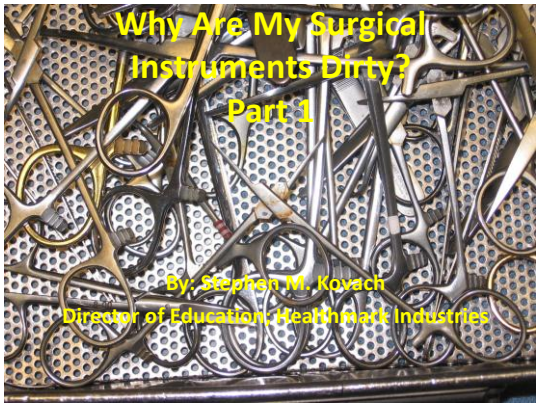
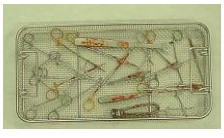
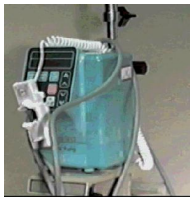


Easy to Clean?

- 16% of the loaner instruments tested positive for blood
  [AORN Journal, 5/2007,Volume 85,#5;page 566)
- When placing the tissue protector on the drill, old dry blood and tissue came out
  (Pennsylvania Patient Safety Authority 2006;page 1)
- Particles of tissue were found in cannulated instruments
  (Pennsylvania Patient Safety Authority 2006;page 1)

We Clean a Lot of Different Items…



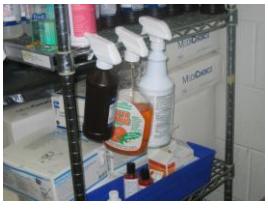


HOW CLEAN ARE THESE?

Remember that no 2 ASCs are alike and we all do not have the same "Tools of the Trade" when it comes to cleaning

Everyday Life…

Chemicals of all kinds



Instruments every place

We still have to get the work done with what we have

Housekeeping Issues

- Handouts, do you have them?
- Who is here today?
- What if I have a question?
- Two part program
  - Objectives
    - Define cleaning
    - Learn the 9 critical factors that impact the cleaning process
    - Review the "tools of the cleaning trade" you need to solve
    - Define and discuss what instrument and equipment testing mean
    - Review a simple Quality Improvement program to help reduce the incidence of dirty instruments
- So, let's get down and "dirty"

Question to everybody here:

How many of you have ever had an issue with a dirty surgical instrument?

Real Life "Dirty" Stuff

- The investigative report said a surgical tool used for inserting a screw in a broken bone was not properly prepared before being sent to be sterilized, containing "biomatter" from a previous patient that should have been removed, the report said

Surgical Site Infections

- A hospital-acquired infection generally costs in the range of **$25,000 to treat**," he said. "This is a huge patient-safety issue."*
- Potential Causes**
  - Break in sterile technique
  - Poor patient health
  - Unclean instruments
  - Unsterile instruments

*http://health.heraldtribune.com/2012/06/22/venice-hospital-re-trains-staff-after-contaminated-instruments-were-used

**CDC 1999/CAH focus group February 2003;Managing I.C. Volume 4, Issue 1

The "Dirty" Facts

- Cleaning is being done in US facilities at
  - 5,000 - Number of hospital surgical facilities
  - 5,876 - Number of freestanding ASCs
  - 8,600 - Number of medical clinics with surgery suites
- By many different type of staff
  - Trained and untrained
- If it is not clean, it might not be sterile

The "Down and Dirty" Facts

- AORN Article 7/95
  - Residual Organic Debris on Processed Surgical Instruments
  - 32 Instruments checked
  - 90.6 % appeared clean
  - Microscopic examination revealed residual debris on 87.3% (27/32) instruments

More "Dirty" Facts

- There has been a growing concern about the effectiveness of decontamination techniques for reusable medical instrumentation in healthcare facilities. Studies have shown the ability of sterilization technologies, which under normal conditions achieve acceptable sterility assurance levels, to be greatly impaired by the presence of residual soil containing serum and salt.
  - Alfa,M., et al, Comparison of Ion Plasma, Vaporized Hydrogen Peroxide, and 100% Ethylene oxide Sterilization to the 12/88 Ethylene oxide Gas Sterilizer, Infection Control and Hospital Epidemiology, 1996; 17:92-100

The Joint Commission National Patient Safety Goals

- NPSG.07.05.01
  - "implement evidence-based practices for preventing surgical site infections"
- Element of performance #3
  - "…implement policies and practices aimed at reducing the risk of surgical site infections. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines.."

The Joint Commission : 2012 Hospital Accreditations Standards (HAS)

The Joint Commission

- Joint Commission EC 02.04.01 – requires accredited facilities to maintain medical equipment inventory
- EC 02.04.04,EP 3 "…identifies the activities, in writing, for maintaining, inspecting, and testing for all medical equipment on the inventory"
  - Mechanical cleaning equipment and sterilizers
  - Endoscopes (flexible and rigid) now included

AAMI News: August 2010.Vol 45,NO8 and AAMI News: January 2011,Vol 46,No 1
http://www.aami.org/publications/AAMINews/Jan2011/eddoscopes.html

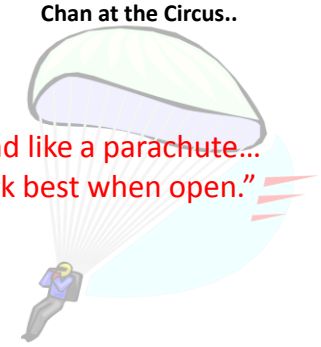
Conflict of Interest

✓The following individual is an industry employee

"I, or a member of my family, or partner, have a significant financial interest of other significant relationship with one or more companies who manufacture products used in the treatment of perioperative patients."

Stephen M. Kovach, Healthmark

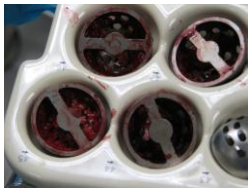
As Charlie Chan said in the movie, Charlie Chan at the Circus..



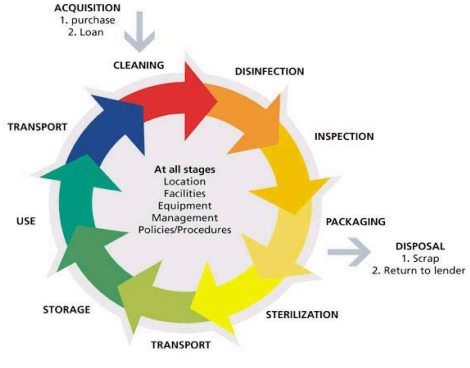
" Mind like a parachute…
Work best when open."

"Any device should be able to be manually cleaned"

Cleaning is essential: Instrument sets as they come back from the operating theatre…



CSSD has its own circle of life. All steps have to be performed well.
We will be talking about cleaning in this circle of life in CSSD.

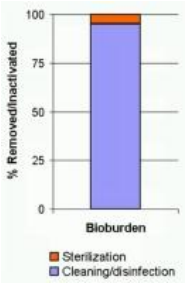


Definition of Cleaning

- Removal of contamination from an item to the extent necessary for further processing or for the intended use
  - In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent organic and inorganic soil (e.g., blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination

The Power of Cleaning

- By cleaning, the population of micro-organisms residing on the materials (known as the bioburden) is reduced considerably
- The initial contamination for a subsequent disinfection or sterilization is considerably lower and thus these processes will be more effective, as many less organisms have to be killed

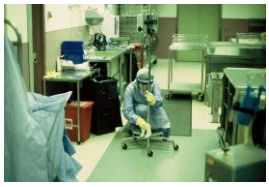


Steps in the Cleaning Process

- Sorting
- Pre-soaking
- Washing
  - Manual
  - Automatic
- Rinsing with tap water
- Rinsing with distilled or de-ionized water
- Drying or draining
- Inspection - yes, inspection, in each step

- ***Water quality*** *(pH, hardness…)*
- ***Temperature*** *(cycles, cleaning solutions,..)*
- ***Chemical activity*** *(cleaning solution)*
- ***Mechanical action*** *(manual or mechanical)*
- ***Items to be cleaned*** *(simple or complex)*
- ***Type of soil*** *to be cleaned off the item (blood, sputum,..)*
- ***Human factor*** *(following the IFU, training, loading,..)*
- ***Verification of the process***
- **Quality Improvement Program**

9 Factors of Cleaning



If it is not clean it cannot become sterile.
It is the combination of these factors that get something clean.

Cleaning Factor #1 Water

- Water's role in cleaning
  - Quality of water (major)
    - Hardness
    - Temperature
    - pH
    - Cleaning chemistries choices
    - Purest source for rinse
  - Examples of poor water quality
    - #1 concern is staining
    - Biofilm

Who Is Telling You What Type of Water to Use?

- Equipment manufacture of your washer, cleaning solutions – label , catalog, IFU
- The government (EPA,FDA,CDC)?
- AAMI –ST 79-3.2.2.2

  "What is the quality of water required for the various decontamination processes, manual and mechanical? What methods will be employed to monitor the quality of water?
  - *3.3.7.1*
  - *7.5.1*
  - *7.5.3.2*
  - *7.5.5*
  - *Annex D*
- Professional groups (IAHCSMM, AORN, APIC) in their guidelines

Remember "WATER"

- **W**ater - quality of the water being used has a direct effect on the outcome, pH, hardness, tap, distilled, or de-ionized
- **A**gitation - helps to suspend soils so detergents can remove them, friction
- **T**emperature and **T**ime - increasing or decreasing the temperature/time changes the rate of chemical reaction
- **E**quipment & **E**mployee - always follow manufacturer's instruction, understand how your equipment and supplies work and ***train your staff in understanding why they are doing each task***
- **R**eaction of cleaning agent - depends on its concentration and the time (exposure time) the cleaner has to work , the higher increases the cleaning power

Cleaning Factor #2 Temperature

- "Hotter is better." Except that this would be wrong.
- "Get the temperature right." The proper water temperature is different for each type of cleaning and for each stage of cleaning.
- The proper temperature also varies with the cleaning agent (e.g., enzyme cleaner, detergent) used.
- Are you using the right temperature at each stage?

Cleaning Factor #2 Temperature

- Low temperature to start (to prevent denaturing) and higher temperature later to maximize detergent cleaning efficiency.
- The denaturing action of heat on blood makes it insoluble enough to interfere with rapid cleaning. Start with a cool rinse.
- Use the recommended temperatures for all cleaning agents.

Factor #3 Cleaning Activity Cleaning Solutions

- Lots of choices each have their own + or –
- The four basic classes of enzymes are:
  - Lipase - breaks down fats and greases
  - Protease - breaks down protein
  - Cellulase - breaks down cellulose such as wood, cotton, and paper
  - Amylase - breaks down carbohydrates and starches
- Manual detergent cleaners
- Low foaming - neutral
- Cleaners for ultrasonic equipment
- Cleaners for mechanical cleaners (washer-sterilizers/washer-decontaminators)
- Acid & alkaline cleaners
- Selected for suitability to job

How Do Cleaning Solutions Work?

- Three types of energy that are needed for good cleaning:
  - Chemical energy: provided by the soap or detergent (poor water = poor outcome)
  - Thermal energy: provided by warm or hot water
  - Mechanical energy: provided by a machine or manual (hands)

Reaction of Cleaning Agents

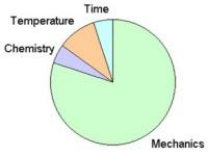
- Speed and Concentration: Medical facilities that must turn instruments around quickly cannot rely on simple water to do the job. Water must be made more powerful through chemical assistance, enzyme, detergent, high pH, temperature, and physical assistance through spray agitation. Each of these elements need time and specific concentration to work.

Dilution & temperature get it right !

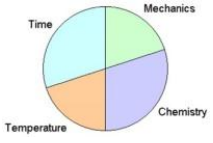
Illuminate the temperature of manual baths and ultrasonic cleaners with TempaCheck-LC™ liquid crystal thermometer

Cleaning Factor #4 Mechanical Action

- How do we do this?
  - Manual
    - Hand power
      - Scrubbing, brushing, flushing, soaking
  - Mechanical
    - Sonic
    - Medical automatic washer
    - Cart washer
    - AER
    - Other
  - Combination of both



Manual cleaning: The vast majority of the cleaning action is caused by the mechanical action



Machine cleaning: A large share of the cleaning action is now taken over by chemistry, temperature, and time

Manual Cleaning

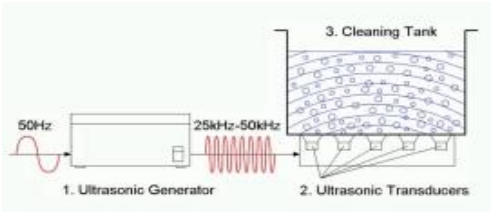
- Try to have a three-tank sink
- Try to have an air hose
- Try to have a water hose
- Monitor the cleaning area – temperature and humidity
- Monitor the air flow – negative pressure
- Use the Proper P.P.A. for each type of cleaning
- Meter/monitor the dilution of all solutions
- Use the correct type of brush for the job at hand
- Use ST 79 as your guide

Mechanical Action

- Mechanical failure does happen
  - Poor preventive maintenance on equipment
  - Dilution pump failures
  - Pressure problems
  - Sonic equipment not working
  - Broken soap pumps
  - Blocked spinner arms
  - Defective wash pumps
  - Missing arms
  - Overloaded rack
  - One failure will result in a failed process
- Manual process
  - Brushing, flushing
  - Wrong size brush
  - Time and tools

How Does It Work?

- Ultrasonic cleaners work by subjecting instruments to these high frequency, high-energy sound waves. This causes the soil to be dislodged from instruments and drop to the bottom of the tank, or be sufficiently loosened that it will be removed during the rinsing process.
- Ultrasonic vibration at the frequency used for cleaning does not kill microorganisms and infective aerosols may be produced. It is for this reason that the lid of the tank must be tightly closed during operation.



This is how it works. Remember, just because it makes a "humming noise" doesn't mean it is cleaning.

Cavitation at Work

http://www.ultrawave.co.uk/pages/Ultrasonic-Technology-54.php
Picture from web address

- The photograph shows ultrasonic cleaning in action on a pair of surgical forceps. The formation of bubbles can be clearly seen forming around the item.
- As the bubbles implode and cavitation occurs, the cleaning solution rushes into the gap left by the bubble. The fluid makes contact with the forceps, and any bioburden that is present is removed.

Medical Automatic Washer

- Historically, instruments washers were developed from commercial dishwasher technology and adapted to today's science-based requirement.
- Automated washer
  - Designed to increase through-put and consistency
  - Use pressure and detergents through delivery systems
  - Manage the other inputs
- Some have ultrasonic

Medical Automatic Washer

- The FDA regulates the introduction of medical devices in interstate commerce
  - A medical washer-disinfector intended to clean and provide high level disinfection of medical devices must have a FDA-cleared pre-market notification [510(k)] submission before it can be sold. A medical washer intended to clean medical devices or a medical washer-disinfector intended to clean and provide either low or intermediate level disinfection of medical devices is exempt from 510(k) requirements.
  - The majority of M.A.W. found in the hospitals within the United States provide low to intermediate level disinfection and are exempt from the 510 (k) requirements.

Medical Automatic Washers Fall Into Two Very Distinctive Categories on Theory of Operation Which Are:

- North American
  - –Relies on "high impingement" softer chemistry
- European
  - –Relies on "low impingement", high volume, stronger chemistry

Regardless of the Model or the Theory Behind a Medical Automatic Washer or Sonic Cleaner, If They Are Maintained (Preventative Maintenance by a Qualified Person) and Properly Calibrated and Used Accordingly, They All Work.

Stay awake now!!!!

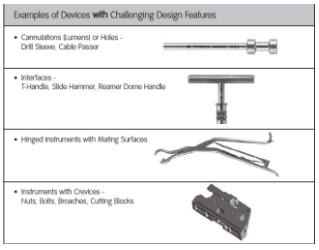
Cleaning Factor #5 Instruments

- Back in the day… 1950, 1960, not much changed
- Since 1970 - change has taken place
  - Long narrow lumens
  - Tiny serrations
  - Multiple parts
  - Various metals and plastics
  - M.I.S. is now the norm, not the exception anymore
  - Incomplete information from the manufacturer on how to clean the item
- Two groups of instruments

Two Groups

- Simple
- Devices without challenging design features
  - Bone spikes
  - Osteotomes
  - Simple surgical instruments

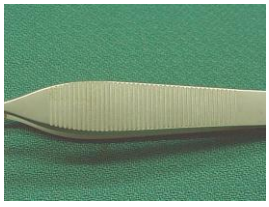
- Complex
- Devices with challenging designs



Did You Really Follow the IFU?

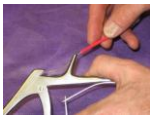
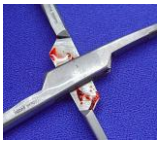
Did You Really Clean this Chuck?

NORMAL SURFACES not really a CLEANING PROBLEM

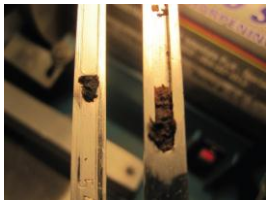



Instruments Provide Physical Challenge to Washing

- Nooks and crannies (Box lock)
- Instruments are stacked one on top another in washer
- Take apart
- Lumen items
- Rongeurs

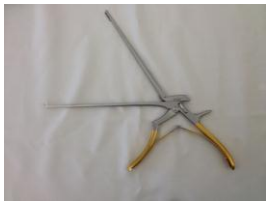




Kerrison Rongeurs

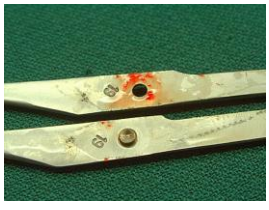



http://www.imsready.com/news/Vikon Brochure_091411.pdf

Solutions – Take Apart Kerrison Rongeurs



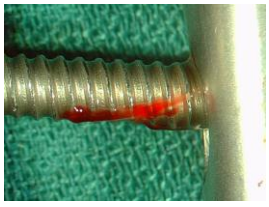
Examples



"Gaps"

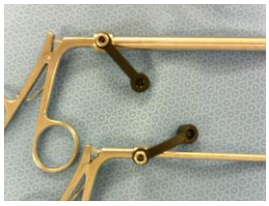
- Investigations into reproducible cleaning of instruments based on a worst-case model
  - Critical box locks – various gaps (0.03-0.42 mm)
    (Central Sterile 1/2011;G.Kirmse)

Examples

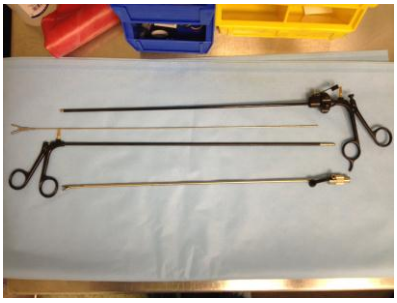



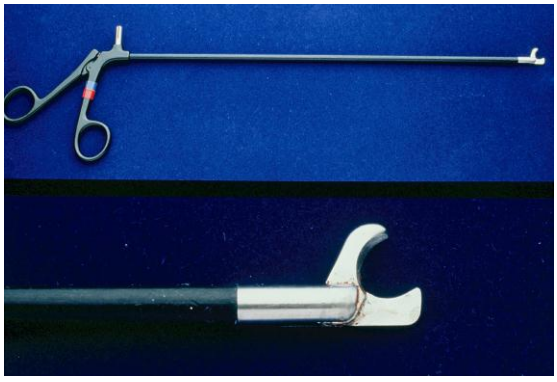
MIS Instrumentation

- Three types
  - Non-ported
  - Ported, not take apart
  - Ported, and take apart
- They have lumens and this is an issue
- We will talk about lumens after MIS instruments in general



How Clean are These?





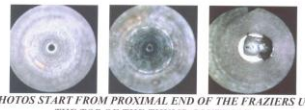
Non-ported MIS Instruments - difficult to clean - get rid of them - NOW!!!!!!

What Was Inside of a Non-ported Instrument

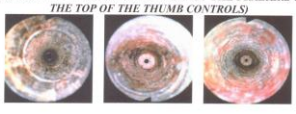
Why We Should Only Have Take Aparts

DO YOUR FRAZIERS LOOK LIKE THIS *NEW* ONE?

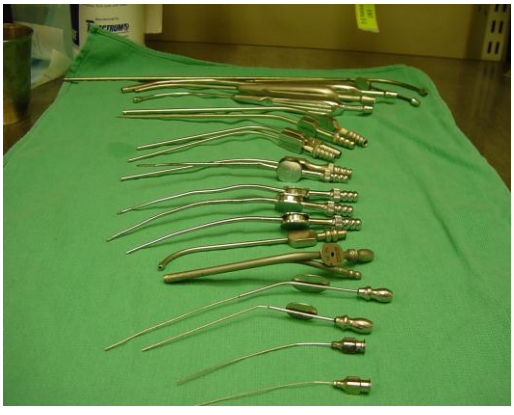
OR LIKE THESE?



(PHOTOS START FROM PROXIMAL END OF THE FRAZIERS UP TO THE TOP OF THE THUMB CONTROLS)



Inside a Suction

Lumens and Cannulated Items

- How can you really see what is inside of them?
- Manufacturers need to give tools to help us look inside.
- Various articles offer support.
  - Blood as a soil on surgical instruments; chemical profile and cleaning detection (Zentr Steril 1998)
  - Manual versus automated methods for cleaning reusable accessory devices used for minimally invasive surgical procedures (YJHIN 1720—1/6/2004—09:05—DMESSENGER—106432— MODEL 6 — pp. 1–9)
- Cleaning efficacy of medical device washers in North American healthcare facilities. (J Hosp Infect (2009), doi:10.1016/j.jhin.2009.06.030)

Cleaning Factor #6 Type of Soil

The presence of organic material such as blood can result in the failure of sterilization or disinfection. This may be because either the organic material protects the microorganisms from exposure to the **process** or because the process may be inactivated by contact with organic material.

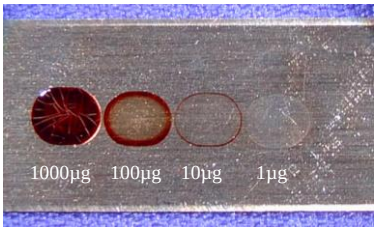
- What is on the instrument?
- Where used?
- Bio-burden
- Blood
- Fibrin

Out of All of the Concerns, Blood Seems to Be the Hardest to Clean and Poses the Highest Risk… So Let Us Look at Blood

Key Components of Blood Soil

- Blood is #1 challenge.
  - Hemoglobin becomes highly insolvent when it dries out
  - Fibrin, the coagulating agent in blood, is inherently water insoluble
- Blood denatures at temperatures above 45°C (110°F).
- When blood denatures, it become highly insolvent. It bonds strongly to the substrate (e.g., the surface of instruments) and it dries out – becoming very resistant to the action of solvents.

Checking for Residues

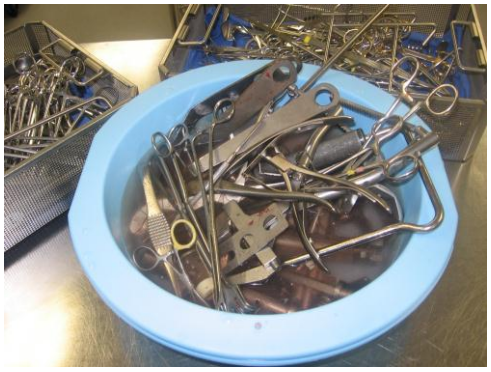


Cleaning Factor #7 Human

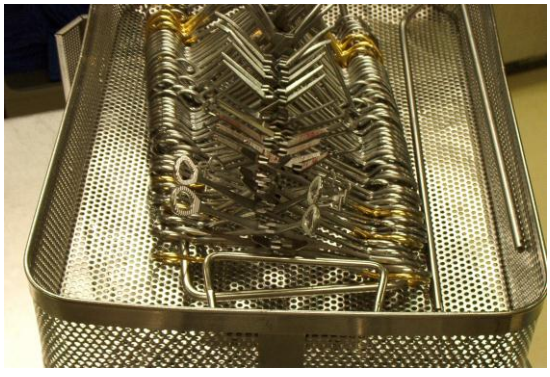
- How the OR and CSSD interact with the instruments after a procedure has a dramatic impact on the net result
  - Pre-clean
  - Pre-soaking or enzymatic spray
  - Overload the basket and racks
  - Disassembling instruments
- Management decision
  - Understand the consequences of your choices
- You can never over-train
  - Certification
  - Yearly testing on process

D.H.T.

- This stands for **D**econtamination **H**olding **T**ime.
- This is the time from when the instrument is last used to when it is received in decontamination and the cleaning process begins. This can very in length of time from just a few minutes to hours or even days.




SYNTHES
Spine



Factors #8 & #9

- Factors 8 & 9 in Part 2
- Quickly talk about disinfection
- Pictures tell the real story
- Close with some pictures

Disinfection is the Next Step

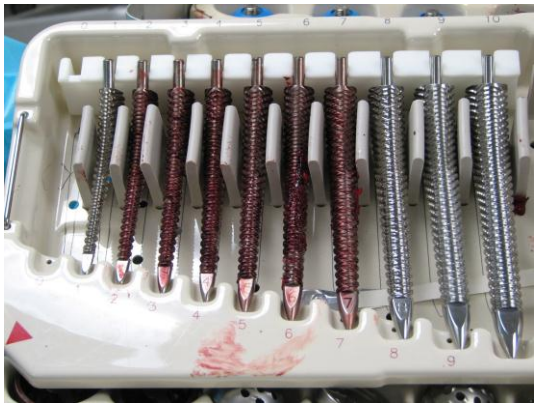
- Disinfection is not cleaning, but if it is not clean you will not have effective disinfection.
- Disinfection destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes.
- "…any organic matter that remains after cleaning lowers the effectiveness of the disinfectant, …with imperfect cleaning, bacteria could survive the disinfection process and infect the next patient..."*
- Spaulding classification

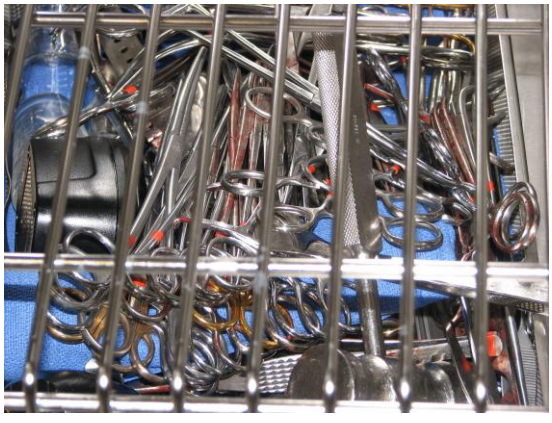
* Spach D., Silverstein F. & Stamm W. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Annals of Internal Medicine* **118**, 117-128 (1993).

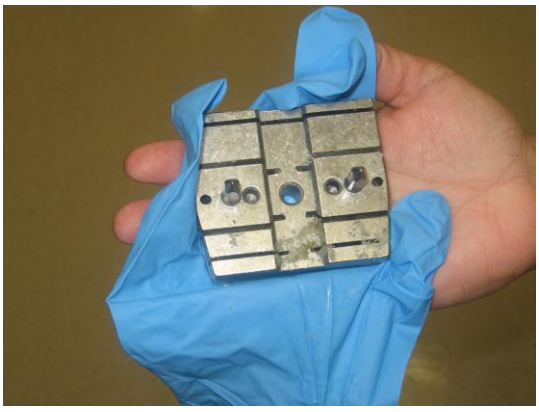
Remember, to help prevent infections, all equipment (carts, instruments, IV pumps, scopes…) must be disinfected between uses according to the Spaulding classifications.

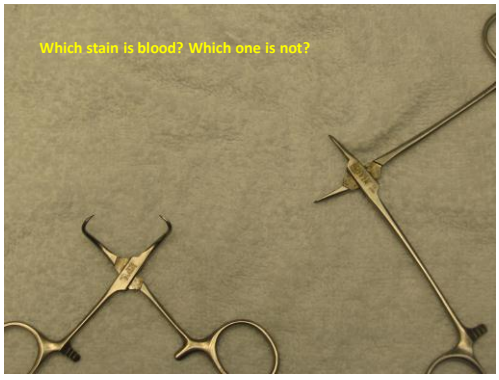
Body Contact	Disinfection Requirements	Spaulding
Intact skin	Low level	Non-critical
Mucous membranes	High level	Semi-critical
Sterile body cavity	Sterilization	Critical

Every picture tells a story….these are the real thing.









These instruments were ready to be assembled.

Break time…see you in a few minutes