

ANTONY, 2019-03-13

SUBJECT : FIELD SAFETY NOTICE regarding SPINEVISION C3 product

Reference	C1-A206N1 revision C
Designation	Pins for Distractor-Compressor
Batch	001927/C

Reporting issue

We have recently been informed of a problem on an instrument used with the C3 system :

- Instrument : Pins for distractor-compressor
- Reference : C1-A206N1 revision C - batch number 001927/C
- Problem detected : this instrument cannot be used with the usual distractor of the system (reference C1-A201)

Please see the pictures below for further details.

Picture of Pins Distractor/Compressor (reference C1-A206N1 revision C)

SPINEVISION SAS
10 rue de la Renaissance
Bâtiment E
euros
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 662 578.80

423 661 693 RCS Nanterre
APE 3250A
N° IC : FR 08423661693





Assembly between the distractor (reference C1-A201) and the pins (revision C) isn't possible



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Analysis

The assembly between the pins and the distractor isn't possible for the revision C of the pins instrument only (reference : C1-A206N1). This is a manufacturing issue which concerns all batches manufactured with revision C.

Action Plan

- Identification of all customers using the revision C of this instrument
- Communication to these customers (present report)
- Communication to competent authorities (according to MEDDEV Vigilance Guidance ref. 2.12-1)
- Return of all concerned instruments to SpineVision HQ ; this return will be directly managed by SpineVision team
- Supply of new pins distractor/compressor to the corresponding customers

For any question, please do not hesitate to contact me.

Sincerely,



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

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