CATEGORY RESOURCE GUIDE

Endomechanicals

Included in this document

(Click to view each section)

Vizient award overview

Awarded suppliers

MS7321 – Applied Medical
MS7322 – Covidien
MS7324 – Johnson & Johnson
MS7325 – Encision Inc.

Distribution

Direct

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

Market landscape

- Technology advancements: Consistent improvements in optics, robotics, materials and miniaturization devices have led to improved surgical precision, patient outcomes and visualization.
- Robotic-assisted surgeries are increasing. Companies like Intuitive Surgical have been leading the charge in this area. Many companies are looking to enter the market in the coming years.
- Demand for minimally invasive procedures has driven the global endomechanical device market up. Aging population and increased bariatric patients are directly linked to the growth of this market.
- Regulatory bodies have consistently established guidelines that ensure patient safety, especially as the robotic surgery space grows.
- Challenges in this industry include increased cost of devices and consolidation of portfolios. There are also potential learning curves with the robotic surgery increases.
- Established competitors: Medtronic, Ethicon, Applied Medical and Encision are the main suppliers on contract for Vizient. Applied is not a full-line supplier, and Encision is an Innovative Technology awardee.
- These surgeries are continuing to move toward alternate site facilities.

Manufacturing insights

Product overview

Endomechanical devices are those used during laparoscopic surgeries in the abdomen. Typically, they assist in removing, attaching or joining organs and are seen in abdominal, thoracic, gynecological, colorectal, bariatric and transplant surgeries, to name a few. Endomechanicals allow for smaller incisions, less morbidity, faster healing, less discomfort and shorter hospital stays when compared with conventional surgical techniques.

Selection factors

The following table provides an overview of some of the general items offered on Vizient endomechanical contracts:

Endomechanical device	Description
Babcock	Used for grasping different types of tissues with atraumatic serrations on the tip
Bipolar forceps	Instruments that grasp, manipulate and coagulate selected tissue, alleviating the need for surgical clips or staples
Bowel sizer	A cylinder of variable diameter, with rounded ends, used to measure the internal diameter of the bowel to prepare for stapling
Cholecystectomy tray	A tray that provides the equipment needed to remove a gallbladder; can include clamps, forceps, needle holders, scissors, clips, suction, electrosurgical devices, insufflator and light source
Clip applier and ligating clips	Used to tie up or constrict vessels like veins, bile ducts and ureters
Cutter and reloads	Used to cut and staple a vessel, creating a joining of or opening between two organs or spaces that normally are not connected
Dissector	Used for tissue dissection by scraping with its light teeth and the possibility of tip rotation; may also be used to remove tissue and bone fragments; can elevate and manipulate delicate tissue
Electrosurgical probe	Used to cut and destroy tissue as well as control bleeding through heat conduction; requires a generator and patient grounding pad
Grasper	Used to lift and mobilize delicate tissue and organs
Hemorrhoidal stapler	Used to remove hemorrhoidal tissue through stapling
Instrument tray	Protects medical instruments by holding them in place during the sterilization process and transporting from one location to another
Knot-tying device	Allows for suture fixation
Needle holder	AKA needle driver or needle forceps; hold and pushes a suturing needle through tissue
Purse string clamp	AKA auto-suture clamp; used for closing round or oval openings by using suture and staples
Scissors	Used to cut tissue and sutures

Endomechanical device	Description
Skin adhesive	Used to close wounds either on its own, with stitches or adhesive tape; forms a protective, waterproof covering
Skin stapler	Used externally to close wounds by compressing the tissue
Specimen retrieval bag	Used for specimen extraction by placing the tissue/organ/specimen in a polyurethane pouch which minimizes spillage and intraoperative contamination
Staple extractor	Removes staples from the skin
Suture	Facilitates deep wound closure; available in absorbable or nonabsorbable, monofilament or braided, natural or synthetic
Trocar	Used to make small, puncture-like incisions in outer tissue layers so a cannula can be inserted and instruments can be introduced
Suturing devices and suture cartridges	Used to line up tissue and seal major vessels

Endomechanicals are considered physician preference items. Selection usually involves a product evaluation and cost analysis. Experience, technology, performance, reliability and ergonomics are some of the factors that drive decision-making.

Reusable instruments may be reprocessed and reused multiple times. The U.S. Food and Drug Administration (FDA) groups these instruments “into one of three categories according to the degree of risk of infection associated with their use:”

- Critical devices: come into contact with blood or normally sterile tissue
- Semi-critical devices: come into contact with mucus membranes.
- Non-critical devices: come into contact with unbroken skin

Disposable instruments or single-use devices are used on one patient during one procedure and then thrown away.

According to the World Economic Forum, healthcare systems account for more than 4% of global CO2 emissions. Collaborate with your surgical teams to identify which instruments reduce power consumption or reduce indirect emissions by in-house reprocessing or which reduces landfill or water consumption.

All decisions need to be guided by risks for contamination and infection, environmental impact, cost-efficiency and time savings.

Raw materials

- Stainless steel
- Titanium
- Copper
- Polyester/Tyvek
- Glass epoxy composite
- Gold/nickel
- Thermochromic epoxy and other epoxies
- Nuv
- Plastics and polymers (ethylene tetrafluoroethylene, polyvinylchloride [PVC], others)
- TPR and Santoprene
- Ceramics
- Alloys (nitinol)
- Silicone
- Sutures/threads
- Wiring/technology such as sensors, electronics
- Polystyrene
- Bone wax

The lastest manufacturing insights are available here.

Regulatory and approvals

Surgical Staplers and Staples

The FDA discusses problems associated with surgical staplers and offers guidance on reporting events.

OSHA Guidelines for Environmental Infection Control in Health-Care Facilities

Find temperature, water, humidity and ventilation standards for surgery and critical care areas, including the endoscopy suite.

Part 878 General and Plastic Surgery Devices

The Code of Federal Regulations (CFR) Title 21 covers tissue adhesive, organ bag, surgical camera and accessories, implantable clip, electrosurgical cutting and coagulation device and accessories, hemostatic device for intraluminal gastrointestinal use, absorbable surgical suture, stainless steel suture, surgical stapler, and implantable staple.

Centers for Medicare and Medicaid Service (CMS) Regulations and Guidance

Search this CMS site for local coverage determination (LCD), national coverage determination (NCD), articles, quality safety and oversight, and more.

Non-awarded suppliers

Other suppliers that offer products but not on Vizient contract:

Non-awarded suppliers	Product offering
3M	Stapling
DeRoyal	Retrieval bags, insufflation, dissectors
ConMed	Clip appliers, insufflation, retrieval bags, dissectors
Microline	Dissectors, graspers, scissors, clip appliers
Teleflex	Stapling, ligation

Logistics insights

Transportation/shipping

Most raw materials are both ordered direct or distributed, with countries often involved in the manufacturing/sourcing of these marterials below:

- U.S.
- Italy
- Germany
- China
- Mexico
- South Korea

See additional freight update here.

Product storage

According to the Centers for Disease Control and Prevention (CDC), sterile instruments and supplies should be stored in covered or closed cabinets.

AORN recommends that sterile supplies should be stored under the following conditions:

- Controlled room temperature: maximum 24-degree C/75-degree F
- Maximum humidity of 60%

- Positive air pressure in relation to adjacent areas
- A minimum of four air exchanges/hour
- Do not use product if the heat indicator has been activated (turns red).
- Before use, inspect all sterile packaging to make sure it has not been compromised (wet, torn or damaged in any way).
- Do not store clean or sterile supplies in corridors, on windowsills or the floor, or under sinks.
- Always follow the manufacturer's instruction for use.

Utilization insights

Clinical contract support resources

Improve Cost Reduction: A Multidisciplinary and Big Picture Approach

This Association for Health Care Resource & Materials Management (AHRMM) educational webinar describes how a large health system standardized endomechanical, suture, trocars and surgical energy across multiple categories.

Environmental Impact of Single-Use, Reusable and Mixed Trocar Systems Used for Laparoscopic Cholecystectomies

The study shows that a reusable trocar system has a lower environmental impact than the single-use and mixed system.

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

- Apply clinical-supply integration.
- Review and align physician preference cards.
- Standardize equipment and compare the cost of the same procedure between different specialties.
- Have regular conversations with physicians on what their costs are for certain procedures.

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 endomechanicals, 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

Build strong relationships with key distribution partners, and confirm that distributors are doing contract refreshes regularly to confirm that pricing and products are accurate. The contracted suppliers send updates every 24 hours to distribution channels to ensure members are accurately positioned.

Best practice strategies

- Single-use devices may only be reprocessed as a part of a contract service by a third-party reprocessing company regulated by the FDA.
- Validated reprocessing instructions and manufacturers for use should readily be available.
- Instruments that evidence oxidation, pitting, cracking or damage markings, discoloration, staining, or that have structural damage may not be released for use.
- Do not reprocess beyond the maximum number of reprocessing cycles or beyond its “useful life.”
- Training and competency checks are essential for all staff and leadership involved in reprocessing.
- Have a replacement plan for items no longer in use.
- Terminally clean instruments immediately.
- Make sure cleaning chemicals are diluted properly and maintained at the proper temperature.
- Identify compromised equipment, even if it delays or reschedules a case.

Vizient offers the following best practices to help members manage disruptions. These suggestions are available to help you gain insight about 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 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 endomechanical 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 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. 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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