Urgent Field Safety Notice (FSN)

Product Name: DePuy S-ROM Noiles Rotating Hinge Femur with Pin

Type of Action: Field Safety Notice

Date: July 2014

Attention: Orthopaedic Surgeons who use S-ROM Noiles Rotating Hinge Femur with Pin

Model names: S-ROM Noiles Rotating Hinge Femur with Pin

Model number:

Product Codes	Description
623401L	S-ROM Noiles Rotating Hinge Femur with Pin, medium, left
623401R	S-ROM Noiles Rotating Hinge Femur with Pin, medium, right
623411L	S-ROM Noiles Rotating Hinge Femur with Pin, small, left
623411R	S-ROM Noiles Rotating Hinge Femur with Pin, small, right
623421L	S-ROM Noiles Rotating Hinge Femur with Pin, X-small, left
623421R	S-ROM Noiles Rotating Hinge Femur with Pin, X-small, right

Batch / lot number of affected devices: All lots

On March 10, 2014, DePuy Orthopaedics, Inc. issued a Field Safety Notice for the S-ROM® Noiles Rotating Hinge Femur with Pin devices because the company identified the potential for holes to develop in the inner and outer flexible pouches that form the sterile barrier for both the femur and the hinge pin. The new packaging design is complete.

New Packaging

The femur and pin components are placed within a protective retainer and then sealed in an inner and outer rigid sterile barrier system (Figure 1). The sterile barrier system is placed within a carton designed to provide additional protection along with IFU. The finished sterile barrier system is then labeled and shrink wrapped.

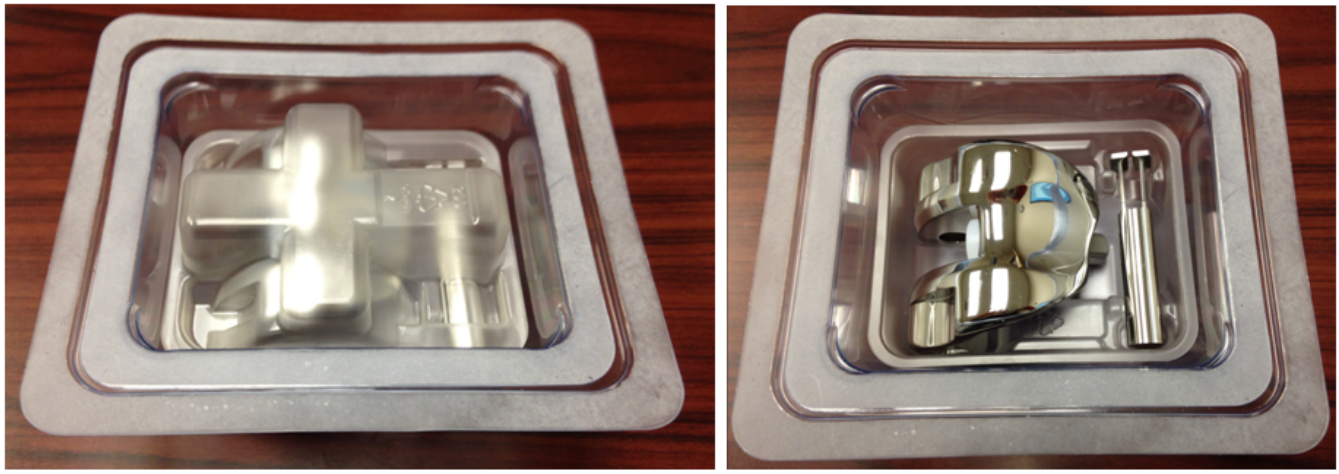

Figure 1: Images of New Packaging Components

Summary of March 10, 2014 Notice

On March 10, 2014, DePuy Orthopaedics, Inc. issued a Field Safety Notice for the S-ROM® Noiles Rotating Hinge Femur with Pin devices (Figure 2) because the company identified the potential for holes to develop in the inner and outer flexible pouches that form the sterile barrier for both the femur and the hinge pin. The outer carton and shrink wrap are intact. Until new packaging was designed and validated, S-ROM Noiles Rotating Hinge Femur with Pin devices without packaging breaches were available to avoid temporarily causing a sudden and complete lack of product availability and the bone loss associated with removing a well-fixed MBT Revision Tibial Tray.

Figure 2: S-ROM® Noiles Rotating Hinge Femur with Pin

Intended Use:

The S-ROM Hinge Knee with Pin is used in revision surgeries when there is significant bone loss or ligament instability.

Reason for Field Safety Corrective Action:

From 1999 through 2013, the company received 45 reports of holes in one or both sterile pouches. The complaint rate for 2010 through 2013 is 0.35%.

Please undertake the following urgent actions:

- Quarantine any affected inventory (by part and lot number) in your distribution warehouse and inventory management systems. Do not use this product.
- Reconcile all recalled returned inventory from hospital's and distribution centers.

Clinical Implications
The S-ROM femur is compatible only with the MBT revision tibial tray. If the S-ROM device were not available when needed, a surgeon would be obligated to use a different hinge knee system, which would require the removal, if present, of the MBT revision tray. If the tray is well fixed, it would cause the potential destruction of good tibial bone during the removal process. Alternatively, the surgeon could use an LPS femoral component. This would require the removal of a larger amount of the femoral bone as compared to what is required for S-ROM hinge femur.

The possible clinical implications related to this issue may include:

- If observed during surgery, the possible clinical implication related to the breaches may include:
  - Surgical Delay: Intra-operative surgical delay of between 15 to 60 minutes may occur when attempting to locate an alternate device or for re-sterilization.

- If not observed during surgery, the possible clinical implication related to the breaches may include:
  - Infection: This would cause the need for medical or surgical intervention should it occur.

The clinical implications above may potentially require additional surgery and/or further revision surgery. The 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

Please provide the attached form in the FSN to Orthopaedic Theatre Managers and surgeons who are users of S-ROM Noiles Rotating Hinge Femur with Pin. This form needs to be completed and returned to Alan O'Sullivan - Recall Coordinator, e-mail: aosulliv@its.jnj.com, Phone +353 21 4914149

Alan O' Sullivan (DePuy)
Recall Coordinator
e-mail – aosulliv@its.jnj.com
Tel no - +353 21 4914149

This FSN has been notified to the appropriate Regulatory Agency.

[redacted]

[redacted]
WW VP Medical Affairs

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

We have checked our current inventory:

(Please check as appropriate)

☐ Yes I have received the FSN

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

Print Name: _____

_____

Signature

_____

Hospital Name

_____

Country

_____

City,

_____

Telephone Number or e-mail address