DePuy Synthes People inspired
JOINT RECONSTRUCTION
COMPANIES OF Johnson & Johnson

# Urgent Field Safety Notice (FSN)

**Product Name: DePuy Synthes -** ATTUNE® Intuition Distal Femoral Jig

**FSCA-identifier:** HHE-103070405

**Type of Action**: Field Safety Notice

**Date:** Oct 2014

**Attention:** Trust Chief Executives, the Clinical Director-Orthopaedic Department, the Orthopaedic Theatre Manager, the Safety Liaison Officer, General Managers – Private Sector Hospitals

**Type of device:** Instrument used for Orthopaedic Knee Joint Replacement

**Model names:** DePuy Synthes - ATTUNE® Intuition Distal Femoral Jig

**Part numbers:** 254400521 and 254400520 (all lots)
DePuy Orthopaedics, Inc. is issuing a Field Safety Notice/device correction for all lots of the ATTUNE® Intuition Distal Femoral Jig (Part Nos. 254400521 and 254400520). This correction is being issued because if the metal pin bushing is overloaded, there is the potential for partial or full displacement of the metal pin bushing along with fracture of the plastic around the metal pin bushing. If the plastic around the metal pin bushing fractures, there is the potential for fragments of the fractured plastic to be left in the patient.

The company is advising an inspection of specific lots of the ATTUNE® Intuition Distal Femoral Jig (Part numbers 254400521 and 254400520), as those instruments may be assembled incorrectly. Theatre Staff and persons involved with the Cleaning and Reprocessing of the device are requested to inspect all inventory for specific lots see “Inspection and Swap-Out of Femoral Jigs for Incorrect Assembly” on Page 2. In the instance that a device is found to be assembled incorrectly it is requested to be returned and exchanged for a correctly assembled device.

**Affected Instruments:**

**Part numbers:** 254400521 and 254400520
**Lot Numbers:** All Lots for Device Correction. See Attachment A for lot specific inspection/swap-out.

**Intended Use:**
The distal femoral jig (Figure 1) allows the surgeon to position the distal cutting block on the anterior condyles at the desired varus / valgus angle and distal resection depth. Proximal-Distal stability of the instrument is achieved by inserting the Intramedullary Rod into the Femoral IM Canal. Pinning the jig on the distal femoral condyles is optional.

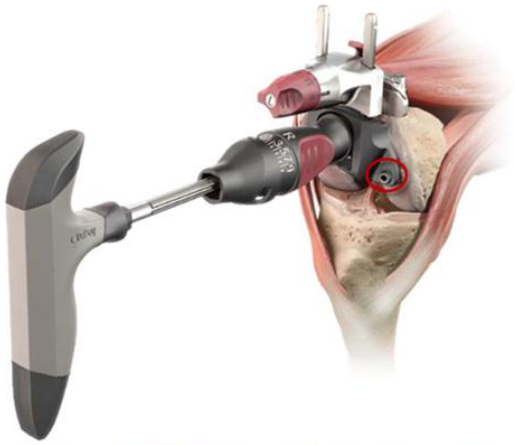


Figure 1: ATTUNE® Intuition Distal Femoral Jig

**Reason for Device Correction with Lot Specific Swap-Out**
During the company's complaints investigation, it was determined that the metal pin bushing has the potential to be displaced during use and therefore allow plastic debris to break from the instrument. This is potentially caused by excessive loading applied during pinning of the jig to the distal femoral condyles. The complaint rate of the bushings partially or fully displacing is 0.018%.

A separate issue was also discovered in which the metal pin bushing was incorrectly assembled during the manufacturing process in some instruments. Metal pin bushings have been displaced in both correctly and incorrectly assembled bushings. Subject to the following guidance and the medical professional's discretion, use of the jig with incorrectly assembled bushings remains acceptable to continue to produce the desired outcome.

**Inspection and Swap-Out of Femoral Jigs for Incorrect Assembly**

Until the instrument swap-out is completed, incorrectly assembled jigs may continue to be used at the discretion of the medical professional. As previously stated, bushings have failed on correctly assembled bushings as well. Therefore, in deciding to continue to use the jig, the medical professional should consider that pinning the jig on the distal femoral condyles is optional and adhere to the information provided in the Medical Professional notice.

**Inspecting the ATTUNE® Intuition Distal Femoral Jig:** Figures 2 and 3 depict correctly versus incorrectly assembled metal pin bushings. Use this as a guide for inspecting affected instruments.

Figure 2: The correctly assembled jig will have the smaller diameter (5.50 mm) end of the metal pin bushing on the jig's top side. The incorrectly assembled jig will have the larger diameter (6.50 mm) end of the metal pin bushing on the jig's top side. The incorrectly assembled jig has a wall thickness of the black plastic surrounding the bushing which is considerably thinner than the wall thickness of the bushing.

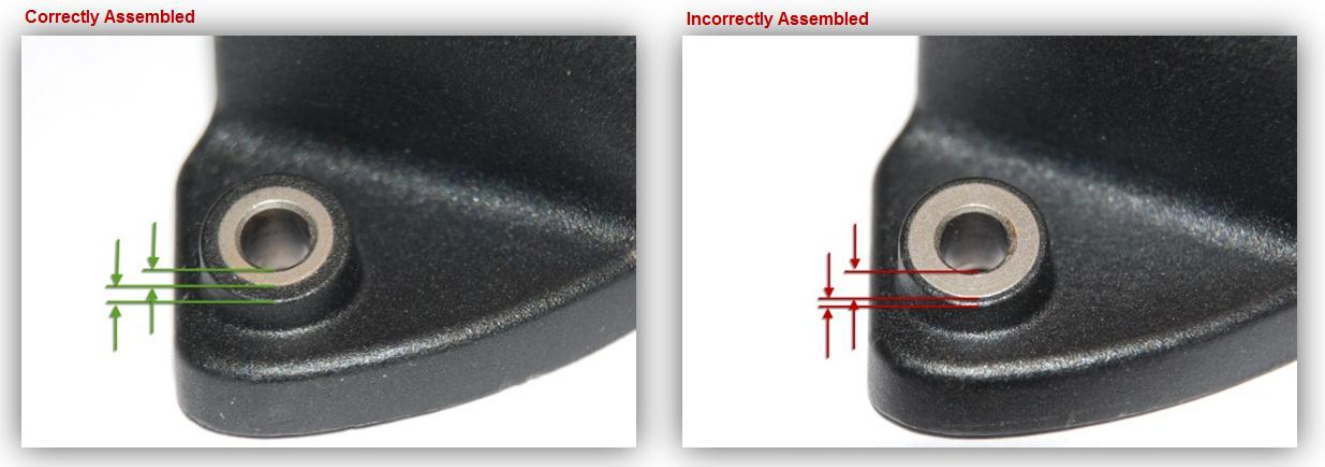



Figure 2: Top of Jig – Comparison of Correctly Assembled vs. Incorrectly Assembled (Inverted Bushing)

Figure 3: The correctly assembled jig will have the larger diameter (6.50 mm) end of the metal pin bushing on the jig's bone side (bottom side). The incorrectly assembled jig will have the smaller diameter (5.50 mm) end of the metal pin bushing on the jig's bone side (bottom side).

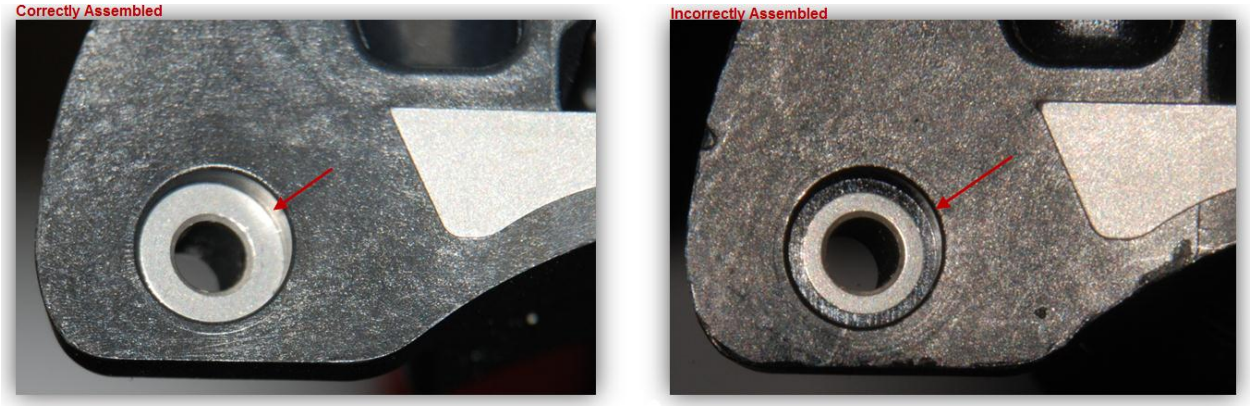



Figure 3: Bottom of Jig (bone side) – Comparison of Correctly Assembled vs. Incorrectly Assembled (Inverted Bushing)

**Device Correction Information**

To reduce the risk of the metal pin bushing displacing and possibly damaging the plastic, the company recommends instrument users follow directions provided in the surgical technique titled, "DePuy Synthes Joint Reconstruction ATTUNE® Knee System Surgical Technique" (Cat. No.0612-10-512). Specifically:

1. Refer to Page 8 of the surgical technique. This section highlights that headed pins should not be over tightened against surfaces of uncut bone. It is recommended to not continue to drive the headed pin once the head contacts the bushing.

"Headed pins are best used to secure blocks against a flat surface such as cut bone, however, if used on uncut bone with a curved surface, be careful that the Headed Pins are not over tightened as this can lead to tilting and malalignment of the block."

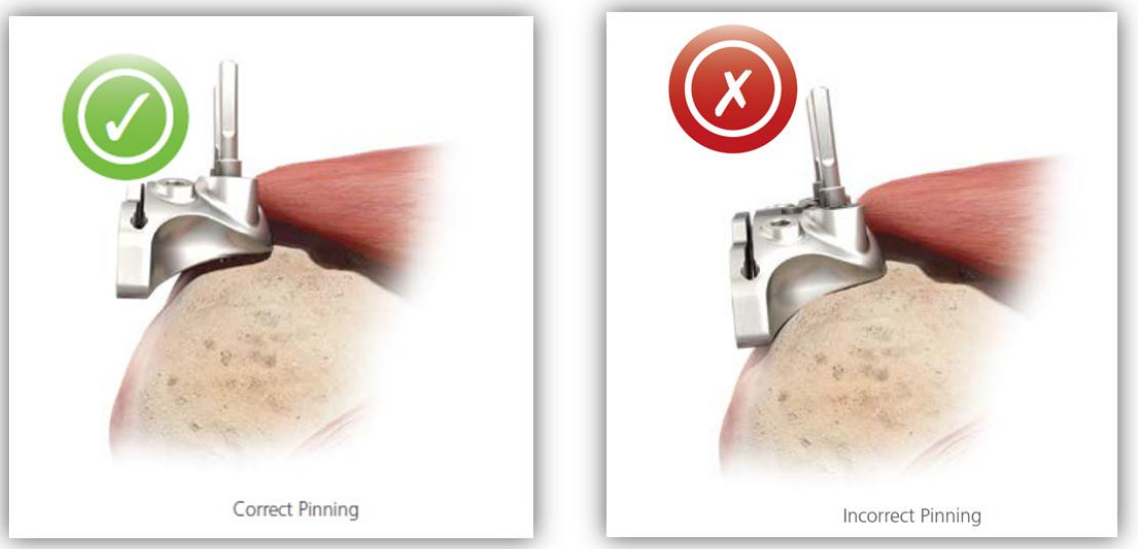



**Figure 4: Images of Correct vs. Incorrect (over tightened) Pinning from Page 8 of the "DePuy Synthes Joint Reconstruction ATTUNE® Knee System Surgical Technique" (Cat. No. 0612-10-512)**

2. Refer to Page 13 of the surgical technique. This section highlights that the use of the pins in the distal resection plate is optional.

   "… The Jig may be pinned temporarily using pin holes in the distal resection plate."

**Units Affected**

There have been 3,082 affected devices distributed worldwide. This device correction and swap-out does not affect any other instruments.

**Depth of Device Correction with Lot Specific Inspection and Swap-Out**

This device correction with lot specific inspection and swap-out provides instructions for notifying Medical Professionals (surgeon users and hospitals /medical facilities) who used/purchased the ATTUNE® Intuition Distal Femoral Jig (Part. Nos. 254400521 and 254400520) and 2) instructions to inspect specific lots.

**Clinical Implications**
If the metal pin bushing displaces, damages, or fractures the plastic and plastic debris is not removed from the patient, clinical implications may include:

- Adverse tissue reaction if the broken piece of the plastic was not removed, the surrounding tissue may become irritated
- Poor joint mechanics if the remaining fragment is left in the joint space
- Pain

The clinical implications above may potentially require revision surgery. Following are general examples of possible risks/hazards of revision surgery:

1. Infection
2. Additional scarring
3. Neural and vascular damage
4. Additional pain to the patient
5. Functional problems resulting from items 1 – 4 above
6. Anesthesia-associated risks

**Transmission of this Field Safety Notice:**

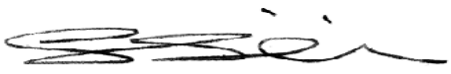
This notice has been sent to you as records indicate that your organization/hospital has purchased the ATTUNE® Intuition Distal Femoral Jig

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where these products may have been transferred.
To confirm receipt of this FSN please complete and return the acknowledgement in Attachment B.
For any enquiries about the ATTUNE® Intuition Distal Femoral Jig contact:

Alan O' Sullivan
Recall Co-Ordinator
e-mail – *aosulliv@its.jnj.com*
Tel no - +353 21 4914149

This FSN has been notified to the appropriate Regulatory Agency.

Sincerely,



Simon Sinclair PhD MB BChir
Worldwide Vice President, Strategic Medical Affairs

**Attachment A: Lots to Inspect for Incorrect Assembly**

| Cat. No. | DePuy Synthes Lot No: | MFG Lot No: |
|---|---|---|
| 254400520 | ABC22844 | C22844 |
| | ABC22845 | C22845 |
| | ABC34279 | C34279 |
| | ABC34280 | C34280 |
| | ABC4107 | C4107 |
| | ABC4108 | C4108 |
| | ABC4112 | C4112 |
| | ABC4113 | C4113 |
| | ABC50741 | C50471 |
| 254400521 | ABB13662 | B13662 |
| | ABB19116 | B19116 |
| | ABB19117 | B19117 |
| | ABB19118 | B19118 |
| | ABB35392 | B35392 |
| | ABB35393 | B35393 |
| | ABB39835 | B39835 |
| | ABB41384 | B41384 |
| | ABB46872 | B46872 |
| | ABB49200 | B49200 |
| | ABB50724 | B50724 |
| | ABB55749 | B55749 |
| | ABB63598 | B63598 |
| | ABB66346 | B66346 |
| | ABB72107 | B72107 |
| | ABB77183 | B77183 |
| | ABB79390 | B79390 |
| | ABB79391 | B79391 |
| | ABB80712 | N80712 |
| | ABC17165 | C17165 |
| | ABC5023 | C5023 |

**Attachment B:**

## This Letter acknowledges receipt of the Field Safety Notice related to ATTUNE® Intuition Distal Femoral Jig

**(Please check as appropriate)**

☐ Yes, I have received the FSN

Please fax or e-mail this completed document to [INSERT DePuy Marketing Company/Affilaite contact details]

Print Name: _____

_____
**Signature**

_____
**Hospital Name**

_____
**City**

_____
**Country**

_____
**Telephone Number or e-mail address**