CATEGORY RESOURCE GUIDE

Facial protection

Included in this document

(Click to view each section)

Vizient award overview

Awarded suppliers

MS7180 – O&M Halyard
MS9250 – Prestige Ameritech
MS9670 – 3M
NE0060 – Kerma Medical Products
NE0120 – SafeSource Direct

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

Overall, mask usage remains elevated following the pandemic but has declined since its peak in 2020-2022. Pricing also remains elevated over pre-pandemic levels. The market is saturated with suppliers following the pandemic, and members typically still have inventory/stockpiles that they are working through; thus, product availability is no longer a concern in this category. Regulatory issues and pandemic/healthcare-related events are potential supply vulnerabilities.

Manufacturing insights

Product overview

This category includes N95 respirators, surgical masks and procedure masks, as well as face shields and protective eyewear.

A surgical N95 respirator is a fluid-resistant, singe-use, disposable respiratory protective device that is National Institute For Occupational Safety and health- (NIOSH-) approved and has been cleared by the Food and Drug Administration (FDA) as a surgical respirator and filters at least 95% of airborne particles. Surgical N95s are available in a flat fold (duckbill) style, a molded cup-shaped style and a flexing style. Surgical N95s should never have ear loops. Surgical N95s protect from exposure to airborne particles and act as a barrier to splashes, droplets and sprays. In a health care setting, they protect from biological aerosols, including viruses and bacteria. A disposable half-mask filtering facepiece respirator (FFR) covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level.

Medical masks are made of different thicknesses and are intended for uses ranging from low to high risk of contamination and meet the American Society for Testing and Materials (ASTM) standards recognized by the FDA. ASTM ratings are based on the masks bacterial (bacterial filtration efficiency [BFE]) and particulate (particle filtration efficiency [PFE]) filtration efficiency and fluid resistance. ASTM-rated masks are tested under ASTM F2100-11 performance requirements and are considered a medical device.

Selection factors

Selection factors are typically dictated by infection control within the facility, especially when determining the appropriate mask for appropriate setting. Another crucial selection factor in this category is fit testing, specific to N95 respirators. When determining the appropriate mask, selection will be based on NIOSH and ASTM standards for both N95s and medical masks.

OEM and manufacturing location

Products are manufactured in the U.S., Mexico and overseas. Below are the manufacturing locations for contracted suppliers:

- O&M Halyard N95s and face masks are manufactured in the U.S. and Mexico.
- 3M N95s are manufactured in the U.S.
- Prestige Ameritech N95s are manufactured in the U.S. and meet Berry amendment compliance with regard to wholly domestically made products and are eligible for reimbursement per the policy details listed below.

Raw materials

Medical masks are made of different materials, including polypropylene, polystyrene, polycarbonate, polyethylene, and polyester. A surgical mask is three or four ply, made from non-woven fabric with a middle layer of melt-blown polymer, most commonly polypropylene.

Surgical N95 respirators are made of a fine mesh of synthetic polymer fibers; specifically the filter is a non-woven polypropylene fabric. It is produced by melt blowing and forms the inner filtration layer. Some surgical N95 respirators contain an exhalation valve to make it easier to breathe. This valve allows unfiltered exhaled air to escape and should not be used where a sterile field is required.

The lastest manufacturing insights are available here.

Regulatory and approvals

NIOSH-approved N95 respirators are tested and certified as meeting the standards established in 42 CFR 84. For detailed information, see the NIOSH Guide to the Selection and Use of Particulate Respirators.

- ASTM F2100-11: 510K approval as appropriate – Class I doesn't require 510k (procedure masks and N95s); Class II (surgical masks) do require 510k approval.
- N95s are exempt from 510k unless intended to prevent specific diseases.
- ASTM has levels 1-3.

ASTM level	Intended use	Applicability
Level 1	• Designed to prevent spray at venous pressure • Provides minimal protection from BFE/PFE and fluid resistance	Non-surgical – general procedures, exams and respiratory etiquette
Level 2	• Designed to prevent spray at arterial pressure • Provides moderate protection from BFE/PFE and moderate fluid resistance	Procedures where moderate amounts of fluid, spray and/or aerosols
Level 3	• Designed to prevent spray at arterial pressure • Provides high protection from BFE/PFE and has the highest level of fluid resistance	Procedures where moderate amounts of fluid, spray and/or aerosols such as orthopedic surgery or trauma

In calendar year 2023 Outpatient Prospective Payment System final rule, the Centers for Medicare and Medicaid Services (CMS) finalized new policy to provide biweekly reimbursements to medical facilities that are using wholly domestically made NIOSH-approved surgical N95 respirators that meet criteria of the Berry amendment. These additional payments are effective for cost reporting periods beginning on or after Jan. 1, 2023.

Non-awarded suppliers

Non-awarded suppliers: Medline, Cardinal Health and other distributors with market share

Logistics insights

Transportation/shipping

The products, which are manufactured overseas and in the U.S., are shipped freight and rail once they reach the U.S. All major ports are utilized for raw materials coming to the U.S.

Distribution centers are located across the U.S. in major distributor warehouses, depending on the supplier. Typically products are distributed, while direct is an option depending on the supplier.

See additional freight update here.

Product storage

Product shelf life for N95s and face masks is typically **five** years. Product should be stored in climate-controlled conditions to maximize shelf life of the product.

Utilization insights

Clinical contract support resources

COVID-19 guide to face masks and filtering facepiece respirators clinical resource guide

Building supply assurance

Potential supply vulnerabilities

Regulatory issues and pandemic/healthcare-related events are potential supply vulnerabilities.

Conservation strategies

Providers can focus on using the appropriate mask for the setting based on infection control protocols and ASTM ratings in order to conserve additional inventory in the event supply is disrupted.

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 facial protection, 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

Novaplus Enhanced Supply

Kerma and SafeSource Direct are part of the Novaplus® Enhanced Supply (NES) Program. A part of Novaplus, the industry's longest-running private label program, NES delivers additional inventory of essential medications and products, including personal protective equipment (PPE), critical to your clinicians' ability to provide immediate and high-quality patient care.

In addition to incremental product in the marketplace, this innovative contracting model helps providers and suppliers increase supply assurance through clearer data insights, diversified relationships, and visibility into logistical and other considerations that affect production – enabling greater stability between supply and demand.

For information, click here.

Novaplus

O&M Halyard 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.

Diversity

Prestige Ameritech and Kerma 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.

Pediatric Program

O&M Halyard participates in the Vizient Pedatric Program. The Vizient Pediatric Program is a supply chain program focused on delivering savings, quality and choice from an industry-leading pediatric product portfolio. Additional information is available here.

Impact Standardization

O&M Halyard participates in the Impact Infection Prevention 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

It is recommended to work closely with your distributor/supplier to ensure correct quantities and manage warehouse inventory accordingly.

Best practice strategies

Stockpiles remain common in this category following the pandemic. Planning for supply disruptions should include holding some safety stock in inventory and working closely with your primary supplier to gain insight into available product. Allocation will typically be based on purchase history, and it will be important to rotate inventory and safety stock in order to continuously use products prior to expiration.

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 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.

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