CATEGORY RESOURCE GUIDE

Safety needles and syringes

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Vizient award overview

Awarded suppliers

MS7861 – Becton Dickinson MS7862 – Cardinal Health MS7863 – Retractable Technologies MS7864 – Smiths Medical ASD MS7865 – Terumo Medical

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.

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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 profiles are one way we're building supply assurance together.



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Market landscape

The Needlestick Safety and Prevention Act (NSPA) was signed into law in November 2000. It mandated the Occupational Safety and Health Administration (OSHA) revise its bloodborne pathogens standard to include specific additional definitions and requirements. As a result, OSHA published May 9, 2001, Revision to OSHA's Bloodborne Pathogens Standard – Technical Background and Summary -- Needlestick Fact Sheet, which clearly details the changes to the standard.

Needle usage is increasing, due to a sicker population, and increasing prevalence of life-threatening procedures. The U.S. leads the world in sales of safety needles. Hospitals purchase the largest number of needles followed by ambulatory surgery centers and clinics.

Manufacturing insights

Product overview

Safety needles and syringes are made with various features to prevent needle stick injuries when dispensing medications either through intramuscular, subcutaneous or intradermal routes, as well as through an IV tubing port. The predominant materials are polyethylene and polypropylene plastic, rubber (for stopper at the end of the plunger) and metal (needles). Some suppliers add silicone to the needle for smooth operation.

These syringes have the same gradations as standard needles.

The safety mechanism is usually found with the needle. The only syringes with safety mechanisms are retractable syringes. These syringes have a mechanism where a button is pressed, and the needle retracts into the barrel of the syringe once used on a patient. This safety mechanism is active, meaning the clinician must press a button to activate the needle withdrawal.

All other syringes can be used with safety or non-safety needles.

Safety needles have a variety of shielding methods. Most employ an "arm" that snaps over the needle after use. The clinician must move that arm to snap it in place. Absent that, the needle point remains uncovered and therefore presents an exposure risk.

Selection factors

The NSPA mandate outlined that clinician choice after trial, and not finances, will solely determine product choice. The goal of using safety mechanisms is to prevent exposures to clinical staff when caring for a patient.

The Vizient contracts include the following options:

- Safety syringes (retractable mechanism)
- Safety hypodermic needles (mechanism that covers the needle through activation)
- Syringe/needle combinations: prepackaged syringes with a pre-attached hypodermic needle.
- Insulin and tuberculin syringes

There are four routes of injection:

- Intramuscular injections into a selected muscle; syringe held at a 90-degree angle
- Intradermal shallow injections into the dermis, which is just under the surface of the skin between the epidermis and the subcutaneous tissue; syringe held at a 10- to 15-degree angle; most commonly used for allergy and TB testing
- Subcutaneous injections given in the fatty tissue under the skin in the subcutaneous tissue; syringe held at a 45degree angle
- Intravenous injections or infusions that are given within the vein; syringe held at a 25-degree angle

There are two categories of safety engineered devices:

- User activated safety devices: These devices require that the safety guard be manually and deliberately activated to cover the sharp. This includes pressing a protective sheath over the needle.
- Passive safety devices: These devices automatically cover the sharp. This includes automatic retractable needle technologies.

Safety features for both must provide immediate permanent containment of the needle by a single hand which must always stay behind the needle.

OEM and manufacturing location

All suppliers' syringes and needles are latex free.

- Becton Dickinson (BD) The supplier has the largest market share and only standard needles and syringes are on contract. Needles and syringes are produced domestically. The syringes are composed of polycarbonate with a rubber stopper and a metal siliconized needle.
- Cardinal (Covidien Monoject) Needles and syringes are produced primarily in Norfolk, Neb., and Deland, Fla. However, late summer 2023, Cardinal shifted some manufacturing to China. The syringes are composed of polypropylene, and the needle is metal.
- Smiths Medical (purchased by ICU Medical) Needles and syringes are produced in Olive Branch, Miss. The syringes are made of polypropylene, and needles are stainless steel.
- Retractable Technologies The needles and syringes are manufactured for the U.S. market in Little Elm, Texas. For the Asian market, the supplier has a new partnership with Double Dove to manufacture in PuDong (near Shanghai), China.
- Terumo The needles and syringes are manufactured in the Philippines. The syringes are made of polypropylene, and the needles are stainless steel and silicone lubricant.

Raw materials

Syringe composition:

- Polycarbonate and/or polypropylene which are the byproducts from the distillation of hydrocarbon fuels
- Ethylene oxide
- Elastomer
- Rubber gaskets (polyisoprene)

Metal (needles) – stainless steel

The lastest manufacturing insights are available here.

Regulatory and approvals

Information from OSHA on the bloodborne pathogens standard as well as the Needlestick Safety and Prevention Act

ISO 7886-1:2017 Sterile Hypodermic Syringes for Use – Part 1: Syringes for Manual Use.

Non-awarded suppliers

- Medline
- Sol Milennium
- B. Braun
- Nipro

Logistics insights

Transportation/shipping

All suppliers except for Terumo manufacture domestically, so onshore transportion occurs via freight (train or truck), and sometimes air.

Terumo manufactures in the Philipinnes. The supplier reports no supply chain issues. The products are shipped to the port of Long Beach, Calif., and then to the two distribution centers in Phoenx, Ariz., and Southaven, Miss. Transit times: 40 to 50 days to Phoenix, 60 to 80 days to Southaven.

During the pandemic, BD had to obtain additional product from Asia via the port of Los Angles/Longbeach, but domestic production is now more than sufficient for the U.S. market.

Distribution centers are located in the Northeast, Midwest and South.

See additional freight update here.

Product storage

- There are no storage considerations, and sterility is guaranteed if the packaging is intact. Use prior to expiration date.
- Store syringes at room temperature in a dry area.
- The Joint Commission recommends that both needles and syringes be stored under lock and key when not in use to prevent unauthorized access.

Utilization insights

Clinical contract support resources

The Centers for Disease Control and Prevention (CDC) offers FAQs regarding safe practices for medical injections, while the U.S. Food and Drug Administration (FDA) offers information regarding 510K approval, product recalls and field actions

Building supply assurance

The focus has been on increased sourcing and warehousing of raw materials, prioritizing high use items, consolidating SKUs and cross training staff. These steps are also being taken:

- Acquisition of raw materials to store and broadening raw material sources for redundancy
- Demand planning with distributor partners

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. For example, some hospitals have reported decreasing their IV solution use by as much as 50% in some care areas by continuing to adhere to the conservation strategies implemented during the recent shortages.

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

- If there is capacity, suggest warehousing additional stock when available. These do not have storage requirements and have a long expiration date; however, it is critical to maintain first-in, first-out (FIFO) practices with storage sites in keeping with sound inventory practices.
- Metrics:
 - DiOH (days inventory on hand)
 - Inventory turns
 - o Average moving cost

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 safety needles and syringes, 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

Retractable Technologies 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.

Planning for disruptions

Distributor recommendations

None

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.

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 in order 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 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 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 |
|------|-------|-----------------|-------|-------|
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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 will 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 additional ancillary products that may be required to

To learn more, please contact: Kylie Taylor, Dir., Assurance., supplyassurance@vizientinc.com. 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.