

MicroPort Orthopedics

FSCA – Identifier : MP\_FSCA20030002

**FIELD SAFETY CORRECTIVE ACTION – Immediate Attention Required****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 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:**

| <b>Item Number</b> | <b>Description</b>           | <b>Description 2</b> |
|--------------------|------------------------------|----------------------|
| <b>PHAC1202</b>    | PROFEMUR® NECK NEUTRAL       | SHORT COBALT CHROME  |
| <b>PHAC1204</b>    | PROFEMUR® NECK NEUTRAL       | LONG COBALT CHROME   |
| <b>PHAC1212</b>    | PROFEMUR® NECK A/R VAR/VAL 2 | SHORT COBALT CHROME  |
| <b>PHAC1214</b>    | PROFEMUR® NECK A/R VAR/VAL 2 | LONG COBALT CHROME   |
| <b>PHAC1222</b>    | PROFEMUR® NECK A/R VAR/VAL 1 | SHORT COBALT CHROME  |
| <b>PHAC1224</b>    | PROFEMUR® NECK A/R VAR/VAL 1 | LONG COBALT CHROME   |
| <b>PHAC1232</b>    | PROFEMUR® NECK A/R 8DG       | SHORT COBALT CHROME  |
| <b>PHAC1234</b>    | PROFEMUR® NECK A/R 8DG       | LONG COBALT CHROME   |
| <b>PHAC1242</b>    | PROFEMUR® NECK A/R 15DG      | SHORT COBALT CHROME  |
| <b>PHAC1244</b>    | PROFEMUR® NECK A/R 15DG      | LONG COBALT CHROME   |
| <b>PHAC1252</b>    | PROFEMUR® NECK VAR/VAL 8DG   | SHORT COBALT CHROME  |
| <b>PHA01202</b>    | PROFEMUR® NECK NEUTRALSHORT  | SHORT                |
| <b>PHA01204</b>    | PROFEMUR® NECK NEUTRAL       | LONG                 |
| <b>PHA01206</b>    | PROFEMUR® NECK NEUTRAL       | X LONG               |
| <b>PHA01212</b>    | PROFEMUR® NECK A/R VAR/VAL 2 | SHORT                |
| <b>PHA01214</b>    | PROFEMUR® NECK A/R VAR/VAL 2 | LONG                 |
| <b>PHA01222</b>    | PROFEMUR® NECK A/R VAR/VAL 1 | SHORT                |
| <b>PHA01224</b>    | PROFEMUR® NECK A/R VAR/VAL 1 | LONG                 |
| <b>PHA01232</b>    | PROFEMUR® NECK 8DG A/R       | SHORT                |
| <b>PHA01234</b>    | PROFEMUR® NECK 8DG A/R       | LONG                 |
| <b>PHA01236</b>    | PROFEMUR® NECK 8DG A/R       | X LONG               |
| <b>PHA01242</b>    | PROFEMUR® NECK 15DG A/R      | SHORT                |
| <b>PHA01244</b>    | PROFEMUR® NECK 15DG A/R      | LONG                 |
| <b>PHA01252</b>    | PROFEMUR® NECK 8DG VAR/VAL   | SHORT                |
| <b>PHA01254</b>    | PROFEMUR® NECK 8DG VAR/VAL   | LONG                 |
| <b>PHA01256</b>    | PROFEMUR® NECK 8DG VAR/VAL   | X LONG               |
| <b>PHA01262</b>    | PROFEMUR® NECK 15DG VAR/VAL  | SHORT                |
| <b>PHA01264</b>    | PROFEMUR® NECK 15DG VAR/VAL  | LONG                 |

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**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.

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**Urgent Field Safety Notice**

Page 3 of 3

MicroPort Orthopedics

FSCA – Identifier : MP\_FSCA20030002

**FIELD SAFETY CORRECTIVE ACTION – Immediate Attention Required**

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**CONTACT REFERENCE PERSON:**

For questions or additional information please contact:

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| <b>Sibel Dizdaroglu, Authorized Rep.</b> |
| 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

FSCA – Identifier : MP\_FSCA20030002

FIELD SAFETY CORRECTIVE ACTION – Immediate Attention Required



## MicroPort Orthopedics Inc.

### Field Safety Corrective Action Acknowledgement Form

FSCA Identifier: *MP\_FSCA20030002*

| 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  |
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| 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                |

**See Attachment A for Specific Lots**

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**Urgent Field Safety Notice**

Page 5 of 3

MicroPort Orthopedics

FSCA – Identifier : MP\_FSCA20030002

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|------------------------------------|--|
| <b>Name (PRINT)</b>                |  |
| <b>Hospital /<br/>Company Name</b> |  |
| <b>Address</b>                     |  |
| <b>Country</b>                     |  |
| <b>Phone Number</b>                |  |

I have received the notification from MicroPort Orthopedics stating that they initiated a voluntary Field Safety Corrective Action of the above referenced products.

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Signature

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Date

Please return completed form to: [PostMarket@ortho.microport.com](mailto:PostMarket@ortho.microport.com)