Preventing Surgical Site Infection Related to Devices Used in Surgery

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Disclosure

oneSource
3M
Aesculap
Pfiedler
Boston Scientific
Stryker
Zimmer

Objectives

1. Discuss quality processes in sterile processing
2. Identify common breeches and key aspects of flexible endoscope reprocessing

Objective

Discuss quality processes in sterile processing

CDC Directive – Sept. 11, 2015
Updated Oct 2, 2015

Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

…Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they (1) are complying with all steps as directed by the device manufacturers, and (2) have in place appropriate policies and procedures that are consistent with current standards and guidelines….

http://www.emergency.cdc.gov/han/han00382.asp

It’s a New Day – Sterile Processing

Instruments increasingly complex
- Longer and more narrow lumens
- Variety of materials
- Expensive – need for rapid turn around

Instructions for use/maintenance (IFU) are problematic

Expanding knowledge base

Intense focus from JCAHO, etc.

Need for critical thinking skills

It’s a New Day

Few credentialing requirements for SPD personnel

Growth in related guidance/standard/regulatory documents

More than ever there is a need for IPs and SPD personnel to collaborate

- There is a mutual need to understand processes and roles

The Instruments

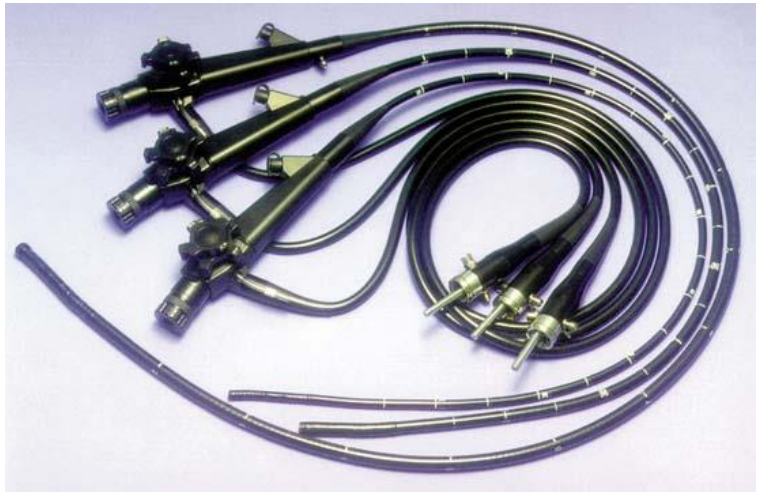
Hard to trace an instrument to an infection yet SPD is often the first place that is investigated when there is a SSI of unknown origin.

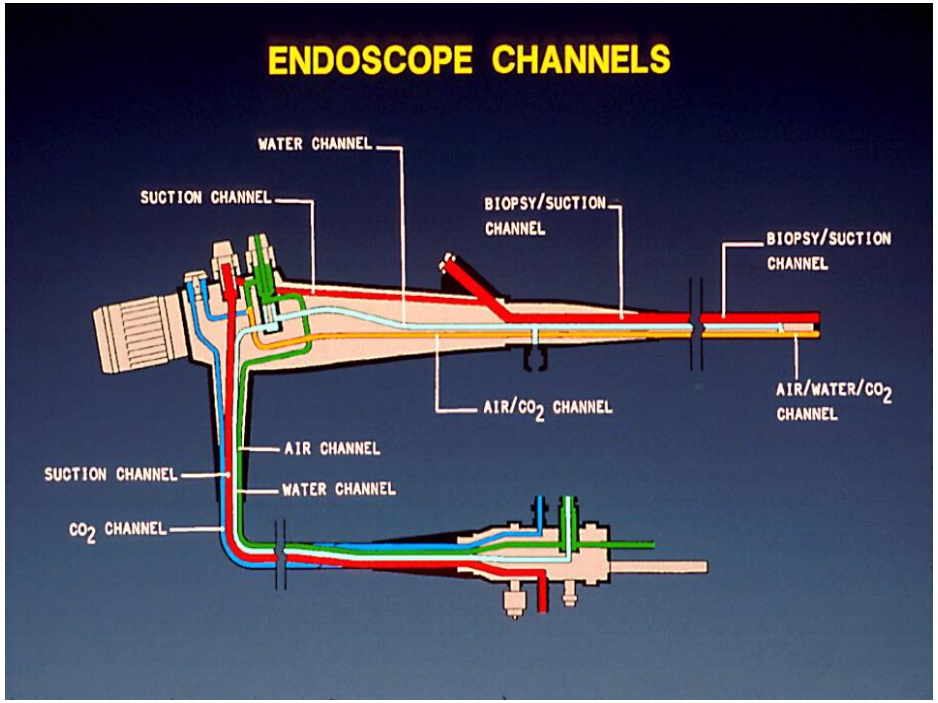
Beginning to gather data tying faulty instrument processing to surgical site infection

- Think endoscopes

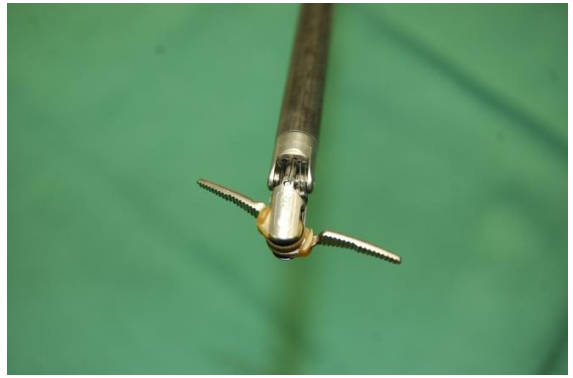
Beginning to gather data tying faulty instrument design to inadequate processing

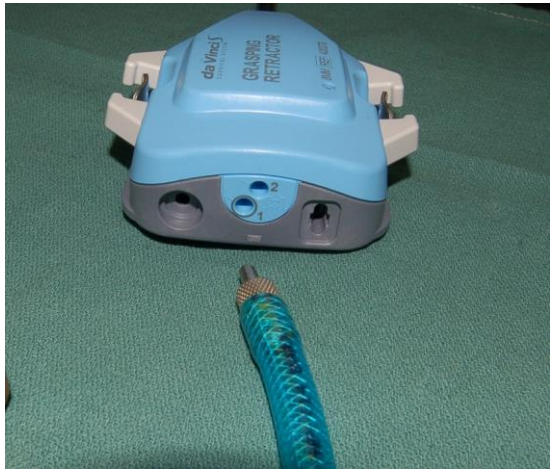
The Instruments

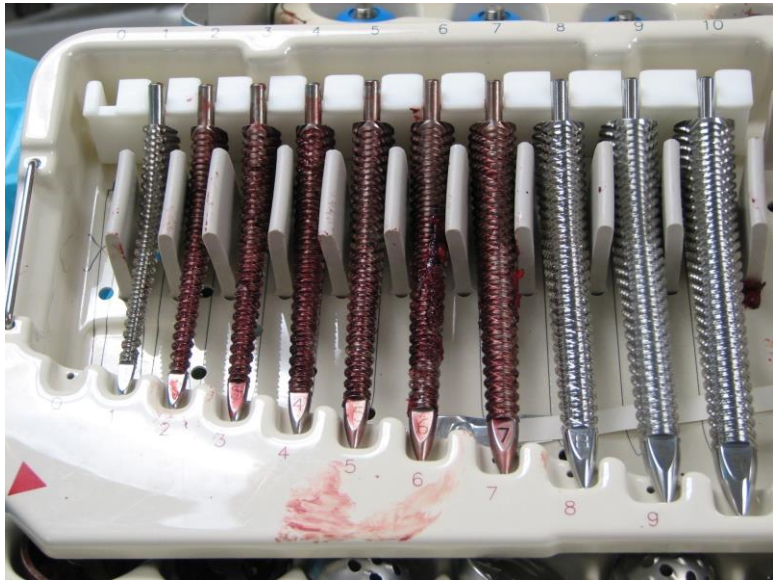




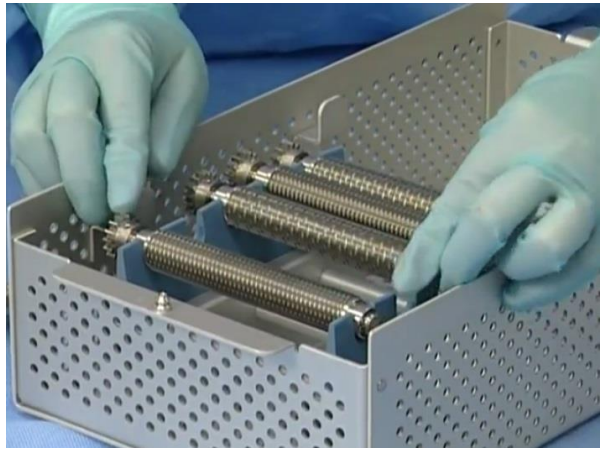
The Instruments







The Instruments



Step 1 - Guidelines /Resources

Gather resources

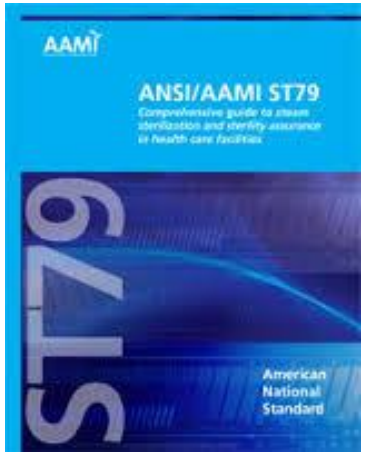
Familiarize staff with professional guidelines

ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance* 2013

ANSI/AAMI ST 91 *Flexible and Semi-rigid endoscope processing in Health Care Facilities* 2015

AORN – *Guidelines and tools for Sterile Processing Personnel* 2014

AORN – *Guideline for Processing Flexible Endoscopes* 2016



Instructions For Use (IFU)

Absent – do not exist

Vague

Lack of standardization (water temp, time, methods etc.)

Hard to obtain

Updates – When? How notified? Dated?

Not comprehensive

Instructions for Use

IFUs must be readily available

Staff must be very familiar with accessing

Need to be up to date

Need to cover wide range of instruments

Must have IFU for washer and other cleaning equipment, sterilizers, packaging, device, monitoring devices (chemical indicators, biological indicators, etc.)

Step 2 - Cleaning at Point of Use

The most critical step in instrument processing is cleaning

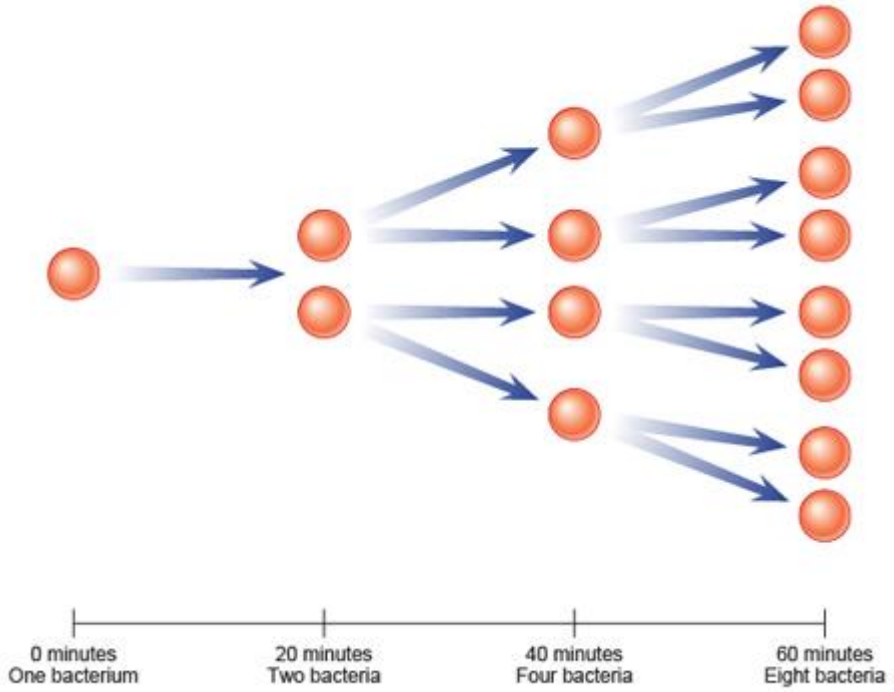
- CLEANING BEGINS AT POINT OF USE
- Many devices difficult to clean
- Delay in cleaning can compromise the sterilization process
- Cleaning can take a long time!

AAMI ST79 sec. 6.3

Tag or otherwise identify damaged instruments

How 1 becomes more than 2 million

One survivor 1
20 minutes 2
40 minutes 4
1 hour 8
2 hours 64
3 hours 512
4 hours 4,096
5 hours 32,768
6 hours 262,144
7 hours 2,097,152!!

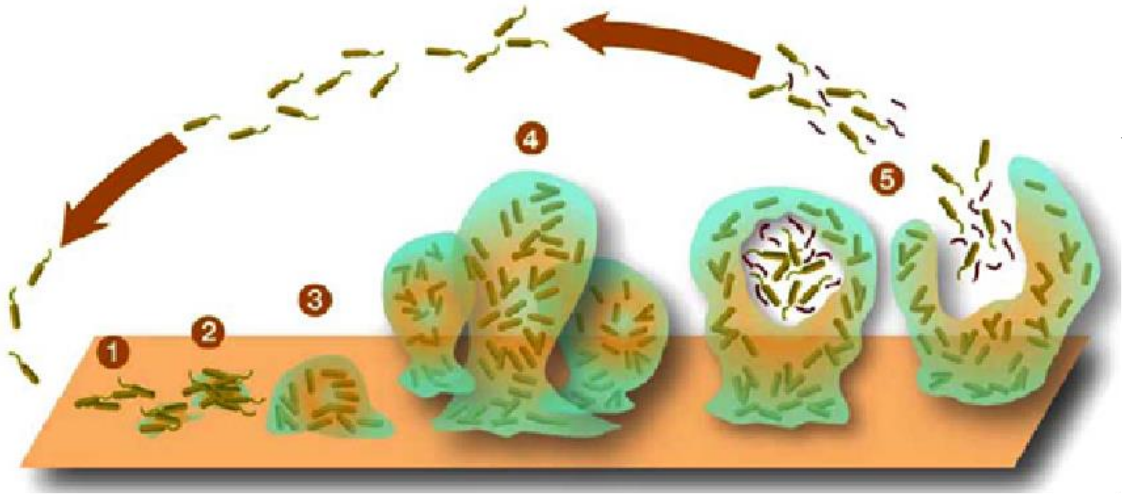


Step 2 - Transport

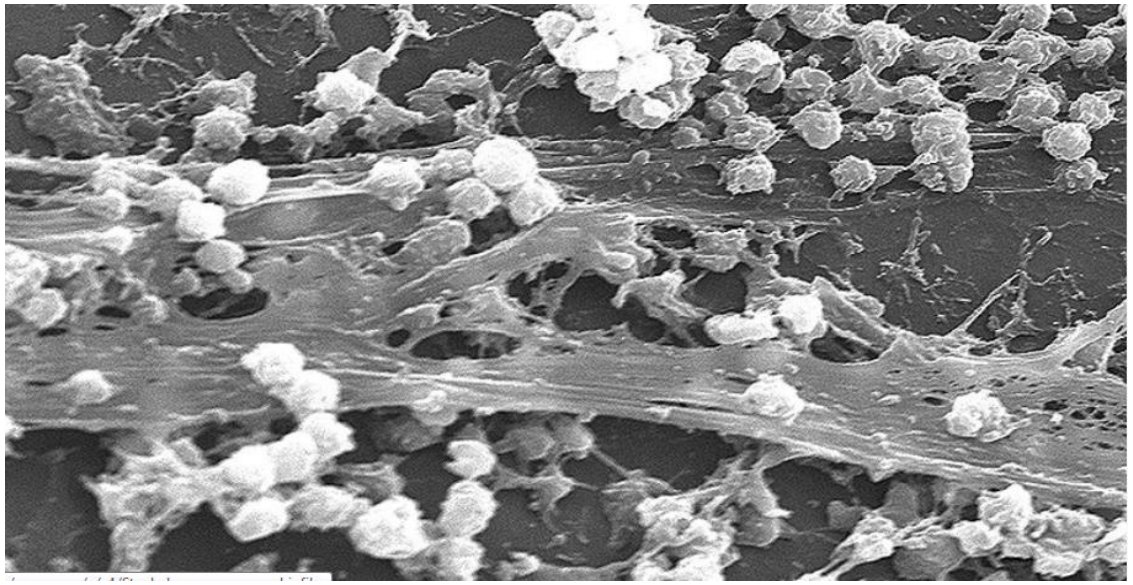
Contaminated instruments transported in leak-proof container, colored or labeled with biohazard symbol

OSHA CFR 29 1910.1030

Biofilms



Staphylococcus aureus on a catheter



Biofilms and Surgery

Many SSIs the result of biofilms

Biofilms love moist lumens

Biofilms love implants – not just joints

- Tissues surrounding implants have reduced blood vessels so less antibiotic delivered to site and fewer macrophages delivered

Infection from biofilm serious – may require 1,000 times dose of antibiotic – encourage resistance

Step 3 - Cleaning

Dedicated decontamination area

- Decontamination area separate from clean area
- Pass through window
- Ambulatory – partition 4 feet high, width of the counter, 4 feet separation

Standard processes

Workflow always dirty to clean

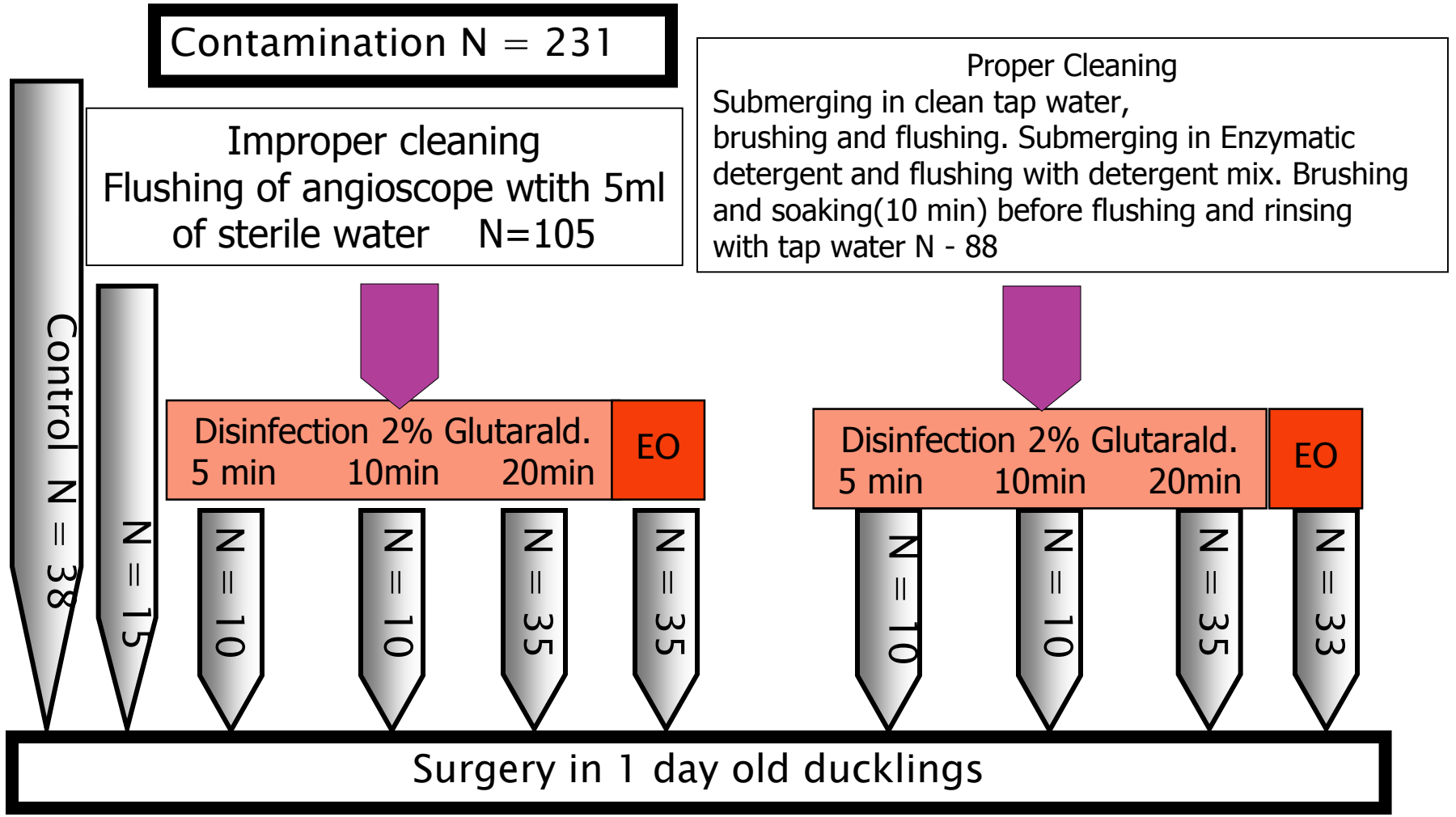
Three sinks ideal

AORN Guidelines for Environment of Care Part ll In: Guidelines for Perioperative Practice – 2016
AAMI ST 79, Sec.3.3.7.1


STERIS

Evaluation of disinfection and sterilization of reusable angioscopes with the duck hepatitis B model

X. Chaufour, MD; K. Vickery, PhD; Sydney, Australia; J Vasc Surg 1999; 30: 277–282.



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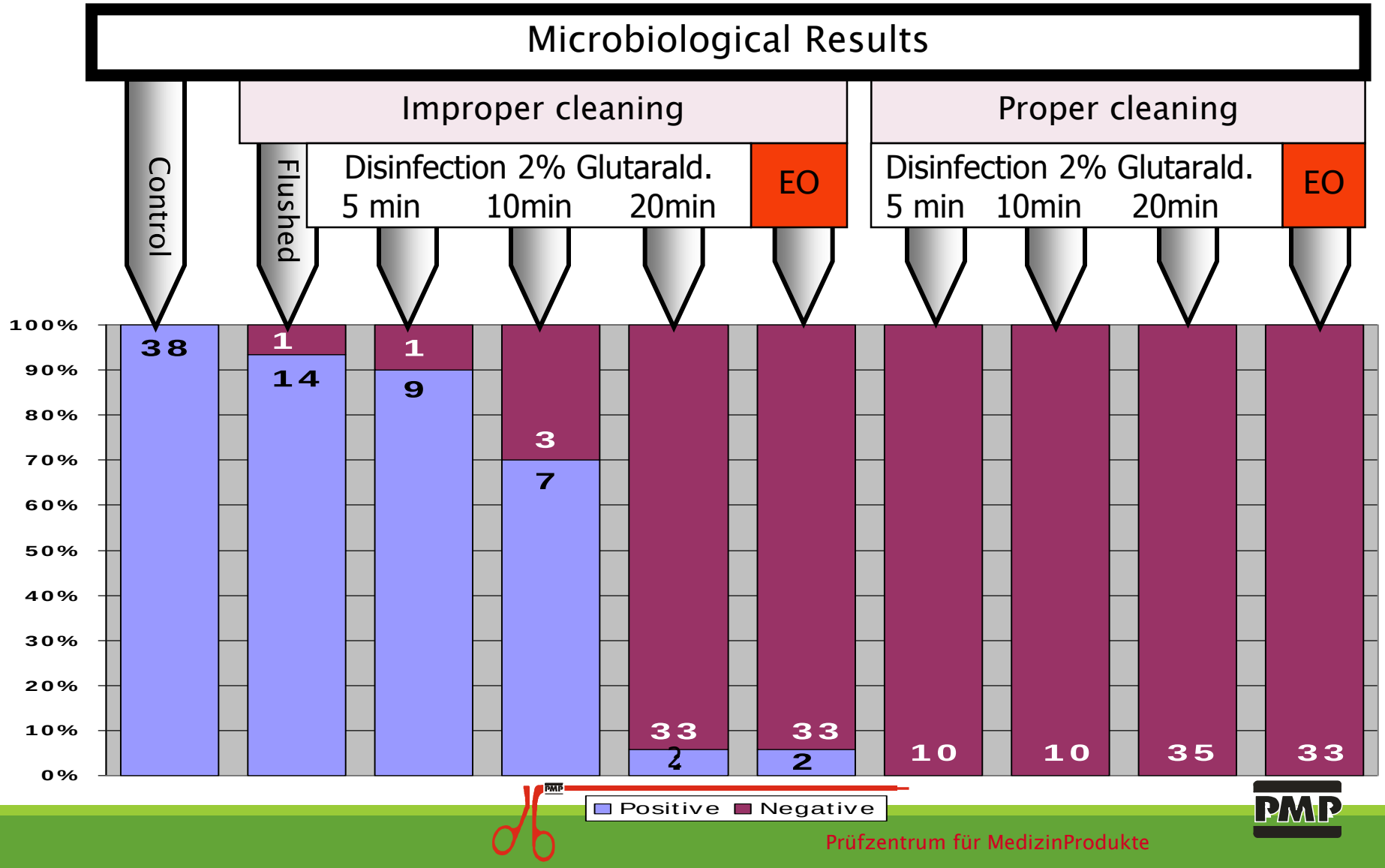


The Detergent

Mechanical Cleaning

Ultrasonic – test daily

Washer/disinfector tested weekly (preferably daily) – documented or recorded

Routine maintenance and preventive maintenance – documented

AAMI ST79, Sec. 7.5.5

Loading the Washer

Load to ensure contact

Not jammed together

Instruments opened

No closed containers

Filter plates removed

What's wrong with this picture?

- Washer-tunnel drain screen not cleaned
- Clean daily

What's wrong with this picture?

- Poor loading technique-need to disassemble reusable rigid containers (remove disposable filter retention plates) so all surfaces are exposed to the cleaning process

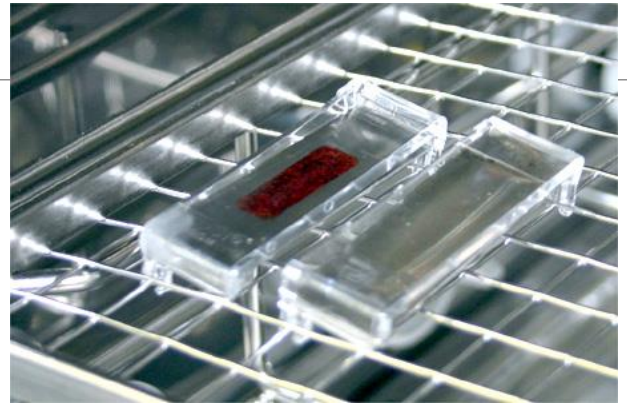
What's wrong with this picture?

- Poor loading technique-instruments cannot be cleaned in a covered rigid container because the instrument surfaces will not come in contact with the detergent or rinse water

What's wrong with this picture?

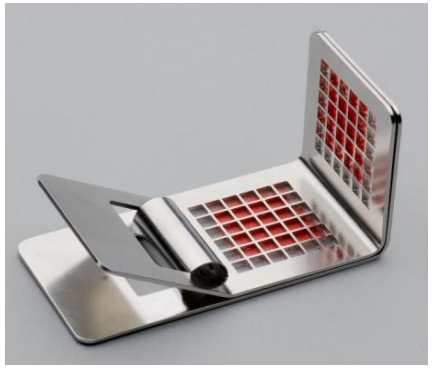
- Poor loading technique-mats should not be placed in the bottom of the trays it prevent (hampers) proper spray coverage of instruments
- Rigid containers are covered
- Poor loading technique-instruments are piled on top of each other

Washer Efficacy Tests

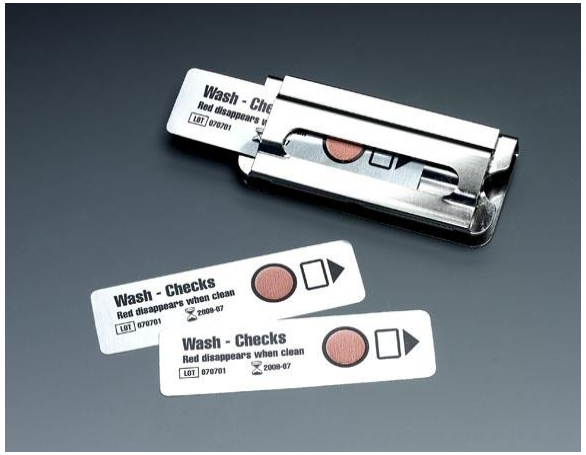


Courtesy Healthmark

Check with manufacturer for placement

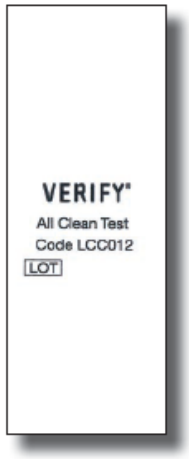


Courtesy Steris Amsco



Courtesy SteriTec

Unused

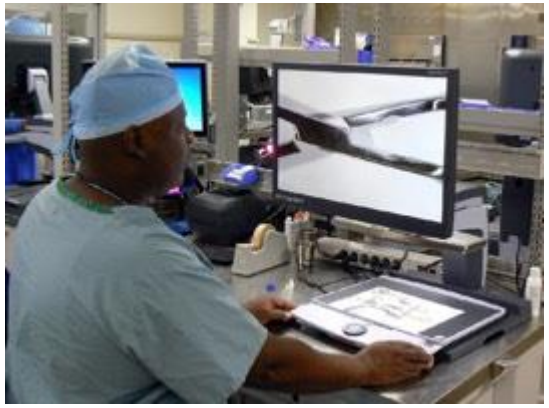


Pass

Step 4 – Inspection
Cleaning – Monitoring, Verifying

Doing nothing is not an option

- Monitoring equipment
- Monitoring cleanliness



http://www.msn.com/?cobrand=toshiba13.msn.com&ocid=TSHDHP&pc=MATBJS
Ongoing Safety Review of Arthroscopic Shavers: FDA Safety Communication

Step 5 - Monitoring Cleaning

The standard for clean is “does it look clean?”

Depends upon what is visible, available light, visual acuity of the person inspecting, available magnification

It is possible to monitor efficacy of mechanical cleaning equipment

It is possible to monitor effectiveness of cleaning

PERIODICALLY PERFORM CLEANING VERIFICATION TEST

AAMI ST 79 sec. 7.5.5

Cleaning – ATP Testing

ATP in all living organisms

- Swab surface
- Measure ATP in a luminator
- Bioluminescence measured in RLU (Relative Light Units)
- Benchmark RLU levels
- Define clean
- Track progress

ATP Testing

Courtesy Ruhof

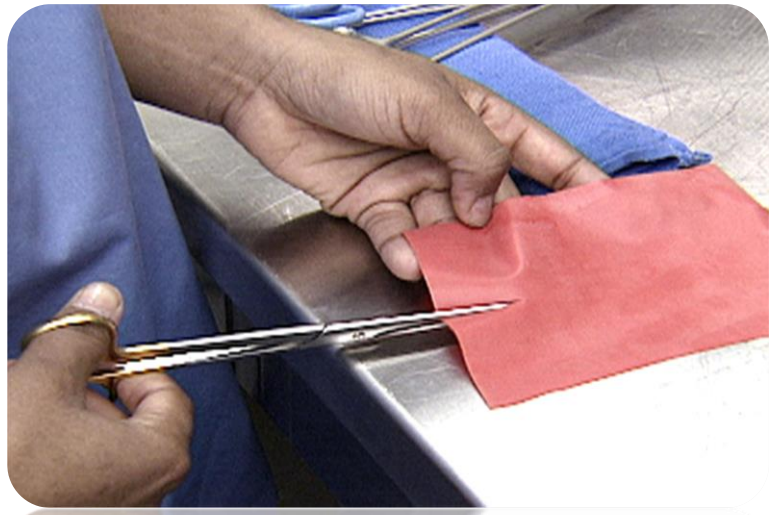
Courtesy 3M

Cleaning – Key Points

- Always disassemble
- Clean as soon after use as possible
  - Don’t forget the container
- Do not allow debris to dry
- Use an enzyme spray if there will be a delay before cleaning
  - Follow IFU
  - Contact time may be limited
- Resources
- Cleaning verification test

- IFU
- Use ultrasonic
- Monitor washer performance
- Daily maintenance - document
- Check dosing tanks

Does It Work?



Do you have a maintenance program for instruments?
Based on volume not on time?

Step 6 - Packaging

Package to ensure contact

Check containers – should be on preventive maintenance schedule as well

- The older the container the greater the risk of loss of integrity

Clean after each use (a wipe is insufficient)

Pouch – not in set unless manufacturer validated

Single or double – according to IFU

New Study Provides Additional Insight Into Efficacy of Sterile Packaging Systems
November 29, 2015**0 Comments**
Posted in News, **Disinfection & Sterilization**, Products & Services

Step 7 - Monitoring

Monitoring tools

- Physical
- Chemical
- Biological

Physical Monitors

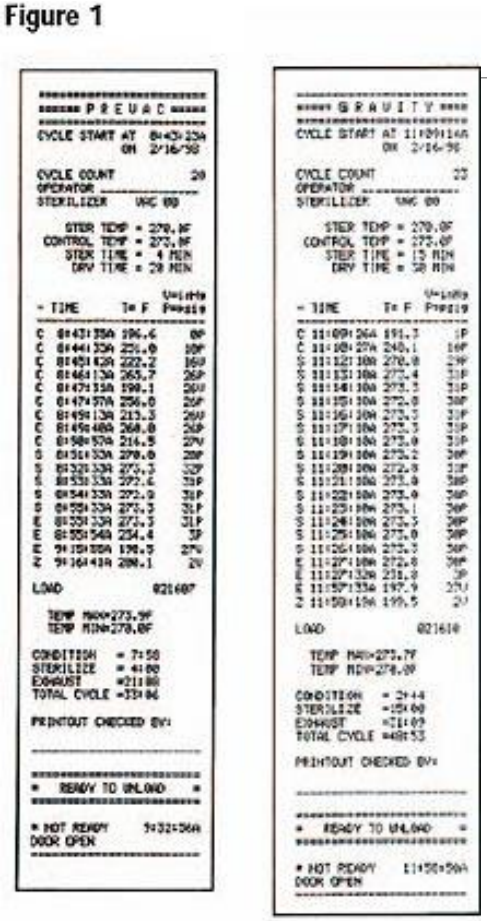
Printouts

Graphs

Digital readouts

Gauges

Figure 1



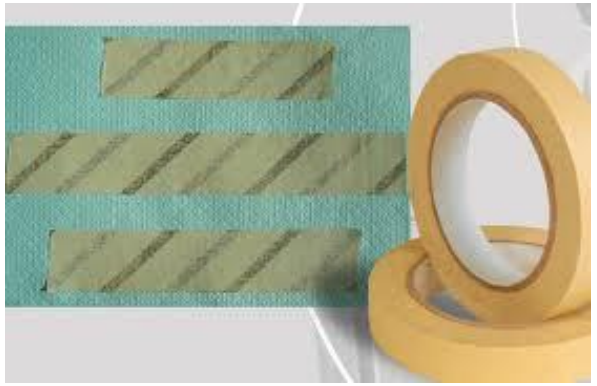
From Century® Steam Sterilizer Operator Manual 129376-510, p.5-23, STERIS Corporation.

Chemical Indicator -Type 1

Process indicator for use with individual items

- Indicates the item as been exposed
- Tape, sticker, indicator

What can go wrong?



Chemical Monitor Type 2

Bowie-Dick

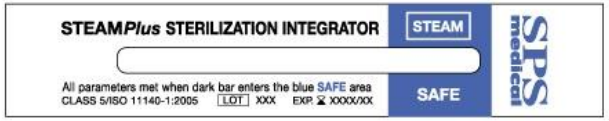
- Tests whether the air is removed and that steam penetrates
- Tests for air leaks
- Tests for presence of non-condensable gasses
- Used in dynamic air removal sterilizers

Chemical Indicators Type 5

Type 5 integrating indicator

- Internal indicator
- Designed to react to all critical variables

Courtesy 3M



Courtesy SPS Medical

Type 6


270°F
132°C
4 mins
VERIFY
SixCess 270F 4 Minute Indicator - Long
3
10
270°F
132°C
3/10 mins
VERIFY
SixCess 270F Flash Indicator
275°F
135°C
3 mins
VERIFY
SixCess 275F 3 Minute Indicator - Long


VERIFY
LCC003
270°F
132°C
4 mins
SixCess 270F 4 Challenge Pack


VERIFY
LCC214
275°F
135°C
3 mins
SixCess 275F 3 Challenge Pack

Internal CI - Placement

Challenging location(s)

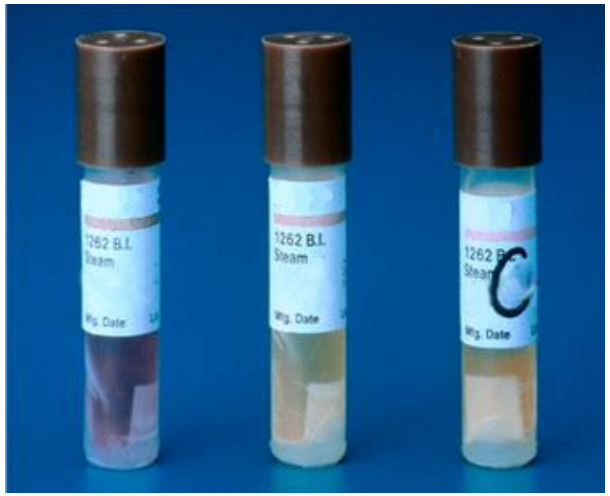
Check container manufacturer/IFU for placement

Multi-layers - one on each layer

Biological Indicators/Monitors

Microorganism specific to the technology

BI specific to the cycle type



- Geobacillus stearothermophilus
  - Steam
  - Hydrogen Peroxide Gas Plasma
  - Peracetic acid
  - Ozone
- Bacillus atropheus
  - ETO

Traditional or early readout – both are BIs

Biological Monitors

Traditional – incubate 24 hrs

Rapid Read – 1 hour and 3 hour

Super Rapid Read Out

- 1 hour Dynamic air removal
- ½ hour Gravity

Must select BI to match the type of cycle. Do not use gravity just because the biological read-out is faster

Biological Monitors

Right BI for cycle

Test every type of cycle

- If same temp then test only shortest exposure

Store BIs according to IFU (Do you need a humidity and temp controlled cabinet????)

Positive control each day sterilizer used in each incubator

Quality Monitoring

Four levels of testing

- Routine load release – every load
- Sterilizer efficacy – periodically
- Qualification testing – after events cause sterilizer to malfunction, installation, relocation, malfunction
- Product testing

Quality Monitoring - *Load Release*

No implant – monitoring optional

- Monitor with
  - BI only in PCD
  - CI only – Type 5 or Type 6 in PCD
  - BI and CI (Type 5) in PCD

Implant – not optional

- Monitor with
  - BI and Type 5 in PCD (May also use Type 6 if desired)

Quality Monitoring - Sterilizer *Efficacy* Testing

When? With what?

- Weekly
- Daily or every day that it is used (preferably every load)
- Full load – PCD with BI – can contain Type 5 CI as well
- For IUSS – empty chamber – monitoring depends upon cycle

Bowie-Dick – run after shortened cycle

Qualification Testing
Installation, Relocation, Malfunctions

Major malfunction includes utilities

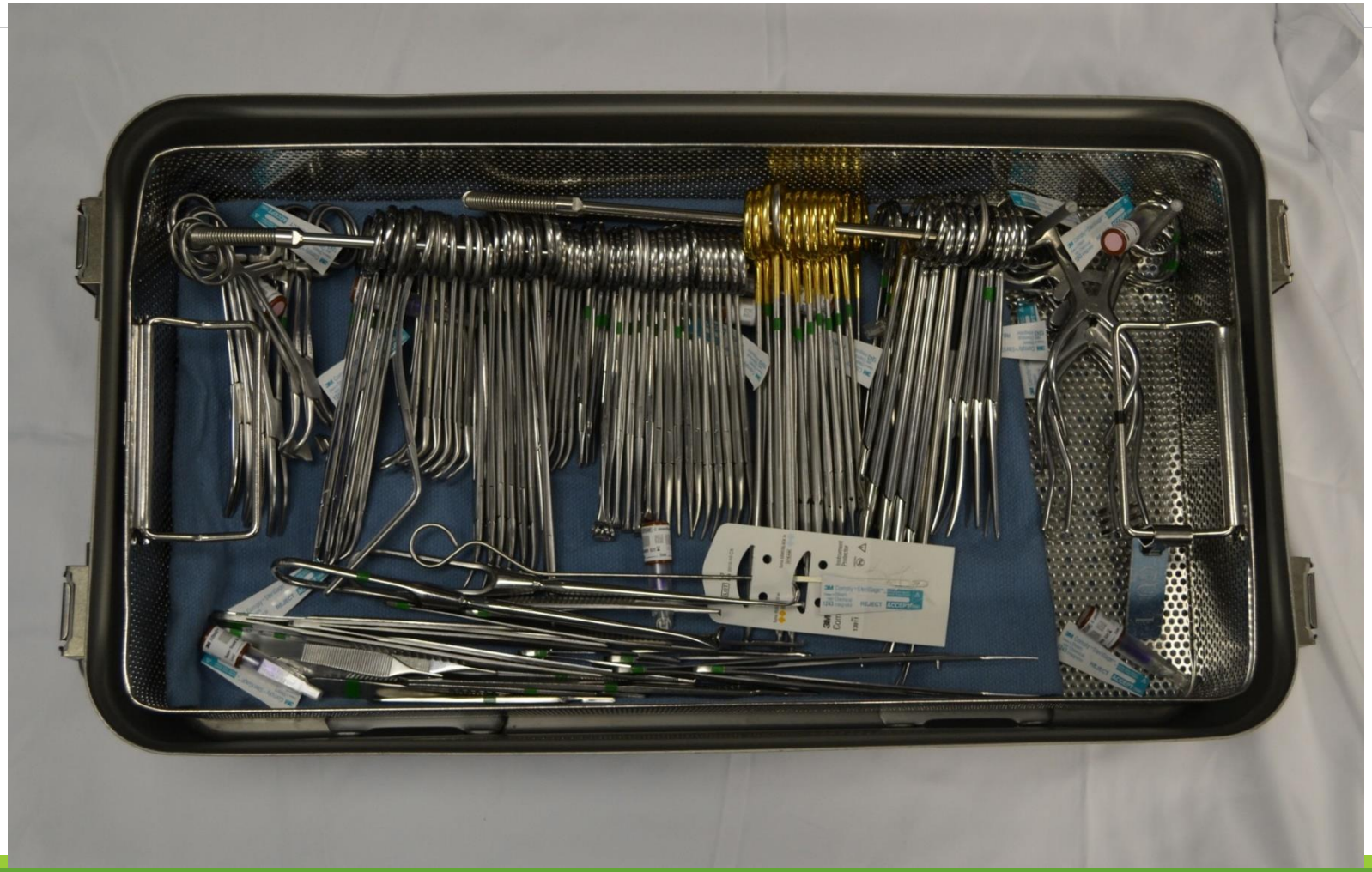
- Water main break, air conditioning repair
- Incomplete air removal, inadequate temp or time

IUSS and 2 cu or larger – empty chamber with PCD with BI (may contain CI) X 3

Table top – fully loaded X 3

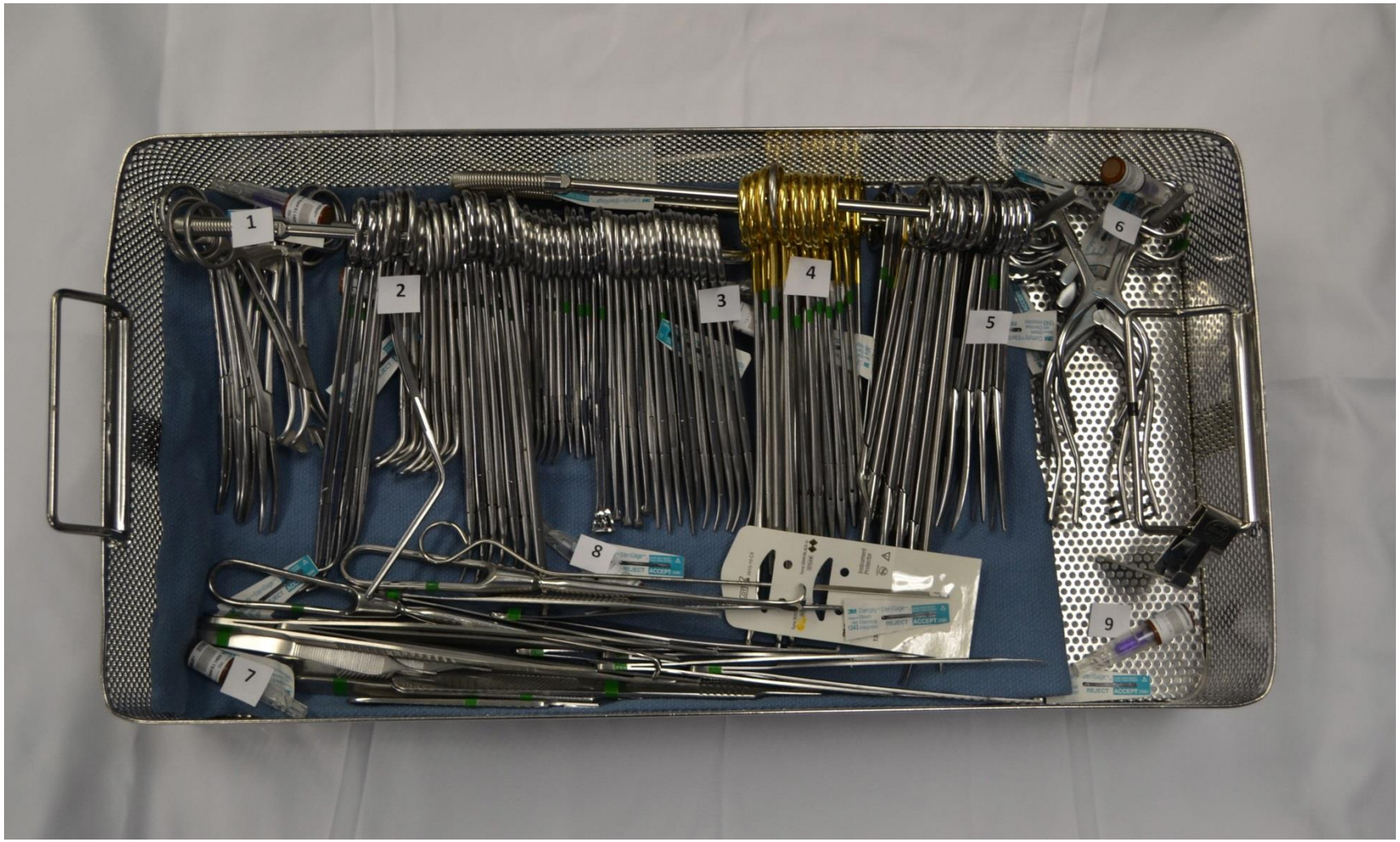
Bowie-Dick test run after BI cycles – need to establish that sterilizer can kill

Quality Monitoring -*Product Testing*




Genesis
V. Mueller
GU TRAY #1
TEST


Genesis
CASE


1
2
3
4
5
6
7
8
9

Sterilizer and Cycle

Autoclave – steam sterilizer

Types of sterilizers and cycles

- Runs only gravity cycles
- Runs gravity and dynamic air removal cycles

Dynamic air removal cycles are preferred

Table top sterilizers usually run only gravity cycles

Step 8 - Storage

Clean, dry, away from traffic

8 to 10 inches above the floor

2 inches from walls

18 inches below sprinkler

4 air exchanges an hour

Solid bottom storage cart

<75 degrees

≤79% humidity

Controlled access

Commercially prepared items reviewed and stored accordingly

No external or corrugated boxes

Policy for cleaning storage bins

Objective

Identify common breeches and key aspects of flexible endoscope reprocessing

Overview

Many instances of patient recall, patient infection and and several deaths

- CRE – 50% mortality

Joint Commission focus

FDA/CDC focus

Mainstream media focus

Lapses by processing technicians

Impossible to process design

- Chances that patient ready scope is contaminated is high
- Recent study suggests 50% of the time scope is contaminated

Cleaning Verification

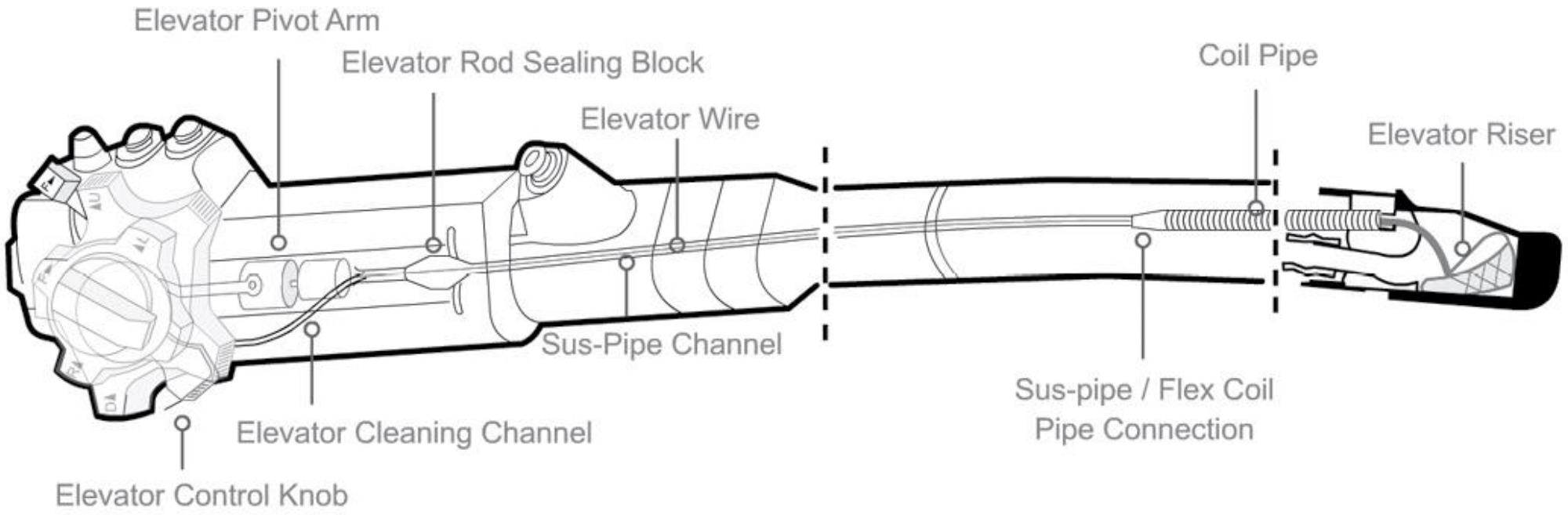
Visual inspection is inadequate to access contamination of cleaned endoscopes

One study of colonoscopies showed that contamination persisted after:

- Manual cleaning (12 of 13)
- High-level disinfection (8 of 11)
- Storage (9 of 11)

Cleaning verification testing is no longer an option

Ofstead CL, Wetzler HP, Doyle EM, et al. Persistent contamination on colonoscopes and gastroscopes detected by biologic cultures and rapid indicators despite reprocessing performed in accordance with guidelines. Am J Infect Control. 2015;43(8):794-801


Elevator Pivot Arm
Elevator Rod Sealing Block
Elevator Wire
Coil Pipe
Elevator Riser
Sus-Pipe Channel
Sus-pipe / Flex Coil
Pipe Connection
Elevator Cleaning Channel
Elevator Control Knob

Endoscopes - Duodenoscope

Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication – August 2015

- Microbiological Culturing
- Ethylene Oxide Sterilization (Pentax 2016 – removed from IFU)
- Use of a Liquid Chemical Sterilant Processing System
- Repeat High-Level Disinfection

Deficiencies Noted - Scopes

- No point of use cleaning
- Delay in processing
- Missing 1 hour window
- Missing IFU
- No QA of test strips
- Incomplete log
- No competency for each model
  - No annual review
- Vendor – brings in and used
- Detergent dilution not accurate

- HLD not labeled
- New equipment with no new training
- No alcohol rinse
- No date tag
- HLD temp not monitored or documented
- Scope cabinet not routinely cleaned –no policy or documentation
- Scopes touching other scopes and cabinet walls
- Handled without gloves

Dirlam Langlay AM, Ofstead CL, Mueller NJ, Tosh PK, Baron TH, Wetzler HP. Reported gastrointestinal endoscope reprocessing lapses: the tip of the iceberg. Am J Infect Control. 2013;41(12):1188-1194

Key Takeaways

Competency for every scope model and company

Cleaning verification test

Certification for processing technicians

Resources – Flexible Scopes

Key Takeaways

- Track scope and accessories to patient on whom used
- Scopes and port buttons processed as a unit
- Do risk assessment for making hang time policy
- Record times from end of procedure to start of clean
- Don’t let scopes touch each other or closet

AAMI ST91 Flexible and Semi-Rigid Endoscope Processing in Health Care Facilities 3/15

AORN Guidelines for Processing Flexible Endoscopes 11/15