Customer Notification

URGENT: Field Safety Notice

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

March 15th, 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 (V-707327) and Twin Tube Probenschlauch (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.

To ensure patient safety, all potentially affected devices should be tested per the Pull-out Test. See **Appendix A**. Devices that successfully pass the Pull-out Test can be returned to stock and be safely used as normal.

Notes:

- Per the relevant IFU, the device should be replaced after having been used for 6 months or having been used intensively for 3 months.
- The Twin Tube and Twin Tube Probenschlauch are physically identical.

Table 1. Potentially Affected Devices

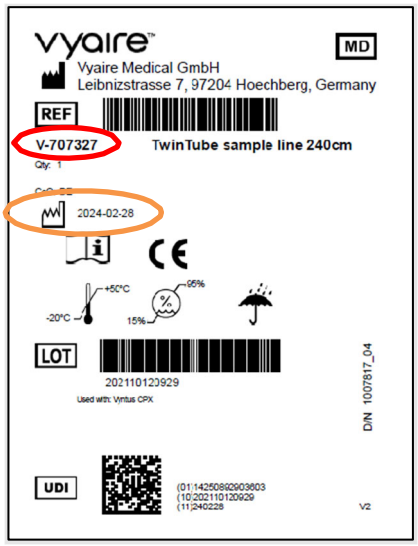
Model/Part Number	Product Description	Lot/Serial Number(s)
V-707327	Twin Tube sample line 240 cm	All Prior to 04I00122
707004	Twin Tube Probenschlauch für Oxycon Pro	All Prior to 04I00122

How to Identify Affected Devices

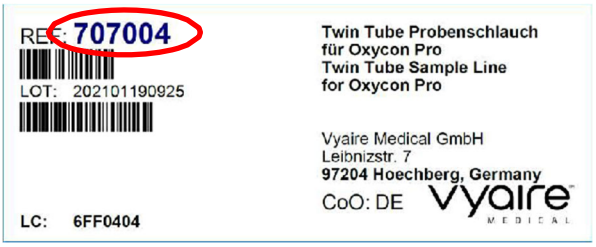
Potentially affected devices can be identified via the manufacture date on the external packaging labeling or the labeling on the device itself. Devices manufactured prior to June 2023 or with a serial number before 04I00122 are potentially affected.

Labeling on the device reads as follows: **[Model/Product Number]-[Version][Year Code][Serial Number]**. The Year Code corresponds to the year the device was manufactured, and the Serial Number is sequential and corresponds to the number of the device manufactured in that year.

To ease identification of potentially affected devices pictorial depictions and examples are provided below.



Example of Twin Tube sample line 240 cm (P/N: V-707327) external packaging labeling with model/product number and manufacture date circled.



Example of Twin Tube Probenschlauch für Oxycon Pro (P/N: 707004) external packaging labeling with model/product number circled.

Example of Twin Tube sample line 240 cm (P/N: V-707327) labeling on the device with serial number circled.

Table 2. Vyaire Year Codes

A	B	C	D	E	F	G	H	I	J
2015	2016	2017	2018	2019	2020	2021	2022	2023	2024

Example:
The labeling on the device in the image above is V-707327 – 04J00354. The serial number is 04J00354, the Year Code is J, 2024, and this is the 354th twin tube manufactured this year. The twin tube in this image was produced in 2024 and is safe to use without a Pull-out Test.

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 confirmed 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 potentially 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**. The email subject line should be labeled "**Response Form: FSCA-24-002-FSN-1**".
- We respectfully request the completed and signed Distributor/End-User Response Form to be returned **no later than April 15th, 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,

Electronically signed by: Jared Cardon
Reason: I approve this document
Date: Mar 15, 2024 19:45 GMT+1

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 unfolding:

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

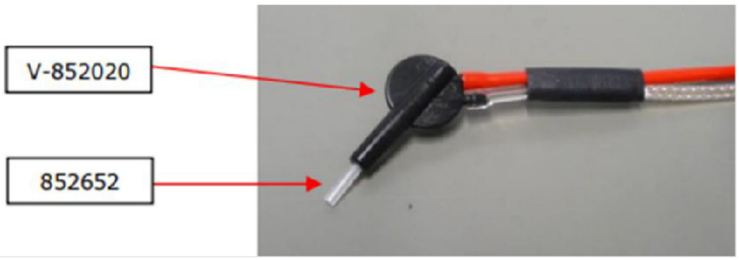


Fig. 5 – Components overview

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

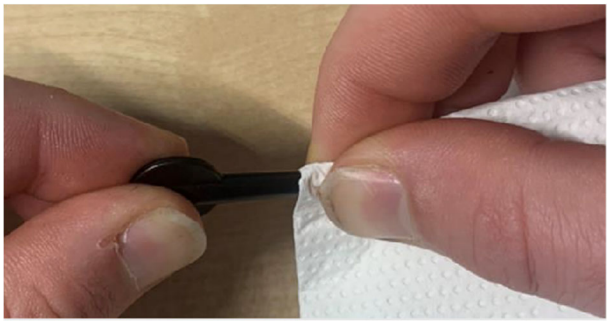


Fig. 7 – Position of the fiber cloth when holding the LDPE tube (852652)

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). **Devices that are kinked or crushed as a result of the Pull-out Test may not be eligible for exchange.**

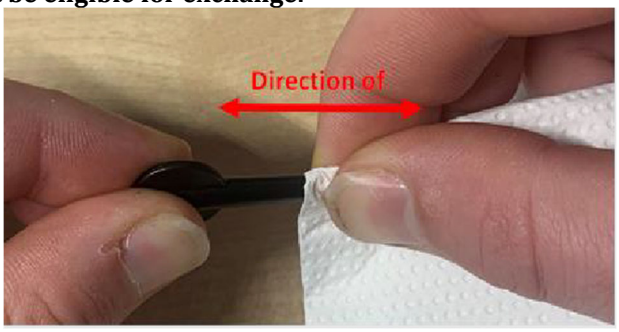


Fig. 8 – Direction of force

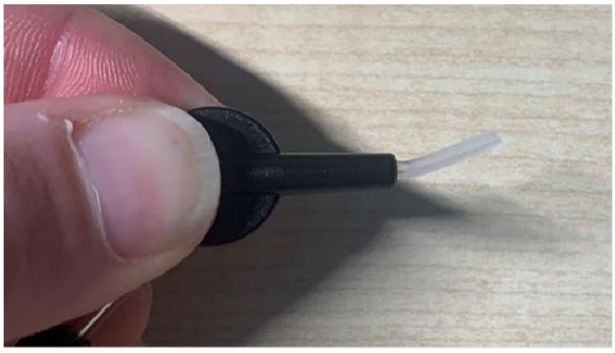


Fig. 9 – Kinking of the LDPE tube

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.

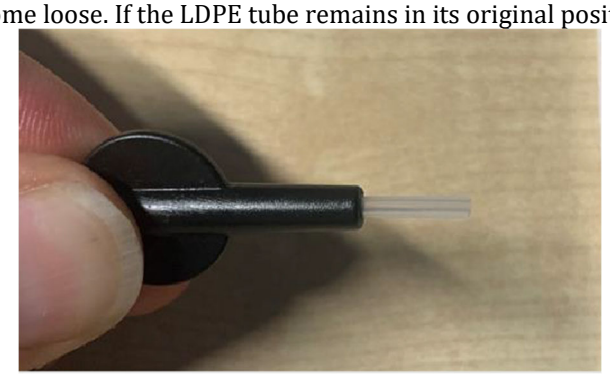


Fig. 10 - Tight Fit LDPE tube

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.
8. **Devices that successfully pass the Pull-out Test can be returned to stock and be safely used as normal.**

Fig. 13 – V-707327

Fig. 14 – 707004

9. After performing the Pull-out Test on all inventory in stock, document the quantity confirmed affected using the Distributor/End-User Response Form and return to **GMB-EMEA-FSCA-RDX-INTL@Vyaire.com**.