Q & A's Document for Healthcare Professionals EN ISO 15223-1 new symbols for SBS

Sterile Barrier Association

Introduction

The Sterile Barrier Association (SBA) created and validated new symbols to inform users about the configuration of Sterile Barrier Systems (SBS) respective packaging systems for sterile medical devices. The objective is to assist healthcare users with performing appropriate aseptic technique.

The purpose of this document is to answer the most common questions related to applying the symbols and using packaging which includes these symbols. The SBA has also developed various videos which are available here in various languages. The video "Sterile Barrier Systems (SBS) – Aseptic presentation, a new way forward" provides guidance on the new symbols. Click here for the English version.

Q.1 Why do we need symbols for identification of SBS configurations?

Reasons for inclusion of such symbols are to control specific risks with aseptic presentation, to comply with the EU-MDR 2017/745 and to provide additional user benefits.

- 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. Together the PP and the SBS are referred to as a packaging system.
- In many cases, there is no difficulty differentiating the two. 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.

Q.2 Do the MDR symbol requirements apply to hospitals?

Only if hospitals customize or manufacture medical devices for use only within the healthcare institution, then the relevant general safety and performance requirements set out in Annex I of the MDR would apply. In this case, the requirements for labelling (see MDR chapter II, article 5) would be mandatory.
Under the MDR, medical device manufactures will start using these symbols for all sterile devices marketed in the European Union.
For reprocessing of medical devices, hospitals must follow the instructions for use of the respective medical device manufacturers which may also include information on packaging.
For consistency, the SBA recommends applying the SBS symbols also to at least multi-layer packaging systems used for hospital sterilization.

For all cases, the SBA recommends confirming the requirement by referring to applicable member states legislation.

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Q.3 Which layers of packaging should be labelled?

The decision to label protective packaging should be an output of the risk evaluation, as part of the packaging system design process to achieve acceptable usability for aseptic presentation. If protective packaging looks like an SBS, then the validated symbols can help to control the risk of unintentional contamination of the sterile field. In the case of paper board protective packaging, normally there is no risk that healthcare professionals consider this an SBS, so there would no labelling required. Depending on the user requirements and the intended use, the manufacturer can label the protective packaging anyway, because it is considered useful for healthcare professionals.

Q.4 Can you provide examples of typical packaging configurations with symbols?

Example of double pouched instrument, showing double SBS symbol on outer pouch and single SBS symbol on the inner pouch.

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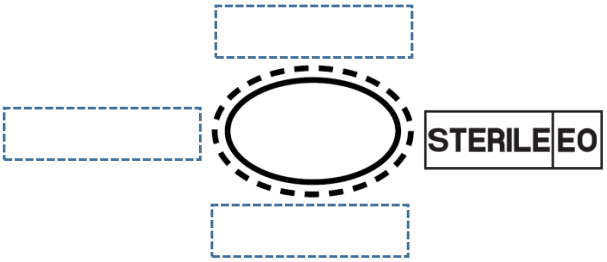
Q.5 How to place the symbols on the packaging:

According to ISO FDIS 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:

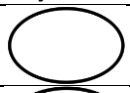
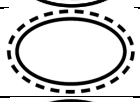
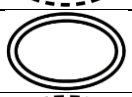
Placement next to the symbol "sterile"	Placement around to the symbol "sterile"
 Depending on the overall label design	 In case of small packages

Notes

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

Q.6 Where can I get graphical files of the symbols?

Detailed descriptions on interpretation and application of the symbols are available in ISO FDIS 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements. This standard is currently in the final voting stage (to be published soon). Symbols are part of the ISO 7000 suite of symbols. Except for the 3-layer version, all symbols are available as graphical data files from the ISO online browsing platform.

Symbol	What it represents & reference
	**Single sterile barrier system** Ref: ISO 7000 - 3707
	**Single sterile barrier system with protective packaging inside** Ref: ISO 7000 - 3708
	**Single sterile barrier system with protective packaging outside** Ref: ISO 7000 - 3709
	**Double sterile barrier system** Ref: ISO 7000 - 3704
	**Double sterile barrier system with protective packaging outside** Note: The 3-layer symbol has been validated, but will not be part of ISO 7000 nor of ISO 15223-1

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Q.7 What printing solutions are available for these labels?

Where possible the symbols should be printed either on labels or directly on the SBS (e.g., with the printer integrated into the heat sealer). If a label is used ensure that this does not interfere with SBS. When printing directly on the SBS it is mandatory to print outside of the sealing area.

Q.8 How are the symbols to be interpreted by the user?

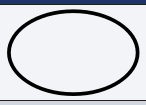
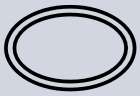
The new symbols are composed of ovals, which are formed either from:
- a solid line which indicates a Sterile Barrier System layer (maintaining sterility) or
- a dashed line which indicates a Protective Packaging layer that is not a validated microbial barrier.

ASEPTIC PRESENTATION: A NEW WAY FORWARD

Symbols identifying sterile packaging configuration

PRINCIPLE OF THE SYMBOLS — Protective Packaging (PP); Sterile Barrier System (SBS)

The symbols will always be accompanied by the symbol sterile STERILE

Symbol	What it represents	Layers of pack from outer to inner	Layers touched by: CIRCULATING NURSE	Layers touched by: SCRUB NURSE WITHIN STERILE FIELD
	Single sterile barrier system		✓	✗
		Sterile Product	✗	✓
	Double sterile barrier system		✓	✗
			✗	✓
		Sterile Product	✗	✓
	Single sterile barrier system with protective packaging inside		✓	✗
			✗	✓
		Sterile Product	✗	✓
	Single sterile barrier system with protective packaging outside		✓	✗
			✓	✗
		Sterile Product	✗	✓

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Q.9 What are the requirements of EN ISO 11607-1/2, the standard for terminally sterilized medical devices?

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 direct requirement to label anything other than the SBS. However, the MDR also requires in annex 1 – General Safety and Performance Requirement 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 objective of the usability evaluation for aseptic presentation, a new requirement of ISO 11607-1: 2019, is to produce evidence that the design including the respective labels allows for easy and safe handling. To comply with this, it is necessary to have a consistent labelling approach. EN ISO 11607-1 includes guidance on symbols in annex E and a reference to the upcoming revised standard for symbols ISO 15223-1, which will be published in 2021.

Q.10 What is the difference between ISO 11607 and EN ISO 11607?

ISO and CEN/CENELEC develop ISO 11607-1 and ISO 11607-2 in collaboration under the Vienna agreement. The only difference in the EN ISO version is the European foreword and the annex Z indicating the presumption of conformity with specific requirements of the European directives or regulations for medical devices. EN ISO 11607-1: 2020 has been published later than ISO 11607-1:2019 without annex Z as discussions are still ongoing regarding harmonization with the MDR.

Q.11 When does the new version EN ISO 11607: 2020 apply?

EN ISO 11607 parts 1 and 2 have been made available on the 15th of January 2020 with a 6 month transition time, the date of withdrawal of the old version is the 31st of July 2020 (see standards.cen.eu)

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.