Date: February 8, 2017

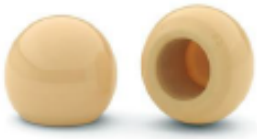
To Whom It May Concern:

MicroPort Orthopedics has initiated a voluntary Field Safety Corrective Action for BIOLOX FORTE 36mm Alumina ceramic heads. Implants will be updated with a label which will state the numerical offset of the ceramic head instead of the current labelling (Short, Medium, Long).

The intent of this letter is to inform you of all known risks potentially associated with the use of the products affected by this voluntary Field Safety Corrective Action and list any action to be taken by you.

***DETAILS OF AFFECTED DEVICES**:*

The following BIOLOX FORTE 36mm Alumina ceramic head part numbers are affected by this recall:



26000010	CERAMIC FEMORAL HEAD 36mm SLT TAPER SHORT NECK
26000011	CERAMIC FEMORAL HEAD 36mm SLT TAPER MEDIUM NECK
26000012	CERAMIC FEMORAL HEAD 36mm SLT TAPER LONG NECK

Please note: Only part numbers 26000010, 26000011, and 26000012 are involved in this recall. No other MicroPort Orthopedics Inc. products are involved in this recall.

DESCRIPTION OF THE PROBLEM AND POTENTIAL RISK:

It was found during MicroPort's investigation that the BIOLOX FORTE 36mm Alumina ceramic head was confirmed to measure approximately 2mm shorter than other MicroPort 36mm femoral heads (Cobalt Chrome and Biolox DELTA Ceramic femoral heads). The ultimate hazard would be joint laxity and/or dislocation, which could result in revision surgery.

ACTIONS TO BE TAKEN BY THE USER:

Our records indicate that you have received the above referenced product(s) however, you should check your inventory to verify this. Return the completed form by Fax: +1-901-451-6032 or by e-mail to: PostMarket@ortho.microport.com.

In the event that any of the affected lots are at your location and have not been used, please follow the advice below:

- Immediately check your internal inventory and quarantine all subject devices
- Circulate this Field Safety Notice internally to all affected parties
- Please inform MicroPort Orthopedics of any adverse event

- Please return any unused devices to your local MicroPort Orthopedics representative.

MicroPort Orthopedics recommends that surgeons maintain their usual follow-up protocol and actions for their patients and ensure that patients are informed about symptoms (particularly pain, instability, difficulty walking and/or performing common tasks) that indicate the need for revision surgery.

TRANSMISSION OF THIS NOTICE:

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.

CONTACT REFERENCE PERSON:

For questions or additional information please contact:

MicroPort Orthopedics
Email: PostMarket@ortho.microport.com

The undersigned confirms that this notice has been sent to the appropriate Regulatory Agency.

MicroPort Orthopedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Safety Corrective Action may create and appreciate your cooperation with our request.

Sincerely,
MicroPort Orthopedics

MicroPort Orthopedics Inc.

Field Safety Corrective Action Acknowledgement Form

FSCA Identifier: MP_FSCA170208

BIOLOX FORTE 36mm Alumina Ceramic Heads
Part Numbers: 26000010, 26000011, and 26000012

Name (PRINT)	
Hospital / Company Name	
Address	
Country	
Phone Number	

I have received the notification from MicroPort Orthopedics stating that they initiated a voluntary Field Safety Corrective Action of the above referenced products.

Signature _____ Date _____

Please return completed form to: PostMarket@ortho.microport.com