Date: 3rd March 2021

URGENT FIELD SAFETY NOTICE
Damaged Packaging for 37 lots of MBT & ATTUNE® Tibial Bases (S+)
Medical Device Product Recall (Removal) – Ref. 1932449

Product Subject to this Notice:

Part Code	Lot / Batch	GTIN	Description
See Table 1	See Table 1	See Table 1	See Table 1

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE AFFECTED PRODUCT

Dear Valued Customer,

Please be advised that DePuy (Ireland) UC is initiating a voluntary removal for the 37 lots listed in Table 1 for MBT & ATTUNE (S+) Tibial Bases due to potential damaged packaging. These implant components are utilized in Total Knee Arthroplasty. The affected tibial bases are designed to be used in cemented applications.

A total of nine (9) complaints received to date reported packaging damage. See Image 1. Our investigation of these complaints determined that product packaging may be compromised, which may present a potential for sterile barrier integrity failure, resulting in the possibility of non-sterile implant or residual packaging materials on the tibial implants. See Image 2. To date, customer complaints have reported only surgical delay.

Image 1: Example of damaged packaging

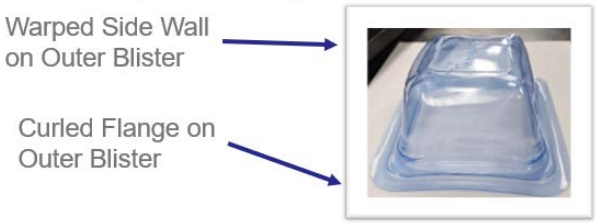

Image 2: Example of residual material on implant surface

Potential Patient Impact

Damaged packaging could impact the seal and result in a sterility breach. Implantation of potentially contaminated product could lead to infection and pain. If presence of polyurethane residue is not detected intraoperatively, and is left in patient, this may potentially impair range of motion in a rotating platform construct; or, cause an inflammatory reaction. No adverse events or injuries have been reported for these issues. Surgical delay is the only harm that has been reported to date.

Patient Communication:

Physicians who have treated patients using the affected lots (see Table 1) should continue to follow up on those patients post-operatively according to the physician's standard of care.

Requested Actions:

Our records show that your facility received one or more of the affected lots manufactured on July 8, 2020. Please take the following actions:

1. Carefully review the information contained in this notice.
2. Return the affected products using the normal returns process. Work with your sales consultant to ensure affected devices are returned and to arrange replacement. To receive replacement product or reimbursement, customers must return the products subject to this notice.

3. Complete **all** fields of the attached Business Response Form. Please make sure to include your facility name and address, account number, name of person completing the form, title, email address, telephone number and signature in the spaces provided.
4. Forward this notice to any personnel in your facility who need to be informed.
5. If any of the products subject to this notice have been forwarded to another facility, contact that facility and provide a copy of this notice to the relevant personnel.
6. Post a copy of this notice in a visible area for awareness of this notice.

Contact Information*:*

At DePuy Synthes, we aim to keep people well at every age and every stage of life. Our primary goal is patient safety and customer satisfaction by providing high quality products. We apologize for any inconvenience that this notice may cause and appreciate your cooperation with our request. If you have any questions, please contact your local DePuy Synthes Sales Consultant.

This Field Safety Notice has been reported to the local competent authority.

Thank you for your attention and cooperation.

Scot Hartley
Business Quality Team Leader
Email:MDFieldActionsUKIrl@its.jnj.com

TABLE 1: Products Subject to this Field Safety Notice (Removal)

Product Code	Lot / Batch	GTIN	Description
129433130	9543538	10603295025788	MBT CEM KEEL TIB TRAY SZ3
129433130	9553989	10603295025788	MBT CEM KEEL TIB TRAY SZ3
129433130	9554547	10603295025788	MBT CEM KEEL TIB TRAY SZ3
129433130	9554548	10603295025788	MBT CEM KEEL TIB TRAY SZ3
129433130	9554551	10603295025788	MBT CEM KEEL TIB TRAY SZ3
129433140	9548774	10603295025795	MBT CEM KEEL TIB TRAY SZ4
129433140	9548777	10603295025795	MBT CEM KEEL TIB TRAY SZ4
129433140	9554569	10603295025795	MBT CEM KEEL TIB TRAY SZ4
150670003	9558300	10603295492054	ATTUNE FB TIB BASE SZ 3 CEM
150670004	9555958	10603295492061	ATTUNE FB TIB BASE SZ 4 CEM
150670005	9554006	10603295492078	ATTUNE FB TIB BASE SZ 5 CEM
150670005	9556397	10603295492078	ATTUNE FB TIB BASE SZ 5 CEM
150670006	9558618	10603295492085	ATTUNE FB TIB BASE SZ 6 CEM
150670007	9557992	10603295492092	ATTUNE FB TIB BASE SZ 7 CEM
150670008	9558238	10603295492108	ATTUNE FB TIB BASE SZ 8 CEM
150670008	9558239	10603295492108	ATTUNE FB TIB BASE SZ 8 CEM
150670009	9555613	10603295492115	ATTUNE FB TIB BASE SZ 9 CEM
150680003	9557372	10603295492153	ATTUNE RP TIB BASE SZ 3 CEM
150680003	9557439	10603295492153	ATTUNE RP TIB BASE SZ 3 CEM
150680003	9557440	10603295492153	ATTUNE RP TIB BASE SZ 3 CEM
150680003	9557450	10603295492153	ATTUNE RP TIB BASE SZ 3 CEM
150680003	9557460	10603295492153	ATTUNE RP TIB BASE SZ 3 CEM
150680004	9557444	10603295492160	ATTUNE RP TIB BASE SZ 4 CEM
150680004	9557445	10603295492160	ATTUNE RP TIB BASE SZ 4 CEM
150680004	9557446	10603295492160	ATTUNE RP TIB BASE SZ 4 CEM
150680004	9557453	10603295492160	ATTUNE RP TIB BASE SZ 4 CEM
150680004	9557455	10603295492160	ATTUNE RP TIB BASE SZ 4 CEM
150680005	9557376	10603295492177	ATTUNE RP TIB BASE SZ 5 CEM
150680005	9557377	10603295492177	ATTUNE RP TIB BASE SZ 5 CEM
150680005	9557457	10603295492177	ATTUNE RP TIB BASE SZ 5 CEM
150680005	9557471	10603295492177	ATTUNE RP TIB BASE SZ 5 CEM
150680005	9557473	10603295492177	ATTUNE RP TIB BASE SZ 5 CEM
150680005	9557476	10603295492177	ATTUNE RP TIB BASE SZ 5 CEM
150680006	9556100	10603295492184	ATTUNE RP TIB BASE SZ 6 CEM
150680006	9556127	10603295492184	ATTUNE RP TIB BASE SZ 6 CEM
150680006	9556128	10603295492184	ATTUNE RP TIB BASE SZ 6 CEM
150680007	9557434	10603295492191	ATTUNE RP TIB BASE SZ 7 CEM

Note: Unique Device Identifier (UDI): UDI = DI + PI
DI = Device Identifier = GTIN | PI = Production Identifier = Lot Number

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Part Number	Part Description	GTIN	Lot Number
See Table 1	See Table 1	See Table 1	See Table 1

Please complete this BRF **within 3 business days upon receipt of the notification** and email this form to MDFieldActionsUKIrl@its.jnj.com , post to Business Quality, Johnson & Johnson, St Anthony's Road, Beeston, Leeds. LS11 8DT or Fax to 0113 307 1808

☐ The facility located the affected product in stock and is returning products (see below). A copy of this letter is being retained in the facility's records. I have read and understand the notification.

Part Number	Lot Number	Quantity

☐ The facility has no affected product for return. A copy of this letter is being retained in the facility's records. I have read and understand the notification.

Your Name:	Facility/Business Name:
Signed*:	Date:
Facility/Business Address, City:	
Account Number:	
J&J Sales Rep (as applicable):	
Date the notification was received:	
Email Address:	Telephone Number:
**Your signature provides confirmation that you have received and understood this notification.*	
Your comments are always welcome:	