

Date: 21 April 2017

URGENT NOTICE:
MEDICAL DEVICE FIELD SAFETY NOTIFICATION-
Product Removal 515379- Impactor for PFNA Blade

Attention:

- Health care providers using the PFNA and PFNA-II systems
- Staff working in operating suites during fracture repair procedures
- Risk Management personnel

Purpose of this Communication:

This is a follow up notice in regards to Synthes GmbH initiated medical device removal of the Impactor for PFNA Blade in December 2016. You are receiving this follow-up as we do not have record of you acknowledging the original notification.

Product Subject to the Removal:

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.

Part Number	Part Description	Lot Numbers
03.010.410	Impactor for PFNA Blade	See Attachment 1 for affected parts. NOTE: Replacement units will begin with lot # L341786 and above.

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 Impacts:

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 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 PFNA 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 replacement unit is provided.

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*

Actions to be taken:

Our records show that your facility received one or more of the product(s) subject to this product removal. Please take the following actions:

1. 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. Replacement parts are becoming available. If you have questions regarding the return and recovery of the part, we ask that you contact your local DePuy Synthes representative.

- b. **If Returning and NOT Replacing:** Quarantine all affected products listed above in a manner that ensures the affected products will not be used. Return any affected product as soon as possible, but within 30 business days of receiving this notice.
2. Please fully complete the attached Verification Section indicating your Option decision.
 3. Forward this notice to anyone in your facility that needs to be informed.
 4. If any of the affected products have been forwarded to another facility, contact their facility to arrange return.
 5. Maintain awareness of this notice until all product listed below have been returned to DePuy Synthes, and keep a copy of this notice.

We apologize for any inconvenience that this product removal (recall) may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your local DePuy Synthes representative.

Thank you for your attention and cooperation.

DePuy Synthes

Anne Brisson
Senior Quality Assurance Manager,
Product Safety and Performance

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Product Removal 515379- Impactor for PFNA Blade

Verification Section

Affected Product:

Part Number(s)	Part Description	Lot Numbers
03.010.410	Impactor for PFNA Blade	See Attachment 1 for affected parts. NOTE: Replacement units will begin with lot # L341786 and above.

Check one of the following:		Total QTY
<input type="checkbox"/>	I acknowledge receipt of this information, and will be returning the noted quantities. However, I will not be requesting replacement product.	
<input type="checkbox"/>	I acknowledge receipt of this information, and choose to REPLACE the following quantity of Impactor(s) for PFNA Blade. Will continue use of the PFNA Impactor until replacements are provided. Indicate Total QTY of Impactors to be returned. <i>NOTE: please place your order for number of replacements required.</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 the replacement system is available. Please replace with the system(s) indicated (Record quantities below): <ul style="list-style-type: none"> • DCS: • DHS: • TFNA 	
<input type="checkbox"/>	I acknowledge receipt of this information, but do not have any affected product in stock; returned quantity is zero.	

CUSTOMER DETAILS	
Facility Name:	
Facility Address:	
Account Number:	
Reply Confirmation Completed by: (Please Print Name)	
Signature and Date: (REQUIRED FIELD)	
Title: (Please Print)	
Telephone Number: (Include Area Code and Extension)	
Email address:	

The above acknowledges receipt of the subject Field Safety Notification, Product removal in reference to the DePuy Synthes Impactor for PFNA Blade.

Please complete and return this page to your local DePuy Synthes representative.

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

Attachment 1

Part Number 03.010.410					
Lot Numbers:					
2140549	2779287	8242870	8904786	9419710	9908203
2544605	2786995	8316329	8938264	9430395	9925480
2554071	2795687	8333012	8938267	9443295	9947458
2568798	2804428	8346409	8954624	9464849	9956732
2569597	2814599	8365683	8954626	9478510	17500681
2569601	2818271	8365684	8979224	9481941	L007710
2618058	2825644	8392887	8979485	9515028	L021644
2618059	7720394	8412005	8989365	9527707	L036242
2663077	7727718	8422158	9052185	9544077	L045816
2663082	7739491	8435439	9068166	9555825	L057687
2663271	7775137	8454497	9078126	9571249	L066979
2679071	7808156	8472076	9092324	9596712	L075568
2679100	7808157	8482400	9120066	9610603	L096182
2688407	7834849	8536990	9143829	9633972	L111682
2698274	7841822	8545304	9143830	9649644	L118869
2714248	7842977	8562547	9173004	9669777	L120492
2720817	7860373	8584178	9173008	9685132	L171370
2720818	7901706	8615985	9173011	9707765	L179837
2720819	7931718	8639579	9182435	9708805	L189000
2724732	7965914	8660612	9182436	9727517	L203780
2732773	7995645	8683004	9208653	9745984	L212043
2734301	8000118	8708138	9221060	9761309	L236940
2740007	8029208	8731352	9248843	9775292	L236941
2747016	8067486	8755180	9251276	9785974	L245797
2748823	8109643	8769609	9269007	9802595	L245801
2752742	8135485	8783044	9291155	9802597	L257656
2757876	8165189	8838421	9311832	9811063	L257659
2761817	8198345	8838425	9319845	9827325	L257660
2765046	8222972	8853040	9349629	9829662	L257662
2772062	8227807	8883922	9360646	9853115	
2777268	8227812	8883923	9387458	9868300	
2778506	8227813	8883924	9406100	9883613	