Date: XX May 2024

URGENT FIELD SAFETY NOTICE (REMOVAL)
EIT Emerging Implant Technologies GmbH Conduit TLIF & PLIF Implants

Products Subject to this Removal:

Part Number	Part Description	Lot Numbers
THI81228	EIT TLIF, H 12mm, 8°, 28/10	128956
THI80932	EIT TLIF, H 9mm, 8°, 32/12	128950
PHI81002	EIT PLIF, H 10mm, 8°, 22/9	132546
PHI81106	EIT PLIF, H 11mm, 8°, 26/9	132548

Dear Valued Customer,

DePuy Synthes Spine has initiated a field safety action (removal) of the EIT Emerging Implant Technologies GmbH Conduit TLIF & PLIF Implants with the part and lot numbers listed in the above table. The subject products are manufactured by EIT Emerging Implant Technologies GmbH. EIT Cellular Titanium® TLIF & PLIF Cages are indicated for use in skeletally mature patients with degenerative disc and instabilities at one or more levels of the lumbar spine with accompanying radicular symptoms, ruptured or herniated discs, and pseudarthrosis or failed spondylodesis.

Our records show that you, or your facility, received one or more units of the product listed above. Please carefully review this notice for the steps that you should take to respond to this field safety action (removal).

Reason for the Field Safety Notice (Removal):
The subject product is being recalled due to improper labeling on some parts in the lot; the label on the outer carton of some of the subject products does not match the actual device in the package.

NOTE: The implants are laser etched with the correct part number and correct lot number.

Potential Patient Impact:
It is likely that a surgeon would notice prior to implantation that the subject product is not the size indicated on the outer carton, resulting in a surgical delay to retrieve a correctly sized product. However, it also is possible that the surgeon may implant the subject product without noticing the size difference. In the latter case, difficulties may arise during cage insertion, potentially resulting in injury to the endplate and surrounding tissues such as the dura and nerve root. In cases where an improperly sized cage is successfully placed, cage migration may result in spinal nerve compression or compromise the fusion.

To date, we have received two complaints related to this issue. No adverse events have been reported.

Health care providers who have treated patients using the subject product should continue to follow those patients pursuant to the health care provider's standard of care.

Please Take the Following Steps:

1. Examine your inventory immediately to determine if you have the subject products and quarantine them immediately. DO NOT USE THE SUBJECT PRODUCTS. See attachment 1 to aid in identifying the subject products.

2. Contact your DePuy Synthes Sales Consultant or contact the customer support services at (enter country contact) to coordinate the return/credits of the subject products.

3. Review, complete, sign, and return the attached Business Response Form (page 3 of this letter) to (enter country contact) within three (3) business days of receipt of this notification.

4. Please complete the attached Business Response Form even if you do not have the subject products on hand.

5. Forward this notice to anyone in your facility that needs to be informed (e.g., those who manage, transport, store, stock, or use the subject products).

6. If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice.

7. Post a copy of this notice in a visible area for awareness and keep a copy for your records.

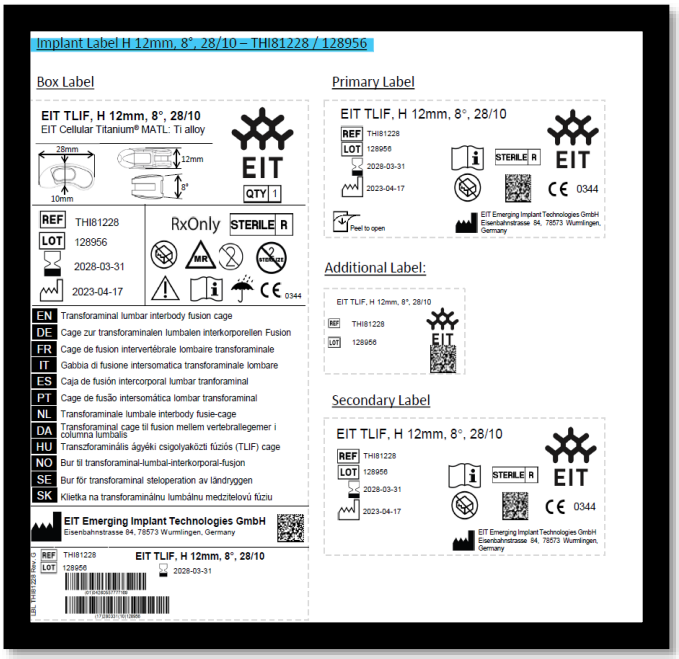
This medical device product recall has been reported to the local competent authority. For a Medical Information request, please visit our website: https://www.jnjmedicaldevices.com/mir. Should you have any other inquiries, please do not hesitate to contact your DePuy Synthes Sales Consultant.

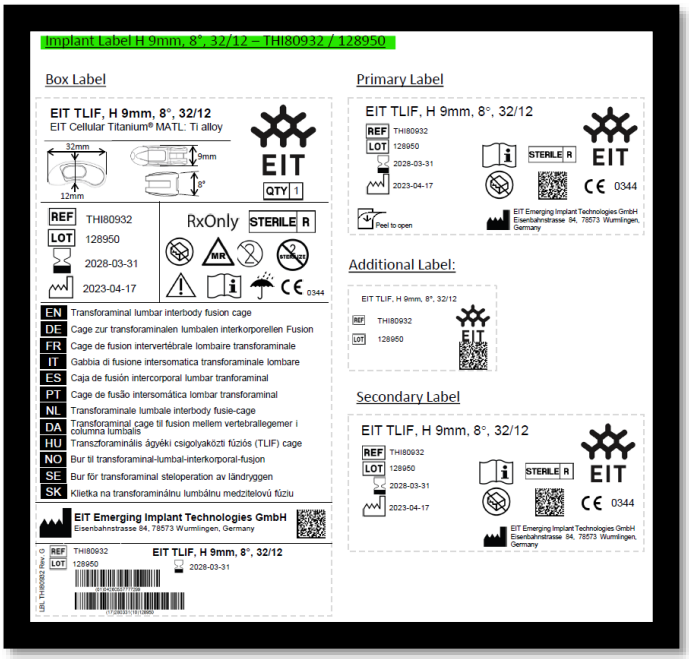
Thank you for your attention and cooperation.

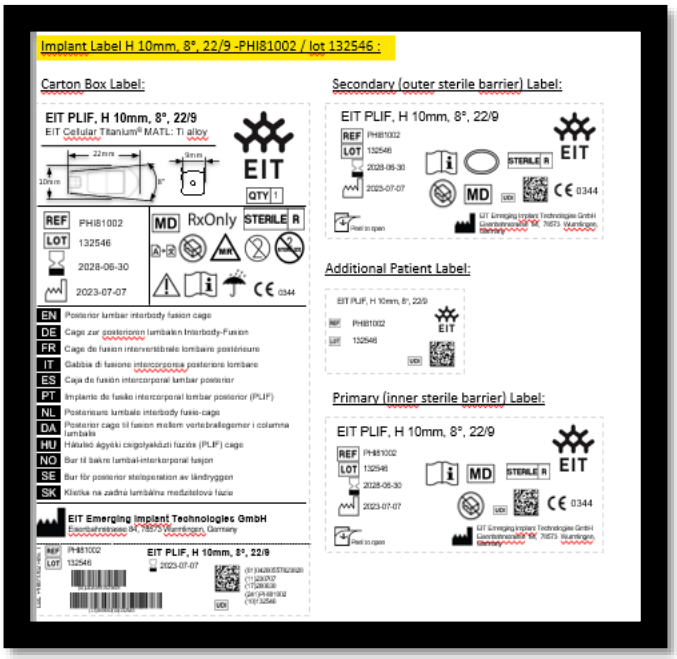
Sincerely,

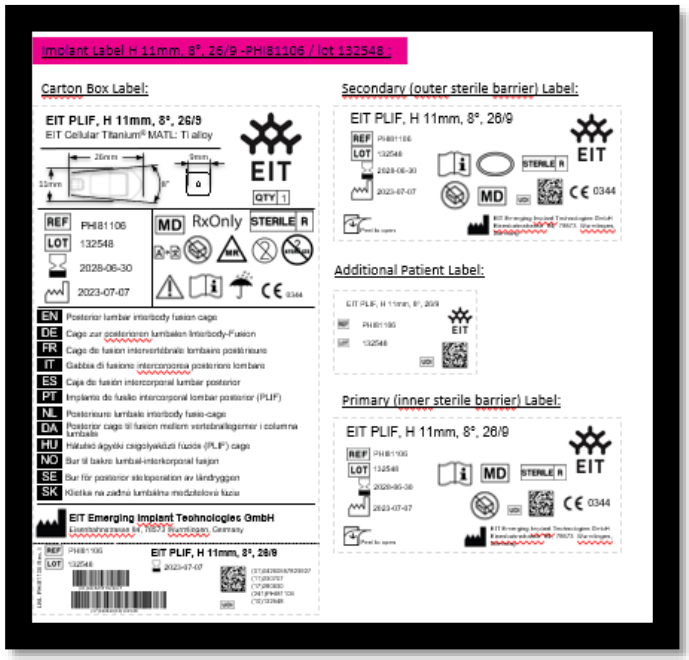
Mona Rehmatullah
Recall Coordinator
Email: OneMD-Field-Actions@its.jnj.com

Identification of the Impacted Product









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☐ **The subject product has been located. A copy of this notice is being retained and I have read and understood the notification. RETURNED Quantity:_____**

☐ **None of the subject product is available for return. A copy of this notice is being retained and I have read and understood the notification.**

Please complete this Business Response Form (BRF) Form within 3 days after the receipt of this notification. Rreturn this form via email to (enter country contact).

- Complete the attached Business Response Form even if you do not have the subject products on hand.

Your Name/Title:	Facility/Business Name:
Signed*:	Date:
Address:	
Account Number:	
Returned Authorization Number	
J&J Sales Rep (as applicable):	
Email Address:	Telephone Number:
Comments (if any):	
**Your signature provides confirmation that you have received and understood this notification.*	