URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015030
Sciatic Nerve Retractors

Please distribute this information to appropriate personnel at your facility.

Dear Valued Customers,

Synthes GmbH is initiating a voluntary medical device recall of certain lots of the Sciatic Nerve Retractors, which are found in the 3.5mm Low Profile Pelvic System. Please note that there is no replacement for these products available at this time. The 3.5 mm Low Profile Pelvic System is intended for pelvic and acetabular reconstructive surgery and fracture fixation.

Our records indicate that you may have inventory that is subject to this recall.

REASON FOR THE RECALL

Micropores may form on the hollow handle of the Sciatic Nerve Retractor during the manufacturing process that is large enough to allow fluids to enter and exit the hollow handle.

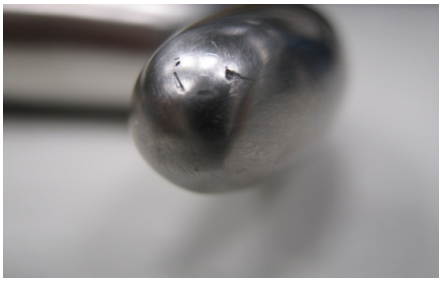

Figure 1: Sciatic Nerve Retractor as identified above

PRODUCTS AFFECTED

This field safety notice involves the following product:

Part Description	Part Number	Lot Number
Retractor for Sciatic Nerve	03.100.013	904732; 908057; 909551; 910819; A7OA17; A7OA26; A7OA30; A7OA37; A7OA43; A7PA10; A7PA20; A7PA30; T100870; T104992; T108114; T114599; T938508; T939338; T939640; T942069; T945414; T946497; T949375; T954443; T958062; T963371; T968151; T968381; T972086; T974174; T974550; T977901; T980418; T980555; T983069; T984285; T987813; T993091; T996572; T999967

Retractor for Sciatic Nerve, long	03.100.014	903786; 904731; 908058; 909552; 910911; A7OA17; A7OA26; A7OA30; A7OA37; A7OA43; A7PA10; A7PA20; A7PA31; T100871; T104993; T108115; T114598;; T932954; T935264; T939339; T945413; T946498; T947785; T954444; T958061; T963372; T968152; T974175; T977904; T980511; T983070; T984228; T987809; T989000; T993092; T996565; T999969 ; T939639

POTENTIAL PATIENT IMPACT

Even with diligent reprocessing/sterilization of the Sciatic Nerve Retractor, subsequent patient(s) may be at risk for infection and adverse tissue reaction due to retained fluids leaking out during use.

In the event that the liquid and/or discoloration is not identified preoperatively and enters the operative theater, there is the potential for surgical delay while a replacement or alternate retractor is requested.

ACTIONS REQUIRED FROM YOU

Please verify whether you have any of the affected products and take the following actions, as appropriate.

If you **DO HAVE** any of the identified affected product(s), please take the following steps:

- Ensure anyone in your facility impacted by this notification reads this letter carefully.
- Immediately identify and quarantine all products listed above in a manner that ensures the affected products will not be used.
- Maintain a copy of this communication with any affected product(s) identified above.
- Complete the Customer Acknowledgement by checking the appropriate box indicating affected product has been located. Also, please indicate the number of devices found and their Lot Number. Please include your name, title, and signature in the spaces provided.
- Return the completed Customer Acknowledgement Form to your local DePuy Synthes contact person.
- Contact your local DePuy Synthes contact person to arrange the return of the affected devices.

If you **DO NOT HAVE** any of the identified affected product(s), please take the following steps:

- Complete the attached Customer Acknowledgement Form by checking the appropriate box indicating that no affected product has been located. Please include your name, title, and signature in the spaces provided. This return documentation acknowledges your receipt of medical device recall information.
- Return the completed Customer Acknowledgement Form to your local DePuy Synthes contact person.
- Note: If the Customer Acknowledgement Form 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 page 4 of the notification.

If any of the affected products has been forwarded to another facility, contact that facility to arrange return and provide them with this letter. Furthermore, keep awareness and a copy of this notice.

The applicable regulatory agencies are being notified.

We apologize for any inconvenience that this Field Safety notification may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes contact person.

Thank you for your attention and cooperation.

Yours sincerely,

Lee Ching Hwee

Senior Regulatory Affairs Executive

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Business Reg No. 52836279L Company Reg No. 197402104W

Attachment 1: Product/Lot Number subject to this recall

Part Description	Part Number	Lot Number
Retractor for Sciatic Nerve	03.100.013	904732; 908057; 909551; 910819; A7OA17; A7OA26; A7OA30; A7OA37; A7OA43; A7PA10; A7PA20; A7PA30; T100870; T104992; T108114; T114599; T938508; T939338; T939640; T942069; T945414; T946497; T949375; T954443; T958062; T963371; T968151; T968381; T972086; T974174; T974550; T977901; T980418; T980555; T983069; T984285; T987813; T993091; T996572; T999967
Retractor for Sciatic Nerve, long	03.100.014	903786; 904731; 908058; 909552; 910911; A7OA17; A7OA26; A7OA30; A7OA37; A7OA43; A7PA10; A7PA20; A7PA31; T100871; T104993; T108115; T114598; T932954; T935264; T939339; T945413; T946498; T947785; T954444; T958061; T963372; T968152; T974175; T977904; T980511; T983070; T984228; T987809; T989000; T993092; T996565; T999969,T939639

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