

Guidance Document

EN ISO 15223-1 new symbols for SBS

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 ISO 15223-1. Reasons for inclusion of such symbols are to mitigate specific risks with aseptic presentation, to comply with new legal requirements deriving from the EU-MDR 2017/745 and to provide additional user benefits.

Why do we need symbols for identification of SBS configurations?

- Sterile medical products are manufactured and processed by Medical Device Manufacturers (MDM's) and in healthcare or reprocessing facilities.
- 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 corrugated 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 or sterile packaging.
- 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

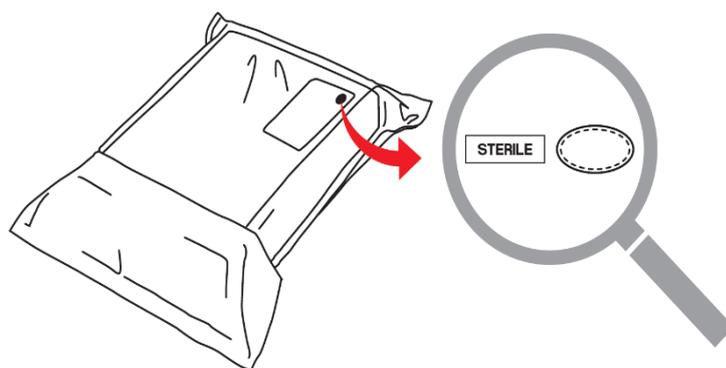
Symbols help to identify and differentiate between SBS and PP to mitigate that risk:

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, in proximity to 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.

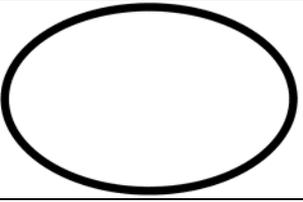
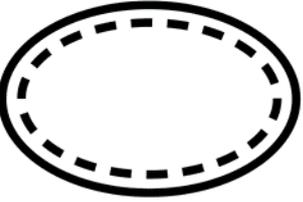
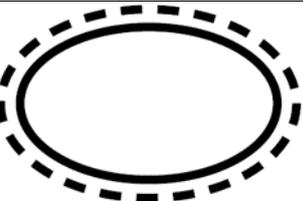
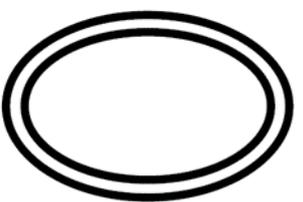
- Operating room staff can easily identify this particular packaging configuration, indicating they should place only the inner pack on the

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sterile field for aseptic presentation.

All new symbols in an overview:

Symbol	What it represents	Recommended handling / usability
	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.
	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.
	Single sterile barrier system inside protective packaging	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.
	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 inside protective packaging	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

A final draft version of EN ISO 15223-1 is due to be published in Q3 2019 and then symbols should be available as graphical data files from the ISO 7000 online shop.

Link to ISO online browsing platform: <https://www.iso.org/obp/ui#iso:pub:PUB400001:en>

Select Search tab; click on Graphical Symbols and search for Sterile Barrier

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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 recognised 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 recognised 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.

Director General

August 2019