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DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating Room Manager

13 October 2016

URGENT NOTICE:
MEDICAL DEVICE FIELD SAFETY NOTICE – FSN452014
FACET WEDGE: Instructions for Use (IFU) & Technique Guide

Instructions for Use (IFU)	IFU Number
FACET WEDGE, Instructions for Use	SE_463713
Technique Guide Description	**Technique Guide Number**
FACET WEDGE, Surgical Technique Guide	036.001.121

Dear Sir/Madam,

Synthes GmbH is initiating a Field Safety Notice for the Instructions for Use (IFU) and Surgical Technique Guide for the FACET WEDGE System.

Our records indicate that you may have inventory that is impacted by this Field Safety Notice.

Reason for this Field Safety Notice:

This Field Safety Notice is being issued in order to communicate changes being made to the Instructions for Use (IFU) and Surgical Technique Guide in order to clarify the intended use of the FACET WEDGE device. The intended use section is being updated to remove stand-alone use of the FACET WEDGE device and clarify multi-level use. In addition, further clarification is being added to the indications section in regards to Pseudarthrosis.

The revised IFU and Surgical Technique Guide contain the following clarifications:

Section	Current	Revision
Intended Use	FACET WEDGE is intended for the fixation of the spine as an aid to fusion through immobilization of the facet joints, with or without bone graft, at single or multiple levels, from L1 to S1. FACET WEDGE can be inserted minimal invasively either to augment other fusion techniques or as a stand-alone device for cases without segmental instability.	FACET WEDGE is intended for the fixation of the spine as an aid to fusion through immobilization of the facet joints, with or without bone graft, at one or two levels, from L1 to S1. FACET WEDGE can be inserted minimal invasively and should only be used to augment other fusion and stabilization techniques.
Indications	– Pseudarthrosis post anterior instrumentation	– Pseudarthrosis post anterior fusion with intact instrumentation

Please note that there has been no change to the design or manufacture of the FACET WEDGE implants or instruments. This Field Safety Notice impacts information in the IFU and Technique Guide only.

Clinical Implications:

A Post Market Clinical Study conducted for the FACET WEDGE system determined that patients implanted with stand-alone FACET WEDGE devices may potentially display signs of radiological non-fusion. Please note that there have been no confirmed complaints of patient harm associated with stand-alone use of FACET WEDGE devices to date. For patients with stand-alone FACET WEDGE devices implanted, there is no recommendation for prophylactic removal. Patients should be monitored in accordance with standard practice for the FACET WEDGE treatment process.

Please be advised that the above referenced updates to the IFU and Surgical Technique Guide documents are currently being implemented by Synthes. The updated IFU document will be included with FACET WEDGE implants under document ID SE_463713 Revision AE and the Technique Guide will become available at www.synthes.com under document ID DSEM/SPN/0816/0550. As we work to implement the IFU updates in our inventory, please note that there have been no updates made to the design or manufacture of these instruments. This Field Safety Notice impacts information in the IFU document and Surgical Technique Guide only.

Customer immediate actions:

1. Review the revisions being made to the Instructions for Use (IFU) and Surgical Technique Guide.
2. Forward this notice to anyone in your facility that needs to be informed.
3. If any of the affected IFU documents or Technique Guides has been forwarded to another facility, contact that facility to inform them of revisions.
4. Maintain awareness of this notice until all IFU documents and Technique Guides have been updated.
5. Keep a copy of this notice.

Applicable Regulatory Agencies have been notified.

We apologize for any inconvenience that this Field Safety Notice may create and appreciate your attention to this matter. Should you have any inquiries, please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

Synthes GmbH

Anne Brisson
Senior Manager, Product Safety and Performance

Michael Jacene
Director, Quality Systems

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Please note that there has been no change to the design or manufacture of the FACET WEDGE implants or instruments. This Field Safety Notice impacts information in the IFU and Technique Guide only.

____ We acknowledge the receipt of this information but do not have Synthes Spine FACET WEDGE devices within our stock at this facility.

____ We acknowledge the receipt of this information and currently have Synthes Spine FACET WEDGE devices within our stock at this facility.

Name/Title (please print): _____

Address: _____

Phone Number: _____

Signature and Date: _____

Please complete and return this page your local DePuy Synthes sales organization.