

URGENT:
MEDICAL DEVICE RECALL

Hoffmann® 3 Pin Chuck

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

Reference Number: RA2026-4313336

13-May-2026

Product Affected

| Catalog Number | UDI-DI | Item Description | Batch Lot # | Engraved Lot # | Distribution Dates |
|----------------|------------------|--|-------------|----------------|--|
| 49229050 | 08858251002872TK | Chuck for Pins 3 Universal for Dia 4,5,6mm | 1544AB | 1544AB | 4-December- 2024 through 30-September- 2025 |
| | | | AN4261 | 3438AB | |
| | | | AP3761 | 3438AB, 4330AB | |
| | | | AR4000 | 4330AB | |
| | | | AU0794 | 4330AB, 6337AB | |

The purpose of this notification is to advise that Stryker GmbH is conducting a recall (removal) for specific lots of Hoffmann® 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. The outer packaging of the Hoffmann 3® Pin Chuck, seen in Figure 1, contains its batch lot number. The part itself is engraved with its semi-finished good lot number, as seen in Figure 2. The associated batch lot number for each engraved semi-finished good lot number can be found in the table above.

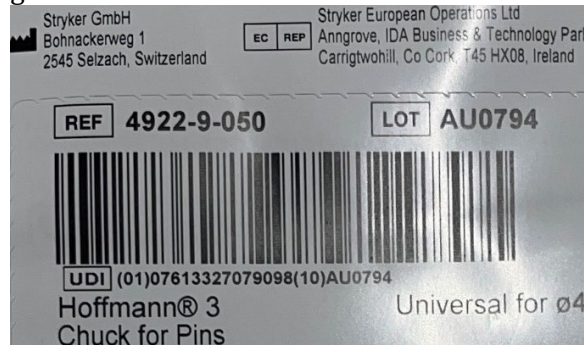


Figure 1: Outer Packaging



Figure 2: Engraved Lot Number

Product issue

Stryker confirmed that certain lots of Hoffmann® 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 memphis.fieldaction@stryker.com.

If adverse reactions or quality issues are experienced with the use of this product, please report the matter to:

- Stryker's Trauma & Extremities division complaint department [traumaextremitiescomplaints@stryker.com]; or
- the FDA MedWatch Serious Injury Reporting Program:
 - Online: By completing and submitting the report online at: www.fda.gov/medwatch
 - Regular mail or fax: Download the form from www.fda.gov or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be 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,

Dannielle Stap
Director, Post Market Quality
Stryker

Trauma & Extremities
Dannielle.stap@stryker.com

Business Reply Form

Account name:
Account Address:

Hoffmann® 3 Pin Chuck

Reference Number: PFAA 4220528 / PFAE 4313336

13-May-2026

Please complete and sign this form. Email the completed form to memphis.fieldaction@stryker.com by **27-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 # | Engraved Lot # | Quantity on hand* |
|----------------|--|--------|----------------|-------------------|
| 49229050 | Chuck for Pins 3 Universal for Dia 4,5,6mm | 1544AB | 1544AB | |
| | | AN4261 | 3438AB | |
| | | AP3761 | 3438AB, 4330AB | |
| | | AR4000 | 4330AB | |
| | | AU0794 | 4330AB, 6337AB | |

*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 | | | |