

Date: 19 March 2018

URGENT FIELD SAFETY NOTICE:
Epoca Stem Extractors and Connection Screws
1124235 – Field Safety Notification

***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 voluntary field safety notification for the part and lot numbers (listed below) of the Epoca Stem Extractors and Connection Screws. The Epoca Revision Set is intended for the extraction and revision of Epoca Shoulder System stem implants.

Potentially Affected Product:

Part Number	Part Description	Lot Numbers
03.401.072	Stem Extractor f/Guide Bar	09-6793, 10-2637, 10-5070, 12-2707, 14-1085, 15-8949
03.401.077	Screw M6x18	10-4566

Reason for Field Safety Notification:

There is a potential for the Connection Screw (P/N 03.401.077) of the Stem Extractor (P/N 03.401.072) to break. This breakage could occur during the step 3 “Head/eccenter removal and humeral stem extraction” shown and described on page 10 of the Surgical Technique “Epoca Revision Set” [DSEM/TRM/0714/0131(1)].



P/N 03.401.072 Stem Extractor, for Guide Bar (03.401.070)
used with 355.250

“To remove the stem, mount and fully tighten the stem extractor using the hexagonal wrench. Mount the ram/guide bar and apply gentle blows.”

Potential Patient Impact:

If the Stem Extractor breaks, the potential impact to the patient includes surgical delay, bone damage, and/or adverse tissue reaction.

Instructions if connecting screw for the stem extractor breaks:

All joint replacement (particularly stem) removals require careful advanced planning to consider all contingencies that might be encountered in these often-challenging cases. Preoperative planning should include:

- Patient medical history
- Individual characteristics of the patient (e.g. bone quality, activity level)
- Implants to be extracted / revised (e.g. type of implant, type of fixation, stability) and cemented or uncemented

The assessment of these elements influences the pre-operative strategy, i.e., whether a longitudinal corticotomy is needed for removal and what type of implant can be re-implanted.

In the event the connecting screw for the stem extractor breaks there are additional known methods available to provide the best chance to complete the removal of the Epoca stem. The standard methods listed below are often necessary even when the stem extractor remains functional.

- Carefully sliding a thin osteotome from proximal to distal adjacent to the stem to loosen the stem.
- Longitudinal corticotomy(s) can be done sequentially to create a loosening effect along the stem in the proximal humeral canal.
- The two above steps can be aided by use of grasping the proximal stem with vice grips that enable longitudinal axial extraction loads to be applied.
- Finally, if these methods fail, a distal humeral cortical window can be made to drive the implant out proximally by impacting the stem distal tip distal to proximal.
- The instrumentation required for these methods include (but is not limited to): ultrasonic bone cement melting, a variety of straight, curved and flexible chisels and osteotomes, gouges, curettes, elongated hooks, vice grips, and a variety of curved and straight tamps.

Actions to be taken:

Our records show that your facility has received the Epoca Stem System or the Epoca Revision Set which are subject to this field safety notification. We ask that you review the information contained in this notification and complete the Verification Section located on page 3 of this letter.

Please take the following actions:

- Review the instructions listed in this notification.
- Forward this notice to anyone in your facility that needs to be informed.
- If any of the affected has been forwarded to another facility, contact that facility.
- Keep a copy of this notice.
- Review, complete, sign, and return the attached reply form on page 3 of this letter to your local sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.

Should you have any inquiries please do not hesitate to contact your sales consultant.

Thank you for your attention and cooperation.

DePuy Synthes



Jody Cadd
Field Action Supervisor
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Verification Section

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03.401.077	Screw M6x18	10-4566

Please note that this is a Field Safety Notification only and it is not required to return the product.

___ We acknowledge receipt of this information and understand the instructions above.

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 field safety notification in reference to Field Action 1124235 – Epoca Stem Extractors and Connection Screws.

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.