

medwork GmbH | Medworkring 1 | 91315 Höchstadt/Aisch

**Company**  
Name  
Address  
Postcode City

Our reference

CAPA 2020-001/FP4526

Date

27.02.2020

**Voluntary product recall "Stiefenhöfer ERCP-Cannula"**

**Urgent safety information**

For the attention of the representative for medical safety, quality management, purchasing, endoscopy

Dear Sirs,

medwork carries out a medical device recall for the following batch numbers of the Stiefenhöfer ERP-Cannula (product number CAN1-A6-18-200-35 / order number 502332) for single use.

A review of our records has shown that your facilities have received products from the affected batches. Please pay attention to the table in the appendix with the affected batches/lot numbers.

We have been informed by our customers that in rare cases the metal head will detach from the instrument during use. In all cases reported to us, the metal head was successfully recovered and there was no impairment of the patient's health. In principle, however, it is possible that stenoses, strictures or unfavourable anatomical conditions may make recovery more difficult.

As a reason for this, unfavourable mechanical properties of the plastic tube were identified, which reduce the holding force of the metal head on the tube.

Measures to be taken by the user:

1. Please stop using all recalled lot numbers listed in the attached table and remove all affected units from your inventory (material storage, endoscopy, central goods issue, receiving and shipping department or other relevant departments).

Put all affected units aside in a secure place for return to medwork.

2. Please forward this message to the medical staff of your institution, as well as to any other specialist institution to which the affected products have potentially been passed on.

3. Please fill out the attached customer reply form and send it to our customer service

By e-mail: [Contact@medwork.com](mailto:Contact@medwork.com)  
By fax: +49(0)9193 / 500 999

If you indicate that the product is being returned, our Customer Service will contact you to arrange the return. Please provide your contact details on the customer reply form.

4. Please return only the affected batches of the named product. You will receive a credit note upon receipt of the products.

5. If products of the mentioned batches have already been used, there is no risk for the patient and further measures are not necessary.


The competent authority in your country has been informed of this safety instruction.

If you have any questions or need help in implementing this safety instruction, please contact our Medical Devices Safety Officer:

Volker Schmitt  
Medworkring 1  
91315 Höchstadt/Aisch  
Germany  
[v.schmitt@medwork.com](mailto:v.schmitt@medwork.com)

We very much regret any inconvenience caused and thank you for your assistance in implementing this measure to ensure patient safety.

With kind regards  
medwork GmbH



Volker Schmitt  
- Head of Product Management -

#### Annexes

- A) List of affected batches / LOT numbers
- B) Customer reply form

**List of affected batches / LOT numbers****Voluntary product recall "Stiefenhöfer-ERCP-Cannula"****Urgent safety information**

Batches affected by the recall / LOT numbers of the article Stiefenhöfer-ERCP-Cannula (product number CAN1-A6-18-200-35 / order number 502332):

Batch / LOT number	Batch / LOT number	Batch / LOT number	Batch / LOT number
22050701	21955932	21953705	21950944
22050694	21955931	21953466	21950943
22050500	21955844	21953465	21950942
22050039	21955793	21953369	21950487
22050038	21955792	21953303	21858146
22050037	21955404	21953302	21858124
21957996	21955403	21953107	21858072
21957991	21955309	21953108	21858071
21957990	21955308	21952947	21857823
21957735	21955119	21952946	21857881
21957704	21955061	21952699	21857880
21957527	21955119	21952571	21857879
21957580	21955060	21952571	21857823
21957451	21954606	21952572	21857519
21956628	21954605	21952028	21857520
21956626	21954604	21952027	21857519
21956626	21954603	21951711	21857460
21956436	21954283	21951710	21857106
21956435	21954283	21951709	21857460
21956286	21954282	21951708	21857461
21956228	21954281	21951707	21857462
21956218	21954280	21951542	21857216
21956105	21954058	21951542	21857380
21955991	21954057	21951541	21857216
21955990	21953707	21951541	21857106
21955989	21953706	21950945	21856995

**Customer reply form****Voluntary product recall „Stiefenhöfer ERCP-Cannula“****Urgent safety information**

An examination of our stock of the mentioned article Stiefenhöfer-ERCP-catheter (product number CAN1-A6-18-200-35 / order number 502332) showed:

- ☐ We have none of the listed batch numbers in our inventory
- ☐ We have the listed batch number(s) in stock for return to medwork

Batch / LOT number	Quantity remaining in pieces

- ☐ I acknowledge receipt of your security information. I further acknowledge that I have forwarded the content of the enclosed safety information to all departments concerned on which this measure has an impact.

<b>Name and address of the institution</b>	
<b>Name and first name in block letters</b>	
<b>Phone number / e-mail</b>	
<b>Date, Signature</b>	

**Please send this form completed by 21.02.2020 at the latest**  
by FAX to **+49 9193 5009-99** or by e-mail to [contact@medwork.com](mailto:contact@medwork.com)