Dirty Instruments in the Operating Room

The Complex and Confusing Process of Cleaning Surgical Instruments

Tim Brooks – August 2012

Presentation Outline

1. In the News
2. History
3. Review Instrument Studies
4. Review 2006 – FMEA
5. Surgical Instrument Classification
6. Surgical Instrumentation Design
7. Instructions for Cleaning by Manufacturer
8. Instrument Washing – Manual & Automation
9. Gain Understanding to the problem

Surgical Instruments are not Engineered to be Washed and Cleaned

They are Designed to Perform a Job

Current Culture

- Operating Room
  - Room turnover is completed as fast as possible in order to get the next procedure in
  - Driven by Surgeon Satisfaction
- Central Sterilization
  - Go as fast you can to keep up with the operating room

Current Healthcare Direction

CMS – Centers for Medicare and Medicaid Services

- **No Payment for Hospital Acquired Infections**
- **40% to 50% Hospital Revenue from CMS – Tax Dollars**
- **SCIP - Surgical Care Improvement Project**
  - **Pre-op Antibiotics**

Industry Focus - Central Sterilization

- Changes to Sterilization Standards – AAMI
- FDA - Challenges to Sterilizer Manufacturers – System-1 & 1e Sterilizers / Disinfector
  - No understanding how hospitals used them
  - No evidence base studies to support claim
- Early Release of Sterilization Cycles Containing Implants – Class-5 or Class-6
  - No evidence based studies to support the need for either product
  - No history of positive BI test resulting in contaminated flash sterilized instruments or sets containing re-processed implants
- Paper count-sheets in sterile trays
  - No evidence based studies to support claim
  - Increased cost of sterilization of instrument sets

Industry Focus - Central Sterilization

- Extended Sterilization Cycles for Orthopedic Loaner Instrument Sets - approximately 137 cycles
  - No evidence based studies to support claim
  - No BI developed to test cycles
- Washer Testing – Long Over Due
  - No water testing currently supporting quality
- FDA Reviewing Medical Device Manufacturer Instructions with Follow-ups
- Web-based service to electronically house instructions with annual fee

Industry Focus - Central Sterilization

- **Computer Systems Developed for Tracking Surgical Instruments**
  - Single most important development however not required
  - Software companies focus on tracking instruments rather then **quality testing**
  - Budget dollars limited
  - Systems not connected to sterilizers

In the News

February 2012 – MSNBC

TODAY Investigates: Dirty surgical instruments a problem in the OR A new report suggests doctors across the country are using surgical tools contaminated with blood and other debris and because the FDA doesn't require hospitals to report it, **many incidents are unknown.....**

April 2012 – CDC

Investigation Uncovers Dirty Surgical Instruments at Houston Hospital. **Human tissue and bone found stuck in shavers and cannulas**. An outbreak of surgical infections at a Houston hospital triggered a CDC inquiry that has found **unsanitary, contaminated surgical tools** in use.

April 2010 – Health and Human Services

Rates Rise for Some Common Hospital Infections. Federal officials say the nation's hospitals are failing to stamp out common infections that can turn life-threatening for patients. **The Health and Human Services department's 2009 quality report**, released Tuesday, finds **"very little progress" on eliminating health care infections. For example, rates of bloodstream infections following surgery increased by 8%**

Nov. 2010 – University Hospital of Columbia MO.

After CMS completed an inspection at **University Hospital in Columbia, Mo**., the hospital publicly posted CMS' findings on the hospital's non-compliance to infection control and housekeeping standards, according to a *Columbia Tribune* news report. Among CMS' long list of deficiencies, specific citations included "residue and debris on sterile instruments in sterile surgical containers."

Published Studies

- 2011 - Infection Control Hospital Epidemiol. Dec;32(12):1179-86. Epub 2011 Oct 17. Outbreak of Pseudomonas aeruginosa surgical site infections after arthroscopic procedures: Texas, 2009.
- 2009 - AORN Congress Poster abstracts Poster #32: The Effect of Single Use Instrumentation on OR Efficiency for Total Knee Arthroplasty: A Multicenter Efficiency Study. Presenters: David McQueen, Rama Ramakrishan, Oren Gleman, David Jasinksi
- 2008 - The Journal of Arthroplasty; 23(7); 984-991 - Kurtz S; Lau, E; Schmier, J; Ong, K; Zhao, K; Parvizi, J. Infection Burden for Hip and Knee Arthroplasty in the United States.
- 2002 - Infection Control and Hospital Epidemiology: Apr: 23(4); 183-189 Whitehouse, J; Friedman, N; Kirkland, K; Richardson, W; Sexton, D. The Impact of Surgical-Site Infections Following Orthopedic Surgery at a Community Hospital and a University Hospital; Adverse Quality of Life, Excess Length of Stay and Extra Cost.

Studies Regarding
Instrument Disinfection

- **2006 United Kingdom Study** – **260** Instruments Tested **66%** Showed Severe Contamination, **27%** Moderate, **7%** Low Level. All the instruments were processed through Automated Washer-Disinfectors

  House Instruments

- **2007 Walter Reed Medical Center Study -** Consignment - Loaner Orthopedic Instrument – 16% of 139 Implant Instrument Sets Tested Positive for Blood Residue

  Traveling Instruments

Known Contaminates

Viable Microorganisms:
- previous patient
- water

Organic: **Foreign Body Contaminate (FBC)**
- previous patient
- water
- detergent
- biofilm (washer or instruments)

Biofilm

- Microbial biofilms develop when microorganisms adhere to surgical instruments and produce extracellular polymers that facilitate adhesion and provide a structural matrix.
- Biofilms on surgical instruments may be composed of Gram-positive or Gram-negative bacteria or yeasts.
- Biofilms are frequently implicated in device-related infections.
  - Tap water plumbing
  - Instrument breakdown
  - Canulated instruments
  - Insulation on instruments
  - Instrument tape
  - Poorly maintained washers
  - Plumbing in washers

Known Contaminates

- TASS - **Toxic Anterior Segment Syndrome**
  - Non-infectious toxic material enters anterior segment of eye during surgery causing inflammatory reaction
    - Water contaminants
    - Residual cleaning chemicals
    - Organic Residuals

Foreign Body Contaminate (FBC)

FMEA - 2006

- Sterilizer Operator Error – no effect on patient care
- Report to Infection Control
- FMEA Process Initiated – 6 Months
- Employee Driven – NO MANAGEMENT
- Employees Identified 139 Failure Points
- 33 Failure Points Related to Instrument Cleaning
- **Instrument Cleaning Process Identified the Greatest Potential for Failure**

	List each risk point below Instrument placed in dirty dumb waiter or elevator and sent down to decontamination	Severity 1-4	Probability 1-4	Detectable 1 - 4	RPN (Risk Priority #) **S x P x D** Score of is action level
1	Instruments walk away	2	1	1	2
2	Instruments lost down dumb waiter	1	3	1	3
3	Some instruments thrown away accidentally	3	4	3	36
4	Not all equipment placed in dirty dumbwaiter	1	3	1	3
5	May receive equipment not suppose to	2	3	1	6

	List each risk point below Instruments taken out of dumb waiter or elevator and sorted	Severity 1-4	Probability 1-4	Detectable 1 - 4	RPN (Risk Priority #) S x P x D Score of is action level
6	Instruments lost down dumb waiter	1	3	1	3
7	Dumb waiter or elevator broken and instruments inside	2	2	1	4
8	Dirty instruments left soaking on top shelf	2	2	4	16
9	Sharps left	3	3	2	18

Failure Points - 139

- **33 Cleaning**
  - Post-op
  - Delivery - Time
  - Sorting
  - Disassembly
  - Washing
    - Manual
    - Sonic
    - Automated
- **106 Sterilization**
  - Sorting - Cooling
  - Assembly
  - Wrap / Package
  - Sterilization Type
  - Sterilization
  - Sterilization Monitoring
  - Storage
  - Pull For Case
  - Set-up For Procedure
  - Use
  - Discover during Procedure

Failure Points - 139

- **33 Cleaning**
  - Post-op
  - Delivery - Time
  - IT – Integrity Testing
    - Sonic
    - IT – Integrity Testing
    - Automated
    - IT – Integrity Testing
- **106 Sterilization**
  - Sorting - Cooling
  - IT – Integrity Testing
  - Assembly
  - IT – Integrity Testing
  - Pull For Case
  - IT – Integrity Testing
  - Set-up For Procedure
    - QA – Sterile Filed
    - Use
    - Discover during Procedure

- Integrity Testing (IT),
- Validation Testing (VT)
- Quality Assurance (QA)

Related to instruction for processing and preventative maintenance requirements from the device manufacturers including healthcare guidelines

Sources of Information

Manufacturers Instructions
- Instrument
- Sterilizer
- Washer
- Chemical
- Disposable Packaging
- Reusable Packaging
- Sterilization Monitoring

Healthcare Guidelines / Rules
- Spaulding Classification
- Good Hospital Practice
- Hospital Standards Organizations
  - AORN
  - AAMI
  - CDC
  - OSHA
  - APIC
  - IAHCSMM – CS Certification
  - AST – Association of Surgical Technologists
  - WHO

Fit into Hospital Policies and Procedures

Surgical Instrument Classification

Spaulding Classification System

- In the mid-1960s Dr. Earl Spaulding developed a framework to guide reprocessing decision making
- The system is based on the patient's risk for infection that various types of instruments or equipment contact can produce

Spaulding Classification System

Classification of devices, processes, and germicidal products			
Device classification	**Device (examples)**	**Spaulding process classification**	**EPA product classification**
Critical (enters sterile tissue or vascular system	Implants, scalpels, needles, other surgical instruments, etc.	Sterilization - sporicidal chemical prolonged contact	Sterilant/disinfectant
Semi-critical (touches mucous membranes [Except Dental])	Flexible endoscopes, laryngoscopes, endotracheal tubes, and other similar instruments	High-level disinfection- Sporicidal chemical; short contact	Sterilant/disinfectant
Non-critical (touches intact skin)	Thermometers, hydrotherapy tanks	Intermediate-level disinfection	Hospital disinfectant with label claim for tuberculocidal activity
3 - Classifications 4 - Levels	Stethoscopes, tabletops, bedpans, etc.	Low-level disinfection	Hospital disinfectant without label claim for tuberculocidal activity

Changes Affecting Spaulding

- Multi-Drug Resistant Organisms (MDRO)
- Manual instrument washing was the primary method for disinfecting instruments and medical devices – minimal automated
- Numerous reusable devices have been converted to disposable due to the inability to disinfect
- Decentralization of surgical instrument and mobile patient equipment management resulting in lack of standardization in processes
  - **Surgery - Endo - CS - EVS – Hospital Materials Management – Off Site**
- **Complexity of Surgical Devices**

Processing Methods Changes

Spaulding Class

Paper System

Sterilization
- **Steam**
- **Steam Flash**
- **EO**
- **Glutaraldehyde**

Cleaning/Washing
- **Manual Hand Washing**
- **Sonic Bath**
- **Minimal Automation**

Today

Paper System &
Computerized Instrument Management

Sterilization/Disinfection
- **Steam**
- **Steam Flash or Immediate Release**
- **EO (Phasing out)**
- **Peroxyacetic Acid (High Level Disinfections)**
- **Gas Plazma - Hydrogen Peroxide**
- **Ozone**

Cleaning/Washing
- **High Impingement Washer Disinfections**
- **Sonic Bath w/Circulating Flow Pumps**
- **Chemical Scope Washer / Disinfectors**
- **Container & Cart Washers**
- **Manual Hand Wash**

Today's Device Classification System

Classification of devices, processes, and germicidal products			
Device classification	**Device (examples)**	**Process classification**	**EPA product classification**
Critical Enters sterile tissue or vascular system and touches mucous membranes	Surgical Instruments Surgical Devices Implants Video Systems Flexible endoscopes and other similar instruments	Sterilization - sporicidal chemical prolonged contact	Sterilant Sterile Packaging
		Sterilization Sporicidal chemical	Sterilant No Packaging
Semi-critical (touches intact skin) 2 – Classification 3 – Levels	Stethoscopes, Countertops, Stretchers, Hospital Beds, Wheelchairs, Mobile Patient Care Equipment IV Pumps & Poles Walls - Floors Surgical Tables and surfaces	High level disinfection	Hospital disinfectant with label claim for multi resistant organisms

Surgical Instrument Bio-Burden Reduction Levels

Reduction level	Process
HIGH LEVEL Automated Mechanical Washer	**Disinfection: Thermal** • Thermal – water temperature 170°F - 220°F • High to medium impingement • Proper racking device • Disassemble instruments to allow contact
INTERMEDIATE LEVEL Manual / Mechanical Hand Washing	**Decontamination:** • Use of physical or chemical • Water temp below - 110°F to 120 °F (safe for staff) • Removal of gross visible bio-burden with brush • Inspection – sort - rack
LOW LEVEL Starts at point of use Manual Process	**Cleaning: Soaking & Sort** • Post-op - utilizing enzyme spray prior to transport • Enzyme detergent soaking in appropriate water temperature • Manual sort and disassembly • Use of ultrasonic cleaning when applicable

AAMI Voluntary Standards

Association for the Advancement of Medical Instrumentation

- **1974 – Standards Committee is Founded**
- **1980 – ST1 - Published first recommended practice "Good Hospital Practice"**
- **2006 - ST79 – ANSI/AAMI – Comprehensive guide to steam sterilization and sterility assurance in health care facilities**

AORN - IAHCSMM

AORN - Guidelines

- First national conference 1954
- AORN *Journal* 1963
- *Standards* published in 1965

IAHCSMM – 1958

- CS Certification 1971
- Recommendation to mandate past ten years

CDC 1999 – Recommendations for reducing surgical site infections. The report offered recommendations for every step of an operation including setup and post-op

Validation of Process

There are no evidence based hospital studies and few if any published industry studies to validate soil reduction levels from a

manual hand wash process through automation addressing

all instrument service lines

Instrument Service Lines

- **General Surgical**
- **Laparoscopic**
- **General Vascular**
- **Orthopedic**
- **Open Heart**
- **ENT**
- **OB / GYN**
- **Dental**
- **Urology**
- **Plastics**
- **Ophthalmic - TASS**
- **Thoracic**
- **Spine**
- **Transplant**
- **Neurosurgical - CJD**
- **Robotics**
- **Ortho Loaner Inst.**

Each instrument service line has specific requirements for quality assurance (IT, VT,QA), inventory management, and supporting re-processing however they cross-over into each others service lines

Instrument Type - Design

Type/Design	Spaulding Class
• Single Structure	– Critical
• Hinged Non Take-a-Part	– Critical
• Take-a-Part	– Critical
• Semi Take-a-Part	– Critical
• Laparoscopic Take-a-Part	– Critical
• Laparoscopic Non Take-a-Part	– Critical
• Electronic - Battery	– Critical
• Pneumatic Gas Powered	– Critical
• Canulated	– Critical
• Insulated or Coated Instruments	– Critical
• Video Systems and Scopes	– Critical

House Instruments - More then 40,000 patterns not including Ortho Loaner

How Does That Calculate

- 370 Bed Hospital
- 8000 surgical procedures annually
- 7,500 Sterilization Cycles/Loads
- 66,000 Items / Packages or Instrument Sets
- 1,400,000 instruments sterilized annually in the packages or sets – including loaner ortho
- 175 instruments per patient
- 1200 Different Instrument Sets
- 65,000 Instruments – Including Ortho Loaner
- $ 8,000,000.00

Surgical Instrumentation Design

General Instruments

Properties of Stainless Steel

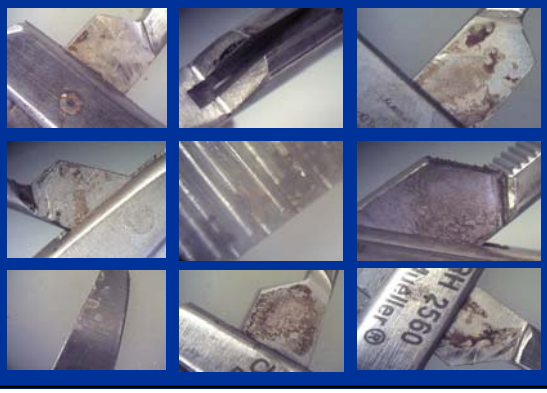
First Failure Point
Biofilm
TASS
FBC

NICKEL
CARBON < Strength & Stainless Properties
IRON < Strong - Malleable Properties
Iron in its pure form is reactive chemically rapidly corroding in moist air and warm temperatures

CHROMIUM < **STAINLESS PROPERTIES**
Chemical Treatment to Establish Passivation Layer

Chromium or Passivation Breakdown
Failure Point

Chromium or Passivation Breakdown



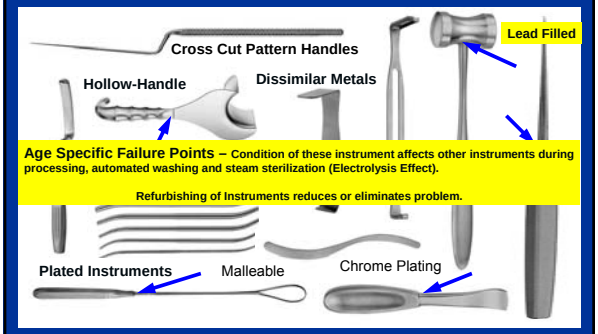
Failure Points Associated to Staining and Passivation Breakdown

1. Extended contact time of bio-burden
2. Poor manual process - **TASS**
3. Skipping the manual altogether - **TASS**
4. Lack of canulated cleaning - **TASS**
5. Utilizing metal wire brushes
6. Over use of stain removers
7. Improper washer cycle settings - **TASS**
8. No DI/RO Water Rinse - **TASS**
9. Improper chemical per oz. application - **TASS**
10. Improper washer installation
11. Stringing Instruments - **TASS**
12. Poorly maintained potable water supply - **TASS**
13. Shortened Rinse Cycle - **TASS**
14. Mixing dissimilar metals with surface breakdown
15. Lack of instrument refurbishing program
16. Poorly designed work processes

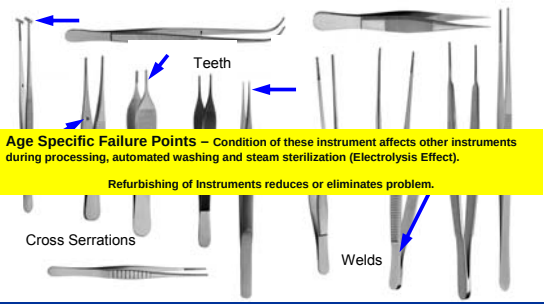
Basic Instrument Set

Single Structure

Subject to Lower Grade Materials & Plating



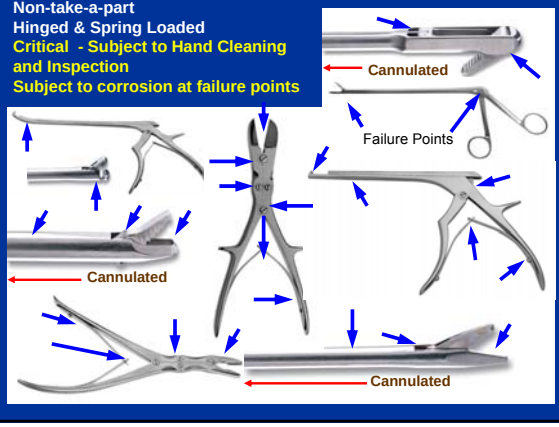
Single Structure - Forceps



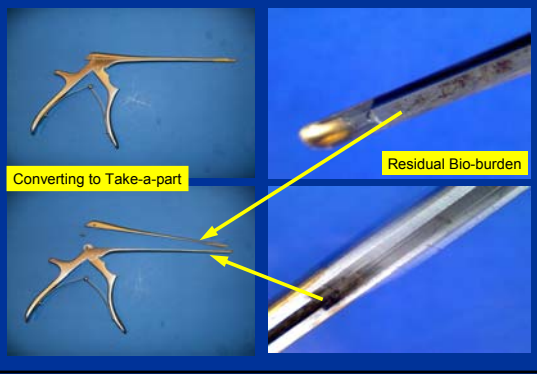
Age Specific Failure Points – Condition of these instrument affects other instruments during processing, automated washing and steam sterilization (Electrolysis Effect).

Refurbishing of Instruments reduces or eliminates problem.

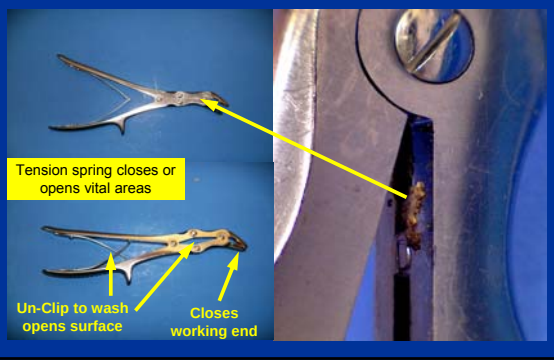
Non-take-a-part
Hinged & Spring Loaded
Critical - Subject to Hand Cleaning and Inspection
Subject to corrosion at failure points



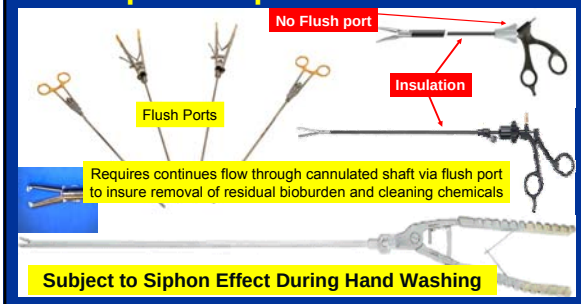
Non-Take-apart Rongeur Failure Points



Non-Take-a-part Tension Spring Rongeurs
Failure Points

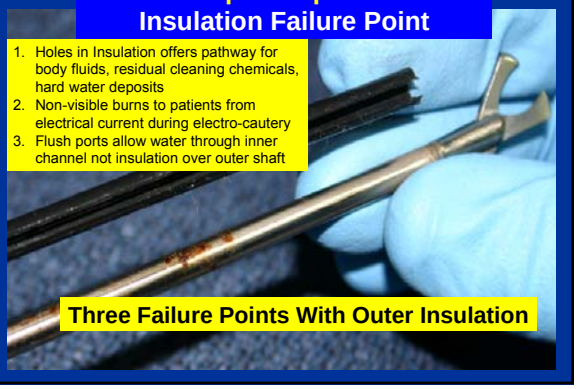


NON-Take-apart Laparoscopic Instruments

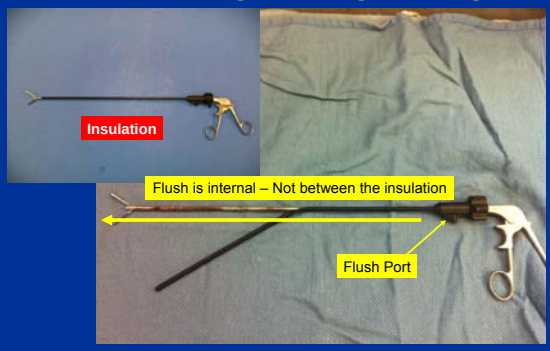


Non-Take-apart Lap Instruments
Insulation Failure Point

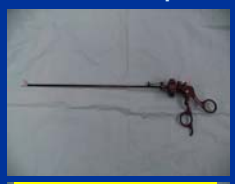
1. Holes in Insulation offers pathway for body fluids, residual cleaning chemicals, hard water deposits
2. Non-visible burns to patients from electrical current during electro-cautery
3. Flush ports allow water through inner channel not insulation over outer shaft



Non-Take-apart Lap Grasper

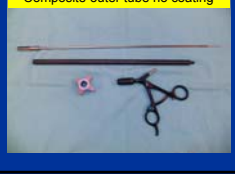


Take-apart Lap Instruments



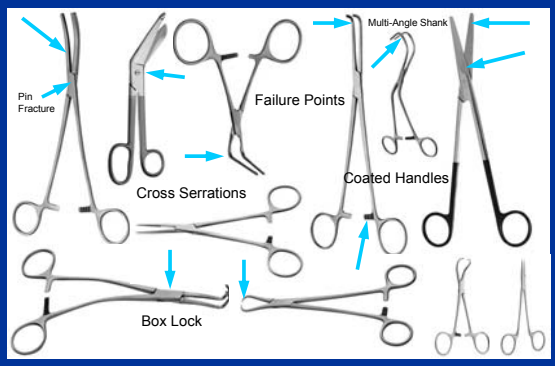
Outer tube coated with flush port

Composite outer tube no coating

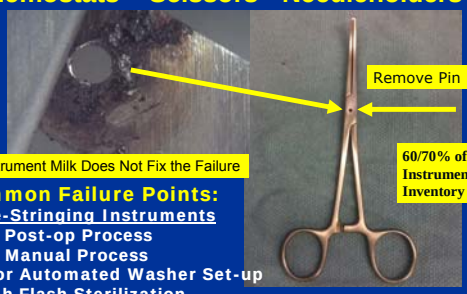


Newest Challenge
Bariatric Lap Instruments

Singled Pin – Most Widely Used



Most Common Failure Points
Hemostats – Scissors - Needleholders



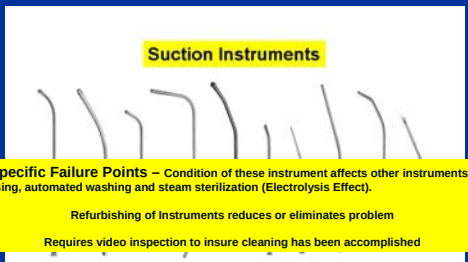
Instrument Milk Does Not Fix the Failure

60/70% of the Instrument Set Inventory

Common Failure Points:

- Pre-Stringing Instruments
- NO Post-op Process
- NO Manual Process
- Poor Automated Washer Set-up
- High Flash Sterilization
- Limited rinsing

Cannulated Suction Handles



Age Specific Failure Points – Condition of these instrument affects other instruments during processing, automated washing and steam sterilization (Electrolysis Effect).

Refurbishing of Instruments reduces or eliminates problem

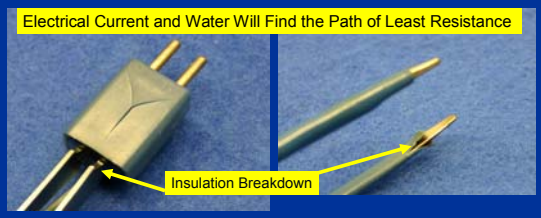
Requires video inspection to insure cleaning has been accomplished

Canulated with and without Chambered Handle

Disposable Available for Most Types

Insulated Bipolar Forceps – Failure Points

Electrical Current and Water Will Find the Path of Least Resistance



Insulated Instruments

Additional Devices

Air Hoses	Arthro-scopes	Resecto-scopes
Batteries	Broncho-scopes	Rhinolaryngo-scopes
Breast Implant Sizers	Camera	Choledo-choscopes
Saws and drills	Couplers	Cryo-probes
Sigmoido-scopes	Colono-scopes	Cysto-scopes
Dermatomes	TEE scopes	Diamond Knives
Duodeno-scopes	ENT Scopes	Entero-scopes
Urethro-scopes	Fiber-optic cables	Flexible biopsy forceps
Gastroscopes	Hystero-scopes	Laparoscopes
Nephro-scopes	Trocars	Light Cables
Phaco handpieces	Sheaths & cannulas	Light Sources
Bovie Cords	Bi-Polar Bovie Cords	

Power equip. and attachments

Manufacturer processing instructions not consistent
Most devices in this group are hand washed

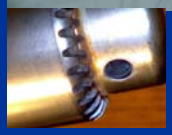
Video Systems - Hand Washed

Video Systems are hand washed unless the hospital has a low impingement flexible scope washer

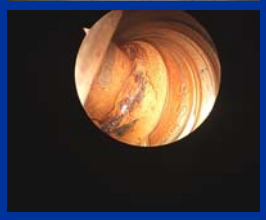
Power Equipment

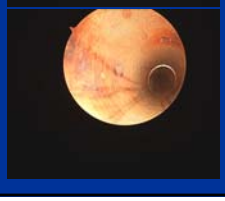
BONE MILL

Canulated



Canulated Drill Systems Attachments





Inner-Workings
Drill System Attachments

Hand washing is the primary cleaning process

Manufacturer dos not repair attachments

Ortho Loaner Instruments

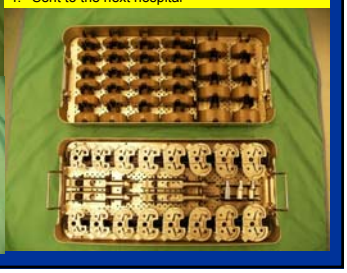
Loaner Instruments are shipped from hospital-to-hospital

Instructions for processing not included with sets

Industry primary concern has been weight of tray and sterilization cycle time, not washing

Ortho Loaner Systems

1. Hand Washed
2. Placed back into slot in the tray and washed in an automated instrument wash
3. Assembled for Sterilization
4. Sent to the next hospital



Hospital To Hospital

35 Sets of Instruments

Approximately 1200 Instruments

Delivered by 5pm – Must be washed, sterilized and ready for a 7am procedure the next morning

Traveling Instruments

Impact on Sterilization

Hospital Sterilization departments can manage as many as 15,000 different instruments from 25 or more different manufacturers;

Not including ortho loaner sets

All with specific cleaning, integrity testing, validation testing, quality assurance, and sterilization instructions that may differ from the hospital ability to process

Without a Computerized Instrument Management System there is minimal ability to track or maintain IT, VT, or QA

Objective - 4

Instructions for Cleaning

Instructions for Cleaning

- **Instrument Manufacturers**
- **Washer Manufacturers**
- **Cleaning Chemical Manufacturers**
- **Standards – AORN – AAMI – CDC – OSHA - WHO & More**

FDA – Following Device Instructions

Confusion Starts when the above refer to

- **Good Hospital Practice**
- **Hospital Policy & Procedure**
- **Alternate instructions**

Key Words & Phrases

- 90° degree angle
- Refer to
- Follow the
- Do not exceed
- minimum of
- All surfaces
- Thoroughly flush
- not recommended
- Hand Wash
- According to
- Deionized
- Distilled
- Demineralized
- STERILE WATER
- Good Hospital Practice
- perform an initial step
- in accordance with
- Stringed
- Mesh/wire basket

Instrument Manufacturer Instructions
Combination of Manual and Automated

- Clean contaminated instruments as quick as possible.
- Open instruments with a joint to a **90° angle**
- For machine cleaning, place the instrument in a **wire basket** suitable for the cleaning process, (make sure the cleaning solution and rinse water from the machine come into contact with **all surfaces** of the instrument)
- Completely dismantle any dismantable instruments
- Preferably dry disposal
- **For wet disposal, always use an active cleaning disinfectant. Rinse the instrument thoroughly with clear, flowing water before** machine cleaning and disinfecting
- If necessary, treat with ultrasound **according to** the **manufacturer's instructions**: for effective mechanical support during manual cleaning for pre-treatment of instruments with dried-on contaminent before machine cleaning
- If cleaning manually or in a machine: **Always follow manufacturer's instructions for detergents and other cleaning solutions**

Instrument Manufacturer Manual Cleaning / Disinfection

- **Place instruments into a suitable disinfectant with active cleaning properties so that all surfaces, inner cavities, lumens and openings come into contact with the solution. Follow the disinfectant manufacturer's instructions**
- After chemical disinfection, always **rinse thoroughly** with clear, flowing water. **Follow the instructions provided by the manufacturer of disinfectant**
- **Remove any dirt still clinging to the instrument with a soft synthetic brush. Do not use a scouring or metal brush**
- Clean any lumens and conduits with soft, round, synthetic brushes.
- **Please note - the lumen and the brush must have the same diameter**
- **Final rinsing should be done with distilled or deionized water**
- **Dry instrument with an absorbent, soft and lint-free cloth**
- **Dry lumens and conduits with compressed air**

Instrument Manufacturer Instructions

Vital instruments may be cleaned with a natural detergent and sterilized by steam or ethylene oxide methods. **Flash sterilization is not recommended for microsurgical instruments.** Cold soaking with glutaraldehyde may damage Vital instruments

Adds Two Additional Metals
Titanium
Gold

Endoscopic Grasper

Three Step Manual Process Required by the Manufacturer

1. **Hand wash the surface of the instrument with a soft nylon cleaning brush to remove any foreign matter**
2. **Thoroughly flush the instrument with enzymatic instrument cleaner**
3. **Then thoroughly flush with demineralized water through the flush port to remove all blood and debris which may obstruct the shaft lumen**

Endoscopic Grasper

STERILIZATION:

- CLEAN AND STERILIZE PRODUCT BEFORE EACH USE. STEAM STERILIZE
- **Sterilization in ethylene oxide is not recommended**
- **Sterilization in liquid solutions is not recommended**
- **Flash sterilization is not recommended**
- **Sterilization at temperatures greater than 275° F (135° C) is not recommended**

Instrument Manufacturer Atraumatic Vascular Clamps

CLEANING

1. **Hand wash** the Atraumatic Vascular Clamps using a low-sudsing, neutral pH (7-9), protein dissolving detergent. **Follow manufacturer's directions** regarding concentration, temperature, and contact time.
2. Totally, immerse clamps during cleaning to prevent **aerosolization**.
3. **Do not exceed two hours soaking in ANY solution.**
4. **Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.** Use of anything other than high quality brushes or lint free cloths designed for clamp cleaning may result in damage to the clamp.
5. **Atraumatic Vascular Clamps can be cleaned manually, mechanically or in an ultrasonic cleaner**

Instructions for Manual Cleaning Instrument Manufacturers

Rinsing Instructions for Manual Cleaning

- **Thoroughly rinse the clamps with distilled water to remove all traces of the disinfecting solution**
- **USE STERILE WATER ON THE FINAL RINSE**

DRYING

- **Clamps must be thoroughly dried to remove residual moisture before they can be stored. Moisture that is not removed may cause clamp corrosion**
- **Use a soft, absorbent towel, cloth, filtered compressed air, or a 70% alcohol rinse to aid the drying process**

From: [mailto: @ .net]
Sent: Tuesday, March 27, 2012 3:19 AM
To: Tim Brooks
Cc:
Subject: sterile water

Tim,
Hi, I have a question. If I opened a bottle of sterile water in sterile processing and date the bottle when done using it, How long can I keep the bottle.

I was told 72hrs. what is your opinion?

, CRCST

Camera Manufacturer Instructions

- Do not Cross-sterilize the device. Using multiple sterilization methods may significantly reduce the performance of the device.
- Soak – Prepare a non-enzymatic detergent, according to the manufacturer's recommendations of 0.25 ounces/gallon tap water at 35-40°C
- Soak the device for a minimum of 15 minutes

- Original Printed Instructions 2006
- Updated 2008/2010

Instrument Manufacturer Instructions in a Washer

Machine Cleaning/Disinfection

- Select the program according to the material (e.g. stainless instrument steel, aluminum) of the instrument to be cleaned
- **Follow the machine manufacturer's instructions**
- Final rinsing to be done with deionized water
- Leave sufficient time for drying
- Remove the instrument from the machine immediately after the program is done

Presoak and Cleaning Manufacturer Instructions

Manual / Ultrasonic applications:

- Dilute 1/8 to ½ fl oz per gallon (1 to 4 ml per Lt of warm water
- Activity increases as water temperature increases
- Soak minimum of 2 to 5 minutes
- Soak time may be longer with dried on proteinaceous materials
- If lower temperatures are used, a longer soak time may be necessary
- Do not exceed 130ºF
- After soaking, rinse thoroughly or transfer to next cleaning operation
- Discard used solutions daily or when visible soiled
- This is a complete product, do not add other chemicals, such as bleach or detergents

2012 Instructions for Cleaning Loaner Ortho Instrument Company

Point of use
- Remove gross soil

Manual Pre-Cleaning
- Soak in enzymatic solution
- **15 minutes (minimum)**
- Rinse using agitation under the water level

Manual Cleaning
- Soak in ultrasonic bath
- 20 minutes (minimum)
- Brush, Operate
- Rinse using agitation under the water level

Pre-Cleaning for Automated Washer
- Soak in ultrasonic bath
- 20 minutes (minimum)
- Brush, operate
- Rinse using agitation under the water level

Washer
- Disinfector
- **Wash - 93°C (200°F)**
- 10 minutes (minimum)
- Rinse
- Dry

Inspection
- Check soil "traps"
- Check operation
- Check straightness
- Check for damage

Automated Washer Instructions

Product Specifications and Operation

Product Specifications:

will reduce or eliminate sonic cleaning, manual washing, and handling risk with its intensive cleaning and thermal disinfection process

Operations:

Loads—Arrange trays of instruments directly onto shelves of the 2, 3, 4, or 5-level wash carts, or arrange utensils on racks and place racks on properly spaced shelves. Use proper injection carts and racks for lumen instruments and glassware. Once the washing cart is loaded, it is transferred to the washer using a transport trolley.

Operators Manual Statement

Advisory - Washer/Disinfector are intended only **to perform an initial step in the processing** of soiled, reusable medical devices. If medical devices will be contacting blood or compromised tissues, such devices must be terminally processed **in accordance with device manufacturer's instructions and/or Good Hospital Practices** before each use in human patients.

Indications For Use - Washer/Disinfector is indicated for use in the cleaning and **low level disinfection** of soiled reusable utensils, trays, glassware, bedpans and urinals, rubber and plastic goods, simple hard-surfaced rigid surgical instruments (such as forceps and clamps) and other similar and related articles found in healthcare facilities.

Operators Manual Instrument Placement Instructions

Always use a rack designed to handle appropriate type of items to be processed

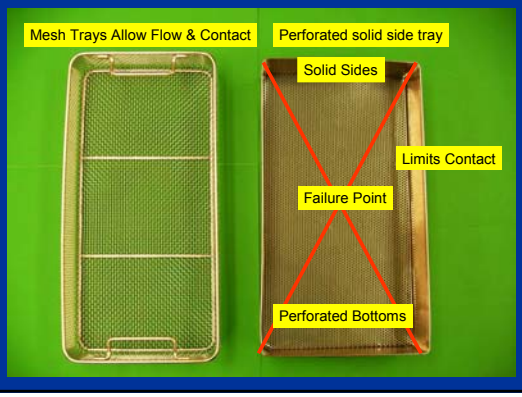
All hinged surgical instruments with handles (such as scissors, hemostats and forceps) must be stringed before being placed in a rack, to optimize cleaning of the hinges

A maximum of 50 items, open at a 90 degree angle, may be placed in each instrument tray

Rack Specifications

- **Two-level manifold rack is designed to hold trays of surgical instruments and hard goods individually on each level**
- Three-level manifold rack is designed to hold a general purpose rack, or one or two instrument trays on the bottom level, a general purpose rack, or one or two instrument trays on the middle level, and one or two instrument trays on the upper level
- Four-level manifold rack is designed to hold one or two instrument trays on each level
- Five-level manifold rack is designed to hold two **mesh instrument trays** on each level

Tray Selection Adds to Reduced Impingement



Cleaning to Sterilization

- **A single set of surgical instruments will have multiple manufactures represented on the count sheet / Instrument set**
- **All with differing cleaning instructions**
- **Instructions are not available to the technician completing the cleaning process in decontamination**
- **Instruction may have multiple steps**
- **Some will have multiple sterilization methods**

Lap Chole Instrument Set

- Take-apart
- Non take-apart
- Hinged
- Single Structure
- Insulated
- Dissimilar Metals

Six Vendors Represented

Objective - 5

Instrument Washing
Manual & Automation

Manual Process

- There is no standard for determining what constitutes safe to handle
- There are water temperature to chemical recommendations ranging 50°F to 140°F
- Maximum allow for hospitals 120°F
- There is no consistent method to measure and maintain water temperature during manual washing
- Water temperature below 109ºF may not activate some detergents/enzymes; water hotter than 140ºF will coagulate the protein (max hospital allow 120°F)
- No ability to maintain chemical to water ratio in most if not all manual sink systems

Failure Points with Manual Instrument Cleaning

1. Following Surgical Instruments and/or Chemical Manufacturers Instructions
2. No access to instructions
3. Staff must memorize
4. Limited to what can be taken apart and visible
5. Chemical Ratio to Water
6. Water Temperature
7. Limited to what staff can see
8. Poor Lighting

Primary Cleaning Tool

Reliance on Visibility

Manual to Automation

The Manual Washing Process Sets Up the Automated Process

Operators Manual Instrument Placement Instructions

Always use a rack designed to handle appropriate type of items to be processed

All hinged surgical instruments with handles (such as scissors, hemostats and forceps) must be stringed before being placed in a rack, to optimize cleaning of the hinges

A maximum of 50 items, open at a 90 degree angle, may be placed in each instrument tray

Washer manufacturer instructions - Position Instruments to allow contact to all surfaces

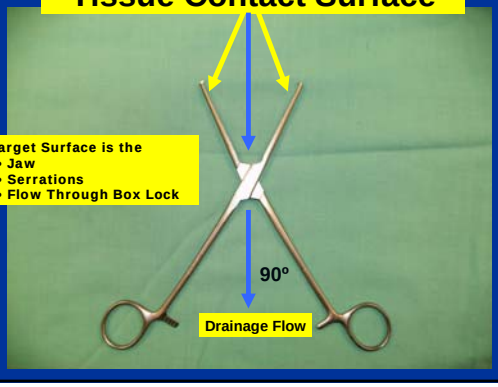
Instrument manufacturer - Open 90º to allow surface contact

How Many Instruments Per Tray Use Mesh Tray

Utilized by Some Hospitals to Save Assembly Time

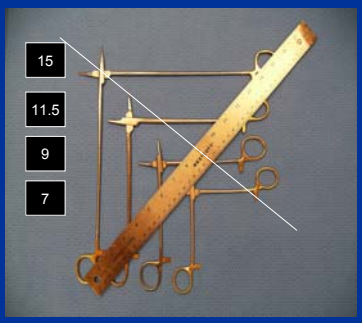
Recommended by the surgical instrument and washer manufacturer

Tissue Contact Surface



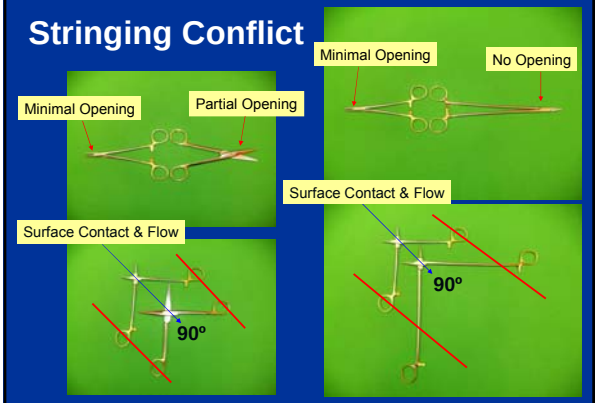
90º = Up to a 15 inch stringer

In total you would need 9 different stringers



Currently there a 2, 3, 4, 6, 9, and 12 inch available

Stringing Conflict



Pre-Stringing Failure Points

There are no studies to support this method or recommendations from instrument manufacturers as to its effectiveness

Adds processing time

Reduces water flow in the automated washer

Must remove from stringer on the clean side to complete IT's

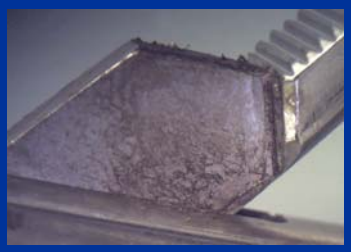
Pre-stringing requires a thorough manual cleaning process adding time to both pre & post washer

Failure Points - Processing stringed instruments in a instrument washer

- Limits washer impingement
- Adds time to decontamination
- Increases post-washer drying time
- Increase post-washer cooling time
- Requires de-stringing to complete integrate testing for scissors, needleholders, and box locks
- No ability to milk box locks - Box locks are completely closed

Inhibits final rinse resulting in potential of foreign body contamination during surgical procedures - TASS

This instrument was hand washed, placed on a stringer, sent through an automated washer. Packaged for sterilization and then given to an instrument repair professional for re-passivation



Automated Washer Design

History of the Home Dishwasher

- Joel Houghton, patented a wooden machine with a hand-turned wheel that splashed water on dishes, in 1850.
- L.A. Alexander, 1865, obtained a patent for a device that used a hand crank and gearing to spin a rack of dishes through the dishwater.
- Permanent plumbing arrived in the 1920s.
- In 1937, William Howard Livens invented a small dishwasher suitable for home.
- Electric drying elements were added in 1940.
- Today's home dishwasher have sanitize cycles

Automated Healthcare Instrument Washer History

- 1980's - First Attempt Was to Converted Sterilizers into Washer Sterilizers - Failed
- Adapted Commercial Dishwashers into the Medical Field
- At least three new version washers released with faster cycles over the past 10 years

Automated Instrument Washing Failure Points

- 60% - Mechanical Water Impingement from Spray Arm Technology – High psi
- 40% from: Chemical / Thermal
  - Cycle Time
  - Cold and Hot Temperature
  - Water Quality - Hardness
  - RO Water Purity
  - Enzyme Dilution
  - Detergent Dilution
  - Lubrication Dilution
  - Rinse cycle

Home Washer

Automated Healthcare Washer

Racking System

No Racking System

Automated Instrument Washing

Instrument Washer
High Volume
Low to High Pressure

Sonic Bath
Washer
Low Volume

Scope Washer
Low Volume
Low Pressure

Cart and Container Washer
Large Capacity – Medium Pressure

Automated Washers Failure Points

- No hospital completed standard for determining what constitutes safe to handle
- No hospital defined load limits – manufactures provide limits however they are not consistent between vendors
- No industry or hospital defined load configurations
- No quantitative studies to support load limits or configurations
- Limited instrument racking systems to improve surface contact
- No studies to support pre-stringing instruments
- No studies to support ortho implants washing

Automated Washers

- **Washers are tested in controlled environment labs under conditions that do not reflect hospital processing**
- **Limited number of instruments types supporting one service line are tested**

Surgical Instruments

- **Surgical instrument manufacturers are not required to provided instructions to the washer manufacturers as to how to clean their products**

  Refer to
  - **Good Hospital Practice**
  - **Alternate Instructions**

Other Factors

- Quality Water and Steam Systems
  - Use of potable water
  - House steam
- Available to Industry
  - Dedicated RO/DI water systems
  - Clean steam generators
  - High filtration systems

Sonic Bath Washing – Failure Points

- When to change water
- Measure chemical to water ratio
- No ability to monitor water temperature
- No rinse cycle in older units
- Time – how long is long enough – average 10 minutes
- No time studies for non-take apart instruments with extended shafts
- Out-patient facilities including dental may utilize only sonic and manual cleaning

Overall Performance of Automated Washers to Manual

Pros:

- Regulated Water Temperatures
- Regulated Chemical Dilutions
- Provides High Impingement
- Improves safer to handle for staff

Cons:

- No Instrument racking system for ring-handled instruments and forceps the bulk of the surgical instrument inventory
- No Dedicated Water Supply Systems

Home Washer

Racking System

Automated Healthcare Washer

No Racking System

Opened and Piled on Top of Each Other
Limiting Impingement in the Washer

What are the Load Limits

Trays Kept Together & Pre-Stringing

- **Completed 5 test per stringer set-up**
  - **Stringed laying on side – 47 instruments**
  - **Stringed standing up – 47 instruments**

Five test completed - all failed

General Lap Tray – 89 instruments

Placing Complete Sets In a Washer Without a Manual Process

Washer Manufacturer State in there instructions that you can do this

Read and Question All Instructions

Most Common Used Racks

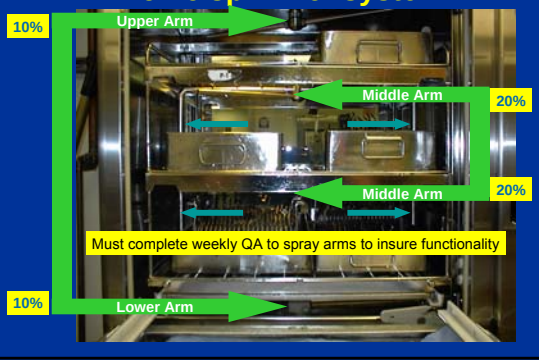
Racks Complete a Pressurized Water System

3-Level

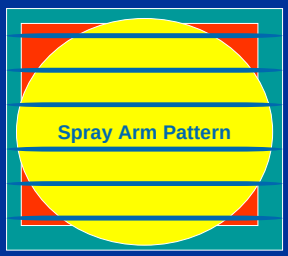
2-Level

General Purpose

Racks complete a circuit similar to a home sprinkler system



Spray Arm Impingement Pattern



General Purpose Basket

40%

Spray Arm – Machine Mounted

Layering

Reduced Impingement

Hold Down Screen

Wire Mesh Basket

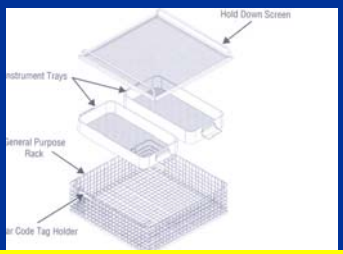
Shelf

20%

Spray Arm – Machine Mounted

Hold-down screen (see Figure 4-7) is designed to retain small miscellaneous objects in place. Use in combination with instrument trays, two-level manifold rack and three-level manifold rack.

Reduces washers ability to complete impingement and there are no studies to support using hold down screens for complete sets



Layering Decreases Impingement Action

2 – Level Rack

Stringer

15%

Spray Arm – Machine Mounted

Highest Impingement

Instrument Tray

Shelf

Spray Arm – Rack Mounted

30%

Reduced Impingement

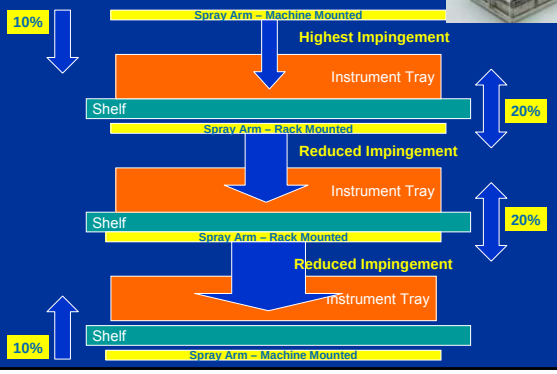
Instrument Tray

15%

Shelf

Spray Arm – Machine Mounted

3 – Level Rack



Racks Developed for Automated Washers

Always use a rack designed to handle appropriate type of items to be processed

Instrument Cradle

Instrument Cradle

Improved Instrument Set-up Resulting in Enhanced Washer Impingement

Trays Kept Together & Pre-Stringing

- **Completed 5 test per stringer set-up**
  - Stringed laying on side – 47 instruments
  - Stringed standing up – 47 instruments

General Lap Tray – 89 instruments

Meeting the Tray Limit Instructions

A maximum of 50 items, open at a 90 degree angle, may be placed in each instrument tray.

89 total instruments – 42 in left tray & 47 in right

RIGID MIS INSTRUMENT RACK

Designed for Lap-Chole and Canulated Instruments

Always use a rack designed to handle appropriate type of items to be processed

Attention needed to
Hospital Instrument Management

What's Needing Attention

- Mandatory Computerized Instrument Management Systems
  - Connected to Sterilizers
  - Connected to washers
  - Connected to Service Provider
  - Support Quality Assurance & Integrity Testing
- Dedicated water and steam systems
- Support from Hospital Quality, Infection Control management, Risk Management

What's Needing Attention

- Develop Automated Instrument Washers Rack Systems to Support Better Surface Contact
- Insure instrument design and structure allows for the cleaning process in the current washer systems
- 510k for manual and automated cleaning and disinfecting required for Instrument manufacturers
- **Managing the surgical set inventory to meet demands**
- Update building requirements to include CS expansion to meet future growth and volume increase

Equipment Needed in Today's Sterilization Departments

- **Video Systems for Inspection**
- **Microscope for Inspection**
- **Spore testing requirements**
- **Water Quality Testing**
- **Steam Quality Testing**
- **Instrument Refurbishing Programs**

Consistency Needed

- **FDA Follow the manufacturers instructions**
  - **Washer**
  - **Instrument**
  - **Chemical**
  - **Device**
- **Increase the FDA's knowledge**
- **AAMI Voluntary Guidelines**
- **CS Training Books**
- **CDC Guidelines**
- **OSHA Recommendation**
- **Delete "Good Hospital Practice"**
- **AIA Building Guidelines require change to insure proper department design and flow**

Education

Areas within Healthcare Requiring Additional

- AHA
- ASHRM
- APIC
- Physician related

Additional Available:

- Steris University – www.sterisuniversity.com
- IAHCSMM – CS Certification
- www.csspdmanager.com

Yuma Regional Medical Center

369 Bed Acute Care Hospital

- **14 operating rooms – 10905 total procedures annually**
- **4 – Suite On-Campus Out-Patient Surgery Center**
- **3 – Suite Off-Campus Out-Patient Surgery Center**
- **2 – Suite Open Heart Program**
- **Imagining Center**
- **4 - Suite Cardiac Cath Lab**
- **Off site Corporate Center with Warehouse and Purchasing**
- **Women's and Children's Center – 350 avg. births per month**
- **6 - Suite Endo Lab**
- **Wound Clinic**
- **Bariatric Clinic**
- **Orthopedic Clinic**
- **Cancer Center**
- **72 Beds Shield for Future Growth**
- **Second Hospital Site Purchased for Future Growth**
- **Admits – 18501**
- **ER Visits – 72057**
- **ALOS – 3.5**
- **Patient Days – 70485**

Director of Surgical Services Materials Management - CSSPD
Yuma Regional Medical Center – 24 years

- **Management Responsibilities:**
  - **Central Sterilization**
  - **SPD – Sterile Supply/Patient Care Equipment Support Hospital Wide**
  - **Operating Room Environmental Services**
  - **Surgical Services and Charge Master Analyst & Auditing**
  - **Capital Asset Management Department of Surgery**
  - **Operating Budget Analyst and Variance Reporting Department of Surgery**
- **Committee Involvement:**
  - **Infection Control Committee**
  - **Chairmen Surgical Services Value Analysis Committee**
  - **Hospital Material Management Value Analysis**
  - **Code Committee**
  - **Operating Room Through-put & Lean Six-Sigma Committee**
  - **OR Executive Committee**
  - **Department of Surgery**
  - **Patient Safety Committee**
  - **Operating Room Design**

Industry Involvement

2007 - Website: www.csspdmanager.com

- **April 2007: Published** - Infection Control Today magazine, ***" Adopting Failure Modes and Effects Analysis (FMEA) in the Healthcare Setting " Sterilization Process***
- **April 2008: Published - Medline Industries** – The OR Connection "Consistency in the Decontamination Process"
- **August 2008: Published - Infection Control Today** – "Steps in the management of Surgical Instrumentation"
- **September 2009: Published** - Massachusetts State Sterile Processing News Letter "Inconsistent Processes in Decontamination" – Sponsored by Mark Duro & Karen Nauss - Caregroup Harvard Education
- **May 2009: Published - Infection Control Today** – High Impingement Washing: A Vital Part of the Instrument Management Process
- **December 2009: Published** - Massachusetts State Sterile Processing News Letter "High Impingement Instrument Washing" - Sponsored by Mark Duro & Karen Nauss - Caregroup Harvard Education
- **September/October 2010: Published – HPN Healthcare Purchasing News** – OR Materials Management – Building Support Structure for Best Practice
- **May 2011: Published – Infection Control Today** – Why Does It Take So Long? The complex and indispensable requirement for instrument reprocessing

Speaking/Presenting – Focus Groups

- **November 2006: Focus group** STERIS Corp, Mentor, Ohio Customer Panel focusing on washer decontamination process
- **October 2007: Speaker/Presenter** - OR Manager, San Diego " Increasing Productivity & Employee Satisfaction in Today's OR…Transforming the Relationship Between the Operating Room and Central Services "
- **October 2007: Focus Group** - OR Manager San Diego CA. " Tells us what you think – About Decontamination and Instrument Processing"
- **February 2008: Webcast Speaker/Presenter** – Surgical Products Magazine – " Bridging the Gap Between the operating Room and the Sterile Processing Department "
- **May 2008: Speaker/Presenter** - Operating Rooms of the Future Conference, Huston Texas
- **March 2008: Speaker/Presenter** – Instrument Management Solutions – Birmingham Alabama "improving Instrument Through-put"
- **April 2008: Speaker/Presenter** - Arizona Chapter IAHCSMM – Improving the Decontamination Instrument Process
- **October 2008: Focus Group** - Denver Colorado, Infection Control and Instrument Management
- **November 2009: - Focus Group –** Cleveland Ohio, New FDA Requirements for Decontamination and Sterilization
- **April 2010: Speaker/Presenter** – Scottsdale Arizona – Scottsdale Healthcare, Mayo Clinic, and Gila River Healthcare – "Protecting Surgical Instruments" – STERIS – Cardinal On-Site Repair
- **January 2011: Focus Group** – Nashville TN – Keeping Your Head Above Water – Best Practice / Six Sigma / Process Improvement / Lean

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- **The Basics of Sterile Processing – Second Edition**
- **STERIS Reliance 444 Single Chamber Washer/Disinfector Operators Manual – 2007-06-26**
- **STERIS Reliance 777 Automated Multi-Chamber Washer/Disinfector Operators Manual – 2004-06-30**
- **Getinge 8668 Washer/Disinfector Product Specifications**
- **IAHCSMM - Lesson Plan CRCST 93 Cleaning and Decontamination of Medical Devices** *[Reprinted from Communiqué: March/April 2007]*
- **STERIS Technical Bulletin #2013 "THE CHEMICAL CLEANING OF SURGICAL INSTRUMENTS (6/99)**
- **STERIS Technical Bulletin #2002 –INSTRUMENT WASHER 320-800-2002(6/99)**

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- Whitehouse, J; Friedman, N; Kirkland, K; Richardson, W; Sexton, D. The Impact of Surgical-Site Infections Following Orthopedic Surgery at a Community Hospital and a University Hospital; Adverse Quality of Life, Excess Length of Stay and Extra Cost. Infection Control and Hospital Epidemiology: 2002 Apr: 23(4); 183-189
- Infect Control Hosp Epidemiol. 2011 Dec;32(12):1179-86. Epub 2011 Oct 17. **Outbreak of Pseudomonas aeruginosa surgical site infections after arthroscopic procedures: Texas, 2009.** Tosh PK, Disbot M, Duffy JM, Boom ML, Heseltine G, Srinivasan A, Gould CV, Berrios-Torres SI.
- Poster #32: The Effect of Single Use Instrumentation on OR Efficiency for Total Knee Arthroplasty: A Multicenter Efficiency Study. Presenters: David McQueen, Rama Ramakrishan, Oren Gleman, David Jasinksi

References

- Poster #34: Reduction in Instrument Tray Flashing Due to High Volumes of Sterilization Wrappers with Compromised Integrity. Presenters: Cynthia Fred, Deborah Stephenson, Sharon Ford
- **Pinto, F, de Souza, R, da Silva C, Mimica L and Graziano, K. Analysis of the microbial load in instruments used in orthopedic surgeries. Am J Infect Control (2009): 1-5**
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