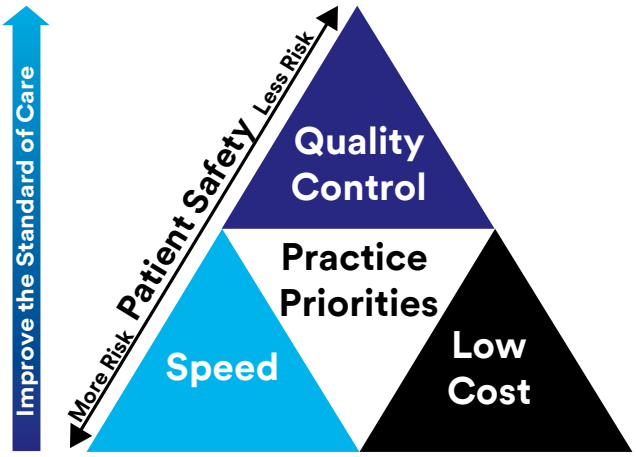
3M Science. Applied to Life.™

A Paradigm Shift in Endoscope Reprocessing

Improving the Standard of Care

Assessing Current Practices



Current practices favor turnover speed and low cost over quality control.
Visual Inspection + High Level Disinfection = High throughput
Cleaning Monitoring + EO Sterilization = **Higher Level of Patient Safety**

Facts: Cleaning Process Monitoring

- Assesses cleaning efficacy by detecting residual organic soil
- Rapid indicator provides quantitative results for Pass/Fail determination
- Generates data for trending and analysis within a Quality Control system

Facts: Ethylene Oxide (EO) Sterilization

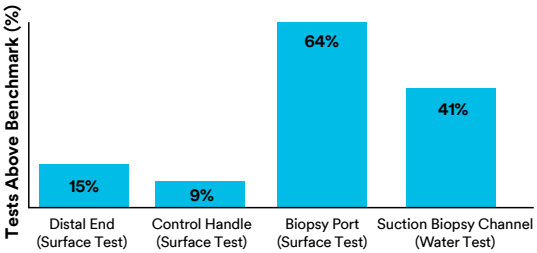
- "Overkill" safety margin + multi-component quality control monitoring system
- EPA mitigation measures implemented in 2010
- Modern sterilizers engineered for safety
- EO sterilization validated by endoscope manufacturers and listed in IFUs
- Documented excellent materials compatibility (most polymers, metals, and ceramics/glasses)[2] – no evidence of damage to endoscopes
- Used in health care settings, medical device, government, and other industries for 50+ years

[1] **Source:** Visrodia KH, Ofstead CL, Yellin HL, Wetzler HP, Tosh PK, Baron TH. The Use of Rapid Indicators for the Detection of Organic Residues on Clinically Used Gastrointestinal Endoscopes with and without Visually Apparent Debris. ICHEJ. August 2014. Vol. 35. No 8.

[2] AAMI TIR17:2008, Compatibility of Materials Subject to Sterilization, Table 1 - Material compatibility.

Flexible Endoscope Manual Cleaning Efficacy[1]

Study used multiple markers (ATP, protein and visual inspection) to evaluate contamination before and after manual cleaning. Results: "Multiple components were sampled during 37 encounters with 12 unique endoscopes. Although there was no visible residue on any endoscopes after manual cleaning, 82% had at least 1 positive rapid indicator test."



Percentage and Location of Rapid Indicator Test Result >200 Relative Light Units (RLUs) - Post Manual Cleaning

Operator Safety Data: Ethylene Oxide Sterilization in Health Care Facilities

Mean exposure levels for operators decline, remaining significantly below OSHA occupational limit (1.0 ppm over 8 hours, TWA), based on personal breathing zone and area monitoring data.

Operator Safety Data: EO Exposure Limits

Statistic	1979 to 1987 (ppm)*	1988 to 2007 (ppm)*	2012 (ppm)**
Arithmetic Mean	2.44 ± 24	0.49 ± 2	0.1218
50th Percentile	0.029	0.026	0.0731
75th Percentile	0.17	0.21	0.135
90th Percentile	0.83	0.83	0.16
Maximum	312	22	10.1
Number of Observations	171	343	647

* Data from OSHA IMIS database as presented in EPA EO Final Work Plan (EPA-HQ-OPP-2013-0244-0017)
** Data from use of passive EO monitors in health care facilities across 33 states and Puerto Rico

EO sterilizers today are engineered for safe use and facilities have implemented practices to improve safety (e.g., area monitoring, operator training). Positive milestones for safety:

- **2008:** U.S. EPA EO Reregistration eligibility decision (RED) requires risk mitigation measures in healthcare facilities, including in-chamber aeration
- **2010-2014:** U.S. EPA Clean Air Act phase-out of HCFC-based products, including mixed gas HCFC/EO sterilant, eliminates positive pressure cycles and large volume EO tanks
- **2015:** Introduction of completely updated 100% EO Sterilizer

3M Health Care
Infection Prevention Division
3M Center, Building 275-4E-01
St. Paul, MN 55144-1000
USA
Phone 1-800 228 3957
Web www.3M.com/infectionprevention