

WEINMANN Emergency Medical Technology GmbH + Co. KG
 PO Box 57 01 53 • 22770 Hamburg • GERMANY

Hamburg, September 23

Important safety information: Field safety corrective action on a medical device

Reference: FSCA MMT_PSS_Winkel 2023-09.01

Sender:
 WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressee:
 Users and operators, and specialist trade partners

Affected medical devices (trade names and article numbers of the products):

The affected products are disposable breathing circuits for MEDUMAT Transport from the production period 10/4/2022 to 5/25/2023. This concerns the following articles:

| WM article no. | Designation |
|----------------|----------------------------------------------------------|
| 28657 | VENTcirc-MMT breathing circuit with BiCheck, 2 m |
| 28483 | VENTcirc-MMT breathing circuit with CO2 and BiCheck, 2 m |
| 28690 | VENTcirc-MMT breathing circuit with CO2, 2 m |
| 28695 | VENTcirc-MMT breathing circuit, 2 m |
| 28688 | VENTcirc-MMT breathing circuit with CO2, 3 m |
| 28227 | VENTcirc-MMT breathing circuit with CO2 and BiCheck, 3 m |
| 15837 | Set of 10, VENTcirc-MMT breathing circuit with CO2, 2 m |
| 15842 | Set of 50, VENTcirc-MMT breathing circuit, 2 m |
| 15840 | Set of 10, VENTcirc-MMT breathing circuit, 2 m |
| 28226 | VENTcirc-MMT breathing circuit with BiCheck, 3 m |

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Center for Production, Logistics, Service
 WEINMANN Emergency
 Medical Technology GmbH + Co. KG
 Siebenstücken 14 • 24558 Henstedt-Ulzburg
 GERMANY

Business Management
 Dipl.-Volksw. Marc Griefahn
 Dipl.-Kfm. Philipp Schroeder
 Dipl.-Volksw. André Schulte

Registration Court
 Hamburg Municipal Court
 Dept. A # 115967
 V.A.T. # DE288367727
 WEEE Reg. # DE 47913245

Creditor ID
 DE35ZZZ00000353971

General Partner
 WEINMANN Emergency
 Management GmbH, Hamburg

Registration Court
 Hamburg Municipal Court
 Dept. B # 38144

Certified QM System meeting
 EC directive 93/42/EEC, Annex II
 (EN ISO 9001/EN ISO 13485)

Banking Connections

Deutsche Bank AG Hamburg
 IBAN DE87 2007 0000 0646 9639 00
 SW FT DEUTDEHH

Hamburger Sparkasse AG
 IBAN DE44 2005 0550 1032 2626 67
 SW FT HASPDEHHXXX

Commerzbank AG Hamburg
 IBAN DE14 2004 0000 0632 0071 00
 SW FT COBADEHHXXX

| | |
|-------|---------------------------------------------------------------------------------|
| 15756 | Set of 50, VENTcirc-MMT breathing circuit with BiCheck, 2 m |
| 15754 | Set of 10, VENTcirc-MMT breathing circuit with BiCheck, 2 m |
| 15839 | Set of 50, VENTcirc-MMT breathing circuit with CO ₂ , 2 m |
| 28691 | VENTcirc-MMT breathing circuit, 3 m |
| 15766 | Set of 10, VENTcirc-MMT breathing circuit with CO ₂ and BiCheck, 2 m |
| 15851 | Set of 10, VENTcirc-MMT breathing circuit with CO ₂ , 3 m |
| 15841 | Set of 25, VENTcirc-MMT breathing circuit, 2 m |
| 15768 | Set of 50, VENTcirc-MMT breathing circuit with CO ₂ and BiCheck, 2 m |
| 15838 | Set of 25, VENTcirc-MMT breathing circuit with CO ₂ , 2 m |
| 15852 | Set of 10, VENTcirc-MMT breathing circuit, 3 m |
| 15767 | Set of 25, VENTcirc-MMT breathing circuit with CO ₂ and BiCheck, 2 m |
| 15855 | Set of 10, VENTcirc-MMT breathing circuit with CO ₂ and BiCheck, 3 m |
| 15755 | Set of 25, VENTcirc-MMT breathing circuit with BiCheck, 2 m |
| 15917 | Set of 10, VENTcirc-MMT breathing circuit with BiCheck, 3 m |

To whom it may concern,

Quality and safety are our top priority. Consequently, applying our accustomed consistency and transparency, we request you to implement this corrective action in fulfillment of your duty to cooperate according to medical device legislation, so that users can continue to deploy our products safely on patients.

You must not use the above listed disposable breathing circuits until the action recommended below has been implemented.

1. Description of problem and cause:

In the course of our regular internal quality control inspections, it has come to our attention that in rare cases the elbow 90° (WM 28821) installed in the disposable breathing circuits listed above does not meet its specifications, and as a result may become detached from the BiCheck sensor (WM 22430).



2. What is the risk to the patient?

The above error can cause an elbow to disconnect during ventilation.

This disconnection is detected by the device's alarm system, and an alarm alerts the user to reconnect it.

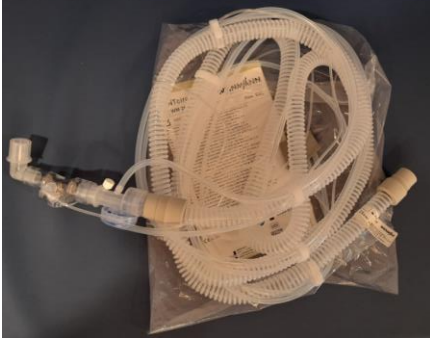
3. Corrective action

We will provide you with a specification-compliant replacement elbow in a large resealable plastic bag (you will need to keep this for later). Replace the elbow as described below. Please note that the breathing circuits are not sterile, even though the original vacuum-packing suggests so. You can safely remove the breathing circuit and carry out the procedure as described below.

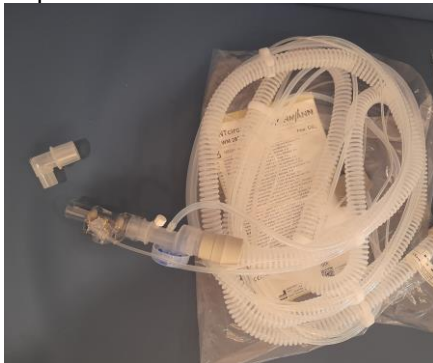
Step 1: Cut open the original bag of the disposable breathing circuit at the top.



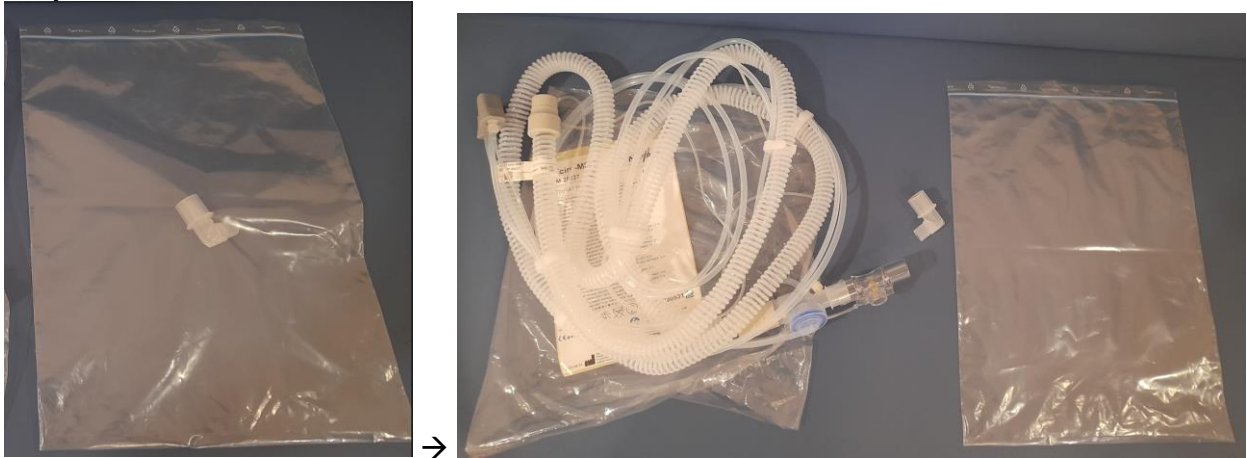
Step 2: Remove the breathing circuit, leaving the article label inside the bag. Do not throw the bag away.



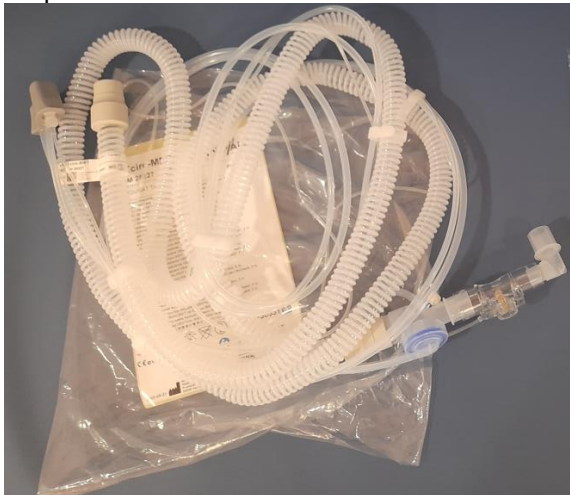
Step 3: Detach the elbow from the breathing circuit and discard it.



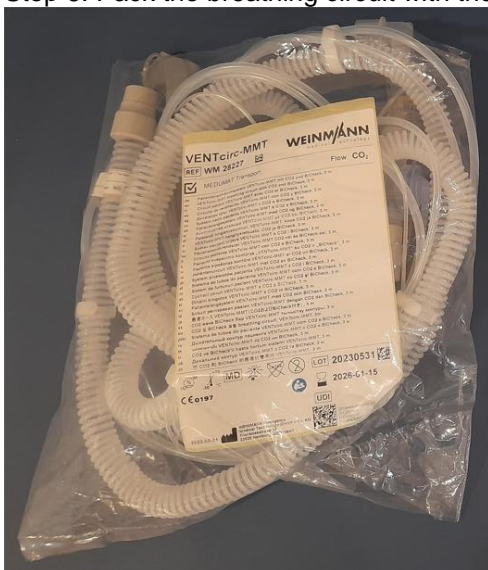
Step 4: Take the replacement elbow out of the plastic bag you received from us. Do not throw the bag away.



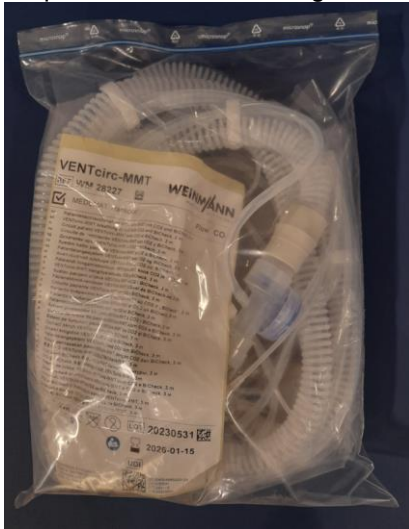
Step 5: Connect the new elbow to the BiCheck sensor of the breathing circuit.



Step 6: Pack the breathing circuit with the replaced elbow back into the original bag containing the label.



Step 7: Place the breathing circuit and bag into the plastic bag and then seal it.



Detailed video instructions on replacing the elbow can also be found at:
[Elbow replacement guide FSCA MMT EW PSS 2023-09.01](#)

We are aware of the inconvenience caused to you by the above action. For sustainability reasons, we have decided against replacing the entire breathing circuit.

4. What action should the addressee take?

Are you a specialist dealer?

- Use the attached **report form** to confirm receipt of this letter no later than **2023-10-20**.
- Make sure that everyone needing to be notified is aware of this safety information.
- If you have existing stocks, please carry out the above action and inform us accordingly.
- Replaced elbows should be scrapped.

If you have already resold or passed on the medical devices:

- Forward a copy of this letter to the customers concerned.
- Have your customers confirm receipt of the letter.
- Send the quantity of replacement elbows to the customer.
- Request your customers in turn to carry out the safety procedure described above.

Are you a user?

- Use the attached **report form** to confirm receipt of this letter no later than **2023-10-20**.
- Make sure that everyone needing to be notified is aware of this safety information.
- If you have existing stocks, please carry out the above action and inform us accordingly.
- Replaced elbows should be scrapped.

Please carry out all corrective action promptly.

This corrective action is mandatory. The responsible authority has been informed of the procedure.

Contact

If you have any questions, or need assistance, please contact your local dealer, or contact us directly:

Phone: +49 40 88 18 96 – 120

E-mail: Kundenservice@weinmann-emt.de.

Best regards,

WEINMANN Emergency
Medical Technology GmbH + Co. KG

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Attachments

Form: "Report back on safety information"

List of affected order numbers

Report back to WEINMANN Emergency by 2023-10-20

on safety information: Reference FSCA MMT_PSS_Winkel 2023-09.01

Please fill in this report form in full and return it by e-mail, fax or mail to:

E-mail: **CustomerService@weinmann-emt.de**

Fax: **+49 40 88 18 96 - 490**

WEINMANN Emergency Medical Technology GmbH + Co. KG
Customer Service
Frohösestraße 12
22525 Hamburg, GERMANY

I hereby confirm receipt of this letter and that I have read, understood and will implement its contents. This letter has been brought to the attention of all users of the product and of other people in my organization who need to be informed.

If the products have been passed on to third parties (applies to specialist dealers, for example), a copy of this information has been passed on to them.

Please complete in full in block capitals:

Company/organization details are identical to those of the addressee above.

Company/organization details differ from those of the addressee as follows:

Customer no.:

Company/organization + address:

I am no longer in possession of the article:

The article has been resold

The article has been used up

Date, signature

Name (in block letters)

Position (in block letters)

e-mail address (in block letters)

List of affected order numbers

According to our records, the following orders are affected within your organization:

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