

**To the ATTENTION of:  
Operating Room Manager**

18 May 2016

**URGENT NOTICE:  
MEDICAL DEVICE RECALL – R2016030  
Flexible Shaft Ø 8.0mm, L 360mm**

Part Description	Part Number	Lot Numbers
Flexible Shaft Ø 8.0mm, L 360 mm for Extraction System for Solid Medullary Nails	351.430	All Lots distributed prior to 03May2016

**Note: this product will be available as a DePuy Synthes evaluation set and authorized for use based on in-house inspection. See below for more information.**

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Number of the Flexible Shaft Ø 8.0mm, L 360 mm for Extraction System for Solid Medullary Nails. These devices are reamers intended for bone reaming, for nail implantation in fractures of the upper and lower extremities, as well as for inserting or removing screws/plates as fixation elements during fracture treatment procedures. Our records indicate that you may have inventory that is impacted by this recall.

Please note that these products are discontinued for sale, and there are currently no replacement devices. However, if your facility needs to extract a solid nail, these devices may be available in the DePuy Synthes evaluation program as L102.570 Solid Nail Extractor Set.

**Reason for the Recall:**

Device did not pass the biological safety evaluation for cytotoxicity following exposure to test conditions. The high growth inhibition levels observed during testing could be attributed to corrosion of the device at solder points. This could potentially be reproduced during use and reprocessing.

**Potential hazard:**

Should the device develop corrosion while in use, the patient could be briefly exposed to potentially cytotoxic material, the consequences of which could be **Adverse Tissue Reaction**, and **Surgical Delay**. The potential risk to patient of complete unavailability of the product is Bone Fracture Intra-op, Neuro-vascular Damage, Damage to Surrounding Structures, Surgical Delay, and Soft Tissue Damage.

At this time, the Solid Nail Extractor is unique because it is the only commercially available device designed to extract a broken Solid Nail via the surgical path used to implant the device. It is much less traumatic than the alternative techniques of fenestration and splitting the bone longitudinally to access the nail fragment(s) and relieve the compressive forces between the bone and the nail/ fragment(s). The professional assessment of the Medical Safety Officer is that the risks to public health of complete unavailability of the product are greater than the risks of maintaining the availability of this instrument for extraction of solid nails through the evaluation program.

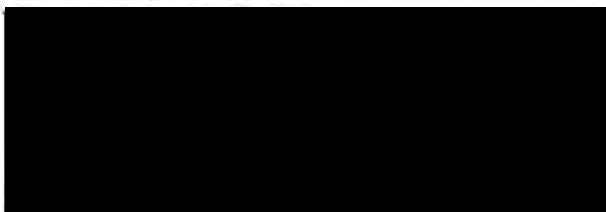
**Customer immediate actions:**

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 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



Cc:

Account Name: \_\_\_\_\_

**URGENT NOTICE:**  
**MEDICAL DEVICE RECALL – R2016030**  
**Flexible Shaft Ø 8.0mm, L 360mm**

**Verification Section**

Part Description	Part Number	Lot Numbers
Flexible Shaft Ø 8.0mm, L 360 mm for Extraction System for Solid Medullary Nails	351.430	All Lots distributed prior to 03May2016

\_\_\_\_ We have located the affected product in stock; returned quantity is documented below.

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

RETURNED DEVICES (including quantity):

\_\_\_\_\_

\_\_\_\_\_

Name/Title (please print): \_\_\_\_\_

Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Signature and Date: \_\_\_\_\_

**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: Product/Lot Subject to this Recall				
Part Description	Product Number	Lot Numbers		
Flexible Shaft Ø 8.0mm, L 360mm	351.430	5080	5003594	5015781
		5081	5006082	5800844
		5082	5007117	5903413
		5000318	5012828	5910995
		5001285	5014258	5923609