Antony,
23-10-2020

URGENT SAFETY INFORMATION (R2019874)

FIELD SAFETY NOTICE REGARDING THE VOLONTARY RECALL OF TL1-A011 & TL1-A012 SPINEVISION PRODUCTS

REFERENCE	TL1-A011	TL1-A012
DESIGNATION	Dura retractor	Nerve roots retractor
BATCH N°	OL2406GF/A OL2525GI/A OL2505GI/A OL1912GI/B OL3010GI/A OL0104GJ/B 65638/B 74991/B 124372/C	OL0104GJ/B OL2505GI/A OL3010GI/A 124373/C 65640/B 74946/B OL1912GI/B

Dear all,

We have recently received a notification from our Notified Body pointing out that two of our instruments that we have classified as class I, the TL1-A011 and TL1-A012, would in fact be class III instruments. Indeed, in view of the name and description of the use of these instruments given in the technical file, the notified body considers that these instruments are in direct contact with the central nervous system.

In order to avoid any incidents, SpineVision S.A.S. has decided to recall all products (TL1-A011 and TL1-A012) from the batches cited above and to stop marketing them on the European market. These instruments will not be replaced.

SPINEVISION SAS
10, rue de la Renaissance
Bâtiment E
92160 ANTONY – France
Phone : +33 (0)1 53 33 25 25
Fax : +33 (0)1 53 33 25 39

S.A.S. au capital de 1 698 640.06 euros
423 661 693 RCS Nanterre
APE 3250A
N° IC : FR 08423661693

IMMEDIATE MEASURES TO BE TAKEN BY THE CLIENT:

- Read this letter carefully and make sure that all relevant services are aware of its content,
- Determine and isolate all devices (TL1-A011 and TL1-A012) with one or more of the above batch number(s)
- A SpineVision representative will contact to help you in the process and organize the recall,
- Complete the form on page 3 of this letter and return it to SpineVision QA&RA vigilance correspondent:
  Julie THENOT, *Quality Assurance and Regulatory Affairs Project Leader*
  Tél : +33 1 53 33 25 25, Mail : corp.quality@spinevision.com
- This notification must be complied with until the action is completed. Please keep a copy of this notification.
- For questions regarding this security notice, please contact us at the following address : corp.quality@spinevision.com

ACTION PLAN:

- Identification of all the customers concerned
- Make a communication to the concerned customers with this letter
- Communicate to Competent Authority (MEDDEV Vigilance Guidance ref. 2.12-1)
- Recall of all products to SpineVision HQ; this recall will be directly managed by the SpineVision team

SpineVision confirms that the French health authority ANSM has been informed of this subject. We apologize for any inconvenience.

Sincerely,

Julie THENOT
Quality Assurance & Regulatory Affairs Project Leader
Tel. +33 1 53 33 25 25
corp.quality@spinevision.com

SPINEVISION®

CONFIRMATION FORM FSCA N° R2019874

URGENT SAFETY INFORMATION

Reference: TL1-A011, TL1-A012
Designation: Dura retractor, Nerve roots retractor
Concerned batches: TL1-A011: OL2406GF/A ; OL2525GI/A ; OL2505GI/A ; OL1912GI/B ; OL3010GI/A ; OL0104GJ/B ; 65638/B ; 74991/B ; 124372/C
TL1-A012: OL0104GJ/B ; OL2505GI/A ; OL3010GI/A ; 124373/C ; 65640/B ; 74946/B ; OL1912GI/B

ACKNOWLEDGMENT OF RECEIPT

(To be completed and returned)

Please complete the following fields:

Client's name	
Address	
Postal code, City	
Contact (Name and function)	
Contact (Direct phone and e-mail)	

By completing and returning this form, I confirm that I have received and read this Field Safety Notice and certify that:

☐ **Our stocks do not contain the medical devices concerned**

☐ **We have destroyed or discarded products from the following batches: …**

☐ **The following batches were removed from our stocks:**

REFERENCE	BATCH N°	QUANTITY
TL1-A011	OL2406GF/A	
	OL2525GI/A	
	OL2505GI/A	
	OL1912GI/B	
	OL3010GI/A	
	OL0104GJ/B	
	65638/B	
	74991/B	
	124372/C	
TL1-A012	OL0104GJ/B	

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	OL2505GI/A	
	OL3010GI/A	
	124373/C	
	65640/B	
	74946/B	
	OL1912GI/B	

For devices withdrawn from stock, please contact SpineVision S.A.S. to organise the return.

Place/Date : ……..

Signature :

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