

Urgent Field Safety Notice

Affected Product: Ceramic Hip Prostheses

FSCA reference: R-2016-24

FSCA action: Device Modification

Date: June 03, 2016

Details of affected product: See below

Dear Surgeon

This letter is to inform you of a voluntary Field Safety Corrective Action (FSCA) in relation to the ongoing use of all Ceramic Hip Prostheses, including femoral ball heads and acetabular cup (shell) liners/inserts that are either manufactured or distributed globally by Smith & Nephew.

This field action has been reported to the relevant competent authorities.

Reason for this Field Action

Ceramic components have been used for many years in hip arthroplasty. Such components may fracture and require revision over time. Recent post-market surveillance suggests that ceramic fragments from fractured ceramic components of hip prostheses may remain in the joint during revision surgery, which can lead to premature wear of revision components if such revision components are made of non-ceramic materials. This can lead to the need for additional revision surgery.

A safety warning has been issued by Smith & Nephew to caution against the use of non-ceramic components for revising fractured ceramic components used in hip arthroplasty.

Information Relating to Patient Safety

In the event a hip prostheses revision is required due to a fractured Ceramic component; to prevent any potential undue wear of the revision components, revisions shall only be performed using a Ceramic femoral ball head.

In the case of a revision involving a fractured Ceramic component, femoral ball head and insert have to be revised. Remove all loose identifiable fragments and thoroughly irrigate and lavage the operative site. A special Ceramic revision femoral ball head* coupled with a metallic taper adaptor should be used, if the femoral taper is intact. Metal or OXINIUM[®] femoral ball heads with a polyethylene insert shall not be used for revising fractured Ceramic components. In case the taper is damaged or no appropriate Ceramic revision femoral ball head* is available, the femoral stem must be revised to provide a suitable femoral taper to attach a new Ceramic femoral ball head.

In case of Ceramic liner/insert fractures, ensure all loose fragments have been adequately removed as noted above. For revision purposes, a polyethylene, Ceramic, or Ceramic-polyethylene (BICON-PLUS[®] only) insert exchange should be possible where the inner acetabular cup taper has not been damaged and the cup remains appropriately positioned.

Notes:

1. For the REFLECTION[®] Acetabular System, an exchange is not possible for fractured Ceramic liners and will also require the revision of the cup.
2. For the R3[®] Acetabular System, if a (fractured) Ceramic liner is removed, a new Ceramic liner must be used to replace it.

Actions to be taken by the user

1. Use Smith & Nephew Hip Systems only in accordance with this safety warning notification.
2. Complete the return slip and forward it to your national Smith & Nephew agency / distributor to confirm receipt of this Field Safety Notice.
3. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.
4. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Affected Products

Ceramic Components	Manufacturer	Article/Catalogue Numbers
BIOLOX [®] OPTION*	CeramTec GmbH (<i>Femoral ball head only</i>)	All
BIOLOX [®] DELTA	Smith & Nephew Orthopaedics AG Smith & Nephew, Inc.	All
BIOLOX [®] FORTE	Smith & Nephew Orthopaedics AG Smith & Nephew, Inc.	All

Smith & Nephew Orthopaedics AG
Oberneuhofstrasse 10d
6340 Baar
Switzerland



Smith & Nephew is committed to distributing only products of the highest quality standards and to providing support to surgeons and patients who use those products.

If you have any questions, please contact us on the following phone number: +41 62 832 27 15 or by e-mail: fieldactions@smith-nephew.com.

Contact Details of Subsidiary / Distributor

Yours sincerely,

A handwritten signature in blue ink that reads "A Weymann".

Andy Weymann, MD
Chief Medical Officer
Advance Surgical Devices Division
Smith & Nephew

Return Slip

Please complete and return this feedback information before June 15, 2016 to the contact specified above to prevent repetitive enquiries.

We confirm the receipt of this Field Safety Notice and confirm that we are aware of this field safety notice (FSN).

Institution: _____

Reference: R-2016-24

Name: _____ Date / Signature: _____