CARL REINER®
Breathing Engineering

URGENT: Field Safety Notice

CTNI-610-400 EasyConnect™ Adapter for 2 to 4 Lumen Jet Catheter

04.07.2024

Attention: Distributors/end users of the EasyConnect™ Adapter for 2 to 4 Lumen Jet Catheter,

The purpose of this notice is to inform you that Carl Reiner GmbH is initiating a voluntary recall action for the product referred to below due to the possibility that the adapter does not sufficiently transmit the breathing gas to the ventilator for pressure measurement. The reason for this is a possibly insufficient connection between the adapter and the jet catheter. This poses a potential risk of barotrauma during the patient's ventilation and could require medical intervention to prevent further injury or damage.

To ensure patient safety, all potentially affected products should be tested with the pressure test. See Appendix A. Products that successfully pass the pressure test can be put back into storage and used safely as usual.

REF	Product name	UDI-DI	Batch / serial number(s)
CTNI-610-400	EasyConnect™ Adapter for 2 to 4 Lumen Jet Catheter	09120057170363	2146

Table 1: Potentially affected products

This safety notice has been submitted to the relevant regulatory authorities and is registered under the reference number GZ 3654035.

We are aware of the inconvenience this action may cause and thank you for your support in this important matter. If you have any other questions or concerns, please contact qm@carlreiner.at.

Best Regards

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Identification of affected products

Potentially affected products can be identified by the LOT on the marking of the outer packaging or the marking on the product itself. Products that have a LOT 2146 are potentially affected. The following image shows where you can read the LOT of the product:

Figure 1: Product Labelling

Measures to be taken by Carl Reiner

- Upon receipt of the completed and signed Customer Response Form, coordination will be made with the customers to return confirmed affected equipment and replace it if necessary.

Actions to be taken by the distributor/end user

- Acknowledge receipt and carefully review this safety information.
- If potentially affected products have been transferred to another site or organization, please forward this safety information and any attachments to the relevant parties.
- Review your current inventory as described above in the section “Identification of affected products” to identify and isolate potentially affected products.
- Perform the pressure test on all current inventory as described in Appendix A to verify that the adapter is working properly prior to use.
- Immediately discard any products that do not pass the pressure test and stop using them.
- Complete the enclosed Customer Response Form and return it to qm@carlreiner.at. Please indicate "Reply form: FSN adapter for jet catheters" in the subject line of your email.
- Please return the completed and signed response form no later than 30 days of receipt.

Appendix A: Pressure Test

This section describes the detailed instructions for checking the potentially affected products for sufficient connection with the Jet catheter.

Required material

Product name	Suitable REF (if more than one listed, select one)
Potentially affected EasyConnect™ Adapter for 2 to 4 Lumen Jet Catheter	CTNI-610-400
Jet Catheter 2 to 4 Lumen	CTFS-524-011 CTFS-526-011 CTFS-534-000 CTFS-544-010 CTFS-546-010
EasyConnect™ Tubing Set	CTNS-220-0S0 CTNS-220-0S1 CTNS-220-1S0 CTNS-220-1S1 CTNS-220-200 CTNS-220-201 CTFS-220-SU1 CTFS-220-SU2
TwinStream Jet Ventilator	CTNS-110-000
Disposable glove	Depending on availability

Table 2: Required material for the pressure test

Test procedure

1. Remove the products from their packaging and connect them as shown in Figure 2.

Figure 2: Connection from left to right: Jet Catheter - Adapter for Jet Catheter - EasyConnect Tubing Set

2. Connect the TwinStream Jet ventilator to the power and gas supply and start it as intended in normal operation. If necessary, refer to the instructions for use of the device.

3. Connect the tubing set to the ventilator.

4. Start ventilation on the ventilator by selecting the "4LUM CAT" mode. Then press the ventilation screen "OK". Start NF-JET and HF-JET using the ON/OFF button. Ventilation now runs with the default settings. See Figure 3-5.

Figure 3: Mode "4LUM CAT" and Ventilation Screen OK

Figure 4: NF-JET ON

Figure 5: HF-JET ON

5. Insert the open end of the jet catheter into a disposable glove. Close the opening as tightly as possible by pressing the connection between the glove and the jet catheter firmly with your hand for 2-3 seconds. **See Figure 6.**
   This will simulate an increase in pressure in the patient's lungs and the glove will inflate rapidly.
   CAUTION: The pressure should reach the upper pressure limit of 25mBar after 2-3 seconds and ventilation should stop. If this does not occur, release the closure with your hand, otherwise the glove could burst if it is pressed for too long.

Figure 6: Pressure test. Ventilation is running. Glove inflates.

6. Evaluate the pressure test as follows:

Evaluation	Response of the ventilator
✓	The glove inflates. The following alarm appears on the ventilator display:  ➔ This means that the connection between the adapter and the jet catheter is good and the breathing gas is being transferred correctly to the ventilator. You can continue to use the adapter as usual.
✗	The glove inflates. Ventilation continues without an alarm. CAUTION: The glove may burst if you compress it for too long! ➔ This means that there is no sufficient connection between the adapter and the jet catheter and you must discard the adapter.

Table 3: Evaluation of the pressure test

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Customer Response Form

1. FSN information (already pre-filled)	
Date	04.07.2024
Product/Product Name	EasyConnect™ Adapter for 2 to 4 Lumen Jet Catheter
REF	CTNI-610-400
Charge/Seriennummer(n)	2146
FSN Reference Number	GZ 3654035

2. Customer details (to be completed by you)	
Customer	
Health Organization Name*	
Address of the Organization*	
Department	
Delivery address, if different from above	
Name of contact person*	
Title or Function	
Telephone number*	
E-Mail*	

3. Customer action that has been carried out (to be completed by you)			
☐	I confirm receipt of the safety information and that I have read and understood its contents.		
☐	**For distributors only:** I have also forwarded the full safety information including attachments to my end-user customers. Date of notification:		
☐	I carried out the pressure test on all of the items in stock and discarded any products that did not pass the test.		
☐	The following batches were discarded and their use discontinued.	Pcs.:	Batch:
		Pcs.:	Batch:
		Pcs.:	Batch:
		Pcs.:	Batch:
		Pcs.:	Batch:
Notes:			

Name*	
Signature*	
Date*	

Required fields are marked with *

Upon receipt of this completed form, we will contact you to arrange the return and exchange of the affected products.

Please send the completed form to: qm@carlreiner.at.

Your organisation's response is our evidence that we need to monitor the progress of the corrective actions.