

## To the ATTENTION of: Operating Room Manager

28 May 2014

### URGENT FIELD SAFETY NOTIFICATION

Part Number / Part Description / Lot Numbers

Part Number	Part Description	Lot Numbers
357.136	Aiming Arm for DFN, combined, for PAD	8305953 7925805 7891008 2072732 7761042 2800254 2670176 2081070 2221713 2134270 2083750 2069617

Dear Valued Customer,

Synthes GmbH is initiating a Field Safety Notification (FSN) for the Distal Femoral Nail Aiming Arm (Part Number 357.136). The affected Lot Numbers are indicated in the table above. Our records indicate that you may have inventory that is impacted by this FSN.

#### Reason for the FSN:

An unknown number of Distal Aiming Arms in the lots identified above were not manufactured to specification. The positioning pins on the Distal Aiming Arm which interface with the insertion handle have been inserted on the wrong side of the tool, and as a result do not fulfill their purpose of sufficiently stabilizing the Distal Aiming Arm on the insertion handle.

#### Potential harms:

There are potential harms associated with the Distal Aiming Arm not being manufactured in accordance to the specifications. Impaired product performance may result in: marginal elongation of surgery time resulting in extended anaesthesia, increase in blood loss, hoarse voice and sore throat due to extended intubation, and increase risk of infection.



In a potential worst case scenario, if index procedure cannot be completed and a replacement instrument and/or implant is required but not readily available in the OR, additional delay will result.

Marginal damage to surrounding structure and bone, due to the potential for misalignment, damage to local structures or bone adjacent to operation site can occur which, without additional treatment, may lead to minor pain. Improper placement of locking implants may theoretically lead to imprecise implant positioning with subsequent implant failure which could potentially require reoperation and the exchange of the failed implant.

There is also the possibility for adverse tissue reaction because of particle reaction or unfavourable response to foreign material created by possible misalignment while drilling. This may trigger a localized reaction which does not lead to permanent impairment.

**Customer immediate actions:**

1. Check whether you have inventory of the product with lot numbers listed above. Inspect the device as indicated below (Inspection of the device) to identify whether devices are conforming or non-conforming.
2. Quarantine all non-conforming products identified under 1).
3. Conforming products do not have to be returned and can be used.
4. Review, complete, sign and return the attached reply form to your local DePuy Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.
5. Return any non-conforming product within 30 business days. A credit note will be issued for the returned items.
6. Forward this notice to anyone in your facility that needs to be informed.
7. If any product listed below has been forwarded to another facility, contact that facility to arrange return.
8. Maintain awareness of this notice until all products listed below have been returned to DePuy Synthes.
9. Keep a copy of this notice.

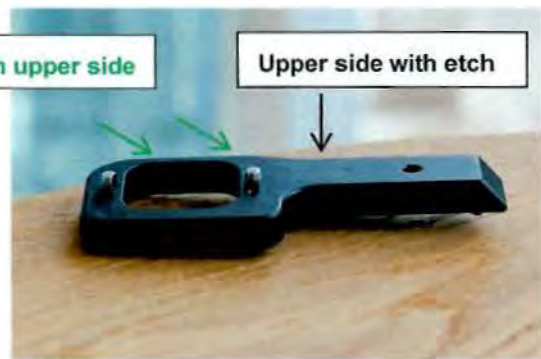
**Inspection of the device:**

1. Inspect whether the pins have been inserted on the upper side of the device as indicated in photos 1 and 2. The device in photos 1 and 2 is manufactured correctly and the device with the pins in this configuration can be used.
2. Incorrect insertion of the pins on the bottom of the device is indicated on photos 3 and 4. The device with the pins in this configuration is non-conforming and the device shall not be used.

**Photo 1. Device conforming**



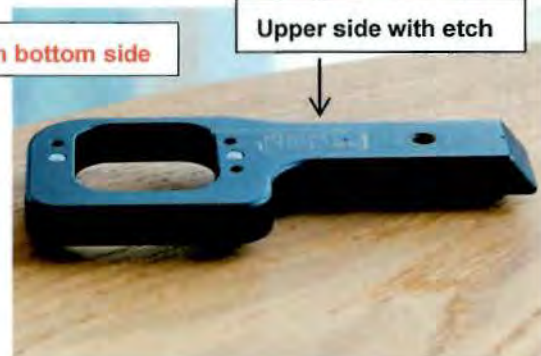
**Photo 2. Device conforming**



**Photo 3. Device non-conforming**



**Photo 4. Device non-conforming**

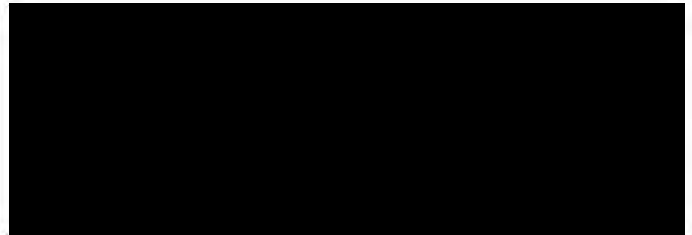
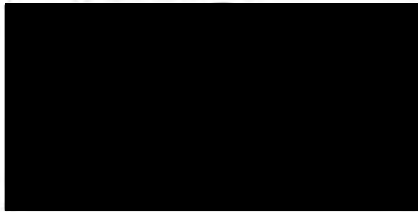


The applicable regulatory agencies are being notified. Synthes GmbH is taking this action voluntarily.

We apologise for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

Synthes GmbH



Cc:



**NOTICE: MEDICAL DEVICE RECALL FSN2013577**

**DFN Distal Aiming Arm**

**Verification Section**

Part Number	Part Description	Lot Numbers
357.136	Aiming Arm for DFN, combined, for PAD	8305953 7925805 7891008 2072732 7761042 2800254 2670176 2081070 2221713 2134270 2083750 2069617

- We have located and identified product in stock as non-conforming, returned quantity is documented below. A copy of this letter is retained for our records.
- We have located and identified product in stock as conforming, quantity is documented below. A copy of this letter is retained for our records.
- We do not have any identified product in stock; returned quantity is zero. We have retained a copy of this letter for our records.

RETURNED NON-CONFORMING DEVICES (including quantity) and/or COMMENTS:

---

QUANTITY OF CONFORMING DEVICES and/or COMMENTS:

---

Hospital name: \_\_\_\_\_

Name/Title (please print) \_\_\_\_\_

Phone Number: \_\_\_\_\_

Signature and Date: \_\_\_\_\_

