CATEGORY RESOURCE GUIDE

Custom procedure trays

Included in this document

(Click to view each section)

Vizient award overview

Awarded suppliers

MS9661 – Cardinal Health
MS9662 – DeRoyal Industries
MS9663 – Medical Action Industries
MS9664 – Medline Indistries

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

Market landscape

Custom procedure trays (CPTs) properly created and stored can save healthcare facility time and money. The CPTs also cut down on risk of infection because single-use items are sterile and prepackaged. But the kits also require regular review to ensure they are eliminated when a procedure becomes obsolete, and they present additional challenges when there are supply constraints. If a CPT is out of stock, it's important to determine which of the many products is the cause before finding a solution. Then you can decide if creating your own CPTs or choosing standardized kits makes most sense for your facility.

Manufacturing insights

Product overview

The creation of CPTs is to provide customized, disposable items used in specific surgical or medical procedures in a single, sterile pack. These preconfigured packs provide cost containment, product reliability, waste reduction and process efficiency, reducing set-up time. Trays can also reduce the risk of infection because all the items are sterile and prepacked as well as prevent cross-contamination because the items are single use. To cover the entire process, a unitized delivery system combines multiple CPTs, which can include prep kits, basin sets, procedure packs and turnover kits.

Trays and delivery systems may be found in almost every healthcare department. Because individual items are prepackaged, there is reduced need to purchase bulk items, facilitating efficient inventory management and decreased procurement time. While there are general or standardized trays, often there is additional waste with unused and unnecessary items. If the facility chooses to keep these items, it must spend the time and money to re-sterilize and store them.

A custom medical procedure tray will expire based on the components inside and how the packaging breaks down over time. Storage factors, device functionality and toxicology of medications are all factors to consider related to the safety of a pack over time.

Selection factors

Vizient contracts offer CPTs and unitized delivery systems. Custom trays allow you to pick the exact items you need for the procedure. You can customize by provider or by procedure. Manufacturers usually have a web-based program that will allow you to assemble and change packs online. The goal of properly configured procedure trays is to perform the highest number of procedures with the minimum set of components/instruments. According to a Vizient consulting director in "How Surgical Tray Standardization Saved One Hospital $50,000 and What You Should Know," tray management is centered on answering four main questions:

- Which instruments should be included?
- In what quantities?
- What surgical procedures will the tray be used on?
- How many trays of each type should be held in inventory?

The following other factors can also be considered:

- What are items covered by your group purchasing organization (GPO) contract?
- What are items on your formulary?
- What are clinically and economically justifiable preference items?
- How do you need the equipment arranged in the tray?
- What would the cost be if you put the tray together yourself?

Raw materials

Raw materials vary by what products are in the CPT.

The lastest manufacturing insights are available here.

Regulatory and approvals

In May 1997, the U.S. Food and Drug Administration (FDA) provided Convenience Kits Interim Regulatory Guidance that has a list of kits organized by medical specialty based on its database at the time. The guidance says, the "FDA intends to exercise its

enforcement discretion, i.e. not require 510(k) clearance, for convenience kits of a type matching one of those included on the attached list, consisting of components that have been cleared through the 510(k) process, and where the assembler/manufacturer is able to reasonably conclude that any further processing of the kit and its components does not significantly affect the safety or effectiveness of any of its components."

Non-awarded suppliers

All major players are on contract.

Logistics insights

Transportation/shipping

- DeRoyal
  - U.S. (near shore) – southwest Virginia and big facilities in Guatemala and Dominican Republic, and a smaller facility in Costa Rica
- Cardinal
  - Kits are made domestically in Fort Mill, S.C., but Cardinal is shifting to a new facility in El Paso, Texas.
  - Sterilization and assembly will be in Texas.
  - There are significant operations in Juarez, Mexico (80%), with 20% in El Paso.
- Medical Action
  - It is the only custom kitting company that does all kitting in Williamsburg, Va.
  - There is no sterilizing in Virginia; trays are sent out to sterilize to a few different locations in the U.S.

This category is heavily tied to distribution.

See additional freight update here.

Product storage

First, upon receiving the trays, they must be inspected for damage like holes or water. Next, the storage area should be clean, airy and above the floor level away from direct sunlight. Follow the manufacturer's instruction regarding stacking and ensure that identification labels are visible to reduce handling.

The most important rule is to maintain the tray sterility. It is also good practice to store the trays close to the point of use.

Utilization insights

Clinical contract support resources

Fine-tuning Your Procedure Pack

This article from AORN offers some best practices in keeping your packs as current and cost effective as possible.

Does Medicare Cover All Surgical Trays?

This article provides the requirements for eligibility to know if Medicare covers surgical trays.

Building supply assurance

Conservation strategies

- Because CPTs are made up of individual components, you first need to determine why you are unable to get your tray. Factors could relate to manufacturing, distributing, raw material, global events, etc. This information will allow you to determine what the recovery time might be.
- One strategy is to make your own customized tray. If you are not sure what items are in the original tray, the manufacturer can provide an itemized list of everything included.
- Standardized procedure trays are another option to consider. While there may be some waste, if having a tray makes more sense than picking individual items, then this option might be the right choice.

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.

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 CPTs, 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

None

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.

- Have a list of standardized trays which would be acceptable alternatives to the custom trays.
- Have a good understanding of what components are in each tray as well as the manufacturers who provide the items. This way, when there is a disruption related to manufacturing or distribution, you will know how to pivot to ensure successful business continuity.
- Schedule a regular cadence with your clinicians and tray provider to review the trays. This will allow you to collaboratively make changes to keep them as efficient and cost effective as possible. Include in this process verification that you have the trays stored in the right place and in the right way to be used at the right time.
- Make sure to cancel trays associated with procedures that are obsolete.

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 a 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 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 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. 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:
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