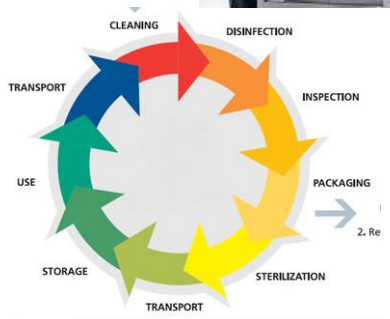
Basic concepts and standard in disinfection and sterilization of surgical instruments

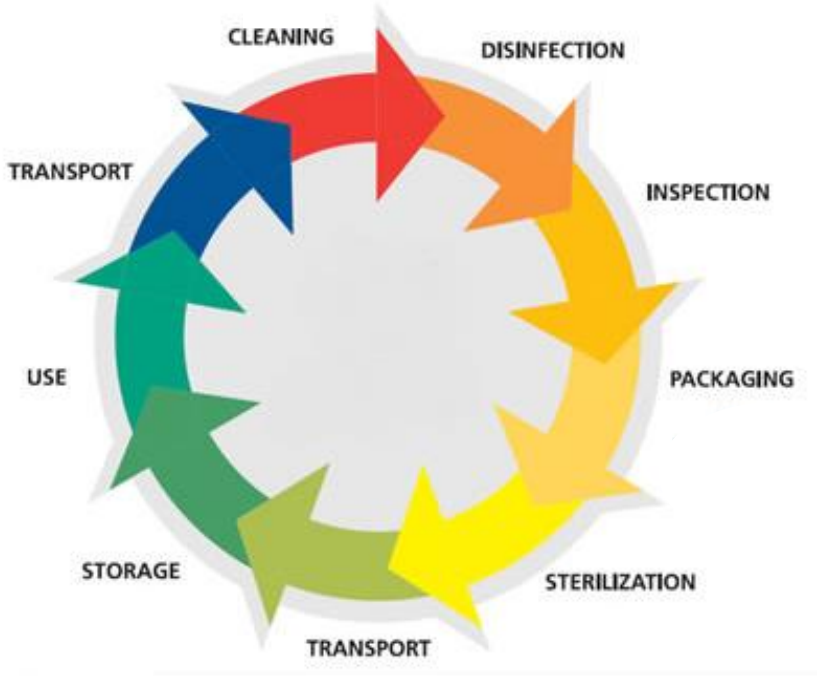


PTY Ching

WHO CC

Hong Kong

The Central Sterile Supply Department (CSSD) is responsible for this series of tasks referred to as instrument reprocessing. It is a complex process driven by the needs of the operating rooms they support.



Therefore, hospitals are working to improve their CSSD to ensure safety and effectiveness.

Rationale

The processes of sterilization and decontamination are **complex**, require specific infrastructure and equipment and involve several steps that need to be correct, from devices collection, receipt by the unit, processing, storage and distributing them throughout the facility. Of utmost importance are also quality control procedures to assess the correct functioning of the equipment.

Guidelines and manuals are very important instrument to provide guidance to health managers and health workers on required infrastructures and standard procedures for effective sterilization, and decontamination reprocessing of medical devices.

Centralize and standardize

Public Health Ontario | Santé publique Ontario

Best Practices for Cleaning, Disinfec
Sterilization of Medical Equipment/
In All Health Care Settings, 3rd editi

May 2013

PIDAC Infectious Diseases Advisory Committee
Infection Prevention and Control

Accessible version: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Update: May 2019

William A. Rutala, Ph.D., M.P.H.[1,2], David J. Weber, M.D., M.P.H.[1,2], and the Healthcare Infection Control Practices Advisory Committee (HICPAC)[3]

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University of North Carolina School of Medicine
Chapel Hill, NC 27599-7030

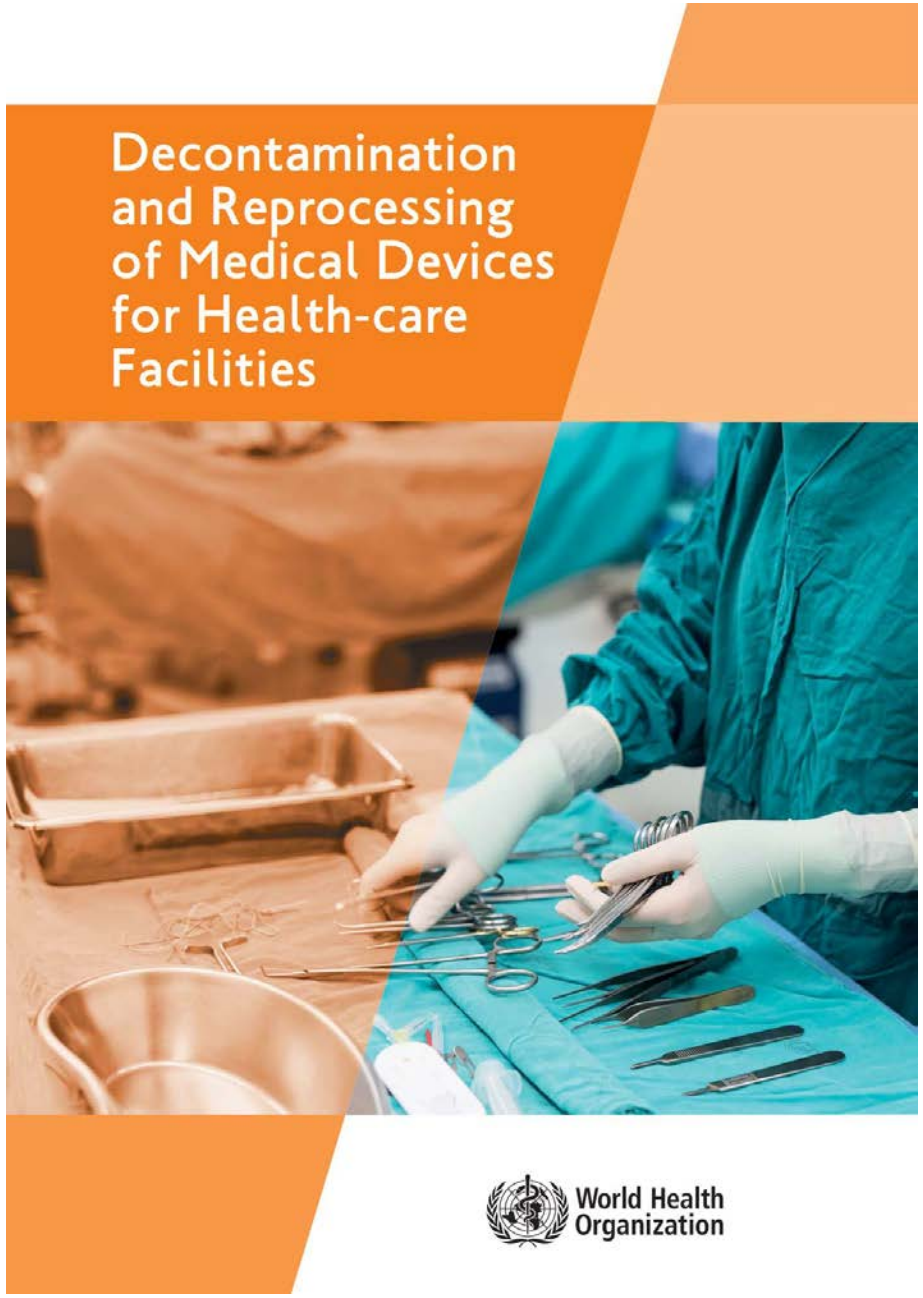
AAMI

ANSI/AAMI ST79:2017

& 2020 Amendments A1, A2, A3, A4 (Consolidated Text)

Comprehensive guide to steam sterilization and sterility assurance in health care facilities

American National Standard



ASIA PACIFIC SOCIETY OF INFECTION CONTROL

THE APSIC GUIDELINES

FOR DISINFECTION AND STERILISATION OF INSTRUMENTS IN HEALTH CARE FACILITIES

http://apsic-apac.org/guidelines-and-resources/apsic-guidelines/

Sterilization and decontamination of instruments and medical devices play a very important role in the prevention of HAIs.

http://www.who.int/infection-prevention/publications/decontamination/en/

Definitions

- Cleaning: removal of all soil from objects/surfaces
- Decontamination: removal of all pathogenic microorganisms from objects to ensure they are safe to handle
- Disinfection: elimination of many or all pathogenic organisms with the exception of bacterial spores
- Sterilization: complete elimination, destruction of all microbial life including spores

CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Spaulding Classification for Medical Devices

In 1972, Dr. Earl Spaulding developed a system for classifying medical instrumentation and equipment

- *Non-critical* – devices that touch intact skin, environmental surfaces – LOW LEVEL DISINFECTION
- *Semi-critical* – devices in contact with intact mucous membranes or skin that is not intact – HIGH LEVEL DISINFECTION
- *Critical* - (high risk) devices enter sterile tissue or bloodstream – STERILIZATION

APIC Text, 2014, Chapter 31, Cleaning, Disinfection and Sterilization

Spaulding Classification for Medical Devices

Device classification	Examples	Spaulding process classification	EPA Product Classification
Critical (enters sterile tissue or vascular system)	Implants, scalpels, needles, other surg. Instruments	Sterilization- Steam sterilization, low temperature sporicidal chemical; prolonged contact	Sterilant/ disinfectant
Semi critical (touches mucous membranes)	Flexible endoscopes, laryngoscopes, ET tubes, vaginal specula	High level disinfection- sporicidal chemical; short contact	Sterilant/ disinfectant
Non critical (touches intact skin)	Stethoscopes, tabletops, bedrails, blood pressure cuffs	Low level disinfection	Hospital disinfectant without label claim for tuberculocidal activity

Decreasing Order of Resistance of Microorganisms to Disinfectants / Sterilization

1.Prions	**- CJD**	Prion Rx
2.Spores	**- Bacillus**	Sterilization
3.Mycobacteria	**- MTB/MAI**	High
4.Non-Enveloped Viruses	**- Polio, Coxsakie**	Intermediate
5.Fungi	**- Aspergillus, candida**	Intermediate
6.Bacteria	**- Staph.aureus, MRSA**	Intermediate
7.Enveloped Viruses	**- HIV, HBV, herpes, SARS CoV1 & 2**	Low

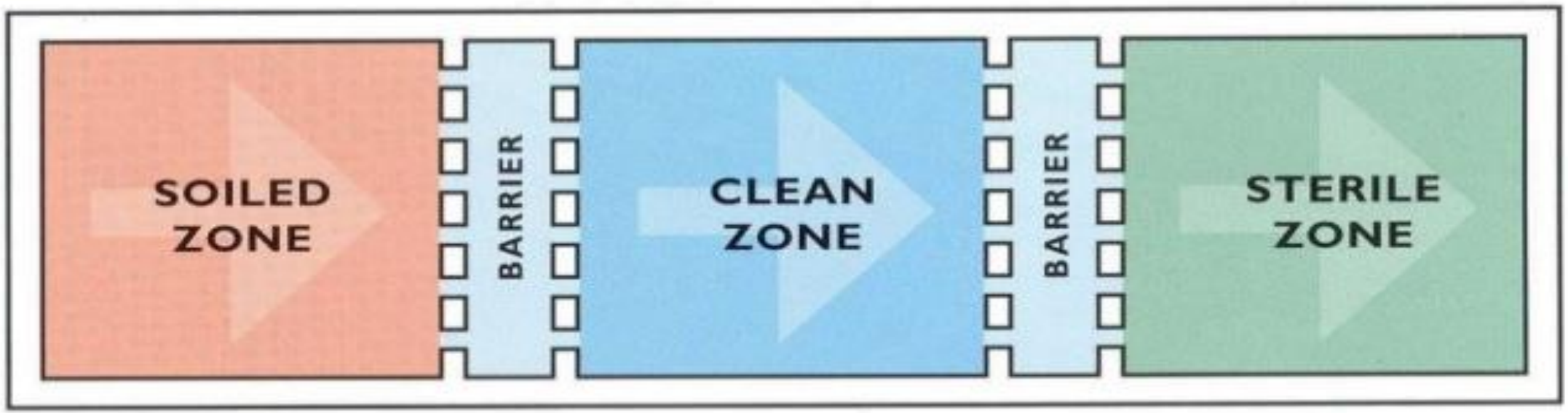
CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, p 33

Basic standards in reprocessing of surgical instruments in CSSD

1. Facility design
2. Handling, collection and transport of contaminated instruments
3. Cleaning and decontamination processes
4. Instrumentation inspection, preparation and packaging
5. Sterilization and monitoring
6. Sterile storage and distribution

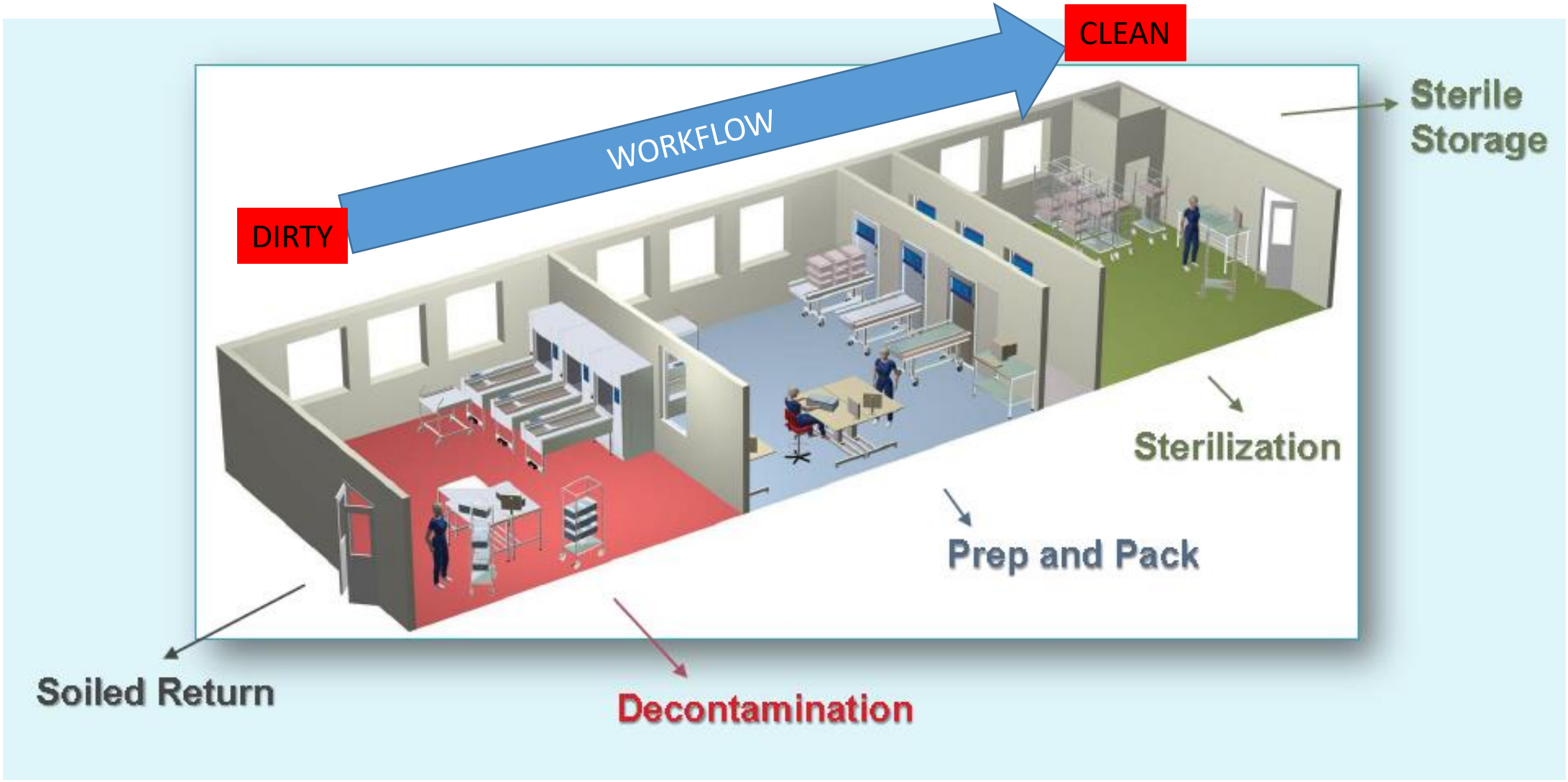
Basic Design of CSSD

GENERAL CSSD DESIGN CONCEPT

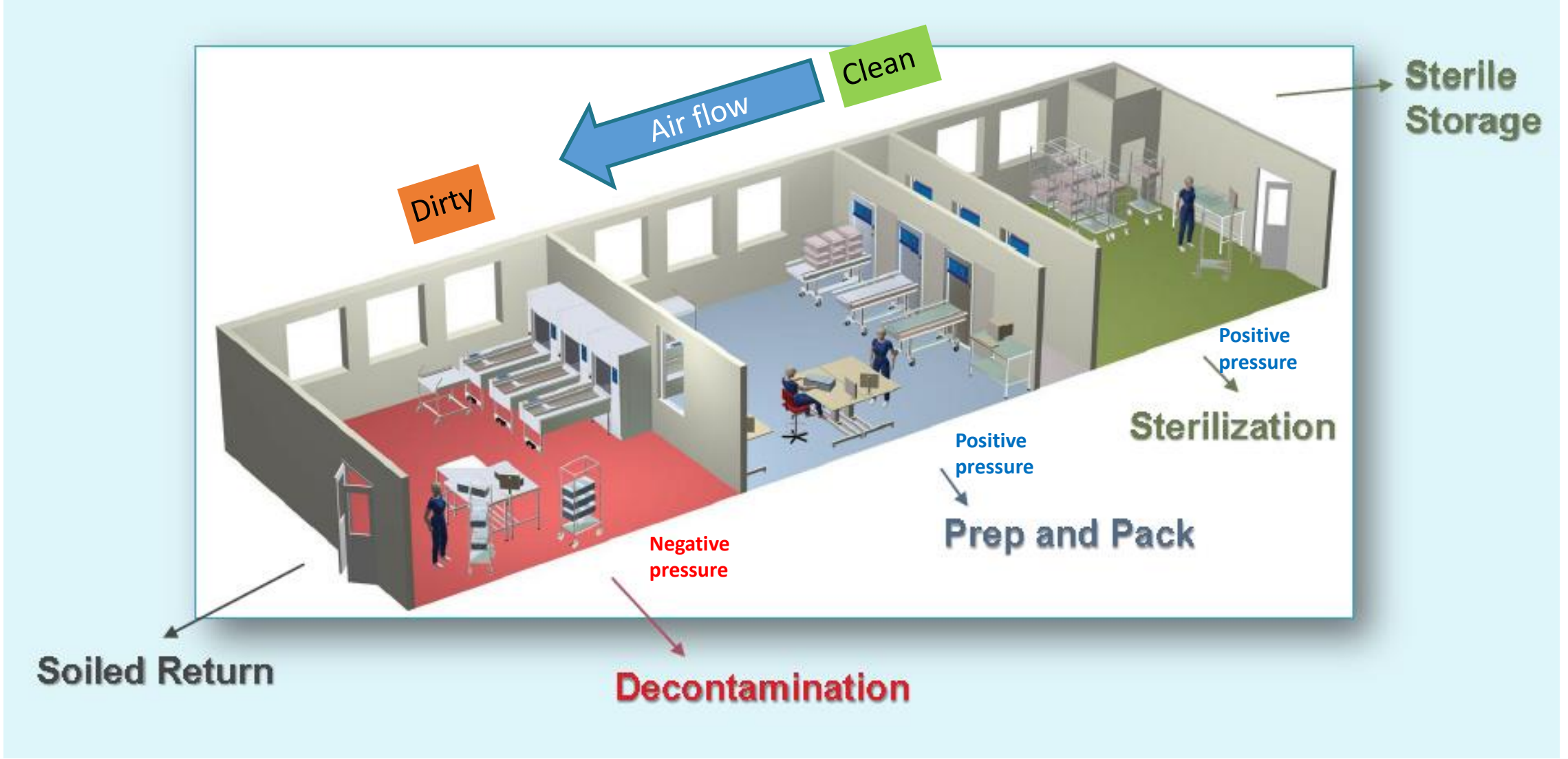


- Physical separation between soiled, clean and sterile zone
- The risk of cross-infection spread by staff is minimized

One Way Workflow of the Sterile Processing Department

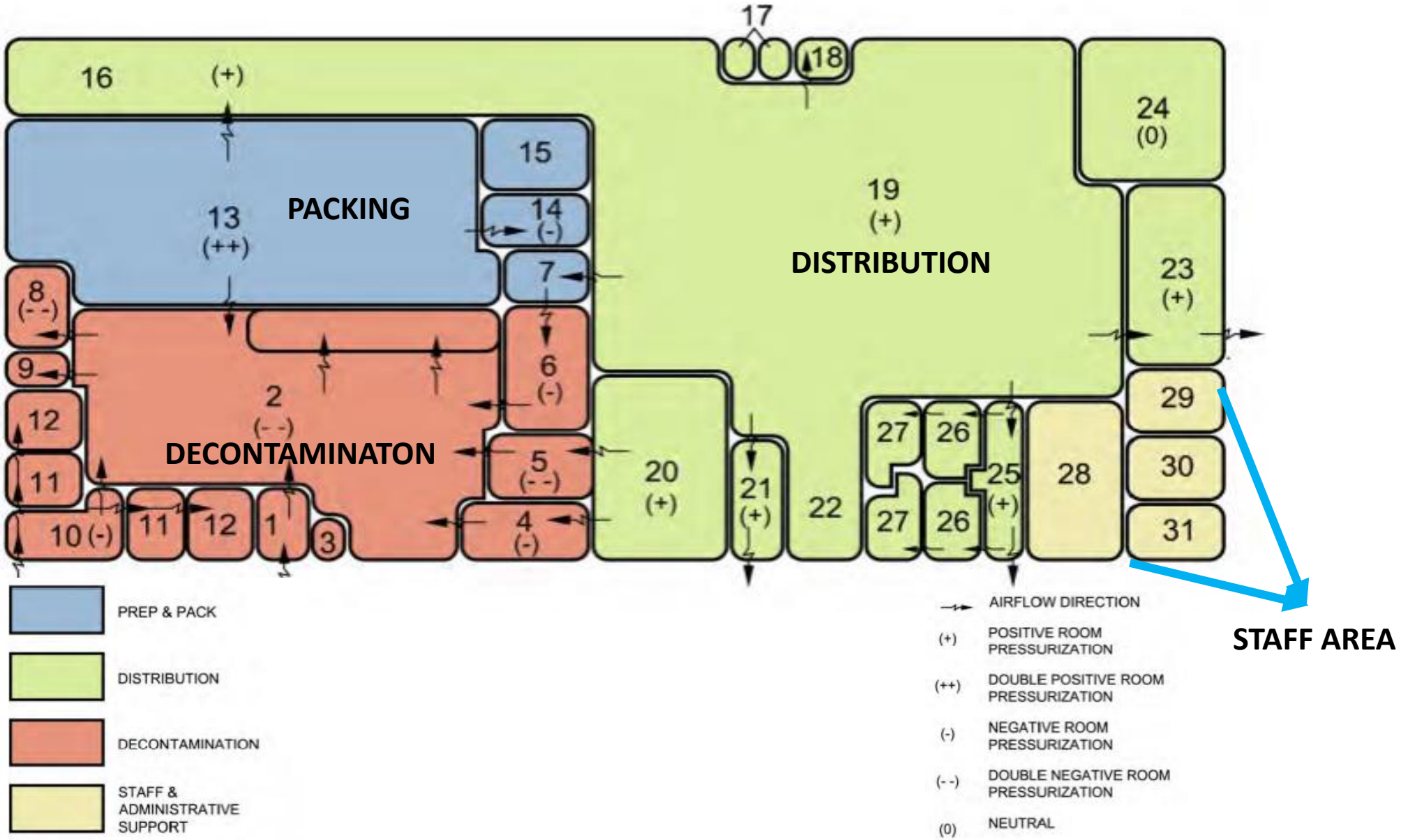


Airflow of the Sterile Processing Department



Relationship Diagram

Air Flow



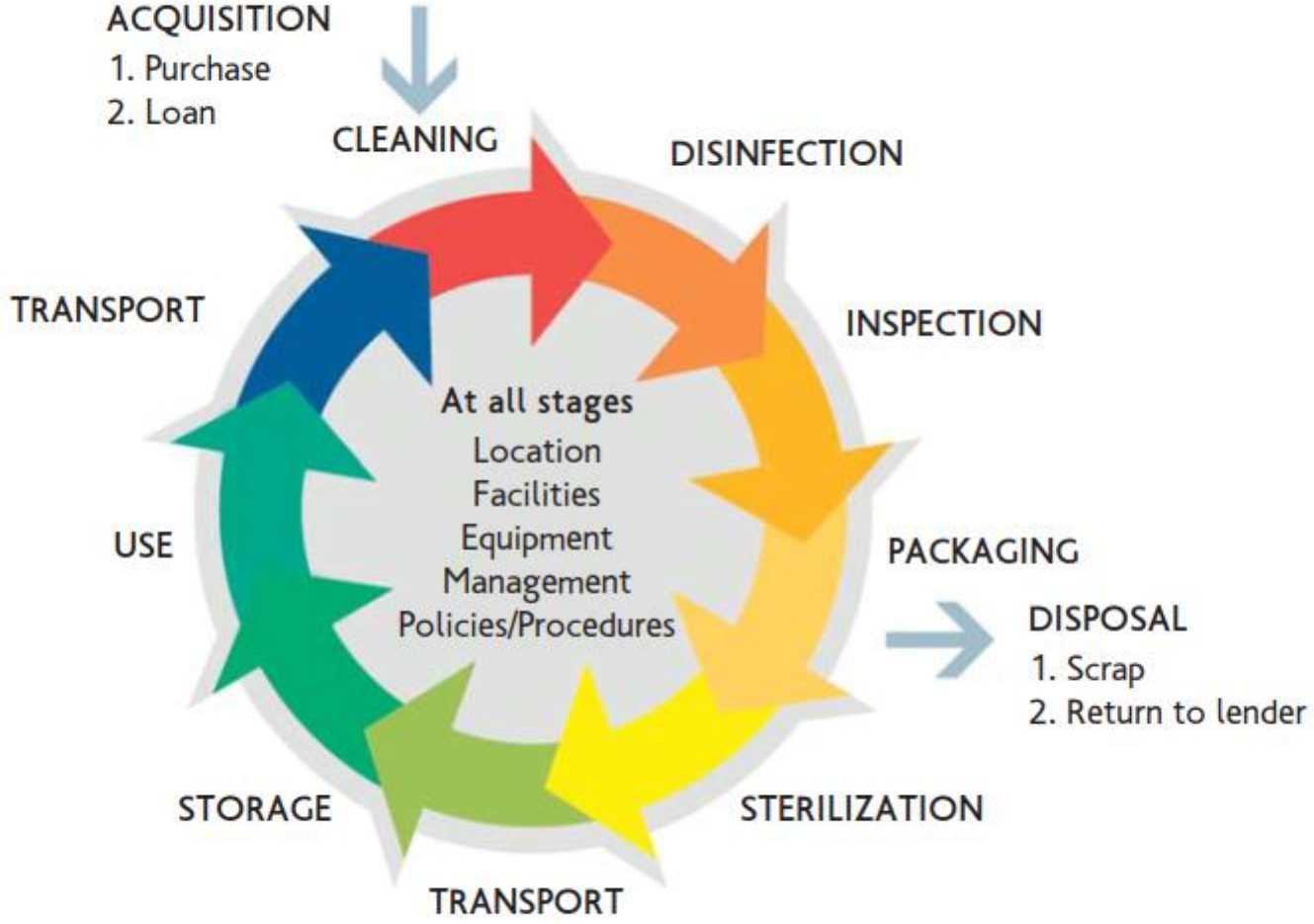
Surgical instruments should be handled centrally in the CSSD with standardize and validated reprocessing procedures

Decontamination and sterilization reprocessing

Concepts of cleaning, disinfection and sterilization

Th

Figure 1. The decontamination life cycle



Source: Health Building Note 13 (HBN13), Department of Health, United Kingdom, 2004

Presoaking

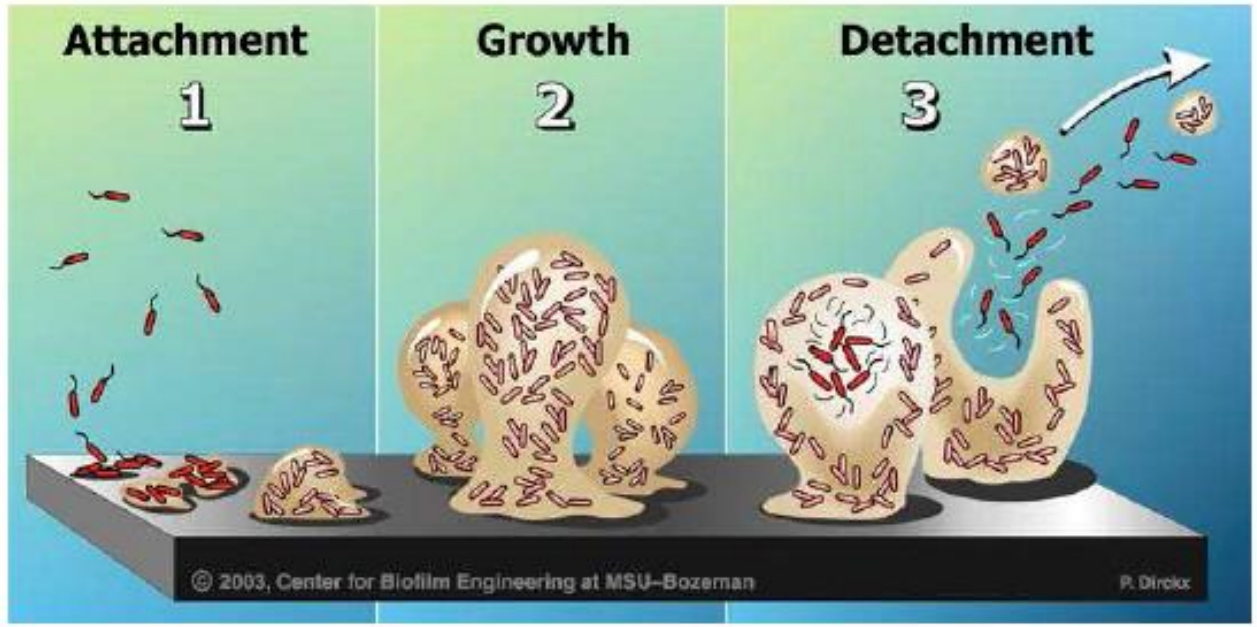
Immediately in the OT

- Prevents soils & proteins from drying on the instruments
- Softens soils and assists with removal
- Prevents biofilm development
- Presoaking the instruments should ideally occur immediately following the procedure
- Sprays, foams, available

Spray-on solutions are typically enzyme formulations designed to break down blood soil and protein, as well as delay drying of organic soils

- **Clean followed by cover with wet towel**

Do you know what is biofilm.....



(Floating)

Biofilm is contrasted with planktonic bacteria, which are a community of microorganisms irreversibly attached to a surface, producing extracellular polymeric substances (EPS), exhibiting an altered phenotype.

Cleaning

- Defined as the physical removal of all visible soil, dust, and other foreign materials
- Effective cleaning will reduce microbial contamination on environmental surfaces & equipment
- Cleaning is the *first and most* important step before disinfection or sterilization can occur

CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Decontamination Area

Machine wash for general instruments

Manual wash for delicate & fine instruments

★ Correct PPE

Decontamination Cleaning & Drying

Automated Cleaning

- The washer disinfector renders its load (i.e. washed goods, surgical instruments, etc.) safe to handle
- Disinfection and cleaning of non-critical goods prevents hospital acquired infections
- Staff safety-cleaning process takes place in a closed chamber which means no risk for splashes and thereby contamination
- Correct drying after cleaning can easily be arranged and integrated into the process

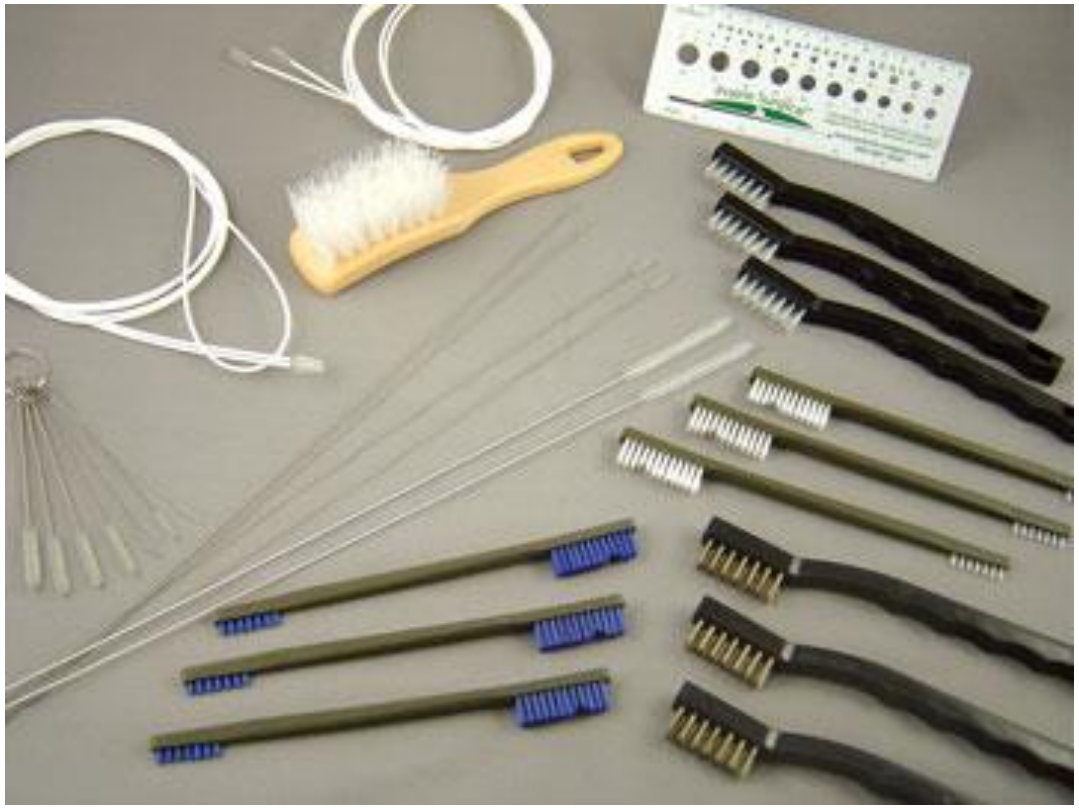
Manual Cleaning

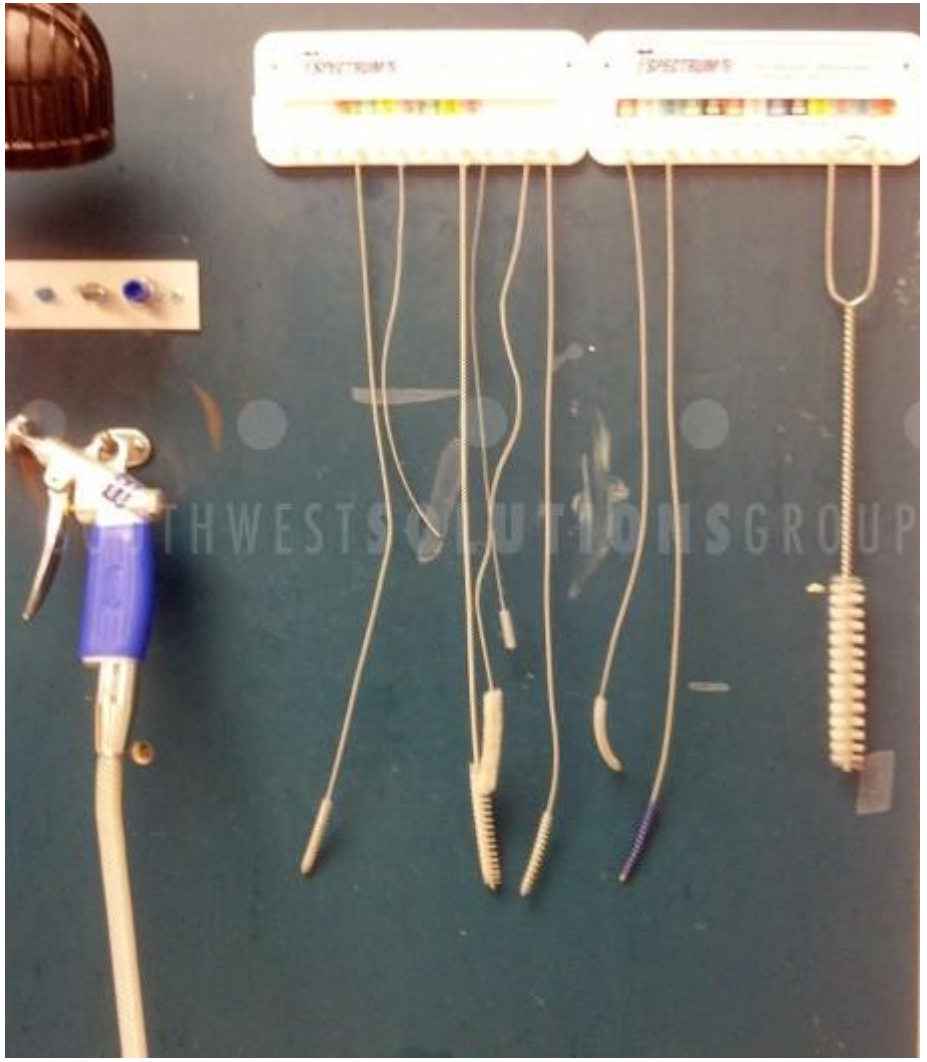
- No automated disinfection of instruments and utensils, increases the risk of contaminations and infections.
- Contamination risk for staff due to exposure to soil and liquids.
- Wet goods may cause re-contamination

Basic Design of CSSD

For basin, rigid containers

DOUBLE DOOR WASHER DISINFECTORS





Clean and disinfect at least daily

IFU for special instrument
Instrument with small channel

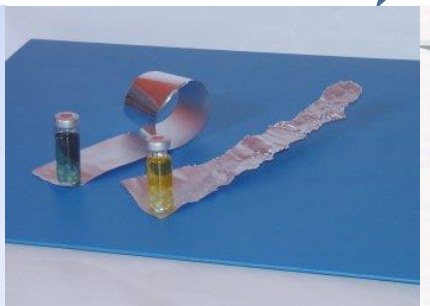
Washer Disinfectors

- Mechanically cleans instruments using a spray action called impingement
- Impingement is the water force making contact with the instrument
- Several cycle processes; final step is heated air drying
- Render instruments safe to handle
- Special test evaluate efficacy of cleaning
- Proper loading is critical (follow manufacturer's IFU)

Ultrasonic Instrument Cleaning

- Effectiveness is based on cavitation: sonic waves generate minute bubbles on instrument surface
- Bubbles then expand, become unstable, then collapse or implode
- Implosion generates very localized vacuum areas that literally dislodges/sucks off the soil
- Use proper solution, change per manufacturer's instructions
- Must clean and maintain machine per manufacturer's instructions
- Change detergent regularly and when dirty

VALIDATION TEST



Factors in Effective Cleaning

- Water quality
- Acceptable washing method
- Cleaning agent
- Proper rinsing and drying
- Layout of the processing area
- Staff training

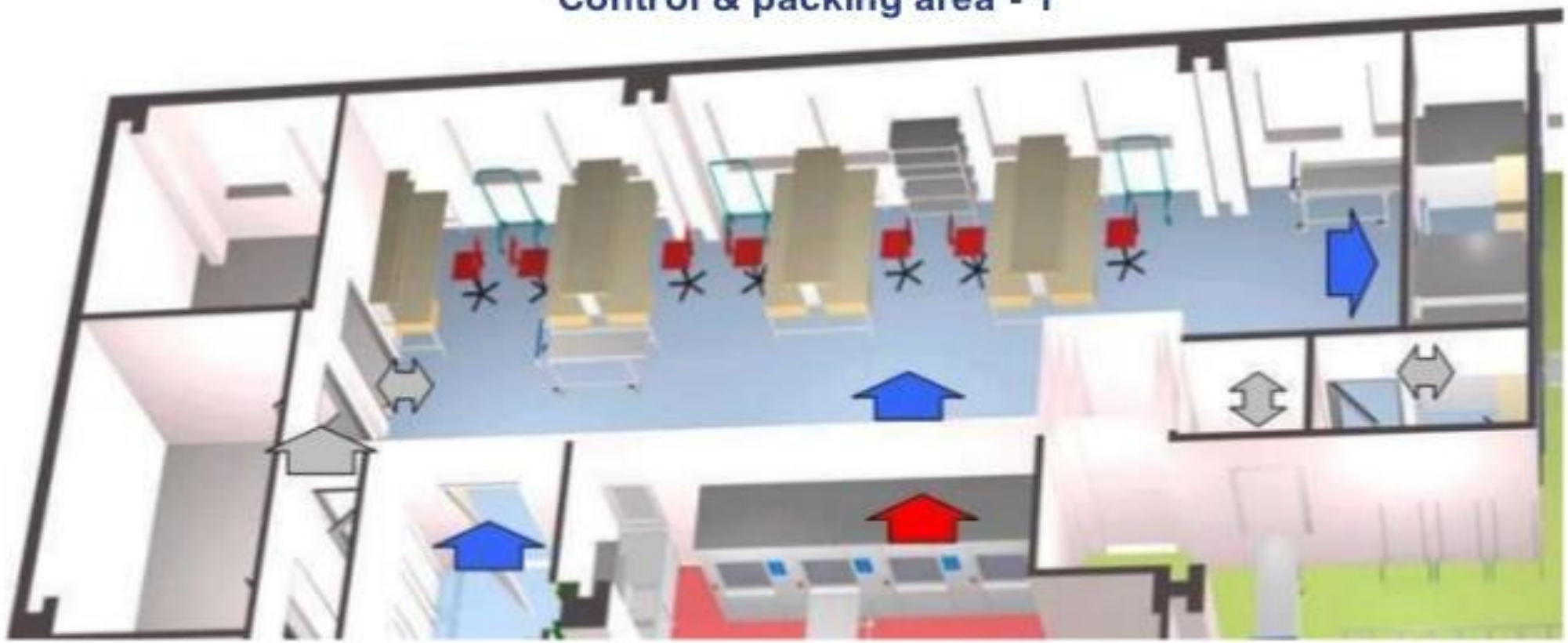
AORN Guidelines for Perioperative Practice. 2015, High-Level Disinfection, IV a.1. p 1DNIN4

Inspection
Prep and Pack

Basic Design of CSSD

TYPICAL CSSD DESIGN

Control & packing area - 1



- A minimum distance of 1500mm between packing tables and minimum 900mm, side facing against a wall, as a good recommendation.
- Packing table located sideways from window avoiding light reflexes on instruments and work surface.

Prep and Pack

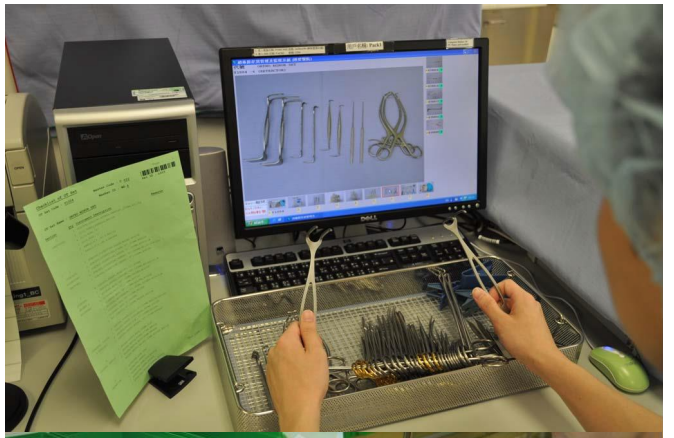
Preparation / inspection

Each instrument must be examined for :

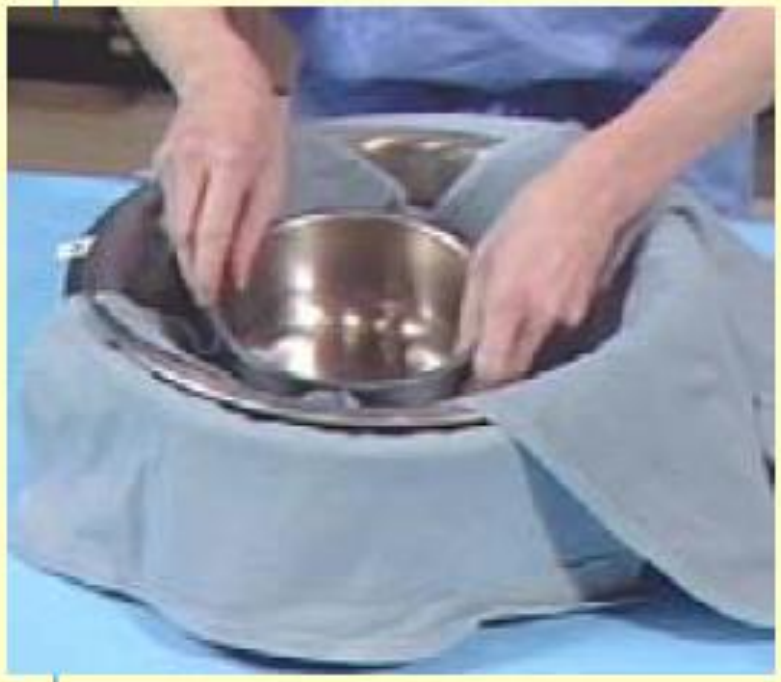
- remaining soils
- functioning properly
- is it worn and needs to be replaced

Packing

- Instrument sets and trays are assembled, wrapped and placed correctly
- Catalogue and pull instruments
- Track and trace instruments and sets
- Verify the sterilizers performed their cycles correctly



BASIN SET – Quantity and Size

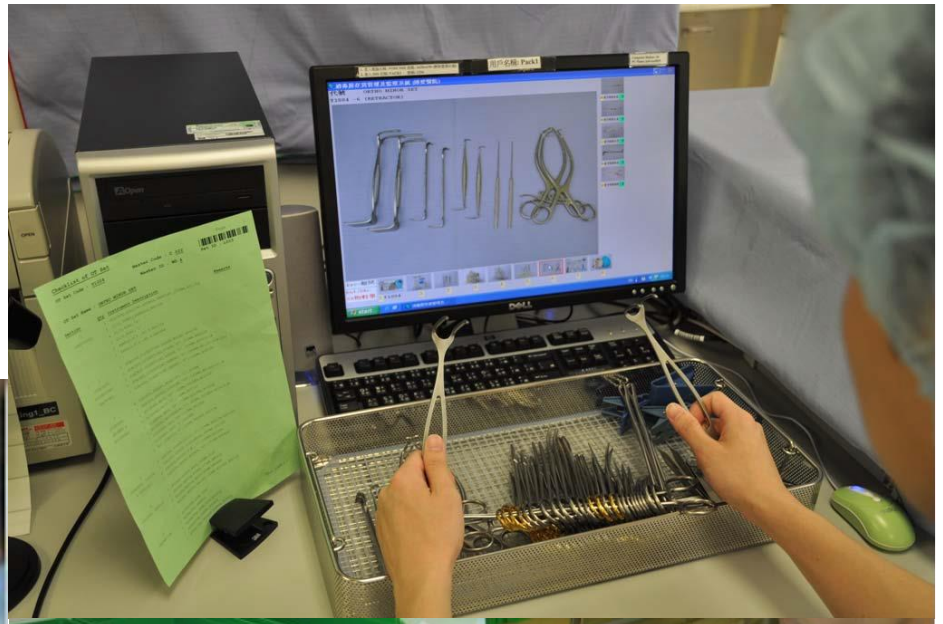


STERILIZE – Qty.1 Item

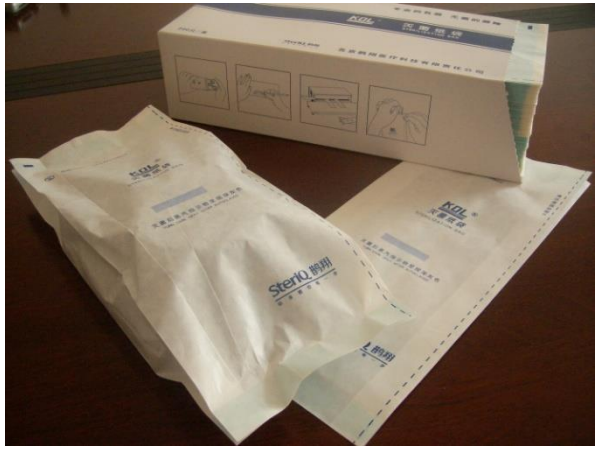
WASH – Qty. 7 Items

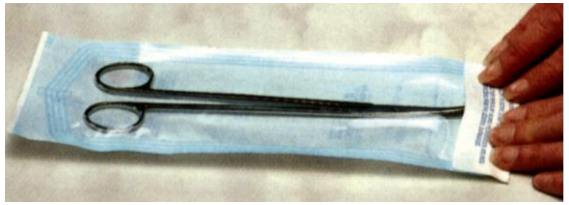
- Separate by towels – from small to large

Checking before packaging – for instrument tracking



Different Packaging



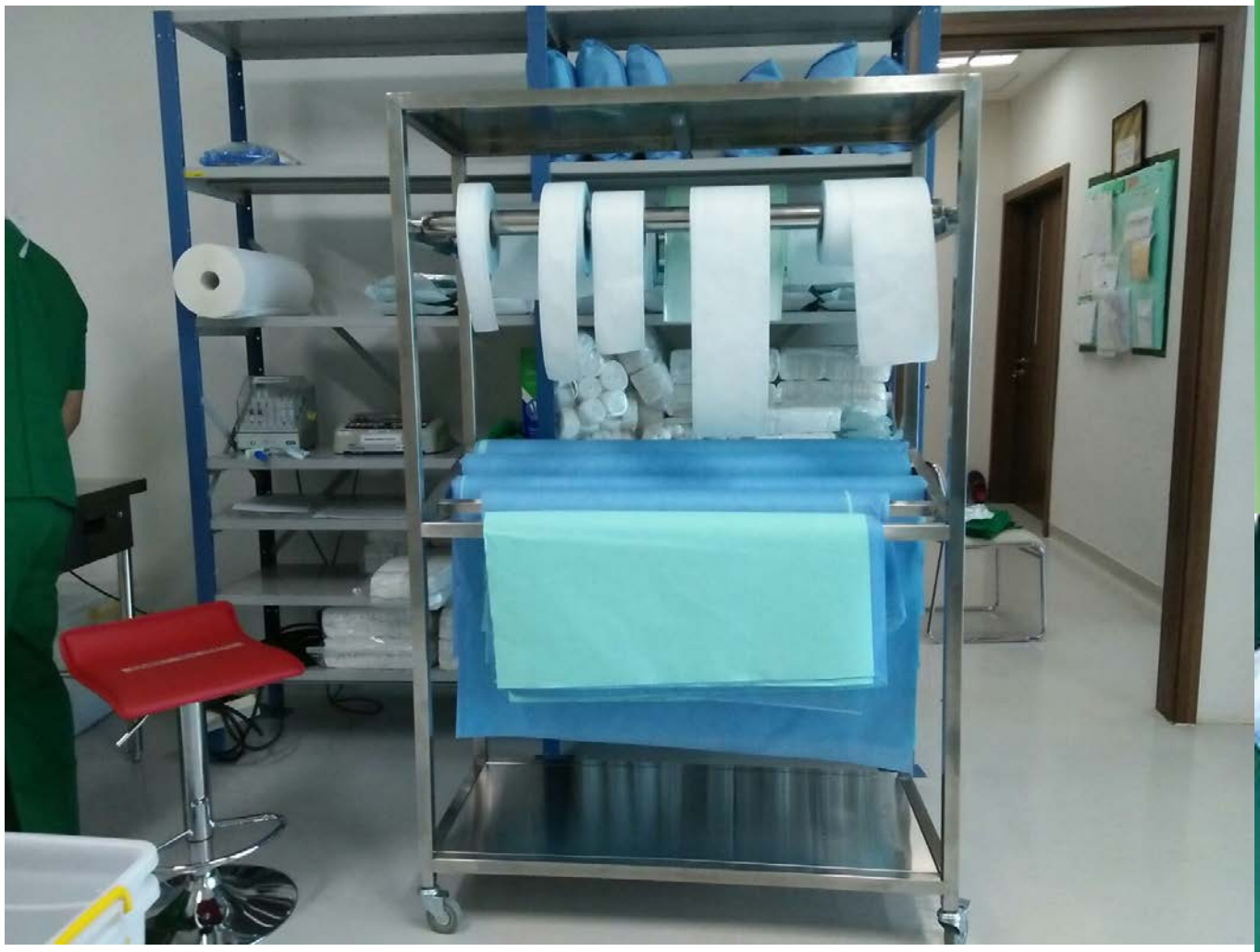


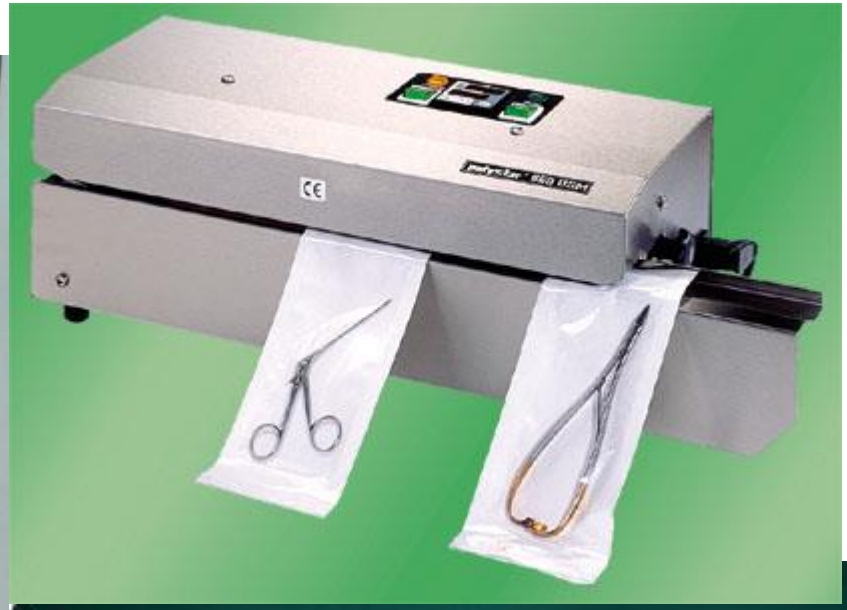
Non-woven wrappers

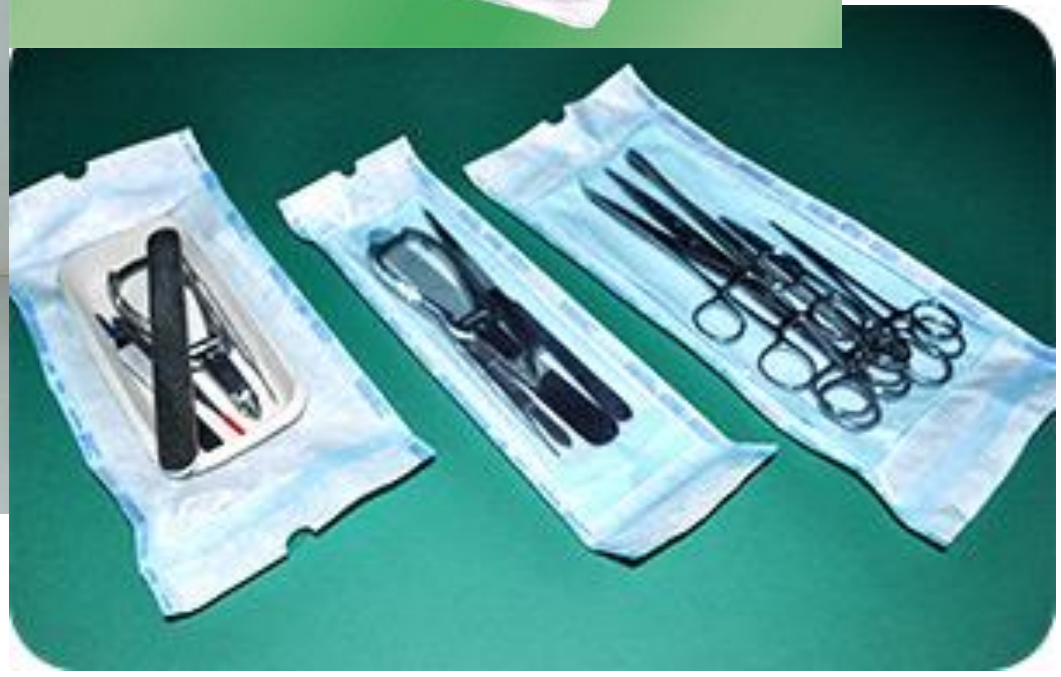
- Hang for at least 2 hrs before use
- In 21-24 degree Celsius and humidity of 30-60%

Light box for checking integrity of linen wrappers and linen gowns and drapes

Tyvek Pouch – need internal indicator

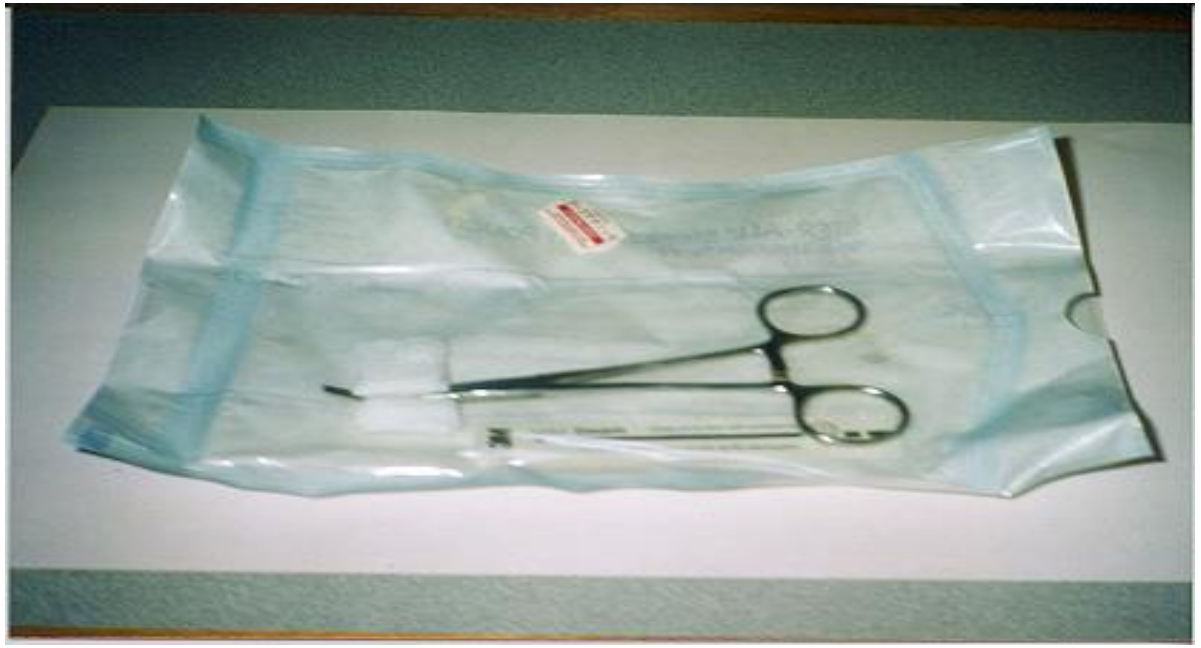






Sharp protectors

Open joints



Internal chemical indicator

Chemical Indicator placed in the tray prior to sterilization

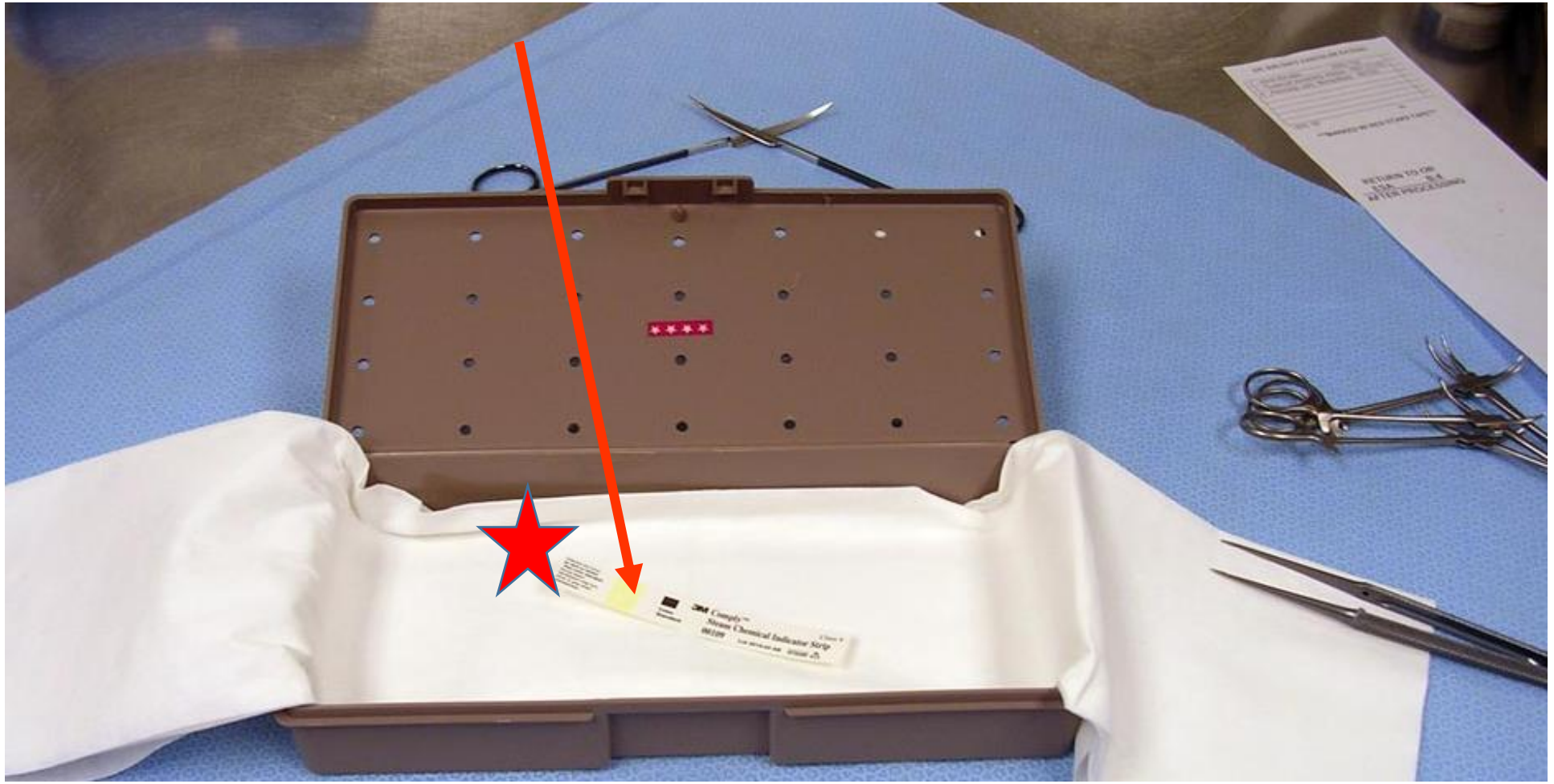


Figure 17. An example of the envelope wrapping method

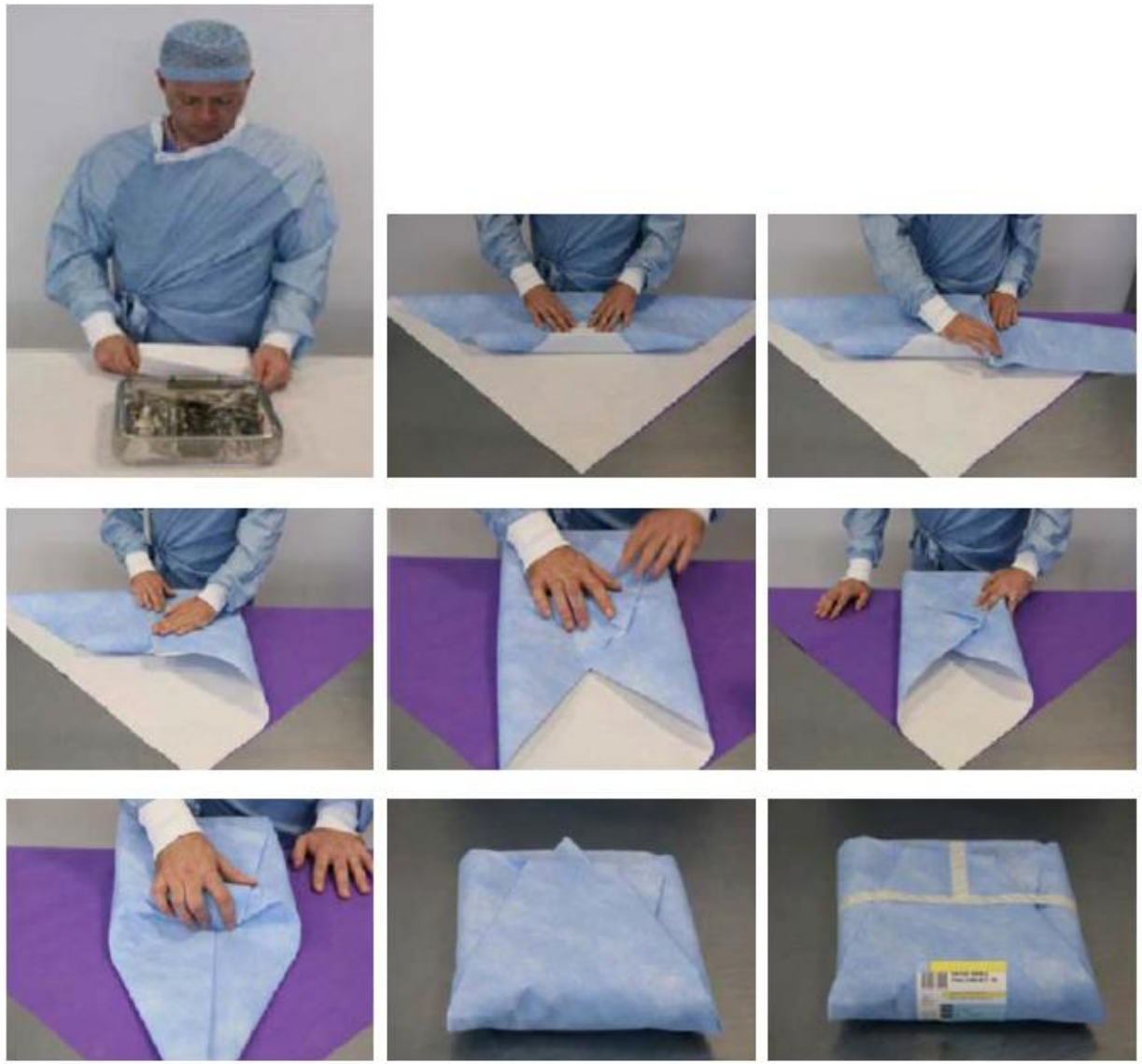
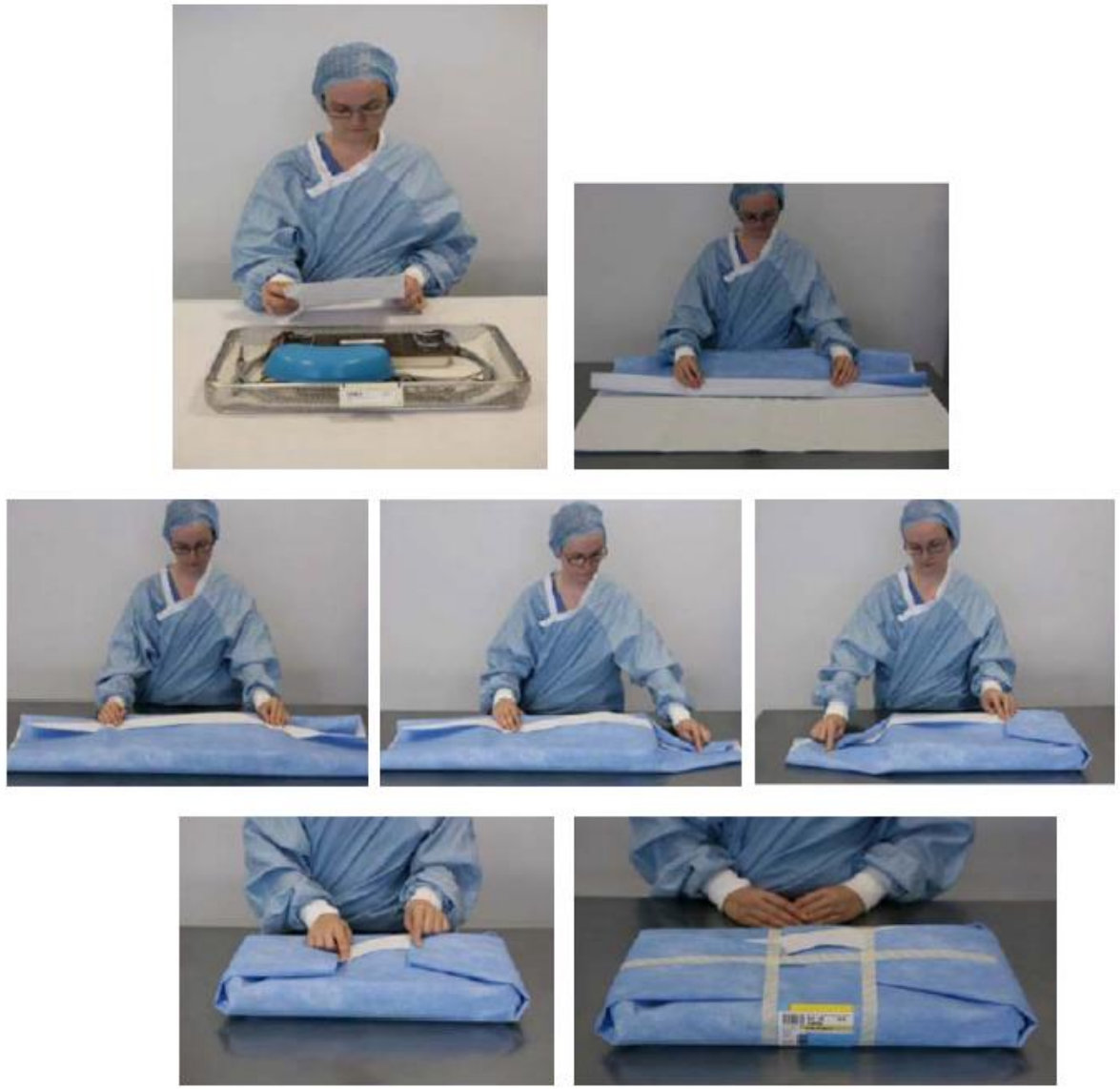


Figure 16. Example of the parcel fold wrapping method



Rigid Sterilization Containers

- Should be sized appropriately for the contained instruments (not too large, not too small)
- Lids need to be closed appropriately and should not be cracked, chipped, etc.
- Materials should be compatible with type of sterilizer chemicals in use

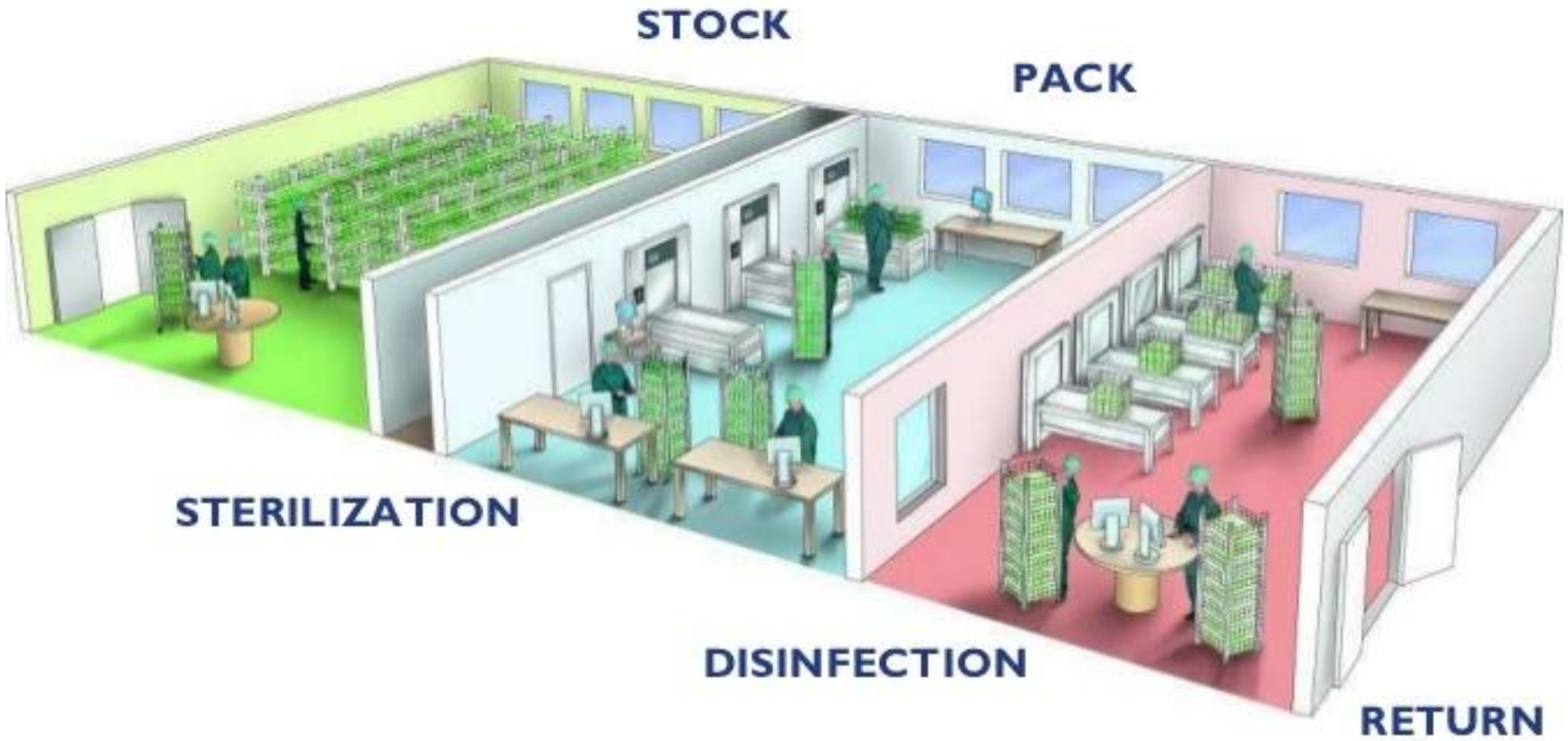
Sterilization

Sterilization is the process used to render a product free from all forms of viable micro-organisms (bacteria, spores, fungi, and viruses)

Including the space for loading, unloading, and cooling

BASIC WORKFLOW IN THE CSSD

Planning of Hospital Infection Control System



Basic Design of CSSD

TYPICAL CSSD DESIGN

Sterile store - 2

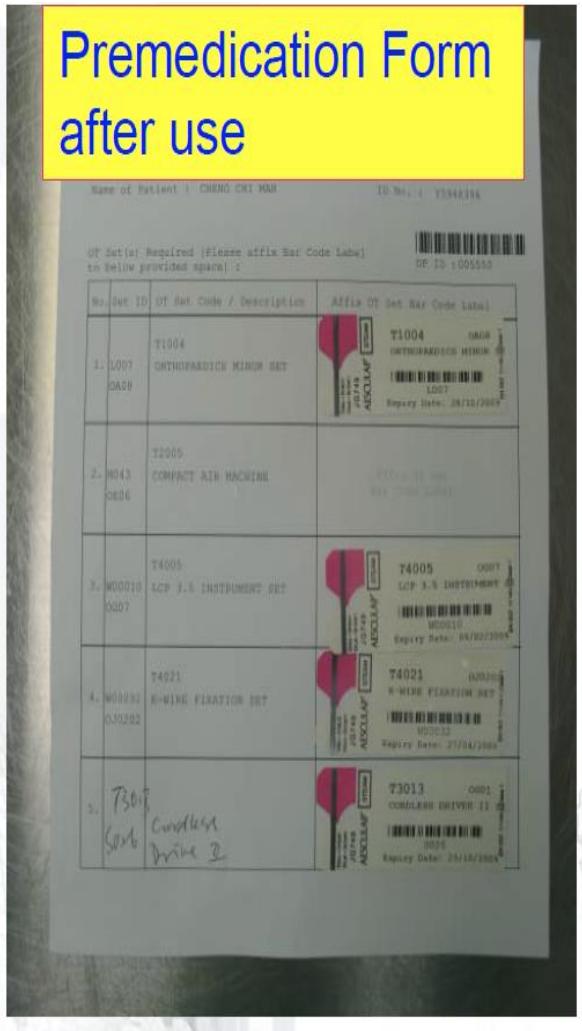
- Open storage units, allowing good ventilation of stored goods as well as a good overview of the content.
- Inspection and recording of sterilized goods to have a tracing function!
- Assembly of goods according to received orders from user.

CAD illustration

Surgical instrument tracking

1. Efficient TSSU service
2. Accurate inventory control
3. Instrument tracking using bar code system
4. Sterility guaranteed
5. Facilitate recall e.g. CJD, sterilization failure

Instrument Tracking – in decontamination area



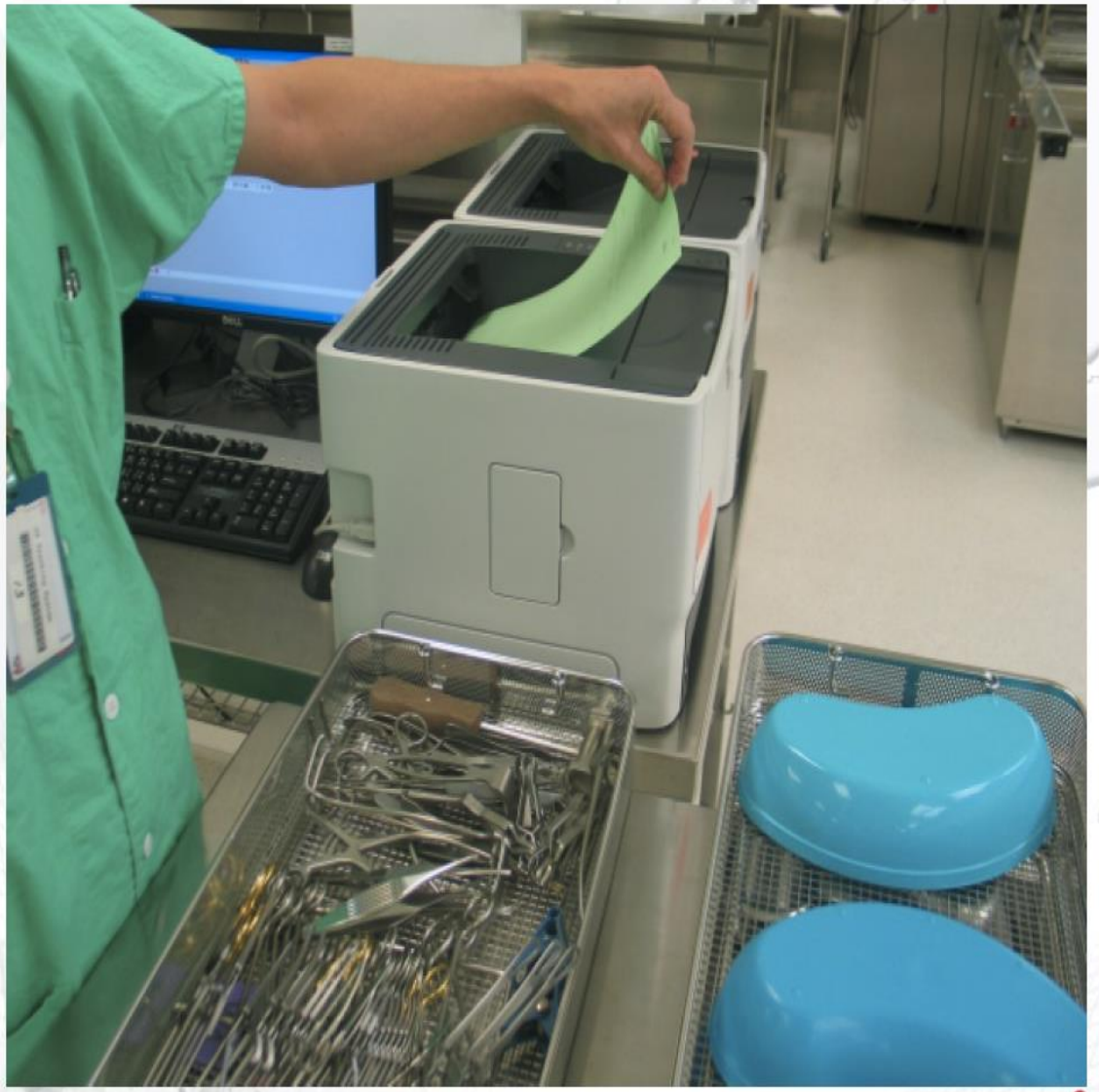
SIS barcode label was stuck
onto the Pre-medication form

Scan barcode of SIS ID
operation ID into Trackin
System

Machine wash for general
instruments

Manual wash for delicate
fine instruments

Packing & Assembly Area



Printing a checklist for Inspection & Assembly

Fairness • Innovation • Respect • Safety • Teamwork
People FIRST

Sterilization Area

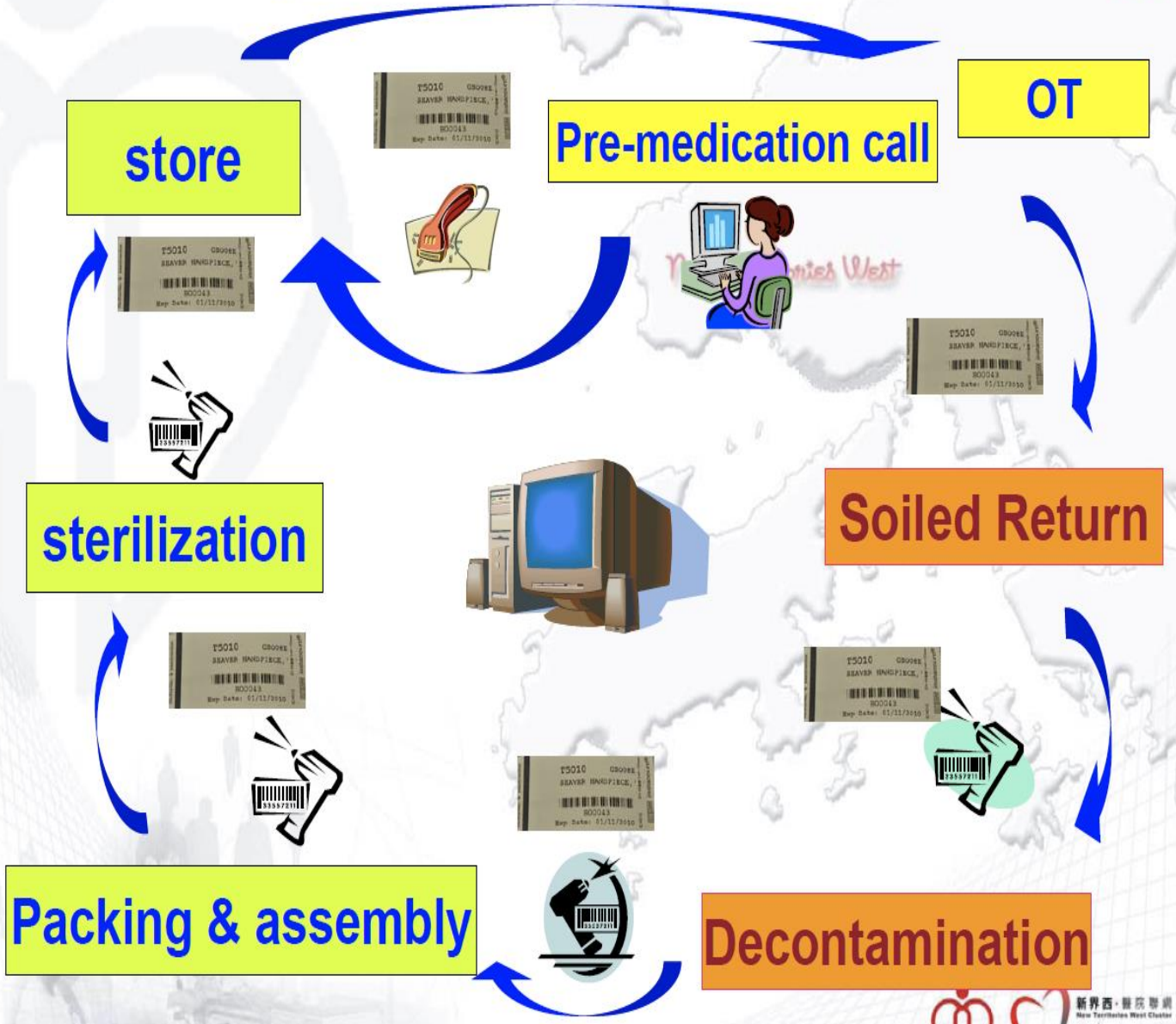
After sterilization, the barcode label is scanned

Sterile Store

OT instruments are stored in its designated locati
of rack in Sterile Store

Fairness • Innovation • Respect • Safety • Teamwork
People FIRST

Tracking SIS throughout its Workflow



Importance of the Manufacturer's Validated Instructions for Use (IFU)

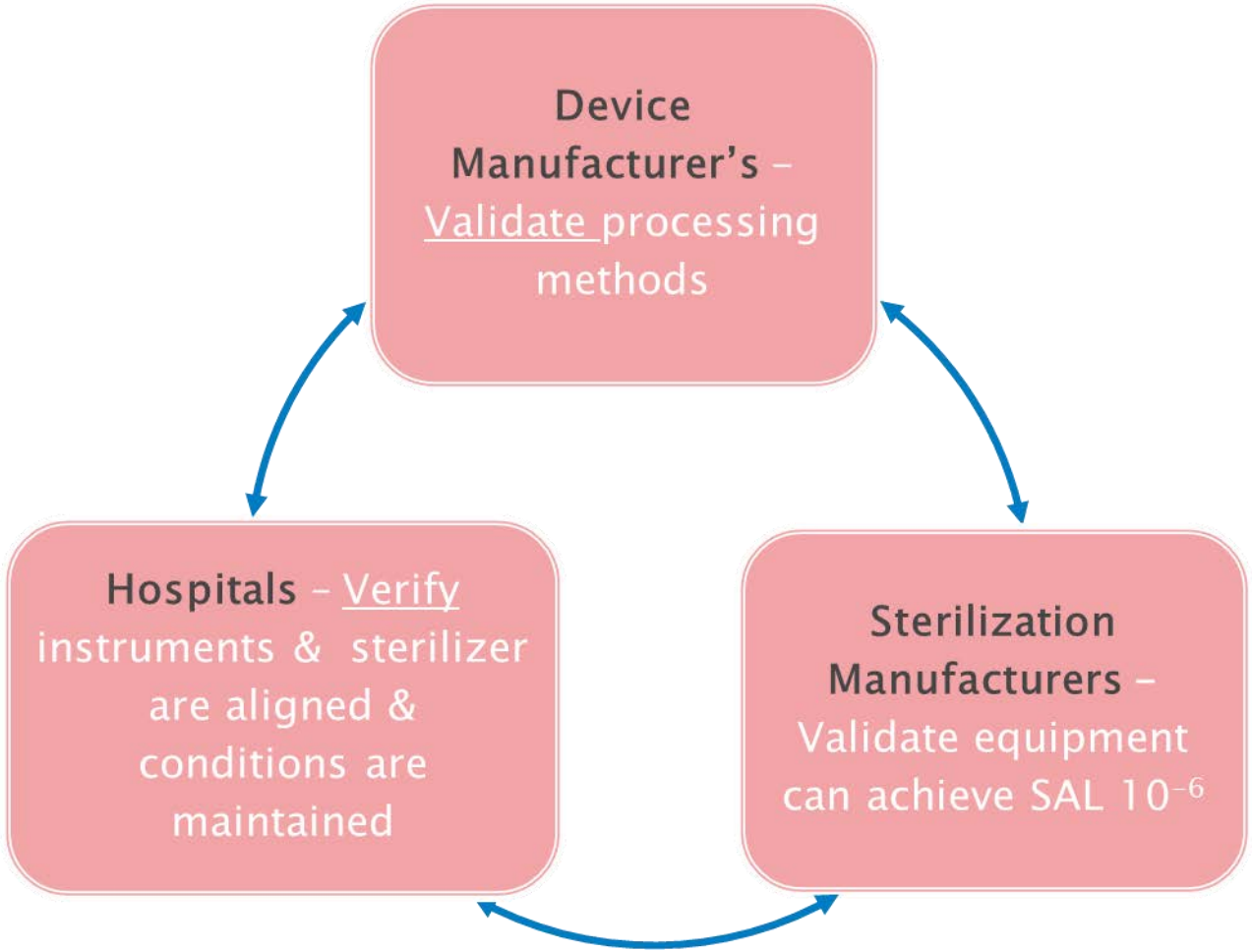
Manufacturer's instructions are essential to quality systems procedure development

The increasing complexity of medical devices and the introduction of new materials can make it more difficult to clean and sterilize medical devices or to gauge the success of these activities.

Written confirmation that the reprocessing instructions have been validated must be obtained from the device manufacturer

Validation of Medical Device Sterilization

Roles & Responsibilities



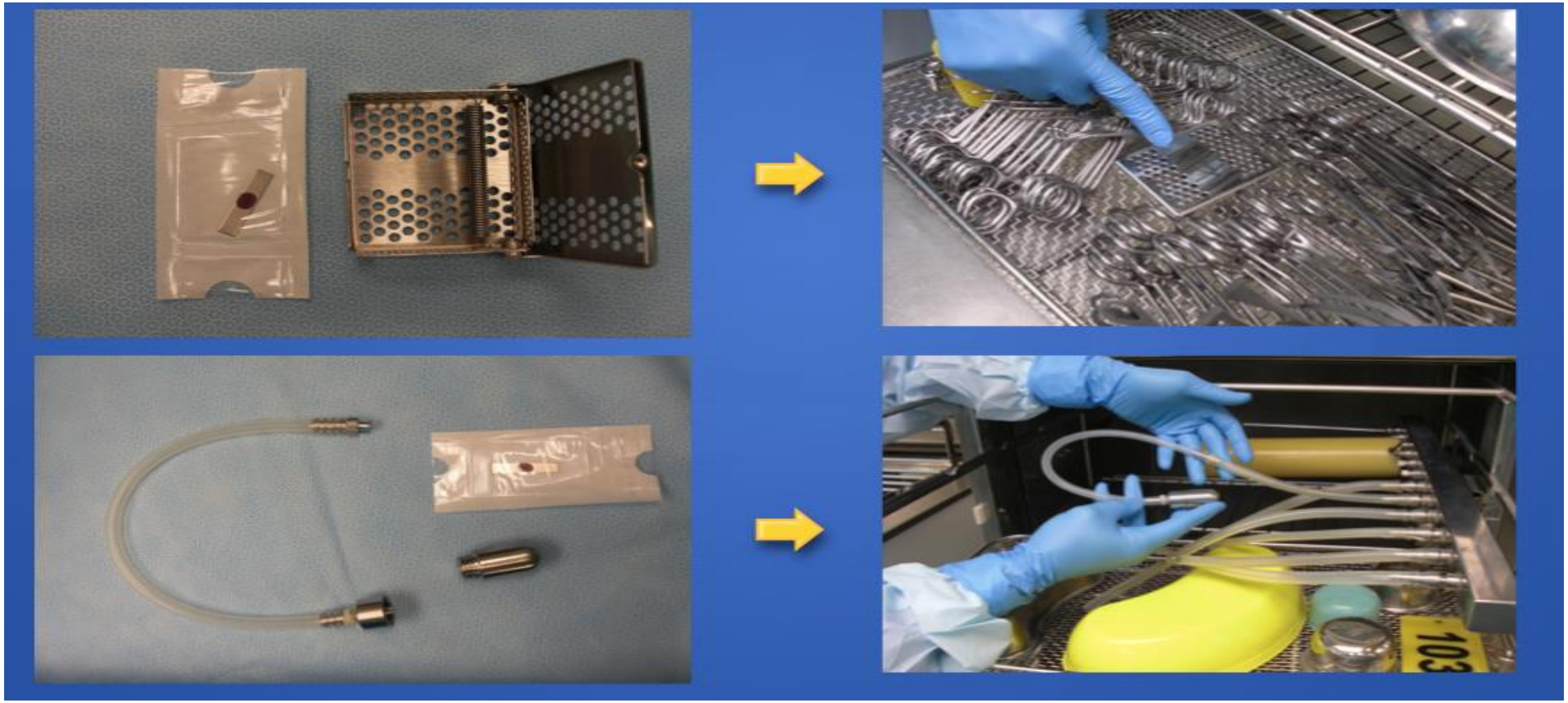
REF: EIN ISO 17664 :2009, AMMI TIR12,& EIN ISO 14937:2009, I& AHCSMM CRCST Lesson 119 • July 2011

Manufacturer's IFU (examples)

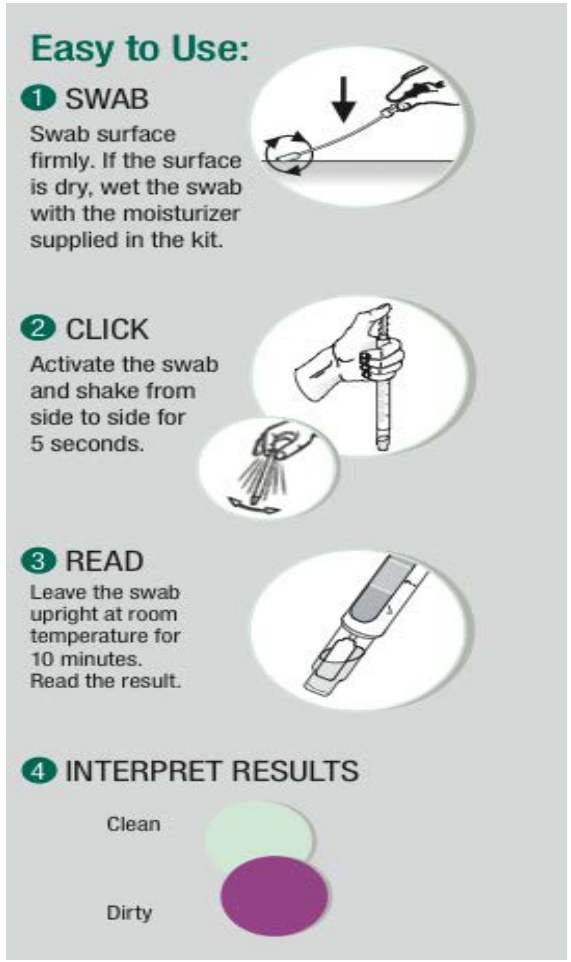
Device	Method	Parameters
Spine Sets	Gravity Prevacuum	Not recommended 270°F for 10 min. *(Does not recommend flash)*
Spine Sets	Gravity Prevacuum	Not recommended 270°F for 15 min.
Hand Instruments	Gravity Prevacuum	270°F for 20 min. 270°F for 10 min.
Power Drive	Gravity Prevacuum	Not recommended 270° - 275°F for 24 min.
Ortho Complex Sets	Gravity Prevacuum	270°F for 28 min. 270°F for 10 min.

The importance of Quality Control Procedures

Daily Cleaning Efficacy



Rapid Audit Tools: Manual Cleaning

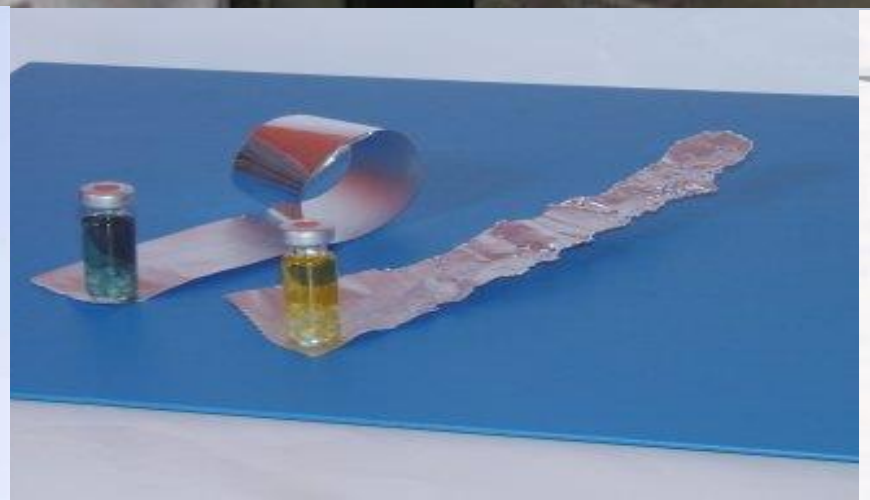


1 Add four drops of moisturiser (water and ethanol, supplied) to the swab (avoiding protein

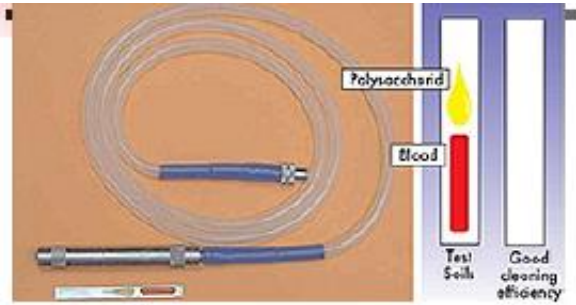
2 Insert the swab back into the tube and push down to activate the test. Shake rapidly from

3M Clean Trace

Ultrasound



Cleaning Monitors for Automated Washers



Flexi check: Endoscope lumen

TOSI Lumchek

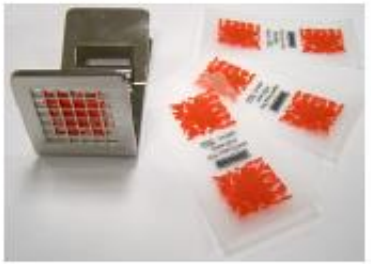
Enzymatic Detergent test

Steritec Wash-Checks

Medisafe Lumen check: Laparoscopic device lumen

TOSI

Sono check

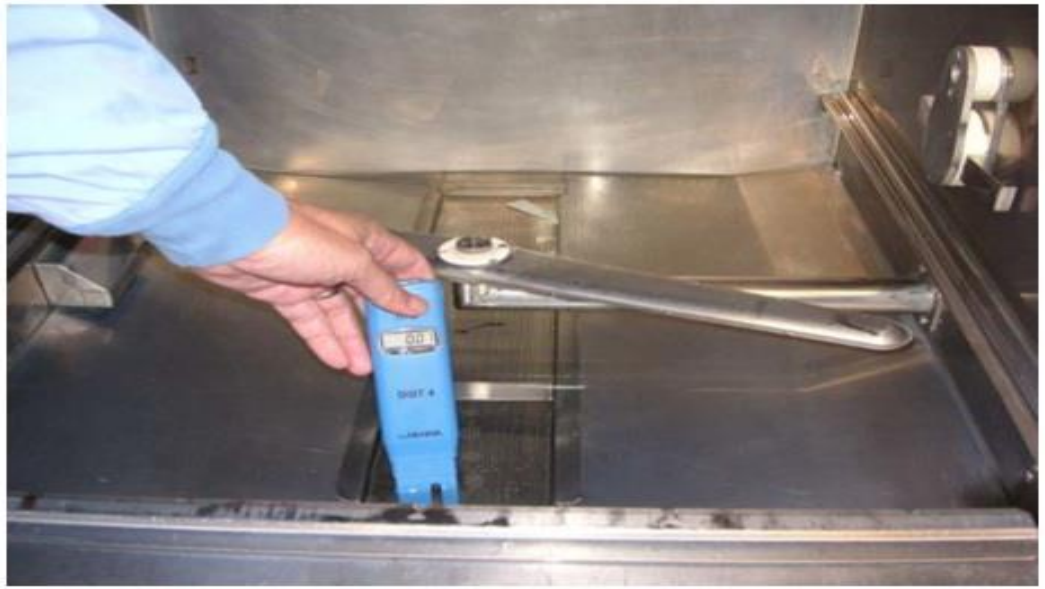


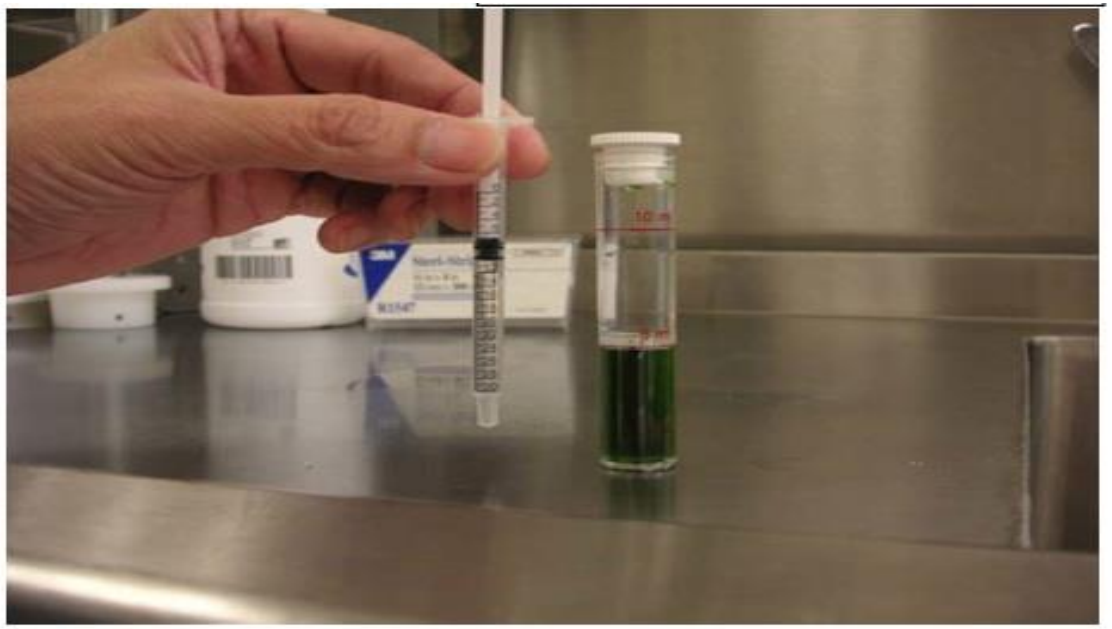
STF Load check

Water Quality

- Conductivity
- Measure the total amount of dissolved solid (TDS) in water
- Unit – milli Siemens / cm
- <0.03mS/cm

- Hardness Measure the amount of Calcium Carbonate in water
- <50mg/L



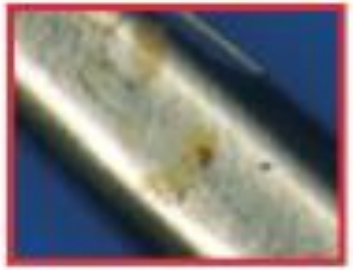


Water Quality

- Effect of hard water – corrosion
  - Chlori
  - <10m





Quality check for pouch packs

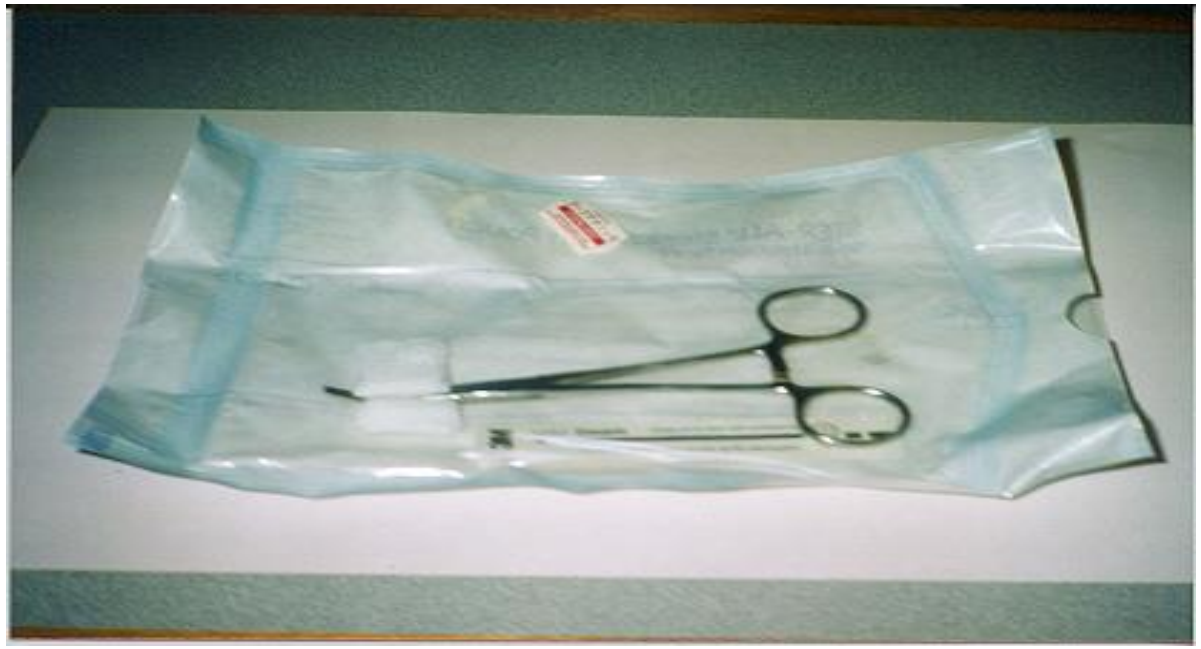


Fig. 1: Add the test dye penetrant to a sealed pouch or reel

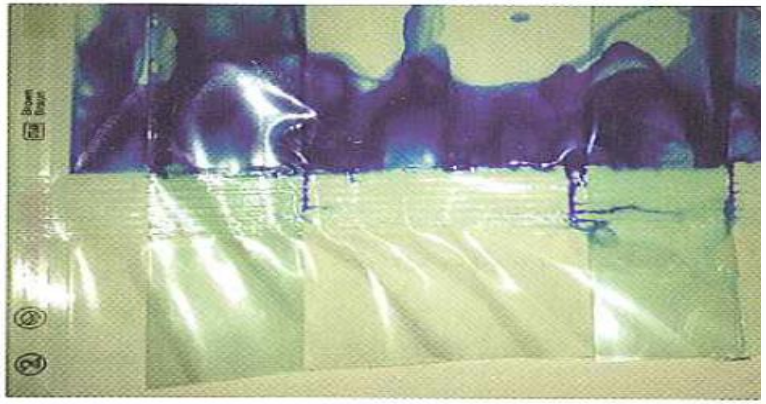


Fig. 2: Channels or defects can be localize using the dye penetrant (here: gusseted pouch, test with hawo InkTest)

Fig. 3: Perfect seal seam (here: gusseted pouch sealed using hawo sealing device, test with hawo InkTest)

Verification of Steam Autoclave

Quality Assurance

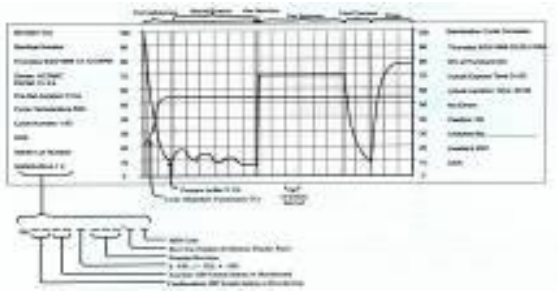
Monitoring of the sterilization cycle

Monitoring of each sterilization machine and every cycle is essential to ensure sterility of the reprocessed medical devices. The available means of monitoring are as follows:

- Physical (notebook, displays and printout)
- Chemical (internal and external indicators)
- Biological

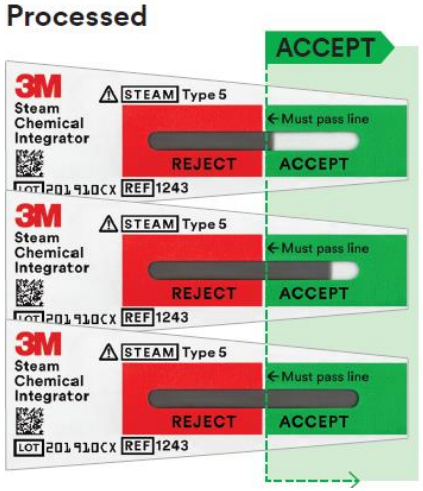
Physical Indicators

e.g. printouts:



Chemical indicators

Bowie Dick Tests
:Daily



Chemical Indicators & Tapes:
: Every Pack,
rigid container

Biological Indicators

: Daily; weekly
Implant Every Load

Steam Sterilization Monitoring

Steam Sterilizer

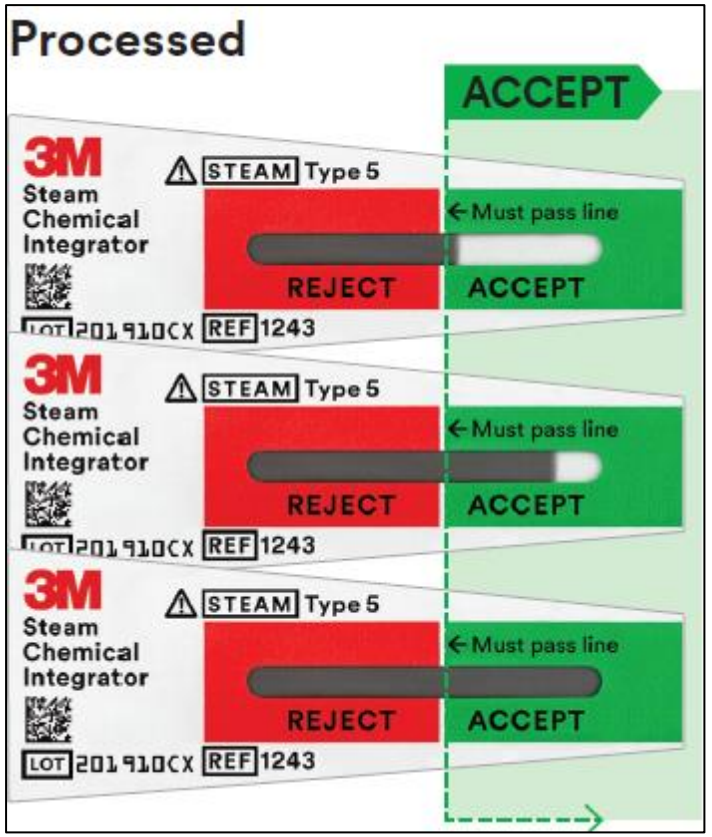
Physical Indicators – printouts

Bowie Dick Tests

Biological Indicator

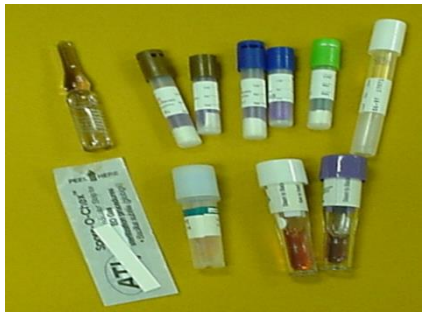
Chemical Indicators & Tapes: Every Pack

Provide visual confirmation of exposure to sterilization process



To verify that the sterilant has reached the center of the tray as recommended by the Association for the Advancement of Medical Instrumentation (AAMI)

Biological Monitoring



- Steam *Geobacillus stearothermophilus*
- Dry heat *B.atrophaeus* (formerly *B.subtilis*)
- EO *B.atrophaeus*
- New low temperature sterilisation technologies
    - Plasma sterilisation (Sterrad) *B.atrophaeus*
    - Peracetic acid - *Geobacillus stearothermophilus*

Storage of Clean/Sterile Supplies

- Store at least
  - 8-10” from the floor
  - 5” from ceiling but 18” from sprinkler head
  - 2” from outside walls
- Use solid bottom shelf
- Use closed cabinets
- Avoid overfilled drawers
- NO RUBBER BANDS!

AORN Guidelines for Perioperative Practice, 2015, pp I. STRI. 16-17

Sterile Storage

- Sterilized items should be properly stored to prevent contamination
- Need segregated area
  - Temperature<24^0 C Humidity should not exceed 70%
  - 4 air exchanges/hour -positive pressure
- Monitor and document daily

AORN Guidelines for Perioperative Practice, 2015, pp I. STRI. 16-17

Basic standards in reprocessing of surgical instruments

1. Facility design
2. Handling, collection and transport of contaminated instruments
3. Cleaning and decontamination processes
4. Instrumentation inspection, preparation and packaging
5. Sterilization and monitoring
6. Sterile storage and distribution

References

- CDC Guidelines for Sterilization & Disinfection in Healthcare Settings, 2008
- AORN Guidelines for Perioperative Practice, 2015.
  - www.aorn.org
- CDC HICPAC Guidelines of Healthcare Facilities
  - www. Cdc.gov/hicpac/pubs.html
- The APSIC Guidelines for Disinfection and Sterilisation of Instruments in Health Care Facilities

  http://apsic-apac.org/wp-content/uploads/2017/01/APSIC-Sterilization-guidelines-2017.pdf


Thank
You
micks