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AEB sind einzusehen unter:
www.silony-medical.com/aeb

Silony Medical GmbH · Leinfelder Straße 60 · 70771 Leinfelden-Echterdingen

To:

SCFA Number: 2018001-1 **SCFA Class: 3** **Date: 21.03.2018**

URGENT SAFETY INFORMATION

1. Identification of affected medical devices	
Article-No. and article description:	**VI-2442 T25 Torque Limiter 10Nm, Org.**
LOT-No.:	**All batches**
Total number of items:	
Supplied with delivery note No	--
Supplied on:	--
2. Description	
Description of the problem of the medical device and the cause:	When using the torque limiter, make sure that they trigger (click). For safety, the tightened screw should be tightened repeatedly. Furthermore, pay attention to the rod length and make sure that they are not too tightly clamped in the screw head. This was not considered in an incident.
Risk assessment for the patients, users and third parties:	If the torque limiter is not fully triggered there is a risk of a too loose screw-rod system in the patient. This can lead to the release of the system after some time. A too tightly clamped rod in the pedicle screw head can cause the screw head to lead to tilting and thus loosening of the screw rod system with slight slippage of the rod.

3. Safety Corrective Field Action	
Safety Corrective Field Action to be conducted:	**Change of the IFU of the affected medical devices.**
Details on Safety Corrective Field Action:	Due to an incident, we would like to point out the following information that we would like to include in our surgical technique. • Note: We recommend ensuring a correct screw seat by repeatedly tightening with the torque limiter. Confirmation by two clicks. • Note that the rod ends protrude 3 to 5mm beyond the last pedicle screw head. The 10-Kant must be completely visible. If necessary, a new bar length must be selected.

Please consider the following:

- Please read this safety information carefully and please send the Reply form **within 24 hours** via Fax to: +**49711-78 25 25 11**
- **Immediate stop of use!** To avoid further hazards to patients, users or third parties, you are obliged to stop the use of all affected medical devices until you have completed the implementation of the safety corrective field action described.
- Please inform all affected employees.
- If you gave the products to third parties, please forward a copy of this safety information and all attachments or inform the contact person indicated below.
- If an affected patient needs to be informed, please forward a copy of this safety information and all attachments.

We thank you kindly for your support. If you have any questions or concerns, please contact me under +49176- 80 31 26 58 or via mail to byilmaz@silony-medical.com.

Kind regards

_____

Date, Signature Safety Officer

Reply

Important Safety Information (Information on a Recall) by Silony Medical

Hospital address:	

Stock in hospital

Please check your stock for affected medical devices and please fill out this form completely. Also if you have already consumed all affected products.

Article number:	**LOT No.:**	**Current stock count:**	**Number of affected medical devices already implanted:**	**Sent back to Silony Medical?**

Confirmation

I have understood the safety information. The actions described in this document have been taken.

I confirm that we have checked our stock and we have secured the affected products.

There are no further affected medical devices in our inventory.

If medical devices need to be send back to the manufacturer, please arrange the pick-up of those devices.

Please reply on the day after receiving the recall at the latest via Fax to +49711-78 25 25 11!

Hospital / Retailer:		Place, Date:
Name in Block Letters:	Position:	Signature: