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Performance Test for Sealing Capability of Rigid Container

Case Study: CSSDs of Tuen Mun Hospital & Pok Oi Hospital, Hong Kong

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HKSSMA - "Outstanding Social Caring Organization Award 2023 & 2024"

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A. Background

- Hospital Authority (HA) a statutory body established in 1990.
- HA manages all 43 public hospitals.
- HA is fully funded by Hong Kong Government
- HA divided Hong Kong hospital services into 7 clusters illustrated in different colors in the map
- I am the ex-Cluster Operation Manager of the New Territories West Cluster and managed 3 CSSDs of Tuen Mun Hospital (TMH), Pok Oi Hospitals (POH) and Tin Shui Wai Hospital (TSWH)

A. Background

Hong Kong Sterile Services Practice before 2012

- No governance in disinfection and sterilization services, no guidelines
- Satellite reprocessing centers in clinical areas by respective specialty nurses
- Chemical disinfectants are widely used for disinfection
- CSSDs– managed by Sterile Supply nurses
- Fibric linen widely use as wrapper and drapes

Traditional CSSD

A. Background

Hong Kong Sterile Services Practice before 2012

- Theatre Sterile Supply Services – managed by Operating Theatre nurses – inadequate knowledge in sterilization sciences
- Immediate-use sterilization without air removal pulsing process is widely used as routine sterilization in operating theatre
- Single door washer disinfector – cross contamination risk
- No Surgical Tracking and Tracing System - Creutzfeldt–Jakob Disease (CJD) – infection control risk
- Rely on biological indicator and chemical indicator to assure sterility

A. Background

醫 院 認 證 計 劃
Hospital Accreditation

Hospital Accreditation Exercise – Assure patient Safety

- Hospital Authority conducted pilot hospital accreditation exercises for 5 public hospitals in 2010 - 2012 by the Australian Council on Healthcare Standards
- Audit team identified significant deficits in sterilization services across 5 pilot hospitals which needed to rectify:-
  1. No governance structure
  2. No Tracking and Tracing system for surgical instrument sets
  3. No demarcation of dirty and clean in decontamination area&other area
  4. Routine flash sterilization method should be eliminated

The Australian Council on Healthcare Standards

Pioneering the Reformation of CSSD through a Pilot Project

Modernize CSSD of Tuen Mun Hospital to merge old CSSD with Theatre Sterile Supplies Unit (TSSU) functions together into one department

Old CSSD

TSSU

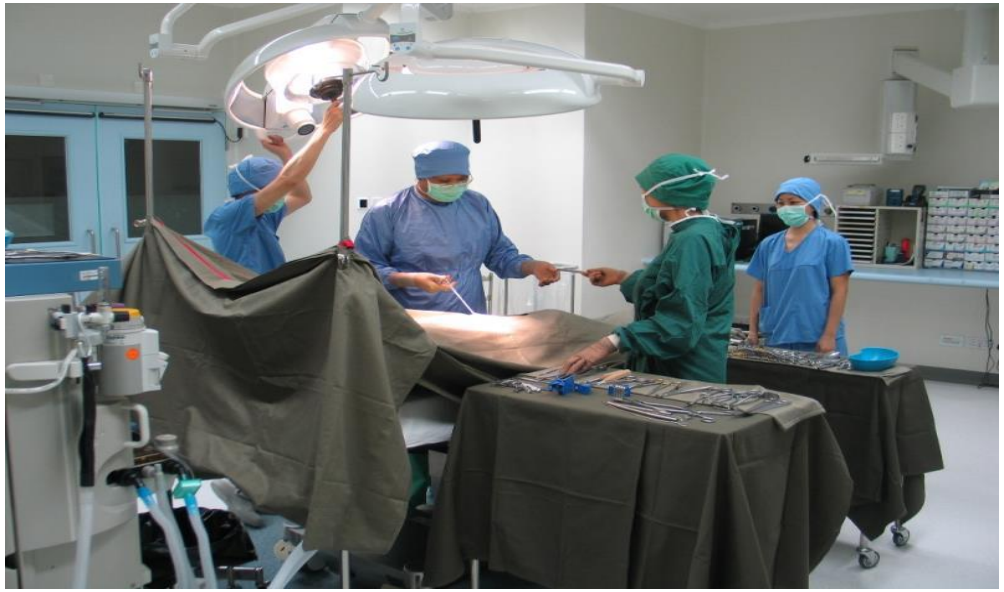
Pioneering the Reformation of CSSD through a Pilot Project

- Renovate CSSD to upgrade the infrastructure from Mar 2011 to Jun 2012 (1.5 year)
- Insufficient surgical instrument inventory for turnover
- Insufficient manpower for reprocessing surgical instrument
- Insufficient space for instrument reprocessing and sterile storage
- Insufficient washer disinfectors and steam sterilizers

Pioneering the Reformation of CSSD through a Pilot Project

Work load shedding strategy to free old CSSD for renovation (1.5 years)

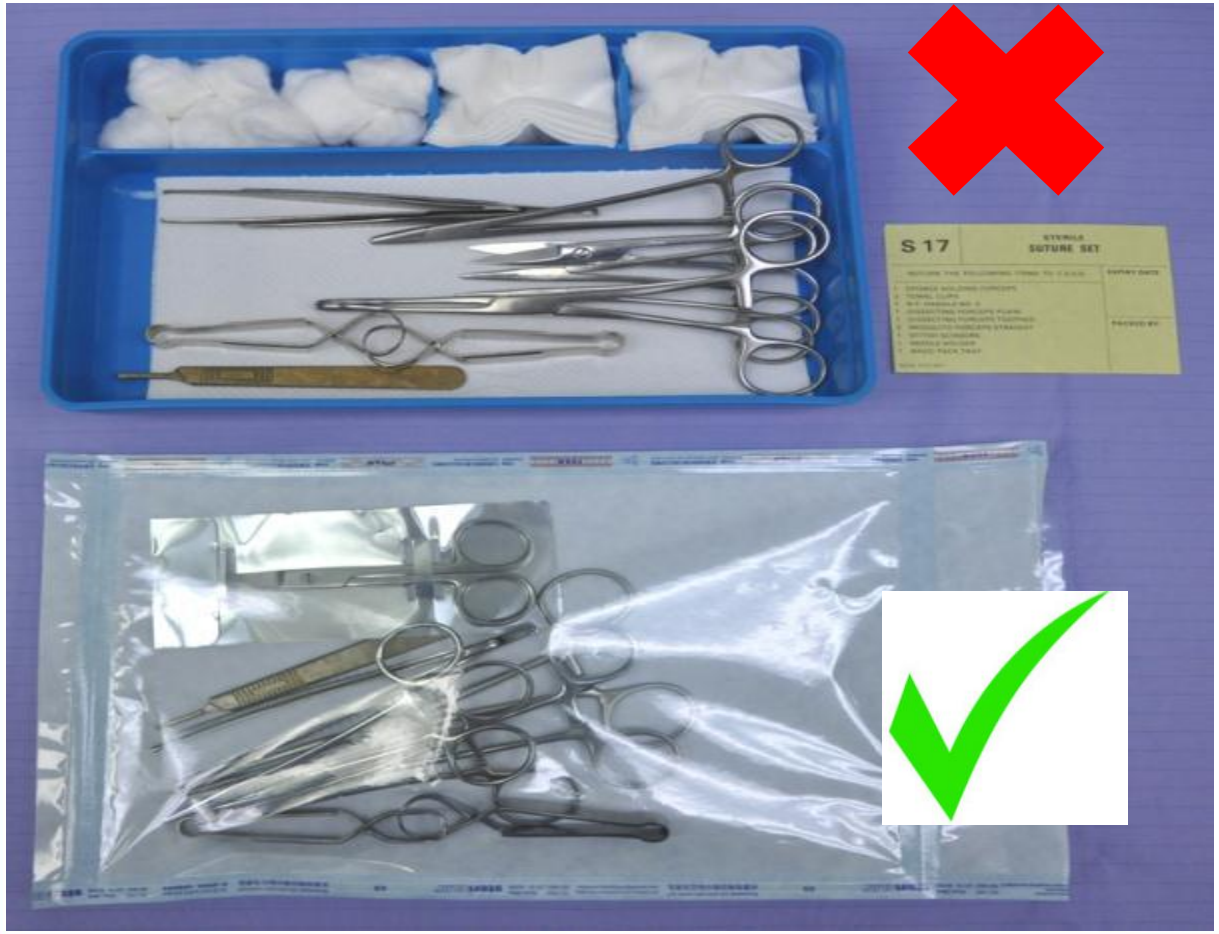
- Phasing out all reusable linen drapes and gown by disposable ones
- Purchase sterile disposable dressing set for simple sterile procedure
- Only provide sterile instrument for clinical sterile procedures

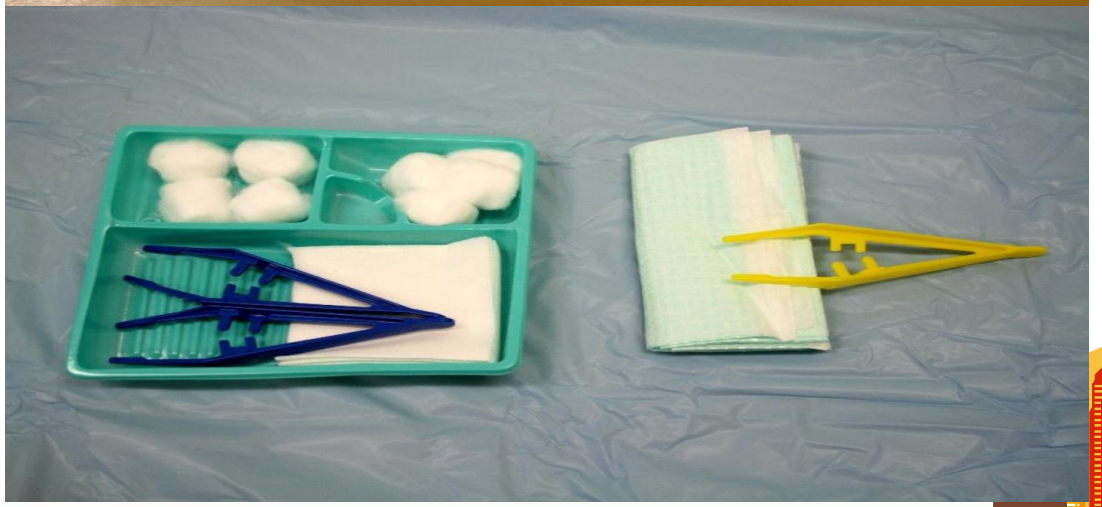


Pioneering the Reformation of CSSD through a Pilot Project

Changes of sterile procedure set in clinical areas

- To convert the ward procedure set by supplying stainless steel instrument peel-able pouches
- Use disposable ward dressing set and the peelable pouches instead.





Pioneering the Reformation of CSSD through a Pilot Project

- Credential
- Training & Development
- Personal hygiene

- Environment design (Health Building note 13 UK)
- Environmental control
- Clean room standard (ISO 14644 class 8)

- Washer disinfector ISO 15883
- Sterilizer EN285, ISO 17665
- Equipment validation: IQ, OQ, PQ
- Routine monitoring & maintenance

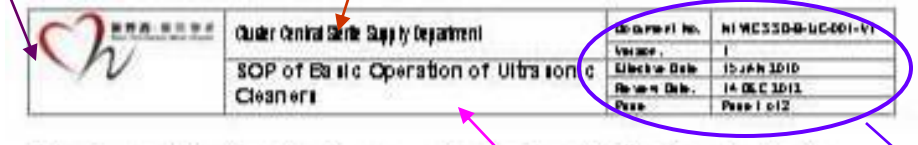
- SOP/guideline
- Workflow
- Traceable
- documentations

- Product realization
- Production process control
- Risk management
- Measure, Analysis and Improvement

Document Control – ISO 13485

NTW Logo

Department



Outer Central Sterile Supply Department

SOP of Basic Operation of Ultrasonic Cleaners

Document No. NTWCSSD-B-UC-001-V1
Version 1
Effective Date 15 JAN 2016
Review Date 14 OCT 2013
Page Page 1 of 12

Aim : To operate the ultrasonic cleaner properly and perform effective ultrasonic cleaning

Frequency: Daily

Person responsible: Workman who is responsible to the ultrasonic cleaner

Procedure:

- Visible soil should be removed before ultrasonic cleaning.
- Make sure proper degassing is performed and the solution reached its working temperature (37 °C in CSSD TMH) at the beginning of each day.
- Follow the manufacturer's recommendations for the safe operating procedure of the ultrasonic cleaner and follow the points outlined below regarding loading and unloading the cleaner.
- Ensure that joints or hinges are opened fully and instruments that need taking apart are fully disassembled before they are immersed in the solution.
- Place instruments in a suspended basket and fully immerse in the cleaning solution, ensuring that all surfaces are in contact with the solution. The solution should be made up in accordance with the manufacturers' instructions.
- Do not overload the basket or overlap instruments, because this results in poor cleaning and can cause wear to the instruments.
- Do not place instruments on the base of the ultrasonic cleaner, because this results in poor cleaning and excessive instrument movement, which can damage the instruments and the ultrasonic cleaner.
- To avoid damage to delicate instruments, a modified basket or tray system might also be necessary depending on operational requirements.
- Ensure the timer to the correct setting as per the ultrasonic cleaner manufacturer's instructions (10 minutes in CSSD TMH). Close the lid and do not open until the cycle is complete.
- Change the solution when it becomes heavily contaminated or at least once a day, because the build-up of debris will reduce the effectiveness of cleaning.
- After ultrasonic cleaning, rinse and inspect instruments for cleanliness, and where possible check for any wear or damage before sterilization

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Topic

Author & Date

Endorsement & Date

Pioneering the Reformation of CSSD through a Pilot Project

Major Improvement in Sterilization Services

1. Centralization of sterile service to reduce satellite reprocessing centers so as to standardize the sterile services
2. Phase out use of chemical disinfectants in clinical area. Thermal disinfection services are provided by CSSD
3. Implementation of Quality Management System in Accordance with ISO 13485 for Medical Devices
4. Elimination of flash sterilization
5. Installation of water treatment plant in CSSD. Reverse Osmosis (RO) water is maintained at high temperature over 75°C to prevent cultivation of gram- negative micro-organism within RO water. The RO water is used for generation for clean steam for steam sterilization

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Pioneering the Reformation of CSSD through a Pilot Project

Major Improvement in Sterile Services

6. Development of corporate-wide Surgical Instrument Tracking System implemented in all government hospitals with surgical operations
7. Development of Governance Structure
   - Establishment of Cluster Disinfection and Sterilization Committee to govern the sterilization practice
   - Phasing out reuse of single use medical devices in Hong Kong
   - Development of Guidelines on Disinfection and Sterilization of Reusable Medical Devices for Operating Theatre – adopt the sterilization best practice

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Pioneering the Reformation of CSSD through a Pilot Project

Guidelines on Disinfection and Sterilization of Reusable Medical Devices for Operating Theatre

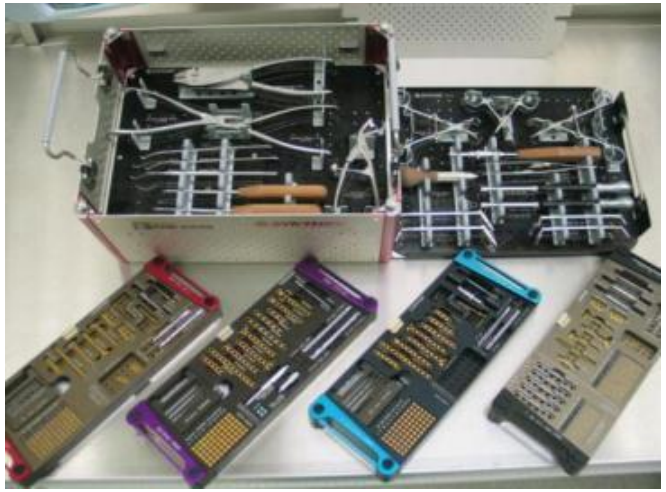
Golden rules in CSSD workflow

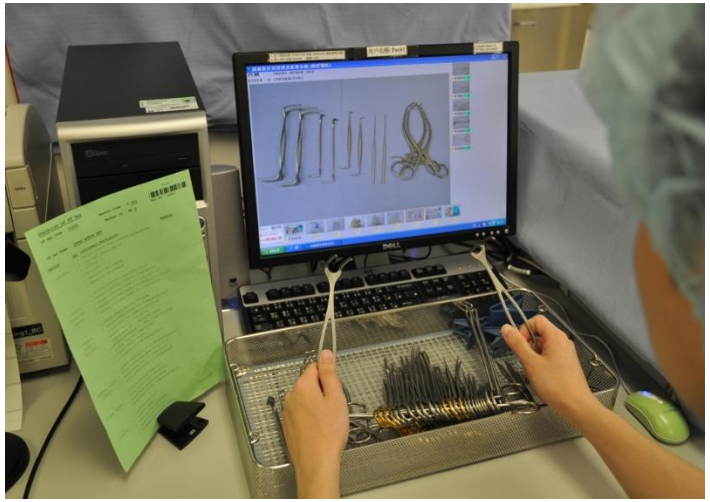
1. **Unidirectional flow of reprocessing Separation of sterilized packs against non-sterilized packs**
2. **Double door for washer disinfectors and all sterilizers**
3. **Demarcation of dirty and clean area**
4. **Control the air flow from clean to dirty area**
5. **Separation of dirty and clean trolleys for transportation**

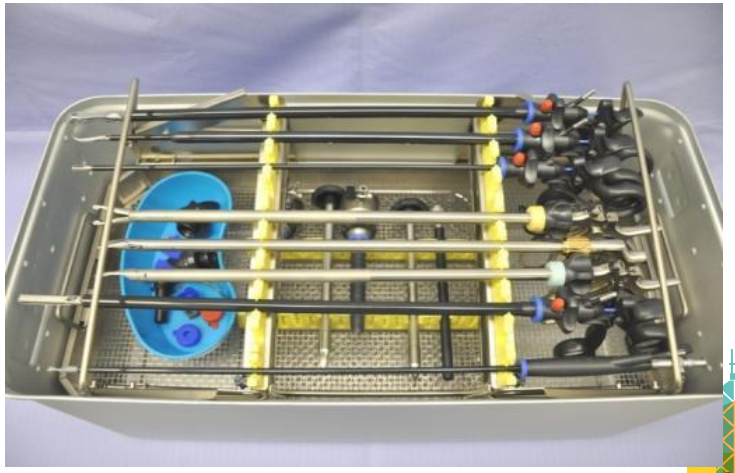
Pioneering the Reformation of CSSD through a Pilot Project

- Soiled surgical instrument washed and packed by operating theatre staff
- Dual Cart transportation system(one dirty one clean)
- CSSD Pok Oi Hospital only sterilize the packed container

A. Background







A. Background

- Purchase large amount of surgical instrument together with sterile containers are purchased to increase the inventory for turnover
- The packed instrument containers are conveyed to CSSD, Pok Oi Hospital for sterilization.
- Sterilized sterile containers were conveyed back to Tuen Mun Hospital for storage and usage
- The study was conducted in the New Territories West Cluster (NTWC), covering:
  - ✓ Tuen Mun Hospital
  - ✓ Pok Oi Hospital
- CSSDs in both hospitals have used rigid containers since 2007 for POH and 2011 TMH

B. Study Overview

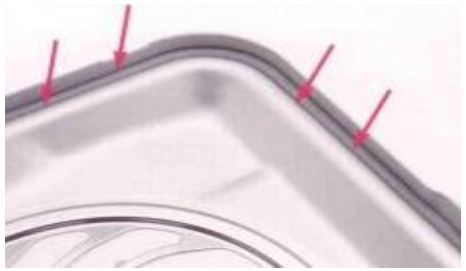
Purpose and Clinical Importance

- Surgical Site Infections (SSIs) are a leading cause of hospital-associated infections, increasing patient morbidity, mortality, and healthcare costs.
- Ensuring sterility of surgical instruments at the point of use is essential to prevent SSIs.
- This study evaluates the sealing capability of rigid sterilization containers used in the CSSDs of Tuen Mun and Pok Oi Hospitals in Hong Kong.
- The goal is to assess whether these containers maintain an effective sterile barrier system (SBS) after steam sterilization.

B. Study Overview

Function of Rigid Sterilization Container

- These containers have been in use for over 30 years, evolving in design and materials.
- Rigid containers are used to maintain sterility of surgical instruments post-sterilization.
- They serve as sterile barrier systems (SBS), protecting contents from microbial contamination and physical damage.
- Key design elements include:
  - ✓Filter system / SBS for sterilant entry/exit
  - ✓Gasket seal to block airborne contaminants
  - ✓Lid compression to ensure airtight closure



B. Study Overview

Risks to Seal Integrity

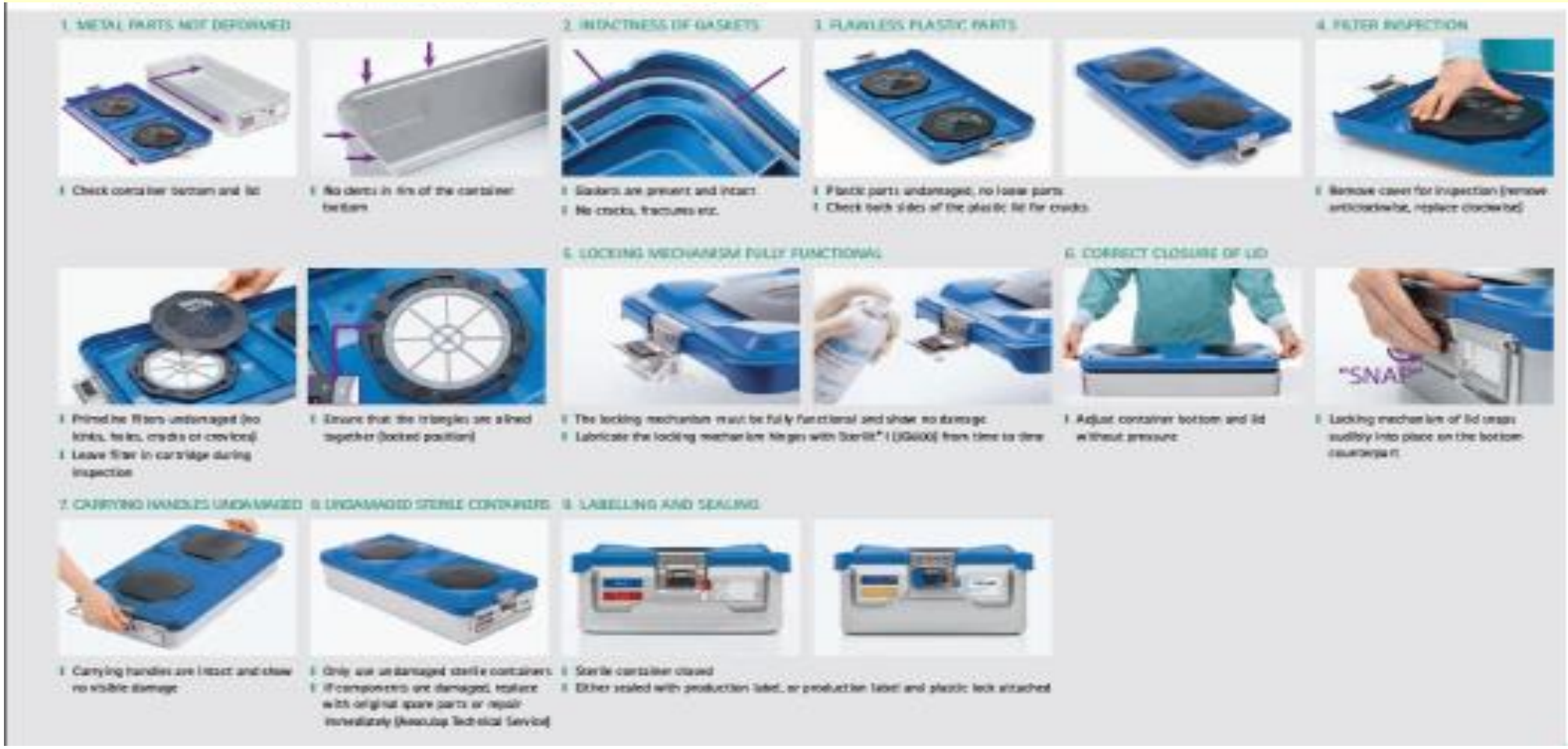
- Despite manufacturer claims of long service life, several factors compromise seal integrity:
  - ✓Gasket deterioration and loss of elasticity
  - ✓Mismatched lids and bases due to wear
  - ✓Repeated reprocessing cycles causing physical degradation

- These issues can lead to seal failure, increasing the risk of contamination and compromising patient safety.
- Air without filter can enter into the container through the leakage point

B. Study Overview

STERILE CONTAINER FUNCTIONAL TEST

Check irregularity through NAKE EYE



B. Study Overview

Limitations of Visual Inspection

- Visual inspection is commonly used to assess container integrity but has significant limitations.
- Microscopic defects such as gasket cracks, flange distortions, and holes as small as 80µm may go undetected. [13]
- Studies show that containers can pass visual checks yet fail functional performance tests.
- Reliance on manual inspection alone may result in false assurance of sterility.

[13] Dunkelberg H, Glende F: Measurement of the microbial barrier effectiveness of sterilization containers in terms of the log reduction value for prevention of nosocomial infections. AJIC: American Journal of Infection Control 2006; 34(5), 285-289.

B. Study Overview

Testing Techniques for Seal Assessment

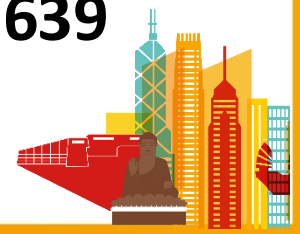
- To overcome limitations of visual inspection, three validation methods were introduced:

1. Water leakage test: Assesses seal under gravitational and lateral pressure
2. Paper test: Detects friction gaps between lid and base
3. Smoke test: Simulates airborne transmission to identify leaks

B. Study Overview

Study Design and Standards

- ISO 11607 Part 1, Clause 4.4.2 mandates validation testing of packaging systems.
- Five requirements include:
  - ✓Defined rationale for test selection
  - ✓Acceptance criteria
  - ✓Repeatability and reproducibility
  - ✓Sensitivity for integrity assessment
- Study timeline:
- Phase 1 (Mar–Aug 2018): Smoke, paper, and water leakage tests on 1,187 containers (65%)
- Phase 2 (Sep 2018–Feb 2019): Smoke test applied to remaining 35% of 639 containers



B. Study Overview

Reprocessing and Storage Protocols

- Sterilization containers undergo a reprocessing cycle similar to surgical instruments:
  - ✓Washer-disinfector cleaning with neutral pH detergent
  - ✓Thermal disinfection (A0 ≥ 600)
  - ✓Drying
  - ✓Inspection, Assembly, Packaging (IAP)
  - ✓Steam sterilization at 134˚C for 3.5 minutes
- Post-sterilization storage conditions:
- Temperature: 18–22˚C
- Relative humidity: 30–70%
- Controlled sterile environment per Hong Kong guidelines

B. Study Overview

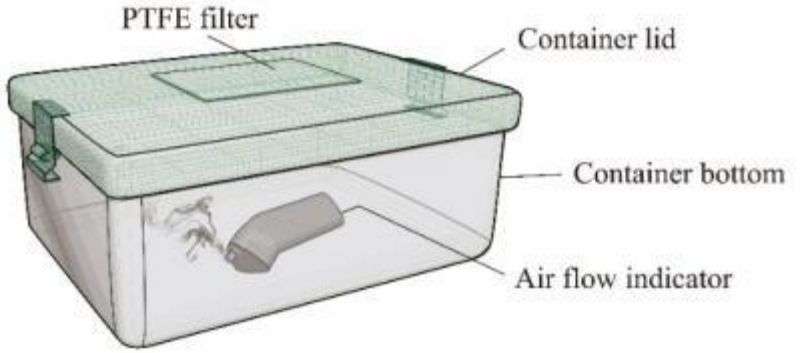
Design, Identification, and Sample Overview

- Sterilization containers are the primary sterile barrier system in TMH and POH CSSDs.
- Each container includes:
  - ✓ Solid aluminum base
  - ✓ Polymer-plastic lid with locking latches
  - ✓ One or two filter retention plates
  - ✓ Reusable PTFE filters as microbial barriers
- Unique identification codes assigned to lids and bases for traceability and reassembly.
- Total containers tested: 1,826
  - ✓ 1,187 in-use containers (first phase)
  - ✓ 30 brand-new controls
- Environmental conditions:
- Temp: 18–22˚C
- RH: 30–70%
- ISO Class 8 particulate level (BS EN ISO 14644-1)

Smoke Test Protocol & Testing Equipment

- **Purpose: Detect seal failure due to pressure differentials.**
- **Tool: Dräger Flow Check smoke gun (Model 6400761)**
- **Smoke produced from ampoule with alcohol-based fluid; matches ambient air density.**
- **Procedure:**
  - ✓ Smoke emitted inside container
  - ✓ Lid latched and observed for 60 seconds
  - ✓ Leaks visible as smoke escapes through gasket
- **Standard holding times:**
  - ✓ Small: 10 sec
  - ✓ Medium: 16 sec
  - ✓ Large: 21 sec
  - ✓ Extra-large: 39 sec
- **Containers passing**

  no smoke leakage during observation



B. Study Overview

Testing Team

- 10 trained CSSD staff conducted all tests.
- Pre-study training and re-demonstration ensured protocol adherence.

Equipment used:

- Dräger Flow Check smoke gun
- Ampoules with alcohol-based smoke fluid
- Timer for observation periods
- MadgeTech PR140 pressure sensor to measure vertical pressure variation between 2nd and 13th floors of Tuen Mun Hospital

B. Study Overview

Water Leakage Test Protocol - Pressure-Based Seal Evaluation

- Based on Association française de normalization (AFNOR) test protocol FDS 98-053.
- Procedure:
  - ✓5 mm water poured into container
  - ✓Lid latched and container placed on absorbent paper for 30 seconds
  - ✓Observed for leakage from gasket
- Water volumes:
  - ✓Small: 300 mL
  - ✓Medium: 500 mL
  - ✓Large: 650 mL
  - ✓Extra-large: 650 mL
- Test repeated on all four sides of each container

B. Study Overview

Paper Test Protocol - Friction-Based Seal Evaluation

- Based on dollar bill method using 80 gsm A4 paper.
- Paper placed halfway across container base; lid latched.
- Container lifted by protruding paper.
- Any slippage or movement = test failure.
- Test repeated along entire seal length for comprehensive assessment.

C. Result and Discussion

Sealing Capability Test from Apr 2018 to Aug 2018

	In use Sterile Container			Control Test
CSSD	Tuen Mun Hospital	Pok Oi Hospital	Both CSSD	Tuen Mun Hosp.
Usage Period	Within 7 years	Over 11 years		New
Container No.	671 out of 1088 (61.67%)	516 out of 738 (69.92%)	1187 out of 1826 (65%)	30
Paper Test				
Pass	631 (94.04%)	327 (63.37%)	958 (80.71%)	30 (100%)
Fail	40 (5.96%)	189 (36.63%)	229 (19.29%)	0 (0%)
Water Leak Test				
Pass	353 (52.61%)	208 (40.31%)	561 (47.26%)	22 (73.33%)
Fail	318 (47.39%)	308 (59.69%)	626 (52.74%)	8 (26.67%)
Smoke Test				
Pass	658 (98.06%)	479 (92.8%)	1,137 (95.79%)	30 (100%)
Fail	13 (1.94%)	39 (7.2%)	50 (4.12%)	

C. Result and Discussion

Sealing Capability Test from Apr 2018 to Feb 2019

	In use Sterile Container			Control Test
CSSD	Tuen Mun Hospital	Pok Oi Hospital	Both CSSD	Tuen Mun Hosp.
Usage Period	Within 7 years	Over 11 years		
Container No.	1088 out of 1088 (100%)	738 out of 738 (100%)	1826 out of 1826 (100%)	30
Smoke Test				
Pass	1063 (97.7%)	691 (93.63%)	1754 (96.06%)	30 (100%)
Fail	25 (2.3%)	47 (6.37%)	72 (3.94%)	

- Management change
- Less frequent use
- Test in weekend

C. Result and Discussion

Aging, Sensitivity, and Method Reliability

- Containers used more than 11 years showed significantly higher failure rates.
- Smoke test for frequently used container had the lowest failure rate (4.21%) but was not necessarily least sensitive.
- Water leakage test showed highest failure rate (52.78%), possibly over estimating due to gravitational pressure.
- Paper test failure rate averaged 19.29%, affected by blind spots and container weight.
- Results highlight the need for routine, hands-on testing protocols.

C. Result and Discussion

Limitations of Visual Inspection

Why Manual Checks Are Insufficient

- All tested containers had passed visual inspection prior to testing.
- Some containers failed all three validation methods despite passing visual checks.
- Tiny gasket cracks and flange distortions were difficult to detect manually.
- Human error and tool limitations contributed to missed defects.
- Reinforces need for objective, standardized testing beyond visual inspection.

Environmental Factors & Pressure Gradient

Impact of Vertical Transport on Seal Integrity

- Pressure difference >5 mbar between 2nd and 13th floors at Tuen Mun Hospital.
- Lower floors had higher pressure; upper floors lower.
- Pressure gradient may drive contaminants into containers during transport.
- Non-woven wrappers less effective under dynamic conditions.
- Highlights risk of contamination during vertical movement in hospitals.

C. Result and Discussion

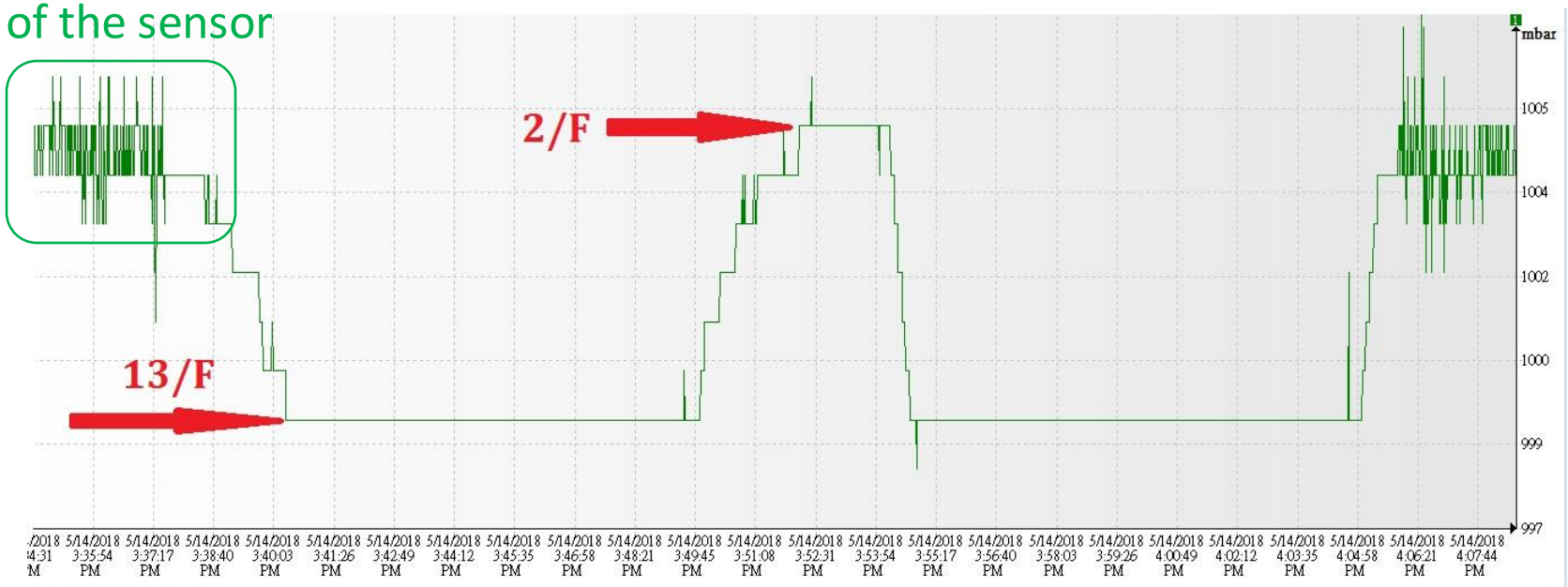
Smoke Test - Airflow Simulation and Clinical Relevance

- Artificial smoke test simulates airborne transmission.
- If smoke cannot escape, microorganisms likely cannot enter.
- Highly visible and user-friendly method.
- **Not affected by weight or pressure** like other tests.
- Most reliable for detecting airflow-related seal failures.
- Unsuitable for this study as the containers with flow inhibition systems (e.g., microStop®).

C. Result and Discussion

Driven by the pressure difference between different floors, there is a risk that airborne microorganisms and contaminates enter through the crack and pinholes of the sterilized containers when transporting the sterilized surgical instruments from higher to lower floors.

The fluctuation was related to the transportation of the sensor



D. Conclusion and Recommendation

Improving CSSD Safety and Container Validation

- Visual inspection alone is insufficient for assessing sealing capability.
- Smoke test is recommended as a routine performance qualification tool.
- Failed containers were repaired and replaced the gasket by new one.
- Re-tested — no smoke leakage observed.
- Pressure gradients during vertical transport pose contamination risks.
- Non-woven wrappers are less effective under dynamic conditions.
- Hospitals should adopt standardized validation protocols and monitor environmental factors.

D. Conclusion and Recommendation

Mandatory Gasket Replacement

- Study revealed progressive wear and tear in gasket seals over time.
- Containers used >11 years showed significantly higher failure rates.
- Seal degradation compromises sterile barrier integrity.
- Based on data, all container gaskets should be replaced every 5 years.
- Gasket replacement must be a mandatory maintenance protocol in CSSD operations.
- "Prevention is better than cure" – Change them better than test them
- Ultimately, contamination risk – reduced. Patient safety - Assurance

E. Key Takeaways

- Process validation assurance sterility
- 5 important criteria for study
  - ✓Defined rationale for test selection
  - ✓Acceptance criteria
  - ✓Repeatability
  - ✓Reproducibility
  - ✓Sensitivity for integrity assessment
- Don’t focus on the requirement of testing the sealing capability of container
- Consumable materials have its life span. regular change of gasket is far more important than testing

E. Key Takeaways

- Sterile barrier system is completely different from bacterial retentive filter
- Sterile barrier system requiring stringent storage conditions and management
- Transportation of sterile goods poses potential contamination risks if the transportation condition varies a lot such as variance in pressure gradient; different relative humidity and temperature
- Using air tight container system with permanent filter may be the best option to minimize the risk.

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