Monitoring The Sterilization Process. Are We Over The Top?

Dr Brian Kirk,
Senior Technical Services Specialist, Sterilization
3M Health Care
Are We Over The Top?

NO!

Get it wrong and you kill the patient!

Clothier Report, 1972

Inquiry into the death of 5 patients receiving contaminated infusion fluids inadequately sterilized.

Conclusion;

“The committee considers that too many people believe that sterilization (of fluids) is easily achieved with simple plant operated by men of little skill under minimum supervision, a view of the task which is wrong in every respect.”
Are We Over The Top?
NO NO!
Get it wrong and you harm the patient!

Dancer et al, 2012
Post surgical site infection resulting from contaminated surgical orthopaedic and ophthalmology sets arising from incorrect control of the sterilization process.

Conclusion;

Inspection of the sterilization plant highlighted inadequate maintenance of autoclave components and poor handling practices by staff. This was compounded by lapses in inspection of surgical sets by theatre staff.
Are we over the top?

No. No, No !!!
Get it wrong and the whole process can be compromised.
Reported on an evaluation of a number of porous load sterilizers in use in Scottish Hospitals.
Conclusion;
“Our findings suggest that a great many high vacuum sterilizers already installed in hospitals are not in proper functioning order.”

55 years on, has this changed ?
Lessons from History

Some of the incidents described earlier gave rise to the body of standards which we all follow today.

Unfortunately memory fades, times change. We get complacent because of lack of incident and new generations see old ideas as unfashionable and antiquated.

However the basic principles do not change.

Despite its unpopularity, we should take heed of the lessons from history.

It can never be “over the top” to exercise due diligence when it comes to sterilization monitoring and control.
**Sterility, Sterilization and Sterility Assurance**

**Sterility** – State of being *free from viable micro-organisms*

**Sterilization** – Validated Process used to render product sterile

**Validation** - Documented procedure for obtaining, recording and interpreting results required to establish that a process will consistently yield product complying with a predetermined specification

- Specification = Sterile Product
  - EN 556-1:2001 (E), Sterilization of Medical Devices – Requirements for medical devices to be designated “Sterile” – Part 1 : Requirements for terminally sterilized Medical Devices.
  - **EN ISO 14937:2000** – Sterilization of Health Care Products – General requirements for characterization of sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

- **Why Validation** – *Because we cannot test for Sterility!*
Sterility Assurance is Achieved By:

Specifying;
Writing a detailed specification explaining what equipment is used, the process steps followed and how it is monitored
Reference to standards and regulatory requirement of great help in this process

Validating;
Documenting and **carrying out** a procedure which provides data showing we get what we want
ie a sterile, safe, efficacious product.
Involves three steps – Installation Qualification, Operational Qualification and Performance Qualification

Routinely Monitoring;
Taking actions to ensure ongoing process efficacy.

STERILE PRODUCT
Why Monitor?

Sterilization processes are special so require validation rather than final product testing.

- We cannot test for Sterility

Each sterilization process is a unique event and so requires monitoring for process efficacy.

- Recorded Evidence for every load.

This is reflected in Sterilization Standards (11135, 11137, 17665) which require validation and then routine monitoring procedures to be in place.
### What should be monitored – Critical Process Variables (CPV)

Variables that contribute to the inactivation of micro-organisms and are critical in achieving successful sterilization.

<table>
<thead>
<tr>
<th></th>
<th>Time</th>
<th>Temperature</th>
<th>Moisture</th>
<th>Relative Humidity</th>
<th>EO Conc’n</th>
<th>Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>![checkmark]</td>
<td>![checkmark]</td>
<td>![checkmark]</td>
<td>![checkmark]</td>
<td>No</td>
<td>Yes But not CPV</td>
</tr>
<tr>
<td>Ethylene Oxide</td>
<td>![checkmark]</td>
<td>![checkmark]</td>
<td>![checkmark]</td>
<td>![checkmark]</td>
<td>No</td>
<td>Yes But not CPV</td>
</tr>
</tbody>
</table>
What do we need to monitor and how?

The microbiocidal efficacy of sterilization processes is achieved by application of certain critical variables

- Eg time of exposure, temperature, presence of moisture, concentration (for chemical sterilization).

In order to have an assurance of sterility we must monitor the application of the critical variables to ensure they have been achieved

Monitoring is achieved using sensors based on:

- Physical
- Biological
- Chemical
  - Indicator devices
Processes

Cleaning
Disinfection
Sterilization

Process Validation
Test Soils
Routine Residual Soil
Quality System – EN ISO 13485

All aspects of sterile product production must be governed by an all embracing quality system which ensures the essential requirements of the MDD are met and that CE marks can be correct applied.

ISO 13485:2003

Medical devices - Quality management systems - Requirements for regulatory purposes

• ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.
Validation and Routine Control of Moist Heat Sterilization

EN ISO 17665-1, 2 and 3

• This standard provides requirements and guidance for the sterilization of Health Care Products using moist heat sterilization.

• The following identifies specific clauses and how they may be complied with.
Products for Sterilization Assurance Exposure Indication

Standard Requirement:
ISO 17665-1; 11. Product Release from Sterilization;

Clause 11.2 *A system shall be specified to ensure that processed and non-processed items are clearly identified.*

Product Choices;
Tapes
Tags
Labels.

NB Segregation is an option but not used in HC
Standard Requirement

ISO 17665-1; 12 Maintaining Process Effectiveness.

Clause 12.1.6 If the sterilization process relies on the removal of air from the sterilizer chamber in order to achieve rapid and even penetration of steam into the sterilizer load, a steam penetration test shall be carried out each day before the sterilizer is used.

This means an independent Daily Bowie and Dick Test shall be carried out (see Clause A.5)
The Bowie and Dick Test (reference method)

- Textile Pack as specified in EN 285 / ISO 17665
- Indicator Sheet complying with ISO 11140-3

In routine use alternative BDT tests may be used compliant to EN ISO 11140-4
  – see A.5.2 of ISO 17665-2
Alternative BD Tests
Disposable test packs which must comply with EN ISO 11140-4

Convenience & Consistent
Remove from box and use
No preparation time
• Laundering / airing / folding textiles
Electronic Versions also
Buyer Beware!
Bowie and Dick Test Performance Study

A number of alternative B&D test products were tested for performance in a mixed pulsing sterilization cycle using;

- chamber leaks
- inadequate vacuum as the failure modes.

Leak Induced in Chamber through needle valve
Vacuum set points changed to create bad vacuum
### Detection of process failures - inadequate evacuation

<table>
<thead>
<tr>
<th>Test</th>
<th>Textile Pack</th>
<th>Indicator Sheet</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
</tr>
</thead>
<tbody>
<tr>
<td>BV 75</td>
<td>NT</td>
<td>NT</td>
<td>Fail -50</td>
<td>Fail 3cm</td>
<td>Fail 2.5cm</td>
<td>Fail 5cm</td>
<td>NT</td>
<td>NT</td>
<td>NT</td>
<td>NT</td>
<td>NT</td>
</tr>
<tr>
<td>BV 100</td>
<td>0.5, 3°C @15th</td>
<td>Pass 2cm</td>
<td>Fail -53</td>
<td>Fail 3cm</td>
<td>Fail 2cm</td>
<td>Fail 4cm</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>BV 150</td>
<td>8, 20°C @15th</td>
<td>4.5, 4.0 cm</td>
<td>Fail – 1122</td>
<td>Fail 4cm</td>
<td>Fail 7cm</td>
<td>Fail 4.5cm</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>BV 200</td>
<td>97°C @15th</td>
<td>6.5 cm</td>
<td>Fail -1160</td>
<td>Fail 5cm</td>
<td>Fail 8cm</td>
<td>Fail 6.0cm</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>BV 250</td>
<td>NT</td>
<td>NT</td>
<td>Fail -1175</td>
<td>NT</td>
<td>NT</td>
<td>NT</td>
<td>Pass</td>
<td>Fail 3cm</td>
<td>Pass</td>
<td>Fail 6cm</td>
<td>Fail 3cm</td>
</tr>
<tr>
<td>BV 300</td>
<td>NT</td>
<td>NT</td>
<td>Fail – 1169</td>
<td>NT</td>
<td>NT</td>
<td>NT</td>
<td>Fail(?) 1.5cm</td>
<td>Fail 2cm</td>
<td>Fail 3cm</td>
<td>Fail 4 cm</td>
<td></td>
</tr>
</tbody>
</table>
Bowie and Dick Test Pack Study
Bad Vacuum Fail – 200 mB set point, 97°C deprn

Appearance of indicator sheets from BDT packs exposed to test cycle employing 200mB set points giving a 97°C depression in textile pack
ISO 17665-1; 10 Routine Monitoring and Control

10.1 Routine Monitoring and Control shall be performed on each operating cycle.

10.4 Delivery of the sterilization process shall be verified from the results of chemical or biological indicator systems, if used, and by confirming that within specified tolerances recorded data from routine monitoring match data from validation.

10.5 For saturated steam processes, the data shall include;

d) the results obtained from a process challenge device.

Biological vs Chemical indicators;

PCD’s
Products for Sterilization Assurance Load Monitoring

Measuring Temperature and Pressure alone is not enough.

The temperature measured in the drain and/or chamber along with chamber pressure will not indicate a problem within the packs caused by small amounts of residual air.

This is why the standards specify use of a:
- Free standing PCD + a sensor – BI or CI
- Inbuilt Air Detector
Products for Sterilization Assurance
Load Monitoring

Biological Indicators (see ISO 11138 series);
Test system containing viable microorganisms providing a defined resistance to a specified sterilization process

Chemical Indicators (see ISO 11140 series);
Test system that reveals change in one or more pre-determined process variables based on a chemical or physical change resulting in exposure to a process.

INSIDE

Process Challenge Device (PCD) (see ISO 17665 series)
Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process
Biological Indicators (ISO 11138) - Formats

Self-contained Biological Indicator (SCBI)

Inoculated Carriers/
Seeded Product

Spore Ampoules

Spore Strips
Biological Indicator – Read Out Time

RIT is determined using an FDA protocol involving multiple sample/batch testing to evaluate the incubation time required to give >97% read out reliability against a 7 day incubation.

Standard Spore Strip: 7 days

Self-contained BI: 48 h

Rapid Readout BI: 10 hours

Rapid Readout BI: 1-4 hours
Chemical Indicators - Types

Type 1 – Process / Exposure Indicators (eg Indicating Tapes, Labels)
Type 2 – Specific Test Indicators (e.g. BDT)
Type 3 – Single variable indicators
- Respond to a single variable in the process e.g. temperature
Type 4 – Multivariable Indicators
- Respond to two or more variables in the process

Type 5 – Integrating Indicators
- Respond in a way which mimics the response of a BI if used in the same process

Type 6 – Emulating Indicators
- Respond to all critical variables of the process at levels associated with acceptable sterilizing conditions e.g. 134 for 3 minutes
Biological and Chemical Indicators and Process Challenge Devices (PCD)

PCD = item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process (air removal and steam penetration)

Home Made

Commerically produced
Products for Sterilization Assurance
Pack Control (CI)

• Chemical Indicators are placed in every pack.
• provide evidence that sterilizing conditions have been met at the point of placement.
• Careful location of the CI in the least accessible (for sterilant penetration) point.
• provides evidence that the whole pack was sterilized.
• Pack Monitoring CI’s have value for producer and user alike
• Standards and Guidance discuss this.
HSE Decontamination Guidance

Part 3 – Recommended Practice for CDU’s

- If chemical indicators are used inside the pack, they should conform to European Standard EN ISO 11140-1 and should be compatible with the pack.

- There should be evidence through measurements, supplemented as necessary by biological indicators or chemical indicators that the sterilisation process was within defined tolerance.

Part 5 – Dental Decontamination

- Packaging should also contain clearly visible chemical indicator strips that give a colour change when sterilising conditions have been achieved during autoclaving.

- There should be evidence through measurements, biological indicators or chemical indicators that the sterilisation process was within defined tolerance.
Application of CI’s for Theatre Teams.
Basic Principles of steam sterilization

If you don’t get the air out....
....you cannot get the steam in to kill the microbes

Residual Air Locates in Packs....
....Preventing steam penetration...
....resulting in incomplete sterilization

The indicator on the outside has changed colour but how do you know the contents are sterile?

Internal Chemical Indicators provide evidence of sterilization conditions being achieved at point of placement
Products for Sterilization Assurance
Pack Control (CI)
Standards (aimed at theatre practitioners)

World Health Organisation (WHO).


Before starting surgical intervention ask

“has the sterility of the instrumentation been confirmed (including indicator results)”

UK Association for Perioperative Practitioners Theatre Checklist;

“3. Once opened, the contents should be checked to ensure there is no residual moisture; internal sterilization monitors are present and valid; and there are no visual signs of contamination….”

Indicators and internal sterilization monitors are mostly chemical indicators of Class 4, 5 or 6
Safe Surgery Saves Lives

The Safe Surgery Saves Lives initiative provides strategies and tools for reducing deaths and complications from surgery worldwide.

We are supporting the World Health Organization’s Safe Surgery Saves Lives initiative to generate global awareness of its importance and inform people that safe surgery contributes to patient safety and the World Health Organization (WHO) Surgical Safety Checklist.

The "WHO Surgical Safety Checklist" is a tool for surgical teams around the world, to ensure:

- operations are carried out at the correct body site
- operations are done with safe anaesthesia
- there are established infection prevention measures
- there is effective teamwork for safer care
- professional endorsement for safer surgical care
- defined measures for better tracking of surgical volume and mortality.

Download a Starter Kit
Download the WHO Surgical Safety Checklist
WHO Surgical Safety Checklist (adopted by AfPP)

“Has sterility (including indicator results) been confirmed?”

• How do theatre staff check this in practice?
• The external process indicator (autoclave tape) provides evidence of pack exposure to a sterilization process but says nothing about the status of the contents.
• An internal Class 5 chemical indicator provides evidence of sterilant penetration and by implication sterility attainment.

Ref: http://whqlibdoc.who.int/publications/2009/9789241598590_eng_Checklist.pdf?ua=1
Ref: http://www.afpp.org.uk/careers/Standards-Guidance
The question is often raised what is meant by “sterility indicator”. Since this device is visually interpreted by the scrub nurse it can only mean a chemical sterilization indicator, preferably class 5 which has performance related to the inactivation of microorganisms.
The AfPP recommends:

1. When sterile product arrives at the hospital site, the delivery should be checked against the delivery note for completeness. The condition of items should be checked to ensure that the packaging is fit for purpose (items failing this initial check should not be not be integrated into the theatre storage facility and should be returned to the SP following non conformance protocol).

2. Before opening sets within theatres, the outer container/wrap should be checked to ensure its integrity as well as the presence of valid labelling and external sterility indicators.

3. Once opened, the contents should be checked to ensure there is no residual moisture; internal sterilization monitors are present and valid; and there are no visual signs of contamination. Any non-conformances should be reported, following local policy.

National Decontamination Programme, theatre support pack, DH, 2009
# US Guidance – AAMI ST 79

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Frequency of use</th>
<th>Application (release of sterilizer, package, load)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical monitors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time, temperature, and pressure recorders, displays, digital printouts, and gauges</td>
<td>Should be used for every load of every sterilizer.</td>
<td>Part of load release criteria.</td>
</tr>
<tr>
<td>Chemical indicators (CIs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>External CIs</td>
<td>Should be used on outside of every package.</td>
<td>Part of load and package release criteria.</td>
</tr>
<tr>
<td>Class I (process indicators)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bowie-Dick-type indicators</td>
<td>For routine sterilizer testing (dynamic-air-removal sterilizers only), should be run, within a test pack, each day in an empty sterilizer before the first processed load. For sterilizer qualification testing (dynamic-air-removal sterilizers only), should be run, within a test pack, after sterilizer installation, relocation, malfunction, and major repairs and after sterilization process failures; test should be run three times consecutively in an empty chamber after BI tests.</td>
<td>Test of sterilizer for efficacy of air removal and steam penetration; part of release criteria for using sterilizer for the day. Part of release criteria for placing sterilizer into service after qualification testing.</td>
</tr>
<tr>
<td>Class 2 (Bowie-Dick)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal CIs</td>
<td>Should be used inside each package.</td>
<td>Part of package release criteria at use site. Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging. Release criteria should include BI results.</td>
</tr>
<tr>
<td></td>
<td>Should be used in periodic product quality assurance testing.</td>
<td></td>
</tr>
</tbody>
</table>


© 3M 2007. All
WHO is responsible to ensure this guidance is followed?

Decontamination Manager is responsible for ensuring packs leaving the department are clean, sterile and fit for use.

- Internal CI’s provide evidence of attainment when pack is used.

The theatre teams are responsible for ensuring patient safety and should follow the WHO surgical safety checklist

- (or a local implementation of the checklist).

One of the requirements is to check the sterility of the pack including the:

- external sterility indicator (process indicator).
- Internal sterility indicator (chemical indicator product).

**NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?**
An open question to the audience

WHO IS RESPONSIBLE?
1-2-3 Comply
Class 5 Chemical Indicator
Steam Sterilization

Best Practice Solution!

3M™ Comply™ SteriGage™
Steam Chemical Integrators 1243

- Parallels the response of a biological indicator strip to the sterilization process
- Moving-front indicators – chemical indicators easiest to read because of the distinct ‘Accept’ or ‘Reject’ readout – no need for interpretation
- Small, convenient size for packs, trays and peel pouches, also available with extenders for large packs

When exposed to a satisfactory sterilization process, they change colour indicating exposure
<table>
<thead>
<tr>
<th><strong>Safe Surgery Checklist</strong></th>
</tr>
</thead>
</table>

**“SIGN IN” (to be read out loud)**

<table>
<thead>
<tr>
<th>Before Induction of Anaesthesia/Anaesthetist/Scrub/Nurse/Midwife</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Confirmed with Anaesthetist/Parent/Guardian</td>
</tr>
<tr>
<td>Site matched? (check verification overlay)</td>
</tr>
<tr>
<td>Has anaesthetic machine been checked?</td>
</tr>
<tr>
<td>Site marked?</td>
</tr>
<tr>
<td>Check with surgeon if problem</td>
</tr>
<tr>
<td>Risk of large blood loss</td>
</tr>
<tr>
<td>Blood Products immediately available?</td>
</tr>
<tr>
<td>Has VTE prophylaxis been undertaken?</td>
</tr>
<tr>
<td>Signature to confirm “Sign in” questions were asked and answered:</td>
</tr>
</tbody>
</table>

**“TIME OUT” (to be read out loud)**

<table>
<thead>
<tr>
<th>Before Skin Incision/Anaesthetist/Scrub &amp; Circulating Name/Midwife</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Confirm that new team members have been introduced to all of the team?</td>
</tr>
<tr>
<td>Verify the patient’s name, DOD, MRN number, procedure and visually check where the incision will be made.</td>
</tr>
<tr>
<td>Verify the patient is positioned correctly</td>
</tr>
<tr>
<td>Is essential imaging displayed and is it consistent with procedure?</td>
</tr>
<tr>
<td>Has antibiotic prophylaxis been given within the last 60 minutes?</td>
</tr>
<tr>
<td>Verify if there are any patient-specific concerns?</td>
</tr>
<tr>
<td>Verify if there are any equipment issues?</td>
</tr>
</tbody>
</table>

Signature to confirm “Time Out” questions were asked and answered: Time: |

**“SIGN OUT” (to be read out loud)**

<table>
<thead>
<tr>
<th>Before drawings are applied/Anaesthetist/Scrub/Nurse/Midwife</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Checklist Co-ordinator verbally confirms:</td>
</tr>
<tr>
<td>The name of the procedure</td>
</tr>
<tr>
<td>Completion of instrument, sponge and needle counts</td>
</tr>
<tr>
<td>Specimen identified and labelled (read specimen labels aloud, including patient name and hospital number)</td>
</tr>
<tr>
<td>To Surgeon, Anaesthetist and Nurse/Midwife</td>
</tr>
<tr>
<td>Any patient specific post-op concerns?</td>
</tr>
<tr>
<td>Anaesthetist</td>
</tr>
<tr>
<td>Surgeon</td>
</tr>
<tr>
<td>Nurse/Midwife</td>
</tr>
<tr>
<td>Signature to confirm “Sign out” questions were asked and answered:</td>
</tr>
</tbody>
</table>

Signature to confirm “Time Out” questions were asked and answered: Time: |

Patient Details (Addressograph label):
Name: ____________________________
Healthcare Record Number: ____________________________
Date of Birth: ____________________________
Resistometer (Steam)
Practical Aspects of Moist Heat Sterilization Validation Workshop.

Specific Issues?
Frequency of testing – SPC / Trend Analysis
Product design and packaging. – combination products
Use of steam and load control.
Suitability of chemical and biological indicators.
Evidence based standards
Presence of water in packs – sterile or not
Lethality of standard cycles.
Relative Humidity of steam
Validation and Ongoing Sterility Assurance

1. Specification – Saying what we want (sterility) and how to get
2. Validation – Proving we deliver what we want
   • IQ – proof of equipment - checks on electrical & mechanical instal.
   • OQ – proof of process – basic tests to ensure equipment works
   • PQ – proof it works for your situation - testing typical loads
3. Routine monitoring – On a regular basis demonstrate our process is working within specification.
   • Physical monitors
   • Microbiological monitors
   • Chemical monitors
4. Periodic re-validation
Process Assurance (Efficacy) is Achieved By;

**Specifying;**
Writing a detailed specification explaining what equipment is used, the process steps followed and how it is monitored.

**Validating;**
Documenting and **carrying out** procedures which provide data showing we get what we want ie a clean, sterile, safe, efficacious product.
Involves three steps – Installation Qualification, Operational Qualification and Performance Qualification.

**Routinely Monitoring;**
Taking actions to ensure ongoing process efficacy.

**CLEAN STERILE EFFECTIVE PRODUCT**
Some countries eg US require extensive use of chemical indicators, particularly use in every pack.

In Europe situation is confused however recent publication indicates guidance from

- WHO
- UK National Decontamination Programme
- UK AfPP

Requires presence of CI’s* in every pack

- *Note the guidance requires the scrub nurse to check the internal “sterility” indicator which implies a CI (what else)
Conclusions

All Cleaning, Disinfection and Sterilization processes must be Specified, Validated and Monitored. There are a range of products available to monitor each stage of the decontamination process. Customers should seek verification that what they want is what the supplier is providing.

THE END – MANY THANKS !!!!
Record Keeping

Integral to good quality system practice (ISO 13485)

Paper

E- records

• Bar code
• 2D etched matrix
• RFID
3 Bar
1 Bar
0.05 Bar

20"  34"  300"  30"

134 °C
Class 5 CI’s moving front

Video from within sterilizer

Does this show the right effect ie accept after 1 minute.