icumedical
human connections

951 Calle Amanacer
San Clemente, CA 92673
www.icumed.com

URGENT: Field Safety Notice

Affected Device(s): Tego® Connector

Date: 09/06/2016

Dear Valued Customer:
Clinical Personnel
Risk Manager
Biomedical and supply chain personnel

ICU Medical Inc. has identified the potential risk of leaking with certain Tego® Connector devices. The potential for leakage could exist when the Tego is connected to the dialysis tubing during the hemodialysis treatment, and may lead to blood loss. ICU Medical has received reports associated with this issue. While the company is investigating a definitive root cause, out of an abundance of caution, the company is recalling lots that could potentially contain this condition.

There have been no reports of adverse patient consequences as a result of this issue.

Product Affected

Our records indicate that you have received some of the affected products. The affected item numbers and lots are provided in Table 1.

Table 1. Affected Product and Lot Numbers

Item No.	Description	Lot No.
D1000	Tego® Connector	3254636, 3255850, 3258004, 3258326, 3258327, 3260656, 3260657, 3261516, 3261517, 3265973, 3265975, 3268523, 3269593, 3269594, 3275465, 3275467, 3278966, 3278967, 3239841, 3239848, 3244021, 3244022, 3244023, 3244558, 3244560, 3246196
NM1000	Tego® Connector	3224799

Action Required

To assure that the affected devices are accounted for, removed from use and returned to ICU Medical, Inc., please follow the instructions below:

Step	Action	
1	Do not use the above identified products. Inspect your inventory for the specific product and their lot numbers listed above.	
	If…	**Then…**
	No affected devices are found:	• Complete sections A & B of the Recall Response Form and return to ICU Medical.

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Step	Action	
	Affected devices are found:	• Quarantine any affected devices • Complete sections A & C of the Recall Response Form as applicable and return to ICU Medical. • Contact ICU Customer Care for a Return Goods Authorization. - Call: +1(866) 829-9025 and select option 8 or - E-mail: customerservice@icumed.com
2	Return completed Recall Response Form to ICU Medical, Inc. via - FAX: +1(801) 264-1755 or - E-mail: recall@icumed.com	

On receipt of the completed Response Form and return of the devices, ICU Medical, Inc. will credit you for any product returned. You will only receive credit for recalled product that you return.

This recall should be carried out to the user level and passed on to all those who need to be aware within your organization or any other organization the device may have been transferred to. Please forward this letter to your customers and on to any end users of the devices.

Should you have any questions or require assistance relating to this recall please contact ICU Customer Service Monday through Friday between the hours of 8:30 AM and 4:00 PM Pacific time:+1-866-829-9025 and select option 8, or e-mail the following address: customerservice@icumed.com. For customers in Europe please contact: customerserviceeurope@icumed.com or call on numbers listed below

Country	Language	Phone Number
France	**French**	**+33 4 9913 30 34**
Belgium	**Flemish**	**+32 2 7007177**
Belgium	**French**	**+32 2 7007177**
Germany	**German**	**+49 2349 7849009**
Italy	**Italian**	**+39 0687 500833**
Others and distributors	**English**	**+44 203 564 3377**

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Please complete the attached Medical Device Recall Response Form and fax to +1(801) 264-1755 or e-mail to recall@icumed.com. Please include the words “Tego Connectors” in the subject line.

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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,

Afsaneh Rafati
Director, Quality and Regulatory Affairs
Email: recall@icumed.com

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Affected Device(s): Tego® Connectors

Section A

Name of Hospital / Facility	
Hospital / Facility Address	
Name	
Email Address	
Telephone Number	
Signature	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

Section B

[ ] I have read and understood the contents of this recall notice and confirm that our inventory has been checked and we have no inventory of the listed products.

Section C

[ ] I have read and understood the contents of this recall notice and confirm that our inventory has been checked, Quarantined, and returned to ICU Medical Inc.:

Item #	Lot #	Quantity Returned (please specify if quantity returned is each device or cases)	ICU RGA Number

Please return to:
ICU Medical Recall Coordinator
E-mail: recall@icumed.com, Please include the words “Affected Device(s): **Tego® Connectors**” in the subject line
Or FAX: +1(801) 264-1755.