

Urgent Field Safety Notice

Three Units of DePuy Joint Reconstruction
Duraloc Option Liner Locking Ring

Product Name: Duraloc® Option LPW Poly Inserts

FSCA-identifier: HHE-103232232

Type of Action: Field Safety Notice

Date: March 22nd 2016

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: Continuing Care Hip Implant

Model Name: Duraloc® Option LPW Poly Inserts

DePuy International is issuing a Field Safety Notice for three specific one-piece lots of the Duraloc® Option LPW Poly Inserts.

Item Number	Lot Number	GTIN Number	Units Affected
159923054CC	8230605	10603295065661	1
159923052CC	8237927	10603295065654	1
159923054CC	8244822	10603295065661	1

Reason for the Field Safety Notice:

A product complaint was received on 22nd Feb 2016 for one unit of product code 159923052CC, lot number 8237927 (Ref: COM-167805) indicating that during revision surgery a Duraloc Option Liner’s locking ring did not fit in the associated acetabular cup. The locking ring is used in the assembly of the liner and cup to provide a mechanism to retain the liner (Figure 1). A size 56mm (73411019) locking ring was inadvertently supplied with the insert instead of a 50mm locking ring (73410985). Intraoperatively, the surgeon modified the ring and implanted the liner.

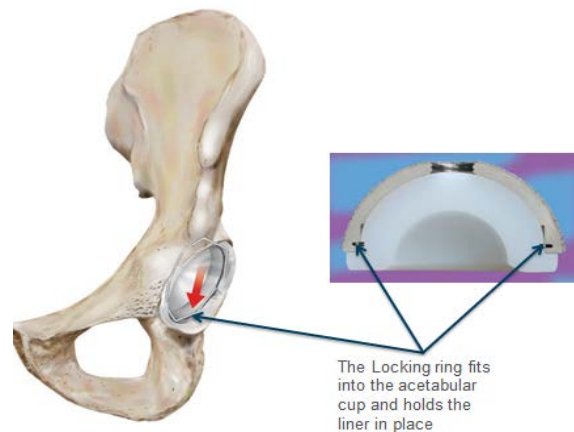


Figure 1

The investigation revealed that the Bill Of Materials (BOM) was incorrect for this and two other Duraloc Option locking ring inserts sold in Germany. The BOM specified a 56mm locking ring (73411019) to be supplied with the insert when it should have specified a 50mm locking ring (73410985).

Action:

The two remaining products were located and customers were informed of the issue. One product was implanted with the appropriate size ring, provided separately by the company. DePuy Synthes will provide an appropriately sized locking ring through the Orthokit process for the third affected product prior to surgery.

Clinical Implications:

Potential risks associated with this product complaint are as follows:

1. Surgical delay
2. Dislocation
3. Loosening

The clinical scenarios described above may potentially require surgery to revise the components.

In the reported complaint described above, the surgeon modified the locking ring intraoperatively and implanted the liner. There was no surgical delay and the company's risk assessment identified no additional risks to the patient, (Ref: COM-167805).

Patient Care:

In relation to the complaint received Ref: COM-167805, the company advises that the treating surgeon follows up the patient in line with routine follow up procedures, to ensure there are no unanticipated complications. In relation to the remaining components where the correct locking ring was provided separately and used, no additional follow-up, other than routine, is required.

Please undertake the following urgent actions:

- Please sign and return the confirmation letter below to the specified DePuy International contact.
- Please ensure all departments and colleagues within your organisation who are impacted by this Field Safety notice are made aware of this action.

Transmission of this Field Safety Notice:

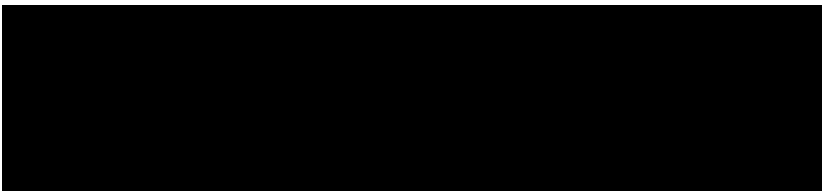
This notice has been sent to you because our records indicate that you have received the affected product. This notice needs to be passed on to all those who need to be aware within your organization.

For any enquiries regarding the Duraloc Option Liner Locking Ring, contact:

Clare Mathers (DePuy), Recall & Vigilance Associate
e-mail -RA-DPYIE-VigilRecall@ITS.JNJ.com
Tel no - +353 21 4914581

This FSN has been notified to the appropriate Regulatory Agency.

Yours sincerely,



ATTACHMENT A

This Letter acknowledges receipt of the Field Safety Notice related to Duraloc® Option LPW Poly Inserts

(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

City

Country

Telephone Number or e-mail address