

October, 2014

FSCA identifier: Product Field Action RA2013-123 Update

Type of Action: Field Safety Corrective Action

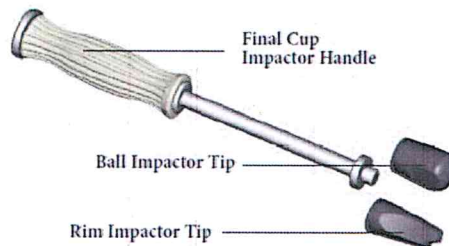
Description: ADM[®]/MDM[®] Ball Impactor Tip and ADM[®] Rim Impactor Tip

Catalog #: 1235-0-013, 1235-0-014

Lot #: All

To whom it may concern:

On September 19th 2013, Stryker[®] Orthopaedics ("Stryker") initiated a voluntary Product Correction for the ADM/MDM Ball Impactor Tip and ADM Rim Impactor Tip, instruments associated with Stryker's Anatomic Dual Mobility (ADM) and/or the Modular Dual Mobility (MDM) Acetabular Systems. Stryker has received complaints associated with cracks and/or fracture of the Ball Impactor Tip and Rim Impactor Tip instruments. Images of each are provided below.



Potential Hazards

Listed below are potential hazards and associated potential harms:

Hazards:

1. Cracked and/or fractured Ball Impactor Tip/Rim Impactor Tip.
2. Loose fragments from Ball Impactor Tip/Rim Impactor Tip.
3. Insufficient locking strength of MDM liner (Ball Impactor Tip only).

Harms:

1. Complications associated with extended surgery time of greater than thirty minutes to retrieve a replacement instrument.
2. Inflammation and allergic reaction if tip fragments enter the wound and remain there post-operatively.

3. Incomplete seating of the MDM liner and the potential for loss of mobility secondary to component disassociation.

Risk Mitigation Factors

The surgical protocols associated with the ADM (ref. LSP64) and MDM (ref. LSP73) Systems have been updated to recommend use of the slotted mallet (cat. no. 1120-1000) to impact the impactor handle when using the tips and to emphasize that the Ball Impactor Tips and Rim Impactor Tips should be inspected for deformation and cracks before use. See attached Product Correction Bulletin for specific details.

Updated protocols, LSP64 Rev. 5 and LSP73 Rev. 3, are available at:

<http://www.stryker.com/en-us/products/Orthopaedics/HipReplacement/Acetabular/mobilebearing/139617>.

The Impactor Tips are reusable instruments. Inspection of reusable devices, as described in the Instructions for Cleaning, Sterilization, Inspection and Maintenance of Orthopaedic Medical Devices (Lit. # LSTPI-B Rev. 2, 08/12; Page 8) indicates that devices exposed to impaction forces must be checked for damage before and after each use. This may mitigate instances in which a cracked or fractured tip is received in the operating room.

A medical assessment of this matter concluded a "limited" severity of harm. While the risk of tip cracking/fracture is associated with a low risk to patient, further mitigation of this risk was achieved by the update to the product bulletin and has heightened user awareness of the failure mode.

Please note that there has been an update to our original timeline as Stryker is pursuing a long-term replacement plan for all ADM/MDM Ball Impactor Tip and ADM Rim Impactor Tip instruments currently located in the field. The redesign activities associated with the new Impactors is now scheduled to be completed by November 2015, which will be followed up with a replacement of the product in the field.

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients.

Yours Sincerely,



Dervillia Murphy
Regulatory Affairs Manager