

MicroPort Orthopedics

FSCA – Identifier: MP_FSCA160621C

FIELD SAFETY CORRECTIVE ACTION – Immediate Attention Required

Date: July 7th, 2016

To Whom It May Concern:

MicroPort Orthopedics has initiated a voluntary Field Safety Corrective Action for ADVANCE[®] HA Coated Tibial Bases.

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:

Item Number	Description
ALL	ADVANCE [®] HA Coated Tibial Bases

DESCRIPTION OF THE PROBLEM AND POTENTIAL RISK:

MicroPort Orthopedics Inc. is voluntarily recalling ADVANCE[®] HA Coated tibial bases regarding a higher than expected revision rate due to component loosening. All lots of the ADVANCE[®] HA Coated Tibial Bases are included in this recall. The hazard would be a patient would require a revision surgery due to the loosening of the Advance HA Tibial Component.

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.

Urgent Field Safety Notice

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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.**

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Field Safety Corrective Action Acknowledgement Form

Item Number	Description	Description Line 2
All	ADVANCE® HA Coated Tibial Bases	

ALL LOTS

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