What to do when you don’t know what to do

Alisha Dorn
August 2019
Objectives

1. Discuss topics to consider when determining how to reprocess one-off items

2. Provide insight into various areas that are assessed when reprocessing one-off items
Brand new IP

CHECKLIST

Where is my checklist?
It is complicated…..

CDC
FDA
AAMI
AORN
One size doesn’t fit all!
Spectrum of IP wisdom

- I have no idea where to even start!!!
- I have heard of this before
- I know where to look
- I have seen this before
- I know all about this!
It is serious stuff

• 2017 JC safety alert

• 74% of all immediate threats to life were from improper sterilization or high level disinfection

• Non compliance had INCREASED between 2009-2016
How are we getting this wrong?

Whaddya mean all my facts are wrong?!?

I copied everything straight off the internet!!
Difference between standards and guidelines

Guidelines

- Provide guidance
- Recommendations
- Evidence Based
- Many guidelines are based on the standards
- Often offer more specific information and guidance

- AORN
- AAMI
- CDC- kind of

Standards

You must follow
You don’t get to pick and choose

- OSHA
- FDA
- EPA
- FDA
<table>
<thead>
<tr>
<th>CDC Categories</th>
<th>Overview</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1A</strong></td>
<td>Strongly recommended strongly supported by research.</td>
<td>Immediately after use, meticulously clean the endoscope with an enzymatic cleaner that is compatible with the endoscope. Cleaning is necessary before both automated and manual disinfection. Category IA.</td>
</tr>
<tr>
<td><strong>1B</strong></td>
<td>Strongly recommended and supported by some research</td>
<td>Discard enzymatic cleaners (or detergents) after each use because they are not microbicidal and, therefore, will not retard microbial growth. Category IB</td>
</tr>
<tr>
<td><strong>1C</strong></td>
<td>Required by state or federal regulations. (often paired with other categories)</td>
<td>Educate health-care workers in the selection and proper use of personal protective equipment (PPE). Category II, IC</td>
</tr>
<tr>
<td><strong>II</strong></td>
<td>Suggested supported by suggestive studies or theoretical rationale. (60)</td>
<td>In hospitals, perform most cleaning, disinfection, and sterilization of patient-care devices in a central processing department in order to more easily control quality. Category II</td>
</tr>
<tr>
<td><strong>No Recommendation</strong></td>
<td>Unresolved issue: insufficient evidence or no consensus</td>
<td>No recommendation is made about routinely performing microbiologic testing of either endoscopes or rinse water for quality assurance purposes. Unresolved Issue.</td>
</tr>
</tbody>
</table>
Know where to find stuff

https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

OSHA
https://www.osha.gov/

Other resources
• AAMI ST79
• AAMI ST91
• APIC
• AORN
• Recent research
Know how to interpret the standards/recommendations
OSHA

1910.1030(d)(3)(ix) Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

**Definitions**

**Blood** means human blood, human blood components, and products made from human blood.

**Contaminated** means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

*Other Potentially Infectious Materials means*

(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.
Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

1. Wear gloves when you think you may be exposed to blood, fluids, tissues or anything containing HIV.

2. Except when in a blood donation center where routine gloving is not needed for all phlebotomists.
Some devices can be prepared for patient reuse following the decontamination process, whereas others should be prepared and subjected to terminal sterilization (e.g., steam sterilization of surgical instruments). The type of decontamination required for a particular contaminated device depends on the biohazard that the device presents. The cleaning and/or microbial process appropriate for a particular device depends on:

a) the device manufacturer’s written IFU;

b) the necessary level of microbial lethality (CDC, 2008); for example, a higher assurance of lethality is needed for items that have been in contact with body tissues, blood, or other bodily fluids than for items that have only been in contact with unbroken skin;

c) the design of the device;

d) the materials from which the device is fabricated (e.g., whether the device can tolerate high temperatures; whether the device is fully immersible);

e) the intended use of the device; and

f) whether the device was exposed to prions, such as the prion that causes Creutzfeldt-Jakob disease (CJD), and thus will require specialized processing steps (see Annex C).
You need to dig a little deeper.....
Some devices can be prepared for patient reuse following the decontamination process, whereas others should be prepared and subjected to terminal sterilization (e.g., steam sterilization of surgical instruments). The type of decontamination required for a particular contaminated device depends on the biohazard that the device presents. The cleaning and/or microbial process appropriate for a particular device depends on

a) the device manufacturer’s written IFU;

b) the necessary level of microbial lethality (CDC, 2008); for example, a higher assurance of lethality is needed for items that have been in contact with body tissues, blood, or other bodily fluids than for items that have only been in contact with unbroken skin;

c) the design of the device;

d) the materials from which the device is fabricated (e.g., whether the device can tolerate high temperatures, whether the device is fully immersible);

e) the intended use of the device; and

f) whether the device was exposed to prions, such as the prion that causes Creutzfeldt-Jakob disease (CJD), and thus will require specialized processing steps (see Annex C).
A Rational Approach to Disinfection and Sterilization

More than 30 years ago, Earle H. Spaulding devised a rational approach to disinfection and sterilization of patient-care items and equipment.14 This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization.1, 13, 15, 17, 19, 20 Spaulding believed the nature of disinfection could be understood readily if instruments and items for patient care were categorized as critical, semicritical, and noncritical according to the degree of risk for infection involved in their use. The CDC Guideline for Handwashing and Hospital Environmental Control 21, Guidelines for the Prevention of Transmission of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) to Health-Care and Public-Safety Workers22, and Guideline for Environmental Infection Control in Health-Care Facilities23 employ this terminology.

Critical Items

Critical items confer a high risk for infection if they are contaminated with any microorganism. Thus, objects that enter sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. Most of the items in this category should be purchased as sterile or be sterilized with steam if possible. Heat-sensitive objects can be treated with EO, hydrogen peroxide gas plasma; or if other methods are unsuitable, by liquid chemical sterilants. Germicides categorized as chemical sterilants include 2.4% glutaraldehyde-based formulations, 0.95% glutaraldehyde with 1.64% phenol/phenate, 7.5% stabilized hydrogen peroxide, 7.35% hydrogen peroxide with 0.23% peracetic acid, 0.2% peracetic acid, and 0.08% peracetic acid with 1.0% hydrogen peroxide. Liquid chemical sterilants reliably produce sterility only if cleaning precedes treatment and if proper guidelines are followed regarding concentration, contact time, temperature, and pH.

Semicritical Items

Semicritical items contact mucous membranes or nonintact skin. This category includes respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades 24, esophageal manometry probes, cystoscopes 25, anorectal manometry catheters, and diaphragm fitting rings. These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are permissible. Intact mucous membranes, such as those of the lungs and the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria, and viruses. Semicritical items minimally require high-level disinfection using chemical disinfectants, glutaraldehyde, hydrogen peroxide, ortho-g-halaldehyde, and peracetic acid with hydrogen peroxide are cleared by the Food and Drug Administration (FDA) and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met (Table 1). When a disinfectant is selected for use with certain patient-care items, the chemical compatibility after extended use with the items to be disinfected also must be considered. High-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The FDA definition of high-level disinfection is a sterilant used for a shorter contact time to achieve a 6 log10 kill of an appropriate Mycobacterium, Pseudomonas, or Clostridium perfringens. Cleaning must be followed by high-level disinfection to build eliminate enough pathogens to prevent transmission of infection.26, 27

Laparoscopes and arthroscopes entering sterile tissue ideally should be sterilized between patients. However, in the United States, this equipment sometimes is used with high-level disinfections on environmental surfaces. However, they often are not adequately cleaned and disinfected, and if the water-disinfectant mixture is not changed regularly (e.g., after every three to four rooms, at no longer than 60-minute intervals), the mapping procedure actually can spread heavy microbial contamination throughout the health-care facility.68 In one study, standard laundering provided acceptable decontamination of heavily contaminated mopheads but chemical disinfection with a phenolic was less effective.68 Frequent laundering of mops (e.g., daily), therefore, is recommended. Single-use disposable towels impregnated with a disinfectant also can be used for low-level disinfection when spot-cleaning of

Accessible version: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/


Update: May 2019

Noncritical Items

Noncritical items are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is "not critical." In this guideline, noncritical items are divided into noncritical patient-care items and noncritical environmental surfaces in 43, 44. Examples of noncritical patient-care items are bedpans, blood pressure cuffs, crutches and computers 45. In contrast to critical and some semicritical items, most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. Virtually no risk has been documented for transmission of infectious agents to patients through noncritical items.37 When they are used as noncritical items and do not contact non-intact skin and/or mucous membranes, Table 1 lists several low-level disinfectants that may be used for noncritical items. Most Environmental Protection Agency (EPA)-registered disinfectants have a 10-minute label claim. However, multiple investigators have demonstrated the effectiveness of these disinfectants against vegetative bacteria (e.g., Listeria, Escherichia coli, Salmonella, vancomycin-resistant Enterococci, methicillin-resistant Staphylococcus aureus), yeasts (e.g., Candida), mycobacteria (e.g., Mycobacterium tuberculosis), and viruses (e.g., poliovirus) at exposure times of 30–60 seconds46–64 Federal law requires all applicable label instructions on EPA-registered products to be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use, and disposal). If the user selects exposure conditions (e.g., exposure time) that differ from those on the EPA-registered product label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 65.

Noncritical environmental surfaces include bed rails, some food utensils, bedside tables, patient furniture and floors. Noncritical environmental surfaces frequently touched by hand (e.g., bedside tables, bed rails) polishes could contribute to secondary transmission by contaminating hands of health-care workers or by contacting medical equipment that subsequently contacts patients 13, 46–48, 51, 66, 67. Mops and reusable cleaning cloths are regularly used to achieve low-level disinfection on environmental surfaces. However, they often are not adequately cleaned and disinfected, and if the water-disinfectant mixture is not changed regularly (e.g., after every three to four rooms, at no longer than 60-minute intervals), the mapping procedure actually can spread heavy microbial contamination throughout the health-care facility.68 In one study, standard laundering provided acceptable decontamination of heavily contaminated mopheads but chemical disinfection with a phenolic was less effective.68 Frequent laundering of mops (e.g., daily), therefore, is recommended. Single-use disposable towels impregnated with a disinfectant also can be used for low-level disinfection when spot-cleaning of...
<table>
<thead>
<tr>
<th>Patient Contact</th>
<th>Examples</th>
<th>Device Classification</th>
<th>Minimum activation level</th>
<th>Efficacy spectrum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact Skin</td>
<td></td>
<td>Non-Critical</td>
<td>Cleaning with low &amp; intermediate disinfection</td>
<td>Most vegetative bacteria &amp; viruses (not including spores, mycobacteria, non-lipid viruses)</td>
</tr>
<tr>
<td>Mucous Membranes or non intact skin</td>
<td></td>
<td>Semi-critical</td>
<td>High level disinfection</td>
<td>All microorganisms except spores</td>
</tr>
<tr>
<td>Sterile areas of the body-including blood</td>
<td></td>
<td>Critical</td>
<td>Sterilization</td>
<td>All viable microorganisms</td>
</tr>
</tbody>
</table>
Some devices can be prepared for patient reuse following the decontamination process, whereas others should be prepared and subjected to terminal sterilization (e.g., steam sterilization of surgical instruments). The type of decontamination required for a particular contaminated device depends on the biohazard that the device presents. The cleaning and/or microbicidal process appropriate for a particular device depends on:

a) the device manufacturer’s written IFU;

b) the necessary level of microbial lethality (CDC, 2008); for example, a higher assurance of lethality is needed for items that have been in contact with body tissues, blood, or other bodily fluids than for items that have only been in contact with unbroken skin;

c) the design of the device;

d) the materials from which the device is fabricated (e.g., whether the device can tolerate high temperatures, whether the device is fully immersible);

e) the intended use of the device; and

f) whether the device was exposed to prions, such as the prion that causes Creutzfeldt-Jakob disease (CJD), and thus will require specialized processing steps (see Annex C).
Materials of device vs intended use

Intended Use

Does it require low level disinfection?
Does it require high level disinfection?
Does it require sterilization?

Materials

Can it be low level disinfected?
Can it be high level disinfected?
Can it be sterilized?
More examples from AAMI

7.5.2.2 Rigid Sterilization Container systems

- General considerations
- Removable filters
- Valves
- Interior baskets
- Process indicators
- Container accessories

In addition to following the manufacturer’s written IFU, the following actions should be taken:

a) Request performance verification test methods from the ultrasonic equipment manufacturer.
b) Perform cavitation testing daily whenever the equipment is in use.
c) Prior to using it, degas the solution in accordance with the ultrasonic equipment manufacturer’s IFU.
d) Avoid placing plastics and soft metal (e.g., lead hands) in the ultrasonic cleaner.
e) Keep the lid closed when the ultrasonic cleaner is in use unless otherwise directed by the device manufacturer’s written IFU.
In addition to following the manufacturer’s written IFU, the following actions should be taken:

a) Request **performance verification test methods** from the ultrasonic equipment manufacturer.

b) Perform **cavitation testing** daily whenever the equipment is in use.

c) Prior to using it, **degas the solution** in accordance with the ultrasonic equipment manufacturer’s IFU.

d) Avoid placing plastics and soft metal (e.g., lead hands) in the ultrasonic cleaner.

e) Keep the lid closed when the ultrasonic cleaner is in use unless otherwise directed by the device manufacturer’s written IFU.
What to do when you cannot fit what the standards require
What does the IFU say?

What is the device used for?

What is the Spaulding Class?

Does the IFU fit Spaulding?

Can I do what the IFU says?
- Ensure all pre-processing instructions are followed prior to cleaning.
- Clean the devices via the automatic cleaning parameters below.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Minimum Recirculation Time</th>
<th>Water Temperature</th>
<th>Detergent Type and Concentration (If applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-wash</td>
<td>15 Seconds</td>
<td>Cold Drinking Water</td>
<td>N/A</td>
</tr>
<tr>
<td>Enzyme Wash</td>
<td>1 Minute</td>
<td>Hot Drinking Water</td>
<td>Detergent: pH-neutral/ enzymatic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>43°C - 82°C (110°F - 179°F)</td>
<td>Concentration: Per the detergent manufacturer's recommendations</td>
</tr>
<tr>
<td>Wash</td>
<td>2 Minutes</td>
<td>Drinking Water</td>
<td>Detergent: pH-neutral cleanser</td>
</tr>
<tr>
<td></td>
<td></td>
<td>43°C - 82°C (110°F - 179°F)</td>
<td>Concentration: Per the detergent manufacturer's recommendations</td>
</tr>
<tr>
<td>Rinse</td>
<td>15 Seconds</td>
<td>Drinking Water</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>43°C - 82°C (110°F - 179°F)</td>
<td></td>
</tr>
<tr>
<td>Pure Rinse</td>
<td>10 Seconds</td>
<td>Treated Water</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>43°C - 82°C (110°F - 179°F)</td>
<td></td>
</tr>
<tr>
<td>Drying</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**STANDARD PREVACUUM STEAM STERILIZATION CYCLES**

**Prevacuum Steam Sterilization Cycle (U.S. “FDA Compliant – WRAPPED”)**
- Conditioning Pulses: 3
- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Dry Time: 30 minutes
- Sterilization Configuration: FDA Cleared Sterilization Wrap (2 layer-1 ply, or 1 layer -2 ply – examples: cellulose, polypropylene, muslin)

**Prevacuum Steam Sterilization Cycle – Immediate Use Steam Sterilization (U.S. “FDA Compliant – WRAPPED”)**
- Conditioning Pulses: 3
- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Sterilization Configuration: FDA Cleared Sterilization Wrap (2 layer-1 ply, or 1 layer -2 ply – examples: cellulose, polypropylene, muslin)

**NOTE:** Devices must be used immediately and cannot be stored for later use.

Immediate Use Steam Sterilization is not recommended as a routine practice. Refer to ANSI/AAMI ST79 for requirements on when to perform and how to control immediate use steam sterilization.

1. Clean lens & surgical products first by following Cleaning Method A (See CLEANING METHODS TABLE)

2. Disinfect by selecting one of the solution types from the Table below:

<table>
<thead>
<tr>
<th>Product Type OK to Use</th>
<th>Alkazide / Alkazyme Solutions</th>
<th><strong>Bleach</strong> Solutions (Sodium Hypochlorite)</th>
<th>Bode Mikrobact Wipes</th>
<th>CavilWipes</th>
<th><em>Cidex OPA</em></th>
<th><em>Glutaraldehyde</em></th>
<th>Perasafe</th>
<th><em>Revital-Ox</em> Resort XL® HLD</th>
<th>Trisol Duo</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIO Lenses (Black &amp; All Colors)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>BIO Lenses (ACS)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Classic Series Lenses (Black &amp; All Colors)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Super &amp; Digital Series Lenses (Black &amp; All Colors)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Mirrored Lenses (3-Mirror Lenses, Mini 4-Mirror Lens, &amp; SLT)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>G-Series Gonio Lenses</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Contact Lenses</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Research Lenses</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Vitrectomy Surgical Lenses - Traditional</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Vitrectomy Surgical Lenses - ACS</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

### Disinfection

- Mucous Membranes or non intact skin
- Semi-critical
- High level disinfection
- All microorganisms except spores
Never reprocess single use items
What if the IFU doesn’t make sense?
MODEL 119

TO USE—Be sure all parts are dry before using. Fill bottle no more than half way to shoulder of the bottle with dry powder. For measured dosages, add desired amount of dry powder to bottle. Do not over-tighten bottle. Grasp the bulb firmly, using the fingers against palm of hand. If necessary, tube can be unthreaded slightly to administer powder in other directions.

TO CLEAN—If powder is kept dry, there is little chance for clogging. If damp powder remains in the tube and becomes caked, unthread tube and remove residue with pipe cleaner. For best results, remove powder, rinse and thoroughly dry the bottle and tube before storing for extended period of time. Do not store with powder in bottle.

TO STERILIZE—Wipe carefully with gauze or absorbent cotton moistened with alcohol or other germicidal solutions suitable for sterilizing purposes.

CAUTION—DO NOT USE HEAT; it may damage the unit.
Rectal Light Handle, Ref 73210:
1. Disconnect the rectal light handle from the power-supply cord and from the endoscopic device.
2. Allow the lamp to cool for at least 5 minutes. Do not proceed until the lamp is comfortably cool to the touch.
3. Unscrew the outer sleeve of the handle by turning it counterclockwise.
4. Using the appropriate ILD wipe, wipe the handle body and the handle cord according to the instructions supplied by the ILD manufacturer.
5. Using the appropriate ILD solution, immerse the outer sleeve and clean it according to the instructions supplied by the ILD manufacturer.

Caution Do not immerse the body of the rectal light handle in any solution. To do so could damage the body of the rectal light handle.
Update: May 2019

William A. Rutala, Ph.D., M.P.H.1,2, David J. Weber, M.D., M.P.H.1,2, and the Healthcare Infection Control Practices Advisory Committee (HICPAC)3

Unlike sterilization, disinfection is not sporidial. A few disinfectants will kill spores with prolonged exposure times (3-12 hours); these are called chemical sterilants. At similar concentrations but with shorter exposure periods (e.g., 20 minutes for 2% glutaraldehyde), these same disinfectants will kill all microorganisms except large numbers of bacterial spores; they are called high-level disinfectants. Low-level disinfectants can kill most vegetative bacteria, some fungi, and some viruses in a practical period of time (≤10 minutes). Intermediate-level disinfectants might be cidal for mycobacteria, vegetative bacteria most viruses, and most fungi but do not necessarily kill bacterial spores. Germicides differ markedly, primarily in their antimicrobial spectrum and rapidity of action.

Protected surfaces should be disinfected at the end of each day or if contamination is evident. If not barrier-protected, these surfaces should be disinfected between patients with an intermediate-disinfectant (i.e., EPA-registered hospital disinfectant with tuberculocidal claim) or low-level disinfectant (i.e., EPA-registered hospital disinfectant with an HBV and HIV label claim).4, 214, 215.
Sani-Cloth® AF3 Germicidal Disposable Wipes is a nonwoven, disposable cloth, pre saturated with a quaternary disinfectant. Recommended for use in hospitals and critical care areas where control of the hazards of cross contamination between treated surfaces is of prime importance. Use on hard, nonporous surfaces and equipment. Disinfects in just three (3) minutes.

**CHEMICAL COMPOSITION**

**Active Ingredients:**
- n-Alkyl (60% C₆, 30% C₇, 10% C₈) dimethyl ethylbenzyl ammonium chlorides: 0.14%
- n-Alkyl (60% C₆, 30% C₇, 10% C₈) dimethyl benzyl ammonium chlorides: 0.14%
- Other ingredients: 98.72%
- TOTAL: 100.00%

Each cloth is saturated with 2.800 parts per million of active quaternary ammonium chlorides.
What does the IFU say?

What is the device used for?

What is the Spaulding Class?

Does the IFU fit Spaulding?

Can I do what the IFU says?

Mini Risk Assessment
Mini risk assessments

• Identify the gaps in the process
• Estimate the likelihood that gap will occur
• Assess the consequence if the failure occurs
• Determine how to mitigate the consequences
Ear light probe tips

What does the IFU say?
What is the device used for?
What is the Spaulding Class?
Does the IFU fit Spaulding?
Can I do what the IFU says?
Risk Assessment

Items are those instruments or objects that either do not ordinarily touch the patient or touch only the externally intact skin. Ear light probe tips used for inserting ear dams into the ear canal are most likely considered non-critical instruments and must be cleaned and then disinfected prior to re-use. NOTE: in the event of gross misuse whereby the probe tip penetrates the ear canal and/or if ear light probe is visibly contaminated with blood it is to be disposed of.

Disinfection of Ear Light Probe Tips used with the Pen Light:

- Following the use of probe tip, detach from pen light being careful not to handle or touch the contaminated portion. NOTE: if the ear light probe tip is visibly contaminated with cerumen and/or blood, it must either be disposed of or cleaned and then sterilized prior to reuse.
- Clean the probe tip surface by wiping its surface completely using either a paper towel, disinfectant towelette, or Kleenex
- Dispose of paper towel, disinfectant towelette or Kleenex into the regular trash
- Disinfect the probe tip surface by wiping its surface complete using a fresh disinfectant towelette or spray the surface of the entire probe tip with disinfectant spray and then wipe the surface with a paper towel.

Sterilization challenges inherent to Ear Light Probe Tips as a function of VA approved sterilants:

The use of heat pressurization via an autoclave may not be used on Ear Light Probe Tips since these items are comprised of plastic and will melt during the procedure. From this perspective, some sterilization centers may erroneously refer to these products as disposable. The ear light probe tips are not one-time use products; they are intended to be reused with multiple patients. In the event gas sterilization is an available, this option is considered suitable. Typically, this process involves the use of Ephylene Oxide although there may be other alternative gases used.
LOW-LEVEL DISINFECTION INSTRUCTIONS
(For Limited Use and Reusable Cuffs Only)
Exposed surfaces of the cuff withstand the successive number of disinfection cycles shown below with no apparent negative effect.

<table>
<thead>
<tr>
<th>CUFF STYLE</th>
<th>DISINFECTION CYCLES ALLOWED</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOFT-CUF</td>
<td>1000</td>
</tr>
<tr>
<td>CLASSIC-CUF</td>
<td>1000</td>
</tr>
<tr>
<td>SENSA-CUF</td>
<td>1500</td>
</tr>
<tr>
<td>DURA-CUF</td>
<td>2000</td>
</tr>
</tbody>
</table>

1. Fill a spray bottle with Enzymatic detergent, such as ENZOL® enzymatic detergent (US) or Clidezyme® enzymatic detergent (UK), prepared according to the manufacturer’s directions.
2. Take precautions to avoid liquid from entering the cuff tubing. Liquid in the tubing may affect blood pressure determination accuracy and damage automatic or manual monitors. Either isolate that area from the spray, or consider using wash plugs.
3. Spray the detergent solution as prepared in step 1 liberally on the cuff and tubing. On heavily soiled areas or areas where soil is dried on, allow the cleaning agent to sit on the cuff and tubing for 1 minute.

   NOTE: Take particular care when cleaning the bulb and control valve on a complete Inflation System. Do not allow fluid to enter back valve or saturate knob. Remove visible contaminants from the periphery and the underside of the control knob.
4. Wipe smooth surfaces with soft clean cloth.
   Use a soft-bristled brush on visibly soiled areas and irregular surfaces.
5. Rinse with copious amounts of water, distilled is preferred.
6. Repeat as necessary.
7. To disinfect, fill a spray bottle with 10% solution of household bleach (5.25% sodium hypochlorite) in distilled water. Spray this solution on the cuff until saturated and allow to sit for 5 minutes.
8. Wipe away excess solution with soft clean cloth.
9. Rinse with copious amounts of distilled water.
10. Allow cuff to air dry before reuse on multiple patients.
Lasers
5.4.1. Handpiece Cleaning Procedure

**Caution**
- Always clean the handpiece immediately after use before stains dry.
- Always disassemble the lens from the handpiece prior to cleaning.
- **Do not** autoclave the lens assembly.

1. Disassemble the handpiece.
2. Remove visible debris by soaking the handpiece parts for ten minutes in a poly-enzymatic detergent (i.e. Enzol\textsuperscript{1}) solution, mixed according to the manufacturer's recommendations.
3. Use a cloth to rub exterior surfaces.
4. Use brush to clean the inner lumen of the handpiece.
5. Rinse well under running water, holding the handpiece parts such that the water will run through them.
6. **Completely immerse the handpiece parts in 70\% isopropyl alcohol for ten minutes. While soaking:**
   - Use a cloth to rub exterior surfaces.
   - **Vigorously** move the handpiece parts inside the alcohol bowl such that the alcohol will run through them.
7. Allow the handpiece parts to air-dry until all alcohol has evaporated.
5.3.2. Cleaning the System

The external surfaces of the system (console and articulated arm) and the footswitch should be cleaned when the system is received, and thereafter as required by the facility’s cleaning protocol.

The outer surfaces of the system and the lens assembly may be wiped clean with a soft, lint-free cloth dipped in 70% isopropyl alcohol, or a hospital-grade disinfectant solution such as Cidex® or equivalent.

The optical lens housed in the lens assembly may be cleaned with a soft, lint-free cloth dipped in 99% isopropyl alcohol, or hospital-grade acetone.

⚠️ Caution

Do not allow the lens to come into contact with water or any water-based product; dry water stains can become hot-spots during laser emission, damaging the lens’ optical coating.
5.4. Handpiece Cleaning and Sterilization

**Warning**

Never use a handpiece that has not been sterilized. Use of non-sterilized accessories creates a potential risk of infection which may each lead to significant medical complications.

5.4.3. Maximum Allowed Sterilization Cycles

The CO2RE handpiece parts are allowed to be subjected to no more than ten sterilization cycles. After the tenth use the handpiece must be properly discarded.
Gravity Cycle

<table>
<thead>
<tr>
<th>Form of Autoclave:</th>
<th>Steam autoclave</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilizer Type:</td>
<td>Gravity displacement</td>
</tr>
<tr>
<td>Method:</td>
<td>Wrapped</td>
</tr>
<tr>
<td>Minimum Exposure Time:</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Minimum Drying Time:</td>
<td>45 minutes</td>
</tr>
<tr>
<td>Temperature:</td>
<td>250°F / 121°C</td>
</tr>
<tr>
<td>Pressure:</td>
<td>~ 1.5 Bar / 22 PSI</td>
</tr>
</tbody>
</table>

**Typical Gravity cycle:**
- 250°F for 30 minutes exposure
- 270°F for 15 minutes exposure
- 275°F for 10 minutes exposure
- 15–30 minutes dry time
- 15–30 minutes dry time
- 30 minutes dry time
1.7.4. Surgical Safety

- Never use surgical accessories that have not been sterilized. Use of non-sterilized accessories creates a potential risk of infection which may each lead to significant medical complications.

To clean and disinfect the handpiece:

Immediately after each treatment session, put the laser in STANDBY and wipe the exterior surface of the handpiece body with a gauze pad moistened with a hospital grade disinfectant solution or alcohol solution. Take care to avoid contaminating the internal optical surfaces of the handpiece. After cleaning the handpiece, dry the area thoroughly prior to the beginning of a laser procedure.
Dig a little deeper
Dig a little deeper

What does the laser do?

Figure 3-3: Beam Scanning Principle
Dig a little deeper

- Stratum corneum
- Stratum lucidum
- Stratum granulosum
- Stratum spinosum
- Stratum basale
- Melanocyte
- Dermis
- Dead cells filled with keratin
- Lamellar granules
- Keratinocyte
- Merkel cell
- Sensory neuron
Handpiece conclusions

• “Non-invasive” procedures when used with the distance gauge for the procedures WE use them for.

• Studies show:
  • Infections for this procedure with this hand piece are related to post procedure environmental pathogen/contamination from an outside source (ie patient finger nails, dirty hands, contaminated moisturizer etc.)
  • Study shows HPV may be isolated from a plume, but not found on the hand piece.

• Steps and parameters for cleaning and disinfection
  ▪ Clean then disinfect
  ▪ What to do when visible debris are present
  ▪ Storage

• Mitigate the risks
  ▪ Don’t use on active infections
  ▪ Clean appropriately
  ▪ Aseptic technique
  ▪ Post procedure care
## Ultrasounds

<table>
<thead>
<tr>
<th>Patient Contact</th>
<th>Examples</th>
<th>Device Classification</th>
<th>Minimum disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intact skin</strong></td>
<td><em>Abdominal ultrasounds</em></td>
<td>Non-Critical</td>
<td>Cleaning with low level disinfection</td>
</tr>
<tr>
<td></td>
<td><em>healthy skin</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mucous Membranes or non intact skin</strong></td>
<td><em>Endocavitary ultrasounds</em>*</td>
<td>Semi-critical</td>
<td>High level disinfection</td>
</tr>
<tr>
<td></td>
<td><em>Unhealthy skin</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sterile areas of the body</strong></td>
<td><em>CVC insertion</em></td>
<td>Critical</td>
<td>Sterilization OR High level disinfection with sterile sheath and sterile gel</td>
</tr>
<tr>
<td></td>
<td><em>biopsies</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Drainages</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>probe contacts</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>puncture site</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>open wound scans</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Locations
Clinics
IR
ED
Cardiology
Surgery
Anesthesiology

Procedures
Aspiration
Drainages
Access
Transvaginal scans
Transrectal scans
Abdominal Injections
Blocks

People
Doctors
Nurse
Practitioners
Residents
Students
Techs
Sonographers
PT
You can do this!!

- I have no idea where to even start!!
- I have heard of this before
- I know where to look
- I have seen this before
- I know all about this!
Questions?
References


https://www.jointcommission.org/issues/article.aspx?Article=ht3SjWOc4PPny4Cr7ZNCloGBxmgG0u8UMjQm6Yb+IOQ=

R.M. Carrico, S. Furmanek, C. English
Ultrasound Probe use and reprocessing: Results from a national survey among U.S. infection preventionists

The Joint Commission Advisory on Safety and Quality Issues
Improperly sterilized or HLD equipment – a growing problem
Available from:
https://www.jointcommission.org/assets/1/23/qs_33a_2017.pdf
Accessed July 1, 2019