LOANER INSTRUMENTATION—TODAY'S ISSUE; TOMORROW'S SOLUTION…

OBJECTIVES

- Discuss the history of loaner instrumentation
- Describe the impact that loaner instruments have on the Central Service department daily
- Identify basic protocols important to each step of the loaner instrument process
- Implementation of a loaner instrument policy at your facility

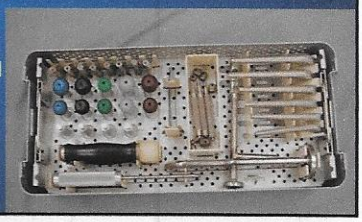
WHY DO I TALK ABOUT LOANER INSTRUMENTATION

- My story….the experience….2003 moved to Texas
- Interview/issues/expectations
- Paul Harvey…

- Experience –
- St. David's = 22,000 in 2009 / 24,000 in 2010
- Avg = 150 per day
- 237 one day record
- 77 = 1 patient record
- Huge impact = huge frustration

What are Loaner Instruments?

- A loaner instrument is…Instruments or sets borrowed from a vendor for emergency or scheduled surgical procedures that will be returned to the vendor following use.



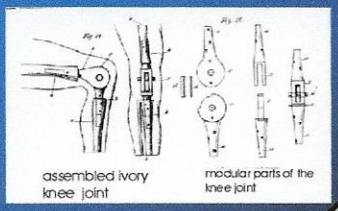
WHY DO WE GET SO MANY LOANERS?

- NEW TECHNOLOGIES
- TRIAL INSTRUMENTS
- SPECIFIC PATIENT NEEDS
- MULTIPLE CASES
- COST ISSUES
- STORAGE ISSUES

The History

- Professor Themistocles Gluck – Germany
- 1880's – 14 total joints
- 1960's – Became common
- Today – Chaos?

The History



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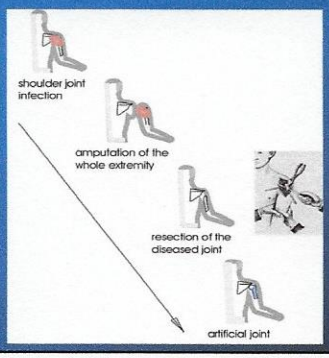

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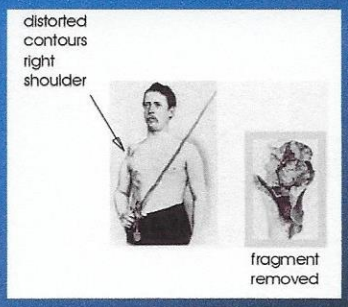
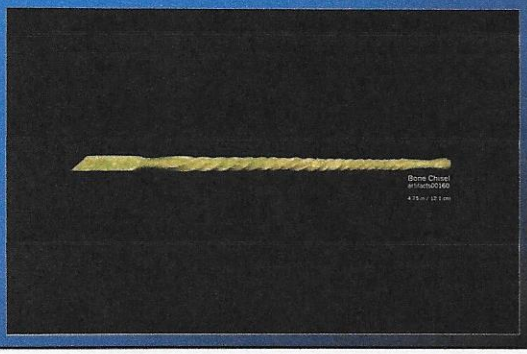


The History

- So, how have instruments changed through the years?

The History



The History

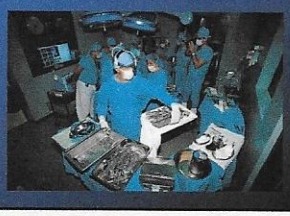
The History

The History

THE ISSUE

LOANERS--THE IMPACT

- Time
- Productivity – Staff & Equipment
- The OR
- The Patient
- The Vendor



Receiving

Receiving

Receiving

- All instruments should be considered contaminated and handled accordingly!
- From the time that they are received at your facility, you accept responsibility for them.

Receiving

- At the time of receipt you should;
  - –Have "Manufacturer's IFU's"?
  - –Ensure that every device is cleaned?
  - – Ensure every device is present— Any missing items?
  - –In working order?

Do you have instructions for every set borrowed or consigned from vendors?

Inventory

- Inventory Control Sheet
  - – Date
  - – Time
  - – Signature of delivery person
  - – Signature of receiving person
  - – Doctor's name
  - – Patients last name
  - – Number of trays
  - – Implant availability

You may receive some push back on this…

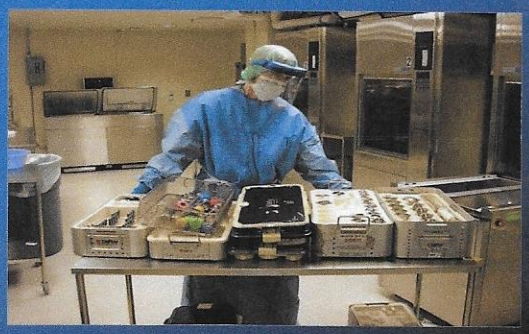
Inventory

- All of the processes mentioned increase quality outcomes.
  - ➢Performing an inventory control check to verify types and numbers of instruments and implants.
  - ➢Perform a quality assurance check by visually inspecting instruments and implants for damage
  - ➢The inventory control sheet should follow the instrument set/s through the entire process.
  - ➢IFU's ensure that proper decontamination is taking place

So, what about taking pictures?

Disinfection

Disinfection



Disinfection

DISCLAIMER....

Never trust the cleaning or sterilization processes of loaner instruments coming in from outside your facility!!!!!!!!!

HAVE YOU EVER DONE THIS WITH BAD OUTCOMES???

Disinfection

- As you know, the decontamination process is the MOST IMPORTANT step in the care and handling of loaner instrumentation.
  - The manufacturer's instructions for cleaning & disinfection must be followed.

The written recommendations of the device manufacturer should always be followed
AAMI ST79 : 7.2.2

Disinfection

Disinfection

- Each manufacturer has specific instructions concerning enzymatic detergents, temperature and mechanical cleaning methods that should be followed when using their product.

How closely do you inspect loaners that come in to your facility?

Inspection

Inspection

- After cleaning and disinfection, the CS/SPD technician must inspect each device for:
  - –Cleanliness
  - –Functionality

Inspection

- Defective instrumentation should be documented and reported to the appropriate person.
  - –Does your facility require a count-sheet from vendors?
  - –What impact do loaner instruments have on sterilization loads?

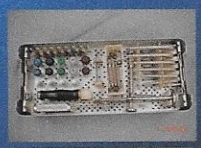
Sterilization

Sterilization

- Ergonomics/Weight
- Sterilization—Gravity vs Dynamic Air Removal
- Vendor Requirements
- Extended Cycles
- IUSS

LOANER TRAYS
(Tray Weights)

AORN used to recommend no more than 16-17 lbs and sterilizer mfg's validate their cycles with 16 lb sets to receive FDA clearance.



LOANER TRAYS—Ergonomics/Weight

•AAMI ST79

New standard covers minimum labeling and performance requirements for rigid sterilization container systems and for instrument cases, cassettes, and organizing trays.

Among other things, ST79 limits **total tray weight to 25 lbs.** This will assist HCW's in 2 very important ways…..

1)Ergonomics – safer to transport, and
2)Sterilization – utilize "standard" cycle parameters.

LOANER TRAYS--Prep and Pack

Loaner Trays should be prepared using:

1. Indicators/Integrators at every level
2. Correct wrap weight
3. Tape
4. Labeling

Sterilization

- Steam is recommended by all healthcare agencies, as the sterilization process of choice whenever possible.
  - Fast
  - Reliable
  - Inexpensive

Gravity Displacement

(Minimum cycle parameters)

Wrapped Instruments
250°F/121°C temperature, 30 min exposure, 30 min dry time
270°F/132°C temperature, 15 min exposure, 30 min dry time
275°F/135°C temperature, 10 min exposure, 30 min dry time

Textile Packs
250°F/121°C temperature, 30 min exposure, 30 min dry time
270°F/132°C temperature, 25 min exposure, 30 min dry time

Wrapped Utensils
250°F/121°C temperature, 30 min exposure, 30 min dry time
270°F/132°C temperature, 15 min exposure, 30 min dry time
275°F/135°C temperature, 10 min exposure, 30 min dry time

Dynamic Air Removal

(Minimum cycle parameters)

Wrapped Instruments
270°F/132°C temperature, 4 min exposure, 30 min dry time
275°F/135°C temperature, 3 min exposure, 16 min dry time

Textile Packs
270°F/132°C temperature, 4 min exposure, 20 min dry time
275°F/135°C temperature, 3 min exposure, 3 min dry time

Wrapped Utensils
270°F/132°C temperature, 4 min exposure, 20 min dry time
275°F/135°C temperature, 3 min exposure, 16 min dry time

IUSS Sterilization

(Minimum cycle parameters)

Gravity-Displacement Sterilizer-Unwrapped
270°F/132°C 3 min exposure for processing nonporous items
270°F/132°C 10 min exposure for nonporous and porous items

Dynamic Air Removal-Unwrapped
270°F/132°C 3 min exposure for nonporous items
270°F/132°C 3 min exposure for nonporous and porous items

Dry times are 0-1 minute.
Some rigid containers are designed for IUSS cycles.
Some sterilizers provide a cycle designed for use with a single wrapper.

Vendor Requirements

- The FDA requires mfg's to validate sterilization parameters for all Containment devices (rigid containers, instrument cases, organizing trays and cassettes) **and provide documentation to users.**
- Heavy and/or complex instrument trays will likely require extended cycle times.

Do your vendors walk in with cleaning & sterilization instructions?

Instructions For Use (IFU)

It is critical to follow the instrument MFR's instructions for use (IFU) with regards to water temperature, cleaning solution, brush type, and cleaning procedures.

For complex devices, specific times will be validated for the soaking, ultrasonic cleaning and/or rinsing.

Extended Cycle Issues

Many users feel that extended cycles have a detrimental effect on efficiency and sterility assurance for healthcare facilities.

For example….

1) Extended cycles tie up the sterilizer and can backlog sterilizer loads needing to be processed. *Does your facility have enough resources for these delays?*

Extended Cycle Issues

2) Devices validated for standard cycles may be damaged in extended cycles. *Do you need to contact each device mfg. before including them inside an extended cycle load?*

3) Barrier characteristics of sterile packaging (disposable wrap, tape and rigid container filters) may be adversely affected. *What testing has been done by mfg's to validate their packaging's barrier effectiveness in extended cycles?*

Extended Cycle Issues

4) Self-contained BI's may not be resistant enough or appropriate to use. ISO standard 12161 (Biological Indicators) states:

"User should not over process the culture medium, as extended sterilization may induce changes that can affect its growth-promoting properties. The ability of culturing medium to promote the growth of low numbers of microorganisms should be demonstrated."

What testing has your SCBI mfg done to validate their media's growth promotion ability in extended cycles?

Extended Cycle Examples

HOW BAD CAN IT BE? REALLY????

EXAMPLE - MFR's Cleaning IFU
SYMMETRY Orthopedic Instruments

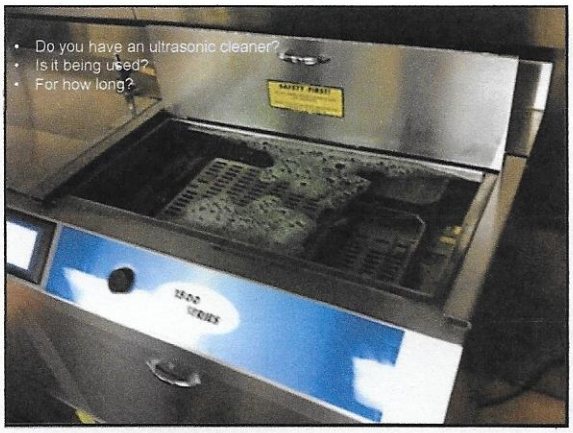
1. Submerge in enzymatic detergent.
2. Flush port with 50 ml enzymatic detergent.
3. Soak for 10 min in protein soluble detergent.
4. Scrub with soft bristled brush (agitate instrument while scrubbing).
5. Rinse with warm tap water (38-49°C)
6. Flush port with 50 ml warm tap water.
7. Place in bath of warm water (agitate by hand for at least 1 min). Repeat this process 2 additional times.

EXAMPLE - MFR's Cleaning IFU
SYMMETRY Orthopedic Instruments

8. Ultrasonic for 10 min with neutral pH detergent (flush port with 50 ml prepared detergent before sonication).
9. Flush port with clean tap water (3 times).
10. Rinse for at least 1 min with tap water.
11. Dry with clean, lint free cloth.
12. Inspect.
13. Lubricate tip mechanism and finger slot (do not lubricate flush port).

EXAMPLE MFR's Cleaning IFU
Zimmer Orthopedic Surgical Instruments

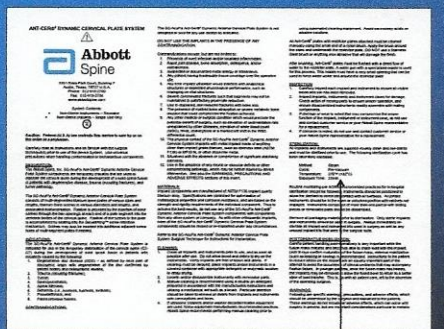
1. Completely submerge instruments in enzyme solution and allow to soak for 20 min.
2. Rinse in tap water for minimum of 3 min.
3. Ultrasonic clean for 10 min.
4. Rinse in purified water for at least 3 min.
5. Repeat sonication and rinse steps.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.



What if you cannot comply?

If this is an issue, you must secure the proper resources, or you must contact the device manufacturer and ask them to revalidate to your standard reprocessing procedures.

Not complying with device MFR's IFUs is a patient safety issue and could cause you to lose accreditation.



25 min @ 270°F (132°C) Pre-vacuum

Examples of MFR's that have at least one device requiring an "extended cycle"

- Abbott Spine
- Acclarent
- Acumed
- Biomet
- Blackstone
- Boss
- Boston Scientific
- CR Bard
- CarboMedics
- Cochlear
- D.O.R.C.
- DePuy Mitek
- DePuy Orthopedics
- DePuy Spine
- Drager
- Elekta
- Eilman
- Elmed
- EMS
- Encision
- Encore
- Estech
- Ethicon
- FCI
- FH Orthopedics
- FlashPak
- Genesis Biologics
- Globus

Examples of MFR's that have at least one device requiring an "extended cycle"

- Gore
- Greenwald
- Hand Innovations
- Heine
- Hitachi Medical Systems
- Hu-Friedy
- Hydrocision
- Innovasis
- Insight
- Integra
- Invuity
- Jardon
- K2M
- Kapp
- Lanx
- LDR Spine USA
- Medacta
- Medartis
- Mednext
- Metronic
- Microline
- Missonix
- Nuvasive
- On-X
- Ortho Development
- Orthofix
- Osteomed
- Pega Medical

Examples of MFR's that have at least one device requiring an "extended cycle"

- Respironics
- Rhein Medical
- Richard Wolf
- Ruggles
- SeaSpine
- Small Bone Innovations
- Spinal Elements
- Spine Weave
- Stryker
- Suprasson
- Surgipro
- Synthes
- The Electrode Store
- Thompson Surgical
- TriMed
- Unisensor
- US Spine
- Vacumetrics
- Varian
- Thoramet
- Viasys
- Vilex
- Wallach
- Welch-Allyn
- Wells-Johnson
- Wexler
- Zimmer

EXAMPLE... les)

SYNTHES ... graphic cases:
- Gravity: ... 22 mins exposure
- Pre-va... 132- ... r 8 mins exposure

SYNTH... Complex Se...
- Gravit... 135°C for 28 m... sure
- Pre-va... 132-135°C for 10 ... osure

Synthes has re-evaluated... sterilization recommendations... understanding our customers NEEDS... standard steam sterilization processes!!!!!!

SYNTHES

"Flash" Sterilization changes to "Immediate-Use"

AAMI, AORN and other organizations have agreed that "flash" is an antiquated term that does not fully describe the various steam sterilization cycles now used to process items not intended to be stored for later use.

"Immediate-Use" is broadly defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field.

Immediate-Use Steam Sterilization

The same critical reprocessing steps must be followed as a safe process does not include short-cuts. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another.

Cleaning, decontamination and rinsing are critical and users must follow and complete all required processing steps regardless of the sterilizer exposure parameters being used. The device Mfg's written instructions for use (IFU) must be followed.

Immediate Use Disclaimer

Smith & Nephew, the Association of Operating Room Nurses (AORN), and the Center for Disease Control (CDC) in Atlanta (USA), do not recommend the use of flash steam sterilization on implants.

Due to the increased risk of contamination, Smith & Nephew encourages the return of all opened porous coated implants for re-cleaning and sterilization.

Immediate Use Sterilization

IUSS should be used only in selected clinical situations and in a controlled manner.

IUSS should not be used with implants, and is not a substitute for insufficient instrument inventory.

IUSS should be considered only if all of the following conditions are met:

WHEN IMMEDIATE USE CONDITIONS ARE RIGHT…

- The device mfg's written instructions are available and followed.
- Items are disassembled and thoroughly cleaned with detergent and water to remove soil, body fats and other substances.
- Lumens are flushed with the cleaning solution and rinsed thoroughly.
- Items are placed in a sterilization container or tray in a manner that allows steam to contact all instrumental parts.
- Measures are taken to prevent contamination during transfer to the sterile field.
- Documentation of cycle information and monitoring results is maintained to provide tacking to the individual patient

Immediate Use Sterilization

VA Directive 7176

Flash sterilization will not be performed for the purpose of routine sterilization of surgical instruments. The flash sterilizer may be used during a surgical procedure for an unanticipated event. It is not recommended for large trays of instruments, such as loaner trays.

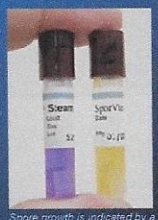
It is not recommended that items with lumens such as suction tubes, and power equipment be flash sterilized due to their complex makeup.

United States Department of Veterans Affairs

Quality Control

Biological Indicator with *Geobacillus stearothermophilus* spores should be used:

- at least weekly in Steam, preferably every day the sterilizer is used and every load that contains an implant.



Spore growth is indicated by a color change in the media during incubation

Quality Control

- For routine release of loads with an implant, a PCD with a BI and a Class 5 Integrating Indicator should be used.

- Whenever possible, the implant should be quarantined until the results of the BI are known.

Handling & Storage

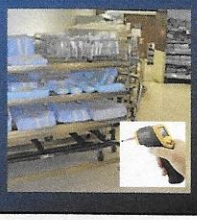
- After sterilization, the instrumentation should be moved to an area of the department with low traffic patterns and away from direct air-flow of cooling vents.

AAMI ST79 8.9.2 2006

Do you have unlimited space in your CS department? Are you able to do this?

LOANER INSTRUMENT HANDLING

All personnel should be trained to minimize the handling of sterile items. Sterilized items should not be touched while cooling and should remain on the sterilizer cart for a minimum of 30 minutes.

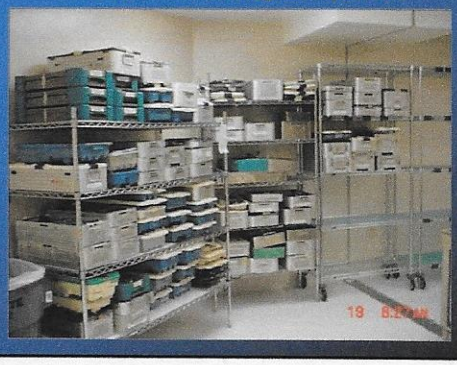


Handling

- Who transports your loaner trays?
- How are your loaner trays transported?
- Do you get holes in loaner trays?
- Does the OR ever rush into your area with a torn wrapper?

What about STORAGE??????

Limited Storage Space



Sterile Storage

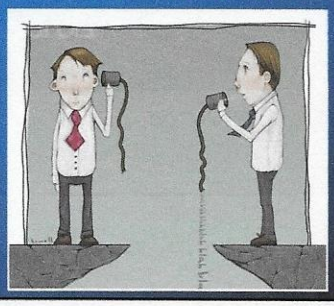
Sterile Instrumentation and supplies should be stored...

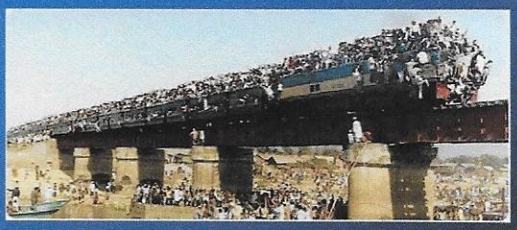
- 2" from outside walls
- 8 to 10" from floor
- 18" from ceiling fixture
- not crunched, bent, compressed, punctured or near any location that could become wet.

What about policies????

PAPER EXERCISE

COMMUNICATION BREAKDOWN





Policies & Procedures

- A partnership must be developed between the OR, CS/SPD and the Vendor!
- Policies & Procedures must be followed to ensure proper "Patient Care" procedures are being followed.
- Policies & Procedures help to ensure that everyone in our areas (both employees & visitors) are **always** on the same page!

Policies & Procedures

- Policies should discuss:
  - Ordering
  - Education
  - Transport in
  - Check-in
  - Processing
  - Charging (if applicable)
  - Post procedure processing
  - Check-out
  - Transportation out

NO CHASING CATS-POLICY

Policies & Procedures (Ordering)

- Who orders your loaner trays?
  - –The doctor
  - –Charge nurse
  - –Materials manager
  - –CS Department

It is imperative to manage this process well.

Who verifies that the right instruments have been ordered?

Policies & Procedures (Transport in)

- Who brings the instruments to your facility?
  - – The vendor
  - – A courier
  - – Cab driver

The picture has been blurred to protect the guilty parties :o)

Policies & Procedures (Transport in)

- Who brings the instruments to your facility?

DON'T WORRY.....
THEY ARE CLEAN.
JUST THROW THEM IN
THE STERILIZER...

Policies & Procedures (Check-in)

- Who & where are instruments checked in?
  - –Decontamination
  - –Check list – count sheet?
  - –Vendor & CS/SPD staff
  - –Quantity
  - –Quality
  - –When?????

Do instruments every come off of the street and go directly to the autoclave?

When do your loaner instruments arrive? What is the expectation?

Policies & Procedures (Processing)

- Decontamination
- Prep & Pack
- Sterilization

Policies & Procedures (Charging)

- Who tracks and charges for your loaners and implants?
  - CS/SPD
  - OR
  - Business manager
  - Materials management

Are you capturing all of your charges?

Are you being charged appropriately?

Policies & Procedures (Post procedure processing)

- How are the instruments processed after use?
  - Decontamination – Properly?

Do the vendors pressure you to get them done quickly? Does the vendor hand wash them?

Have vendors ever walked out of you facility from the OR?

Policies & Procedures (Check-out)

- Who picks up the instruments after use?
  - Vendor
  - Courier
  - When
  - Missing items
  - Broken items

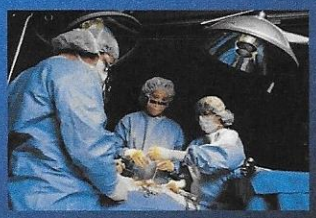
Policies & Procedures (Transportation out)

A picture is worth a thousand words.....

REMEMBER.....

- YOU ARE RESPONSIBLE FOR THE CLEANING AND STERILIZATION OF ANY INSTRUMENTATION USED ON YOUR PATIENTS.....

Behind every loaner tray is a **PERSON!**



Questions??????

REFERENCES & RESOURCES

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