Sterile Barrier Association

Guidance Document
EN ISO 15223-1 new symbols for SBS

This revision of the guidance document includes learnings from applying the symbols and represents the consensus of the members of the SBA.

The Sterile Barrier Association (SBA) created and validated new symbols for Sterile Barrier System (SBS) configurations respective packaging systems for sterile medical devices for inclusion into EN ISO 15223-1. Reasons for inclusion of such symbols are to control specific risks with aseptic presentation, to comply with new legal requirements deriving from the EU-MDR 2017/745 and to provide additional user benefits.

Since the creation of this guidance document, the symbols have been taken over into EN ISO 15223-1 and the standard has been published in the official Journal of the EU as a harmonized standards for the EU MDR and IVDR.

Why do we need symbols for identification of SBS configurations?

- Sterile packaging systems prevent ingress of microorganisms and allow aseptic presentation.
- Sterile packaging systems are composed of at least one sterile barrier system which maintains sterility and allows for aseptic presentation.
- A Protective Packaging (PP) layer is often added to physically protect the SBS and its contents until the point of use. Protective packaging can be outside and also inside the SBS.
- In many cases, there is no difficulty differentiating the two. A paperboard outer dispenser box is obviously not a sterile barrier system but may still be designed to be used as protective packaging for transport and storage. A single sterile barrier system, e.g. a pouch, containing a sterile medical product, may be easily identified as a sterile barrier system.
- There are circumstances however, where it is difficult to differentiate between a validated sterile barrier system and protective packaging that looks like a sterile barrier system. In these cases, risks could arise during aseptic presentation: risks of contaminating the device and/or the sterile field and/or sterile gowns of operating room personnel.

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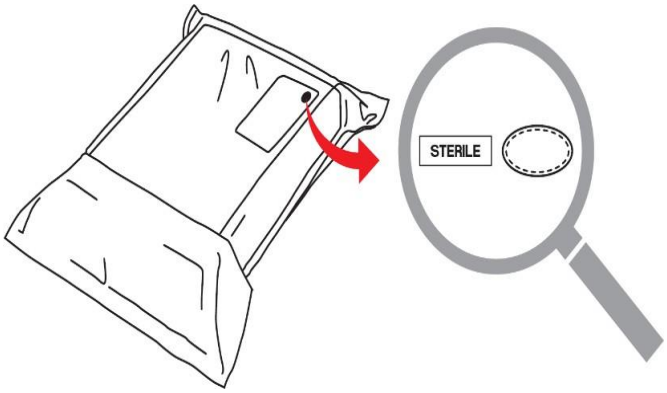
Symbols help to identify and differentiate between SBS and PP to control that risk:

The new symbols are composed from ovals, which are formed either from:

- a solid line which indicates a Sterile Barrier System layer (maintaining sterility) or
- a dashed line which indicates a Protective Packaging layer that is not a validated microbial barrier.

The symbols shall be printed on the label which identifies the medical device, adjacent to or in combination with the symbol 'sterile'. A typical packaging system configuration for sterile medical products could be made from a header bag, containing sterile products which are wrapped in protective packaging. The protective packaging does not provide validated barrier properties but is used to provide an aseptic presentation tool. In the diagram shown below:



- The outer solid line oval represents the header bag which is the Sterile Barrier System.
- The dashed line oval indicates that the medical product is wrapped in a protective packaging layer for aseptic presentation.
- The protective packaging layer does not provide validated barrier properties.
- Operating room staff can easily identify this packaging configuration, indicating they should place only the inner pack on the sterile field for aseptic presentation.

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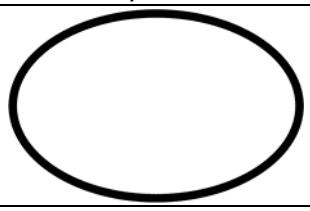
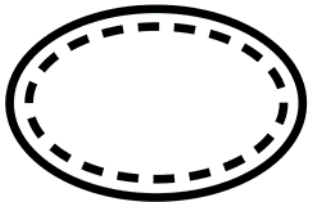
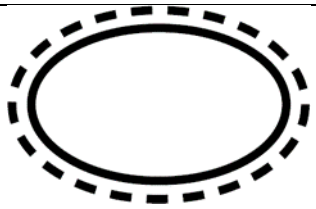
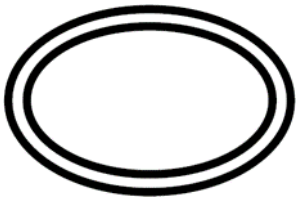
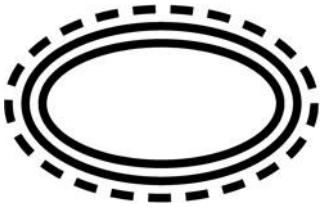
All new symbols in an overview:

Symbol	What it represents	Recommended handling / usability
	Ref: ISO 7000 - 3707 Single sterile barrier system	Aseptic presentation technique requires opening by an assistant nurse. (Sterile) Scrub nurses or surgeons must not touch the outer surface of the packaging. Pack must not be placed on sterile surfaces.
	Ref: ISO 7000 - 3708 Single sterile barrier system with protective packaging inside	Aseptic presentation technique requires opening of the outer packaging by an assistant nurse. Sterile nurses or surgeons must not touch the surface of the outer packaging. The inner layer with the sterile product may be handled by sterile personnel. Product in inner layer can be placed on sterile surfaces.
	Ref: ISO 7000 - 3709 Single sterile barrier system with protective packaging outside	Aseptic presentation technique requires opening by an assistant nurse. Sterile nurses or surgeons must not touch the outer surface of the sterile packaging. Pack must not be placed on sterile surfaces.
	Ref: ISO 7000 - 3704 Double sterile barrier system	Aseptic presentation technique requires opening of the outer sterile packaging by an assistant nurse. Sterile nurses or surgeons must not touch the outer surface of the sterile packaging. Outer packaging must not be placed on sterile surfaces. The inner sterile packaging may be handled by sterile personnel and can be placed on sterile surfaces.
	Double sterile barrier system with protective packaging outside	Aseptic presentation technique requires opening of the outer protective packaging and the outer sterile packaging by an assistant nurse. Sterile nurses or surgeons must not touch the outer surface of the sterile packaging. Outer packaging must not be placed on sterile surfaces. The inner sterile packaging may be handled by sterile personnel and can be placed on sterile surfaces.

Note: The 3-layer symbol has been validated but will not be part of ISO 7000 nor of ISO 15223-1.

Detailed descriptions on interpretation and application of the symbols are available in ISO 15223-1:2021 and EN ISO 15223-1:2021

Except for the 3-layer version, all symbols are available as graphical data files from the ISO 7000 online shop.

https://www.iso.org/obp/ui#iso:grs:7000:3704 https://www.iso.org/obp/ui#iso:grs:7000:3707
https://www.iso.org/obp/ui#iso:grs:7000:3708 https://www.iso.org/obp/ui#iso:grs:7000:3709

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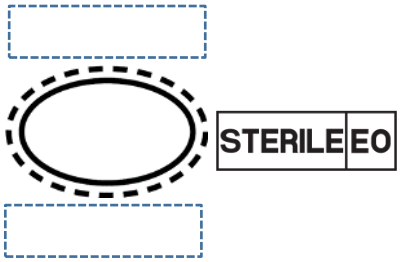
The placement of the symbols on the packaging:

According to EN ISO 15223-1:2021, the symbols shall be placed on the label which identifies the medical device, **adjacent to or in combination with** the symbol 'sterile'. The following combinations are possible:

Placement next to the symbol "sterile"	Placement within the symbol "sterile"
 Depending on the overall label design	 In case of small packages

Notes

- The symbol sterile will indicate the method of sterilisation, the table above indicates a medical device that has been sterilised using ethylene oxide as an example
- The manufacturer should determine the appropriate size for the symbol to be legible for its intended use.

Which layers of packaging should be labelled?

The MDR requires the packaging which maintains the sterile condition of a device ('sterile packaging') to have an indication permitting the sterile packaging to be recognized as such. The MDR does not specify which layers of packaging must be labelled.

ISO 11607-1: 2019 requires in subclause 6.1.8: "If the packaging system to be opened at the point of use consists of more than one packaging layer, the sterile barrier system(s) shall have an indication to be recognized as such."

According to ISO 11607, there is no requirement to label anything other than the SBS. However, the MDR also requires in annex 1 - GSPR 11.1, that the design allows for easy and safe handling and […] prevent microbial contamination to eliminate, or reduce as far as possible, the risk of infection to the patient.

The decision to label protective packaging should be an outcome of the risk evaluation, and

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packaging system design process to achieve acceptable usability for aseptic presentation. If protective packaging looks like an SBS, then the validated symbols should be used to control the risk of unintentional contamination of the sterile field. In the case of paper board protective packaging, the risk is low that healthcare professionals consider this an SBS, so no labelling would be required. Depending on the user requirements and the intended use, the manufacturer can decide the need to label the protective packaging if it is considered useful for healthcare professionals.

The objective of the usability evaluation for aseptic presentation, a new requirement of ISO 11607-1: 2019, is to demonstrate evidence that the design including the respective labels allows for easy and safe handling.

When conducting a usability evaluation, it is essential to consider the specific use case when assessing what is important in terms of labelling.

With commodity products packaged in double sterile barrier systems, it is possible that many different use cases apply with a wide range of potential users, and it is recommended to take a conservative approach when deciding which layers need SBS labels. For a commodity product in a double pouch, it can be possible for example, that one user removes the outer SBS, and another user decides to keep the still packaged product for another use scenario. In this case it can be important to apply SBS labelling on both SBS to leave no ambiguity. The picture below shows an example of double pouched instrument, showing double SBS symbol on outer pouch and single SBS symbol on the inner pouch.

On the other side, for a high-risk implantable device, the use case will be typically very defined and limited. The device will typically be handled only by trained personnel, and it is often the key focus of a given surgery. The packaging configuration with a double sterile barrier system will be designed for this use case and it is not intended to be used further on or to be stored

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with a single sterile barrier. The usability evaluation can be done for this specific use case to demonstrate that the risk of confusion is well under control so that it is normally not necessary to label all layers of the packaging. Labelling this last layer could even promote the storage of the device in a single barrier, which can lead to an unacceptable risk to the patient.

The figure below shows an example of a double sterile barrier system with an implantable device with labelling only on the outer sterile barrier system.

Double Barrier Package: Transparent Side

Double Barrier Package: Labeled Lid Side

Outer Barrier Removed

Inner Barrier

Note: The examples and pictures above have been chosen to illustrate the principles and are not exhaustive of the situations that can exist.

About the SBA

The Sterile Barrier Association (SBA) is the European trade association for companies who produce Sterile Barrier Systems (SBS) and associated equipment and accessories for the healthcare industry. Its mission is to be the recognized expert association in the healthcare industry, promoting the use of and providing education on the most suitable single use sterile barrier systems to ensure patient safety.

Most of the SBA members manufacture in Europe, many are global companies. All members are registered to ISO 9000 or another recognized higher level quality management system and many incorporate elements of GMP in their protocols. The majority are certified to EMAS or ISO 14001 as an environmental management system.

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