



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 409978 Johnson & Johnson Medical Pty Ltd t/a DePuy Synthes - Modular Cathcart Fracture Head Hip Ball - Metallic femoral head prosthesis

**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 Fracture Head Hip Ball - Metallic femoral head prosthesis

Product Type	Single Device Product	Effective Date	2/06/2023
<b>GMDN</b>	33175 Metallic femoral head prosthesis		
<b>Functional Description</b>	The Modular Cathcart Unipolar Head Hip Ball, via the use of a tapered sleeve, fixates onto the implanted femur and articulates directly with the patient's acetabulum. It is manufactured from cobalt chrome alloy. The head shape has an orthocentric geometry, to replicate the normal femoral head shape.		
<b>Intended Purpose</b>	Modular Cathcart Fracture Head Hip Balls are intended to replace the natural femoral head in 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		
<b>Variant information</b>	Diameter (mm) 41 - 60		

### Specific Conditions

No Specific Conditions included on Record

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