stryker

URGENT:

MEDICAL DEVICE RECALL

STRYKER HOFFMANN LIMB RECONSTRUCTION FRAME

Attn: Health Care Professionals, Operators of Medical Devices, Distributors

Product Field Action Number: RA2024-3619280

xx-May-2024

Product affected

Catalog number	GTIN	Product description	Batch #	Distribution Dates
49339100	07613252611035	Wire Tensioner Hoffmann LRF	J43995	21/Feb/2017 – 06/Feb/2018

The purpose of this notification is to advise you that Stryker is conducting a field action on one specific lot of WIRE TENSIONER HOFFMANN LRF. Please refer to the table above for catalog and lot numbers within the scope of this field action that were identified as disseminated to distributors and end users.

Product description

The Wire Tensioner provides tightening assistance in combination with the wire bolt offset adaptors for tension loads on the wires of 50kg, 90 kg, and 130 kg. This is used in the Hoffmann LRF (Limb Reconstruction Frame, HLRF) System.

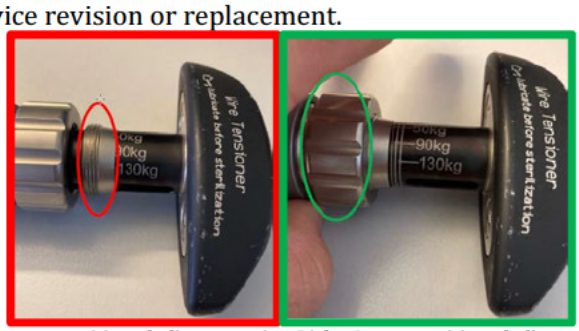
The Hoffmann LRF (Limb Reconstruction Frame, HLRF) System provides external fixation components to build a circular external fixation frame. The devices are modular external fixation devices intended to provide temporary stabilization of bones and bone fragments.

Product issue

Stryker has identified a nonconformance in one specific lot of Wire Tensioner Hoffmann LRF. Specifically, the adjustment ring may become loose, even if the device has been used successfully over a longer period. The wire tension can then no longer be set correctly.

Potential risks

The hazards associated with this issue are a loss of function of the instrument and potentially insufficient rigid fixation of the external fixation device. The nonconformance is detectable during pre- and postoperative reprocessing but not always during surgical use. The potential harms are prolonged episode of care and device revision or replacement.



Left: Incorrect position of adjustment ring; Right: Correct position of adjustment ring

Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions.

1. Immediately check your internal inventory to locate the product(s) listed on the attached Business Reply Form, remove them from their point of use, and isolate/quarantine the unit(s) to prevent accidental use.
2. Sign and return the enclosed Business Reply Form by email to <xxxxxx@stryker.com> to confirm receipt of this notification/documenting product disposition.
    a. **Response is required, even if you may not have any physical inventory on site anymore.** It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also eliminate the need for us to send further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.
3. Upon receipt of the completed Business Reply Form, Stryker will contact you to arrange for the return of your product(s).
4. Maintain awareness of this communication internally until all required actions have been completed within your facility.
5. If you have further distributed the affected product, please notify the applicable parties at once about this recall. You may copy and distribute this notification letter.
    a. If possible, inform us if any of the subject devices have been distributed to other organizations, including contact details.
    b. If you are a distributor, note that you are responsible for notifying your affected customers.
6. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: email:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1 and EU 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action and regret any inconvenience caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market.

Sincerely,

stryker

Business Reply Form

Account number:
Account name:
Account Address:

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Please complete and sign this form. Email the completed form to <fieldaction@stryker.com> by <**MMM DD YYYY**>.

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog number	Product Description	Batch #	Quantity on hand*
49339100	Wire Tensioner Hoffmann LRF	J43995	

*If all devices have been used and no affected devices are available for return, please enter 0 (zero).

Form completed by:

Printed Name		**Title**	
Signature		**Phone**	
Date		**Email**	

If you have further distributed any affected product, please indicate to whom:

Product(s) Distributed		**Quantity** Distributed	
Facility Name		**Contact Person**	
Full Address			

☐ **I have read and understand the instructions provided and acknowledge receipt of the subjected FSN.**

☐ **I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of subjected devices noted in this letter.**

Name (print)_____Signature_____Date :