

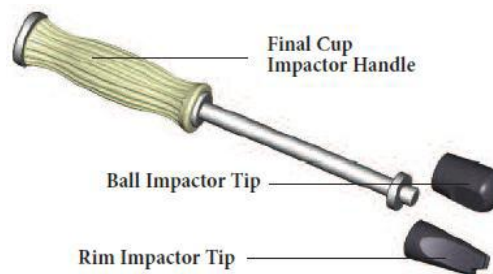
September 30, 2013

URGENT: Field Safety Notice

FSCA identifier: Product Field Action RA2013-123
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

Dear Distributor:

On September 19th, 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.

Additionally, please note that 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.

Regarding any ADM/MDM Ball Impactor Tip and ADM Rim Impactor Tip instruments in your possession, please follow the below advice:

1. Circulate this Field Safety Notice and Product Correction Bulletin internally to all interested/affected parties.
2. Maintain awareness of this Notice and Product Correction Bulletin internally within your facility.
3. Inform Stryker if any of the subject devices have been distributed to other organisations. *(Please provide contact details so that Stryker can inform the recipients appropriately).*
4. Complete the attached customer response form. *(This will preclude the need to Stryker to send any reminder notice)*
5. Please inform Stryker of any adverse events.
6. Return the completed form to your local Stryker Representative.

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please contact your local Sales Representative.

Yours Sincerely,
