

Hazard Alert

Date: April 12, 2012

MITCH TRH MODULAR HEADS

Stryker Australia, following consultation with the Ministry of Health, MEDSAFE, is issuing this Hazard Alert concerning the MITCH TRH Modular head.

Reports from national joint registries in the United Kingdom and Australia confirm that use of the MITCH TRH modular head/acetabular cup in combination with the Accolade femoral stem results in significantly higher revision rates than seen for all other total hip prosthesis. As a result of these findings, Stryker has cancelled the WAND entry and will no longer supply the Mitch TRH modular head in the New Zealand market.

Action to be taken

Stryker have issued a letter to surgeons to inform them of this hazard alert and advise them to contact all of their patients who have the MITCH TRH modular head implanted (estimated to be 50 patients).

In line with international guidelines such as those published by the MHRA for patients with metal on metal hip replacements <http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON149600> it is recommended that patients who have total conventional hip replacements with MITCH TRH acetabular components should be followed up more frequently than normal.

Background

Due to the increased focus on metal-on-metal total hip replacement results of late, Stryker feels it is timely and responsible to ensure that surgeons and their patients have as much information as possible, and you are encouraged to discuss these matters with Stryker and/or your patients.

It is important to note the following:

- A review of AOA NJRR data reveals that the revision rate for the Accolade Femoral Stem when used for primary total conventional hip replacement with cementless fixation is in line with that of all other Total Conventional Hip Replacements.
- The revision rate of the MITCH TRH modular head combined with the Exeter V40 stem is 2.8% at 3 years, which is in line with the average for all Other Total Conventional hip replacements.
- The MITCH TRH System when used for hip resurfacing has a low and acceptable revision rate compared to other total resurfacing hip replacements.

Even though the Cumulative percent revision rate of the MITCH TRH/Exeter V40 combination is in line with that of other Total Conventional Hip Replacements, its current overall revision rate is 0.97 revisions per hundred observed years which is higher than the revision rate of other total conventional hip replacements (0.81 revisions per hundred observed years), and the revision rate of this combination is higher than that of Exeter with other cup/head combinations.

Further, the revision rates of the MITCH TRH Modular Head/Cup when used in combination with the ABGII and Restoration Femoral stems are also higher than expected although based on low numbers of implants.

In Australia/New Zealand, the MITCH TRH system – manufactured by Finsbury Orthopaedics Ltd. (UK)¹ was made available in May 2006 by Stryker for both resurfacing and total hip indications. Stryker supplied the MITCH TRH modular heads for total hip replacement procedures until August 2011.

¹ MITCH TRH was manufactured by Finsbury Orthopaedics Ltd. and distributed by Stryker between May 2006 and October 2011. Finsbury Orthopaedics Ltd. was acquired by DePuy Orthopaedics, Inc. in December 2009.

If you have any further enquiries, please contact your local Sales Representative or Hugh Griffin on 0800 787 9287.

Yours sincerely,

Lachlan McKenzie
Regulatory Affairs Manager,
Stryker Australia & New Zealand