CATEGORY RESOURCE GUIDE

IV pumps, tubing and solutions

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Vizient award overview

Awarded suppliers

IV01011 - Baxter Healthcare IV01012 - ICU Medical Sales IV01013 - CareFusion Solutions

Distribution

Both direct and distributed through the following distribution channels:

Medical-surgical Pharmacy

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Questions? Contact disasterresponse@vizientinc.com, pharmacyquestions@vizientinc.com, novaplus@vizientinc.com.

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Making supply uncertainty a thing of the past, not the future

To help members maintain supply assurance for essential products, Vizient shares insights via category resource guides on vizientinc.com. These category-specific documents contain comprehensive manufacturing, logistics and utilization insights to help members source supplies with confidence. Category resource guides are one way we're building supply assurance together.

Market landscape

It is estimated that about 20 million IV saline bags are used per month in the U.S. (*Journal of Health Contracting*, 2018). In recent years, manufacturing and supply chain disruptions, as well as natural disasters, have impacted the availability of IV drugs and solutions in the health care setting. Most recently, damage caused by major hurricanes impacting the manufacturing capabilities of IV solutions resulted in critical shortages nationwide, with available stock of only a few days in some hospitals.

Because it is difficult to impossible to predict the next natural or human-made event impacting supply chain availability of these products, it is imperative that health care and supply chain leaders take a proactive approach in developing, implementing and sustaining strategies that will assist in conserving medications and solutions leading to new and improved standards of care.

Lessons learned from Vizient member feedback and the Sourcing Operations Clinical Solutions team as a result of managing through recent shortages will help provide insight into priority actions required to mitigate risks and minimize disruption in patient care during potential future IV drugs and solution shortages.

Vizient is at the forefront of providing insight into industry trends as well as helpful information about impacted supplier status and contracted product coverage. We will take whatever actions are available to help mitigate the impact of this shortage on your organization and patients, and we will seek opportunities to provide stability in an unstable market.

Vizient will do the following:

- Monitor the IV drugs and solutions market
- Work with contracted suppliers to collect and communicate information
- Provide helpful tools and resources to assist members in managing supply

Manufacturing insights

Product overview

IV administration sets help ensure easier control of the rate, duration and quantity of fluid delivered for fewer mistakes and assurance to patience about receiving the best care. Fluid nutrients and medications are often administered as a way to get fast results as the fluid goes directly into the bloodstream. The method can also be used in many settings, from hospitals and nursing homes to private residences, whether delivering nutrients or medications like insulin, hormones, antibiotics, chemotherapy drugs and pain relievers.

Typically, a few pieces are needed for an IV set:

- A sterile plastic or glass container for the fluid-form nutrient or medication; for ease of use with all types of solution containers, a vented/non-vented or "universal" spike is essential. (Keep the vent closed with collapsible plastic containers/bags and open with glass, semi-rigid plastic and other non-collapsible containers.)
- A **single drip attachment** for an observable flow rate; it also helps with fewer bubbles, and a connector that links the unit to an access device
- For flow control, a long, sterile tube and clamp
- Y-sets that make a second infusion possible from one line
- Have control over the exact flow rate and amount delivered with an infusion pump. Without a pump, you will need to use "gravity drip" – the fluid container is placed above the patient and a clamp controls the flow.



Different IV types

The IV tube, or catheter, can be inserted into a variety of locations in the body:

- **Peripheral IVs:** Used in peripheral veins, including the arms, hands, legs and feet, they are the most commonly used IV therapy.
- **Central IVs:** These catheters are inserted through a vein that empties into a large vein within the torso, such as the superior vena cava, or the inferior vena cava, ending in the core. These veins have a faster blood flow, so the central IV lines are the choice for fluids like chemotherapy medication. that could irritate the blood vessel lining. Because the medication is delivered close to the heart, this line provides fast distribution throughout the body. And these larger catheters can deliver several medications in multiple parallel compartments, or lumen. During delivery, the central lines can also measure central venous pressure and other factors. Central IVs also have several risks that include thromboembolism, gas embolism, infection and bleeding. Veins can also be hard to find so skilled clinicians must insert them. If the IV is not properly sited, damage to the carotid artery, pleura and other parts of the body is possible.

Types of central IVs

Central IV types are determined by placement:

- **PICC lines:** This IV goes through a sheath into a peripheral vein and then the line is guided upward into the superior vena cava, where it can be left for months or even years without replacement. It is typically used long-term in chemotherapy, antibiotic therapy, total parenteral nutrition and other therapies. Like with all catheters, there is a risk of infection such as bacteria entering the body via the PICC line, but the PICC has less risk because the insertion point is generally cooler and dryer for lower bacterial growth.
- **Tunneled, or Hickman, catheter:** These IV lines are tunneled through the skin insertion point to reach the vein. Bacteria growth is minimized because there's much less chance of skin bacteria entering the vein.
- Port central venous lines: Often referred to by a brand name such as MediPort or Port-a-Cath, this central venous line has a small, silicone covered reservoir instead of an external connector. Implanted beneath the skin, the port can deliver medication for years. Medication is injected through the silicone that self-seals and maintains its integrity through hundreds of piercings. For long-term use, an anticoagulant must be used to monthly flush the line to avoid the potential risk of embolization. Even though ports require a skilled clinician to perform a complex installation, ports are typically the IV therapy of choice for long-term intermittent treatment because of their convenience and lower risk of infection. And the ports are typically easy to remove in an outpatient setting.
- **Midline catheter:** These catheters are inserted into a peripheral vein but advance further than a peripheral IV, while terminating in a central vein.

Types of IV infusions

The following three IV infusions are the main ones used:

- **Continuous or intermittent infusion**. Used mostly with patients suffering from fluid and/or electrolyte imbalances; this is in contract to patients who need intermittent medication requiring a secondary IV or IV push.
- Secondary, or piggyback, IV. This is a second IV that is attached to the tubing, which is preferred over inserting multiple catheters. In this situation, the secondary bag is higher than the primary bag so the medication in the secondary bag isn't contaminated by the primary bag fluid. In addition, the primary bag fluid flushes any residue from the secondary IV.
- IV push. A syringe filled with medication is inserted into an access port sited in the primary tubing to deliver the medication through the port. To prevent vein irritation or too quickly administering the medication, the syringe plunger is slowly pushed to dispense the medication. The medication is frequently followed by a "flush" a second fluid injection to help medicine enters the bloodstream as expected. No IVF drip is required. Medication is pushed into the IV catheter through a free port on the short extension tubing. Not all medications can be

administered with an IV push. For example, an IV push for potassium results in a medication spike that could prove fatal to the patient.

IV pumps available

IV pumps come in two main categories: large-volume and small-volume. The large-volume pumps generally are best for delivering nutrient solutions. Some of these pumps are stationary and for use in hospitals. The small-volume pumps are the choice for hormones such as insulin and medications such as analgesia. Some of these pumps are portable – with some even made for charity events and battlefields. Some of the smallest pumps are syringe pumps that are mostly reserved for neonatal and micro-preemie populations.

Some other variations include the following:

- Large-volume pumps: These pumps typically have a peristaltic pump that pushes through fluids with computercontrolled rollers squeezing the tubing. There are also pumps that use a series of fingers that press on the tube to move the fluids.
- **Small-volume pumps**: A computer-controlled motor usually powers these pumps, turning a screw that depresses a plunger on a syringe. There are also some of the smallest devices that utilize osmosis, where a salt solution bag absorbs water across a membrane to force out the medicine. Changes in the salt concentration and pump volume carefully control the delivery rate. A syringe typically recharges these pumps.

IV pump technology is constantly being updated but sometimes older technologies are used, like with clockwork pumps. One spring controls the infusion and another rings an alarm when the infusion is complete. These pumps are still used with animals and pumps with small volume.

Infusion types controlled by IV pumps

Trained medical professionals can program IV pumps for a variety of infusion types, including the following:

- When regular pulses of medication are required, a **continuous infusion** is used to administer usually between 500 nanoliters and 10 milliliters. The pump can be programmed for a specific pulse rate.
- To alternate low and high infusion rates, an **intermittent infusion** with preprogrammed infusion periods is used.
- With **patient-controlled infusion**, patients simply press a pad or button when they feel they need medication, and the pump typically has a predetermined maximum delivery rate to prevent overdoses. Often this infusion type is used for pain management for patient-controlled analgesia (PCA).
- In **long-term infusion** treatments, the delivery provides parenteral nutrition mimicking mealtimes (10-12 hours per day).
- Time of day infusions are based on circadian cycles required to dispense some medications.

Selection factors

Choosing the correct equipment for your facility can be daunting with the number of technological advancements for IV administration – even if you're buying several different devices. Factors to consider when purchasing include the following:

- Types of fluids administered Nutrients require large-volume pumps, while hormones or medications call for smallvolume pumps.
- **Safety features** Investigate safety features to ensure they meet your facility's needs and patient safety requirements.

Raw materials

Raw materials include: packaging film (including plastic components), tyvek, resin, polypropylene, PVC, HDPE, nylon and printing ink. Note, IV bag excipients harmful to pregnant women, pedatric and neonatal populations include DEHP (and

other phthalates), bisphenol A, PVC and parabens. B. Braun was the first manufacturer to eliminate DEHP and PVC from IV bags and sets. These excipients are endocrine disrupters and disproportionately affect males in utero, male newborns and young children.

The lastest manufacturing insights are available here.

Regulatory and approvals

The applicable regulatory framework for infusion pumps is based on regulation 21 CFR 880.5725.

In 2017 the Food and Drug Administration (FDA) launched an infusion pump improvement initiative. From 2005 through 2009, the FDA received about 56,000 reports of adverse events associated with the use of infusion pumps, including numerous injuries and deaths.

Some of the problems:

- Software defects
- User interface issues
- Mechanical or electrical failures

Improvement initiative:

- · Establish additional requirements for infusion pump manufacturers
- · Proactively facilitate device improvements
- Increase user awareness

FDA guidance on infusion pumps: overview

Non-awarded suppliers

Infusion products are daily high-use items. All suppliers in this space contract at comittment and spend volumes for best pricing. IV solutions are typically contracted with the IV pump provider for additional full-line value.

All major providers are contracted with Vizient, and we continue to monitor for new market entrants.

Logistics insights

Transportation/shipping

IV solutions are manufactured in North and South America.

See additional freight update here.

Product storage

Always follow manufacture guidelines on product storage and care. Care of infusion pumps for patient safety

Utilization insights

Clinical contract support resources

Vizient Center for Pharmacy Practice Excellence has a drug shortage mitigation strategy to assist with the management of the ExactaMix valve set shortage. The document provides clinical and operational recommendations, such as utilizing ready-to-use Parenteral Nutrition (PN) products for adult patients to conserve inventory for neonatal and pediatric patients requiring custom compounded Total Parenteral Nutrition (TPNs). Additionally, the mitigation strategy includes a list of the various operator manual reports available to assess the precision of the ExactaMix compounders, if extending use of the valve set.

Building supply assurance

Conservation strategies

The health care supply chain industry is experiencing some changes in market conditions for IV drugs and solutions as a result of recent natural disasters. In the forefront on industry challenges, Vizient is providing insight into industry trends as well as helpful information about impacted supplier status and contracted product coverage. We will take whatever actions are available to help mitigate the impact of this shortage on your organization and patients, and we will seek opportunities to provide stability in an unstable market. For additional information, click here.

Sustaining conservation strategies

Because predicting the next supply shortage is impossible, it is important that health care providers not only adopt and implement care practices strategies to conserve critical products and supplies but also sustain leading practices that will help ensure the availability of essential products post-recovery and into the future. Some hospitals have reported decreasing their intravenous solution use by as much as 50% in some care areas by continuing to adhere to the conservation strategies implemented during the recent shortages.

Health care providers and other leading organizations have identified and recommend the following actions:

- Additionally, with other products and services do the following:
 - Assess and identify all hospital services.
 - Identify and list critical products, supplies and resources required to sustain operation of those areas identified and ranked in the first step.
 - Maintain the internal planning team document with accurate information. Review and update the document on a routine basis with current employee contact information. If a team member no longer works in the organization, identify the replacement and communicate the information to all stakeholders.
 - Communicate practice changes and procedures frequently to staff and stakeholders.
 - Hold regularly scheduled planning meetings in the absence of a supply chain shortage or event. This will help to ensure that identified processes and protocols remain relevant and any issues requiring revisions and/or updates are addressed in advance of a shortage or disaster.

If your organization has implemented conservation strategies for IV solutions, or any other category, please share your information here. The information you share will be anonymous unless you grant Vizient permission to share.

IV Solutions Blueprint

The IV Solutions Blueprint was developed around key functions and processes identified, implemented and evaluated by Yale-New Haven Hospital to address IV solutions shortages. Part of the Leading Practice Blueprint library, this resource is part of our ongoing efforts to share insight into the latest industry trends and best practices, as well as to manage ongoing IV drugs and solutions challenges.

The blueprint serves as a guide to developing your organization's conservation strategy, and includes an action plan and implementation guide to assist members with the following:

- · Managing inventory in the event of a product recall or back order
- Managing volume requirements for seasonal events (e.g., flu season)

Supply chain programs

Environmentally Preferred Sourcing Program

The Environmentally Preferred Sourcing (EPS) Program provides the necessary framework for your health care organization to implement and maintain an environmentally friendly program that supports your organization's overall sustainability objectives.

You can access the broadest, most cost-effective portfolio of environmentally preferred products in the industry – more than 450,000 contracted products in more than 1,400 agreements – as well as expert insights and analytics to advance your organization's environmental and sustainability initiatives.

Planning for disruptions

Distributor recommendations

Our medical-surgical and pharmacy Authorized Distributors have offered the following recommendations for members purchasing through distributors:

- Review your policies and procedures as to who should get IV therapy and for how long. Develop conservation strategies with the IV team and pharmacy.
- Facilitate collaboration with the local manufacturer and distributor representatives to ensure timely product delivery\.
- Evaluate whether it is appropriate for your facility to purchase direct rather than through your distributor to manage inventory.
- Anticipate your inventory level, and order in advance of your regular schedule.

Best practice strategies

Vizient offers the following best practices to help members manage IV drugs and solutions. These suggestions are available to help you gain insight about how the industry is managing IV drugs and solutions challenges.

If your inventory is low

Vizient is committed to bringing hospitals, manufacturers, distributors and other industry leaders together to talk about this issue and any long-term implications. We feel continued dialogue about the issue by experts and industry stakeholders will be crucial to ultimately arriving at a solution to this vexing issue. During critical supply periods, members should continue to order their normal levels of products to ensure continued availability for all institutions.

If you begin to experience a shortage, do the following:

- Evaluate your IV solutions supply.
- Contact your local supplier representative and report exactly how many days of supply you have left.
- If you are not getting a response from your supplier, contact us so we can facilitate communication between member and supplier; provide whether you are ordering direct or through distribution (med/surg or pharmacy), and indicate supplier and distributor (if applicable).
- We encourage you to continue the conversation within your organization, with your peers, and with the manufacturers and distributors to identify ways to manage your ongoing IV solutions needs.
- Implement conservation strategies.
- Submit inquiries to IV_questions@vizientinc.com.

Expedite supply resolution

To expedite resolution for supply issues, contact your local supplier and provide the following information:

- The description and item number of the product that is experiencing a shortage
- Whether you are purchasing directly or through an Authorized Distributor
- Days of supply remaining in your inventory

If expanding your facility

We suggest members notify suppliers when expanding their facilities to assist in planning and anticipate increases in allocations. You should consider notifying your suppliers of at least three months ahead of the completion of your facility to ensure sufficient capacity of IV solutions.

Building supply assurance together

Collaboration among suppliers, distributors, members and Vizient strengthens the assurance of supply for all stakeholders. Our wealth of experience, actionable data and predictive planning helps to strengthen supply assurance. Further, our work with stakeholders focuses on improving supply chain risk mitigation as we collaborate to enhance data, increase supply visibility and expand inventory access.

Four themes keep us centered and are the pillars of our supply chain assurance efforts: insights, access, enablement and advocacy. Learn more about our supply assurance strategy.

In the event of a supply disruption, Vizient will publish a product disruption brief to the Supply Assurance webpage. Curated by Vizient experts, these documents provide a summary of current conditions and strategies to manage productlevel disruptions.

In addition to our disruption briefs, Vizient also compiles the monthly Supply update executive summary which tracks all known supply chain disruptors, including current market challenges, category-specific product updates and recovering markets.

Whether a supply disruption is the result of a natural or human-made disaster, it is imperative that members are informed. The Vizient Disaster Preparedness webpage was developed to help providers meet supply chain needs before, during and after an event. The Supply Update section of the guide is updated on a frequent and routine basis with communication from all awarded suppliers that have manufacturing facilities in areas impacted by a disaster. Additionally, a status update list of those manufacturers whose operations have been affected, as well as a list of impacted product(s), will be maintained and updated as that information is received from suppliers.

The importance of an internal planning team

Identifying an internal planning team is imperative to managing supply, mitigating risks and sustaining operations during a supply shortage. According to the Supply Chain Disaster Preparedness Manual developed by the CDC, internal teams should consist of representatives from supply chain, purchasing, emergency management, each clinical/care delivery area, inventory staff, receiving and distribution staff. Relative to medication and solutions, Vizient member feedback indicated the pharmacy department as an integral member to the internal team, as clinical/pharmacy practice changes may occur. Additional members may include the facilities safety manager, security, risk management, legal, marketing and communications, and public relations.

A simple internal team planning document will help to identify, contact and quickly convene relevant team members. See the sample below:

Name	Title	Department/role	Phone	Email

Once an internal team is identified, additional considerations before beginning the development and implementation of a recovery plan include the following:

- The team's goals
- The responsibilities of each planning team member
- Other department/team members who may need to be involved
- Frequency of team meetings
- How the goal/mission be accomplished
- · How information will be documented and communicated to the broader audience
- A current framework for success either within your facility or from a leading organization

Stakeholder communication

During supply chain product disruptions, it is vital that accurate and timely information is disseminated to internal and external stakeholders. The following actions should be considered in an effort to facilitate and ensure informed decisions:

- Designate the point person or persons who will be responsible for developing, disseminating and monitoring all communications coming from the internal planning team.
- The internal planning team should collaborate key messages/information to stakeholders, such as changes in policies and/or practice changes.
- Clearly communicate the roles and responsibilities of all staff based on the agreed upon recovery plan. If there are changes to the plan at any time, timely communication of those changes will help to increase risk mitigation and minimize interruption of patient care.
- Establish communication mechanisms for information exchange. Examples include but are not limited to regularly scheduled briefings and meetings, in-services, staff trainings, live/recorded webinars, memos and emails.
- Determine the frequency of reminders and updates regarding supply disruption status and anticipated resolution.
- Frequent updates and reminders after a supply disruption has been mitigated or eliminated help to ensure ongoing success and sustainability of best practices.

Supply management and logistics

A leading practice identified in managing recent shortages is a centralized management approach of impacted product codes. A key responsibility of the internal planning group is to identify all affected product codes and to determine the amount of supply on hand, expected and any allocation protocols implemented by the supply source. Once the current product status is determined, the following actions are recommended:

- Update and maintain an accurate inventory list. Each care area that utilizes any product code on the inventory list should identify a point person to collect on hand and usage levels on an agreed upon frequency. That information should be reported back to the internal planning team. Inventory can either be managed by care delivery areas or in a centralized manner.
- Identify space in the facility to store, manage and distribute product. Designate authorized personnel responsible for maintaining the inventory (expiration dates temperature, ventilation, utilization, equipment maintenance and repair, etc.).
- Develop and seek approval for the inventory management protocol and communicate this information to all stakeholders.
- Update and maintain accurate purchase order and allocation protocols from the contracted supplier and your group purchasing organization (GPO).
- Update and maintain accurate emergency contact information for all suppliers as well as internal stakeholders. This process should be done at least every six months.

• Review the inventory management status on an agreed upon frequency with the internal planning group. Assess for barriers to its effectiveness, implement any changes necessary and communicate those changes to all stakeholders.

Planning for all levels of care and ancillary products

Feedback from lessons learned indicated the need to include all levels of care and ancillary products, if applicable, in the conservation plan. If your provider system has children's hospitals, ambulatory surgery centers, outpatient clinics and/or long-term care facilities, utilization and logistics of products and supplies must be incorporated into the plan. Additionally, it is vital that ancillary products are considered when contemplating allocations and purchase orders. During the recent drugs and solutions shortages, as large volume solution bags went on back order, smaller volume bags, compounding products, and syringes also went on back order because of practice changes. Therefore, conservation planning should include actual and the additional ancillary products that may be required to sustain a clinical and/or operational practice change



As the nation's largest member-driven health care performance improvement company, Vizient provides solutions and services that empower health care providers to deliver high-value care by aligning cost, quality and market performance. With analytics, advisory services and a robust sourcing portfolio, we help members improve patient outcomes and lower costs.