TECHNICAL SPECIFICATION

ISO/TS 16775

First edition
2014-05-15

Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2

Emballages des dispositifs médicaux stérilisés au stade terminal — Lignes directrices relatives à l'application de l'ISO 11607-1 et l'ISO 11607-2

Reference number
ISO/TS 16775:2014(E)

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Published in Switzerland

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 198, *Sterilization of health care products*.

Introduction

Sterile barrier systems need to ensure the sterility of their contents until opened for use and ensure aseptic presentation.

The sterile barrier system, depending on conditions of handling, distribution or storage, may provide adequate protection for the sterile medical device. In circumstances where the packaged and sterilized device undergoes repeated handling, additional protective packaging may need to be combined with the sterile barrier system to create a packaging system.

Each establishment should evaluate the performance of each sterile barrier system or packaging system before selection and implementation to ensure conditions for sterilization, storage, and handling can be met. Each establishment that manages sterile items should have a documented plan of education on how to store, handle and transport sterile items.

Regional differences in quality management systems and other requirements exist and these might involve different approaches to human resource management. In any case however a sound education process is a key element and facilities should ensure that its personnel are aware of the relevance and importance of their packaging and sterilization activities for the safety of the patient.

ISO 11607-1 specifies the requirements for materials, sterile barrier systems, and packaging systems, including the qualification of the packaging system design and evaluation of that design, ISO 11607-2 specifies the requirements for packaging process validation. Both of these documents provide standards to ensure medical device protection, the ability to sterilize, maintenance of sterile package integrity and aseptic presentation. The scope of each of these standards applies to health care facilities and wherever medical devices are packaged and sterilized. It is recognized that the circumstances of the application of these standards will be different when they are used in a health care facility from when they are used by a medical device manufacturer or reprocessor.

The conditions of use of this guidance may vary widely around the world. ISO 11607-1 and ISO 11607-2 and this guidance document provide a guideline for use, subject to interpretation by circumstance and regulatory environments. In some regions of the world health care facility compliance to the series ISO 11607 is a national or regional regulatory requirement, in some regions the series ISO 11607 is considered guidance for health care facilities. For instance, it is recognized that in certain regions or regulatory applications conformance to ISO 11607-1 may be demonstrated but not conformance to ISO 11607-2, which requires process validation by the user. In other regions, where compliance to both ISO 11607-1 and ISO 11607-2 is a national regulatory requirement, this document will also provide guidance on performing validation. Clause 3 of this guidance document is applicable to health care facilities and Clause 4 is applicable to industry. Further guidance is given in Annexes A to S that may be applicable to health care facilities and/or industry, as indicated.

In Europe ISO 11607-1 assists the conformity assessment procedure for manufacturers and is designed and used as a tool for demonstrating compliance with the relevant essential requirements of the Medical Device Directive. Compliance with the standard is always voluntary.

At the time of publication of this document, Amendments to ISO 11607-1 and ISO 11607-2 are in the ballot process. This guidance document already considers the revised versions with the understanding that specific references to numbering may have changed. Annex B of ISO 11607-1 on test methods has been extensively revised and should be considered when available.

Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2

1 Scope

This Technical Specification provides guidance for the application of the requirements contained in ISO 11607-1 and ISO 11607-2. It does not add to, or otherwise change, the requirements of ISO 11607-1 and/or ISO 11607-2. This is an informative document, not normative. It does not include requirements to be used as basis of regulatory inspection or certification assessment activities.

The guidance can be used to better understand the requirements of ISO 11607-1 and/or ISO 11607-2 and illustrates some of the variety of methods and approaches available for meeting the requirements of those International Standards. It is not required that this document be used to demonstrate compliance with them.

Guidelines are given for evaluation, selection and use of packaging materials, preformed sterile barrier systems, sterile barrier systems and packaging systems. Guidance on validation requirements for forming, sealing and assembly processes is also given.

This Technical Specification provides information for health care facilities (see Clause 3) and for the medical devices industry (see Clause 4).

It does not provide guidance for applications of packaging materials and systems after their opening. In the use of packaging for other purposes such as a "sterile field" or transport of contaminated items, other regulatory standards will apply.

2 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11607-1 and ISO 11607-2 and the following apply.

2.1
packaging system
combination of the sterile barrier system and protective packaging

[SOURCE: ISO/TS 11139:2006, 2.28]

Note 1 to entry: The packaging system includes the sterile barrier system and the protective packaging. However, if the sterile barrier system protects the medical device, facilitates aseptic presentation, and is resilient enough not to require additional protective packaging, the sterile barrier system would also fulfil the requirements of a packaging system. Protective packaging is not always necessary however aseptic opening/presentation has to be ensured in all cases.

2.2
protective packaging
configuration of materials designed to prevent damage to the sterile barrier system and its contents assembly until the point of use

[SOURCE: ISO/TS 11139:2006, 2.37]

Note 1 to entry: National or regional regulations may require that protective packaging is used to avoid the potential contamination of the surgical environment. These regulations may also require that the protective packaging is removed prior to introduction of the sterile barrier system into the surgical environment.

Note 2 to entry: Protective packaging protects the sterile barrier and the contents. Examples would include a dust cover, a box, transport tray.

2.3
sterile barrier system
SBS
minimum package that prevents ingress of microorganisms and allows aseptic presentation of product at the point of use

[SOURCE: ISO/TS 11139:2006, 2.44]

2.4
preformed sterile barrier system
sterile barrier system that is supplied partially assembled for filling and final closure or sealing

EXAMPLE Pouches, bags, and open reusable container.

[SOURCE: ISO/TS 11139:2006, 2.31]

Note 1 to entry: Preformed sterile barrier systems exist in a wide range of forms. The examples listed above are not intended to be all inclusive.

3 Guidance for health care facilities

IMPORTANT — Written instructions for use should be obtained from the packaging material and/or medical device manufacturer concerning their recommendations for sterilization and the subsequent maintenance of sterility of a sterile barrier system.

3.1 Test methods

For guidance on the requirements for test methods contained in ISO 11607-1 and ISO 11607-2, see the health care annexes of this document.

3.2 Guidance for conformance to ISO 11607-1

3.2.1 General guidance for materials, preformed sterile barrier systems and sterile barrier systems

3.2.1.1 Preformed sterile barrier systems should be evaluated before purchase and use. Therefore, the supplier should consider providing a statement of compliance to the applicable sections of ISO 11607-1 for the materials and/or preformed sterile barrier systems to be purchased. Before introducing associated components (e. g. labels, tapes, tray liners) into production, users should confirm that they will be suitable for use in their specific applications and conditions of use.

3.2.1.2 The key concepts that apply to all packaging materials and components are as follows:

a) they should be made of known and traceable materials with processes capable of meeting the requirements of ISO 11607-1 (see requirements in ISO 11607-1:2006, 5.1.3, 5.1.4 and 5.1.5);

b) they should be non-toxic, for guidance see A.3.3 (see requirement in ISO 11607-1:2006, 5.1.6);

NOTE 1 If the sterile barrier system or associated components contain natural rubber latex, the sterile barrier system should be labelled indicating natural rubber latex is present.

c) there should be documented evidence that the ingress of microorganisms can be prevented when demonstrated under test conditions which consider sterilization process, handling, distribution, transport and storage (see requirement in ISO 11607-1:2006, 5.1.6 and 5.2);

d) they should have a demonstrated ability to meet the required physical properties for materials and closures (such as weight or grade, seal width and seal strength), resist tearing or puncture, be capable of opening or peeling in a continuous and homogenous manner, without delamination tearing (see requirements in ISO 11607-1:2006, 5.1.7 and 5.1.9);

e) they should be compatible with the intended sterilization process and parameters capable of producing a sterile medical device (see requirement in ISO 11607-1:2006, 5.3);

f) they should be compatible with the labelling system; if present, have colour fast printing inks that do not degrade, fade or become illegible after exposure to the intended sterilization process (see requirement in ISO 11607-1:2006, 5.4);

g) they should be protected from the effects of environmental conditions (e.g. relative humidity, direct sunlight or fluorescent light, temperature) during storage (see requirement in ISO 11607-1:2006, 5.5 and Clause 7);

NOTE 2 Suggested storage conditions and shelf life should be provided by the material or preformed sterile barrier system manufacturer. If anticipated or actual storage is outside these conditions the manufacturer should be consulted.

h) they should allow aseptic presentation.

NOTE 3 Instructions for aseptic presentation should be provided by the manufacturer of the medical device and/or packaging system.

NOTE 4 The internet is a useful tool for finding information on materials, see Annex N.

3.2.2 Design and development guidance for packaging systems (ISO 11607-1:2006, 6.1 and 6.2)

3.2.2.1 Selection criteria

When a health care facility determines which packaging system to use, the design and development guidance for those packaging systems should be considered (see requirements in ISO 11607-1:2006, 6.1 and 6.2). When a health care facility uses a contract packager or sterilizer additional considerations are necessary (see Annex P).

The materials and systems chosen should:

a) be intended for use in medical packaging applications, as stated by the manufacturer;

b) be supported by technical information from the manufacturer confirming that it meets the requirements of ISO 11607-1 that relate to materials;

c) provide adequate protection for the medical device(s) during specified intended storage and transportation conditions to the point of use;

d) allow for and be compatible with the intended sterilization process, and have the ability to withstand conditions of the chosen process;

NOTE Not all materials are appropriate for all sterilization processes. Information on compatibility with a given sterilization process is typically provided by the manufacturer of the medical device and/or packaging system. For further explanation of challenges of common sterilization processes see Annex B.

e) maintain sterile barrier integrity until its time of use;

f) ensure aseptic presentation at the point of use;

g) allow a method of closure that is tamper evident;

h) allow for ease of identification of contents.

The user of the packaging materials should ensure that the sterile barrier system or packaging system complies with ISO 11607-1, that requirements concerning product compatibility are met and that processes for packaging, sterilization, storage and distribution are validated and controlled.

3.2.2.2 Selection considerations

The selection process at the health care facility should include an evaluation of the ability of both the sterile barrier system and protective packaging (if required) utilized to maintain the integrity of that sterile barrier system until its time of use and permit aseptic presentation at the point of use.

The choice of packaging components will be dependent on the risk associated with the medical device, its conditions of use, the storage and transport requirements and health care procedures practiced at the facility. These risks should be analysed by the health care facility and procedures put in place to mitigate/control those risks (see Annex K).

To choose the most appropriate material for the sterile barrier system and/or packaging system, the following should be considered:

a) Duration and conditions of storage may affect the type of sterile barrier system or packaging system needed. Some items may be stored for some time before use and may require a more durable sterile barrier system and/or the addition of protective packaging. The more the sterile barrier system or packaging system is handled the greater the probability that cracks, lid deformation, gasket damage, tears, holes or material separation may occur.

b) Size, weight and shape of the item to be sterilized should be considered. Some items will require more durable or more flexible sterile barrier systems than others.

c) If multiple types of packaging components are to be used it is important to verify that components are compatible with each other as well as the product contained inside and the intended sterilization process.

d) The means and conditions of transport should be considered. While in some cases routes are exclusively inside the facility, they can also be between different facilities. Exposure of the packaging systems to the uncontrolled environment may significantly increase the risk of loss of integrity of the package, compromise aseptic opening or contaminate the contents.

3.2.2.3 Assembly considerations

The following aspects should be considered:

a) Medical devices should be oriented to facilitate aseptic presentation.

b) Sharp items should be shielded so that the user is protected from injury and the sterile barrier system and medical device is protected from damage.

c) Associated components can be used inside the sterile barrier system in order to ease or facilitate the organization, drying or aseptic presentation (e. g. inner wrap, instrument organizer tray, tray liners or a containment device around the medical device).

d) The protection devices or associated components should:

   1) be non-toxic, be intended for use in medical packaging applications, as stated by the manufacturer;

   2) provide protection of the medical device(s) during storage and transportation to the point of use;

   3) allow for and be compatible with the intended sterilization process, and have the ability to withstand conditions of chosen process;

NOTE 1 Not all materials are appropriate for all sterilization processes. Information on compatibility with a given sterilization process is typically provided by the manufacturer. For further explanation of challenges of common sterilization processes see Annex B.

4) not undergo chemical or physical change to such an extent that the performance or safety is impaired or the medical device that they contact is adversely affected;

5) not compromise aseptic presentation;

6) allow for easy identification of contents;

7) be stored in a controlled environment to maintain cleanliness and fitness for use.

e) The weight of the packaging system and its contents should not exceed national regulations for manual handling.

NOTE 2 Current national regulations range from about 5 kg to 11,4 kg.

3.2.2.4 Labelling considerations

Part of the selection process should include consideration of how labelling is to be accomplished. The facility's labelling procedure for the sterile barrier system or packaging system should include the following:

a) When identification is performed in a health care facility:

— for pouches and reels the label should be placed on the film if applied before sterilization or on either side if after, the label should not conceal the device;

— for pouches and reels printing or writing should be placed outside the area enclosed by the outside dimensions of the seals;

— care should be taken when applying labels to filled sterile barrier systems so as not to damage packaging materials or contents.

b) Writing on wrapped packages should be on the closure tape, not directly on wrappers.

c) Special labels intended for a specific sterilization process may be written on. If these labels are used they should not impede the sterilization process (i.e. should not block the breathable area of the package).

d) Labelling should remain securely adhered to the sterile barrier system through the sterilization process and storage until the point of use.

e) Labels or closure tapes used as labels, and their adhesive systems should be non-toxic.

f) Only non-toxic ink that is suitable for use with the chosen sterilization process should be used.

g) Ballpoint pens or any writing instrument with the potential for creating a hole or puncture in the sterile barrier system should not be used.

3.2.2.5 Regulatory considerations

Specific national or regional regulatory requirements may apply. These requirements should be considered during the selection process for a sterile barrier system and/or for a packaging system.

3.2.2.6 Common choices for sterile barrier systems

3.2.2.6.1 General

Sterile barrier systems can be manufactured using mainly, but not limited to, the following concepts:

— sealable pouches and reels; and/or

— sterilization wrap; and/or

— reusable container.

Aspects to be considered in using these systems follow.

3.2.2.6.2 Sealable pouches and reels (preformed sterile barrier systems)

Sealable pouches and reels are typically purchased in two forms:

— The continuous roll or reel type is sealed along both edges. The roll is unwound and cut to the desired length. The medical device is placed between the two layers and both ends are sealed.

— The pouch is pre-cut to a specific size and sealed on three sides. The medical device is placed inside the pouch and the fourth side is sealed.

The following aspects should be considered:

a) The size of the pouch and the strength of the packaging materials should be based on the medical device which is going to be packaged. Items either too large for a package or with sharp edges will put extra pressure on the seals and the materials. This may cause rupture. There should be enough space to make seal closure possible. Too many small items in the sterile barrier system may cause the items to move around, rupture the seal, penetrate or abrade the package materials. Thin or fragile materials can be damaged during handling, transport, and distribution.

b) If not specified otherwise by the manufacturer the preformed sterile barrier system should be filled up to a maximum of 75 % of the inner surface area of the porous side. Care should also be taken to ensure that the distance from the seals is increased for products of greater height.

c) When two pouches are used, the inner pouch should be able to move within the outer pouch. This allows penetration of the sterilant and prevents the pouches from sticking together during the sterilization process. Folding of the inner pouch in order to fit into the outer pouch or folding of the outer pouches should be avoided in order to prevent stressing or damage to the sterile barrier system. For combining two pouches made from film and porous material it is important that film meets film and porous material meets porous material for identification of content and permeation of sterilant.

d) All pouch seals, including closure seal, should be smooth, i.e. without folds, bubbles, or wrinkles.

e) Self-seal pouches and those closed with tape may provide less security than heat sealed pouches. Sealing procedure should dictate that folds and closures should not be skewed, and care should be taken to ensure that both corners are well sealed, in order to ensure a complete closure across the entire end. Correct tape placement is critical to provide complete closure and thus sterile barrier system integrity. Special attention should be paid to proper method of closure to ensure package integrity.

f) Sealing devices should be able to control and monitor critical process parameters (e.g. temperature, pressure, sealing time/speed) in accordance with their validation criteria (e.g. alarms, warning system or machine stop in the event of any critical process parameter deviation). Operators should not modify critical process parameters unless they have been suitably trained, fully comply with appropriate operating procedures and stay within the validation process. The sealer should be capable of attaining the sealing conditions suggested by the preformed sterile barrier system

manufacturer. Sealing devices manufactured and intended for preformed sterile barrier systems should be used.

g) Closing accessories that compress the package or medical device should not be used (e.g. ropes, string, elastic bands, paperclips, staples or similar items).

h) The pouch should be loaded so that the enclosed medical device will be presented aseptically. For instance, the grip of the medical device should be placed toward the opening end. It should be noted that the seal areas are considered non-sterile when opened.[108]

i) The pouch should be opened according to the manufacturer instructions, if there is a specific orientation needed to prevent fibres delamination when opening that orientation should be followed. The formed package should show by design which direction the packaging has to be opened (e.g. arrow sign, shape of seal).

j) Reels (rolls) are used for the packaging of medical devices of diverse dimensions that do not easily fit standard preformed pouch sizes. Due to the fact that the packaging is sealed on two sides the pointed seal (chevron) is missing. In the absence of the chevron, the peel direction for reels should be provided by the manufacturer. Additionally, it is advisable to have more space above the seal that is intended to be opened according to the manufacturer's information.

NOTE In most areas of the world, certain sterile barrier systems, which are not peelable and require cutting to gain access to the product inside, are used in lieu of peelable preformed sterile barrier systems. For example, some of the sterile barrier systems formed using either sterilization bags, header bags, or pouches produced using reel material constructed from one layer of porous material and one layer of plastics film, sealed together along the parallel sides. In these applications, there is a greater risk of the product coming into contact with the non-sterile outer surface of the sterile barrier system and extra care should be taken to ensure aseptic presentation. This is achieved by cutting the top off and then inverting to allow the medical device to drop out onto a suitable surface without touching the outsides.

3.2.2.6.3 Sterilization wrap

Sterilization wrap comes in many sizes and grades to accommodate a wide range of applications. It is also available in single use or reusable fabric forms. Careful consideration should be given to the item to be wrapped and the technique to be used. Sterilization wrap can be used for wrapping of individual medical devices or medical devices in instrument cases, cassettes or instrument organizing trays.

The following aspects should be considered:

a) The grade of the sterilization wrap should be chosen according to the size, shape and weight of the medical devices to be wrapped or based on guidelines within the health care facility and wrap manufacturer's recommendations for use.

b) The size of the sterilization wrap should be selected to achieve adequate coverage of the item being packaged. It is essential to wrap the item securely to prevent gaps, billowing and air pockets from forming. The item should not be wrapped too tightly as this could create holes or tears in the wrap. It is also necessary that the sterilization wrap be large enough to accommodate movement of the wrap during the sterilization cycle without ripping or tearing. When choosing sheets of sterilization wrap the wrapper should be large enough to cover the medical device, but it should not be so big that it has to be wrapped several times around the medical device, as this may impede sterilant penetration.

c) Proper wrapping technique is essential to provide a tortuous pathway to impede microbial migration into the sterile barrier system. A wrapping technique can be used if the manufacturer has demonstrated the efficacy of this technique and recommends it for this application (see 3.2.2.1). The wrapping method chosen should allow aseptic presentation of the medical device. The health care facility should verify or validate the application in its own facilities per national or regional regulations. National standards or professional guidelines for wrapping techniques may be available. Examples are given in Annex C.

d) The sterilization wrapping technique should be designed in a manner that the opened wrapper should drape away from the sterile field.

e) The assembly surface area for wrapping should be flat, smooth, of adequate size, well lit and clean.

f) The wrapped package should be designed in a manner so that all edges are secured and do not interfere with aseptic presentation into the sterile field.

g) Closure systems should provide evidence of tampering.

h) Indicator tape is the most common closure for wrapped packages and there are different kinds of tape based on the method of sterilization. There are different tapes designed for use on woven or nonwoven wrappers. Closures that compress the package or medical device should not be used (e.g. ropes, strings, elastic bands, paperclips, staples or similar items).

i) When reusable fabrics are used as sterilization wrap there are additional requirements to ensure the suitability of the wrap prior to each use (see requirements in ISO 11607-1:2006, 5.1.11 and 5.1.12).

3.2.2.6.4 Reusable containers

A rigid reusable container is designed to hold medical devices and accessories and is sterilized without exterior wrapping. This container typically consists of a bottom or base with carrying handles and a lid that is secured to the base by a latching mechanism. It may contain a basket or tray to hold medical devices. The container incorporates a means for air evacuation and sterilant penetration. In regional or other standards it may be referred to as a "rigid container" or a "reusable container".

Instrument cases, cassettes or organizing trays are containment devices but not sterile barrier systems. They should be contained in a sterile barrier system.

When using rigid containers the following should be considered (see requirements in ISO 11607-1:2006, 5.1.10):

a) Only filters which are proven to be compatible with the specific container, particular sterilization process and capable of maintaining sterility should be used. Filter manufacturer should give documented evidence that demonstrates these capabilities.

b) Containers should be inspected and prepared in accordance with the manufacturer's instructions.

c) Tamper evident devices appropriate for the sterilization process should be secured in accordance with the container manufacturer's instructions and indicate that the sterile barrier system has not been opened intentionally or accidentally and therefore the contents exposed to potential contamination before intended use.

d) Each container should have a visible identification label and/or information card unless the container is designed for emergency-use sterilization and used for that purpose. ID label and card should be appropriate for the sterilization process.

e) The sealing surfaces of the base and lid should be inspected for damage at each time of use to ensure the proper closure of the container.

f) The instrument organizing tray dimensions should be suitable for use with the specific container and sterilization method.

g) Procedures should be in place for the cleaning, disinfecting and maintenance processes for containers after each use. These processes should be validated. Containers should not be used beyond the manufacturer's stated usable life (see requirements in ISO 11607-1:2006, 5.1.12). Procedures should be in place to ensure that the manufacturer's stated usable life is not exceeded (see requirements in ISO 11607-1:2006, 5.1.12).

h) As with all sterile barrier systems, to ensure aseptic presentation the outside of the container and the joint between top and bottom should not come in contact with sterilized contents.

3.2.2.7 Protective packaging

Protective packaging may be used to protect or prolong the shelf life of properly packaged and sterilized items that could be subjected to environmental challenges or multiple handling. Transportation or movement of the sterile barrier system in particular may require protective packaging to be applied to ensure that transportation and handling does not affect the sterile barrier system. Sterilized packages should be handled as little as possible. Loss of sterile barrier system integrity is regarded as event related rather than time related, this is why it is so crucial to guard against damage to the sterile barrier system.

When protective packaging is used, the sterile barrier system should be clearly identifiable. Protective packaging is designed to provide additional protection against damage and outside elements. If any protective packaging is to be applied after steam sterilization, it should be applied once the items are thoroughly cool and dry.

National or regional regulations may require that protective packaging is used to avoid the potential contamination of the surgical environment. These regulations may also require that the protective packaging is removed prior to introduction of the sterile barrier system into the surgical environment.

3.2.3 Packaging system performance testing (ISO 11607-1:2006, 5.3, 5.4, 5.5, 6.3)

Before any packaging system is used in a facility for the first time, its performance should be tested. Performance testing should allow verification on how well the sterile barrier system or packaging system holds up to the rigors of anticipated conditions of handling, distribution and transportation, before and after sterilization. The sterile barrier system needs to maintain its integrity without any holes, tears or seal/closure rupture that may be caused by the imposed stresses.

Performance testing should:

a) be evaluated through all the intended processes of sterilization, handling, distribution and storage, up to the point of use;

b) be evaluated for expected worst-case scenarios. In determining these, a number of factors should be considered. These include but are not limited to:

   1) Assembly of sterile barrier systems which contain the medical device configuration which presents the greatest challenge to the sterile barrier system (e.g. biggest, heaviest, most dense, sharpest items see ISO 11607-1:2006, 6.3.4).

   2) Samples for verification testing should be prepared to allow monitoring of the efficacy of the sterilization process depending on national or regional requirements for the monitoring of sterilization efficacy. Examples include but are not limited to biological, chemical indicators or process challenge device (PCD) by measuring and recording of physical parameters using thermocouples or data loggers. Determination of suitability may be carried out concurrently with validation of the sterilization process(es) to be used. Medical devices should be packaged and sterilized in accordance with the instructions of the manufacturer of the medical device and preformed sterile barrier system.

   3) Sterilization of the sterile barrier system in the intended sterilization process, considering mixed loads or fully loaded sterilizer chambers.

   4) Distribution / handling / storage / opening of the sterile barrier system.

Consideration should be given to the environment and other conditions in which the sterile barrier system or packaging system will be stored. Product pressed tightly into bins and storage locations increases the chance of shear action between two sets of packaged medical devices and can be detrimental causing pinholes and tears.

It is particularly important to consider all conditions of storage and distribution, as many sterilization sites are not adjacent to the point of use.