October 25th, 2019

[redacted]
[redacted]
Chemin du pré fleuri 3
1228 Plan-Les-Ouates
Switzerland

Reference: FSCA-06-2019

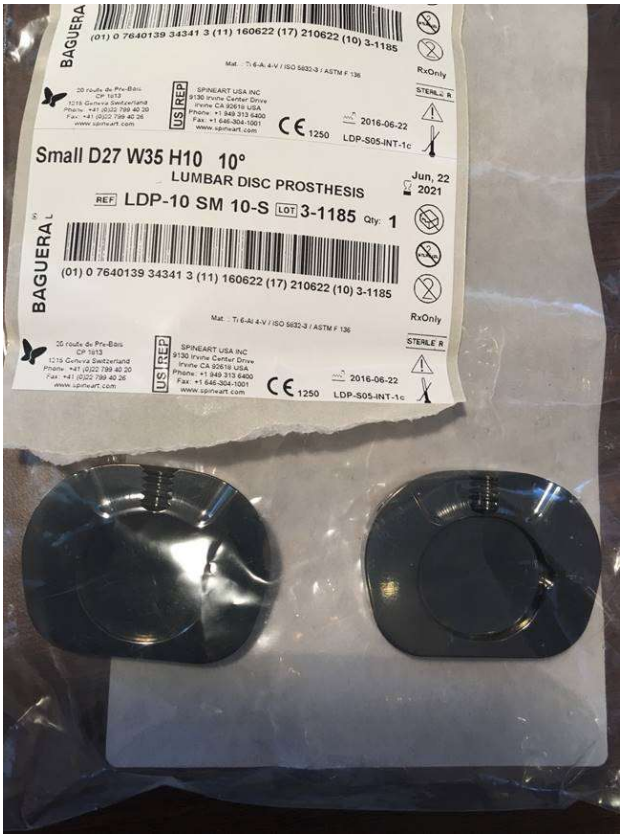
Dear All,

This is to inform you of a product recall involving 1 lot of Baguera L Disc prosthesis.
This recall has been initiated further to the detection of a mispackaging error.

Product information	**Manufacturer**
Lumbar Disc Prosthesis Small D27 W35 H10 10° Ref LDP-10 SM 10-S Lot # 3-1185	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

Event description:

A mispackaging issue has been detected on 23.10.2019 : 2 inferior plates were found in the packaging of LDP-10 SM 10-S instead of 1 inferior plate plus 1 superior plate. The picture below was provided.

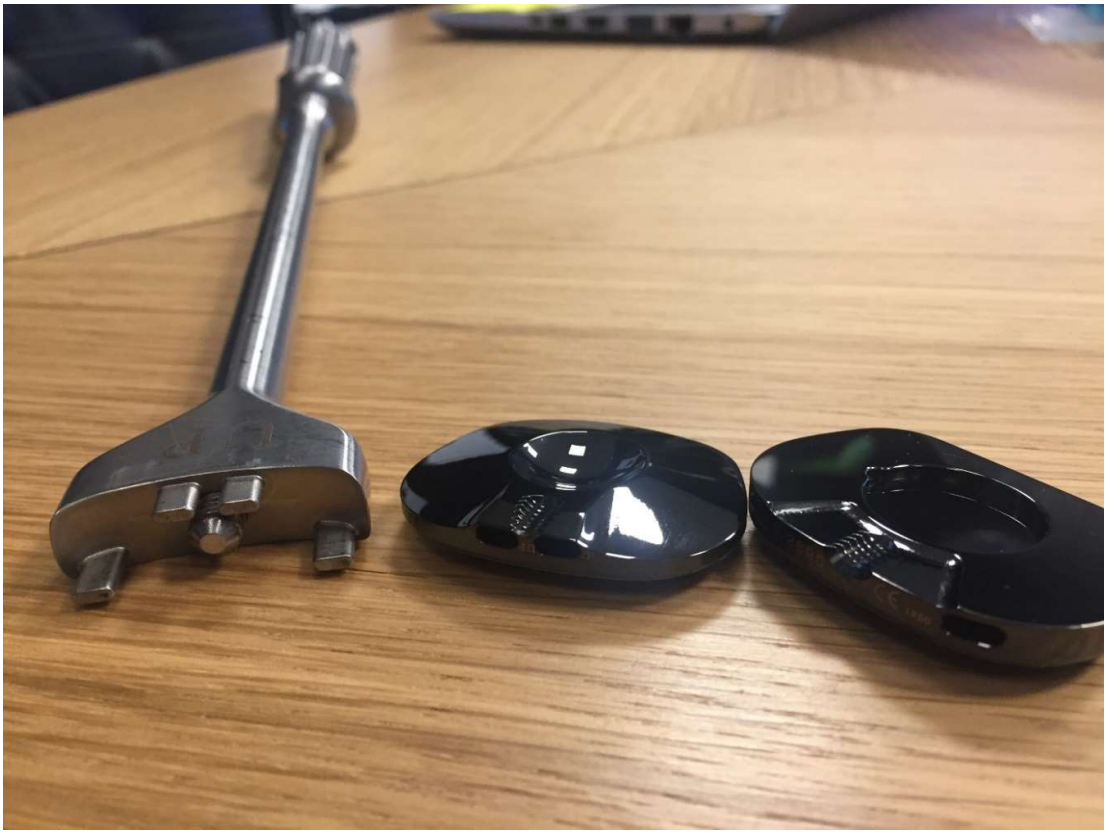


Extent of the Issue:

The root cause has been found to be a wrong selection of plates when performing the packaging process. The operators placed 2 inferior plates in the same packaging instead of 1 inferior plate and 1 superior plate.
This is a human error. The rest of the lot could partially have the same issue.

Risk evaluation:

3 cases are possible:
Case 1: an inferior plate and a superior plate were provided in the packaging: there is no issue as it is the standard and normal configuration.
Case 2: 2 inferior plates were provided. The surgeon would then immediately detect the issue as it is not possible to assemble both inferior plates on the core, in the implant holder.
Case 3: 2 superior plates were provided. The surgeon would then immediately detect the issue as it is not possible to assembly both superior plates on the core, in the implant holder.



The tool is designed in a such a way that it is not possible to use it with 2 identical plates.

Conclusion of risk evaluation:

There is no risk for the patient as it is not possible to assemble 2 identical plates in the plate holder.

Immediate actions already implemented:

1/ Identify locations of all parts from this lot.

2/ Contact the supplier in charge of packaging and open a NC to confirm the root cause and propose an efficient action plan.

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 Geneva (Chemin du Pré Fleuri 3, 1228 Plan-les-Ouates, Switzerland). E-mail: regulatory@spineart.com.
5. All returned products will be exchanged.

All products retrieved from the field will be exchanged as soon as others are available.

Validated by:	[redacted]
Date:	25 Oct 2019

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.