DePuy Synthes
JOINT RECONSTRUCTION
COMPANIES OF Johnson & Johnson

Urgent Field Safety Notice (Recall)

12 Specific Lots of the GLOBAL® UNITE® Platform Shoulder System

Product Name: **GLOBAL® UNITE® Platform Shoulder System**

FSCA-identifier: **PIE 1013757**

Type of Action: **Field Safety Corrective Action (Recall)**

Date: Dec 2017

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: GLOBAL® UNITE® Platform Shoulder System

Model Name: Global Unite Anatomic Bodies 135 degree Sizes 10 and 12, Global Unite Fracture Bodies Size 10, 0, +5 and -5.

DePuy Ireland UC is voluntarily recalling 12 lots of the GLOBAL® UNITE® Platform Shoulder System. The device is being recalled because the screw in specific lots of the GLOBAL UNITE Anatomic Body and GLOBAL UNITE Fracture Body was inverted during assembly to the body, which will cause the humeral stem to sit proud and may cause surgical delays (See Figure 1 and Figure 2). Further distribution or use of the affected lots is to cease immediately.

Stem & Body Engagement with Correct Screw Assembly

Stem & Body Engagement with Incorrect Screw Assembly

Figure 1: Images of Stem and Body Engagement

Correctly Assembled

Incorrectly Assembled

Note: Image above is a DNI Sample Part

Figure 2: Images of GLOBAL® UNITE® Anatomic Body.

Recalled Implants:

Catalog No.	Lot No.	GTIN	Description
110030000	8556802	10603295004356	GLBL UNITE ANT BODY 135 SZ 10
110030000	8556803	10603295004356	GLBL UNITE ANT BODY 135 SZ 10
110030000	8556804	10603295004356	GLBL UNITE ANT BODY 135 SZ 10
110030000	8556805	10603295004356	GLBL UNITE ANT BODY 135 SZ 10
110030000	8583381	10603295004356	GLBL UNITE ANT BODY 135 SZ 10
110030100	8556910	10603295004387	GLOBAL UNITE BODY SZ 10 -5
110030100	8556951	10603295004387	GLOBAL UNITE BODY SZ 10 -5
110030100	8605849	10603295004387	GLOBAL UNITE BODY SZ 10 -5
110030110	8564487	10603295004394	GLOBAL UNITE BODY SZ 10 0
110030110	8572431	10603295004394	GLOBAL UNITE BODY SZ 10 0
110030120	8610357	10603295004400	GLOBAL UNITE BODY SZ 10 +5
110040000	8527674	10603295004417	GLBL UNITE ANT BODY 135 SZ 12

Intended Use:
The GLOBAL UNITE Platform Shoulder System is intended for cemented or uncemented total shoulder or hemi-shoulder replacement procedures.

Reason for Recall
An investigation determined that the screw in the anatomic and fracture bodies of recalled lots may have been incorrectly assembled. This screw is used for fixation of the body to the humeral stem. The occurrence rate for the incorrect assembly causing a significant surgical delay is 0.008%. See Figure 2 on Page 2.

Units Affected
Since August 25, 2017, there have been approximately 128 affected devices sold worldwide. This recall does not affect any other catalog numbers or lots of the GLOBAL UNITE Platform Shoulder System.

Depth of Recall
This device recall provides instructions for notifying medical facilities that may have used, purchased or received the affected lots of the GLOBAL UNITE Platform Shoulder System. The purpose of this device recall is to remove the affected devices and to notify medical professionals of the possible effects of using the affected device.

Clinical Implications
The possible clinical implication related to affected lots of the GLOBAL UNITE Platform Shoulder System's incorrect assembly include a potential surgical delay of 15 to 59 minutes.

Patient Communications
DePuy Ireland UC is not recommending prophylactic revision. The company recommends that surgeons discuss potential clinical implications and risks with symptomatic patients that received the affected lots and may have experienced a surgical delay.

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

- Please cease using the affected components immediately.
- Medical facilities are to determine if any of the recalled components are still on hand, and return affected components immediately to their Sales Consultant for credit following normal procedures.
- Review this notice and complete the Acknowledgement section (Attachment A) to signify that your facility has been informed of this recall. Return the completed Acknowledgement to your Sales Consultant within one (1) week 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 need to be informed.
- If any affected product has been forwarded to another facility, contact that facility immediately to communicate this field action with the facility/facilities.
- Notify surgeons at your facility by providing them with a copy of this notice to ensure surgeons are aware of this recall notice.
- Maintain a copy of this notice with the affected devices.

Transmission of this Field Safety Notice:
This notice has been sent to you as records indicate that your organisation/hospital has purchased the affected lots of the GLOBAL® UNITE® Platform Shoulder 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 A to your DePuy Synthes representative.

For any enquiries about the GLOBAL® UNITE® Platform Shoulder System FSN contact:

Clare Mathers
Vigilance and Recall Associate
E-mail – RA-DPYIE-VigilRecall@ITS.JNJ.com
Tel no - +353 21 4914581

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

Sincerely,

John Wright, MD
Franchise Medical Leader - JMP
WW Vice-President, Medical Affairs

ATTACHMENT A

This Letter acknowledges receipt of the Field Safety Notice related to GLOBAL® UNITE® Platform Shoulder System Recall FSCA-identifier: PIE 1013757

(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 Johnson & Johnson AB, att. Complaint team Nordic, Box 4014, 169 04 Solna. E-mail: RA-ITSUS-JJMSweden@its.jnj.com Fax: 08-6262230

Please list the Lot numbers and Quantities of affected devices to be returned:

_____

Print Name: _____

_____
Signature

_____
Hospital Name

_____
City

_____
Country

_____
Telephone Number or e-mail address