DePuy Synthes
JOINT RECONSTRUCTION
COMPANIES OF Johnson & Johnson

## Urgent Field Safety Notice (Recall)

# SIGMA® HP PFJ Cemented Trochlear Implants (all lots)

*** No other SIGMA® HP Implants and no SIGMA® Total Knee System Implants are affected by this recall. ***

**Product Name:** **SIGMA® HP PFJ Cemented Trochlear Implants**

**FSCA-identifier:** **PIE 1029177**

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

**Date:** December 2017

**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:** SIGMA® HP PFJ Cemented Trochlear Implants for use in knee surgery

**Model Name:** SIGMA® HP PFJ Cemented Trochlear Implants.

DePuy Orthopaedics, Inc. is voluntarily recalling the SIGMA® HP PFJ Cemented Trochlear Implants, which is a standalone component of the partial knee system (see Figure 1). This decision is based on elevated revision rates observed as part of the company's post market surveillance process. Further distribution or use of the affected implants is to cease immediately, and the product is now discontinued. The company recommends that surgeons use alternative implants or consider a total knee replacement.

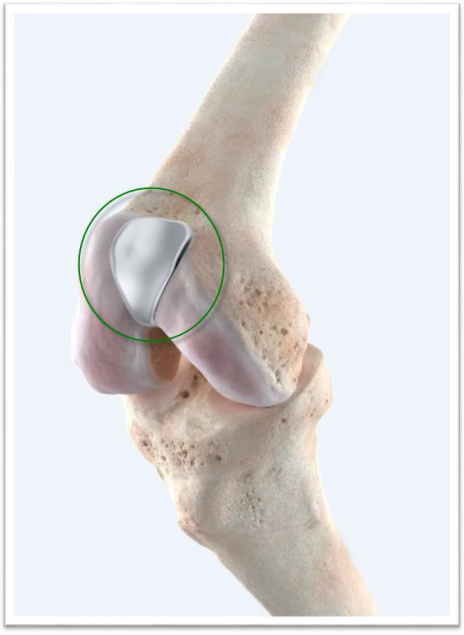

*Figure 1: Image of the recalled SIGMA® HP PFJ Cemented Trochlear Implants*

**Clinical Implications**

The possible clinical implications related to the affected SIGMA HP PFJ Cemented Trochlear Implants include poor joint mechanics (malalignment, instability, and/or dislocation/subluxation).

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

1. Infection
2. Additional or increased 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

**Patient Communications**
DePuy Orthopaedics, Inc. is not recommending prophylactic revision in the absence of symptoms. The company recommends that surgeons discuss potential clinical implications and risks with symptomatic patients who received the affected implants.

**Recalled Implants:**

| Catalog No. | Description | Lot No. | GTIN |
|---|---|---|---|
| 102403100 | SIGMA HP Cemented Trochlea Size 1 Narrow Left | All Lots | 10603295001614 |
| 102403200 | SIGMA HP Cemented Trochlea Size 2 Narrow Left | All Lots | 10603295001621 |
| 102403300 | SIGMA HP Cemented Trochlea Size 3 Narrow Left | All Lots | 10603295001638 |
| 102403400 | SIGMA HP Cemented Trochlea Size 4 Narrow Left | All Lots | 10603295001645 |
| 102403500 | SIGMA HP Cemented Trochlea Size 5 Narrow Left | All Lots | 10603295001652 |
| 102404100 | SIGMA HP Cemented Trochlea Size 1 Narrow Right | All Lots | 10603295001669 |
| 102404200 | SIGMA HP Cemented Trochlea Size 2 Narrow Right | All Lots | 10603295001676 |
| 102404300 | SIGMA HP Cemented Trochlea Size 3 Narrow Right | All Lots | 10603295001683 |
| 102404400 | SIGMA HP Cemented Trochlea Size 4 Narrow Right | All Lots | 10603295001690 |
| 102404500 | SIGMA HP Cemented Trochlea Size 5 Narrow Right | All Lots | 10603295001706 |

**Intended Use**
The SIGMA HP PFJ Cemented Trochlear Implants are designed to be used individually to address isolated patellofemoral degeneration or in conjunction with the SIGMA® HP Femoral Unicondylar implant for the treatment of various degenerative knee conditions.

**Units Affected**
Since 2006, there have been approximately 7500 affected devices sold worldwide. **This recall does not affect any other SIGMA® HP implants or any of the SIGMA® Total Knee System Implants.**

**Depth of Recall**
This device recall provides instructions for notifying medical facilities that may have used, purchased, or received the affected lots of the SIGMA HP PFJ Cemented Trochlear Implants. The purpose of this device recall is to remove the affected devices and to notify medical professionals of the possible effects of using the affected device.

**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 components immediately.
- Medical facilities are to determine if any of the recalled components are still on hand, and return affected components immediately to their Sales Consultant for credit following normal procedures.

- Review this notice and complete the Acknowledgement section (Attachment A) to signify that your facility has been informed of this recall. Return the completed Acknowledgement to your Sales Consultant within one (1) week of this notice.
- Retain a copy of the completed Acknowledgement Form in your files along with this notice.
- 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.
- Notify surgeons at your facility by providing them with a copy of this notice to ensure surgeons are aware of this recall notice.
- Maintain a copy of this notice with the affected devices.

**Transmission of this Field Safety Notice:**
This notice has been sent to you as records indicate that your organisation/hospital has purchased the affected product codes of the SIGMA® HP PFJ Cemented Trochlear Implants.

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 A to your DePuy Synthes representative.

For any enquiries about the SIGMA® HP PFJ Cemented Trochlear Implants FSN 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.

Sincerely,

John Wright, MD
Franchise Medical Leader - JMP
WW Vice-President, Medical Affairs

# ATTACHMENT A

**This Letter acknowledges receipt of the Field Safety Notice related to SIGMA® HP PFJ Cemented Trochlear Implants Recall FSCA-identifier: PIE 1029177**

**(Please check as appropriate)**

☐ Yes, I have received the FSN

☐ Yes, I have/will return the affected devices

Please fax or e-mail this completed document to
Johnson & Johnson AB,
att. Complaint team
Nordic, Box 4014, 169 04
Solna. E-mail: RA-ITSUS-JJMSweden@its.jnj.com
Fax: 08-6262230

Please list the Lot numbers and Quantities of affected devices to be returned:

_____

Print Name: _____

_____
**Signature**

_____
**Hospital Name**

_____
**City**

_____
**Country**

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