URGENT: FIELD SAFETY NOTICE

FSCA 3008524126-8-8-12-001

August 7, 2012

Dear Distributor/Hospital,

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

ISKD - Intramedullary Skeletal Kinetic Distractor (Limb Lengthener)

F12-255-305	F12-345-395NS	T12-245-295
F12-255-305NS	F12-345-425	T12-255-305
F12-255-335	F12-345-425NS	T12-255-305NS
F12-255-335NS	T10-215-265	T12-255-335
F12-300-350	T10-255-305	T12-255-335NS
F12-300-350NS	T10-255-335	T12-300-350
F12-300-380	T10-300-350	T12-300-350NS
F12-300-380NS	T12-215-265	T12-300-380
F12-345-395	T12-215-265NS	T12-300-380NS

There is a possibility that the ISKD limb lengthener may stop distracting post-operatively during treatment, which may result in premature bone consolidation (limb not achieving the desired length) leading to revision surgery to remove and/or replace the device.

Our records indicate that you have received ISKD limb lengthening devices. We recommend discontinuing distribution and/or use of these devices. For patients currently having an ISKD limb lengthener implanted, we recommend continuing their prescribed post-operative activities and radiographic follow-up.

All ISKD Limb Lengtheners 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 August 20, 2012.

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

If the recalled devices shipped to you have been further distributed to hospitals, surgeons and/or other distributors, 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.

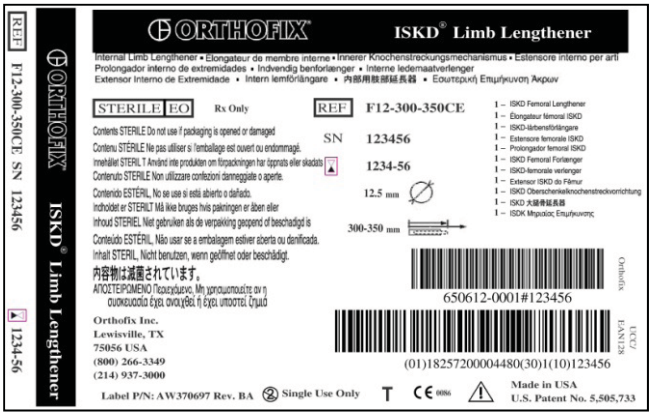
.

PRODUCT RETURN INSTRUCTIONS

ISKD - Intramedullary Skeletal Kinetic Distractor (Limb Lengthener)

1) **Identify and remove <u>all</u> ISKD Limb Lengtheners 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 Inc. using the enclosed Return Authorization sheet. Credit will be issued upon receipt of the returned product at Orthofix.**

3) **If the recalled devices shipped to you have been further distributed to hospitals, surgeons or other distributors, 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 fax to the Orthofix Srl. Customer Service at fax +39 0456719380, <u>even if you do not have any ISKD devices in your possession</u>.**

Tracking and Verification Form

ISKD - Intramedullary Skeletal Kinetic Distractor (Limb Lengthener)

All ISKD Limb Lengtheners 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 August 20, 2012.

(Check boxes 1 and 2, either 3 or 4, and either 5 or 6):

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 distributed or transferred affected product.**

5. ☐ **I have verified that no affected product was sold to any hospital or surgeon.**

6. ☐ **I have identified all hospitals, surgeons, and/or other distributors who received affected product, have provided them with the Field Safety Notice, and collected devices remaining in their inventory (reported in the table above).**

Distributor Name: _____

Assigned RMA #: _____

Authorized Signature: _____

Please Print or Type: _____ _____

Name and Title Date

FAX COMPLETED FORM TO +39 045 6719380

3451 Plano Parkway | Lewisville, Texas 75056 USA
www.orthofix.com