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

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

FSCA Number: 2022-001 FSCA Class: 1

Date: 14th February 2022

URGENT SAFETY INFORMATION

1. Identification of affected medical devices	
Article-No. and article description:	S-VI-6500 VERTICALE SI Cement Kit VI-6510 VERTICALE SI Cement Adapter VI-6700.2 VERTICALE SI Screw Driver Outer Sleeve VI-6700.3 VERTICALE SI Screw Driver shaft
LOT-No.:	

Article number	Affected LOT(s)
S-VI-6500	001IN1220
VI-6510	053WS1119 053WS1119 140WS0121
VI-6700.2	798504IN0120 798403IN0120 023901IN0421 024001IN0421
VI-6700.3	29875IN0120 29872IN0120 798404IN0120 798505IN0120 971303IN0121

GTIN:	S-VI-6500: 4054896058276 VI-6510: 4054896056319

	VI-6700.2: 4054896058221 VI-6700.3: 4054896061139
2. Description	
Description of the problem of the medical device and the cause:	We suspect a design error of the product: The thread design of the sleeve (VI-6700.2), which is needed for the cement augmentation of the screw, is very fine (M7x0.5). This can lead to jamming/ canting of the thread of the screw to be implanted. Removal of the sleeve is thus made more difficult or removal is not possible. If the sleeve cannot be removed, the screw would have to be removed and reinserted.
Risk assessment for the patients, users and third parties:	If the sleeve cannot be removed, the implant is removed at the same time as the sleeve is pulled out. This leads to a delay in the operating time and requires another implant to be inserted.
3. Safety Corrective Field Action	
Safety Corrective Field Action to be conducted:	Send all affected medical devices back to the manufacturer.
Details on Safety Corrective Field Action:	See next pages

Please consider the following checkboxes if performed:

☒ Please read this safety information carefully and please send the Reply form within 24 hours via Fax to:

+49 711 78 25 25 11
sba@silony-medical.com

☒ Please inform all affected employees about this urgent safety information.

☒ 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.

Please consider, in case of a Safety Corrective Field Action is defined as "Send all affected medical devices back to the manufacturer":

☒ 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 return all affected products immediately to the following address:

Silony Medical Europe GmbH
FSCA Nummer: 2022-001
Leinfelder Strasse 60
70771 Leinfelden-Echterdingen
Germany

The returned products will be replaced by new products. Silony Medical GmbH will immediately take appropriate measures to avoid a recurrence of similar deviations.

We thank you kindly for your support. If you have any questions or concerns, please contact our Safety Officer under +49 711 78 25 25 0 or via mail to sba@silony-medical.com.

Kind regards

[redacted]

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:

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 returned 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 +49 711 78 25 25 11 or by mail to sba@silony-medical.com

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