Endoscopy Technology and Clinical Advancements

Erin Kyle, DNP, RN, CNOR, NEA-BC
Challenges call for innovation – and innovation leads to progress.
Endoscopy
the beginning

Philipp Bozzini (1773-1809)
Classic Challenges in Endoscopy

- Visualization
- Illumination
- Optics
Modern Challenges in Endoscopy

- Artificial Intelligence
- Navigation
- Infection Prevention
Gastrointestinal Endoscopy

Bozzi (1805) (Edmonson JM, 1991)

Fibreoptics: Hirschowitz and Curtiss (1963) (Edmonson JM, 1991)

SD/CCD

HD/magnification (late 1990's)

Narrow Band Imaging (2004)


Linked Colour Imaging (2015)

The Wolfe-Schindler gastroscope (1920's) (Edmonson JM, 1991)

Olympus EVIS-1 Videoendoscope (1980's) (Olympus)

Chromoendoscopy (1990's)


Fujinon Intelligent Colour Enhancement (2005)


Blue Light Imaging (2014)
Urology

• Narrow band imaging (NBI)
  • 2005
  • Light from 2 wavelengths: blue (415 nm) and green (540 nm)
  • Bladder cancer diagnosis

• Autofluorescence
• Optical coherence
Pulmonology

• Flexible bronchoscope commercialized - 1968
• From the eyepiece to a video screen – 1987
• First therapeutic use of bronchoscope – 1980 – Nd:YAG Laser
• Autofluorescence bronchoscopy
• EBUS – early 2000’s – ultrasound transducer at the tip
• 2018 - Electromagnetic navigation-based technology
• 2019 - Robotic-assisted endoluminal bronchoscopy for minimally invasive lung procedures, Shape-sensing technology
Navigation in Pulmonology

From Implications of Shape-Sensing Robotic Bronchoscopy in a Lung Cancer Practice: https://youtu.be/CUyjBatRLfA?t=424
Key Takeaways

• The challenges that we have faced in visualization, illumination, and optics for diagnosis and treatment of disease has resulted in profound innovation over the past 200 years of endoscopy.

• The challenges that we face today are leading to even more innovation in more advanced applications such as navigation and minimally invasive procedures.

• Innovations in infection prevention are foundational for patient safety in endoscopy
Infection Prevention in Endoscopy

Because of recent outbreaks associated with multi-drug resistant organisms among patients who have undergone endoscopic procedures, best practices and technology advancements in the area of infection prevention will be the focus of the remainder of today’s presentation and part 2 of this series next week.
References


Ambu Company History
Pioneering Single Use Endoscopy

Jens Kemp
Vice President of Marketing
Ambu
Ambu, a Danish company was founded in 1937 by German Engineer Holgar Hesse. Ambu is historically known for inventing the self-inflating manual resuscitator.

IN 1953

Dr. Hesse meets Dr. Henning Ruben

The launch of the first ventilation bag is considered a milestone in emergency medical technique and quickly becomes established internationally.

However, doctors will not allow a new product to be demonstrated on patients, so Dr. Hesse and Dr. Ruben invent a training manikin, which can be given artificial respiration by "bag resuscitation", mouth-to-mouth or mouth-to-nose.

The new Ambu inventions result in a change of sector and earnings parameters. Hospitals and emergency services buy the new Ambu products in large numbers, as do the military sector.
Today Ambu is a rapidly growing Global Medtech Company

Supplies medical devices for hospitals and ambulances and specialty clinics

Global R&D & manufacturing including USA

4,000 employees worldwide, almost 1,000 in the US

Revenue 2019/20: USD 583m 26% growth
Ambu has a long legacy of developing breakthrough innovations. In 2009 Ambu launched the world’s first single use endoscope.
In 2006 we asked ourselves: How & where was Ambu going to develop in the future and how do we move to more technology intensive products

Trend towards low cost image sensors

Gold Standard Diff Airways still reusable

Single use electronics + Ambu’s expertise and manufacturing platform for single use MD (plastics) + Markets that have not changed to single use
aScope 1 was launched in 2009 to address availability issues in the OR, ER & ICU for gold standard in difficult airway management

- 13% of airway deaths were associated with difficult tracheal intubation
- ICU was the setting for less than 20% of events, but counted for almost half the deaths
- More than 60% of ICU events resulted in death or brain damage compared to 14% in anesthesia
- Immediate access to a fiberscope for airway inspection or difficult airway management was a recurrent problem
Today Ambu is the market leader in single use endoscopy with a clear ambition to be the most innovative single use endoscope company.

- Global pioneer and leader of single-use endoscopy
- Largest manufacturer of SU scopes >1M scopes last year
- Market leading R&D and innovation within single use endoscopy 300+ R&D FTEs
- One of the fastest growing companies in MedTech

Ambu US today
- ~400,000 Ambu single use endoscopes used per year in US
- 3,000 US hospitals using Ambu single use endoscopes
- More than 95% of the top 500 US hospitals using Ambu Single Use bronchoscopes
- Endoscopy field team of 300+ including close to 100 clinical specialists providing training and education for our customers
- ALL major GPOs have Ambu single use endoscopes on contract

Pulmonology • ENT • Urology • GI
At the core of Ambu is a unique R&D engine...

**Modularization**

- Enabling next generation diagnostics, e.g. Ultra HD, ultrasound

**Rapid product introduction**

- Refining diagnostic assessments to improve outcomes and workflows

**Enhanced Visualization**

- Enabling next generation diagnostics, e.g. Ultra HD, ultrasound

**Artificial Intelligence**

- Refining diagnostic assessments to improve outcomes and workflows

**Workflow Compatibility**

- Facilitating integration of diagnostic and therapeutic tools

The Endoscopy Evolution: From Reusable to Single-Use
...Which allows us to scale our innovation output considerably
20 product launches planned for the next three years

~4x more products launches than in the previous three years
Rapid growth in the past 10 years and strong market drivers

Infection control
Convenience & flexibility
Economics
Single use endoscopy market expected to grow to $2.4bn in 2024
Technology & Innovation
Regulations

14/13 15/16 17/18 18/19 19/20 20/21

14 40 96 200 364 560 618 1,085 1,300-1,400
Multiple companies are now developing single use endoscopy and more are coming.
Thank you
Flexible Endoscope Processing

Erin Kyle, DNP, RN, CNOR, NEA-BC
Endoscope Processing Rooms or Areas

- One or two-room design
- Physically separated from patient care areas
- Unidirectional workflow
- Keep doors closed
- HVAC design parameters
- Safe work environment
Precleaning at the Point of Use

As soon as possible after removal from the patient

Before organic material has dried on surface or in the channels

Steps described in the IFU
Transporting

As soon as possible after the procedure

Closed container or closed transport cart
- Leak proof
- Puncture resistant
- Large enough to contain all contents

Labeled with biohazard legend

Endoscope IFU for timeframe
- Delayed processing procedures
Leak Testing

As described in the IFU

Before manual cleaning

Leak test failure

• Remove from service for repair or replacement
Manual Cleaning

As soon as possible after leak testing

In accordance with the IFU

• Endoscope
• Cleaning solution

Submerge

Exterior surfaces – clean & soft, lint-free cloth or sponge

Channels and distal end – clean brush

Actuate while cleaning

Elevator mechanism – raise and lower while brushing
Inspecting the Endoscope

- Use illumination and magnification for inspection.
- Inspect internal channels using a camera or borescope.
  - cleanliness
  - missing parts
  - clarity of lenses
  - integrity of seals and gaskets
  - physical or chemical damage
  - moisture
  - function
High-Level Disinfection (HLD)
Liquid Chemical Sterilization (LCS)

- Automated systems preferred over manual processing
- Follow IFU for endoscope and automated endoscope reprocessor (AER)
- Verify securement of connectors
- AERs have cleaning, HLD, rinse, and dry cycles
  - Depends on the model
- Dry the endoscope surfaces and lumens with pressure-regulated instrument air
Packaging and Sterilization

• If endoscope IFU allows, package and sterilize the endoscope
• Sterilization is preferred over HLD
Storing

- Drying cabinet is preferred
- If drying cabinet not available, closed cabinet with HEPA-filtered air with positive pressure
- Cabinet should be clean
- Valves open and removed parts detached, but with the endoscope
- Visual identification of ready-to-use endoscope
- Interdisciplinary team to determine storage time (“hang time”)

[Image: drycabinet_filter.jpg]
[Image: drycabinet_filter.jpg]
Maintaining Records

Records of endoscope processing that are traceable to the procedure and patient:

Include in records related to flexible endoscope procedures:

- date & time of processing
- patient identifier
- procedure
- identity of the practitioner performing the procedure
- identity of the endoscope & disposable endoscope accessories used during the procedure
Initial and ongoing education and competency assessment

- Controlling processing environment
- Manufacturer’s IFU for the endoscope, processing supplies, equipment, and accessories
- Leak testing
- Manual cleaning
- Inspecting (eg, lighted magnification and use of borescope)

- HLD processes
- LCS (liquid chemical sterilization) processes
- Packaging and sterilization
- Storage
- Records and traceability
- Quality assurance measures

Certification

Performance audits
• Controlling processing environment
• Leak testing
• Manual cleaning
• Inspecting (e.g., lighted magnification and use of borescope)
• HLD processes
• LCS (liquid chemical sterilization) processes

• Packaging and sterilization
• Storage
• Records and traceability
• Quality assurance measures
• Loaned endoscopes, accessories, and equipment
Quality Management

• Interdisciplinary team
• Water quality
• Preventative maintenance
  • Endoscopes
  • Automated endoscope repressors (AERs)
  • Other equipment (eg, drying cabinets)
• Performance audits
• Evaluate need for microbiologic surveillance cultures
References & Resources

Flexible Endoscopy  Endoscope Reprocessing

• Over the past 50 years, flexible endoscopy has become a valuable clinical instrument in nearly every health care specialty.

• Reusable flexible endoscopes and the effort to ensure they are made ready for patient use – reprocessing – have evolved in an interlocking cadence of progress.

• Often, the two critically connected components – endoscopes and reprocessing – evolved at different, disconnected paces – creating challenges.

• Recently, the evolution of reusable endoscopes has challenged the sustainability of cost-effective and time efficient reprocessing.
Correlating Evolutions: A history and overview
Endoscope Technology and Complex Reprocessing

Rigid -> Flexible Fiberoptic -> Flexible Video -> Model and MFG variation and expansion -> Flexible Interventional Scopes (EBUS, Duodenoscopes)

Soap / Detergent -> Formaldehyde -> Glutaraldehyde -> OPA -> Peracetic Acid -> EtO -> Gas Plasma

Soaking -> Rinsing -> Leak Testing -> Channel Scrubbing -> Point-of-Care cleaning -> Air Drying -> Part, Port Removals -> Damage / Repairs -> Transport and Storage

FDA / CDC -> Societal Guidelines -> HICPAC -> Multi-Society Guidelines -> Manufactures Instructions for Use -> Joint Commission -> Inpatient Outpatient Surgery Center Variations -> Superbug Updates

The Endoscopy Evolution: From Reusable to Single-Use
Why is there still risk regarding endoscopes and reprocessing?

- The complexity of the entire picture requires consistent adherence to processes and verifications across a wide-array of stakeholders in a high-pressure environment.
- Increases in patient-throughput and point of care locations not always met with capital or labor investment to support – leading to time crunches and pressurized scenarios.
- Equipment maintenance – ensuring no minor or major damage that could influence efficacy.
- Endoscopes and associated procedures continue to evolve in complexity.
- Superbug and other complex organic challenges.

What about the perfect execution on reprocessing?
Complexity Even in Ideal Performance of Reprocessing: Systematic Reviews of Contamination and Infection Risk

**Duodenoscopes**
- Contamination Rate: 15.3%
- Patients with an infection attributable to duodenoscopes: 1 in 50
- Patient Infection Rate: 2%
- Patients with an infection attributable to duodenoscopes: 1 in 50

**Bronchoscopes**
- Contamination Rate: 15.2%
- Patients with an infection attributable to bronchoscopes: 1 in 38
- Patient Infection Rate: 2.8%
- Patients with an infection attributable to bronchoscopes: 1 in 38

**Sources:**
The Reprocessing Sustainability Challenge: Increasing patient throughput and point of care sites for endoscopy

- Hospitals would like to increase endoscopy patient throughput
- Reprocessing limitations will require more process and investment to meet demand – adding to cost, complexity, and attention
- Ultimately - How to expand endoscopy use and point-of-care sites without adding to the process creating bottlenecks and pressure on stakeholders

Are there ways to increase capacity while simplifying process?
Single-Use Flexible Endoscopy Solution:

- Solves design and process complexity challenges all together
- Improves workflow efficiency for clinicians – simple, plug-and-play use
- Endoscopes are ready when needed at point of care
- Eliminates all costs associated reusable scope inventory, reprocessing, repair, loaners, leak testing, transport, storage
- Eliminates the risk associated with Superbug and aggressive organisms
- Alleviates training demands with simple compliance approach

No reprocessing required

Simplify point-of-care compliance without adding to the burden of staff and SPD
Ambu

Innovating for Life

Endoscopy Solutions for:
- Pulmonology / Critical Care / OR
- Gastroenterology
- Otolaryngology
- Urology
- Anesthesia
- Emergency Medicine
Thank you!

Questions?