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
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

assembled ivory knee joint

modular parts of the knee joint
The History

- Shoulder joint infection
- Amputation of the whole extremity
- Resection of the diseased joint
- Artificial joint
The History

distorted contours right shoulder

fragment removed
The History

• So, how have instruments changed through the years?
The History
The History
LOANERS--THE IMPACT

• Time
• Productivity – Staff & Equipment
• The OR
• The Patient
• The Vendor
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 Instructions”?
  – 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
  - Number of implants

You will probably 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.

So, what about taking pictures?
Disinfection
Disinfection

DISCLAIMER....

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

What do your loaner instrument sets weigh?
LOANER TRAYS—Ergonomics/Weight

• AAMI ST77: 2006, (Mfg’s document referenced in 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, ST77 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
Sterilization Preparation

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
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?
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?*
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*
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?
# Sterilization Instructions

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Minimum Temperature</th>
<th>Minimum Exposure Time / Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum</td>
<td>132 - 134°C</td>
<td>8 mins / 20 min dry time for metal or metal/poly trays and 45 mins for all poly trays.</td>
</tr>
<tr>
<td></td>
<td>134 - 137°C</td>
<td>5 mins / 20 min dry time for metal or metal/poly trays and 45 minutes for all poly trays.</td>
</tr>
</tbody>
</table>
### Zimmer Recommendations for Care, Cleaning, Maintenance and Sterilization for Zimmer Manual Orthopaedic Surgical Instruments

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Temperature</th>
<th>Sterilization Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum</td>
<td>270°F/132°C</td>
<td>4 mins</td>
</tr>
</tbody>
</table>

8 mins for wrapped Universal Instrument Cases without defined load configurations. 18 mins for Acetabular reamer system.

Note: Gravity displacement sterilization cycles are not recommended because cycle times are too long to be practical.
EXAMPLES (Extended Cycles)
SYNTHES® General graphic cases:
• Gravity: 132-135°C for 22 mins exposure
• Pre-vacuum: 132-135°C for 8 mins exposure

SYNTHES® Complex Sets:
• Gravity: 132-135°C for 28 mins exposure
• Pre-vacuum: 132-135°C for 10 mins exposure
February 2, 2009

Re: New Information on the Sterilization Recommendations of Synthes Devices, i.e. Implants, Instruments, and Cases

This letter is to inform you that Synthes has recently re-evaluated our sterilization recommendations with the intent of understanding our customer's need for standard hospital steam sterilization processes. The evaluation of fluid flow determined that re-qualification of our medical devices for sterilization in standard sterilizer parameters was warranted for the purpose of improving upon previously established sterilization test protocols. Testing has provided data which supports a sterilization assurance level (SAL) of 10^-6 using a standard hospital steam autoclave cycle, e.g., 4 minutes @ 132°C. New test protocols were established utilizing the “overall method” and sterilization performance criteria outlined in AAMI ST-2 and ISO 17665-2000. The new test protocols utilized worst-case devices for sterilization with respect to the device design, material, class, and volume.

The new parameters are as follows:

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Minimum Sterilization Exposure Time</th>
<th>Minimum Sterilization Exposure Temperature</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization</td>
<td>4 minutes</td>
<td>132°C (270°F)</td>
<td>20 minutes</td>
</tr>
</tbody>
</table>

Notes:
1. Dry times may be highly variable due to differences in packaging materials (e.g., wax, various polyethylene), sterilization conditions, sterilizer efficacy, device materials, load mass, sterilizer performance, and varying cool-down times. The user should employ valid methods (e.g., visual inspection) for achieving adequate drying, where differences between the manufacturer’s recommendations and the user’s results differ.
2. These parameters are only valid for devices that are adequately cleaned.
3. These parameters are only valid for a properly loaded, maintained, and calibrated AAMI compliant sterilizer.
4. These parameters cannot be used for the Synthes Power Drive Unit, PN: 550.100.

Henceforth, our process for changing our sterilization recommendations to standard cycle times is an ongoing process that will require further changes within our systems in order to replace older labeling with the new recommendations. This letter may serve as supporting documentation of Synthes current and updated sterilization recommendations.

If you have any further questions or concerns, please contact our Synthes Customer Service at 1-800-423-0322 or Synthes Sterility Assurance Department at 619-725-6836.

Thank you for your attention in this matter.

Sincerely,

[Signature]
Global Sterility Assurance Manager

[Signature]
Chetangi J. Judd, RN (MSN), CIC
Sterility Assurance Specialist
FLASH Sterilization & LOANER TRAYS

AORN cautions facilities that flashing should only be used when there is insufficient time to process by the preferred wrap or container method.
Flash sterilization should be used only in selected clinical situations and in a controlled manner.

Flash sterilization should be considered only if all of the following conditions are met:
FLASH Sterilization

**CSA** (Canadian Standards Association)

Flash sterilization should only be employed in situations where individual items (i.e. dropped instruments) require immediate sterilization.

Flash sterilization is employed when time does not permit the use of preferable wrapped sterilization procedure. Good processing practices are particularly important because of the difficulties associated with aseptically delivering devices sterilized by this method to the point of use.
FLASH 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.
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.
Handling & Storage

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

AAMI ST79:8.9.2 2006

Do you have unlimited space in your CS department? Are you able to do this?
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.
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???
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
Policies & Procedures (Transport in)

- Who brings the instruments to your facility?
  - The vendor
  - A courier
  - Cab driver
Policies & Procedures (Transport in)

• Who brings the instruments to your facility?

DON'T WORRY… THEY ARE CLEAN, JUST THROW THEM IN THE FLASH 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 “flash 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
(Check-out)

• Who picks up the instruments after use?
  – Vendor
  – Courier
  – When
  – Missing items
  – Broken items
Policies & Procedures (Transportation out)
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

Association for the Advancement of Medical Instrumentation (AAMI)
1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795
703-525-4890  Fax: 703-276-0793  Website: www.aami.org

Association of periOperative Registered Nurses (AORN)
2170 South Parker Road, Suite 300  Denver, CO  80231-5711
800-755-2676  Fax: 303-750-3212  Website: www.aorn.org

American Society for Healthcare Central Service Professionals (ASHCSP)
One N. Franklin Avenue, Suite 2800  Chicago, IL  60606
312-422-3700  Fax: 312-422-4577  Website: www.ashcsp.org

International Association of Healthcare Central Service Material Management (IAHCSMM)
213 W. Institute Place, Suite 307  Chicago, IL 60610
312-440-0078  Fax: 312-440-9474  Website: www.iahcsmm.org