

Supply Chain Resource Council (SCRC) Report

June 10, 2024

Executive Summary

This month Council members discussed some of the effects due to the recall of Chinese manufactured plastic syringes, sourcing challenges of Integra Craniotomy Kits, and the FDA's Letter to Health Care Providers regarding the Getinge Intra-Aortic Balloon Pump (IABP), Cardiohelp system and HLS Sets. Hurricane preparedness and Helium inventory rounded out our topics. Similar to last month, we have a post-meeting Field Update regarding NISOH acceptance and rescission of Champak respirators. Details can be found in the full report below, and on our newly developed [Supply Chain Resource Council webpage](#).

▲ Field Updates

- **Disruptions associated with alternately sourced syringes due to the Chinese Manufactured Plastic Syringe recalls.** Several disruptions were reported by SCRC members. As hospitals are converting to alternate syringes, some are finding that these syringes are not working with their syringe pumps. Other challenges include product allocations either through primary distributor channels or BD. It was reported that BD Paracentesis Trays are being shipped without the previously included 60ml syringe. Difficulty sourcing alternate control syringes was also reported.
- **Cranial Access Kits are becoming increasingly difficult to source.** While not a high-volume item, this is a critical product and concern over the shortage is growing with the summer months traditionally seeing a higher utilization of these kits due to head trauma injuries. Interim solutions include purchasing the drill and drill bits individually from Integra or, directly from alternate suppliers Medtronic and Phasor.

Providers should expect a Dear Customer letter in a week or so from Integra with information regarding a "get healthy" date. The letter will be forwarded to all SCRC members, once I have received a copy.

Below are the affected products codes as shared by an SCRC member. Please share any additional manufacturer catalog numbers that should be included in this list.

Integra codes unable to get (entire line of products is currently unavailable):

INSHITH
INSHITHRZN
INSHITHND
INS5HND

Integra/Codman sub codes unable to get (entire line of products currently unavailable):

82-6614

Medtronic codes unable to get:

46156
46154

Natus codes unable to get (entire line of products currently unavailable to us since we would use as subs):

HITHND

- **FDA letter to Health Care Providers regarding the Getinge Intra-Aortic Balloon Pump (IABP) and Cardiohelp system and HLS Sets.** The FDA recommends that health care facilities transition away from use of these devices and seek alternatives, if possible. [The FDA recognizes that alternative treatment options are limited and has provided recommendations for health care providers.](#)

- Per the letter:
 - Getinge has issued twelve (12) voluntary recalls from January 1, 2023 through April 11, 2024 in the U.S. for the Cardiosave IABP. Of these, the FDA has classified eight (8) as a Class I recall.
 - Getinge initiated eight (8) voluntary recalls from January 1, 2023 through April 11, 2024 for the Cardiohelp system, including the HLS Set. Of these, the FDA has classified one (1) as a Class I recall.

According to an [ECRI recommendations and information report](#) on alternative devices, Teleflex is the only FDA-cleared alternative to the Cardiosave device. Attached is the Dear Valued Customer Letter from Teleflex.

- **Integra Bactiseal.** Integra LifeSciences has temporarily halted shipments and production of all Bactiseal® products, including Bactiseal EVDs, Bactiseal Shunt Catheters and Bactiseal Catheters provided with programmable valves. See the attached Dear Valued Customer letter for more details and impacted products.
- **Take Action to Prepare for Hurricane Season.** The FDA encourages medical device stakeholders (such as health care providers, medical device manufacturers and distributors) to prepare for hurricane season, which began on June 1, 2024. For more information, [click here to view the FDA bulletin](#).
- **This was the first month** without a kit manufacturer recall notice associated with the Nurse Assist, LLC Class I Recalls for Sterile Water and Saline. There are currently no reports that the Nurse Assist or kit manufacturer recalls are impacting patient care or hospital inventory levels. [Click here to review the full list of kit manufacturer recalls](#).
- **With the acceptance of the Messer bid to acquire the Federal Helium System** by the Bureau of Land Management (BLM), The question around helium availability was posed to the members. No shortages were reported.

More information can be found on both the [BLM](#) and [Messer](#) websites. For additional insights on the helium market, you can [read the USGS Report here](#).

▲ Supply Chain Watch List – current situations under observation

- **In the East Coast Port contract negotiations**, the union representing port workers from Maine to Texas halted labor talks Tuesday. The call for higher wages comes after the International Longshoremen’s Association (ILA) canceled master contract talks on Tuesday with the United States Maritime Alliance (USMX).
- **FedEx Pilots** voted overwhelmingly in favor of a strike, if needed, on May 15th.

▲ Field Updates – Post-Meeting Developments

The National Institute for Occupational Safety and Health (NIOSH) has honored a request by Champak Enterprise Co., Ltd. to voluntarily rescind five NIOSH respirator approvals issued to Champak Enterprise Co., Ltd.

As of June 1, 2024, any respirator marked with a NIOSH approval label and approval number listed in the table below is no longer NIOSH approved. The NIOSH [Certified Equipment List](#) no longer includes these approval numbers:

Approval Number	Part/Model
84A-7229	AP520S, AP520M, AP520L
84A-7230	AP520VS, AP520VM, AP520VL
84A-7832	AP521VS, AP521VM, AP521VL
84A-7842	AP522VL
84A-8080	AP921VM, AP921VL

The complete text of NIOSH CA 2024-1082 may be found at: <https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/respprotect/CA-2024-1082.html>

About the Supply Chain Resource Council (SCRC)

The Supply Chain Resource Council (SCRC) is comprised of over 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 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) senior 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.*