Surgical Site Infection – A Surgeons Perspective

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STERRAD : Gas Plasma Sterilizers

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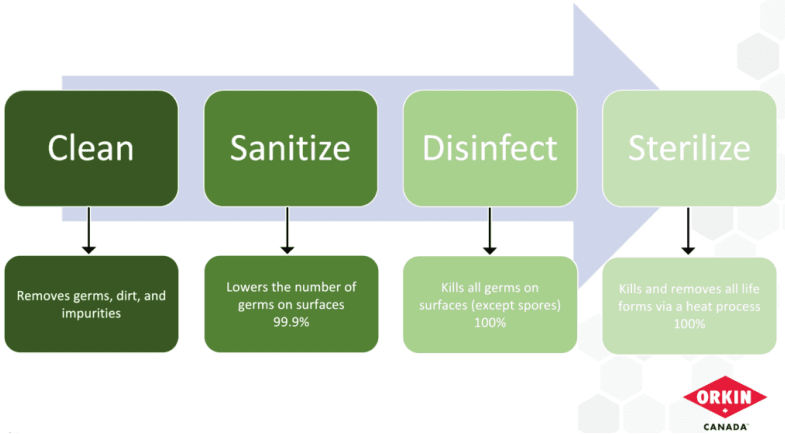
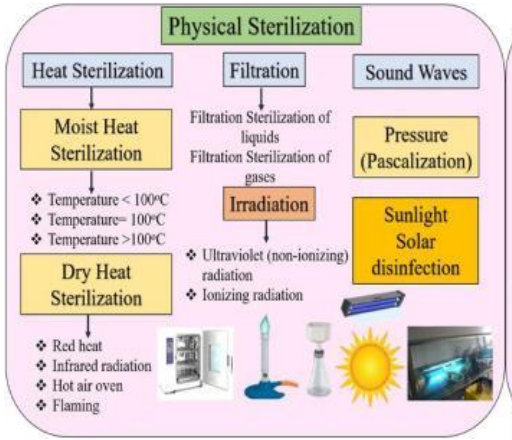
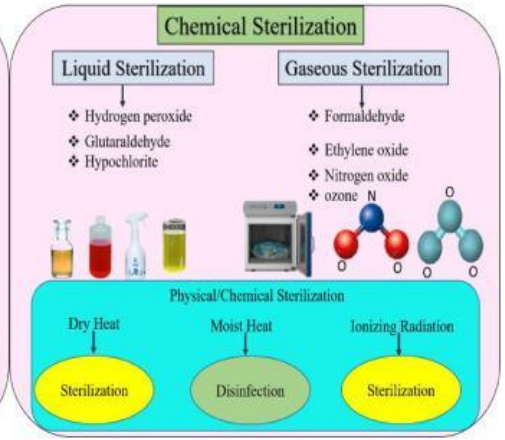
ASP
Advanced
Sterilization
Products
SOTS
2023
BANGALORE

My Talk







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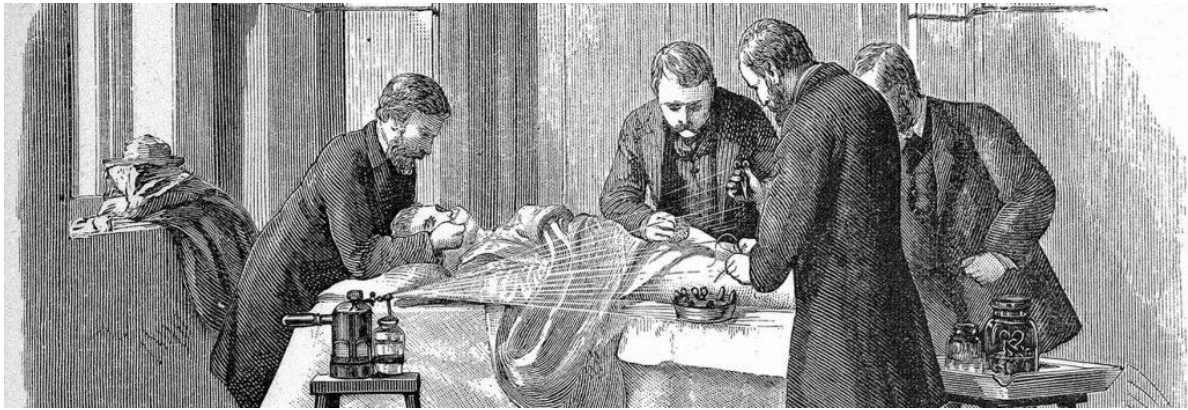
Evolution

History

- In 1862, **Louis Pasteur** developed pasteurization process.
- **Joseph Lister,** in 1867, used a carbolic solution spray on the wounds of his patients.
- **Charles Chamberland,** developed the first pressure steam sterilizer, or autoclave in 1876.



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Sources of SSI Pathogens

- Patients Flora
  - From Skin, GI Tract, Mucous membranes
  - Due to Inadequate Skin Prep
  - Seeding from Pre-Existing Sites of Infection
- Surgical Personnel Flora
  - Inadequate Hand Hygiene
  - Breaks in Aseptic Technique
- Contaminated Instruments (Most Common)
  - Surgical Instruments
  - Medical Devices in Operating Room

Common SSI Pathogens

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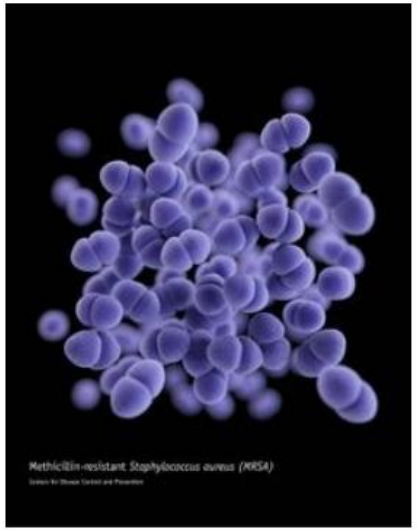
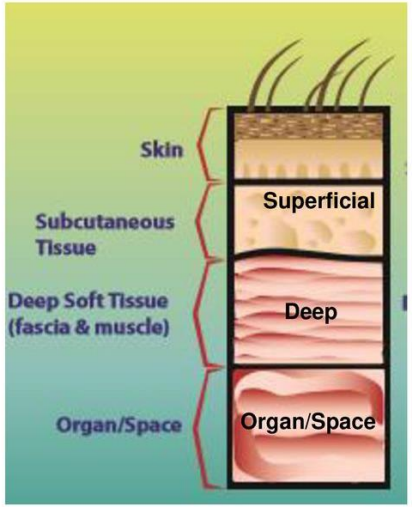
Staphylococcus aureus – 21%
Escherichia coli – 14%
Coagulase-negative Staphylococci – 8%
Enterococcus faecalis – 8%
Pseudomonas aeruginosa – 5%
Bacteroides - 5%



SSI Types

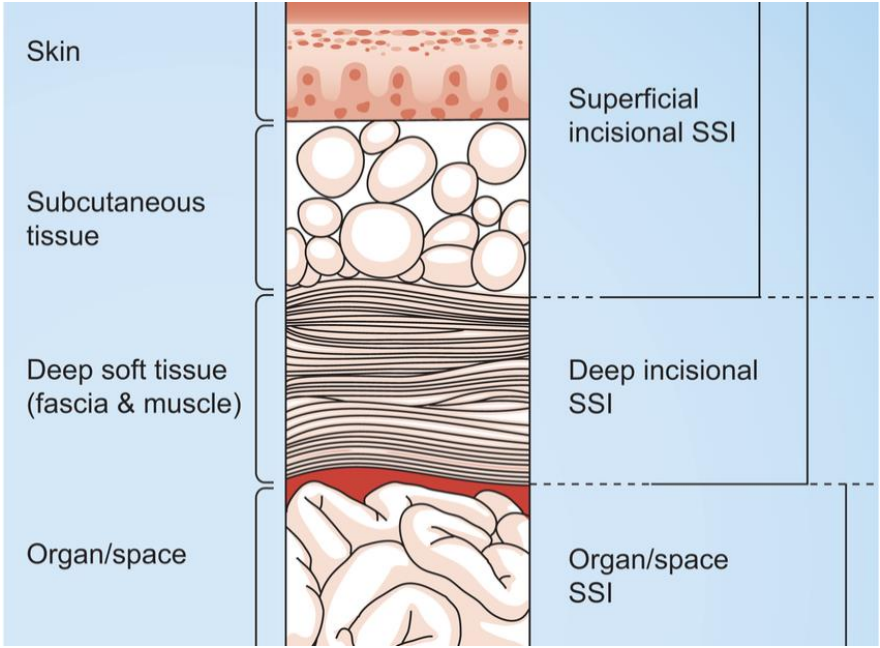
Definition of SSIs according to their superficial or deep site



Superficial incisional SSI
1. Purulent drainage from incision
2. Cultures+ from aseptically obtained fluid or tissues in incision
3. Incision opened by a surgeon : signs of infection ± cultures+
4 - Diagnosis of SSI by surgeon

Deep incisional SSI
1. Purulent drainage from incision
2. Dehiscence or opening by surgeon + signs of infection and cultures+
3. Intraoperative diagnosis of deep SSI, or by pathologist ou by imaging

Organ/Space SSI
1. Purulent drainage from the organ/space
2. Cultures+ from organ/space sample
3. Intraoperative diagnosis of deep SSI, or by pathologist ou by imaging



ACS NSQIP wound classification

- American College of Surgeons National Surgical Improvement Program defines wounds (incisions)by a 4-stage classification system

Clean	Uninfected operative wounds without inflammation; respiratory, alimentary, genital or uninfected urinary tracts are not entered
Clean/ Contaminated	Operative wounds in the respiratory, alimentary, genital or uninfected urinary tracts are electively entered; without unusual contamination
Contaminated	Open, fresh, accidental wounds, operations with major breaks in sterile technique or gross spillage from the gastrointestinal tract, and incisions in which acute, non-purulent inflammation is encountered
Dirty	Old traumatic wounds with retained devitalized tissue or those that involve existing clinical infection or perforated viscera

ACS NSQIP wound classification

- Wounds that are contaminated or dirty have a higher incidence of surgical site infections than those that are clean or clean/contaminated
- Expected rates of SSIs are risk adjusted based on the assessment and documentation of wound class
- Clean wound class cannot be assigned for appendectomy, bile duct procedures, cholecystectomy, small bowel, colon or rectal surgeries and vaginal hysterectomies
- Duration of labor and estimated blood loss utilized in risk adjustment for C sections

Surgical site infection (SSI)

- Estimated 157,000 surgical site infections associated with inpatient surgeries in 2011
- SSIs are associated with a mortality rate of 3% with 75% of SSI-associated deaths directly attributable to the SSI
- Organizations can choose which procedures to monitor but must report on those required by CMS, state, etc. and include Takes place during an operation where at least one incision is:
- ·Made through the skin or mucous membrane or
- ·Reoperation via an incision that was left open during a prior operative procedure
- ·Takes place in a OR defined as a patient care area that meets criteria for OR (includes C section, interventional radiology or cardiac catheterization lab)
- ·Type of SSI reported is based on the deepest level of infection where SSI criteria are met during the surveillance period
- ·All elements required to meet SSI criteria usually occur within a 7-10-day time frame with no more than 2-3 days between elements with elements being related to each other
- ·Up to 3 pathogens can be recorded for each SSI

Surgical site infection (SSI)

- Also determined on the status of the infection at the time of surgery (PATOS)

- PATOS SSIs are still reported but not in the SSI count in the organizational metrics
- PATOS is determined via evidence of an infection or abscess at the start of or
- during the index surgical procedure
- Three levels of infection:

    - Superficial

        Deep incisional

        - Organ/space infection

- *Note: CMS expanded SSI code to allow for coding of the 3 levels in alignment
- with NHSN criteria

Preparation of Surgical Patient

- Identify and treat remote infections before elective operation
  - Postpone elective operation until infection resolved
- **Do not remove hair** unless will interfere with the operation
  - If necessary, remove hair immediately before the operation with **clippers** immediately prior to procedure
- Encourage tobacco cessation for minimum of 30 days prior to surgery
- Ensure skin around incision site is free of gross contamination prior to antiseptic skin preparation

Surgical Hand Antisepsis

- Remove rings, watches, and bracelets before beginning the surgical hand scrub
- Remove debris from underneath fingernails using a nail cleaner under running water
- Perform surgical hand antisepsis using either an antimicrobial soap or an alcohol-based hand rub with persistent activity before donning sterile gloves
- When using an alcohol-based surgical hand-scrub product with persistent activity, allow hands and forearms to dry thoroughly before donning sterile gloves

Operating Room Ventilation

- Maintain positive pressure ventilation in the operating room and adjoining spaces
- Maintain the number of air exchanges, airflow patterns, temperature, humidity, location of vents, and use of filters in accordance with recommendations from the most recent version of the Facilities Guidelines Institute – Guidelines for Design and Construction of Hospitals and Outpatient

Hospital Role in SSI Prevention

- Ensure policies and practice reflect current evidence based practices
  - CDC guidelines
- Ensure staff competency upon hire and at least annually
  - Return demonstration to ensure competency
  - New hire orientation
  - Annual skills fair
- Perform SSI surveillance
- Develop an adherence monitoring program for SSI prevention practices
- Provide feedback to frontline staff and leaders
  - Present adherence results with SSI incidence to surgeons, perioperative services, and surgical units

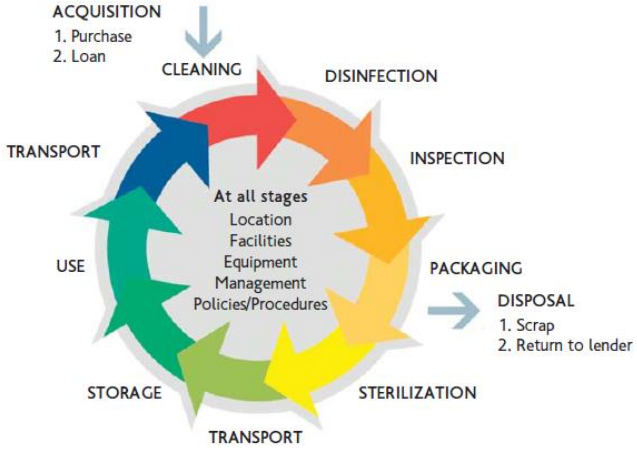
Adherence Monitoring for SSI Prevention

- OR observations
- Hand hygiene
- Safe injection practices
- Environmental cleaning and disinfection
- Device reprocessing
- High level disinfection of reusable devices
- Sterilization of reusable devices

General aspects of sterilization

The life cycle of decontamination illustrates the salient features of decontamination, each step being as important as the next (Figure 1). This section describes three important features for a sterile service: risk assessment, quality assurance and environmental cleaning. Further sections will deal with specific aspects of sterile services.

Figure 1. **The decontamination life cycle**



Reprocessing Surgical Instruments

- Sterilize all surgical instruments according to published guidelines and manufacturer's recommendations
- Immediate-use steam sterilization should never be used for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time.
  - This practice should be **reserved only for** patient care **items that will be used immediately** in emergency situations when no other options are available.
- Refer to CDC HICPAC 2008 Guideline for Disinfection and Sterilization in Healthcare Facilities for additional recommendations.

RISK ASSESSMENT IN STERILE SERVICES

Table 1. **Level of decontamination**

Cleaning	The physical removal of body materials, dust or foreign material. Cleaning will reduce the number of microorganisms as well as the soil, therefore allowing better contact with the surface being disinfected or sterilized and reducing the risk of soil being fixed to the surface. Removal of soil will reduce also the risk of inactivation of a chemical disinfectant and the multiplication of microorganisms. The removal of contamination from an item to the extent necessary for further processing or for intended use. [ISO/TS 11139]
Disinfection	The destruction or removal of microorganisms at a level that is not harmful to health and safe to handle. This process does not necessarily include the destruction of bacterial spores.
Sterilization	The complete destruction or removal of microorganisms, including bacterial spores. **Sterility** State of being free from viable microorganisms. **Sterilization** Validated process used to render a product free from viable microorganisms.

RISK ASSESSMENT IN STERILE SERVICES

Table 2. **Policy for the local decontamination of reusable equipment according to the Spaulding classification**

Risk category	Recommended level of decontamination	Examples of medical devices
High (critical) Items that are involved with a break in the skin or mucous membrane or entering a sterile body cavity	Sterilization	Surgical instruments, implants/prostheses, rigid endoscopes, syringes, needles
Intermediate (semi-critical) Items in contact with mucous membranes or body fluids	Disinfection (high level)	Respiratory equipment, non-invasive flexible endoscopes, bedpans, urine bottles
Low (non-critical) Items in contact with intact skin	Cleaning (visibly clean)	Blood pressure cuffs, stethoscopes

RISK ASSESSMENT IN STERILE SERVICES

Table 3. **Establishing the method to be used**

Questions to be asked	Assessment to be carried out
1. What is the purpose of the device?	Is it an invasive device
2. Manufacturer's reprocessing instructions	In contact with mucous membranes, skin, body fluids or potentially infectious material Table 2 will assist in assessing the level of decontamination required
3. Can the item be reprocessed?	Can it be cleaning properly and has the SSD the available resources for cleaning and sterilization of the item
4. Are the resources and facilities required for cleaning, disinfection or sterilization available locally?	Look at what is available. If possible, do not compromise on the level of decontamination required due to the lack of resources/facilities.
5. How soon will the device be needed?	Can the item be sent to a central department for processing, such as an SSD, or does it have to be processed at the point of use? Are there sufficient devices for the number of patients

RISK ASSESSMENT IN STERILE SERVICES

Table 4. **A summary of decontamination processes and measurements for validation and their application**

PROCESS	WHAT IS MEASURED AND WHEN?	
Cleaning	Daily Use of detergent and disinfectant	Per item Cleaning results by visual control or by using a cleaning test
Disinfection	Daily Use of disinfectant by concentration, temperature and pH of disinfectant	Per load Time of exposure
Chemical sterilizers		Per process Biological indicator Chemical indicators Physical indicator Per item External indicators
Moist heat (steam sterilizers)	Daily Bowie-Dick test for steam penetration in porous loads (pre- vacuum autoclave) (Helix test for hollow lumen instruments, if available.) Clean the chamber every week	Per process Biological indicator Chemical indicators Physical parameters met as per PQ Per item External indicators

Wet Packs- SSI

The wet packs leads to Biofilm formation and that lead to cause for SSI

Wet Packs are not Sterile

EO / ETO Sterilizers

- Alternative for STEAM Sterilizer
- Ideal for Destroying Bacteria. Fungi and Spores
- Used for Delicate Instruments- Heat and Moist

BUT

ETO gas is carcinogenic, explosive and mutagenic.

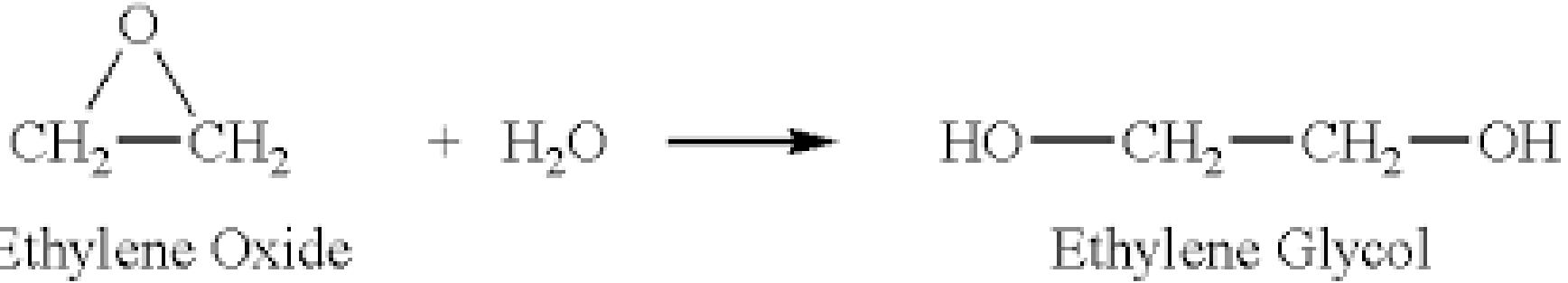
Disadvantages

Excessively Long cycle- 12 hours to 72 hours
Safety concerns - **carcinogenic** to humans
Toxicity issues - toxic residues on surgical instruments and tubing
Not recommended for flexible scope
Eto is flammable
Requires special room conditions, safety equipment and separate ventilation system

Ethylene Glycol

•All The Medical Devices must be Dried with the Air Gun Especially on the Lumens- if a small ounce of water is present on the instruments- EO gas produces ETHYELENE GLYCOL- Which is Highly "Poisonous" which will remain on the polymers

FORMULA (I)



Alternate Technology for Medical Devices

STERRAD Gas Plasma Sterilizers

5 REASONS TO USE STERRAD FOR STERILIZATION

1. RAPID TURNAROUND TIME

With a STERRAD machine, the sterilisation process typically takes around 75 minutes, and some STERRAD models even work within a 45-minute time frame or shorter. This helps you guarantee that your surgical team is ready to go for its next procedure within an hour.

2. COST-EFFECTIVENESS

Not only is the STERRAD system itself surprisingly affordable, but the lack of plumbing, monitoring, and ventilation support expenses also is a cost-saver for your practice. Because of the gentleness of the advanced sterilisation process, your surgical instruments will last longer, needing to be repaired and replaced much less often than if you were using other sterilisation methods.

3. NO DAMAGE TO INSTRUMENTS

Studies have shown that hydrogen peroxide based, low-temperature sterilisation does less damage to medical instruments than traditional autoclaves. This means you'll have longer surgical instrument life and lower costs for instrument repairs over the useful life of your equipment.

5 REASONS TO USE STERRAD FOR STERILIZATION contd..

- 4 STRONG MANUFACTURER SUPPORT AND EDUCATION
- STERRAD machines and consumables are manufactured by Advanced Sterilisation Products (ASP), a division of Ethicon (a Johnson & Johnson company). Advanced Sterilisation Products have a wide range of support and educational options including the ASP University. The ASP University provides many courses and training overviews and it even has online continuing education courses. The STERRAD system comes with industry-leading support from Advanced Sterilisation Products to ensure that the equipment is used correctly and to the full benefit of your surgical team. In fact, the STERRAD Sterility Guide is considered groundbreaking within the industry. The guide is available online and is updated in real time, so you can always find the latest information on instrument validation and system compatibility. In addition, you'll find that the STERRAD line is designed with simplicity and ease-of-use in mind; this thoughtful design can tremendously limit the potential for human error. Many systems operate with the simple push of one button.
- 5. VERSATILE RANGE OF STERRAD STERILISERS
- STERRAD does not take a one- size-fits-all approach to sterilisation. Instead, their STERRAD sterilisers are a diverse product line to ensures that your practice and surgical team can choose the optimal system that best meets the needs of the practice and its patients. Some of the newest models even minimise workflow interruptions before they occur through built-in quality assurance features that can help encourage and guarantee industry compliance.
- For example, the STERRAD 100S system can improve load tolerance and provide faster sterilisation in diffusion- restricted areas. It can also retrofit the original STERRAD 100 for faster cycles.
- The STERRAD 100NX is considered the most advanced sterilisation technology. It includes features such as network connectivity for remote monitoring, touch-screen displays, a hydrogen peroxide monitor and more.
- The STERRAD NX is a compact version that can be used virtually anywhere in a healthcare setting. Its two-tiered chamber and two cycle options can be cart-mounted and easily transferred wherever sterilisation is needed.
- The STERRAD NX with ALLClear is the compact STERRAD NX sterilizer with ASP's new ALLClear technology.

Remember

If it’s not clean and dry, it’s not sterile!