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## **Urgent Field Safety Notice**

### **Additional Instructions for Use**

concerning

Neo-Pneumocath for adults 10 F - 50 cm (REF: 503 011)  
and further PNEUMOCATH® / NEO-PNEUMOCATH® / THORACATH® - models

**Please refer to the attached article list (Annex I).**

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01.09.2020

**Procedure number:** FSCA200001

**Sender:**

intra special catheters GmbH  
Oststraße 2  
D-66780 Rehlingen-Siersburg  
www.intra-online.de

**Recipient:**

Distributors and users

**Description of the problem including the identified cause:**

- The background to the corrective action is an incident reported by a user concerning the product "Neo-Pneumocath for adults 10 F - 50 cm" with the article number 503 011.
- The user described a deficiency in the connection of the catheter on the metal mandrel at the three-way stopcock. Due to this deficiency, the user said that before the catheter was finally fixed to the patient, the catheter had disconnected from the metal mandrel on the three-way stopcock and had been pulled into the pleural space by negative suction.
- A user error is not excluded by intra special catheters GmbH. For this reason, the Instructions for Use have been adapted so that the connection of the catheter to the metal mandrel of the three-way stopcock and the fixation of the catheter to the patient is more clearly indicated. Products placed on the market in the future will already contain the following ***additional application instructions***.
- intra special catheters GmbH classifies the risk for patients as very low if the product continues to be used correctly in accordance with the previous instructions for use.
- There are no risks for patients who have already been treated with affected products.

**We currently inform all customers to take the following measures:**

1. According to our documentation you have received products to which this **Urgent Field Safety Notice** applies. Please add this **Urgent Field Safety Notice** to the previous instructions for use to ensure that users take the ***additional application instructions*** into account.
2. If you are a distributor, pass on this **Urgent Field Safety Notice** to your customers who have received products from the attached list of articles (Annex I).
3. For our verification of the effectiveness of the field corrective action, please confirm that you have received this notification by filling in the attached CUSTOMER CONFIRMATION (Annex II).
4. As corrective action, the following ***additional application instructions*** apply in addition to the existing instructions for use.

**Necessary information to be followed by the user:**

**Additional application instructions:**

**1.**

Immediately after placement of the catheter, it must be fixed in place (e.g. with adhesive tape) so that it cannot be pulled into the pleural space by any negative pressure!

**2.**

From placing the pleural drain until the pleural drain is attached (e.g. with adhesive plaster) to the skin of the patient, it is absolutely necessary to fix it with one hand. The fixation may only be released when the final fixation of the catheter is ensured.

**3. (does not apply to models with Fix-Adapter)**

The catheter must be pushed as far as possible onto the metal mandrel of the three-way stopcock. The catheter must be held at the end to avoid kinking the tube. Afterwards, it is essential to check that the catheter is firmly seated on the metal mandrel.

**Notification obligation for distributors:**

If you are a distributor and/or have to comply with a notification obligation within or outside the EEA/CH/TR, please notify your local competent authority of this measure. Please forward the notification and all communications with your local competent authority to intra special catheters GmbH.

**Transmission of the information described here:**

Please ensure in your organisation that all users of the above products and other persons to be informed are aware of this **Urgent Field Safety Notice**. If you have supplied the products to a third party, please forward a copy of this information or inform the contact person below.

Please keep this information at least until the action has been completed.

**Contact person:**

Should you require further information or assistance regarding this matter, please contact:

Contact: Mr Jörg Staudt  
Mail: [info@intra-online.de](mailto:info@intra-online.de)  
Phone: +49(0)6835-92260  
Fax.: +49(0)6835-922622

Signature



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**Annex I**

**List of articles**  
to  
**Urgent Field Safety Notice**

concerning

Neo-Pneumocath for adults 10 F - 50 cm (REF: 503 011)  
and further PNEUMOCATH® / NEO-PNEUMOCATH® / THORACATH® - models

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01.09.2020

**All batches!**

Article number:	Product description:	Size:	UDI-DI:
503 001	Pneumocath for adults	50 cm - 8 F	04025562500016
503 002	Pneumocath for children	40 cm - 8 F	04025562500023
503 003	Pneumocath for premature and newborns	30 cm - 6 F	04025562500030
503 003S	Pneumocath for premature and newborns	30 cm - 6 F	04025562500047
503 011	Neo-Pneumocath for adults	50 cm - 10 F	04025562500115
503 012	Neo-Pneumocath for children	40 cm - 10 F	04025562500122
503 014	Neo-Pneumocath fix Emergency model	50 cm - 10 F	04025562500146
503 015	Onko-Pneumocath to Weritz	50 cm - 10 F	04025562500153
503 037	Neo-Pneumocath for adults with silicone tube	50 cm - 10 F	04025562500375
503 111	Neo-Pneumocath for adults complete set	50 cm - 10 F	04025562501112
503 201	Pneumocath fix for adults	50 cm - 8 F	04025562502010
503 203	Pneumocath fix for premature and newborns	30 cm - 6 F	04025562502034
503 211	Neo-Pneumocath fix for adults	50 cm - 10 F	04025562502119
503 401	Pneumocath for adults complete set	50 cm - 8 F	04025562504014
503 401F	Pneumocath for adults complete set with hypodermic needle	50 cm - 8 F	04025562504021
503 403	Pneumocath for premature and newborns complete set	30 cm - 6 F	04025562504038
503 501	Pneumocath for adults with Pneumovent complete set	50 cm - 8 F	04025562505011
503 503	Pneumocath for premature and newborns with Pneumovent complete set	30 cm - 6 F	04025562505035
503 611S	Neo-Pneumocath fix for adults with Pneumovent and LL complete set	50 cm - 10 F	04025562506124
503 711	Neo-Pneumocath for adults Seldinger technique	50 cm - 10 F	04025562507114
503 903	Pneumocath Set	30 cm - 6 F	04025562509033
90001	Thoracath for adults	50 cm - 8 F	04025562500900

Jörg Staudt



Signature

**CUSTOMER CONFIRMATION**

to

**Review of the effectiveness of the field corrective action FSCA200001**

For our verification of the effectiveness of the field corrective action, please complete the fields below and send the signed CUSTOMER CONFIRMATION by e-mail to [info@intra-online.de](mailto:info@intra-online.de) with the subject "FSCA200001". Please contact [info@intra-online.de](mailto:info@intra-online.de), if you require further information or assistance on this matter.

Name:	
Position:	
Company / Institution:	
Street:	
City:	
Postal Code:	
Phone number:	

I hereby confirm that

1. I have read and understood this **Urgent Field Safety Notice** and, if necessary, I have informed all persons in my organisation to be notified. Yes  No
  
2. if products have been resold to third parties, to have identified these third parties and to have passed on the **Urgent Field Safety Notice** to these third parties or to have informed intra special catheters GmbH of these third parties who still have to be informed, by listing them below Yes  No

Company / Institution:	address information:	e-mail address:

Date \_\_\_\_\_

Signature \_\_\_\_\_