Synthes GmbH
Luzernstrasse 21
4528 Zuchwil
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Tel. +41 32 720 40 60
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http://www.depuysynthes.com/

Date: 11 November 2019

URGENT FIELD SAFETY NOTICE
USS II Polyaxial 3D Heads – Medical Device Product Removal

Product Subject to this Removal:

Part Number	Part Description	Lots	GTIN
04.607.402	USS-II Polyaxial 3D-Head f/R ø6 TAN green	See Attachment 1	07611819186361
04.607.402S	USS-II Polyaxial 3D-Head f/R ø6 TAN green	See Attachment 1	07611819950337

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT WHICH IS THE SUBJECT OF THIS NOTICE

Dear Sir/Madam:
Synthes GmbH is initiating a voluntary medical device product removal of USS II Polyaxial 3D Heads. The product information is listed above and in Attachment 1. The USS II Polyaxial 3D Head is part of the USS II Polyaxial System which is a posterior pedicle screw fixation system (T1-S2) designed to provide stabilization of the spine in skeletally mature patients.

Reason for the Medical Device Product Removal:
A complaint trend was identified for unusual intra-operative sounds associated with use of the subject medical device and cracking of the USS II Polyaxial 3D Head ring.

Potential Patient Impact:
Intra-operative or post-operative breakage of the USS II Polyaxial 3D Head rings may result in loosening of the rods which may cause poor spinal mechanics, non-union or malunion, pain, dislocation, and/or loosening.

Serious surgical delay could occur if a cracked USS II Polyaxial 3D Head ring is identified and corrected intra-operatively. Minor surgical delay could occur if audio cues cause surgery to be paused while the source of the noise is investigated, but no crack or breakage is identified.

Synthes GmbH is not recommending prophylactic revision in the absence of symptoms. The company recommends that surgeons perform routine clinical follow-up and discuss potential clinical implications and risks with symptomatic patients who received the affected implants.

Actions to be taken:
Our records show that your facility has received the product subject to this medical device product removal. Please take the following actions:

1. Examine your inventory immediately to determine if you have product subject to this action on hand and quarantine the product.

2. Review, complete, sign and return the attached reply form on 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.

3. Return the affected products within 30 business days.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any of the subject product has been forwarded to another facility, contact that facility to arrange return.

6. Keep a copy of this notice visibly posted for awareness until the product subject to this action has been returned. While processing your returns, please maintain a copy of this notice with the product subject to this action and keep a copy for your records.

This medical device product removal has been reported to the local competent authority. We apologize for any inconvenience that this removal may create 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,

Shannon Rook
Senior Regulatory Specialist, Field Actions
srook@its.jnj.com
Business Phone: (610) 314-2088

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Verification Section

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Please complete this Customer Acknowledgement Form **within 5 business days upon receipt of the notification (even if you do not have product to return)** and return to your local DePuy Synthes sales organization**.**

☐ **I have read and understand the notification**

☐ **We have no affected product for return**

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:	

☐ **We have affected product and are returning the following devices:**
If you have affected product to return, please complete section below and attach this Customer Acknowledgement Form with your product return.

Part Number	Part Description	Lot Number	Number of Devices to be Returned	RA #
04.607.402	USS-II Polyaxial 3D-Head f/R ø6 TAN green			
04.607.402S	USS-II Polyaxial 3D-Head f/R ø6 TAN green			

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

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Attachment 1

Part Number	Part Description	Lots	GTIN
04.607.402	USS-II Polyaxial 3D-Head f/R ø6 TAN green	2L33452, 2L33453, 2L33454, 2L33455, 2L33456, 2L40721, 2L40723, 2L40726, 2L40728, 2L49034, 2L51832, 2L68992, 2L69276, 2L71755, 2L71756, 2L71757, 2L71758, 2L71759, 2L71760, 2L79940, 2L79941, 2L80404, 2L80405, 2L80406, 2L80407, 2L80408, 2L80409, 2L80410, 2L80411, 2L80412, 2L91858, 3L06928, 3L06929, 3L06930, 3L08448, 3L08450, 3L08452, 3L08454, 3L08456, 3L15896, 3L15897, 3L15898, 3L15899, 3L15900, 3L15902, 3L15903, 3L15904, 3L15913, 3L15915, 3L15923, 3L15925, 3L15927, 3L15929, 3L24559, 3L24895, 3L26702, 3L26703, 3L28898, 3L28901, 3L28907, 3L28910, 3L28913, 3L28916, 3L28918, 3L37334, 3L38172, 3L38173, 3L38177, 3L59044, 3L59046, 3L59048, 3L69189, 3L93646, 3L93647, 3L93947, 3L93948, 3L93949, 4L12495, 4L12515, 4L12517, 4L12530, 4L12534, 4L15295, 4L15296, 4L15297, 4L15298, 4L15299, 4L22644, 4L22645, 4L22646, 4L31959, 4L44336, 4L44338, 4L49656, 4L49661, 4L49663, 4L57553, 4L57557, 4L66081, 4L66084, 4L66086, 4L75574, 4L84351, 4L86152, 5L23583, 5L35404, 5L23582, 5L23581, 5L02812, 5L15714, 5L15717, 5L23579, 5L15721, 5L15719, 5L15718, 5L15679, 5L15682	07611819186361
04.607.402S	USS-II Polyaxial 3D-Head f/R ø6 TAN green	2L33799, 2L36789, 2L43711, 2L54942, 2L63125, 2L86917, 2L94099, 3L38612, 3L41799, 3L50599, 3L53014, 3L59638, 3L88502, 4L56205, 4L63893, 4L63915, 4L63961, 5L37753, 5L44576, 5L48010, 5L52249, 5L09577	07611819950337