



Urgent Field Safety Notice

EIT Cellular Titanium® Lumbar Interbody Fusion Cage: PLIF Shaver (PET1XX00)

FSN 2015-P-001

Information on safe use of PLIF shaver

Date: June 12, 2015
Attn: EIT PLIF distributors and surgeons
Regarding: PLIF shaver

The following devices are the subject to this field safety notice:

REF	Description	LOT
PET10700	Shaver, H 7 mm	All
PET10900	Shaver, H 9 mm	All
PET11100	Shaver, H 11 mm	All
PET11300	Shaver, H 13 mm	All
PET11500	Shaver, H 15 mm	All

Description of the problem:

EIT has received customer complaints that the PLIF Shaver has broken during surgery. Each complaint was for the head of the Shaver breaking by one of the notches.

The preliminary investigation has determined that the surgeon can apply force that exceeds the device strength. Specifically, the surgeon can apply bending forces when the Shaver is used with the PLIF Straight Handle (PET00910) and torque forces when the Shaver is used with the PLIF T-Handle (PET00920) that exceed the capability of the Shaver (PET1XX00).

If the Shaver head breaks, care must be taken in removing the broken device to avoid damaging the anatomy. Further, there may be a delay in completing the surgery when the surgeon retrieves the broken piece of the device (if applicable) from the patient.

Advice on action to be taken by the user:

To avoid failures of the Shavers, do **not** use large bending or torque forces when using the Shaver with either the PLIF Straight Handle, or the PLIF T-Handle.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization. In addition, your cooperation in communicating this Field Service Notice to your PLIF set users is highly appreciated.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

EIT Emerging Implant Technologies GmbH, Heubergweg 8, D-78532 Tuttlingen
T +49 (0) 7461 17169-00, F +49 (0) 7461 17169-09, info@eit-spine.de, www.eit-spine.de

Bank Details: Kreissparkasse Tuttlingen, Account: 8564885, IBAN: DE62 6435 0070 0008 5648 85, BIC/SWIFT: SOLADES1TUT
USt-IdNr: DE815490026, Amtsgericht Stuttgart: HRB-Nr: 748370, General Manager: Stephanie Eisen



Contact reference person:

EIT Emerging Implant Technologies GmbH
Heubergweg 8
78532 Tuttlingen
Germany

Regulatory information

[REDACTED]
Director QA / RA
T: +49 (7461) 171 69-00
[REDACTED]

Medical information

[REDACTED] MD PhD
VP Marketing & Research
T: +31 [REDACTED]
M: +31 [REDACTED]

Regulatory notification:

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency(ies).

Signature

[REDACTED]

EIT Director Quality Assurance / Regulatory Affairs