AHRMM
Advancing Health Care through
Supply Chain Excellence

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Supply Chain Resource Council (SCRC) Report

November 13, 2023 Meeting

Executive Summary

There are a number of recalled products commonly used including syringes, chlora-prep, sterile saline and water whose potential impact to patient care is concerning and being carefully monitored by AHRMM and SCRC members. The council also discussed expanding opportunities as a group to include evaluating Global Trade Identification Number (GTIN) disparities with the goal of enhancing clinical and supply chain UDI workflows and patient safety initiatives. More details can be found in the full report below.

▲ Shortage Updates

- **Fetal Scalp Electrodes.** This shortage situation, first reported back in November 2022, continues to impact health care organizations. Cardinal Kendall™ Fetal Spiral Electrodes have been utilized in the absence of the Philips product, however, demand continues to outpace supply. Philips and the FDA have agreed to continued use and availability of Philips's Fetal Spiral Electrodes for medically necessary situations. The latest *Dear Customer letter* from Philips has a number of acknowledgements that facilities must agree to if they choose to use the Philips FSEs.

- **Sterile Saline and Water.** Nurse Assist, LLC issued an Urgent Field Safety Notice dated November 8th covering Sterile 0.9% Saline, USP and Sterile Water, USP under the following 12brand names and 77 associated part numbers/UDIs; Nurse Assist, Stericare, Cardinal, Halyard, Idexx, Mac Medical, McKesson, MediChoice, Medline, SOL, Trudell, and Vyaire. Customers are being instructed to quarantine and not use any of the "affected devices" in their inventory. Expiration dates range from November 1, 2023 to September 18, 2025 for all part numbers, with the exception of part number 1030A (USP STERILE WATER SYRINGE, UDI+B15010304N), which has an expiration date range from November 1, 2023 to September 18, 2028.

  Details can be found in the attached Urgent Safety Field Notice. AHRMM is asking supply chain leaders to share their strategies in addressing this situation.

- **Cardinal Monoject™ Luer-Tip Syringes.** Cardinal Health is recalling some of its syringes branded as "Cardinal Health Monoject syringes" for incompatibility with syringe pumps. The dimensional changes made to the affected Cardinal Health Monoject syringes when used with syringe pumps may result in pump performance issues such as overdose, underdose, delay in therapy and delays in occlusion alarms. *Links to more information can be found below.*

  https://www.fda.gov/medical-devices/medical-device-recalls/cardinal-health-recalls-monoject-disposable-syringes-incompatibilities-syringe-pumps?utm_medium=email&utm_source=govdelivery

  Furthermore, the U.S. Food and Drug Administration issued a Letter to Health Care Providers alerting providers and facilities not to use Cardinal Health Monoject syringes with syringe pumps or patient-controlled analgesia (PCA) pumps while the FDA further evaluates this issue. The use of Cardinal Health Monoject syringes with syringe pumps or PCA pumps may result in infusion pump performance issues including overdose, underdose, delay in therapy, and delays in occlusion alarms. *Links to more information can be found below.*

  https://www.fda.gov/medical-devices/letters-health-care-providers/do-not-use-cardinal-health-monoject-syringes-syringe-pumps-and-pca-pumps?utm_medium=email&utm_source=govdelivery

- **Multiple shortages for Olympus vacuum curettage products.** These products, identified in the attached *Olympus Recovery letter* continue to pose a challenge for some SCRC members. Below is an overall summary as well as a suitable substitute for the 3/8" tubing set.
    - VC-10 pumps are on backorder due to a shortage of a key component. The backorder situation is expected to last through the end of the year.
    - 3/8" (#23116) tubing sets are experiencing delays of some components. If you are in immediate need, Olympus has validated and recommends MedGyn Inc., Catalog Item No. 022310 as a suitable substitute for Catalog Item No. 23116.
    - Their Vacurette manufacturer has updated product packaging to ensure that all products meet Olympus quality standards. Backorders will be ongoing, and Olympus expects to be on a rolling backorder as demand continues to exceed capacity.
- **Eye Lubricant.** Consumers have been warned by the FDA not to purchase or use certain eye drops from several major brands due to the risk of eye infection. Cardinal Health Inc. has initiated a voluntarily recall for all lots of six **Leader** brand ophthalmic products. Additionally, Harvard Drug Group, LLC also initiated a voluntary nationwide recall for all lots of two **Rugby Laboratories** brand eye drops. The agency has updated the **list** of products to include the national drug codes (NDCs) that have been confirmed and will provide additional information as it becomes available. This is creating an issue for health care organizations with ocular hospitals. At the time of this meeting, no alternative products had been identified. *Links to more information can be found below.* AHRMM is asking supply chain leaders to share their strategies in addressing this situation.

  https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-certain-eye-drops-several-major-brands-due-risk-eye#eyedrops
- **BD Chlora-Prep.** BD issued a letter to health care providers alerting them to the potential for rolling backorders of BD ChloraPrep™ 1 mL, FREPP 1.5 mL, and 3 mL Applicators. Designated recovery dates for these products are listed as January and February of 2024. Details can be found in the *attached Dear Customer letter*.
- **BD DEHP mis-labeled product.** A pulse survey was sent to SCRC members to assess the level of impact related to this recall; Low, Medium or High. Responses ranged across all three impact levels with a majority in the low to mid-range. Two council members stated during the call that their clinical, pharma and risk management teams were evaluating potential DEHP-Free alternative products.
- **CO2 Availability.** Council members shared that they are not experiencing issues with inventory levels or sourcing of CO2.

▲ Supply Chain Watch List — supply shortages causing concern in the field

- **Panama Canal.** Drought conditions continue to cause lower water levels in the freshwater lake that supports the Panama Canal, reducing the number of daily vessel transits to 25 as of November 3rd. Should drought conditions persist, Canal authorities have indicated vessel transits could be reduced to as low as 18 starting Feb 1, 2024. Other notable statistics include:
    - Over 40% of U.S. consumer products from Asia pass through the Panama Canal. While the percentage of medical supplies is unknown, the question has been raised in hopes of better understanding the potential impact to the health care supply chain.
    - Alternative routes, including the Suez Canal, can add up to 20 days additional transit time.
- **Israel-Hamas War.** Impact on global supply chains is minimal at this time. Variables identified that could change the level of impact include a prolonged or expanded conflict. Pharma drug, API and technology

▲ Other Items to Report

- **NIOSH Rescissions of Dentec Safety Specialist Corp.** The National Institute for Occupational Safety and Health (NIOSH) has honored a request by Dentec Safety Specialists Corp. to voluntarily rescind 30 NIOSH respirator approvals issued to Dentec Safety Specialists Corp. As of October 20, 2023, any respirator marked with a NIOSH approval label with the below approval numbers are no longer NIOSH approved. The NIOSH **Certified Equipment List** no longer includes these approval numbers:

23C-0264	23C-0266	23C-0268	23C-0270	23C-3306	84A-0905
84A-0907	84A-0909	84A-0911	84A-0944	84A-0946	84A-0948
84A-0950	84A-0952	84A-2011	84A-2012	84A-2568	84A-2569
84A-2570	84A-2571	84A-2572	84A-5282	84A-5283	84A-5284
84A-5285	84A-5286	84A-7843	84A-7845	84A-7847	84A-7849

- **NIOSH Rescissions of Honeywell International Inc.** The National Institute for Occupational Safety and Health (NIOSH) has honored a request by Honeywell International Inc. to voluntarily rescind 26 NIOSH respirator approvals issued to Honeywell International Inc. As of November 13, 2023, any respirator marked with a NIOSH approval label with the below approval numbers are no longer NIOSH approved. The NIOSH **Certified Equipment List** no longer includes these approval numbers:

84A-0593	84A-0594	84A-0595	84A-0596	84A-0597	84A-0598
84A-0599	84A-0600	84A-0601	84A-0602	84A-0603	84A-0604
84A-0605	84A-0606	84A-0607	84A-0608	84A-0609	84A-0610
84A-0612	84A-0613	84A-0614	84A-0615	84A-0616	84A-0901
84A-0902	84A-0903				

- **UDI-DI (Device Identifier)/GTIN compliance.** Council members discussed disparities between supplier GTIN information on labels and the Global UDI Database (GUDID), multiple device identifiers, etc. with broad acceptance to begin compiling and sharing this level of information as a group. These discrepancies are impacting more and more organizations as adoption of the UDI in their clinical and supply chain workflows increases.

  One senior supply chain leader stated, "Getting this aligned and moving this forward probably would have the biggest impact on supply chain that anything we could talk about going forward."

About the Supply Chain Resource Council (SCRC)

The Supply Chain Resource Council (SCRC) is comprised of more than 90 supply chain and health care leaders from across the health care field with the goal of understanding the extent and impact supply shortages and disruptions are having within the hospital and patient care settings, as well as a capturing and documenting solutions to these challenges. Information collected during these calls is drafted into a report and shared with AHA, AHRMM and Professional Management Group (PMG) leaders, the White House Response Team, various Federal Agencies and the broader health care field. *The content of this report represents information, strategies and solutions from SCRC members but does not necessarily reflect policy positions of the AHA.*