Kidney Community Emergency Response

FDA: Class 2 Device Recall

KCER Release Date: January 18, 2017

www.kcercoalition.com/resources/alerts-and-recall-notifications/

Tego Connector Recall

Tego Connector, Item No. D1000, NM1000

The Tego Needle Free Access Device is intended for use as an accessory to a vascular access device (catheter) used in Hemodialysis or as an accessory to an Intravascular Administration Set for the administration or withdrawal of fluids to a patient through a cannula or needle placed in the vein or artery. The Tego is a needle-free capping device which closes the end of the catheter. The Tego will permit access to the catheter without the use of needles and therefore passively aid in the reduction of needle stick injuries.

Code Information
3239841, 3239848, 3244021, 3244022, 3244023, 3244558, 3244560, 3246196, 3254636, 3255850, 3258004, 3258326, 3258327, 3260656, 3261516, 3261517, 3265975, 3268523, 3269593, 3269594, 3275467, 3278966, 3278967, 3224799

Recalling Firm/Manufacturer
ICU Medical, Inc.
951 Calle Amanecer
San Clemente CA 92673-6212

For Additional Information Contact
949.366.2183

Manufacturer Reason for Recall
ICU Medical Inc. has identified a potential risk of leaking with certain Tego Connector devices.

FDA Determined Cause
Under investigation by firm

Action
The firm, icumedical, sent an "URGENT: Medical Device Recall Notification" letter dated 8/24/16 to all their customers. The letter describes the product, problem and actions to be taken. The customers were instructed to quarantine any affected devices; remove from use, return to ICU medical, Inc.; and complete and return the recall response form to ICU Medical via fax (801) 264-1755 or at recall@icumed.com (even if you do not have any affected product). Customers with questions are instructed to contact ICU customer service Monday through Friday between 8:30AM and 4:00PM Pacific Time, (866) 829-9025 and select option 8 or email the following: customerservice@icumed.com.

For more information: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=149342