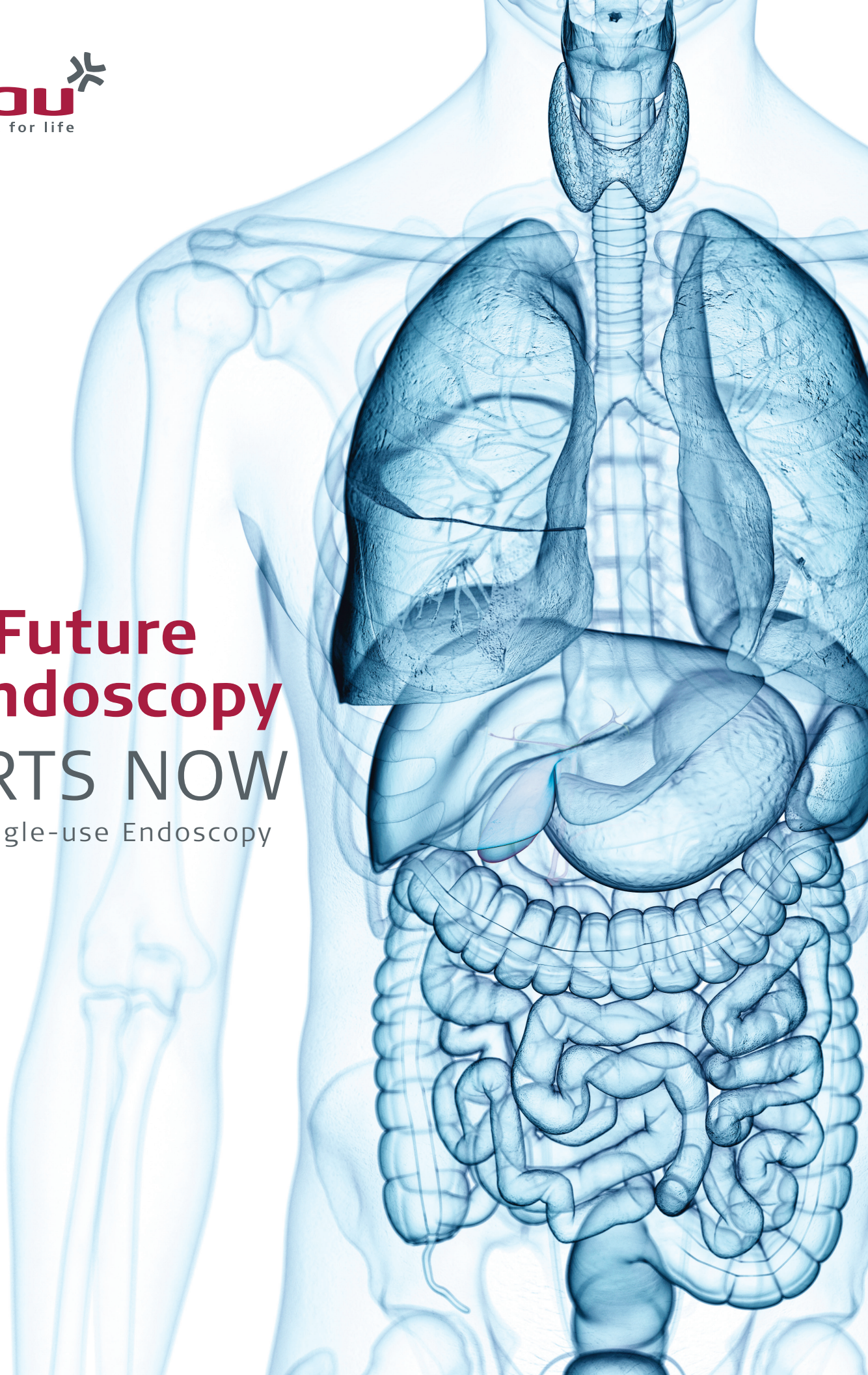
Ambu

Ideas that work for life



The Future of Endoscopy

STARTS NOW

Sterile Single-use Endoscopy

Single-use
Endoscopy is the Future

- No reprocessing
- No cross-contamination
- No availability issues
- Transparent contracts
- Cost-effective setup

We want to simplify endoscopy

The single most important question in healthcare today is how to improve patient outcomes with the resources available. And as the world population increases and life expectancy expands, the pressure mounts on hospital budgets, workflow efficiency and, ultimately, patient safety.

Flexible endoscopes raise specific problems because they are costly to purchase, reprocess and repair, they are not always available when you need them, and their use risks exposing patients to infections.

We believe that the challenges in flexible endoscopy should be addressed with single-use devices, and for more than a decade we have been harnessing the technology. In 2009, we launched the world's first single-use flexible endoscope: The Ambu® aScope™. Today, the aScope is used for pulmonary endoscopies in the OR and ICU at more than 3,000 hospitals across the globe. Single-use endoscopy has proven its worth in pulmonary endoscopy and the next step is to bring the advantages of single-use to other clinical areas.

Therefore, we now make you a promise: By the year 2020, we will offer sterile single-use scopes within the segments of pulmonary, urology, ENT and GI – including single-use duodenoscopes, gastroscopes and colonoscopes.

There is no doubt in our minds that a new and sterile scope for each and every patient is a great step forward for modern healthcare.

We are dedicated to making this future happen.

Lars Marcher
President & CEO
Ambu

There is a need for change in endoscopy

Increasing concern of cross- contamination is led by outbreaks

Los Angeles Times

Superbug linked to 2 deaths at UCLA hospital; 179 potentially exposed

By CHAD TERHUNE and CHAD TERHUNE FEB 18, 2015 | 6:14 PM

Nearly 180 patients at UCLA's Ronald Reagan Medical Center may have been exposed to potentially deadly bacteria from contaminated medical scopes, and two deaths have already been linked to the outbreak.

The Times has learned that the two people who died are among seven patients that UCLA found were infected by the drug-resistant superbug known as CRE — a number that may grow as more patients get tested. The outbreak is the latest in a string of similar incidents across the country that has top health officials scrambling for a solution.

UCLA said it discovered the outbreak late last month while running tests on a patient. This week, it be[gan] to notify 179 other patients who were treated from October to January and offer ther[m] [e]stimates, if the infection spreads to a person's bloodstre[am] [p]atients.

FDA News Release

FDA warns duodenoscope manufacturers about failure to comply with required postmarket surveillance studies to assess contamination risk

For Immediate Release

March 9, 2018

EXECUTIVE BRIEF

Top 10 Health Technology Hazards for 2018

A Report from Health Devices

ECRI Institute is providing this abridged version of its 2018 Top 10 list of health technology hazards as a free public service to inform healthcare facilities about important safety issues involving the use of medical devices and systems. The full report—including detailed problem descriptions and ECRI Institute's step-by-step recommendations for addressing the hazards—is available to members of certain ECRI Institute programs through their membership web pages.

The List for 2018

1. Ransomware and Other Cybersecurity Threats to Healthcare Delivery Can Endanger Patients
2. Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk
3. Mattresses and Covers May Be Infected by Body Fluids and Microbiological Contaminants
4. Missed Alarms May Result from Inappropriately Configured Secondary Notification Devices and Systems
5. Improper Cleaning May Cause Device Malfunctions, Equipment Failures, and Potential for Patient Injury
6. Unholstered Electrosurgical Active Electrodes Can Lead to Patient Burns
7. Inadequate Use of Digital Imaging Tools May Lead to Unnecessary Radiation Exposure
8. Workarounds Can Negate the Safety Advantages of Bar-Coded Medication Administration Systems
9. Flaws in Medical Device Networking Can Lead to Delayed or Inappropriate Care
10. Slow Adoption of Safer Enteral Feeding Connectors Leaves Patients at Ri[sk]

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

AJIC American Journal of Infection Control

ELSEVIER

CrossMark

Major article

Persistent contamination on colonoscopes and gastroscopes detected by biologic cultures and rapid indicators despite reprocessing performed in accordance with guidelines

Cori L. Ofstead MSPH[a,b,*], Harry P. Wetzler MD, MSPH[a], Evan M. Doyle BS[a], Catherine K. Rocco RN, MSN, CNOR[a], Kavel H. Visrodia MD[c], Todd H. Baron MD[d], Pritish K. Tosh MD[b]

Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients

Between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different instances of antibiotic-resistant infections that sickened at least 250 patients worldwide.

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Infections Associated with Reprocessed Duodenoscopes

In fall 2013, the Centers for Disease Control and Prevention (CDC) alerted the FDA to a potential association between multi-drug resistant bacteria and duodenoscopes. Upon further investigation, it became clear that these cases of infection were occurring despite confirmation that the users were following proper manufacturer cleaning and disinfection or sterilization instructions.

FDA GUIDANCE ON REPROCESSING

FDA issues final guidance on reprocessing of medical devices

MAR 2015

FDA WARNING LETTERS ISSUED

FDA issues warning letters to Olympus, Pentax and Fujifilm for failing to report MDRs to FDA on reusable scopes

AUG 2015

FDA WARNING STATEMENT

FDA issues safety communication regarding infections caused by reprocessing process on flexible bronchoscopes

SEPT 2015

IMPROPER CLEANING SPREADING DISEASES

Inadequate "Cleaning of Flexible Endoscopes Before Disinfection Can Spread Deadly Pathogens" is #1 on ECRI Top 10 Health Technology Hazards for 2016

NOV 2015

CDC SAFETY ALERT ISSUE

CDC releases "Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC "

JAN 2017

FDA WARNING LETTERS ISSUED

FDA warns Olympus, Pentax and Fujifilm to prevent infections associated with the transmission of bacteria from contaminated duodenoscopes

MAR 2018

Reusable endoscopy

A complex and costly setup putting patients at risk

Risk of Cross-Contamination

Despite increased reprocessing requirements, cross-contamination remains a major issue.

Extensive Reprocessing Setup

100+ steps of cleaning, major surveillance and documentation burden.

Availability Issues

Procedure delay or even cancellation due to unavailable scopes.

High Cost-in-Use

High capital investment plus repair and reprocessing costs.

Complex Contracting

Complex and non-transparent contracts on scopes, repair etc. binding the hospital.

Single-use endoscopy

A simple and cost-effective setup eliminating infection risks

Eliminating Risk of Cross-Contamination

Sterile out of the pouch. Personal scope for each patient, never been in contact with other patients.

No Reprocessing

Scopes are discarded after use – no cleaning, documentation, surveillance or auditing on proper reprocessing.

No Availability Issues

No more “where is my scope?” Always a new scope at hand ensuring a fully functional scope for each patient.

Low Cost-in-Use

Minimal upfront investment. No cost for repair, reprocessing or added investment when guidelines change.

Transparent Contracting

Increased flexibility and simplicity for the hospital.

In 2009, Ambu launched the world's first single-use flexible endoscope

Ambu's single-use visualization products used in more than 3,000 hospitals worldwide

1/3

More than ⅓ of our aScope customers already use aScope more than reusable scopes

Several major facilities have gone fully disposable on selected procedures

"The convenience and the safety of having the scopes right here has been a game changer for us.

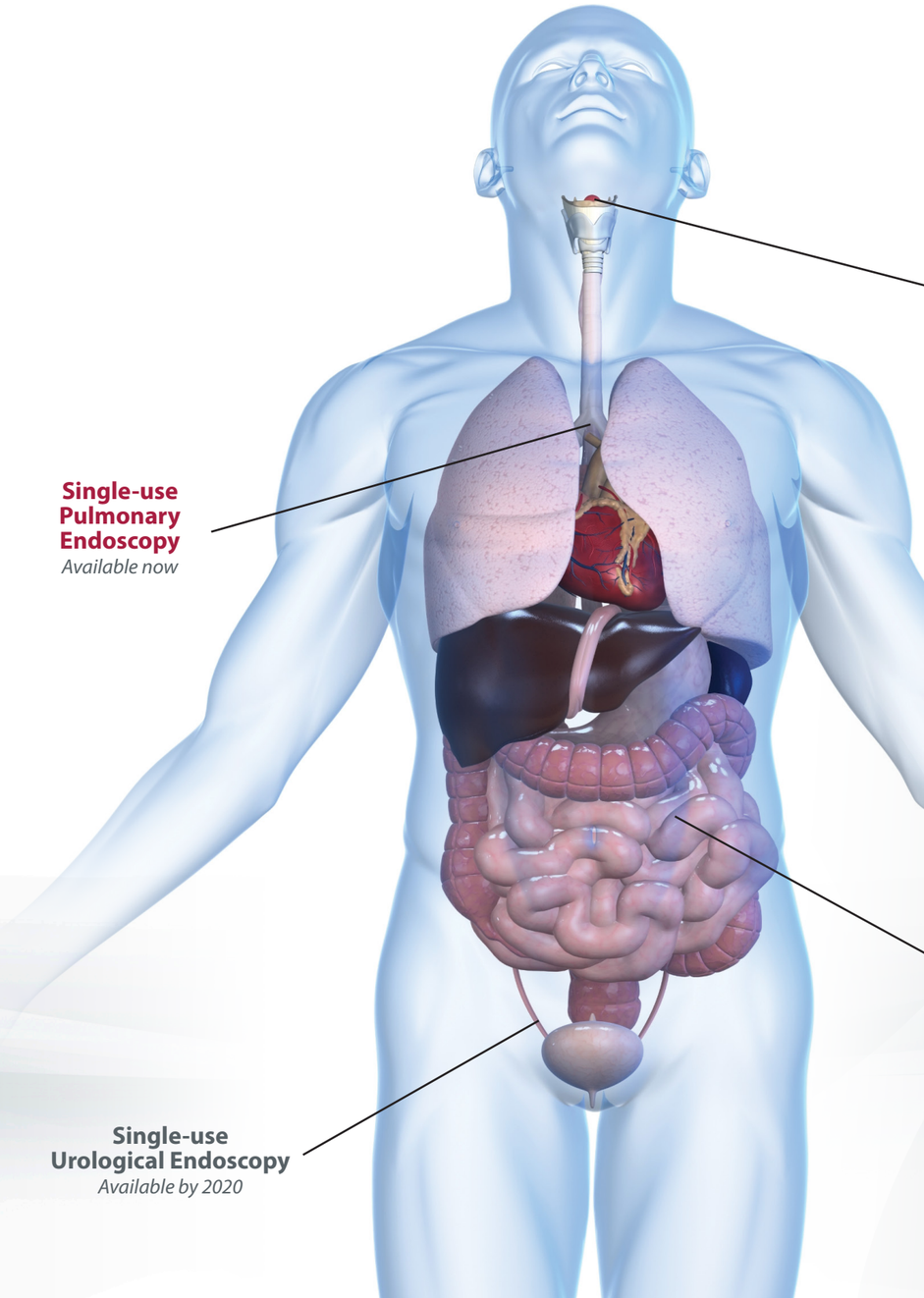
The two main advantages are: it is so quick, efficient and available that it allows us – in the patient who has a suspected pulmonary infection – to get in and get the appropriate microbiological sampling – often before the time the first dose of antibiotic is administered.

The second advantage, which is probably equally important, is it's a disposable scope. In the ICU, we're dealing with resistant organisms, and reusable scopes can be colonized. They can have their channels contaminated. With single-use scopes, you use it and throw it away. And you have a sterile new scope for the next patient. It's great from an infection prevention point of view, as far as we're concerned, as well.

Eric C. Feucht, MD
Critical Care Medicine and Medical Director of Respiratory Therapy at Metro Health Hospital in Ann Arbor

By 2020, Ambu will provide single-use across all flexible endoscopy areas

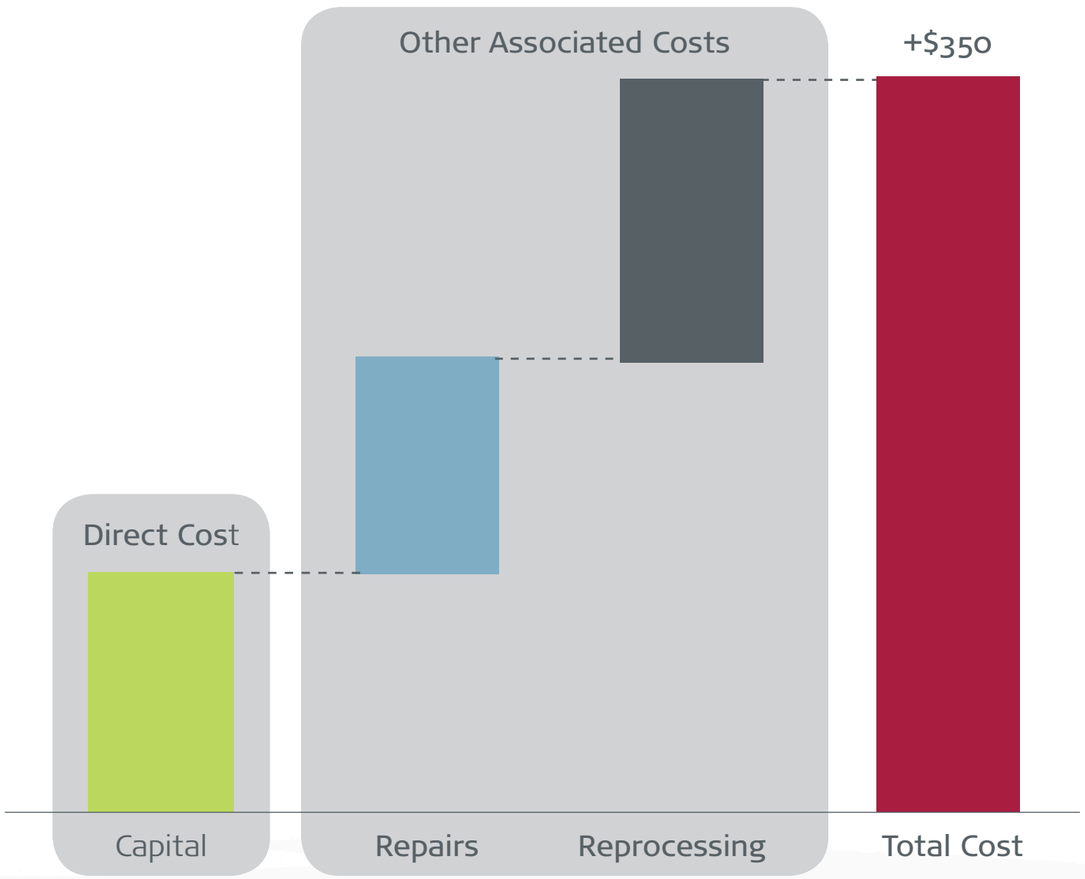
Ambu will offer scopes within all flexible endoscopy areas including sterile, single-use HD duodenoscopes, colonoscopes and gastroscopes



A positive effect on your bottom line

Cost-effectiveness has been documented in multiple studies

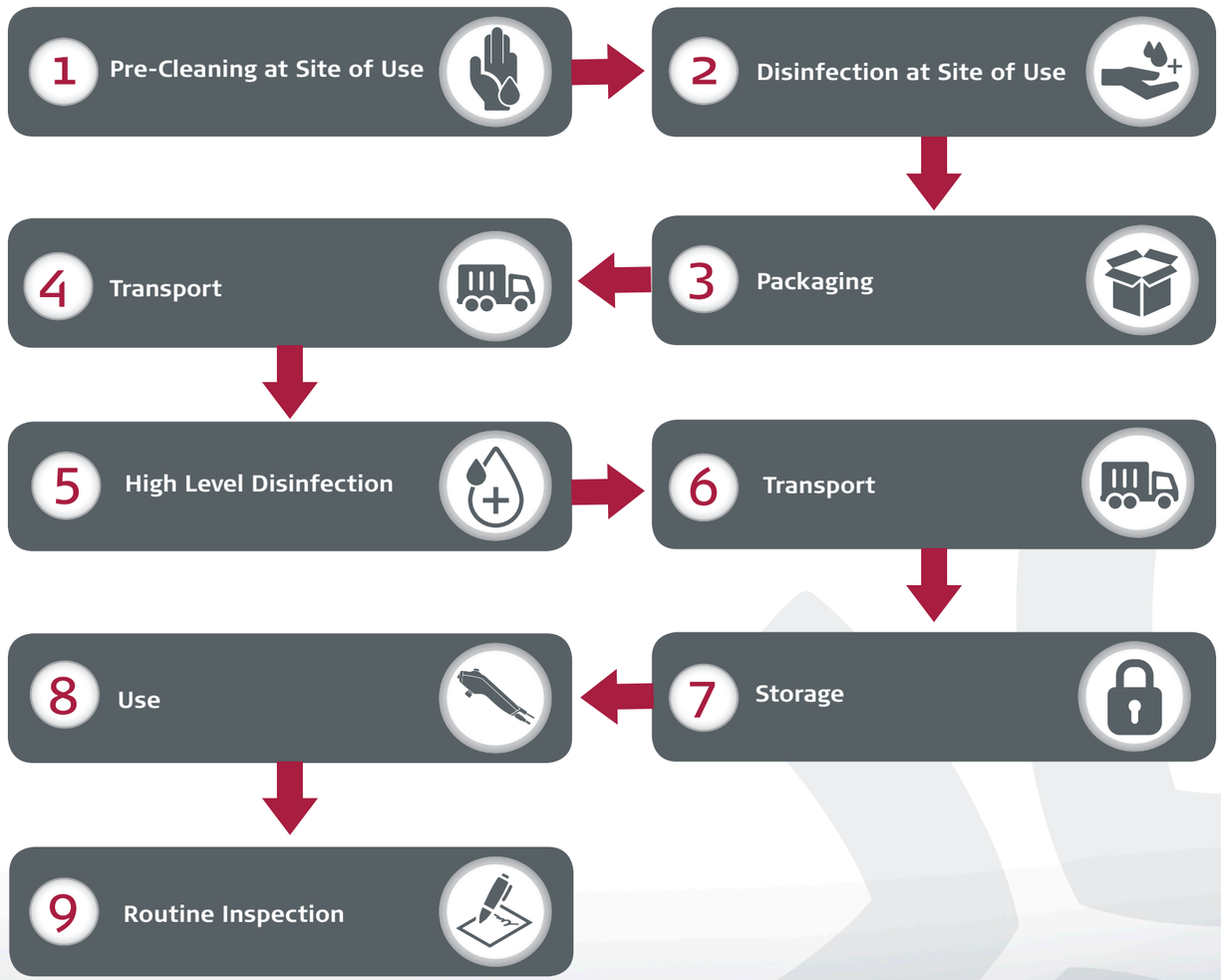
In pulmonary endoscopy, we have shown the cost-savings of going single-use.



Reusable: Average cost burden of more than $350 for every procedure

Single-use: Cost of Ambu pulmonary scope $300 for every procedure

Comprehensive reprocessing is complex, time-consuming, and costly [1,2,3,4,5,6,7]



> **Despite being unable to account for every aspect of reprocessing, the costs are staggering – from $114.07 to $280.71 for one endoscope.**[8]

Cori L. Ofstead et al 2017

"The basic design of the reprocessed endoscope has remained virtually unchanged for over half a century since the advent of the first flexible endoscope in the 1960s. The endoscopist, and device manufacturers, have been limited by the physical constraints of the endoscope working channel. A disposable platform can change this by enabling the development of endoscopes tailored to the requirements of the accessory. This can open new frontiers of endoscopic intervention.

Kenneth F. Binmoeller, MD, FACG, FASGEDirector,
Interventional Endoscopy Services California Pacific Medical Center

"I believe disposable endoscopy will play a very important role in gastroenterology. Patients are understandably concerned about recent reports of infection transmission. We need to explore the possibility of using disposable devices in GI endoscopy.

Klaus Mergener, MD, MBA, FASGE,
FACG, AGAF, FACP, FACPE
Affiliate Professor of Medicine, University of Washington, Seattle, WA

"A cost-effective, sterile, single-use endoscopic portfolio for the GI space will instantly change the entire practice of gastroenterology. All the concerns with reprocessing and potential cross-contamination would be eliminated. When utilization begins, sterile, single-use endoscopes will represent a classic example of the term "disruptive technology" as applied to endoscopy.

Bergein (Gene) F Overholt, MD,
Past President ASGE, Co-Founder of Gastrointestinal Associates, Knoxville, US

1. J. Kovaleva et al. 2013; Review "Transmission of Infection by Flexible Gastrointestinal endoscopy and Bronchoscopy" Clinical Microbiology Revives April 2013 vol. 26 no. 2 231-254
2. ECRI institute https://www.ecri.org
3. CDC Guideline 2008.Disinfection and Sterilization in Healthcare Facilities
4. FDA Reprocessing of Reusable Medical Devices: Information for Manufacturers https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/
5. AAMI Releases 'Must-Have' Guide for Endoscope Reprocessing http://www.aami.org/newsviews/newsdetail.aspx?ItemNumber=2468
6. CDC safety alert September 11, 2015 "Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices" https://emergency.cdc.gov/han/han00382.asp
7. CDC release from the Healthcare Infection Control Practices Advisory Committee (HICPAC) January 25, 2017. "Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC" https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html
8. Cori L. Ofstead et al 2017. "A GLIMPSE AT THE TRUE COST OF REPROCESSING ENDOSCOPES: RESULTS OF A PILOT PROJECT" In International Journal of Healthcare Central Service Material Management (www.iahcsmm.org)

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