stryker

URGENT:
MEDICAL DEVICE RECALL

HOFFMANN LRF

Attn: Health Care Professionals, Operators of Medical Devices, Distributors
Recall Number: PFA 3211895
February??, 2023 / ?? February 2023

Product affected

Catalog number	UDI	Product description	Lot Code	Distribution Dates
49330400	07613327094640	Transport Strut Hoffmann LRF	see Attachment A	20-May-2019 to 11-Oct-2022

The purpose of this notification is to advise you that Stryker is conducting a voluntary recall of specific lots of Hoffmann LRF Bone Transport Struts. Please refer to Attachment A for a list of the lot numbers that were identified as shipped to distributors and end users.

Product description

The Hoffmann LRF (Limb Reconstruction Frame, HLRF) System provides external fixation components to build a circular external fixation frame. The Transport Strut Hoffmann LRF is used in combination with circular rings to build both, Bone Transport Frames and Bone Lengthening Frames.

Product issue

Stryker has identified a nonconformance in specific lots of Hoffmann LRF Bone Transport Struts. Specifically, the thread pitch is oversized at the distal end of the threaded rod, and as a result the distal ring fixation cannot be locked between 0-50mm of the threaded rod (see Figure 1).

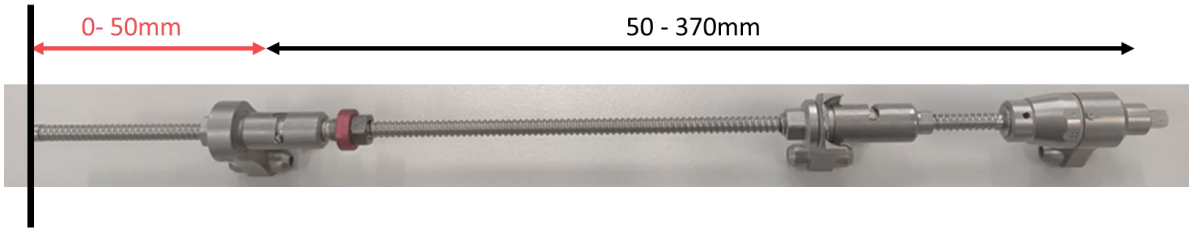

Figure 1: Image of Strut, nonconforming section identified in red, 0-50 mm at the distal end

Potential risks

The hazard associated with this issue has the potential for intra-operative (frame building) or post-operative (frame extension) complications.
The malfunction of the struts can be detected intraoperatively, during the construction of the frame. In this case a backup device (Transport Strut Hoffmann LRF of a lot which is not affected by this Field Action) could be utilized or the frame build can be modified to prevent usage of the most distal 50 mm of the strut during the transport treatment.
If the malfunction went undetected intraoperatively, a medical intervention may be needed to prevent a leg length difference. We anticipate this is unlikely to occur, as the pins should not be placed close to the joint, and the adjustment of the struts to

the 0-50 mm (distal) range is anticipated to only be utilized on patients with a very long tibia (>46cm).

Recommendations We recommend that physicians verify at the next routine check-up whether an adjustment of the struts will be impacted by the affected area 0-50 mm (distal) during the course of treatment.

Actions needed

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 <xxx@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. Spread awareness of this communication internally until all required actions have been completed within your facility.
5. Inform Stryker if any of the subject devices have been distributed to other organizations. If so, provide contact details so that Stryker can inform the recipients appropriately.
6. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations.

If you have any questions or concerns, please contact Customer Service +1 800 XXX XXXX.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action by the target date <MMM DD YYYY> 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,

Meghan Wells
Product Field Action Manager
Stryker
Trauma & Extremities
meghan.wells@stryker.com

Once again, please email <xxx@stryker.com> with the enclosed acknowledgement of this notification.

Attachment A: Product Affected

Product Number	Product Description	Lot Code
49330400	Transport Strut Hoffmann LRF	D32158
49330400	Transport Strut Hoffmann LRF	D32160
49330400	Transport Strut Hoffmann LRF	D32161
49330400	Transport Strut Hoffmann LRF	D32162
49330400	Transport Strut Hoffmann LRF	D32163
49330400	Transport Strut Hoffmann LRF	D32164
49330400	Transport Strut Hoffmann LRF	D34343
49330400	Transport Strut Hoffmann LRF	D34344
49330400	Transport Strut Hoffmann LRF	D40690
49330400	Transport Strut Hoffmann LRF	D41629
49330400	Transport Strut Hoffmann LRF	D41630
49330400	Transport Strut Hoffmann LRF	D41631
49330400	Transport Strut Hoffmann LRF	D44713
49330400	Transport Strut Hoffmann LRF	D56099
49330400	Transport Strut Hoffmann LRF	D57346
49330400	Transport Strut Hoffmann LRF	G12002
49330400	Transport Strut Hoffmann LRF	G13595
49330400	Transport Strut Hoffmann LRF	G16331
49330400	Transport Strut Hoffmann LRF	G16332
49330400	Transport Strut Hoffmann LRF	G16333
49330400	Transport Strut Hoffmann LRF	G26278
49330400	Transport Strut Hoffmann LRF	G29759
49330400	Transport Strut Hoffmann LRF	G29760
49330400	Transport Strut Hoffmann LRF	G32730
49330400	Transport Strut Hoffmann LRF	G32731
49330400	Transport Strut Hoffmann LRF	G32735
49330400	Transport Strut Hoffmann LRF	G45119
49330400	Transport Strut Hoffmann LRF	H30398
49330400	Transport Strut Hoffmann LRF	H30399
49330400	Transport Strut Hoffmann LRF	H30794
49330400	Transport Strut Hoffmann LRF	H32791
49330400	Transport Strut Hoffmann LRF	H38231
49330400	Transport Strut Hoffmann LRF	H40330
49330400	Transport Strut Hoffmann LRF	H46396
49330400	Transport Strut Hoffmann LRF	H55576
49330400	Transport Strut Hoffmann LRF	H58071
49330400	Transport Strut Hoffmann LRF	H61935
49330400	Transport Strut Hoffmann LRF	H64013
49330400	Transport Strut Hoffmann LRF	H66392
49330400	Transport Strut Hoffmann LRF	H68903
49330400	Transport Strut Hoffmann LRF	K26870
49330400	Transport Strut Hoffmann LRF	K36310
49330400	Transport Strut Hoffmann LRF	K36311
49330400	Transport Strut Hoffmann LRF	K36312
49330400	Transport Strut Hoffmann LRF	K41103
49330400	Transport Strut Hoffmann LRF	K57214

stryker

Business Reply Form

Account number:
Account name:
Account Address:

HOFFMANN LRF

Recall Number: PFA 3211895

February ??, 2023 / ?? February 2023

Please complete and sign this form. Email the completed form to **<xxx@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	Lot Code	Quantity on hand*
49330400	Transport Strut Hoffmann LRF		
49330400	Transport Strut Hoffmann LRF		
49330400	Transport Strut Hoffmann LRF		
49330400	Transport Strut Hoffmann LRF		
49330400	Transport Strut Hoffmann LRF		
49330400	Transport Strut Hoffmann LRF		

*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, if possible:

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