Date: July 10, 2020

To Whom It May Concern:

MicroPort Orthopedics has initiated a voluntary Field Safety Corrective Action for PROFEMUR® Titanium and Cobalt Chrome modular necks, all lots.

The intent of this letter is to notify you of a voluntary recall of PROFEMUR® Titanium and Cobalt Chrome 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	Description 2
PHAC1202	PROFEMUR® NECK NEUTRAL	SHORT COBALT CHROME
PHAC1204	PROFEMUR® NECK NEUTRAL	LONG COBALT CHROME
PHAC1212	PROFEMUR® NECK A/R VAR/VAL 2	SHORT COBALT CHROME
PHAC1214	PROFEMUR® NECK A/R VAR/VAL 2	LONG COBALT CHROME
PHAC1222	PROFEMUR® NECK A/R VAR/VAL 1	SHORT COBALT CHROME
PHAC1224	PROFEMUR® NECK A/R VAR/VAL 1	LONG COBALT CHROME
PHAC1232	PROFEMUR® NECK A/R 8DG	SHORT COBALT CHROME
PHAC1234	PROFEMUR® NECK A/R 8DG	LONG COBALT CHROME
PHAC1242	PROFEMUR® NECK A/R 15DG	SHORT COBALT CHROME
PHAC1244	PROFEMUR® NECK A/R 15DG	LONG COBALT CHROME
PHAC1252	PROFEMUR® NECK VAR/VAL 8DG	SHORT COBALT CHROME
PHA01202	PROFEMUR® NECK NEUTRALSHORT	SHORT
PHA01204	PROFEMUR® NECK NEUTRAL	LONG
PHA01206	PROFEMUR® NECK NEUTRAL	X LONG
PHA01212	PROFEMUR® NECK A/R VAR/VAL 2	SHORT
PHA01214	PROFEMUR® NECK A/R VAR/VAL 2	LONG
PHA01222	PROFEMUR® NECK A/R VAR/VAL 1	SHORT
PHA01224	PROFEMUR® NECK A/R VAR/VAL 1	LONG
PHA01232	PROFEMUR® NECK 8DG A/R	SHORT
PHA01234	PROFEMUR® NECK 8DG A/R	LONG
PHA01236	PROFEMUR® NECK 8DG A/R	X LONG
PHA01242	PROFEMUR® NECK 15DG A/R	SHORT
PHA01244	PROFEMUR® NECK 15DG A/R	LONG
PHA01252	PROFEMUR® NECK 8DG VAR/VAL	SHORT
PHA01254	PROFEMUR® NECK 8DG VAR/VAL	LONG
PHA01256	PROFEMUR® NECK 8DG VAR/VAL	X LONG
PHA01262	PROFEMUR® NECK 15DG VAR/VAL	SHORT
PHA01264	PROFEMUR® NECK 15DG VAR/VAL	LONG

DESCRIPTION OF THE PROBLEM AND POTENTIAL RISK:

MicroPort Orthopedics Inc. is replacing the package insert for all affected products with the most recent revision (150803-8).

PROFEMUR® Titanium and Cobalt Chrome modular neck package inserts have been revised over time. As a new revision of the package insert is released, existing package inserts for modular neck products in the field have not been replaced.

Please note: the current package insert is always publicly available for surgeons and the general public at http://ortho.microport.com/index.cfm/ifus/.

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 advises end users to 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_FSCA20030002***

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See Attachment A for Specific 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.

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