“Are Your Patients at Risk? The Impact of Infection Control in Supply Chain and SPD”

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Objectives

- Understand the importance of compliance with national standards in infection prevention
- Review methods to prevent cross contamination and improve patient safety by proper reprocessing and handling of devices
- Discuss the importance of competencies for all personnel handling sterile packages

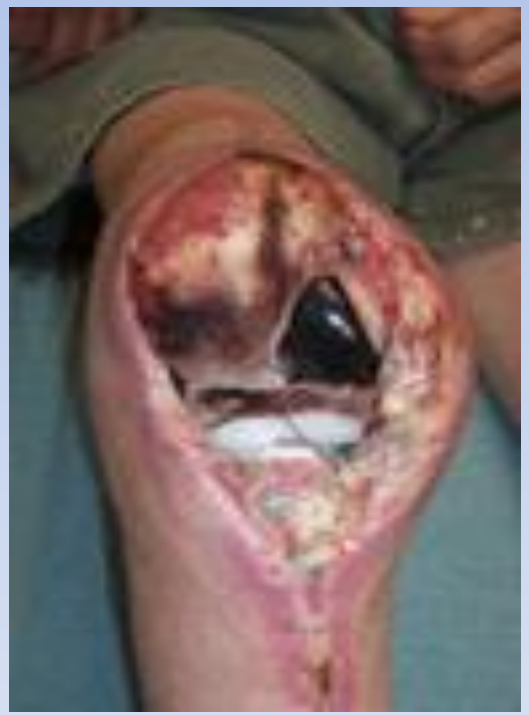
CDC

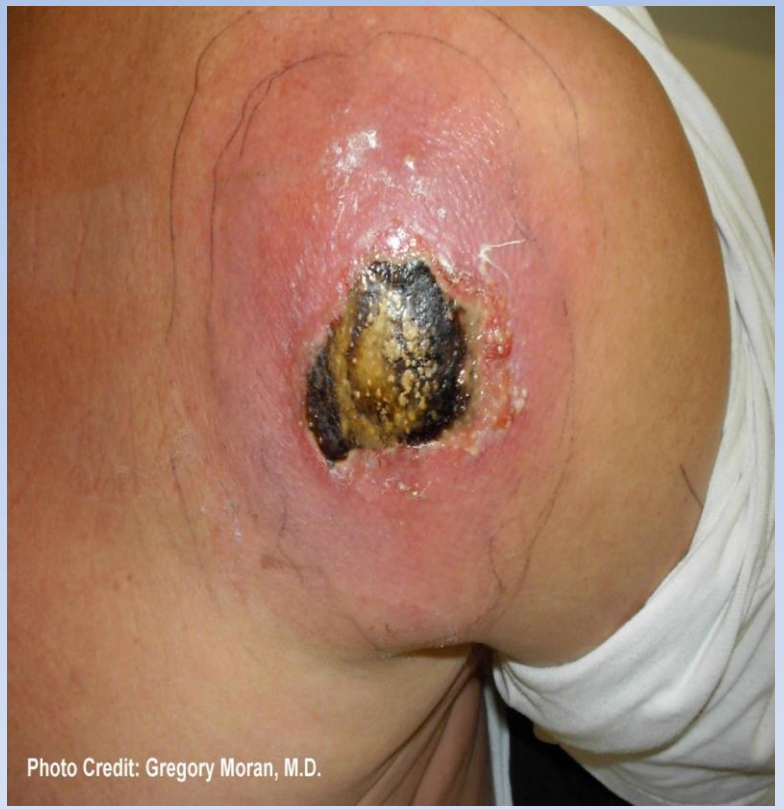
- Most patients who have surgery do not develop an infection.
- Infections develop in about 1 to 3 out of every 100 patients who have surgery.
- According to the CDC, each year, U.S. hospitals experience 1.7 million health-care associated infections (HAIs), causing roughly 99,000 deaths at a cost of $37-$45 billion dollars.

Surgical Site Infections

- An estimated 40 to 60 percent of these infections are preventable.
- 38% of all nosocomial infections in surgical patients are surgical site infections.
- 4 to 16% of all nosocomial infections are SSIs.
- 2 to 5% of operated patients will develop SSI.
- SSI increases the patients length of stay in the hospital by an average of 7.5 days

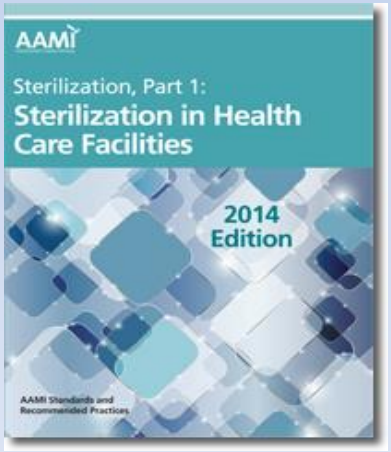
MRSA Infections





Surveys for Infection Prevention

- The Joint Commission uses two (2) sources for processing areas:
  - The Association for the Advancement of Medical Instrumentation ST-79 (www.aami.org). *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (2013).*
  - *CDC Guideline for Disinfection and Sterilization in HCFs (2008)*



Where it Starts

- Receiving Dock
  - Clean?
  - Stock not placed on the floor?
  - Delivered ASAP (especially items sensitive to environmental changes)
- Delivery carts clean?
- If LUM used, are bins cleaned daily? Carts?
- Who removes cardboard boxes? When?

Sterility Maintenance

- Need to protect and maintain sterility until item(s) used
- Packaging can affect sterility maintenance
- Stock rotation's effect on sterility maintenance
- Mishandling’s effect on sterility maintenance

Maintenance of Sterility

- 3 conditions that can compromise sterility
- Moisture
- Soil
- Physical damage
- A**ll affected by storage/handling**

Moisture

- Can be caused by excessive humidity
- AAMI standard is maximum 70% humidity in sterile storage areas
- Placing sterile pack on/near fluid (e.g. sink)
- Leaks from ceilings
- Wet hands
- Wet packs
- Coffee? Liquids?

Soil

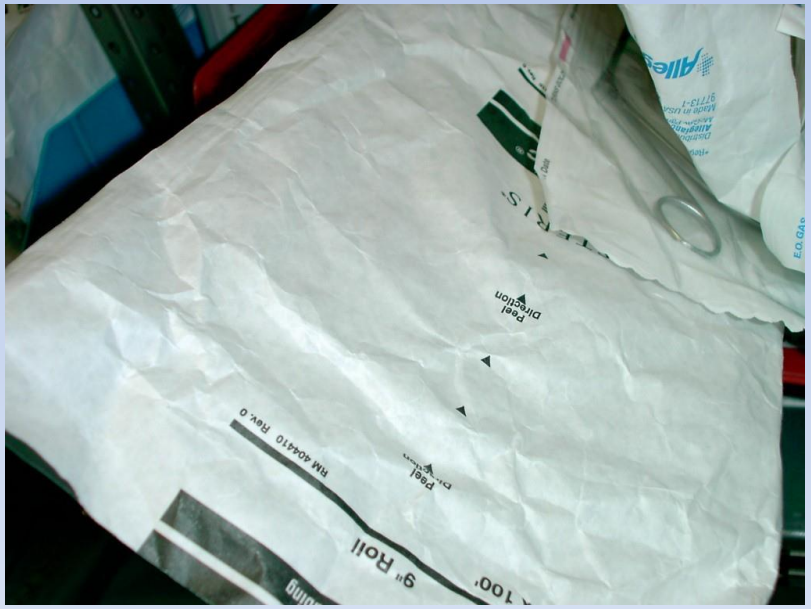
- Sterile packs should not be stored on dirty/dusty shelves or tote bins
- Storage locations need to be disinfected monthly or more frequently if needed
- Soil from unclean hands can be compressed into packs

Physical Damage

- Properly Stored Small Items

Physical Damage

- Should a peel pack look like this?
- Crushing due to excessive handling and/or overcrowding in storage



How Many Things Wrong here?

Sterile Storage

- Sterilized items should be properly stored to prevent contamination
- Need segregated area
  - Temperature 68- 75^{o}F (AAMI)
  - Humidity should not exceed 70%
  - 4 air exchanges/hour - positive pressure
  - Monitor and document daily

Sterile Storage

- Employees 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
- 18” from sprinkler heads (fire code)

8-10” Off the Floor, Solid Bottom Shelf

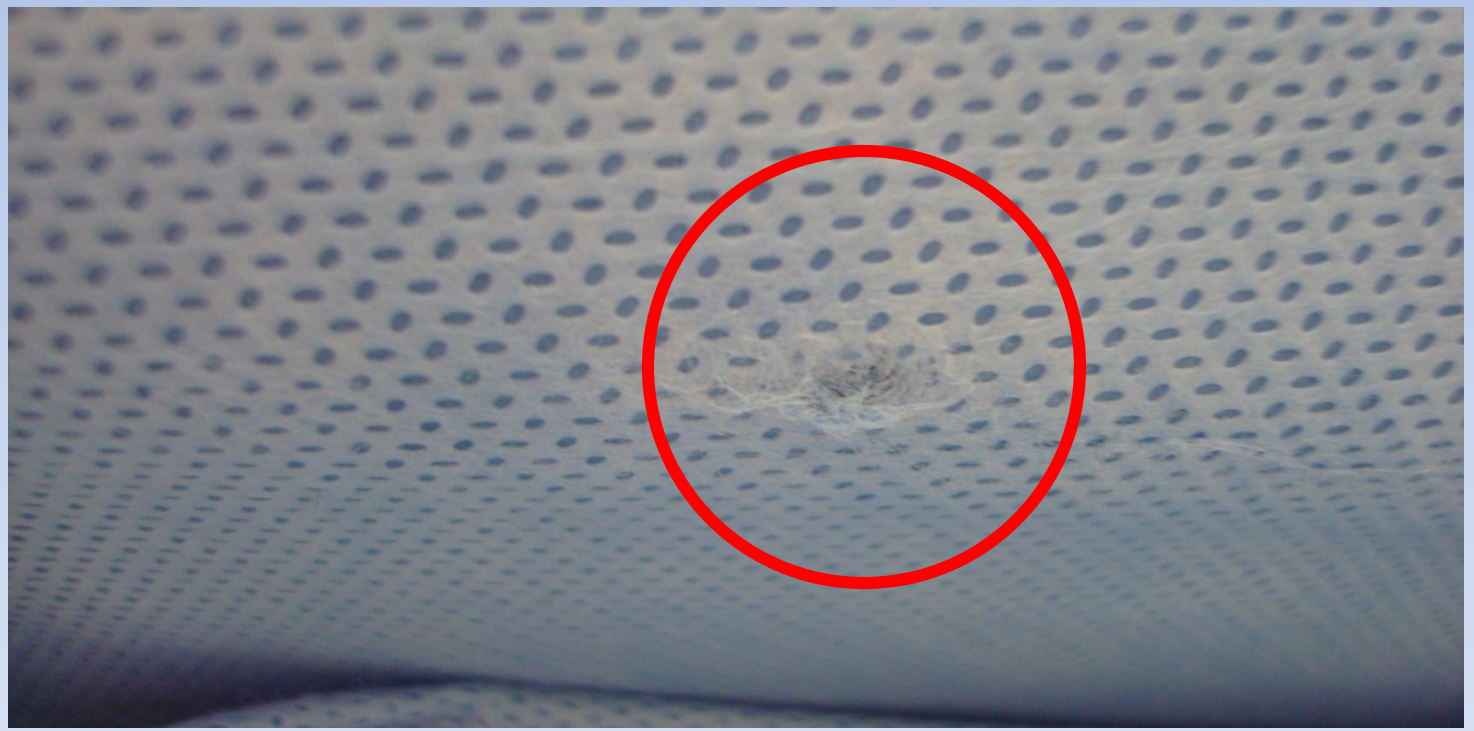
At Least 18” From Ceiling Fixtures

Sterile Storage

- Solid top and bottom shelves
  - Can use plastic overlays
  - Tote bins
- Need to limit traffic
- All personnel entering area must be properly attired (scrub suit or cover gown, head cover) to keep contaminates to a minimum
- Handwashing facilities available

Sterile and ready to use?????

Abraded Wrapper



Soil

- Dust on implants in storage
- Outside shipping cartons considered contaminated
- Can harbor vermin as well as microbes including fungus

Physical Damage

- Improper handling
- What's wrong with this picture?

Physical Damage

- Due to location of defect, classically a result of excessive weight from a heavier tray placed on top

Physical Damage

- Items being returned to SPD – unused on cases
- Is this acceptable?

Manufacturer's Instructions for Use

- It all starts here!

Alcon®/Grieshaber®

45.0037.4g

Directions for use

REF 335.00 Foreign Body Forceps

1. Description

The Alcon / Grieshaber Foreign Body Forceps consists of a handle and diamond coated jaws which open and close by activation of the spring loaded lever. The locking collar prevents complete closure of the jaws and thus damage to the diamond coating and enables effective cleaning and sterilization. They are used worldwide in modern ophthalmic surgery in famous hospitals for many years. These devices are produced according to the latest methods and standards and on the highest level of function and design.

2. Indications

Removal of foreign bodies, where tough gripping is required.

3. Precautions

a) The instrument may be used only by well trained physicians and personnel.

b) Always disengage the locking collar during surgery and reengage it for reprocessing and storage.

c) After the reprocessing, prior to each use the instrument must be thoroughly inspected for correct function, wear and damage

d) The instrument has to be returned to our Customer Support Department, if any damage or changes in its characteristics are observed.

e) Refer additionally to the safety instructions of the used cleaning and disinfecting solutions and to the hospital's hygienic instruction.

Patient Safety

- Device manufacturers have the responsibility to support label claims of reusability by providing
  - complete and comprehensive written instructions for the cleaning of their products.
  - Device manufacturers should provide users with one validated manual cleaning method and, if applicable one automated cleaning method.

FDA

- FDA places the responsibility totally on the medical device manufacturer to
  - consider the reprocessing equipment and methods HCFs routinely use when designing their devices
- Covers the design, testing, labeling of MDs for reprocessing

User Responsibility

- **Users must comply with and replicate exactly ALL cleaning, disinfection and/or sterilization instructions**
- Any changes, modifications or deletions makes the facility fully liable for the safety and efficacy of the device

Loaner Instrumentation

- Major impact on patient safety and infection control
- Instrumentation requires extended cleaning and sterilization cycles
- May require extended soaking in enzymatic detergent
- Multiple (10-30) trays can be brought in for a single case

Loaner Instrumentation

- Need a strict Loaner Policy to ensure
  - Instruments brought in with sufficient time to completely reprocess according to the written manufacturer's IFUs
  - May require 48-72 hours in advance of surgery based on # of procedures being performed
  - If multiple procedures scheduled, are sufficient instruments provided to prevent "quick turns" where employees are forced to take short cuts?

Loaner Instrumentation

- Are the trays/instruments in good condition?
- Do we have the most current IFUs?
- Is there a count of instruments upon receipt and before return?
- Can we even comply with the IFUs?
  - Sufficient ultrasonic cleaners (should have one for each mechanical washer)

Specialty Procedures?

- If processing ophthalmic instruments, do you have a policy and procure to prevent Toxic Anterior Segment Syndrome?

TASS

- Toxic Anterior Segment Syndrome (TASS) – main focus by AAMI and AORN
- TASS - an acute inflammatory response of the anterior chamber of the eye.
  - May lead to severe visual impairment if it is not recognized and treated in a timely manner.
- Many causes including detergents, water quality, steam quality, instruments, etc.
- Major concern is when **endotoxins** form

TASS

- Outbreaks of TASS have often been linked to the failure to follow the processing procedures recommended by the instrument manufacturer
- 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).
- Also in AAMI ST-79 as an Annex

TASS Prevention

- An adequate inventory of the necessary intraocular surgical instruments should be maintained in order to allow for the timely processing of instruments between cases.
- Major issue in surgery centers
- Insufficient inventory of instruments leads to short cuts in cleaning

TASS Prevention

- 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.**

CJD Prevention

- CJD (Creutzfeldt-Jakob Disease) and related diseases are infectious disorders
- Cause progressive neurological disease
- Can have extended incubation periods.
- Caused by prions (infectious proteins) 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

- 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.**

Sentinel Event Alert

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."

New Hampshire 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

New Hampshire 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)**

New Recommendations

- 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

- One method - 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 LEGIBALLY written on the card.

Patient Care Equipment

- Manufacturer's IFUs for cleaning all equipment available
- Cleaned and disinfected according to the IFU
- How transported to Decontamination area?
- Biomedical tag on all equipment? Staff confirms equipment inspection current
- After HLD how is equipment stored to protect from re-contamination
- How does the end user know equipment was processed? (e.g. tag, plastic bag)

Cleaning Impact

- Same procedures apply regardless of where cleaning takes place
- Using correct PPE
  - Facial protection – must protect from splashes from ALL angles (goggles and face shield with fluid resistant mask)
- Sinks marked with water level – ensure all detergents diluted properly – can interfere with cleaning and improper rinsing

Decontamination

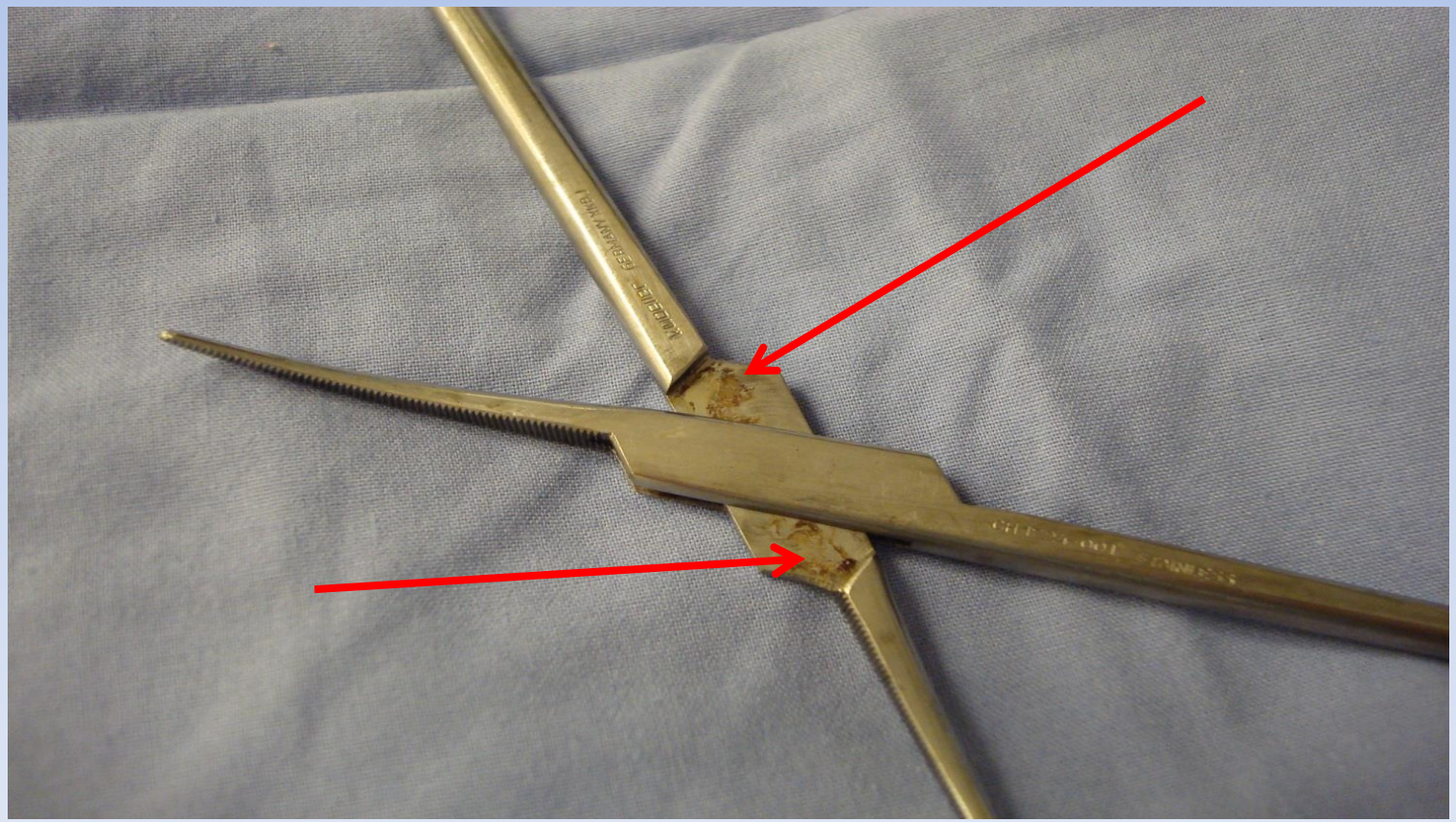
- Monitoring water temperature for enzyme detergents if recommended by the IFU
- Monitoring temp and humidity levels – affects growth of microorganisms
- Environmental Cleaning – daily
- Sufficient type and quantity of processing equipment to meet patient needs and comply with IFUs

Prep and Packaging

- Correct temperature and humidity levels
  - 35-60% humidity
  - 68-73 deg F.
- Temperature and humidity can adversely affect packaging materials; can dehydrate or make excessively moist impacting in sterilization

Prep and Packaging

- Items inspected for cleanliness using lighted magnification?



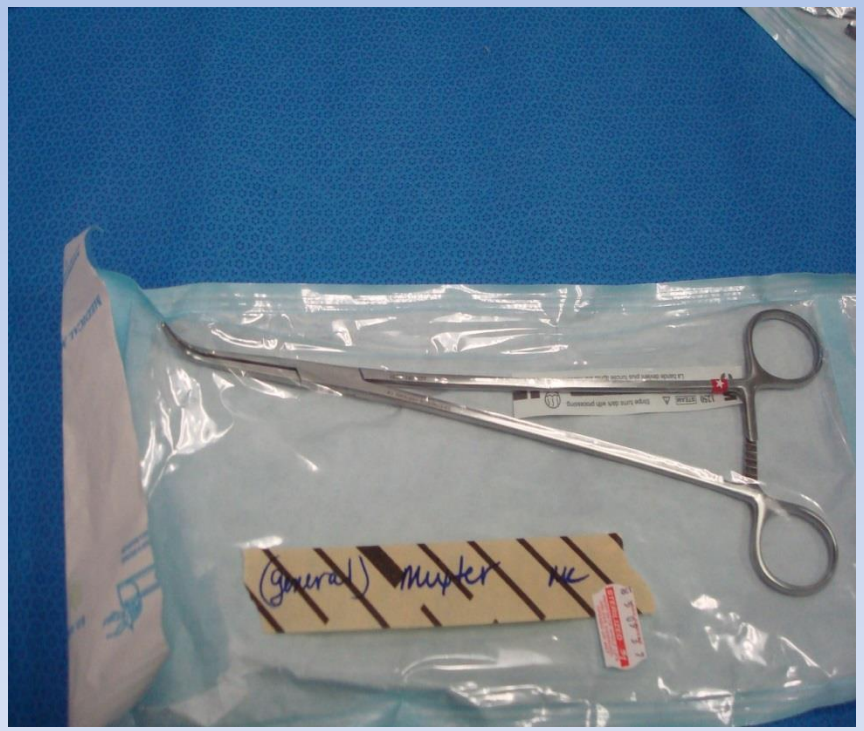
Instrument Marking Tape

- Must be maintained
- When flaking or peeling off, microorganisms, blood and body fluids can adhere to the adhesive and be difficult to remove

Incorrect Packaging

- Peel packs must be packaged correctly
- No double pouching unless validated by the mfr
- Inside pouch must lay flat inside outer pouch – interferes with correct air removal and sterilant penetration

Proper Assembly



- Jaws MUST be open before, during and after sterilization
- Use tip protectors or other devices
- Cannot achieve sterilization unless ALL surfaces make contact with the sterilant

Packaging Materials

- Paper wrap – in compliance with IFUs?
  - Some require weighing trays and using specific weight of the wrapper based on weight of the tray
  - Not all validated for Sterrad, EO, gravity cycles
- Rigid Containers – complying with IFUs?
  - Performing BI testing annually to verify effective sterilization inside the container?
  - Inspected before each use to ensure sterility maintenance?

Sterilization

- Following ALL manufacturer's IFUs
- Many items require special cycles and extended exposure tmes
- May require additional steam sterilizer capacity
- Need reference chart for staff

High Level Disinfection

- Must comply with IFUs for all chemicals nd the device mfr
- Does the HLD require a specific temperature? Is it monitored and documented?

IFU Policy

- Need a policy to review the IFU BEFORE an item is purchased.
- Prevents issues with reprocessing
- Once the device gets into the facility – it is too late

Handwashing

- One of the most important parts of infection prevention!
- 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
- Use of hand sanitizers in clean areas (e.g. case carts)

Process Improvement

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

Personnel Considerations

- Credentials for Manager
- Annual Competencies for SPD staff
  - Who performed them?
  - Specific?
  - Who performed competency assessment on person who performs the competencies?
- Orientation Guide
  - Detailed
- Staff certified
  - Certification current?
- Continuing Education provided routinely and documented?

Competencies

- Should be performed for all new procedures, equipment
- Should require return demonstration
- #1 cause of medical errors is lack of training/education (Institute of Medicine)
- Is a liability and patient safety issue

Processing Equipment

- There is a preventive maintenance program for all processing equipment
- Equipment is serviced in accordance with the manufacturer's recommendations for PM
- Impacts on cleaning and sterilization

Conclusions

- There are MANY ways that Materiels Management and Sterile Processing impact on patient safety and infection control
- While not a complete list, this should identify some of the major factors to address

Conclusion

- Infection prevention should be a way of doing business everyday, not just when we are expecting surveyors
- As healthcare reimbursements continue to decrease, we ALL must be diligent and practice good infection practices each and everyday

References

- Association for the Advancement of Medical Instrumentation. "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities", ST-79, 2013.
- Centers for Disease Control. Guides for Disinfection and Sterilization in Healthcare Facilities, 2008.
- Centers for Medicare and Medicaid Survey Guidelines 2013.