Customer
Address 1
Address 2

Urgent Medical Device Field Safety Corrective Action

Attention: Hospital Director, Risk Management, Medical Device Vigilance Coordinator

August 10, 2011

Name of the product	Reference	Batch
OPTILAVAGE SPLASH SHIELD 	4424	0000587852 0000589014 0000601675 0000611003 0000627498 0000628925 0000632644

Dear Biomet Customer,

This Field Safety Notice is to inform you of an Urgent Medical Device Field Safety Corrective Action initiated by Biomet France Sarl which involves the product listed above. Our records indicate that we have shipped products from the affected batches to your hospital. We are requesting that you immediately locate and discontinue use of any of the products from these batches. The products must be returned to Biomet or to your local Biomet Distributor at the address on the cover letter.

Please read the remaining information for an explanation of this request:

The Optilavage Splash Shield is used with the Optilavage system (reference 4410, 4418), to prevent splashing of fluids and debris during preparation of bone bed for joint replacement using bone cement.

During an internal quality inspection at one of our affiliates, a non-conformity was detected on the sealing part of the breather bags which are mainly used as primary and secondary packaging for the Optilavage Splash Shield.

An adverse health outcome may occur if due to damaged inner and/or outer packaging the product is no longer sterile. If the surgical staff does not recognize the condition of the breather bags prior to surgery, the possible adverse health outcome for the patient is an elevated risk of infection.

In such cases, antibiotics may be required. In rare circumstances, depending on the severity of the infection, the surgeon may decide that the patient might require a surgical intervention.

Biomet France SARL
58 Avenue de Lautagne – B.P.75 – F-26903 Valence Cedex 9
Téléphone : (33)04 75 75 91 00 – Fax : (33)04 75 75 91 01 – www.biomet.fr

What you need to do:

1) To assist us with this action please discontinue immediately the use of any of the products identified in this notice.

2) Locate any affected products and remove them from your inventory. Please place the products in a quarantine area pending return to Biomet or to your local Biomet distributor.

3) Please pass this information on to all in your organization who are using or ordering 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.

We thank you in advance for paying attention to this matter. Please sign and return the “Fax-back form” enclosed, and indicate the number of products that you expect to return. Kindly acknowledge that you have received, duly read and will fully comply with this notice.

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

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

Yours sincerely,

Biomet Contact
Quality and Regulatory Affairs Director

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