

Risk Management Strategies regarding Steam Sterilization of Medical Devices

Kirmse, G.
Aesculap AG, Technical Competence Center, Tuttlingen, Germany



Background

How can we make sure, it works properly?

Multiple Activities

Vacuum Test

Process Indicator

Bowie Dick Test



Helix Test

Indicator per Set

Validation

Process Testing

Sterile Barrier

Dryness Inspection

AIM: Find a proper Risk Management Strategy !

RESULTS FROM 150 CONSULTANCIES + LITERATURE

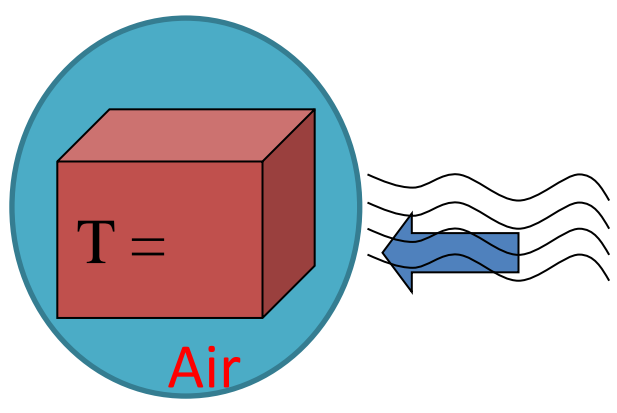
- Parameters not met (Machine Error, slow heating): rarely
 - Indicator Errors (1)
 - low influence of geometry (2)
 - Steam Penetration Tests helpful (3)
- Wet Sets (more than 80% of hospitals)
 - from 1 to 48/ month, up to 1% of sets
 - detected, but cancellation of cases
- Damaged soft Packs (folding, handling, storage)
 - difficult to detect (4,5)
- Damaged Containers (lack of inspection)
- Soft packs compromised by moisture (6,7)
 - severe results (8)

Key Message: Current Quality Measures in Steam Sterilization partly focus in the wrong direction. Effective Strategies are "worst case"-testing, steam penetration monitoring, a robust sterile barrier system and education of personnel.

Methods: Failure Mode and Effect Analysis (FMEA)

Basic Failures in Steam Sterilization

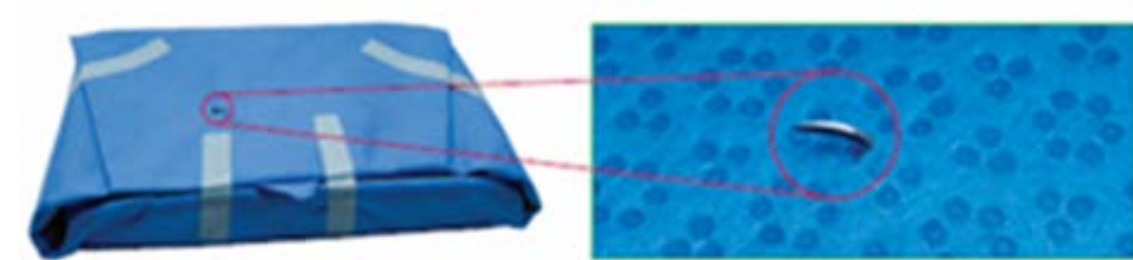
1. Sterilization Condition not reached
Time – Temperature - Contact



2. Sterile Goods not dry



3. Sterile Barrier Compromised



Risk Evaluation and Risk Management adapted from ISO14971 and VDI5700

 not acceptable, reduce risk
 reduce risk, as low as reasonably possible (alarp)
 acceptable
 (according to U. Zimmermann, Freiburg, Germany)

Probability

very likely					
likely					
plausible					
unlikely					
very unlikely					
	very low	low	severe	critical	catastrophy

Probability

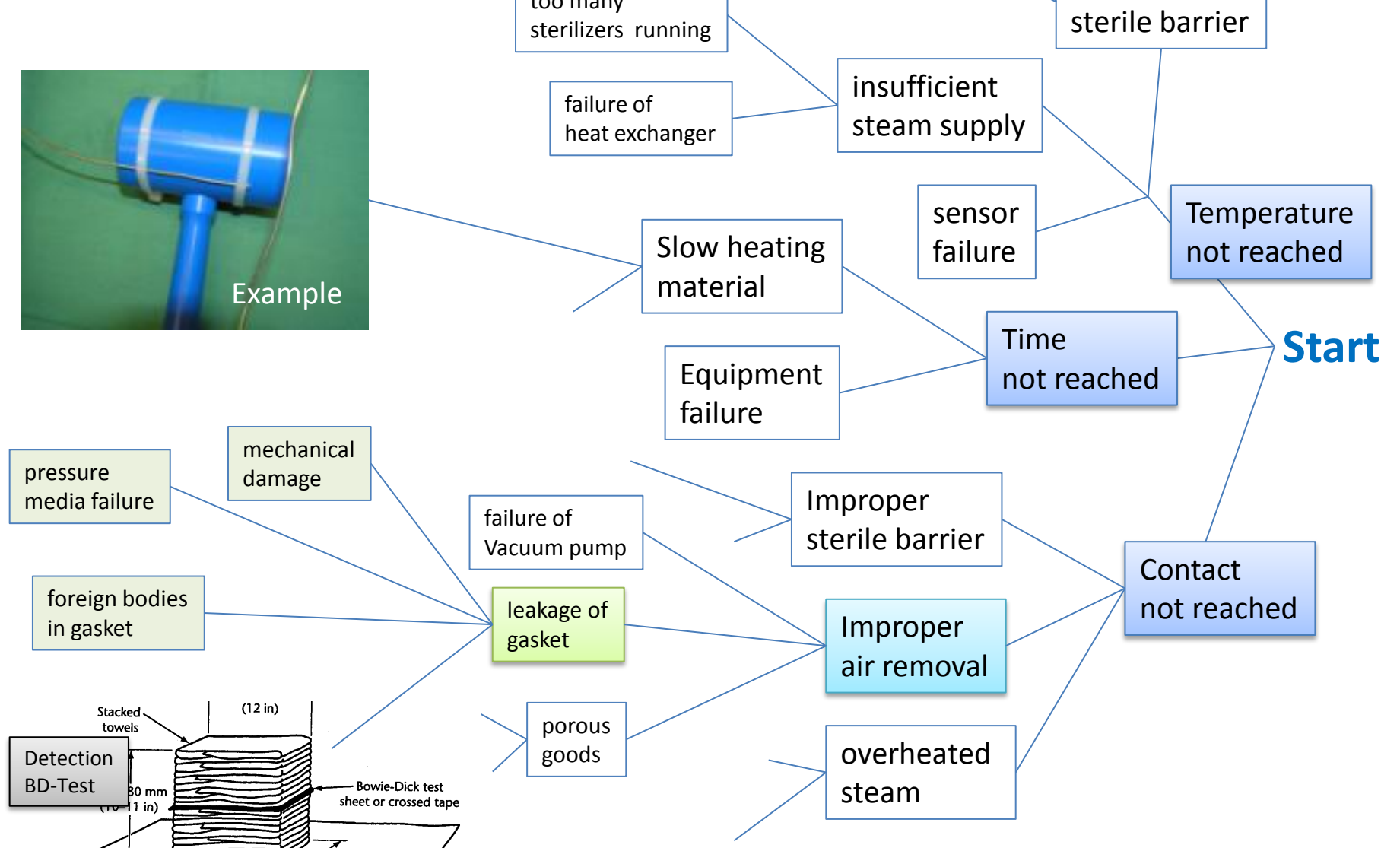
Probability	Consequence	Consequence
very likely	1 per month or more	catastrophy death or severe injury
likely	2-11 times per year	critical irreversible injury
plausible	6-10 times in 10 years	severe reversible injury
unlikely	1-5 times in 10 years	low temporary discomfort
very unlikely	1 time in 20 years or less	very low little discomfort

Risk Management



Consequences: depending on patient condition
=> Work on „Occurrence“ (Equipment, Education) and „Detection“

Root Cause Analysis –Example (Fish Bone Technique)



Systematic Analysis of all potential Failure Modes
 • Risk of Occurrence (Risk of Effects)
 • Potential of Detection (Inspection, Indicators ...)

Results

- Wet Sets and Compromised Sterile Barrier systems are by far more frequently responsible for Sterility Failures than Process Failures
- Risk of slight parameter deviations is limited (2, 9)
- Indicators w/o challenge packs do not provide much additional extra information beyond sterilizer data (3)
- Little Damages of rigid Containers impose little risks and can be detected visually (10)
- Damaged or compromised soft packs are hard to detect and have lead to severe consequences (4,8), recommended practices frequently not kept
- Education of personnel is crucial



EFFECTIVE PRECAUTIONARY MEASURES

- Process Qualification (Validation / Verification)
 - Testing under worst case conditions
 - Defining loads and packaging
- Qualified Personnel
 - Parametric release
 - Equipment Inspection
- Robust Sterile Barrier System
 - Inspection, Proper Handling
- Steam penetration tests
 - depending on load
- Process Indicators

LESS EFFECTIVE

- Chemical Indicators per Set (Tolerances)
- Biological Indicators
 - with Challenge Pack
 - w/o Challenge Pack

Biological Indicators (ISO 1138)

- ca 10⁵ -10⁶ spores
- D-Value of 10-25s at 134°C
- 0,5-2,5min holding time to pass
- additional effect by heating phase

Chemical Indicators

- e. g. Tolerances: Designed for 134°C, 300s, Class 5 (ISO 11140)
- minimum 132,7°C
- minimum 255s
- steam saturation 85%



Assumption: Sterilizer with 10 STE used for 8 loads per day, Daily Cost, material and work time, based on €20/h, German prices

Test	Cost	Daily Cost	Information
Validation	€3000/year	€12	Sterilizer Performance
Parametric Release	48min /day	€16	Sterilization, Drying, Documentaion
BD Test	€2-8/piece 10min	€6-12	Steam penetration porous
Helix Test Per load	€0,50/piece	€4	Steam penetration lumen
Class 1 per set	€0,10/piece	€8	Process ves/no
Class 6 per set	€0,60/piece	€48	Sterilization per set
BI per day	€6 /piece 10min	€9,30	„Sterilization performance“
BI per Impl Load	4x/day	€46,50	„Sterilization performance“

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