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Denzlingen, 25-Jul-2018

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Urgent Safety Information

Corrective action: Recall of

Item No. 41.0609a.wol - Uretero-Renoscope, 7.5/10 Fr., L : 425 mm, lateral view, with instrument bridge

Item No. 41.0614a.wol - Uretero-Renoscope, 6/7.5 Fr., L : 425 mm, lateral view, with instrument bridge

Item No. 41.0630a - Nephroscope, 10/19 Fr., L: 220 mm, autoclavable

Recipients:

Users and operators of Uretero-Renoscopes with working channels 7.5/10 Fr. and 6/7.5 Fr. and of Nephroscopes with working channels 10/19 Fr., each with lateral view and detachable instrument bridge.

Identification of affected medical devices:

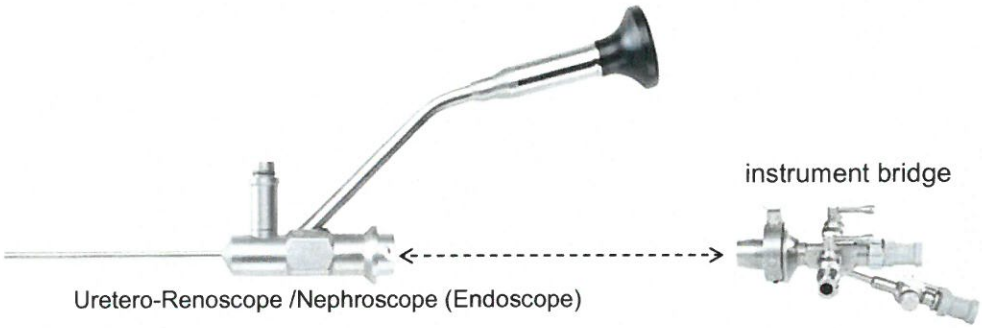

Figure 1: Exemplary illustration of Uretero-Renoscope /Nephroscope with detachable instrument bridge.

This recall concerns to the following item numbers of Uretero-Renoscopes /Nephroscopes, shown on the left-hand side in figure 1, with the following serial number ranges:

Item No.	Serial number ranges, boundary values included:
41.0609a.wol	from SN 834589 to SN 840993
41.0614a.wol	from SN 834705 to SN 842977
41.0630a	from SN 842193 to SN 842483

Table 1: Involved endoscopes and the corresponding serial number ranges.

The affected endoscopes can be identified by checking the laser marking direct on the main bodies of the endoscopes, shown in figure 2 and 3.

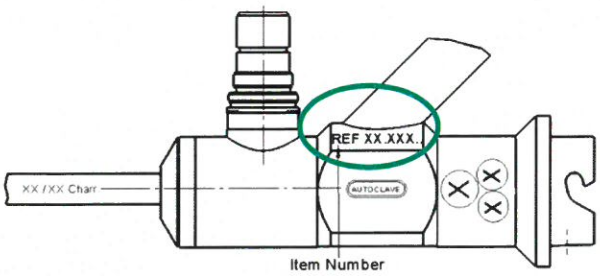

Figure 2: Position of item no. on the main body of Uretero-Renoscope/Nephroscope

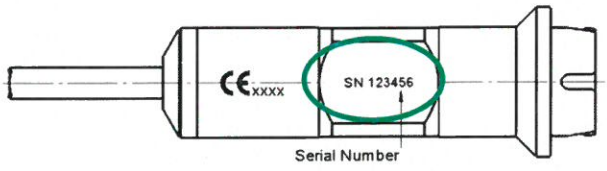

Figure 3: Position of serial no. on the main body of Uretero-Renoscope/Nephroscope

Description of the problem including the determined cause:

The locking mechanism of the detachable instrument bridge is not able to latch completely onto the corresponding interlock notch of the deficient endoscopes due to a mechanical manufacturing-fault at the main body of the endoscopes referenced above. An unintended detachment of the instrument bridge during the application of the referenced products with inserted instruments in a surgery could lead to unintended movements or breakage of the instruments.

In 90% of the applications, the failure of an incomplete latching of the bridge onto the corresponding interlock notch of deficient endoscopes can be detected during the functional test, which is mandated in the corresponding instructions for use.

To this day, no patient hazards or injuries have been noticed in correlation with this problem.

Which measures are to be taken by the recipient?

It is strongly recommended that users and operators of the endoscopes mentioned above immediately check if their own devices are involved in this corrective action under consideration of the affected serial numbers, mentioned above in table 1. Any identified Uretero-Renoscope /Nephroscope, which is included in the range of affected serial numbers, is not allowed to be used anymore and must be sent back using the below mentioned address.

Reconsignment to:	**SCHÖLLY FIBEROPTIC GmbH** Robert-Bosch-Strasse 1-3 79211 Denzlingen Germany

Afterwards, a flawless Uretero-Renoscope /Nephroscope will be sent back free of charge.

We apologize for the inconveniences in correlation with this measure and are grateful for your understanding and your cooperation.

Disclosure of the information described above:

Please ensure that all users of the above mentioned products and other individuals to be informed in your organization are aware of this “Urgent Safety Information”. Please forward a copy of this information or inform the contact person listed below if you have distributed the products to a third party.

Please keep this information on file at least until the action has been completed.

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

Please fill in the enclosed feedback form and send it to the contact person stated therein.

Contact persons:

Contact person for this safety information	**Contact person for technical questions**
SCHÖLLY FIBEROPTIC GmbH	**SCHÖLLY FIBEROPTIC GmbH**
Armin Träger	Johannes Bauer
Robert-Bosch-Strasse 1-3 79211 Denzlingen Germany	Robert-Bosch-Strasse 1-3 79211 Denzlingen Germany
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E-Mail: vigilance-2018-02@schoelly.de	E-Mail: vigilance-2018-02@schoelly.de

Best regards

SCHÖLLY FIBEROPTIC GMBH

[redacted]

[redacted]

We urgently ask you to fill out and sign the following form.
Please send it back by fax or e-mail to the attention of:

SCHÖLLY FIBEROPTIC GmbH
Armin Träger - Department QM | RA

Fax: +49 7666 908-385
E-Mail: vigilance-2018-02@schoelly.de

We thank you in advance for your support and cooperation.

Feedback form concerning the recall of

Uretero-Renoscope 41.0609a.wol | Uretero-Renoscope 41.0614a.wol | Nephroscope 41.0630a

Please mark the appropriate information and complete the following requests:

☐ We acknowledge the receipt of this safety instruction for our information.

☐ We do not use any of the involved endoscopes at our institution.

☐ The following endoscopes with corresponding serial-numbers are used at our institution and will be sent back immediately:

Item No.	Serial number(s)
41.0609a.wol	
41.0614a.wol	
41.0630a	

Information concerning the institution:

Name:	Complete address:

Information concerning the contact person of the institution:

Name:	Department:
Phone:	E-Mail:
Date:	Signature: /Stamp