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

Urgent Field Safety Notice (FSN)

Product Name: DePuy - LCS COMPLETE RPS Knee System

FSCA-identifier: 103108200-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: LCS COMPLETE RPS Femoral and the LCS COMPLETE RPS Insert.

DePuy Orthopaedics, Inc. is voluntarily issuing a Field Safety Notice (FSN) for all lots of the LCS® COMPLETE™ RPS Knee System (See Attachment A). The FSN is being issued due to the potential occurrence of pain when the native patella is not resurfaced, as reported in the Australian Registry. When using the LCS Complete RPS Knee System, the patella must be resurfaced. Failure to resurface the patella has been associated with a higher incidence of postoperative patello-femoral pain potentially leading to a secondary procedure.

DePuy Orthopaedics, Inc. was recently notified by Australia's regulatory authority, the Therapeutic Goods Administration (TGA), that the LCS® COMPLETE™ RPS Knee System has a higher rate of revision than the class of PS knee systems based on recent data from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). After further analysis of the AOANJRR data, DePuy Orthopaedics, Inc. determined that the LCS COMPLETE RPS Knee System has higher rates of revision in Australia when the native patella is not resurfaced when compared to other unresurfaced PS implants. The need for a second surgery to resurface the native patella is due to an increased incidence of postoperative patello-femoral pain.

Affected Implants: See Attachment A

Intended Use
The LCS COMPLETE RPS Knee System is intended for total knee replacement and consists of an LCS COMPLETE RPS Femoral implant and the compatible LCS COMPLETE RPS Insert.

The LCS COMPLETE RPS Knee System is indicated for cemented use in cases of osteoarthritis and rheumatoid arthritis. The RPS inserts and femoral implants are indicated where a higher than normal degree of post-operative flexion is required.

Figure 1: LCS COMPLETE RPS Knee System

Background:

DePuy Orthopaedics, Inc. was recently notified by Australia's regulatory authority, the Therapeutic Goods Administration (TGA), that the LCS COMPLETE RPS Knee System has a higher rate of revision than the class of PS knee systems based on recent data from the AOANJRR. After further analysis of the AOANJRR data, DePuy Orthopaedics, Inc. determined that the LCS COMPLETE RPS Knee System has higher rates of revision in Australia when the native patella is not resurfaced when compared to other unresurfaced PS implants. The need for a second surgery to resurface the native patella is due to an increased incidence of postoperative patello-femoral pain.

Table 1: Yearly Cumulative Percent Revision of Primary Total Knee Replacement by Model and Patella Usage (All Diagnoses)

Model	Patella Usage	1 Yr	2 Yrs	3 Yrs	4 Yrs
LCS PS	Patella Used	0.3 (0.0, 2.2)	1.4 (0.5, 3.7)	2.4 (1.1, 5.4)	3.3 (1.5, 7.1)
	No Patella	3.6 (2.0, 6.5)	9.7 (6.9, 13.7)	11.5 (8.3, 15.7)	12.9 (9.6, 17.4)
Other Total Knee	Patella Used	0.9 (0.8, 0.9)	1.6 (1.6, 1.7)	2.2 (2.1, 2.2)	2.6 (2.5, 2.7)
	No Patella	1.1 (1.1, 1.2)	2.3 (2.3, 2.4)	3.1 (3.0, 3.2)	3.6 (3.6, 3.7)

The data above represents analysis provided by the AOANJRR per ad hoc request 1545 on 330 resurfaced and 305 unresurfaced LCS COMPLETE RPS Knees. (Note: In Australia this was known as LCS PS.) When the

patella was resurfaced with an LCS COMPLETE RPS Knee, the cumulative revision rates were not significantly different when compared to other resurfaced implants.

DePuy Orthopaedics, Inc. also investigated complaints received since 2006 and found the global complaint rates are as follows:

- LCS COMPLETE RPS Femoral Implants global complaint rate is 0.51%.
- LCS COMPLETE RPS Inserts global complaint rate is 0.75%.

According to data from the AOANJRR, failure to resurface the patella has been associated with a higher incidence of postoperative patello-femoral pain, potentially leading to a secondary procedure. As a result, the company is warning against use of the LCS COMPLETE RPS Knee System without resurfacing the native patella.

Units Affected
Since 2006, 15,571 LCS COMPLETE RPS Femoral Implants and 17,732 LCS COMPLETE RPS Inserts were sold in the U.S. and 3,263 LCS COMPLETE RPS Femoral Implants and 3,546 LCS COMPLETE RPS Inserts were sold outside of the U.S. This device correction does not affect any other LCS COMPLETE Knee femoral implants or inserts.

Device Correction Actions:
The company is taking the following steps for this device correction:

1. Advise users to resurface the patella with any of the LCS COMPLETE Knee patella implants when implanting the affected implants.
2. Revise product literature to include verbiage around the requirement to resurface the patella with any of the LCS COMPLETE Knee patella implants when implanting the affected implants.
3. Users are also reminded that product complaints should be reported through the normal complaint reporting process.

Depth of Action:
This device correction provides instructions for notifying users that purchased the affected LCS COMPLETE RPS Knee System. The purpose of this device correction is to make users aware of the issue and actions to take.

Clinical Implications
If the LCS COMPLETE RPS Knee System is implanted and the native patella is not resurfaced, the patient may experience patello-femoral pain, potentially requiring a secondary procedure. Following are examples of possible risks/hazards of secondary procedures:

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. The company recommends that surgeons discuss potential clinical implications and risks with symptomatic patients that received the LCS COMPLETE RPS Knee System with an unresurfaced patella.

Transmission of this Field Safety Notice:

This notice has been sent to you as records indicate that your organization/hospital has purchased the LCS COMPLETE RPS Knee System
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 LCS COMPLETE RPS Knee System 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,

[redacted]

Worldwide Vice President, Strategic Medical Affairs

Attachment A: LCS COMPLETE RPS Femoral Implants & Inserts			
Cat. No.	**Barcode / GTIN**	**Cat. No.**	**Barcode / GTIN**
129411010	10603295022824	129417120	10603295023494
129411020	10603295022831	129417122	10603295023500
129411030	10603295022848	129417125	10603295023517
129411040	10603295022855	129417210	10603295023524
129411050	10603295022862	129417212	10603295023531
129411060	10603295022879	129417215	10603295023548
129411070	10603295022886	129417217	10603295023555
129412010	10603295022893	129417220	10603295023562
129412020	10603295022909	129417222	10603295023579
129412030	10603295022916	129417225	10603295023586
129412040	10603295022923	129417310	10603295023593
129412050	10603295022930	129417312	10603295023609
129412060	10603295022947	129417315	10603295023616
129412070	10603295022954	129417317	10603295023623
129416110	10603295022961	129417320	10603295023630
129416112	10603295022978	129417322	10603295023647
129416115	10603295022985	129417325	10603295023654
129416117	10603295022992	129417410	10603295023661
129416120	10603295023005	129417412	10603295023678
129416122	10603295023012	129417415	10603295023685
129416125	10603295023029	129417417	10603295023692
129416210	10603295023036	129417420	10603295023708
129416212	10603295023043	129417422	10603295023715
129416215	10603295023050	129417425	10603295023722
129416217	10603295023067	129417510	10603295023739
129416220	10603295023074	129417512	10603295023746
129416222	10603295023159	129417515	10603295023753
129416225	10603295023098	129417517	10603295023760
129416310	10603295023104	129417520	10603295023777
129416312	10603295023111	129417522	10603295023784
129416315	10603295023128	129417525	10603295023791
129416317	10603295023135	129417610	10603295023807
129416320	10603295023142	129417612	10603295023814

Attachment A: LCS COMPLETE RPS Femoral Implants & Inserts			
Cat. No.	**Barcode / GTIN**	**Cat. No.**	**Barcode / GTIN**
129416322	10603295023159	129417615	10603295023821
129416325	10603295023166	129417617	10603295023838
129416410	10603295023173	129417620	10603295023845
129416412	10603295023180	129417622	10603295023852
129416415	10603295023197	129417625	10603295023869
129416417	10603295023203	129417710	10603295023876
129416420	10603295023210	129417712	10603295023883
129416422	10603295023227	129417715	10603295023890
129416425	10603295023234	129417717	10603295023906
129416510	10603295023241	129417720	10603295023913
129416512	10603295023258	129417722	10603295023920
129416515	10603295023265	129417725	10603295023937
129416517	10603295023272	129495040	10603295271819
129416520	10603295023289	129495050	10603295271826
129416522	10603295023296	129495060	10603295271833
129416525	10603295023302	129495410	No GTIN available - part has been inactive since 2008
129416610	10603295023319	129495412	No GTIN available - part has been inactive since 2008
129416612	10603295023326	129495415	No GTIN available - part has been inactive since 2008
129416615	10603295023333	129495417	No GTIN available - part has been inactive since 2008
129416617	10603295023340	129495420	No GTIN available - part has been inactive since 2008
129416620	10603295023357	129495510	No GTIN available - part has been inactive since 2008
129416622	10603295023364	129495512	No GTIN available - part has been inactive since 2008
129416625	10603295023371	129495515	No GTIN available - part has been inactive since 2008
129416710	10603295023388	129495517	No GTIN available - part has been inactive since 2008
129416712	10603295023395	129495520	No GTIN available - part has been inactive since 2008
129416715	10603295023401	129495610	No GTIN available - part has been inactive since 2008
129416717	10603295023418	129495612	No GTIN available - part has been inactive since 2008
129416720	10603295023425	129495615	No GTIN available - part has been inactive since 2008
129416722	10603295023432	129495617	No GTIN available - part has been inactive since 2008
129416725	10603295023449	129495620	No GTIN available - part has been inactive since 2008
129417110	10603295023456	129696040	10603295271840
129417112	10603295023463	129696050	10603295271857
129417115	10603295023470	129696060	10603295271864
129417117	10603295023487		

Attachment B:

This Letter acknowledges receipt of the Field Safety Notice related to LCS COMPLETE RPS Knee System

(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