Urgent Field Safety Notice (FSN)

Product Name: DePuy Specialist 2 Intramedullary Rod (SP2 IM Rod)

FSCA-identifier: DVA-107305-HHE

Type of Action: Field Safety Notice

Date: Feb 2013

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: Orthopaedic Knee Instrument

Model names: DePuy Specialist 2 Intramedullary Rod (SP2 IM Rod)

Part Number: 966120

Batch / lot number of affected devices: See Attachment A.

DePuy Orthopaedics, Inc. is issuing a Field Safety Notice (FSN) for specific lots of the Specialist 2 (SP2) Intramedullary (IM) Rod due to the potential for the rod to break, leaving fragments in the patient.

The SP2 IM Rod is used in both primary and revision Sigma knee procedures to align the femoral locating device and distal femoral cutting block. It can also be used with the IM tibial resection.

The SP2 IM rods are not being removed from the market. The purpose of this Field Safety Notice is to provide additional information on how to use the SP2 IM rods to minimize the potential for breakage.

Background: DePuy has identified the potential for the SP2 IM Rod to fail due to fatigue when excess leverage is applied at the tip. 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 (see picture Appendix B). It is at the top of this groove that fracture can occur. DePuy has received 9 complaints since 2008 regarding the tip breaking with 8 complaints where the tip was left in the patient.

DePuy is currently investigating a material change to the rod to reduce the possibility of the tip fracturing. Changes have/will be made to the Surgical Techniques to include the guidance below.

DePuy would like to emphasize several technical points regarding the use of the rod that may further reduce the incidence of tip fracture:

1. Avoid using excessive force to drive the rod into the IM canal. If a large amount of force is required to insert the rod, the femoral canal may be overly bowed, or the distal entry hole may be too tight to permit the rod to center in the canal. Should this be encountered, using a shorter IM rod may be more appropriate. Enlarging the distal entry hole may help as well.

2. The rod tip is much stronger when the sleeve slot is in compression. This can be achieved by making sure the slot on the modular handle (the landmark for locking the rod to the handle) is facing medially when the rod is inserted on a right knee, or laterally on a left knee.

3. Do not use the rod as a slap hammer to remove a well-fixed SP2 distal femoral locating device. This can lead to high stress concentrations in the rod tip. If set pins are well-fixed to the distal femur, use a ronjeur to release the set pins.

4. The rod should not be used as a femoral distractor to pull the femur away from the tibia. In lieu, use a bone hook or use a U-shaped retractor.

5. Check the condition of the rod on a regular basis. Return any rods showing signs of cracks in the distal tip near the sleeve groove.

Clinical Implications:

In remote circumstances, the possible clinical implications related to the SP2 IM Rods fracturing with tips left in the patient include:

- Significant Surgical Delay due to attempted retrieval of remaining fragments
- Minor bone damage due to attempted retrieval of remaining fragments
- Adverse Tissue Reaction
- Pain due to potential bone remodeling or during Magnetic Resonance Imaging (MRI)

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 Rod (SP2 IM Rod)

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.

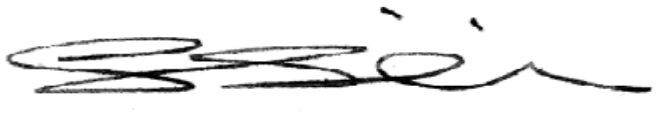
To confirm receipt of this FSN please complete and return the acknowledgement in Appendix C.

For any enquiries about the Specialist 2 Intramedullary Rod (SP2 IM Rod) 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
WW VP Medical Affairs

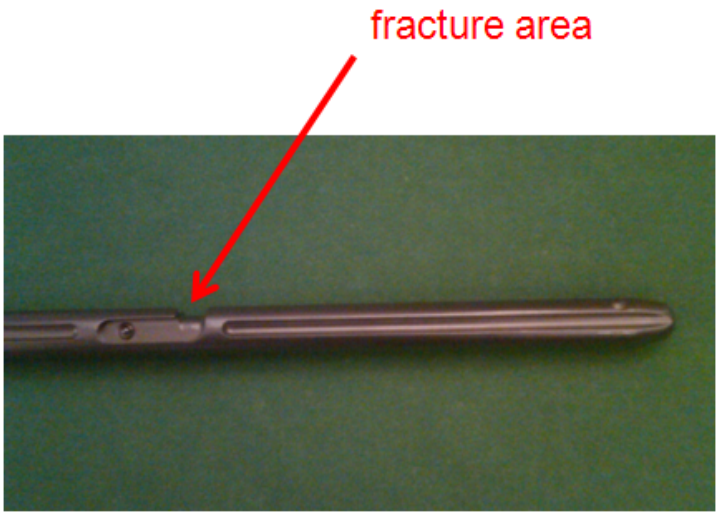
Attachment A: Affected Lot Numbers

Part Number: 966120

Label Lot Number	Etch Lot Number (Manufacturing Lot)
C3JHN4	H0808
C3JHS4	H0908
C3JHF4	H1008
C4GA54	
C4GCC4	
C4GBT4	
C52F74	H1108
C52GV4	H1208
C52GL4	
C67N14	
C98CS4	H0109
C98BF4	
DE5P34	H0309
DE5RP4	
DF4H44	
DG9LK4	H0409
DG9L64	
DJ5E34	
DK3E34	H0509
DK3FE4	
EB5FV4	H0210
D95AN4	
EB5GH4	H0310
EC9JY4	
EF4DJ4	
EJ7AP4	H0410
ES2G64	H0510
EJ7A34	
ES2HA4	H0610
ES2HY4	H0710
EX5L44	
EX5MS4	H0810
E2SD44	H0910
FA4G94	H0211

Label Lot Number	Etch Lot Number (Manufacturing Lot)
FD8MP4	H0311
FH8JA4	
FH8JX4	H0611
TBACC	TBACC
TBACZ	TBACZ
FJ4E74	TBAGG

Attachment B: Photograph of SP2 IM Rod and potential fracture area



Appendix C:

This Letter acknowledges receipt of the Field Safety Notice [ref. DVA-107305-HHE] dated [INSERT DATE] issued by DePuy Orthopaedics.

(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