Xavier DE BUCHERE
VP Global RA & QS
Chemin du pré fleuri 3
1228 Plan-Les-Ouates
Switzerland

17 mars 2023

Reference: *FSCA-01-2023*

Dear All,

This is to inform you of a product recall involving the below mentioned products:

References	Designations	Batch number
JLT-PL 02 08-S	LATERAL LUMBAR TI-LIFE PLATE SMALL	4-8826 5-0643 5-2431 5-4142 5-5377 6-3212 6-6557
JLT-PL 02 10-S	LATERAL LUMBAR TI-LIFE PLATE SMALL	5-0644 5-4143 5-5378 6-3211 6-4734 6-4735 6-5488 6-6556 7-0682
JLT-PL 02 12-S	LATERAL LUMBAR TI-LIFE PLATE SMALL	4-8828 5-4144 5-5379 6-1563 6-3216 6-4732 6-4733 6-5489 6-6558 6-7645 6-8734
JLT-PL 02 14-S	LATERAL LUMBAR TI-LIFE PLATE SMALL	4-8829 5-5380 5-8439 6-0714

		6-1564
JLT-PL 02 16-S	LATERAL LUMBAR TI-LIFE PLATE SMALL	4-8830 5-4145 6-0726 6-3217 6-5490
JLT-PL 02 18-S	LATERAL LUMBAR TI-LIFE PLATE SMALL	No batch number on the field
JLT-PL 02 20-S	LATERAL LUMBAR TI-LIFE PLATE SMALL	No batch number on the field
JLT-PL 04 08-S	LATERAL LUMBAR TI-LIFE PLATE LARGE	4-8845 5-4146 6-0725
JLT-PL 04 10-S	LATERAL LUMBAR TI-LIFE PLATE LARGE	4-8831 5-4147 6-0722
JLT-PL 04 12-S	LATERAL LUMBAR TI-LIFE PLATE LARGE	4-8832 5-4148 5-8438 6-0721 6-3209
JLT-PL 04 14-S	LATERAL LUMBAR TI-LIFE PLATE LARGE	4-3861 4-8833 5-4149
JLT-PL 04 16-S	LATERAL LUMBAR TI-LIFE PLATE LARGE	5-4150
JLT-PL 04 18-S	LATERAL LUMBAR TI-LIFE PLATE LARGE	5-4151
JLT-PL 04 20-S	LATERAL LUMBAR TI-LIFE PLATE LARGE	No batch number on the field

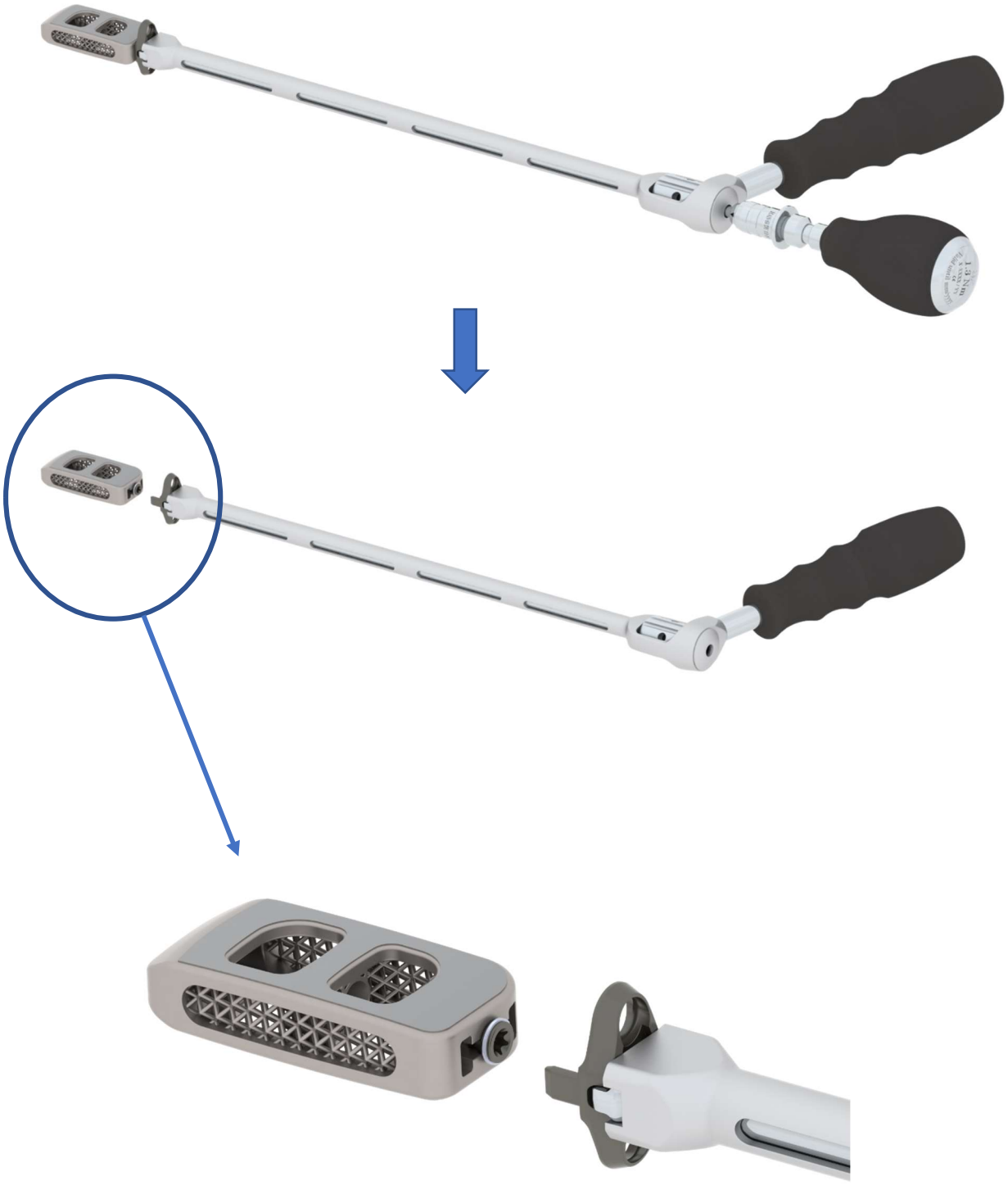
Product information:	**Manufacturer :**
- Product Name: *LATERAL LUMBAR TI-LIFE PLATE* - Reference: *see table above* - Batch Number: *see table above*	SPINEART SA Chemin du Pré Fleuri, 3 1228 Plan-les-Ouates Switzerland **Contact Name:** Xavier DE BUCHERE VP Global QS & RA

- Instructions For Use (IFU*): OCT-2019-REF-JUT-LL-IF-WW* - Surgical technique: o *SEP-2021-REF-JUT-LL-ST-FR* o *SEP-2021-REF-JUT-LL-ST-EN* o *SEP-2021-REF-JUT-LL-ST-GE* o *SEP-2021-REF-JUT-LL-ST-SP*	Email Address: xdebuchere@spineart.com Telephone: +41 22 570 12 97 ---------- **European Representative :** ALPES CN ARCHAMPS 80 rue Douglas Engelbart 74160 Saint Julien en Genevois France **Contact Name:** Chloé DUHAMEL Senior Operation Manager Email Address : cduhamel@spineart.com Telephone: +33 428 38 36 40

Event description:

We have received 7 complaints since June 2022 on JULIET Lateral Lumbar Ti-Life Plates. These implants are Lumbar Interbody Devices indicated for intervertebral body fusion procedures.

These plates disassembled from the Screw Plate during the insertion into the cage as shown in the pictures below.



Surgeons decided to use other Plates to complete the surgeries without any consequences for the patients.

Two types of cases have been reported:

- **Case 1: disassembly occurred during the preparation stage before implantation**

During the assembly of the pre-assembled plate/screw into the cage on the operative room table, the surgeon or the nurse immediately encountered the disassembly issue. In any case, the detection is obvious for the operative members.

- **Case 2: disassembly occurred during the surgery when removing the implant Holder**

During the assembly of the pre-assembled plate/screw into the cage in-situ (inside the patient), the surgeon realizes the disassembly when pulling-out the implant holder. The plate remains connected to the instrument. The detection is obvious for the operative members as well.

Risk Evaluation:

1/ Detection of the Issue:

The issue is always detected by the surgeon.

2/ Occurrence of the Issue:

This product line has been launched in December 2019. A total of 1823 devices have been implanted.

7 complaints have been reported to SPINEART for a total of 11 defected devices which represents a complaint rate of 0.6%.

The occurrence of this type of defect can then be considered as low.

No lot effect has been found.

No specific country is concerned.

3/ Severity:

a) **Surgery Delay:** the impact on the surgery time reported throughout the complaints is always inferior to 30 min which can be considered as minimal and without any consequences for the patient.

For one of the complaints received, the surgery was delayed by less of 1 hour because the surgeon decided to remove all the devices implanted including the cage itself.

b) **Plate replacement:** If the issue occurs, the surgeon should proceed as followed:

1- Unscrew the Plate screw of the cage with the screwdriver,

2- Scrap the current plate assembly,

3- Use a new set of pre-assembled plate/screw (a minimum of 2 sets of pre-assembled plates/screws per size are part of the device listing). The cages are to be used with the corresponding plate or higher plate which means that a plate with the same heigh than the cage can be used but also a plate with higher height.

4- In the case of 0° and 8° cages, a pre-assembled plate/screw is not mandatory as described in the surgical technique

Mitigations:

The following mitigations must be considered:

- The complaint rate is very low.
- Delay of surgery time to remove the plate is less of 30 minutes.
- The use of the plate is only mandatory for Hyperlordotic cages (about 19% of the surgeries) as described in the Surgical Technique. In a worst case situation where the surgeon would decide to remove all implants and complete the surgery, the delay would be less of 1 hour.
- There is absolutely no risk of disassembly after the surgery.

Conclusion of risk evaluation:

Severity, occurrence and so risks have been identified as very low.

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. It will be translated into the languages of the countries concerned.

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