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	URGENT: Medical Devices Recall Field Safety Notice(FSN)	Reference	FORM-0395
		Revision	01
	FSCA-03-2025		

Xavier de Buchère
VP Global RA & QS
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Switzerland

July 3rd 2025

Reference: FSCA-03-2025

Dear All,

This is to inform you of the recall of one batch of 87 PERLA® TL cannulated fenestrated polyaxial screws.

Indications

The PERLA®TL system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (painful degeneration of the disc), spondylolisthesis, trauma, spinal stenosis, deformities (i.e. scoliosis, kyphosis, or lordosis), tumor and failed previous fusion (pseudarthrosis). The PERLA®TL system is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients. When used for posterior non-cervical pedicle screw fixation in pediatric patients, the PERLA®TL system is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PERLA®TL system is indicated to be used in conjunction with bone cement to augment fixation in vertebrae with compromised bone quality. The PERLA®TL system is intended to be used with autograft and/or allograft.

Product information:	**Manufacturer :**
- Product Name: cannulated fenestrated polyaxial screw - Reference: MPF-PS 65 40-S - Batch Number: 8-4528 - Basic UDI-DI: N/A - Instructions For Use (IFU*):* MAR-2023-REF-PER-TL-IF-WW	SPINEART SA Chemin du Pré Fleuri, 3 1228 Plan-les-Ouates Switzerland **Contact Name:** Xavier de Buchère VP Global QS & RA Email Address: xdebuchere@spineart.com Telephone: +41 22 570 12 97 ---

- Surgical technique: JUL-2023-REF-PER-TF-ST-EN	**European Representative :** Alpes CN SAS Rue Douglas Engelbart 80 Abc3 Technopole Archamps 74160 Archamps France **Contact Name:** Claudine Amafroid Responsable Assurance Qualité Production Email Address : regulatory@spineart.com Telephone: +33 4 28 38 36 40 / +33 6 40 46 61 13

Event description

We received an incident report on June 24, 2025, from Hôpital Privé Eure-et-Loir, which was recorded in our system under the reference number CPT-3953.

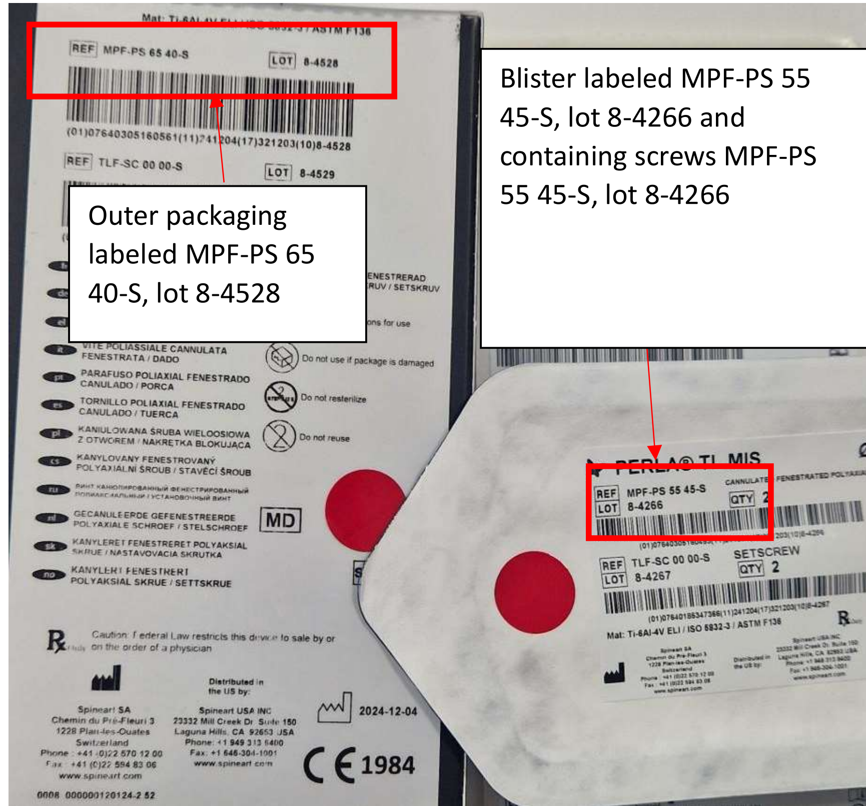
The product involved in the incident is a PERLA® TL polyaxial perforated cannulated screw, reference MPF-PS 65 40-S, lot 8-4528.

It was reported that during surgery, the nurse noticed, upon opening the box, that the reference number on the blister did not match the one on the outer packaging (box):

- The blister label indicated reference MPF-PS 55 45-S, lot 8-4266
- The outer packaging (box) label indicated MPF-PS 65 40-S, lot 8-4528

Another box of screws from a different lot was used to complete the procedure.

The nurse also verified the dimensions of the screws contained in the blister labeled MPF-PS 55 45-S, lot 8-4266, and confirmed that they matched this reference.



The screws are packaged in pairs, along with two setscrews, in each box.

Extent of the issue

Upon being informed of the issue, Spineart analyzed the Device History Records (DHR) for the PERLA® TL polyaxial perforated cannulated screws from lots 8-4528 (250 screws manufactured) and 8-4266 (46 screws manufactured).
No anomalies were identified during the manufacturing process.

An inspection of 66 boxes (132 screws) from lot 8-4528, still available in our stock, showed that 6 boxes (12 screws) contained:

- either a blister labeled MPF-PS 55 45-S, lot 8-4266,
- or a patient label corresponding to the same lot,
- or both the blister and the patient label from that lot.

One of these boxes was opened, confirming that the screw inside matched reference MPF-PS 55 45-S, lot 8-4266.

A partial mix-up occurred between the blisters, patient labels, and external packaging of these two batches.
Batch 8-4266 was not distributed, except for a few blisters mistakenly packaged in external packaging labeled as batch 8-4528.
Therefore, all batches present in the field can be identified by their external label from batch 8-4528.

Affected reference	Affected lot	Affected country	Quantity distributed and not implanted	Quantity distributed and implanted
MPF-PS 65 40-S	8-4528	France	56	38
MPF-PS 65 40-S	8-4528	Italy	8	0
MPF-PS 65 40-S	8-4528	Switzerland	16	0
MPF-PS 65 40-S	8-4528	United States	7	9

There are currently 87 screws, reference MPF-PS 65 40-S, lot 8-4528, still on the field and subject to this recall.

We have also identified 47 implanted screws from the same lot.

Risk evaluation and conclusion:

Risk evaluation:

Case 1: The hospital personnel detects the error (blister and/or patient label marked MPF-PS 55 45-S, lot 8-4266).

In this case, another box of screws is used, allowing the surgeon to proceed with the procedure. As a result, the risk to the patient or healthcare professional is limited to a surgical delay of less than 30 minutes.

Case 2: The hospital personnel does not detect the error (blister and/or patient label marked MPF-PS 55 45-S, lot 8-4266)

- **Situation 1:** Only the patient label is incorrect (MPF-PS 55 45-S / lot 8-4266), but the blister is correct (MPF-PS 65 40-S / lot 8-4528).
  In this situation, the implanted screw is compliant and corresponds to what the surgeon intended to implant. There is no risk to the patient, but traceability is compromised (incorrect lot number and reference recorded in the patient file).

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- **<u>Situation 2:</u>** Only the blister is incorrect (MPF-PS 55 45-S / lot 8-4266), but the patient label corresponds to the expected lot (MPF-PS 65 40-S / lot 8-4528).
  In this situation, one or two screws measuring 45mm in length and 5.5mm in diameter are implanted instead of a screw measuring 40mm in length and 6.5mm in diameter. The potential risks include perforation of the anterior vertebral body wall during the operation and reduced screw anchorage.
  Traceability is compromised because the patient labels do not correspond to the implanted screw(s).

- **<u>Situation 3:</u>** Both the blister and patient labels are incorrect (MPF-PS 55 45-S / lot 8-4266).
  In this situation, one or two screws measuring 45mm in length and 5.5mm in diameter are implanted instead of a screw measuring 40mm in length and 6.5mm in diameter. The potential risks include perforation of the anterior vertebral body wall during the operation and reduced screw anchorage.
  Traceability is compromised because the patient labels correspond to the implanted screw(s) but do not match the box reference.

Conclusion of risk evaluation:

The entire lot 8-4528 is not affected by the mix-up. However, due to the possible presence of incorrect blisters and/or patient labels, and the potential risks outlined above, we have decided to recall the MPF-PS 65 40-S screws from lot 8-4528 that have been distributed in the field.

We recommend that the concerned centers perform radiographic follow-up for each screw implanted from the affected batch, to be conducted immediately post-operatively or at 1 month, then at 3 months, and finally at 6 months.

<u>Immediate actions already implemented by Spineart:</u>

1. Identify locations of involved parts.

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

3. Open an internal investigation to identify the root cause and put in place actions required (CAPA-0101).

Please be informed that all concerned competent authorities are informed of this FSN. It will be translated into the languages of the countries concerned.

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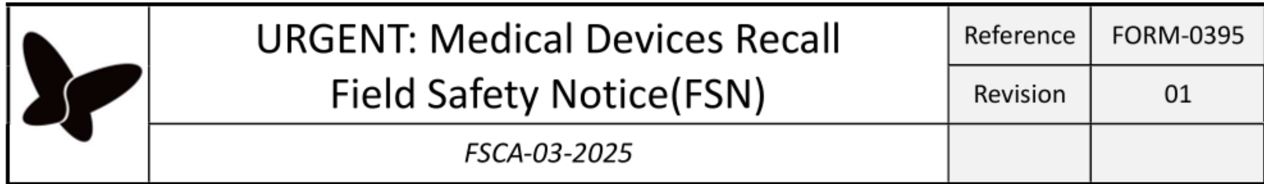

Please be informed that this recall does not expose patients to a risk of disruption of access to care insofar as SPINEART can replace the recalled batches.

Surgeons and healthcare professionals should consider how to inform patients implanted with these devices.

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

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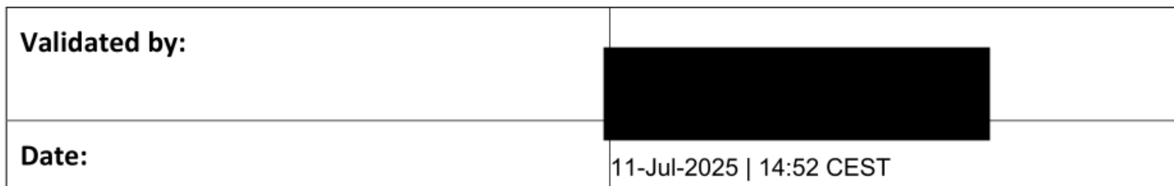
   356 rue de la tour
   ZA l'éculaz
   74930 REIGNIER-ESERY
   FRANCE

   E-mail: regulatory@spineart.com

5. All returned products will be exchanged.



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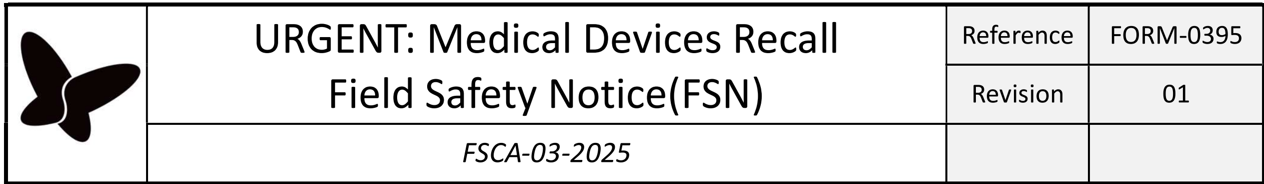

Response form: Spineart SA MEDICAL DEVICE RECALL

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