Urgent Field Safety Notice (FSN)

Product Name: RECLAIM® Taper Sleeve Protector Instrument

Type of Action: Field Safety Notice

Date: June 2014

Attention: Orthopaedic Surgeons who use the RECLAIM® Taper Protector Instrument

Model names: RECLAIM® Taper Protector Instrument

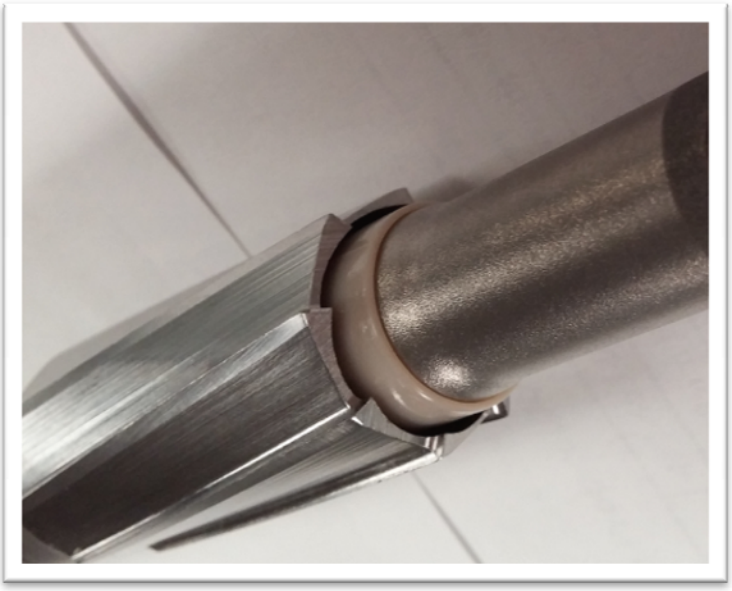
Background:
DePuy Orthopaedics, Inc. is issuing a Field Safety Corrective Action and Field Safety Notice on all lots of the RECLAIM® Taper Sleeve Protector instrument because the product can be difficult to remove from the distal stem both before surgery and after proximal reaming. The immediate remedy is for all users to discard the affected taper sleeve protector prior to stem implantation.

Photograph of RECLAIM® Taper Sleeve Protector Instrument shown on RECLAIM® Distal Stem

The Affected Single-Use Instrument is sold separately or assembled to the RECLAIM Stem:

Product Codes: See Attachment A
Lot Numbers: All Lots

Intended Use:
The RECLAIM® Taper Sleeve Protector is a single-use instrument which may either be sold separately or assembled to the taper of the RECLAIM® Distal Stem .The taper sleeve protector is intended to ensure the locking taper surface of the distal stem is protected during proximal preparation. The taper sleeve protector remains on the distal stem locking taper until the proximal body is ready to be inserted over the distal stem implant.



Reason for Field Safety Corrective Action:
There have been reports that the RECLAIM® Taper Sleeve Protector instrument can be difficult to remove from the distal stem both before surgery and after proximal reaming, and there is a risk the sleeve may fracture. Additionally, there are reports that the taper sleeve protector is being removed prior to implantation of the distal stem, which does not reflect instructions provided in the Surgical Technique. As a corrective measure, a change will be implemented to remove the taper sleeve protector.

Evaluation of the RECLAIM® Taper Sleeve Protector
Because potential patient harms related to the difficulty in removing the taper sleeve protector were identified, DePuy Orthopaedics, Inc. evaluated the impact of removing the taper sleeve protector from the distal stem before use. To verify removal of the taper sleeve protector would not adversely impact the surgery, the company conducted a tolerance analysis. The tolerance analysis showed that if the taper sleeve protector is not used, there is still sufficient clearance between the distal stem taper and proximal reamer to ensure the reamer will not contact the stem taper. In addition, validation testing confirmed that the taper sleeve protector is not needed to protect the taper from residual bone present between the proximal reamer

and stem taper while reaming. Testing also confirmed that even with the guide post positioned on the distal stem in a worst case condition, the proximal reamer did not contact the distal stem taper.

The company also consulted with design surgeons and developed a strategy to eliminate the taper sleeve protector from the system going forward. As a result of removing the taper sleeve protector, the company is evaluating whether there is a need for a protective component to be used during the distribution process.

As a result of the above evaluation, the company is providing the following Field Safety Corrective Action /Information on the Use of the RECLAIM® Taper Sleeve Protector Instrument on the RECLAIM® Stem:

1. **Immediate Remedy:** Discard the RECLAIM® Taper Sleeve Protector instrument before stem implantation.

2. **Changes to the literature:** Documents are revised as follows:
   - RECLAIM® Revision Hip System's Surgical Technique # DSUS/JRC/0614/0200 – pages 11, 12, 13, 16, 30, 34, 35 (figure numbering from pages 11 to 27 were also revised): Removed information regarding taper sleeve protector.

3. **Change:** The company consulted with design surgeons and developed a strategy to eliminate the taper sleeve protector from the system. As a result of removing the taper sleeve protector, the company is evaluating whether there is a need for a protective component to be used during the distribution process.

Units Affected
From May 2011 through May 2014, 17,581 affected tapered sleeve protector instruments were manufactured. This Field Safety Corrective Action does not affect any other RECLAIM® components.

Depth of Device Correction
This impacts hospitals/user facilities currently using the RECLAIM® Taper Sleeve Protector instrument which may either be sold separately or assembled to the taper of the RECLAIM® Distal Stem. Neither the RECLAIM® Taper Sleeve Protector instrument nor RECLAIM® stem are being removed from the market.

The purpose of this notification is to inform hospitals/user facilities to discard the RECLAIM® Taper Sleeve Protector instrument before surgery, to notify hospitals/user facilities of changes

to literature and IFU, and to notify hospitals/user facilities of the company's decision to eliminate the taper sleeve protector from the system.

Clinical Implications
Potential clinical implications for patients who may have had surgery with a RECLAIM® Taper Sleeve Protector instrument may include:

If observed during surgery, the possible clinical implications related to the RECLAIM® Taper Sleeve Protector instrument being difficult to remove from the distal stem both before surgery and after proximal reaming:

1. Surgical Delay: Intra-operative surgical delay of between 15 to 60 minutes may occur when attempting to retrieve the pieces if the sleeve fractures during attempted removal of the sleeve from the stem or if the sleeve is difficult to remove.
2. Bone Fracture: If the protective sleeve cannot be removed and stem removal is required, bone fracture may occur during surgery that requires surgical preparation or implant insertion due to inadequate instruments or inappropriate implant sizing and geometry.

After surgery, if there is a fracture and not all of the pieces are removed, the possible clinical implications related to the matter may include:

1. Poor mechanics and/or loss of function if the sleeve fractures and piece(s) cannot be found or removed.
2. Adverse tissue reaction if the sleeve fractures and piece(s) cannot be found or removed.
3. Pain if the sleeve fractures and piece(s) cannot be found or removed.

The implications indicated above could 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
5. Functional problems resulting from items 1 – 4 above
6. Anesthesia-associated risks

DePuy Orthopaedics, Inc. is not recommending prophylactic revision or additional follow up in the absence of symptoms.

Transmission of this Field Safety Notice:

This notice has been sent to you as records indicate that your organisation/hospital has purchased the RECLAIM® Taper Sleeve Protector instrument

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.

For any enquiries about the RECLAIM® Taper Sleeve Protector instrument:

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.

WW VP Medical Affairs

Attachment A

Part Numbers

Part Number	Brand Name
197614140	RECLAIM DISTAL TAPERED 14X140
197614190	RECLAIM DISTAL TAPERED 14X190
197615140	RECLAIM DISTAL TAPERED 15X140
197615190	RECLAIM DISTAL TAPERED 15X190
197616140	RECLAIM DISTAL TAPERED 16X140
197616190	RECLAIM DISTAL TAPERED 16X190
197617140	RECLAIM DISTAL TAPERED 17X140
197617190	RECLAIM DISTAL TAPERED 17X190
197618140	RECLAIM DISTAL TAPERED 18X140
197618190	RECLAIM DISTAL TAPERED 18X190
197619140	RECLAIM DISTAL TAPERED 19X140
197619190	RECLAIM DISTAL TAPERED 19X190
197620140	RECLAIM DISTAL TAPERED 20X140
197620190	RECLAIM DISTAL TAPERED 20X190
197621140	RECLAIM DISTAL TAPERED 21X140

Part Number	Brand Name
197621190	RECLAIM DISTAL TAPERED 21X190
197714190	RECLAIM DISTAL TAPERED 14X190A
197715190	RECLAIM DISTAL TAPERED 15X190A
197716190	RECLAIM DISTAL TAPERED 16X190A
197716240	RECLAIM DISTAL TAPERED 16X240A
197717190	RECLAIM DISTAL TAPERED 17X190A
197717240	RECLAIM DISTAL TAPERED 17X240A
197718190	RECLAIM DISTAL TAPERED 18X190A
197718240	RECLAIM DISTAL TAPERED 18X240A
197718290	RECLAIM DISTAL TAPERED 18X290A
197719190	RECLAIM DISTAL TAPERED 19X190A
197719240	RECLAIM DISTAL TAPERED 19X240A
197719290	RECLAIM DISTAL TAPERED 19X290A
197720190	RECLAIM DISTAL TAPERED 20X190A
197720240	RECLAIM DISTAL TAPERED 20X240A
197720290	RECLAIM DISTAL TAPERED 20X290A
197721190	RECLAIM DISTAL TAPERED 21X190A
197721240	RECLAIM DISTAL TAPERED 21X240A
197721290	RECLAIM DISTAL TAPERED 21X290A

Part Number	Brand Name
197722190	RECLAIM DISTAL TAPERED 22X190A
197722240	RECLAIM DISTAL TAPERED 22X240A
197723190	RECLAIM DISTAL TAPERED 23X190A
197723240	RECLAIM DISTAL TAPERED 23X240A
197723290	RECLAIM DISTAL TAPERED 23X290A
197724190	RECLAIM DISTAL TAPERED 24X190A
197724240	RECLAIM DISTAL TAPERED 24X240A
197725190	RECLAIM DISTAL TAPERED 25X190A
197725240	RECLAIM DISTAL TAPERED 25X240A
197725290	RECLAIM DISTAL TAPERED 25X290A
197726190	RECLAIM DISTAL TAPERED 26X190A
197726240	RECLAIM DISTAL TAPERED 26X240A
197727190	RECLAIM DISTAL TAPERED 27X190A
197727240	RECLAIM DISTAL TAPERED 27X240A
197727290	RECLAIM DISTAL TAPERED 27X290A
197729190	RECLAIM DISTAL TAPERED 29X190A

Attachment B

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