CATEGORY RESOURCE GUIDE

Endoscopy equipment and accessories

Included in this document:

(Click to view each section)

Vizient award overview

Awarded suppliers

CE7341 – Olympus America
CE7342 – Zimmer US
CE7343 – Stryker Sales
CE7344 – Richard Wolf Medical Instruments
CE7345 – Pentax of America
CE7346 – Karl Storz
CE7347 – Fujifilm Healthcare America
CE7348 – ConMed
CE7349 – Covidien
CE7351 – Total Scope

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

Market landscape

The global endoscopy equipment market is projected to reach $40.6 billion by 2027 as hospitals invest in purchasing technologically advanced endoscopy instruments and expanding endoscopy units as well as ongoing advancements in endoscopic technologies to ensure patient safety and achieve more accurate, precise, and reliable diagnoses and treatments. Due to COVID-19, the number of endoscopic procedures decreased tremendously. In addition, the shortage of healthcare professionals due to the increased cases of COVID-19 infection and supply chain disruptions along with changing regulations to curtail the infection in major regions resulted in a significant impact on the global market growth in 2020.

The pandemic also hindered the production of semiconductor chips, which are a key element in endoscopic medical devices. Many endoscopy suppliers were challenged with this supply shortage, resulting in depletion through inventory and reducing or pausing the manufacture of devices. This led to extensive lead times, more than 12 months.

Manufacturing insights

Product overview

Endoscopy is a minimally invasive procedure that uses a long, thin tube to look inside the body. Other than for observation, endoscopies can be ordered to collect biopsies, confirm a diagnosis or to help remove tumors, foreign objects or small organs.

The global endoscopy equipment market is projected to reach $40.6 billion by 2027, which is a 7% increase from 2022. Wireless displays and monitors with 3-D-compatible endoscopes account for most of this growth. The increase in the aging population means an increase in colorectal screenings which will be a significant factor as well. Colonoscopies are considered a gold standard for colorectal cancer screening in the U.S.

Below is a list of some of the endoscopy procedures performed in healthcare facilities:

Endoscopy	Area	Specialist
Arthroscopy	Joints	Orthopedic surgeon
Bronchoscopy	Lungs	Pulmonologist
Colonoscopy	Cecum, colon, rectum and anal canal	Gastroenterologist
Colposcopy	Cervix, vagina and vulva	Gynecologist
Cystoscopy	Urinary bladder	Urologist
Endoscopic retrograde cholangiopancreatography (ERCP)	Biliary or pancreatic ductal systems	Gastroenterologist
Enteroscopy	Duodenum, jejunum and ileum	Gastroenterologist
Esophagogastroduodenoscopy	Esophagus, stomach and duodenum	Gastroenterologist
Hysteroscopy	Uterus	Gynecologist
Laparoscopy	Abdomen or pelvis	General Surgeon
Laryngoscopy	Throat	Otolaryngologist (ENT)
Mediastinoscopy	Mediastinum (area between the lungs)	Thoracic surgeon
Proctoscopy	Anal, rectum or sigmoid colon-	Gastroenterologist
Sigmoidoscopy	Rectum and sigmoid colon	Gastroenterologist
Thoracoscopy (pleuroscopy)	Pleural cavity (between lungs and chest wall)	Pulmonologist
Transnasal esophagoscopy	Esophagus	Gastroenterologist
Ureteroscopy	Ureter	Urologist

A typical endoscope includes an eyepiece, opening for wires and instruments, a flexible shaft, flexible tip, and flexible shaft transmitting light, air and water as illustrated below:

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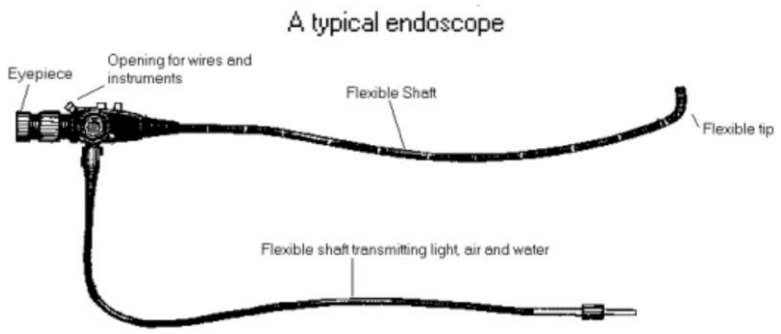

The Code of Federal Regulations Title 21 section 876.1500 divides the endoscopes and accessories into class I and II devices:

Class I	Class II
Bulb adapters	Endoscopes
Binocular attachments	Single-use magnetic retriever
Eyepiece attachments	Single-use sterile scissors
Teaching attachments	Single-use endoscopic grasping/cutting instrument
Inflation bulbs	Light sources
Measuring devices	Sponge carrier
Photographic equipment	Transformer
Smoke removal tubes	Guidewire
Battery boxes	Cameras
Bite blocks	
Cleaning brushes	

Other accessories include stopcock, connectors, needle tips, forceps, graspers, dissectors, knot pushers, Babcock forceps, trocars, obturators, sheaths, instrument seals, tissue traps, Toomey syringes, aspiration filters, fluid canisters, ring bands, vacuum curettes, evacuators, sterilization trays, cords, cables, vessel-sealing electrodes, insufflation tubing and video lenses.

Selection factors

Systems typically include a video processor, display monitor, light source, video camera and endoscope. When evaluating endoscopes, consider the following:

Reusable	Disposable
Advanced diagnostic/therapeutic procedures	Reduces risk of infection
Greater maneuverability	Minimizes cross contamination
Higher image quality	No maintenance costs
More sturdy	No cleaning and reprocessing considerations
Better suction power	
Easier passage of instruments through insertion channel	
Cleaning and reprocessing considerations	
Repair cost considerations	

Some other areas of consideration are the following:

- Resolution and compatibility features
- Angular field
- Focus range
- Bending angle of the distal end
- Instrument compatibility with accessories
- Diameter
- Cleaning compliance
- The possibility of full immersion in disinfectants
- Stationary or portable units
- Display features

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There are two main categories of endoscopes:

Endoscope	Characteristics	Specialties
Flexible	Agile; lenses consist of flexible fibers; limited bending capacity allowing user to explore different angles and small cavities; comes in fiberoptic which allows image to be seen directly or through a mounted camera or videoscopic where the images are transmitted directly to a monitor	Bronchoscopy, colonoscopy and esophagogastroduodenoscopy
Rigid	Short metal tubular telescope containing lenses, fiber optic bundles for light transmission and video chips for image transmission; no bending capacity; offers the best image quality and resolution	Urology, gynecology, ENT, arthroscopy, endoscopic spine surgery and general surgery

For the AORN Guideline Quick View for flexible endoscopes, go here.

Raw materials

Metals, polymers and glass (as lenses) are used in the insertion tube and distal tip of endoscopes. Raw materials also include stainless steel, metal, silicone rubber, latex rubber, polyethylene, polyurethanes and Teflon. Another important material used in endoscopes is the semiconductor manufacturing concerning charges coupled device (CCD) and complementary metal-oxide-semiconductor (CMOS) used for the distal sensor of the endoscope.

The lastest manufacturing insights are available here.

Regulatory and approvals

Essential Elements of a Reprocessing Program for Flexible Endoscopes – HICPAC

Healthcare Infection Control Practices Advisory Committee and the Centers for Disease Control and Prevention (CDC) provide guidance regarding the strategies and practice around reprocessing endoscopes.

Information about Automated Endoscope Reprocessors (AERs) and U.S. Food and Drug Administration's (FDA's) Evaluation

The FDA evaluates AERs (class II devices) for safety and effectiveness.

Medical Device Reporting (MDR): How to Report Medical Device Problems

The tool allows the FDA to monitor device performance, detect potential device-related safety issues and contribute to benefit-risk assessments of post-market products.

CFR – Code of Federal Regulations Title 21 Medical Device Reporting

This covers general provisions, requirements for individual adverse event reports, user facility reporting requirements, importer reporting requirements and manufacturer reporting requirements.

Infections Associated with Reprocessed Duodenoscopes

This provides the FDA's ongoing activities related to duodenoscopes.

New Survey Process for Duodenoscopes/Endoscopes/Reusable Medical Devices

Survey results show that there continues to be problems with cleaning and disinfecting reusable medical devices. Centers for Medicare and Medicaid Services (CMS) provides a link to its hospital infection control surveyor worksheet as a self-assessment tool.

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Non-awarded suppliers

Boston Scientific, Medtronic, Arthrax and Smith & Nephew also offer endoscopic instruments and accessorieis.

Logistics insights

Transportation/shipping

The majority of endoscopic suppliers manufacture their products in Japan, Germany, Mexico and the U.S. Products are sold directly through suppliers. Semiconductor chips are produced primarily in Taiwan, China, Japan and South Korea.

See additional freight updates here.

Product cleaning

Below are some of the revisions for ST91, which provides a comprehensive practice guide for each stage of processing flexible endoscopes:

- There should be one sink for leak testing, one sink for manual cleaning and one sink for critical rinsing.
- Training and competencies should be completed before someone's first "solo assignment." Certification in flexible endoscope processing should be done within two years of employment.
- Mechanically clean and immerse endoscope accessories in low-foaming detergent immediately after use.
- Use ultrasonic cleaning while in immersing solution to remove debris from crevices.
- Rinse and flush with clean water.
- Lubricate with mineral oil.
- Autoclave or gas sterilize by ethylene oxide (EtO).
- Monitor water quality across all stages of endoscope processing.
- Cleaning frequencies, which include terminal cleaning, must be established for the environment.
- Keep endoscope and accessories moist during transport. Confirmation of appropriate hand-off must be documented.
- Cleaning must occur within the manufacturer's recommended time.
- For more recommendations, refer to Reprocessing and Reuse of Endoscopic Accessories.

Product storage

Below are some recommendations from The Joint Commission:

- Be compliant with all building code requirements.
- Review temperature and humidity requirements – ASHRAE Standard 170- 2008.
- There must be a positive pressure relationship to adjacent areas.
- Minimum outdoor air exchange is two/hour.
- Minimum total air exchange is four/hour.
- Maximum relative humidity is 60%.
- Temperature range is 72 to 78 F or 22 to 26 C.
- Instruments are stored so sterility is not compromised.
- Supply areas must be clean, well ventilated and protect from contamination, moisture, dust, temperature extremes and humidity extremes.

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Utilization insights

Clinical contract support resources

Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC)

The committee provides guidance to assist healthcare facilities with developing a reliable, high-quality system for endoscope reprocessing.

American College of Gastroenterology (ACG)

ACG offers guidelines for diagnosis, management and quality indicators of various medical conditions affecting the gastrointestinal (GI) tract.

Building supply assurance

Conservation strategies

The National Library of Medicine published a study in January 2023 addressing “practical measures for environmental sustainability in endoscopy.” The following represent good suggestions for conservation strategies in general:

- Reduce unnecessary endoscopy procedures. To ensure the appropriateness of endoscopy procedures, endoscopy units can establish guideline-supported referral pathways, enhance departmental vetting procedures and provide regular educational activities to update emerging evidence for appropriate use of endoscopy.
- Identify alternative diagnostic testing methods such as serological testing or home stool testing kits.
- Use a multidisciplinary team to plan complex cases. By placing the patient on the appropriate specialist list, you can avoid redo procedures.
- Augment training with simulation and online image libraries to conserve on actual equipment.
- Wherever possible, try to avoid single-use, disposable endoscopes. While they reduce reprocessing and cross-contamination, they increase plastic pollution which negatively affects the carbon footprint.

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:

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 endoscopy, or any other category, share your information here. The information you share will be anonymous unless you grant Vizient permission to share.

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Supply chain programs

Pentax of America participates in the Vizient Pedatric Program, a supply chain program that focuses on delivering savings, quality and choice from an industry-leading pediatric product portfolio. Additional information is available here.

Total Scope 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

Distributor recommendations

All awarded suppliers offer products through direct sales.

Best practice strategies

The following are some recommendations from American Society for Gastrointestinal Endoscopy (ASGE):

- A staff member directly engaged in an endoscopy procedure or in cleaning should don full personal protective equipment (PPE), including impervious gowns, hair covers, booties, face or eye shields, and gloves.
- With moderate sedation, a registered nurse (RN) can monitor the patient and perform interruptible tasks if another RN, licensed practical nurse (LPN) or unlicensed assistive personnel (UAP) is available to join the team if more technical assistance is needed.
- Non-sterile procedure rooms are held to the same standards as operating rooms.
- A terminal cleansing plan should include methods, as well as chemical agents for cleaning and disinfecting.
- Environmental cleaning should not be performed around IV solutions or anything that could be damaged by splash contamination.
- Verify and document expiration dates of marked supplies.
- Maintain material safety data sheets for all chemicals used for training.
- Follow the manufacturer's directions on the use, handling and cleaning of devices.
- If single-use devices are reused, a policy must be created that guides each reuse and determines when it is no longer safe for reuse.

Guideline Summary: Processing Flexible Endoscopes

The Association for Professionals in Infection Control and Epidemiology (APIC) provides guidance to perioperative, endoscopy and sterile-processing personnel for processing all types of reusable flexible endoscopes and accessories.

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 about 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 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.

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- 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 endoscopy 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 suppliers.

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:

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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

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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.

To learn more, please contact:
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As the nation's largest member-driven health care performance improvement company, Vizient provides solutions and services that empower health care providers to deliver high-value care by aligning cost, quality and market performance. With analytics, advisory services and a robust sourcing portfolio, we help members improve patient outcomes and lower costs.

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