31.05.2023

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**Urgent Field Safety Notice**

**regarding**

Grip Module V2.0, 5-times-use for Morzellator System

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| **Originator:** | TROKAMED GmbH<br>Kleine Breite 17<br>78187 Geisingen<br>Germany |
| **Recipient:** | Users, operators and distributors of the product |
| **Identification of affected medical devices:** | Name: Grip Module V2.0, 5-times-use for Morzellator System<br>Item Code: 02-33117<br>Lot/Batch Numbers:<br>147271, 147637, 148308, 148312, 148549, 148550, 148720, 148721, 149159, 149839, 150466, 151941, 151969, 152362, 152464, 152471, 152753, 152837, 153071, 153072, 153073, 154158, 154195, 154951, 155368, 155630<br>This product is a reusable instrument for a maximum of five applications. |
| **Description of the problem including the identified cause:** | Problem:<br>In rare cases, the Cutting Module may continue to rotate even though the activation switch on the Grip Module has been released.<br><br>Cause:<br>The problem is due to a faulty switch function. The contact distances of the switch may be too small.<br><br>Risks:<br>When the product is used as intended, the Cutting Module is covered by the Protection Sleeve while not morcellating tissue.<br>Only during morcellation, the Cutting Module is extended out of the Protection Sleeve by 1 mm. This is done solely under the surgeon's vision.<br>A Cutting Module rotating in the Protection Sleeve is not a risk of injury to patients, users or third parties.<br>The limited functionality of the Grip Module could cause a change in operating room procedures and thus lead to a delay in surgery.<br>To date, we have not received any reports of patient harm attributable to the circumstances described. |

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| **What measures are to be taken by the recipient?** | • *Inform the medica! personnel using the product about the problem as well as the safe use of the product:*<br>▸ *Always follow the directions in the Instructions for Use for the correct use of the "CUT - NO CUT" adjustment ring.*<br>▸ *Use the toot switch for activation for the batches mentioned.*<br>▸ *If you nevertheless use the manual switch for the mentioned batches and if the cutting module continues to rotate after releasing the activation switch, then proceed as follows:*<br>o *Immediately set the adjustment ring to the "NO CUT" position.*<br>o *Disconnect the control cable of the Grip Module trom the Control Unit.*<br>o *To continue the operation, use the Foot Pedal to activate the cutting function of the affected Grip Module or use another Grip Module.*<br>• *File a copy of this letter in an easily accessible location with the product's Instructions for Use.*<br>• *Complete the enclosed acknowledgement of receipt and send it to the specified email address by 15.06.2023.* |

**Disclosure of the information described herein:**
*Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this* **Urgent Field Safety Notice.** *If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.*

*Please keep this information at least until the action has been completed.*

*The Federal Institute for Drugs and Medica! Devices in Germany (BfArM) has received a copy of this Urgent Field Safety Notice.*

*We apologize for any inconvenience this may cause you. If you have any questions or concerns about this notification, please contact the person below.*

## Acknowledgement of receipt/ Confirmation that the specified measures have been carried out by the user/operator.

## Send as PDF to: Alexander.Wolff@Trokamed.de

Please complete and return this letter by 15.06.2023.

☐ We do not have any affected items in house.

☐ We have the following items in the house:

| Item Code | Batch | Quantity |
|---|---|---|
| 02-33117 | | |
| 02-33117 | | |
| 02-33117 | | |
| 02-33117 | | |
| 02-33117 | | |

**Please do not return any affected goods to us unrequested!**

We hereby confirm that we have taken note of this urgent safety information and will follow the measures specified on page 2.

Company/Hospital: _____

Address: _____

_____

Name: _____

Position: _____

Date: _____

Signature: _____