



URGENT - FIELD SAFETY NOTICE

Illico, TARGETING NEEDLE, 11G, STERILE PACKAGED

November 6, 2020 (Ref: 2020-005)

Field Safety Corrective Action (Recall/Withdrawal)

November 6, 2020

Attention: ZIMMO Trading Company Ltd. (Authorised Representative)

Details on affected devices:

Description: TARGETING NEEDLE, 11G, STERILE PACKAGED

Part Number: 73701-11

Lot: 23360

Description of the problem:

It was recently discovered that the Tyvek packaging failed bubble leak testing of for a sample of products from lot 23360. At this time, we do not believe that all the units are compromised, but it is very difficult to visually identify if the sterile barrier is intact or not. Based on the potential risk of using a non-sterile instrument in surgery which could result in an infection we are requesting all units to be returned and to report any adverse events associated with the affected product.

Our records indicate that your facility may have received the affected product included in this recall. We are requesting that you immediately quarantine all units of this product and contact Alphatec Spine, Inc. to return the products accordingly.

Advise on action to be taken by the user:

- Upon receipt of this Field Safety Notice, please review your inventory to determine if this affected PN: 73701-11 Lot: 23360 is in your possession.
- If this product is within your possession, please quarantine any remaining units and contact Alphatec Spine International Customer Service Department (internationalcs@alphatecspine.com) immediately for instructions on how to return



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this affected product. All shipping instructions will be provided, including replacement product and/or credit.

- Please fill out page 3 of this letter to confirm that you have read this notification and have taken all necessary actions as described in this notification.
- Please return a signed copy using one of the methods below:
 - Mail to: **Alphatec Spine, Inc.,**
5818 El Camino Real,
Carlsbad, CA 92008
ATTN: Product Return (Ref: 2020-005)
 - Email to: jmarkovich@atecspine.com

Contact reference person:

Jeremy Markovich
Director, Regulatory and Clinical Affairs
Alphatec Spine, Inc.
Phone: +1 760.494.6893
jmarkovich@atecspine.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Thank you for your cooperation and please contact Alphatec Spine, Inc. if you have any questions.

A handwritten signature in black ink, appearing to read 'Jeremy Markovich'.



URGENT - FIELD SAFETY NOTICE

Notification: Product Field Action (Recall)

We have reviewed our inventory and have determined the following regarding these parts:

The Product Name DOES NOT exist in our inventory. The devices have been previously consumed or discarded:

(Include 'Part Number', 'Lot Number', 'Quantity Consumed', and/or 'Name Of Consignee Notified' based on applicable recall requirements)

The Product Name exists in our inventory, and will be returned immediately:

(Include 'Part Number', 'Lot Number', and/or 'Quantity Returning' based on applicable recall requirements)

Other:

By signing below, the undersigned certifies as to the accuracy of the statements above on behalf of the distribution agent listed below.

Read and agreed:

Print Name: _____

Title: _____

Signature/Date: _____

Name of Distributor: _____