

19 Dec 2016

**URGENT NOTICE:  
MEDICAL DEVICE RECALL – 515379  
Impactor for PFNA Blade**

*Please distribute this information to appropriate personnel at your facility.*

Dear Sir/Madam,

Part Description, Part and Lot Numbers

Part Number(s)	Part Description	Lot Numbers
03.010.410	Impactor for PFNA Blade	All Lots

Synthes GmbH is initiating a medical device recall of the Impactor for PFNA Blade. The PFNA impactor is part of the PFNA and PFNA-II systems used for treating high energy fractures in younger patients and low energy fractures in older patients. It is used to insert the PFNA blade, by applying gentle blows with a hammer to the distal end of the impactor.

Our records indicate that you may have inventory that is impacted or have been using affected product(s).

**Reason for the Recall**

This voluntary recall was initiated because Synthes Trauma received product complaints for breakage in the PFNA Blade Impactor, where the handle detached from the shaft of the instrument. It has been identified that a laser weld breakage, partial or complete, can occur in the PFNA Blade Impactor where the handle detaches from the internal shaft of the instrument.

**Potential Patient Impact:**

In the event that the laser welding of the handle cracks, the handle may loosen or separate from the instrument. If the issue is detected during use, a marginal surgical delay may occur if the handle cracks, loosens, or separates. An additional impactor for the PFNA blade (356.823) is listed in the PFNA-II Surgical Technique guide as an “alternative instrument” and may be available for use in the set. If not available, a replacement would be needed.

Infection could potentially result if the handle is loosened from the shaft and allows body fluids (i.e. blood, bony debris) to enter the interior of the impactor’s handle. As the shaft and handle are one part, they would not be separated during cleaning. Thus, the presence of the foreign material would remain hidden in the device and could potentially reduce the efficacy of the sterilization process. In addition, the hidden debris could enter the surgical site (of subsequent patients) during surgery. Irrigants used during surgery may also loosen /liquefy the debris and potentially contaminate the surgical site.

Should alternative methods or systems/devices not be available resulting in non-operative treatment there may be an increase morbidity and mortality, or other potential patient risks.

**Alternative Options available from DePuy Synthes:**

- **Option 1: TFNA system**  
The TFNA system is similar to PFN, PFNA, and PFNA-II and is the recommended alternative solution. However, product availability is limited and may not be immediately available for replacement. If choosing this option, please review and understand **IMPORTANT NOTE** below regarding interim continued use and risks for the PFNA Impactor until TFNA system availability.
- **Option 2: Impactor for PFN Blade (P/N 356.823)**  
This impactor is no longer available for purchase or distribution from Synthes. However, it is able to be used with the PFNA and PFNA-II systems and is an option if your facility has this item available.
- **Option 3: DHS System and DCS System**  
These systems address the majority of the indicated fracture types treated with PFNA, with the exception of fractures with no lateral buttress. These types of fractures cannot be adequately treated. It is important to have both systems fully functional and available. Additional risk may be incurred using this system as DHS and DCS at time require larger surgical incision and direct vs. indirect reduction techniques.
- **Option 4: Continued use of the Impactor for PFNA Blade until Replacement Availability**  
With the known Potential Patient Impacts/Risks, continue use of the existing PFNA Impactor until availability of an alternative solution or replacement is available.

**IMPORTANT NOTE:** The Impactor for the PFNA Blade will continue to be made available until an alternative treatment method can be secured due to the potential risks to public health of complete unavailability of a treatment option

**Customer immediate actions:**

1. Carefully review the above **Potential Patient Impacts** and **Alternative Options**. Determine which Option path your facility will take.
2. Immediately review your inventory to identify affected products.
  - a. If Replacing: Manage all inventory until your facility units are fully replaced;  
Return any affected product as soon as possible, but within 30 business days of receiving replacement product.

- b. If Returning and not Replacing: Quarantine all affected products listed above in a manner that ensures the affected products will not be used.
3. Please fully complete the attached verification Section (page 4 of this notification), indicating your Option decision.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any of the affected products have been forwarded to another facility, contact their facility to arrange return.
6. Maintain awareness of this notice until all product listed below have been returned to DePuy Synthes.
7. Keep a Copy of this Notice.

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.

Yours Sincerely,



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Lee, Ching Hwee  
Associate Manager, Regulatory Affairs

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**Affected Product:**

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Impactor for PFNA Blade	03.010.410	All Lots

Please check (√) accordingly:

Check one of the following:	Total QTY
<input type="checkbox"/> I acknowledge receipt of this information, and will be returning the noting quantities. However, will not be requesting replacement product.	
<input type="checkbox"/> I acknowledge receipt of this information, and will choose to REPLACE the following quantity of Impactor(s) for PFNA Blade when available. Will continue use of the PFNA Impactor until replacements are available. <i>Note: Follow-up notification will be sent when replacement Impactors start to become available.</i>	
<input type="checkbox"/> I acknowledge receipt of this information, and will CHANGE to a different system. Will continue use of the PFNA Impactor until replacements are available. Please replace with the system(s) indicated <b>(Record quantities below):</b> <ul style="list-style-type: none"> <li>• DCS:</li> <li>• DHS:</li> <li>• TFNA</li> </ul>	
<input type="checkbox"/> I acknowledge receipt of this information, but do not have any affected product in stock; returned quantity is zero.	

**Please sign, date and stamp below.** Your signature provides confirmation that you have received and understood this notification.

\_\_\_\_\_  
Customer Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Signature & Date

\_\_\_\_\_  
Stamp (*Stamp shall bear facility name*)

Please complete this Verification Section and return to your Depuy Synthes representative or fax it to +65 6720 0750 within **(5) five business days** of receipt of the Field Safety Notice.