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Quality Product Director
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1228 Plan Les Ouates
Switzerland

October 08, 2018

Reference: FSCA-02-2018

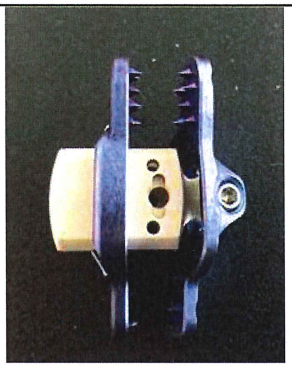
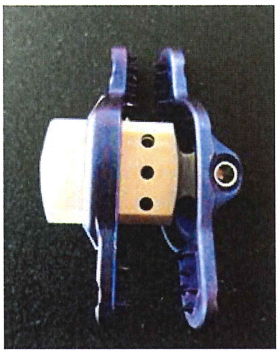
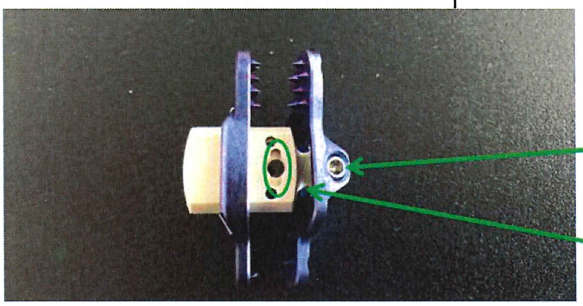
Dear All,

This is to inform you of a product recall involving the below mentioned products in your sales area:

Reference	Batch number
PAD-IM WT 12-S	4-0705
PAD-IM WT 14-S	3-6652
PAD-IM WT 14-S	4-0706
PAD-IM WT 16-S	3-8750
PAD-IM WT 16-S	4-0866
PAD-IM WT 16-S	4-0867

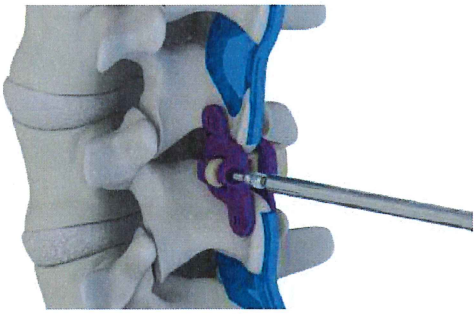
Description of the problem:

There is an error in the assembly of the device. We can observe below that, due to this misassembling, the revision screw is located on the opposite to the implant holder connexion site.

Good set up	Wrong one
	
	

This revision screw will not be accessible in case of revision surgery despite in the surgical technique below describing that the revision screw shall be unscrewed during a revision to remove the implant.

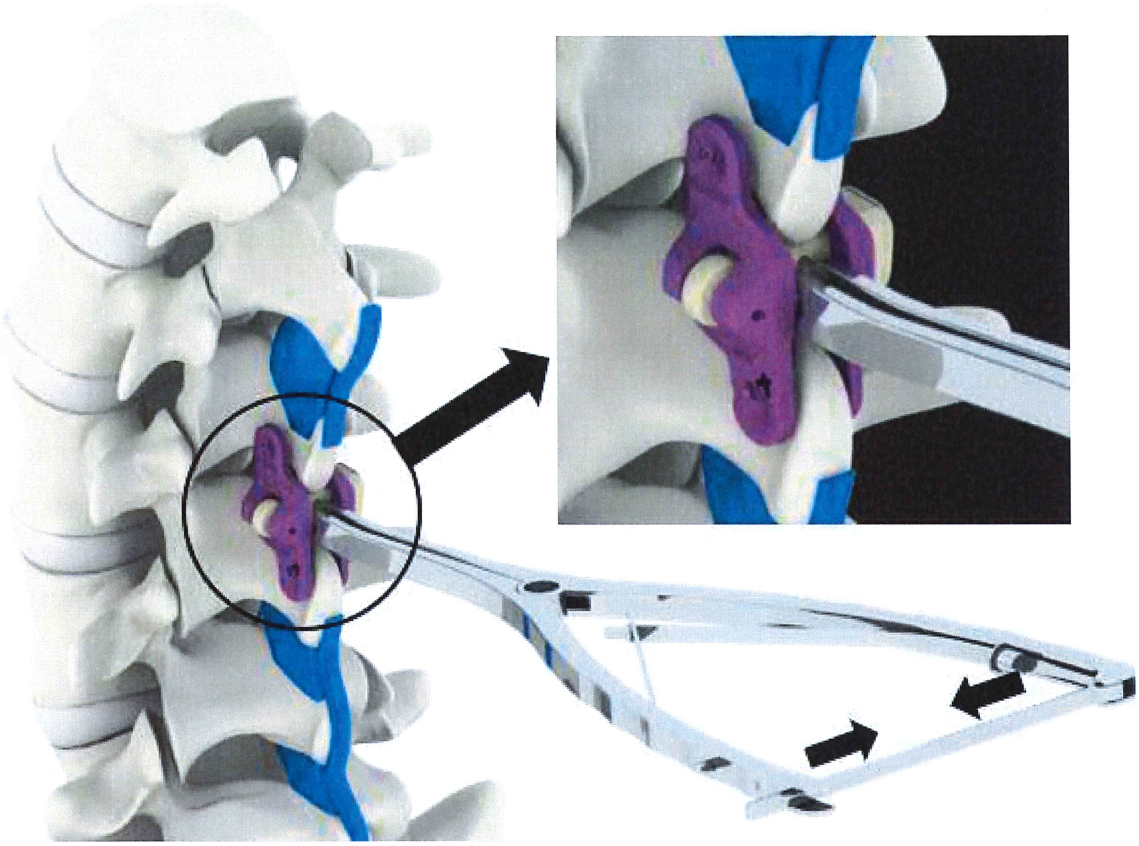
REVISION



In case of revision, use the REVISION SCREWDRIVER to take out the screw and remove the implant.

This misassembling is easily detectable before implantation but in case this device is implanted and if a revision surgery is needed, the surgical technique has to be adapted:

We may recommend using the following Spineart instruments to distract the device allowing its removal from the spinous process;
Distractor Forceps CPF-IN 31 00-N or ELL-IN 00 07-N.
To do this, put the clamps between the 2 plates at the place of the implant holder then distract carefully.



Out of an abundance of caution, we have decided to recall the concerned products.
Please carefully follow instructions detailed below:

1. Immediately examine your inventory and quarantine product subject to recall.
2. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall by using this document.
3. Collect and quarantine all products.
4. Sent back all products to: **SLI (Spineart Logistic International)**
   80 rue Douglas Engelbart
   Bâtiment ABC 3
   Technopole Archamps
   74160 Saint Julien en Genevois
   France
5. All returned products will be exchanged with batches already available in our warehouse.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Contact reference person:

Romain DOMANGE
+41 22 570 12 89
E-mail: regulatory@spineart.com.

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

Signature

Response form: Spineart SA MEDICAL DEVICE RECALL

Please complete the following table and send it to Spineart Geneva regulatory department: regulatory@spineart.com as soon as possible

Reference	Batch	Location (Warehouse/ hospital Name…)	Quantity initially sent	Quantity implanted	Qty scrapped	Quantity returned to Spineart

Contact name and signature:	
Date:	

Thank you very much in advance for your prompt answer.
Best regards