

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

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 Confidential business information 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 _____