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Urgent safety information

Jena, 29.04.2024

Re: O-ring replacement required for MultiCut Blade 400 and MultiCut Blade 350

Article	Art. No.	LOT *
MultiCut Blade 350	839-3200-000	5877, 5878
MultiCut Blade 400	839-3300-000	5458, 5619, 5620, 5621, 5622, 5623, 6832, 6834, 6840

* you can find the LOT number on each blade (laser marking).

The target group of this information are users (clinics, physicians) and distributors of MultiCut Blades.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Dear Sir or Madam,

Asclepion Laser Technologies GmbH, Brüsseler Straße 10, 07747 Jena, Germany, informs you with this letter that the replacement of an O-ring on the MultiCut Blades mentioned above is necessary in order to fully maintain the suction power of the blades.

Problem:

Since the beginning of 2024, we have received various feedback that the suction power of the MultiCut Blades can decrease during use.

MultiCut Blades are intended for use in transurethral mechanical morcellation and removal of adenoma after enucleation of the prostate. They are used in conjunction with the following Asclepion devices:

Art.	Art. No.
MultiCut Solo Morcellator	J19-3000-000
MultiPulse HoPLUS	J19-1181-000 J19-1150-000

Investigation:

A vacuum is required for suction in the blades. For this purpose, the blades must be sealed in the handpiece. Sealing is achieved by using an O-ring (Fig. 1). This seal is not sufficient under certain circumstances. This is due to the mechanical load on the blade caused by the simultaneous use of an endoscope. This acts selectively on the blade and can cause a mechanical effect. In these cases, the vacuum drops and the suction power decreases.

Only the above-mentioned lots are affected.

The O-ring is located on the part of the blade that is attached to the handpiece:



Figure 1

A surgery can also be completed with reduced suction power. The associated extension of the operation time increases the likelihood of side effects occurring during the surgery. The patient's recovery time may be negatively affected.

There are no further risks for users or patients.

Necessary actions:

Replacing the O-ring

The O-ring responsible for the seal (2 mm) must be replaced with another (2.2 mm). This can be done very easily by the user or distributor, a technician is not required. Detailed instructions can be found below.

Please only use the O-rings enclosed with this letter. If you have not received any O-rings or the quantity received is not sufficient, please inform us at vigilance@asclepion.com. We will then send you O-rings immediately.

The replacement must then be carried out immediately in accordance with the following instructions:

1. Carefully remove the existing O-Ring (thickness: 2mm) marked in the Figure 1. Tweezers or a screwdriver may assist in extracting the ring from the groove (Figure 2 and Figure 3).



Figure 2



Figure 3

2. Install the new thicker O-ring into the groove. Ensure the ring fits securely into place within the groove (Figure 4 and Figure 5).

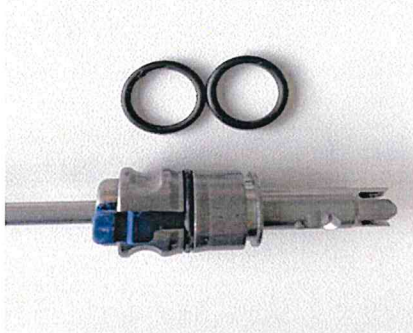


Figure 4



Figure 5

The thicker O-Ring will effectively prevent suction losses that may have been experienced with the specified batches during treatment. This replacement will not impact the pluggability of the blades into the handpiece.

Disposal of the replaced O-ring

The replaced O-ring must be disposed to prevent accidental reuse.

Other

The actions must be carried out before any further operation is performed on one of the affected blades.

Please complete the response form attached and return it to us after the procedure has been carried out. This is necessary so that we can monitor the implementation of the measures.

We apologize for any inconvenience caused by this measure.

If you have any questions, please get in touch with the following contact persons in our company:

Ekaterina Weiß
Product Management Surgery
Tel: 0049 3641 7700 305
E-Mail: ekaterina.weiss@asclepion.com

or

Christiane Hildebrandt
PRRC
Tel: 0049 3641 7700 252
E-Mail: christiane.hildebrandt@asclepion.com

Kind regards,

Christiane Hildebrandt
PRRC

Ekaterina Weiß
Product Management Surgery

Enclosure: Response form

Response form for a security measure

I am	User	<input type="checkbox"/>	Distributor	<input type="checkbox"/>
Name				
Address				
Contact person				
Titel/Function				
Phone				
E-Mail				

Please indicate below which measures have been completed.	
<input type="checkbox"/>	I have received, read and understood the contents of the Urgent Safety Information.
<input type="checkbox"/>	The information and the associated measures have been brought to the attention of all affected users.
<input type="checkbox"/>	The O-rings of the affected products have been replaced.
<input type="checkbox"/>	The replaced O-rings were destroyed.
<input type="checkbox"/>	There are no affected products in our company.
Name:	
Sign:	
Date:	

Please return the completed form to us by 15.05.2024 either in written form to
Asclepion Laser Technologies GmbH

Christiane Hildebrandt
Brüsseler Straße 10
07747 Jena
Germany

or scanned by e-mail to
vigilance@asclepion.com