X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342
Phone: (800) 903-0640
Direct: (937) 847-8400
Fax: (937) 847-8410
www.x-spine.com

Urgent Field Safety Notice

Product: Calix P Peek Lumbar System and Calix T PEEK Lumbar System
FSCA-identifier : 3005031160-5/17/16-001-R
Type of action: Removal

Date: 5-23-2016

Attention: ///////////////

Details on affected devices:

Device Name: Calix P PEEK Lumbar System and Calix T PEEK Lumbar System Lot Numbers: All lots
Part Numbers: See Attachment A Part Numbers

Description of the problem:

The trials and rasps within the TLIF and PLIF sets may become detached from the inserter assembly part number X034-0015. The risk to health is low. Detachment of the inserter from the trial is readily visible to the surgeon. A spare inserter is provided in case of this device malfunction.

Advise on action to be taken by the user:

1. The affected hospital and surgeon should be notified of this action immediately.
2. Complete the attached Medical Device Return Response Form and return it with any affected product in inventory to X-Spine Systems immediately. **All trials and rasps with the associated caddies are to be returned.**
    a. Contact Customer Service at 800-903-0640 ext. 2143 Jessica Lalich
    b. Customer Service will provide an RMA# to be referenced on the return
    c. Customer Service will provide a return shipping label
3. No action should be taken with product that has been implanted. This action is not in regards to the implants in the system.
   A replacement trial and rasp set will be provided.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. The appropriate Competent Authorities have been notified.

Contact reference person:
X-spine Systems, Inc.
Attn: Jessica Lalich
452 Alexandersville Road
Miamisburg, OH 45342
+011 937.847.8400 Extension 2143

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PLIF Trial/Rasp Part Listing	
Part #	Component Description
X034-0970	22mm x 10mm x 6mm PLIF Trial
X034-0971	22mm x 10mm x 7mm PLIF Trial
X034-0972	22mm x 10mm x 8mm PLIF Trial
X034-0973	22mm x 10mm x 9mm PLIF Trial
X034-0974	22mm x 10mm x 10mm PLIF Trial
X034-0975	22mm x 10mm x 11mm PLIF Trial
X034-0976	22mm x 10mm x 12mm PLIF Trial
X034-0977	22mm x 10mm x 13mm PLIF Trial
X034-0978	22mm x 10mm x 14mm PLIF Trial
X034-0979	22mm x 10mm x 15mm PLIF Trial
X034-0980	22mm x 10mm x 16mm PLIF Trial
X034-1050	26mm x 10mm x 6mm PLIF Trial
X034-1052	26mm x 10mm x 8mm PLIF Trial
X034-1054	26mm x 10mm x 10mm PLIF Trial
X034-1056	26mm x 10mm x 12mm PLIF Trial
X034-1058	26mm x 10mm x 14mm PLIF Trial
X034-0990	22mm x 10mm x 6mm PLIF Rasp
X034-0994	22mm x 10mm x 10mm PLIF Rasp
X034-1053	26mm x 10mm x 9mm PLIF Trial
X034-1055	26mm x 10mm x 11mm PLIF Trial
X034-1057	26mm x 10mm x 13mm PLIF Trial

TLIF Trial/Rasp Part Listing	
Part #	Component Description
X034-0340	**28mm x 10mm x 6mm TLIF Trial**
X034-0341	**28mm x 10mm x 7mm TLIF Trial**
X034-0342	**28mm x 10mm x 8mm TLIF Trial**
X034-0343	**28mm x 10mm x 9mm TLIF Trial**
X034-0344	**28mm x 10mm x 10mm TLIF Trial**
X034-0345	**28mm x 10mm x 11mm TLIF Trial**
X034-0346	**28mm x 10mm x 12mm TLIF Trial**
X034-0347	**28mm x 10mm x 13mm TLIF Trial**
X034-0348	**28mm x 10mm x 14mm TLIF Trial**
X034-0349	**28mm x 10mm x 15mm TLIF Trial**
X034-0350	**28mm x 10mm x 16mm TLIF Trial**
X034-0360	**28mm x 10mm x 6mm TLIF Rasp**
X034-0364	**28mm x 10mm x 10mm TLIF Rasp**

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Medical Device Correction Return Response

Acknowledgement and Receipt Form

Response is Required

«AddressBlock»
5/17/2016

Calix P PEEK Lumbar System

Calix T PEEK Lumbar System

I have read and understand the instructions provided in the date of this correction letter. ☐ Yes ☐ No

Any adverse events associated with recalled product? ☐ Yes ☐ No

If yes, please explain: _____

_____

Affected Product Information (list appropriate qty. of product)				
Device Name	**Part Number**	**Lot Number**	**Qty. in Inventory**	**Qty. Returned**

Please provide any additional information as applicable	

Distributors/Sales Representatives:

1. I have checked my stock and will be:
   - ☐ Returning any product on hand via **RMA # _____**
   - ☐ Will not be returning any product because it has been implanted and have provided details above
   - ☐ I did not receive this product

2. I have identified and notified my customers that were shipped or may have been shipped this product by:
   - ☐ Mail with a copy of the initial recall notice
   - ☐ Email, see attached correspondence
   - ☐ Phone call
   - ☐ Fax with a copy of the initial recall notice

Signature of Receipt _____

Name/Title	
Phone:	
Email:	

Please fax completed response form with attention to Kriss Anderson to 937.847.8410, email: kanderson@x-spine.com or mail to 453 Alexandersville Road, Miamisburg, OH 45342.