# Workshop on Prevention of surgical Site Infection

## Guard by TSSU

October 4,2009

# TSSU

- TSSU - Theatre Sterile Supply Unit
- Function-

**Clinical:** Prepare operation instrument/ Implantables/Consumables

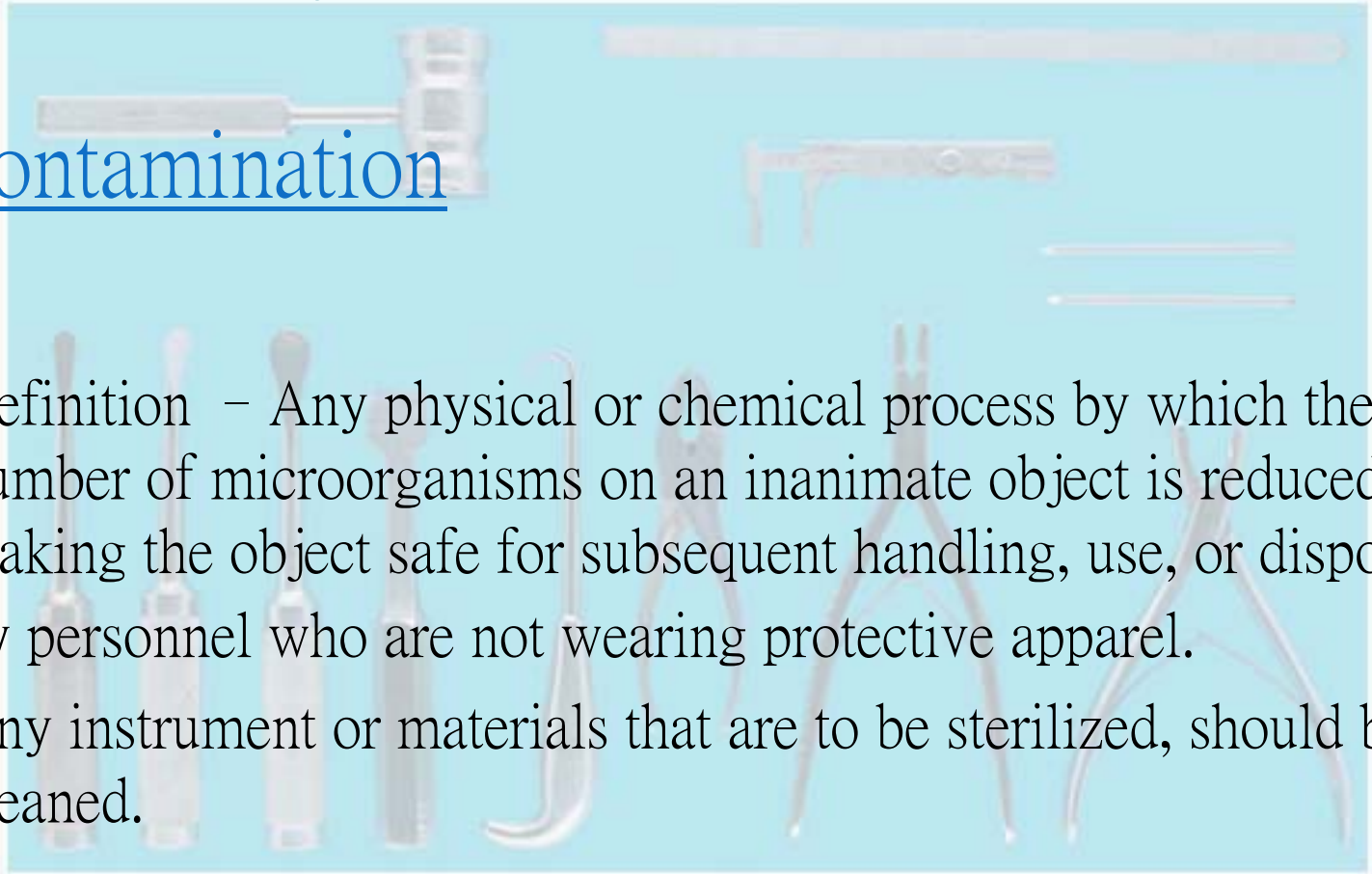
Infection control

**Administrative:**

Budget planning and control,
Purchasing and material control

# Handling of Medical devices

## (Instrument/Implantables/Reusable consumables)



## Decontamination

- Definition – Any physical or chemical process by which the number of microorganisms on an inanimate object is reduced, making the object safe for subsequent handling, use, or disposal by personnel who are not wearing protective apparel.
- Any instrument or materials that are to be sterilized, should be cleaned.

# Decontamination

A. Cleaning

1. Removal of all visible dirt, tissue, blood and foreign particles.
2. Removal of breeding ground for surviving micro-organisms.
3. Reducing the bioburden

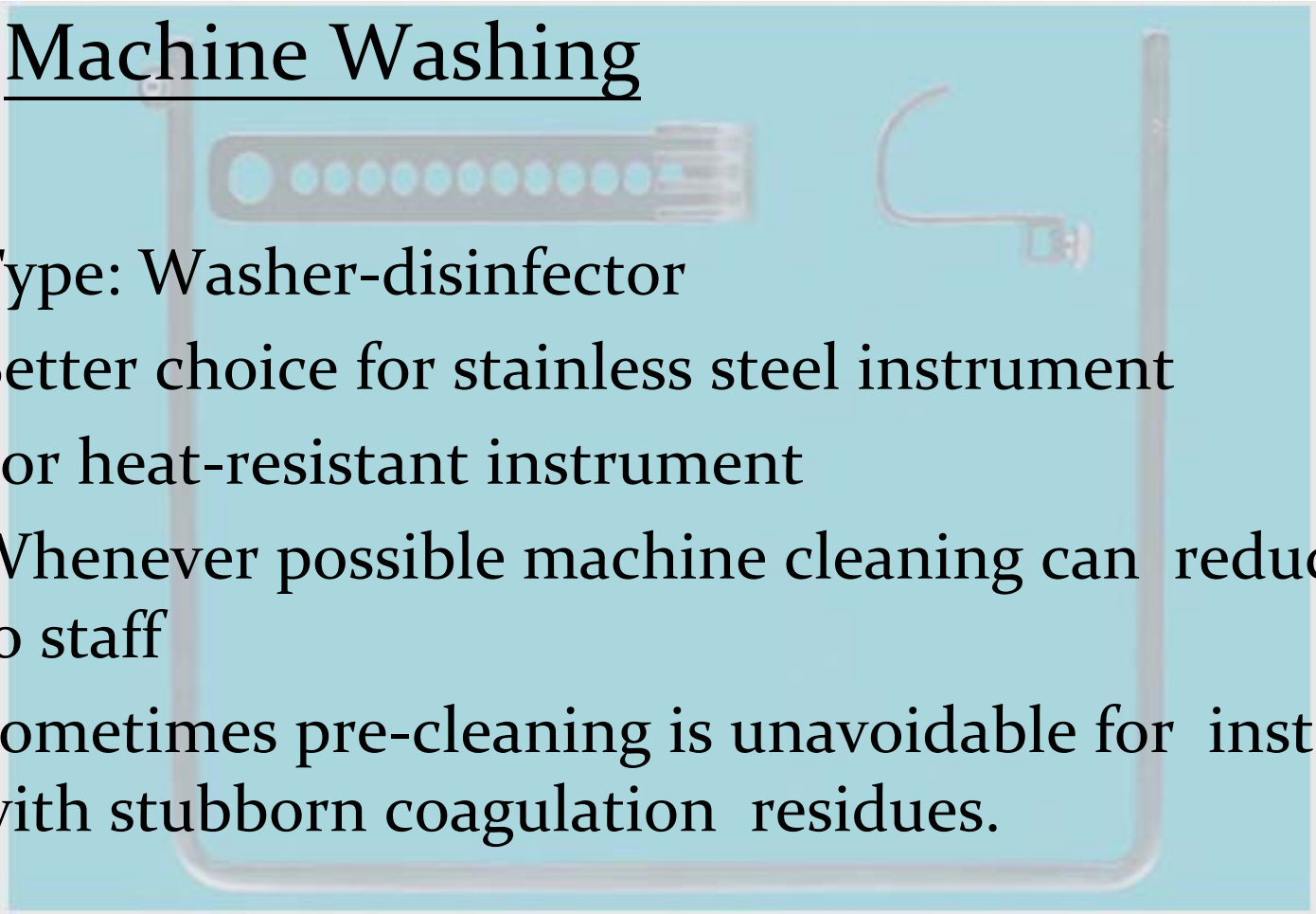
# Decontamination

## B. Importance of quick cleaning after use

1. When organic soils (blood, tissues etc.) are left to dry, they will adhere tightly to the underground and be more and more difficult to remove.
2. In some countries, theatre nurse will submerge the used instrument in a disinfectant solution to prevent drying up.
3. Decontaminate the instruments as soon as possible.
4. Usually theatre nurse will wipe the instrument to facilitate decontamination before returning to TSSU.

# Decontamination

## C. Machine Washing



1. Type: Washer-disinfector
2. Better choice for stainless steel instrument
3. For heat-resistant instrument
4. Whenever possible machine cleaning can reduce risk to staff
5. Sometimes pre-cleaning is unavoidable for instrument with stubborn coagulation residues.

# Decontamination

## C. Machine Washing

Steps:

- Pre-wash- Cold water without any additives to remove coarse dirt
- Cleaning- Carried out at temp. of 40-60 °C with neutral PH or alkaline cleaning agent
- First rinse- Adding an acidic neutralizer to facilitate the removal of alkaline detergent residues
- Second rinse- Further rinse with water
- Thermal disinfection- Take place of water with appropriate temp. and exposure time.

# Ao Value Concept

(European Standard prEN DIN ISO 15 883-1)

**A yardstick for the lethality effect against microorganisms in moist heat disinfection processes.**

- For disinfection processes aimed at

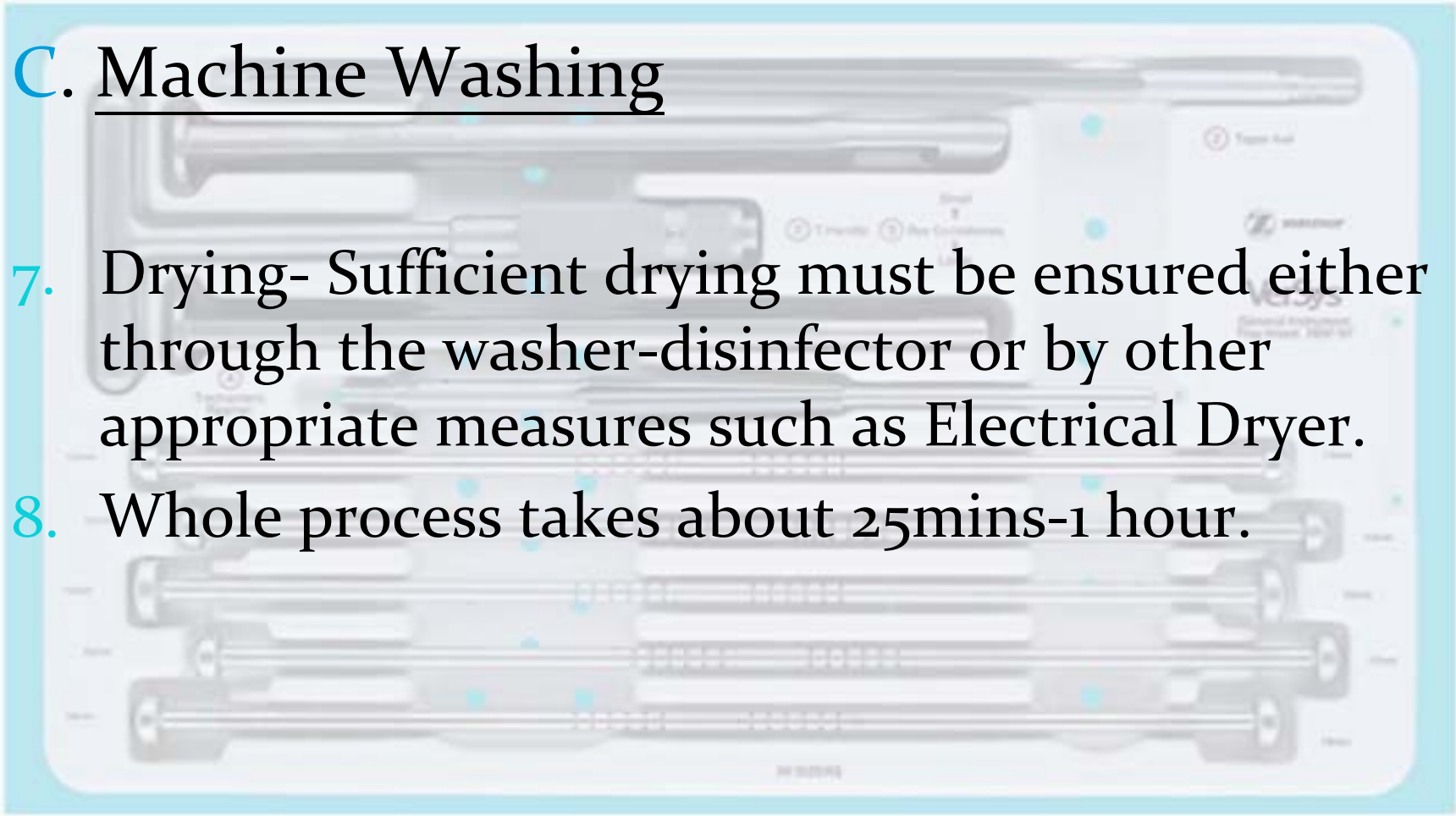
  bacteria, including mycobacteria, fungi and heat-sensitive viruses, Ao Value 600 is defined, corresponding to hold time 80 ℃ for 10 min or 90℃ for 1 min

# Ao Value Concept

- Against Heat-Resistant Viruses, e.g. hepatitis B, Ao value of 3000 must be chosen, corresponding to a temp of 90℃ for 5 min or 93℃ for 2 min 30 sec
- In general Ao value of 3000 for disinfection of surgical instrument is recommended

# Decontamination

## C. Machine Washing



7. Drying- Sufficient drying must be ensured either through the washer-disinfector or by other appropriate measures such as Electrical Dryer.
8. Whole process takes about 25mins-1 hour.

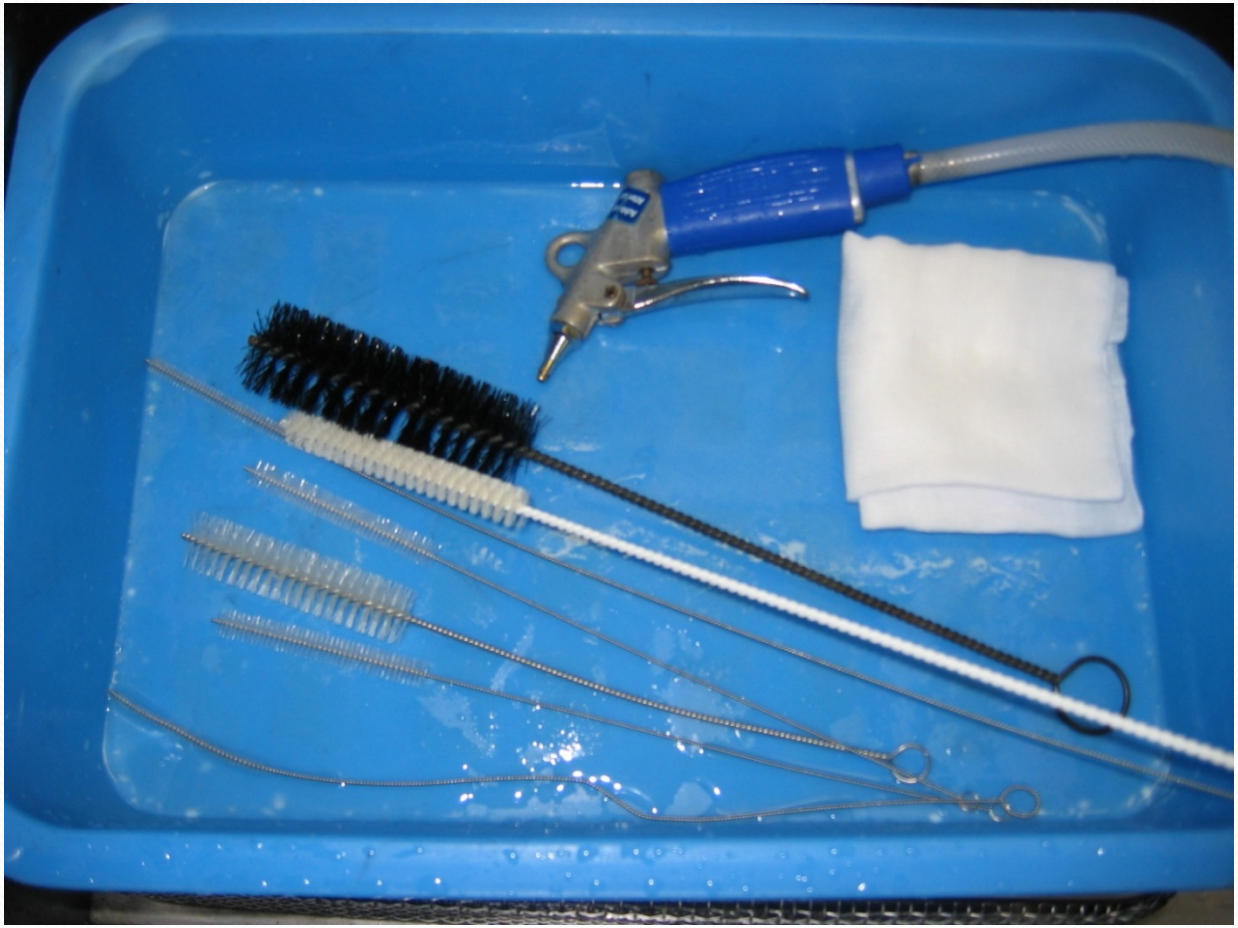
# Decontamination

## D. Manual Cleaning

1. - Delicate Instrument such as Diamond knife, micro-instrument
   - Power machine such as motor handpiece
   - Navigation instrument
   - Endoscopes
2. Use Enzymatic detergent with or without disinfection action
3. Use Cleaning Tools: Soft cloths, plastic brushes, spray gun and hand shower

# Tools for Manual Cleaning

# Tools for Manual Cleaning



# Decontamination

## E. Ultrasonic Cleaning

1. Normal cleaning by brushes, flushing etc., will not be able to reach all surfaces.
2. By Ultrasound, the cleaning action can take place at any location in or on an instrument where water can reach.
3. Good choice for cleaning stainless steel instruments.
4. The process of cavitation can remove small particles even from hidden/unreachable places on the instruments without any damage.
5. As an effective mechanical method supporting manual cleaning.
6. For removing tenacious encrustrations before or after machine treatment.

# Ultrasonic Cleaner

# Disinfection

Definition - chemical or physical process of destroying most forms of pathogenic micro-organisms except bacterial spores.

Level of Disinfection

- High level – Kill all bacteria, viruses, and fungi.
- Intermediate level – Kill most bacteria, viruses, and fungi.
- Low level – Kill most vegetative bacteria, fungi and the least resistant viruses.

# Disinfection

Type of Disinfection

- Thermal disinfection- As discussed before
- Chemical disinfection-

  Common liquid chemical disinfectants:

  Cidex (High level disinfection)

  Cidex OPA (High level disinfection)

  Alcohol 70-95% (Intermediate Level disinfection)

# Disinfection

## Spaulding's Classification of patient care items

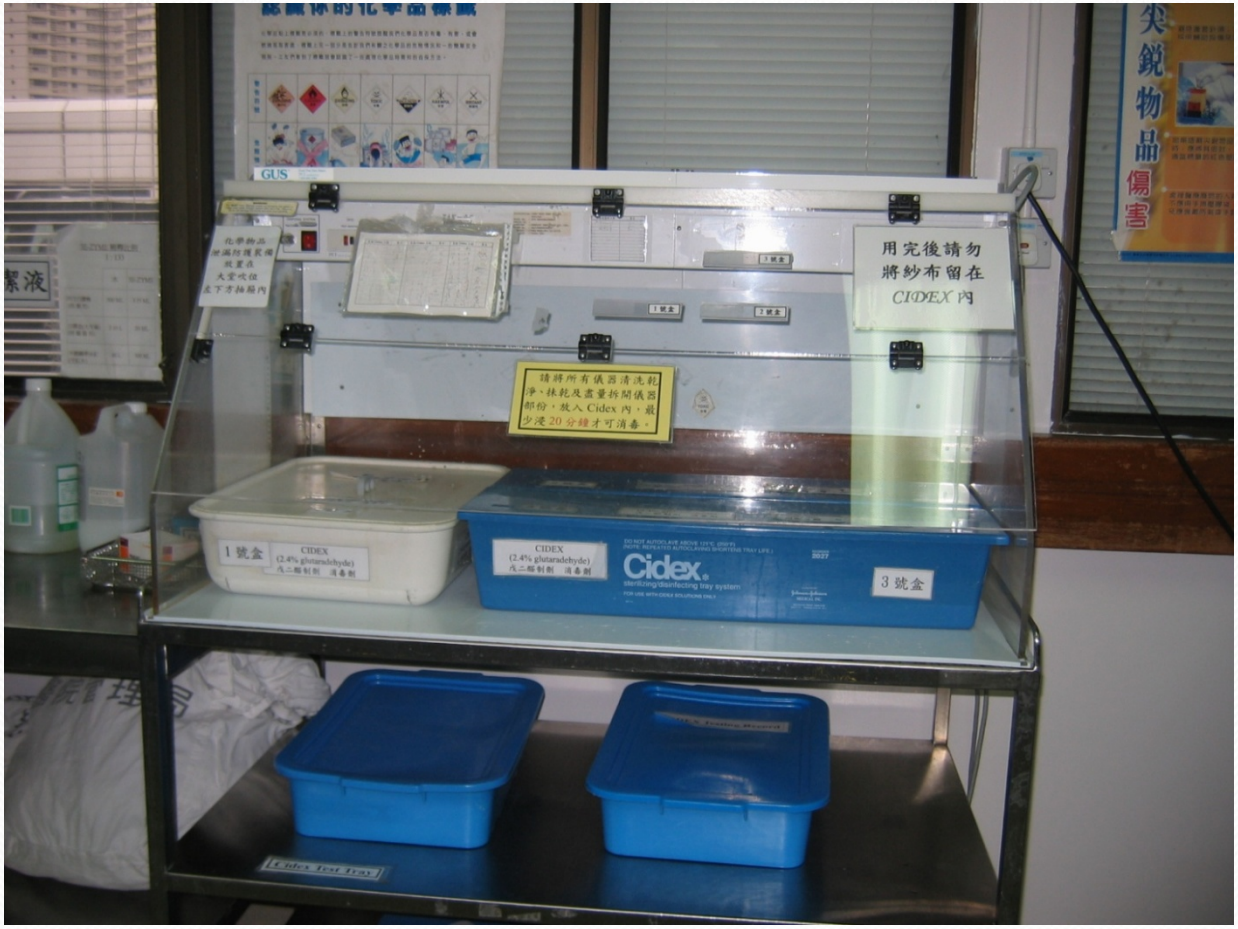
(Earle H. Spaulding, a well known microbiologist)

Critical items – Enter sterile tissue, break the mucosal barrier, or come into contact with the vascular system. Sterilization is required.

Semi-critical item – Come into contact with non-intact skin and mucous membranes and required high level disinfection.

Non-critical item – Contact only with intact skin. Intermediate or low-level disinfection is adequate.

# Disinfection



# Disinfection

- The effectiveness of the disinfectants used should be proven under clean condition in accordance with European standards (EN) or equivalent local guidelines.

- Pay attention to the room temperature, duration of necessary contact, concentration and expiry date.

# Sterilization

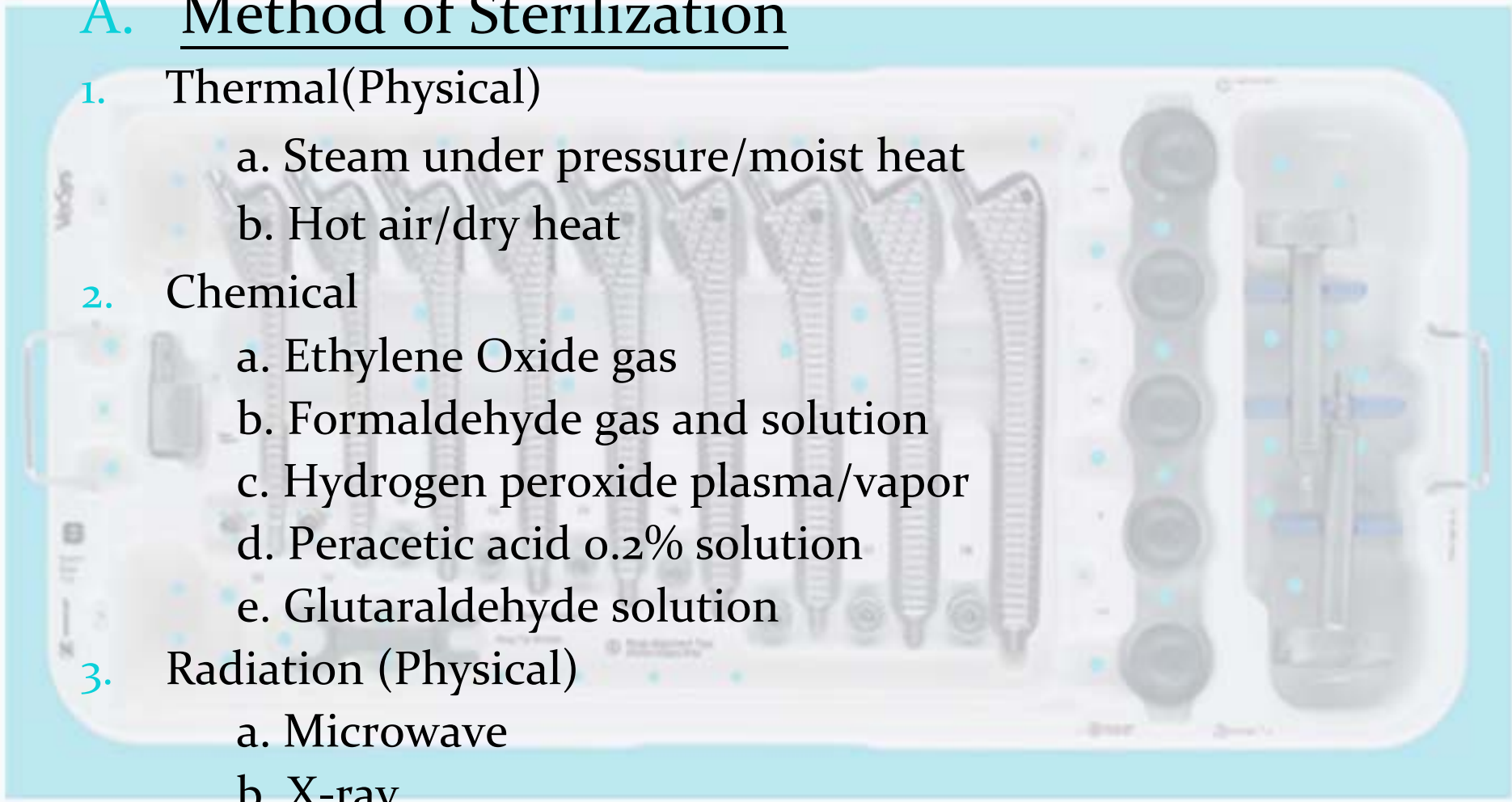
Definition - Process by which all pathogenic and nonpathogenic microorganisms, including spores, are killed.

- The sterilizer is a piece of equipment used to attain either physical or chemical sterilization.

# Sterilization

## A. Method of Sterilization

1. Thermal(Physical)
    a. Steam under pressure/moist heat
    b. Hot air/dry heat
2. Chemical
    a. Ethylene Oxide gas
    b. Formaldehyde gas and solution
    c. Hydrogen peroxide plasma/vapor
    d. Peracetic acid 0.2% solution
    e. Glutaraldehyde solution
3. Radiation (Physical)
    a. Microwave
    b. X-ray



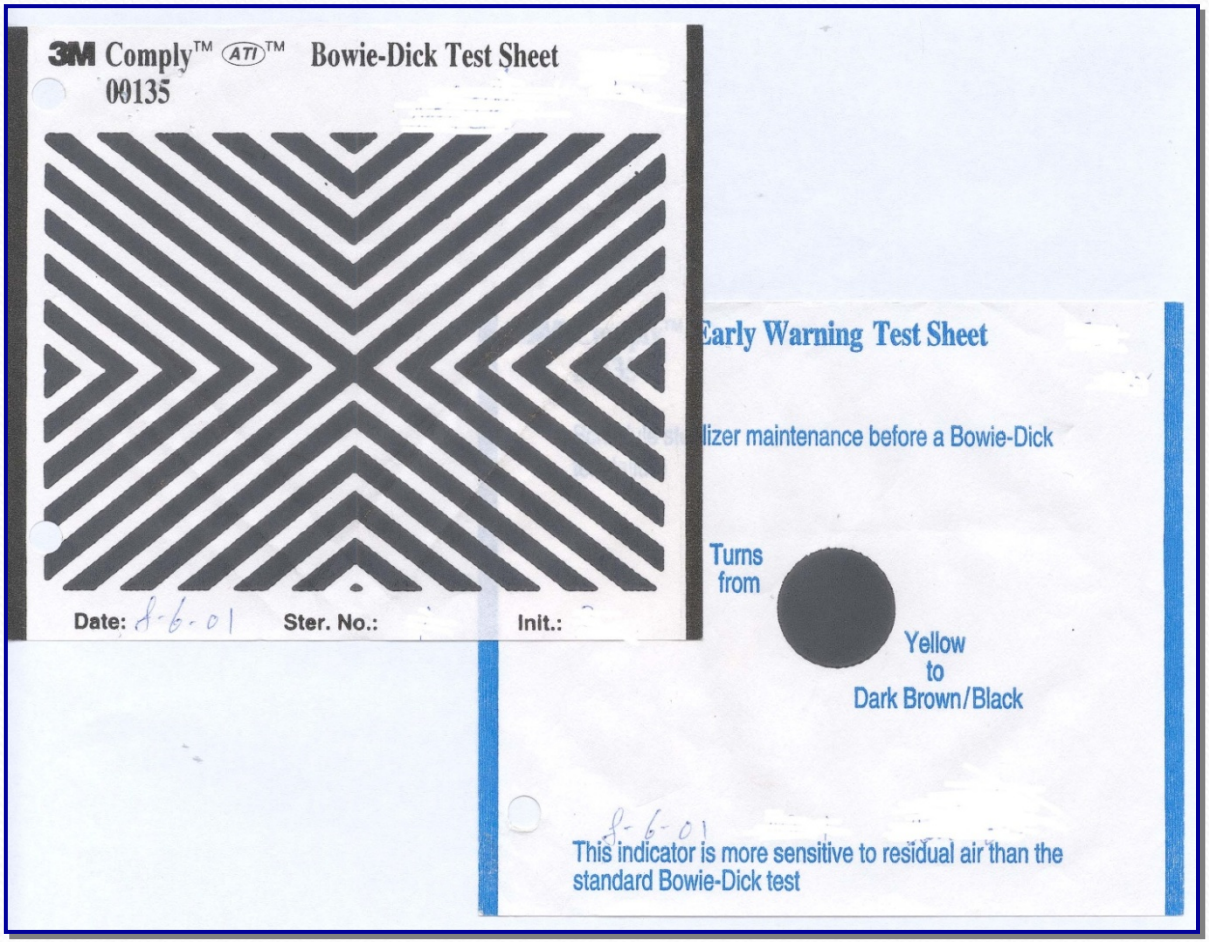
# Sterilization

## B. Monitoring of Sterilization cycle

### 1. Mechanical indicators

- Gauges, thermometers, timers, recorder
- Automatic controls, locking devices and alarm system
- Physical parameters are reviewed and maintained for each cycle.
- Bowie & Dick Test (Air removal test) is performed daily (steam sterilizers)
- Leak Test (Test the function of gaskets and pipes) is performed daily or weekly. (Steam sterilizers)
- Pay attention for the $H_2O_2$ dosage. injection times, pressure, cycle time. (Plasma sterilizers)
- Preventive maintenance includes periodic calibration, lubrication, and function checks by qualified personnel is performed per 6 months/yearly.

# Bowie and Dick pack



# Sterilization

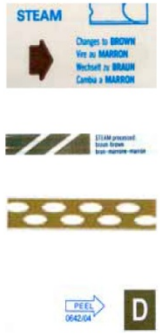
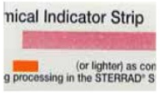
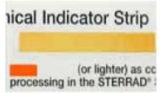
2. **Chemical indicators**

- External indicators tape or label should be clearly visible on the outside of every package to differentiate between sterilized and unsterilized items

- An Internal indicator may be placed inside a package to assess the penetration of sterilant.

- If the chemical reaction of the indicator does not show the expected result, the item should not be used

# Colour Chart of Sterilization Chemical Indicators

| | Steam Sterilization | | EO Sterilization | | Plasma Sterilization | | Formalin Sterilization | |
|---|---|---|---|---|---|---|---|---|
| | Before | After | Before | After | Before | After | Before | After |
| Tape |  |  |  |  |   |   | | |
| Pouch |   |   |  |  |  |  |  |  |
| Strip |   |   |   |   |   |   |   |   |
| Bag |  |  | | | | | | |

# Sterilization

## 3. **Biological indicators**

- A biologic indicator is a preparation of living spores that are resistant to the sterilizing agent.
- The preparation may be supplied in a self-contained system (e.g. dry spore strips) or in a sealed vials or ampoules of spores in suspension.
- To perform the test, a BI that has been exposed to the sterilant and an unprocessed biologic unit (control) from the same lot number are incubated for the same period of time.
- If sterilization has occurred, the processed BI will not grow any microorganisms while the control will grow microorganisms and display a change in colour.

# Sterilization

# Sterilization

3. Biological indicators

- Biological testing is required at regular intervals.
- Frequency: **Steam Sterilization**

AAMI - At least weekly, preferably daily

AHA - Once a day

AORN -At least weekly, preferably daily and with each load of implants

(Consideration of workload and quick turnover need)

# Sterilization

3. Biological indicators

**Plasma Sterilization**

Every Load

(HA policy – No premature release of plasma sterilized items before BI result is normal from 30/9/2009)

**EO Sterilization**

AAMI – Every Load

AHA – Every Load

AORN – Every Load

# Sterilization

## 3. **Biological indicators**

- If a biological testing result is abnormal, all medical devices must be considered recalled and reprocessed since the last normal BI result.
- There should be protocol for each hospital for the management of abnormal finding of sterilizers.

## Protocol for management of abnormal findings in sterilization monitoring in TSSU PWH

The following is the protocol for monitoring of Sterilizers in TSSU, PWH. It is based on the recommendation of Dr. T. Ng (Dept. of Microbiology) and agreed by O.T. Committee members on 13.12.2000.

| Circumstance | Physical Indicator (PI) | Chemical Indicator (CI) | Biological Indicator (BI) | Use of that sterilizer | Implantables | Instrument Packs | Notification |
|---|---|---|---|---|---|---|---|
| 1 | √ | □ | | NO | Reprocess all products of that load with other sterilizer | | - Duty in charge<br>- E&M Dept. |
| | X | √ | | | | | |
| 2 | √ | √ | | YES | Release (Quarantine if possible) | Release | |
| 3 | √ | √ | Quality assurance Cycle √ | YES | Release | Release | |
| 4a. | √ | √ | X | *Trial run & Repeated BI with simulated load* | Reprocess those not released from the last negative BI cycle. | Quarantine those not released of that period until the repeated BI is negative. | - Duty in charge & docume the incident<br>- TSSU Manager<br>- E&M Dept.<br>- Check and rearrange with O.T. any booked case requiring the use of reprocessed implantables |
| b. | √ | √ | Repeated √ | YES | Release | Release | |
| c. | √ | √ | Repeated X | NO | | Recall & reprocess those unused sterile packs from the last negative BI cycle. | Additional steps :<br>- Check and rearrange with O.T. any booked case requiring the use of reprocessed instrument.<br>- O.T., CCOT, 6E, LKS Eye/ENT Clinics<br>- Infection Control Unit<br>- DOM of A&ICU<br>i. COS, Dept. of A&ICU<br>ii. Risk Management Committee |
| 5 | √ | X | X | NO | Reprocess those not released from the last negative BI cycle. | Recall & Reprocess those sterile packs in the cycle having failed P1 or C1 from the last negative B1 cycle | - Duty in charge & document the incident<br>- TSSU Manager<br>- E&M Dept.<br>- Check and rearrange with O.T. any booked case requiring the use of instruments<br>- O.T., CCOT, 6E, LKS Ey ENT Clinics.<br>- Infection Control Unit<br>- DOM of A&ICU<br>i. COS<br>ii. Risk Mx. Committee |
| | X | √ | | | | | |

Note : √ = Acceptable result
□ = Fail result

***Points to Note:***

***1) Continue incubate the positive BI till 48hrs to observe the color change (請封好樽菌以免乾水).***

***2) Stop using the problemed Sterilizer until checked normal by E&M staff.***

# Sterilization

Validation of the sterilization process:

1. Physical parameters
2. Chemical testing
3. Biological testing

# Storage

- After sterilization, the sterile items must be stored in accordance with the rules and provisions governing sterile supplies.
- Medical devices are handled and stored has a direct impact on their shelf life.
- If roughly handled or packed too tightly may have the risk of tearing or damaging the package and lead to contamination.
- Instruments should be stored away from direct sunlight (degrade the packaging material)

# Storage

- The ideal store room should be clean and air-condition with Hepa filter and with positive pressure.
- Limited working staff.
- Reduce handling and transportation of sterilized items
- Stock rotation (First in-First out)
- AAMI recommended practice for storage of sterilized items:
  1. 8-10 inches from the floor
  2. 18 inches from the ceiling
  3. 2 inches from the outside walls
  4. Temp. 18-22°C
  5. Humidity 35-70%

# Shelf Life

- 'Time doesn't contaminate products, events do' (Mayworm 1984)
- Factors contribute to the contamination of products:
  - Bioburden
  - Air movement
  - Traffic
  - Location
  - Temperature
  - Humidity
  - The barrier properties of the wrap material

# Shelf Life (NTEC)

| 包裝物料<br>Packing Material | 病房儲存環境<br>Ward Storage Area |
|---|---|
| 單紙袋<br>Single Paper Bag | 四星期<br>4 Weeks |
| 單管帶<br>Single Pouch | 四星期<br>4 Weeks |
| 雙包裝布<br>Double Linen Wrappers | 四星期<br>4 Weeks |
| 雙包裝紙 / 紙袋<br>Double Paper Wrappers / Paper Bags | 四星期<br>4 Weeks |
| 金屬容器<br>Metal Container | 三個月<br>Three Months |
| 玻璃試管<br>Glass Tube | 三個月<br>Three Months |
| 單管帶 + 膠袋<br>Single Pouch + Dust Cover | 不適用<br>Not Applicable |
| 雙包裝布 + 膠袋<br>Double Linen Wrappers + Dust Cover | 三個月<br>Three Months |
| 雙包裝紙 / 紙袋 + 膠袋<br>Double Paper Wrappers / Paper Bags + Dust Cover | 三個月<br>Three Months |

# Instrument Tracking & Tracing

- Software that allows the facility to monitor the productivity of processing personnel and track the use and inventory of surgical instrument sets.

- **Tracking** : To identify an item and its location

- **Traceability** : Trace a device through the decontamination life cycle after each and every use.

# Instrument Tracking & Tracing

## Advantage :

For abnormal BI finding

- Trace the product from the affected cycles of a particular sterilizer
- For each particular item with its unique code, we can find the particular patient.
- Then we can inform the related surgeons or ICN to closely monitor the patient or take preventive measures.

# Instrument Tracking & Tracing

## Advantage :

For retained instrument or parts of instrument (Sentinent event)

For Infectious case (such as CJD)

- Enable total traceability of the medical devices should a problem arises.
- Quarantine the instrument until the infectious disease is confirmed.

# Coordination of TSSU Staff and OT Staff

Instrument Flow :

TSSU Instrument return after operation

↓

Decontamination Area

↓

Checking/Packing Area

↓

Sterilization Area

↓

Sterile Store

↓

Operating Theatre

* There are strict protocols to ensure the instruments are properly treated in each area

# Coordination of TSSU Staff and OT Staff

**Operating Theatre**

- Check and receive Sterilized items
- Checking of the package : Any torn out area
  Any dirt
  Expiry date
  External chemical indicator
- Proper way in opening the package to the sterile field
- Checking the chemical indicator inside the pack
- Return to TSSU for any abnormality found.

＊Each OT staff should follow the protocols to ensure the sterility of each item before use on patient

# Coordination of TSSU Staff and OT Staff

## Conclusion

- The relationship between TSSU staff and OT staff is complex and synergistic.
- OT staff relies on the TSSU staff to provide complete instrumentation processed to the appropriate degree of safety for patient use.
- TSSU staff relies on OT staff to return used sets in a safe-to-process condition without the risk of concealed blades or other sharps that pose a risk for injury.
- Mutual respect and cooperation between the two specialty areas is the best interest of safe and efficient patient care.

# Reference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*Thank You !!!*