



05.12.2022

## URGENT SAFETY INFORMATION

### Product Recall

Regarding: Pressure Monitoring Sets and Arterial Extension Lines  
Article number(s): see attached article list  
Batch number(s): see attached article list

**To the responsible persons in medical management, purchasing management, intensive care units, accident and emergency departments, surgery, nursing management, materials management, continuing nursing education (and all other departments which may possibly have received and used these products).**

CODAN pvb Critical Care GmbH requests that all users **stop using** the above product batch(es) **with immediate effect**. Please read the following related information:

#### *Description of the miss function:*

The potentially affected pressure monitoring sets and extensions may leak at the male luer lock of the pressure monitoring line.

#### *Explanation of potential risks for patients, users or other persons:*

Due to the high number (8 leaks → failure rate 0.27%) of currently known leakages of the affected pressure monitoring line, we are recalling all potentially affected products.

All potential risks to be considered in this context are classified as low and are rated as acceptable:

- air entry into the peripheral arterial or central arterial pathway,
- unintentional fluid/blood loss,
- risk of infection for the patient/user,
- possible delay in monitoring the patient due to the necessary change of set.

A copy of this „URGENT SAFETY INFORMATION“ has been submitted to the competent higher federal authority, BfArM (Federal Institute for Drugs and Medical Devices).

Please keep this information until the following measures have been completed.



## What needs to be done?

To assist us with this action, please ensure that all of the products affected are immediately identified and quarantined to prevent them from being used. The article and batch numbers are located on each individual package and each packaging unit.

Please complete the attached form and return it by email before **8. December 2022** to:

Name of company:	[REDACTED]
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The email address can be found on the form. We will contact you immediately to make arrangements for the replacement of the goods.

Please forward this information to all departments within your organization which use or order the affected products. Please ensure that a copy of this letter is also forwarded to all other institutions that have received the affected goods from you.

We apologize for any inconvenience you may suffer as a result of this action.

Please do not hesitate to contact us if you have any questions.

For questions related to this action, please contact:	Name: <b>Herr Patrick Fröhlich</b>	Tel: <b>+49 (0) 4363511550</b>
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Thank you for your assistance in this matter.

Yours sincerely

Signature:

[REDACTED]

Name:

[REDACTED]

Position:

[REDACTED]



## Article list:

The following batches of the articles listed below may be affected by the potential defect:

REF	Description	Batch
71.2075	Arterial extension line	977332
		977708
74.6105	Monitoring set with CVP limb	977388
74.6274	Monitoring set, single	977364
		977648
74.6462	Monitoring set, single	977626



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Please send your response by email:

<b>Email :</b>	<b>codan@codanpvbmedical.de</b>
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Please fully complete this response form and place a cross in the applicable boxes.

**Please complete and return this form even if you have no more of the listed products in stock.**

If you do still have the affected goods in your possession, please enter the remaining quantities.

- We no longer have any of the affected goods in stock
- We still have the following quantities of the affected goods in stock (please enter quantities in the table)

Article number	Batch number	Quantity

The goods must be collected from the address given below. We are requesting

- replacement goods
- a credit note

**Please do not return any goods to us without being requested to do so.**

Name of institution:			
Department from which goods are to be collected, if applicable:			
Name of contact person: (please use block capitals)			
Street:		Tel.:	
Building number:		Fax:	
Postal Code:		Email:	
City:			
Country:			

Date: \_\_\_\_\_

Signature: \_\_\_\_\_