

MicroPort Orthopedics

FSCA – Identifier : MP_FSCA150803

FIELD SAFETY CORRECTIVE ACTION – Immediate Attention Required

Date: August 11th, 2015

To Whom It May Concern:

MicroPort Orthopedics has initiated a voluntary Field Safety Corrective Action for PROFEMUR® Neck Var/Val Long CoCr, part number PHAC1254, all lots.

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	Description Line 2
PHAC1254	PROFEMUR® NECK VAR/VAL 8DG	LONG COBALT CHROME

DESCRIPTION OF THE PROBLEM AND POTENTIAL RISK:

MicroPort Orthopedics Inc. has seen an unexpected rate of postoperative fractures of the femoral neck component, PHAC1254.

A potential fracture cannot be detected during surgery, by visual inspection or any other diagnostic technique. Should a fracture occur the patient may experience sudden pain, instability and difficulty walking/performing common tasks. Due to the sudden pain and loss of mobility, it is expected the patient will recognize immediately the device is not functioning properly and seek medical attention. A fractured femoral neck will need revision surgery to correct.

PLEASE NOTE: NO other fractures have been reported with any other size in the PROFEMUR® COCr Neck family.

ACTIONS TO BE TAKE BY THE USER:

Our records indicate that you did receive the above referenced product:

- Immediately check inventory and quarantine all subject products
- **COMPLETE AND RETURN** the attached FSCA Acknowledgement
- Inform MicroPort Orthopedics of any adverse event immediately
- Return any affected product to MicroPort Orthopedics, please see your local distributor for details

MicroPort Orthopedics does not recommend prophylactic revision surgery but does advise that you continue to monitor patients according *standard follow up protocol*.

TRANSMISSION OF THIS NOTICE:

This notice needs to be passed on to all those who need to be aware within your organization.

Urgent Field Safety Notice

Page 2 of 3

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CONTACT REFERENCE PERSON:

For questions or additional information please contact:

Victor Bernardo, Authorized Rep.
MicroPort Orthopedics BV
Phone: +31 (0) 205 450 176
Email: VBERNARDO@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.

Victor Bernardo

Authorized Representative

MicroPort Orthopedics BV

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MicroPort Orthopedics Inc.

Field Safety Corrective Action Acknowledgement Form

FSCA Identifier: MP_FSCA150803

Item Number	Description	Description Line 2
PHAC1254	PROFEMUR® NECK VAR/VAL 8DG	LONG COBALT CHROME

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: VBERNARDO@ortho.microport.com