Ultrasonic Cleaning

THE HISTORY OF AN IMPORTANT CLEANING STEP FOR SURGICAL INSTRUMENTATION
PRESENTATION OBJECTIVES

Describe a brief history of ultrasonic technology

Understand the importance of following manufacturer’s instructions for use (IFU’s)

Implement proper equipment in the cleaning process

Why hospitals must monitor cleaning efficacy

Understand the importance of CSPD in patient safety
Our Ancient Heritage

From the dawn of recorded history man appears to have practiced in one form or another the process of purification or disinfection the latter a precursor of sterilization

“Principles and Methods of Sterilization in Health Sciences”
John J. Perkins
PRIMARY MATERIAL USED FOR SURGICAL INSTRUMENTS

HUMAN HANDS
Greek/Roman Period
332 BC-395AD

COPPER/COPPER ALLOY
Dark Ages
476AD

IRON/STEEL
1000 AD

STAINLESS STEEL
PLASTIC/POLYMERS
20th Century
Hippocrates, (born c. 460 bc, island of Cos, Greece—died c. 375 bc, Larissa, Thessaly), ancient Greek physician who lived during Greece’s Classical period and is traditionally regarded as the father of medicine.

There was not yet a distinction between philosophy and science, including the science of medicine. Hippocrates was the first to separate medicine from philosophy and to disprove the idea that disease was a punishment for sin.
INSTRUMENTS FOUND NEAR HIPPOCRATES GRAVE
Ignaz Semmelweis (1818 Budapest-Vienna 1865)

Semmelweis discovered that the incidence of puerperal fever (also known as "childbed fever") could be drastically cut by the use of hand disinfection in obstetrical clinics. Puerperal fever was common in mid-19th-century hospitals and often fatal, with mortality at 10%–35%. Semmelweis proposed the practice of washing hands with chlorinated lime solutions in 1847 while working in Vienna General Hospital's First Obstetrical Clinic, where doctors' wards had three times the mortality of midwives' wards.
Semmelweis's observations conflicted with the established scientific and medical opinions of the time and his ideas were rejected by the medical community. Some doctors were offended at the suggestion that they should wash their hands.
LOUIS PASTEUR

Born
December 27, 1822
Dole, France

Died
September 28, 1895 (age 72)
Marnes-la-Coquette, France

Nationality:
French

Fields:
Chemistry Microbiology
Pasteur was responsible for disproving the doctrine of spontaneous generation.

He performed experiments that showed that without contamination, microorganisms could not develop. Under the auspices of the French Academy of Sciences, he demonstrated that in sterilized and sealed flasks nothing ever developed, and in sterilized but open flasks microorganisms could grow.

This experiment won him the Alhumbert Prize of the academy.
MOdern Day Surygery

WHO IS OUR NEXT PIONEER?

MOdern Day CSPD
In 1879, Listerine mouthwash was named after this next person for his work in antisepsis.
JOSEPH LISTER

Born: April 5, 1827
West Ham, England

Died: February 10, 1912

Nationality: English

Fields: Scientist
While still a student, Lister had decided not just to practice medicine, but also to conduct research to improve medical knowledge.

Lister observed that 45 to 50 percent of amputation patients died from sepsis.

Intrigued by Pasteur’s findings, Lister conducted his own experiments which confirmed the Frenchman’s discoveries. Lister was now motivated to develop "antiseptic" techniques for wounds.

He advocated the use of carbolic acid to kill the germs present in surgical instruments and on the hands of surgeons before any surgery was performed.
Lister instructed surgeons under his responsibility to wear clean gloves and wash their hands before and after operations with 5% carbolic acid solutions. Instruments were also washed in the same solution and assistants sprayed the solution in the operating theatre.
The more carbons and hydrogens the more dangerous

**FORMULA: C₆H₆O**
CARBOLIC ACID = PHENOL

Phenol, also known as carbolic acid

Requires careful handling due to its propensity to cause chemical burns.

An aromatic organic compound

Phenol was first extracted from coal tar

Phenol is also a versatile precursor to a large collection of drugs, most notably aspirin

It is a white crystalline solid that is volatile.

The major uses of phenol involve its conversion to precursors to plastic

Phenol is also used as an oral anesthetic/analgesic in products such as Chloraseptic
In 1876, Lister traveled to the US to present his ideas at the International Medical Congress in Philadelphia. In attendance was William W. Keen (1837–1932) of Jefferson Medical College in Philadelphia, who had garnered a formidable reputation in cranial surgery. Keen was one of the few surgeons who realized the practical importance of infection control, and he became one of the first American surgeons to implement Lister’s system.
William William Keen

**Observe**

William William Keen, Jr. was the first brain surgeon in the United States. He also saw Franklin D. Roosevelt when his paralytic illness struck, and worked closely with six American presidents.

**Adopt**

When Joseph Lister came to Philadelphia in 1876, Keen heard his views on antisepsis in surgery and was one of the first American surgeons to adopt Lister’s system.

**Practice**

Keen was one of the first surgeons to successfully remove a brain tumor (1888). He also assisted the American surgeon Joseph Bryant in removing the left upper jaw of U.S. president Grover Cleveland (1893) for a malignant tumor.
<table>
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<th>9 UNFAMILIAR THINGS YOU WOULD FIND IN A 1900 OPERATING ROOM</th>
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As upscale care in New York shifts from urban locales in the early 1900s, Knickerbocker Hospital remains in the city to serve a mostly poor, immigrant population. Undeterred by high mortality from sepsis in a pre-antibiotics era, chief surgeon John Thackery pushes medicine’s boundaries, pioneering...
EARLY 1900 PROCEDURES FOR BRAIN SURGERY

All carpets and unnecessary furniture were removed.

The walls and ceiling were carefully cleaned the day before operation.

The woodwork, floors, and remaining furniture were scrubbed with carbolic solution.

This solution also sprayed in the room on the morning preceding.

The patient's head was shaved, scrubbed with soap and water.

The surgical instruments were boiled in water for 2 hours.

New deep-sea sponges (elephant ears) were treated with carbolic and sublimate solutions before usage.

The surgeon's hands were cleaned and disinfected by soap and water, alcohol, and sublimate solution.
Although principles of cleanliness and sterility were slow to become universally accepted, the surgeons who implemented them found new confidence to explore more complicated procedures.
American engineer who was responsible for notable advances in design and application of pressure steam sterilizers. **He promoted the modern concept of sterile supply centralization for hospitals.**
Sterilization/Washer Companies

**AMSCO/STERIS**
American Sterilizer Company
Founded in 1894

**GETINGE**
Founded in 1904
In Sweden

**BELIMED**
Founded in 1968
FINALLY! 1900-1930’s

A focus on washers

“Centralization” mentioned for Central Service work to be accomplished was brought to the forefront

Successful surgeries are more prominent

Science was proving things **MUST** be cleaned and there was standardization coming to light.

Not everyone’s opinion “on how to do things”
SOMETIMES IT TAKES A LONG TIME TO WORK SMART
Ultrasonic Cleaning

Makes its Debut in 1952
In 1952, ultrasonic cleaning was taken out of the laboratory

First used in production by Bendix Corporation in Davenport, Iowa

The focus of Bendix was to pioneer Ultrasonic Cleaning applications in industrial environments

Ultrasonic cleaning was highly effective and popularity radically grew

Including medical equipment, electronics, aircraft, missile manufacturing and auto makers
Published the article called ‘Ultrasonics: Unheard Progress’ in March of 1959

The article focuses on research and applications for ultrasonics

Fast-growing companies that were building ultrasonic tanks to clean anything from electric shavers to ball-point pens to entire cash registers

The article quoted that “Some day we’ll be cleaning clothes with ultrasonic equipment.”

The possibilities seemed endless!
ULTRASONIC CLEANING involves the use of high-frequency sound waves (above the upper range of human hearing, or about 18 kHz).

In a process termed cavitation, micron-size bubbles form and grow due to alternating positive and negative pressure waves in a solution.

The bubbles subjected to these alternating pressure waves continue to grow until they reach resonant size.

Just prior to the bubble implosion, there is a tremendous amount of energy stored inside the bubble itself.
The implosion event, when it occurs near a hard surface, changes the bubble into a jet about one-tenth the bubble size, which travels at speeds up to 400 km/hr toward the hard surface.

With the combination of pressure, temperature, and velocity, the jet frees contaminants from their bonds with the substrate.

Ultrasonic cleaning has the ability to reach into small crevices and remove entrapped soils very effectively.
ULTRASONIC PRECISION CLEANING IN OTHER APPLICATIONS

Musical Instrument Ultrasonic

Jewelry Ultrasonic

Golf Clubs Ultrasonic

Automotive Ultrasonic
Note: Ultrasonic cleaning is required by many device manufacturers in their IFU’s

For example:
Depuy
Stryker
Medtronic
Zimmer
Cooper Surgical
Symmetry
Wolf
Storz
Following the IFU
Instructions for Use (IFU) By Merriam Webster Dictionary

SIMPLE DEFINITION

a statement that describes how to do something
an order or command
the action or process of teaching : the act of instructing someone
Instructions for Use (IFU) By Merriam Webster Dictionary

FULL DEFINITION

1. a: precept <prevailing cultural instructions>
   b: a direction calling for compliance: order usually used in plural <had instructions not to admit strangers>
     c: an outline or manual of technical procedure: directions
     d: a code that tells a computer to perform a particular operation
   2: the action, practice, or profession of teaching
“INSTRUCTION FOR USE” WHO IS ACCOUNTABLE FOR THEM?

- It is a mutual responsibility
- Begins with the medical device manufacturer
  - Validate their product
  - Provide instructions for use
- Test labs
  - Conduct a validation
- FDA
  - Approves or disapproves the test labs
  - Review and ultimately give the approval for the IFU
WHAT IS THE PROBLEM?

Healthcare facilities are in the news for bad outcomes

Impossible/Unreasonable Instruction for Use (IFU’s)

Very complex instrumentation is being introduced

Medical facilities are not getting reimbursed for

- Healthcare Acquired Infections (HAI’s)
  - Surgical Site Infections (SSI’s)

Huge patient safety issues are arising

Reduction of educational personnel in hospitals due to rising costs, and reduced reimbursement

Capital equipment is not a priority for Central Service (We are not sexy like surgery)
Trays of medical devices await decontamination after use. With some surgeries now requiring more than 15 trays, hospitals are struggling for space. University of Michigan Health System
Seattle Children’s Hospital says incorrect cleaning of surgical instruments may have put 12,000 pediatric patients at risk.
Detroit Medical Center: Plan to address issues with sterile tools OK'd by state
1 in 25 hospital patients has at least one healthcare-associated infection

There were an estimated 722,000 HAIs in U.S acute care hospitals in 2011.

About 75,000 hospital patients with HAIs died during their hospitalizations

Surgical site infections from any inpatient surgery 157,500

The overall annual direct medical costs of HAI to U.S. hospitals ranges from $28.4 to $33.8 billion

Content source: Centers for Disease Control and Prevention National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP)
EXAMPLE A: HEART RETRACTOR IFU (22 MINUTES)

The following cleaning and sterilization procedure have been tested and found to be effective:

1. Disassemble the device. Inspect all surfaces of the device and remove all tissue debris, blood, fluids, and other foreign matter.

2. Clean the device as follows: (This process was for validating the effectiveness of the following cleaning cycle)
   a) 10 minute soak in Vesphene IIse or equivalent,
   b) 10 minute Ultrasonic in Vesphene IIse or equivalent
   c) Scrub with soft bristle brush to remove all tissue debris, blood, etc.
   d) Rinse

3. Lubricate per usual surgical instrument procedure.
EXAMPLE B: MFG’s CLEANING IFU
ORTHO SURGICAL INSTRUMENTS (49 MINUTES)

1. Completely submerge instruments in enzyme solution and allow to soak 20 min.
2. Rinse in tap water for minimum of 3 minutes
3. Ultrasonic clean for 10 minutes
4. Rinse in purified water for at least 3 min.
5. Repeat sonication and rinse steps.
6. Remove excess moisture from the instrument with a clean absorbent and non shedding wipe.
EXAMPLE C: MFG’s IFU ORTHO SURGICAL INSTRUMENTS  
(47 MINUTES VS. 52 MINUTE)

MANUAL CLEANING

1. Soak in enzymatic solution 15 minutes (minimum)
2. Rinse using agitation under the water level.
3. Soak in ultrasonic bath 20 minutes (minimum)
4. Brush, Operate
5. Rinse using agitation under water level.

AUTOMATIC CLEANING

1. Soak in ultrasonic bath 20 minutes (minimum)
2. Brush, Operate
3. Rinse using agitation under the water level
4. Place in washer disinfectors wash time 10 minute (minimum)
Following the IFU

Challenge to get the information
Having the right tools (equipment)
Time constraints
Not enough surgical instruments
Customers understanding our issues
Department space
Support and collaboration
1. **Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments that are not of simple design.** Orthopedic instruments with any features such as multiple components, lumens/cannulations, blind holes, mated surfaces, connectors and internal mechanisms should be cleaned following the rigorous manual or combination cleaning procedure outlined in this reprocessing manual except where specifically indicated.
“AAMI ST 79 - 7.5.5… Disinfection and sterilization cannot be ensured unless the cleaning process is successful… it is incumbent upon professionals in the field to seek out whatever means are available and practical to verify this function... A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically…”
“Cleaning is critical because residual organic material (e.g., blood, bone, proteinaceous material) can inactivate disinfectants; moreover, if a device is not cleaned thoroughly, sterility may not be achieved”

Source: Zimmer, Instrument Care, Cleaning and Sterilization Instructions
Biofilm forms when bacteria adhere to surfaces in aqueous environments and begin to excrete a slimy, glue-like substance that can anchor them to all kinds of material – such as metals, plastics, soil particles, medical implant materials, and tissue.
I just can't go with the flow anymore. I've been thinking about joining a biofilm.

This Slime Smile created by Jamie Pennington
WHY FOLLOW THE IFU?

CSPD is absolutely critical to key initiatives in the hospital
- Patient Safety
- Operational Efficiency
- Financial Performance

Patients, Surgery, Surgeons, Families, Friends, ALL Depend on YOU!
If you choose to not follow the IFU's....... You can ALWAYS work for “Meals ON Wheels”

CENTRAL STERILE SUPPLY DOES MAKE A DIFFERENCE!
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Thank You
Questions?