CATEGORY RESOURCE GUIDE

Infusion therapy

Included in this document

(Click to view each section)

Vizient award overview

Awarded suppliers

MS9731 – Cardinal Health
MS9732 – LSL Industries
MS9733 – Medical Action
MS9734 – Medline Industries

Distribution

Both direct and distributed through the following distribution channels:

Medical-surgical

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

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

The infusion therapy kits market primarily includes distributors who provide kitting services. Many factors are dependent on component selections, and there is usually opportunity for kit standardization.

Manufacturing insights

Product overview

Infusion therapy is the administration of medication, fluids or nutrients directly into the bloodstream. While there are several options available for delivery, most often this is accomplished through a peripheral or central line IV. According to the U.S. Food and Drug Administration (FDA), a convenience kit is defined as having, “two or more different devices that are packaged and sealed in a single container, and the container is supplied sterile for the convenience of the user. The container is intended to remain sealed and the contents sterile until the contents are about to be used on a patient.” A medical procedure kit “consists of one or more medical devices, packaged together to facilitate a single surgical or medical procedure. A medical kit may be a convenience kit.”

Characteristics of kits are that they hold multiple devices, are in a single container and are sterile until the contents are to be used on a single patient. Some kits have components where, once the kit is opened, must be thrown away if not used. Some kits might have items, like stainless steel instruments, which are intended by the manufacturer to be reprocessed and reused.

Vizient infusion therapy contracts include IV start/dressing change kits, central venous catheter dressing change kits and customized IV or dressing change kits. While kits are not mandatory for performing procedures as items may be pulled individually, the purpose of kits is for the convenience of the user. Additionally, using kits standardizes best practices, creates efficiency, saves time and money, and reduces storage space and waste.

Selection factors

Typically, an IV start kit includes a tourniquet, a site antiseptic, gauzes, tape, a window dressing, and sticker to label the IV with your initials, date and time. If a patient needs a longer lasting IV, the doctor may choose a peripherally inserted central catheter (PICC). These catheters are inserted into large veins above the patient’s heart.

Convenience kits may include economy components which the manufacturer makes or has manufactured under its company name. Kits may also contain premium components that are outsourced and do not bear the manufacturer’s name. The following are devices that may be found in each type of kit:

Component	IV start kit	Central venous catheter dressing change kit
ABD pad		X
CHG applicator	X	X
CHG catheter disk dressing		X
CHG IV securement dressing		X
CHG prep pad	X	
CHG swabsticks	X	
PVP ampule	X	
PVP ointment	X	X
PVP swabsticks		X
Alcohol prep pad	X	
Alcohol swabsticks		X
Bandage	X	
Cotton-tip applicator		X
Drape	X	X
Forceps, wire		X
Gauze	X	X
IV securement dressing	X	
IV sponge drain		X
IV stabilization device	X	
Latex gloves*		X
Mask		X
Nitrile gloves		X
PICC/CVC securement + IV advanced securement dressing		X

Component	IV start kit	Central venous catheter dressing change kit
Pad soft cloth dressing		X
Polybag with twist tie		X
Prep site pad		X
Scissors, straight, wire		X
Scissors, wire, sharp/blunt		X
Skin closure reinforced		X
Skin protection pad		X
Skin protectant swabstick		X
Skin wipe		X
Stabilization device		X
Tape (economy or premium) or transparent	X	X
Tape measure		X
Topical skin adhesive swabstick		X
Transparent film dressing (economy or premium)	X	X
Tourniquet	X	
Towel	X	X
Tubing securement device	X	
Tubing securement device, pediatric	X	
Vinyl gloves	X	X
Wipe, no-string barrier		X
Wrap		X

**Note: The Centers for Disease Control and Prevention (CDC) warns about exposure to latex products. A latex allergy can cause dermatitis, respiratory issues and anaphylactic shock.*

If your best practice requires devices that are not found in a standardized kit, then you may choose to add them, creating a custom kit.

Raw materials

Tray: resin

Common tray components:

- Disposable tourniquet: styrene, ethylene, butadiene, polypropylene
- Gauze: cotton
- Transparent dressing: resin
- Medical tape: polypropylene, paper
- Antiseptics: isopropyl alcohol/ chlorhexidine gluconate/povidone iodine, polypropylene

The lastest manufacturing insights are available here.

Regulatory and approvals

Unique Device Identification: Convenience Kits

The unique device identification (UDI) system was established by the FDA to identify devices through manufacturing, distribution and point of use. Individual devices packaged within the immediate container of a convenience kit are excepted from the UDI labeling requirements, provided that a UDI is on the label of the immediate container of the convenience kit because it is itself considered a device.

Association for Health Care Resource & Materials Management (AHRMM) Awareness Brief: Draft Guidance for UDI Convenience Kits

AHRMM provides a quick reference to the draft guidance for UDI convenience kits.

Infusion Therapy Standards of Practice

This eighth edition covers infusion therapy practice, patient and clinician safety, infection prevention and control, infusion equipment, vascular access device selection and placement, vascular access device management, vascular access device complications, other infusion devices, and infusion therapies.

Sterilized Convenience Kits for Clinical and Surgical Use; Final Guidance for Industry

The FDA asks manufacturers and end users to consider the following questions regarding components of the kit:

- Does the exposure to heat during the sterilization process cause the material in a device to degrade before the labeled expiration date?
- Does the sterilization process (e.g., vacuum effects, radiation) affect the form, fit or function of a device component?
- Does the sterilization process affect the package integrity for devices?

Non-awarded suppliers

Trinity Sterile and Vygon also offer infusion therapy kits.

Component original equipment manufacturers (OEMs) include (but are not limited to) 3M, BD, Johnson & Johnson, Centurion/Medline, LSL, Cardinal, O&M Halyard, Garflex, Bard and PDI.

Logistics insights

Transportation/shipping

Raw materials are manufactured/sourced from the U.S., Mexico, China and Pakistan.

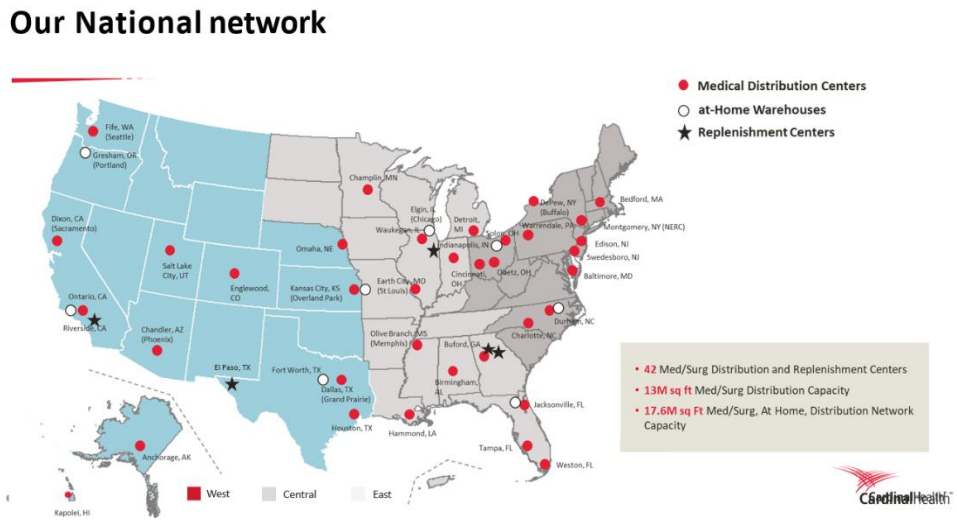
Kit production locations:

- Cardinal – Juarez, Mexico, and El Paso, Texas
- Medline – produced in Mexico and North Carolina/EtO sterilized in Arizona
- O&M – produced in North Carolina/EtO sterilized in Tennessee

Finished good kits are primarily shipped to distribution centers or directly to customers via freight or air.

Primary points of entry: El Paso (Cardinal)

Days to process can vary; however, more than 20 raw material trailers are received and processed each day at Cardinal manufacturing facilities.



See additional freight update here.

Product storage

- Follow manufacturer's recommendations for storage of the product.
- Store in clean and dry areas, protected from dust, moisture and temperature extremes.
- Do not store in corridors, windowsills, on the floor or under sinks.
- Transport supplies enclosed or on covered carts, bins, totes or plastic bags.
- Minimize supplies in patient rooms/care areas.
- Always inspect packaging for any breach of sterility prior to storing and using.
- Each kit will contain an expiration date if one or more components within the kit has a specific shelf life. This varies based on components in the kit, but primarily falls between 12 and 24 months from date of manufacture.

Utilization insights

Clinical contract support resources

Aseptic vs. Clean Technique

The Joint Commission tool compares aseptic and clean techniques. "Aseptic technique, a method used to prevent contamination with microorganisms, is recommended by the evidence-based guidelines for all instances of insertion and care of central venous catheters." This applies to inserting PICC lines, performing dialysis, inserting catheters, running IVs and dressing wounds to name a few.

Routine vs. Clinically Indicated Rotation of Peripheral Intravenous Access Based on Comfort, Cost and Complications

The pilot study performed by John Hopkins indicated re-site of short peripheral IV access should only be done when clinically indicated which reduces hospital cost and nursing task time but improved patient satisfaction.

Building supply assurance

Conservation strategies

Because predicting the next supply shortage is impossible, it is important that healthcare providers not only adopt and implement care practices strategies to conserve critical products and supplies, but it is equally as important to sustain leading practices that will help ensure the availability of essential products post recovery and in the future. Healthcare providers and other leading organizations have identified and recommend the following actions:

- Validate the necessity of starting an IV or inserting a central venous catheter.
- If the dressing is intact and clean, without any signs of infection, verify if a dressing change is necessary.

Additionally, with other products and services:

- 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 infusion or any other category, share your information here. The information you share will be anonymous unless you grant Vizient permission to share.

Supply chain programs

LSL Industries is a Vizient diversity supplier. Vizient's Supplier Diversity Program supports the development of minority-, woman-, disability-, LGBT- and veteran-owned business enterprises that meet high-quality standards. We also strive to work with suppliers who proactively seek strategic partnerships with diverse companies. For more information, click here.

Medline and Cardinal participate in the Impact Specialty Care Standardization Program, which improves procurement processes on commonly purchased products and financially reward standardization efforts while reducing product variation and improving procurement processes on commonly purchased products. Since 1996, members have earned more than $1.5 billion in cash rebates through the programs. With 12 programs to choose from and built-in flexibility within each program, it's easy to gain additional value beyond price for your organization. For more information, click here.

Planning for disruptions

Best practice strategies

Vizient offers the following best practices to help members manage disruptions. These suggestions are available to help you gain insight on how the industry is managing supply challenges.

- Know the components in your kits and understand the issues that could cause a disruption in your kit manufacturing and distribution.
- Be prepared to have components pulled individually should kits not be available.

If your inventory is low

Vizient is committed to bringing hospitals, manufacturers, distributors, and the industry together to talk about this issue and any long-term implications. We feel continued dialogue around the issue by experts – hospitals, manufacturers, distributors and industry – will be crucial to ultimately arriving at a solution to 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:

- Evaluate your current supply.
- Contact your local supplier representative and report exactly how many days' supply you have left.
- If you are not getting a response from suppliers, contact Vizient so we can facilitate communication between member and supplier; provide whether you are ordering direct or through distribution (medical/surgical or pharmacy), and indicate supplier and distributor (if applicable) when you contact Vizient.
- 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 infusion needs.
- Submit inquiries to disasterresponse@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' 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 at least three months ahead of the completion of your facility to ensure sufficient capacity.

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 product-level disruptions.

In addition to our disruption briefs, Vizient also compiles all known disruptions into the monthly Supply Update Executive Summary which tracks all 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 a supplier.

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. For example, 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

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