# CATEGORY RESOURCE GUIDE

# Patient positioners

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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.

# Vizient award overview

#### Awarded suppliers

MS1021 - Cardinal Health MS1022 - DeRoyal Industries MS1023 - The Soule Co. MS1024 - US Surgitech

#### Distribution

Both direct and distributed through the following distribution channels:

Medical-surgical

vizient



# Market landscape

The patient positioner market is very fragmented with several large suppliers that have full line (both disposable and reusable positioners) and many smaller companies that focus on one type of product over the other. To select these critical healthcare products, providers consider several clinical, ergonomic and economic factors. Most patient positioners are manufactured domestically or near shore but require a variety of raw materials that must be procured. In addition, the Food and Drug Administration (FDA) provides pre-market clearance and approval, post-market surveillance and establishment of standards to ensure quality and safety.

# **Manufacturing insights**

### **Product overview**

The market for patient positioners includes both disposable and reusable positioners as well as positioning straps. Disposable positioners are made of foam and are single use. Reusable positioners can be used multiple times and can be made from gel or vinyl-covered foam.

Subcategories include the following:

- Arm board strap
- Arm positioners
- Body positioners
- Head positioners
- · Hip abduction pillows
- Laminectomy arm cradles
- Foot positioners
- Knee positioners
- Lumbar positioners
- Positioning kits

### **Selection factors**

The selection of surgical patient positioning products is a critical aspect of healthcare procurement, ensuring patient safety, comfort and optimal surgical outcomes. Several factors come into play when making these decisions: clinical, ergonomic and economic considerations.

#### **Clinical factors**

**Patient safety and comfort:** The primary concern in selecting patient positioning products is ensuring the safety and comfort of the patient during surgery. Products should minimize the risk of pressure injuries, nerve compression and musculoskeletal strain (Cohen, 2018).

**Surgical site accessibility:** Positioning products should facilitate optimal access to the surgical site. Adjustable features and flexibility are crucial to accommodate different surgical procedures (ACA, 2019).

**Infection control:** The materials used in positioning products should be easily cleanable and resistant to microbial growth, reducing the risk of surgical site infections (APIC, 2020).

**Radiolucency:** For procedures requiring imaging guidance, such as fluoroscopy or C-arm, positioning products with radiolucent properties are essential to avoid obstructing the view of the surgical field (Schueler et al., 2017).

#### **Ergonomic factors**

**Healthcare worker ergonomics**: Consideration should be given to the ergonomic design of positioning products to minimize strain and discomfort for healthcare personnel during surgery (ADA, 2021).

**Ease of use and adjustment:** Products should be user friendly and allow for quick and precise adjustments to accommodate different patient sizes and surgical positions (AORN, 2020).

**Compatibility:** Compatibility with existing surgical tables and equipment is crucial to ensure seamless integration and functionality (AST, 2021).

#### **Economic factors**

**Cost-effectiveness:** Balancing the clinical and ergonomic requirements with the budget constraints of the healthcare facility is essential. Evaluating the total cost of ownership, including maintenance and replacement costs, is important (HSCA, 2018).

**Product lifespan:** Longer lifespan and durability can lead to cost savings over time. Products with a proven track record of longevity may be more economically viable (Shaffer et al., 2019).

**Warranty and support:** The availability of warranties and after-sales support can reduce the financial burden of maintenance and repairs (ABA, 2020).

**Environmental impact:** Assess the environmental sustainability of the positioning products, taking into account factors like recyclability and energy-efficient manufacturing processes (Green Healthcare Program, 2021).

### **OEM** and manufacturing location

The majority of products are manufactured domestically or near shore.

#### **Raw materials**

The manufacturing of surgical patient positioning products involves several primary raw materials to ensure safety, comfort and efficacy in the operating room. These materials are selected to meet regulatory standards, enhance patient care and minimize infection risk. The primary raw materials used in manufacturing surgical patient positioning products include the following:

**Foam materials:** Foam materials, particularly medical-grade polyurethane foam, are commonly used for padding in surgical positioning products. This foam provides cushioning to support patients' bodies during surgery, reducing the risk of pressure ulcers and discomfort.

Vinyl or polyurethane covers: These materials are easy to clean and disinfect, making them suitable for use in sterile environments like operating rooms.

**Straps and fasteners:** Surgical positioning products use various types of straps and fasteners to secure patients in the desired position. These may be made from nylon, polyester or other durable textiles to ensure patient safety and stability.

**Gel pads:** Gel pads are often integrated into surgical positioning products to distribute pressure evenly and reduce the risk of pressure sores. These pads are typically composed of medical-grade silicone gel.

The lastest manufacturing insights are available here.

#### **Regulatory and approvals**

The FDA and Centers for Medicare and Medicaid Services (CMS) are the primary regulatory agencies governing the production and use of surgical patient positioning products in the U.S. The FDA ensures the safety and effectiveness of these devices through pre-market and post-market regulatory activities, while CMS may establish reimbursement policies that impact their adoption in healthcare settings.

#### FDA

The FDA is a federal agency responsible for regulating medical devices, including surgical patient positioning products. These products fall under the category of Class I or Class II medical devices, depending on their complexity and associated risks.

The FDA's role includes pre-market clearance or approval, post-market surveillance, and the establishment of quality and safety standards for these devices.

The FDA regulates surgical patient positioning products under its Medical Device Regulation program, and relevant regulations can be found in Title 21 of the Code of Federal Regulations (CFR), specifically in Parts 800 to 899.

Title 21 CFR 880.6960 covers surgical patient positioners, and it outlines the regulatory requirements for these products, including labeling, performance standards, and quality control.

Find more information here.

#### CMS

CMS is responsible for administering the Medicare and Medicaid programs, which provide healthcare coverage to a significant portion of the U.S. population.

CMS may establish reimbursement policies and guidelines related to the use of surgical patient positioning products. These policies can impact healthcare providers' decisions regarding the selection and use of these products.

CMS primarily focuses on reimbursement and payment policies, but its regulations can indirectly influence the adoption and utilization of medical devices, including surgical patient positioning products, in healthcare facilities.

#### **Non-awarded suppliers**

Non-contracted suppliers include Xodus, Medline and Stryker. There are several other non-contracted suppliers that may only focus on one type of product and may not offer a full line.

# **Logistics insights**

### Transportation/shipping

Both direct and distributed

See additional freight update here.

#### **Product storage**

Proper storage helps prevent contamination, damage, and degradation of these critical medical devices.

Some key guidelines include the following:

#### Temperature and humidity control

- Store surgical patient positioning products in a controlled environment with a temperature range between 15° and 30°C (59° and 86°F).
- Maintain relative humidity levels between 30 and 60% to prevent moisture-related issues.

From AORN. (2021), Guideline for Sterile Technique. Association of periOperative Registered Nurses

#### Clean and dry storage area

- Ensure that the storage area is clean, dry, and free from dust, dirt and contaminants.
- Use shelving or racks to keep products off the floor to avoid potential contamination.

From AORN (2021), Guideline for Sterile Technique. Association of periOperative Registered Nurses

#### Proper packaging

- Maintain products in their original packaging or in a designated storage container that provides protection from environmental factors.
- Label storage containers clearly with the product name, expiration date and lot number.

From FDA (2018), Design Considerations for Devices Intended for Home Use: Guidance for Industry and FDA Staff

#### First-in, first-out (FIFO)

Implement a FIFO system to ensure that older stock is used before newer stock to minimize the risk of product expiration.

From AORN (2021), Guideline for Sterile Technique. Association of periOperative Registered Nurses

#### Examine for damage and integrity

- Regularly inspect packaging for any signs of damage or compromise, such as punctures, tears or leaks. Damaged products should be removed from inventory.
- Check for the integrity of any seals, closures or sterile barriers.

From AORN (2021), Guideline for Sterile Technique, Association of periOperative Registered Nurses

#### **Documentation and rotation**

- Maintain comprehensive records of product inventory, including purchase dates, expiration dates and lot numbers.
- Implement a rotation system to use older stock first, and regularly update inventory records.

From AORN (2021, Guideline for Sterile Technique. Association of periOperative Registered Nurses

#### Security and access control

• Restrict access to the storage area to authorized personnel only to prevent theft, tampering or unauthorized use. From FDA (2018), Design Considerations for Devices Intended for Home Use: Guidance for Industry and FDA Staff, FDA

# **Utilization insights**

#### **Clinical contract support resources**

None

# **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 practice 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 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.

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

#### Supply chain programs

#### **Diversity**

The Soule Co. and US Surgitech are Vizient diversity suppliers. 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.

#### Novaplus

DeRoyal Industries is a Vizient Novaplus® supplier. Through Novaplus, access to products goes deep with more than 15,000 individual line items – including numerous high-demand items. The brand encompasses a broad range of categories needed across the care continuum, such as anesthesia, business products and services, diagnostic imaging, food, laboratory, medical, orthopedic, pediatric, pharmacy, respiratory and surgical. Today as the capabilities, expertise and purchasing power of Vizient grow, we offer expanded value so you unlock even more from your private-label purchasing.

For more information, click here.

#### **Impact Standardization**

Cardinal Health, DeRoyal Industries and US Surgitech participate in the Impact Patient 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**

#### **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 of 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 Centers for Disease Control and Prevention (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



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.