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Four ways to support a growth strategy for single-use and reusable flexible endoscopes

Single-use, flexible scopes (SUFS) are appearing in all endoscope specialty categories. Manufacturers of reusable, flexible scopes (RFS) that have expanded into the SUFS market have new competitors from scope-adjacent industries and emerging suppliers, who are offering solely disposable options.

The market is also encountering innovations for the care and handling of scopes to address the latest guidelines and general improvements in patient outcomes. Some of that innovation includes:

- **Single-use flexible scopes and modular, disposable flexible scopes**
- **New scope storage cabinets with HEPA filters and forced air drying**
- **Scope tracking software**
- **Enhanced automated endoscope reprocessors (AER)**
- **Automated leak testers**
- **Robotic-assisted flexible endoscopes**
- **AI-embedded imaging for enhanced diagnostic and therapeutic outcomes**

These new products further polarize the conversation about quality, workflow and prioritizing capital spend. As a result, health systems face mounting challenges with product and usage comparisons. Proactive suppliers that offer the educational tools necessary for providers to understand this market, especially during a challenging economy, will earn a competitive advantage.

Vizient sees this shift as an opportunity for partnerships. These technological advancements are an opportunity to address the complex scope market while moving toward continuous improvements in financial performance and patient safety. Here are four ways manufacturers can contribute:

1. Keep providers abreast of rapidly changing regulations and guidelines

The U.S. Food and Drug Administration (FDA), in June 2021 and April 2022, recommended disposable flexible scope components or fully disposable scopes if available.[1] The safety communication also described updates on preferred cleaning and reprocessing methods for reusable devices.

Other governing bodies have updated RFS guidelines that will change current workflows, add to reprocessing times and financially impact sites that don't have a suitable reprocessing infrastructure, capital equipment resources, and staffed and trained departments. Suppliers can work with these sites to provide valuable product guidance, which could lead to upselling opportunities or new contracts.

Governing bodies' impact on RFS and SUFS

U.S. Food and Drug Administration (FDA)[1,2]

- Recalled the most egregious duodenoscope
- Recommended disposable flexible scope components or fully disposable scopes if available

Association for the Advancement of Medical Instrument (AAMI)[3]

- Recommended single-use scope valves and caps
- Recommended against manual disinfection
- Recommended forced air drying to reprocessing and/or storage
- Recommended including monitoring of water in rinse phase and HEPA filters in storage
- Recommended location specifications of reprocessing equipment
- Recommended enhanced training and certification with reprocessing

Environmental Protection Agency (EPA)

- Proposing new emission control and monitor rules for EtO manufacturers
- Proposing prohibiting certain uses of EtO where alternatives exist
- Proposing required controls and PPE to reduce exposure to EtO

2. Help providers determine how disposable and reprocessed scopes meet their sustainability initiatives

Sustainability is a major consideration around the use of these devices. The U.S. healthcare industry already accounts for 8-10% of greenhouse gas emissions and produces 6-7 million tons of waste annually, or roughly 30 pounds of waste per patient each day.[4] Adding more waste to the equation by introducing SUFS needs closer inspection and accurate comparison of current processes to justify the environmental impact and/or apply offsetting efforts to the mission of sustainability. It may not be easy for health systems to reduce their environmental footprint, especially during difficult financial times. However, many sustainable measures result in a generous return on investment.

When evaluating the sustainability profile of single-use and reusable, flexible endoscopes, it's important to consider the environmental impact of all stages in the life cycle of the endoscope—including manufacturing, transport, use, reprocessing, maintenance and disposal.

Studies comparing utility consumption, environmental footprint and medical waste based on scope classification can help as a foundation for directional results. However, the nature of each care site's volume, case mix and equipment used for case turnover is unique. Each care site will have its own restrictions that impact its sustainability solution, and these solutions will shift over time.

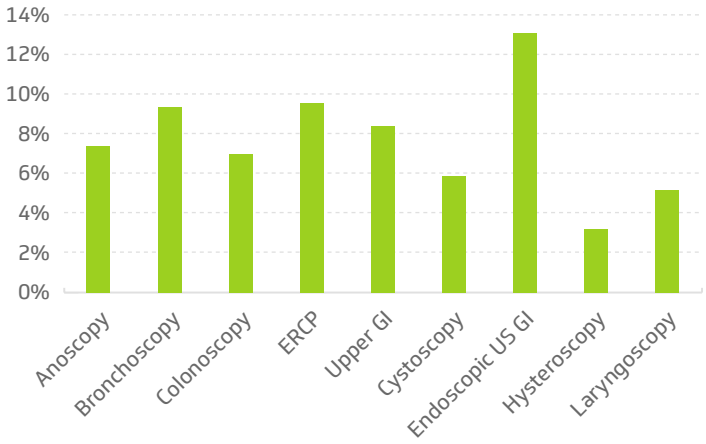
SUFS claim to be fully recyclable; however, the burden falls on the manufacturer or site of care for ecological disposal. It's crucial for manufacturers to offer recycling programs or to coordinate with third-party partnerships to aid in recycling or waste disposal. Many providers will require this in contractual agreements moving forward.

Environmentally preferred purchasing programs that provide attribute data and labeling for healthcare products will expand and continue their influence on device selection. These Environmental Sustainability Scorecards on supplies, devices and equipment provide transparency on efforts and progress with initiatives.[4] They are a means of demonstrating accountability and aspiration with metrics to guide the path of improvement for suppliers and providers.

3. Be aware of procedural growth and site of care change

The three-year projections from Sg2®, a Vizient company, indicate 6% growth for endoscopy procedures in cumulative outpatient settings.[5] The hospital outpatient departments (HOPD) endoscopy market already witnessed a significant shift of care from the acute care setting to hospital outpatient departments ambulatory surgery centers (ASC), and this trend continues to expand to physician offices. While the ASC market continues its momentum in procedural growth, Sg2 projects three-year growth for urgent care (6.9%), clinics of various types (~ 6.4%), outpatient rehab (5.2%), physician offices (4.7%) and even home care (3.2%)[5]. This growth adds pressure on these alternate sites that may not have the means and infrastructure to follow the new guidance. SUFS are a well-suited solution for these unique scenarios.

Endoscopy 3-year growth % by procedure alternate sites of care



Source Impact of Change®, 2023; Proprietary Sg2 All-Payer Claims Data Set, 2021; The following 2021 CMS Limited Data Sets (LDS): Carrier, Denominator, Home Health Agency, Hospice, Outpatient, Skilled Nursing Facility; Claritas Pop-Facts®, 2023; Sg2 Analysis, 2023.

Positive procedural growth along with updated recommendations from governing authorities and financial and workflow stressors will allow for greater acceptance of SUFS, even if recycling programs aren't fully developed. Since a standardized solution for all sites of care isn't available, suppliers can play a part in the short- and long-term strategic needs of individual sites versus a one-size-fits-all approach. This strategy will require more detailed and transparent value analysis support.

Opportunity to test SUFs viability

- Restricted emergency use
- Down time during RFS repair
- Down time from extended reprocessing times
- Use with procedures that inflict scope damage
- Use with novice teams prone to scope damage
- Special condition patients (immunocompromised or those with MRSA)

Considering the cost of major capital equipment and facility renovations needed to be compliant, the SUFS alternatives are practical options—even if only as a temporary solution. SUFS are also a novel option during situations that weren't easily remedied with a reinvestment in RFS inventory.

4. Collaborate with the health system's value analysis team

The rapidly evolving mix of disposable and reusable flexible scopes creates a complex decision-making process that value analysis committees must navigate carefully. Suppliers should be aware that product evaluations now go beyond transactional and budget-focused considerations like unit-to-unit comparison or simple cost analysis. Instead, providers incorporate decision factors like clinical outcomes, use of resources and systemwide impact in a new transformational approach to value analysis. (See Transformational value analysis: How optimizing supply spend savings can maximize health system performance).[6]

For suppliers to transition from the role of vendor to collaborator, they must approach their organizational relationships differently and prepare to contribute to the product selection beyond transactional sales. This new process requires suppliers to build an intimate knowledge of the organizations they serve. Also, they must understand their size, scale, sites of care, assets, clinical capabilities, strategic goals, clinical quality and unique outcome goals. Suppliers must understand how each organization approaches value analysis and the rules of engagement for supplier collaboration, including VAT structure.

Conclusion: building a value-added partnership

As healthcare facilities continue to migrate to enhanced RFS and the new SUFS, this is an ideal time for manufacturers to support their customers with cost analyses based on the hospital's volume, practices, current structure, tailored cost calculations and guidance to move to an optimized and compliant state. Manufacturers who can provide more evidence-based support and use-case scenario insights will have an advantage over those providing only features and benefits, anecdotal findings or a one-size-fits-all approach.

Even established physician preference items (PPI), once considered invincible, are being challenged. Recent supply chain constraints demonstrated that unavoidable concessions are possible. Further consolidation and standardization for efficiencies will impact commodity and specialty products. Manufacturers and providers should collaborate to determine where there's elasticity in true PPI and quality needs.

Finding the balance, cost of challenges and opportunity

- Cost of device, equipment, disposables
- Cost of utilities
- Cost of renovation or infrastructure change
- Lifecycles
- Facility-wide impact
- Quality acceptance and needs
- Workflow impacting time and personnel
- Supply assurances
- Impact on environmental stewardship
- Patient outcomes

Because not all data is transferable from different endoscopy specialties and sites of care, this can be a challenging task for providers and suppliers. However, imagine the benefit of being a trusted advisor through collaborative efforts that help providers reach product decisions that meet or exceed all their goals.

The stakes are high as the number of competitors has doubled with the introduction of SUFS and with facilities streamlining and standardizing suppliers. While a complete transition to SUFS may be the desired outcome for a manufacturer, there may be better strategies for various locations, departments and sites of care within a health system.

Manufacturers should also consider alternate purchasing options, such as fee-for-use or costs associated with clinical outcomes. Creative solutions that reduce risk and further disruption are welcomed. Insightful, tailored analysis versus a direct device comparison is needed to evaluate complete strategic cost transformation as healthcare sites of care balance profitability and patient care.

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