DePuy Synthes People inspired™
JOINT RECONSTRUCTION
COMPANIES OF Johnson & Johnson

Urgent Field Safety Notice (FSN)

Product Name: DePuy - RECLAIM® Assembled Implant Inserter Adaptor

FSCA-identifier: 103120736-HHE

Type of Action: Field Safety Notice

Date: March 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: Devices used in Orthopaedic Knee Joint Replacement.

Model names: RECLAIM® Assembled Implant Inserter Adaptor.

DePuy Orthopaedics, Inc. is voluntarily issuing a Field Safety Notice (FSN) for one lot of the RECLAIM® Assembled Implant Inserter Adaptor Instrument (Figure 1). The instrument is being recalled because it may fracture during surgery and there is the potential for plastic pieces to be left in the patient. Further distribution and use of the instrument are to cease immediately. Back-table assembly of the Distal Stem and Proximal Body will no longer be an option.

Affected Instrument:

Part Number: 2975-00-920
Lot Number: SO2018074
Bar Code GTIN: 10603295156192

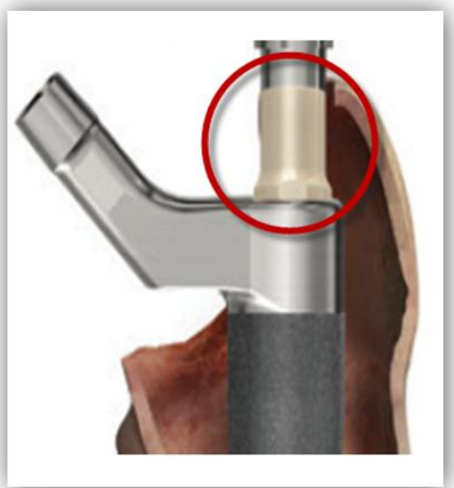


Figure 1: RECLAIM® Assembled Implant Inserter Adaptor Instrument

Intended Use

The RECLAIM Assembled Implant Inserter Adaptor is a non-sterile, re-usable, optional instrument used only when the RECLAIM Implants (Distal Stem, Proximal Body, and Bolt) are assembled on the back table. It threads onto the RECLAIM Distal Stem Inserter and sits in the Proximal Body Counterbore to allow the surgeon to drive the implant construct into the prepared femur.

Reason for Recall
On February 6, 2015, a complaint was received regarding the RECLAIM Assembled Implant Inserter Adaptor breaking during insertion of the RECLAIM stem. The complaint noted that all pieces were retrieved from the patient, and surgery time was not extended. No patient harms were identified on the complaint, and no other reports have been received regarding this failure mode. The company performed investigational testing that confirmed the failure mode.

Because there is the potential for the instrument to fracture during impaction and potential for fragments to be left in a patient, DePuy Orthopaedics, Inc. is voluntarily removing the instruments.

Units Affected
Since January 2015, one affected instrument has been distributed in the US, and two affected instruments have been distributed internationally. This recall does not affect any other instruments.

Depth of Recall
The purpose of this instrument recall is to remove the affected instruments and to notify the Hospital/User of the possible clinical implications of using the affected instrument during surgery.

Clinical Implications
If the affected RECLAIM Assembled Implant Inserter Adaptor fractures during surgery the possible clinical implications are:

- If observed during surgery:
    - Surgical Delay: Intra-operative surgical delay of up to 2 hours to retrieve debris from the broken instrument.
- If all debris is not removed during surgery:
    - Adverse tissue reaction: The surrounding tissue may become irritated.
    - Poor joint mechanics.
    - Pain.
    - 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
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 potential symptoms and follow up recommendations.

Transmission of this Field Safety Notice:

This notice has been sent to you as records indicate that your organization/hospital has purchased the RECLAIM® Assembled Implant Inserter Adaptor.

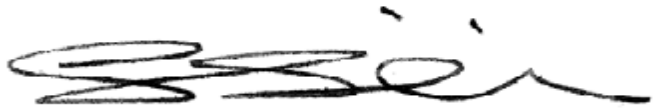
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where these products may have been transferred.

To confirm receipt of this FSN please complete and return the acknowledgement in Attachment B.
For any enquiries about the the RECLAIM® Assembled Implant Inserter Adaptor 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
Worldwide Vice President, Strategic Medical Affairs

Attachment B:

This Letter acknowledges receipt of the Field Safety Notice related RECLAIM® Assembled Implant Inserter Adaptor

(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