
3M
Science.
Applied to Life.™
Patients Vary.
Our Standards Don't.
Healthcare Associated Infections (HAI's) are the most common complication affecting patients in Hospitals.[1]
Patient safety and best practice start in the CSSD.

There are five essential steps in sterile processing:

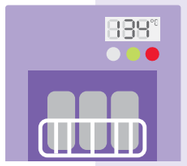
1) Clean, 2) Prep & Pack, 3) Sterilise, 4) Store, and 5) Use.
The threat of SSIs caused by non-sterile devices makes following every step in the sterilisation process absolutely critical.

Clean & Decontaminate

- Use cleaning agents that are capable of removing visible organic and inorganic residues. *AS/NZS 4187:2014*
- Clean medical devices as soon as practical after use as soiled materials become dried onto the instruments. *AS/NZS 4187:2014*
- Testing should be performed to assess efficacy of cleaning of medical devices. *AORN 2016, AS/NZS 4187:2014*

Prep/Pack

- Surgical instruments should be inspected and evaluated for cleanliness and functionality after decontamination. *AORN, AS/NZS 4187:2014*
- Ensure that packaging materials are compatible with the sterilisation process. *AS/NZS 4187:2014*
- A chemical indicator should be placed on the outside and inside of every pack to be processed unless the internal indicator is readable through the package material. *WHO 2016, ACORN 2016*



Sterilise

- Ensure Performance Qualification testing (both Physical & Microbiological) is carried out by suitably trained in-house personnel or a suitably experienced and qualified external contractor. *AS/NZS 4187:2014*
- An essential element of sterility assurance is the Sterilisation process monitoring. Devices for this include Physical Monitors, Chemical Indicators and Biological Indicators. *AAMI ST79 2013*
- An RMD shall not be released from reprocessing until all acceptance criteria for release of the RMD have been met. This includes correct results for all cycle records and monitoring indicators. *AS/NZS 4187:2014*

Store

- Means of preserving the integrity and impermeability of the packaging by keeping the sterilised materials in appropriate storage must be available. *AS/NZS 4187:2014, WHO 2016*
- Ensure the sterile storage area is a well-ventilated area that provides protection against dust, moisture, insects and temperature and humidity extremes. *AS/NZS 4187:2014*

Use/Track

- Include in a quality control program for sterilised items: a steriliser maintenance contract with records of service; a system of process monitoring; a visual inspection of packaging materials; traceability of load contents. *AS/NZS 4187:2014*
- Indicators should be used to determine sterility before item is introduced onto the sterile field…the nurse responsible should confirm the sterility by evaluating the sterility indicator. *WHO 2016, ACORN 2016*

Healthcare Associated Infections (HAI's) are the most common complication affecting patients in Hospitals.

Each Year around

200,000 HAI's are **contracted by patients in Australia.**

Reference: *NSQHS Standard.*

How do we manage this risk?

The Australian Commission on Safety and Quality in Healthcare NSQHS standards state that ***"Reprocessing of equipment and instrumentation meets current best practice guidelines."***

Total national number of bed days due to

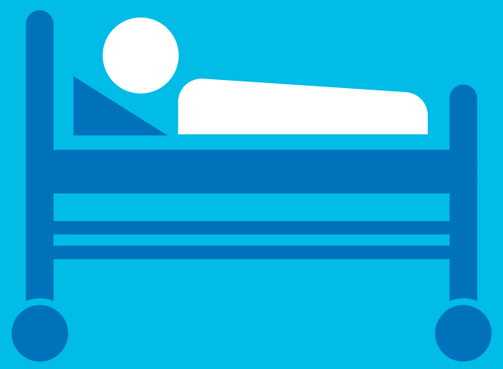
Surgical Site Infections

for a one year period was estimated to be

206,527 bed days.

Reference in the *NSQHS Standard 3*

NSQHS 3.16.1 states **"Compliance with relevant national or international standards and manufacturer's instructions for cleaning, disinfection and sterilisation of reusable instruments and devices is regularly monitored"**



What does the international community say about managing the Risk of SSI in relation to CSSD?

Using National and International standards as suggested in the Australian Commission on Safety and Quality in Healthcare, **what does Best Practice look like?**

Criteria for Load Release	AS/NZS 4187:2014	ANSI/ AAMI ST79: 2013	AORN 2016	APSIC 2017	CDC 2008	World Health Organisation (WHO) 2016	Best Practice
Equipment							
Temperature	Every Load	Every Load	Every Load	Every Load	Every Load	Every Load	**Every Load**
Pressure	Every Load	Every Load	Every Load	Every Load	Every Load	Every Load	**Every Load**
Time	Every Load	Every Load	Every Load	Every Load	Every Load	Every Load	**Every Load**
Bowie & Dick test	Daily	Daily	Daily	Daily	Daily	Daily	**Daily**
Load							
Biological Indicator (BI) in test pack	Optional	Weekly, Preferably Daily	Weekly, Preferably Daily	Minimum Daily	Weekly, Preferably Daily	Minimum Daily	**Weekly, Preferably Daily**
Biological Indicators - Implants test pack		Every Load	Every Load	Every Load	Every Load	Every Load	**Every Load**
Chemical Indicator (CI) in test pack	Optional	Optional	Optional			Every Load	**Every Load**
Pack							
Internal Chemical Indicators	Optional	Every Pack	Every Pack	Every Pack	Every Pack	Every Pack	**Every Pack**
Exposure							
External Chemical Indicators	Every Pack	Every Pack	Every Pack	Every Pack	Every Pack	Every Pack	**Every Pack**

"A Quality Monitoring Program that **includes Physical monitors** (eg printouts, digital readings, graphs, gauges), **Chemical Indicators**, and **Biological Indicators** should be used to verify that conditions necessary for steam sterilisation have been met".

Reference: VI.c. (p827) AORN 2016 guidelines (Strong evidence).

Sterilisation process monitoring devices include **Physical monitors, Chemical Indicators and Biological Indicators.**

Each of these devices plays a distinct and specific role in sterilisation process monitoring, and **each is indispensable to sterility assurance** [AAMI ST79:2013]

Monitoring Critical Variables in the Sterilisation process

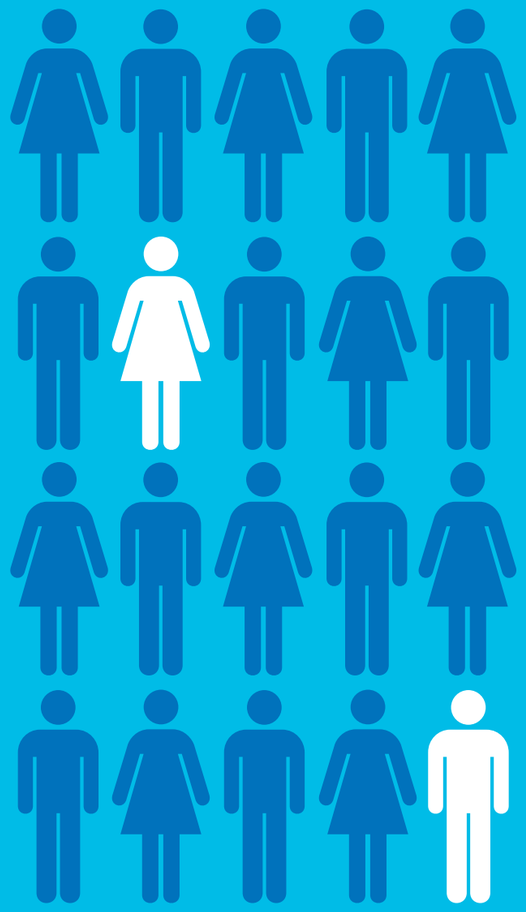
	Equipment	Load	Pack
Purpose	Confidence in the Steriliser efficiency	Indicates pack contents exposed to correct conditions	Confidence that pack contents exposed to correct conditions
Steriliser gauge/printout	✓	✗	✗
Bowie & Dick test	✓	✗	✗
Chemical Indicator tape	✗	✗	✗
Biological Indicator in test pack	✓	✓	N/A
Internal Chemical Indicator (Type 5)	✓ In test pack	✓ In test pack	✓

NB: A biological indicator remains the ONLY direct method for detection of lethallity of spores in a sterilisation cycle.[6]

Who gets the results?	CSSD	CSSD	Theatre

Possible reasons why indicators may fail in load or pack monitoring

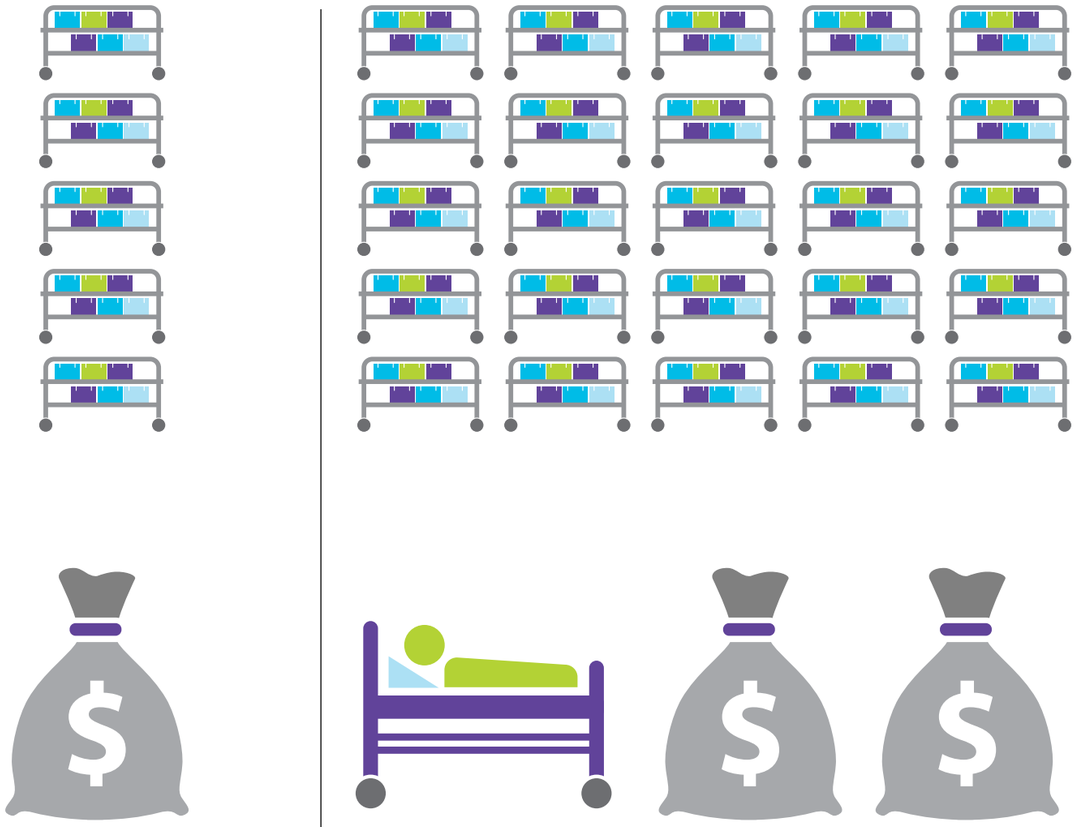
Incorrect pack orientation
Too many packs in the load
Placing packages too close to each other
Incorrect cycle selection
Inadequate steam quality



How is your **patient safety compromised?**

A reminder on why this is important. What if you do get a BI failure?

A failure in one of the measures of the sterilisation process would require your Recall Procedure to be put into place immediately, to **recall every load since the last negative BI result.***



Daily BI

x5

loads impacted

Weekly BI

x25

loads impacted

*Based on a CSSD that processes 5 loads per day

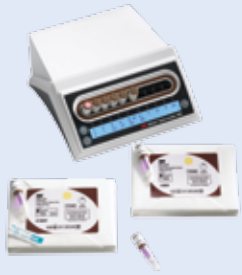
What does the **Risk Profile** in your CSSD look like today?

Criteria for Load Release	Best Practice	Current Practice today	What do you want to do?	By when?
Equipment				
Temperature	Every Load			
Pressure	Every Load			
Time	Every Load			
Bowie & Dick test	Daily			
Load				
Biological Indicator (BI) in test pack	Weekly, Preferably Daily			
Biological Indicators - Implants test pack	Every Load			
Chemical Indicator (CI) in test pack	Every Load			
Pack				
Internal Chemical Indicators	Every Pack			
Exposure				
External Chemical Indicators	Every Pack			

Today, someone’s immediate family member is visiting the operating theatre.

Patient Safety in Surgery starts in the CSSD.

How can 3M help?

Control	Frequency	Reference ISO standard	Available 3M Product	
Equipment	Daily	**ISO 11140-4** **ISO 11140-3**	Comply 1300 Bowie Dick Test Pack	
			Comply 1301 Bowie Dick Test Pack	
			4208 ETS	
Load	Daily	**ISO 11138-1** **ISO 11138-3**	Attest™ 490 Super-Rapid Auto-Reader (1 hour result)	
			1492V Biological Indicaators (box 50)	
			41482V Biological Indicator + Type 5 Sterigage Integrator Test Pack (24 Test Packs + 24 Controls)	
			Attest™ 390 Rapid Auto-Reader	
			1291/1292 Biological Indicators (box 50)	
			1296 Rapid Biological Test Pack (25 test packs + 25 controls)	
Pack	Every Pack	**ISO 11140-1**	Type 5 Comply Sterigage Steam Chemical Integrators (1243A)	
Exposure	Every Pack	**ISO 11140-1**	Comply Tape 1322-12mm	
			Comply Tape 1322-18mm	
			Comply Tape 1322-24mm	
			Comply Tape 1355-18mm	
			Comply Tape 1355-24mm	

Always read the label and use only as directed

3M

3M Infection Prevention Division

3M Australia Pty Limited
Bldg A, 1 Rivett Road
North Ryde NSW 2113
1300 363 878
www.3M.com.au/healthcare

References:

1. The Australian Commission on Safety and Quality in Healthcare NSQHS Standard 3 2012: factsheet
2. AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisations
3. Centers for Disease Control and Prevention, Guideline for Disinfection and Sterilisation in Healthcare Facilities, 2008
4. The APSIC guidelines for disinfection and sterilisation of instruments in health care facilities, 2017
5. World Health Organisation (WHO), Decontamination and Reprocessing of Medical Devices for Health-care Facilities 2016
6. ANSI/AAMI ST79:2013, Comprehensive guide to steam sterilization and sterility assurance in health care facilities
7. Association of periOperative Registered Nurses (AORN), Guidelines for Perioperative Practice, 2016 Edition.