

SCALING SINGLE-USE ENDOSCOPE MANUFACTURING TO MEET MARKET DEMAND

Reusable Endoscopes and the Need for Innovation

Endoscopes perform an invaluable role in healthcare, enabling a skilled physician to insert a narrow, flexible tube with a light, camera and instrument channel into a patient's organs or body canals to diagnose and treat medical conditions and diseases. They are used for such procedures as bronchoscopy (lungs and air passages), cholangioscopy (bile ducts), colonoscopy (colon and rectum), duodenoscopy (small intestine), gastroscopy (esophagus, stomach and small bowel), and ureteroscopy (bladder and ureter). As patient demand for minimally invasive surgeries grow, so too will the market for endoscopes. Sales are slated to reach \$46 billion USD by 2025.ⁱ

Reusable endoscopes, like many other surgical devices, have been used across patients and procedures. As a consequence, reusable endoscopes are extremely robust but are also incredibly costly and complex to maintain. They can range in cost between \$20,000 to \$40,000 for an upper endoscopy or colonoscopy device to \$80,000 to \$120,000 for a system that explores the upper and lower gastrointestinal tract.ⁱⁱ In addition, they must be sterilized with harsh agents after every treatment, which costs between \$140 and \$280 per scope.ⁱⁱⁱ More importantly, reprocessing is a seven-^{iv} to 10-part^v process involving hundreds of individual steps^{vi} that must be followed scrupulously to avoid leaving residual bacteria on devices, which could harm the patients they're subsequently used on. In 2018, a study detected microbial growth on 71% of the endoscope samples collected for research from three U.S. hospitals.^{vii}

The risk of transmitting multi-drug resistant bacteria across patients and procedures has spurred multiple interventions from the U.S. Food & Drug Administration, culminating in its 2019 recommendation that hospitals and endoscopy facilities transition away from reusable endoscopes to single-use alternatives.^{viii} That move now seems especially prescient given the current global pandemic, which is creating greater infection risks than ever before.

COVID-19 to Drive Market Adoption of Single-Use Devices

The COVID-19 pandemic may decrease non-emergency endoscopy procedures over the short-term. However, healthcare providers' renewed concerns about cross-contamination among patients will ultimately accelerate the purchase and adoption of single-use endoscopes, increasing the disposable endoscope market to \$3.1 billion USD by 2026.^{ix} It is possible, too, that single-use endoscopes may soon be mandated by regulators, making it critical to move ahead now, to have a full product offering ready to scale if this development occurs. This paper is designed to help

manufacturing leaders consider the full range of electronic and mechanical requirements with developing single-use endoscopes, so that they can make effective strategic partnership and device development decisions as they build business in this important and fast-growing market.

The Pros and Cons of Reusable Versus Single-Use Endoscopes

As they purchase devices, hospital decision-makers consider such factors as:

Reusable Endoscopes	Single-Use Endoscopes
They have high acquisition costs, as devices require mechanical resilience and integrate more connections.	They have lower acquisition costs, as devices are simpler, have fewer layers and don't need to withstand heavy sterilization.
Inaccurate use can overload and damage devices, creating costly repairs.	There are no repair costs associated with single-use. They are disposed of immediately after treatment.
They have high reprocessing costs (disinfection, surveillance, maintenance and repair), which increases device downtime.	There are no reprocessing costs, as devices are disposed of after a single use.
They can create the risk of cross-contamination (now increasing due to the COVID-19 pandemic).	There are no risks of cross-contamination, as devices are only used for a single procedure.
They will increasingly become an obsolete technology.	Single-use endoscopes will continue to develop in sophistication, becoming the preferred technology.
Reusable endoscopes have a significant environmental impact. They require operators to wear disposable PPE for cleaning and use disposable cleaning equipment and harsh chemical disinfectants.	Although disposable after one use, single-use endoscopes don't require additional PPE for cleaning, cleaning equipment or harsh chemical disinfectants.

Source: Based on *Endoscopy International Open* article and other materials.¹

Key Variables to Consider When Developing Single-Use Endoscopes

So, what are the key considerations for developing and scaling your single-use endoscopy business and how can TE Connectivity (TE) help you achieve your goals? TE offers the following insights from experience developing high-performance medical devices that span endoscopes and beyond.

Ensuring end-user acceptance

Your goal: Helping clinicians transition from a reusable scope, which they are comfortable with, to a single-use device is a change management challenge. You want to make it as easy as possible for physicians to adopt single-use endoscopes by providing a similar experience to what they have trained with and grown accustomed to using.

How TE helps: TE can provide cost-effective, single-use endoscopes that offer the same image quality and mechanical performance as reusable scopes, with familiar handling and control in pushability, tracking and torque transfer to rotate and stabilize the camera and instrument channel. While single-use devices must deliver exceptional mechanical and electrical performance, they don't require the mechanical resilience that reusable scopes do due to their repeated usage and complex reprocessing requirements. TE solutions take this change into account, allowing for single-use price points with performance comparable to multi-use constructions.

Leveraging platform solutions

Your goal: As a medical device original equipment manufacturer (OEM), you know that leveraging a platform solution can save you time and money. Platform solutions offer validated designs with available test data from day one. By using platform solutions, you can skip several stages in the design process, taking products to market faster. And when it comes to ordering, single-use endoscope components and solutions should be available on a fast turnaround basis.

How TE helps: TE has developed a complete platform to demonstrate both the mechanical and electronic viability of its single-use bronchoscope solutions. We leverage our platform to develop endoscopes for other applications, including gastroscopes, with less effort and customization than would be required if we were building them from the ground up. You'll gain the ability to extend your offering more quickly, increasing your market share and profitability.

Differentiation through customization

Your goal: We know there is no one-size-fits all solution for single-use endoscopy. Your feature and functional requirements may vary depending on the endoscopic application and your chosen design.

How TE helps: We have the ability to customize solutions to meet variable requirements. For example, we can customize cable design and packaging to enable the use of complementary metal oxide semiconductor (CMOS) video sensors that are appropriate for any given endoscopic procedure. Our engineers leverage simulation and direct measurement tools such as real-time oscilloscopes to predict and optimize video performance for use with analog and digital sensors across a range of resolutions. These cable and CMOS sensor assemblies can be implemented directly into your device. And when it comes to your single-use endoscope, we don't just support complex full assemblies: We can provide you with discrete components and sub-assemblies too. That way, you can reserve customization for high-value requirements while simplifying and accelerating production overall.

TE Offers Endoscope Components and Full Solution Development

From discrete components to complex full solutions



Sole-sourcing vs. integrating components

Your goal: As a manufacturer, you need to determine the right balance between in-house manufacturing and outsourcing to provide desired functionality at the cost point you are looking to achieve. Many manufacturers increasingly favor speed-to-market over controlling most supply chain processes. As a consequence, they prefer to work with partners who can provide integrated solutions.

How TE helps: Sole-sourcing with TE provides multiple advantages, including increasing accountability for the end-to-end quality of your device; providing customization options; and accelerating speed, which you can use to gain market share. TE offers in-house custom cable and steerable shaft development and integration services, providing you with end-to-end manufacturing services. The benefits of having all key endoscopy technologies under one roof has an impact on innovation, too. For example, TE can consolidate the mechanical steering actuators and CMOS sensor integration into a single tipping process to shorten the final rigid tip length, providing physicians with the ability to track deeper into patient anatomy and traverse tight bends.

Continually optimizing solutions

Your goal: You'd like to work with a partner who is innovative and proactively improving solutions and processes to provide your end-users with better performance and value. You want to stay ahead of the market by offering the best solutions.

How TE helps: TE engineers are continually searching for innovative ways to streamline development and improve device performance and cost. For example, TE can integrate electronic components such as CMOS and LEDs into the distal tip of the device through direct printing of circuitry onto molded components, through the use of MID or via integration of flex circuits. We can accomplish all of these tasks in-house. Direct circuitry printing gives TE the flexibility to try multiple configuration concepts at the prototype stage with minimal tooling time and expense, while flex circuit options enable use of our innovative automated cabling solutions to support lower-cost, high-volume production. You can select prototype and production methods based on your needs.

In addition, we use mechanical characterization to gather baseline data on the performance of reusable and single-use endoscope predicates. We combine the data gathered with our technical knowledge of steerable catheter design to optimize low-cost single-use endoscope solutions that achieve and, where possible, exceed predicate performance.

TE's Single-Use Endoscope Capabilities at a Glance

TE's single-use endoscope solutions offer:

- Custom cables for off-the-shelf CMOS sensors to enhance their performance while reducing costs

- Advanced simulation and testing to optimize endoscope design
- Dedicated engineers and equipment to support rapid prototyping
- Enhanced push, track, flex and torque performance for access, stability, positioning and targeting of the scope camera and instrument channel
- Full vertical integration with all key technologies under one roof
- Fine wire automation to manufacture cables at 10 times the speed of manual processes

How TE Has Built Its Medical Device Business

In addition to our home-grown innovation, TE has made strategic acquisitions to increase our technical capabilities and the scope of our medical device portfolio, benefitting our customers. These acquisitions include:



The Value TE Provides as Your Partner of Choice

We know that the medical device market is incredibly competitive. We seek to be your partner of choice for single-use endoscopes, by providing the full range of capabilities and services you require to achieve your financial, business and technical objectives. Here is how we add value to our partnership with you:

Legacy of innovation: TE taps its expertise in manufacturing other high-precision medical devices to develop single-use endoscopes that offer both performance and cost advantages. We bring more than 22 years of experience in innovating complex steerable catheters and 48 years of experience in designing and building fine wire cable assemblies to our endoscope development work.

Sourcing and optimizing optical components: Manufacturers must select the right camera and light source for their single-use endoscopes. Cameras are one of the most expensive components of a single-use endoscope, as they must deliver high-resolution output. However, innovations in lens manufacturing methods and materials can drive cost down as well as streamlining manufacturing. TE leverages its relationship with a strategic partner to obtain CMOS sensors that provide the desired resolution and performance for your solution. To further improve the image performance of off-the-shelf CMOS sensors, we conceptualize custom cable designs based on sensor and device requirements. We use in-house advanced tools to simulate cable performance, optimizing the design upfront. We build prototypes for the best-performing concepts and test actual performance, which can be compared back to the simulations, making iterations to the design where needed. At this stage, we can also subject the prototype to environmental and mechanical stressors to verify the design under the stresses it will see in the actual use environment. This process offers our customers an optimized custom cable design for better sensor performance, faster and more cost-effectively.

Developing a steerable shaft: TE has developed high-performance steerable catheters for a myriad of medical applications, including coronary, structural heart, peripheral and neurovascular applications. TE has manufactured single-use devices for utilization with reusable endoscopy for many years, in the areas of needle biopsy, balloon dilation catheters and delivery systems for device implantation across a wide range of endoscopic procedures. In the development phase of mechanical shaft

performance, we utilize in-house biaxial testing to benchmark the compression, torque and flexibility of single-use and reusable endoscope predicates. This baseline data converts what an end-user experiences to quantitative engineering data that can be enhanced and optimized. This is achieved using metal composites in forms such as braid/coil wire and hypotubes which are embedded within a polymer matrix to deliver enhanced performance that physicians can rely on for access, stability positioning and targeting within the patient anatomy being treated. As a result, a shaft with equivalent kink resistance, enhanced torque performance and greater flexibility can be designed within an optimal footprint.

Moving from prototyping and testing: We leverage advanced electrical simulation and real-time testing to model and simulate video cable performance, optimizing designs quickly and reducing prototype iterations. TE can also perform in-house reliability and functional testing on your finished device, enabling you to know with certainty how it will perform in actual use.

Handling volume production: TE offers skilled labor, extensive cleanroom space and lower-cost facilities to support your growing business. We have dedicated product development teams in the state of Oregon, U.S. and the city of Galway, Ireland. Our Center of Excellence in Guaymas, Mexico, is home to our proprietary fine wire automation process.

Fine wire automation for scale: TE has invested in automation equipment that streamlines fine wire preparation and soldering processes, enabling us to scale with market demand, driving your sales and profitability. Our automation system is unique in that preparation processes begin during cable manufacturing, eliminating unnecessary handling and reducing the risk of human error. The system can process up to 10 cables at one time, helping to reduce labor-intensive fine wire termination times for high-volume productions.

How TE Can Help You Build Your Single-Use Endoscopy Business

You want to grow your single-use endoscopy business. TE can help you develop your platform, build both standard and customized solutions and capture market demand. Our medical business has more than 4,000 employees, of which 450 are experienced design engineers who are focused on developing exceptional solutions to meet your requirements. Count on TE to deliver an extraordinary customer experience, provide you with engineering innovation and creativity, and work to continually optimize processes, while manufacturing your products at scale. We want to serve as your preferred partner as we work together to build medical devices that increase the standard of care globally, save lives and deliver better outcomes for healthcare providers and patients.

[Learn more at TE.com/medical](https://www.te.com/medical)

ⁱ "GLOBAL \$46 BN ENDOSCOPY DEVICES MARKET TO 2025," PRESS RELEASE, RESEARCHANDMARKETS, MARCH 15, 2019, [HTTPS://WWW.GLOBENEWSWIRE.COM/NEWS-RELEASE/2019/03/15/1755128/0/EN/GLOBAL-46-BN-ENDOSCOPY-DEVICES-MARKET-TO-2025.HTML](https://www.globenewswire.com/news-release/2019/03/15/1755128/0/EN/GLOBAL-46-BN-ENDOSCOPY-DEVICES-MARKET-TO-2025.HTML)

ⁱⁱ MIHAI CIOCIŢLAN, "LOW-COST DISPOSABLE ENDOSCOPE: PROS AND CONS," ONLINE ARTICLE, *ENDOSCOPY INTERNATIONAL OPEN*, 2019 SEP; 7(9), [HTTPS://WWW.NCBI.NLM.NIH.GOV/PMC/ARTICLES/PMC6715437/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6715437/)

ⁱⁱⁱ "Low-Cost Disposable Endoscope," *ibid*.

^{iv} "Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee," Centers for Disease Control and Prevention, pages 2-3, updated June 28, 2017, https://www.cdc.gov/hicpac/pdf/flexible-endoscope-reprocessing.pdf?TB_iframe=true&width=921.6&height=921.6

^v RICK DANA BARLOW, "THE FULL SCOPE OF REPROCESSING: INTROSPECTION AND INTERVENTION," ONLINE ARTICLE, *HEALTHCARE PURCHASING NEWS*, OCTOBER 28, 2019, [HTTPS://WWW.HPNONLINE.COM/STERILE-PROCESSING/ARTICLE/21110528/THE-FULL-SCOPE-OF-REPROCESSING-INTROSPECTION-AND-INTERVENTION](https://www.hpnonline.com/sterile-processing/article/21110528/the-full-scope-of-reprocessing-introspection-and-intervention)

^{vi} "FDA Executive Summary," *Reducing the Risk of Infection from Reprocessed Duodenoscopes*, Report, 2019, Page 25, <https://www.fda.gov/media/132187/download>

^{vii} "Disposable Endoscopes Market Size, Share & Trends Analysis Report by Application (Bronchoscopy, Proctoscopy, Arthroscopy), by End Use (Hospitals, Diagnostic Centers, Clinics), and Segment Forecasts, 2020 – 2027," Report Description, Grandview Research, published March 2020, <https://www.grandviewresearch.com/industry-analysis/disposable-endoscopes-market>

^{viii} "INFECTIONS ASSOCIATED WITH REPROCESSED DUODENOSCOPES," U.S. FOOD & DRUG ADMINISTRATION, WEBPAGE, CURRENT AS OF AUGUST 29, 2019, [HTTPS://WWW.FDA.GOV/MEDICAL-DEVICES/REPROCESSING-REUSABLE-MEDICAL-DEVICES/INFECTIONS-ASSOCIATED-REPROCESSED-DUODENOSCOPES](https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscopes)

^{ix} "DISPOSABLE ENDOSCOPES MARKET VALUE TO HIT US\$ 3.1 BN BY 2026," PRESS RELEASE, ACUMEN RESEARCH AND CONSULTING, AUGUST 8, 2019, [HTTPS://WWW.PRNEWSWIRE.COM/NEWS-RELEASES/DISPOSABLE-ENDOSCOPES-MARKET-VALUE-TO-HIT-US-3-1-BN-BY-2026--300898729.HTML](https://www.prnewswire.com/news-releases/disposable-endoscopes-market-value-to-hit-us-3-1-bn-by-2026--300898729.html)

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