Urgent Field Safety Notice (FSN)

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

Type of Action: Field Safety Notice

Date: March 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

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

Background:
The company has 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.

The purpose of this communication is to create awareness of potential packaging issues and indicate actions required by the hospital, surgeon and OR staff.

S-ROM Noiles Rotating Hinge Femur with Pin devices without packaging breaches may continue to be used 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 1: S-ROM® Noiles Rotating Hinge Femur with Pin

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.

A package redesign is underway to resolve this issue. Pre-implantation inspection of the implant's packaging will allow the surgeon to determine whether there are any breaches in the packaging of individual S-ROM Noiles Rotating Hinge Femur with Pin devices. Implants with intact packaging may be used as intended.

Please undertake the following actions:

The affected components may be used until packaging has been redesigned and affected devices are swapped out under the following conditions:

- For all revision cases in which affected devices may be used the DePuy Account manager/sales representative should be contacted and the OR staff/surgeon must be made aware of this potential issue.
- Additional implants are available prior to surgery
- Affected device packaging is inspected prior to implantation.
- All departments and colleagues within your organisation, or to organisations that you have transferred the device to, who are impacted by this Field Safety Corrective Action notification are made aware of this action.

Reason for Field Safety Corrective Action:

From 1999 through 2013, DePuy received 45 reports of holes in one or both sterile pouches (Figure 2). The complaint rate for 2010 through 2013 is 0.35%. It is believed that these holes result from repeated shipments of the product over a number of years.

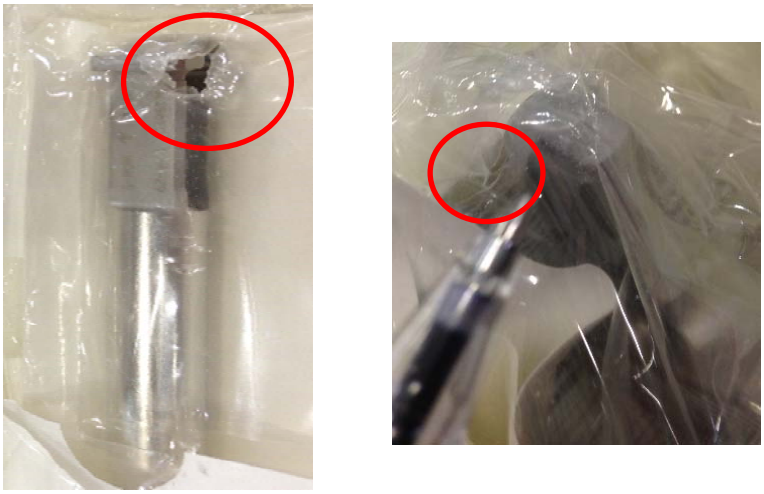


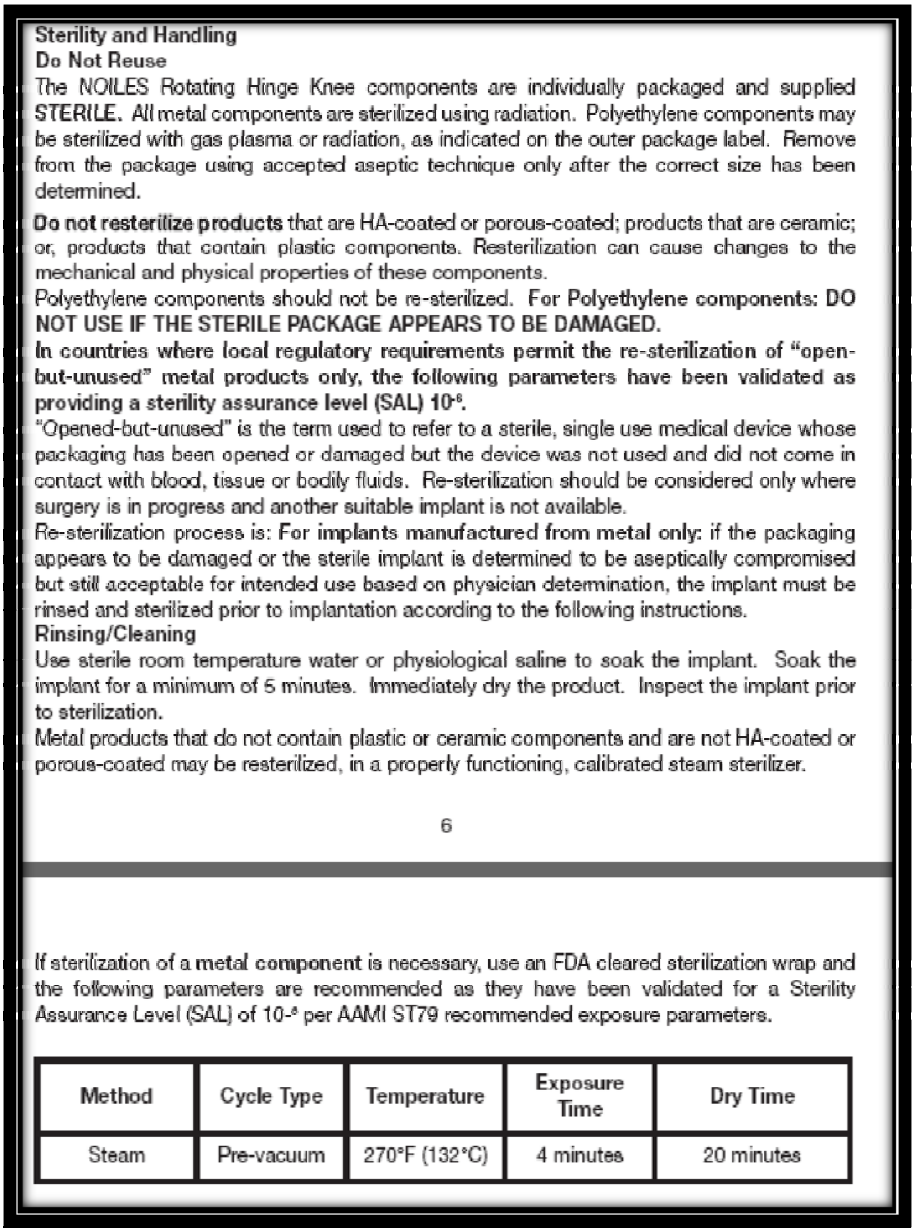
Figure 2: S-ROM® Noiles Rotating Hinge Femur with Breaches/holes in Inner and Outer Pouches

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

Packaging
The product is packaged with separate inner and outer flexible Tyvek/PET/LDPE pouches. The pin and femoral component are packaged separately in an individual set of pouches. Both individually packaged components (pin and femoral) are placed in a two piece carton that is lined with foam. The IFU is placed on top of the product, covered with foam component, and the top half of the carton. The carton is labeled and shrink wrapped.

Immediate Inventory Management Actions

1. **Inventory**:
    a. Once a final redesign of the packaging is available, a formal swap-out of the current devices will be completed/
2. **Use of Current Products**:
    a. The Instructions for Use (IFU) (refer to IFU 0902-00-787 Current revision D) address intra-operative re-sterilization of implants manufactured from metal only. The femoral component contains a polyethylene subcomponent. Therefore, if holes are discovered in the package containing the femoral component during the pre-implantation inspection, the device cannot be used. If holes are detected in the package containing the pin, which is all metal, the pin can be re-sterilized intra-operatively in accordance with the instructions in the IFU. Below is verbiage from the IFU pertaining to re-sterilization (Figure 3):



Sterility and Handling

Do Not Reuse

The NOILES Rotating Hinge Knee components are individually packaged and supplied **STERILE.** All metal components are sterilized using radiation. Polyethylene components may be sterilized with gas plasma or radiation, as indicated on the outer package label. Remove from the package using accepted aseptic technique only after the correct size has been determined.

Do not resterilize products that are HA-coated or porous-coated; products that are ceramic; or, products that contain plastic components. Resterilization can cause changes to the mechanical and physical properties of these components.

Polyethylene components should not be re-sterilized. **For Polyethylene components: DO NOT USE IF THE STERILE PACKAGE APPEARS TO BE DAMAGED.**

In countries where local regulatory requirements permit the re-sterilization of "open-but-unused" metal products only, the following parameters have been validated as providing a sterility assurance level (SAL) 10^{-6}.

"Opened-but-unused" is the term used to refer to a sterile, single use medical device whose packaging has been opened or damaged but the device was not used and did not come in contact with blood, tissue or bodily fluids. Re-sterilization should be considered only where surgery is in progress and another suitable implant is not available.

Re-sterilization process is: **For implants manufactured from metal only:** if the packaging appears to be damaged or the sterile implant is determined to be aseptically compromised but still acceptable for intended use based on physician determination, the implant must be rinsed and sterilized prior to implantation according to the following instructions.

Rinsing/Cleaning

Use sterile room temperature water or physiological saline to soak the implant. Soak the implant for a minimum of 5 minutes. Immediately dry the product. Inspect the implant prior to sterilization.

Metal products that do not contain plastic or ceramic components and are not HA-coated or porous-coated may be resterilized, in a properly functioning, calibrated steam sterilizer.

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If sterilization of a **metal component** is necessary, use an FDA cleared sterilization wrap and the following parameters are recommended as they have been validated for a Sterility Assurance Level (SAL) of 10^{-6} per AAMI ST79 recommended exposure parameters.

Method	Cycle Type	Temperature	Exposure Time	Dry Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes	20 minutes

Figure 3: Instructions for Use (IFU) (refer to IFU 0902-00-787 Current revision D)

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.

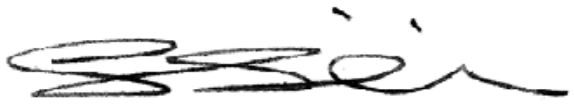
The clinical implications above may potentially require additional surgery and/or further revision surgery. The following are general examples of possible risks/hazards of revision surgery:

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.



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Simon Sinclair. PhD MB BChir
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