

URGENT-FIELD SAFETY NOTICE

To: Alphatec Spine Customers/Distributors
From: Richard Welch, Sr. Director of Compliance
Date: 11 Mar 2016
Re: Field Safety Corrective Action (FSCA) – Osseofix Sterile Package Implant 5.5mm

A. ***Product Information***

Reference Number	Description	Affected Lot Number(s)
21298-55	Osseofix Sterile Package Implant 5.5mm Size	697770 697771 698986 698987 698988 701193 701768

The OsseoFix Spinal Fracture Reduction System is intended to be used for the treatment of acute, painful vertebral compression fractures by providing internal fixation and stabilization using a titanium implant in conjunction with OsseoFix+ PMMA bone cement. These implants are not intended for placement in the cervical spine.

B. ***Reason for the Field Safety Corrective Action (FSCA)***

January through February 2016 Alphatec Spine, Inc. received multiple complaints asserting a non-conformity within the inside diameter of the Osseofix Inserter Cannula preventing full insertion of the Implant Removal Tool. Alphatec has confirmed a limited number of cannulas assembled into the seven (7) finished product lots identified above were manufactured incorrectly and may contain a partial or full obstruction.

An obstructed cannula may be too small for or present a barrier to the insertion of subsequent materials and/or instruments post implant deployment. The physician may experience difficulty and much resistance while injecting bone cement and/or attempting to use the cannula removal instrument.

Not all cannulas within the identified lots are non-conforming. Alphatec has determined the non-conformities are specific to sterile device sets containing cannulas manufactured by a specific second source supplier. The non-conforming cannulas are confined to two

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(2) subassembly lots from this second source supplier. These non-conforming cannulas were in turn assembled into seven (7) finished product lots which contain both conforming cannulas from a primary source supplier as well as the non-conforming cannulas from the second source supplier.

To address this concern, Alphatec Spine is implementing a voluntary Field Safety Corrective Action (FSCA). Our records indicate that your facility has received a portion of the affected product included in this FSCA.

C. *Potential Risks*

Short-Term Risk:

If the obstruction is of enough significance, use of the removal instrument may be prohibited and require un-deployment and removal of the implant and cannula together as a unit. Un-deployment and removal of the implant and cannula together as a unit may extend the procedure time. Un-deployment and removal of the implant and cannula together as a unit may lead to procedure related complications.

The device is not approved for use nor intended for placement in the cervical spine. The consequences described above along with those consistent with off-label use of the device at the C1 thru C7 locations remain unchanged.

Long-Term Risk:

There are no expected long-term health consequences associated with this non-conformity upon successful implant and subsequent removal of the cannula.

Mitigation:

Any mitigation is limited to detection and replacement prior to use. General surgical procedure requires the assisting clinician to verify the fit and function of each component/instrument prior to the procedure.

D. *Instructions*


- Please review promptly your inventory to determine if any of the affected product is within your possession.
- Please abstain from sale and/or use and contact Alphatec Spine International Customer Service (internationalcs@alphatecspine.com) for instructions on how to carry out a product return. All shipping instructions will be provided, including arrangements for product replacement.

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- Please fill out the last page of this letter to confirm that you have read this notification and have taken all necessary actions as described herein. Please return a signed copy using one of the methods below:
 - Mail to: **Alphatec Spine, Inc.,
5818 El Camino Real,
Carlsbad, CA 92008
ATTN: Richard Welch**
 - Email to: rwelch@alphatecspine.com
 - Fax to: 1-800-431-7729 to Richard Welch (Recall Coordinator)
- Please share this notice with all those who need to be aware within your organization or any organization where the affected product has been transferred.
- Please transfer this notice to other organizations on which this FSCA has an impact.

Thank you for your cooperation. The undersigned confirms this Field Safety Notice has been provided to the appropriate regulatory authorities.

Kind regards,



Richard Welch
Sr. Director Compliance
Alphatec Spine, Inc.

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RE: Field Safety Corrective Action (FSCA) - Osseofix Sterile Package Implant 5.5mm

We have reviewed our inventory and have determined the following with regard to the affected product:

- The Osseofix Sterile Package Implant 5.5mm DOES NOT exist in our inventory. The devices have been previously consumed or discarded:**

Lot Number: _____ Quantity Consumed: _____

Lot Number: _____ Quantity Consumed: _____

Lot Number: _____ Quantity Consumed: _____

Lot Number: _____ Quantity Consumed: _____

Lot Number: _____ Quantity Consumed: _____

- The Osseofix Sterile Package Implant 5.5mm exists in our inventory, and will be returned without undue delay:**

Lot Number: _____ Inventory Quantity: _____

Lot Number: _____ Inventory Quantity: _____

Lot Number: _____ Inventory Quantity: _____

Lot Number: _____ Inventory Quantity: _____

Lot Number: _____ Inventory Quantity: _____

Lot Number: _____ Inventory Quantity: _____

- Other:**

By signing below, the undersigned certifies as to the accuracy of the statements above on behalf of the customer/distributor listed below.

Read and agreed:

Print Name: _____

Title: _____

Signature/Date: _____

Name of Distributor: _____