



STERILIZATION



MICROBIOLOGICAL



SAFETY
HEALTHCARE RESILIENCE

When Crisis Threatens the **Sterilization Chain**

Microbiological Strategies for Resilience
and Continuity of Safe Healthcare Services

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Why Does Sterilization Resilience Matter?



CRISIS =



Higher Demand

+



Fewer Resources

+



Greater Risk



Clinical workload surge

- More surgeries and urgent procedures
- Higher demand for sterile instruments



Infrastructure disruption

- Power and water instability
- HVAC and utility interruptions



Supply-chain interruptions

- Packaging materials and indicators
- Delays in consumables and spare parts



Workforce pressure

- Staff shortages and fatigue
- Higher probability of human error



Crisis increases the need for sterilization assurance.



Sterilization Is a Chain — Not a Machine



Every link contributes to patient safety.



A weakness in any step
can compromise the entire process
and increase the risk of infection.



Sterilization is a system,
not just the performance of a single sterilizer.

Where Can Crisis Break the Chain?

Crisis can disrupt multiple elements of the sterilization system, increasing the risk of contamination and infection.



Disruption at any point can compromise the entire chain and increase the risk of healthcare-associated infection.



From Quality Control to Resilience

In crisis, the question is not only whether the process works, but whether it can remain safe under stress.

Routine Quality Control

Focus: Process performance under normal conditions



“Is the process working correctly?”



Follow validated procedures



Routine monitoring



Detect deviations



Ensure compliance with standards



Resilience in Crisis

Focus: Maintaining safety under disruption



“Can the process remain safe under stress?”



Anticipate vulnerabilities



Absorb operational shocks



Adapt resources and workflows



Recover safe operations



Learn and improve the system



Anticipate
Identify risks



Absorb
Maintain core function



Adapt
Adjust and innovate



Recover
Restore safely



Learn
Strengthen the system



Resilience is not lowering the standards — it is preserving validated safety while adapting to changing conditions.



What Is Microbiological Resilience?

The capacity of a sterilization system to anticipate, detect, respond to and recover from process disruptions while **maintaining microbiological safety**.



Microbiological safety must be maintained even during disruption.

Key Components



Risk
anticipation



Robust
monitoring



Interdisciplinary
response



Evidence-based
decisions



Learning
and improvement



The Evolving Role of the Microbiologist

TRADITIONAL ROLE



Detection

Identify process failure



RESILIENCE-ORIENTED ROLE



Prediction

Identify and assess risks



Prevention

Support risk reduction



Investigation

Interpret results and analyze causes



Assurance

Provide evidence for safe processes

COLLABORATION FOR SAFE STERILIZATION



CSSD



Infection Prevention



Microbiology



Biomedical Engineering



Surgical Teams



From detecting failures to anticipating and preventing them.



Three Layers of Sterilization Monitoring

No single monitoring method is sufficient by itself.

01



Mechanical Monitoring

- Time
- Temperature
- Pressure

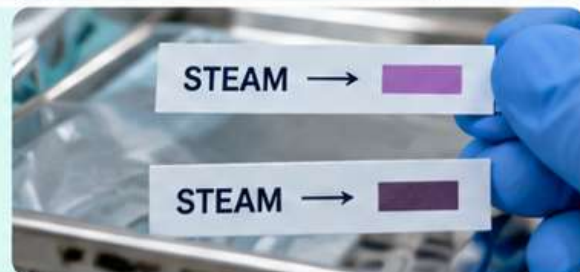


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Chemical Monitoring

- Exposure to process conditions
- Verifies critical parameters

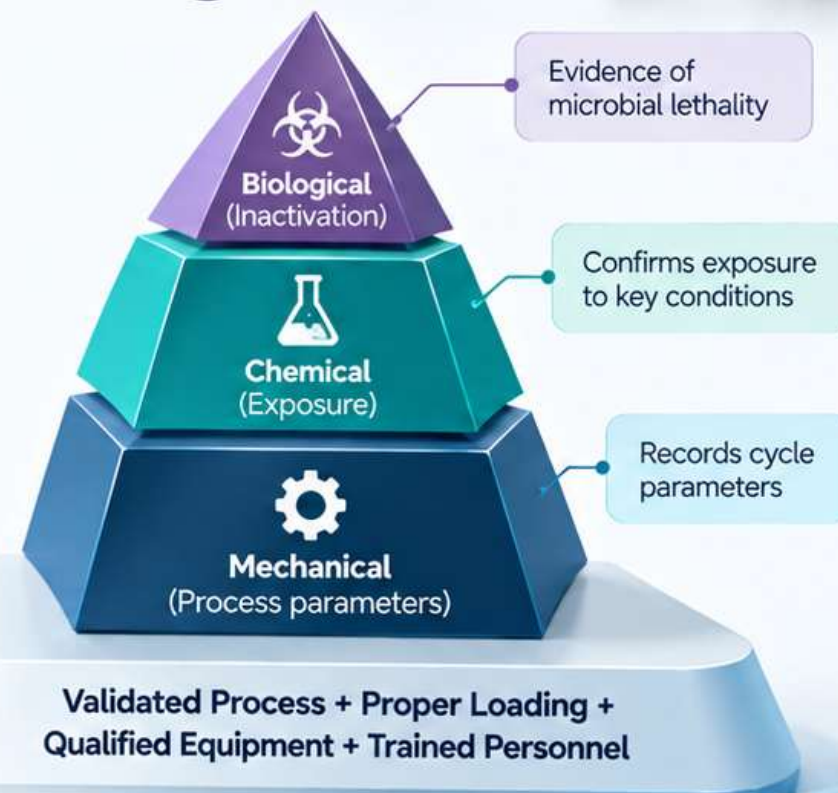


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Biological Monitoring

- Microbial inactivation challenge
- Confirms process lethality

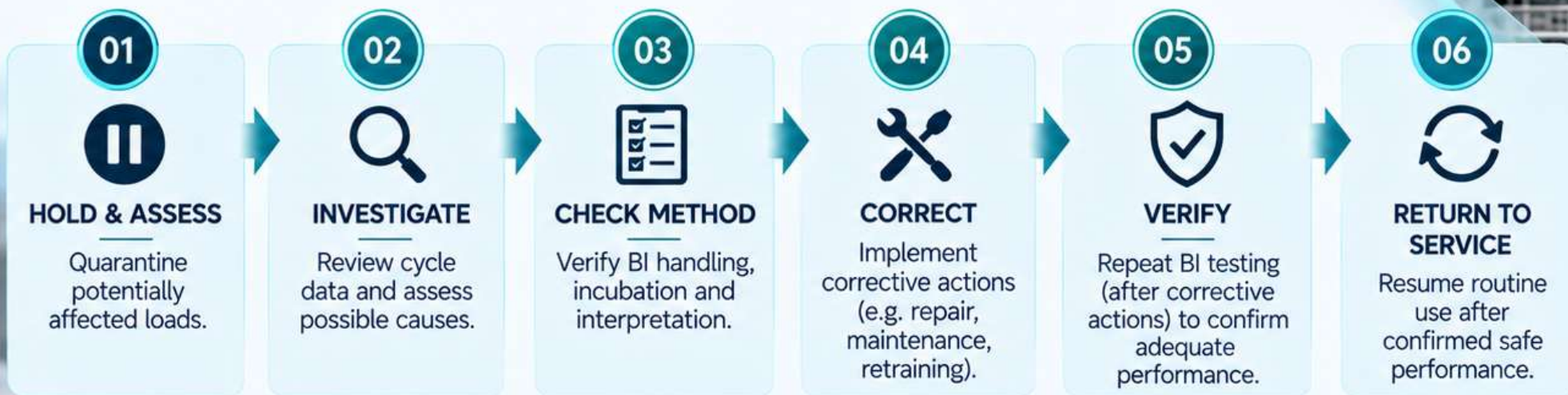


Combined monitoring supports **sterilization assurance** and patient safety.



When the Biological Indicator Is Positive

A systematic response is essential to identify the cause, determine the impact and ensure safe recovery.



STEAM

One positive BI does not automatically require recall of all **nonimplantable items**; evaluate cycle records and repeat tests.



NON-STEAM

Use **conservative** recall assessment for potentially affected loads.



Review:



Cycle parameters



Chemical indicators



Load (e.g. implants)



Operator



Maintenance



Protect patients. Document the decision. Verify safe recovery.



The 5R Model for Resilient Sterilization

A practical framework to maintain microbiological safety and continuity of sterilization services during crisis.



The 5R model helps turn crisis into an opportunity to build a **stronger and safer** sterilization system.



A Crisis Scenario — Power Outage, Water Disruption and Surgical Surge

Multiple challenges, one critical goal: maintain microbiological safety.



CRISIS EVENTS



Power outage

- Sterilizers and washers offline
- Loss of monitoring systems
- Limited lighting and ventilation



Water disruption

- No or low water supply
- Reduced water quality
- Impact on cleaning and generator systems



Surgical surge

- Increased number of emergency surgeries
- Higher demand for sterile equipment
- Pressure on staff and resources



DECISION-MAKING BASED ON THE 5R MODEL

01



RECOGNIZE

Assess the situation

- Identify risks and critical impacts
- Evaluate available resources
- Prioritize essential services

02



REDUCE

Mitigate risks

- Activate contingency plans
- Use alternative resources (e.g. backup power)
- Optimize workflows and triage cases

03



RESPOND

Implement actions

- Suspend non-urgent cases if needed
- Ensure safe cleaning and sterilization
- Coordinate with clinical, engineering and infection prevention teams

04



RECOVER

Restore safe operations

- Inspect and test equipment
- Verify process performance (mechanical, chemical and biological monitoring)
- Return to full service when safe

05



LEARN

Strengthen the system

- Analyze what worked and what failed
- Update protocols and contingency plans
- Improve preparedness for future crises

KEY ACTIONS DURING THE CRISIS



Use backup power for critical equipment



Ensure alternative water supply or validated water quality management



Prioritize and triage surgical cases



Maintain essential monitoring (mechanical, chemical and biological)



Ensure clear communication and defined roles



DO NOT COMPROMISE



Do not lower sterilization standards



Do not release unmonitored loads



Do not use suspected or unverified equipment



Even in crisis, the goal remains the same: **safe, sterile equipment for every patient.**



Flexibility in Operations — Rigidity in Safety

In a crisis, we can adapt how we work, but we must not compromise what keeps patients safe.



What Can Adapt?

Flexibility helps maintain services during crisis.



Scheduling and workflow

Adjust work shifts, prioritize urgent cases



Resource allocation

Use available equipment, alternative sites



Staffing and roles

Cross-training and redeployment



Supply management

Use alternative suppliers and equivalent products



Service prioritization

Focus on emergency and time-critical procedures



Interdepartmental collaboration

Coordinate with clinical, engineering and infection prevention teams



What Cannot Be Compromised?

These are essential for microbiological safety.



Validated processes

Follow evidence-based standards and manufacturer's instructions



Required monitoring

Mechanical, chemical and biological monitoring (without unjustified reduction)



Proper cleaning

Effective cleaning must always precede sterilization



Approved parameters

Maintain validated time, temperature, pressure and other critical parameters



Equipment performance

Use only properly functioning and maintained equipment



Qualified personnel

Ensure trained and competent staff



Adapt to the situation. Maintain the standards. Protect every patient.



Resilience Must Be Built Before the Crisis

Proactive planning, preparation and training build a stronger, safer sterilization system.

01 RISK ASSESSMENT



- Identify hazards and vulnerabilities
- Assess impact on sterilization services
- Prioritize key risks



02 CONTINGENCY PLANS



- Develop and document emergency plans
- Define alternative resources and sites
- Establish clear roles and communication



03 RESOURCES AND INFRASTRUCTURE



- Ensure backup power and validated water supply
- Maintain critical equipment
- Secure essential supplies and alternative suppliers



04 TRAINING AND SIMULATION



- Train staff on emergency procedures
- Conduct simulation exercises
- Strengthen interdepartmental collaboration



05 MONITOR AND REVIEW



- Evaluate effectiveness of plans and drills
- Update policies and protocols
- Incorporate lessons learned



KEY ELEMENTS FOR PRE-CRISIS PREPARATION



Functional backup systems (power, water, equipment)



Adequate supply chain and inventory strategy



Trained and cross-trained personnel



Clear policies and procedures



Interdepartmental coordination (CSSD, infection control, engineering, clinical teams)



Regular drills and evaluation



A resilient sterilization system is the result of preparation, not improvisation.



Three Take-Home Messages

Key points to remember for a safer, more resilient sterilization system.

1 STERILIZATION IS A SYSTEM

Microbiological safety depends on the entire chain — from cleaning to storage and use.



2 MAINTAIN MICROBIOLOGICAL SAFETY DURING CRISIS

Even under pressure, we must not compromise validated processes, monitoring or release criteria.



3 RESILIENCE MUST BE BUILT BEFORE THE CRISIS

Proactive planning, resources, training and interdepartmental collaboration create a stronger and safer system.



A resilient sterilization system protects patients today and is better prepared for tomorrow.



When the System Is Under Stress, Safety Must Not Be.



Power
Disruption



Water
Disruption



Surgical
Surge



A resilient
sterilization system



Protects patients
today



And is better
prepared for tomorrow.

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