

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2015-RN-00100-1
Product Name/Description ⁱⁱⁱ	M2a 38 Acetabular Cup, M2a 38 Femoral Head, M2a Magnum Tri-Spike Acetabular Cup & M2a Magnum Femoral Heads ARTG Numbers: 98098 & 117715
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	6/02/2015
Responsible Entity ^{vii}	Biomet Australia Pty Ltd
Reason / Issue ^{viii}	<p>Biomet Australia has initiated this Hazard Alert following analysis of data collected by the Australian National Joint Replacement Registry (NJRR) which revealed that these specific implants have a higher than expected revision rate when used as part of metal on metal (MoM) total conventional hip arthroplasty constructs.</p> <p>Use of these implants has declined since 2008, with the last use of these implants in metal on metal total hip replacements (THRs) recorded in 2011. It is important to note that this Hazard Alert does not relate to the use of the Magnum acetabular Cup in combination with the Active Articulation dual mobility hip bearing system which is a polyethylene/metal construct.</p>
Recall Action ^{ix}	Hazard Alert
Recall Action Instructions ^x	<p>M2A 38 system and M2a Magnum Femoral Head are in the process of being cancelled from the Australian Register of Therapeutic Goods (ARTG). Surgeons are advised that patients who have received a MoM implant require careful, specific follow up, particularly if the implant is known to have a higher than expected rate of revision as in this case. Biomet is referring surgeons to the 'Recommendations for follow-up of patients with metal-on-metal hip implants' published in the TGA website.</p> <p>For more details, please see https://www.tga.gov.au/alert/biomet-m2a-metal-metal-total-hip-replacement-implants</p>
Contact Information ^{xi}	02 9878 6100 - Biomet Australia

Footnotes

ⁱ Type of Product: Medicine, Medical Device, or Biological

ⁱⁱ TGA Recall Reference: Unique number given by the TGA

ⁱⁱⁱ Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference