Hofspoor 3
3994 VZ Houten
The Netherlands
www.icumed.com

URGENT: FIELD SAFETY NOTICE

Tego™ Silicone Seal Issues

15th January 2026

Dear Valued Tego™ Customers:

ICU Medical is issuing this letter to notify you of potential issues affecting specific lots of the Tego™ products. This notification details the issue and the affected lots.

Overview of the Issue:
ICU Medical has identified lot-specific issues with the silicone seal on the Tego device. The identified silicone seal defects include: silicone seal doming (see Figure 1), which occurs because of a loose silicone seal which may bulge at the top surface or separate from the Tego body and may potentially result in fluid leaks; and silicone seal tearing (see Figure 2), which can potentially result in a collapsed silicone seal which may lead to occluded fluid flow or fluid leaks.

Figure 1: Silicone Seal Doming

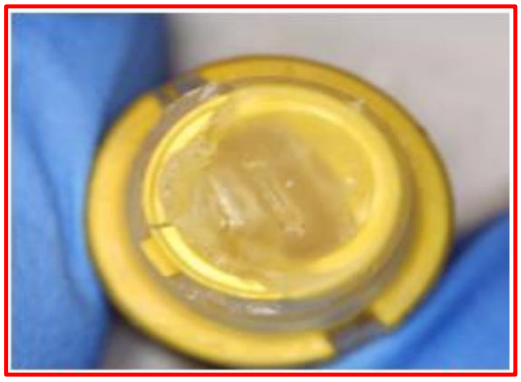

Figure 2: Silicone Seal Tearing

Potential Risk:
To date, ICU Medical has received nine (9) reports of serious injury, and zero (0) deaths associated with this issue. If the Tego device has a doming or tearing issue, this may result in a delay in therapy and/or fluid leakage, interruption in therapy, or air infused into the body. The risk of fluid leakage and air infused into the body can be mitigated by following the IFU statement listed below:

- Clamp line before disconnecting from Tego, and between dialysis sessions per established clinical and catheter manufacturer's practices.
- Clamp vascular access device before disconnecting a device (blood line, blood withdrawal device, syringe).

Affected Products:
The affected item and lot numbers distributed in the EMEA region are provided in Table 1, below:

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Table 1: Affected Product

Item Number	Product Description	Lot Number					
D1000	Tego™ Connector	13768000	13858987	13955847	14027552	14115073	14224627
		13772666	13859857	13959944	14027553	14115074	14224630
		13778923	13859858	13971720	14037604	14131561	14226006
		13778925	13859859	13971761	14041792	14131562	14226007
		13791783	13867514	13971773	14041793	14131563	14226009
		13791784	13876508	13979279	14041795	14131564	14226011
		13794984	13882259	13979290	14041797	14135720	14226013
		13801101	13882260	13979293	14041798	14135721	14228828
		13806761	13887205	13986399	14056397	14135722	14244977
		13806762	13887206	13999996	14056398	14135725	14244978
		13812988	13887997	13999997	14063791	14145004	14244980
		13812990	13894351	14000001	14063792	14162155	14251976
		13822693	13894352	14000003	14071894	14170227	14251977
		13822697	13903974	14015462	14071895	14170231	14251980
		13825588	13903975	14015467	14087321	14183938	14251983
		13828548	13910272	14021608	14087322	14183940	14251984
		13828553	13938363	14021611	14090801	14183941	14251985
		13833876	13938366	14021613	14097662	14192702	14251986
		13833877	13943704	14027546	14100193	14192703	14265939
		13848444	13949234	14027547	14100198	14201160	14265940
		13854647	13953954	14027549	14110503	14201165	14300979

Required Actions for Customers

When using the device, all instructions, including warnings and cautions contained in the Instructions for Use must be followed with heightened awareness. Please complete the following actions below.

1. Check all inventory locations within your institution for the affected Tego products listed in Table 1 and discontinue use. Destroy all affected products following your institution's process for destruction. If destroying is not immediately possible at your facility, then the product should be quarantined until disposal.

2. Share this notification with all potential users of the device, to ensure they are aware of this notification. If the devices are used at another location, please ensure this communication is delivered there.

3. Complete and return the attached Customer Response Form to EMEA-FSN@icumed.com within 10 days of receipt to acknowledge your understanding of this notification.

4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to **YOU**. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com

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Follow up Actions by ICU Medical:
ICU Medical will provide credit to affected customers upon receipt of a completed Customer Response Form to certify product destruction. Credit shall be provided if the form is received within 120 days of receipt of this notification. For further inquiries, please contact ICU Medical using the following information.

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

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	ProductComplaintsPP@icumed.com	To report adverse events or product complaints
ICU Medical Customer Service	https://www.icumed.com/about-us/contact-us	Additional information or assistance

Your local Competent Authority has been notified of this action.

ICU Medical is committed to patient and clinician 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 of Quality, ICU Medical BV

- See Response form below

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URGENT: FIELD SAFETY NOTICE - RESPONSE FORM

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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 EMEA-FSN@icumed.com, If you have questions about this form please contact EMEA-FSN@icumed.com or your local sales representative.

Customer Number (Refer to the original email subject line for your CNXXXXXX /customer number)	
Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

Please select one:

☐ I have **NO** affected products (complete and return this form to the e-mail address above)

☐ **YES**, I have affected products, I have notified users in my facility and I have followed the instructions provided to me and destroyed all affected items (see table below)

If you have affected product on hand, please complete table 1 below:

TABLE 1

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction

If you have distributed the product further, please complete table 2 below with collated information received from your customers and respond to ICU Medical with the overall information.

TABLE 2

Item / SKU Number	Lot Number	Quantity destroyed locally (Eaches)	Date of Destruction

Adverse events and complaints associated with the use of this product should be reported and emailed to ICU Medical's Global Complaint Management Department at ProductComplaintsPP@icumed.com.

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ADDITIONAL AFFECTED PRODUCT DESTROYED

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction