Orthopedic Instrumentation and its Challenges for Reprocessing

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Conflict of Interest

✓The following individual is an industry employees

"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

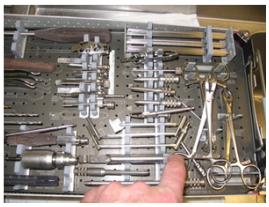
Who is hear today ?

- Surgeons
- PA
- Nurses
- Surgical technicians
- Administrators
- Medical device manufactures
- Others
- Have you ever had a dirty instrument during surgery ?
  - Why do you think this happened ?

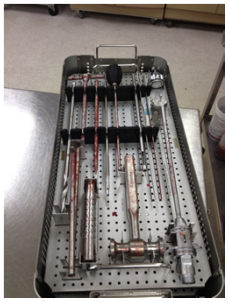
No place for instruments that are dirty and not functioning.

Easy to Clean ?

- 16% of the loaner instruments tested positive for blood
  (AORN Journal; 1/2007; Volume 85, #1; 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)



Real Life Stuff

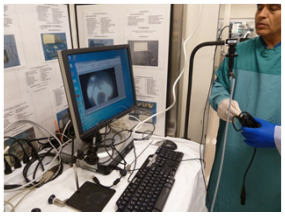


- The investigative report said a surgical tool used for inserting a screw in a broken bone was not properly prepared before being sent to be sterilized, containing “biomatter” from a previous patient that should have been removed, the report said.

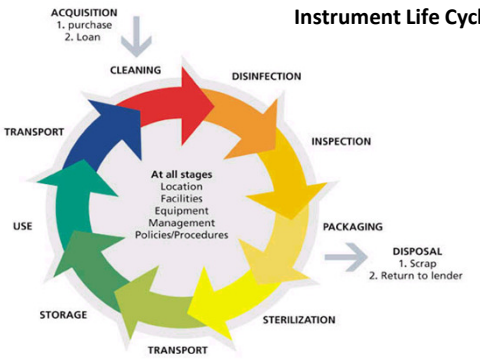
TODAY
Investigates:
Dirty Surgical Instruments a Problem in the OR
February 22, 2012

The outcome

- Change in cleaning instructions
- Added a inspection (a general example)
  - ….Visually inspect the handpiece…we recommend using a scope to visually inspect the lumens of the handpiece…

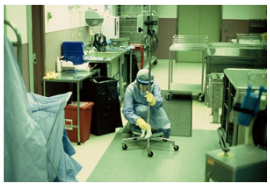


Instrument Life Cycle



9 Factors of Cleaning

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



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

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
- MIS is now the norm, not the exception
- Incomplete information from the manufacture on how to clean the item
- Two group of Instruments

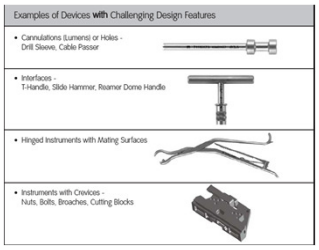
Two Groups

•Simple

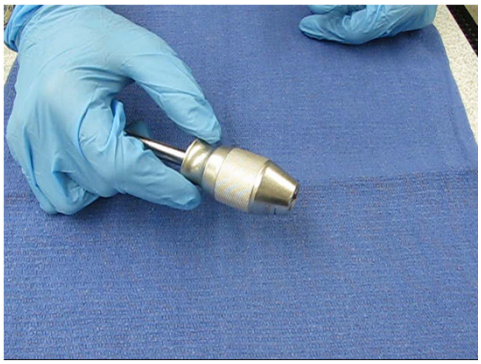
•Devices without challenging design features

- Bone spikes
- Osteotomes
- Simple surgical instruments

- Complex
- Devices with challenging designs



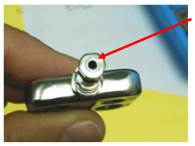
Did you really clean this chuck?



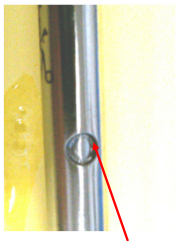
“Following directions”

Bio-Tenodesis Drivers

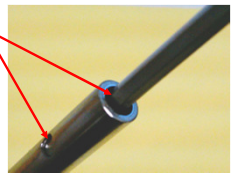
Issue: Unable to clean between the inner and outer shaft.



Able to clean by placing brush down the center cannula



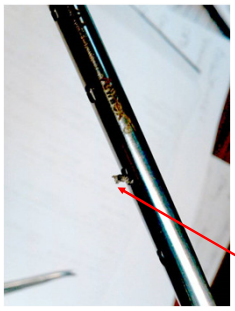
Driver moves up and down to a set point, unable to clean in between

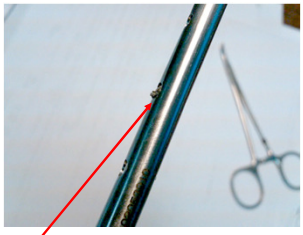


Unable to clean between the inner and outer shaft. Debris gets trapped and isn't seen until it is over clogged (like a sink drain)

Mary Velasco, ACE-CRCST, Manager SPD

First Reported Event of Cleaning Issues November 2010

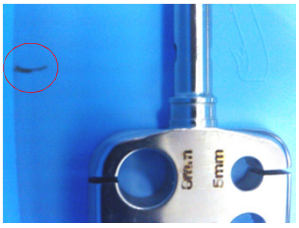


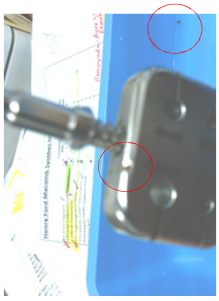


Gross Debris coming out between the inner and outer shaft. Unable to clean properly to make it safe for use.

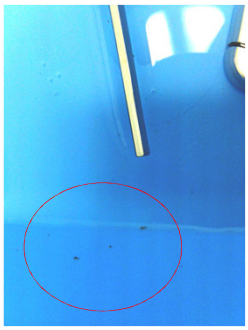
New Concern when Doctor had to have the instrument, soaked in peroxide and debris came out of a clean instrument that the vendor brought in for use September 2011.

Areas circled in red are debris particles that came out of the drivers





More Pictures from September 2011



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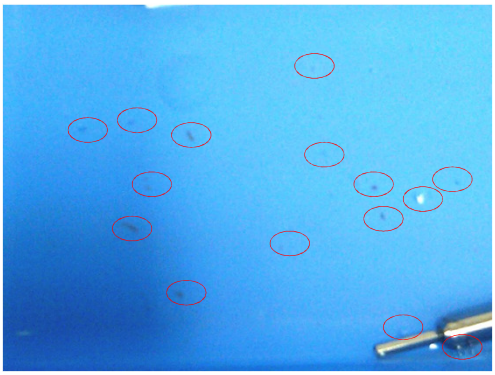
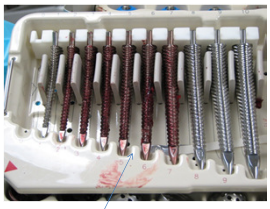


How instruments are returned after use

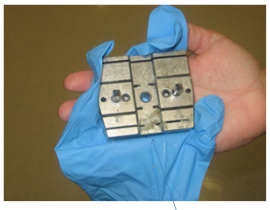
- Turn around time and functionality
  - How they are used
  - How they are returned
  - D.H.T.
    - This stands for **D**econtamination **H**olding **T**ime.
    - This is the time from when the instrument is last used to when it is received in decontamination and the cleaning process begins. This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

Examples of Orthopedic

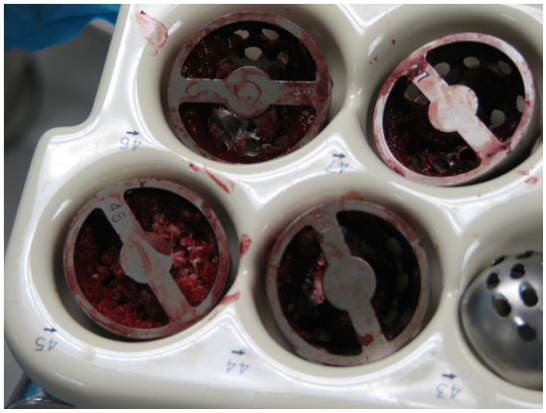
Instruments with crevices

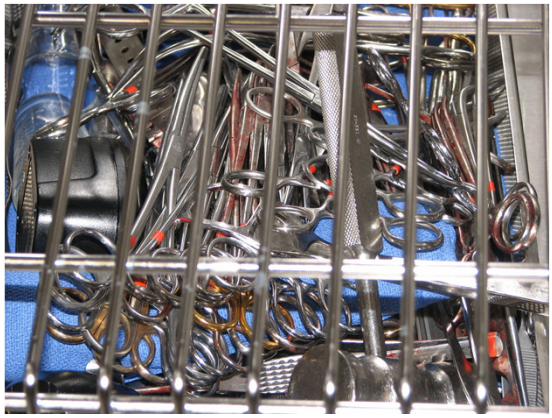


This was the way it came back to CSSD from the OR



Sterilized from CSSD

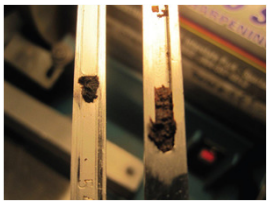




Solutions

- More team work
  - At the facility
    - Surgical staff and reprocessing staff
    - Support certification of the reprocessing staff
    - Scheduling
      - Equipment and needs
      - Turn around time
      - Loaner equipment
    - Walk awhile in each other shoes
      - Have reprocessing staff watch cases for a day
      - Tour there department
    - Proactive
      - QA policy on tray
        - » Highlight trays that are an issue
  - Between the end user and manufacture
    - Design medical device with cleaning and sterilization in mind
      - Kerrison rongeurs
      - Better training for the reprocessing staff
    - IFU need to be updated
- Questions

Kerrison Rongeurs



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

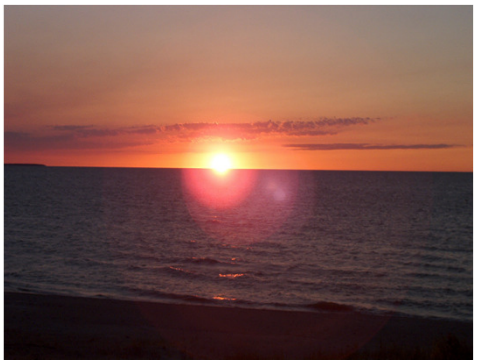
Solutions – take apart

Famous Quotes

"Always do what is right when people are looking" - Mark Twain

"Quality is doing the work right when nobody is looking" - Henry Ford

"What gets measured is improved" - Peter Drucker



The sun is setting on this presentation…
enjoy the rest of the meeting.

Thank You

- Healthmark
- My Family
- All of You for attending and wanting to share information
- Fill out the evaluation form

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