Hello!

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I am here because I love to give presentations.

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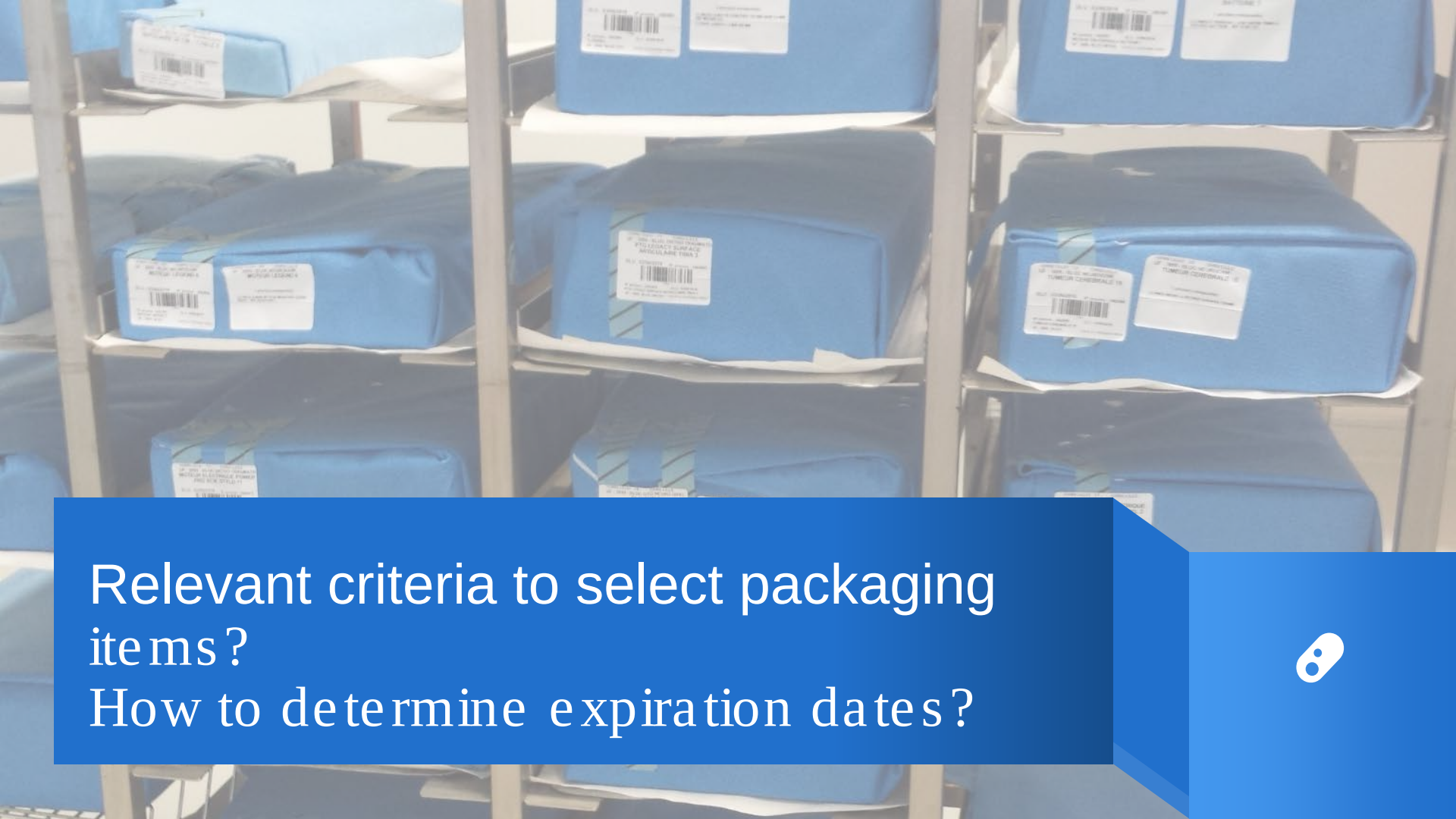


Relevant criteria to select packaging items?

How to determine expiration dates?

Wording for patient‘ safety

Assume

Think

Presume

Maybe

Uncertainty

Vagueness

imprecision

…..

HABITS

Validation

Record

Proof

Evidence

Control

Monitoring

Pragmatism

…..

EVIDENCE BASED PRACTICES

Packaging: issue

- Provide sterility after sterilisation and **keep** it
- Essential step of the process
- Participates in patient’s safety
- Shall not be the weak link

Packaging: Objectives?

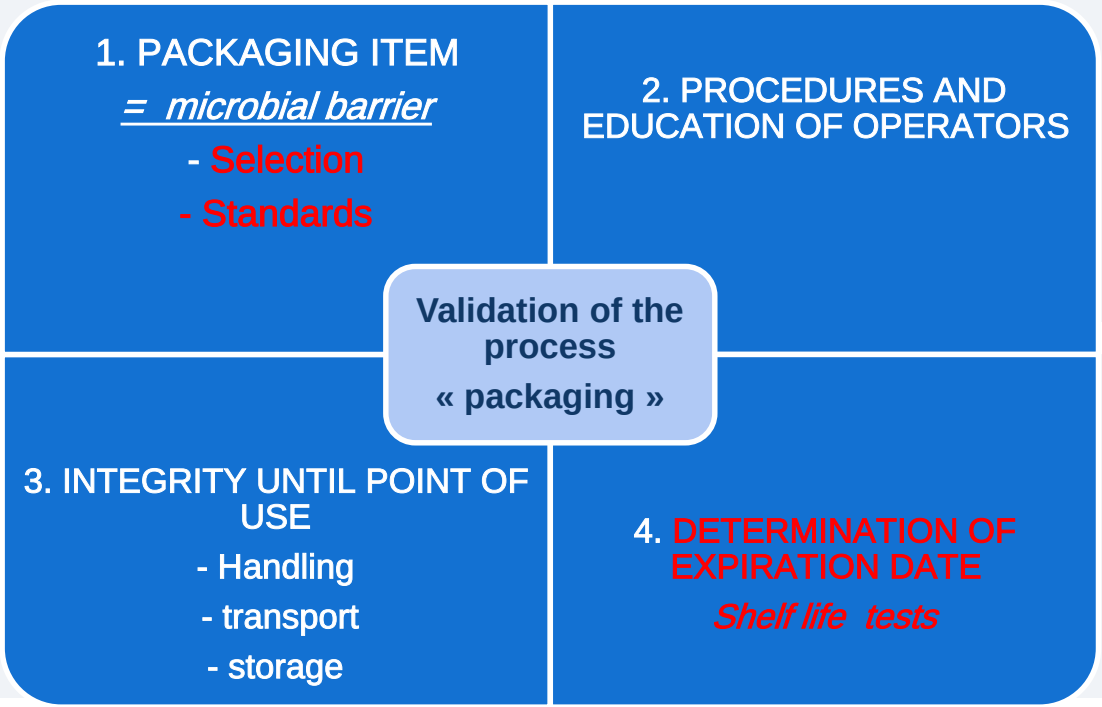
Preserve sterility of RMD until the point of use

Aseptic presentation and easy opening

MD's physical protection from damage and environment

Allow sterilisation

Packaging: Key factors?



Normative and regulatory context

1

ISO 11607

- Since 2006, different international packaging standards have been harmonized into one single document, applicable worldwide.

- *" This document is written as a general (horizontal) standard considering a wide range of potential materials, medical devices, packaging system designs and sterilization methods. It can be applied by* ***suppliers of materials or of preformed sterile barrier systems****, by* ***medical device manufacturers*** *or* ***health care facilities***

- *"Packaging for terminally sterilized medical devices should be designed and manufactured* ***to ensure that the MD can be sterilized and remain sterile*** *under documented storage and transport conditions until the sterile barrier system is opened or*

- Part 1: Requirements for materials, sterile barrier systems and packaging systems (rather for manufacturers)

- Part 2: Validation requirements for forming, sealing and assembly processes (for users in healthcare facilities)

ISO 11607 : points of interest for HCF

01	Definitions	✓ SBS (system barrier sterile) ✓ PP (protective packaging) ✓ PS (packaging system)
02	Recommendation on different critical points which have to be evaluated	✓ Evaluation by manufacturers/suppliers ✓ Evaluation by HCF is also required
03	Criteria and methods to test	✓ performance ✓ resistance ✓ permeability ✓ …
04	Validation requirements	✓ Elements to build a validation plan

ISO 11607 Definitions

- The Sterile Barrier System (SBS) is "*the minimum package that minimizes the ingress of microorganism and allows aseptic presentation of the sterile contents at the point of use*"
- The protective packaging (PP) if "*the configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use*"
- The packaging system (PS) is "*the combination of a sterile barrier system and protective packaging*".

SBS = Microbial barrier

PP is optional (risk analysis)

ISO 11607 : critical points for **healthcare facilities :**

Microbial barrier

Section 5.1.6 - *The following properties shall be evaluated*: **Microbial barrier**

Section 5.1.7 *Materials, **e.g. wrapping materials**, paper, plastic film, **nonwovens** or **reusable fabrics**, shall meet the following general performance requirements* : …. Materials shall have **microbial barrier properties which are consistent** with the specified acceptance criteria

Section 5.2.3 *Porous materials shall provide an **adequate microbial barrier to microorganisms**.*
Note : Evaluation of the microbial barrier properties of porous materials **can be done by challenging samples with an aerosol of bacterial spores or particulates**, under a set of test conditions which specify the flow rate through the material, microbial or particulate challenge to the sample, and duration of the test

ISO 11607 : critical points for **healthcare facilities :**

Stability testing

Section 5.1.6 *The following properties shall be evaluated*: ….**Any use by date limitations for pre sterilization storage and shelf life limitations for post sterilization storage**.

Section 8.3.1 **Stability testing** shall demonstrate that the **sterile barrier system maintains integrity over time**.
.

Section 8.3.2 **Stability testing** shall be **performed using real time aging**

ISO 11607 : critical points for **healthcare facilities :**

Maintenance of sterility

NOTE 1 See ANSI/AAMI ST65:2013 and Reference [21]. **The loss of sterility is regarded as event-related rather than time-related**.

Section 6.1.7 - Maintenance of sterile barrier integrity may be used to demonstrate **maintenance of sterility**.

ISO 11607 : critical points for **healthcare facilities :**

Requirements to fulfill (HCF)

Validation of packaging processes: HCF have to validate their packaging processes

Evaluation, selection : preformed sterile barrier systems should be evaluated before purchase and use.
HCF should ask (and obtain…) manufacturers for evidences about the claimed properties of packaging materials
Includes :
- recommandations for sterilization
- Maintenance of sterility

Correct use of packaging materials

Relevant criteria to select packaging items

2

How to select a packaging system?

How to select a packaging system?

- Check that the packaging items meet the standards requirements of ISO 11607
- Certificates:
  - which testing methods?
  - Which results?
  - which laboratory?

How to select a packaging system?

- Risk analysis including transport, storage :
  - SBS?
  - PP?

Sterility = Microbial barrier + Integrity

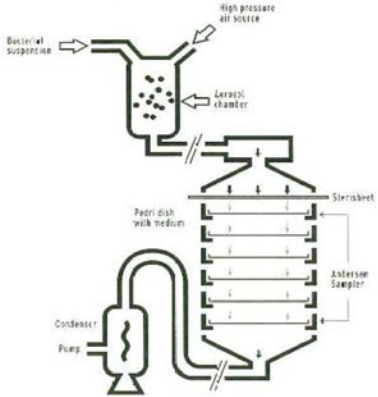
- Packaging items = combination of 2 parameters

Microbial barrier & Resistance

Evaluation of Microbial barrier

Evaluation often uses the BFE test (bacterial barrier efficency)

- the sheet is exposed to 2200 bacteria pushed by pressure
- bacteria which passed through are trapped on a bacterial culture medium



Evaluation of Microbial barrier :

Results of the BFE test = percentage

$$\frac{\text{Nb of bacteria which did not succeed to pass through}}{\text{total number of bacteria}}$$

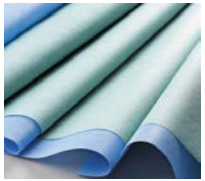
The higher the % is, the better the microbial barrier is

Test on what? 1 or 2 sheets together?

BFE	Nb of bacteria passing through the sheet
50%	1100
70%	660
90%	220
95%	110
97%	66
99%	22
≥ 99,9%	0-2

BFE test on different types of SBS

- A supplier must provide the results of BFE test

:	Paper Crepe	Non woven	SMS	New linen	Reused linen
					
BFE	>99,9%	99,8%	>96%	75%	59%

Linen:

It is not a microbial barrier !!!

=

- FORBIDDEN in a lot of countries
  + Bring particles (dust) in CSSD and OR

+ deposit of residual laundry compounds on instruments while sterilization

Containers / Microbial barrier

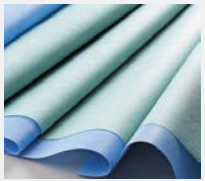
- Tested by manufacturer : when new
- What after uses?
- Controls recommanded by manufacturers = visual controls
- scientific?
- operator dependant
- To limit risks: maintenance

Containers / Microbial barrier

- Solution to use containers safely : add a crepe to ensure that the microbial barrier is effective

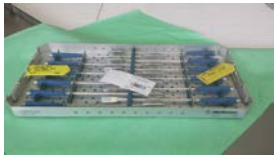
- Easier to take the tray out aseptically

Evaluation of Resistance

	Container	Linen	SMS	Non woven	Paper crepe
	++++++	++++	++++	+++	++
					

Evaluation of sets to pack

- Sets:
  - Size?
  - Weight?
  - Sharp edges?



Other parameters:

- Transport?
  - On site ?
  - Road?
  - Proper carts?

- Storage conditions

Summary : to make a relevant choice of packaging items

01	Evaluation of microbial barrier properties	✓ Tests from suppliers ✓ Certificates ✓ Check the authenticity of certificates
02	Evaluation of r	✓ Visual ✓ To link with storage and transport conditions
03	situation in the department	✓ Washers to clean the containers? ✓ Types of sets to pack
04	Local conditions	✓ storage ✓ transport

SHELF LIFE’s TESTS :

A CONTRIBUTION TO EFFICIENT PRACTICES

2

Shelf life tests: objectives

- Determine the expiration date in a scientific way
- Input to the validation of the process

Shelf life tests are essential to know

- What happens after sterilization?
- What happens during transport?
- What happens during storage?
- How long can the packaging maintain sterility?

And to determine relevant expiration dates

How to do it in HCF?

- Limited ressources
- Tests can be done in partnership with the supplier of packaging items

Which kind of data do we need in HCF?

- Already demonstrated :

Loss of sterility is regarded as event related rather than time related,

The question is:

- How long can MY kind of packaging maintain sterility after sterilization, transportation, storage, multiple handlings ???
- In HCF conditions

HCF CONDITIONS ?

- Steam sterilization :

In France , prevacuum and 134°C 18minutes

(= can be considered as a worst case scenario!!)

- Transportation:
  - Lift
  - Road
- Storage:
  In OT or CSSD
- Multiple handlings

SHELF LIFE Tests in HCF

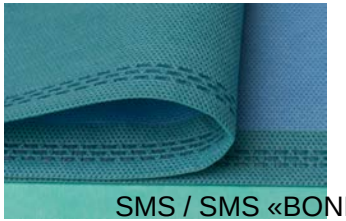
- Impossible to carry out in HCF
- Must come from manufacturers
- Studies in partnership between manufacturers and HCF

CONTEXT of the STUDY

- At STERINORD Lille University Hospital
- Take advantage of the launch of a new packaging materials :
  DUO® and BONDED®

to make a shelf's life study in partnership with the supplier

Cellulose / SMS « DUO »



SMS / SMS «BONDED »

The study

Aim:

- How long can the packaging keep the content sterile in real conditions of use?
- Determine expiration dates according to the results

Method:

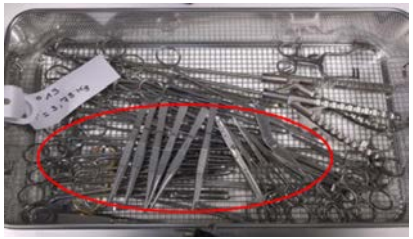
- Premise = pakaging item have demonstrated their sterile barrier properties efficiency (manufacturer data)
- In a HCF: **regular conditions of use**
- **Test the sterility of 6 instruments in a mesh tray wich have undergone steam** sterilization, transport and storage in HCF conditions
- aftert 6 months and 12 months of storage and weekly handling

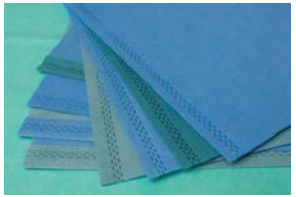
- By a third party (ICARE/ France)
- Partnership with the Manufacturer of the wraps (STERIMED)

The study

- Material

Same instruments in each set (clamps and scissors)





10 sets ½ DIN 1,06 to 1,11 kg
wrapped with DUO® 90x90cm
cellulose/SMS (enveloppe folding)

10 sets DIN 3,78 to 3,82kg
Packed with BONDED ® 100x1000cm
SMS/SMS
(enveloppe folding)

The study

Conditions:

- Sterilization in a steam sterilizer (prevacuum) at 134°C 18 minutes.
- Transport by road , lift and storage in CSSD (storage area)
- Handling every week

Sterility testing

- Step 1 = Test validation:
  - Growth media:
    - Liquid growth medium with thioglycolate
    - Liquid growth medium with casein and soya hydrolysate
  - Assessment of the fertility of the growth media for:
    - S.aureus
    - B.subtilis
    - P.aeruginosa
    - C.sporogenes
    - C.albicans
    - A.brasiliensis

Sterility testing

Step 2 =

- 3 clamps in each growth medium (1000 ml)
- Incubation
  - 14 days 30/35°C (thioglycolate)
  - 14 days 20/25°C (casein soya hydrolysate)

- Check at 7 days and 14 days
- No growth = sterile
- Negative control (same without clamps)
- Positive control : same + inoculum 10/100 UFC

Results

No growth
ALL the clamps and scissors are sterile after 6 months and 12 months

Now expiration date for RMD in the hospital is

12 months after sterilization

the expiration date policy of RMD at Sterinord

- Expiration dates are determined according tests carried out in our CSSD or others with same conditions
- *Eachtest* is significant only for one kind of packaging
- Each set of RMD is labelled : « Sterile unless the package is opened or damaged “
- the storage conditions are regularly audited

Consequences of a longer expiration date

Savings

- Less reprocessing
- Save time:
  - CSSD Operators
  - OR nurses
- Save wear and tear of instruments
- Save packaging items…..

➔ SAVE MONEY

Conclusion of the study

- The study allows us :
  - To set up the use by date in a scientific way
  - To fulfill the recommandations of ISO 11607 in terms of validation: we have now evidences to base the use by date system

- Our results can be adapted in all HCF using the same packaging items

(sterilization applied is a worst case /transportation & storage are « regular »)

- EVIDENCE BASED PRATICES

Take home messages

- Packaging is an essential step of the reprocessing of RMD
- Validation is required with special attention to:
  - The selection of packaging items
  - The education of operators
  - Determination of expiration dates
- Purchasing process shall include the users

WFHSS Guidelines

- https://wfhss-guidelines.com/

Thank you for
your attention!!!