SPINEVISION®

Antony,
17-07-2019

URGENT SAFETY INFORMATION (R1913257)

FIELD SAFETY NOTICE REGARDING THE RECALL OF SPINEVISION ULIS PRODUCT

REFERENCE	IS1-A316	IS1-A317
DESIGNATION	Tube Interne Persuader	Persuader
BATCH N°	75779/A 76277/A/B 77252/B 77253/B 72091/001 R75779/A/B	75846/A 76276/A/B 77585/A/B 76276/B 72091/001 R77585/A/B

Dear all,

We have been recently informed that during a surgery in Italy, the IS1-A317 and IS1-A316 of our U.L.I.S. system presented a malfunction. Indeed, during the maneuver (push the rod in the bottom of the head of the pedicle screw) the persuader (IS1-A317) was locked above the screw head and it was impossible to unscrew the internal tube IS1-A316 from the persuader. It has been impossible to remove the persuader (IS1-A314 and IS1-A316) from the head of the screw without removing the screw at the same time. It led to an additional surgery time.

In order to continue our investigation and to avoid any further incidents, SpineVision S.A.S. has decided to recall all products (IS1-A317 and IS1-A316) from the batches cited above.

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

S.A.S. au capital de 1 698 479.64 euros
423 661 693 RCS Nanterre
APE 3250A
N° IC : FR 08423661693

The new persuader U.L.I.S. composes of IS1-A316 and IS1-A317 has been designed to make surgery more comfortable for the surgeon. This instrument is not the only way to finish the surgery. The U1-A224 push rod, the U1-A312 rocker and the former IS1-A311 persuader can also allow the same maneuver to bring the rod in the screw head like it can be done with the IS1-A316 and IS1-A317 pair.

SpineVision undertakes to verify in the kits containing the IS1-A316 and the IS1-A317 that at least one of the references (U1-A224, U1-A312, IS1-A311) is present and is also committed to provide at least one of these references in the opposite case.

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 if your inventory contains devices with lot number (s) below and isolate them if it is the case :
  - IS1-A316
    - 75779/A
    - 76277/A/B
    - 77252/B
    - 77253/B
    - 72091/001
    - R75779/A/B

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- IS1-A317
  - 75846/A
  - 76276/A/B
  - 77585/A/B
  - 76276/B
  - 72091/001
  - R77585/A/B

- A SpineVision representative will contact to help you in the process and organize the recall

- Complete the form on page 5 of this letter and return it to SpineVision QA&RA Manager:
  Anaëlle GALLEGO, *Quality Assurance and Regulatory Affairs Manager*
  Tél : +33 1 53 33 25 52
  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

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ACTION PLAN :

- Identification of all the customers concerned by the lots mentioned above
- Make a communication to the concerned customers with this letter
- Communicate to Competent Authority (MEDDEV Vigilance Guidance ref. 2.12-1)
- Recall of all affected batches to SpineVision HQ; this recall will be directly managed by the SpineVision team
- Investigation of the relevant references to determine the cause

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

Sincerely,

Anaëlle GALLEGO
Quality Assurance and Regulatory Affairs Director
Tel. +33 1 53 33 25 52
Corp.quality@spinevision.com

SPINEVISION®

CONFIRMATION FORM FSCA N° R1913257

URGENT SAFETY INFORMATION

Reference : IS1-A317, IS1-A316
Designation : Persuader, Tube Interne Persuader
Concerned batches: 75779/A, 76277/A/B, 77252/B, 77253/B, 72091/001, R75779/A/B, 75846/A, 76276/A/B, 77585/A/B, 76276/B, R77585/A/B

ACKNOWLEDGMENT OF RECEIPT

Please complete the following fields:

Client N°	
Hospital	
Address	
Postal code, City	
Contact (Name and function)	

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**

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

BATCH N°	QUANTITY
75779/A	
76277/A/B	
77252/B	
77253/B	
72091/001	
R75779/A/B	
75846/A	
76276/A/B	
77585/A/B	
76276/B	
R77585/A/B	

Place/Date : .....

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