Design Issues with Reusable Medical Devices
During the June Summit some of the challenges for reprocessing reusable devices were identified and talked about:

- Complex Devices
- Human Factors
- User Error
- Detailed Labeling (instructions)

Today we’d like to talk about these challenges and overcoming some of these challenges as applied to flexible endoscopes.
Design Challenges

- Flexible endoscopes are widely and increasingly used as a non-invasive instrument in many ways they are representative of the challenges associated with reprocessing reusable devices.
- Where applicable the use of noninvasive devices reduces the risks associated with more rigorous surgeries and procedures.
While the *reported* cases of (iatrogenic and nosocomial) infections directly attributed to the use re-useable medical devices are relatively low, they are serious and are invariably linked to breaches in reprocessing protocols.

Reprocessing involves the medical device itself, the reprocessing hardware, chemistry and the people that reprocess the device.

The link between infections and breaches in protocols suggests that improvements in human performance can positively affect outcomes.

Design inputs, outputs, and constraints are considered.
Design Output – Superior Clinical Outcome

Contrast

Sharpness

Resolution
Fiberscope vs. Videoscope

J F-B3 (1978)

EVI S Exera courtesy of Dr. Roy Soetikno VAPA
Common Design Challenges for Reusable Devices and Flexible Endoscopes

• The need to meet the critical design inputs results in highly complex devices:
  ▸ Long narrow interconnected channels/lumens
  ▸ Sophisticated materials:
    ▪ Polymers, metals, adhesives and resins
  ▸ Advanced electronics and optics
    ▪ Densely packed for size reduction
    ▪ Heat transfer and energy consumption are considered
Differences in coefficient of thermal expansion create challenges.

- Metal, glass, polymers, resins, etc. all expand at different rates and to different final dimensions when heated.
- This can cause material stress, fracture, or failure of seals if different materials are rigidly joined together.
Common Design Challenges for Reusable Devices and Flexible Endoscopes

- The very same design requirements that make these devices so remarkably effective in clinical outcome require careful attention to cleaning and reprocessing.

- Good instrument design is the first step to safe & effective instrument reprocessing.

- There have been advances and significant design improvements with endoscopes themselves and expectations for improvements in the future.
Fully immersible endoscope introduced in 1983

Total Cleanability

Finally, a Scope That Fully Meets Cleanability Requirements

The effective cleaning and disinfection of fiberoptic endoscopes has always been an area steeped in controversy. Medical committees in virtually every country have reached the conclusion that endoscopes should be totally cleaned and disinfected between cases. Recently, the controversy over cleaning and disinfection has become more heated. Fear of cross contamination from hepatitis and other infections diseases has increased the desire for a totally cleanable and disinfectable fiberscope.

OES has made this goal a reality. OES fiberscopes are totally immersible in harsh disinfectants. All exterior surfaces of the control section, universal cord and insertion tube were designed to be totally cleanable with a soft sponge. All internal components and surfaces (valves, channels, etc.) have been designed to be removable or totally accessible to a cleaning brush. Residue build-up caused by inadequate cleaning was once a major hindrance to total disinfection. This is no longer a problem with OES.
Single Channel Flexible Bronchoscope  2006

Resistant to heat and pressure

Enhanced durability to withstand steam sterilization
Changes in materials

Example of Material Changes Made to Improve Durability Against Oxidizing Agents

- Eliminated all anodized aluminum parts
- Used chemically resistant polymers
- Used electrostatically applied paints for improved adhesion and durability
- Used stainless steel to increase durability
Improvements in Design Geometry

Eliminate steps, sharp corners, abrupt changes, particularly on internal spaces
Avoid dead-end cavities

Back side of the angulation knob

Older model – cavity
Recent model – covered
Let’s switch from the device to the reprocessing

- As flexible endoscope design has advanced the reprocessing machines, chemicals and fundamental processes continue to evolve.
- Recently AER manufacturers began introducing AER’s with cleaning claims, reducing manual steps and simplifying instructions.
- The net result is enhanced human performance and increased compliance with protocols.
- New technologies are being advanced to more fully automate reprocessing narrow lumened medical devices, for example in June we saw a presentation on Two Phase Flow.
The Reprocessing machines and chemistry

- Reprocessing reusable devices involves a sterilizer, washer, disinfector and associated chemistry.

- Instructions for Use reference the chemistry and capital equipment.

- There have been recent and significant advances in the area of chemistry, including a reduction in contact time, increases in efficacy and more environmentally friendly chemistry.
Common Cleaning Challenges in Design-Reprocessing - Chemistry

- Chemistry plays a fundamental role in the cleaning and reprocessing of re-useable medical devices.
- The two fundamental design criteria for chemistry are efficacy and material compatibility.
Overcoming Design Challenges

Reprocessing reusable devices involves the human interaction between the device, the reprocessing machine, and the steam or chemical. Improvements in device design continues to enhance reprocessing. Improvements in chemistry and machinery