Date: 21 December 2021

URGENT FIELD SAFETY NOTICE (REMOVAL):
Universal Chuck

Product Subject to this Removal:

Part Number	Part Description	Lot(s)	GTIN
03.043.001	Universal Chuck	20229201, 20911101 21210202, 21781103	761233416797

Dear Valued Customer,

DePuy Synthes is initiating a medical device recall (removal) of all lots of the Universal Chuck described above due to a potential issue with the design of the top cap.

The Universal Chuck is an Instrument Handle provided as an alternative instrument available for use in the TN-ADVANCED™ Tibial Nailing System (TNA), TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA), RFN-ADVANCED™ Retrograde Femoral Nailing System (RFNA), FRN-ADVANCED™ Femoral Recon Nailing System (FRNA), and Flexible Monobloc Reamers.

Reason for the Medical Device Recall:

The subject product is being recalled due to a potential issue with the design of the top cap of the Universal Chuck. The top cap may loosen and detach if the Universal Chuck becomes jammed and the user attempts to manually free the device. (See figure A).

Figure A:
Top cap which may loosen and detach

Potential Patient Impact:

The Universal Chuck is an alternative instrument, therefore it is not required to be used in all procedures. If the Universal Chuck is used and becomes jammed and the user attempts to free the device manually, the top cap could become loose and detach. In the unlikely event, the top cap is loosened and detached, there is a potential for the internal ball bearings (16 total) to fall out onto the surgical field. This may lead to surgical delay or, and if not recovered, adverse tissue reaction and infection.

To date, there have been (24) reported complaints related to this issue. However, no adverse events have been reported.

If the subject product has been used, medical staff may continue to follow up with patients post-operatively according to the surgeon's standard of care.

Please take the Following Steps:

1. Examine your inventory immediately to determine if you have the subject products and quarantine the subject product. DO NOT USE THE SUBJECT PRODUCT.
2. Contact your DePuy Synthes Sales Consultant to coordinate the return/credits of the subject product.
3. Review, complete, sign, and return the attached business response form (page 3 of this letter) to your local DePuy Synthes Sales Representative.
4. Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products).
5. If any of the subject product has been forwarded to another facility, contact that facility and provide them with this notice.
6. Post a copy of this notice in a visible area for awareness and keep a copy for your records.

This medical device product recall has been reported to the local competent authority.

We apologize for the inconvenience that this recall may cause and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes Sales Consultant. For Medical Information request, please visit our website: https://www.jnjmedicaldevices.com/mir.

Thank you for your attention and cooperation.

Sincerely,

Mona Rehmatullah
Senior Recall Coordinator
Email: OneMD-Field-Actions@its.jnj.com

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Business Response Form

Product Subject to this Removal:

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☐ The subject product has been located. A copy of this notice is being retained and I have read and understood the notification. RETURNED Quantity:_____

☐ None of the subject product is available for return. A copy of this notice is being retained and I have read and understood the notification.

Please complete this Business Response Form (BRF) Form within 3 days after the receipt of this notification and return to your local DePuy Synthes Sales Representative.

Your Name/Title:	Facility/Business Name:
Signed*:	Date:
Address:	
Account Number:	
J&J Sales Rep (as applicable):	
Email Address:	Telephone Number:
**Your signature provides confirmation that you have received and understood this notification.*	