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smith&nephew

Dear Dr.,

This letter is to inform you of our recent field action regarding specific batches of R3 Forte Ceramic Liners.

Based on internal laboratory testing data, specific batches of R3 Forte Ceramic Liners have the potential to fail sooner than anticipated. An internal investigation has determined that certain batches were assembled outside our manufacturing specifications. This has the potential to reduce the strength of the liners. As a result, we are voluntarily withdrawing the affected batches of this component from the market.

The Ceramic liners we are withdrawing are used with the R3 Acetabular Primary Cup System. The other components of this system will remain on the market. The R3 Delta Ceramic Liners are unaffected by this field action and remain available for use.

If patients present with pain or loss of function they should be radiologically checked for possible component breakage. In patients without symptoms who have received an affected batch of R3 Forte Ceramic Liner we recommend you continue to utilize standard follow-up protocol.

Here is a summary of the key facts:

- *in vitro* testing shows that there may be a potential for the specified liners to fail sooner than anticipated.
- As a result, we are voluntarily withdrawing the specific batches of R3 Forte Ceramic liners from the market.

We regret that this has occurred and any inconvenience it may cause you, your patients, or your staff. All of us at Smith & Nephew value the relationship we have with our customers, and our approach to this issue reflects our overriding concern for patients and the physicians who treat them. As patient demands on joint implants increase, so does our commitment to delivering the most advanced implant technology to the market.

If you have any further questions please feel free to contact me directly

Best regards,

[redacted]

Medical Director Europe
Smith & Nephew Orthopaedics

FIELD SAFETY NOTICE

--- URGENT ---
FIELD SAFETY CORRECTIVE ACTION

Recall

R3° BIOLOX® forte Ceramic Acetabular Liners
Ref. no.:

Part #'s	Batch #'s
71331648	09KT36252, 10DT41428, 10FT43676, and 10FT43679
71331650	09KT36253, 10DT41528 and 10FT43085
71331652	09JT35943, 10CT40613, 10DT41486, 10FT43294, and 10FT43611
71331654	09HT34970, 09HT34971, 09JT35865, 10DT41337, 10FT43295, 10FT43677, and 10FT43680
71331656	09KT35979, 10DT41487, and 10DT41736
71331662	09KT36324, 10DT41489, and 10FT43061

March 10, 2011

DESCRIPTION OF THE PROBLEM

During the manufacturing process for several batches of R3 Ceramic Liners, the titanium rings were pressed onto the ceramic component with a higher force than specified. This has the potential to result in lower than expected strength for the liners.

Affected liners could potentially fracture earlier and at a higher rate than expected. In case of liner fracture an immediate surgical revision is necessary.

To date Smith & Nephew have not received any reports related to breakage of the liners affected by this recall.

REPORTING TO NATIONAL COMPETENT AUTHORITIES

All relevant National Competent Authorities have been advised of this FSCA.

ACTIONS TO BE TAKEN BY THE CUSTOMER / USER

- ■ Identify and quarantine affected devices
- ■ Order replacement as appropriate
- ■ Report any failure or other observations made in patient follow-up to your Smith & Nephew Subsidiary, Distributor, or to the manufacturer
- ■ Return not implanted devices to your distributor
- ■ For follow-up of patients implanted with affected devices follow your standard protocol.

Please maintain awareness on this notice and resulting action. This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

FIELD SAFETY NOTICE

RETURN INSTRUCTIONS

Exchange will be organized by the sales representative

CONTACTS

For questions, please contact:

Mr. Elmar von Agris, Quality Manager (Elmar.vonAgris@smith-nephew.com)

For general Information:

Legal manufacturer of the devices is: Smith & Nephew, Inc., Memphis, USA

The field action is coordinated in Europe and Middle East by: Smith & Nephew Orthopaedics AG, Aarau, Switzerland