

GUIDANCE DOCUMENT

Usability of sterile barrier systems for medical devices

The packaging around medical devices that allows those devices to be sterilised, provides a microbial barrier and maintains sterility effectively up to the point of use is known as a sterile barrier system (SBS). A sterile barrier system is an essential part of a sterile medical device and plays an essential role in the fight against health care associated infections. In order to maintain the sterility of a medical device, it is important that the sterile device, in its sterile barrier system, is not only transported and stored according to recommended conditions, but it is also used correctly at the point of use. Packaging designs should consider all usability aspects as part of the risk management process to minimize user errors and to protect the patient. This includes easy and correct product identification, excellent label readability and the ability to present the product aseptically which is also a regulatory requirement.

According to **EN ISO 11607-1** aseptic presentation is defined as *introduction and transfer of a sterile product using conditions and procedures that exclude microbial contamination.*

The ability to present a product in an aseptic manner is a key design feature of the SBS:

6.2.2 The sterile barrier system shall allow the product to be presented in an aseptic manner

5.1.9 c) Peel-open characteristics (of a sterile barrier system) shall be continuous and homogeneous, without delamination or tearing of the material that can affect aseptic opening and presentation.

Presenting a product in an aseptic manner requires the application of proper **Aseptic Technique** adapted to the specific design of the sterile barrier system. The objective of the aseptic technique is to prevent microbial contamination of the products occurring by non-sterile hands, the outside of the sterile barrier system, clothes, surfaces, equipment - anything potentially charged with bio-burden that could come in contact with the product when it is removed from the sterile barrier system.

The following are general principles that apply to all peelable sterile barrier systems opened in an operating room environment, the most demanding of all environments. These principles and process steps can be used when designing a device/sterile barrier system to optimize package usability in particular aseptic presentation or when verifying that the design actually works as intended. The SBA has produced a video on the subject which is available [here](#).

Proper aseptic technique normally requires 2 interacting persons,

- a person wearing sterile gloves, face mask and gown as per local applicable procedure, often referred to as the scrubbed person
- a second person to open the sterile barrier systems and to present the products. This person should wear appropriate clothes, face mask etc. and perform appropriate hygiene control following local procedures and practices to minimize the recontamination potential of the sterile products and the sterile field.

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A sterile field is created following local applicable procedures, typically with a sterile drape over a table to place the sterile products onto before they are used during a procedure. It is important to protect the unpacked, exposed device from microbial contamination through breathing, talking or the shedding of particles and micro-organisms originating from the skin of personnel when reaching over the device. Excessive movement in the area should be avoided and the time of exposure before the device is used should be minimized.

Aseptic Presentation in 6 Steps for peelable sterile barrier systems:

1. **Inspect:** the sterile barrier system must have full integrity to maintain sterility. Key aspects to consider are punctures, holes or seal channels or openings, anything that would compromise integrity, and as a consequence could result in a loss of sterility.
2. **Read** the label, the symbols or indicator if available
 - a. Check if it is the correct device, set or kit (product identification)
 - b. Check the use-by-date to make sure that it has not expired
 - c. Check the sterilisation indicator if applicable
 - d. Look for any specific checks or actions required depending on the device, the procedure to be performed or the traceability requirements to be fulfilled.
3. **Position:** the person opening the package should be positioned close to the scrubbed person in an area with sufficient room, with an appropriately controlled environment and with sufficient light. There should also be a supporting clean table space available depending on the type of sterile barrier system to be opened.
4. **Open:** the seals of the sterile barrier system should be peeled slowly and evenly such that
 - a. the peeling is started on the specified side of the SBS
 - b. the peeling direction is respected if specified
 - c. the creation of particles is minimize during the peeling operation
 - d. the materials are not tearing or delaminating
 - e. the product is maintained in position and does not come in contact with the unsterile areas of the sterile barrier system (the seal area is considered unsterile)
 - f. the arms and the body do not enter into the area above the opening of the SBS that is being created
 - g. an opening is created large enough to remove the product without touching unsterile areas. (It may be necessary to fold the flaps backwards to create sufficiently large openings)

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5. **Present and Transfer:** the device should be presented to the scrubbed person making sure that there is no contact with any unsterile areas during the transfer. It is then placed securely on the sterile field. A direct transfer to the sterile field by the person that opened the SBS is practiced, but is not recommended, (e.g. by tossing it onto the table) since there is a higher risk of contamination of the device and the sterile field.
6. **Discard:** the sterile barrier system is discarded following local procedures and practices.

Usability aspects of sterile barrier systems shall be considered in the context of the clinical environment when designing a sterile barrier system and when defining the way the product(s) is (are) positioned in the SBS. It should also be described in the instructions for use. Usability evaluations should be conducted to verify that the design actually meets the design criteria.

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