SPINEVISION
INNOVATION THAT MATTERS

Antony,
20 Dec 2022

FIELD SAFETY NOTICE (FSCA R2234469)

FIELD SAFETY NOTICE REGARDING THE VOLONTARY RECALL OF

U1-A326 and U1-A327 CORONAL ROD BENDER

REFERENCE	U1-A326	U1-A327
DESIGNATION	Right coronal rod bender	Left coronal rod bender
BATCH N°	618779/B 630355/B 661633/B	618780/B 630357/B 661634/B

Dear Madam or Sir,

SpineVision has recently been made aware some rod breakage that occured during surgeries. These rod breakage leads to a short lengthening of the surgical procedure due to the replacement of the broken rod, without any adverse event. After investigation, the root cause has been attributed to the use of frontal bending irons (ref. U1-A326 and U1-A327), revision B.

The risk analysis determines that this rare event occurred during the surgery and therefore is automatically detected by the surgeon, the risk for patients is very limited. Nevertheless, in order to avoid unnecessary lengthening of the surgical procedure SpineVision has decided to perform a voluntary recall. The design of the instrument will be revised, in the meantime, the revision A of the instrument may continue to be used.

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IMMEDIATE MEASURES TO BE TAKEN BY THE CLIENT:

- Read this letter carefully and make sure that all relevant stakeholders are aware of its content,
- Segregate the frontal bending irons, ref. U1-A326 and U1-A327, revision B (identified on the lot number xxxxxx/B)
- In case of need, use the revision A of frontal bending irons ref. U1-A326 and U1-A327 or contact SpineVision in case of replacement need
- Return the acknowlegdement back before January 30th, 2023 to SpineVision.
- A SpineVision representative will contact to help you in the process and organize the recall,
- For questions regarding this security notice, please contact us at the following address : corp.quality@spinevision.com

the French competent authority ANSM has been informed of this subject. We apologize for any inconvenience.

Sincerely,

[redacted]

VP Quality Assurance & Regulatory Affairs
Tel. +33 1 53 33 25 25
corp.quality@spinevision.com

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CONFIRMATION FORM FSCA N° FSCA R2234469

FIELD SAFETY NOTICE

Reference: U1-A326, U1-A327
Designation: Right coronal rod bender ; Left coronal rod bender
Concerned batches: U1-A326: 618779/B ; 630355/B ; 661633/B
U1-A327: 618780/B ; 630357/B ; 661634/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 devices concerned by this recall**

☐ **We have segregated the devices and we DO NOT need a replacement and ask Spinevision to organize the return of the products**

☐ **We have identified and send back to SpineVision and we NEED a replacement:**

REFERENCE	BATCH N°	QUANTITY
U1-A326	618779/B	
U1-A326	630355/B	
U1-A326	661633/B	
U1-A327	618780/B	
U1-A327	630357/B	
U1-A327	661634/B	

Date : .....

Stamp and Signature :