDN	33695 Femoral head bipolar component		
Functional Description	The Self Centering Bi-Polar Head is a hemi-hip femoral head consisting of a outer CoCr cup and an inner UHMWPE insert with plastic retaining ring to be used with a femoral hip stem and modular metal ball with a head diameter corresponding to the inside diameter of the Self-Centering Hip polyethylene insert to replace the femoral head and neck in hemi-hip replacement.		
Intended Purpose	Self-Centering Bi-Polar Head Prosthesis is the femoral head component of 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	Diameter (mm) Inner Diameter: 22.225 or 28 Diameter (mm) Outer Diameter: 39 - 65		

Specific Conditions

No Specific Conditions included on Record

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