Judging a Book By Its Cover: Assessing Sterile Barrier Packaging Systems

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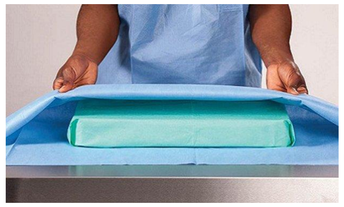
ISO 11607-1 (2020)

One of the most common sources of infectious agents causing healthcare-associated infections (HAIs) includes medical equipment. Clinical care nurses have the opportunity to help prevent HAIs by performing, monitoring, and assuring compliance with aseptic work practices as they handle such medical equipment.

The design of sterile barrier system (SBS) packaging has a direct effect on the potential transmission of infectious agents throughout clinical settings. The medical device industry can assist nurses and other clinical staff in this goal by ensuring the design of their packaging facilitates successful aseptic presentation to sterile fields.



The latest version of ISO 11607-1 (2020) explicitly calls for human factors evaluation of sterile barrier systems to validate that users can effectively handle and open the packaging as designed without compromising the sterility of the items inside.

Section 7 of ISO 11607-1 dictates that "***a documented usability evaluation shall be conducted to demonstrate that the sterile contents can be aseptically removed from the sterile barrier system for presentation***", meaning that medical device manufacturers should validate that their device packaging is able to be used by target end users to maintain aseptic technique.

In designing a usability study for assessing aseptic presentation, the standard specifically calls for evaluation of the following:

a. the ability to **identify where to begin opening**;
b. the ability to **recognize and perform the technique required to open the sterile barrier system without contaminating or damaging the contents**; and
c. the ability to subsequently **present the contents aseptically into the sterile field**.

Formative and summative aseptic evaluations of packaging systems can be conducted in conjunction with other formative and summative studies where usability of the device itself is being evaluated, or they can be conducted as standalone studies focused solely on the usability of the packaging.

Aseptic Methods & Success Criteria

When designing aseptic presentation studies, it is important to pre-determine what potential presentation techniques may be used, because there are often multiple methods of successfully aseptically presenting a device.

Because SBS packaging designs vary widely, this will involve researching how the particular type of device is typically presented in the intended use environment(s) and also thinking carefully about which parts of the packaging (single barrier vs. multiple barriers, individually wrapped components?) and contents inside must remain sterile. From this exercise, the success criteria can be defined.

Example: Imagine a chest drain is packaged within a cardboard tray that is wrapped with blue central supply room (CSR) wrap and then encased in a sealed Tyvek/Nylon sterile pouch.

Users may opt for the '**Picking Technique**', where they open the outer pouch and present the CSR-wrapped product inside for the sterile person to pick out.

Or, they may choose the '**Placing Technique**' where they place the wrapped device on a prep table and open the CSR wrap to reveal the contents inside for a sterile person to pick up and bring into the sterile field when ready.

The success criteria for each of the above may be slightly different depending on the presentation technique chosen by the participant. For example:

A. The ability to identify where to begin opening.
1. ***Picking Technique****: User opens the sterile pouch from the intended opening;*
2. ***Placing Technique****: User opens the sterile pouch and CSR wrap from the intended openings.*

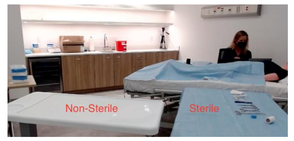
B. The ability to recognize and perform the technique required to open the sterile barrier system without contaminating or damaging the contents.
1. ***Picking Technique****: User opens the pouch without contaminating or damaging the contents inside.*
2. ***Placing Technique****: User opens the pouch and the CSR wrap without contaminating or damaging the contents inside.*

C. The ability to subsequently present the contents aseptically.
1. ***Both Techniques****: User does not breach sterility when presenting the contents.*

Aseptic Study Design Considerations

When executing an aseptic presentation usability evaluation, it's critical to introduce as much **realism** into the study environment as possible to minimize potential study artifacts. Tips to keep in mind:

- **Clearly delineate which areas of the test environment are considered sterile vs. non-sterile**. This can effectively be done with the use of blue drapes and by staging the types of surfaces, equipment, and accessories that healthcare professionals might have on hand in each area.



- **Wear the appropriate personal protective equipment (PPE).** Non-sterile healthcare professionals whose job it is to present devices to the sterile field aseptically may not wear any gloves during the setup process, or they may wear basic nitrile gloves. However, the sterile person receiving the device would be wearing sterile gloves (and possibly a gown, mask, hair net and booties, depending on the intended use environment). In one of our recent studies, an LHF team member acted as the sterile "confederate" and dressed accordingly.

- **Explicitly communicate the intended job roles and use scenarios to the participant**. The success of the evaluation hinges upon the study participant understanding whether they are acting as the non-sterile person (often called a Circulator in the OR setting) or the sterile person (often called the Scrub Nurse in an OR setting) and what the end goal of the task is (i.e., get the device into the hands of the Scrub Nurse without breaching sterility, or open the device onto a prep table without breaching sterility).

If use errors, use difficulties, or close calls are observed during the evaluation, standard root cause probing techniques should be leveraged to determine whether the design of the SBS packaging contributed to any of the issues.

If there are patterns of use errors or difficulties related to packaging design, the SBS system may need to be redesigned or additional information may need to be provided to users.

The manufacturer is then responsible for conducting a second aseptic presentation usability evaluation to validate that the new design or the new instructions lead to successful results.

References:
- Gastmeier P, Stamm-Balderjahn S, Hansen S, et al. How outbreaks can contribute to prevention of nosocomial infection: analysis of 1,022 outbreaks. Infect Control Hosp Epidemiol. 2005 Apr;26:357–61. [PubMed] [Reference list]
- https://www.ncbi.nlm.nih.gov/books/NBK2683/

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