

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

11 June 2015

**URGENT NOTICE:  
MEDICAL DEVICE RECALL – R2014943  
Guide Wire 2.8mm, L 180mm w/ thread**

Part Description, Part- and Lot Numbers

| Part Description | Part Number | Lot Numbers                         |            |
|------------------|-------------|-------------------------------------|------------|
|                  |             | Guide Wire 2.8mm, L 180mm w/ thread | 03.007.020 |
|                  |             | 5819131                             | 6127126    |
|                  |             | 6031040                             | 7614870    |

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part and Lot Numbers of the DePuy Synthes 2.8mm Guide Wire, Length 180mm with Thread. The 2.8mm Guide Wire is an instrument used to guide the insertion of the olecranon osteotomy nail. The guide wire is removed once the olecranon osteotomy nail is implanted.

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

**Reason for the Recall**

Upon evaluation, it was discovered that certain lots of the identified 2.8mm Guide Wire were labeled with the incorrect material as detailed below:

| Part Number | Part Description                    | Correct Material | Material as Labeled |
|-------------|-------------------------------------|------------------|---------------------|
| 03.007.020  | Guide Wire 2.8mm, L 180mm w/ thread | CoCrW/Ni Alloy   | Stainless Steel     |



Figure 1 - Incorrect Label for Part 03.007.020



Figure 2 - Correct Label for Part 03.007.020

**Potential Hazard:**

Patients with nickel sensitivity may have a reaction to metallic implants which include nickel. The observed label error does not pose a risk to patients with nickel sensitivity for the following reasons:

- The 2.8mm Guide Wire is an instrument used to guide the insertion of the olecranon osteotomy nail. The guide wire is removed once the olecranon osteotomy nail is implanted.
- Both CoCrWNI Alloy (L605) and implant grade Stainless Steel (ASTM F138) are implant materials which contain nickel. L605 has a nominal nickel content of 10% and implant grade ASTM F138 contains between 13% and 15% nickel. Therefore, L605 has a lower nickel content compared to ASTM F138.
- As the affected 2.8mm Guide Wire is made to the design specified with the L605 alloy, there is no effect to the mechanical properties or function of the device caused by stating the material on the package label as "stainless steel".

**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 4 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 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

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Synthes GmbH

Field Action Manage

Cc:

Worldwide Director Complaint Management

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

**URGENT NOTICE:**  
**MEDICAL DEVICE RECALL – R2014943**  
**Guide Wire 2.8mm, L 180mm w/ thread**

**Verification Section**

**Part Description / Part Number:**

| Part Description                    | Part Number | Lot Numbers |         |
|-------------------------------------|-------------|-------------|---------|
| Guide Wire 2.8mm, L 180mm w/ thread | 03.007.020  | 5695693     | 6031041 |
|                                     |             | 5819131     | 6127126 |
|                                     |             | 6031040     | 7614870 |

\_\_\_\_ 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.