Urgent Field Safety Notice (Recall)
DePuy Synthes Specific Lots of the Specialist 2 Intramedullary (SP2 IM) Rod 400mm Instrument (PN 96-6120)

Product Name: Specialist 2 Intramedullary (SP2 IM) Rod 400mm Instrument

FSCA-identifier: DVA-107305-HHE

Type of Action: Field Safety Corrective Action (Recall)

Date: September 2015

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: Specialist 2 Intramedullary (SP2 IM) Rod 400mm Instrument (PN 96-6120)

DePuy Orthopaedics, Inc. is issuing a voluntary recall for specific lots of the Specialist 2 Intramedullary (SP 2 IM) Rod 400mm Instrument (PN 96-6120) – See Figure 1. Further distribution or use of affected lots of these instruments is to cease immediately. This action involves two alloy mixes associated with the same rod. Specifically, it has been determined that there is potential for SP2 IM Rod 400mm Instruments (96-6120) manufactured with 455 stainless steel (SS) or 17-4 SS to fracture and leave a portion of the rods in patients (see Figures 1 and 2). The "Actions to Take" section of this notice provides return and replacement directions. Please review the "Instrument Options" section for alternatives to the SP2 IM Rod 400mm Instrument (96-6120).

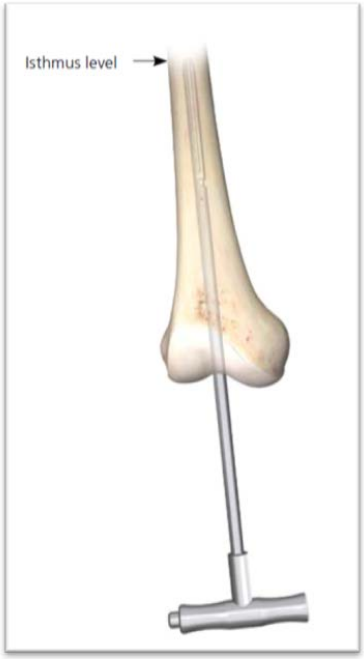

Figure 1: Image of SP2 IM Rod (PN 96-6120)

Affected SP2 IM Rod 400mm Instruments:

Part Number (PN): 96-6120
Lot Numbers: See Attachment A
Barcode / GTIN: 10603295246893

Intended Use:

The SP2 IM Rod 400mm Instrument (PN 96-6120) is used in both primary and revision P.F.C.® SIGMA® knee procedures to align the femoral locating device and distal femoral cutting block. Also, it is used with the IM tibial resection. This rod is included with the P.F.C.® SIGMA® Specialist® 2 (SP2 / SPII) Primary Knee Instruments, the P.F.C.® SIGMA® Specialist® 2 (SP2 / SPII) Revision Knee Instruments, and P.F.C.® SIGMA® High Performance (HP) Primary Knee Instruments.

Reason for Recall

For the affect lots, complaints have been received which state that the rod fractured and a portion of the rod was left in the patient (see Figure 2). All of the complaints involved the SP2 IM Rod 400mm Instrument (PN 96-6120) made with 455 SS alloy. The company has identified the potential for the SP2 IM Rod 400mm Instrument (PN 96-6120) made with 455 SS alloy to fail due to fatigue and/or overload when excess leverage is applied to the SP2 IM Rod 400mm Instrument (PN 96-6120). There is a deep J-shaped groove at the tip of the rod, which allows a sleeve to lock into place when used in revision cases. It is within this groove that fracture can occur.

Figure 2: Image of SP2 IM Rod highlighting area of potential fracture / Image of SP2 IM Rod fragment in a radiograph

The SP2 IM Rod 400mm Instruments (PN 96-6120) made from 17-4 SS, distributed between May 1995 and February 2001, are being included in this recall notice to retrieve any instruments remaining in the market. The company has received no complaints of SP2 IM Rod 400mm Instruments (PN 96-6120), made from 450 SS, fracturing and leaving a portion of the rod in the patient, and these lots are not being recalled.

Timeline for Materials Used in the SP2 IM Rod 400mm Instrument (PN 96-6120)	
Dates Manufactured	**Materials**
April 4, 1995 to June 22, 2001	17-4 SS: Recalled
2002 to 2008	450 SS: Not Recalled
August 27, 2008 to October 2, 2012	455 SS: Recalled
2013 to Current	450 SS: Not Recalled

Instrument Options

DePuy is committed to providing you with swap-out instruments as soon as possible to minimize any surgical disruption. In the meantime, medical professionals may opt to use other sizes of the SP2 IM Rods:

- 200mm SP2 IM ROD (PN 96-6122)
- 300mm SP2 IM ROD (PN 96-6121)

These instruments fit into the following instrument kits:

- Kit # 96-6550: Base Femoral Instruments
- Kit # 96-6583: SP2 TB REV and WED TRLS ST TRAY
- Kit # 96-6584: Specialist 2 IM ROD and Sleeve Sterilization Tray
- Kit # 2178-64-100: MBT Revision Preparation Case
- Kit # 9505-02-800: SIGMA HP Base Femur and Tibia
- Kit # 9505-02-823 SIGMA HP Quick Base Case

Units Affected

Approximately 445 SP2 IM Rod 400mm Instruments (PN 96-6120) from the affected lots have been distributed outside the U.S. and are involved in this recall.

Depth of Recall

This instrument recall provides instructions for notifying medical professionals that may have purchased the affected instruments. The purpose of this instrument recall is to remove affected instruments and provide direction for replacing affected instruments.

Clinical Implications

If the affected SP2 IM Rod 400mm Instrument (PN 96-6120) fractures during surgery and a portion of the rod is left in the patient, the possible clinical implications are:

- If observed during surgery:
    - Significant surgical delay due to attempted retrieval of remaining rod
    - Minor bone damage due to attempted retrieval of remaining rod

- If not observed during surgery:
    - Adverse tissue reaction may occur because the fractured rod, if not removed from within the bone, can act as a stress riser causing remodeling of bone and inflammation
    - Pain due to potential bone remodeling or during Magnetic Resonance Imaging (MRI)

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. If a surgeon performed a procedure with an affected instrument and experienced a fractured instrument, 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 instrument removal and request acknowledgement of the notice. Please take the following actions:

- Cease using the affected lots of the SP2 IM Rod 400mm Instruments (PN 96-6120) 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.
- Kits containing SP2 IM Rod 400mm Instruments (PN 96-6120) include:
    - PFC SIGMA SP2 Primary Instrument Sets

- SIGMA HP Primary Instrument Sets
- PFC Sigma TC3 Revision Instrument Sets

- Replacement SP2 IM Rod 400mm Instruments (PN 96-6120) will be provided. In the interim, please reference the section titled, "Instrument Options," in this notice for alternatives to the SP2 IM Rod 400mm Instrument (PN 96-6120).
- Review this notice and complete the Acknowledgement section Attachment B to signify that your facility has been informed of this device correction. 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.
- 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 instrument recall with the facility/facilities.
- Notify surgeon users at your facility by providing them with a copy of this notice to ensure surgeon users are aware of this instrument recall.

Transmission of this Field Safety Notice:

This notice has been sent to you as records indicate that your organization/hospital has purchased the Specialist 2 Intramedullary (SP2 IM) Rod 400mm Instrument (PN 96-6120).

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 Specialist 2 Intramedullary (SP2 IM) Rod 400mm Instrument (PN 96-6120) 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.

Yours sincerely,

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

Attachment A: Affected Etch Lots of the SP2 IM Rod 400mm Instrument (PN 96-6120)*

Etch Lot Number
H0808
H0908
H1008
H1108
H1208
H0109
H0209
H0309
H0409
H0509
H0210
H0310
H0410
H0510
H0610
H0710
H0810
H0910
H0211
H0311
H0611
TBACC
TBACZ
TBAGG
TBCOJ
H01-01
H0530
H02-01

Etch Lot Number
H03-01
H04-01
H05-01
H06-01
H07-01
H08-01
H09-01
H10-01
H11-01
H01-00
H02-00
H03-00
H04-00
H05-00
H06-00
H07-00
H08-00
H09-00
H10-00
H11-00
H12-00
H01-99
H02-99
H03-99
H04-99
H05-99
H06-99
H0302

Etch Lot Number
H07-99
H08-99
H09-99
H10-99
H11-99
H12-99
H01-98
H02-98
H03-98
H04-98
H05-98
H06-98
H07-98
H08-98
H09-98
H10-98
H11-98
H12-98
H01-97
H02-97
H03-97
H04-97
H05-97
H06-97
H07-97
H08-97
H09-97
H1101

Etch Lot Number
H10-97
H11-97
H12-97
H01-96
H02-96
H03-96
H04-96
H05-96
H06-96
H07-96
H08-96
H09-96
H10-96
H11-96
H12-96
H01-95
H02-95
H03-95
H04-95
H05-95
H06-95
H07-95
H08-95
H09-95
H10-95
H11-95
H12-95

*** In addition to the lots above, return any devices with the lot number for SP2 IM Rod 400mm Instrument (PN 96-6120) located at the distal end of the instrument (see Figure 3).**

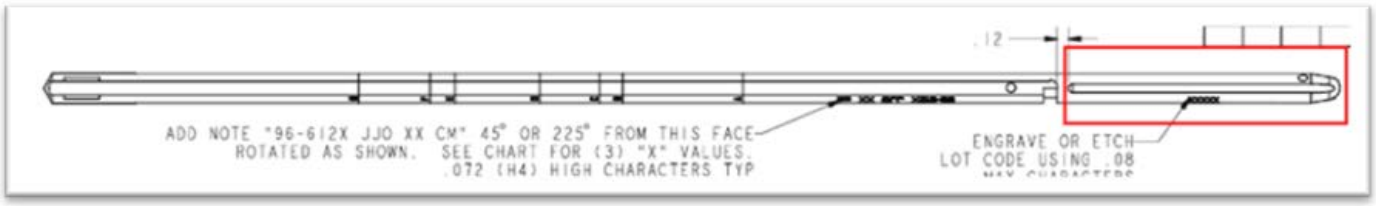

Figure 3: Drawing of SP2 IM Rod highlighting location of 17-4 SS lot etch

ATTACHMENT B

This Letter acknowledges receipt of the Field Safety Notice related to Specialist 2 Intramedullary (SP2 IM) Rod 400mm Instrument Product

(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 [INSERT DePuy Marketing Company/Affiliate contact details]

Print Name: _____

_____
Signature

_____
Hospital Name

_____
City

_____
Country

_____
Telephone Number or e-mail address