URGENT: Field Safety Notice

Twin Tube (V-707327) and Twin Tube Probenschlauch (707004) – Separation of Nozzle

March 8th, 2024

Attention: Distributors/End-Users of the Twin Tube and Twin Tube Probenschlauch,

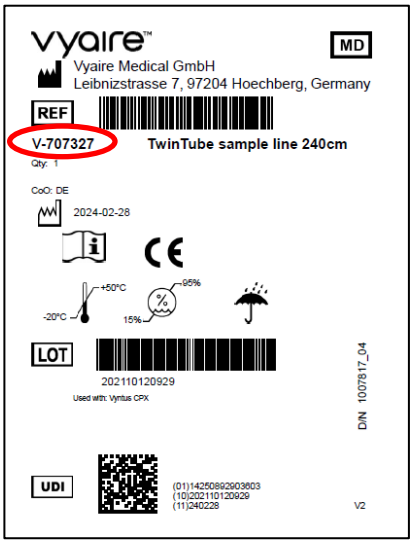
The purpose of this communication is to inform you that Vyaire Medical GmbH is conducting a voluntary field action for the Twin Tube sample line 240 cm (V-707327) and Twin Tube Probenschlauch für Oxycon Pro (707004) due to the potential of the nozzle separating during patient use. The separated component may fall into the patient's mouth resulting in a potential choking hazard which may lead to an airway obstruction, requiring medical intervention to prevent further injury or harm.

Table 1. Potentially Affected Devices

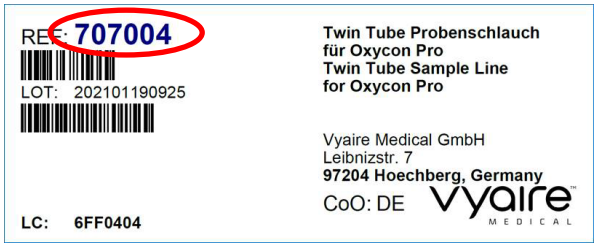
Model / Part Number	Product Description	Lot Number(s)	Quantity
V-707327	Twin Tube sample line 240 cm	All Prior to June 2023	8,452
707004	Twin Tube Probenschlauch für Oxycon Pro	All Prior to June 2023	1,449

How to Identify Affected Devices

Potentially affected devices can be identified via labeling. To ease identification of potentially affected devices pictorial depictions of labels are provided below.



Twin Tube sample line 240 cm (P/N: V-707327)



Twin Tube Probenschlauch für Oxycon Pro (P/N: 707004)

ACTIONS TO BE TAKEN BY VYAIRE:

- Coordinate with Distributors/End-Users upon receipt of the fully completed and signed Distributor/End-User Response Form to return affected devices and exchange as required.

ACTION TO BE TAKEN BY THE DISTRIBUTOR/END-USER:

- Confirm receipt and thoroughly review the contents of the Customer Notification Package (includes this notification and the Distributor/End-User Response Form).
- If potentially affected devices have been transferred to another location or organization, please forward the complete Customer Notification Package to the respective parties.
- Inspect current inventory on-hand as described above under "**How to Identify Affected Devices**". A 100% physical inventory inspection should immediately be performed to identify and isolate affected devices.
- Perform the Pull-out Test on all current inventory on-hand as described in **Appendix A**, "**Pull-out Test**", to verify the adhesive is adequate prior to use.
- Fully complete the attached Distributor/End-User Response Form and return it to **GMB-EMEA-FSCA-RDX-INTL@Vyaire.com**.
- We respectfully request the completed and signed Distributor/End-User Response Form to be returned **no later than April 8th, 2024** or within 30 days of receipt.

This FSN has been notified to the appropriate Regulatory Agencies.

We recognize the inconvenience this issue may cause your facility and thank you for your support in this important matter. For any additional questions or concerns, please contact Vyaire at **GMB-EMEA-FSCA-RDX-INTL@Vyaire.com**.

Sincerely,

Jared Cardon
Director QRA Management

Appendix A: Pull-out Test

This document describes the exact instructions for checking the Twin Tubes for sufficient strength between the LDPE tube (852652) and the sample connector (V-852020). The two components are previously bonded together in a 2-step bonding process.

Required Materials:

1x Twin Tube sample line (V-707327/707004)
1x Fiber cloth/disinfecting wipe

1. Original packaging of the Twin Tube sample line displayed below (V-707327 and 707004).

Fig. 1 – V-707327

Fig. 2 – 707004

2. Open the plastic packaging by folding:

Fig. 3 – Opened Twin Tube packaging

3. Remove the complete Twin Tube sample line (V-707327/707004) from the packaging and grasp the sample connector (V-852020) with one hand as shown in Figure 4 below. In addition, prepare the fiber cloth/disinfectant wipe and take it in the other hand.

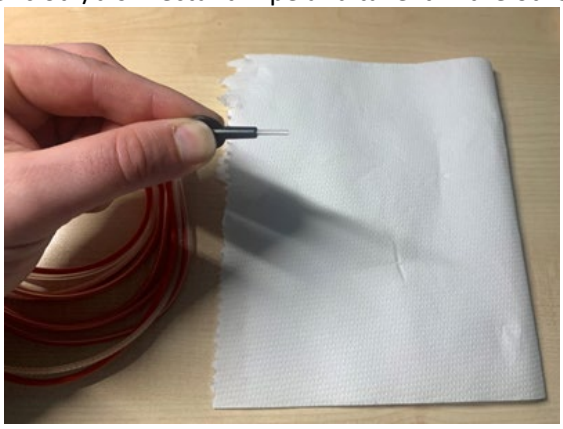


Fig. 4 – Twin Tube sample line (V-707327/707004) test structure

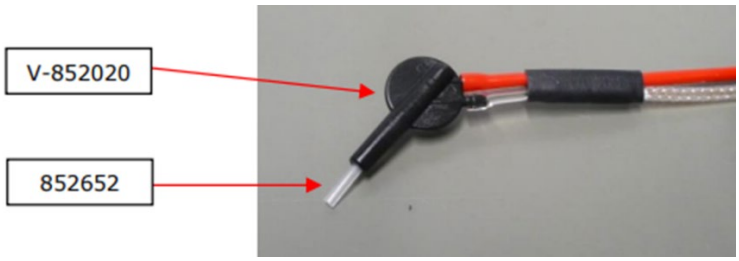


Fig. 5 – Components overview

4. Use the fiber cloth/disinfectant wipe to wrap around and grip the transparent LDPE tube (852652) as much as possible. Ensure that only the LDPE tube is held with the cloth.

Fig. 6 – Gripping the LDPE tube (852652) using the fiber cloth/disinfectant wipe

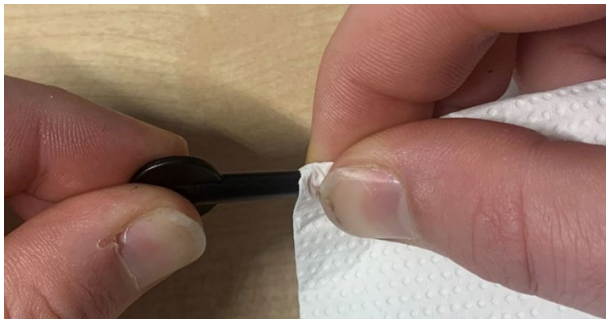


Fig. 7 – Position of the fiber cloth when holding the LDPE tube (852652)

5. Check the LDPE tube (852652) for tight fit by using a fiber cloth/disinfectant wipe. Apply a linear force as shown in Fig. 8. The force applied should correspond to normal disinfection wiping movements. A maximum force similar to that used to remove a USB stick serves as a guideline. Ensure that no permanent damage is caused by kinking or crushing the LDPE tube (852652) (see Fig. 9).

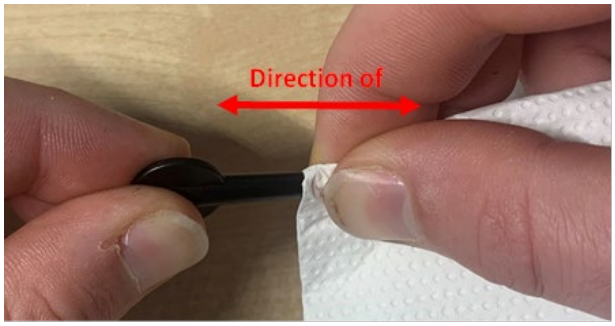


Fig. 8 – Direction of force

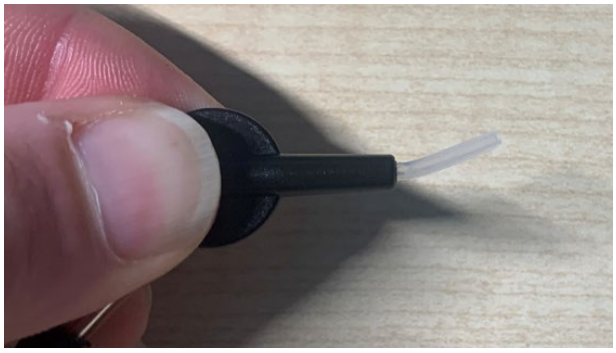


Fig. 9 – Kinking of the LDPE tube

6. Evaluation of the pull-out test. Due to the linear extraction force, the LDPE tube must not move or come loose. If the LDPE tube remains in its original position, the test is considered passed.

Fig. 10 - Tight Fit LDPE tube

Fig. 11 - Loosening the LDPE tube

Fig. 12 - Pulling out the LDPE tube

7. After a successful test, put the Twin Tube sample line back into the original packaging and close it.

Fig. 13 – V-707327

Fig. 14 – 707004

8. After performing the Pull-out Test on all inventory in stock, document the quantity affected using the Distributor/End-User Response Form.

FSCA-24-002-FSN-1 DISTRIBUTOR/END-USER RESPONSE FORM
Twin Tube (V-707327) and Twin Tube Probenschlauch (707004) – Separation of Nozzle Acknowledgment and Verification Form

Product Name: Twin Tube (V-707327) and Twin Tube Probenschlauch (707004)
Reference: See attached Customer Notification.
FSCA Identifier: FSCA-24-002

Name of Healthcare Facility/Distributor	
Address of Healthcare Facility/Distributor	
Email address	
Telephone number	
Name of person completing form (Please Print)	

The following person shall be contacted to coordinate the action (please complete if different than above)

Name	
Telephone Number	
Email	

Indicate the quantity in stock and quantity affected after performing the Pull-out Test.

Model / Part Number	Quantity in Stock	Quantity Affected
V-707327		
707004		

If product has been further distributed, please indicate the model/part number, facility, facility contact, and quantity below. Attach a second page if needed.

Model/Part Number	Facility Name	Facility Contact (email)	Quantity

By signature completion of this form, I certify the following:

- I have received the full Customer Notification Package comprising the Field Safety Notice (FSCA-24-002-FSN-1) and the Distributor/End-User Response Form.
- I have read and understand the contents of this Field Safety Notice and confirm that I understand all instructions noted within this notification.
- I have performed a **100% physical inventory inspection** and I have accurately reported the quantity in stock above.
- I have performed the **Pull-out Test** on all quantity in stock and I have accurate reported the quantity affected above.
- Applicable to **Distributors Only**: I have further notified my End-User customers with the complete Customer Notification Package (indicate method and date of notification below).
  Date of Notification: _____

Signature of person completing form	

We will contact you upon receipt of this completed form to coordinate the return and exchange of affected devices.
Please return this form to: **GMB-EMEA-FSCA-RDX-INTL@Vyaire.com**.

Model/Part Number	Facility Name	Facility Contact (Email)	Quantity