

Date: 30 Dec 2016

URGENT NOTICE:
MEDICAL DEVICE FIELD SAFETY NOTIFICATION-
Product Removal 555531- Radial Head Prosthesis System

*PLEASE DISTRIBUTE THIS INFORMATION TO THE 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 product removal of the DePuy Synthes Radial Head Prosthesis System. The DePuy Synthes Radial Head Prosthesis System is intended for primary and revision joint replacement of the radial head.

Product Subject to this Removal:

Part Number	Part Description	Lot Number
See Attachment 1	See Attachment 1	See Attachment 1

Reason for Recall:

The entire DePuy Synthes Radial Head Prosthesis System is affected by this removal, however it is the radial stem that has the possibility of loosening post-operatively at the stem bone interface. Based on the currently available data, we believe the cause to be multifactorial (including possible product characteristics, operative and patient factors), but we have not been able to fully characterize these factors. Consequently, we have not been able at this time to issue further instructions to surgeons that might lead to a reduction in issue rate and have decided to remove the DePuy Synthes Radial Head Prosthesis Stem from the global market.

Health care practitioners that have treated patients using the DePuy Synthes Radial Head Prosthesis System should continue to follow those patients in the usual manner.

The DePuy Synthes Radial Head Prosthesis System, except for the stem, will be available upon request for revision surgeries in which only the head would be replaced using the evaluation or loaner set programs only.

Potential Impacts:

If the radial stem becomes loose post-operatively, the following may occur; Device Loosening, Osteolysis, Poor Joint Mechanics, Pain, Bone Fracture – Post-operatively, and Soft tissue Damage (Soft Tissue Irritation).

Actions to be taken:

Our records show that your facility has received one or more of the product(s) subject to this product removal.

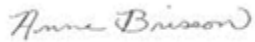
1. Immediately review your inventory to identify and quarantine all affected products listed above in a manner that ensures the affected products will not be used.
2. Review, complete, sign and return the attached reply form on page 3 of this letter to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product as soon as possible, but within 30 business days. A credit note will be issued for the returned items.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any of the affected products has been forwarded to another facility, contact that facility to arrange return.

6. Maintain awareness of this notice until all products listed below have been returned to DePuy Synthes.
7. Keep a copy of this notice.

We apologize for any inconvenience that this product removal (recall) 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.

DePuy Synthes



Anne Brisson

Senior Quality Assurance Manager,
Product Safety and Performance

URGENT NOTICE:
MEDICAL DEVICE FIELD SAFETY NOTIFICATION-
Product Removal 555531- Radial Head Prosthesis System

Verification Section

Product Subject to this Removal:

Part Number	Part Description	Lot Number
See Attachment 1	See Attachment 1	See Attachment 1

___ We have located the identified product in stock; returned quantity is documented below.

RETURNED DEVICES (Per part number including quantity): _____

___ We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.

CUSTOMER DETAILS	
Facility Name:	
Facility Address:	
Account Number:	
Reply Confirmation Completed by: (Please Print Name)	
Signature and Date: (REQUIRED FIELD)	
Title: (Please Print)	
Telephone Number: (Include Area Code and Extension)	
Email address:	
RA#: (IF applicable)	

The above acknowledges receipt of the subject Field Safety Notification, Product removal in reference to the Radial Head Prosthesis System.

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

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.

Attachment 1

Part number	Description
03.402.006	6MM STRAIGHT TRIAL RADIAL STEM 24MM
03.402.007	7MM STRAIGHT TRIAL RADIAL STEM 26MM
03.402.008	8MM STRAIGHT TRIAL RADIAL STEM 28MM
03.402.009	9MM STRAIGHT TRIAL RADIAL STEM 30MM
03.402.010	10MM STRAIGHT TRIAL RADIAL STEM/32MM
03.402.018	18MM TRIAL RADIAL HEAD STANDARD HEIGHT/11.5MM
03.402.020	20MM TRIAL RADIAL HEAD STANDARD HEIGHT/12.0MM
03.402.022	22MM TRIAL RADIAL HEAD STANDARD HEIGHT/12.5MM
03.402.024	24MM TRIAL RADIAL HEAD STANDARD HEIGHT/13.0MM
03.402.026	26MM TRIAL RADIAL HEAD STANDARD HEIGHT/13.5MM
03.402.028	28MM TRIAL RADIAL HEAD STANDARD HEIGHT/14.0MM
03.402.106	6MM CURVED TRIAL RADIAL STEM 40MM
03.402.107	7MM CURVED TRIAL RADIAL STEM 42MM
03.402.108	8MM CURVED TRIAL RADIAL STEM 44MM
03.402.109	9MM CURVED TRIAL RADIAL STEM 46MM
03.402.110	10MM CURVED TRIAL RADIAL STEM 48MM
03.402.218	18MM TRIAL RADIAL HEAD 2MM HT EXTENSION/13.5MM
03.402.220	20MM TRIAL RADIAL HEAD 2MM HT EXTENSION/14.0MM
03.402.222	22MM TRIAL RADIAL HEAD 2MM HT EXTENSION/14.5MM
03.402.224	24MM TRIAL RADIAL HEAD 2MM HT EXTENSION/15.0MM
03.402.226	26MM TRIAL RADIAL HEAD 2MM HT EXTENSION/15.5MM
03.402.228	28MM TRIAL RADIAL HEAD 2MM HT EXTENSION/16.0MM
03.402.418	18MM TRIAL RADIAL HEAD 4MM HT EXTENSION/15.5MM
03.402.420	20MM TRIAL RADIAL HEAD 4MM HT EXTENSION/16.0MM
03.402.422	22MM TRIAL RADIAL HEAD 4MM HT EXTENSION/16.5MM
03.402.424	24MM TRIAL RADIAL HEAD 4MM HT EXTENSION/17.0MM
03.402.426	26MM TRIAL RADIAL HEAD 4MM HT EXTENSION/17.5MM
03.402.428	28MM TRIAL RADIAL HEAD 4MM HT EXTENSION/18.0MM
03.402.618	18MM TRIAL RADIAL HEAD 6MM HT EXTENSION/17.5MM
03.402.620	20MM TRIAL RADIAL HEAD 6MM HT EXTENSION/18.0MM
03.402.622	22MM TRIAL RADIAL HEAD 6MM HT EXTENSION/18.5MM
03.402.624	24MM TRIAL RADIAL HEAD 6MM HT EXTENSION/19.0MM
03.402.626	26MM TRIAL RADIAL HEAD 6MM HT EXTENSION/19.5MM
03.402.628	28MM TRIAL RADIAL HEAD 6MM HT EXTENSION/20.0MM
03.402.701	Sizing Dish for Radial Head Prosthesis
03.402.710	Canal Finder for Radial Head Prosthesis
03.402.711	Planer for Radial Head Prosthesis
03.402.712	Offset Planer for Radial Head Prosthesis
03.402.716	6MM BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS

Part number	Description
03.402.717	7MM BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS
03.402.718	8MM BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS
03.402.719	9MM BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS
03.402.720	10MM BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS
03.402.721	6MM BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS
03.402.722	7MM BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS
03.402.723	8MM BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS
03.402.724	9MM BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS
03.402.725	10MM BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS
03.402.726	6MM OFFSET BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS
03.402.727	7MM OFFSET BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS
03.402.728	8MM OFFSET BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS
03.402.729	9MM OFFSET BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS
03.402.730	10MM OFFSET BROACH/STRTGHT TIP FOR RADIAL HEAD PROSTHESIS
03.402.731	6MM OFFSET BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS
03.402.732	7MM OFFSET BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS
03.402.733	8MM OFFSET BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS
03.402.734	9MM OFFSET BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS
03.402.735	10MM OFFSET BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS
03.402.740	STEM INSERTER/EXTRACTOR FOR RADIAL HEAD PROSTHESIS
03.402.741	OFFSET STEM INSERTER/EXTRACTOR FOR RADIAL HEAD PROSTHESIS
03.402.744	Impactor, convex, for Radial Head Prosthesis
04.402.006S	6MM TI STRAIGHT RADIAL STEM 24MM-STERILE
04.402.007S	7MM TI STRAIGHT RADIAL STEM 26MM-STERILE
04.402.008S	8MM TI STRAIGHT RADIAL STEM 28MM-STERILE
04.402.009S	9MM TI STRAIGHT RADIAL STEM 30MM-STERILE
04.402.010S	10MM TI STRAIGHT RADIAL STEM 32MM-STERILE
04.402.026S	6MM TI CURVED RADIAL STEM 40MM-STERILE
04.402.027S	7MM TI CURVED RADIAL STEM 42MM-STERILE
04.402.028S	8MM TI CURVED RADIAL STEM 44MM-STERILE
04.402.029S	9MM TI CURVED RADIAL STEM 46MM-STERILE
04.402.030S	10MM TI CURVED RADIAL STEM 48MM-STERILE
09.402.018S	18MM COCR RADIAL HEAD STANDARD HEIGHT/11.5MM-STERILE
09.402.020S	20MM COCR RADIAL HEAD STANDARD HEIGHT/12.0MM-STERILE
09.402.022S	22MM COCR RADIAL HEAD STANDARD HEIGHT/12.5MM-STERILE
09.402.024S	24MM COCR RADIAL HEAD STANDARD HEIGHT/13.0MM-STERILE
09.402.026S	26MM COCR RADIAL HEAD STANDARD HEIGHT/13.5MM-STERILE
09.402.028S	28MM COCR RADIAL HEAD STANDARD HEIGHT/14.0MM-STERILE
09.402.218S	18MM COCR RADIAL HEAD 2MM HT EXTENSION/13.5MM-STER
09.402.220S	20MM COCR RADIAL HEAD 2MM HT EXTENSION/14.0MM-STER
09.402.222S	22MM COCR RADIAL HEAD 2MM HT EXTENSION/14.5MM-STER
09.402.224S	24MM COCR RADIAL HEAD 2MM HT EXTENSION/15.0MM-STER

Part number	Description
09.402.226S	26MM COCR RADIAL HEAD 2MM HT EXTENSION/15.5MM-STER
09.402.228S	28MM COCR RADIAL HEAD 2MM HT EXTENSION/16.0MM-STER
09.402.418S	18MM COCR RADIAL HEAD 4MM HT EXTENSION/15.5MM-STER
09.402.420S	20MM COCR RADIAL HEAD 4MM HT EXTENSION/16.0MM-STER
09.402.422S	22MM COCR RADIAL HEAD 4MM HT EXTENSION/16.5MM-STER
09.402.424S	24MM COCR RADIAL HEAD 4MM HT EXTENSION/17.0MM-STER
09.402.426S	26MM COCR RADIAL HEAD 4MM HT EXTENSION/17.5MM-STER
09.402.428S	28MM COCR RADIAL HEAD 4MM HT EXTENSION/18.0MM-STER
09.402.618S	18MM COCR RADIAL HEAD 6MM HT EXTENSION/17.5MM-STER
09.402.620S	20MM COCR RADIAL HEAD 6MM HT EXTENSION/18.0MM-STER
09.402.622S	22MM COCR RADIAL HEAD 6MM HT EXTENSION/18.5MM-STER
09.402.624S	24MM COCR RADIAL HEAD 6MM HT EXTENSION/19.0MM-STER
09.402.626S	26MM COCR RADIAL HEAD 6MM HT EXTENSION/19.5MM-STER
09.402.628S	28MM COCR RADIAL HEAD 6MM HT EXTENSION/20.0MM-STER
68.402.001	Modular Tray 1, for Instruments, for Radial Head Prosthesis, size 1/1, without Contents, Vario Case™
68.402.002	Modular Tray 2, for Instruments, for Radial Head Prosthesis, size 1/2, without Contents, Vario Case™
68.402.003	Modular Tray 3, for Broaches, for Radial Head Prosthesis, size 1/1, without Contents, Vario Case™
68.402.004	Modular Tray 4, for Trial Implants, for Radial Head Prosthesis, size 1/2, without Contents, Vario Case™