

Address of the affected customer / user

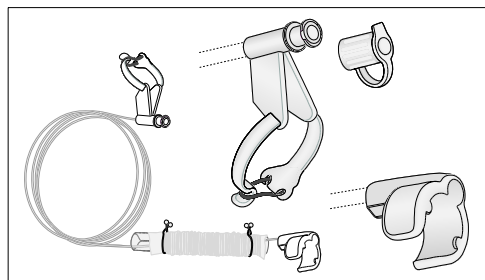
Ovesco Endoscopy AG
 Dorfackerstrasse 26
 72074 Tübingen/Germany

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 Fax +49 7071 965 28 260
 E-Mail info@ovesco.com
 www.ovesco.com

20.08.2018

Recall of AWC batch – Additional Working Channel with Ovesco-REF numbers:

- 200.57.01 AWC – Additional Working Channel
 Affected LOT numbers: 808916 and 809381
- 200.57.04 AWC – Additional Working Channel
 Affected LOT numbers: 808917 and 809382



Sitz der Gesellschaft:
 Tübingen

Handelsregister:
 Amtsgericht Stuttgart
 HRB 727 461

USt-IdNr.:
 DE 217051960

Vorstand:
 Prof. Dr. med. Marc O. Schurr
 Prof. Dr. med. Thomas Gottwald

Vorsitzender des Aufsichtsrats:
 Frank Ramsperger

Bankverbindung:
 Baden-Württembergische Bank
 SWIFT-BIC: SOLA DEST 600
 Konto 452 030 4
 IBAN
 DE62 6005 0101 0004 5203 04

Kreissparkasse Tübingen
 SWIFT-BIC: SOLADES1TUB
 Konto 109949
 IBAN
 DE43 6415 0020 0000 1099 49

Ladies and Gentlemen,

A routine quality check has shown that it may be difficult to use the AWC with instruments like forcepses. This obviously comes as a result of increased friction both alongside and at the tip of the AWC, especially when longer and thicker endoscopes are being used.

Neither patients nor users or third parties are or have been subject to any risks.

Because this product does not comply with the quality policy of Ovesco Endoscopy AG, all instruments of the above batches that have been delivered shall therefore be recalled as a precautionary measure.

Our records indicate that we have delivered the following Additional Working Channels to you:

| REF number | LOT number | Amount |
|------------|------------|--------|
| | | |

Thus we would ask you to no longer use the according instruments in order to avoid any inconvenience due to the above-mentioned issues.

Please send us these products together with the attached feedback form at your earliest convenience to the following address:

Ovesco Endoscopy AG
Customer Service
Pfrondorferstrasse 4
72074 Tübingen

In order to facilitate the return of the products, we will enable you to return the goods free-of-charge by sending you a prepaid shipping label.

Upon request, we shall transfer the purchase price for the returned goods immediately or offer you a replacement device in the coming weeks. We would like to inform you that we have taken appropriate measures in order to eliminate these difficulties.

Please accept our apologies for any inconvenience that our product or its recall may have caused you. If you have questions or need further information, please don't hesitate to call our Customer Service at the following number: +49 7071 96528-160, fax +49 7071 96528-260, email: service@ovesco.com. You may also contact our respective field service agent.

We thank you for your support and understanding.

Sincerely,

Matthias Leenen, M.Sc.
Head of Quality Management & Regulatory Affairs

Attachment

Attachement 1: Feedback form

FEEDBACK FORM

AWC – Additional Working Channel

Please send us this form per fax or email.

Customer Service Department

Fax: +49 707196528 260

Email: service@ovesco.com

- We no longer have the affected product on stock.

- We are returning affected products and would like to have:
 - Reimbursement of the purchase price
 - Replacement device

HOSPITAL _____ LOCATION _____

NAME _____ DEPARTMENT _____ PHONE _____

SIGNATURE _____ DATE _____