CATEGORY RESOURCE GUIDE

Reusable handheld surgical instruments

Included in this document

(Click to view each section)

Vizient award overview

Awarded suppliers

MS6641 – Aesculap
MS6642 – CareFusion
MS6643 – Integra LifeSciences
MS6644 – Novo Surgical
MS6645 – Aspen Surgical Products
MS9244 – Ceek Woman's Health

Distribution

Both direct and distributed through the following distribution channels:

Medical-surgical

Want to receive weekly Supply Assurance updates?
Update your preferences through our Subscription Manager by selecting Supply Assurance Weekly Digest.

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

The reusable handheld surgical instruments market is a mature market with a fragmented supplier footprint. This category has been impacted by production cost pressures primarily due to the price increases in raw materials (stainless steel), labor and transportation.

Key suppliers: Aesculap (B Braun), Becton Dickinson, Integra, Novo Surgical and Symmetry Surgical (Aspen)

Manufacturing insights

Product overview

Reusable handheld surgical instruments are essential tools used in a variety of medical procedures to perform precise and controlled tasks. These instruments are designed to be sterilized and used repeatedly, which leads to reduced healthcare costs and minimizes waste. They are engineered with exceptional precision, constructed from high-quality materials for durability and are designed for specific functions. This category covers only reusable instruments which can be used in general or specialty surgeries. Reusable surgical instruments are primarily forged in Germany which produces industry standard premium grade instruments. Products manufactured outside of Germany may be considered economy grade. Some products found within this category include the following:

- Cutting instruments: scissors and scalpels used for cutting tissues
- Grasping instruments: forceps and clamps designed to grasp and hold tissues
- Hemostatic instruments: hemostats and ligature instruments used to clamp blood vessels and control bleeding
- Needle holders: vital for suturing wounds and securing tissues
- Retractors: used to hold back tissues or organs to provide access to a surgical site

Selection factors

Material and durability

The choice of material for surgical instruments is critical. Stainless steel, particularly 316L stainless steel, is commonly preferred due to its corrosion resistance, durability and ease of sterilization.

Precision and functionality

Ensure that the instruments are designed with precision and functionality in mind. They should be ergonomically designed for ease of use and precise manipulation during surgeries.

Sterilization compatibility

Compatibility with various sterilization methods is crucial. Instruments must withstand autoclaving and other sterilization processes without compromising their functionality or integrity.

Ergonomics and handling

Ergonomic design is paramount to reduce surgeon fatigue and improve maneuverability. Instruments with comfortable grips and ergonomic handles enhance the surgeon's control and precision during procedures.

Maintenance and reprocessing

Consider ease of maintenance and reprocessing. Instruments should be designed for easy disassembly and cleaning to minimize the risk of contamination.

Cost-effectiveness

Assess the total cost of ownership, including initial purchase cost and ongoing maintenance expenses. While high-quality instruments may have a higher upfront cost, they can be more cost-effective in the long run due to their durability.

Regulatory compliance

Ensure that the instruments meet regulatory standards and guidelines, such as those set by the Food and Drug Administration (FDA) in the U.S. or the CE mark in Europe. Compliance is essential to ensure the safety and quality of the instruments.

Supplier reputations and support

Evaluate the reputation of the supplier or manufacturer. A reputable supplier is more likely to provide quality instruments and excellent customer support.

Instrument tracking and traceability

Consider instruments that come with a tracking system for easy identification, tracking of usage and ensuring timely maintenance.

OEM and manufacturing location

Much of the forging is completed primarily in Germany; however, the manufacturing process may be finished in other locations overseas or in the U.S.

Raw materials

Stainless steel, titanium and silver

The lastest manufacturing insights are available here.

Regulatory and approvals

FDA classification:

- Class I devices include instruments with low to moderate risk, such as basic surgical scissors and forceps.

510(k) clearance:

- Manufacturers of Class II reusable surgical instruments typically need to submit a 510(k) premarket notification to the FDA. This process requires demonstrating substantial equivalence to a legally marketed predicate device. The FDA reviews the submission to ensure safety and effectiveness.

Quality Systems Regulation (QSR):

- Manufacturers must adhere to the FDA's Quality Systems Regulation (21 CFR Part 820), which establishes requirements for the design, manufacturing and quality control of medical devices, including surgical instruments. Compliance with QSR helps ensure the consistent production of safe and effective instruments.

Standards and guidelines

In addition to FDA regulations, there are several industry standards and guidelines that manufacturers and healthcare facilities should follow when dealing with reusable handheld surgical instruments:

AAMI TIR12:2010:

The AAMI provides **t**echnical **i**nformation **r**eports (TIRs) relevant to medical devices. TIR12:2010 offers guidance on the cleaning validation of reusable medical devices, which includes surgical instruments.

ANSI/AAMI ST79:2017:

This standard from the American National Standards Institute (ANSI) and AAMI provides comprehensive guidance on steam sterilization and sterility assurance in healthcare facilities. Proper sterilization is crucial to ensure the safety of reusable surgical instruments.

ISO 17664:2017:

The International Organization for Standardization (ISO) provides guidelines on the validation of cleaning processes for reusable medical devices. ISO 17664:2017 outlines the principles and provides guidance for cleaning validation of such devices.

Non-awarded suppliers

Non-contract suppliers include Medline, Teleflex and Cooper Surgical; they may not provide a full line in this category.

Logistics insights

Transportation/shipping

The products/raw materials are typically manufactured/sourced in Germany.

They are ordered direct.

See additional freight update here.

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. 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:

- 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 reusable handheld surgical instruments, 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

Diversity

Novo Surgical 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

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.

