

Supply Chain Resource Council (SCRC) Report

July 8, 2024

Executive Summary

This month Council members discussed the current shortage situation concerning the BD Bactec Blood Culture Bottles. Following this meeting, we've had conversations with both BD and the FDA with content from these conversations, and resource links, included in this report. We would like to acknowledge and thank our colleagues at the FDA and BD for their time and aligned goals of information sharing and transparency.

Chinese manufactured plastic syringes, cranial access kits, shunt valves, and Beckman Coulter chemistry reagent shortages rounded out our discussions. Similar to last month, we have Field Updates and/or Post-Meeting Developments including NISOH acceptance and rescission of 3 manufacturers respirators.

Details can be found in the full report below, and on our newly developed [Supply Chain Resource Council webpage](#).

▲ Field Updates

- **BD Bactec Blood Culture Bottles** are now on manual allocation due to manufacturing issues (not raw material shortages as previously stated) that will limit BD's supply of BACTEC™ blood culture vials and ability to meet full global demand. The following information is what we have learned during conversations with representatives from BD and the FDA.
 - BD BACTEC™ blood culture vials are being allocated manually in an effort to best mitigate any impact to patient care.
 - As an additional stopgap measure, BD's former supplier of glass vials will restart production to help fill the intermittent gap in supply. Glass vials are expected to be available and in the market sometime this Fall.
 - It is our understanding that the glass vials will be produced for the following products:
 - SKU - 442021 10 Anaerobic/F Culture Vials.
 - SKU - 442794 Myco/F Lytic Culture Vials.
 - No "get-well" date has been identified. BD will provide another supply update in September.
 - Similar to pandemic supply shortage management, health care organizations should consider centralizing inventory, if possible, to manage utilization, and to review clinical practices.

Below are the following products that may be impacted:

SKU	Product Name
442023	BD BACTEC™ Plus Aerobic/F Culture Vials
442021	BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials
442020	BD BACTEC™ Peds Plus™/F Culture Vials
442022	BD BACTEC™ Plus Anaerobic/F Culture Vials
442024	BD BACTEC™ Standard Anaerobic/F Culture Vials
442027	BD BACTEC™ Standard/10 Aerobic/F Culture Vials
442794	BD BACTEC™ Myco/F Lytic Culture Vials

One health care organization stated they were unable to centralize their inventory due to the number stock locations throughout the organization. They have made changes to their order sets in EPIC, specifically for repeated orders for these products in an effort to minimize any waste or duplication.

Additional information and related links:

- BD’s *customer letter* is attached and here is a [link to their latest press release](#).
 - BD has established a [microsite to provide ongoing information](#).
 - The FDA has shared the following [letter to health care providers](#) which recommends laboratories and health care providers consider conservation strategies to prioritize the use of blood culture media bottles, preserving the supply for patients at highest risk. *A PDF copy of the letter is attached.*
 - The CDC Division of Laboratory Systems (DLS) convenes regular Laboratory Outreach Communication System (LOCS) calls. [Join their next DLS call on Monday July 15, 2024, at 3:00 PM Eastern time](#) for more information regarding the blood culture bottles. Prior to the call, questions may be submitted to DLSinquiries@cdc.gov.
- **Disruptions continue to be experienced by SCRC members associated with alternately sourced syringes due to the Chinese Manufactured Plastic Syringe recalls.** Providers are managing through the use of alternative suppliers and inventory utilization management. However, the proprietary nature and relationship between the syringes and how pumps are programmed is making it extremely difficult to change from one syringe manufacturer to another. Supply chain departments are also experiencing an increased reliance on manual intervention measures with procedure packs now being affected, and the staff hours necessary to individually source and pair the syringes with these packs. On a positive note, no impacts to patient care were reported.
 - **Beckman Coulter chemistry reagent Cystatin C shortages were reported by SCRC members.** Members are currently able to manage the through the shortage at this point in time.

▲ Supply Chain Watch List – current situations under observation

- **Cranial Access Kits and Shunt Valves**, while not high-volume items affecting all hospitals, they are critical for those organizations with high utilization rates. There is growing concern now that we are in the summer months where volume is traditionally higher due to head trauma injuries.

▲ Field Updates and/or Post-Meeting Developments

- **The White House has released an Executive Order** titled, **“White House Council on Supply Chain Resilience.”** AHA feedback is that the brief is general in nature, but puts more of a focus on national and international supply chain issues.
- **NIOSH Rescission requests have been honored** for the following companies: SAS Safety Corporation; Allegro Industries; Venus Safety & Health Pvt., Ltd. 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:

Voluntary Rescission of four SAS Safety Corporation:

Approval Number	Part/Model
84A-7858	Bandit 8600 Series Half Mask Air Purifying Respirator with Chemical Cartridge and Filter
84A-8079	Model 311 Half Mask Air Purifying Respirator with Filter
84A-8113	Model BreatheMate Half Mask Air Purifying Respirator with Filter
84A-8149	Model 312 Full Facepiece Air Purifying Respirator with Chemical Cartridges and Filter

The complete text of **NIOSH CA 2024-1083** may be found at: <https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/respprotect/CA-2024-1083.html>

Voluntary Rescission of one NIOSH respirator approval issued to Allegro Industries:

Approval Number	Part/Model
19C-0433	Model #9910E Economy Hood Supplied Air Respirator

The complete text of **NIOSH CA 2024-1084** may be found at: <https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/respprotect/CA-2024-1084.html>

Voluntary Rescission of two NIOSH respirator approvals issued to Venus Safety & Health Pvt., Ltd.:

Approval Number	Part/Model
84A-5634	Model CN95 ME N95 Filtering Facepiece Respirator
84A-9365	Model 50-73-4200 N95 Filtering Facepiece Respirator

The complete text of **NIOSH CA 2024-1085** may be found at: <https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/respprotect/CA-2024-1085.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.*



Advancing Health in America
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