ZIMMER BIOMET
Your progress. Our promise.™

URGENT PRODUCT RECALL
JUNE 13, 2016

HTR (Hard Tissue Replacement) Polymer Implants
Part Number: See attached
Lot Numbers: See attached

Contact Name:
Distributor Name:
Address:
City, State Zip:

Dear Valued Customer / Distributor,

This notice is to inform you of an Urgent Product Recall by Biomet Microfixation which involves the Hard Tissue Replacement (HTR) Polymer Implants that have been consigned and/or invoiced to your distributor account.

The Biomet Microfixation team has initiated this action after identification of voids within the seals of the sterile packaging of the HTR implants. These voids may compromise the sterility of the implant, therefore leading to a risk of infection. Biomet Microfixation is requesting the following actions be taken:

This action requires the location and discontinued use of the items identified on page two of this notice, and their return to Biomet Microfixation. Specifically, you are REQUIRED to take the following steps:

- Locate and remove from circulation the items invoiced to your account as identified on page two of this notice.
- Carefully follow the instructions on the enclosed "FAX Back Response Form". Fax a copy of the Response Form to 904-741-9425 after receiving this notice and quarantining the product in your account.
- Use the FedEx label in this packet; this will be Biomet Microfixation's method of tracking your return.
- If you have further distributed these items to medical facilities, you MUST notify them of this action by providing the recipient a copy of this notice. This letter MUST be given to the person responsible for receiving recall notices. However, you are responsible for locating and returning these items.

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Health care professionals and consumers may report serious adverse events or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone:

- Online: www.fda.gov/MedWatch/report.htm
- Regular Mail: Use postage-paid FDA form 3500 available at www.fda.gov/Medwatch/getforms.htm and mail to Medwatch, 5600 Fishers Lane, Rockville, MD 20852-9787.
- Fax: (800) FDA-0178
- Phone: (800) FDA-1088

Thank you in advance for your assistance and prompt attention to this matter. The Biomet Microfixation team apologizes for any inconvenience resulting from this field action. If you have any questions please contact Kira Busto at 1-800-874-7711 or 904-741-4400, extension 9574, Monday through Friday, 8am-4pm ET. After business hours, please contact Kira Busto at 812-614-9499 with any questions.

Sincerely,

Jay Sharma
Quality Manager
Biomet Microfixation

The following units have been invoiced to your account:

Part Number	Lot Number	Quantity

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Fax Back Response Form

Attention:	Kira Busto
Fax Number:	904-741-9425
Regulatory Action:	Medical Device Recall
Description:	HTR PMMA Polymer Implants
Lot Number(s):	See attached

Instructions:

1. Fully complete the sections below.
2. FAX back the Response Form completed, **within three (3) business days** to FAX # 904-741-9425
3. For return items, ship the package via priority carrier utilizing the label attached, and **include a copy of this FAX Back Response Form with your shipment**. The box will be returned to:

   Recall #: 0001032347-6/13/2016-001R
   Biomet Microfixation
   Attn: Kira Busto
   1520 Tradeport Drive
   Jacksonville, FL 32218

Please check the appropriate boxes:

☐ We have the following items (or were located at the hospital) referenced in the enclosed letter and are quarantining them until return:

Part Number:	Lot Number:	Quantity:

☐ We have physically checked ALL inventory and hospital locations and we do not have the following affected product:

Part Number:	Lot Number:	Quantity:

Company/Distributor Name:	
Contact Name/Title:	
Phone Number:	
Address:	
Contact Signature:	