URGENT: FIELD SAFETY NOTICE
FSCA 3008524126-02/01/13-001-R

January 30, 2013

Dear Distributor/Hospital,

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

Firebird Spinal Fixation System
Parallel Rod Connector (52-6800) and Axial Rod Connector (52-6700)

There is a possibility that the Set Screw sub-component of the Parallel Rod Connector Assembly (PN 52-6800) and Axial Rod Connector (52-6700) may crack during final tightening, which may result in a surgical delay of more than 30 minutes while the Parallel Rod Connector or Axial Rod Connector is removed and replaced with an alternate Parallel Rod Connector Assembly (PN 52-6800 or alternate PN 52-6805).

Our records indicate that you have received Firebird Spinal Fixation Parallel Rod Connector and Axial Rod Connector devices. Please refer to the attached inventory summary sheet. We recommend discontinuing use of these devices.

All Firebird Spinal Fixation System Parallel Rod Connectors and Axial Rod Connectors are to be identified and removed from inventory immediately. Once identified and removed, all affected units must be returned to Orthofix within 10 working days from receipt of this notification, or no later than February 13, 2013.

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

Please ensure that any surgeons who received, may have received, or may receive affected units are immediately provided 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.

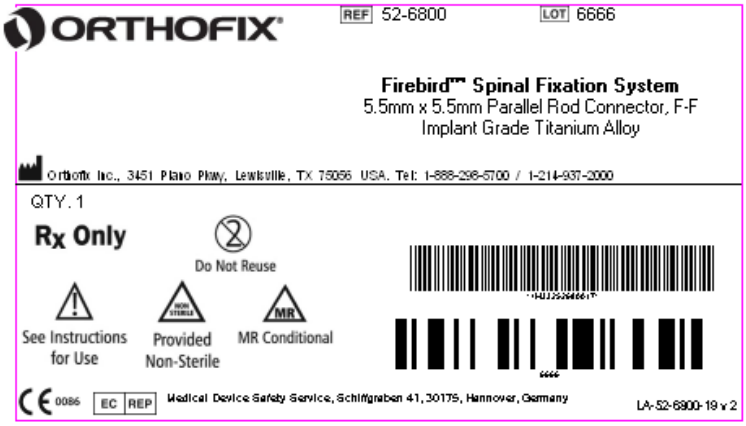
If you have any questions regarding the removal and return of this product to Orthofix, please contact Orthofix Customer Service by telephone at 800-266-3349. Should you have any other questions or concerns, please contact [redacted], Regulatory Affairs, by telephone at 214-937-[redacted] or by e-mail at [redacted]Orthofix.com. Thank you for your assistance with this matter.

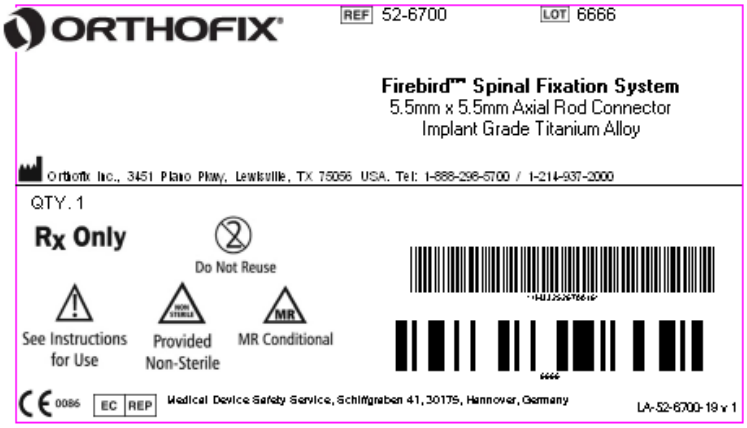
PRODUCT RETURN INSTRUCTIONS

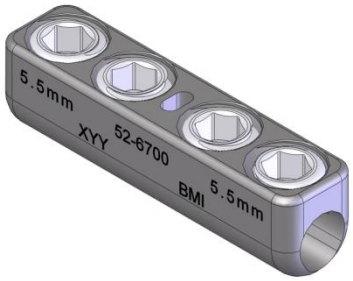
Firebird Spinal Fixation System
Parallel Rod Connector (52-6800) and Axial Rod Connector (52-6700)

1) Identify and remove <u>all</u> Firebird Spinal Fixation System Parallel Rod Connectors (52-6800) and Axial Rod Connectors (52-6700) devices from your inventory.

An example of the package labels and pictures of the device are shown below:







2) Contact your Customer Service Representative at 888-298-5700 to arrange the return of affected devices to Orthofix.

3) Complete the enclosed Tracking and Verification Form and fax to the Orthofix Inc. Regulatory Affairs Department at fax 214-937-3322, <u>even if you do not have any Firebird Spinal Fixation System Parallel Rod Connectors and Axial Rod Connectors in your possession</u>.

Tracking and Verification Form

Firebird Spinal Fixation System

Parallel Rod Connectors (52-6800) and Axial Rod Connector (52-6700)

All Firebird Spinal Fixation System Parallel Rod Connectors and Axial Rod Connectors are to be identified and removed from inventory immediately. Once identified and removed, all affected units must be returned to Orthofix within 10 working days from receipt of this notification, or no later than February 13, 2013.

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

1. ☐ **Acknowledgement. I acknowledge receipt of the Firebird Spinal Fixation System 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):**

Product Number	Lot Numbers	Quantity Being Returned
52-6800	ALL	
52-6700	ALL	

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 214-937-3322

3451 Plano Parkway | Lewisville, Texas 75056 | 800-266-3349
www.orthofix.com