stryker

URGENT:
MEDICAL DEVICE RECALL

Hoffmann® II Carbon Connecting Rod Cracking

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

Reference Number: RA2026-4365088

XX-July-2026

Product Affected

Catalog number	UDI-DI	Product description	Batch Lot #
50796030	04546540389893	Connecting Rod Hoffmann® II Micro Ø 3 x 30mm	All lots
50796040	04546540389909	Connecting Rod Hoffmann® II Micro Ø 3 x 40mm	
50796050	04546540389916	Connecting Rod Hoffmann® II Micro Ø 3 x 50mm	
50796060	04546540389923	Connecting Rod Hoffmann® II Micro Ø 3 x 60mm	
50796090	04546540389930	Connecting Rod Hoffmann® II Micro Ø 3 x 90mm	
50796120	04546540389947	Connecting Rod Hoffmann® II Micro Ø 3 x 120mm	
50796150	04546540389954	Connecting Rod Hoffmann® II Micro Ø 3 x 150mm	

The purpose of this notification is to advise that Stryker is conducting a recall on certain catalog numbers of Hoffmann® II Carbon Connecting Rods. Please refer to the table above for the catalog and lot numbers in scope of this recall that were identified as disseminated to distributors and end users.

Product description

The Hoffmann® II Micro External Fixation System is intended to provide stabilization of open and/or unstable fractures in children and adults where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting or other means of internal fixation in conjunction with commercially available Fixation Pins and/or Kirschner Wires. The system is intended to stabilize fractures of the humerus, elbow, wrist, maxillo-facial area, forearm, hand, ankle and foot.

The Hoffmann® II Carbon Connecting Rods are used to connect the APEX pins to each other via couplings in order to obtain a stable frame.

The Hoffmann® II Micro External Fixation System consists of different types of clamps, couplers, rods, a lengthener, pins and wires. This system is intended to stabilize fractures of the humerus, elbow, wrist, maxillo-facial area, forearm, hand, ankle and foot.

The Hoffmann® II Carbon Connecting Rods have a diameter of 3mm and are offered in lengths of 30mm, 40mm, 50mm, 60mm, 90mm, 120mm, and 150mm. These connecting rods are made of carbon composite material with epoxy coating.

Product issue

Subsequent to product complaints, Stryker has confirmed that cracking of the Hoffmann® II Carbon Connecting Rods may occur following cleaning and sterilization performed during initial processing as well as subsequent reprocessing. Continual reprocessing cycles were found to increase the risk of cracking the rods. No injuries have been reported associated with this issue. 26 malfunctions have been reported.

Potential risks

The hazard associated with this issue is insufficient rigid fixation causing loss of mechanical stability. The cracks are detectable preoperatively, reference Figure 1. In the event that cracks are detected intraoperatively, prolongation of surgery or change of surgical method may occur. In the event that the cracks are not detected, a construct failure may occur which could necessitate a revision surgery to prevent permanent harm.

Figure 1: Hoffmann® II Carbon Connecting Rod End with cracking

Action needed by Customers and Distributors

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 listed on the attached business reply form.
2. Review the product issue and risks as communicated in this Safety Notice and communicate the issue as appropriate in your organization.
3. Cracking of the Hoffmann® II Carbon Connecting Rods may occur following cleaning and sterilization. Until further notice, **the subject devices are limited to single use only. Following the first use, discard the devices in accordance with your facility's established procedures.**
4. Instruct all relevant personnel that affected product must be inspected for cracking and other damage prior to use.
5. **Conduct visual inspection of product issues prior to each use as set forth in the product's Instructions for use. Specifically, the following steps will help identify cracking of the rods:**
   - **Before every operation, ensure that all devices to be used during the operation function correctly with each other.**
   - **Inspection is recommended prior to surgery to determine if product has been damaged during storage.**
6. **If cracking is found to be present**, isolate/quarantine non-conforming parts as appropriate in your organization and report the matter to Stryker's Trauma & Extremities division complaint department at xxxx@stryker.com. If cracking is not observed, normal care and post-operative follow-ups should be maintained.
   Note: Any rods with cracks should be returned as part of the complaint process. Return instructions will be provided by the complaint department upon receiving the report.
7. Return the enclosed business reply form by email to confirm receipt of this notification.
   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 negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete the form even if you no longer have any of the subject devices in your physical inventory.
8. Maintain awareness of this communication internally until required actions have been completed within your facility.
9. If you have further distributed the affected product, please notify the applicable parties. 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, so that we can inform the recipients appropriately.
   b. If you are a distributor, note that you are responsible for notifying your affected customers.

10. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations. For questions or concerns, please contact XXXXXX@stryker.com

    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: E-mail:

In line with the recommendations of the Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 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,
Post Market Quality

Business Reply Form

Account name:
Account Address:

Hoffmann® II Carbon Connecting Rods

Reference Number: RA2026-4365088

Please complete and sign this form. Email the completed form to **XXXX@stryker.com** by **XX-July-2026**.

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

Catalog Number	Lots	Qty Received	Inspection: Quantity of product with cracking	Inspection: Quantity of products with no cracking

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			

Please note that if you notice a cracking on the roads a product complaint should be raised to the following e-mail address: xxxxx@stryker.com