Doc. Ref. FSN202502

From Orthofix Srl Quality Compliance

TO WHOM IT MAY CONCERN

Urgent: Field Safety Notice ref. FSCA202502

Subject: **VOLUNTARY MEDICAL DEVICE RECALL**

HALF PIN L120MM D4.0MM THREAD D4.0XL18MM PACK OF 2 STERILE, code reference 99-50-2511M

In Attachment A is reported the list of code and batches involved in this action.

Details of the FSCA	
Date	**July 25, 2025**
Reference Contact	Orthofix Srl Customer Service Department Orthofix Srl Via delle Nazioni, 9 - 37012 Bussolengo (Verona) Italy e-mail: customerservice@orthofix.it and complaintintl@orthofix.com – tel. +39 045 6719000 – fax. +39 045 6719380
Affected Products	Please kindly refer to Attachment A for the list of the affected product lots.
Details of the FSCA	Product code 99-50-2511M HALF PIN L120MM D4.0MM THREAD D4.0XL18MM PACK OF 2 STERILE (lots listed in Attachment A) was sterilized using Beta radiation, whereas the validated method for sterilizing this product is Gamma sterilization. Orthofix has not been made aware of any adverse patient outcomes as a result of this issue as this event was found internally. Please note that **only** the code 99-50-2511M (pack of 2) with lots indicated in Attachment A are affected by this issue. All other configurations of Half pins (reference code 99-50-2511-single packed sterile and reference code 50-2511-single packed non-sterile and half pins included in kit) **are not** the subject of this action and can be distributed and used.
Risk for patient	Use of not validated sterilization method may lead to a non-sterile product which may result in infection and extended surgical time if the screws need to be replaced.

Immediate Actions Required – PLEASE REPLY BY AUGUST 5, 2025	
For Distributors	Immediately cease any further distribution of the affected devices. Immediately identify the products in your warehouse which are involved in this action, remove them from inventory and return to Orthofix Srl (see contact details above). Please ensure that all who received, or who may have received, affected units from you are provided immediately with this Field Safety Notice. Please fill in the **REPLY FORM** with all the above information and send to Orthofix.
For Hospitals	Do not use any products involved in this action and immediately return to your local distributor or directly to Orthofix Srl (see contact details above).
Products already used on patient	For patients who have undergone a surgical procedure using a half pin involved in this action, we recommend continuing their prescribed post-operative activities and follow-ups as recommended by their physician. Should patients experience any reaction post-operative please contact us at customerservice@orthofix.it and complaintintl@orthofix.com.

ATTACHMENT A - List of lots reported on the label of the devices involved in the FSCA202502

Product code	Product Description	Label Lot
99-50-2511M	HALF PIN L120MM D4.0MM THREAD D4.0XL18MM PACK OF 2 STERILE	B5332685
99-50-2511M	HALF PIN L120MM D4.0MM THREAD D4.0XL18MM PACK OF 2 STERILE	B5355666
99-50-2511M	HALF PIN L120MM D4.0MM THREAD D4.0XL18MM PACK OF 2 STERILE	B5398749
99-50-2511M	HALF PIN L120MM D4.0MM THREAD D4.0XL18MM PACK OF 2 STERILE	B5447654

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

Respectfully,

Gianluca Ricadona (Jul 25, 2025 10:26:51 GMT+2)

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