Urgent Field Safety Notice (Recall)
15 Lots of the ACETABULAR CUP INTRODUCER (32mm)

Product Name: ACETABULAR CUP INTRODUCER (32mm)

FSCA-identifier: PIE 746814

Type of Action: Field Safety Corrective Action (Recall)

Date: October 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: Instrument used in Orthopaedic Hip Joint Replacement.

Model Name: ACETABULAR CUP INTRODUCER (32mm)

DePuy International, Ltd. is issuing a voluntary recall for 15 lots of the ACETABULAR CUP INTRODUCER (32mm) (Figure 1) because the nylon ejector slug may melt during the autoclave process, which may cause the ejector to be inoperable and the cup introducer to be difficult to remove after cup placement. Further distribution or use of the recalled lots of the ACETABULAR CUP INTRODUCER (32mm) instruments is to cease immediately.

Figure 1: Images of ACETABULAR CUP INTRODUCER (32mm) and Nylon 6 Slug

Recalled Instruments:

Part Number:	962636000
GTIN:	10603295243588
Lots:	0SA218440, 0SA218441, 0SA218445, 0SA218446, 0SA220370, 0SA220364, 0SA201670, 0SA201674, 0SA203021, 0SA218442, 0SA218443, 0SA218444, 0SA203017, 0SA203019, 0SA203015

Intended Use:
The cemented cup introducer is used to insert Cemented Cups e.g. Marathon. The nylon slug component allows the introducer to be removed from the cup when it is in the correct location.

Reason for Recall
The company received six (6) reports that after autoclaving the ACETABULAR CUP INTRODUCER (32mm), the nylon slugs melted and rendered the instruments' triggers unfunctional. After investigating, it was determined that an incorrect raw material was certified and used to produce the affected lots. The occurrence rate for this issue is 6.03%.


Figure 2: Image of melted slug

Units Affected
Since July 2015, there have been 116 ACETABULAR CUP INTRODUCER (32mm) distributed worldwide. This recall does not affect any other lots or instruments.

Depth of Recall
This recall notice is provided to medical facilities and surgeons that may have received, purchased, or used the affected ACETABULAR CUP INTRODUCER (32mm). The purpose of this instrument recall is to remove the affected instruments and to notify medical professionals of the possible effects of using the affected instruments.

Clinical Implications
The possible clinical implications related to slugs melting in the ACETABULAR CUP INTRODUCER (32mm) include:

If the affected instrument's nylon slug melts and is not detected prior to use:

- Significant surgical delay to remove the cup introducer.
- Poor joint mechanics, dislocation or loosening if the cup's placement is disturbed when removing the cup introducer.

The implications indicated above could potentially require revision surgery. Following are general examples of possible risks/hazards of revision surgery:

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 International, Ltd. is not recommending prophylactic revision in the absence of symptoms in patients on whom these instruments may have been used. The company recommends that surgeons discuss potential clinical implications and risks with symptomatic patients. Sharing this information will allow surgeons to discuss the issue and provide follow up recommendations.

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 instruments immediately.

- The company recommends that surgeons discuss potential clinical implications and risks with symptomatic patients. Sharing this information will allow surgeons to discuss the issue and provide follow up recommendations.
- 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 International, Ltd. 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 DePuy Synthes Orthopaedics 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 instruments.

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 ACETABULAR CUP INTRODUCER (32mm).

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.

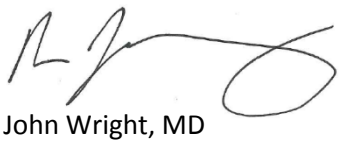
To confirm receipt of this FSN please complete and return the acknowledgement in Attachment A to your DePuy Synthes representative.

For any enquiries about the ACETABULAR CUP INTRODUCER (32mm) FSN 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.

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 ACETABULAR CUP INTRODUCER (32mm) Recall

(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