



Name
Chairman of Medical Board/Head of Department
Name of Organisation
Address

Urgent safety information
Updating the instructions for use
for
C-MAC® video laryngoscopes

October 21, 2019

Sender:

Karl Storz Endoskope SE und Co. KG, Dr.-Karl-Storz Strasse 34, D-78532 Tuttlingen, Germany

Addressee:

All users and operators

Identification of the medical products concerned:

8403AX	C-MAC® video laryngoscope MAC #3
8403AXC	C-MAC® video laryngoscope MAC #3
8403BX	C-MAC® video laryngoscope MAC #4
8403BXC	C-MAC® video laryngoscope MAC #4
8403DXC	MILLER C-MAC® video laryngoscope #0
8403EXC	C-MAC® video laryngoscope MAC #0
8403GXC	MILLER C-MAC® video laryngoscope #1
8403HX	C-MAC® video laryngoscope D-BLADE
8403HXX	C-MAC® video laryngoscope D-BLADE
8403HXP	C-MAC® video laryngoscope D-BLADE
8403KXC	C-MAC® video laryngoscope MAC #2
8403MXC	C-MAC® video laryngoscope MILLER #2
8403NXC	C-MAC® video laryngoscope MILLER #3
8401AX	C-MAC® video laryngoscope #3
8401AXC	C-MAC® video laryngoscope MAC #3
8401BX	C-MAC® video laryngoscope MAC #4
8401BXC	C-MAC® video laryngoscope MAC #4
8401DXC	MILLER C-MAC® video laryngoscope #0
8401GX	C-MAC® video laryngoscope MILLER #1
8401GXC	MILLER C-MAC® video laryngoscope #1
8401HX	C-MAC® video laryngoscope D-BLADE
8401HXP	C-MAC® pediatric video laryngoscope D-BLADE
8401KXC	C-MAC® video laryngoscope MAC #2



Description of the problem including the identified cause:

KARL STORZ Endoskope is aware of cases in which the cover glasses of the camera and/or the LED lighting on the video laryngoscopes were no longer present after reprocessing. There are no known cases involving patients.

There is a risk that unnoticed damage to the cover glasses could cause them to come loose during use.

What measures are to be taken by the addressee?

Please read this safety information carefully and forward it to the appropriate places in your organization.

Destroy the outdated manuals for the C-MAC® video laryngoscope.

Replace the operating instructions with the updated version (download via <https://www.karlstorz.com/de/en/media-library.htm> 96076011EN for C-MAC® 8401XX and 96076019EN for C-MAC® 8403XX). A printed edition is available on request.

Train your employees on the new instructions for use, especially chapter 5.1 and the validated reprocessing procedures, as well as the approved chemicals – chapter 7

Fill in the attached reply and return it to KARL STORZ Endoskope. This confirms that all old instructions for use have been destroyed and that the personnel have been trained in the new instructions for use.

No further treatment is required for treated patients.

If you have carefully checked the laryngoscope before and after use according to the old instructions for use, there is no danger for the patients/users/third parties.

Passing on the information described here:

Please ensure in your organization that all users of the above products and other persons to be informed are aware of this **Urgent Safety Information**. If you have passed the products on to third parties, please forward a copy of this information or contact the person listed below.

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

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

Contact person:

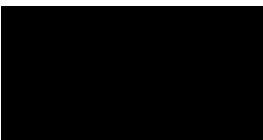
Robert Herz

Karl Storz Endoskope SE & Co. KG

Tel.: +49 7461 708 7348 (during business hours)

Fax: +49 7461 708 45581

Yours sincerely,



Karl Storz Endoskope SE & Co. KG



Feedback form

This is not a product recall – please do not return any products!

We hereby confirm that all instructions for use for the C-MAC® 8401 XX and 8403 XX video laryngoscope models have been destroyed or withdrawn from circulation. We also confirm that personnel have been trained on the updated instructions for use.

Please send this form to:

vigilance@karlstorz.com

or

Fax: +49 7461 708 45581

or by post to

KARL STORZ Endoskope SE und Co. KG

attn. Robert Herz

Dr.-Karl-Storz Strasse 34

D-78532 Tuttlingen, Germany

Hospital or organization (stamp):

I confirm that I have read and understood the safety information and that I have implemented it accordingly.

Name: _____

Title/position: _____

Signature: _____

Date: _____