DePuy Synthes People inspired
JOINT RECONSTRUCTION
COMPANIES OF Johnson & Johnson

Urgent Field Safety Notice (FSN)

Product Name: DePuy Synthes - ATTUNE® INTUITION™ Impaction Handle, ATTUNE® INTUITION™ Impactors

FSCA-identifier: HHE - 103077730 Impaction Handle / HHE – 103082178 Impactors

Type of Action: Field Safety Notice/device correction

Date: Nov 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™ Impaction Handle, ATTUNE® INTUITION™ Impactors

DePuy Orthopaedics, Inc. is issuing a Field Safety Notice/device correction of all lots of ATTUNE® INTUITION™ Impaction Handle (Part. no. 254401017) and Impactors (Part. nos. 254401003, 254401004, and 254401006). Affected instruments have the potential to fracture during impaction. If not observed during surgery, broken pieces of the instruments may be left in the patient.

Affected Instruments:

Product	Lot #
254401017	All Lots
254401003	All Lots
254401004	All Lots
254401006	All Lots

Intended Use

The ATTUNE INTUITION Impaction Handle (See Figure 1) is a re-useable instrument utilized in knee replacement procedures. The instrument interfaces with several related ATTUNE instruments: keel punch, tibial tower, evaluation bullet, fixed bearing tibial impactor, rotating platform tibial impactor, and femoral impactor, for the purpose of impaction, extraction, and insertion applications at steps within the surgical procedure. Due to the frequency of its use, two impaction handles are supplied in each kit.

Figure 1: ATTUNE® INTUITION™ Impaction Handle (Part. no. 254401017)

The ATTUNE® INTUITION™ Impactors (Part. nos. 254401003, 254401004, and 254401006) are re-useable instruments utilized in knee replacement procedures. The three affected impactors (See Figure 2) are used at various times within the surgical flow. Each impactor is used to impact the final ATTUNE implant or trial into the joint and mates with the ATTUNE® INTUITION™ Impaction Handle (Part. no.254401017).

Figure 2: ATTUNE® INTUITION™ Impactors (Part. nos. 254401003, 254401004, and 254401006)

Reason for a Field Safety Notice/device correction:
Complaints have been received indicating that the ATTUNE® INTUITION™ Impaction Handle (Part. no.254401017) lever has fractured during impaction. Should the lever fracture, there is the potential for fractured pieces of the device, or the inner spring, if released, to be left in the patient if not observed during surgery. The reported occurrence rate is 0.04%. No patient harms have been reported in cases where the levers have fractured.

Figure 3: Fractured ATTUNE® INTUITION™ Impaction Handle

Complaints have also been received that the ATTUNE® INTUITION™ Impactors (Part. nos. 254401003, 254401004, and 254401006) have broken and produced small pieces. Should a fracture occur and not be observed during surgery, there is the potential for these small fractured pieces of the instrument to be left in the patient. No patient harms have been reported in cases where the impactors have fractured. The reported occurrence rates are as follows: 0.25% for fixed bearing tibial impactors (Part. no. 254401003), 0.08% for rotating platform tibial impactors (cat. no. 254401004), and 0.23% for femoral component impactors (Part. no. 25440106) is 0.23%.

Figure 4: Fractured ATTUNE® INTUITION™ Impactors

Field Safety Notice/device correction Actions:
To reduce the possibility of leaving fragments in patients, the company suggests adhering to the instructions for use (IFU), which include inspecting the ATTUNE® INTUITION™ Impaction Handle (Part. no.254401017) and Impactors (Part. nos. 254401003, 254401004, and 254401006) to ensure that no instruments or pieces of instruments are left in the surgical site prior to closure. The IFU is Part. No. 0902-00-836 Rev D. Highlights from the IFU include:

1. From Page 4 of the IFU: "Ensure that no instruments or pieces of instruments are left in the surgical site prior to closure, as they may not be detectable using imaging techniques such as X-ray or MRI and patient injury may result."

2. From Page 5 of the IFU: "Visually inspect the instrument and check for damage and wear. Cutting edges should be free of nicks and have a continuous edge, jaws and teeth should align properly, moveable parts should have smooth movement, locking mechanisms should fasten securely; long, thin instruments should be free of bending and distortion."

Units Affected
Since May 2013, there have been 7,944 ATTUNE® INTUITION™ Impaction Handle (Part. no. 254401017) and 12,987 ATTUNE® INTUITION™ Impactors (Part. nos. 254401003, 254401004, and 254401006) distributed worldwide. This device correction does not affect any other instruments.

Depth of Field Safety Notice/device correction:
This device correction provides instructions for notifying Medical Professionals (surgeon users and hospitals /medical facilities) who may have used the affected ATTUNE® INTUITION™ Impaction Handle (Part. no.254401017) and Impactors (Part. nos. 254401003, 254401004, and 254401006). The purpose of this Field Safety Notice/device correction is to make users aware of the issues and actions to take.

Clinical Implications

ATTUNE® INTUITION™ Impaction Handle (Part. no.254401017): The possible clinical implications related to this issue may include:

- If the instrument fractures and debris is not removed from the patient, clinical implications may include:
  - Adverse tissue reaction if the broken piece of the instrument was not removed, the surrounding tissue may become irritated.
  - Surgical Delay: Intra-operative surgical delay of between 15 to 60 minutes may occur when attempting to retrieve the fragment(s).
  - Pain
- If the instrument fractures during surgery, clinical implications may include:
  - Minor Injury to User, if the spring releases out of the trigger area of the handle.

ATTUNE® INTUITION™ Impactors (Part. nos. 254401003, 254401004, and 254401006): The possible clinical implications related to this issue may include:

- If the instrument fractures and debris is not removed from the patient, clinical implications may include:
  - Poor Joint Mechanics
  - Adverse tissue reaction if the broken piece of the instrument was not removed, the surrounding tissue may become irritated.
  - 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™ Impaction Handle, ATTUNE® INTUITION™ Impactors

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™ Impaction Handle, ATTUNE® INTUITION™ Impactors 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 B:

This Letter acknowledges receipt of the Field Safety Notice related to ATTUNE® INTUITION™ Impaction Handle, ATTUNE® INTUITION™ Impactors

(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