URGENT: MEDICAL DEVICE RECALL
Field Safety Notice FSCA-12-2022

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Switzerland

March 31st, 2022

Reference: FSCA-12-2022

Dear All,

This is to inform you of a product recall involving one batch of Scarlet ® AC-T, the Cervical Secured Lordotic Cage.

Product information	**Manufacturer**
Cervical Secured Lordotic Cage Small D12 W15 H06 Ref: SCA-AC LS 06-S Batch: 5-9556	SPINEART SA Chemin du Pré Fleuri, 3 1228 Plan-les-Ouates Switzerland **Contact Name:** Xavier de BUCHERE VP Global QS & RA Email Address: xdebuchere@spineart.com Telephone: +41 22 570 12 97

Event description:

We received a complaint on March 31st, 2022, registered under CPT-1876 on our system.

The product concerned by the complaint is the Cervical Secured Lordotic Cage Small D12 W15 H06.

This implant is dedicated to the cervical spine surgery, it has been designed for anterior cervical arthrodesis.

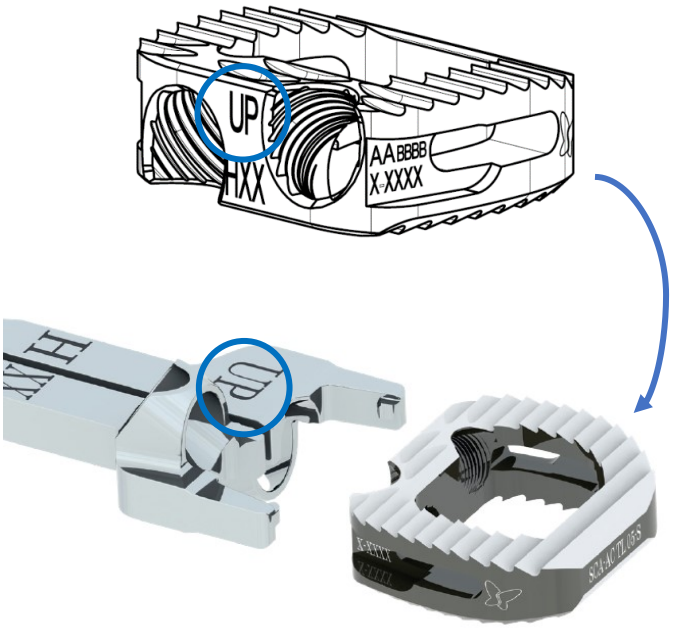
During the surgery, the surgeon could not attach the Cervical Cage into the implant holder. He decided to use another cervical cage reference (the anatomical cage, reference SCA-AC TS 06-S) to perform the surgery.

Extent of the Issue:

When informed, Spineart checked the DHR of the Cervical Secured Lordotic Cage, batch 5-9556 (which is composed of 125 parts) and did not find out any issue during the manufacturing step.

1 part from this batch 5-9556, that was available in our stock, has been checked, and we found out that the mark "UP" (laser marking) on the cage was not in the correct position. The "UP" marking was on the lower part of the cage and not on the upper part of the cage (see picture below of a correctly marked cage).

Note: the "UP" marking is laser marked on the implant holder and on the Cervical Cage in order to facilitate their attachment (see picture below).



The result of this incorrect marking is that the cage cannot be attached into the implant holder, as defined in the surgical technique, before the implantation.

The check of the Cervical Cage marking consists in a visual inspection. This inspection was not precise enough to detect this issue.

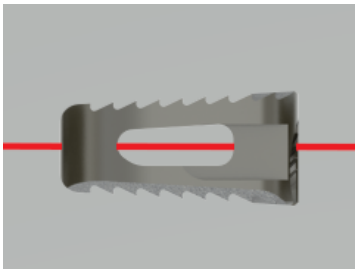
Risk evaluation:

<u>Case 1</u>: The Cervical Cage has been implanted turning the implant holder over

In this case, the Cervical Cage is implanted in the correct position, i.e. with the "UP" marking on the upper part of the cage. The implant holder is turned over to allow the cage to be fixed before implantation. Therefore, the risk for the patient or the healthcare professional is only a surgery delay that should be less of 30 minutes. Consequently, the risk is estimated to be minimal.

<u>Case 2</u>: The Cervical Cage has been implanted turning it over

In this case, the Cervical Cage is implanted upside down, in order to allow its fixation on the implant holder, i.e. with the "UP" marking located on the lower part of the cage, but, due to the symmetrical geometry of the cage, there is no impact for the patient.



Therefore, the risk for the patient or the healthcare professional is only a surgery delay that should be less of 30 minutes. Consequently, the risk is estimated to be minimal.

<u>Case 3</u>: Another Cervical Cage has been implanted

The surgeon can decide to use another Cervical Cage (depending on his expertise, the surgeon can decide to use another cage with the same reference or a cage with another reference). Therefore**,** the risk for the patient or the healthcare professional is only a surgery delay that should be less of 30 minutes. Consequently, the risk is estimated to be minimal.

Conclusion of risk evaluation:

The whole batch 5-9556 is impacted by the manufacturing issue. To avoid the risk of a potential surgery delay, we decided the recall of the parts SCA-AC LS 06-S, for the batch 5-9556, which are on the field.

Note: all the other batches for the other references of the Scarlet Cervical Cages available in our stock have been checked and no other issue with the "UP" marking has been found. We assess that this is an isolated case concerning the batch 5-9556.

Immediate actions already implemented by Spineart:

1/ Identify locations of all non-implanted parts.

2/ Open an internal investigation to identify the root cause and put in place required CAPA.

Please be informed that all concerned competent authorities are informed of this FSN.

Strategy for conducting the recall:

Following actions must be executed as soon as possible:

1. Immediately review your inventory and quarantine concerned products if any.
2. You may have further distributed this product; please identify concerned 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 with the enclosed Response Form to Spineart warehouse
   SPINEART SLI, ATTN LAURE-ALLISON VERBOUX,
   80 RUE DOUGLAS ENGELBART
   FR-74160 ST JULIEN EN GENEVOIS).
   E-mail: regulatory@spineart.com.
5. All returned products will be exchanged.

Validated by:	
Date:	

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.