

URGENT:
MEDICAL DEVICE RECALL

Hoffman® 3 Pin Chuck

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

Reference Number: RA2026-4313336

22-April-2026

Product Affected

Catalog Number	UDI-DI	Item Description	Batch Lot #	Distribution Dates
49229050	08858251002872TK	Chuck for Pins 3 Universal for Dia 4,5,6mm	1544AB	4-December-2024 through 30-September-2025
			AN4261	
			AP3761	
			AR4000	
			AU0794	

The purpose of this notification is to advise that Stryker GmbH is conducting a recall (removal) for specific lots of Hoffman® 3 Pin Chucks. Please refer to the table above for the catalog and lot numbers within scope of this recall that were identified as shipped to distributors and end users.

Product description The Hoffmann 3 Modular External Fixation System is used to provide stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts or other means of internal fixation.

Product issue Stryker confirmed that certain lots of Hoffman 3 Universal Pin Chucks contained inhomogeneous coating with out-of-specification coating thickness and color. This nonconformance was discovered via product complaint.

Potential risks The hazard associated with this nonconformance is that the parts are not fully functional. The heterogeneity of the Ni PTFE coating may accelerate degradation and compromise device performance. Additionally, the discoloration of the device may be perceived to the user to be unclean, contaminated, or contain debris, however the device is only discolored. If a device contains heterogeneous coating, an additional device may be required resulting in prolongation of surgery.



Figure 1: Heterogeneous coating of the Pin Chuck

Actions 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, remove them from their point of use, and isolate/quarantine the unit(s) to prevent accidental use.
2. Review the product issue and risks as communicated in this Recall Notice and communicate the issue as appropriate in your organization.
3. Return the enclosed business reply form by email to confirm receipt of this notification/document product segregation.
 - 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.
4. Upon receipt of the completed business reply form, Stryker will contact you to arrange for the return of your product(s).
5. Maintain awareness of this communication internally until required actions have been completed within your facility.
6. 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.
7. 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 xxxxx@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:

Hoffman® 3 Pin Chuck

Reference Number: **RA2026-4313336**
22-April-2026

Please complete and sign this form. Email the completed form to **XXXXX@stryker.com** by **6-May-2026**.

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 #	Quantity on hand*
49229050	Chuck for Pins 3 Universal for Dia 4,5,6mm	1544AB	
		AN4261	
		AP3761	
		AR4000	
		AU0794	

*If 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			

- 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 _____