Synthes GmbH
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Date: 02 April 2018

URGENT FIELD SAFETY NOTICE:
Sciatic Nerve Retractors – 1144719 – Product Removal

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 below part and lot numbers of Sciatic Nerve Retractors. These devices are part of the 3.5mm Low Profile Pelvic System and intended for drawing back soft tissue during orthopaedic surgery.

Product Subject to this Removal:

Part Number	Part Description	Lot Numbers
03.100.013	Retractor f/Sciatic Nerve	T104992, T114599, T140390, T140674, T140675, T140676, T140677, T141539, T143644, T144855, T145296, T145589, T145819, T146660, T147930, T148624, T149725, T149726, T151370, T152806, T152807, T153692, T155648, T156708, T160394, T939640, T987813
03.100.014	Retractor f/Sciatic Nerve long	T104993, T108115, T114598, T140566, T140665, T140670, T140671, T140673, T141540, T143687, T144854, T145585, T145590, T145932, T146657, T147929, T148552, T148553, T149727, T149728 T151369, T151488, T152808, T152809, T153884, T155649, T958061

Reason for Recall:
There is the potential for micropores to form on the hollow handle of the Sciatic Nerve Retractor. The pores may increase in size, allowing fluid to enter the hollow handle.

Discoloration and moisture were identified within the packaging of the above-mentioned Sciatic Nerve Retractors indicating that these pores may be present in the affected devices.

Potential Impacts:
It is possible that fluids may enter the hollow handle of the Sciatic Nerve Retractor during surgery. Thus, even with diligent reprocessing/sterilization of the retractor, subsequent patients may be at risk for infection and adverse tissue reaction due to retained fluids leaking out during use.

Additionally, if the discoloration and/or moisture are not identified preoperatively, there is a potential for surgical delay due to the time required to investigate and decide next steps.

Actions to be taken:
Our records show that your facility has received one or more of the products subject to this removal. Please take the following actions:

1. Immediately review your inventory to identify and quarantine the 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.

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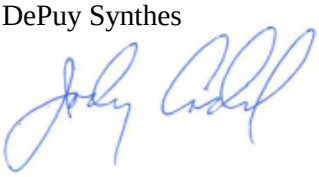
3. Return the affected products within 30 business days. A credit note will be issued for the returned items. **Please note, there are no replacement products available at this time**.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If the affected products have been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until the products have been returned.
7. Keep a copy of this notice.

This product removal (recall) has been reported to the local competent authority. We apologize for any inconvenience that this 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



Jody Cadd
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Verification Section

Product Subject to this Removal:

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____ We have located the identified product in stock; returned quantity is documented below.
RETURNED DEVICES (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 Sciatic Nerve Retractors***.***

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