

Department: Customer Service  
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Your ref. • Your message dated • Our ref. VKK/mu-jes • Date xx.xx.2015

### **Urgent Safety Information**

#### **Safety measure concerning Morcellator Angle Hand Piece 8307011**

##### **Addressees:**

Users, operators, distributors

##### **Identification of medical products concerned:**

Morcellator hand piece, product no. **8307011** for Morce Power Plus.

##### **Description of problem:**

Ladies and Gentlemen,

A modification to the angle handpiece with the target of simplifying the handling during system assembly by reducing the number of components, resulted in an incompatibility with the cutting tube nuts of versions V1 and V2.

Due to the missing thread in the area of the sealing cap holder, it is no longer possible to fasten the cutting tube nuts, versions V1 and V2, for fastening the cutting tube in conjunction with sealing units 83075011 and 83075021.

If contrary to our expectations the modified angle hand piece without thread is used (which will not provide the possibility of fastening the cutting tube nuts, versions V1 and V2, in conjunction with sealing units 83075011 and 83075021), a fastening of the cutting tube is not guaranteed. When applied, the cutting tube will not cut because it will be pushed back manually into the sheath of the trocar sleeve in an uncontrolled manner.

##### **Measures to be taken by the addressee:**

The product can still be used. Due to the design without a thread in the area of the sealing cap holder (inner sleeve with three grooves), for fastening the cutting tube it is absolutely necessary to use the optimized sealing units (optional Ø 12-15 mm, item no. 643301131/1130 as well as Ø 20 mm item no. 643301132/0856/0861). This allows the use without the cutting tube nuts of versions V1 and V2. If necessary you will get one sealing unit each as a free-of-charge replacement.

Together with this letter you also receive an updated manual which replaces the previous version.

For verification management purposes with regard to this **urgent safety information**, please return the enclosed reply form to our fax no. **+49 7043 351360** by **April 24, 2015**. Please mark on the form whether you need a sealing unit, and if so, what type.

Please keep this information at least until the measure is completed.

**The information described here must be passed on as follows:**

Please make sure that in your organization all users of the aforementioned products and all other persons to be informed gain knowledge of this urgent safety information.

If you have passed on the products to third parties, please also pass on a copy of this information to such third parties or inform our contact persons below.

**Measures taken by the manufacturer:**

This urgent safety information will be sent out to all customers concerned by April 10, 2015. Together with this safety information the changed manual will also be sent out.

The national authority in charge (*Bundesinstitut für Arzneimittel und Medizinprodukte* in Bonn) has been informed about this **urgent safety information**.

**Contacts:**

If you have any questions regarding safety please contact:

Herr Heiko Sailer  
Head of Quality Management and  
Safety Manager  
Tel.: ++49 7043 35 1108  
Fax: ++49 7043 93 0048  
E-Mail: heiko.sailer@richard-wolf.com

If you have technical questions please contact:

Herr Thilo Musikant  
Head of Customer Service and  
Repair Workshops  
Tel.: ++49 7043 35 4189  
Fax: ++49 7043 35 1360  
E-Mail: thilo.musikant@richard-wolf.com

We apologize for any inconvenience caused by the problem.

With best regards,

**Richard Wolf GmbH**

i.V. Heiko Sailer  
Leiter Qualitätsmanagement  
und Sicherheitsbeauftragter

i.V. Thilo Musikant  
Leiter Kundenservice  
und Reparatur-Werkstätten

Enclosure

# Response Fax

return by fax to +49 7043 35 1209

## Urgent Safety Information relating to the Morcellator Handpiece 8307011

We hereby confirm receipt of this **Urgent Safety Information**

Please provide us replacement free of charge (please tick):

83075011 Sealing unit complete with tissue and instrument seal  $\varnothing$  12/15 mm

83075021 Sealing unit complete with tissue and instrument seal  $\varnothing$  20 mm

Comment:

Customer

.....

Name

.....

Department

.....

Road

.....

Zip Code/City

.....

Tel./Fax

.....

Email

.....

Place/Date

.....

Signature/

Stamp .....

We would like to take this opportunity to thank you for your understanding and your cooperation.