Medical Device Safety Alert: Synthes GmbH Impactor for PFNA Blade

Medical device manufacturer, Synthes GmbH, has issued a medical device safety alert concerning its Impactor for PFNA Blade [Part Number: 03.010.410; Lot Numbers: All Lots].

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

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.

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 the manufacturer:

- 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, users are advised to 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 the manufacturer. However, it is able to be used with the PFNA and PFNA-II systems and is an option if the user’s 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, users may continue to use the existing PFNA Impactor until availability of an alternative solution or replacement is available.

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

According to the local supplier, the affected products are distributed in Hong Kong.

If you are in possession of the affected products, please contact your supplier for necessary actions.

Posted on 16 December 2016

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Last Revision Date : 16 December 2016