



0208-006-008-R Rev. 03

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CRF#: 2020-036

## Customer Notification

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### **URGENT: Field Safety Notice**

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

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**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.

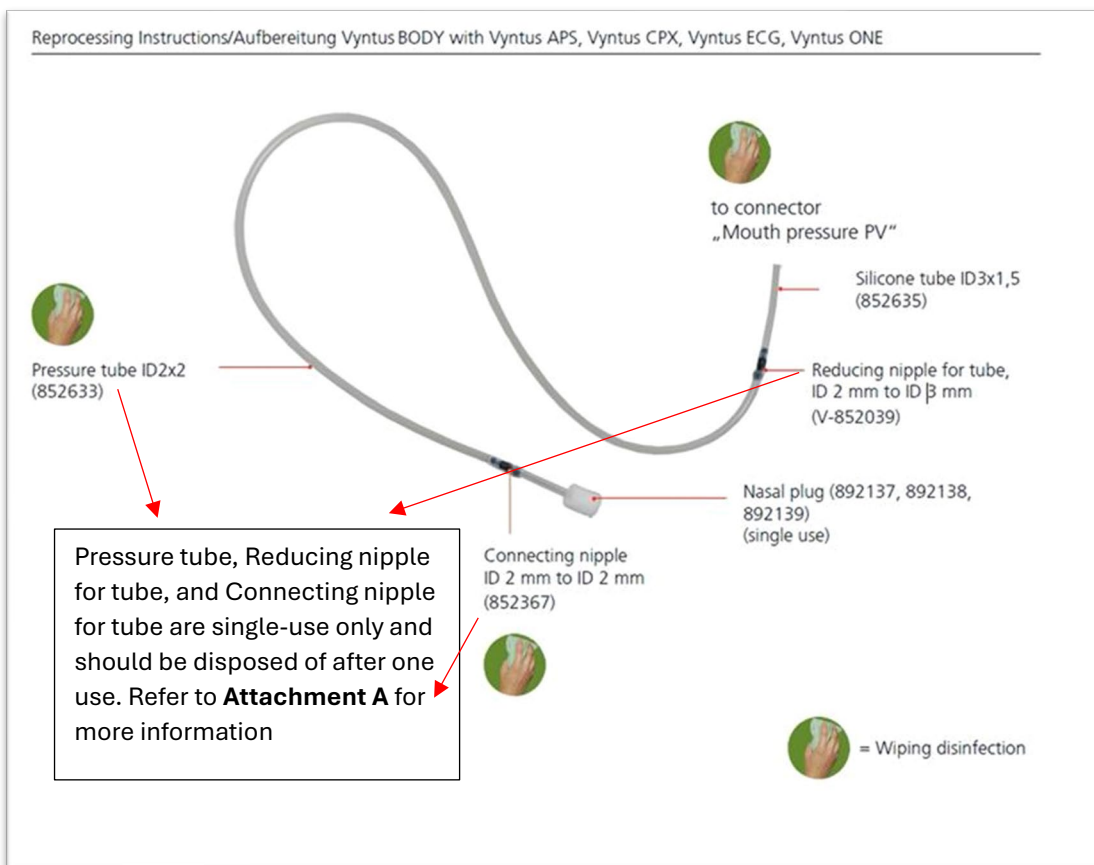
It has been identified that the Reprocessing Instructions do not contain proper reprocessing instructions for the cleaning, disinfection, and disposal of some components (V-708052 Connection set+ 706188 Elbow 45° with tubing) - associated with these testing features.

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 Vyair 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@jaegerdx.com](mailto:GMB-EMEA-FSCA-RDX-INTL@jaegerdx.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@jaegerdx.com](mailto:GMB-EMEA-FSCA-RDX-INTL@jaegerdx.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      |  |