

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

13 March 2015

**URGENT NOTICE:  
MEDICAL DEVICE RECALL – R2014515  
Sleeve for ASLS, Ø 5.0 mm, Resorbable**

**Part Description, Part- and Lot Numbers**

Part Description	Part Number	Lot Numbers
Sleeve for ASLS, Ø 5.0 mm, resorbable	08.025.044.01S	8586243

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Number of the Sleeve for ASLS, Ø 5.0 mm, resorbable. ASLS (Angular Stable Locking System) is intended for use with Synthes Cannulated Titanium Intramedullary Nails. It is issued as an alternative to standard locking screws/bolts. ASLS is used for the operative treatment and stabilization of long bone fractures of the upper and lower extremities, according to the specific indications of the respective nail system.

Our records indicate that you may have inventory that is impacted by this recall or have been using affected product(s) from a loaner set.

**Reason for the Recall:**

It was discovered that the label of the part and lot number described above listed the incorrect sterilization and expiration date.

Incorrect Expiration Date listed on label	Actual Expiration Date
2018-06	2017-07

Incorrect Sterilization Date listed on label	Actual Sterilization Date
2014-06	2013-10

**Potential hazard:**

There is currently no identified patient harm because the product shelf life is conforming until July 2017. After July 2017, the product is considered to be expired.

If the affected part and lot number described above were to be used past the expiration date of July 2017, malunion/non-union may occur.

To date, there are no reports of adverse events.

**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

  
Charles Goldberg  
Worldwide Director Complaint  
Management

Cc:

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

**URGENT NOTICE:  
MEDICAL DEVICE RECALL – R2014515  
Sleeve for ASLS, Ø 5.0 mm, Resorbable**

**Verification Section**

**Part Description / Part Number:**

Part Description	Part Number	Lot Numbers
Sleeve for ASLS, Ø 5.0 mm, resorbable	08.025.044.01S	8586243

\_\_\_\_ 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):**

\_\_\_\_\_  
\_\_\_\_\_

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.