**Urgent Field Safety Notice (Recall)**
**DePuy Synthes Specific Lots of SIGMA® High Performance (HP) MBT Non-Keel Punch Knee Instrument**

**Product Name:** SIGMA® High Performance (HP) MBT Non-Keel Punch Knee Instrument

**FSCA-identifier:** 103209819-QRB

**Type of Action**: Field Safety Corrective Action (Recall)

**Date:** January 2016

**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 in Orthopaedic Knee Joint Replacement.

**Model names:** SIGMA® High Performance (HP) MBT Non-Keel Punch Knee Instrument

DePuy Orthopaedics, Inc. is voluntarily recalling 10 lots of the SIGMA® High Performance (HP) MBT Non-Keel Punch Knee Instrument (see Figure 1). Please cease further distribution and use of the affected lots.

The affected instrument lots are being recalled due a design change that inadvertently increased the instrument's height. During the trialing process, this may cause the surgeon to select an insert that is too thin (See Figure 2).

**Affected Instruments:**

Part Number: See Attachment A
Lot Numbers: See Attachment A
Barcode / GTIN: See Attachment A

**Intended Use**
The HP MBT Non-Keel Punch is designed to be used as an option in stabilizing the tibial trial during trial reduction.


Figure 1: Image of SIGMA HP MBT Non-Keel Punch Knee Instrument

**Reason for Recall**

Through a complaint investigation, it was discovered that a design change to the instrument inadvertently increased the height of the punch. This change causes a gap of 0.063 inches (1.6 mm) between the trial and the affected instrument (see Figure 2). During the trialing process, this may cause the surgeon to select an insert that is too thin.

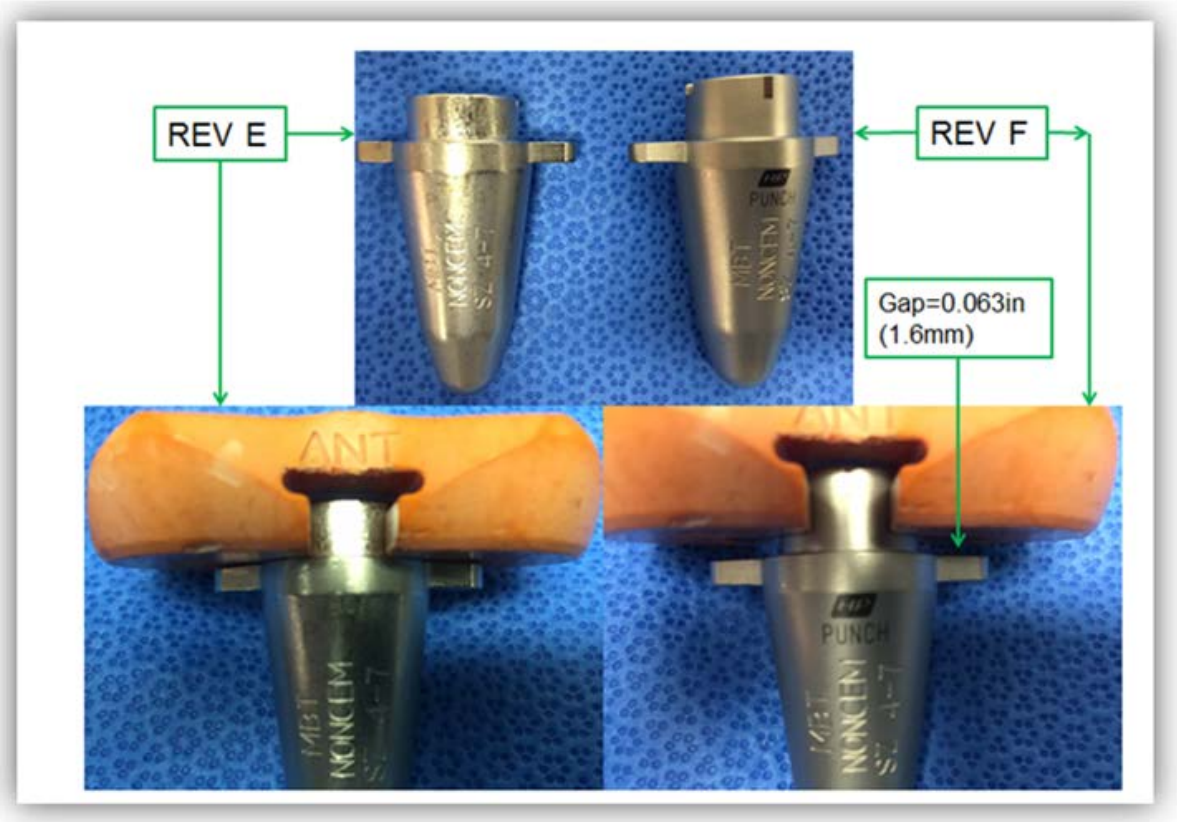


Figure 2: Image illustrating the connector height change created by the design change

**Alternative Instruments:**

Medical professionals may opt to use the following instruments, as outlined in the SIGMA® Classic Surgical Technique, cat. no. 0612-89-510:

- 950502022 HP MBT Spiked Evaluation Bullet Size 1-3
- 950502023 HP MBT Spiked Evaluation Bullet Size 4-7
- 950502099 MBT Evaluation Bullet Size 1-3
- 950502098 MBT Evaluation Bullet Size 4-7

**Units Affected**
Since August of 2013, approximately 351 affected instruments were distributed worldwide. This recall does not affect any other lots or instruments.

**Depth of Recall**
This recall notice provides instructions for notifying Medical Professionals who may have used the affected lots of the SIGMA® HP MBT Non-Keel Punch Knee Instrument. The purpose of this device recall is to remove affected instruments and to notify medical professionals of the possible effects of using the affected instrument.

**Clinical Implications**
If the affected lots of the SIGMA® HP MBT Non-Keel Punch Knee Instrument are used, the possible clinical implications are:

- If observed during surgery:
  - Significant surgical delay due to the punch becoming dislodged from the inserter and alternative instruments are needed to remove the punch from the joint space

- If not observed during surgery:
  - Dislocation or Spin Out of the Insert
  - Poor Joint Mechanics

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 if there is a bone fracture
5. Functional problems resulting from items 1 – 4 above
6. Anesthesia-associated risks

DePuy Orthopaedics, Inc. is not recommending prophylactic revision in the absence of symptoms in patients on whom these instruments may have been used. The company recommends that surgeon users discuss potential clinical implications and risks with symptomatic patients. Sharing this information will allow surgeons to discuss the issue and provide follow up recommendations.

**Steps to Take**
The purpose of this communication is to inform you of this recall and request acknowledgement of the notice. Please take the following actions:

- Please cease using the affected instruments immediately.
- Medical facilities are to determine if any of the recalled instruments are on hand, and return affected instruments immediately to their DePuy Synthes Sales Consultant or return them to DePuy Orthopaedics, Inc. for credit following normal procedures.
- Review this notice and complete the Acknowledgement section Attachment B to signify that your facility has been informed of this recall. Return the completed Acknowledgement to your DePuy Synthes Orthopaedics Sales Consultant within four (4) weeks of this notice.
- Retain a copy of the completed Acknowledgement Form in your files along with this notice.
- Notify surgeon users at your facility by providing them with a copy of this notice to ensure surgeon users are aware of this recall. These instruments may have been used with the MBT Tibial Tray Implants: part number 1294-31-110, 1294-31-115, 1294-31-120, 1294-31-125, 1294-31-130, 1294-31-140, 1294-31-150, 1294-31-160, and 1294-31-170.
- Forward this notice to others in your facility that need to be informed.
- If any affected product has been forwarded to another facility, contact that facility immediately to communicate this field action with the facility/facilities.
- Maintain a copy of this notice with the affected instruments.

**Transmission of this Field Safety Notice:**

This notice has been sent to you as records indicate that your organization/hospital has purchased the SIGMA® High Performance (HP) MBT Non-Keel Punch Knee Instrument.

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 to your DePuy Synthes representative.

For any enquiries about the SIGMA® High Performance (HP) MBT Non-Keel Punch Knee Instrument contact:

Bríd Horgan
Recall Associate
E-mail – *RA-DPYIE-VigilRecall@ITS.JNJ.com*
Tel no - +353 21 4914128

Notification of this FSN has been provided to the appropriate Regulatory Agency.

## Attachment A- Affected Lots of SIGMA® High Performance (HP) MBT Non-Keel Punch Knee Instrument

| Part Number | GTIN | Lot | Description |
|---|---|---|---|
| 950502016 | 10603295227366 | ABB92402 | SIGMA®HP MBT Cemented Punch size 1-1.5 |
| 950502016 | 10603295227366 | ABC95378 | SIGMA® HP MBT Cemented Punch SZ 1-1.5 |
| 950502017 | 10603295227373 | ABB84491 | SIGMA®HP MBT Cemented Punch size SZ 2-3 |
| 950502018 | 10603295227380 | ABB92358 | SIGMA® HP MBT Cemented Punch size SZ 4-7 |
| 950502020 | 10603295227403 | ABC33125 | SIGMA® HP MBT Noncemented Punch size 2-3 |
| 950502020 | 10603295227403 | ABB81733 | SIGMA® HP MBT Noncemented Punch size SZ 2-3 |
| 950502020 | 10603295227403 | ABB81732 | SIGMA® HP MBT Noncemented Punch size SZ 2-3 |
| 950502021 | 10603295227410 | ABB88807 | SIGMA®HP MBT Noncemented Punch size SZ 4-7 |
| 950502021 | 10603295227410 | ABB39952 | SIGMA® HP MBT Noncemented Punch size SZ 4-7 |
| 950502021 | 10603295227410 | ABC33123 | SIGMA® HP MBT Noncemented Punch size SZ 4-7 |

**ATTACHMENT B**

## This Letter acknowledges receipt of the Field Safety Notice related to SIGMA® High Performance (HP) MBT Non-Keel Punch Knee Instrument Product

**(Please check as appropriate)**

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

☐ Yes, I have received the FSN

☐ Yes, I have/will return the affected devices

Print Name: _____

_____
**Signature**

_____
**Hospital Name**

_____
**City**

_____
**Country**

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