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Customer Notification

URGENT: Field Safety Notice

FSCA 25-001- VYNTUS products with SNIP/RHINO Option – REPROCESSING INSTRUCTIONS

2025-AUG -18

Attention: Distributors/End-Users of Vyntus products with SNIP/RHINO Option,

The purpose of this communication is to inform you that Jaeger Medical, formerly known as Vyaire Medical GmbH, is voluntarily notifying customers regarding the Vyntus devices with the optional Rhinomanometry and Sniff Nasal Inspiratory Pressure (SNIP) features.

- Rhinomanometry allows for the evaluation of ventilatory function of the nose.
- SNIP allows for the non-invasive measurement of inspiratory muscle strength.

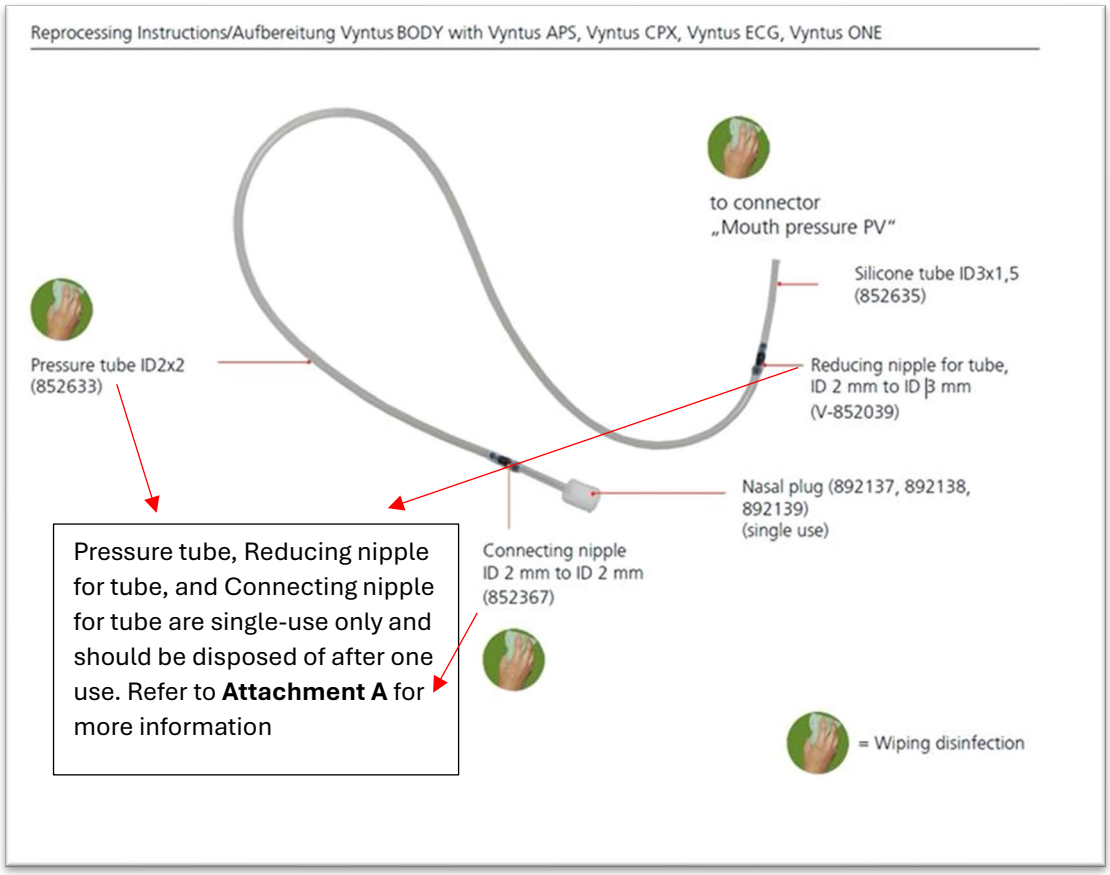
It has been identified that the Reprocessing Instructions do not contain proper reprocessing instructions for the cleaning, disinfection, and disposal of some components (V-708052 Connection set+ 706188 Elbow 45° with tubing) - associated with these testing features.

To ensure patient safety and compliance, all potentially affected devices should be disposed of after single use.

Details of the Issue:

- The affected devices listed in **Attachment A**, of this notification, lack appropriate cleaning and disinfection instructions in the current Reprocessing Instructions; therefore, they are designed as single use only and must be disposed of after use.
- No complaints of serious injury or adverse events have been reported related to the missing information.
- An update will be made to the Reprocessing Instructions, to ensure there are correct instructions regarding reprocessing, and all impacted components are described as single use.

Image of impacted products and components.



V-708052 Connection part for the following options:

Table 1 Affected part including affected part V-708052

Model/Part Number	Product Description
V-570303	SNIP Option for Vyntus PNEUMO/IOS/APS
V-578603	SNIP Option for Vyntus ONE/BODY
V-570304	Rhinomanometry Option for Vyntus PNEUMO/IOS/ APS
V-578604	Rhinomanometry Option for Vyntus BODY/ONE

706188 Elbow 45° with tube and adapter part for the following options:

Table 2 Affected part including affected part V-706188

Model/Part Number	Product Description
V-570304	Rhinomanometry Option for Vyntus PNEUMO/IOS/ APS
V-578604	Rhinomanometry Option for Vyntus BODY/ONE

How to Identify Affected Devices

Potentially affected devices can be identified via the model/part number on the external packaging labeling or the labeling on the device itself. Refer to **Attachment A** of this notification for a complete list of devices, article numbers and associated pictures.

Actions to be taken by Jaeger Medical (formerly Vyaire Medical GmbH):

- Coordinate with Distributors/End-Users to ensure acknowledgment of the single use SNIP/RHINO components. As part of this process, impacted customers will be required to complete a response form confirming:
    - All impacted customers received the notification regarding the affected product and need to confirm use of these components as single use only.
- Ensure that all impacted customers receive the correct instructions in their respective language.
- Track customer responses and take appropriate actions to ensure compliance.

Action to be taken by the Distributor/End-User:

- Confirm receipt and thoroughly review the contents of the Customer Notification Package (including this notification and the Distributor/End-User Response Form).
- Fully complete the attached Distributor/End-User Response Form and return it to GMB-EMEA-FSCA-RDX-INTL@jaegerrdx.com. The email subject line should be labeled "Response Form: FSCA-25-001".
- We respectfully request the completed and signed Distributor/End-User Response Form to be returned no later than 01 OCT 2025 or within 30 days of receipt.

This FSN has been distributed 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 Jaeger Medical at GMB-EMEA-FSCA-RDX-INTL@jaegerrdx.com

Sincerely,

Jared Cardon

Director QRC

Attachment A:

Device	Article-No.	Picture
Pressure tube	852633	
Connection nipple	852367	
Silicone tube	852635	
Reducing nipple	V-852039	
Adapter	852195	
45° Elbow piece with tube adapter	706188	
Silicone tube	852632