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

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

To:

FSCA Number: 2020-001 FSCA Class: 1

Date: 13th November 2020

URGENT SAFETY INFORMATION

1. Identification of affected medical devices	
Article-No. and article description:	**RI-1342** **ROCCIA Hooked Implant Driver**
LOT-No.:	**40490MP0214** **41633MP0215** **41797MP0515** **43051MP0316** **43332MP0516**
GTIN:	**04054896002514**
Single Registration Number (SRN):	**n/a**
Total number of items:	
Supplied with delivery note No.:	

Supplied on: (Date)	
2. Description	
Description of the problem of the medical device and the cause:	**In case of high force exposure, it can happen that the hook of the impact instrument breaks and remains in the intervertebral disc compartment of the patient. The instrument is not intended for permanent stay in the patient.**
Risk assessment for the patients, users and third parties:	**Since the material is not qualified and approved as an implant, we do not have any information regarding long-term biocompatibility.**
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**
- ☒ 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: **2020-001**
An der Weide 27
28195 Bremen
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

_____

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:**

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

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