Urgent Field Safety Notice (Recall)

CONCORDE LIFT™ (all lots)
No other CONCORDE™ products are affected by this removal

Product Name: CONCORDE LIFT ™

FSCA-identifier: PIE 1446036

Type of Action: Field Safety Corrective Action (Recall)

Date: April 2019

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: The CONCORDE LIFT™ Expandable Interbody Device is a lumbar intervertebral body fusion device.

Model Name: CONCORDE LIFT™

DePuy Synthes Spine is initiating a Voluntary Product Recall on behalf of Medos International SARL for the CONCORDE LIFT™ Implants. This decision is based on an identified complaint trend for post-operative loss of cage height and cage migration observed as part of the company's post market surveillance process. Further distribution or use of the affected implants is to cease immediately.

The overall complaint rate for all CONCORDE LIFT™ implants post-operative loss of cage height is 0.342% (3.42 out of every 1,000). The complaint rate for all CONCORDE LIFT™ implants post-operative loss of cage height resulting in a revision surgery is 0.124% (1.24 out of every 1,000).

The overall complaint rate for all CONCORDE LIFT™ implants post-operative cage migration is 0.155% (1.55 out of every 1,000). The complaint rate for all CONCORDE LIFT™ implants post-operative cage migration resulting in a revision surgery is 0.093% (0.93 out of every 1,000).

Figure 1: CONCORDE LIFT™ Implant

The company recommends that surgeons use alternative implants. The following are a sample of the alternatives that are available:

- CONCORDE™ ProTi 360°™ Interbody System
- OPAL™ Spacer System
- CONCORDE™ Bullet Lumbar Interbody System

Possible Clinical Implications

The possible clinical implications related to the affected CONCORD LIFT™ Implants may include the following, although all of these have not been observed as of the date of this notice:

- Poor spine biomechanics to various extents (loss of intervertebral disc space height or spine alignment)
- Pain to various extents
- Reversable or irreversible spinal nerve injuries
- Malunion/nonunion (failure of fusion)

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

1. Infection
2. Blood loss
3. Additional or increased scarring
4. Neural and vascular damage
5. Additional pain to the patient
6. Anesthesia-associated risks
7. Functional problems resulting from items above

Patient Communications

DePuy Synthes Spine is not recommending prophylactic revision in the absence of symptoms.
The company recommends routine clinical and radiographic post-operative evaluation per standard surgical practice. Should the patient report any change in or development of new-onset symptoms, clinical and radiographic evaluation should be completed in a timely manner.

Revision Surgery

If a revision is deemed clinically necessary, instruments are available to support the surgery.
To order, please contact your local Sales Consultant.

Recalled Implants

All lots of the following product codes that have been distributed are affected by this recall. Affected lot numbers that were distributed are listed in Attachment A.

Catalog No.	Brand Name	Product Description	Lots	GTIN
197809221C	CONCORDE LIFT™	CONCORDE LIFT, CON 9X21X8 MM	All lots- see Attachment A	10705034534541
197809226C	CONCORDE LIFT™	CONCORDE LIFT, CON 9X26X8 MM	All lots- see Attachment A	10705034534589
197811221C	CONCORDE LIFT™	CONCORDE LIFT, CON 11X21X8 MM	All lots- see Attachment A	10705034534626
197811226C	CONCORDE LIFT™	CONCORDE LIFT, CON 11X26X8 MM	All lots- see Attachment A	10705034534664
197809223L	CONCORDE LIFT™	CONCORDE LIFT, LRD 9X23X10 MM	All lots- see Attachment A	10705034534565
197809227L	CONCORDE LIFT™	CONCORDE LIFT, LRD 9X27X10 MM	All lots- see Attachment A	10705034534602
197811223L	CONCORDE LIFT™	CONCORDE LIFT, LRD 11X23X10 MM	All lots- see Attachment A	10705034534640
197811227L	CONCORDE LIFT™	CONCORDE LIFT, LRD 11X27X10 MM	All lots- see Attachment A	10705034534688

Indications For Use
The CONCORDE LIFT™ Expandable Interbody Device

- is a lumbar intervertebral body fusion device
- is indicated for use with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine, L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The CONCORDE LIFT™ Expandable Interbody Device can be implanted via posterior or transforaminal approach.

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 Business Reply Form (Attachment B) to signify that your facility has been informed of this recall. Return the completed Business Reply Form to your Sales Consultant within one (1) week of this notice.
- Retain a copy of the completed Business Reply 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 CONCORDE LIFT™ Implants.

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 Business Reply Form in Attachment B to your DePuy Synthes Spine representative.

For any enquiries about the CONCORDE LIFT™ Implants FSN contact:
Bríd Horgan
Recall Associate
E-mail – DPYUS-SpineFieldActions@its.jnj.com
Tel no - +353 21 4914128

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

Attachment A Lot/ Product code combinations

Product Code	Batch
197809221C	CA5GL64
197809223L	CA5GL68
197809226C	CA5GL66
197809226C	CA5GN95
197809227L	CA5GL70
197809227L	CA5GN96
197809227L	CA5GQ88
197811221C	CA5GR63
197811221C	CA5GN84
197811223L	CA5GL69
197811226C	CA5GL63
197811226C	CA5GQ85
197811226C	CA5GL63
197811227L	CA5GQ88

Attachment B- Business Reply Form

Product Name/Code	Description of the Notification
CONCORDE LIFT™ Implants	FSCA-identifier: PIE 1446036, Voluntary Product Recall

Please complete this Customer Acknowledgement Form **within 5 business days upon receipt of the notification (even if you do not have product to return)** and fax or email this form to **[Affiliate to enter contact details/info].**

☐ **I have read and understand the notification**

☐ **We have no affected product for return**

Your Name:	Facility/Business Name:
Signed*:	Date:
Facility/Business Address, City:	
J&J Sales Rep (as applicable):	
Date the notification was received:	
Fax Number:	Telephone Number:
**Your signature provides confirmation that you have received and understood this notification.*	
Your comments are always welcome:	

☐ **We have affected product and are returning the following devices:**
If you have affected product on hand to return, please complete section below and attach this Customer Acknowledgement Form with your product return.

Product Name/Code	Lot/Batch No.	Number of Devices to Be Returned
197809221C		
197809226C		
197811221C		
197811226C		
197809223L		
197809227L		
197811223L		
197811227L		

Returns Number (if applicable):_____