	URGENT: Medical Devices Recall **Field Safety Notice (FSN) FSCA-03-2024**	FORM-0395 00

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Reference: FSCA-03-2024

Dear All,

This is to inform you of a product recall involving 11 devices of cervical disc prosthesis BAGUERA® C.

The BAGUERA® C is a prosthesis intended as a replacement for a cervical intervertebral disc. The prosthesis is composed of 2 titanium plates (1 superior plate and 1 inferior plate) and a mobile PE nucleus.

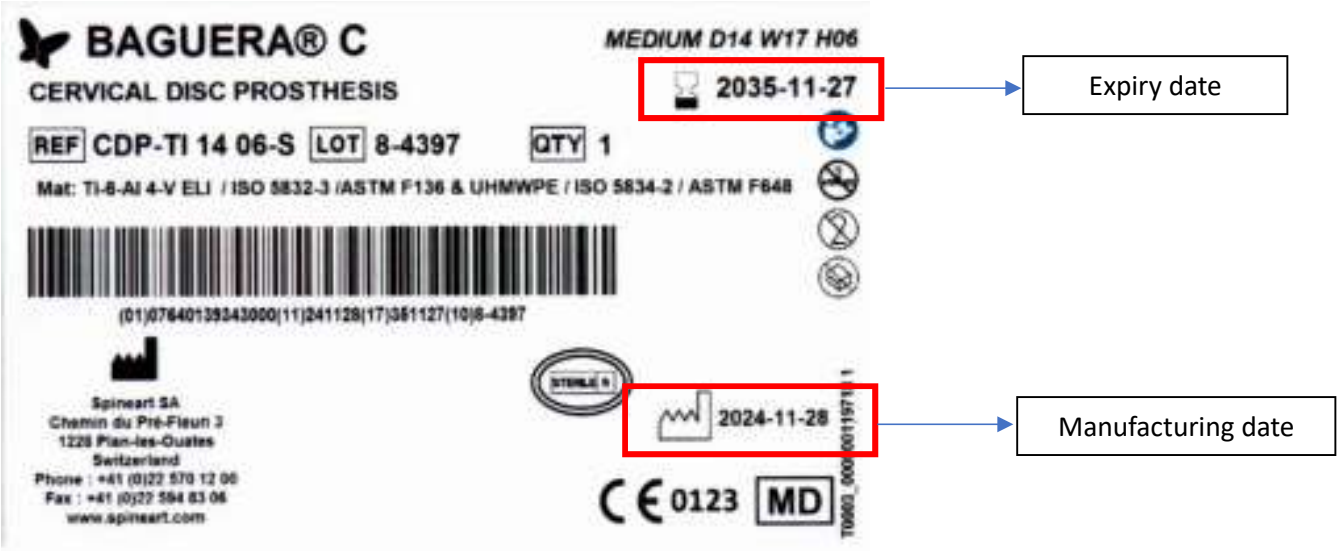
Product information:	**Manufacturer :**
- Product Name : cervical disc prosthesis BAGUERA® C - References: CDP-TI 13 05-S and CDP-TI 13 06-S - Batch Numbers: 8-4394 and 8-4395 - Instructions For Use (IFU*):* AUG-2024-REF-BAG-IF BC 02-E	SPINEART SA Chemin du Pré Fleuri, 3 1228 Plan-les-Ouates Switzerland **Contact Name:** Xavier DE BUCHERE VP Global QS & RA Email Address: xdebuchere@spineart.com Telephone: +41 22 570 12 97 ----------

- Surgical techniques: o SEP-2024-REF-CDP-TI-RM-EN	**European Representative :** Alpes CN SAS Rue Douglas Engelbart 80 Abc3 Technopole Archamps 74160 Archamps France **Contact :** Claudine Amafroid Responsable Assurance Qualité Production Adresse Email: regulatory@spineart.com Téléphone: +33 4 28 38 36 40 / +33 6 40 46 61 13

Event description and extent of the issue:

During the label verification step of the batch numbers 8-4396 and 8-4397, an error was detected on the expiry date. The labels show an expiry date of 11 years instead of 8 years.

In the following example, the expiry date indicated is 2035-11-27, whereas it should be 2032-11-27.



Exemple of non-conform label

Internal investigation led to the conclusion that 5 batches are affected by this non-conformity: 8-4394, 8-4395, 8-4396, 8-4397 and 8-4454.

Affected reference	Affected batch number	Quantity manufactured	Quantity distributed on the field	Affected country (country which received the devices with a non-conform label)
CDP-TI 13 05-S	8-4394	50	9	Switzerland, Germany, India and New Zealand
CDP-TI 13 06-S	8-4395	23	2	India
CDP-TI 14 05-S	8-4396	65	0	N/A
CDP-TI 14 06-S	8-4397	23	0	N/A
CDP-TI 16 05-S	8-4454	56	0	N/A

There are currently 11 devices belonging to 2 batches (reference CDP-TI 13 05-S, batch 8-4394 and reference CDP-TI 13 06-S, batch 8-4395) that have been distributed on the field and that are affected by this recall.

Risk evaluation:

Case 1: the surgeon uses the device within 8 years after of the date of manufacture

In this case, there is no risk to the patient.

Case 2: the surgeon uses the device more than 8 years after the date of manufacture

In this case, the sterility of the device is not guaranteed. There is a risk to the patient.

Conclusion of risk evaluation:

The risk assessment shows a risk to the patient if the device is used more than 8 years after the date of manufacture.

We have decided to recall and replace the devices on the field.

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Immediate actions already implemented by Spineart:

1. Identify locations of all affected devices.

2. Inform locations that they must immediately quarantine the impacted parts and return them for replacement.

3. Open an internal investigation to identify the root cause and put in place actions required (NC-0000337 and CAPA-1364).

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:	DS [redacted] DocuSigned by: [redacted]
Date:	12-Dec-2024 | 15:01 CET

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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 (Ware-house/ 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