

To the ATTENTION of:  
Operating Room Manager

24 July 2015

**URGENT NOTICE:**  
**MEDICAL DEVICE RECALL – R2014539**  
**Wraps for Medullary Nails**

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Numbers
Wrap f/Medullary Nails	900.510	All lots

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above Nail Wrap for Trauma Nails. The Wrap for Medullary Nails (Figure 1) is intended **for single use** as a protective sheath specifically for Universal Femoral Nails, Universal Tibial Nails, Unreamed Tibial Nails, and Stainless Steel Tibial Nails during steam sterilization by the hospital. Please note that this product was discontinued by DePuy Synthes in 2014, and there is no replacement.

Our records indicate that you may have inventory that is impacted by this recall.

**Reason for the Recall:**

Although the product is labeled for single use, customers may be reusing the canvas wrap to sterilize nails. Synthes GmbH has verified that a nail can be sterilized within the canvas wrap, but does not have sufficient testing for the device to be considered a multi-use item. The decision to recall was made to address the potential for multiple use of the wrap.



Figure 1: Wrap for Medullary Nails

**Potential hazard:**

At this time we have not identified an increased risk of patient harms or other safety signal for those nails potentially sterilized in a canvas wrap.

**Customer immediate actions:**


1. Immediately identify and quarantine all unused 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.

The applicable regulatory agencies are being notified.

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.

Synthes GmbH

  
Pierre van Iwaarden  
Field Action Manager

Mark Verhageer on behalf  
of Pierre van Iwaarden.  
Cc:



Anne Brisson  
Senior QA Manager,  
Product Safety and Performance

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

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**Verification Section**

**Part Description / Part Number:**

Part Description	Part Number	Lot Numbers
Wrap f/Medullary Nails	900.510	All lots

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

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

RETURNED DEVICES (including quantity):

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

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

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

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

**Please complete and return this page 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.