Requirements for Packaging

S 1

S 2

The choice of packaging material is not only of very great importance for the sterilization department. It also is for the hospital and especially for the patient. For the sterilization department it determines the way of working. It's,for example, a very big difference if one opts for "soft" packaging than if one opts for containers.

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For the hospital and, in particular, the operating theatre, it determines the safety of the patient. The packaging and above all its integrity should ensure the sterility of the medical devices until the moment of use. That this is easier said than done and that important choices will have to be made,certainly with regard to the quality of the products, is beyond dispute.

1.The Medical Device Directive

S 4

Allow me first to situate packaging in the broader context of the European Medical Device Directive 93/42 / EEC (MDD).

S 5

Sterile barrier systems (SBS) are considered to be “accessories” to medical devices. They are class 1 devices (generally regarded as low risk) and the responsibility for the conformity assessment lies with the sterile barrier manufacturer. Devices that have to meet the essential requirements of the MDD must bear the CE marking of conformity when placed on the market.

S 6, 7

It is usual, to avoid confusion with the CE mark for the final product, for SBS's to carry the CE mark on the sales packaging rather than on the individual bag, pouch or sheet.

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Harmonized standards (EN) facilitate compliance with the essential requirements of the MDD.

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Whilst the essential requirements are obligatory, the standards remain voluntary.

S 10

But because the EN are the technical translation of the essential requirements, applying the norms automatically means conformity to the MDD and this is an obligation. Products meeting the norm offer conformity to the regulations, certainty to the CSSD, confidence to the user and safety to the patient!

S 11

The two-part standard EN/ISO 11607 harmonizes the requirements of ISO-11607:2000 and EN 868-1 into one global standard. This standard, ISO 11607- Packaging for terminally sterilized medical devices, consists of 2 documents: Part 1:2009: "Requirements for materials, sterile barrier systems and packaging systems" and Part 2: 2006: "Validation requirements for forming, sealing and assembly processes". One of the most critical issues in the development of the new standard was that the working group realized that the terminology was one of the major deficiencies of the existing standard. So the group decided to develop a set of four key

definitions that would be used consistently throughout both parts of the standard. These are the following:

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- Sterile Barrier System (SBS): The minimum packaging that prevents the ingress of microorganisms and allows for aseptic presentation at the point of use.
- Preformed sterile barrier system: The sterile barrier that is supplied partially assembled for filling and final closure or sealing, e.g., pouches, bags, and open reusable containers.
- Protective packaging: The packaging configuration designed to prevent damage to the sterile barrier system and its content from the time of assembly until the point of use.
- Packaging system: The combination of sterile barrier system and protective packaging.

One of the most critical characteristics of a sterile barrier system and packaging system for sterile medical devices is the assurance of sterility maintenance.

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The development and validation of packaging processes are crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users of sterile medical devices.

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EN 868 2 to 10 series describe the technical requirements imposed on specific types of packaging material. However one warning for the user: as is usually the case with EN, these are minimal requirements. It is possible, rather probable that the practice in your hospital is more demanding.

EN 868-2: Sterilization wrap

-Plain paper:
The maximum equivalent pore size diameter shall not exceed 50 µm… The water repellency of the wrap shall be such that the penetration time is not less than 30 s…

-Creped paper:
The maximum equivalent pore size diameter shall not exceed 50 µm…
The water repellency of the wrap shall be such that the penetration time is not less than 20 s…

EN 868-3: Paper for use in the manufacture of paper bags and in the manufacture of pouches and reels...the average of the pore diameters of the ten test pieces shall be lower or equal to 35 µm. No value shall be greater than 50 µm. The water repellency of the paper shall be such that the penetration time is not less than 20 s…

EN 868-4: Paper bags

EN 868-5: Heat sealable pouches and reels of material manufactured from paper and plasticThe overall width of the heat seal(s) shall not be less than 6 mm… If a process indicator is printed on the pouches the printing shall be in accordance with EN 867-2 and shall be not less than 100 mm2 in area.

EN 868-6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation. Paper specified in this part of series EN 868 is intended for use in part or complete manufacture of pouches or fill packs and lidding material for packs. ….the average of the pore diameters of the ten test pieces shall be lower or equal to 20 µm. No value shall be

greater than 30 µm. The water repellency of the paper shall be such that the penetration time is not less than 20 s…

EN 868-7: Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilization by ethylene oxide or irradiation

EN 868-8: Re-usable containers for steam sterilizers conforming to EN 285
A full size container, i.e. of one sterilization module size, shall be designed and constructed to allow a total load of up to 10kg to be sterilized in a sterilizer conform to EN 285.
Unless a maximum number of use-cycles is indicated by the manufacturer, the materials and construction of the container shall be such that the container will have a serviceable life of not less than 500 use-cycles.
The service life of the gasket shall be not less than 100 use-cycles or 6 months, whichever is the less.

EN 868-9: Uncoated nonwoven materials of polyolefines

EN 868-10: Adhesive coated nonwoven materials of polyolefines

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2.Overview of packaging materials

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2.1 Paper

100% wood pulp, 1 layer.For bags, paper-film pouches.Paper was the first alternative that replaced textile. It has a smaller pore size than textile. Because of its structure it has a depth effect: the micro-organisms are captured in the fiber layers. As a result it will, for micro-organisms, under normal conditions, be impossible to

penetrate dry paper. However, moisture may be a transport medium. During sterilization steam penetrates through the packaging. When paper is wet, it loses much of its original strength. Therefore stress in paper should be prevented. In other words the freshly sterilized packaging may not be manipulated before it is cooled down to ambient temperature!

S 17

That wet packages can cause serious problems was demonstrated by Stefanie Dancer in the article and presentation (WFHSS Turkey, 2013): “Investigation of an increase in surgical site infections among Orthopaedic and Ophtalmology patients”. Deadly infections were a result of the inadequate maintenance of autoclave components and poor handling practices by staff.

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2.2 Creped Paper

100% wood pulp, 1 layer. Creping is used to adjust the paper’s stretch and thickness, both of which have an effect on softness and absorbency. It is stronger than paper. It is the most cost effective material.

S 19

2.3 Softened creped paper

100% wood pulp, 1 layer. Additional softening of the paper is done on an off machine dry creper. These processes can weaken the crepe slightly but medical packaging can benefit from greater softness and stretch.

S 20

2.4 Reinforced creped paper

80% wood pulp and synthetic surface binders (Acrylic), 1 layer. A combination of drape-ability and softness with strength and water repellency.

S 21

The disadvantage of paper and of the various types of crepe is that they have a low tensile and tear resistance. They are less flexible and also more easily permeable to water. The material also has more memory so that it can rebound at the opening of a set. This complicates an aseptic technique.
But they are excellent moisture regulating and are vapor-permeable.They have also very good barrier properties.

S 22

2.5 Wet laid nonwoven

Wood pulp and synthetic fiber blend (Polyester), 1 layer. It is a with binders reinforced material, strong and well drapable. The pores are small thus guaranteeing a microbial barrier. Virtually lint free and a higher fluid repellency.

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2.6 100% synthetic fibers

Spunbound/ Meltblown/ Spunbound nonwoven.
Polypropylene, multi-layer (The meltblown layer –microfiber- makes the microbial barrier).The material with the highest mechanical resistance.They are far-reaching waterproof, good tensile and tear resistant. The condensate, that drips from the instruments, remains

in the package and must be removed during drying. This can result in wet packages. They are suitable for H2O2 sterilization.

S 25

Most of the synthetic fiber nonwovens and nonwovens are alcohol repellent so that they can be used also as a sterile field

S 26

2.7 Tyvek: polyolefines

Polyethyelene fibers for peel packs. They combine tear resistance, durability, breathability and microbial barrier. Not compatible with steam sterilization at 134° C (Spunboundpolyolefines melt in high temperature processes). Compatible with ethylene oxide and low temperature oxidative sterilization.

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2.8 Preformed packaging systems

2.8.1 Heat sealable pouches and reels

A peel pouch is typically constructed of a film on one side and either paper, nonwoven, polypropylene/polyolefıne on the other.
The big advantage of this kind of packaging is that the content is clearly visible. The peel-open system assures dust-free aseptic opening and presentation. The pouch should be such that when peeling it open, not the paper nor the laminate will tear. It should open neatly along the seals. A chemical indicator (Class 1) should be on the pouch indicating whether a product was processed.

S 29

The content should not be tightly surrounded by the packaging material (To avoid stress on the seal). It should be able to move freely inside the pouch. It is recommended that the packages should be filled to no more than three quarters of their length and minimum 2 cm of empty space should be allowed around each instrument. The medical device should be oriented to ensure aseptic opening – in other words correctly positioned inside the pack to enable easy removal of the package.

S 30

Where double packaging is required, it is important to position porous material against porous material and laminate against laminate because penetration of air and steam is only possible through the paper side. The inner packaging must not be folded so that the passage of steam is unhindered. The inner pouch should fit freely in the outer pouch (1 number bigger). Closures that compress the package should not be used (e.g.: ropes, strings, elastic bands, paper clips, staples).

S 31

Sealing is the most critical step in the process. The seal must be at least 6 mm wide.When you know that a Japanese study by Takako Kami showed that in 5% of normal peel packs and 10% in peel packs with gusset the sealing was inadequate, this raises serious questions.

S 32

In the poster: “Incomplete closure of gusset type sterilization pouch in clinical use” Ikeda once again pointed out the risk when sealing this kind of pouches. Peel packs with gusset are very difficult to close and are thus to avoid. The same applies to self-seal pouches of which the closing cannot be guaranteed either.

S 33

Making yourself bags out of reels is also not the best idea. By the "chevron" preformedpeel packs can be opened to the state of art. The “chevron” is lacking in homemade pouches making opening problematic.

S 34

If you do decide to use reels (in some cases there are no alternatives) just keep in mind the following recommendation:The reel is cut to the desired length.

S 35

When measuring the size, it is important to allow extra space for sealing the package and also for a flap with which the package can then be easily opened. Rolls are normally marked with a symbol indicating the correct peeling direction.

S 36

Writing or printing on pouches should only take place on the film side or on the paper outside the seals. The writing instrument should not have the potential for creating a hole or puncture in the SBS, i.e. ballpoint pens should not be used. Only markers intended for the appropriate method of sterilization should be used.

S 36 bis

If labels are used they must not impede the sterilization process, i.e. must not block the breathable area of the package. Labels must not cover the seals or any necessary information such as indicators.

S 37

If possible the peel packs should be placed upright (vertically on their sides) in the sterilizer, using partitions if necessary. Not too tight together, such that a hand can slide in between them. If it is not possible to place the packages upright, they can be placed flat with the porous material facing down. The packages should not be folded and they must not touch the chamber walls. The basket should not be packed too full, as the packages expand during the sterilization process and they must also to be allowed to breathe freely.

After sterilization any unnecessary handling of the packages should be avoided, as this would increase the risk of contamination.
The level of protection is considerably enhanced by using 2 layers – in other words by double pouching.

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Fiber free opening and aseptic presentation: The seals on the upper corner of the packs should be unattached first. The package should then be opened by pulling the laminate away from the paper material slowly and evenly to prevent the fibers from breaking and thereby causing contamination.

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2.8.2 Sterilizing containers

Well-designed containers offer the following features:
-Air removal and steam access through filters or valves.
-They ensure maintenance of sterility during storage.
-The lid can be removed completely from the bottom part thus facilitating aseptic opening.
-Labeling systems offer clear identification of the content.
-A tamper protection device shall give a clear indication whether a container was opened.

S 40

According to Dutch standards containers should be used with an inner packaging which is closed with sterilization tape. This gives a two-layer concept whereby aseptic opening becomes possible.
The inner packaging covers after opening the exterior, thus creating a sterile field.
A full size container is constructed to allow a total load up to 10 kg.

S 41

Disadvantages of containers include that:
-If condensation is not sufficiently removed there is a danger for wet loads. An appropriate sterilization program and load are required.
-The obligatory washing and disinfecting of the container after each use which means that more washing capacity has to be available. A container must be treated as an instrument of the set.
-The hermetic sealing of the container is guaranteed by the quality of the sealing system and by the way it is applied in the lid. All seals have to be checked regularly in order to detect changes in their integrity and porosity.

S 42

That this is not superfluous was demonstrated in checks made in 7 French hospitals. 30% of the containers were discovered to be leaking (Christophe Lambert).

S 43

2.9Cotton

Cotton is not suitable to use as SBS. The openings between the treads are too large and thus the fabric does not provide an adequate microbial barrier. Between brackets: Whenever textile is used, e.g. as

protective packaging it should contain its natural humidity. In other words it should be conditioned. If textile is too dry it may cause overheating of the steam and thus a failing sterilization. All linen packaging material should be held at room temperature (18°C to 22°C) and at a relative humidity ranging from 35% to 70% for a minimum of 2 hours prior to sterilization.

S 44

2.10Schimmelbush drums

Schimmelbush drums are not suitable as SBS neither. They can be used as protective packaging, mechanical protection of its content.In the past, most sterilizers had vertical round chambers. For various chamber sizes, drums were available. To allow steam in the drum the wall was perforated. Problems are that the metal band of the drum is closed after sterilization and thus the content may be recontaminated immediately after sterilization. The band does not provide an adequate closure, thus contaminated air can be sucked inside the drum. Also the lid does not provide a proper seal. Drums have hinged lids, hindering aseptic opening.

S 45

3.Recommendations for the use of the different materials

Creped paper in double layer packaging:
Weight up to 3 kg.
For small, medium-sized trays, light packs.

Reinforced creped paper in double layer packaging:
Weight up to 6 kg.
For small surgical trays.

Nonwoven in double layer packaging:
Weight up to 12 kg.
For surgical instrument trays.

In Europe these days more and more use is being made in packaging of a combination of one layer SMS and a layer of nonwoven to package sets. SMS on the outside because of the better mechanical strength, nonwoven inside for a better distribution of water in order to avoid humidity problems and wet loads.

S 46

Wrapping should not be too tight, but also not too loose. In order to obtain an optimal steam penetration in a pack, the packaging may in relation to the medical devices not be too big.

If a sterilization cycle must be repeated due to a malfunction or a cycle is aborted before completion, packages must be repacked prior to being placed into another sterilization cycle.

Dutch guidelines say that textile packages may have a weight of maximum 6 kg. The weight of a net of instruments (without packaging) must not exceed 8.5 kg. Heavier instruments trays may only be sterilized if by means of validation has been proven that the sterilization process is also effective for this load.

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4. Single or double wrapping?

What does the norm say? Packaging system should consist of a SBS and a protective packaging. There are 2 possible ways:

1. SBS made of 2 layers + 1 layer for protective packaging: The packaging system is thus made of 3 layers.

2. SBS made of 2 layers, whereby the outer packaging plays a double part: barrier and protection.

There is scientific proof available for double sequential wrapping.

S 48

1.David Duweltz (Arjo Wiggins) gives in a presentation the results of various packaging materials which have been subjected to the Bacterial Filtration Efficiency Test (ASTM F2101). This shows that double wrapping is better.

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2.Overthrow and Adrie de Bruijn have proven the effectiveness and superiority of double packaging in their articles which are published in Zentral Sterilization.

S 50

3.Dunkelberg proved that double packaging is better also for peel packs.

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5.How to wrap?

In the same study Overthrow also concluded that the way in which the sterilization wrap was folded, particularly with all cellulose based products such a creped paper, can make a substantial difference to the barrier efficiency of the final pack. Until a few years double sequential wrapping was recommended. Why?
-Bacterial filtration was improved.
-Guaranteed aseptic opening.
-Possibility to combine different generation wraps and offer a combination of the best characteristics and benefits of each

generation of products.
-Possibility to have a color coding.

These packaging systems for several years are challenged by new forms of packaging that allows simultaneous wrapping. The package is wrapped only once, but it requires a double-layered material bound on 2 or 4 sides and a by the manufacturer recommended way of wrapping.

The most widely used traditional methods, for sequential wrapping, are the envelope and the parcel method.

S 52

The most common and recommended folding is envelope folding. Because:
-It creates a more tortuous path which means a better barrier against the penetration of microorganisms. –The design is validated by event related sterility maintenance studies.
–It reduces handling during opening thanks to the tab.

S 53

Personally I prefer the parcel fold for the ease of wrapping.

S 54

A remark about wrapping out of my own practice.In contrast to a number of departments we put the packaging material beforehand on the packaging tables. This is a lot easier and more efficient than the use of trolleys for sheets which means that for each set each time the packaging material has to be laid out as well.

S 55

6.Recommendations for loading the sterilizers

Dennhofer says the following in “Wissenwertes uber die Dampfsterilisation im Gesundheitswesen”: The way of loading of the sterilizer will, in practice, not affect the evacuation of air, but it will affect the drying process.

S 56

When loading one has especially to take into account the products standing above each other. At the top the material is placed that generates little condensate and/or of which little condensate drips. Instruments and other heavy products of which a lot of condensate can run off are placed at the bottom. This especially goes for containers that can store a lot of heat and that produce a lot of condensate. If there is another container beneath the container the jointly produced condensate will flow off without affecting the drying at the end of the cycle. However, if a soft packaging is placed under a container it becomes completely wet. Because it is compressed by the overpressure this additional water is collected on the packaging. A sufficient drying is therefore difficult.

S 57

During evacuating overpressure is created in each package. Soft packaging releases the pressure and inflates. Thereby, the condensate that has accumulated at the bottom of the package, is pressed through the paper or nonwoven. It drips on the other goods. When there is another soft packaging inflated under a soft packaging, the condensate flows also off from this packaging. The products are dry. However, if there is a container under a soft packaging than it will cool down by the evacuated condensate. The stored heat is no longer sufficient to vaporize the combined amount of water. The container will not become really dry. Containers may, if suitable for

this purpose, be stacked on top of each other without drying problems. Soft packaging on the other hand should not be placed directly on top of each other or directly on containers because the water (in between them) will not be sufficiently removed. Filters and valves of containers may also not be covered: containers can be compressed by the external pressure in the sterilization phase.

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7. Opening sterile packages

-Before it is opened the package should be inspected for the appropriate appearance of the external indicator and the physical integrity of the packaging.
-Remove the outer wrap before entering in the OR not to introduce exterior contaminating elements.
-Enter the OR with the inner wrap only. If the material is a nonwoven resistant to disinfectants, it can be used as sterile field.

So far some practical information and some thoughts about the various types of packaging materials and how to use them. Good luck.

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Wim Renders,

Brugge, 23/02/2017