

Ovesco Endoscopy AG Friedrich-Miescher-Straße 9 72076 Tübingen Germany

Clinical users of the Ovesco colonic FTRD system from Ovesco Endoscopy AG



**Recall Ovesco article 200.70 colonic FTRD® Set, LOT 856866**

17-Jan-25

Dear Sir or Madam,

We would like to inform you today about a voluntary recall of the following product from our company:

- 200.70 colonic FTRD® Set
- LOT 856866

In this LOT, an incorrect endoscope sleeve was accidentally included. This sleeve is too short for the system. This does not lead to any functional limitation of the FTRD, but in some cases of full-thickness resection in the colon, the sleeve may be too short.

**Ovesco Endoscopy AG**  
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72076 Tübingen/Germany

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www.ovesco.com

Place of business:  
Tübingen, Germany

Company Register:

VAT identification number:

Executive Board:

Chairman Supervisory Board:

Bank information:

o o o o v e s c o		Ovesco Endoscopy AG Friedrich-Miescher-Straße 9 72076 Tübingen   Germany	REF 200.70
<b>colonic FTRD Set</b> <span style="float: right;">Made in Germany</span>			
1x colonic FTRD®			CE 0297
1x FTRD® Marking Probe			
1x FTRD® Grasper			
<b>LOT 856866</b>	01 604260206311010 17 270831 103123456		
2024-09-19			
2027-08-31	Rev. 17		

In order to avoid inconveniences caused by the above-described shortened endoscope sleeve, we kindly ask you to no longer use the affected colonic FTRD sets.

As these products do not meet the quality standards of Ovesco Endoscopy AG, all colonic FTRD sets of LOT 856866 that have already been delivered and are still with our customers will be recalled. We will, of course, replace the recalled products for you.

To make the replacement and return process as easy as possible, please complete the attached feedback form and send it by e-mail to Ovesco Customer Service (e-mail: [service@ovesco.com](mailto:service@ovesco.com)).

Upon receipt of your feedback, we will promptly send you the replacement delivery along with a return label for the products still in your possession

We regret the incident and would like to sincerely apologize for the inconvenience caused.

Yours sincerely,

Tübingen, 17 Januar 2025

Katrin Steinbrecher  
Director Quality Management & Regulatory Affairs

Enclosure  
Feedback form

## FEEDBACK FORM

Article 200.70 colonic FTRD Set  
LOT 856866

We kindly request the return of this form via email or fax to:

Department Customer Service

Fax: +49 707196528-260

E-Mail: [service@ovesco.com](mailto:service@ovesco.com)

We no longer have any affected product in stock .

We are returning affected products

Quantity: \_\_\_\_\_

HOSPITAL \_\_\_\_\_ LOCATION \_\_\_\_\_

NAME \_\_\_\_\_ DEPARTMENT \_\_\_\_\_ PHONE \_\_\_\_\_

SIGNATURE \_\_\_\_\_ DATE \_\_\_\_\_