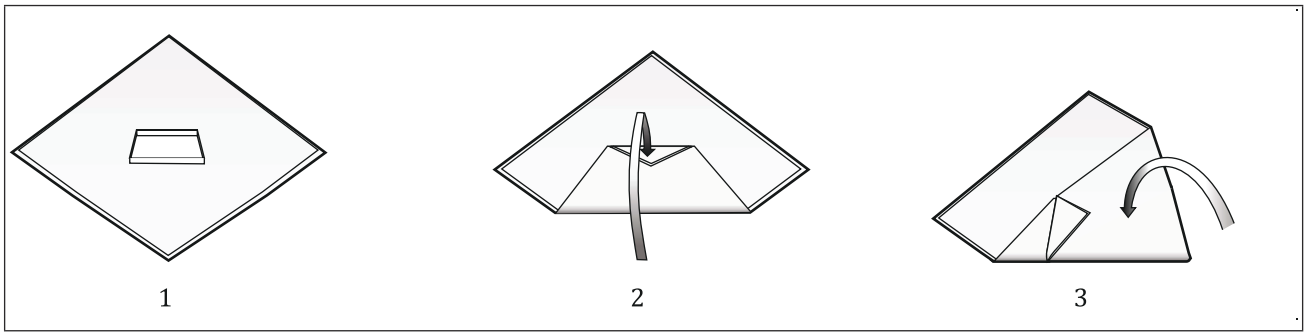


Figure B.1 — Simultaneous double envelope method steps 1 to 3

Step 1:

The medical device(s) is/are placed on the middle of the sheet in such a way that its edges form a right angle with the sheet diagonals.

Step 2:

The sheet is drawn upwards over the broader side of the medical device(s) and folded back parallel to the longitudinal edge so that the sterilization load is completely covered. Thereby, a triangle (corner) is formed which enables aseptic opening.

Step 3:

The same procedure as shown in step 2 is carried out from the right to the left.

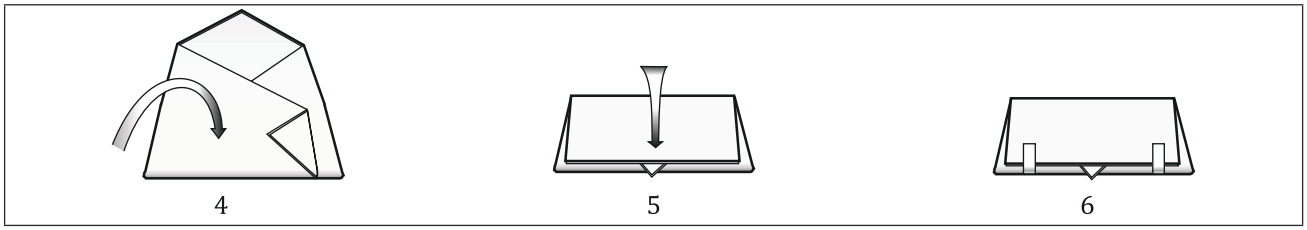


Figure B.2 — Simultaneous double envelope method steps 4 to 6

Step 4:

The same procedure as shown in step 3 is carried out from left to right.

Step 5:

The last part of the sheet is now drawn over the medical device(s) to be wrapped. The corner of the sheet to be covered is tucked into the envelope until it just sticks out.

Step 6:

The sheet is closed with a suitable closure system with or without process indicator.

The unwrapping steps for aseptic presentation are illustrated in Figure B.3. This figure illustrates the simultaneous double wrapping, but the single wrapping works in the same way. A usability evaluation (see 5.22 of this document) should be performed considering the actual use conditions and environment.

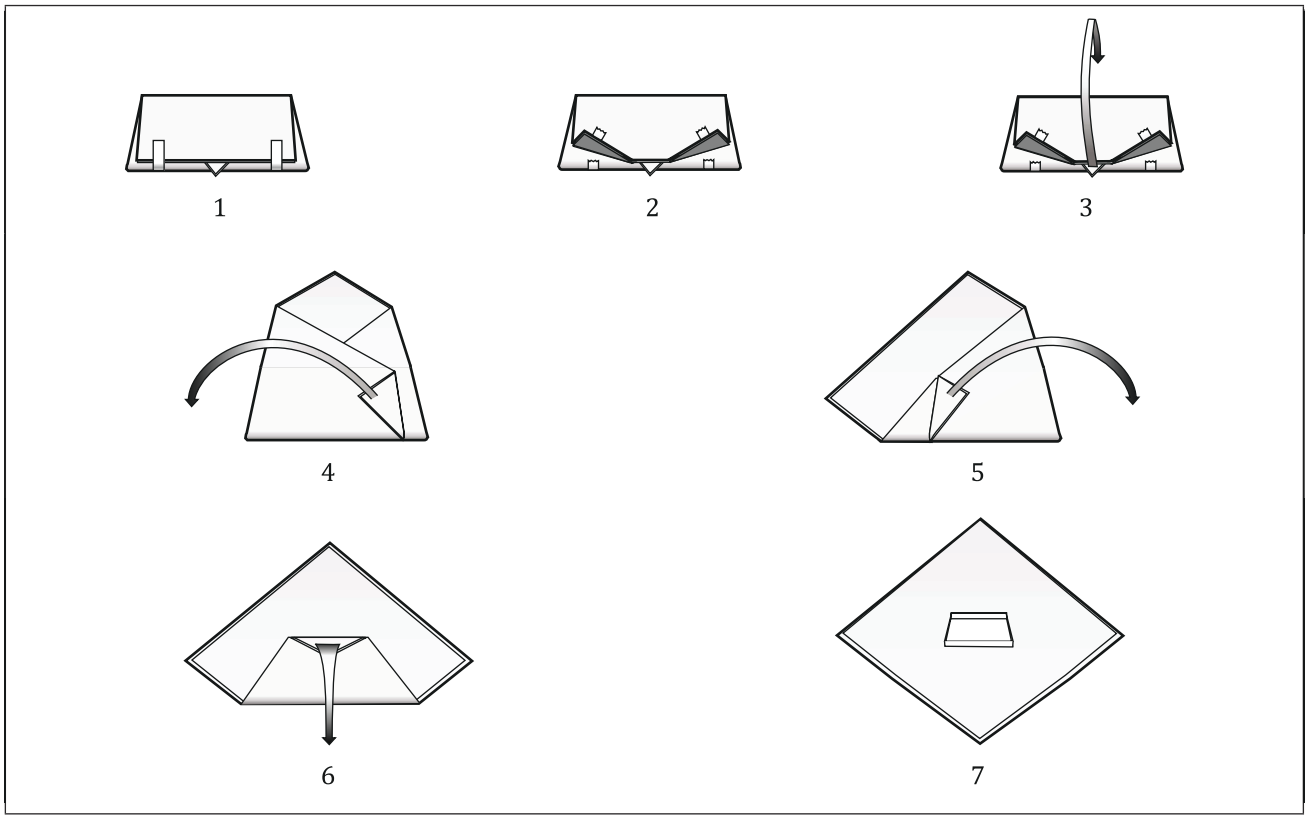
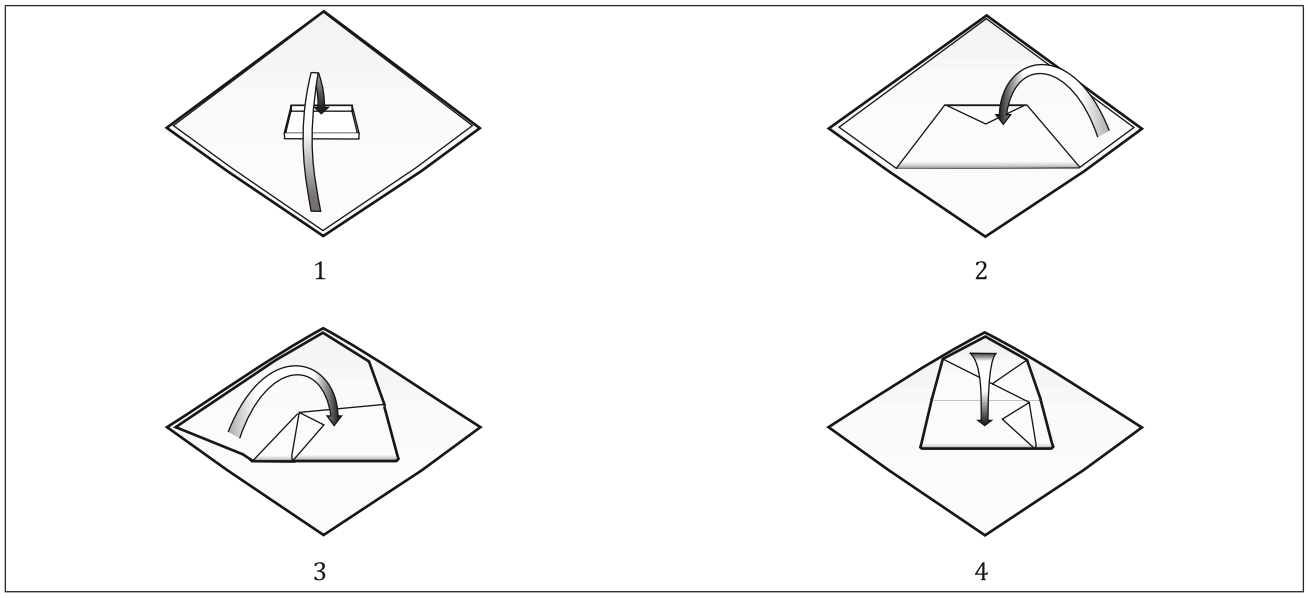


Figure B.3 — Aseptic opening of simultaneous double envelop wrapping

B.4.3.3.2 Sequential double envelope method

Figure B.4 illustrates the sequential double envelope method.



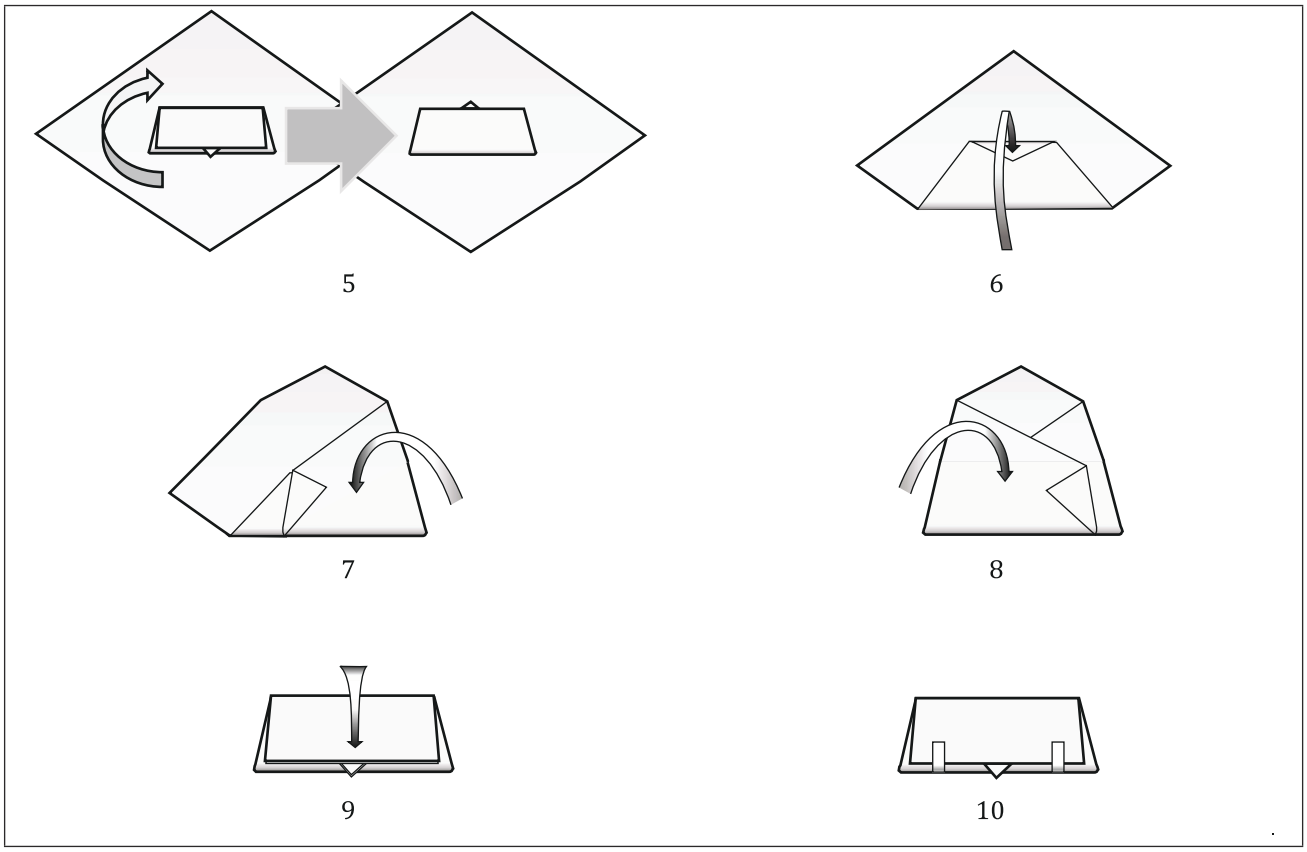


Figure B.4 — Sequential double wrapping envelope method

The unwrapping steps for aseptic presentation are illustrated in Figures B.5 and B.6. These figures illustrate the unwrapping sequential double envelope. A usability evaluation (see 5.22 of this document) should be performed considering the actual use conditions and environment.

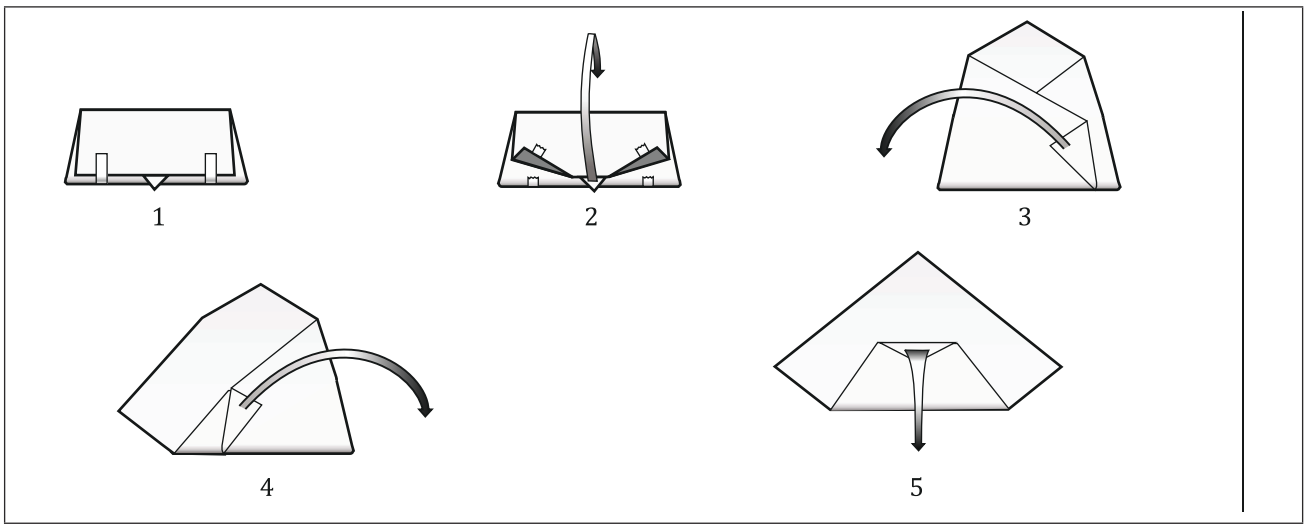


Figure B.5 — Aseptic opening of sequential double envelope wrapping by the non-sterile nurse

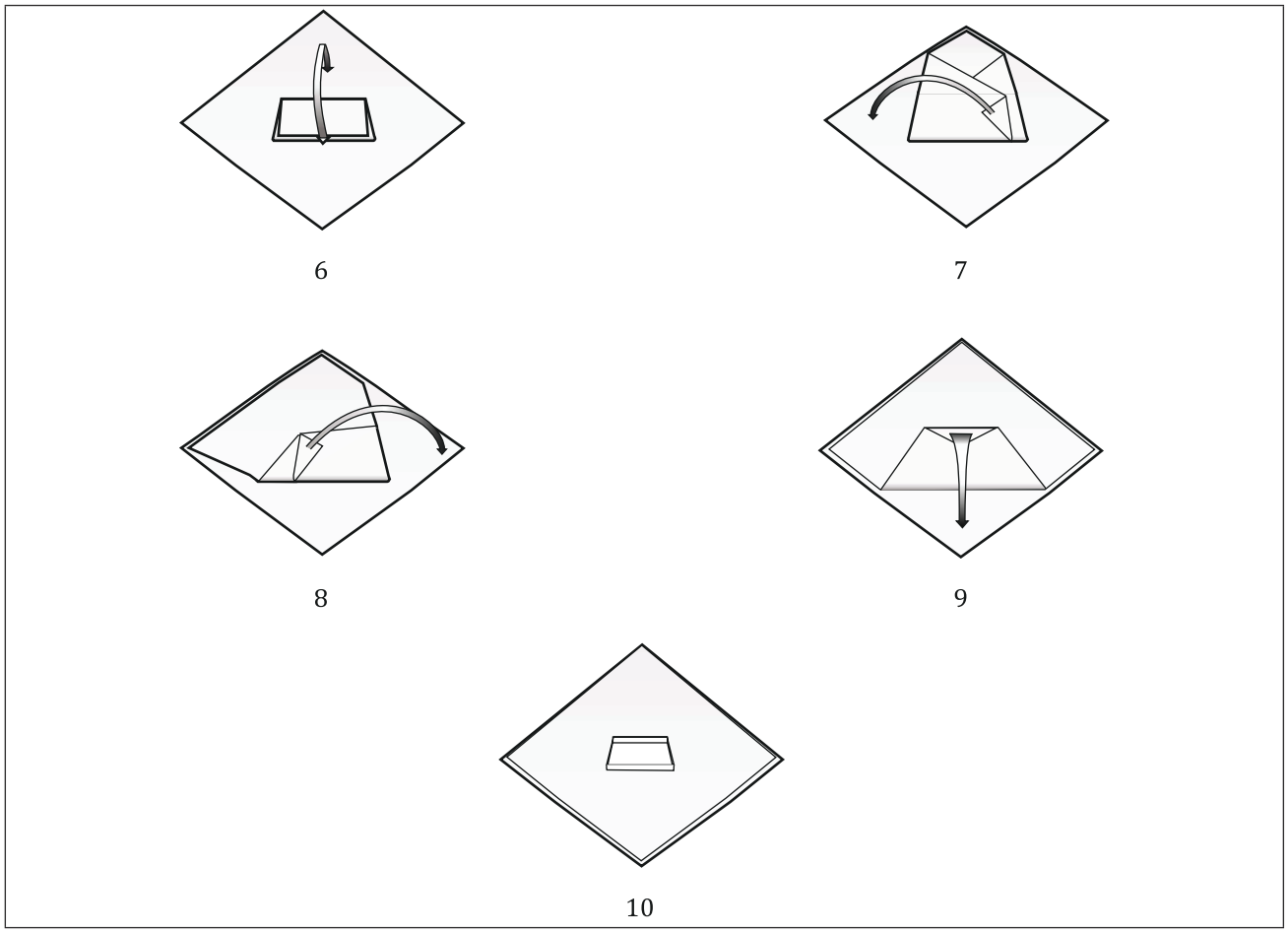


Figure B.6 — Aseptic opening of simultaneous double envelop wrapping by the sterile scrub nurse

B.4.3.4 Square fold / parallel wrapping method

B.4.3.4.1 Simultaneous double square fold / parallel wrapping method

The steps for simultaneous square fold / parallel wrapping are illustrated in Figures B.7 to B.9.

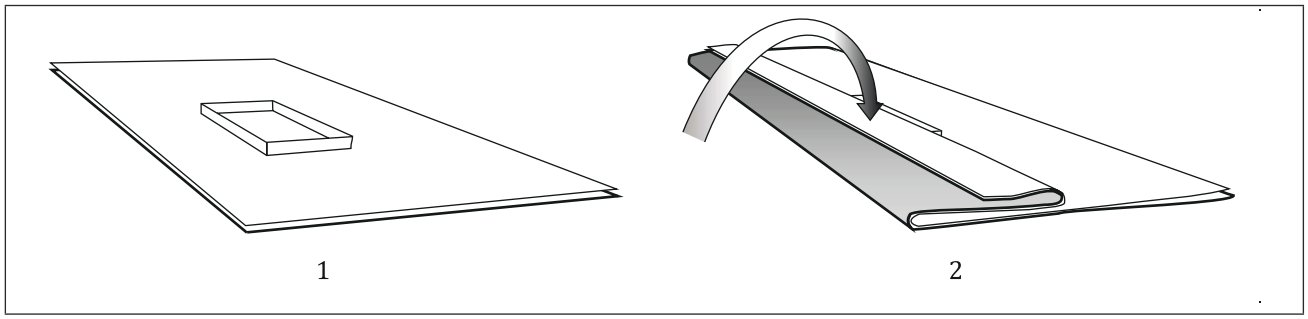


Figure B.7 — Simultaneous square fold / parallel wrapping steps 1 to 2

Step 1:

The medical device(s) is/are placed in the middle of the sheet.

Step 2:

The front side of the sheet is wrapped over the medical device(s). The edge of the sheet is folded back outward approximately to the level of the medical device(s).

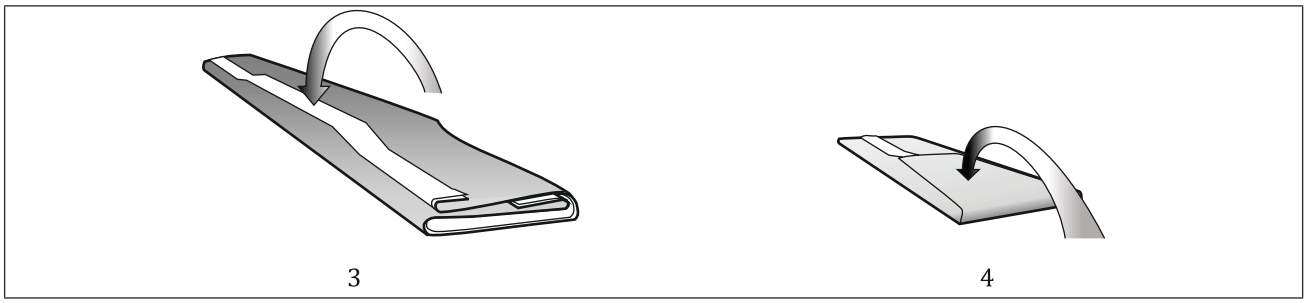


Figure B.8 — Simultaneous square fold / parallel wrapping steps 3 to 4

Step 3:

The back side of the sheet is folded forward. The edge of the sheet is folded outward so that the sheet ends with the forward upper edge.

Steps 4 and 5:

The wrap is folded at the sides and laid over the medical device(s).

Step 6:

The sheet is closed with a suitable closure system with or without process indicator.

Figure B.9 — Simultaneous square fold / parallel wrapping steps 5 and 6

The unwrapping steps for aseptic presentation are illustrated in Figure B.10. This figure illustrates the unwrapping of the square fold simultaneous double wrapping. A usability evaluation (see 5.22 of this document) should be performed considering the actual use conditions and environment.

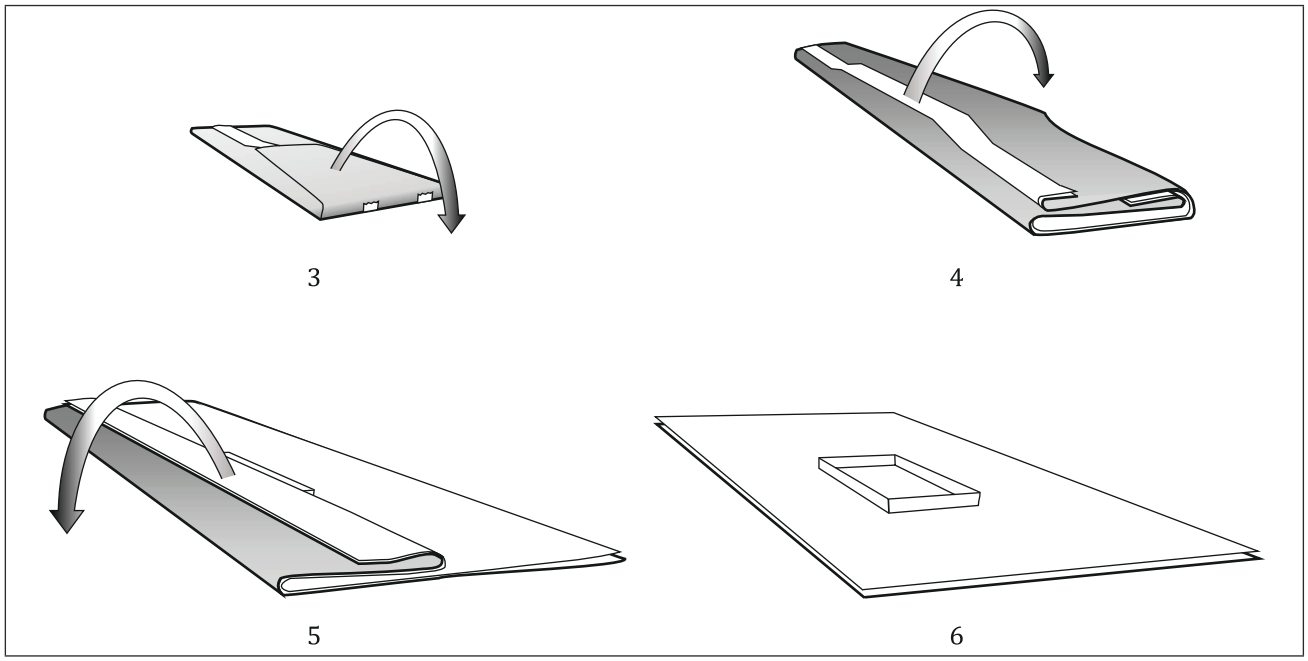


Figure B.10 — Aseptic opening of square fold simultaneous double wrapping by the non-sterile nurse

B.4.3.4.2 Sequential double square fold / parallel wrapping method

Figure B.11 illustrates the sequential double square fold or parallel wrapping method.

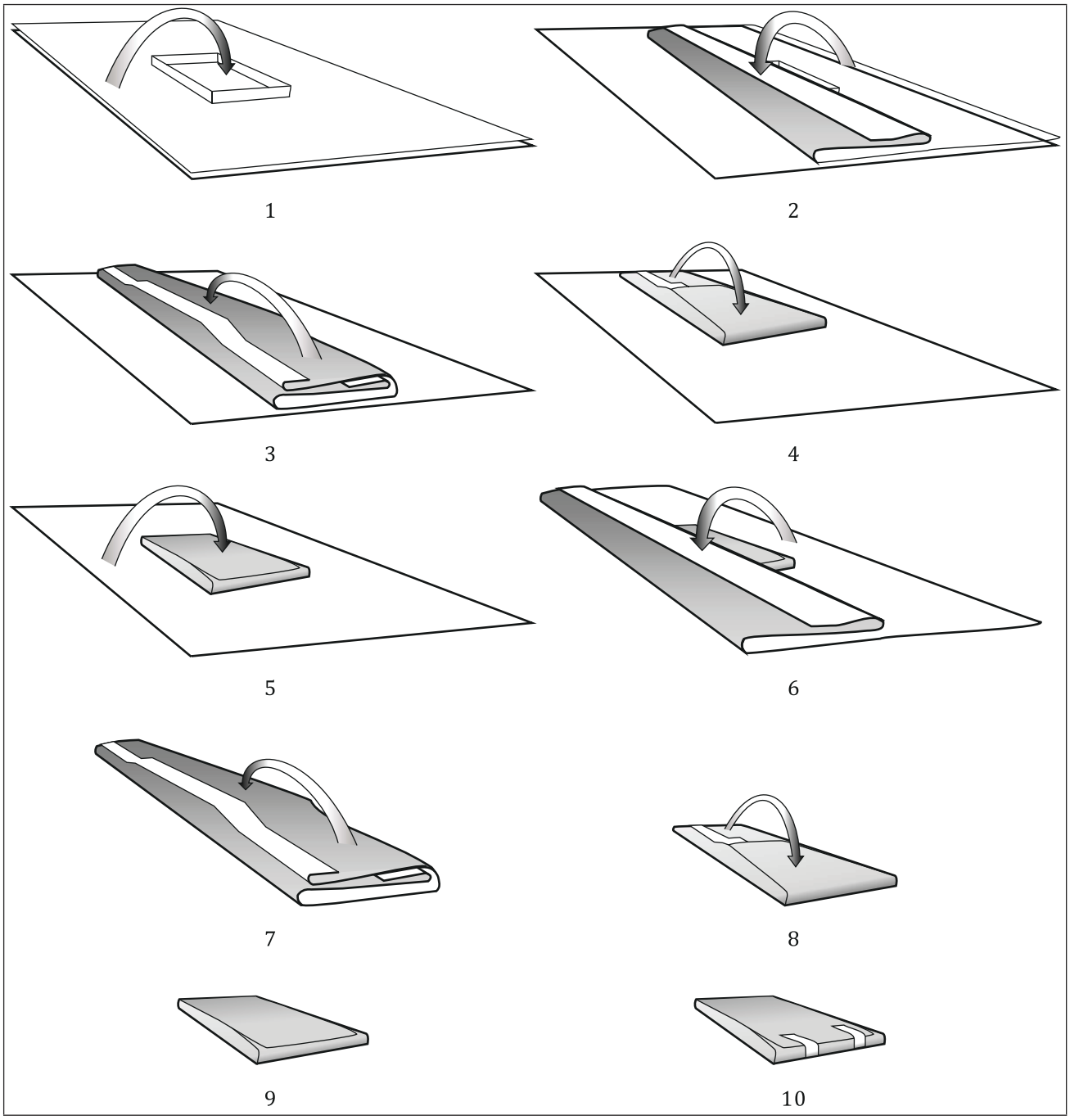


Figure B.11 — Square fold sequential double wrapping

The unwrapping steps for aseptic presentation are illustrated in Figures B.12 and B.13. These figures illustrate the square fold sequential double wrapping. A usability evaluation (see 5.22 of this document) should be performed considering the actual use conditions and environment.

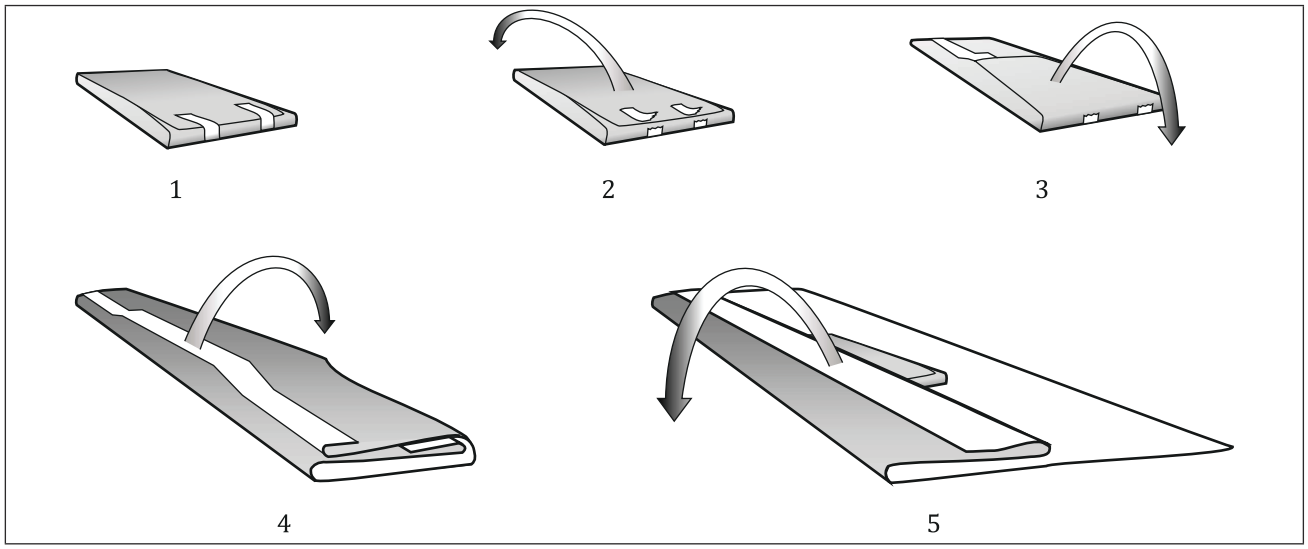


Figure B.12 — Aseptic opening of square fold sequential double wrapping by non-sterile nurse

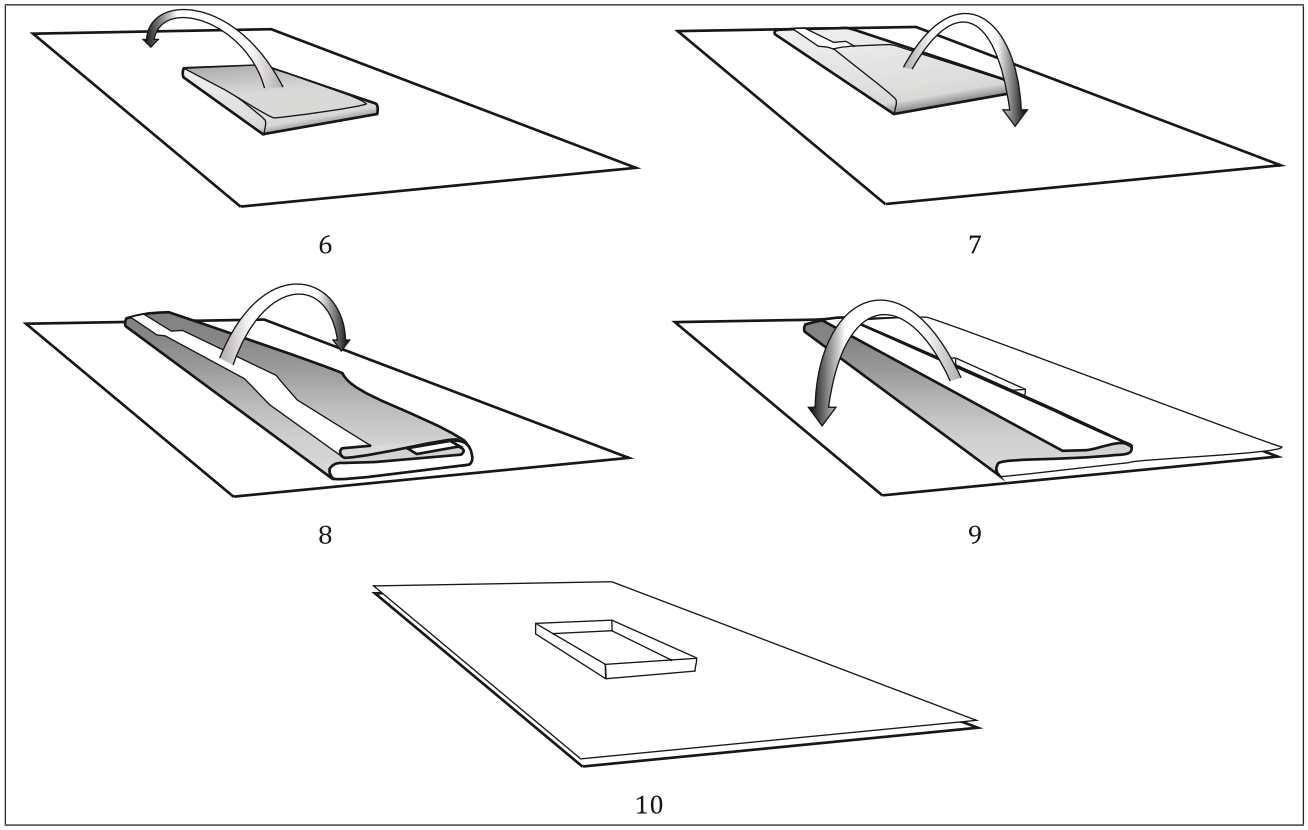


Figure B.13 — Aseptic opening of square fold sequential double wrapping by sterile scrub nurse

B.4.4 Reusable containers

A rigid reusable container is designed to hold medical devices and accessories and is sterilized without exterior wrapping. Reusable containers typically consist of a bottom or base with carrying handles and a lid that is secured to the base by a latching mechanism. It can contain a basket or tray to hold medical devices. The reusable container incorporates a means for air evacuation and sterilant penetration. In regional or other standards, it can be referred to as a "rigid container" or a "reusable container".

Instrument cases, cassettes or organizing trays are containment devices but not SBSs. They should be contained in an SBS.

When using rigid reusable containers, the following should be considered (see requirements in ISO 11607-1:2019, 5.1.10):

a) Only filters which are proven to be compatible with the specific reusable container, particular sterilization process and capable of maintaining sterility should be used. Filter manufacturer should give documented evidence that demonstrates these capabilities.

b) Reusable containers should be inspected and prepared in accordance with the manufacturer's instructions.

c) Tamper evident devices appropriate for the sterilization process should be secured in accordance with the reusable container manufacturer's instructions and indicate that the SBS has not been opened and therefore the contents exposed to potential contamination before intended use.

d) Each reusable container should have a visible identification label and/or information card. ID label and card should be appropriate for the sterilization process.

e) The sealing surfaces of the base and lid should be inspected for damage at each time of use to ensure the proper closure of the reusable container.

f) The instrument organizing tray dimensions should be suitable for use with the specific reusable container and sterilization method.

g) Procedures should be in place for the cleaning, disinfecting and maintenance processes for reusable containers after each use. These processes should be validated. Reusable containers should not be used beyond the manufacturer's stated usable life (see requirements in ISO 11607-1:2019, 5.1.12). Procedures should be in place to ensure that the manufacturer's stated usable life is not exceeded (see requirements in ISO 11607-1:2019, 5.1.12).

h) As with all SBSs, to ensure aseptic presentation the outside of the reusable container and the joint between top and bottom should not come in contact with sterilized contents.

B.4.5 Protective packaging

Protective packaging can be used to protect or prolong the shelf life of properly packaged and sterilized items that could be subjected to environmental challenges or multiple handling. Transportation or movement of the SBS in particular could require protective packaging to be applied to ensure that distribution and handling does not affect the SBS. Sterilized packages should be handled as little as possible. Loss of SBS integrity is regarded as event related rather than time related, therefore it is so crucial to guard against damage to the SBS.

When protective packaging is used, the SBS should be clearly identifiable. Protective packaging is designed to provide additional protection against damage and outside elements or against damage from the device itself. In this sense protective packaging can be outside of the SBS or inside, but in both cases the objective is to protect the SBS against loss of integrity (e.g. trays, baskets, etc.). Some devices come with a protection (e.g. a tip protector) that is an accessory of the device and it can be used to protect the SBS and the end user. The IFU should be consulted to see if it is appropriate to leave these protectors on the devices during sterilization as some protectors might adversely affect the sterilization process. If protective packaging is to be applied after steam sterilization, it should be applied once the items are thoroughly cool and dry.

To facilitate aseptic presentation, trays can be wrapped with sterilization wrap prior to placement in an SBS (see figures B.14 and B.15).

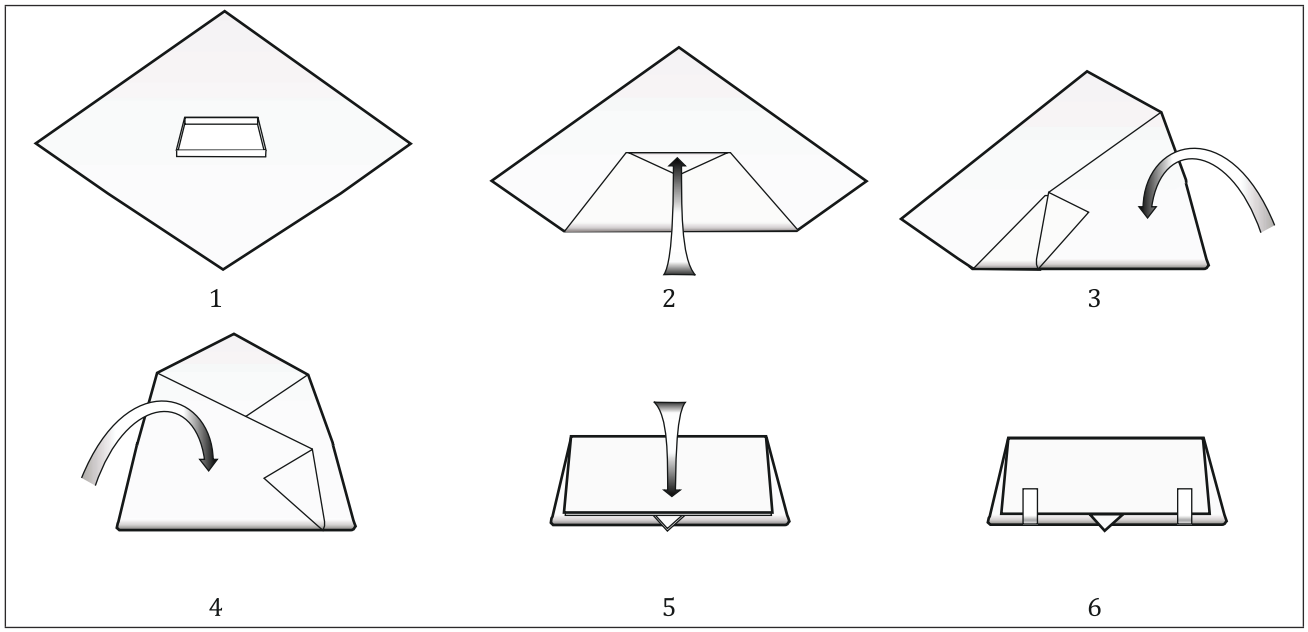


Figure B.14 — Single Envelop Method for inner wrap – wrapping

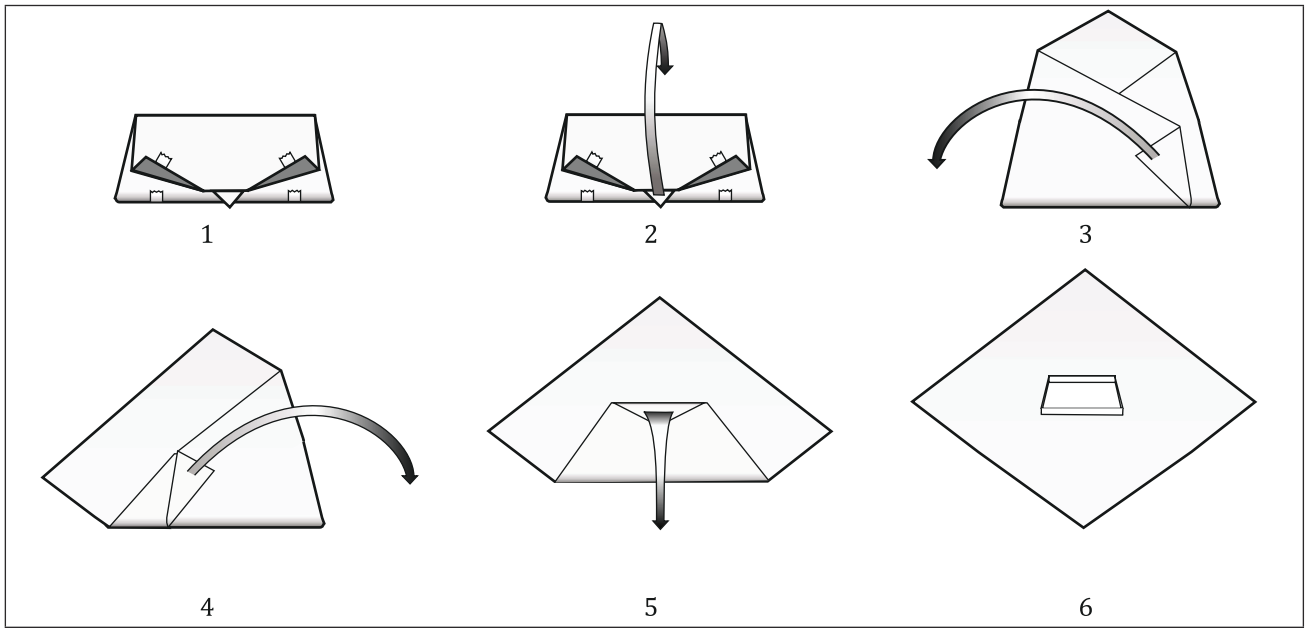


Figure B.15 — Single Envelop Method for inner wrap –Aseptic opening

National or regional regulations can require that protective packaging is used to avoid the potential contamination of the surgical environment. These regulations can also require that the protective packaging is removed prior to introduction of the SBS into the surgical environment.

B.5 Packaging system performance testing (ISO 11607-1:2019, 8.2)

Before any packaging system is used in a facility for the first time, its performance should be tested. Performance testing should allow verification on how well the SBS or packaging system holds up to the rigours of anticipated conditions of handling, distribution and storage, before and after sterilization. The SBS needs to maintain its integrity without any holes, tears or seal/closure rupture that can be caused by the imposed stresses.

Performance testing should:

a) be evaluated through all the intended processes of sterilization, handling, distribution and storage, up to the point of use;

b) be evaluated for expected worst-case scenarios. In determining these, a number of factors should be considered. These include but are not limited to:

   — Assembly of SBSs which contain the medical device configuration which presents the greatest challenge to the SBS (e.g. biggest, heaviest, most dense, sharpest items see ISO 11607-1:2019, 8.2.2).

   — Samples for verification testing should be prepared to allow monitoring of the efficacy of the sterilization process depending on national or regional requirements for the monitoring of sterilization efficacy. Examples include but are not limited to biological, chemical indicators or process challenge device (PCD) by measuring and recording of physical parameters using thermocouples or data loggers. Determination of suitability can be carried out concurrently with validation of the sterilization process(es) to be used. Medical devices should be packaged and sterilized in accordance with the instructions of the manufacturer of the medical device and preformed SBS.

   — Sterilization of the SBS in the intended sterilization process, considering mixed loads or fully loaded sterilizer chambers.

   — Handling / distribution / storage / opening of the SBS.

Consideration should be given to the environment and other conditions in which the SBS or packaging system will be stored. Packaged products pressed tightly into bins and storage locations increases the chance of shear action between two sets of packaged medical devices and can be detrimental causing pinholes and tears.

It is particularly important to consider all conditions of storage and distribution, as many sterilization sites are not adjacent to the point of use.

After performance testing, healthcare facilities should visually inspect the sample SBSs for package integrity (no holes or tears) and seal integrity, then verify that sterilization parameters have been achieved.

If more thorough testing is desired, alternative test methods can be found in ISO 11607-1:2019, Annex B.

If an SBS is designed to be reusable and a degradation of performance characteristics is predicted by the manufacturer (see ISO 11607-1:2019, 5.1.11 and 5.1.12) the monitoring or inspection system used should clearly identify when the end of the useful life has been reached as defined by the manufacturer.

B.6 Sterile barrier system stability evaluation (shelf life) (ISO 11607-1:2019, 8.3)

Evaluation on the ability of the SBS materials or preformed SBSs to maintain their performance characteristics and seal integrity over time is normally performed by the manufacturer of the preformed SBS (see also requirements in ISO 11607-1:2019, 8.3.6).

NOTE 1 Suggested storage conditions and shelf life can be provided by the material or preformed SBS manufacturer. If anticipated or actual storage is outside these conditions the manufacturer should be consulted.

However, even though the materials have been shown to be an acceptable microbial barrier, the healthcare facility should demonstrate that the assembled SBS or packaging system can maintain integrity under the anticipated environmental conditions until the time of use.

Loss of SBS integrity is regarded as event related rather than time related and is dependent on the performance of the SBS or packaging system, as well as the possible interaction between the medical device and the selected SBS, the storage conditions, the conditions during transport and the amount of handling. Appropriate storage environment includes a wide variety of considerations, i.e. preventing