Australian Government
Department of Health
Therapeutic Goods Administration

LFIT Anatomic CoCr V40 femoral heads (used in hip replacements)

Hazard alert – risk of adverse events due to potential taper lock failures

27 September 2016

Consumers and health professionals are advised that Stryker Orthopaedics, in consultation with the TGA, has issued a hazard alert for a specific range of LFIT Anatomic CoCr V40 femoral heads.

LFIT Anatomic CoCr V40 femoral heads are modular components used in total hip replacement procedures.

It has been identified that some LFIT Anatomic CoCr V40 femoral heads manufactured before 2011 have a higher than expected incidence of taper lock failures. The taper lock is the part of the implant that connects the femoral head to the femoral neck.

If this occurs, the patient could experience:

- loss of mobility
- pain
- inflammation
- adverse local tissue reaction
- dislocation
- joint instability
- broken bones around the components
- leg length discrepancy

- need for revision surgery

This issue has been identified in four products, while three other products with similar specifications have also been included in the hazard alert as an additional precaution.

The affected products are:

Item number	Head diameter	Offset
6260-9-236	36 mm	+5
6260-9-240	40 mm	+4
6260-9-244	44 mm	+4
6260-9-340	40 mm	+8
6260-9-344	44 mm	+8
6260-9-440	40 mm	+12
6260-9-444	44 mm	+12

Information for consumers

If you or someone you provide care for has received a LFIT Anatomic CoCr V40 femoral head as part of a total hip replacement, be aware of this issue.

If you have any questions or concerns about this issue, talk to your health professional.

Contact the implanting orthopaedic surgeon if you experience unexpected pain, loss of mobility, inflammation, instability or other problems related to your implant.

Information for all health professionals

Patients with an affected implant should be followed up by the implanting orthopaedic surgeon if possible, particularly if they complain of unexpected pain, loss of mobility, inflammation, instability or other problems related to their implant.

Information for orthopaedic surgeons

Stryker Orthopaedic has written to orthopaedic surgeons who have implanted affected LFIT Anatomic CoCr V40 femoral heads to provide further information about this issue.

The increased incidence of taper lock failures relates to possible taper lock interface inconsistency.

Potential hazards associated with this issue are:

- disassociation of the femoral head from the hip stem
- fractured hip stem trunnion
- increased metallic debris
- insufficient range of movement
- insufficient soft tissue tension
- noise
- loss of implant
- bone fixation strength
- increased wear debris (polymetric)
- implant construct with a shortened neck length.

If you are managing the treatment of a patient who has an affected LFIT Anatomic CoCr V40 femoral head, you are advised to maintain routine follow-up protocol for those patients.

If you have any questions or concerns about this issue, contact Stryker Orthopaedic on 02 9467 1000.

Reporting problems

Consumers and health professionals are encouraged to report problems with medical devices (/reporting-problems). Your report will contribute to the TGA's monitoring of these products. For more information see the TGA Incident Reporting and Investigation Scheme (IRIS) (/medical-device-incident-reporting-investigation-scheme-iris).

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.

Category: Alert/Advisory, Medical devices safety
Tags: hip replacements

URL: https://www.tga.gov.au/node/731371 (//www.tga.gov.au/alert/lfit-anatomic-cocr-v40-femoral-heads-used-hip-replacements)