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Baxter Response to ExactaMix Valve Set Constraints

Baxter is experiencing a significant constraint for our ExactaMix Valve Sets required for the ExactaMix Automated Compounding Device. This constraint is a result of a resin shortage required to make the valve cap on the finished valve set. The ExactaMix Valve Set is designed specifically for the ExactaMix Automated Compounding Device, and currently there are no alternative sets available on the U.S. market.

We recognize that this constraint causes significant challenges in patient care, and we are exploring every avenue to minimize disruption and deliver on our mission of saving and sustaining lives. We have conferred with the American Society for Parenteral and Enteral Nutrition (ASPEN), American Society of Health-System Pharmacists (ASHP), Children's Hospital Association (CHA), Institute for Safe Medication Practices (ISMP), and National Home Infusion Association (NHIA). We have developed a process that deploys valve sets to the most vulnerable populations with the highest need and limited therapeutic or operational alternatives, specifically neonates who are dependent on parenteral nutrition (PN). We continue to confer with these organizations to support and assist in educating institutions on potential conservation considerations as they navigate this constraint. One resource is accessible here: [ASPEN | Baxter ExactaMix Automated Compounding Device \(ACD\) Valve Set Supply Disruption Considerations \(nutritioncare.org\)](#).

Below is a summary of Baxter's current actions:

- Deploying available supply to the most vulnerable patient populations, most notably neonates who are dependent on parenteral nutrition (PN).
- Identifying and securing contracts with alternate resin suppliers. Baxter has identified an alternative supplier and is currently in the process of validating the alternate resin, creating redundancy to support backfilling the current shortage and to mitigate potential future issues.
- Actively and consistently engaging our current supplier regarding the gravity of the shortage and patient impact.
- Conferring with advocacy organizations, including the American Society for Parenteral and Enteral Nutrition (ASPEN), American Society of Health-System Pharmacists (ASHP), Children's Hospital Association (CHA), Institute for Safe Medication Practices (ISMP), and National Home Infusion Association (NHIA) to drive further awareness of the constraint and leverage these platforms to help communicate important information.
- Conferring with the FDA to help address the shortage from other suppliers and potential increases in market demand.
- Dedicating Baxter medical resources to help support customers' decision-making with respect to facility specific conservation plans.

While we are actively exploring the above mitigation strategies, per the ExactaMix Operator Manual, to maintain delivery accuracy, the valve set must be replaced after it has delivered 150 L of fluid or been installed for 24 hours, whichever comes first. Presently, there is no internal Baxter data available to support extending the valve set usage beyond these parameters. We understand the substantial strain this constraint creates for you. We are working closely with healthcare systems impacted by the evolving and dynamic needs of this situation, and it is our commitment to provide updates as we identify additional strategies and support for managing patient care.



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