EUROSPINE
Life matters, We care.

Selon le modèle Annexe 5 du MEDDEV2.12-1rev7

To XXXXXXXXXXXXX
XXXXXXXXXXXXX
XXXXXXXXXXXX
At……..,

URGENT – FIELD SAFETY NOTICE

AFFECTED PRODUCT: Metallic Cervical Interbody Fusion Cage
IDENTIFICATION OF CORRECTIVE ACTION: RP006/22
TYPE OF ACTION: Batch Recall

Dear customers,

DETAILS

1) To:
Director, local correspondent of vigilance, service and health professionals.
2) Affected products:
See appendix 01.
3) Intended use of the devices
HRCCm cages are indicated in skeletally mature patients to perform a cervical arthrodesis (limited to 3 levels) between C2 and T1 vertebra for:
- Radiculopathy refractory to non-operative treatment, and/or myeloradiculopathy (neck pain, arm pain, and/or a functional neurological deficit in a specific nerve root situated between C2 and T1 vertebra),
- With at least one of the following conditions confirmed by imaging (CT, MRI, or X-rays):
▪ Herniated nucleus pulposus,
▪ Degenerative disc.

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Limited Company with Capital of 15243 Euros - SIRET 419 399 738 00030 – APE 514N -
INTERCOMMUNITY NUMBER : FR04419399738 –WEB www.eurospine.com – Email :
eurospine.company@orange.fr

4) Reasons for the FSCA

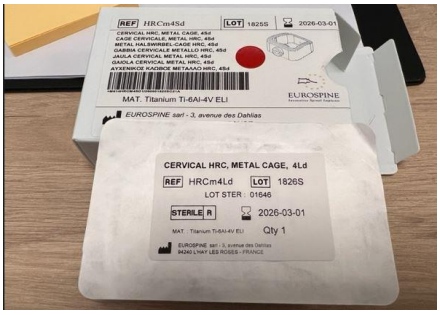
On October 7, 2022, the Henri Mondor AP-HP Hospital in Créteil informs us that during a surgical intervention and when opening an HRCm4SD lot 1825S cage, the person found that the internal label did not correspond to the box label.

The box label says HRCm4SD lot 1825S and the inner label says HRCm4LD lot 1826S.

When packaging these sterile cages, the packaging contractor used internal labels from another product that do not match the box labels.

This is a labeling error, the use of internal labels that do not match the product box labels, this is a regulatory non-compliance that directly impacts the identification and traceability of the product and which has no impact on the safety and performance of the sterile cage in question.

The information indicated on the primary packaging label (Reference: HRCm4Ld and batch number: 1826S) is incorrect and does not correspond to the correct information indicated on the secondary packaging label (Reference: HRCm4Sd and Batch No. batch: 1825S).



5) Potential Risk

This is a labeling error, the use of internal labels that do not match the product box labels, this is a regulatory non-compliance that directly impacts the identification and traceability of the product and which has no impact on the safety and performance of the sterile medical devices concerned because only the primary packaging label is incorrect, the box labels remain accurate.

6) Measures implemented by EUROSPINE SARL

As a safety measure, Eurospine is undertaking a voluntary recall of all products from batch 1825S and batch 1826S listed in appendix 01.

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INSTRUCTION FOR CORRECTIVE/PREVENTIVE ACTIONS

Actions required by users

Our records indicate that we have available at your institution devices affected by this notification.

Kindly Thank you to:

- Identify all affected devices present in your institution and place them in quarantine. Our representative will make an appointment with you as soon as possible to proceed to an exchange of product.
- Complete and return the attached form by which you confirm that you have read this safety information.
- Disseminate this information to all concerned within your institution
- For hospitals that have implanted non-compliant cages, self-adhesive compliant internal labels will be provided by Eurospine to bring the patient files and implant cards of the patients concerned into compliance.

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OTHERS

The relevant competent authorities have been informed of this action.
According to MEDDEV 2.12-1 Rev. 7, we remind you that it is necessary to report adverse reactions observed in the use of these devices to the relevant competent authorities and / or directly to EUROSPINE SARL.

In accordance with Article L. 1111-2 of the Public Health Code, it is up to the surgeon or healthcare professional to consider the procedures for informing patients already implanted with these devices.

For any questions, our Quality department is available by phone at +33 (0) 1 46 86 60 07 or email: jk@eurospinecompany.com

L'hay Les Roses At 2022-10-12
Quality Manager

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ACKNOWLEDGEMENT FORM
RETURN OF PRODUCTS

Name of organisation:	
Internal Reference Eurospine:	**RP006/22**
Designation of product	**Metallic Cervical Interbody Fusion Cage**
Part number of product:	**See appendix 01**
Lot:	**See appendix 01**

INFORMATIONS TO COMPLETE BY ORGANISATION

Thank to check your inventory. Thanks to complete, to sign and to send back this form to ensure the acknowledgement of this present return of products

☐ I acknowledge receipt of this Field Notice from Eurospine to inform me of voluntary return of products reference .....lot...

☐ I pass this form to all those individuals who need to be aware *within our organization (and/or our clients)*

☐ I checked the presence of concerned products in my inventory *within our organization (and / or our clients)* and I have not located devices

☐ I checked the presence of concerned products in my inventory *within our* organization *(and / or our clients)* and the units identified below were placed under quarantine.

IDENTIFICATION OF PRODUCT

Organization (and/or clients)	Part number of product	Lot	Quantities distributed by Eurospine	Quantities located in inventory	Quantities considered as lost, destroyed, implanted

INSTRUCTIONS FOR RETURN

1- Complete and return this form ***WITHIN A WEEK*** to Quality Manager by fax: +33 1 46 86 66 52 *or by E-mail: jk@eurospinecompany.com*
2- Eurospine will contact you to organize the return of concerned products
3- Put inside of package a copy of the present form
4- When it's appropriate, please ensure that a certificate of decontamination is attached to concerned products

Contact Name		**Stamp of organisation**	
Fonction			
Signature			
Phone		**Date**	

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Appendix 01: LIST OF CONCERNED REFERENCES

Batch 1825S		
Designation	Reference	Batch number indicated on the box label
Metallic Cervical Interbody Fusion Cage	HRCm4SD	1825S
Metallic Cervical Interbody Fusion Cage	HRCm5SD	1825S
Metallic Cervical Interbody Fusion Cage	HRCm6SD	1825S
Metallic Cervical Interbody Fusion Cage	HRCm7SD	1825S
Large Metallic Cervical Interbody Fusion Cage	HRCm5LD	1825S
Batch 1826S		
Designation	Reference	Batch number indicated on the box label
Large Metallic Cervical Interbody Fusion Cage	HRCm4LD	1826S
Large Metallic Cervical Interbody Fusion Cage	HRCm5LD	1826S
Large Metallic Cervical Interbody Fusion Cage	HRCm6LD	1826S
Large Metallic Cervical Interbody Fusion Cage	HRCm7LD	1826S

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