Medical Packaging

A high-level overview of the requirements of medical packaging standards

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Learning Objectives

- What are the key medical packaging standards and what is their global impact?
- What are the basic functions of medical packaging?
- Why it is so difficult to test for sterility?
- What is the process to overcome these difficulties and to achieve a high level of patient protection?

Global Medical Packaging Standards

EN ISO 11607-1:2006 *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.*

- PART 1 FOCUS IS ON MATERIALS AND DESIGN

EN ISO 11607-2:2006 *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.*

- PART 2 FOCUS IS ON PACKAGING PROCESS VALIDATION

EN ISO 11607 Global Status

US

- Adopted as American National Standard without revision
- “Recognized” by the FDA Centers for Devices and Radiological Health (CDRH)

Europe

- Both documents approved as European Norms (EN)
- Harmonized Standard (published in the Official Journal)

EN ISO 11607 Global Status

Japan

- Japanese versions available from Japan Association for Medical Instrumentation (JAMI)
- Adopted as Japanese National Standard

China

- Previous version adopted as National Standard
- Current versions undergoing adoption as Chinese National Standard

Other Known Adoption Activities

- Taiwan, Singapore, Australia, Korea, Canada,
- Russia (previous version) …

Medical Packaging

Sterilisation of packaged devices

Sterilisation Processes

Radiation

- Gamma
- Electron beam

Gaseous

- Ethylene oxide

Low temperature oxidative

- VHP

High temperature steam

…

Key Questions:

- Does the packaging material allow for sterilisation?
- Is the material compatible with the sterilisation process?
- After sterilisation, does the material and the package preserve sterility?

Sterility

Sterility is defined as being
free from living germs or micro-organisms

Historically: sterility viewed as absolute condition

Today: using sterility assurance level (SAL) to express probability of survivors (typically 10^{-6})

Before 1970: sterility test to assess sterilization efficiency

The problem: with sterility testing, there is no meaningful statement possible regarding the entire population

The Limitations of Sterility Testing

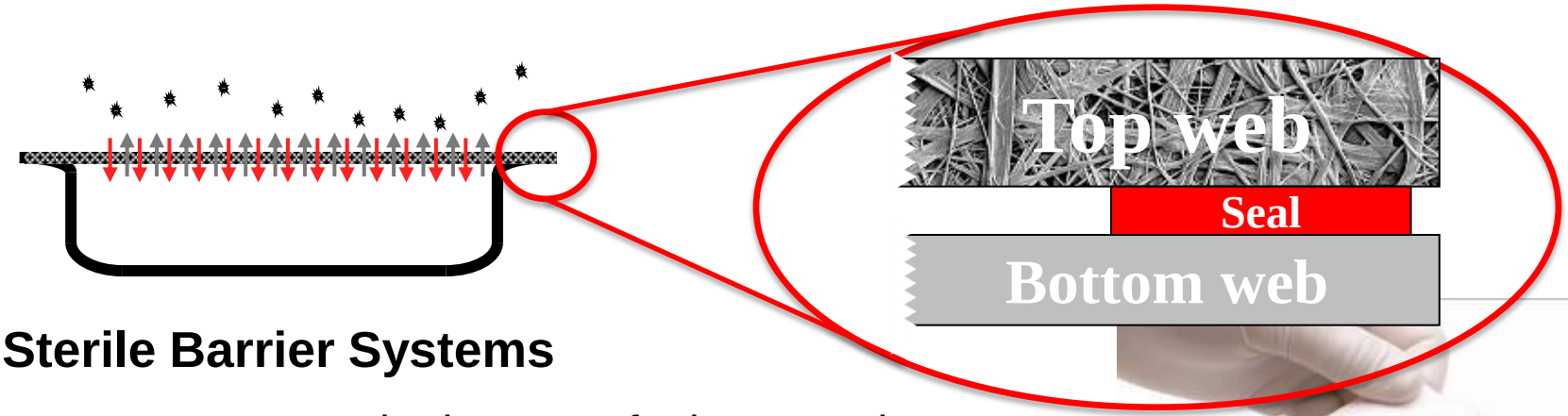
Let's assume the SAL of a batch is 10^{-2} which is relatively high.

- With one sample, the probability to accept that batch is $1\text{-}10^{-2} = 99\%$
- With 2 samples $(1\text{-}10^{-2}) \times (1\text{-}10^{-2}) = 98\%$
- With n samples $(1\text{-}10^{-2})^n$
- With 20 samples the batch is still accepted in 82% of the cases
- With 300 samples (with no false positives or negatives) the batch is accepted in 5% of the cases, which is still not really acceptable.
- With a SAL of $10^{-6} \rightarrow$ 3 million samples to achieve a similar confidence.

Conclusion

- Sterility cannot be verified
- What cannot be verified, needs to be validated
- For this reason sterilisation and medical packaging standards introduce
  - a number of requirements that have to be met and
  - validation steps that have to be followed successfully
- The overall objective is to achieve a high level of patient safety and protection

Sterile Barrier Systems



Sterile Barrier Systems

- Must prevent the ingress of microorganisms in order to maintain sterility

Films and non-porous materials

- Must be free of holes and cracks

Porous barrier materials

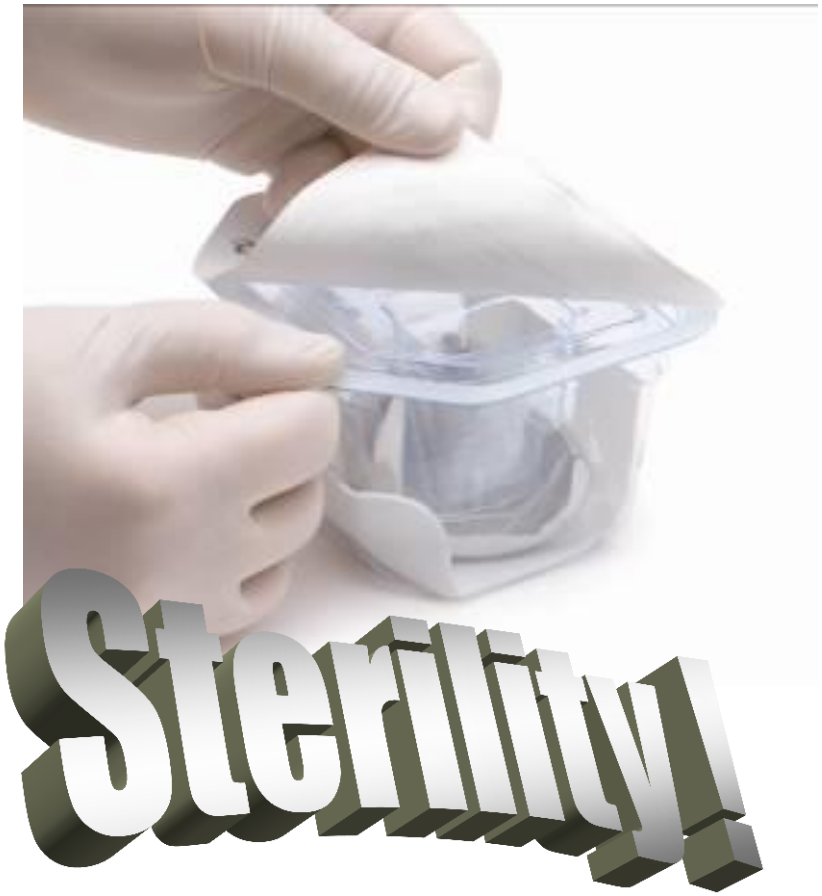
- Allow the sterilisation gazes to enter and exit the package
- Allow the package to adapt to changing pressures and temperatures as well as volume changes
- Adequate **Microbial Barrier Properties** are required!

Integrity of seals must be guaranteed

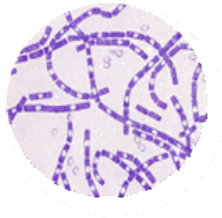
Protection through Transportation & Storage

Performance & Stability Testing is required to qualify the design

Handling & Aseptic Opening



Basic Functions of Medical Packaging



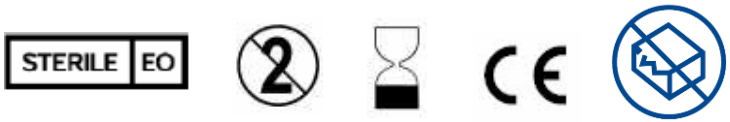
Allow for sterilization

Product protection

- Physical protection from damage and environment
- Maintain sterility and integrity until point of use
- Microbial barrier

Easy opening and aseptic presentation

Identify the product, clearly state information and cautions



In Summary…

What do EN ISO 11607 - Parts 1 & 2 Say?

International Standards, EN ISO 11607 – Parts 1 & 2 "*Packaging for terminally sterilized medical devices",* simply state that

You must:

- Design to minimize the safety hazard while meeting the requirements
- Test your package (validate the design)
- Validate your packaging process

And maintain your packaging process under control

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