URGENT: FIELD SAFETY NOTICE
E1-Tapered Liner

Date: 1st August 2012

Product Description: E1-Tapered 10º +3mm Liner 32/39

Product Part Number: E1-103239

Lot Number: All lots manufactured

FOR THE ATTENTION OF CLINICAL DIRECTORS / HEADS OF ORTHOPAEDIC DEPARTMENTS / TRAUMA DEPARTMENTS / OPERATING DEPARTMENTS / STERILE SERVICES DEPARTMENTS / PROCUREMENT / SUPPLIES / RISK MANAGEMENT

Dear Biomet Customer,

This Field Safety Notice is to inform you of an Urgent Medical Device Field Safety Corrective Action initiated by Biomet Spain Orthopaedics S.L. which involves the product listed above. Our records indicate that we have shipped products from the affected part number to your hospital. We are requesting that you immediately locate and discontinue use of any of the products with the part number E1-103239 and follow the recommendations listed below. The affected products must be returned to Biomet or to your local Biomet Distributor at the address on the cover letter.

The reason for this action:

The E1 Tapered liner is intended to substitute the acetabular part of the hip in combination with a cup. The uncemented cups are in direct contact with the acetabulum; they house the liner which contacts with the prosthetic femoral head. The joint between the cup and the liner is formed by conical adjustment.

Biomet Spain Orthopaedics S.L. has initiated this Field Safety Correction Action following the investigation on a reported event. It has been confirmed that in a few cases the affected product does not properly fit in the acetabular cup. This implies that the insert could not be impacted in the cup and another liner had to be used.

The conclusion of the investigation shows that there is a potential interference between the cup and the liner which is a design related issue.

Possible risks:

If the surgeon recognizes the potential interference, a delay in surgery may occur due to the fact that the surgeon is forced to take another liner.

Otherwise, if the surgeon does not recognize the potential interference (it may appear that the liner is fitted properly, however it will not be fully seated) and proceeds with the surgery, the following consequences might happen:

- Wear of the metal sleeve/cup due to micro-movements;
- Abnormal wear of the plastic component; or
- In cases of dislocations, a potential dissociation of the liner and the cup may occur that prevents a surgeon from doing a closed reduction, which may lead to a revision surgery.

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The probability of this scenario occurring has been determined as remote. Based on this probability it can be expected that the majority of liners already implanted will not encounter any of the before mentioned consequences.

What you need to do:

1) To assist us with this action please immediately discontinue the use of any product identified with the concerned part number.

2) Locate any products with the mentioned part number and remove them from your inventory as soon as possible. Please place the affected products in a quarantine area pending return to Biomet or to your local Biomet distributor.

3) Please pass this information on to each person in your organization that uses or orders these products. Additionally, please ensure that a copy of this letter is provided to any other organization to which the affected products may have been transferred.

4) Sign and return the enclosed "Fax-back form", and indicate the number of products with the concerned batch that you expect to return. This confirms that you have received, duly read, understand and will fully comply with this notice.

We thank you in advance for your attention to this matter.

Please accept our sincere apologies for any inconvenience caused by this matter.

If you have any questions regarding this communication, please contact your Biomet local contact.

Yours sincerely,

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