Date: 8 December 2022

URGENT FIELD SAFETY NOTICE

ANSPACH™ EMAX™ 2 Plus/EG1™ Electric Systems-Craniotome Attachments

Products in Scope:

Part Number	Part Description	Serial Number	GTIN
CRANI-A	6.5cm Adult Crani Attachment	All	00845384001720
CRANI-A-01	6.5cm Adult Crani, Thin FT Plate	All	00845384001737
CRANI-A-G1	Adult Craniotome	All	00845384016410
CRANI-A-R	R Rotating Adult Craniotome	All	00845384001744
CRANI-L	7.5cm Large Craniotome Attachment	All	00845384001751
CRANI-L-G1	Adult Craniotome, Large	All	00845384016427
CRANI-L-R	Rotating Large Craniotome	All	00845384001768
CRANI-P	6.5cm Pediatric Craniotome	All	00845384001775
CRANI-P-G1	Pediatric Craniotome	All	00845384016403

Dear Valued Customer,

DePuy Synthes has initiated a voluntary Field Safety Notice (notification) of the Craniotome attachments for ANSPACH™ EMAX™ 2 Plus/EG1™ Electric Systems. The Craniotome attachments are intended for cutting and shaping bone including the spine and cranium by trained medical/surgical personnel.

All lots of the subject devices are covered by this field safety notice. Our records show that your facility has received one or more of the products(s) listed in the table above. There is no anticipated supply disruption for these products. There is no requirement to return your inventory of the products subject to this notification if the inventory at your facility has been returned to DePuy Synthes Power Tools or an authorized service site at a minimum of every 12 months for product inspection.

Reason for the Field Safety Notice:
DePuy Synthes has received two complaints from China indicating that the ball bearings in the CRANI-A (ANSPACH Power Tools Adult Craniotome Attachment) came out of the attachment, possibly during removal of the attachment, intra-operatively. Exact circumstances are unknown. However, the affected attachments were used well beyond the recommended service interval of 12 months. Use of the ANSPACH craniotome attachments outside of the required service interval and/or displaying end of life indicators may result in device damage. Extreme care must be exercised to ensure that if damage occurs and fragments are released from the damaged device, then the surgical field must be examined to prevent foreign bodies from being left in the patient. Therefore, it is hereby notified through this field action that to ensure equipment operates as designed, read and follow the manufacturer's instructions, including those for proper service and maintenance. As per the "Recommended Manufacturer Inspection Interval" section in the Instructions for Use (IFU), the equipment should be returned to DePuy Synthes Power Tools at a minimum of every 12 months so that a full product inspection can be performed. Failure to follow the recommended inspection intervals provided in the IFU may result in serious patient injury.

Please take the Following Steps:

- Review your inventory and make a plan to follow the suggested manufacturer inspection interval of 12 months associated with your product, as specified in the IFU.
- Review, complete, sign, and return the attached business response form (page 3 of this letter) to your local DePuy Synthes Sales Representative.
- Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the devices subject to this action).
- If any of the subject device has been forwarded to another facility, contact the facility and provide them with this notice.
- Contact your Product Support Team at [Insert country specific information here] for additional support as needed.

This field safety notice has been reported to the local competent authority.

We apologize for any inconvenience that this notification may cause and appreciate your cooperation with our request.

Thank you for being a DePuy Synthes Power Tools Customer.

Sincerely,

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

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Business Response Form

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CRANI-L-R	Rotating Large Craniotome	All	00845384001768
CRANI-P	6.5cm Pediatric Craniotome	All	00845384001775
CRANI-P-G1	Pediatric Craniotome	All	00845384016403

Please complete this Business Reply Form (BRF) within 3 days after you have been notified and return this form via email to [Insert country specific information here].

☐ **By signing this form, I am confirming that I have read and understood the notification.**

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