

URGENT: FIELD SAFETY NOTICE

Item No.	Description
F29	Siegen Päd. I / Custom line Siegen Paed I
F29K	Siegen Päd. I NEO / Custom line Siegen I NEO
F30	Siegen intensiv Päd. / Custom line Siegen Paed intensive
SN1003	Verbindungsleitung 29 cm / Custom line Frankfurt Hoechst
SN1064	R-Ventilverbinder klein 4-fach / 4-way check valve CON, small

22 October 2018

Dear Valued Customers:

Director of Risk Management
Director of Nursing
Director of Materials Management

ICU Medical, Inc. is issuing this Urgent Field Safety Notice to notify you of a recall of some IV administration sets. This product notification details the issue and the required steps for you to perform.

Issue:

ICU Medical received reports of tubing separations on certain IV administration sets and out of an abundance of caution, ICU Medical is issuing this notification.

Potential Risk:

If tubing separations are not identified prior to use of the IV administration set, there is a potential for interruption of therapy during infusion to occur. Tubing separations could potentially lead to leakage prior to or during use, exposure to hazardous medication, blood loss, air embolism, or contamination of the line with possible infection. To date, ICU Medical has not received any reports involving a serious injury or death related to this issue.

Affected Product:

Our records indicate that you have received some of the affected products, which were distributed in Germany, Austria and Switzerland between September 2016 and August 2018. The affected products are identified in Table 1.

Required Actions for Users:

- 1) Please complete the attached response form and return it to the fax number or e-mail address on the form, even if you do not have the affected product. In addition, this notification should be carried out to the user level and passed on to all those who need to be aware within your organization or to any other organization the device may have been transferred. *If you have distributed the product further, notify your accounts that received the product identified in the Affected Product section of this notification and ask them to contact ICU Medical representative to receive a Response Form.*
- 2) Upon receipt of the completed response form and return of the affected product, ICU Medical will credit you for any product returned. You will only receive credit for product that you return. NOTE: Credits for product purchased through distributor will be credited by the distributor.

Follow-up Actions by ICU Medical:

ICU Medical is in the process to implement corrective actions to resolve the issue as quickly as possible. As such, product replacement is not yet available.

For further inquiries, please contact ICU Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	EMEA-Quality@icumed.com	To report adverse events or product complaints
ICU Customer Service	DistributorsEurope@icumed.com	Additional information or assistance relating to this recall including availability of replacement product

The Bfarm, SwissMedic and Ages have been notified of this action.

ICU Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,



Corine Broekhuizen
Director, Quality and Regulatory Affairs
ICU Medical BV

Enclosures:

- Affected Product and Lot Numbers
- Response Form

Table 1: Affected Product and Lot Numbers

Item No.	Description	Lot No.		
F29	Siegen Päd. I / Custom line Siegen Paed I	3295947	3325600	3340487
		3335443	3303856	3393828
		3377303	3385382	3406853
		3417489	3429788	3420309
		3436991	3436994	3480276
		3502984	3494614	3554492
		3563017	3566971	3586326
F29K	Siegen Päd. I NEO / Custom line Siegen I NEO	3315263	3393699	3397679
		3406855	3420310	3497963
		3554493	3559610	3559608
		3573774		
F30	Siegen intensiv Päd. / Custom line Siegen Paed intensive	3364235	3406856	3427107
SN1003	Verbindungsleitung 29 cm / Custom line Frankfurt Hoechst	3364264	3364564	3377269
		3377138	3393892	3406907
		3473400	3473399	3473401
		3480367	3490742	3486059
		3502706	3527705	3552545
		3545334	3556378	3559508
SN1064	R-Ventilverbinder klein 4-fach / 4-way check valve CON, small	3305875	3315208	3320903
		3377181	3377123	3393902
		3401074	3606374	3622382

URGENT: FIELD SAFETY NOTICE RESPONSE FORM

Item No.	Description
F29	Siegen Päd. I / Custom line Siegen Paed I
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Check your inventory and complete the information below, even if you do not have the affected product. Failure to complete all sections of this page may result in improper, delayed or denied credit.

Please return the completed form to DistributorsEurope@icumed.com, EMEA-Quality@icumed.com or your ICU Medical sales representative.

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name of Person Completing this Form	
Signature of Person Completing this Form	
Date	

I have **NO** affected product (complete and return this form to the e-mail above).

YES, I have affected product (complete and return this form to the e-mail above).

If affected product is not being returned, please explain below:

- Have you distributed the product further to the retail level? YES___ NO___
 - If yes, have you notified your retail customers? YES___ NO___ (if no, explain below)

Lot Number	Quantity to be returned	Wholesaler/Distributor Name If you purchased from Wholesalers/Distributors include name, address, city, state, zip, quantity from each, and invoice number. If you purchased directly from ICU Medical leave this section blank.	PO, debit memo or invoice
		1.	
		2.	