DePuy Ireland UC
Loughbeg, Ringaskiddy
Co. Cork, Ireland

Date: 22 August 2023

URGENT FIELD SAFETY NOTICE
ATTUNE™ CEMENTLESS CR FEMUR – Incorrect Size (1 lot only)
Medical Device Product Recall (Removal) – Ref. 2293230

Product Subject to this Removal:

Part Number	Part Description	Lot	GTIN
1504-01-204	ATTUNE CR Femoral Right Size 4 Porous	3883327	10603295041474

Dear Surgeon,

By letter of 11Aug2023 (Attachment 1), DePuy Ireland has initiated a medical device recall (removal) of one lot of the ATTUNE™ Cementless CR Femurs listed in the above table. The ATTUNE™ Cementless Total Knee System is intended for cementless use within the ATTUNE™ Total Knee Replacement System. Porous coated implants may be used with or without cement.

Our records show that one of your patients may have been implanted with the subject product. Please carefully review this notice for the steps that you should take in response to this medical device recall.

Reason for the Medical Device Recall:
A complaint reported that the subject product was packaged and labeled as a size 4, but the implant had the dimensions of a size 5. It was confirmed that this issue is limited to a single affected lot of 12 implants.

Potential Patient Impact:
If a surgeon detects a gap or overhang of the oversized implant, they may replace it with a correct-sized implant if available, or change to a cemented technique, resulting in a surgical delay. Bone Fracture is also possible when the improperly fitted implant is removed.

If the incorrect size is not detected, it is possible that the following may be observed:

- Loosening, Poor Joint Mechanics, and Pain: If the discrepancy between the labeled implant size and actual implant size is not identified, there may be a sub-optimal bone to implant interface which could result in early loosening. If a cemented technique was used, the expected performance will be similar to a primary cemented case.

- Soft Tissue Irritation, Adverse Tissue Reaction, and Osteolysis: If a size 4 Cruciate Retaining (CR) tibial insert is used, the unintended mismatch in femoral to tibial insert size could result in early wear.

- The subject products are compatible with a size 5 Tibial Polyethylene Insert. A size 5 femoral component is compatible with a Rotating Platform (RP) or Fixed Bearing (FB) tibial base size 3, 4, 5, 6 or 7.

Surgeons who have treated patients using the subject lot should continue to follow those patients pursuant to their standard of care and may consider more frequent follow-up depending on the activity level and needs of an individual patient. We encourage surgeons to communicate with patients who have had surgery in which these femoral components have been used. Sharing this information will allow surgeons to discuss the possible risks and further treatment options.

This medical device product recall has been reported to the local competent authority and your hospital or facility has also been notified and provided with Attachment 1. **For a Medical Information request, please visit our website: https://www.jnjmedicaldevices.com/mir.** Should you have any other inquiries please do not hesitate to contact your DePuy Synthes Sales Consultant.

DePuy Ireland UC
Loughbeg, Ringaskiddy
Co. Cork, Ireland

Thank you for your attention and cooperation.

Sincerely,

Shannon Rook

Digitally signed by Shannon Rook
DN: c=US, o=JNJ, ou=Subscribers, cn=Shannon Rook, 0.9.2342.19200300.100.1.1=1030460
Reason: I am the author of this document.
Date: 2023.08.22 09:33:36 -04'00'
Adobe Acrobat version: 2020.013.20064

Shannon Rook
Staff Field Action Coordinator
OneMD-Field-Actions@its.jnj.com

DePuy Ireland UC
Loughbeg, Ringaskiddy
Co. Cork, Ireland

Attachment 1

Date: 11 August 2023

URGENT FIELD SAFETY NOTICE
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Product Subject to this Removal:

Part Number	Part Description	Lot	GTIN
1504-01-204	ATTUNE CR Femoral Right Size 4 Porous	3883327	10603295041474

Dear Valued Customer,

DePuy Ireland is initiating a medical device recall (removal) of one lot of the ATTUNE™ Cementless CR Femurs listed in the above table. The ATTUNE™ Cementless Total Knee System is intended for cementless use within the ATTUNE™ Total Knee Replacement System. Porous coated implants may be used with or without cement.

Our records show that your facility received one or more units of the subject lot. Please carefully review this notice for the steps that you should take to respond to this medical device recall.

Reason for the Medical Device Recall:
A complaint reported that the subject product was packaged and labeled as a size 4, but the implant had the dimensions of a size 5. It was confirmed that this issue is limited to a single affected lot of 12 implants.

Potential Patient Impact:
A surgeon may detect a gap or overhang of the oversized implant and replace it with the correct-sized implant if available, resulting in a surgical delay. Bone Fracture is also possible if the surgeon removes the improperly fitted implant and inadvertently causes damage to the bone.

If the incorrect size is not detected, it is possible that the following may be observed:

- Loosening, Poor Joint Mechanics, and Pain: If the discrepancy between the labeled implant size and actual implant size is not identified, there may be a sub-optimal bone to implant interface which could result in loosening requiring revision surgery.
- Soft Tissue Irritation, Adverse Tissue Reaction, and Osteolysis: If a size 4 Cruciate Retaining (CR) tibial insert is used the unintended mismatch in sizes could result in early wear. A Rotating Platform (RP) or Fixed Bearing (FB) tibial base will be compatible as long as it is a size 3, 4, 5, 6 or 7.

A surgeon-focused communication will be released following this notification to provide further details.

Health care providers who have treated patients using the subject lot should continue to follow those patients pursuant to the health care provider's standard of care and may consider more frequent follow-up depending on the activity level and needs of an individual patient. For questions, or to consult with an in-house DePuy Synthes physician on this issue, please submit a Medical Information Request via our website: https://www.jnjmedicaldevices.com/mir or reach out to your sales consultant for assistance.

DePuy Ireland UC
Loughbeg, Ringaskiddy
Co. Cork, Ireland

Please take the Following Steps:

1. Examine your inventory immediately to determine if you have the subject lot and quarantine the product.
2. Contact your DePuy Synthes Sales Consultant to coordinate the return of any affected devices or call customer service following the typical returns process in order to acquire a return number prior to shipping product.
3. Review, complete, sign, and return the attached business response form (page 3 of this letter) to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.
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 devices subject to this action).
5. If any of the subject lot 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 any inconvenience that this recall may cause and appreciate your cooperation with our request. For a Medical Information request, please visit our website: https://www.jnjmedicaldevices.com/mir. Should you have any other inquiries please do not hesitate to contact your DePuy Synthes Sales Consultant.

Thank you for your attention and cooperation.

Sincerely,

Shannon Rook
Staff Field Action Coordinator
OneMD-Field-Actions@its.jnj.com

DePuy Ireland UC
Loughbeg, Ringaskiddy
Co. Cork, Ireland

URGENT FIELD SAFETY NOTICE
ATTUNE™ CEMENTLESS CR FEMUR – Incorrect Size (1 lot only)
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Business Response Form

Product Subject to this Removal:

Part Number	Part Description	Lot	GTIN
1504-01-204	ATTUNE CR Femoral Right Size 4 Porous	3883327	10603295041474

☐ The impacted lot 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 lot is available for return. A copy of this notice is being retained and 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:
**Your signature provides confirmation that you have received and understood this notification.*	

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

Please complete and return this page to your local DePuy Synthes sales organization.