



## THE ROLE OF STERILE PROCESSING IN PATIENT SAFETY AND INFECTION CONTROL

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### OBJECTIVES

- To describe the impact of Sterile Processing on Patient Safety and Infection Control focusing on
- Training, Education and Certification
- Decontamination
- Preparation and Packaging
- Sterilization
- Sterile Storage
- Describe methods for compliance

### IMPORTANCE OF STERILE PROCESSING

- Guardian of spread of infection via medical devices and equipment
- Responsible for majority of processing of devices used throughout hospital
- No facility could function without them
- Major responsibility, little pay or recognition

### SPREAD THE WORD

- All states need to unify and require certification for sterile processing personnel in hospitals and surgery centers
- Certification elevates the competency levels of the practitioners
- Win-win for everyone!

### WIIFM????????????????

- What's in it for me (WIIFM)?????
  - Improved esteem
  - Improved performance
  - Job security
  - Improved morale
  - Fewer errors
  - Increased salaries!!!!!!!!!!!!
- **What's are the risks when best practices not followed?**

### AREAS OF IMPACT

- Transport of soiled devices
- Decontamination
- Preparation/Assembly
- Sterilization
- Sterile Storage
- Transport of Sterile Product

# Transport of Soiled Items

## TRANSPORT OF SOILED ITEMS

- If not performed correctly contamination can occur with
  - patients
  - employees
  - environment
- All items must be confined and contained

## TRANSPORT OF SOILED ITEMS

- Use of closed or covered carts
- Plastic tote bins
- Plastic bags (for non-sharps)
- Do not transport instruments in solution
  - can create spills

## IMPROPER TRANSPORT OF SOILED INSTRUMENTS



## DECONTAMINATION AREA

- Cleaning is the **FIRST** step in the sterilization process
- Must be done correctly
- Must have the device manufacturer's written instructions for cleaning the device
- We must do it right each time with no short cuts!

# Decontamination

## DECONTAMINATION AREA

- SPD technician needs to read and follow the instructions carefully
- Must use correct detergent
  - some detergents can deteriorate materials or cause allergic reactions in patients
  - cannot just use any detergent - only those tested by the device manufacturer as safe to his device and the patient

## DAMAGED CONTAINER FROM HIGH ALKALINE DETERGENTS



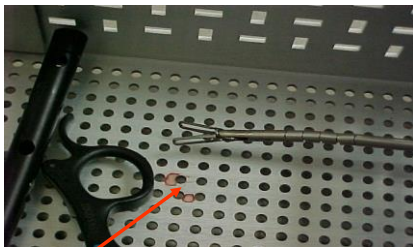
## DECONTAMINATION AREA

- Must use and measure the detergent correctly
- Use a measuring cup to measure the detergent
- Use a gallon jug to measure the water level in the sink
- Detergents are usually high pH
- If you have proportioners to dispense your detergent, still should have sink marked as a back-up if the mechanical system does not work

## DECONTAMINATION AREA

- If detergents not diluted properly, damage to the instrument/device can result and/or the device may not be properly cleaned
- Detergent residues can interfere with disinfection or sterilization – RINSE THOROUGHLY
- Correct cleaning implements needed.
- Lumens especially problematic
  - must have correct size (diameter) and length of brush to thoroughly clean inside lumens

## INEFFECTIVE CLEANING



## DECONTAMINATION AREA

- Must have sufficient equipment to get the job done correctly
- Need for specialty equipment (e.g. endoscopic instrument cleaners)
- Document the efficacy of the process (cleaning effectiveness testing)

## ULTRASONIC LUMEN CLEANER



## PROBLEM AREAS

- Pyrogen formation
  - Debris left behind after sterilization can cause illness; i.e. fever- when some bacteria die they release a toxin which, if enters the bloodstream of the patient, can cause severe illness
  - May result in giving antibiotics when not necessary
  - Improperly cleaned items can result in patient infections, delayed cases (need to re set up room) even death!

## TASS

- Toxic Anterior Segment Syndrome - an acute inflammatory response of the anterior chamber of the eye. This inflammatory response may lead to severe visual impairment if it is not recognized and treated in a timely manner.



## TASS - CAUSES

- Detergent residues, endotoxins, denatured ophthalmic viscoelastic devices (OVDs), preservatives, and residues from sterilization processing can all induce TASS and cause severe damage to ocular tissue

## TASS

- Particular care must be taken in the processing of intraocular surgical instruments to help ensure that foreign substances or materials associated with the instruments will not be introduced into the anterior chamber of the eye during surgery.

## TASS

- Outbreaks of TASS have often been linked to the failure to follow the processing procedures recommended by the instrument manufacturer

## TASS

- Specific instrument cleaning and sterilization recommendations intended to diminish the risk of TASS associated with intraocular surgical instruments have been published by the American Society for Cataract and Refractive Surgery (ASCRS, 2006).

## RECOMMENDATIONS

- An adequate inventory of the necessary intraocular surgical instruments should be maintained in order to allow for the timely processing of instruments between cases.
- Adequate time must be allowed for processing instruments according to the manufacturer's instructions; otherwise, the cleaning and sterilization of the instruments will be ineffective.

## TASS

- A designated cleaning area and equipment specific to the cleaning of intraocular surgical instruments should be identified.
- Whenever possible, intraocular surgical instruments should be processed separately from general surgical instruments and equipment in order to reduce the potential for cross-contamination by material or residue from the general surgical instruments

## TASS

- Instruments should be precleaned immediately following use.
- Gross debris should be removed, and **instrument lumens should be flushed with sterile distilled water or another suitable agent as recommended**

## TASS

- Only cleaning agents that have been recommended by the manufacturer should be used.
- Particular attention should be paid to the specified concentration of cleaning agent and to the recommended water quality.

## TASS

- Final rinsing of the instrument should be performed with sterile, distilled, or deionized water, unless otherwise specified by the manufacturer.
- The water used to clean or rinse instruments should be discarded after each use.

## TASS

- If an ultrasonic cleaner is used to process the instruments, it should be emptied, cleaned, rinsed, and dried at least daily or, preferably, after each use.
- Brushes and other cleaning tools should be cleaned and sterilized as recommended by the manufacturer at least daily or, preferably, after each use.

## TASS

- Cleaning and sterilization equipment should be properly maintained.
- Otherwise, foreign materials such as endotoxin or heavy metals may be deposited onto the instruments during processing and induce TASS.

## ENDOTOXINS

- Potentially toxic, natural compounds found inside pathogens such as bacteria.
- Classically, an "endotoxin" is a toxin, and is a structural component in the bacteria which is released mainly when bacteria are lysed.

## ENDOTOXIN

- Although the term "endotoxin" is occasionally used to refer to any cell-associated bacterial toxin, it is usually associated with the outer membrane of Gram-negative bacteria such as *E. coli*, *Salmonella*, *Shigella*, *Pseudomonas*, *Neisseria*, *Haemophilus*, and other leading pathogens.

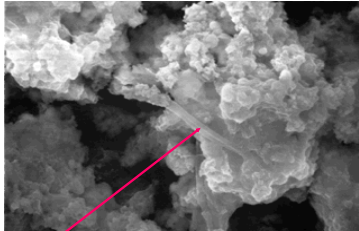
## PYROGENS

- Endotoxins, which are produced by gram-negative bacteria and found within the cell membrane, account for an estimated 99% of the pyrogens found on the surface of medical devices.
- The term "*pyrogen*," literally "*heat generating*," refers to any substance
- Patient develops febrile response

## BIOFILMS

- Are produced by microorganisms and consist of a sticky rigid structure of organic contaminants
- Slime layer anchored firmly to a surface and provides a protective environment for microorganisms to grow

## BIOFILM



## BIOFILMS

- Generally form on any surface that is exposed to non-sterile water or other liquids and is consistently found in many environments including industrial and medical systems
- Use enzymatic foam or gel in lieu of enzymatic soaks for long periods of time

## DECONTAMINATION AREA

- Standard Precautions
  - all items must be treated as if infected
  - SPD technicians need to be protected from blood and other body fluids by wearing personal protective equipment to meet the task
    - cuffed, heavy duty gloves (fitted at the wrist)
    - head cover (not PPE), shoe covers (water repellent), impervious gown, face shield or goggles that prevent splashes from **ALL** angles and impervious mask when aerosols present

## DECONTAMINATION AREA

- Standard Precautions
  - avoid injuries from sharps (needles, sharp instruments)
  - Use metal mesh gloves (e.g. Kevlar) or sponge stick to sort through instruments
  - Don't reach blindly into container
  - No counting of instruments in Decontam!

## DECONTAMINATION

- Keep Decontamination area neat and clean due to high microbial levels in this area
- Clean, facility laundered scrub suit should be provided
  - AAMI standard (ST-79, 2006)

## DECONTAMINATION AREA

- Need proper equipment for cleaning
  - Automated washers (washer decontaminators), ultrasonic cleaners, automated scope cleaners, steam guns, etc.
- Need proper physical design - area large enough to accomplish cleaning
- Negative pressure air to keep contaminants from other areas of the hospital-10 AE/hour

### DECONTAMINATION AREA

- Non-skid flooring
- At least 2 sinks- large and deep enough to hold a set of instruments for soaking/cleaning
- Need a 3-well sink for manual cleaning
- Effective cleaning cannot be accomplished with inadequate facilities/equipment!

### PROBLEM AREAS

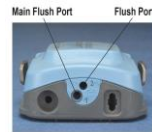
- Scheduling of cases back-to-back in OR does not permit sufficient time to properly clean instruments per manufacturer's instructions
- Loaner instruments do not arrive in sufficient time to properly clean them
- Lack of in-servicing from loaner companies for SPD staff

### PROBLEM AREAS

- New, more sophisticated instruments that defy cleaning
- We are negligent when we do not follow procedures
- How do we defend this action?
- Need to get Risk Management, Process Improvement and IC involved

### ROBOTIC INSTRUMENTS

- Requires careful manual cleaning
- 10-step process
- Sonic clean at end
- No automated cleaning permitted
- Need special high pressure hose



### HOW MUCH TIME??????????

- Need to document the time needed to process sets
- Robotic instruments take 20 minutes EACH to clean alone!

# Handwashing



# Prep and Packaging

## HANDWASHING

- One of the most important parts of infection control!
- Needs to be performed frequently and correctly
  - before starting work, after using bathroom, after removing gloves, before and after eating, before changing tasks, when handling sterile packages, when applying dust covers, after removing PPE

## PREPARATION AND PACKAGING

- Need to have manufacturer's instructions on hand for all devices; how to assemble/package for sterilization and what sterilization method
  - Without this information the device may not be safe/sterile
- Need a variety of packaging materials and sizes to accommodate all devices

## PREPARATION AND PACKAGING

- Need clean, well lighted area to inspect all devices after cleaning
- Clean scrub suits, head covers for staff – laundered by the facility!
- Lighted magnifying lamps on each work table for inspection of instruments
- Positive pressure air with 10 AE/hour
- Adequate space to get job done **CORRECTLY!**

## INSTRUMENT SAFETY

- Are scissors always tested for sharpness?
- Are insulated instruments tested for integrity of insulation each time they are used?
  - Is the testing of EACH instrument documented?
- Is power equipment lubricated and tested per the manufacturer?
- Are rigid scopes tested for visualization?

## INSULATED LAP INSTRUMENT



### INSULATION TESTER (REUSABLE)



### PREPARATION AND PACKAGING

- Packaging materials can affect sterility
- Paper (non-wovens) superior to cloth due to moisture/bacterial barriers
- Cloth (muslin) least effective barrier to bacterial and no barrier to moisture

### RIGID CONTAINERS

- Rigid containers provide best protection for devices; can stack sets in storage
- Need to be inspected each time they are used
  - Integrity of gasket
  - Filter retention mechanism
  - Dents, defects on lid and base
  - **MUST** be washed (not wiped out) after each use: manual, mechanical

### RIGID CONTAINERS

- Must comply with the container manufacturer's limit on the weight of instrument sets inside
- Cannot substitute filter material
- Need to perform BI testing of containers Pre-purchase and annually

### RIGID CONTAINERS

- Place all instruments to ensure contact with the sterilant
- Distribute evenly in container
- **MUST use correct size container - can cause damage to instruments if container too small**
- Use of absorbent materials, silicone mats, etc. -- check with container manufacturer.

### RIGID CONTAINERS

- Do NOT assume you can use even towels inside containers
- Must have written information from container manufacturer regarding what, if any items you can place inside container
- Silicone mats can be problematic – can cause pooling of water

# Sterilization

## PREPARATION AND PACKAGING

- Must use packaging materials correctly
- Paper-plastic pouches should only be used for light weight, small items (1-2)
- All seals on packages must be without creases
- Must use packaging as directed, no folding over edges, cutting to size, etc.
- All air removed from pack before sealing
- Ineffective packaging/methods can lead to contamination/damage to devices
- If double pouching, do not fold over inside pouch
- Was pouch validated for doubling?

## STERILIZATION

- Effective sterilization requires
  - proper cleaning
  - proper assembly
  - proper packaging materials and methods
  - proper loading of the sterilizer
  - proper sterilization method

## STERILIZATION

- Effective sterilization requires (continued)
  - proper sterilization parameters
  - proper handling after sterilization
- All of these factors are affected by sterile processing personnel
- Errors in one or more tasks can result in a non-sterile device

## STERILIZATION

- The correct sterilization methodology is required
- Steam - should always be used unless otherwise directed by the device manufacturer
- Requires contact with all surfaces of the device

## STERILIZATION

- Multi-part items should be disassembled
- No metal against metal (e.g. basins inside basins) unless wicked with absorbent material to draw steam between surfaces
- Lumens flushing with distilled water immediately before sterilization
  - If being processed in pre-vacuum steam – only if the device manufacturer recommends
  - If being processed in gravity, must still flush

### STERILIZATION

- Ethylene oxide gas - requires gas, heat and humidity.
- 100% or mixtures available
- Requires long aeration times to remove ETO residuals
- Residuals can be toxic to the employee and patient

### STERILIZATION

- Minimum aeration times – exact time and temperature must be specified by the device manufacturer
  - 122°F (50° C) - 12 hours
  - 130°F (54.4° C) - 10 hours
  - 140°F (60 ° C) - 8 hours
- Must have heat and time
- Cannot rinse off ETO residuals

### STERILIZATION

- SPD should avoid placing one-of-a-kind items in ETO
- Need alternate method for processing
- Need to document temperature and length of time for aeration to ensure items safe

### STERILIZATION

- Low temperature gas plasma/ Hydrogen Peroxide Gas Plasma
  - not suited for all devices
  - identify length and diameter of lumens
  - need to make sure items dry prior to sterilization
  - need non-cellulose packaging materials (no paper, cloth)

### STERILIZATION

- Improper loading of sterilizers can result in sterilization failure
- Items must be loaded to ensure adequate contact with the sterilant - no overloading!
- For steam, all items that can retain water should be tilted on their side

### WHAT'S WRONG WITH THIS?



### ARE THESE LOADED CORRECTLY????



### LOADED CORRECTLY?



### STERILIZATION

- Place linen items and paper-plastic pouches on top shelves of sterilizer and metal items on bottom
- Place paper-plastic pouches inside pouch separator or basket - place on edge
- Need lot control number to track devices in the event of a sterilization failure

### WET PACKS

- Need to know if packs are dry at the END of the cycle
- We do not hold inside sterilizer with door open to DRY, but to COOL
- After sterilization/cooling open and observe for
  - "dew" on instruments
  - Moisture in towel/mat
  - Water inside tray (look under instruments!)
- Need to resolve

### WET PACKS

- Additional dry time? 30 min sufficient?
- Break down set into two
- AAMI and AORN recommend maximum weight of 25 pounds of sets
- ST-77 requires loaner sets not weigh more than 25 pounds including the container!

### WET PACKS



## STERILIZATION

- Need expiration date or statement that items will remain sterile until packaging damaged
- Should **not** use event related dating if muslin is the packaging material
  - does not provide moisture or bacterial barrier
  - greatest risk of contamination is with muslin

## STERILIZATION

- All sterilization cycles must be monitored to ensure all sterilization parameters were met
  - include chemical indicator inside all packs/trays
  - include biological test at least weekly-preferably daily and with all implants
  - read and sign sterilizer printout/chart at the end of each cycle and before items removed
    - **DO YOU KNOW WHAT YOU ARE SIGNING?**

## STERILIZATION

- Need sterilization log to document all items processed in each load (for recall)
- Records should be specific
- All sterilization records (logs, printouts/charts, BI test results, etc.) should be retained according to facility's attorney recommendations

## STERILIZATION

- After sterilization
  - Steam - requires thorough cooling of devices to prevent re-contamination by hands
  - Pores open on packaging until cool
  - Items should remain untouched on sterilizer cart for 30 minutes to 2 hours or more!
- All packs/devices should be handled as little as possible after sterilization
- Use infrared thermometer gun to verify temp before handling (72-80°F)

## INFRARED THERMOMETER



## CJD

- Creutzfeldt-Jakob Disease
- 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

### WHAT IS CJD ?

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

### CJD

- vCJD identified in 1996 in UK
- vCJD facts
  - distinguishable from sporadic type
  - no cases in US to date

### INCIDENCE OF CJD

- 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

### IATROGENIC CASES

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

### TREATMENT

- None - disease is 100% fatal
- Research
- plasminogen to bind with disease protein
- Trials with two drugs

### GENERAL PRECAUTIONS

- 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
- What about spinal or neuro loaners?
- All loaner instruments used for high risk tissue cases should be processed as “suspect instrumentation before and after use”.
-

## 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.**

## 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.

## CJD EXPOSURE

- 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)



## TISSUE AND EXPECTED CONCENTRATION OF CJD AGENT

- **LOW TO NO RISK**
- Blood, urine, adrenal gland, feces, heart, bone marrow, muscle, nasal mucus, peripheral nerves, saliva, gingiva, sputum, tears

## CURRENT INFORMATION

- No known cases of transmission from a patient to a health care worker, including neurosurgeons, nurses or morticians

# What To Do???

## PRECAUTIONS FOR PATIENTS WITH

- Rapidly progressive dementia
  - Possible Creutzfeldt-Jakob disease (CJD)
  - Gertsman-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).
- In addition, any patient admitted for a brain biopsy without a lesion present should be suspect for CJD.

## CDC AND WHO RECOMMENDATIONS

- **Ineffective** treatment methods for CJD
  - Alcohol
  - Boiling
  - Detergents
  - Dry Heat
  - EO
  - Formaldehyde
  - Formalin
- Glutaraldehyde
- Hydrogen Peroxide
- Iodophors
- Ionizing/UV Radiation
- Peracetic acid
- Phenolics
- Steam sterilization

## EXTREME PROTOCOLS - 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

### ACTION

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

### ACTION

- How will patients be identified?
  - History
  - Patient questionnaire
- Only need to focus on patients with a history having high risk surgery (brain, spinal cord, eye)
- Method for communication of patients identified

### POLICY CONSIDERATIONS

- If using a Pre-Op assessment form, require that form be completed and FAX'd back to OR Booking before case scheduled
- Any patient admitted for brain biopsy without lesion is suspect

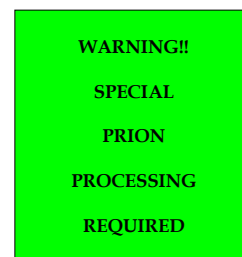
### POLICY CONSIDERATIONS

- Infection Control **MUST** be immediately advised
- Infection Control notifies SPD
- Need method for OR to identify instruments used on high risk patients-high risk tissue (eye, brain, spinal cord instrumentation)

### POLICY CONSIDERATIONS

- 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

### SPECIAL IDENTIFICATION LABEL



### 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 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.

### POLICY CONSIDERATIONS

- OR should have available
  - Disposable suction
  - 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

### POLICY CONSIDERATIONS

- Steam sterilize as follows:
  - Pre-vacuum steam 270-273°F, 28-30 psig
    - 18 minutes sterilization time
  - Gravity displacement steam 250°F, 15-17 psig
    - 60 minutes sterilization time

### POLICY CONSIDERATIONS

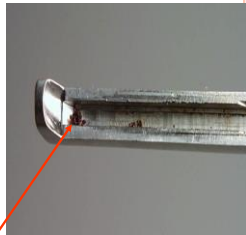
- Need to clearly document entire process
- Loaner spinal instruments - should be treated as suspect
- Wash - sterilize at 18 minutes unwrapped, then package and sterilize with usual cycle

## 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

- **IMMEDIATE USE (FLASH) 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

## 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.

## TRACEABILITY TO THE PATIENT

- On method is 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 **LEGIBALLY** written on the card.



## TRACEABILITY TO THE PATIENT

- 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.

### TRACEABILITY TO THE PATIENT

- 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

### STERILE STORAGE

- Sterilized items should be properly stored to prevent contamination
- Need segregated area
  - Temperature should not exceed 75°F (AAMI) (23.89°C)
  - Humidity should not exceed 70%
  - 4 air exchanges/hour - positive pressure

### STERILE STORAGE

- SPD technicians need to keep all storage locations clean and disinfected
  - clean at least monthly
  - check integrity of packaging of all items
  - Clean shelves and storage bins
- Keep all items 8 in. (20.32 cm) to 10 in. (25.40 cm) above floor
- Keep at least 2 in. (5.08cm) from outside wall

### STERILE STORAGE

- Keep away from fire sprinklers
- Need to keep visitors out
- All personnel entering area must be properly attired (scrub suit or cover gown, head cover) to keep contaminants to a minimum
- Stacking of sets discouraged unless in rigid container
- Avoid crushing of packs in storage

### PROCESS IMPROVEMENT

- Need a system of process improvement monitoring to ensure compliance with all stated policies
- Report to Infection Control
- Correct deficiencies
- Need tracking system to document processes and verify productivity of department

### CONCLUSIONS

- Sterile Processing has a major impact on infection control and patient safety
- Devices used in surgery must be sterile and safe when used
- Sterile Processing staff need to be knowledgeable in all aspects on processing to ensure the safety of the device

## CONCLUSIONS

- Sterile Processing personnel need to be educated in the proper processing methods
- The SPD Department needs adequate facilities to perform essential services
- The SPD Department needs to be kept clean with daily damp mopping of floors
  - routine cleaning of vents, ceilings, walls

## CONCLUSIONS

