Date: July 10, 2020

To Whom It May Concern:

MicroPort Orthopedics has initiated a voluntary Field Safety Corrective Action for PROFEMUR® Long Titanium Modular Necks, all lots.

The intent of this letter is to notify you of a voluntary recall of PROFEMUR® Long Titanium Modular Necks and 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	
PHA01204	PROFEMUR® NECK NEUTRAL	LONG
PHA01214	PROFEMUR® NECK A/R VAR/VAL 2	LONG
PHA01224	PROFEMUR® NECK A/R VAR/VAL 1	LONG
PHA01234	PROFEMUR® NECK 8DG A/R	LONG
PHA01244	PROFEMUR® NECK 15DG A/R	LONG
PHA01254	PROFEMUR® NECK 8DG VAR/VAL	LONG
PHA01264	PROFEMUR® NECK 15DG VAR/VAL	LONG

DESCRIPTION OF THE PROBLEM AND POTENTIAL RISK:

MicroPort Orthopedics Inc. continues to receive reports of fracture of PROFEMUR® Long Titanium modular necks.

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.

ACTIONS TO BE TAKEN 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 to *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.

CONTACT REFERENCE PERSON:

For questions or additional information please contact:

Sibel Dizdaroglu, Authorized Rep.
MicroPort Scientific Coöperatief U.A.
Phone: +31 20 545 01 00
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.

Sibel Dizdaroglu
Authorized Representative
MicroPort Scientific Coöperatief U.A.

MicroPort Orthopedics Inc.

Field Safety Corrective Action Acknowledgement Form

FSCA Identifier: MP_FSCA20030001

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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.

I have _____ units of the recalled device on hand and am returning _____ units of the recalled device.

_____ _____

Signature Date

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