Objectives

- To discuss breaches in processing of flexible scopes
- To identify best practices in the reprocessing of flexible scopes
- To review sterilization for immediate use
- To discuss best practices for processing of devices from known or suspect CJD patients

Issues

- "Endoscopes are the "grandfather" of all specialty devices"
- Most instances of nosocomial infections occurring through instrumentation is caused by flexible fiber optic scopes
- Dealing with microbes that are more resistant than ever
- Lack of properly trained personnel
- Endoscopes very expensive – pressure to book as many cases as possible
  ◦ Reduced reimbursements
  ◦ Cleaning suffers when time is short
- JC focusing on endoscopes =, laryngoscopes handles and blades and Immediate Use sterilization

Breaches

- Infections with carbapenem-resistant Enterobacteriaceae (CRE) are increasing among patients in medical facilities.
- CRE that produce Klebsiella pneumoniae carbapenemase (KPC) have been responsible for much of the increase in the United States.
- However, New Delhi metallo-β-lactamase (NDM)-producing CRE have the potential to add to this burden.
- Since first reported in 2009, through 2012, 27 patients with NDM-producing CRE have been confirmed by CDC from isolates submitted by state laboratories.
- Since January 2013, a total of 69 patients with NDM-producing CRE have been identified in the United States; 44 patients were from northeastern Illinois.

Endoscopes in the News

- Multiple Outbreaks of a “Nightmare Bacteria’ Linked to Contaminated Endoscopes in the U.S and Europe: Has a Smoking Gun Been Found?”
- HCMC tells 2,600 patients device wasn’t properly disinfected. The risk associated with the ultrasound endoscope is low, the hospital said, but it informed those affected. (June 22, 2010)

Endoscopes in the News

- Seattle Children’s Hospital Investigated Over Dirty Instruments 01/24/2014
- Scopes used during colonoscopies were found to have been cleaned improperly at Seattle Children’s Hospital.
- As a result of the oversight, approximately 100 children are at risk. Following an investigation by the hospital, a lapse in the facility’s cleaning process was discovered.
3M Study of Endoscopes

- A new study discovered that an average of 15 percent of flexible endoscopes used to examine GI tracts and colons at five hospitals were harboring "bio-dirt"—cells and other material from previously examined patients. This was even after the instruments had been cleaned.

- Study author Marco Bommarito, Ph.D., lead research specialist at 3M’s infection prevention division. Published 6/7/2013

Breaches

- About 10,000 patients who underwent endoscopies at three U.S. Veterans Affairs hospitals between 2003 and 2009 were warned four years ago that they might have been exposed to blood-borne pathogens from contaminated instruments.

- In 2010, the Palomar Medical Center in San Diego notified 3,400 patients that they could receive free tests for diseases after having had endoscopies with potentially dirty equipment.

- Researchers for the study analyzed 275 flexible duodenoscopes, gastroscopes and colonoscopes. They found a cleanliness failure rate of 30 percent, 24 percent and 3 percent for each type of those endoscopes respectively.

CDC

- Approximately 46.5 million surgical procedures* and even more invasive medical procedures—including approximately 39 million gastrointestinal endoscopies**—are performed each year.

- Each procedure involves contact by a medical device or surgical instrument with a patient’s sterile tissue or mucous membranes.

- A major risk of all such procedures is the introduction of pathogens that can lead to infection

Issues

- A major risk - introduction of pathogens that can lead to infection.

- Failure to properly disinfect or sterilize equipment carries not only risk associated with breach of host barriers but also risk for person-to-person transmission (e.g., hepatitis B virus) and transmission of environmental pathogens (e.g., Pseudomonas aeruginosa). [CDC]

Factors Impacting on HLD/Sterilization

- Cleaning of the devices

- Organic and inorganic load present
  - E.g. type and level of microbial contamination

- Concentration of and exposure time to the germicide

- Physical nature of the object (e.g., crevices, hinges, and lumens)

- Presence of biofilms

- Temperature and pH of the disinfection process
Cleaning
- **Cleaning** - removal of visible soil (e.g., organic and inorganic material) from objects and surfaces
  - Can be performed manually or mechanically using water with detergents or enzymatic products
- Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.
  - Sterilant or HLD cannot make direct contact with all surfaces of the device

Type and Level of Microbial Contamination
- Flexible endoscopes acquire high levels of bioburden (population of viable microorganisms on a product and/or a package – AAMI ST-79) because of the cavities they enter
- CDC reports that the bioburden found on flexible gastrointestinal endoscopes after use has ranged from $10^5$ to $10^{10}$ (10,000,000,000– bil)

Chemicals
- FDA maintains a list of cleared liquid chemical sterilants and high-level disinfectants that can be used to reprocess heat-sensitive medical devices, such as flexible endoscopes
- Always follow the chemical manufacturer’s instructions for use

Microbial Contamination
- Highest levels found in the suction channels
- Studies have shown that proper cleaning reduces the level of microbial contamination by 4–6 log (safe to handle)

Microbial Contamination
- The highest level of microbial contamination is found in suction channels

Disease Transmission
- Major reasons for transmission were:
  - Inadequate cleaning
  - Improper selection of a disinfecting agent
  - Failure to follow recommended cleaning and disinfection procedures
  - Flaws in endoscope design or automated endoscope reprocessors
Factors Affecting Cleaning/HLD

- Design flaws
- Damage from use/handling
- Different designs
  - Bronchoscope – frequent flushing of liquid through suction channel into lung. Highest risk of transmitting infection from patient to patient
  - Colonoscope – most physical abuse due to insertion path; most frequently needs repair
  - Duodenoscope – side-viewing; invasive procedures; hardest to clean

Factors Affecting Cleaning/HLD

- Number and Location of Microorganisms
  - The larger the number of microbes, the more time a germicide needs to destroy all of them
  - Reinforces the need for scrupulous cleaning of medical instruments before disinfection and sterilization.
  - Reducing the number of microorganisms that must be inactivated through meticulous cleaning
    - Increases the margin of safety when the germicide is used according to the labeling
    - Shortens the exposure time required to kill the entire microbial load

Proper Protocols for Reprocessing Flexible GI Scopes

- Available Resources
  - SGNA
  - ASGE
  - AAMI (ST-58)
  - AORN
  - Multi-Society Guideline
  - CDC
- There are approximately 34 steps in the cleaning process.
  - None can be overlooked.

Pre-Treatment in the Procedure Room

- After removal of scope from patient and while still wearing PPE:
  - Wipe external surface of insertion tube with wet cloth and enzymatic solution (diluted properly)
  - Dispose of cloths between patients
  - Place distal end of scope in enzyme detergent
  - Suction solution through biopsy/suction channel until solution visibly clean

Transport of Used Scopes

- Should alternate suctioning fluid and air rather than fluid alone - helps to remove debris from lumens
- Immediate flushing of biopsy/suction channels helps prevent drying of organic and inorganic debris in lumens

Transport of Used Scopes

- Transport to Decontam room in enclosed container or biohazard bag (avoid tightly coiling scope in transit)
Transport of Used Scopes
- Transport containers should be disinfected after each use
- Reprocessing should not take place in the procedure room

Multiple Channels
An endoscope may contain internal channels. Just like the outside of the endoscope, these internal channels can become contaminated with microorganisms.

Manufacturer’s Instructions
- **NEVER** reprocess a scope without written instructions from the scope manufacturer
- Use the cleaning agents, cleaning implements and disinfecting/sterilizing agents VALIDATED by the manufacturers

Decontamination
- Must wear PPE (gloves, impervious gown, eye protection, head cover)
- Perform leak test following scope manufacturer’s instructions - must be performed before immersion of the scope into cleaning solutions to prevent damage

Leak Testing
- Leak testing before fully immersing scope in fluid is the single most effective means of preventing flexible scope damage due to fluid invasion.
- Follow scope manufacturer’s instructions for process.

Powered Leak Testers
- Electric powered leak testers are preferable because they provide a continuous flow of air that prevents fluid from invading the scope during inspection.
Manual Leak Testers

- If using the hand-operated leak tester, extra care and time must be taken.

Damage from Fluid Invasion

Decontamination

- Follow scope manufacturer’s instructions if leak detected
- MANUAL cleaning MUST be performed before any automated cleaning
- What about reprocessors validated for no pre-cleaning?!

Decontamination

- Do not reuse cleaning solution - make fresh solution for each scope
- Use cleaning brush for one scope
- If single use, discard
- If reusable, clean and disinfect before reuse

Enzyme Detergents

- May be affected by
- concentration
- Water quality
- Temperature of solution
- Should monitor water temperature

Sinks

- Sinks should not be so deep that personnel must bend over to clean instruments.
- An ideal decontamination sink is approximately 36 inches (91 centimeters [cm]) from the floor and 8 to 10 inches (20 to 25 cm) deep, enabling a person of average size to work comfortably without undue strain on his or her back;
  - foot stools should be readily available to accommodate shorter employees.
Sink Requirements

Sinks
- Must be large and deep enough to fully immerse scope
- Should be located in separate room where all cleaning is performed

Decontamination
- Elevator channels - require special attention
- Very small lumens - cannot be cleaned properly in automated system alone
- Need to use 2-5ml syringe to flush out channels x 3 times
- Despite adapters for automated systems still must be manually cleaned first

Elevator Channel
- Fine wire of elevator channel

Detergent Use
- Discard enzymatic cleaners (or detergents) after each use because they are not microbicidal and, therefore, will not retard microbial growth

Automated Flushing
- Provides consistency in pressure used
- Less repetitive motion for staff
- Alternative is to flush all recommended channels with syringe times 3.
Automated Flushing Device

Automated Flushing
- Units available to facilitate flushing
- Eliminates human factor
- Units need to be tested daily for proper volume of water
- Units may require decontamination
- Tubing requires decontamination
  - Document the pressure testing and decontamination

High Level Disinfection/Sterilization
- Should be performed in a separate room from the cleaning
- Issues with cross contamination
- HLD accepted as the standard for GI scopes
  - More cost effective
  - Quicker turn around
- Need for sterilization of GI scopes due to C. difficile not substantiated by scientific evidence

HLD Room

Automation
- Units can
  - Clean only
  - Disinfect only
  - Clean and disinfect
  - Sterilize only
- Check mfrs instructions before purchasing

Automated Cleaning
- Place endoscope and all accessories in soaking basin
- Start machine and allow to complete all cycles
- If a final alcohol rinse is not included in the automated re-processor, this step should be done manually followed by purging all channels with air
Automated Reprocessor

Connection to correct adapter critical

Automated Endoscope Reprocessors
- Cycles of
  - Leak testing
  - Wash – enzymatic detergent
  - Reused or single use HLD
  - Filtered water rinse
  - Alcohol rinse
  - Dry

AERs vs Manual Process
- Automated endoscope reprocessors (AER) offer several advantages over manual reprocessing
  - Automate and standardize several important reprocessing steps
  - Reduce the likelihood that an essential reprocessing step will be skipped
  - Reduce personnel exposure to high-level disinfectants or chemical sterilants.

Manual High Level Disinfection
- Follow manufacturer’s instructions
- Verify efficacy of the solution (MEC testing) before each use – document results
- Some strip mfrs recommend QA testing of the test strips – document results
- Time soak using a timer
- At end of soak time purge all high level disinfectant from all channels using forced air

Manual HLD
- Completely immerse the endoscope in the high-level disinfectant, and ensure all channels are perfused.
- As soon as is feasible, phase out nonimmersible endoscopes

Full Immersion
High Level Disinfection

- Rinsing - must be thoroughly rinsed
- Usually 3 separate rinses
- Do not re-use water. Fresh water for each rinse
- Sterile water preferred since tap water is not pure

Delayed Reprocessing

- If reprocessing is delayed beyond one hour, extended soaking/cleaning protocols may be required.
- Follow the scope manufacturer's instructions for delayed reprocessing.
- Can occur when scopes are used on Nursing Units or ER during off hours. What is the process for ensuring these scopes get cleaned within an hour?

Drying

- Purge all channels with air (P. Aeruginosa loves to live in moist environment!)
- Flush all channels with alcohol
- Alcohol purges should be used even when sterile water is used for rinsing
- Purge all channels with air. Remove all adapters

Drying/Storage

- Dry exterior of scope with lint free towel
- Rinse and dry all removable parts. DO NOT RE-APPLY
- Store hung in a vertical position with no coils
- Should be in dust free, well-ventilated closet

Drying/Storage Cabinet

- Attach label to document scope cleaned/HLD (CDC)
- AORN recommends that a scope that has not been used for 5 days should be completely reprocessed before use (RP 2009)
Storage Cabinets
- Some have sealed cabinets
- May have dessicate bags to remove humidification
  - Must follow instructions for removal of moisture from bags – one mfr recommends microwaving

Accessories
- Re-usable biopsy forceps will penetrate mucosal barriers therefore they must be sterile for each patient
- Requires ultrasonic cleaning to clean in between coils of wire
- Must be sterilized - most can be done in steam
- Do NOT process accessories in AER unless validated

Documentation
- Maintain Log with the following information
  - Name of Patient
  - Medical Record #
  - Document scope cleaned
  - Document the HLD/sterilization process
  - Procedure

Documentation
- Endoscopist
- Serial # of the scope used – track to patient
- Mechanism to verify scope was processed before placing in storage
  - Tag
  - Identify date, name of person performing the process

Tag for Processed Scopes

HIGH LEVEL DISINFECTION FORM
Date:____________________________
CLEANED BY____________________________
Time in____________________________
Time Out____________________________
Total Soak____________________________
HLD by____________________________

DESCRIPTION OF ITEM
Scope Serial # (if applicable)
CLEANED BY (MDC)
Time in
Time Out
Total Soak
HLD by

TAG FOR PROCESSED SCOPES
CLEANED THEN
High Level Disinfected
With OPA
Date:
Initials: ______________________
Remove Tag Before Use
Channel Check

- Product capable of testing virtually any lumened instrument for residual organic soils, including flexible endoscopes, no matter the channel size.
- Tests for three common organic soils at once: blood, protein and carbohydrates.

Training and Competencies

- All personnel processing flexible scopes and accessories must be thoroughly trained and competent.
- General Scope Competency
- Scope specific competencies
- AER competencies
- HLD competencies

Reminders

Verify competencies before personnel process scopes independently.
Perform annual competencies on all scope processing personnel.
Use “tell one, show one, do one” method for teaching.
Encourage certification for processing personnel (www.sterileprocessing.org).
- Certified Flexible Endoscope Reprocessor.

Important Reminder

- Enzyme solution should only be used ONCE (for one patient) then discarded.
- Use brushes of correct diameter to ensure thorough cleaning of all internal lumens.
- Only use brush for one scope and discard or clean/disinfect.

Reminders

- Follow all scope manufacturer’s instructions for use carefully – keep on file in processing area (one copy in Decontam, one in clean area).
- Follow the HLD/sterilant mfrs instructions for use:
  - Water quality
  - Soak time
  - Temperature of solution/concentration.

Reminders

- Use specific brushes as recommended.
- Use brushes for one patient then discard or reprocess.
- Verify all adapters are compatible with the scope being processed.
- The carrying case used to transport clean and reprocessed endoscopes outside the health-care environment should not be used to store an endoscope or to transport the instrument within the health-care facility.
Reminder…..

- A contaminated endoscope should never be placed in the carrying case because the case can also become contaminated.
- When the endoscope is removed from the case, properly reprocessed, and put back in the case, the case could re-contaminate the endoscope.
- A contaminated carrying case should be discarded (Olympus America, June 2002, written communication).

CJD – The Hidden Danger

What is CJD?

- Rare, fatal brain disorders which cause rapid, progressive neurological deterioration
- Causes microscopic vacuoles in neurons
- Brain becomes and appears “sponge like”
- "sporadic" CJD - most common - identified and named in 1920

CJD

- Proteinaceous infected materials = PRION
- Virus-like but do not fit into any known category of microbe
- Do not react to any of the known disinfection/sterilization methodologies

CJD

- Can have extended incubation periods.
- Caused by prions - very resistant to all measures of decontamination and sterilization routinely used in healthcare facilities.
- Need a proactive process to prevent cross infection of patients.
CJD
- Comprises 85-90% of all cases
- Refers to those cases in which there is no known source or cause
- Refers to those cases with no evidence of prior or subsequent generations affected by the disease
- Incubation period can be as long as 40-50 years!
- Rapid, progression of disease - diagnosis may not be made before death
- Initial diagnosis often Alzheimer’s or stroke. CJD not suspected/patient old and die; no follow-up

FACTS
- JCAHO issued a Sentinel Event Alert for CJD in 2001 and 2013
- 1% of the cases (267) are iatrogenic (induced inadvertently by a physician or surgeon or by medical treatment or diagnostic procedures)
- Occurred due to direct contact with high-risk tissue

Sentinel Event Alert : 9-18-2013
- The Joint Commission would like to clarify the recommendations in Sentinel Event Alert #20: Exposure to Creutzfeldt-Jakob Disease (CJD) regarding the recommended practice of quarantining equipment:
  - To minimize the possibility of using neurosurgical instruments that have been potentially contaminated during procedures performed on patients in whom CJD is later diagnosed, health care facilities should consider using the specific evidence-based sterilization guidelines outlined by the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), or the American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) ST79:2010 Annex C.

Iatrogenic Cases
- 1% of the cases - 267 documented cases
- Due to direct contact with high-risk tissue

<table>
<thead>
<tr>
<th>Mode of Infection</th>
<th># of Pts</th>
<th>Agents entry into brain</th>
<th>Mean incubation period</th>
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<tbody>
<tr>
<td>Instrumentation</td>
<td>4</td>
<td>Intracerebral</td>
<td>20 mo (13-28)</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>2</td>
<td>Intracerebral</td>
<td>18 mo (16-20)</td>
</tr>
<tr>
<td>Tissue Transfer</td>
<td>2</td>
<td>Intracerebral</td>
<td>18 mo (16-18)</td>
</tr>
<tr>
<td>Corneal transplant</td>
<td>2</td>
<td>Optic nerve</td>
<td>17 mo (16-18)</td>
</tr>
<tr>
<td>Dura mater</td>
<td>71</td>
<td>Cerebral surface</td>
<td>5.5 years (1.5-10)</td>
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<tr>
<td>Implant</td>
<td></td>
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<tr>
<td>Tissue Extract</td>
<td></td>
<td>Hematogeneous</td>
<td>12 years (5-30)</td>
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<tr>
<td>US</td>
<td>22</td>
<td>Hematogeneous</td>
<td>15 years (12-16)</td>
</tr>
<tr>
<td>Gonadtrophin</td>
<td>4</td>
<td>Hematogeneous</td>
<td>15 years (12-16)</td>
</tr>
</tbody>
</table>

Plan of Action
- There should be precautions for all patients with known or suspected prion disease and for those at high risk for the development of a prion disease
- BH Policy includes "All loaner instruments used for high risk tissue cases will be processed as suspect instrumentation before and after use"
### Precautions Needed For Patients With

- Rapidly progressive dementia
- Possible Creutzfeldt-Jakob disease (CJD)
- Gersmann-Straussler-Scheinkler (GSS)
- Fatal familial insomnia (FFI)
- Variant Creutzfeldt-Jakob disease (vCJD)
- Recipients of human growth hormone, gonadotrophin or human dura mater grafts (all from brain).
- Any patient admitted for a brain biopsy without a lesion present should be suspect for CJD.

### Screening Patients

- Recommended that patients scheduled for spinal cord, posterior eye or brain procedures, including pituitary, (high risk tissues) require a pre-operative assessment, which will be a permanent part of the medical record.

### Further Precuations

- BH Policy includes “In the event of an emergency
- Patient cannot answer the Perioperative Screening questions or
- Due to an emergency there is insufficient time to perform the assessment without impacting on the successful outcome of the patient - the patient is identified as a suspect CJD patient.”

### CJD Exposure

- A North Carolina hospital says 18 patients were exposed to a rare and fatal brain disease after “extra precautions should have been taken, but were not.”

- XXX Hospital said surgical tools used on a patient suspected of having Creutzfeldt-Jakob disease should have been subjected to “enhanced sterilization procedures” to remove CJD-linked proteins called prions. Instead, the instruments underwent the normal, less stringent sterilization process and were subsequently used in 18 neurosurgery patients, according to the hospital.

- “Our standard procedure is to apply the enhanced sterilization process to surgical instruments that are used on any patient who is suspected or confirmed of having CJD in order to prevent possible transmission,” the hospital said in a statement. “There were reasons to suspect that this patient might have had CJD. As such, the extra precautions should have been taken, but were not.”

### CJD Exposure

- Rare Brain Disease Confirmed in N.H. Patient, 15 Others Possibly Contaminated

- Health officials have confirmed that a New Hampshire man who died in August following neural surgery had a rare, degenerative brain disease, raising alarms for 15 other patients who may have been contaminated by the same instruments.

- Autopsy results showed the unidentified man, who underwent surgery in May at XXX Medical Center in XXX N.H., had contracted sporadic Creutzfeldt-Jakob disease – a degenerative brain disorder spread by infected brain tissue and cerebrospinal fluid and is characterized by rapidly progressive dementia.

- Earlier this month, the New Hampshire Department of Health and Human Services contacted eight patients who may have been exposed to the rare brain disease after undergoing neurosurgery that used shared hospital equipment. The patients have since been notified on the positive autopsy results.

- An additional five patients in Massachusetts and two in Connecticut who underwent surgery using the same potentially contaminated equipment were also warned of the risk of possible exposure. (Loaner instruments)
Facts on Transmission

- Depends on dose and route of entry of prion
- No cases of growth hormone transmission or corneal transmission after newer methods of purifying hormones and screening of tissue occurred in US

Tissue and Expected Concentration of CJD Agent

- **HIGH RISK** - brain (including pituitary), spinal procedures, dura mater, posterior eye tissue (including retina and optic nerve)
- **MEDIUM RISK** - CSF, kidney, liver, lymph node, spleen, (WHO - lung, placenta)
- **LOW TO NO RISK** - Blood, urine, adrenal gland, feces, heart, bone marrow, muscle, nasal mucus, peripheral nerves, saliva, gingiva, sputum, tears

Action to Be Taken

- Develop policy/procedure
- Need administrative support
- Educate surgeons and employees FIRST
- Implement policy
- Monitor for compliance
- Assess and refine process as needed

Committee Members

- Establish Committee with
  - Infection Prevention
  - Risk Management
  - Materials Management
  - Perioperative Services
  - Sterile Processing/Central Service

Policy Considerations - OR

- How will patients be identified?
  - History
  - Patient screening tool
  - Only need to focus on patients with a history having high risk surgery (brain, spinal cord, posterior eye)
  - Understand most patients/surgeons not aware of CJD history
  - Method for communication of patients identified

Policy Considerations - OR

- If using a Pre-Op screening form, how will this information get back to the OR? (e.g. FAX)?
- BH policy includes screening for any patient admitted for brain biopsy without lesion is suspect (if no lesion why the biopsy???)
Policy Considerations - OR

- Pre-op screening form should include specific questions regarding family history, blood transfusions, travel to UK and Europe during specific time periods
- Surgeon should notify OR scheduling office
- Screen patients in Pre-Admission area (most successful)

SAINT BARNABAS HEALTHCARE SYSTEM
Perioperative Screening Form for Patients Who Are At Risk for Creutzfeldt-Jakob Disease (CJD)

Patient Name:_______________________ Screened by:______________________
Date:___________ Surgeon:________________________
Procedure:_____________________________________________________________

This form is to be used for all patients scheduled for eye, spinal cord (including laminectomy cases) and brain cases.

- If a brain biopsy is scheduled for a patient and there is no lesion present, CJD precautions should automatically be implemented.
- This form must be completed by the operating room if the patient is determined to be at risk for CJD.

Does the patient have:

- Rapidly progressive dementia?
- Suspected CJD or variant CJD (vCJD)?
- Gertsmann-Straussler-Scheinker (GSS)?
- Fatal familial insomnia (FFI)?

Has the patient received:

- Human growth hormone prior to 1992?
- Gonadotrophin prior to 1992?
- Human dura mater graft prior to 1992?
- Corneal transplants prior to 1992?

Has the patient:

- Spent 5 years in Europe since 1980?
- Spent more than 3 months in the United Kingdom from 1980-1996?
- Received a blood transfusion in the United Kingdom from 1980-1996?
- Spent more than 6 months on a United States military base in Europe between 1980-1996?

If the answer to ANY of the above questions is YES, the CJD policy must be implemented.

Re-approved 11/17 – June Perioperative, Sterile Processing and Infection Control Councils

Policy Considerations - OR

- Need method for OR to notify SPD and Infection Control
- Need method for OR to identify instruments used on high risk patients-high risk tissue (posterior eye, brain, pituitary, spinal cord instrumentation)
- To limit contamination of instruments and devices, OR personnel should not open any devices/instruments unless needed for the procedure.

Policy Considerations - OR

Suggest bright colored adhesive label to affix to outside of red bag or container

Wording “ATTENTION - SPECIAL PRION PROCESSING REQUIRED”

SPD needs to develop mechanisms to ensure staff aware of special processing needs for prions

NOTE: Only those instruments/devices that contact high risk tissue need to be labeled with the Special Prion Processing label.

Special Identification Label

WARNING!!
SPECIAL PRION PROCESSING REQUIRED

In the OR

- OR personnel should place all devices/instruments requiring special prion processing in rigid containers per OSHA regulations for transfer of contaminated instruments/sharps.
- Affix a “SPECIAL PRION PROCESSING” adhesive label to the container, bin or red-bag (for non-sharps).
Policy Considerations - OR
- Instruments should be sprayed with an enzyme foam.
- Cover instruments with a towel moistened with sterile water (not saline) to keep soils moist.
- Instruments should immediately be sent to SPD for reprocessing.

In SPD
- Instruments should immediately be decontaminated (delays in cleaning can impact on reduction of prions)
- Carefully remove instruments/devices from their container/bin/bag.
- Make sure all instruments opened, disassembled for cleaning.

In SPD
- Use method of identifying instruments requiring “Special Prion Processing” inside basket.
- Process in enzyme pre-soak, ultrasonic cleaner and mechanical washer (if device permits).
- No special cleaning protocols required
  - Single use lumened devices should be used

Green Autoclavable Tag
- Use method of identifying instruments requiring “Special Prion Processing” inside basket.
- Process in enzyme pre-soak, ultrasonic cleaner and mechanical washer (if device permits).
- No special cleaning protocols required
  - Single use lumened devices should be used

Policy Considerations
- Steam sterilize as follows:
  - Pre-vacuum steam 270°F, 28-30 psig
    - 18 minutes sterilization time
  - Gravity displacement steam 250°F, 15-17 psig
    - 60 minutes sterilization time

CJD-Recommendations for Processing
- Ineffective treatment methods for CJD
  - Alcohol
  - Glutaraldehyde
  - Boiling
  - Hydrogen Peroxide
  - Detergents
  - Iodophors
  - Dry Heat
  - Ionizing/UV Radiation
  - EO
  - Peracetic acid
  - Formaldehyde
  - Phenolics
  - Formalin cycles
  - Routine Steam sterilization cycles
Extreme and Unwarranted Protocols for Prions (WHO)

- Standard autoclave cycles extended 1-2 hrs
- Sterilize everything at 18 min at 270°F
- Sterilize 3 min x 6 cycles at 270°F (Neth)
- Expose surfaces to 1N NaOH (caustic/corrosive) for 30-60 min
- Exposure of surfaces to NaOCl (bleach) for 30-60 minutes

Policy Considerations

- OR should have available
  - Disposable suctiones
  - Disposable craniotomy sets
  - Covers for power equipment
  - Preferable to use non-powered drills or ensure disposable protective equipment covers are used to prevent aerosolization of prions or use powered equipment validated for prion inactivation

Policy Considerations

- High risk instrumentation -
  - if devices can be thoroughly decontaminated (no lumens), clean with usual procedures
  - Items with lumens should be discarded (can pre-soak in 1:10 bleach first for 30 minutes

Standard Precautions

- Should be used for all patients with known or suspected CJD.
  - Gloves should be worn for the handling of blood and body fluids (i.e. secretions and excretions).
  - Masks, gowns and protective eyewear should be worn if exposure to blood or other material that is potentially infectious to mucous membranes or skin is anticipated

Specimens/Tissue Samples

- Standard decontamination of tissue samples (i.e. formalin) or specimens may not inactivate CJD, all tissue samples should be handled using standard precautions (i.e. gloves).
- Tissue samples and specimens should be labeled as “biohazard” and as “suspected CJD” before being sent to the laboratory.

Precautions

- No special precautions are required for disposal of body fluids.
- Regulated medical waste (i.e. bulk blood, pathological waste, microbiological waste and sharps) should be managed per state regulations.
- Laundry should be managed as required by the Occupational Safety & Health Administration (OSHA) rule on bloodborne pathogens. No additional precautions are required.
- Food utensils - no special precautions are required
Policy Considerations

- Need to clearly document entire process
- Loaner spinal instruments or other loaners used on high risk tissue - should be treated as suspect
- Wash - sterilize at 18 minutes unwrapped, then package and sterilize with usual cycle

Policy Considerations

Kerrison rongeurs require special considerations - impossible to clean
Decontaminate, process on special cycle, have instrument repair company open and clean out
Reprocess

Policy Considerations

IUSS STERILIZATION SHOULD NOT BE USED FOR ANY KNOWN OR SUSPECT INSTRUMENTATION

- Items that require only LTGP or EtO sterilization should be discarded. These methodologies are INEFFECTIVE against prions

Policy Considerations

BH – Loaner Instrumentation

- All loaner instrumentation (i.e. spinal or neuro loaner instruments) that are used in high-risk tissues should, upon receipt from the representative:
  - Decontaminated as usual – pay particular attention to lumened devices
  - Sterilized, unwrapped using the prion inactivation cycles recommended.
  - Wrap and re-sterilized per manufacturer's instructions.

Powered Equipment

- For ease of cleaning and to minimize percutaneous injury and generation of aerosols, use non-powered drills/saws or ensure that disposable protective equipment covers are available for power instruments.
- NOTE: Several companies provide disposable craniotomy and brain biopsy sets. Disposable instruments should be of high quality.

Traceability to the Patient

- Contaminated items that have been in contact with high-risk tissue and have not been processed according to these recommendations (e.g., medical devices used for brain biopsy before diagnosis) should be recalled and appropriately reprocessed.
Traceability to the Patient

- A tracking system should be in place that permits recall of devices used on high-risk tissue and high-risk patients.
- System should permit identification of the patient on which the devices were used, the date they were used, the procedure performed, and the surgeon’s name.

- BH - SPD will affix a Patient Record card to all trays that will be used on high-risk tissue.
- The specific name of the tray and number (e.g., Crani Set #4) must be legibly written on the card.

- A lot control label is affixed to the card. The label should not obscure the tray information.
- SPD should attach the load card to the tray with autoclave tape in the space provided.
- In the OR – when the tray is opened, the Patient Record card for each tray should be removed.
- Detach at the perforation on the card.

- If the tray is used on the patient, the record card should be securely attached to the patient record with tape or a staple ensuring the tray information is not obscured.
- Any tray received without a load card should not be used.
- Traceability can also be performed using a tracking system.

Environmental Considerations

- Non-critical surfaces contaminated with high-risk tissue (e.g., lab) can be decontaminated with 1:10 dilution of bleach.
- To minimize environmental contamination, use cover sheets on work surfaces.

- Non-critical equipment contaminated with high-risk tissue should be cleaned then disinfected with 1:10 dilution of bleach.
- Bleach can have adverse effects on materials.
- Expose all surfaces to the bleach.
Low Risk Tissues from High Risk Patient
- Clean devices as usual; disinfect and/or sterilize with convention protocols
- Environmental surfaces contaminated with low risk tissues/fluids require only standard disinfection

No-Risk Tissue from High Risk Patient
- Clean/disinfect devices using conventional procedures
- Endoscopes (except neuro endoscopes) would be contaminated with no-risk tissue - use SGNA recommended procedures for cleaning/disinfection
- Environmental surfaces contaminated with no risk tissues/fluids require only standard disinfection

Occupational Exposure
- Avoid self inoculation with sharps
- Can clean percutaneous exposure using 0.5% sodium hypochlorite for several minutes and then washing with soap and water (note scientific evidence does not support percutaneous exposure route)

Occupational Exposure
- Mucous membrane exposure to infectious tissue/fluids should be managed by irrigating the mucous membranes thoroughly with saline for several minutes
- Pathology - expose all instruments to 1:10 bleach for 30 minutes

Other Considerations
- WHO document based upon political issues associated with CJD in Europe
- Use of sodium hydroxide and/or bleach with destroy instruments
- Use of sodium hydroxide or bleach to sterilize instruments inside sterilizer will null-void sterilizer warranty
- Potential for employee injury

CJD - Conclusion
- Remember, the only thing which remains constant with microorganism is their ability to change to adapt to adverse changes in their environment
- If we are prepared for CDJ it may not get an upper hand
**CJD - SUMMARY**
- Sentinel Event Alert requires we take action
- Develop policies based upon good scientific evidence
- Educate all personnel, including physicians
- Monitor compliance

**Problem**
- CDC, FDA and WHO do NOT agree on methods of inactivation
- causes confusion for facilities
- AAMI standards based on what occurs in the US with prion disease

**IMMEDIATE USE STEAM STERILIZATION**
"AKA FLASH"

**Flash Sterilization**
- Traditionally been used to describe steam sterilization cycles where
  - unwrapped medical instruments are subjected to an abbreviated steam exposure time
  - then used promptly after cycle completion without being stored.
- In contrast to traditional "terminal sterilization" cycles, where instruments are sterilized within containers, wrappers, or primary packaging designed to maintain the instruments' sterility and allow the devices to be stored for later use.

**Immediate use steam sterilization**
- The term "immediate-use steam sterilization" more accurately reflects the current use of these processes.
- Concept, name endorsed by AAMI, AORN, AAAHC, APIC, ASC Quality Collaboration
Reprocessing Personnel

- Should be knowledgeable and capable of exercising critical thinking and judgment
- Should implement standardized practices.
- **The supervising organization is responsible for ensuring appropriate training, education, and competency of staff and ensuring that the necessary related resources are provided.**

References

- Examples of standards and practices can be found with
  - Association for the Advancement of Medical Instrumentation (AAMI)
  - Association of periOperative Registered Nurses (AORN)
  - Centers for Disease Control and Prevention-Healthcare Infection Control Practices Advisory Committee (CDC-HICPAC).

Sterilization personnel

- Should be educated regarding the different types of steam sterilizers
  - (i.e., gravity-displacement and dynamic air removal—pre-vacuum, high vacuum, and steam-flush-pressure-pulse sterilizers)
  - the different types of steam sterilization cycles (i.e., gravity-displacement and dynamic air removal cycles) used in health care facilities.

Sterilization cycles/dry time

- Sterilization cycles with little or no dry time are efficacious when used in compliance with validated written instructions provided by
  - the device manufacturers
  - sterilization equipment manufacturers
  - and (if applicable) container manufacturers
  - and when done in accordance with professional guidelines.

Process

- Cleaning, decontamination, and rinsing are critical and users must follow and complete all required processing steps regardless of the sterilization exposure parameters being used.
- Aseptic transfer from the sterilizer to the point of use is critical to protect items from contamination
- Only items sterilized and packaged in materials cleared by the FDA for maintenance of sterility can be stored.

Process

- The device manufacturer’s written instructions for reprocessing any reusable device must be followed.
- The cycle parameters required to achieve sterilization are determined by the design of an instrument, the characteristics of the load, the sterilizer capabilities, and the packaging (if used).
Survey Personnel

- Personnel that sterilize medical items should be knowledgeable and capable of exercising critical thinking and judgment.
- The regulatory or accrediting agency should evaluate whether the organization’s leaders ensure that training, education, and resources are provided and the competency of staff is validated.

Survey Personnel

- Quality management is important to ensure compliance with processes and relating those processes to outcomes.
- Sterilization process monitoring is essential to ensure that sterilization practices are efficacious.
- Examples of process monitoring tools are physical indicators, biological indicators, and chemical indicators.
- Instrument inventories should be sufficient to meet anticipated surgical volume and permit the time to complete all critical elements of reprocessing.

Contraindications for SSIU

- Implants, except in a documented emergency situation when no other option is available.
- Post-procedure decontamination of instruments used on patients who may have Creutzfeldt–Jakob disease (CJD) or similar disorders.
- Devices or loads that have not been validated with the specific cycle employed.
- Devices that are sold sterile and intended for single-use only

Key points to remember

- Looking at all aspects of the sterilization method or cycle.
- Examples of findings would be a high percentage of steam sterilization using SSIU as well as exclusive use of this process for certain types of instruments.

Focus

- Process-related issues involving the way that a given sterilization method is executed.
- Examples of findings would be
  - failure to adequately clean the instruments before sterilization
  - lack of chemical indicators
  - transporting uncovered instruments back to the operating room after they have been sterilized.

Focus

- Identify the critical steps of disinfection and sterilization to determine if the process is appropriate.
  - Cleaning and decontamination,
    - All visible soil must be removed prior to sterilization because steam and other sterilants cannot penetrate soil, particularly organic matter.
    - Manufacturers’ instructions are available for all instruments; these include directions for the cleaning and decontamination process.
    - Some smooth metal instruments may be easily brushed clean, while complex products may require disassembly and special cleaning techniques. Many manufacturers specify that an enzymatic soak be used as well.
Focus
- Sterilization
  - Steam sterilization of all types, including flashing, must meet parameters (time, temperature and pressure) specified by both the manufacturer of the sterilizer, the maker of any wrapping or packaging, and the manufacturer of the surgical instrument.
  - In addition to these instructions, chemical and biological controls must be used as designed and directed by their manufacturers.

Closed Containers
- Observe instruments from the time they leave one operating room to when they are returned to the next.
- Ask health care workers to provide the manufacturers’ instructions for instrument sterilization, and to describe and demonstrate how instruments are being cleaned and decontaminated according to those written instructions.
- Observe the cleaning of instruments. Rinsing is rarely enough to properly remove soil from instruments; meticulous cleaning is needed.

Focus
- Verify that staff members are wearing appropriate personal protective equipment.
- Observe the sterilization process. The surveyor will ask for the manufacturer’s instructions for the following items: the sterilizer, wrapping or packing, and the instruments.
- Review sterilization logs. Surveyors will ask about physical, chemical and biological monitors
- Observe the return of instruments to the sterile field and verify that they are being protected from recontamination.

JC Focus
- Storage or return to the sterile field.
  - Each newly sterilized instrument must be carefully protected to ensure that it is not re-contaminated.
  - SSIU items may be transported in “flash pans” or other devices specifically designed for the prevention of contamination during and after the steam process.

Remember
- IUSS is a multi-step process
- Each step must be performed correctly to achieve and maintain sterility
  - Handling contaminated items at the point of use
  - Placing hot items in cool sterile water can adversely affect life of device/instrument
- IUSS sterilizers were designed for a single instrument….not sets!
AORN

- "IUSS" should be used in carefully selected clinical situations when certain parameters are met.
  - Correct work practices
  - Correct delivery of the device after sterilization
  - Monitoring of procedures for compliance

Reasons for Flash Sterilization

- Inadequate inventory of instrumentation
- Booking cases back-to-back
- Not aware of turn-around time for wrapped sterilization in SPD
- Items not available from SPD when needed
- Dropped, contaminated items

Unacceptable........

- Insufficient instrumentation for cases
- Items not available from SPD as requested
- Putting surgeons’ schedule ahead of patient safety

If you MUST perform SSIU

- Make sure all the steps are followed
- Make sure all personnel trained and educated in flash sterilization
- Determine competencies initially and verify annually
- Monitor compliance with policies

SSIU

- Knowing all this, you should work to limit all flash sterilization unless emergency
- If SSIU must be performed make sure all the steps are followed

IMPORTANT

- Must obtain and comply with all device manufacturer’s instructions before any SSIU sterilization is attempted
- Compile list of devices with cleaning and sterilization requirements
- Ask yourself –
  - Can I clean the device according to the instructions?
  - Can I replicate the sterilization cycle type/time?
AORN
- AORN's Recommended Practice on Sterilization (2009)
- Flash sterilization should be kept to a minimum
- Should only be used in selected clinical situations and in a controlled manner
- Items are placed in a closed sterilization container or tray, validated for flash sterilization

Flash Containers
- Are closed and remain closed throughout the process
- Have been validated for flash cycles
- Ensure container can be used for the cycle type(s) you will use

AORN
- Flash sterilization should not be used as a substitute for insufficient instrumentation

Flash Containers
- Must ensure flash containers properly cleaned and maintained
- AAMI and AORN recommend that flash containers be cleaned AFTER EACH USE (document)
- Requires special BI testing before purchase
- If venting or filter replacement required, document on log form

Rust and Corrosion on Flash Container – Never Washed

Do It Right!
- Monitor and review printouts to verify cycle parameters
- Use BI and a Class V integrator to monitor implant loads
- Document all cycle information and monitor results
Sterilization Parameters

- Flash sterilization should not be used for wrapped items
- Unwrapped items only
- Difference in SSU and terminal sterilization – NO DRY TIME!

Pre-Vacuum SSU

- Routine instruments - no lumens, no porous materials
- Items with lumens and/or porous materials
- Specialty devices
- 3 min @270°F (132°C); 28-30 psig pressure
- 4 min @ 270°F (132°C); 28-30 psig pressure
- As recommended by device or container manufacturer

High Speed Gravity SSU

- Routine instruments - no lumens, no porous materials
- Items with lumens and/or porous materials
- Specialty devices
- 3 min @270°F (132°C); 28-30 psig pressure
- 10 min @ 270°F (132°C); 28-30 psig pressure
- As recommended by device or flash container manufacturer

Quality Assurance Monitoring

- Policies and Procedures
- Must be developed for flash sterilization
- Should be followed consistently wherever flash sterilization is performed in the health care facility

Documentation

- Need to develop policies and procedures in cooperation with infection control concerning notification of the infection control professional following the malfunction
- All sterilizer malfunctions and follow up actions shall be documented and records maintained
- The contents of the load processed in the malfunctioning sterilizer are considered non-sterile and shall not be used

Documentation

- Load records should contain (minimum)
  - General contents of the load
  - Duration and temperature of the exposure phase of the cycle
  - The initials or other identification of the sterilizer operator
  - The number or other identification of the sterilizer
  - Date and time of cycle
Documentation
- Reason items being flashed
- Verify items decontaminated
- Room and surgeon
- Can affix patient ID label to back of log or use patient ID#
- Verify results of CI and BI (when performed)

For each sterilizer maintain records of
- Results of BI monitoring
- Any necessary follow up for positive BI
- Results of the Bowie-Dick testing
- Record of repair and preventive maintenance

Physical Monitoring
- Physical monitors
  - Includes time, temperature and pressure recorder, displays, computer printouts and gauges
  - When time temperature recordings are provided sterilizer operator shall ensure at the beginning of the day that all recording devices are ready for use;
    - paper is present on the roller
    - paper is aligned properly
    - pen is functional
    - correct date is indicated/printout legible

At the end of each cycle sterilizer operator shall:
- examine the recording document (chart or printout)
- verify that the correct temperature was attained and maintained for the correct exposure time
- sign the recording document before items are remove

Record Keeping
- Charts/Records shall be maintained with the sterilization records in the department using the sterilizer or in another designated filing area
- Sterilization records should be maintained as required by state or local statutes or as recommended by the facilities’ legal counsel

Chemical Indicators
- Characteristics
  - Sterilization process monitoring devices
  - Designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizer chamber
Chemical Indicators
• Characteristics
  • Sterilization process monitoring devices
  • Designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizer chamber

Chemical Indicators
• CI intended to detect potential sterilization failures that could result from personnel errors or sterilizer malfunctions
• The “pass” response of a CI does not prove that the item accompanied by the CI is sterile

Use of CIs
• Use in each tray or container being processed
  • Class 5 integrator recommended
  • After the sterilization cycle has been completed interpret the CI results in accordance with the written instructions of the manufacturer

CIs
• Class 4 provides information on 2+ parameters of the SSIU cycle
• Class 5 provides information on all the critical parameters of the SSIU cycle

Selection of BIs
• Select BIs consisting of spores of geo-Bacillus stearothermophilus that comply with AAMI standards of selection of BIs
• Only BIs that have been specifically validated and recommended for use in flash cycles should be used
• Pre-vacuum and gravity cycles may require different BIs
Frequency of Use of BIs
- Initial installation testing
- After any major repairs
- Perform at least weekly preferable daily
- Any loads containing implantable devices
- Each type of tray configuration
- Each type of cycle

Routine BI Testing
- **GRAVITY DISPLACEMENT FLASH:**
  - Place one or more BI's and a CI in the tray configuration to be tested
  - Perforated, mesh bottom open surgical tray
  - Rigid sterilization container
  - Protective organizing case
  - Single wrapped surgical tray (Express cycle)

Routine BI Testing
- **PRE-VACUUM FLASH**
  - Perform Bowie-Dick test first
  - Place one or more BI’s and a CI in the tray configuration to be tested
    - Perforated, mesh bottom open surgical tray
    - Rigid sterilization container
    - Protective organizing case
    - Single wrapped surgical tray (Express cycle)

Installation/Relocation/Major Repair Testing
- 3 consecutive BIs (for each major cycle)
- 3 consecutive Bowie-Dick tests (if pre-vacuum sterilizer)
- All performed under conditions that simulate flash sterilization conditions
- All must be negative to put sterilizer back into use

Bowie-Dick Air Removal Test
- Detects air leaks in pre-vacuum sterilizers
- It is not a sterility assurance test
- Test pack and procedures are described in AAMI

Bowie-Dick Test
- UNEXPOSED
- FAIL
- PASS
- Uneven color change is indicative of a failed test.
Sterilizer Care and Maintenance
- Keep Instruction Manuals readily available to the staff
- Need to retain as long as the sterilizer is in use

Care of Flash Sterilizers
- Inspected/cleaned per the sterilizer manufacturer’s instructions
- DAILY - clean drain line basket, gasket, exterior surface, check paper supply, ink cartridge/recording pen
- WEEKLY - clean chamber drain line (if indicated), interior chamber walls

Where is the Drain Line Basket?

Clogged Drain Line Basket

Process Improvement
- General rationale
  - CQI is imperative to the flash sterilization process in order to minimize risk and assure a sterile product for the patient
  - Decontamination and aseptic transfer are as important as the sterilization cycle itself and should be part of the total process performance measurement

Quality Process
- Decontamination area
- Containment of contaminated items
- Work practices
- Installation, care, and maintenance of sterilizers
- Sterilization process
- Aseptic handling and transfer
Remember
• SPEED IS AMILITANT FORCE AGAINST EFFECTIVE STERILIZATION
  
  Dr. John Perkins

Therefore
• Routine flash sterilization is NOT in the best interest of the patient
• Whenever a process is wet, contamination is likely.
• Does not provide the same standard of care
• Decontamination is a major problem
• JC focusing on flash sterilization due to the potential patient safety issues

How to Improve
• Make a standard to only flash in emergency situations
• Document the emergency
• Review flash logs to identify additional sets/items needed
• Educate surgeons regarding time needed between cases
• Only flash if manufacturer has provided evidence of the safety and efficacy of the process

Laryngoscope Handles & Blades
• Infection Prevention and Control (CAMH / Hospitals)
• Laryngoscope Blades - New | October 24, 2011
• How should we process and store laryngoscope blades?
• According to the CDC’s Healthcare Infection Control Practices Advisory Committee (HICPAC), laryngoscope blades are "semicritical" items, which are defined as, "Items that directly or indirectly contact mucous membranes of the respiratory tract. They should be sterilized or subjected to high-level disinfection before reuse."

Therefore
• Decontamination issues major problem
• All agencies focusing on SSU sterilization due to the potential patient safety issues
• Most manufacturers no longer provide flash instructions therefore the sterilizer operator would be liable for any sterility issues

Therefore
• Routine flash sterilization is NOT in the best interest of the patient
• Whenever a process is wet, contamination is likely.
• Does not provide the same standard of care
• Decontamination is a major problem
• JC focusing on flash sterilization due to the potential patient safety issues

How to Improve
• Form CQI Committee
• Include Risk Management, QI, SPD, Infection Control and OR (including a Surgeon)
• Committee has more power to make change
Laryngoscope blades are semicritical items. Recommendation IIIA1b (pages 57-58) states how semicritical items must be processed and packaged:

- Follow the scope and handle manufacturer’s instructions for cleaning and disinfection.

After disinfection, proceed with appropriate rinsing, drying, and packaging, taking care not to contaminate the disinfected items in the process (308:310). CATEGORY IA*. Joint Commission surveyors will evaluate processes related to laryngoscope blades to ensure that they are safe for use on the next patient.

They will check that laryngoscope blades are:

- Processed via either sterilization or high-level disinfection.
- Packaged in some way. HICPAC guidelines do not specify the manner in which laryngoscope blades should be packaged.
- Stored in a way that would prevent recontamination. Examples of noncompliant storage would include unwrapped blades in an anesthesia drawer, as well as unwrapped blades on top of a code cart.

Laryngoscope handles are considered contaminated after use and must be processed prior to use on the next patient.

After disinfection, proceed with appropriate rinsing, drying, and packaging, taking care not to contaminate the disinfected items in the process (308:310). CATEGORY IA*.

Note that laryngoscope handles are considered contaminated after use and must be processed prior to use on the next patient. Most manufacturers suggest a low-level surface disinfectant be utilized on the surface of the handle, but processes vary by manufacturer. As is the case with all medical devices, the manufacturer’s indications for use (IFU) must be followed. Please also check your state for additional law or regulation; we are aware of at least one state that requires additional processing.

REMEMBER

IF YOU WANT THE RAINBOW.....YOU HAVE TO PUT UP WITH THE RAIN

Dolly Parton
QUESTIONS????????????????????

Email: nancy.chobin@att.net

THANK YOU!!!!!!!