

31.05.2023

Urgent Field Safety Notice

regarding

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

Originator:	TROKAMED GmbH Kleine Breite 17 78187 Geisingen 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 Item Code: 02-33117 Lot/Batch Numbers: 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 This product is a reusable instrument for a maximum of five applications.
Description of the problem including the identified cause:	<p><u>Problem:</u> In rare cases, the Cutting Module may continue to rotate even though the activation switch on the Grip Module has been released.</p> <p><u>Cause:</u> The problem is due to a faulty switch function. The contact distances of the switch may be too small.</p> <p><u>Risks:</u> When the product is used as intended, the Cutting Module is covered by the Protection Sleeve while not morcellating tissue. 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. A Cutting Module rotating in the Protection Sleeve is not a risk of injury to patients, users or third parties. The limited functionality of the Grip Module could cause a change in operating room procedures and thus lead to a delay in surgery. To date, we have not received any reports of patient harm attributable to the circumstances described.</p>

<p>What measures are to be taken by the recipient?</p>	<ul style="list-style-type: none"> • Inform the medical personnel using the product about the problem as well as the safe use of the product: <ul style="list-style-type: none"> ➤ Always follow the directions in the Instructions for Use for the correct use of the "CUT - NO CUT" adjustment ring. ➤ Use the foot switch for activation for the batches mentioned. ➤ 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: <ul style="list-style-type: none"> ○ Immediately set the adjustment ring to the "NO CUT" position. ○ Disconnect the control cable of the Grip Module from the Control Unit. ○ To continue the operation, use the Foot Pedal to activate the cutting function of the affected Grip Module or use another Grip Module. • File a copy of this letter in an easily accessible location with the product's Instructions for Use. • Complete the enclosed acknowledgement of receipt and send it to the specified email address by 15.06.2023.
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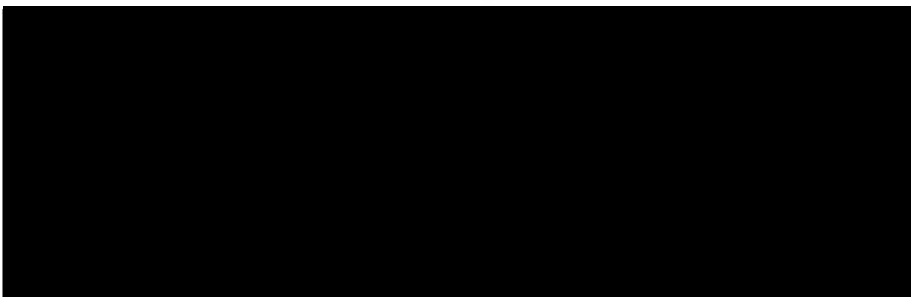
Disclosure of the information described herein:

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 Medical 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.



2023_VIG_105233_Morcellator

**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: _____