August 12, 2016

To: **Hospitals and Surgeons**

Subject: **URGENT FIELD SAFETY NOTICE - REMOVAL**

FSN/FSCA: **FA 2016-09**

Affected Product: Dynesys pedicle Screw + Set Screw, 6.0x35

Material: 01.03760.035

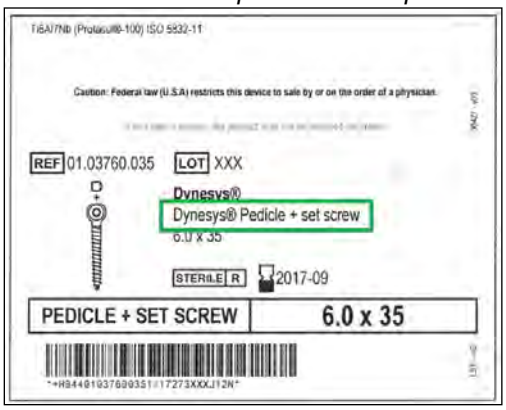
Batches: 2832117, 2849705, 2854476, 2854477

Dear Sirs,

Zimmer GmbH is initiating a voluntary removal of 4 lots/ batches of Dynesys pedicle Screw, Size 6.0x35 that may be in your inventories. Please see above for the involved combination material number/ lot number.

It is identified that the product description on the labels contains incorrect information regarding the Hydroxy-Apatite Coating (HA). Indeed the information “HA” appears in the product description on the label but the product reference and the product inside are without HA coating.

***Picture 1**: incorrect product description*



***Picture 2**: correct product description*

Our records indicate that you may have received one or more of the affected products.

Risks

1) Due to erroneous description on the label, a slight delay might occur during surgery to get a new available product with correct label.
2) No harm is expected to the patient due to the erroneous information on the label.

Your Responsibilities

1. Review the notification immediately and ensure affected personnel are aware of the contents without delay.
2. Assist your Zimmer Biomet sales representative with the quarantine of any affected device.
3. Your Zimmer Biomet sales representative will remove the affected device, if any, from your facility.
4. Complete the Certification of Acknowledgement from (Attachment 1) and return to fieldaction.emea@zimmerbiomet.com.
5. **If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.**

Vigilance/ Reporting Information

This voluntary notification will be reported to the local Competent Authorities.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 or any relevant requirements to the local health authority in your country.

Please keep Zimmer GmbH informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at winterthur.per@zimmerbiomet.com, or to your local Zimmer Biomet representative.

Kind regards,

_____

[redacted]

ZIMMER BIOMET

Attachment 1
Certificate of Acknowledgement

FSN/FSCA: FA 2016-09

Affected Product: Dynesys pedicle Screw + Set Screw, 6.0x35

Material: 01.03760.035

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Please email or fax the completed form to your local Zimmer Biomet contact

Fax / Email _____ / _____

By signing below, I acknowledge that I have received and understand the content of the Urgent Field Safety Notice – Removal, and that the required actions have been taken in accordance with the notice:

1. Return parts in inventory
2. Fill the list below
3. Sign the form

Product reference	Quantity received	Quantity to return
Material: 01.03760.035		

☐ All parts received were implanted.

Printed Name: _____

Signature: _____

Hospital Name: _____

Hospital Address: _____

Phone Number: _____

Please maintain a copy of your completed form with your internal records.