

#### **April 2024 SUPPLY UPDATE EXECUTIVE SUMMARY**

This Supply Update Executive Summary provides a quick look at the potential supply chain disruptors around the world. For complete supply details, view the full Supply Update available exclusively for our providers.

# The EPA has finalized a new rule for the sterilizer EtO.

Uncertainty remains about what the sale of the Federal Helium System means for supply, while shipping disruptions continue, energy prices are expected to remain elevated and greater U.S. semiconductor chip production is anticipated later this year. Also, the latest product category concerns that affect providers are detailed.

## **Market conditions**

The U.S. Environmental Protection Agency (EPA) finalized its <u>new rule for ethylene oxide (EtO)</u> for commercial sterilization facilities. We are reviewing the rule to determine potential impacts and will update our <u>brief</u> as we know more. Other resources: <u>Fact Sheet:</u> <u>Overview of the Final Air Toxics Rule</u>, <u>Video Presentation: Final Rule Overview</u> and <u>Regulatory Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations</u>

Some other key issues that continue to affect the supply chain include the following:

- Helium: The sale of the Federal Helium System reserves on Jan. 25 to a private owner continues to cause uncertainty, with at least some shutdown in production anticipated as the sale is finalized and the transfer occurs. Helium is used in everything from party balloons to magnetic resonance imaging (MRI) machines and quantum computers. Currently, the helium market is stable even as there is a tight supply predicted until at least the end of this year.
- Shipping disruptions: Dangerous shipping conditions in the Red Sea and drought conditions at the Panama Canal have increased delays and costs of shipping, forcing rerouting of vessels to avoid the problematic canals. Houthis from Yemen have attacked merchant ships in the Red Sea, while drought conditions have reduced daily ship transits, although in February the transits increased to 27 from 24 in January; the 2023 normal was 38. The shock of the Houthi attacks combined with ships running behind schedule led to a quick jump in spot rates that have gone down in February and March, while still elevated. Long term, this could result in U.S. West Coast backlogs returning, higher consumer shipping rates and potential raw material delays if the issues persist.
- **Semiconductor chips:** Shortages are improving but significant improvement may not occur until later this year when new U.S. factories come online. Also, China restricting exports of key raw materials, gallium and germanium, has not yet affected production.
- Energy: While U.S. oil production was extremely high in 2023 and is expected to remain elevated, four primary factors have kept oil prices high, with upward pressure expected to continue: long-term conflicts with potential of escalation, economies unexpectedly growing, Saudi Arabia continuing production cuts through 2024 and demand growing faster than anticipated, especially from developing countries.

# **Recovering categories**

Adhesive drapes, mammography equipment, medical tapes, PEG tubes, sharps containers and vascular closures

## Updates by category

## Medical, surgical and integrated logistics

- 3M convective air warming Bair Hugger warming blankets extended lead times are expected with varied recovery.
- Covidien/Medtronic endotracheal tubes Taperguard and Hi-Lo are still experiencing challenges with recovery expected in the
  next few weeks.
- Cardinal has issued an urgent medical device correction for *Monoject Enteral Syringes* and continues to have limited supply of
  Monoject Luer Lock Syringes, with rolling back orders and allocations; non-sterile sizes are released from hold, while sterile ones
  are not. Amber ENFit syringes are off hold.
- In facial protection, 3M is experiencing delayed lead times after significant demand increases.
- 3M bld/fld wrm pediatric set 10/case is on back order along with the Ranger irrigation *fluid warming* set 10/case with recovery anticipated for June. Expect seven- to 14-day delays.
- In hemodynamic monitoring, Edwards Lifesciences has a supply disruption for Swan-Ganz continuous cardiac output catheters; recovery is now expected in April; intermittent cardiac catheters are not affected.
- The Food and Drug Administration (FDA) is warning not to use recalled saline (0.9% sodium chloride) and sterile water medical products manufactured by Nurse Assist and sold under various brands. ICU Medical also continues to experience intermittent shortages of *irrigation solutions in sterile water* at least through Q4; plans to fully transition to alternative SteriCare irrigation by Q1 2025.



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- **Monitoring electrodes** continue to be constrained; some of Cardinal and 3M recovery is months away; 3M neonatal electrode outages are improved, and some are resolved. Cardinal has upgraded its manufacturing processes and equipment for long-term increased capacity, with some products recovered.
- The latest recovery updates are available for Philips back orders on several **noninvasive ventilator products** due to testing validation; most XL parts and V60 circuits are available.
- Rolling back orders are possible for Cardinal *open suction catheters* because of manufacturing delays on select products due to raw material packaging shortages; Nurse Assist's recall of *small sterile water bottles* used in some open suction kits has affected the respiratory open suction category. The FDA has also issued an <u>FDA safety communication</u>.
- The FDA has updated its ongoing quality and performance evaluation of *plastic syringes* made in China, with additional recommendations and actions announced. Find complete details and the latest mitigation strategies here.
- An updated list is available for 3M skincare products placed on manual allocation as a result of high demand.
- In December, Cardinal issued an urgent medical device correction for Medi-Vac CRD Suction Canister Liners, which may
  experience loss of suction on low or low intermittent suction settings. In addition, Cardinal's estimated recovery for select suction
  canisters experiencing delays due to a new production machine: CRD is expected in the fall and Flex by summer, while Cardinal's
  highest volume line, Guardian, has recovered.
- 3M has had back orders on its blade **surgical shaving clipper** (No. 9660) with shipping returned Jan. 15 and a caution statement issued. BD offers an alternative but is not accepting new customers; buying product may be possible with conversion contact your local BD rep.
- Due to increased demand, O&M Halyard has rolling back orders on *surgical drapes and standard packs*, with return to normal expected in April; *gowns* are also on rolling back orders expected into late Q2.
- Medtronic issued an urgent medical device recall for various Shiley adult flexible tracheostomy tubes; Flex disposable adult tubes
  are in a good state, while some other codes on back order are expected to recover in April; ICU Medical stock is good, now doubling
  safety stock levels.

## Medical devices and physician preference items

- Integra LifeSciences issued a voluntary medical device recall for PriMatrix, SurgiMend and Revize biologic surgical mesh
  products; alternatives may be available; back orders expected through April.
- Getinge lifted the temporary ship-hold of several *intra-aortic balloon catheters*, effective Jan. 8, after experiencing intermittent ship-holds starting in December for a self-imposed inspection; no issues were found. All back orders resolution expected mid-May.
- In *tourniquet cuffs*, Stryker has begun to stock and ship high runner cuffs; the supplier is working to increase product for low runner cuffs; latest updates are provided. Zimmer and ASP Global are taking on new providers.

### Capital

- After a temporary ship-hold on all *GI endoscopes* due to the Japan Noto Peninsula earthquake, Olympus operations have been
  restored for GI flexible endoscopes with 150 day lead time expected; all other flexible endoscopes are available. Service and repair
  are being prioritized to ensure care continuity.
- **Exam room equipment** suppliers have lead times for several products.
- The latest lead times are available for Stryker LifePak, HeartSine *external defibrillators*; Philips has updated backlogs, with some shipping normally, and Zoll has updated extended lead times on some products.
- The FDA has a Class II Correction (Recall) of Philips *fetal spiral electrodes*; Cardinal anticipates supply recovery in November with backlogs due to demand increases with Philips leaving the market.
- **Stretcher** lead times continue improving, with new lead times available.
- Philips is experiencing manufacturing challenges with a number of **ventilator airway adapter** codes resulting in product back orders, with anticipated recovery extended to Q2.

### Facilities and construction

Find the latest up-to-date information affecting facilities and construction in the Facilities and Construction Market Insights.

## Food

- Recovery is expected in Q2 for certain Abbott Nutrition medical nutritional products that have been at low inventory or out of stock; non-acute care products have been affected most with acute care receiving priority. Abbott is increasing production of alternative products. Nestle has discontinued certain product to prioritize high-use products and those impacted by Abbott.
- Natural disasters and disease have led to lower orange crop numbers and higher **orange juice** prices. Alternative juices or fruit should be considered.
- Find the latest up-to-date information affecting food assurance in the Food for Thought Supply Chain newsletter.

# Pharmacy:

• Find the last four weeks of the drug shortage digest on the pharmacy resources tab at the bottom of the Vizient Assurance webpage <a href="here">here</a> (make sure you're signed in).