Customer address

Attention to vigilance correspondent

Ecully, June 28th, 2021

Ref: FSN-20210329
ID: Customer name

URGENT – SAFETY ACTION	
Devices concerned:	**twin peaks** **TLIF spine surgery**
REF:	**395IT1**
Description: Lot:	**Impactor, TLIF cage** **214495, 214494**
UDI-DI :	**366342260537**
Action:	**Product recall**

Dear Customer,

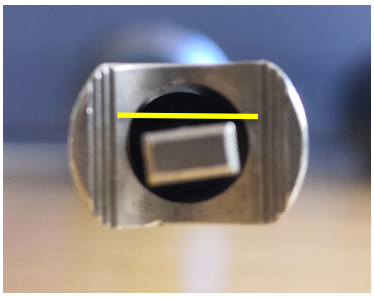
We inform you that Spineway SA is voluntarily initiating the product recall FSN-20210329 on the medical devices listed above.

Details on affected devices

The Impactor, TLIF cage reference 395IT1 is intended to insert the cage inside the intervertebral space. The devices affected by this recall are the first design version, because the latest versions have a locking system in the open position, not allowing the problems to recur.

Description of the issue

We have been informed of difficulties upon removal of the impactor, this turns and blocks. For these instruments we observe in open position a slight angle deviation of the retention axis from a horizontal plane (see photo below). Therefore, the removal is not allowing easy. This could occur when using the first version of the 395IT1 impactor.



Patient risk

Extra time may be needed to remove the instrument. In the worst situation, the cage cannot be implanted.

Actions to do

We rely on your diligence to:

1. Promptly transmit this notice to any organization, department, or person to whom the affected devices were delivered so that the indicated corrective actions can be effectively implemented while they are in your/their possession.

2. Identify where devices are located.

3. Complete the attached customer response form and return it to us within 7 days of receipt of this notification by Fax to +33(0)4 78 38 10 17 or email vigilance@spineway.com

4. Return the customer follow-up form within 7 days as soon as you receive this notification. Spineway SA could deliver new generation instrument for replacement.

We inform you that we have notified the French competent authority.

We apologize for the inconvenience, and we thank you for your understanding and cooperation.

Our customer service and I are staying at your disposal for any further information.

Yours sincerely

Florence LAUCK
Quality and Regulatory Affairs Department Director
Tel : +33(0)4 72 77 01 52 / Fax : +33(0)4 78 38 10 17/ Email : quality.flc@spineway.com

CUSTOMER FOLLW UP FORM
Product recall

Spineway **– twin peaks instrument**
TLIF spine surgery

Attention to,

SPINEWAY SA
7, Allée Moulin Berger – 69 130 ECULLY – FRANCE
Tel : +33 (0)4 72 77 01 52 – Fax : +33 (0)4 78 38 10 17
vigilance@spineway.com

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Does the information contained in the present safety corrective action FSN-20210329 have to be notified to your health authorities? ☐ YES ☐ NO

If YES, please send us the proof of the notification.
If NO, please justify:
……
……

Please inspect your stock, storage and using places and record the results below:

Reference	**Description**	**Lot**	**Quantity delivered by Spineway**	**Quantity in your inventory** To be fullfilled
395IT1	Impactor, TLIF cage	214495		
395IT1	Impactor, TLIF cage	214494		

If you have delivered a concerned device, please note hereafter the identification of the person and organization you delivered:

Name: …… Adress: ……

Contact name:		Company stample :	
Position :			
Date and visa:			
Phone :		Email :	