Disinfection & Sterilization in OT

Disinfection
- A physical or chemical process that eliminates many or all pathogenic micro-organisms on inanimate objects with exception of bacterial spores

Sterilization
- The complete elimination or destruction of all forms of microbial life including spores

In OT
- Critical items
- Strict aseptic technique
- MD used in surgical procedures need to be sterile or HLD
- Reprocess of reuse MD & SUDs

Patient safety
- “To prevent the pathogenic microorganisms to contaminate the human body, is the most important factor today” (WHO, 2002)
- Duty of Care to protect the patient.
- The Very First Requirement in Hospitals that should do the sick no harm

What are microorganisms
- = microbes, germs
- Microorganisms are tiny living creatures that cannot be seen with the naked eye; they are visible only under the microscope (from around 1000-fold magnification).

Spore

Florence Nightingale

Bacteria

Viruses

Fungi

Protozoa
Spores

- Some bacteria are masters of survival and can change into spores.

Decontamination

Decontamination is a combination of processes, including cleaning, disinfection and sterilization, used to render reusable medical devices safe for further use. Cleaning is an essential prerequisite to ensure effective disinfection/sterilization.

Risks from Inadequate Decontamination Reprocessing

- Cross infection
- Misdiagnosis
- Harmful to handling personnel
- Induce corrosion to instruments
- Affect the efficacy of the disinfection or sterilization process

Spaulding Classification

- Earle H. Spaulding believed that how a MD will be disinfected depended on the devices ultimate intended use
  - Critical items (high risk)
  - Semi-critical (Intermediate risk)
  - Non-critical (Low risk)

Classification of Risk

<table>
<thead>
<tr>
<th>Risk</th>
<th>Application</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Items in close contact with a break in the skin or mucous membrane or introduced into a sterile body area</td>
<td>Sterilization</td>
</tr>
<tr>
<td>Medium</td>
<td>Items in contact with intact skin, mucous membranes or body fluids – infected or immunocompromised patients</td>
<td>Sterilization or disinfection required</td>
</tr>
<tr>
<td>Low</td>
<td>Items in contact with healthy skin or mucous membranes or not in contact with the patient</td>
<td>Cleaning</td>
</tr>
</tbody>
</table>

Critical Items

- Penetrates skin or mucous membranes
- Introduce into blood stream or normal sterile areas of the body
- Require Sterilization
- E.g. All items used in surgical procedure, implants
### Semi-critical items
- Intermediate risk
- Touch mucous membranes and non intact skin
- Require HLD
- E.g. Flexible endoscopes
- By Washer Disinfector (AER)/Chemical disinfectant

### Non-critical items
- Low risk
- Touch only intact skin, environmental surfaces
- E.g. Stethoscopes, Bed Pan
- Environment cleaning
- By alcohol, hypo 6, detergent, water

### Disinfection Level
<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Most vegetative bacteria, fungi and the least resistant viruses (Flaviviridae)</td>
</tr>
<tr>
<td>Medium</td>
<td>Most bacteria, viruses and fungi (e.g., Hepatitis A virus)</td>
</tr>
<tr>
<td>High</td>
<td>All bacteria, viruses and fungi (e.g., Bacillus subtilis, Clostridium tetani)</td>
</tr>
</tbody>
</table>

### Disinfection
- Resistance of micro-organisms
- Interaction time
- Cleanliness of device
- Presence of organic matter
- Temperature
- Concentration
- Surface contact
- Water Quality

### Resistance of micro-organisms to HLD

<table>
<thead>
<tr>
<th>Micro-organisms</th>
<th>Resistance to HLD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most resistant</td>
<td></td>
</tr>
<tr>
<td>Prions (TSE’s)</td>
<td></td>
</tr>
<tr>
<td>Spores</td>
<td></td>
</tr>
<tr>
<td>e.g. B. subtilis, C. tetani</td>
<td></td>
</tr>
<tr>
<td>Mycobacteria</td>
<td></td>
</tr>
<tr>
<td>e.g. M. tuberculosis</td>
<td></td>
</tr>
<tr>
<td>Non-enveloped viruses</td>
<td></td>
</tr>
<tr>
<td>e.g. Adenovirus, Norwalk virus</td>
<td></td>
</tr>
<tr>
<td>Fungi</td>
<td></td>
</tr>
<tr>
<td>e.g. Candida species, Cryptococcus species</td>
<td></td>
</tr>
<tr>
<td>Vegetative Bacteria</td>
<td></td>
</tr>
<tr>
<td>e.g. Pseudomonas, Proteus</td>
<td></td>
</tr>
<tr>
<td>Enveloped viruses</td>
<td></td>
</tr>
<tr>
<td>e.g. Hepatitis A &amp; B, HIV</td>
<td></td>
</tr>
</tbody>
</table>

### Mechanism of Disinfection
- Disinfectants can act on microorganisms in two different ways: **growth inhibition** (bacteriostasis, fungistasis) or **lethal action** (bactericidal, fungicidal or virucidal effects).
- Action on the external membrane of the bacterial wall, cytoplasmic membrane, energy metabolism, cytoplasm and nucleus.
Method of Disinfection

<table>
<thead>
<tr>
<th>Thermal</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling</td>
<td>Detergent</td>
</tr>
<tr>
<td>Pasteurization</td>
<td>Antiseptic Disinfectant</td>
</tr>
<tr>
<td>100°C, 10-15 mins</td>
<td>Glutaraldehyde (Cide)</td>
</tr>
<tr>
<td></td>
<td>Alcohol 70%</td>
</tr>
<tr>
<td></td>
<td>Hibitane</td>
</tr>
<tr>
<td></td>
<td>Peroxide</td>
</tr>
</tbody>
</table>

Use for:
- Environment
- Medical devices and equipments
- Surgical Instrument

Use of Disinfectant

- Throughout cleaning before disinfection
- Base on risk of infection
- Appropriate PPE and environment control
- Ensure manufacturer's instruction and effective date
- Fresh preparation, avoid contaminated diluting solution
- Appropriate mixing and concentration
- Rinse thoroughly
- Prevention of recontamination

Common Disinfectant

<table>
<thead>
<tr>
<th>Alcohol</th>
<th>Hibitane</th>
<th>Chlorine &amp; Chlorine compound</th>
<th>Phenols</th>
<th>Iodine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid action</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fast evaporation</td>
<td></td>
<td>No residue effect</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No residue</td>
<td></td>
<td>effect</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aseptics,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>working</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>surface</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flammable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e.g. 70%</td>
<td></td>
<td>Alcohol</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HLD: Glutaraldehyde – 2% Cidex

- Advantages
  - Numerous use studies published
  - Widely used disinfectant
  - Relatively inexpensive
  - Excellent materials compatibility
- Disadvantages
  - Respiratory irritation from vapour
  - Pungent and irritating odor
  - Relatively slow mycobactericidal activity
  - Coagulate blood and fix tissues to surfaces
  - Allergic contact dermatitis

HLD: Ortho-phthalaldehyde (OPA)

- Fast acting High Level Disinfectant (5 Mins)
- Better bactericidal and mycobactericidal activity than glutaraldehyde
- Excellent materials compatibility
- Not a known irritant to eyes and nasal passages
- Weak odor
- No environmental limits

Use of Cidex /i

- PPE: nitrile gloves & Googles
- Accessible Spillage kit
- Good ventilation: operate in Fume Hood & tight lid covered
- Pre-use test: OPA test strips
  - Minimum Effective Concentration (MEC): 0.3%
- Wipe dry before immerse
- Working temperature & time
- Rinse thoroughly: 3 consecutive immersion in adequate volume of sterile or filtered water for at least 1 mins
Ortho-phthalaldehyde
Contraindication
• Urological procedures - reports of patients who have experienced 'anaphylaxis-like' reactions after repeated cystoscopy (typically after 4-9 treatments).

• Contraindicated for reprocessing of urological instruments used on patients with history of bladder cancer.

Peracetic Acid C₂H₄O₃ and H₂O₂

• acetic acid + hydrogen peroxide → peracetic acid
  \[ \text{O O} \]
  \[ \text{CH₃-C-OH} + \text{H₂O₂} \rightarrow \text{CH₃-C-OH} + \text{H₂O} \]
• No harmful decomposition product
• For endoscopes disinfection

How does peracetic acid disinfection work?
Peracetic acid as a disinfectant oxidizes the outer cell membrane of microorganisms. The oxidation mechanism consists of electron transfer. When a stronger oxidant is used, the electron is transferred to the microorganism much faster, causing the microorganism to be deactivated rapidly.
• pH and temperature do influence peracetic acid activity

Formaldehyde
• Use as disinfectant and sterilant both in liquid and gaseous states
• LTFS
• Exposure hazards: Potentially carcinogen
• Formaldehyde (e.g. 4%) : Prepare viral vaccines, preserve anatomical specimens, reprocessing haemodialyzers

Thermal disinfection
• Disinfection by heat - Thermal disinfection
  - The first choice for all situations
  • Moist heat steam or water
    -effective
    -quick
    -controllable
    -environment friendly
    -economical

Pre treatment before reprocessing
Recommended in ISO 15883-1

Phases of WD

• Preliminary rinse – in cold water without any additional substances so as to remove coarse soils
• 2. Cleaning – at a temperature of 40 – 60 °C cleaning is conducted with the dosed detergents
• 3. Intermediate rinse – the cleaning solution is removed by means of hot or cold water
• 4. Disinfection – thermal disinfection is conducted with demineralised water at a temperature between 80 and 93 °C. To destroy hepatitis B viruses, which are particularly heat resistant, a temperature of at least 90 °C is needed for 5 minutes or 85 °C for 16 (see AO concept)
• 5. Drying

Ao Concept
• Temperature – Time Relationship
• ISO 15883
• Measure for killing of microorganisms in moist heat process
• Temperature persist over a period of time will have a predictable effect on microorganisms that have a specific level of resistance
Disinfection - $A_0$-value

$A_0$ is based on temperature and time

Time reference in seconds to reach a specified disinfection efficacy at 80 °C

$$A_0 = \sum_{10}^{10} (T-80)/z \Delta t$$

It denotes the time equivalent in seconds at 80 °C which generates a certain resistance to microorganisms with a defined $Z$ value.

$Z$ value is the increase in temperature required to reduce the D value of a particular microorganism by 90% (the most resistant species have D value=10°C).

D value is the time required at a particular temperature to kill 90% of a population of the respective microorganism.

Recommendations in most countries

<table>
<thead>
<tr>
<th>Flusher Disinfector</th>
<th>Washer Disinfector</th>
</tr>
</thead>
<tbody>
<tr>
<td>$A_0$ 60</td>
<td>$A_0$ 600</td>
</tr>
<tr>
<td>$A_0$ 3000</td>
<td></td>
</tr>
</tbody>
</table>

Bed pans, bowls etc | Containers | Surgical Instruments

Non-critical | Semi-critical | Critical

Based on a risk analysis regarding critical matters.

Ao Value for Thermal Disinfection

<table>
<thead>
<tr>
<th>Temperature</th>
<th>$A_0=3000$</th>
<th>$A_0=600$</th>
<th>$A_0=60$</th>
</tr>
</thead>
<tbody>
<tr>
<td>°C</td>
<td>Sec</td>
<td>Min</td>
<td>Sec</td>
</tr>
<tr>
<td>65</td>
<td>94868</td>
<td>1591.1</td>
<td>19074</td>
</tr>
<tr>
<td>70</td>
<td>30000</td>
<td>500</td>
<td>6000</td>
</tr>
<tr>
<td>75</td>
<td>9487</td>
<td>159.1</td>
<td>1897</td>
</tr>
<tr>
<td>80</td>
<td>30000</td>
<td>50</td>
<td>600</td>
</tr>
<tr>
<td>85</td>
<td>949</td>
<td>15.8</td>
<td>190</td>
</tr>
<tr>
<td>90</td>
<td>590</td>
<td>20</td>
<td>120</td>
</tr>
<tr>
<td>93</td>
<td>150</td>
<td>2.5</td>
<td>30</td>
</tr>
<tr>
<td>95</td>
<td>95</td>
<td>1.6</td>
<td>19</td>
</tr>
</tbody>
</table>

Sterilization

- Validated process used to render a product free of all forms of viable microorganisms.

Methods of Sterilization

Based on material and objects to be sterilized:

- Chemical agents
- Physical agents
- Mechanical removal methods
  - Filtration
- Radiation
- Sterilization in OT: Steam under pressure, Low Temp Sterilization
  - Gaseous Sterilization
  - EO
  - Formaldehyde
  - H2O2 Gas Plasma

Sterilization in OT

Steam under pressure

Low Temp Sterilization

- Gaseous Sterilization
- EO
- Formaldehyde
- H2O2 Gas Plasma
Sterilisation processes

- **Steam sterilisation** at around 134°C for 45 min to 1 h
- **Hot-air sterilisation** at 180°C for 2 to 3 h
- **Formaldehyde sterilisation** at 50-70°C for 4-6 h
- **Ethylene sterilisation** at 50-60°C for 15-18 h
- **Hydrogen Peroxide sterilisation** at 40-60°C for Gentle on materials, 45-60 min

![Dry Heat Sterilization](Hot Air Sterilisation)

Microorganisms and spores are much more resistant to moist heat than dry heat. For dry heat, the following temperatures are recommended:
- Dry Heat (160°C): 120 mins.
- Dry Heat (170°C): 60 mins.
- Dry Heat (190°C): 30 mins.

**Low temperature sterilization**

- Ethylene Oxide (環氧乙烷)
- Peracetic Acid (過醋酸)
- Formaldehyde (甲醛)
- H2O2 Gas Plasma (過氧化氫等離子)
- Ozone (臭氧)
- Radiation (放射性)
- Glutaraldehyde (戊二醛)

**Ethylene Oxide Sterilization**

- Colorless, flammable, explosive gas
- Used in the industry mainly, for heat/moisture sensitive material and long, narrow lumens (tested with Ø = 3 mm and length of 4.5 meter)
- Good sporicidal effect

**Process**

- Low temperature sterilization, 55-60°C
- Exposure time: 1 hr / Cycle time: 3hrs45 mins

**Advantage:**

- Little effect on the material

**Disadvantage:**

- Poisonous
- Needs to be “degassed” afterwards and must always be tested on gas residuals after the cycle
- Not very environmentally friendly and explosive during the degassing phase

**Percacetic Acid (Steris System)**

- Rapid cycle: (< 30 mins)
- Environmental friendly
- Some material incompatible e.g., Alur
- Immersible instruments only e.g., flexible endoscopes
- Point of use system (keep for 1 hour after process)
- BI not a/v
**Chemical sterilization**

**Formaldehyde (HCOH)**

*Used for:*
- Heat sensitive instruments
- Long narrow lumens (tested with biological indicators: Ø = 2 mm and length of 1.5 meter)

*Process:*
Low temperature +5°C - 80°C LTSF is considered to be a chemical-physical process

*Inactivation of micro-organisms by coagulation of protein and methylation of nucleic acids by exposure of load to mixture of formaldehyde and steam

*Disadvantage:*
Poisonous in large amounts (Max exposure: 0.75 ppm during a full working day)
Formaldehyde is absorbed into some material and needs a longer cycle time to "clean" the products, at the end of the cycle -> RINSE before use

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**Gas Plasma Sterilization**

**Hydrogen Peroxide**

*What is Plasma?*
- Plasma is the fourth state of matter in addition to: Solids, liquids and gases
- Plasma is a collection of charged particles that contain positive ions and electrons that exhibit some properties of gas
- But differ from a gas because they are good conductors of electricity and affected by a magnetic field
- Lightening is a common example of plasma

*Hydroperoxide - a chemical*

Hydrogen peroxide is a molecule containing two oxygen atoms and two hydrogen atoms

Hydro-peroxide inactivates microorganisms by attacking the cell membrane, DNA, RNA and other vital cell components.
The DNA-chains are damaged and the cell dies (both bacteria and spores, as well as other microorganisms)
By creating a vacuum the effect increases heavily
Hydrogen peroxide - much more effective in gas form than in liquid form

*Hydrogen peroxide - H₂O₂*

*Gas format*
Low temperature sterilization, < + 40-50°C

*Used for heat and moisture sensitive material*

*Method not suitable for:*
- Absorbing material
- Liquids
- Silver
- Dead-end lumen
- Certain instrument stated by the manufacturer
- Never implants – in case of residuals!
- Less than 1 mm lumen

*Use of booster device for long cannulated instruments (100 cm length)*
- Wrapping Material: Non woven polypropylene wrapping material
- Pouches made from Tyvek
- Gas plasma indicator tape / Chemical indicators to be used
Hydrogen peroxide $H_2O_2$

**Advantage:**
- Little damage for instruments
- Biodegradable after process

**Disadvantage:**
- Hydrogen peroxide is primary irritant and can cause bleaching or ulceration
- The process runs in deep vacuum - dry instruments prior to cycle
- Some medical material absorbs hydrogen peroxide
- Expensive
- Special packaging material (not absorbing)
- Good work practices will include good ventilation (10 air exchanges per hour), a continuous gas monitor for hydrogen peroxide as well as good work practices and training of personnel

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Typical Operating Cycle

5 Phases to sterilization cycle

- 1. Vacuum
- 2. Injection
- 3. Diffusion
- 4. Plasma
- 5. Ventilation

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Steam Sterilization

During the injection phase, 1.8 ml of 59% or 79% hydrogen peroxide is injected into the chamber. Hydrogen peroxide will be degassed during deep vacuum and will inactivate microorganisms.

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The holding time is the **time** necessary for the inactivation of a certain amount of microorganisms with a specific resistance.

<table>
<thead>
<tr>
<th>Spore from:</th>
<th>Inactivation time, in min., at a temp.</th>
<th>100°C</th>
<th>115°C</th>
<th>120°C</th>
<th>124°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacillus anthracis</td>
<td>1-60</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Geobacillus steamtherophilus</td>
<td>8-12</td>
<td>1-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacillus subtilis</td>
<td>300</td>
<td>10-20</td>
<td>5-10</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Clostridium botulinum</td>
<td>300</td>
<td>45</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clostridium tetani</td>
<td>20-60</td>
<td>5</td>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Steam sterilisation

Used for more than 90% of everything that shall be sterilized

Media: Steam and high temperature

**Advantage:**
- Cost effective
- Environmental friendly
- Secure
- Little damages on objects
- Easy to validate – distinct values

**Disadvantage:**
- Good water quality (not available everywhere)
- Not suitable for heat and moisture sensitive materials

Steam and pressure

Saturated Steam

The steam must be totally vaporized and must not contain any waterdrops.
Prevents moisture! Max. < 3.5 % of non-condensable gases

Negative effect
Longer sterilisation time (extra drying)
Wet packages and instruments!

Temperature & Time

The temperature during sterilisation phase must be kept at

- > **121 °C** at least 15 minutes in the chamber/ on the surface
- Or
- > **134 °C** at least 3 minutes in the chamber/ on the surface

Pressure

When creating a certain pressure the temperature will follow!

It must correspond to the temperature on the steamtable

<table>
<thead>
<tr>
<th>Pressure</th>
<th>Absolute pressure</th>
<th>Temp.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.00</td>
<td>3.013</td>
<td>133.69</td>
</tr>
<tr>
<td>2.05</td>
<td>3.063</td>
<td>134.25</td>
</tr>
<tr>
<td>2.10</td>
<td>3.113</td>
<td>134.82</td>
</tr>
</tbody>
</table>

Steam Sterilizer

The spore coat protects the spore and its DNA.

Moisture is necessary for the heat to be transferred into the spore core and inactivate it.
Bench Top Sterilizers
Two Types of Bench Top Sterilizers:
• With vacuum
• Without vacuum

<table>
<thead>
<tr>
<th>Classification of Sterilizers</th>
<th>Suitable for Processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type N (Downward displacement)</td>
<td>Unwrapped solid instruments for immediate use</td>
</tr>
<tr>
<td>Type S (Vacuum)</td>
<td>Items specified by the autoclave manufacturer</td>
</tr>
<tr>
<td>Type B (Vacuum)</td>
<td>Unwrapped &amp; wrapped solid and cannulated instruments. Porous loads – dispos, gowns</td>
</tr>
</tbody>
</table>

Design Differences in Sterilizers

Porous Load
• Mechanical evacuation of air from chamber
• Exhaust from chamber is sampled and heated to an air-in chamber prior to sterilization
• Ability to sterilize wrapped, cannulated instruments

Downward Displacement
• Uses the principle that air is heavier than steam
• Steam is introduced into the chamber
• Steam pushes air downward by gravity
• When sterilization temperature is achieved valve closes
• Not suitable for wrapped, unsterilized instruments

Porous Load Sterilizer Cycle (Pre vacuum)
1. Air Removal Phase (Pre vacuum phase)
   • Air is mechanically removed from the chamber (and load) by a succession of deep vacuum and steam pulses at sub-atmospheric pressures.
   • 3-4 negative pulses will effectively remove 99% of all air in the chamber.
2. Positive / Negative Pulsing:
   • The process continues to remove air from the chamber and load by a succession of steam pulses at super-atmospheric pressures.

3. Sterilization Phase:
   • Temperature reach 134°C - 136°C for at least 4 minutes or 121°C - 123°C for at least 15 minutes
4. Drying Phase:
   • The sterilized load is mechanically evaporated from the chamber using a vacuum pump supported by a water cooled heat exchange (condenser).
   • Air is admitted into chamber (equalisation phase)
5. Air Admission into Chamber (Equalisation Phase):
   • At the end of the drying phase the chamber will return to atmospheric pressure by the admission of filtered air.

Pre-conditions for approved sterilization

The instruments must be
• Clean and disinfected
• Cool before cycle
• Packed
• Free from air
• Dry before cycle
• Dismantle

To maintain the sterility after the process instrument needs a barrier.
**Factors contribute to sterilization**

- Loading in tray
- Loading in chamber

**Loading technique**

- Proper function of sterilizer
- Parameter
- Chemical & biological indicators
- "Indicators do not prove sterilization"

**Release of sterile items**

- Proper loading
- Effective Barrier & Package integrity
- Proper handling: transfer & storage
- Documentation: track & trace
- Ensure by Quality assurance system: Validation

**We can assure sterility Quality**

- Proper loading
- Effective Barrier & Package integrity
- Proper handling: transfer & storage
- Documentation: track & trace
- Ensure by Quality assurance system: Validation

**Validation**

- A documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with predetermined specification

**Control, Monitor, Validation**

- Indicators
- Training & Qualification
- Documentation
- Maintenance
- Routine check
Thermal Couple

Temperature Data Logger

Protection & Precaution

- PPE
- OSH
- Sharps handling
- Universal precaution
- Minimal handling
- Automatic processing

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All you do advocate to patient safety
Thank you