CATEGORY RESOURCE GUIDE

Regional anesthesia

Included in this document

(Click to view each section)

Vizient award overview

Awarded suppliers

MS1170 – FlatTech
MS7304 – Medovate
MS8920 – B. Braun 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.

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.

Market landscape

Regional anesthesia is preferred to general anesthesia because it has faster recovery time with fewer side effects (nausea). Drug shortages have included availability of trays with and without anesthesia pharmaceuticals. Use of peripheral nerve block (PNB) is growing quickly with the ability to monitor pain with a pain pump as opposed to narcotics. Ultrasound technology replacing nerve stimulators means echogenic needles and catheters have better visibility. Selection factors include needle length and gauge, bevel type, and tip design.

Manufacturing insights

Product overview

Regional anesthesia is a medical technique that involves the administration of anesthetic agents to specific regions of the body, blocking the sensation of pain in that area while allowing patients to remain awake or lightly sedated. Some examples are epidural and spinal anesthesia, PNBs and facial plane blocks. The general components of regional anesthesia include various types of anesthesia needles as well as single-use sterile trays containing local anesthetics, needles, catheters, drapes and antiseptic skin preparation solutions.

Anesthesia needles

- Spinal needles
- Epidural needles and catheters
- PNB needles, stimulators and accessories

Anesthesia trays

- Spinal trays
- Epidural trays
- Combined spinal and epidural trays
- PNB trays

Selection factors

Needle length

The choice of the needle length depends on the specific block. For instance, deeper blocks, such as sciatic nerve block, will require longer needles (eg, 100 to120 mm). The use of ultrasound can help determine the distance of the trajectory toward the target nerve. A needle that is too short will not reach the target site, while a long needle may be difficult to maneuver and may be advanced too deeply. Needles should have markings for monitoring of the depth of penetration into the tissue. The correct needle length (shortest possible) will allow for better handling and manipulation.

Needle gauge

The gauge of a needle refers to its diameter. Smaller gauge numbers indicate larger-diameter needles, while larger gauge numbers indicate smaller-diameter needles. The choice of needle gauge depends on the type of nerve block being performed as well as the patient’s characteristics. Thicker, lower gauge needles (e.g., 18 g or 20 g) are often preferred for procedures requiring a larger volume local anesthetic, such as epidural blocks, as they allow for faster injection. Thinner, higher-gauge needles (e.g., 25 g or 27 g) are suitable for more delicate procedures like PNBs.

Bevel type

Needles can have different bevel types, including Quincke, short bevel, and pencil-point. The choice of bevel type can impact the distribution of local anesthetic and the risk of complications. Quincke needles are commonly used for spinal anesthesia while pencil-point needles are generally preferred for epidural procedures.

Tip design

Needle tips vary in design, with options such as sharp, atraumatic or a combination of both. Sharp-tipped needles are designed for easy penetration of tissues, making them suitable for PNB procedures. Atraumatic or blunt-tipped needles are used to reduce the risk of tissue trauma, especially in procedures where precision is required.

Source: Equipment for regional anesthesia – NYSORA/NYSORA

OEM and manufacturing location

B. Braun manufactured in Allentown, Pa., and Santo Domingo, Dominican Republic

B. Braun suppliers

City	State	Country
Chattanooga	Tennessee	U.S.
Chicago Heights	Illinois	U.S.
Corona	California	U.S.
Deland	Florida	U.S.
Grand Rapids	Michigan	U.S.
McPherson	Kansas	U.S.
Memphis	Tennessee	U.S.
Millville	New Jersey	U.S.
Mundelein	Illinois	U.S.
New London	Wisconsin	U.S.
Oshkosh	Wisconsin	U.S.
Pleasant Prairie	Wisconsin	U.S.
Raleigh	North Carolina	U.S.
Rocky Mountain	North Carolina	U.S.
Sangareddy District	Telangana	India
Shelbyville	Kentucky	U.S.
Yangju-Si	Gyeonggi-Do	China

Raw materials

B. Braun: Because this category is kits, there are too many raw materials to list, and they vary per SKU.

The lastest manufacturing insights are available here.

Regulatory and approvals

510(k) premarket notification

Manufacturers must typically submit this notification to the Food and Drug Administration (FDA) to demonstrate that the device is substantially equivalent to a legally marketed predicate device.

Quality System Regulation (QSR)

Also known as 21 CFR Part 820, QSR is a set of FDA regulations established to ensure the quality and safety of medical devices. These regulations are crucial in the healthcare industry to guarantee that medical products and devices meet specific quality standards and do not pose undue risks to patients.

Labeling requirements (Title 21 of the Code of Federal Regulations, Section 801.109)

Also known as 21CFR § 801.109, this FDA regulation governs the labeling of medical devices. Labeling of regional anesthesia trays and needles should include essential information regarding intended use, warnings, contraindications and instructions for use (IFU)

Biocompatibility testing – ISO

Standards such as International Organization for Standardization (ISO) 10993 require manufacturers to conduct and provide evidence of biocompatibility testing. This testing is essential to assess the compatibility of materials used in medical devices with the human body.

Sterilization validation – ISO

Sterilization methods used in the manufacturing process must be validated to ensure that the devices are free from harmful microorganisms. Validation should follow recognized standards, including ISO11135 for ethylene oxide sterilization (21 CFR § 820.30).

Post-market surveillance

Manufacturers have an ongoing responsibility to monitor the performance and safety of their devices once they are on the market. This includes reporting adverse events and taking corrective actions if issues arise (21 CFR § 803).

510K

FDA drug safety communication: Updated recommendations are provided to decrease risk of spinal column bleeding and paralysis in patients on low molecular weight heparins.

Non-awarded suppliers

Teleflex – epidurals, PNBs and single-shot PNBs

Becton Dickinson – a full line of standard spinal, epidural and combined spinal-epidural (CSE) trays with safety-engineered devices, such as the BD SafetyGlide needle

Medline – block trays, spinal needles and fits

Logistics insights

Transportation/shipping

Mostly distributed with some direct at an extra fee

See additional freight update here.

Product storage

Regional anesthesia products should be stored in a controlled environment with a temperature range between 59 and 86°F to maintain their stability. They should be stored on clean, well-organized shelves with access to these products restricted to authorized personnel only. The integrity of their sterile packaging should be maintained until ready for use to prevent contamination. Routines should be established for monitoring and inspecting these products – this includes checking for damage, expiration dates and signs of contamination.

Average shelf life is for kits/trays is five years without drugs. With drugs, the shelf life is about two years. All other products are an average of five years as well.

Utilization insights

Clinical contract support resources

- Guidelines for Regional Anesthesia in Obstetrics
- Benefits, Risks and Best Practice in Regional Anesthesia
- Regional Analgesia – Risks and Benefits

Building supply assurance

Potential supply vulnerabilities

None

Conservation strategies

Resources include the following:

- Healthcare Industry Resilience Collaborative (HIRC)
- Supply Risk Solutions

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 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.

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

- Contact the supplier for alternatives.

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 regional anesthesia, 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

Impact Standardization

B. Braun participates 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

Distributor recommendations

Vizient distributor

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.

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

