Who Do You Believe?

Complying With Manufacturers' Instructions

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Objectives

- **Discuss the importance of IFUs and manufacturer's instructions for instrument reprocessing**
- **Understand how critical thinking and objective evidence can contribute to best practices and acquisition of best products**
- **Review why validation has become an FDA requirement for medical device manufacturers**
- **Understand how information you receive from vendors needs to be reviewed with good common sense, and instructions may need to be reconciled with practice requirements**

Background

- Sophistication of medical/surgical procedures has resulted in new generation of instruments and medical devices
- Devices vary in size, weight, complexity, immersibility
- Vary in cleaning, disinfecting and sterilization processes

AAMI TIR-12

Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

- Originally published 2005; updated 2010
- TIR is not a national standard; technical information report
- Addresses medical device design considerations to ensure products can be safely and effectively reprocessed
- Includes information on common healthcare facility decontamination, cleaning, disinfection, and sterilization processes

Impact of TIR-12

- Medical device manufacturers are responsible for providing clear written instructions on handling, cleaning, disinfection, testing, packaging, sterilization, and aeration
- Medical device manufacturers must test to validate these written claims and instructions
- Healthcare personnel need to verify manufacturers' data and instructions, and have resources to follow them through
- Ask questions when considering the purchase of a new device

Healthcare Personnel

- Responsible to make sure that the cleaning methods recommended can be duplicated in their environment
- Ensure all instructions followed correctly
- May require training by device manufacturer
  - On-site preferred
  - Hands-on
  - Return demonstration
  - Competency verification

Training

- For especially challenging devices with complicated cleaning protocols
  - Multi-part devices, devices with narrow lumens, powered equipment
  - Provide training materials (e.g. videos/manuals) to enhance personnel education
- The device manufacturer should consult with manufacturers of cleaning products and equipment to develop cleaning instructions

Healthcare Ethics

- Ethics matter according to the National Center for Ethics in Health Care
  - "How can we model honesty, forthrightness, and trustworthiness?"
  - "How do we build and maintain trust?"
  - Integrity, commitment, respect, and excellence
  - Core characteristics: trustworthy, accessible, agile, innovative, integrated, and delivering quality

Critical Thinking

- **Critical thinking means gathering data and making decisions based on fact**
- Unfortunately, some companies grab your attention with supposed "facts," when in reality these may be unverified claims, marketing jargon, or designed to cast doubt on your decisions
- FDA requires medical device manufacturers to provide instructions for use (IFUs), reprocessing instructions, and now validated cleaning data.
  - This can provide the empirical data needed to make sound decisions

Regulatory Requirements

- FDA enforces AAMI documents including TIR-12
- FDA requires MDMs to validate their product label claims of reusability and provide complete and comprehensive written instructions for:
  - Cleaning, disinfection, testing, packaging, sterilization, drying and aeration (if applicable)
- Users must verify MDM instructions in their facility utilizing their own equipment and resources

Understanding Requirements

- Manufacturers' compliance with AAMI standards is voluntary
- Not legally obligated to comply unless they claim to do so (most do)
- Manufacturers are required to report to the FDA:
  - Any medical device-related patient injuries or deaths
  - Malfunctions that could cause injury/death

Sterilization Instructions

- Manufacturers are required to provide users with IFUs which may include:
  - Listing of 510ks
  - Claims like:
    - Event-related sterility maintenance
    - Lumens
    - Internal and external stacking
    - Compatibility with current sterilization modalities
  - Reprocessing instructions
  - Useful life of product

Cleaning Instructions

- Manufacturers of devices intended for reuse should provide to the user, in writing, specific information regarding:
  - Type and necessary quality of the water (e.g., distilled water, deionized water, water treated by reverse osmosis, filtered water, or hard or softened tap water)
  - Type and quality of cleaning agents and cleaning accessories that should be used
  - Handling and preparation of devices for cleaning
  - Manual or mechanical method that should be used for cleaning, rinsing, and drying

Validation Testing

- Validation is intended to address the worst-case scenarios or attributes of the products in the family
- Neither AAMI nor FDA requires manufacturers to test every device on the market, but to validate a worst case scenario from a family of products
  - May select a master product that is the worst case and this can be used to represent the family
- Product related variables can possibly affect the ability to clean/sterilize products

Validation of Cleaning Process

- To assure users that an item can be successfully decontaminated, device manufacturers should develop:
  - Decontamination recommendations that provide for thorough cleaning and meet clinical markers
  - Can be performed in the healthcare facility using commonly available chemicals, supplies, and equipment
  - Can be duplicated by healthcare personnel

Validation of Cleaning Process

- Procedure can be easily understood by the user
  - E.g. diagrams and step-by-step instructions are helpful to personnel
  - Are in alignment with the recommendations of professional organizations and with OSHA regulations for minimizing occupational exposure to bloodborne pathogens (29 CFR 1910.1030)
  - Include a method by which users can verify effective decontamination

Wall Reference Chart

Validation of Cleaning Process

- MDM must use scientifically valid methods and show that the recommended cleaning process is effective in removing the simulated soil from all surfaces of the device that could come in contact with:
  - Patient
  - Accessible to tissue
  - Blood
  - Body fluids
  - Other organic materials

Design Considerations

- When designing devices, small, narrow openings should be avoided
  - Can provide sites for corrosion
  - Can harbor microorganisms
  - How can they be cleaned?
  - Do they need to be flushed?
  - Is your sterilizer validated for the internal diameter of the lumen?
  - Is your sterilization container validated for the internal diameter of the lumen?

Labeling, Mislabeling, Confusion

- While design process should include risk assessment, have you seen warnings, cautions, or potential for device damage noted on the labeling?
- Have you wondered why your vendor tells you one thing, and the IFU says another?
- Mislabeling and misinformation can create confusion, and even contribute to hospital acquired infections (HAIs)

Do you Believe the Standards or Your Vendor?

- All guidelines say that all medical devices, including rigid reusable container systems, must be washed, rinsed, and dried after each use
  - Why are manufacturers instructing users to use environmental cleaners instead, or not clean or touch surfaces at all?

Wet Packs Are Sterile?!?

- AAMI guidelines clearly state that reusable packaging for terminal sterilization must be dry for transport and storage
- Have you heard that, "Wet packs are actually sterile water"?
- One company even claims a shelf life for wet containers and claims in their IFU that it is not of importance
  - Example, "It is not the packaging's main goal to reach a dry result. … The water inside is sterile."
- Do you agree?

How Accurate Are Your IFUs?

- Some are confusing
- Some are too brief
- Some are too detailed
- Some are downright wrong and misleading

When IFUs are not Explained **OR FOLLOWED**…..

This is the result

Reconciling

- How to reconcile manufacturer's recommendations and IFUs with good common sense

- Let's see some examples

EXAMPLE 1: XXX Spine Instruments IFU

- Clean microsurgical instruments separate from routine instruments
- Disassemble devices which can be disassembled
  - **If the device has a sliding mechanism or hinged joints, clean all areas where fluids can accumulate**
  - Clean all cannulated instruments using a brush of appropriate diameter and length to clean all interior surfaces of cannula
  - Rinse thoroughly
- Use a neutral pH enzymatic detergent to soak instruments. Use a soft brush to remove any tissue or blood. Rinse
- Place all levels in ultrasonic cleaner and process for **10 minutes**
- **Place all levels of set in washer/decontaminator**

XXX Spinal Instruments IFU con't

- Steam sterilize as follows:
- Pre-vacuum steam sterilize
- TEMP. 270°F – 275°F (132°-135°C)
- TIME: 6 minutes exposure

What's Wrong with XXX Spinal IFU

- IFU does **not** tell us **what** to disassemble or **how**!
- Does not specify if all the levels of the container can be washed together or separated
- Gives a range of sterilization temperatures. In the US we can only use 250°F gravity for 30 minutes; 270° pre-vac for 4 minutes or 275° for 3 minutes pre-vac
- We cannot use 272, 273, 274 as they are not validated for use in the US. IFU does not specify this

Example 2: XXX Clamp IFU

- Remove Instrument Clamp from Vertical Bar
- Remove Vertical Bar from Table Clamp
- Immerse the XXX clamp System in ***soap***
- Sterilize using moist heat

Example 2: XXX Clamp – Revised IFU

- Remove Instrument Clamp from Vertical Bar
- Remove Vertical Bar from Table Clamp
- Immerse the Fast clamp System in a detergent based water solution and leave to soak for a minimum of 5 minutes
- Use a soft brush to dislodge any tissue or blood
- Do not use automated cleaning
- Sterilize using moist heat

  Minimum sterilization parameters = 121 deg C @ 2 bar for **15 minutes using Gravity Displacement** with 10minutes minimum dry time.

What is Wrong with Revised IFU for Clamp?

- This was the revised IFU received after company was informed they would be reported to the FDA
- Still unacceptable--sterilization cycle does not meet AAMI minimum standards
- It does state **minimum** standards, however they can confuse processing technician that all they need is 15 minutes exposure at 250°F gravity displacement

Example 3: XXX SPINE INSTRUMENTS

- Cleaning Instructions for Complex Instruments that cannot be disassembled:
- Rinse/flush device and internal components with an Enzymatic cleaner
- Actuate device
- Scrub device for 3 minutes with soft bristle brush
- Soak in cleaner for 30 minutes in fresh cleaner
- **Shake device for 30 minutes on mechanical shaker at 250 osc/minute**

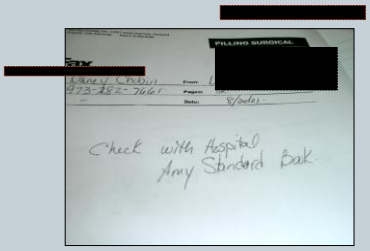
XXX SPINE INSTRUMENTS con't

- Transfer to fresh cleaner and scrub for 3 minutes
- Flush internal components with syringe while actuating device for 1 minute
- Rinse with fresh DI water three separate times
- Sonicate device in fresh enzymatic cleaner for 30 minutes
- Scrub device for 3 minutes with soft bristle brush
- Flush internal components with syringe while actuating device for 1 minute
- Rinse with fresh DI water three separate times
- Achieved a 3.38 Log Reduction

XXX Spine Explanation

- Soak in cleaner for 30 minutes in fresh cleaner
  - (What does this mean????)
- Shake device for 30 minutes on mechanical shaker at 250 osc/minute
  - **Turns out this is a paint mixer machine – Do you have one in your department?**

This Will Help?????



Drying

- Minimum vs REQUIRED
- Some manufacturers now recommending dry times of 55-70 minutes!

Extended Cycles

- Some manufactures have validated for extended cycles
- No BIs or CIs currently on market validated for extended cycles
- Most packaging materials have not been validated for extended cycles
- Never place items in an extended cycle unless recommended
- Ties up sterilizer for single item (can get small sterilizer for these cycles)

Extended Cycles

- Devices validated for "usual" cycle may be damaged in extended cycles – don't assume you can place other items in an extended cycle
- Barrier characteristics of packaging materials (and container filters) may be adversely affected
  - Check with packaging manufacturer for extended cycle validation
- Get all the information in writing
- Don't assume

Why are IFUs Not Followed by SPD?

- IFU are not available/current
- IFUs not conveniently located
- IFU are not easily followed
- The equipment and tools to follow them are not available in SPD
- Not enough time/insufficient staffing to follow all the steps

Practice Problem Areas – Cleaning

- Taking short cuts in cleaning
  - Manufacturer recommends 45-60 minutes of sonication – Staff gives 5 min – Who will know?
  - Manufacturer recommends 45-60 minutes of soaking in an enzyme – Staff soaks 2 minutes – Who will know?
  - Washing multi-level sets with all levels inside container
- Not reading the IFUs
  - Assuming device gets cleaned "as usual"

REALLY??

REALLY????

Problem Areas – Cleaning

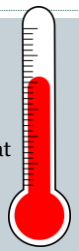
- Not having sufficient/proper processing equipment to comply with IFUs
  - Should have one sonic for each washer – may need more if lots of extended cleaning protocols
- OR does not send instruments to SPD immediately at the end of the surgery
  - One manufacturer recommends that cleaning be initiated no later than 30 minutes after use of the retractor
  - Some MDMs now recommending cleaning be implemented immediately after use
  - How can SPD comply without the cooperation of the end user?

Problem Areas – Cleaning

- Staff not trained/educated in all instruments/devices
  - Who did the training? How much time?
    - Attend inservice if provided by the sales rep
    - Ask for their IFUs to follow along – see if they comply with their company's IFUs
  - Was the device actually used?
  - Was a return demonstration required?
  - Was a competency assessment performed?
- Are reference materials readily available?

Problem Areas – Sterilization

- Not verifying manufacturer's IFUs for cycle type (gravity or pre-vac) and exposure time
- Most facilities have MULTIPLE different cycles in use
- One transducer is validated for 60 minutes at 270°F pre-vac!
- What happens when you get an IFU with a temperature of 273° or 274°F?



Problem Areas – Sterilization

- If you have sterilizers that operate at 270°F., what do you do when the IFU gives a temperature of 275°F. and visa versa?
- What about: sterilize pre-vacuum steam at 270-280°F. for 3 minutes?
- What about drying?
  - If IFU says minimum of 8 minutes – do you use it?
  - Are you checking – we have about 15% of Orthopedic or Neuro spine sets that require 50-70 minutes dry time!

It **IS** Your Responsibility

- Don't rely on sales reps to get information for you
- Obtain from the company's home office
  - Most current information
- Verify ALL information
  - If unclear, cycles not accurate, etc.
- Don't accept verbal information
- Ask questions
- Get information in writing
- Date them when received/update routinely

How to Comply

- Get the IFUs
- Having them on a computer does **not** meet the standard…questions to consider
  - Are people checking the book/computer?
  - How do you monitor compliance?
  - Is the info posted, so staff can see them?
- Who reviews the IFUs for accuracy, safety, compatibility with AAMI approved cycles?
- Don't depend on staff to "find and read"
- Provide in-services, perform competencies with return demonstrations

How to Comply

- Make videos of the in-services as reminders
  - For new employees
  - For staff members who infrequently process the device (e.g. overnight shift personnel)
  - Ask for videos from the company
- Visit the company's website – many have in-services on their webpage that can downloaded or accessed on line
- Ask the company for reference charts

Summary

- Check the sources of information
  - IFUs should be validated based on reliable, reproducible data and based on guidelines by official bodies
  - Caution: Some manufacturers' recommendations may not be based on objective study results, and may not be trustworthy
- IFUs should be clear and current
- Taking shortcuts from IFUs can lead to serious problems
- It is up to you to use validated best practices, review the information provided, question and think critically about unproven claims or info that simply makes no sense
- Infection prevention and patient safety is in your hands

To Report Problems/Issues

http://www.fda.gov/Safety/MedWatch/default.htm

References:

- **AAMI –*Comprehensive Guide to Steam Sterilization & Sterility Assurance in HCF, 2006, Annex I, 2008, Annex II, 2009, Annex III, 2010 Annex IV, 2012.***
- ***AORN Recommended Practices***
- ***AAMI TIR 12* -Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 2010**
- ***Basics of Sterile Processing, fourth edition***
- **National Center for Ethics in Health Care, U.S. Dept. of Veterans Affairs, www.ethics.va.gov**