URGENT FIELD SAFETY NOTICE: RA2018-1931878

STRYKER SPINE: Tritanium PL

ATTN: Risk Manager, Operating Room Director, Materials Manager

November XX, 2018

FSCA identification: Product recall RA2018-1931878

Action type: Field Safety Corrective Action

Product description: Tritanium PL cages

Catalogue Numbers: See Appendix A

Lot Number: All

Initiating Event

Stryker's Spine division received product inquiries about Tritanium PL cage fractures occurring intra-operatively and post-operatively. Therefore, Stryker Spine has made the conservative decision to update the Surgical Technique (STG) to caution against misuse, which includes the use of surgical techniques that fall outside the approved instructions for use.

Potential Hazards and Harms

There are two potential hazards associated with this event:

1. The implant may fracture during insertion and potentially result in a surgical delay.
2. Post-operative fracture of the implant may occur which could potentially result in a revision surgery.

Summary of Surgical Technique Guide updates:

The Surgical Technique Guide (STG) has been updated to include the following precautions to discourage misuse:

- Do not use the implant as the sole method for distraction, as this may cause damage to the implant.
- Do not twist, cantilever or perform a twist/distract method of insertion. This may result in damage to the implant.

Pictures have also been added to further illustrate the misuse techniques mentioned above.

In addition to the precautions added to the STG, further clarification and formatting of existing surgical steps (i.e. distraction, sizing, insertion) have also been updated.

Please visit https://www.stryker.com/us/en/spine/products/tritanium-pl.html to view the final updated version on the STG.

Product Description

The Tritanium PL cage is a hollow, bullet-shaped cage that consists of a configuration of both solid and porous sections that are built using Laser Rapid Manufacturing (LRM) applying Stryker's proprietary Tritanium® In-Growth technology. The cage is manufactured entirely from Titanium Alloy (Ti6Al4V (ASTM F1472)). The porous sections are designed and optimized to have a micron mean pore diameter and porosity that aids in biological fixation of the cage. These porous sections are located on the superior and inferior surfaces of the cage as well as on the internal surfaces of the cage. The solid structures are located on the external side surfaces of the cage (Figures 1 & 2 shown below).

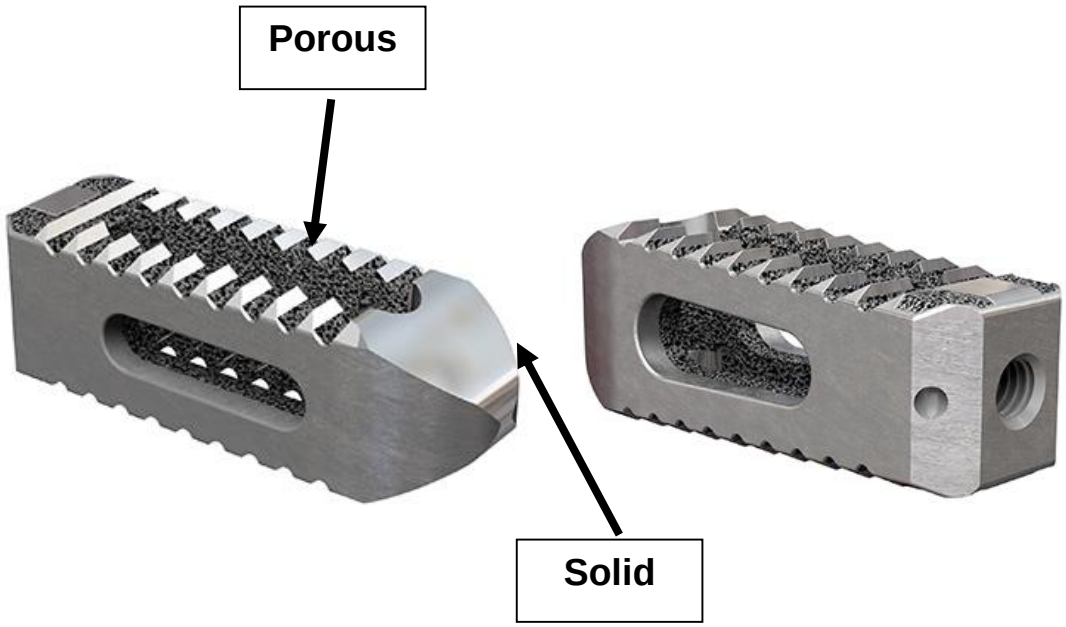

Figure 1: Depicts the porous sections of the cage which are located on the superior and inferior surfaces.

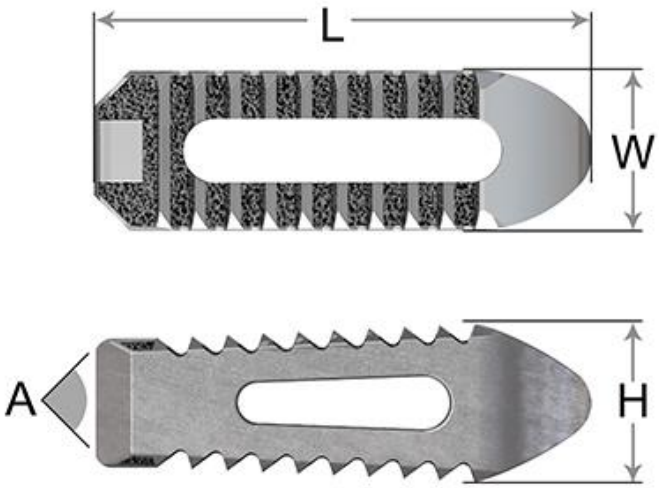

Figure 2: Illustrates the solid structures that are located on the external side surfaces of the cage.

Actions Needed

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Circulate this Field Notice internally to all interested/affected parties.

2. Maintain awareness of this notice internally until all required actions have been completed within your facility.

3. Inform Stryker if any of the subject devices have been distributed to other organisations.
    a) Please provide contact details so that Stryker can inform the recipients appropriately.
    b) If you are a Distributor, note that you are responsible for notifying your affected customers.

4. Please inform Stryker of any adverse events concerning the use of the subject devices.
    a) Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

5. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

6. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA

We request that you respond to this notice within **XXX** calendar days from the date of receipt.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: email:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours Sincerely,

AKNOWLEDGEMENT FIELD SAFETY NOTICE: RA2018-1931878

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Catalogue Numbers: See Appendix A

Lot Number: All

I acknowledge receipt of the Field Safety Notice for RA2018-1931878 and can confirm that:

☐ **I have read and understood the product field notice from Stryker Spine (dated November XX, 2018) stating that they initiated a voluntary correction of the STG associated with the implants with catalog numbers listed.**

☐ **We have further distributed subject devices to the following organisations:**

Facility Name:	
Facility Address:	

Form completed by:

Contact Name		**Contact Facility**	
Signature		**Contact Position**	
Contact address		**Contact Tel No**	
		Contact Fax No	
		Contact e-mail	

PLEASE COMPLETE AND FAX THIS FORM TO X

FIELD SAFETY NOTICE: RA2018-1931878 Appendix A:

Product Name	Tritanium PL
Catalog Number	48950070, 48950076, 48950080, 48950086, 48950090,48950096, 48950100, 48950106, 48950110, 48950116, 48950120, 48950126, 48950130, 48950136, 48950140, 48950146, 48951070, 48951076, 48951080, 48951086, 48951090, 48951096, 48951100, 48951106, 48951110, 48951116, 48951120, 48951126, 48951130, 48951136, 48951140, 48951146, 48952070, 48952080, 48952090, 48952100, 48952110, 48952120, 48952130, 48952140, 48953070, 48953080, 48953090, 48953100, 48953110, 48953120, 48953130, 48953140, 48954076, 48954086, 48954096, 48954106, 48954116, 48954126, 48954136, 48954146, 48955076, 48955086, 48955096, 48955106, 48955116, 48955126, 48955136, 48955146, W48950090, W48953090, W48955096, 48950066, 48954066, 48951092, 48951112, 48951132, 48950092, 48950112, 48950132,48956086, 48956096, 48956106, 48956116, 48956126, 48956136, 48956146, 48956140, 48957092, 48957112, 48957132, 48956112, 48956132, 48952092, 48952112, 48952132, 48953092, 48953112, 48953132, 48950102, 48950122, 48950142, 48951102, 48951122, 48951142, 48956076, 48956092, 48956102, 48956122, 48956142, 48953102, 48953122, 48953142