
URGENT: Field Safety Notice – FINAL NOTIFICATION

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

2025 DEC 04

Final Notification**RE:** FSCA-25-001 Field Safety Notice SNIP and Rhinomanometry Components for the Vyntus Devices
Part Numbers V-570303, V-578603, V-570304, V-578604 Improper Reprocessing Instructions

Attention: Distributors/End-Users of the SNIP and Rhinomanometry Components for the Vyntus Devices,

Please note that this closure letter serves as the final notification for this FSCA and replaces any further reminders.

Following our Field Safety Corrective Action (FSCA) notification dated 18 AUG 2025, we hereby confirm completion of all corrective actions related to the reprocessing instructions in the IFU and labelling updates for the above-referenced products.

The FSCA was initiated to address the proper reprocessing instructions for the cleaning, disinfection, and disposal of some components that are part of an optional kit (V-708052 Connection set for Vyntus Body and ONE; V- 706188 Elbow 45° with tubing set for Vyntus Pneumo) - associated with these testing features.

A Field Safety Notice (FSN) was distributed to all affected consignees, advising them of the insufficient detail of reprocessing instruction in the IFU and clarifying that the affected parts are intended for **single use only**. Consignees were asked to acknowledge receipt and understanding of this information.

The following actions have been completed:

- Updated Instructions for Use (IFU) to include proper instructions regarding reprocessing, and all impacted components are designed as single use only.
- Revised product labelling to align with the updated IFU content and ensure compliance.
- Distributed updated IFU and labelling materials in PDF format to all affected customers and distributors.
- Implemented the revised IFU and labelling in production.

Verification of these updates has been completed under CAPA-0000001150 and the revised versions are now in full circulation.

Please download the updated Instructions for Use (IFU) using the following link:

<https://jaegerdx.eifu.com/> - V-781998 Reprocessing Instr. Version 13.00, V-781996 Version 09.00

In addition, the updated instruction of the IFU is provided in **Attachment A** for your review.

Customer acknowledgments have been received confirming receipt of the FSN and implementation of the updated IFU and labelling. A summary of customer responses is maintained in Jaeger's Quality Management System and is available upon request.

Based on the completed corrective actions, multiple documented outreach attempts, and verification from distributors, we conclude that all reasonable and proportionate measures have been taken in accordance with EU FSCA requirements. No further complaints, incidents, or field issues related to the subject of this FSCA have been reported since completion. Accordingly, corrective action is considered effective.

Jaeger Medical confirms that all actions related to the IFU and labelling update FSCA have been completed and verified as effective. Please note that this closure letter serves as the final notification for this FSCA and replaces any further reminders. We therefore consider this FSCA closed from our side. Please confirm whether you also consider the action closed from your side, or if additional documentation is required.

Please direct any inquiries or questions to the following email address:

GMB-EMEA-FSCA-RDX-INTL@jaegermedical.com

Sincerely,

Electronically signed by: Stephanie Batz
Reason: I am the author of this document
Date: Dec 4, 2025 09:17:33 CST

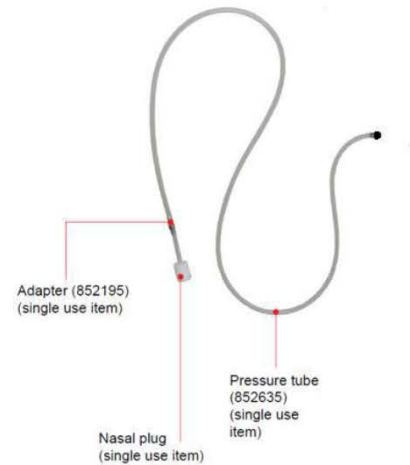
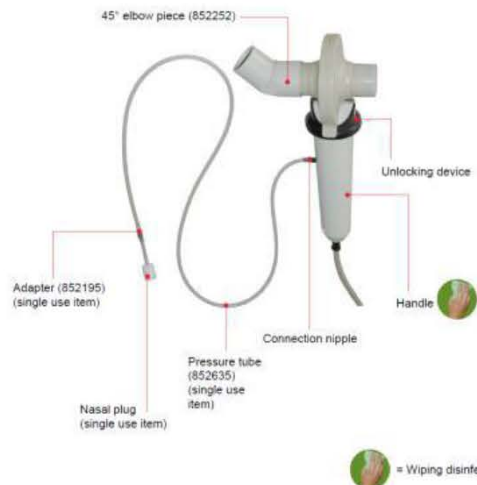
Stephanie Batz, RRT
Mgr. Post Market Surveillance and Complaints

Single-Use Only Components – Do Not Reuse

The following parts are intended for single use only and must be disposed of after use.

Vyntus Pneumo SNIP

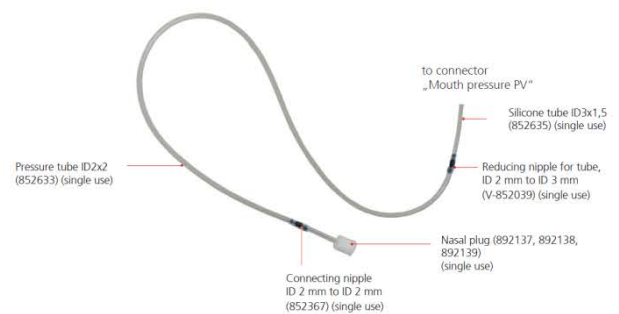
Disassembly **SNIP** Option



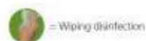
Please dispose of the nasal plug immediately after the measurement.

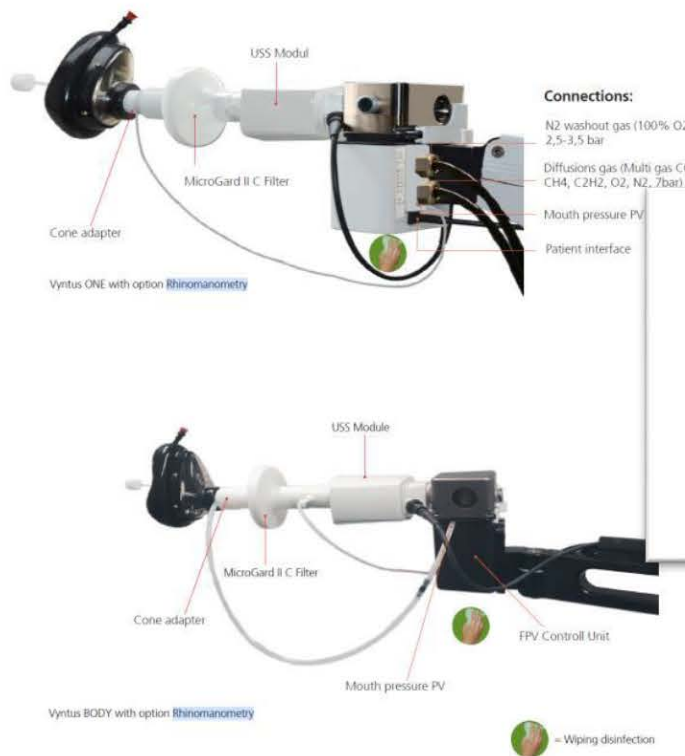
- Disconnect the nasal plug from the adapter (852195).

Vyntus ONE/BODY SNIP



Vyntus BODY with Option **SNIP**




Connections:

N₂ washout gas (100% O₂, 2,5-3,5 bar)

Diffusions gas (Multi gas CO, CH₄, C₂H₂, O₂, N₂, 7bar)

Mouth pressure PV

Patient interface


Vyntus Pneumo RHINO
