

MicroPort Orthopedics

FSCA – Identifier: MP_FSCA22100002

FIELD SAFETY CORRECTIVE ACTION – Immediate Attention Required

Date: 27 October 2022

To Whom It May Concern:

MicroPort Orthopedics has initiated a voluntary field action for two lots of EVOLUTION® MP Tibial Bases, ETPKN2PL lot 1916559 and ETPKN7SL lot 1916715.

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 to list any action to be taken by you.

DETAILS OF AFFECTED DEVICES:

Item Number	Description	Lot
ETPKN2PL	EVOLUTION® MP Tibial Base Keeled Nonporous Size 2+ Left	1916559
ETPKN7SL	EVOLUTION® MP Tibial Base Keeled Nonporous Size 7 Left	1916715

DESCRIPTION OF THE PROBLEM AND POTENTIAL RISK:

One confirmed incident has been received that ETPKN2PL lot 1916559, size 2 Evolution MP Tibial Base, was opened during surgery and contained ETPKN7SL lot 1916715, size 7 Evolution MP Tibial Base, in the packaging.

As a result of this incident, a field action has been initiated for ETPKN2PL lot 1916559 and ETPKN7SL lot 1916715 due to a potential for mislabeled product.

MicroPort has confirmed that the entire lots are not affected and the majority of each lot should contain the correct product, however the exact number of affected items in each lot is unknown.

The physical devices for both ETPKN2PL lot 1916559 and ETPKN7SL lot 1916715 are laser marked with the correct part number, lot number, and size. A size 7 tibial base is significantly larger than a size 2 tibial base, and these implants are not cross compatible with tibia preparations or mating devices. Based on this information it is expected that the issue would be identified intraoperatively, and no incorrect devices would be implanted. Any surgeries already successfully completed without incident would have involved unaffected products.

If the problem is encountered, the most likely outcome is the need to acquire a backup device and implants are usually readily available due to the hospital or sales representative having replacement stock. However, there is a risk of delay in surgery if the same size device is not available and a different size implant must be selected.

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

Urgent Field Safety Notice

Page 2 of 3

MicroPort Orthopedics

FSCA – Identifier: MP_FSCA22100002

FIELD SAFETY CORRECTIVE ACTION – Immediate Attention Required

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:

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.

MicroPort Orthopedics

FSCA – Identifier: MP_FSCA22100002

FIELD SAFETY CORRECTIVE ACTION – Immediate Attention Required



MicroPort Orthopedics Inc.

Field Safety Corrective Action Acknowledgement Form

FSCA Identifier: MP_FSCA22100002

Item Number	Description	Lot
ETPKN2PL	EVOLUTION® MP Tibial Base Keeled Nonporous Size 2+ Left	1916559
ETPKN7SL	EVOLUTION® MP Tibial Base Keeled Nonporous Size 7 Left	1916715

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 and will return any affected products.

Signature

Date

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