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

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Nebraska Medicine

SERIOUS MEDICINE. EXTRAORDINARY CARE.®

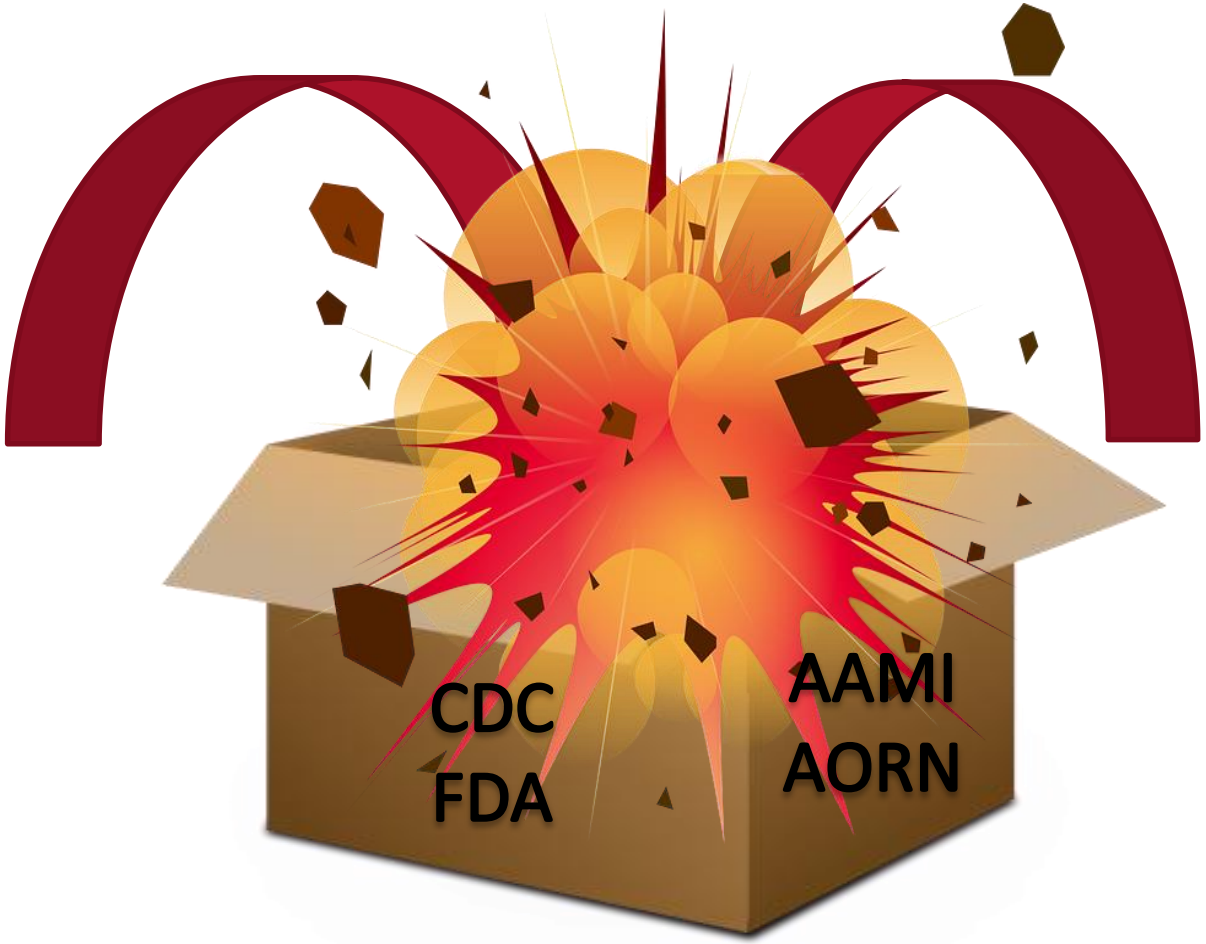
Objectives

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

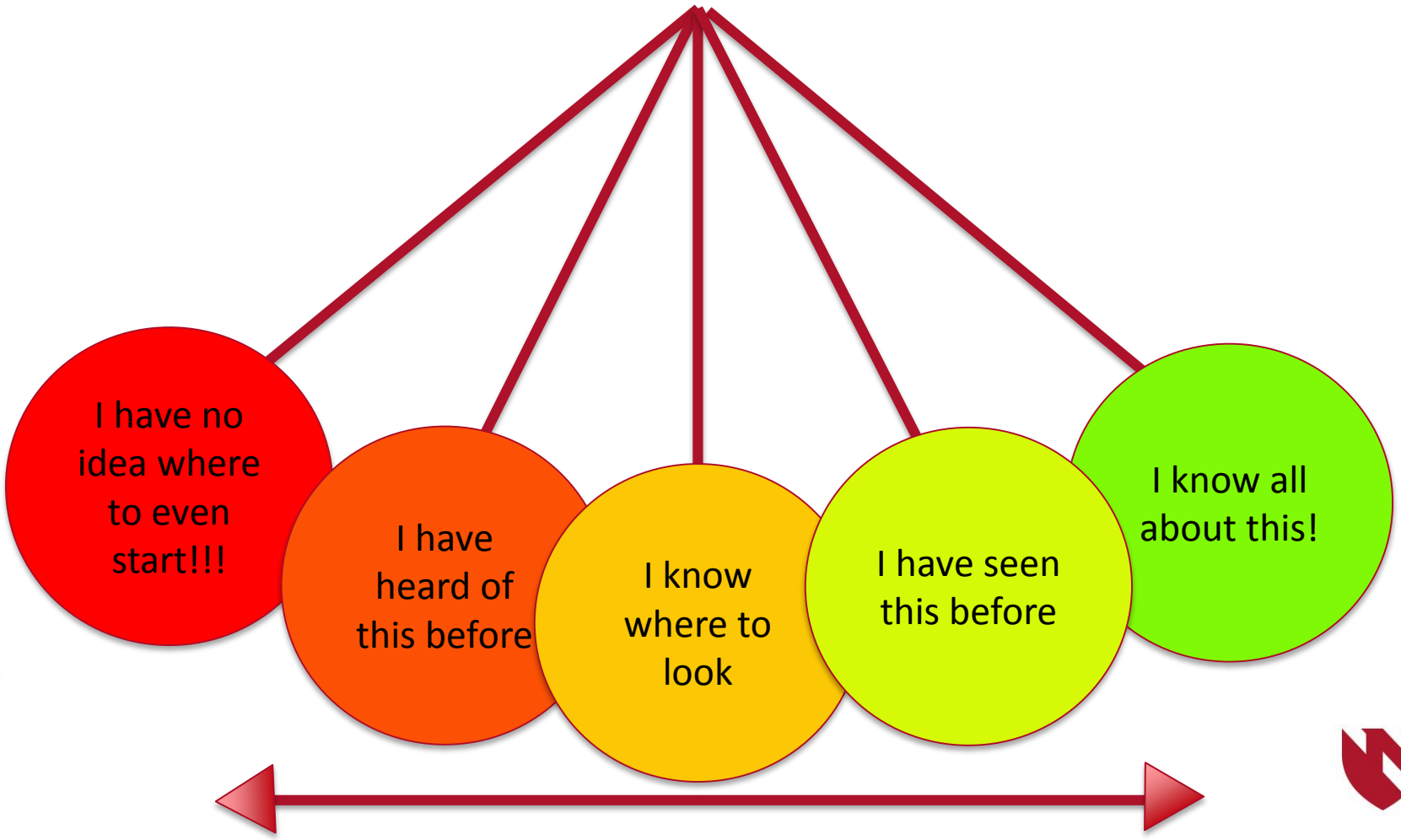
Brand new IP

It is complicated…..



One size doesn’t fit all!

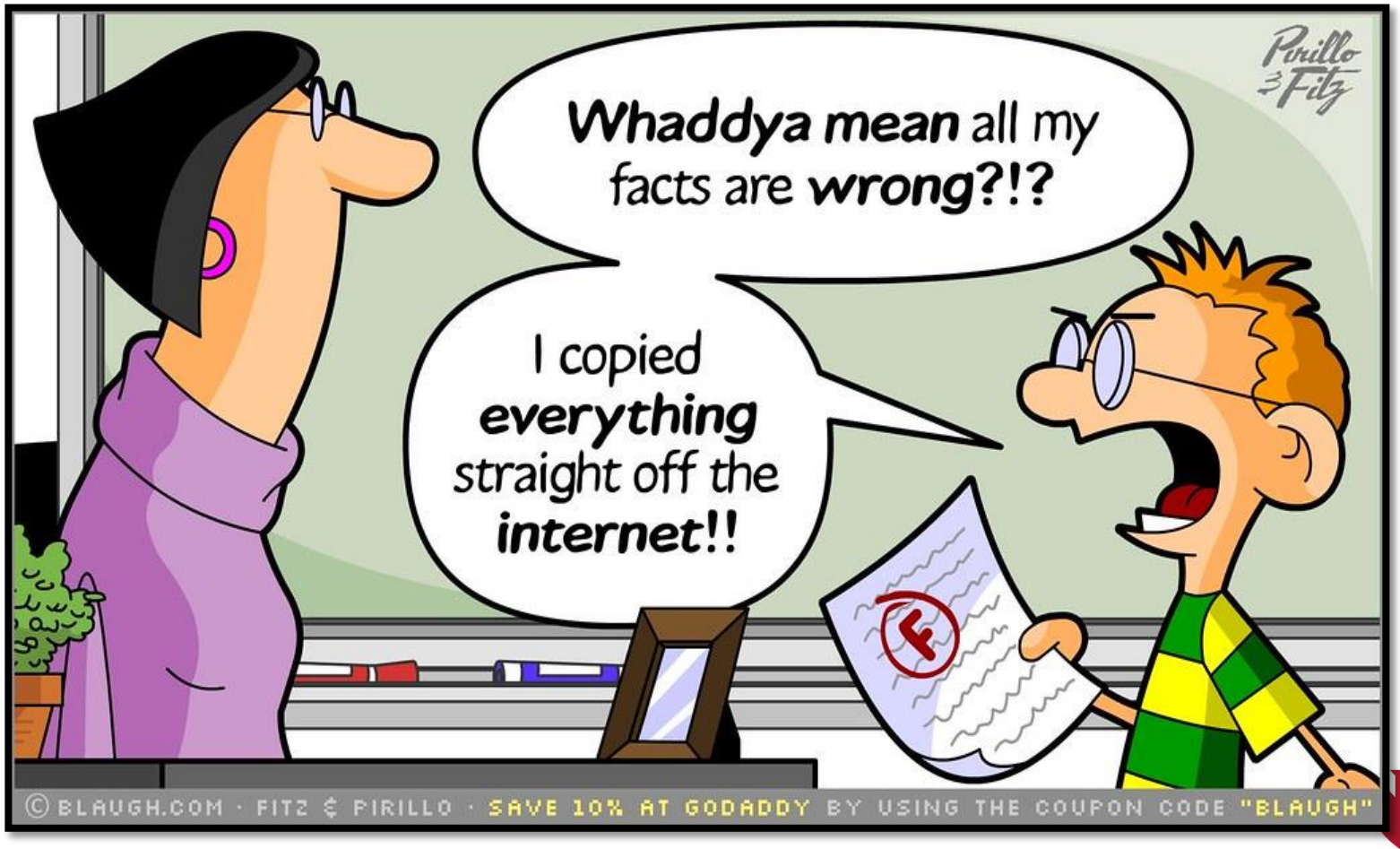
Spectrum of IP wisdom



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?



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

CDC Categories

1A	Strongly recommended strongly supported by research.	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.
1B	Strongly recommended and supported by some research	Discard enzymatic cleaners (or detergents) after each use because they are not microbicidal and, therefore, will not retard microbial growth. Category IB
1C	Required by state or federal regulations. (often paired with other categories)	Educate health-care workers in the selection and proper use of personal protective equipment (PPE). Category II, IC
II	Suggested supported by suggestive studies or theoretical rationale. (60)	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
No Recomm-endation	Unresolved issue: insufficient evidence or no consensus	No recommendation is made about routinely performing microbiologic testing of either endoscopes or rinse water for quality assurance purposes. Unresolved Issue.

Know where to find stuff

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
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

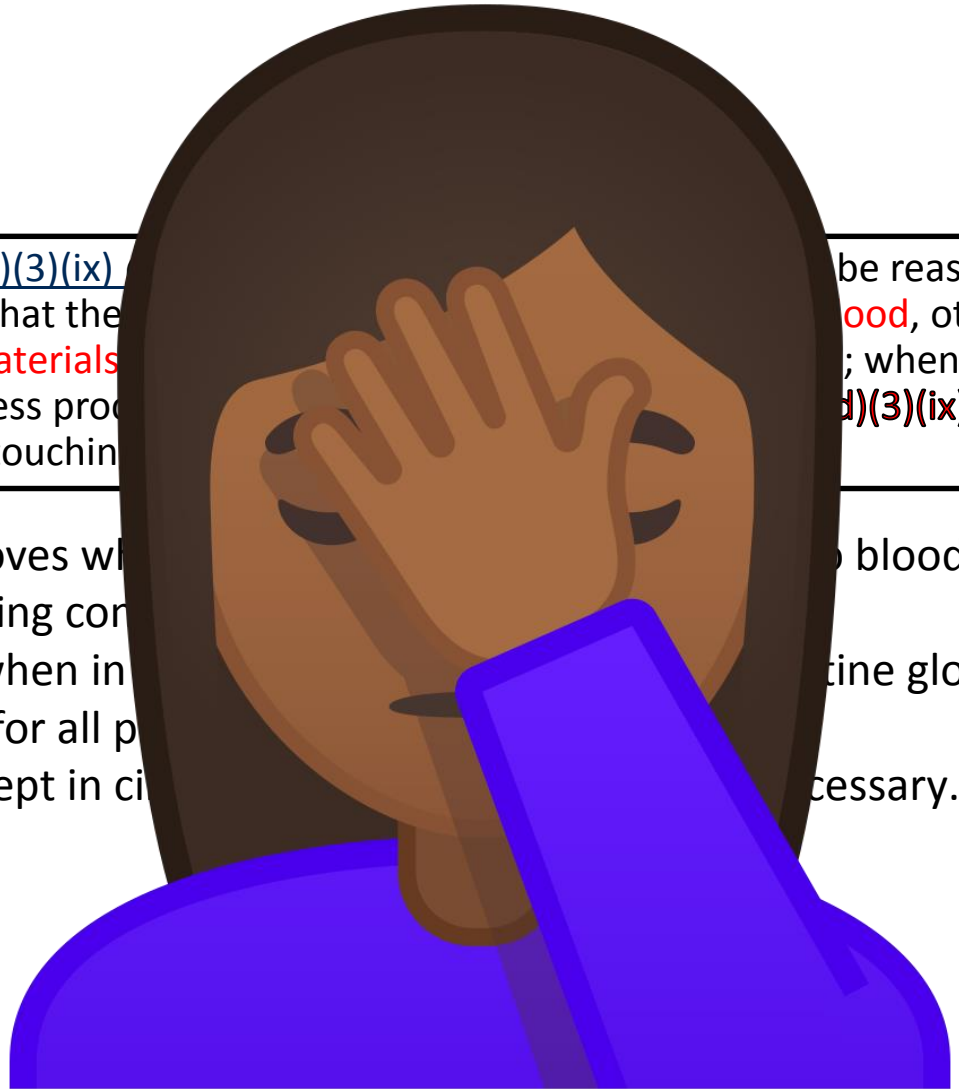
Definitions

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.

1910.1030(d)(3)(ix) (be reasonably anticipated that the ood, other potentially infectious materials ; when performing vascular access proc d)(3)(ix)(D); and when handling or touchin



1. Wear gloves wh blood, fluids, tissues or anything cor
2. Except when in tine gloving is not needed for all p
    1. Except in ci cessary…..

AAMI

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).

You need to dig a little deeper.....

AAMI

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

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Update: May 2019

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 use of the items. 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 Workers*22, and *Guideline for Environmental Infection Control in Health-Care Facilities*23 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 EtO, 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*-phthalaldehyde, 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* species. Cleaning followed by high-level disinfection should 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 undergoes only high-level disinfection between patients. 28-30 As with flexible endoscopes, these devices can be difficult to clean and high-level disinfector sterilize because of intricate device design (e.g., long narrow lumens, hinges). Meticulous cleaning must precede any high-level disinfection or sterilization process. Although sterilization is preferred, no reports have been published of outbreaks resulting from high-level disinfection of these scopes when they are properly cleaned and high-level disinfected. Newer models of these instruments can withstand steam sterilization that for critical items would be preferable to high-level disinfection.

Rinsing endoscopes and flushing channels with sterile water, filtered water, or tap water will prevent adverse effects associated with disinfectant retained in the endoscope (e.g., disinfectant-induced colitis). Items can be rinsed and flushed using sterile water after high-level disinfection to prevent contamination with organisms in tap water, such as nontuberculous mycobacteria, 10, 31, 32 *Legionella*, 33-35 or gram-negative bacilli such as *Pseudomonas*. 1, 17, 36-38 Alternatively, a tapwater or filtered water (0.2µ filter) rinse should be followed by an alcohol rinse and forced air drying. 28, 38-40 Forced-air drying markedly reduces bacterial contamination of stored endoscopes, most likely by removing the wet environment favorable for bacterial growth. 39 After rinsing, items should be dried and stored (e.g., packaged) in a manner that protects them from recontamination.

Some items that may come in contact with nonintact skin for a brief period of time (i.e., hydrotherapy tanks, bed side rails) are usually considered noncritical surfaces and are disinfected with intermediate-level disinfectants (i.e., phenolic, iodophor, alcohol, chlorine) 23. Since hydrotherapy tanks have been associated with spread of infection, some facilities have chosen to disinfect them with recommended levels of chlorine 23, 41.

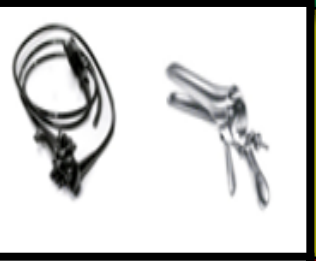
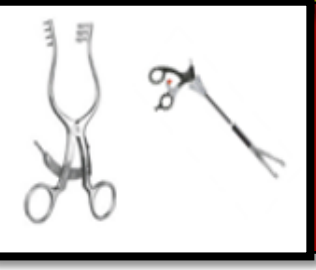
In the past, high-level disinfection was recommended for mouthpieces and spirometry tubing (e.g., glutaraldehyde) but cleaning the interior surfaces of the spirometers was considered unnecessary. 42 This was based on a study that showed that mouthpieces and spirometry tubing become contaminated with microorganisms but there was no bacterial contamination of the surfaces inside the spirometers. Filters have been used to prevent contamination of this equipment distal to the filter; such filters and the proximal mouthpiece are changed between patients.

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 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 products 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.

Noncritcal 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) potentially 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 mopping 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

Spaulding

Patient Contact	Examples	Device Classification	Minimum activation level	Efficacy spectrum
Intact Skin		Non-Critical	Cleaning with low & intermediate disinfection	Most vegetative bacteria & viruses (not including spores, mycobacteria, non-lipid viruses)
Mucous Membranes or non intact skin		Semi-critical	High level disinfection	All microorganisms except spores
Sterile areas of the body- including blood		Critical	Sterilization	All viable microorganisms

AAMI

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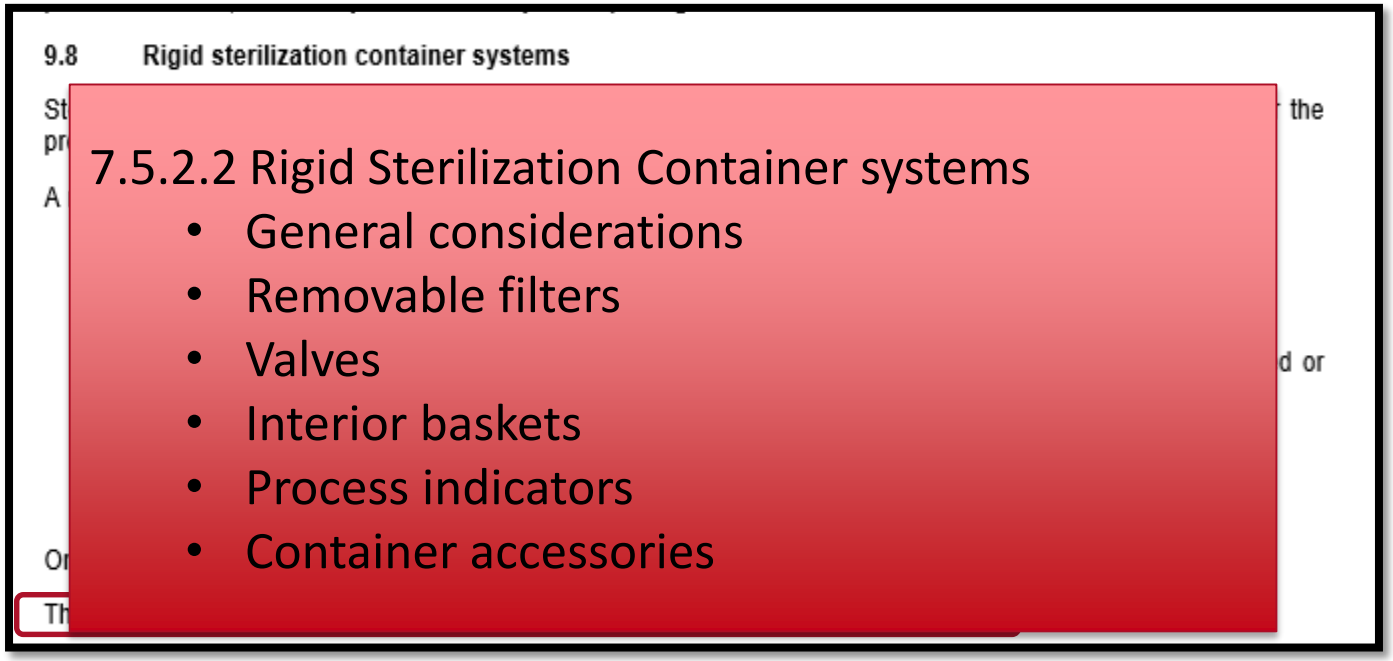
e) the intended use of the device; and

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	Materials
Does it require low level disinfection?	Can it be low level disinfected?
Does it require high level disinfection?	Can it be high level disinfected?
Does it require sterilization?	Can it be sterilized?

More examples from AAMI



9.8 Rigid sterilization container systems

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.

More examples from AAMI

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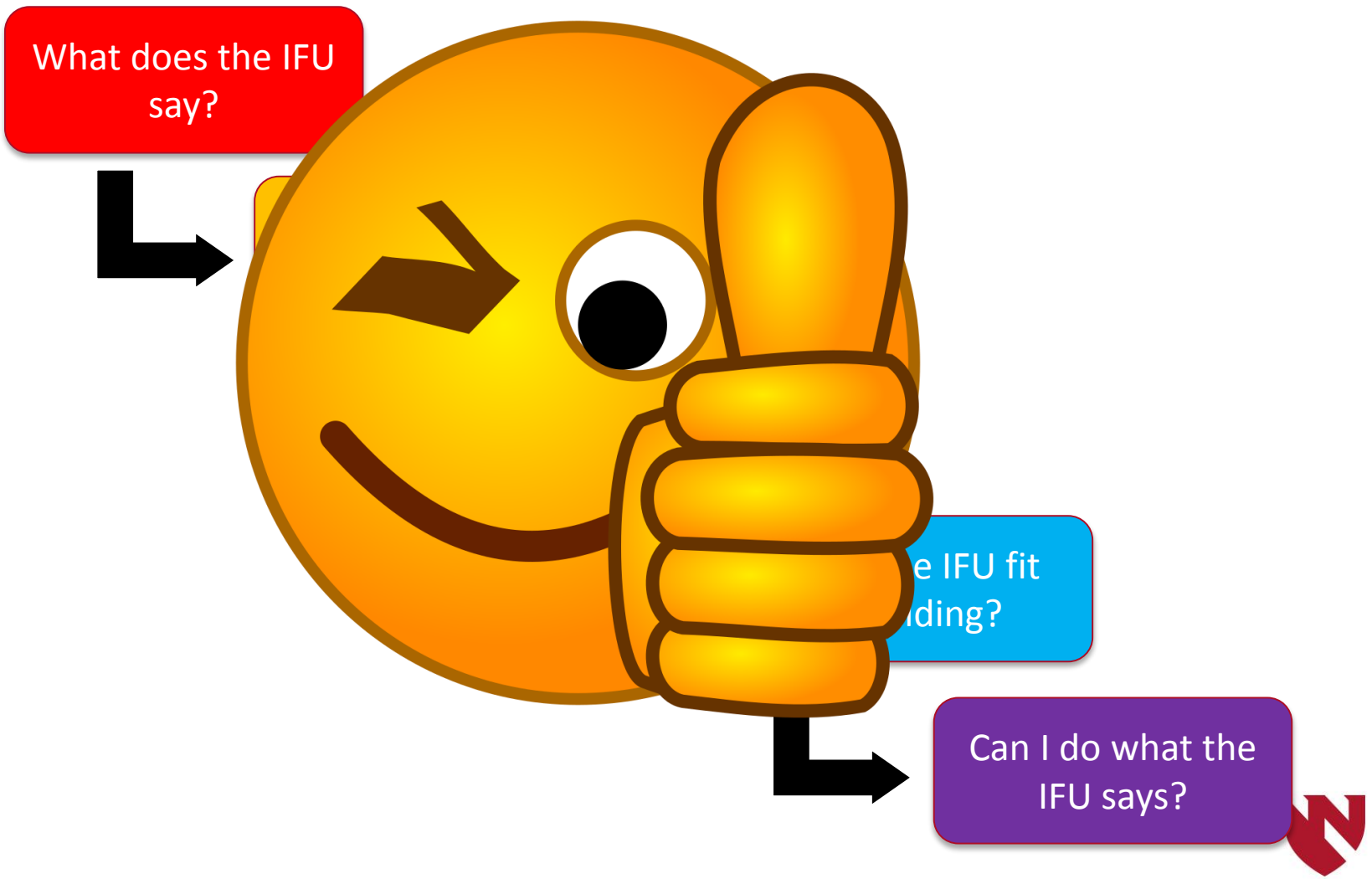
e) Keep the lid closed when the ultrasonic cleaner is in use unless otherwise directed by the device manufacturer's written IFU.

What to do when you cannot fit what the standards require


What does the IFU say?
e IFU fit
ding?
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.

Phase	Minimum Recirculation Time	Water Temperature	Detergent Type and Concentration (If applicable)
Pre-wash	15 Seconds	Cold Drinking Water 1°C - 16°C (33°F - 60°F)	N/A
Enzyme Wash	1 Minute	Hot Drinking Water 43°C - 82°C (110°F - 179°F)	• Detergent: pH-neutral/enzymatic • Concentration: Per the detergent manufacturer's recommendations
Wash	2 Minutes	Drinking Water 43°C - 82°C (110°F - 179°F)	• Detergent: pH-neutral cleanser • Concentration: Per the detergent manufacturer's recommendations
Rinse	15 Seconds	Drinking Water 43°C - 82°C (110°F - 179°F)	N/A
Pure Rinse	10 Seconds	Treated Water 43°C - 82°C (110°F - 179°F)	N/A
Drying	N/A	N/A	N/A

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.

Reference:ANSI/AAMI ST79: (current revision) Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

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?

A HALMA COMPANY

DISINFECTION

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:

Product Type ✓ OK to Use	Alkacide / Alkazyme	**Bleach Solutions (Sodium Hypochlorite)	Bode Mikorbac Tissues	CaviWipes	*Cidex OPA	*Glutaraldehyde	Perasafe	*Revital-Ox™ Resert XL® HLD	Tristel Duo
BIO Lenses (Black & All Colors)		✓	✓	✓	✓	✓	✓		✓
BIO Lenses (ACS)		✓	✓	✓	✓	✓	✓		✓
Classic Series Lenses (Black & All Colors)		✓	✓	✓	✓	✓	✓		✓
Super & Digital Series Lenses (Black & All Colors)		✓	✓	✓	✓	✓	✓		✓
Mirrored Lenses (3-Mirror Lenses, Mini 4-Mirror Lens, & SLT)	✓	✓	✓	✓	✓	✓		✓	✓
G-Series Gonio Lenses		✓	✓	✓	✓	✓		✓	✓
Contact Lenses		✓	✓	✓	✓	✓			✓
Research Lenses			✓	✓	✓	✓			
Vitrectomy Surgical Lenses - Traditional		✓	✓	✓	✓	✓			✓
Vitrectomy Surgical Lenses - ACS		✓	✓	✓	✓	✓			✓
Surgical Lens Access:		✓	✓	✓	✓	✓			✓
Sterilization Cases		✓	✓	✓	✓	✓			✓

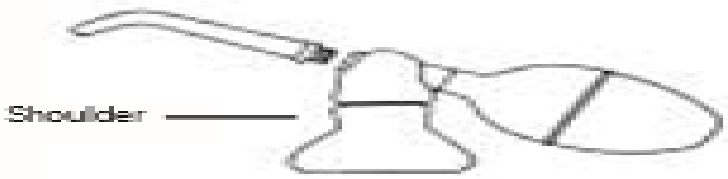
Mucous Membranes or non intact skin		Semi-critical	High level disinfection	All microorganisms except spores

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.

What does the IFU say?

What is the Spaulding Class?

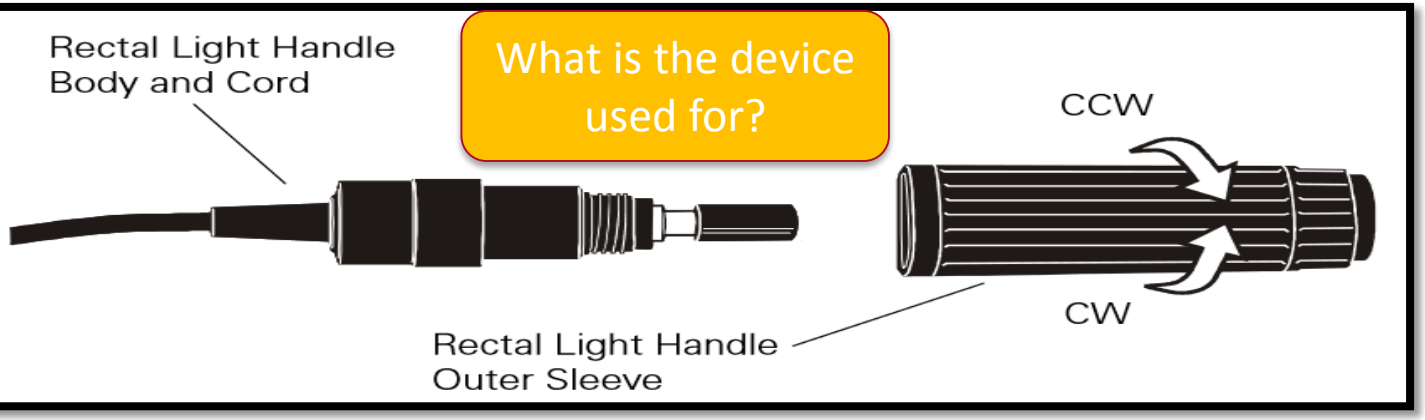
Does the IFU fit Spaulding?

Can I do what the IFU says?

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.



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

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

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 sporicidal. 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) [43, 214, 215].

TECHNICAL DATA BULLETIN

Sani-Cloth® AF3
GERMICIDAL DISPOSABLE WIPE

EPA Reg. No. 9480-9

PRODUCT DESCRIPTION

Sani-Cloth® AF3 Germicidal Disposable Wipe 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 (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chlorides	0.14%
n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chlorides	0.14%
Other ingredients	99.72%
TOTAL	100.00%

Each cloth is saturated with 2,800 parts per million of active quaternary ammonium chlorides.

EFFICACY

BACTERIAL ORGANISM EFFICACY

MULTI-DRUG RESISTANT BACTERIA:

Acinetobacter baumannii, Multi-Drug Resistant [ATCC 19606]
ESBL Producing *Escherichia coli* (*E. coli*) [ATCC BAA-196]
Escherichia coli – NDM-1 Positive [CDC 1001728]
ESBL Resistant *Klebsiella pneumoniae* [ATCC 700603]
Klebsiella pneumoniae · Carbapenem Resistant [ATCC BAA-1705]
Klebsiella pneumoniae · NDM-1 Positive [CDC 1000527]
Community Acquired Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) [NARSA NRS384] [Genotype USA 300]
Community Acquired Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) [NARSA NRS123] [Genotype USA 400]
Methicillin Resistant *Staphylococcus aureus* (MRSA) [ATCC 33592]
Streptococcus pneumoniae – Penicillin Resistant [ATCC 700677]
Vancomycin Resistant *Staphylococcus aureus* (VRSA) [NARSA VRS1]
Vancomycin Resistant *Enterococcus faecalis* (VRE) [ATCC 51575]

Test Method Used:	Modified AOAC Germicidal Spray Method for Hard Surface Disinfection
Organic Soil Load:	5% Fetal Bovine Serum
Exposure Time:	3 minutes at 68-69.8°F
Incubation:	2-8 days at 95-98.6°F
Results:	No growth observed

BACTERIA:

Bordetella bronchiseptica [ATCC 10580]
Bordetella pertussis [ATCC 12743]
Burkholderia cepacia [ATCC 25416]
Campylobacter jejuni [ATCC 29428]
Enterobacter aerogenes [ATCC 13048]
Escherichia coli [ATCC 11229]
Escherichia coli O157:H7 [ATCC 35150]
Klebsiella pneumoniae [ATCC 4352]
Listeria monocytogenes [ATCC 19111]
Proteus vulgaris [ATCC 9920]
Pseudomonas aeruginosa [ATCC 15442]
Salmonella enterica [ATCC 10708]
Serratia marcescens [ATCC 14756]
Shigella dysenteriae [ATCC 11835]
Staphylococcus aureus [ATCC 6538]
Streptococcus pyogenes [ATCC 19615]
Vibrio cholera [ATCC 11623]
Yersinia enterocolitica [ATCC23715]

Test Method Used:	Modified AOAC Germicidal Spray Method for Hard Surface Disinfection
Organic Soil Load:	5% Fetal Bovine Serum
Exposure Time:	3 minutes at 68-69.8°F
Incubation:	2-6 days at 95-98.6°F
Results:	No growth observed

MYCOBACTERIUM BOVIS - BCG (TB):

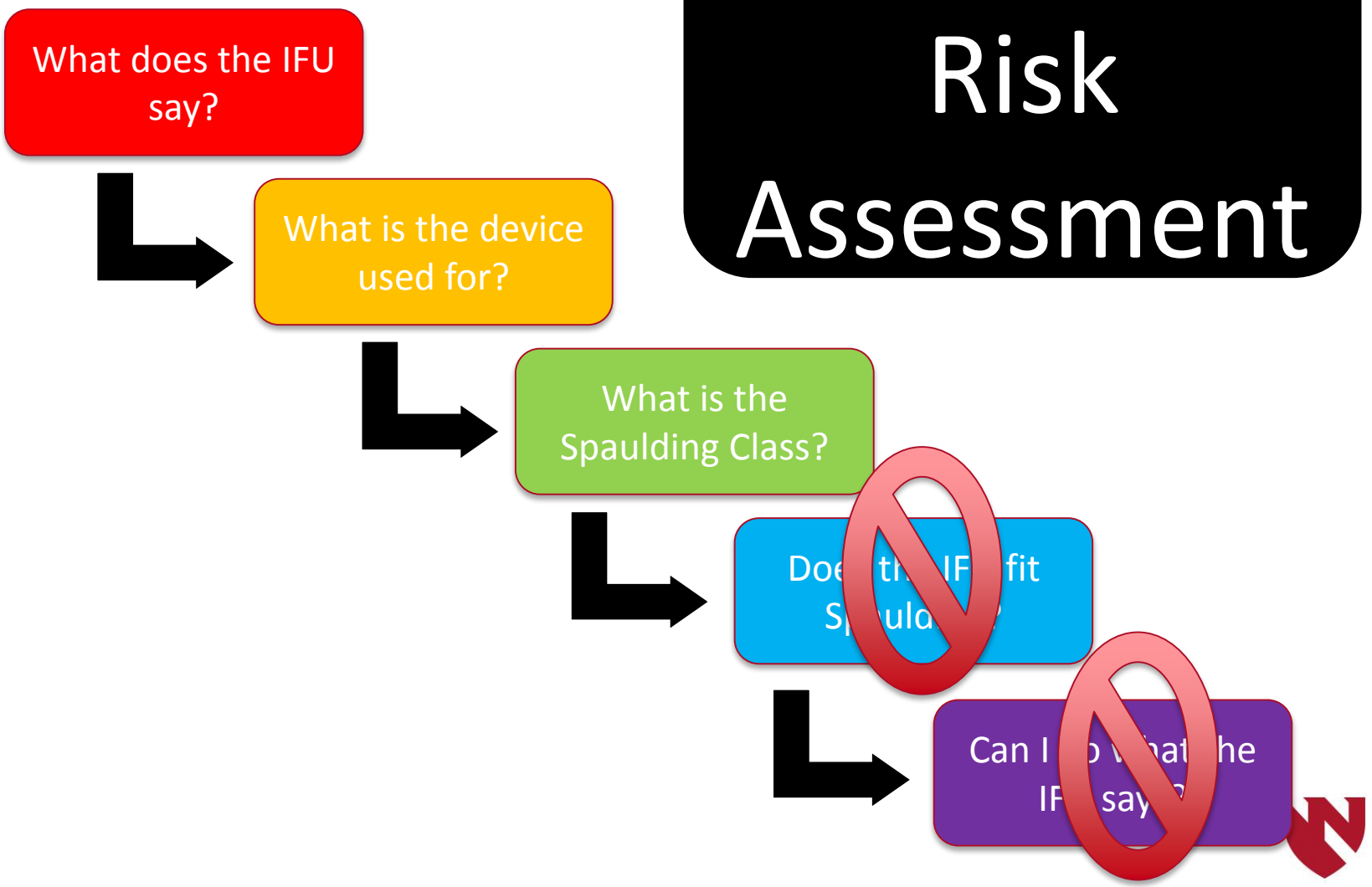
Test Method Used:	Modified AOAC Tuberculocidal Method for Pre-saturated Towelettes for Hard Surface Disinfection
Organic Soil Load:	5% Horse Serum
Exposure Time:	3 minutes at 68°F
Incubation:	90 days at 98.6°F
Results:	No growth observed

PATHOGENIC FUNGI EFFICACY

YEAST ORGANISM: Candida albicans [ATCC 10231]

Test Method Used:	Modified AOAC Germicidal Spray Method for Hard Surface Disinfection
Organic soil load:	5% Fetal Bovine Serum.
Exposure Time:	3 minutes at 69.8°F
Incubation:	3 days at 77.86°F
Results:	No growth observed

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.

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

LOW-LEVEL DISINFECTION INSTRUCTIONS
(For Limited Reuse and Reusable Cuffs Only)
Exposed surfaces of the cuff withstand the successive number of disinfection cycles shown below with no apparent negative effect.

CUFF STYLE	DISINFECTION CYCLES ALLOWED
SOFT-CUF	1000
CLASSIC-CUF	1000
SENSA-CUF	1500
DURA-CUF	2000

1. Fill a spray bottle with Enzymatic detergent, such as ENZOL® enzymatic detergent (US) or Cidezyme® 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 soultion 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

Laser -Cleaning

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†) 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.

Laser- Cleaning

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.

Lasers
Disinfection and Sterilization

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 *CO_2RE* 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

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

Typical Gravity cycle:

250°F for 30 minutes exposure	15–30 minutes dry time
270°F for 15 minutes exposure	15–30 minutes dry time
275°F for 10 minutes exposure	30 minutes dry time

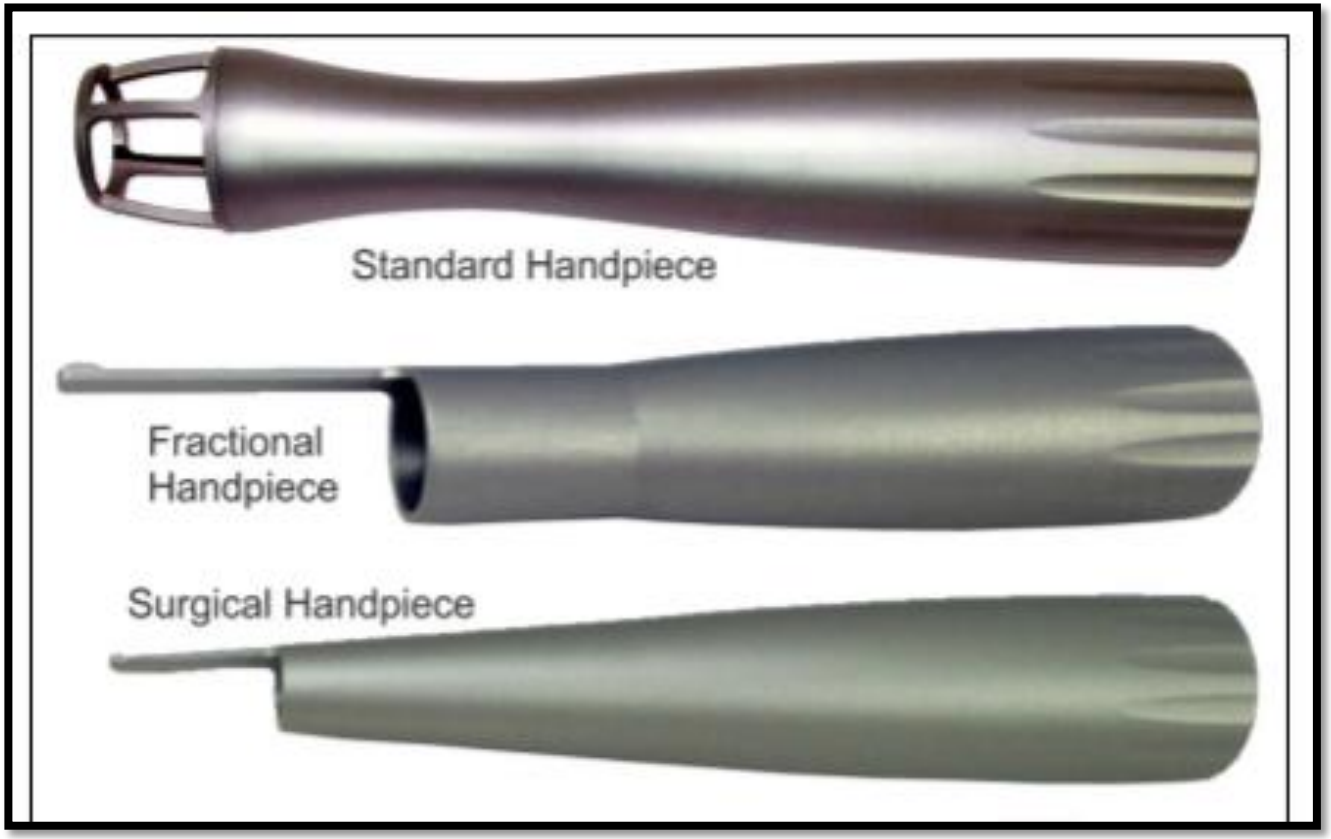
1.7.4. Surgical Safety

- 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?

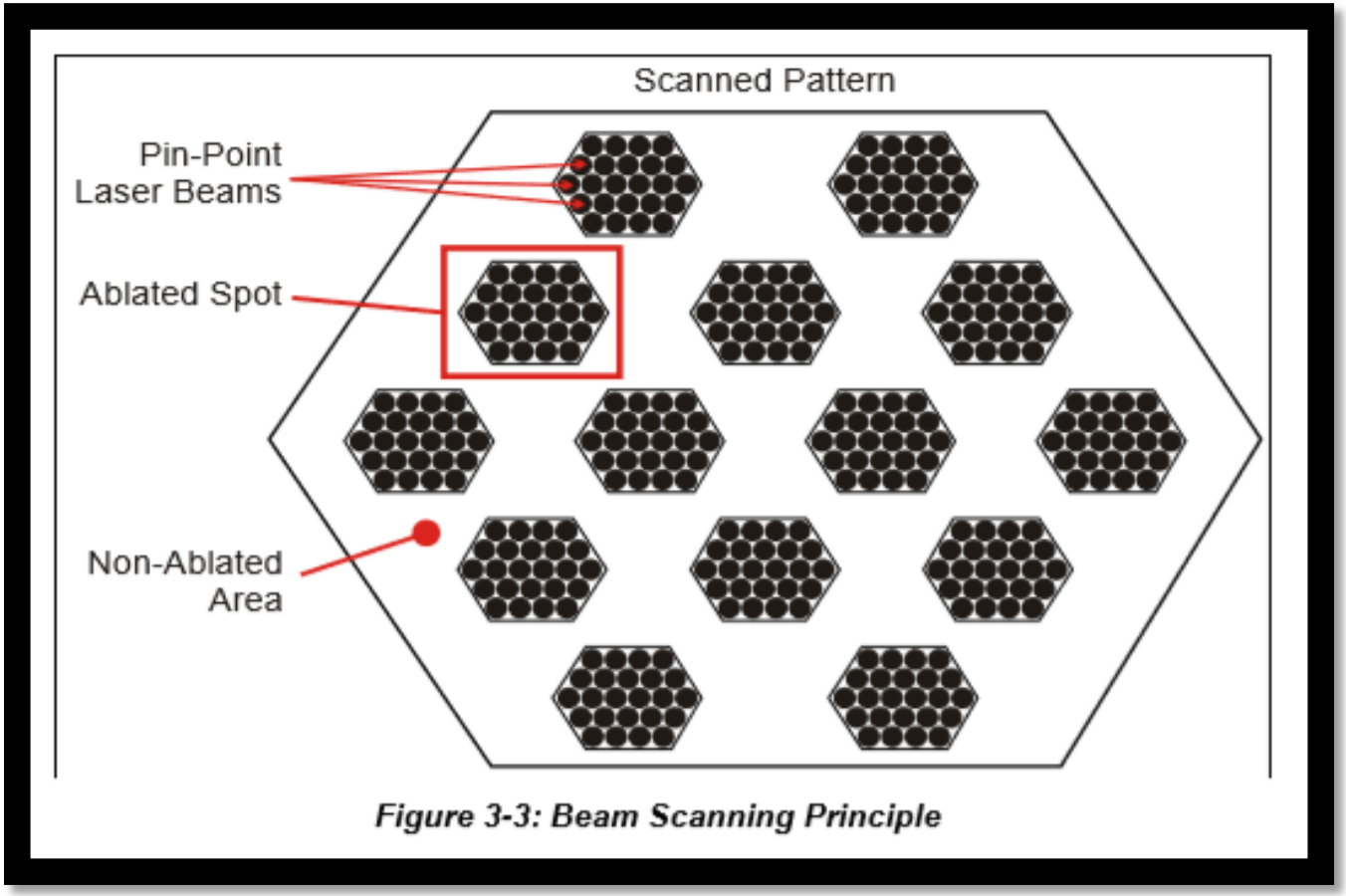
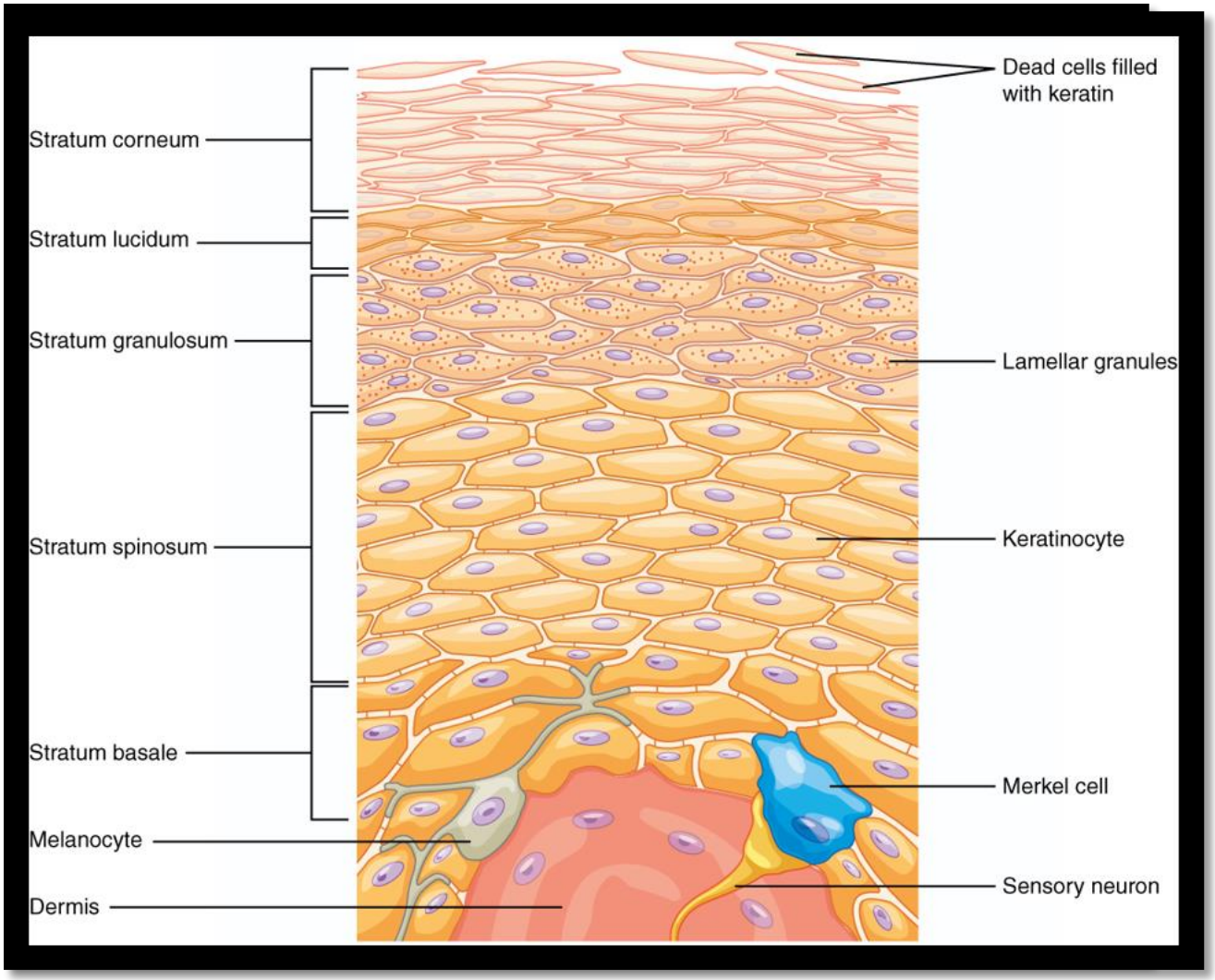


Figure 3-3: Beam Scanning Principle

Dig a little deeper



Handpiece conclusions

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

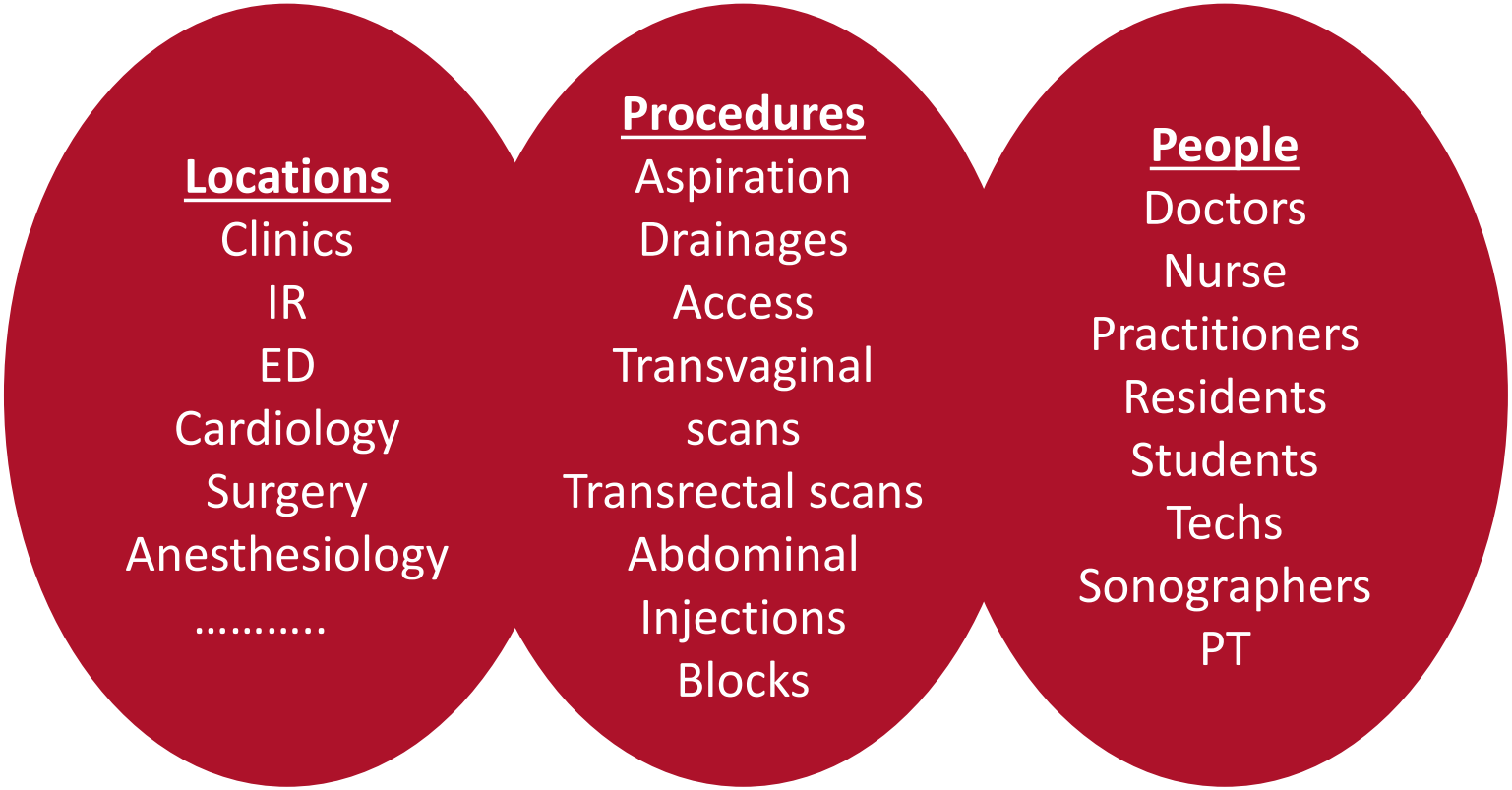
- Studies show:
  - Infections for this procedure with this hand piece are related to post procedure environmental pathogen/contamination from an outside source (ie patient finger nails, dirty hands, contaminated moisturizer etc.)
  - Study shows HPV may be isolated from a plume, but not found on the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

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

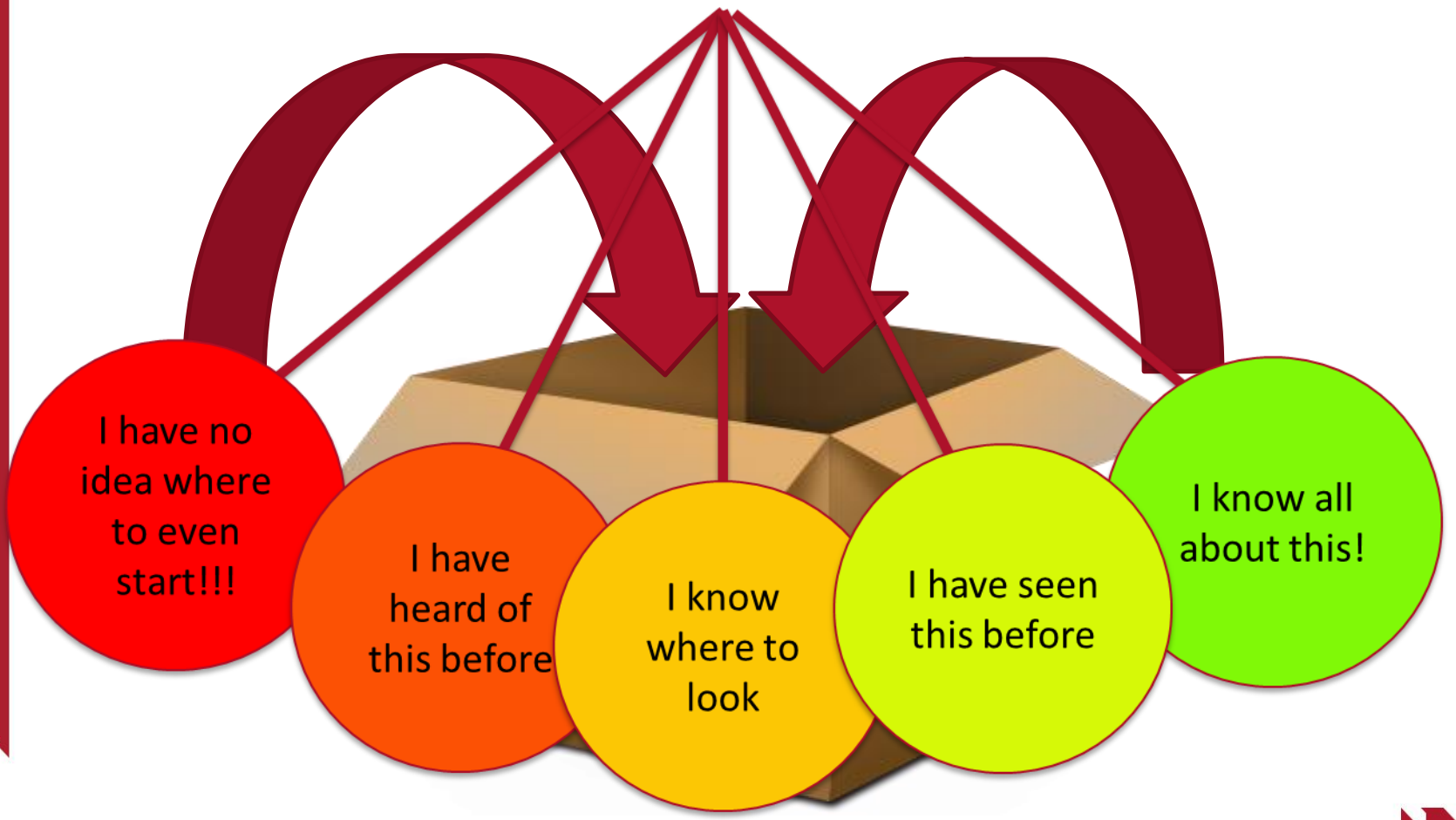
- Mitigate the risks
  - Don’t use on active infections
  - Clean appropriately
  - Aseptic technique
  - Post procedure care

Ultrasounds

Patient Contact	Examples	Device Classification	Minimum disinfection
Intact skin	• Abdominal ultrasounds • healthy skin	Non-Critical	Cleaning with low level disinfection
Mucous Membranes or non intact skin	• Endocavitary ultrasounds** • Unhealthy skin	Semi-critical	High level disinfection
Sterile areas of the body	• CVC insertion • biopsies • Drainages • probe contacts puncture site • open wound scans	Critical	Sterilization OR High level disinfection with sterile sheath and sterile gel


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!!



Questions?

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The Joint Commission Advisory on Safety and Quality Issues
Improperly sterilized or HLD equipment – a growing problem
Available from:
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Accessed July 1, 2019