

■ HUM GmbH, Zum Pier 79, D-44536 Lünen

Adresszeile\_2  
Adresszeile\_3  
Straße  
PLZ Ort  
Land

# Important Safety Instructions

## Recall of the Instructions for Use of AEROTube ET – Endotracheal Tubes

Sender: HUM Gesellschaft für Homecare und Medizintechnik mbH

Addressee: Users, Operators, Specialist Retail Partners

### Affected Medical Devices

### **AEROTube®-ET01-SET, Endotracheal Tube-Set, with cuff**

Article no.	Article description
HET01-50M-SET	AEROTube®-ET01-50M-SET Endotracheal tube-Set, cuffed, Murphy eye, sterile single packed, 5,0 mm, CH 20
HET01-55M-SET	AEROTube® - ET01-55M-SET, Endotracheal tube-Set, cuffed, Murphy eye, sterile single packed, 5,5 mm, CH 22
HET01-60M-SET	AEROTube - ET01-60M-SET, Endotracheal tube-Set, cuffed, Murphy eye, sterile single packed, 6,0 mm, CH 24
HET01-65M-SET	AEROTube® - ET01-65M-SET, Endotracheal tube-Set, cuffed, Murphy eye, sterile single packed, 6,5 mm, CH26
HET01-70M-SET	AEROTube® - ET01-70M-SET, Endotracheal tube-Set, cuffed, Murphy eye, sterile single packed, 7,0 mm, CH28
HET01-75M-SET	AEROTube® - ET01-75M-SET, Endotracheal tube-Set, cuffed, Murphy eye, sterile single packed, 7,5 mm, CH30
HET01-80M-SET	AEROTube® - ET01-80M-SET, Endotracheal tube-Set, cuffed, Murphy eye, sterile single packed, 8,0 mm, CH32
HET01-85M-SET	AEROTube® - ET01-85M-SET, Endotracheal tube-Set, cuffed, Murphy eye, sterile single packed, 8,5 mm, CH34
HET01-90M-SET	AEROTube® - ET01-90M-SET, Endotracheal tube-Set, cuffed, Murphy eye, sterile single packed, 9,0 mm, CH36

■ Deutschland | Germany  
HUM Gesellschaft für Homecare und Medizintechnik mbH  
Zum Pier 79 | D-44536 Lünen  
FON +49 (0)231 880885-0  
FAX +49 (0)231 880885-58  
E-Mail: sales@hum-online.de  
Internet: www.hum-online.de

■ Büro China | Office China  
HUM Homecare and Medical Technology  
A45 F9 North Tower, Poly V Mansion  
Xiancun RD 11, Pearl River New City, Tianhe District  
Guangzhou, 510627 Guangdong, China  
FON +86 20 66691812  
FAX +86 20 66691812 999  
E-mail: china-office@hum-online.de

■ IK-Nr. | Code of the institution  
330 592 869  
Ust.-ID-Nr. | Sales Tax Identification Number  
DE180373438  
Registergericht | Commercial Register Number  
Dortmund HRB 17477  
Geschäftsführer | General Manager  
Dietmar Uhlenbruch

■ Bankverbindung | Bank Account  
Sparkasse Dortmund  
BLZ 440 501 99  
Konto 491 006 250  
IBAN: DE28 4405 0199 0491 0062 50  
BIC/SWIFT: DORTDE33XXX  
WEEE-Reg.-Nr: DE 55961085

■ HUM GmbH, Zum Pier 79, D-44536 Lünen

## AEROTube®-ET01, Endotracheal tube

Article no.	Article description
HET01-100	AEROTube® - ET01-100, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 10 mm, CH 40
HET01-100M	AEROTube® - ET01-100M, Endotracheal tube, cuffed, Murphy eye, sterile single packed, 10,0 mm, CH 40
HET01-20	AEROTube® - ET01-20, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 2,0 mm, CH 08
HET01-25	AEROTube® - ET01-25, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 2,5 mm, CH 10
HET01-25M	AEROTube® - ET01-25M, Endotracheal tube, cuffed, Murphy eye, sterile single packed, 2,5 mm, CH 10
HET01-30	AEROTube® - ET01-30, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 3,0 mm, CH 12
HET01-30M	AEROTube® - ET01-30M, Endotracheal tube, cuffed, Murphy eye, sterile single packed, 3,0 mm, CH 12
HET01-35	AEROTube® - ET01-35, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 3,5 mm, CH 14
HET01-35M	AEROTube® - ET01-35M, Endotracheal tube, cuffed, Murphy eye, sterile single packed, 3,5 mm, CH 14
HET01-40	AEROTube® - ET01-40, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 4,0 mm, CH 16
HET01-40M	AEROTube® - ET01-40M, Endotracheal tube, cuffed, Murphy eye, sterile single packed, 4,0 mm, CH 16
HET01-45	AEROTube® - ET01-45, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 4,5 mm, CH 18
HET01-45M	AEROTube® - ET01-45M, Endotracheal tube, cuffed, Murphy eye, sterile single packed, 4,5 mm, CH 18
HET01-50	AEROTube® - ET01-50, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 5,0 mm, CH 20
HET01-50M	AEROTube® - ET01-50M, Endotracheal tube, cuffed, Murphy eye, sterile single packed, 5,0 mm, CH 20

■ Deutschland | Germany  
 HUM Gesellschaft für Homecare  
 und Medizintechnik mbH  
 Zum Pier 79 | D-44536 Lünen  
 FON +49 (0)231 880885-0  
 FAX +49 (0)231 880885-58  
 E-Mail: sales@hum-online.de  
 Internet: www.hum-online.de

■ Büro China | Office China  
 HUM Homecare and Medical Technology  
 A45 F9 North Tower, Poly V Mansion  
 Xiancun RD 11, Pearl River New City, Tianhe District  
 Guangzhou, 510627 Guangdong, China  
 FON +86 20 66691812  
 FAX +86 20 66691812 999  
 E-mail: china-office@hum-online.de

■ IK-Nr. | Code of the institution  
 330 592 869  
 Ust.-ID-Nr. | Sales Tax Identification Number  
 DE180373438  
 Registergericht | Commercial Register Number  
 Dortmund HRB 17477  
 Geschäftsführer | General Manager  
 Dietmar Uhlenbruch

■ Bankverbindung | Bank Account  
 Sparkasse Dortmund  
 BLZ 440 501 99  
 Konto 491 006 250  
 IBAN: DE28 4405 0199 0491 0062 50  
 BIC/SWIFT: DORTDE33XXX  
 WEEE-Reg.-Nr: DE 55961085

■ HUM GmbH, Zum Pier 79, D-44536 Lünen

HET01-55	AERObube® - ET01-55, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 5,5 mm, CH 22
HET01-55M	AERObube® - ET01-55M, Endotracheal tube, cuffed, Murphy eye, sterile single packed, 5,5 mm, CH 22
HET01-60	AERObube® - ET01-60, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 6,0 mm, CH 24
HET01-60M	AERObube® - ET01-60M, Endotracheal tube, cuffed, Murphy eye, sterile single packed, 6,0 mm, CH 24
HET01-65	AERObube® - ET01-65, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 6,5 mm, CH 26
HET01-65M	AERObube® - ET01-65M, Endotracheal tube, cuffed, Murphy eye, sterile single packed, 6,5 mm, CH 26
HET01-70	AERObube® - ET01-70, Endotracheal tube, uncuffed, Murphy eye, sterile single packed, 7,0 mm, CH 28
HET01-70M	AERObube® - ET01-70M, Endotracheal tube, cuffed, Murphy eye, sterile single packed, 7,0 mm, CH 28
HET01-75	AERObube® - ET01-75, Endotracheal Tube, uncuffed, Murphy eye, sterile single packed, 7,5 mm, CH 30
HET01-75M	AERObube® - ET01-75M, Endotracheal Tube, cuffed, Murphy eye, sterile single packed, 7,5 mm, CH 30
HET01-80	AERObube® - ET01-80, Endotracheal Tube, uncuffed, Murphy eye, sterile single packed, 8,0 mm, CH 32
HET01-80M	AERObube® - ET01-80M, Endotracheal Tube, cuffed, Murphy eye, sterile single packed, 8,0 mm, CH 32
HET01-85	AERObube® - ET01-85, Endotracheal Tube, uncuffed, Murphy eye, sterile single packed, 8,5 mm, CH 34
HET01-85M	AERObube® - ET01-85M, Endotracheal Tube, cuffed, Murphy eye, sterile single packed, 8,5 mm, CH 34
HET01-90	AERObube® - ET01-90, Endotracheal Tube, uncuffed, Murphy eye, sterile single packed, 9,0 mm, CH 36
HET01-90M	AERObube® - ET01-90M, Endotracheal Tube, cuffed, Murphy eye, sterile single packed, 9,0 mm, CH 36
HET01-95	AERObube® - ET01-95, Endotracheal Tube, uncuffed, Murphy eye, sterile single packed, 9,5 mm, CH 38
HET01-95M	AERObube® - ET01-95M, Endotracheal Tube, cuffed, Murphy eye, sterile single packed, 9,5 mm, CH 38

■ Deutschland | Germany  
 HUM Gesellschaft für Homecare  
 und Medizintechnik mbH  
 Zum Pier 79 | D-44536 Lünen  
 FON +49 (0)231 880885-0  
 FAX +49 (0)231 880885-58  
 E-Mail: sales@hum-online.de  
 Internet: www.hum-online.de

■ Büro China | Office China  
 HUM Homecare and Medical Technology  
 A45 F9 North Tower, Poly V Mansion  
 Xiancun RD 11, Pearl River New City, Tianhe District  
 Guangzhou, 510627 Guangdong, China  
 FON +86 20 66691812  
 FAX +86 20 66691812 999  
 E-mail: china-office@hum-online.de

■ IK-Nr. | Code of the institution  
 330 592 869  
 Ust.-ID-Nr. | Sales Tax Identification Number  
 DE180373438  
 Registergericht | Commercial Register Number  
 Dortmund HRB 17477  
 Geschäftsführer | General Manager  
 Dietmar Uhlenbruch

■ Bankverbindung | Bank Account  
 Sparkasse Dortmund  
 BLZ 440 501 99  
 Konto 491 006 250  
 IBAN: DE28 4405 0199 0491 0062 50  
 BIC/SWIFT: DORTDE33XXX  
 WEEE-Reg.-Nr: DE 55961085

■ **HUM GmbH**, Zum Pier 79, D-44536 Lünen

Dear Sir or Madam,

In order to guarantee the safety of our medical devices, we ask you, as a part of your duty to collaborate in accordance with the medical devices legislation, to implement the corrective measures described below, so that users can continue to use our medical devices safely on patients.

### **Problem Description**

When using one of our AEROTube ET – Sets on the patient, the intubation stylet inserted into the endotracheal tube couldn't be removed with normal effort after successful intubation.

The friction between the stylet and the inner wall of the endotracheal tube is the cause of the difficult extraction of the stylet. Anatomic conditions of the patient can make this even more difficult.

So far, we have only received one feedback from the market since 2011.

### **Risk to the patient**

The stylet can't be removed from the endotracheal tube. This can result in the user having to extubate the patient and insert a new endotracheal tube. This could lead to a delay of patient ventilation.

Through moistening of the stylet with lubricant gel before inserting of the Endotracheal Tube, the risk can most widely be avoided.

### **Corrective Actions**

In the enclosed instructions for use **GBA-ET01\_3, Revision 0, dated 15.09.2011 there are no instructions for using a lubricant gel during an intubation with a stylet.**

The following corrective measures must therefore be carried out:

- Please check your inventory and block all affected products until the measures have been implemented.
- Fill out the question form in the attachment completely, even if you no longer have the affected products in stock.
- If you have forwarded affected products to third parties, please ensure that your customers are immediately informed of this recall by forwarding this letter. Your customers must then also fill out the response form and send it back to us.
- Please destroy the instructions for use enclosed in the outer packaging.

Based on the data on the answer sheet, we will immediately send you a corresponding number of updated instructions for use and warning stickers.

■ **Deutschland | Germany**  
HUM Gesellschaft für Homecare  
und Medizintechnik mbH  
Zum Pier 79 | D-44536 Lünen  
FON +49 (0)231 880885-0  
FAX +49 (0)231 880885-58  
E-Mail: [sales@hum-online.de](mailto:sales@hum-online.de)  
Internet: [www.hum-online.de](http://www.hum-online.de)

■ **Büro China | Office China**  
HUM Homecare and Medical Technology  
A45 F9 North Tower, Poly V Mansion  
Xiancun RD 11, Pearl River New City, Tianhe District  
Guangzhou, 510627 Guangdong, China  
FON +86 20 66691812  
FAX +86 20 66691812 999  
E-mail: [china-office@hum-online.de](mailto:china-office@hum-online.de)

■ **IK-Nr. | Code of the institution**  
330 592 869  
Ust.-ID-Nr. | Sales Tax Identification Number  
DE180373438  
Registergericht | Commercial Register Number  
Dortmund HRB 17477  
Geschäftsführer | General Manager  
Dietmar Uhlenbruch

■ **Bankverbindung | Bank Account**  
Sparkasse Dortmund  
BLZ 440 501 99  
Konto 491 006 250  
IBAN: DE28 4405 0199 0491 0062 50  
BIC/SWIFT: DORTDE33XXX  
WEEE-Reg.-Nr: DE 55961085



■ **HUM GmbH**, Zum Pier 79, D-44536 Lünen

- Please enclose the new instructions for use **ID 4153071, Rev. 1.0, 28.08.2020** and the additional safety information **ID 4153550, Rev. 1.0, 31.08.2020** in the outer packaging.
- Label the outer packaging with the enclosed warning sticker.
- Alternatively, you can also send the products back to us.

Please take this action **IMMEDIATELY!**

We need a response from every customer notified. Please send us the completed response form by no later than 15.09.2020.

We apologize for the inconvenience this action may cause to you and we thank you for your understanding for this measure.

Please contact us at the specified contact if you have any questions regarding this recall and its handling.

**Contact:** Daniel Schnabel, Tel.: +49 231 88 08 85-61, E-Mail: [schnabel@hum-online.de](mailto:schnabel@hum-online.de)

Best regards

**HUM**  
Gesellschaft für Homecare  
und Medizintechnik mbH



Dietmar Uhlenbruch  
Geschäftsführer



ppa. Daniel Schnabel  
Qualitätsmanagementbeauftragter

■ **Deutschland | Germany**  
HUM Gesellschaft für Homecare  
und Medizintechnik mbH  
Zum Pier 79 | D-44536 Lünen  
FON +49 (0)231 880885-0  
FAX +49 (0)231 880885-58  
E-Mail: [sales@hum-online.de](mailto:sales@hum-online.de)  
Internet: [www.hum-online.de](http://www.hum-online.de)

■ **Büro China | Office China**  
HUM Homecare and Medical Technology  
A45 F9 North Tower, Poly V Mansion  
Xiancun RD 11, Pearl River New City, Tianhe District  
Guangzhou, 510627 Guangdong, China  
FON +86 20 66691812  
FAX +86 20 66691812 999  
E-mail: [china-office@hum-online.de](mailto:china-office@hum-online.de)

■ **IK-Nr. | Code of the institution**  
330 592 869  
Ust.-ID-Nr. | Sales Tax Identification Number  
DE180373438  
Registergericht | Commercial Register Number  
Dortmund HRB 17477  
Geschäftsführer | General Manager  
Dietmar Uhlenbruch

■ **Bankverbindung | Bank Account**  
Sparkasse Dortmund  
BLZ 440 501 99  
Konto 491 006 250  
IBAN: DE28 4405 0199 0491 0062 50  
BIC/SWIFT: DORTDE33XXX  
WEEE-Reg.-Nr.: DE 55961085

■ **HUM GmbH**, Zum Pier 79, D-44536 Lünen

## Reply form

*Recall of the instructions for use AEROTube® ET- Endotracheal Tube*

Please fill out this reply form and send it to us by e-mail, fax or post to:

E-Mail: [qualitymanagement@hum-online.de](mailto:qualitymanagement@hum-online.de)

Fax: +49 231 880 885 58

Postal Address: HUM Gesellschaft für Homecare und Medizintechnik mbH  
Zum Pier 79  
44536 Lünen

- We hereby confirm receipt of the letter. We have read and understood the content and will implement all measures immediately. All users and operators of the product and other persons to be informed, have received the letter for their knowledge.**

### Please fill in completely in block letters:

Sender: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Contact Person: \_\_\_\_\_

Phone number: \_\_\_\_\_ Fax number: \_\_\_\_\_

\_\_\_\_\_

Date/signature: \_\_\_\_\_

- We still have \_\_\_\_\_ SU of the AEROTube® ET-Endotracheal Tube / Endotracheal Tube-Sets in our inventory.**
- We no longer have these products in stock.**

■ **Deutschland | Germany**  
HUM Gesellschaft für Homecare  
und Medizintechnik mbH  
Zum Pier 79 | D-44536 Lünen  
FON +49 (0)231 880885-0  
FAX +49 (0)231 880885-58  
E-Mail: [sales@hum-online.de](mailto:sales@hum-online.de)  
Internet: [www.hum-online.de](http://www.hum-online.de)

■ **Büro China | Office China**  
HUM Homecare and Medical Technology  
A45 F9 North Tower, Poly V Mansion  
Xiancun RD 11, Pearl River New City, Tianhe District  
Guangzhou, 510627 Guangdong, China  
FON +86 20 66691812  
FAX +86 20 66691812 999  
E-mail: [china-office@hum-online.de](mailto:china-office@hum-online.de)

■ **IK-Nr. | Code of the institution**  
330 592 869  
Ust.-ID-Nr. | Sales Tax Identification Number  
DE180373438  
Registergericht | Commercial Register Number  
Dortmund HRB 17477  
Geschäftsführer | General Manager  
Dietmar Uhlenbruch

■ **Bankverbindung | Bank Account**  
Sparkasse Dortmund  
BLZ 440 501 99  
Konto 491 006 250  
IBAN: DE28 4405 0199 0491 0062 50  
BIC/SWIFT: DORTDE33XXX  
WEEE-Reg.-Nr: DE 55961085



**Please note!**

## **Urgent safety information**

**Change in the instructions for use**

**AEROTube® Endotracheal Tubes and Endotracheal Tube Sets**

Dear user,

With this safety information we would like to inform you about the change in the instructions for use of our AEROTube® endotracheal tubes and endotracheal tube sets.

For the safe use of the AEROTube® endotracheal tubes and endotracheal tube sets, please consider the supplementary safety notes in the instructions for use enclosed with the product.

The change affects chapter “6. General warnings and precautionary measures”, in which the following safety-related information has been added:

***6.5 When using the AEROTube® endotracheal tube sets, remove the guide pin (stylet) from the tube before intubation and moisten it with a suitable lubricant.***

***6.6 If intubation is performed using a guide pin (stylet), moisten the stylet with a suitable lubricant before intubation.***

Failure to comply with these instructions may result in the stylet not being able to be pulled out of the tube with normal force after successful intubation. This can lead to a delay in ventilation.

By moistening the stylet with lubricant before inserting the endotracheal tube, the risk can be avoided widely.

Best regards,  
Your HUM team