Urgent Field Safety Notice (Recall)

All Lots of the DePuy Synthes Reach System Handle Instrument
Part Number 950505154

Product Name: Reach System Handle Instrument

FSCA-identifier: 103189242 (HHE)

Type of Action: Field Safety Corrective Action (Recall)

Date: November 2015

Attention: Trust Chief Executives, the Clinical Director of the Orthopaedic Department, the Orthopaedic Theatre Manager, the Safety Liaison Officer, General Managers of Private Sector Hospitals, Distributors.

Type of device: Instrument used in Knee Joint Replacement

Model Name: Reach System Handle

Affected Reach System Handle Instruments:
Part Number: 950505154
Batch/Lot Number of Affected Devices: All lots

DePuy (Ireland), a legal manufacturer for Johnson & Johnson Medical (Suzhou) Ltd designed products, is issuing a **voluntary recall** for all lots of the Reach System Handle (Part Number 950505154). The Reach System Handle affected by this recall should not be used or distributed further. It has been determined that insufficient welding may allow the pin to detach from the handle body hole.

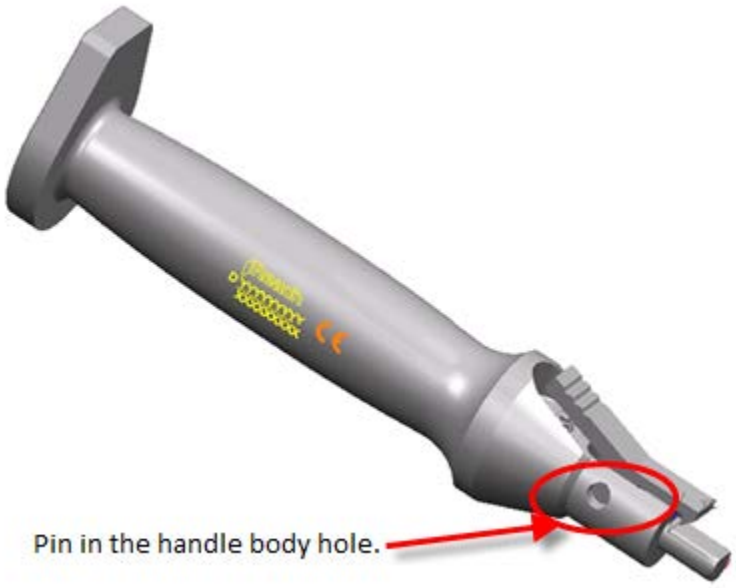


Figure 1: Reach System Handle (Part Number 950505154) with the Pin in the handle body hole.

Intended Use:
The Reach System Handle (Part Number 950505154) is used in primary knee replacement procedures.

A Reach System Handle can be connected to the following instruments:

- Femoral Implant Impactor (950505103)
- Femoral Implant Impactor (950505134)
- Tibial And Insert Impactor (950505104)
- Tibial And Insert Impactor (950505135)
- All Poly Tibial Impactor (950505507)
- Femoral Inserter (950505105)
- Femoral Inserter (950505535)
- Modular Tibial Cemented Punch Size 1.5-3 (950505167)
- Modular Tibial Cemented Punch Size 4-5 (950505168)

Please refer to the SIGMA® Fixed Bearing Reach Instrument Surgical Technique (CA#DSEM/JRC/0614/0051 Issued: 10/14).

Instrument Options
DePuy will provide replacement instruments as soon as the issue is corrected and replacement instruments are manufactured. To minimise any surgical disruption, medical professionals may opt to use the following instrument kits as alternatives:

- PFC® SIGMA® Specialist 2 Primary Knee Instruments
- SIGMA® High Performance (HP) Primary Knee Instruments

Units Affected
Approximately 189 units of the Reach System Handle (Part Number 950505154) have been distributed and are affected by this recall.

Depth of Recall
This instrument recall provides instructions for notifying medical professionals that may have received the affected instruments. The purpose of this instrument recall is to remove all affected instruments.

Reason for Recall
Johnson & Johnson Medical (Suzhou) Ltd. has received one complaint that the pin for the lever connection has detached during use, causing the lever, spring and pin to disassemble from the handle body. No adverse events have been reported.

Clinical Implications:
The following harms may occur if the pin detaches from the instrument and is left in the patient:

- Pain
- Poor Joint Mechanics
- Adverse Tissue Reaction
- Surgical Delay, Significant – This could occur if a piece of the instrument is missing and the surgeon must locate it to ensure it has not been left in the operative site.

If a surgeon has performed a procedure with an affected instrument that broke during the procedure, and the pin is believed to have been retained in the surgical site, DePuy (Ireland) recommends that surgeons discuss potential clinical implications and risks with the patient. These may include the necessity to re-operate in order to retrieve the retained pin.

Steps to Take
The purpose of this communication is to inform you of this instrument removal and request acknowledgement of the notice. Please take the following actions:

- Cease using the affected part (Part Number 950505154) of the Reach System Handle immediately.

- Medical facilities are to determine if any of the recalled instruments are on hand, and return affected instruments immediately to their DePuy Synthes Sales Consultant or return them to DePuy Orthopaedics, Inc. for credit following normal procedures. Reach System Handle Instrument (Part Number 950505154) is included in the following kit:
    - Reach Instrument Sets (Set Numbers: MK002, K400, K401, K402, K406 and K407).
- Review this notice and complete the Acknowledgement section Attachment A to signify that your facility has been informed of this device recall. Return the completed Acknowledgement to your DePuy Synthes Orthopaedics Sales Consultant within two (2) weeks of this notice.
- Retain a copy of the completed Acknowledgement Form in your files along with this notice.
- Forward this notice to others in your facility that may need to be informed.
- If any affected product has been forwarded to another facility, contact that facility immediately to communicate this instrument recall with the facility/facilities.
- Notify surgeon users at your facility by providing them with a copy of this notice to ensure surgeon users are aware of this instrument recall.

Transmission of this Field Safety Notice:

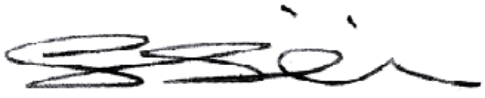
This notice has been sent to you as records indicate that your facility has received the Reach System Handle.

For any enquiries about the Reach System Handle Instrument (Part Number 950505154) Field Safety Notice contact:

Bríd Horgan
Recall Associate
E-mail – *RA-DPYIE-VigilRecall@ITS.JNJ.com*
Tel no - +353 21 4914128

Notification of this FSN has been provided to the appropriate Regulatory Agency.

Yours sincerely,



Simon Sinclair PhD MB BChir
Worldwide Vice President, Strategic Medical Affairs

Attachment A

This Letter acknowledges receipt of the Field Safety Notice related to Reach System Handle Instrument (Part Number 950505154).

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

(Please check as appropriate)

☐ Yes I have received the FSN

☐ I have/ will return the affected units

Print Name: _____

_____

Signature

_____

Hospital Name

_____

Country

_____

City,

_____

Telephone Number or e-mail address