Date: September 27, 2022

URGENT FIELD SAFETY NOTICE (REMOVAL)
Incorrect Drill Guide Included with BME SPEED™ Implant Kit (1 Lot)

Subject Product:

Part Number	Part Description	Lot	UDI/DI
SE-1512	BME SPEED™ Implant Kit 15X12mm	MSE210184	00810633020166

Dear Valued Customer,

Synthes GmbH is initiating a field safety notice (FSN) to remove one lot of the BME SPEED™ Implant Kit. The subject product is used in fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

Our records show that you or your facility received one or more units of the subject product listed above. Please carefully review this notice for the steps that you should take to respond to this FSN (removal).

Reason for the FSN (Removal):
The subject product is being removed because it contains the incorrect size drill guide and will not prepare the bone correctly for the size of the implant included in the sterile kit. Note: Drill guides in the kits are correctly marked with their size.

Potential Patient Impact:
In the event the incorrect drill guide is used, there is the potential for bone damage due to incorrectly placed drill holes for the implant included in the kit.

If the user notices that the incorrect drill guide has been provided with the kit, they will likely request another kit to complete the procedure, potentially causing a surgical delay. If another kit is not available or if the replacement kit also has the same product issue, the surgeon may opt to complete the procedure through an alternative standard of care method of fixation. This change in procedure may constitute a surgical delay and may require additional surgical exposure resulting in soft tissue damage and/or additional bone cuts (bone damage) despite the similar initial bone and soft tissue preparation.

To date, we have received one (1) complaint related to this issue. There were no adverse events reported for the complaint.

Health care providers who have treated patients using the subject product should continue to follow those patients pursuant to the health care provider's standard of care.

Please Take the Following Steps:

1. Examine your inventory immediately to determine if you have the subject product and quarantine it immediately. DO NOT USE THE SUBJECT PRODUCT.
2. Return the subject product using the normal returns process. Work with your sales consultant to return subject product. To receive replacement product or reimbursement, customers must return the product subject to this removal.
3. Review, complete, sign, and return the attached Business Response Form (page 3 of this letter) to [enter email] within three (3) business days of receipt of this notification. Please include in the email subject: FA 2162303 DRILL GUIDE
4. Please complete the attached Business Response Form even if you do not have the subject product on hand.

5. Forward this notice to anyone in your facility that needs to be informed (e.g., those who manage, transport, store, stock, or use the subject product).
6. If any of the subject product have been forwarded to another facility, contact that facility and provide them with this notice.
7. Post a copy of this notice in a visible area for awareness and keep a copy for your records.

This medical device product removal has been reported to the relevant Health Authorities. If you have any questions, please contact your local DePuy Synthes Sales Consultant. For Medical Information request, please visit our website: https://www.jnjmedicaldevices.com/mir.

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

Sincerely,

KIMBERLY LONG

Digitally signed by KIMBERLY LONG
DN: c=US, o=JNJ, ou=Subscribers, cn=KIMBERLY LONG, 0.9.2342.19200300.100.1.1=169611
Reason: I attest to the accuracy and integrity of this document.
Date: 2022.09.28 08:18:29 -04'00'
Adobe Acrobat version: 2020.013.20064

Kimberly Long
Staff Quality Systems Recall Coordinator
Email: OneMD-Field-Actions@its.jnj.com

URGENT FIELD SAFETY NOTICE (REMOVAL)
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Business Response Form

Subject Product:

Part Number	Part Description	Lot	UDI/DI	Quantity Returned
SE-1512	BME SPEED™ Implant Kit 15X12mm	MSE210184	00810633020166	

- ☐ **The subject product has been located. A copy of this notice is being retained and I have read and understood the notification.**
- ☐ **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. Please return this form via email to [enter email]. Please include in the email subject: FA 2162303 DRILL GUIDE

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.*	