

Urgent Field Safety Notice (FSN)

Product Name: DePuy Charnley Pin Retractor & Handle Set

FSCA-identifier: HHE-103055017

Type of Action: Field Safety Corrective Action (Recall) – Return of device to the manufacturer

Date: August 2014

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: Orthopaedic Hip Joint Replacement Instrument

Model names: DePuy Charnley Pin Retractor & Handle Set

Part Numbers: 962004000

Lot #'s affected:

OSA-149328
OSA-161157
OSA-181610

DePuy international Ltd. is issuing a device recall of the Charnley Pin Retractor & Handle Set of the above part and lot numbers due to the potential of breakage of the small extraction peg away from the pin.

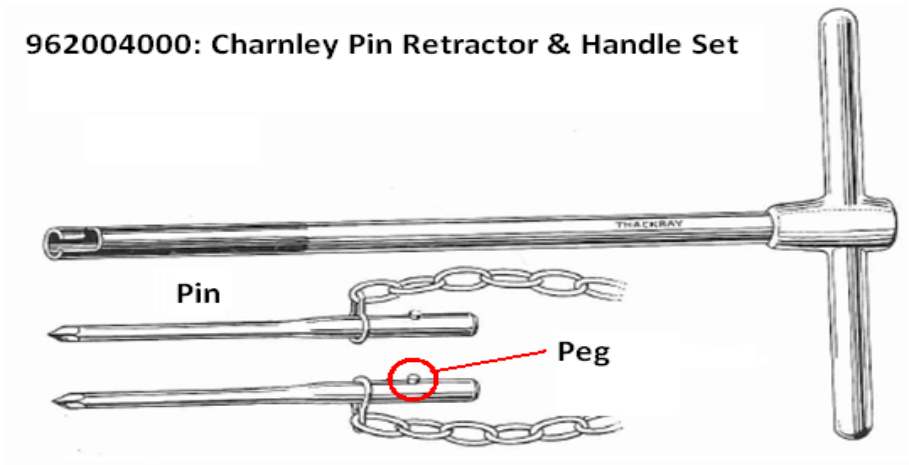
Reason for Recall

Analysis of the pegs from the above affected lots shows the existence of microscopic cracks in the weld region. This could lead to decreased strength and a greater risk of instrument fracture under what would be normally acceptable conditions; therefore a recall is being issued.

Four (4) reports of peg fracture have been received since October 2013.

This instrument assembly facilitates the insertion and extraction of two pins into and out of bone in the incision area, thereby holding the incision soft tissue open during the surgical procedure.

The image below shows the area of potential peg breakage.



Intended Use

This instrument assembly facilitates the insertion and extraction of two pins into and out of bone in the incision area, holding the incision soft tissue open during the surgical procedure.

Depth of Recall action:

This recall affects Part Number 962004000 and three Lot Numbers OSA-149328; OSA-161157 and OSA-181610.

Clinical Implications

If the peg fractures, a potential exists that the small broken peg may remain in the joint space following wound closure. The following potential harms have been identified: Soft Tissue Damage; Poor Joint Mechanics; Pain and Surgical Delay.

DePuy is not recommending individual patient follow up as a result of this matter.

Transmission of this Field Safety Notice:

This notice has been sent to you as records indicate that your organization/hospital has received this device of the affected part and lot number(s) above.

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.

Return of affected devices to the manufacturer:

Your DePuy Synthes Account Manager or Customer Services Representative will contact you to arrange return and credit for devices returned.

Any devices you wish to return should be sent to the following address:

Returns Department
European Distribution Center
Johnson & Johnson
Rue du Luxembourg
B-6180 Courcelles
Belgium

To confirm receipt of this FSN please complete and return the acknowledgement in Appendix A.

For any enquiries regarding this matter please contact:

Alan O' Sullivan
Recall Co-Ordinator
E-mail – aosulliv@its.jnj.com
Tel no - +353 21 4914149

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

Yours sincerely,



Simon Sinclair PhD MB BChir
WW VP Strategic Medical Affairs
DePuy Synthes

Appendix A:

This Letter acknowledges receipt of the Field Safety Notice [ref. HHE-103055017] related to the recall of DePuy Charnley Pin Retractor & Handle Set, issued by DePuy Int. Ltd.

(Please check as appropriate)

Yes, I have received the FSN

Yes, I have/will return the affected devices

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

Print Name:

Signature

Hospital Name

City

Country

Telephone Number or e-mail address