

# Minimizing Ethylene Oxide and Glutaraldehyde Use

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## Take Home Messages

1. Balance sporicidal, virucidal, and bactericidal effectiveness vs. human health effects and environmental toxicity of wastes
2. Check material compatibility with delicate medical devices and equipment repair costs
3. Consider cost per cycle, useful life of product, and cycle time

## First Consider the Device\*...

- ✳Critical
  - Enters sterile tissue or vascular system (e.g., surgical instruments, cardiac and urinary catheters, implants)
- ✳Semi-Critical
  - Contacts mucous membranes or non-intact skin (e.g., endoscopes, respiratory therapy and anesthesia equipment, diaphragm rings)
- ✳Non-Critical
  - Contacts intact skin (e.g., bedpans, blood pressure cuffs, crutches)

\*Spaulding scheme



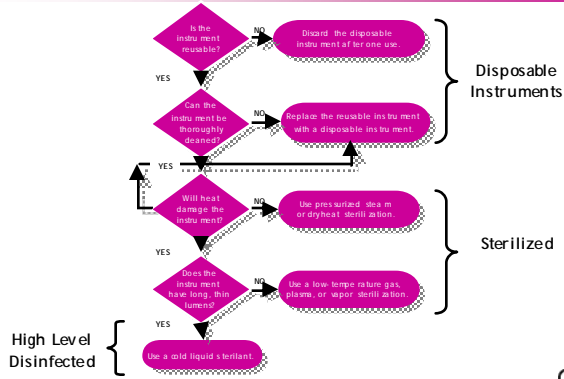
## Which Determines...<sup>1</sup>

- Sterilization:
  - ✳Validated process used to render a product free of all forms of viable microorganisms.
- Disinfection:
  - ✳Destruction of pathogenic and other kinds of microorganisms by thermal or chemical means. Destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores.

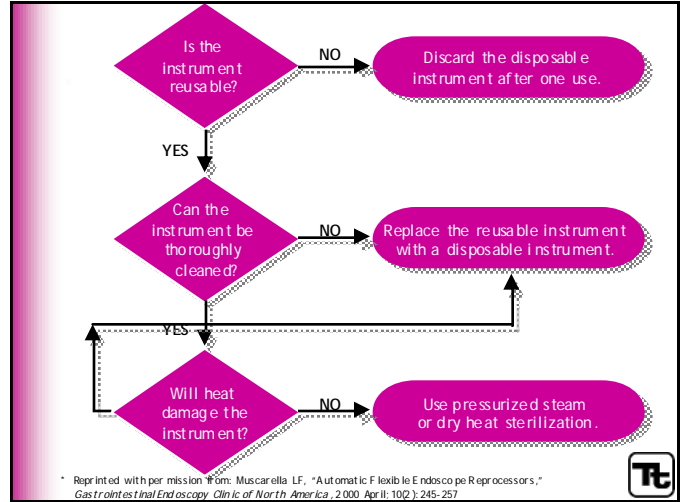
<sup>1</sup> Rutala, W. A., "Draft Guidelines for Disinfection and Sterilization in Healthcare Facilities," HICPAC 2b, CDC 02/20/2002



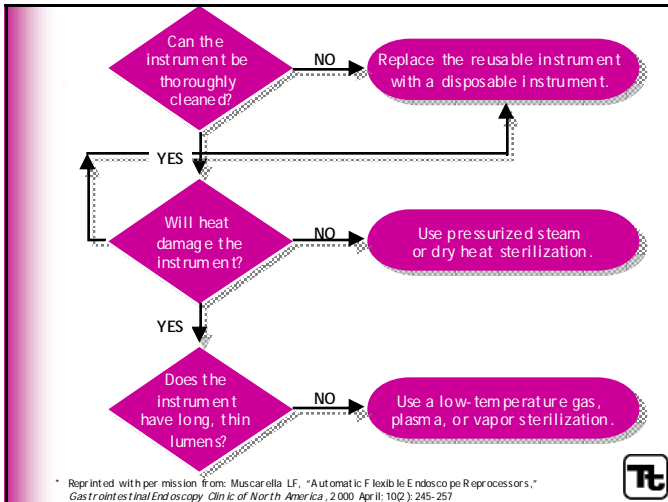
# Reprocessing Algorithm\*



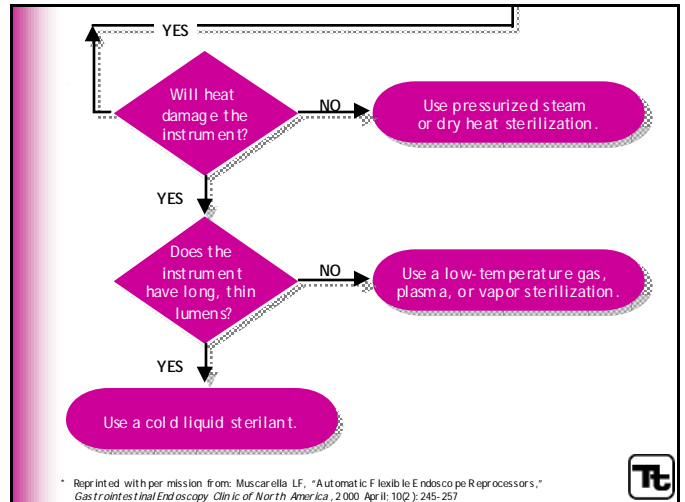
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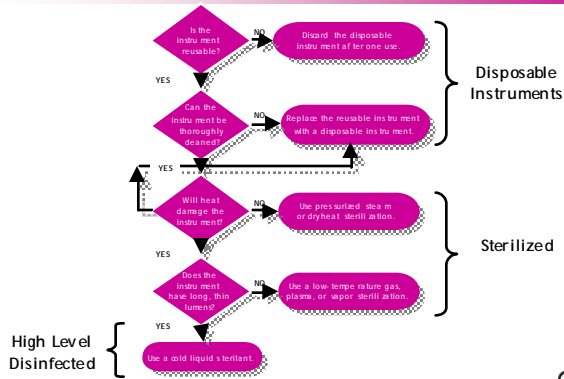
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## Reprocessing Algorithm\*



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## Ethylene Oxide and Glutaraldehyde

- Ethylene Oxide (EtO) is a sterilant, glutaraldehyde is a high-level disinfectant
- Both do not damage heat- and moisture-sensitive instruments
- Should be managed in a centralized area



## Why Eliminate EtO?

- Known carcinogen
- Probable teratogen
- Neurotoxin
- May damage CNS
- Increasing regulatory concerns



## 3-Step Approach to Eliminating EtO

1. 2. 3.

*EtO Use Inventory*

*Evaluate methods of eliminating EtO sterilization for each instrument*

*Establish a "working group" to ensure sterilization standards aren't compromised*



## EtO Alternatives

### Steris

(Steris Corporation)

- Peracetic acid sterilant
- but...*
- "Just In Time" approach
- Not a drop-in replacement

### Sterrad

(Johnson & Johnson Corporation)

- Plasma-phase hydrogen peroxide sterilant
- but...*
- Some manufacturer limitations



## Steris System Considerations

### Pros

- ❖ Sterilizer -- if scope used within 2 hours and processed in covered tray (high level disinfected if alcohol purged and forced-air dried)
- ❖ Small footprint
- ❖ Closed, automated system



### Cons

- ❖ Must use S-20 concentrate in System 1/P6000 processor only
- ❖ Cannot process ERCP scopes
- ❖ Materials incompatibility with Olympus GI scopes
- ❖ Irritant -- may not bring relief to those suffering from asthma or other respiratory sensitization
- ❖ Highly toxic material, Class II combustible, Class II Unstable, Class II or III organic peroxide
- ❖ Higher repair costs with other flexible and rigid scopes



## Sterrad Decision Tree

### 1. Is the reprocessible medical device made of the following materials?

- |                       |                           |
|-----------------------|---------------------------|
| ▪ Aluminum            | ▪ Polymethyl methacrylate |
| ▪ Brass               | ▪ Polyphenylene sulfone   |
| ▪ Delrin Acetal Resin | ▪ Polypropylene           |
| ▪ Ethylvinyl Acetate  | ▪ Polystyrene             |
| ▪ Glass               | ▪ Polyurethane            |
| ▪ Kraton Polymers     | ▪ Polyvinyl chloride      |
| ▪ Neoprene            | ▪ Silicone elastomers     |
| ▪ Nylon               | ▪ Stainless Steel         |
| ▪ Polycarbonate       | ▪ Teflon                  |
| ▪ Polyethylene        | ▪ Titanium                |
| ▪ Polyetherimide      |                           |



## Items NOT Recommended for Sterrad Processing



- Non-Sterrad instrument mats and trays
- Any item that is not completely dry
- Items or materials that absorb liquids



## Sterrad Decision Tree



*If no, contact medical device manufacturer for information*

*If yes, continue to next question.*



## Sterrad Decision Tree

2. Does the reprocessable medical device have a lumen?



*If no, contact medical device manufacturer for information*

*If yes, continue to next question.*



## Sterrad Decision Tree

3. Is the lumen made of stainless steel, polyethylene, or Teflon?



*If no, continue with processing.*

*If yes, continue to next question.*



## Items NOT Recommended for Sterrad Processing

- Items whose design permits the surfaces to collapse onto each other unless some method is used to keep the surfaces separated.
- Devices with internal parts, such as sealed bearings, that cannot be immersed



- Lumen lengths and diameter limitations
- **Ultimately, consult the "Compatible Device" list**



## Sterrad Decision Tree

4. Proceed with processing if the lumen conforms to the dimensions listed below:

Teflon/Polyethylene

Inside Diameter

6 mm or larger

Length

310 mm or shorter



Single Stainless Steel Lumen

Inside Diameter

1 mm or larger

2 mm or larger

3 mm or larger

Length



125 mm or shorter

250 mm or shorter

400 mm or shorter



## EtO Alternatives

Sterilization Process	Cycle Time	Cycles per Shift	Cost per foot <sup>3</sup>
 EtO	17 hours	0.5	\$11 - \$12
 Sterrad	50 minutes	9	\$8.50
 Steris	30 minutes	16	~ \$6 per cycle



## Non-EtO Technology Costs

### Sterrad

- Processor \$65,000 to \$130,000
- \$216 to \$265 per case (\$43 to \$53 per cassette, or \$9 to \$10 per cycle)

### Steris

- Processor \$18,200
- \$128 per case, \$7 per cycle



## Costs/Benefits Not Quantified

- Transaction cost of reduction effort
- Value of quicker sterilization time
- Increased availability of instruments
- Instrument upgrade/replacement costs
- Eliminates chance of EtO incident



## Disinfection Levels

- High-level

- Capable of killing bacterial spores, and is therefore expected to kill all other microorganisms



- Intermediate-level

- Destroys all vegetative bacteria, including tubercle bacilli, viruses, and fungus spores

- Low-level

- Destroys all vegetative bacteria (except tubercle bacilli), some viruses and fungi



## Cold Liquid Disinfection Methods

- Glutaraldehyde

- Cetylaldehyde-G (3.2%)
- Cidex (2.4, 2.5, 3.4%)
- MedSci (3%)
- Metricide (2.5, 2.6, 3.4%)
- Omnicide (2.4, 3.4%)
- Procide (2.4%)
- Rapidcide (2.5%)
- Sporicidin (1.12/1.93% glut/phenol)
- Wavicide-01 (2.5%)

- Hydrogen Peroxide

- Sporox (7.5%)

- Hydrogen Peroxide/  
Peroxyacetic Acid

- EndoSpore Plus (7.5/0.23%)
- Peract 20 (1.0/0.08%)

- ortho-Phthalaldehyde

- Cidex OPA (0.55%)

- Peroxyacetic Acid

- Steris S-20 (35%)



## Disadvantages of Glutaraldehyde

- Severe irritant - may cause asthma and respiratory sensitization (although not cancer or reproductive harm)
- Skin sensitizer
- Low exposure limits
  - 0.2 ppm NIOSH REL
  - 0.05 ppm ACGIH TLV
  - Proposed 0.015 ppm Ceiling Limit in CA



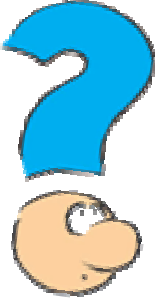
## OPA vs. Glutaraldehyde

- Low vapor pressure therefore minimal inhalation risk
- Switch can be accomplished relatively quickly compared to installing engineering controls
- No regulatory or recommended exposure limits so no associated monitoring
- Reduces disinfection time to 12 min. manual and 5 min. automated processing (from 20 min. for glutaraldehyde)
- Allows twice the disinfection cycles before solution failure



## OPA Considerations

- \* Unknown long-term health effects or cross-sensitivity to other aldehydes
- \* No validated air sampling method
- \* Precautionary principle requires same engineering controls as glutaraldehyde
- \* 4 times the cost of glutaraldehyde



## Time Out: Comparing Cycle Times



### Glutaraldehyde *(\$5 per bottle)*

- 20 minutes per cycle  
= 24 cycles per 8 hour shift



### Cidex OPA *(\$25 per bottle)*

- 12 minutes per cycle (manual)  
= 40 cycles per 8 hour shift
- 5 minutes per cycle (automated)  
= 96 cycles per 8 hour shift



## Benefits of Quicker Process Time

- Increased availability of instruments and medical devices
- Decreased inventory requirements
- Increased personnel availability

*Patients get treated sooner!*



## Relative Cost Considerations



\$20 Difference in cost of OPA vs. glutaraldehyde-based products



\$15K Cost of each reprocessor



\$30K Cost of each endoscope



## The Built Environment

- Isolation of cleaning and disinfection process from clinical procedure areas
- Separation of clean and dirty areas
- Process flow from dirty to clean, with no cross-over encouraged between the two
- Engineering controls of vapor-generating activities and equipment
- Safety equipment (eyewash, shower, spill containment, emergency shut-off)



## Scope Wash Room



## Local Exhaust Ventilation



## Take Home Messages

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