URGENT: FIELD SAFETY NOTICE

FSN 3008524126-1-20-15-001

January 20, 2015

Orthofix Inc. is conducting a **Field Safety Corrective Action** relevant to the following medical device:

ISKD - Intramedullary Skeletal Kinetic Distractor (Limb Lengthener)

Model Number	Serial Number
F12-255-305	1552104A
F12-255-305	1552105A
F12-255-305	1552106A

There is a possibility that these ISKD limb lengthening devices could distract beyond the intended treatment length.

Our records indicate that you have received an affected ISKD limb lengthening device. Do not use any products involved in this action and immediately return them to Orthofix (see contact details below). For patients who already have an affected ISKD limb lengthener implanted, we recommend close radiographic follow-up with an adjustment of post-operative activities as described in the attached letter to Health Care Providers.

ISKD Limb Lengtheners with the above serial numbers are to be identified, removed from inventory, and returned to Orthofix Srl. within 10 working days from receipt of this notification, or no later than January 30, 2015.

Credit will be issued upon receipt of the returned product at Orthofix.

If the recalled devices shipped to you have been further transferred to other hospitals or physicians, please ensure that all who received, or who may have received, affected units from you are provided immediately with this Field Safety Notice.

We request your complete cooperation in assisting us with this removal. The actions listed in the enclosed Product Return Instructions are to be taken immediately.

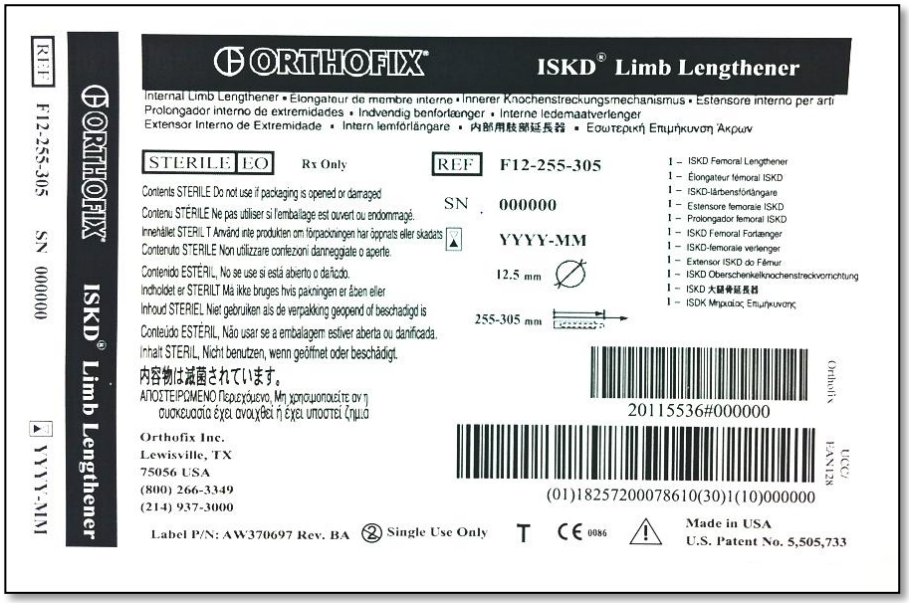
If you have any questions regarding the removal and return of this product to Orthofix Srl., please contact Orthofix Customer Service by telephone at +39 045 6719000 or e-mail at CustomerCare@Orthofix.it.

PRODUCT RETURN INSTRUCTIONS

ISKD - Intramedullary Skeletal Kinetic Distractor (Limb Lengthener)

1) Identify and remove any unused ISKD Limb Lengtheners with serial numbers 1552104A, 1552105A, and 1552106A from your inventory.

An example of the package label and a picture of the device are shown below:



2) Package and return the product to Orthofix Srl, referencing the RMA number provided to you by Customer Service. Credit will be issued upon receipt of the returned product at Orthofix.

3) If the recalled devices shipped to you have been further transferred to other hospitals or physicians, ensure that all who received, or who may have received, affected units from you are provided immediately with this Field Safety Notice.

4) Complete the enclosed Tracking and Verification Form and send it via fax to Orthofix Srl. Customer Service at +39 0456719380, <u>even if you do not have any affected ISKD devices in your possession</u>.

Tracking and Verification Form

ISKD - Intramedullary Skeletal Kinetic Distractor (Limb Lengthener)

ISKD Limb Lengtheners with serial numbers 1552104A, 1552105A and 1552106A are to be identified, removed from inventory, and returned to Orthofix Srl. within 10 working days from receipt of this notification, or no later than January 30, 2015.

(Check boxes 1 and 2, and either 3 or 4):

1. ☐ **Acknowledgement. I acknowledge receipt of the ISKD Field Safety Notice.**

2. ☐ **Verification. I have verified that all areas where product could be located have been checked (inventory, shipping/receiving, hospitals, transfers to other distributors, etc.).**

3. ☐ **I have identified / located affected product and will return the following product to Orthofix (attach additional pages as needed):**

Model Number	Serial Number(s)

4. ☐ **I do not have affected product, nor have I transferred affected product.**

Hospital/Physician Name: _____

Assigned RMA #: _____

Authorized Signature: _____

Please Print or Type: _____ _____

Name and Title Date

FAX COMPLETED FORM TO +39 045 6719380

January 20, 2015

Dear Health Care Provider,

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F12-255-305	1552105A
F12-255-305	1552106A

For patients who already have an affected ISKD limb lengthener implanted, there is a possibility that these devices could distract beyond the intended treatment length. The affected devices may distract a maximum of 80mm instead of the specified 50mm.

Prior to implantation, your device pre-distraction calculation may have been based on a 50mm lengthener. However, because the device implanted may distract 80mm there is a risk that patient distraction may be 30mm in excess of what was calculated.

We recommend close radiographic follow-up with adjustment of post-operative activities once desired lengthening has been achieved.

The Orthofix Medical Director is available to discuss options for over-distraction mitigation on a case-by-case basis with the implanting surgeon.

We apologize for any inconvenience this may cause and should you have any questions or concerns, please contact [redacted], Orthofix Regulatory Affairs, by telephone at [redacted] or by e-mail at [redacted]@Orthofix.com.