600 N. Field Drive
Lake Forest, IL 60045
www.icumed.com

UPDATED IMPORTANT PRODUCT INFORMATION

List Number: 14951-88, Primary PLUM™ Set

22 September 2023

Dear Valued Plum Customers:
Director of Risk Management
Director of Nursing
Director of Pharmacy

Update to notice from 11 May 2023 (updated content shown in red font): ICU Medical has updated the notice to include additional affected lots of affected Primary PLUM sets (list number 14951-88). This revised communication is being issued to make you aware of the complete range of affected lots.

ICU Medical identified a Plum Set that is incorrectly labeled and is voluntarily issuing this product notification which details the issue and the required steps for you to perform.

Issue:
ICU Medical identified that Plum Set 14951 is labeled as "This device is not made with plasticizer Diethylhexylphthalate (DEHP)." However, the drip chamber of this set contains small amounts of DEHP.

Potential Risk:
The affected set contains DEHP in the drip chamber. A study concluded that the potential daily exposure to DEHP from this product is less than 0.0009 mg/kg/day for an adult and 0.0063 mg/kg/day for a child. These levels are below the 60 mg/kg/day No Observed Adverse-Effect Level (NOAEL) cited in U.S. Food and Drug Administration (2017), *Safety Assessment of Di(2-ethylhexyl)phthalate (DEHP) Released from PVC Medical Devices*.

To date, ICU Medical has not received any reports of adverse events related to this issue.

Affected Product:
The affected product is identified in the table below:
Changes to the affected lot ranges from the initial notice are listed with * and in red font in the table below.

List Number	Description	Lot Numbers	
14951-88	Primary PLUM Set CLAVE™ Secondary Port, Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 104 Inch	4571111	5869615
		4571112	5882940
		4740299	5999722
		4740300	6430755
		4766530	7538750
		5287427	7882732
		5354920	8300734
		5434234	*9034730
		5560843	11269882
		5634865	*11269914
		5720872	*13493297
		5787360	

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Required Actions for Users:

1. Inform potential users of the product in your organization of this notification and complete and return the attached Response Form to ICUmedical3061@sedgwick.com **within ten days of receipt.** Please complete the response form, even if you do not have affected product, to acknowledge your understanding of this notification.
2. If you have distributed the product further, immediately notify your accounts that received the product identified in the Affected Product section of this notification and ask them to contact Sedgwick at 1-877-244-0947 (M-F, 8am-5pm ET) to obtain a response form.

Follow-up Actions by ICU Medical:

ICU Medical changed the drip chamber to a version without DEHP to match the labeling.
For further inquiries, please contact ICU Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-844-654-7780 or ProductComplaintsPP@icumed.com	To report adverse events or product complaints
Customer Service	1-866-829-9025, option 8 or customerservice@icumed.com (M-F, 8:00 am – 6:00 pm CT)	Additional information or assistance

Adverse reactions 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 at 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,

Mary J. Ferreira
Director, Field Actions

Enclosures:

- Response Form