Synthes GmbH
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Date: 9Dec2016

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:

Synthes GmbH is initiating a medical device removal 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.

Product Subject to this Removal:

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

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 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

Actions to be taken:
Our records show that your facility has received one or more of the product(s) subject to this product removal.

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;

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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 removal (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.

DePuy Synthes

Anne Brisson
Senior Quality Assurance Manager,
Product Safety and Performance

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MEDICAL DEVICE FIELD SAFETY NOTIFICATION-
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	All Lots

	Check one of the following:	**Total QTY**
	I acknowledge receipt of this information, and will be returning the noting quantities. However, will not be requesting replacement product.	
	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. ***Note:*** *Follow-up notification will be sent when replacement Impactors start to become available*.	
	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 **(Record quantities below):** • DCS: • DHS: • TFNA	
	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 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.

BONIFARM d.o.o.

10000 ZAGREB, Hondlova 2/10, Hrvatska

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Žiro račun kod Zagrebačke banke: 2360000-1101877706 MB: 02031965
IBAN: HR5323600001101877706 OIB: 06492595723

Agencija za lijekove i medicinske proizvode
Odjel za sigurnosnu primjenu lijekova i medicinskih proizvoda
Odsjek za medicinske proizvode
Ksaverska cesta 4
10000 Zagreb

Zagreb, 25.7.2017.

Predmet: **Povlačenje medicinskog proizvoda Impaktor za PFNA oštricu, prijava Sigurnosne korektivne radnje te Sigurnosna obavijest - 515379**

Poštovani,

Zaprimili smo obavijest tvrtke Synthes GmbH o povlačenju medicinskog proizvoda impactor za PFNA oštricu te posljedičnoj Sigurnosnoj korektivnoj radnji i potrebi dostavljanja Sigurnosne obavijesti korisnicima - 515379.

Razlog ovog dobrovoljnog povlačenja rezultat je pritužbi na proizvod zbog lomljenja impaktora za PFNA oštricu, gdje je ručka odvojena od baze instrumenta. Utvrđeno je da se kod Impaktora za PFNA oštrice može pojaviti lom, djelomični ili potpuni na mjestu laserskog zavarivanja, gdje se ručka odvoji od unutarnje baze instrumenta. Potencijalna opasnost: u slučaju da ručka pukne na mjestu laserskog zavarivanja, ručka se može olabaviti ili odvojiti od instrumenta. Ako se problem otkrije tijekom uporabe, može doći do marginalnog kašnjenja kirurškog zahvata ako se ručka slomi, olabavi ili odvoji. Dodatni udarni Impaktor za PFNA oštricu (356.823) naveden je u vodiču za kiruršku tehniku PFNA-II kao "alternativni instrument" i može biti dostupan za upotrebu u setu. Ako nije dostupan, potrebna je zamjena. Posljedično se potencijalno može razviti infekcija ako se ručka odmakne od osovine i dopušta tjelesnim tekućinama (npr. krv, koštani ostaci) prodrijeti u unutrašnjost ručke motora. Budući da su osovina i ručka jedan dio, tijekom čišćenja ne bi se odvojili. Tako bi prisutnost stranog materijala ostala skrivena u uređaju i mogla bi potencijalno smanjiti djelotvornost sterilizacijskog procesa. Osim toga, skrivene bi krhotine mogle prodrijeti na mjestu kirurškog zahvata (naknadnih pacijenata) tijekom operacije. Uređaji za pranje koje se koriste tijekom operacije mogu također otpuštati / ukapati krhotine i potencijalno zagađivati mjesto kirurškog zahvata. Ako ne budu dostupne alternativne metode ili sustavi / uređaji, neoperativni tretman može povećati obolijevanje i smrtnost, uvodeći druge moguće rizike bolesnika. Glavni uzrok: preliminarni uzrok je jakost laserskog zavarivanja koji je nedostatan za održavanje udarnih sila od umetanja i vađenja oštrice

Na temelju navedenog, proizvođač je odlučio povući zahvaćene serije navedenog proizvoda.

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Ovim putem dostavljamo Sigurnosnu korektivnu radnju i Sigurnosnu obavijest vama na pažnju i procjenu.

S poštovanjem,

Marinko Bilušić, dr. med.
specijalist kliničke farmakologije i toksikologije,
Odgovorna osoba za vigilanciju za
Medika d.o.o.

BONIFARM d.o.o. Zagreb, Hondlova 2/10