URGENT MEDICAL DEVICE CORRECTION

Tego™ Silicone Seal Issues

19 DECEMBER 2025

Dear Valued Tego™ Customers:

- Director of Dialysis and Infection Prevention
- Director of Nursing
- Director of Risk Management
- Director of Pharmacy

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 items. See Appendix A for a list of affected items.

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, it may result in an occluded fluid path identified by the inability of the user to inject or withdraw blood product with a syringe. Damaged seals may also result in a delay in therapy and/or fluid leakage, interruption in therapy, exposure to biological contaminants 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 in the precautions and instructions for use sections of the IFU:

- Precaution: Clamp line before disconnecting from Tego, and between dialysis sessions per established clinical and catheter manufacturer's practices.

- Instructions for Use: Clamp vascular access device before disconnecting a device (blood line, blood withdrawal device, syringe).

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 Appendix A 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 marketaction@mailac.custhelp.com within **10 days of receipt** to acknowledge your understanding of this notification.

4. If you have distributed affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to marketaction@mailac.custhelp.com

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 1-(866)-216-8806	To report adverse events or product complaints
Customer Service	customerservice@icumed.com 1-(800)-258-5361	Additional information or technical assistance
Field Service Processing	marketaction@mailac.custhelp.com	Assistance with Customer Notifications and Response Forms

The U.S. Food and Drug Administration (FDA) has been notified of this action. Adverse events or quality problems experienced with the use of this product may be reported to the FDA''s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Complete and submit the report Online: www.fda.gov/medwatch/report.htm

Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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,

Joe Canavan

Vice President, Quality and Regulatory Affairs

Enclosures (Separate Documents)**:**

- Response Form
- Frequently Asked Questions

Appendix A

Item Number	Product Description	UDI	Lot Number		
D1000	Tego™ Connector	01008406190260591728090130011O	13791784	14226012	13828548
			13791785	14244971	13910270
			13801100	14216156	13949234
			13822693	14226008	14097662
			13867513	14226010	14115075
			13876507	14228825	14131561
			13876508	14265940	14145003
			14265943	14265941	14170227
			14027549	14226013	14244970
			14115076	13801099	14307684
			14162155	14000000	14037605
			14201163	14145004	13838931
			13859857	13971761	13986399
			13894353	13979279	14021610
			13953954	13979308	14027551
			13953956	13982887	14036500
			13955847	13986330	14036503

			13959944	13986393	14056400
			13910272	14300979	14292935
			13999997	13903976	14307683
			14036501	13979303	14292936
			14041790	13986440	14300977
			14135722	13979306	14201162
			14201161	13867512	14216157
			13838935	13838933	13772666
			13894351	13848445	13806763
			13959950	13943712	13828553
			13999999	13979290	13833878
			14015464	13979298	13894352
			14036498	14015463	14041792
			14056399	14021612	14041797
			14110502	14090800	14063790
			13768000	14170232	14135723
			13778925	14251980	14201160
			13806762	14289207	14226009
			13833877	14307685	14265942
			14087322	14015459	13986406
			14097661	14179721	14027548
			14135725	14183938	14041793
			14145005	13801101	14115073
			14201165	13848442	14131563
			14251979	13986339	14150877
			13794980	13982888	13938366
			13825588	14041800	14219694
			13828551	14244972	13971744
			14170231	14100193	14192702
			14183941	14219693	13778922
			14244977	13903977	14226006
011-D1000	Tego™ Connector	01008406190067851729120130011014228823	14228823		