

## Field Safety Notice

**Affected Product:** Ceramic Hip Prostheses  
**FSCA reference:** PER-12  
**FSCA action:** Revision of the Instructions for Use (IFU)  
**Date:** October 31, 2016  
**Details of affected product:** See below

Ceramic Component	Manufacturer	Part Number / Lot Codes
BIOLOX <sup>®</sup> <i>delta</i>	Corin Limited	All

Dear Surgeon

Data from sources external to Corin suggest that ceramic fragments from fractured ceramic components may remain in the joint following revision surgery, which can lead to premature wear of revision components if such revision components are made of non-ceramic materials.

As a result we wish to inform you that the instruction within the IFU for Corin's BIOLOX<sup>®</sup> *delta* ceramic components have been updated in respect of recommended actions in the case of revisions.

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

### **Information Relating to Patient Safety**

The Instructions for Use (IFU) are being revised to include the following information in the 'Warnings & Precautions' section:

"In the case of revision due to a fractured ceramic component, when keeping a well fixed stem, the modular head must be replaced with a Biolox Option<sup>3</sup> modular head where available. If a Biolox Option modular head is not available, in addition to revising the modular head, the femoral stem must also be revised to provide a suitable taper to which a new ceramic femoral ball head can be attached. In the event of revision not due to fracture of a ceramic component, when keeping a well fixed stem, the modular head must be replaced with a metal modular head or a Biolox Option ceramic modular head only."

<sup>3</sup>Not available in the USA

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### **Actions to be taken by the user**

1. Use Corin Limited products only in accordance with the revised Warnings & Precautions language above.
2. Complete the return slip and forward it to Corin Vigilance 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 organisation.
4. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

If you have any questions, please contact us on the following phone number +44 (0)1285 884781 or by e-mail: [vigilance@coringroup.com](mailto:vigilance@coringroup.com).

Yours sincerely



Corin Limited

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## Response Form

Please complete and return this feedback information before November 25, 2016 to the details specified below 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: PER-12

Name: \_\_\_\_\_

Date / Signature: \_\_\_\_\_

Please return response form to:

Email: [vigilance@coringroup.com](mailto:vigilance@coringroup.com)

Fax: +44 (0)1285 884730

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