Date: 09 January 2023

Dear Valued Customer,

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

Please distribute this information to appropriate personnel at your facility.

To The Attention of:

Operating Room Manager/Surgeon

Johnson & Johnson 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

Johnson & Johnson 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.

Customer Immediate Actions

Our records indicate that your facility may have ordered or are a user of the product(s) subject to this medical device field safety notice. Please take the required actions as follows:

- 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 customer acknowledgement letter (Attachment A of this letter) to your Johnson & Johnson sales consultant or contact person.
- 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. Inform Johnson & Johnson if further facilities are affected.
- Contact Johnson & Johnson sales consultant or contact person for additional support as needed.
- Please keep a copy of this notice for your awareness and records.

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

We apologize for any inconvenience that this notification may cause and we appreciate your cooperation with our request. Should you have any inquiries, please do not hesitate to contact your Johnson & Johnson sales consultant or contact person.

Thank you for being a DePuy Synthes Power Tools Customer.

Kind Regards,

Jennifer Tseng

Digitally signed by Jennifer Tseng
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Jennifer Tseng
Johnson & Johnson Sdn. Bhd.,
Head of Commercial Quality Malaysia & Indonesia

Attachment A: Customer Acknowledgement Letter

Attachment A: Customer Acknowledgment Letter

Attention: Hospital Personnel

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CRANI-P	6.5cm Pediatric Craniotome	All	00845384001775
CRANI-P-G1	Pediatric Craniotome	All	00845384016403

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

Hospital name: _____

Name/Title (please print): _____

Phone Number: _____

Signature and Date: _____

Note: If the verification section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual in Attachment A: Customer Acknowledgment Letter.

Please complete and return Attachment A: Customer Acknowledgment Letter to our Johnson & Johnson sales organization.

Johnson & Johnson Sdn. Bhd. (Co. No. 3718-D)
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