

Kunde

**Field Safety Notice**  
for a corrective action in the field  
**- Recall -**

Tuttlingen, June 3<sup>rd</sup>, 2020

Reference number: 18044-23  
Address: Users, operators, distributors

**Identification of the medical devices concerned:**

Product category: Instrument  
Trade name: DeBakey needle holder 23 cm  
Product/article no.: 18044-23  
Lot numbers: 8170368 and 8180673  
Delivery No. **11801813 of September 05, 2018, 10 pcs. (Lot 8170368)**

Dear customer,  
we hereby inform you of a recall regarding the DeBakey needle holder 23 cm as well as the potential cause and the corrective measures to be taken in this connection.

**Description of error**

DUFNER has been made aware that the tungsten carbide plate, which is intended to hold the sewing needle securely, can break when holding the sewing needle under pressure. This can happen with instruments of the two lot numbers listed above. Since the fragment of the broken hard metal plate can remain in vivo in unfavorable cases, DUFNER has decided to recall the product from the market due to this risk.

**Patient risk:**

A breakage of the tungsten carbide plate can lead to:

- impairment or injury to the tissue in the patient's operating field
- a re-operation due to remaining fragments of the tungsten carbide plate
- damage to soft tissue due to fragment removal
- delays/extensions of the operation time

**Please take the following measures immediately:**

1. Immediately remove all products of the affected article number with the named lots from your warehouse or from affected instrument trays to prevent further use.
2. With this letter you will receive a confirmation form, please fill it in completely, sign it and send it back to us after receiving this information. If you do not own any affected products, please fill out the confirmation form **anyway** and fax it to +49 (0)7461/79419 or mail it to [d.moehrle@dufner-tuttlingen.de](mailto:d.moehrle@dufner-tuttlingen.de).
3. Send back to us immediately all products still in stock. After receipt of the goods we will send you a credit note and clarify with you the further procedure.
4. Pass this information on to all staff in your institution, who should be informed.
5. If one of the listed products has been forwarded to another institution, please contact them so that they can return the goods to us

**Forwarding of the corrective action:**

Please ensure that all users of the affected products within your organization and also all other affected persons receive this information through the Field Safety Notice. If products have been passed on to third parties, please also send them a copy of the Field Safety Notice or inform our contact person to contact the third parties.

Please retain this information until all affected products have been returned to us.

The national authorities will be informed of this FSNA. The Federal Institute for Drugs and Medical Devices has received a copy of this Field Safety Notice.

**Contact person:**

Please contact us if you have any questions:

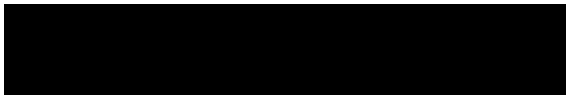
DUFNER Instrumente GmbH  
Fabrik für ärztliche Instrumente  
Föhrenstraße 9  
78532 Tuttlingen  
Germany

Safety officer for medical devices  
Dietmar Möhrle  
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Tel. +49 (0)7461/3697

We apologize for the inconvenience caused by this product recall and thank you in advance for your kind assistance. Should you have any questions regarding the execution of this recall, please contact your local DUFNER sales representative.

Many thanks for your cooperation.

Yours sincerely,



DUFNER Instrumente GmbH

## Confirmation form for recall regarding

Product category: Instrument  
Trade name: DeBakey needle holder 23 cm  
Product/article no.: 18044-23  
Lot numbers: 8170368 and 8180673

Please return this form to us immediately by fax or e-mail, even if you no longer have any stock of the listed product.

- ☐ There is no longer any stock of the product concerned. In the column "Quantity returned in pieces" this was noted with the quantity 0.
- ☐ We acknowledge receipt of this information. There is still stock of the product concerned.

Please enclose this confirmation form with the return shipment.

Product description	LOT-No.	Returns quantity in pieces
DeBakey Needle holder 23 cm	8170368	
DeBakey Needle holder 23 cm	8180673	

We hereby confirm the complete audit of our inventories:

Institution: \_\_\_\_\_

Name in print/function: \_\_\_\_\_

Phone number: \_\_\_\_\_

Signature/date/stamp: \_\_\_\_\_

Please return this confirmation form to one of the following addresses:

fax number: +49 (0)7461/79419

e-mail: d.moehrle@dufner-tuttlingen.de

Postal address: DUFNER Instrumente GmbH, Föhrenstraße 9, 78532 Tuttlingen