Date: July 7th, 2016

To Whom It May Concern:

MicroPort Orthopedics has initiated a voluntary Field Safety Corrective Action for Metal on Metal - Total Hip Arthroplasty (THA) indication. Implants will be updated with a label which states what part numbers can be used with the Conserve Cup product and the Instructions for Use have been revised to remove the Metal on Metal THA indication. The product will receive the new label and IFU and then distributed. Attachment B includes the new IFU.

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**:*

1) CONSERVE® Shell
2) DYNASTY® Metal Liner
3) PROCOTYL® Metal Liner
4) LINEAGE® Metal Liner

See Attachment A for part number list.

DESCRIPTION OF THE PROBLEM AND POTENTIAL RISK:

Investigation of the Metal on Metal THA systems shows an increasing overall trend in revisions from 2009 to present, and it was found that there was a specific hazard/harm for "suspected tissue reaction to metal debris". The potential for a patient reaction when implanted with Metal on Metal THA is a known risk for this product technology. The typical impairment of tissue reaction is reversed by revision surgery to remove the old device and replace it with a new device.

ACTIONS TO BE TAKE 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 on 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.

MicroPort Orthopedics

MicroPort Orthopedics Inc.

Field Safety Corrective Action Acknowledgement Form

FSCA Identifier: MP_FSCA160621B

See Attachment A for part number list

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: PostMarketQuality@ortho.microport.com