

Date: 12 January 2021

URGENT FIELD SAFETY NOTICE
Universal Femoral Sleeves (5 lots)
used with S-ROM Noiles, LPS, SIGMA, and LCS Knee Products
Medical Device Product Recall (Removal) – Ref. 1914026

Products Subject to this Removal:

Part Number	Part Description	Lots	GTIN
129453216	Universal Femoral Sleeve Fully Porous 31mm	J85Y90, J86T23	10603295026273
129453226	Universal Femoral Sleeve Fully Porous 34mm	J86T20	10603295026303
129453236	Universal Femoral Sleeve Fully Porous 40mm	J8790J	10603295026334
129453246	Universal Femoral Sleeve Fully Porous 46mm	J85Y92	10603295026365

Dear Valued Customer,

DePuy Orthopaedics, Inc. (DePuy Synthes) is initiating a medical device recall (removal) of the Universal Femoral Sleeves lots listed in the above table. It has come to our attention that the taper dimensions of certain Universal Femoral Sleeves may be out of specification. The Universal Femoral Sleeves are used primarily in revision surgeries with the S-ROM Noiles, LPS, SIGMA, and LCS Knee products. Please distribute this notice to the appropriate personnel at your facility who need to be aware of this recall and keep a copy of this notice with the subject product.

Our records show that your facility received one or more of the subject products that were manufactured between Aug 31, 2020 and Sept 08, 2020. Please carefully review this notice for the steps that you should take in response to this medical device recall (removal).

Reason for the Medical Device Recall:

The products subject to this action are being recalled because the taper dimensions may be out of specification due to a production issue during the manufacturing of these lots.

Potential Patient Impact:

If the taper dimensions are out of specification, it is possible that the following may be observed:

- Significant surgical delay if the product fails to engage and a new set of implants has to be sourced.
- Poor joint mechanics, loosening, and pain due to inadequate taper engagement.
- Adverse tissue reaction due to the generation of debris from abrasion of a non-secure taper.

Please note that as of the date of this communication, we have not received any complaints for the subject products.

Health care providers who have treated patients using the Universal Femoral Sleeves subject to this recall should continue to follow those patients pursuant to the health care provider's standard of care.

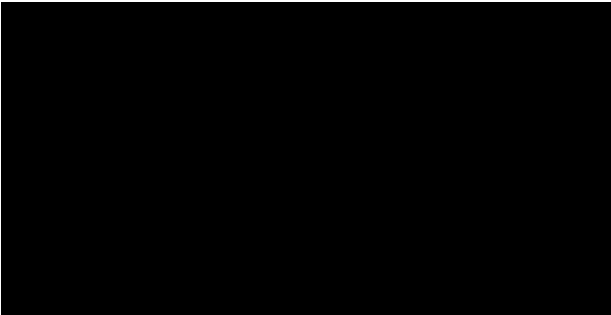
Please take the Following Steps:

1. Examine your inventory immediately to determine if you have the lots subject to this recall 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 product 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 (removal) 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. Should you have any inquiries please do not hesitate to contact your DePuy Synthes Sales Consultant.

Thank you for your attention and cooperation.

Sincerely,



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Business Response Form

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129453246	Universal Femoral Sleeve Fully Porous 46mm	J85Y92	10603295026365

The impacted lots have been located. A copy of this letter is being retained and I have read and understood the notification.
 RETURNED Quantity/lot number(s): _____

For product returns: Please call customer service following the typical returns process in order to acquire a return number prior to shipping product. Please enclose a photocopy of the completed Business Response Form as a packing slip in the box containing the product(s) you are returning. Return all identified affected product to: GMED Healthcare | JDE 8.12 Returns Dept. | ATTN: Universal Femoral Sleeves Field Action (SS NR-0150485) | Rue de Luxembourg 5 | ZI Trazegnies | BE - 6180 Courcelles | Belgium | TEL: 32-7-146-9404

No impacted lots are available for return. A copy of this letter 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.