g) Closing accessories that compress the package or medical device should not be used (e.g. ropes, string, elastic bands, paperclips, staples or similar items).

h) The pouch should be loaded so that the enclosed medical device will be presented aseptically. For instance, the grip of the medical device should be placed toward the opening end. It should be noted that the seal areas are considered non-sterile when opened[81].

i) The pouch should be opened according to the manufacturer instructions. If a specific peel direction is needed to prevent delamination or shedding of fibres during opening, then that peel direction should be followed. The formed package should show by design which direction the packaging has to be opened (e.g. arrow sign, shape of seal).

j) Reels are used for the packaging of medical devices of diverse dimensions that do not easily fit standard preformed pouch sizes. In the absence of the chevron, the peel direction for reels should be provided by the manufacturer. Additionally, it is advisable to have more space above the seal that is intended to be opened according to the manufacturer's information. For pouches formed from reels, to reduce the risk of fibre release in the seal area at opening and support aseptic opening it is important utilize validated conditions that permit peelability.

k) Attention should be paid to the importance of conducting scheduled maintenance and calibration of the sealing equipment and periodic validation of the sealing process.

B.4.3 SBS sterilization wrap

B.4.3.1 General

Sterilization wrap comes in many sizes and grades to accommodate a wide range of applications. It is also available in single use or reusable fabric forms. Careful consideration should be given to the item to be wrapped and the technique to be used. Sterilization wrap can be used for wrapping of individual medical devices or medical devices in instrument cases, cassettes or instrument organizing trays.

The following aspects should be considered:

a) The grade of the sterilization wrap should be chosen according to the size, shape and weight of the medical devices to be wrapped or based on guidelines within the healthcare facility and wrap manufacturer’s recommendations for use.

b) The size of the sterilization wrap should be selected to achieve adequate coverage of the item being packaged. It is essential to wrap the item securely to prevent gaps, billowing and air pockets from forming. The item should not be wrapped too tightly as this could create holes or tears in the wrap. It is also necessary that the sterilization wrap be large enough to accommodate movement of the wrap during the sterilization cycle without ripping or tearing. When choosing sheets of sterilization wrap the wrapper should be large enough to cover the medical device, but it should not be so big that it has to be wrapped several times around the medical device, as this could impede sterilant penetration.

c) Proper wrapping technique is essential to provide a tortuous pathway to impede microbial migration into the SBS. A wrapping technique can be used if the manufacturer has demonstrated the efficacy of this technique and recommends it for this application. The wrapping method chosen should allow aseptic presentation of the medical device. The healthcare facility should verify or validate the application in its own facilities per national or regional regulations. National standards or professional guidelines for wrapping techniques can be available. Examples are given in this annex.

d) The sterilization wrapping technique should be designed in a manner that the opened wrapper should drape away from the sterile field.

e) The assembly surface area for wrapping should be flat, smooth, of adequate size, well-lit and clean.

f) The wrapped package should be designed in a manner so that all edges are secured and do not interfere with aseptic presentation into the sterile field.

g) Closure systems should provide evidence of tampering.

h) Indicator tape is the most common closure for wrapped packages and there are different kinds of tape based on the method of sterilization, various strengths of tapes are also available. There are different tapes designed for use on woven or nonwoven wrappers. Closures that compress the package or medical device should not be used (e.g. ropes, strings, elastic bands, paperclips, staples or similar items).

i) When reusable fabrics are used as sterilization wrap there are additional requirements to ensure the suitability of the wrap prior to each use (see requirements in ISO 11607-1:2019, 5.1.12).

— Manufacturer should provide instructions for use, cleaning/laundering, and storage so that barrier qualities are not compromised by improper handling or use of wrappers. The healthcare facility should establish procedure based on those instruction to conform with ISO 11607-1:2019, 5.1.12 b).

— The continued acceptability of each type of wrapping material should be monitored and maintained by means of a quality assurance system that includes an inspection of all wrappers before using them for packaging. ISO 11607-1:2019, 5.1.10 requires that manufacturer provide guidance on inspection technique. Possible inspection techniques are by means of a light table and by doing a water resistance test. In case of integrity issues, the material should not be used anymore.

NOTE Annex B of ISO 11607-1: 2019 includes a list of appropriate tests, for example ISO 811[82].

— It is important that the manufacturer provides information about microbial barrier and maintenance of integrity over time in relation to the repeated use. Instruction for use should also include information on how the end of service life can be recognized by users.

— The components of a wrapper (e.g. glues, threads, bias binding, any mending or repair materials) should be compatible with the base material and should not compromise the microbial barrier of the completed product.

B.4.3.2 General information about wrapping methods

The drawings below illustrate several methods for wrapping medical devices prior to sterilization. These examples are not intended to describe the only methods for wrapping as there are other acceptable methods available. Wrapping can be performed sequentially or simultaneously.

Different methods can be used for the different layers, however for any wrapping method, it should be ensured that the end users opening the package

— understand how the wrapping is performed;

— understand the configuration of the wrapping in terms of SBS and protective packaging (see 5.17 of this document on double entry packages);

— can aseptically present the sterile contents (see usability evaluation in B.7).

Care should be taken to limit the area covered by tape and labels to ensure adequate porous area for effective sterilization and drying. The acceptability of a wrapping method is dependent upon the medical devices to be wrapped and should be determined by the user.

B.4.3.3 Envelope method

B.4.3.3.1 Simultaneous double envelope method

The wrapping and unwrapping steps are illustrated in Figures B.1 to B.4.

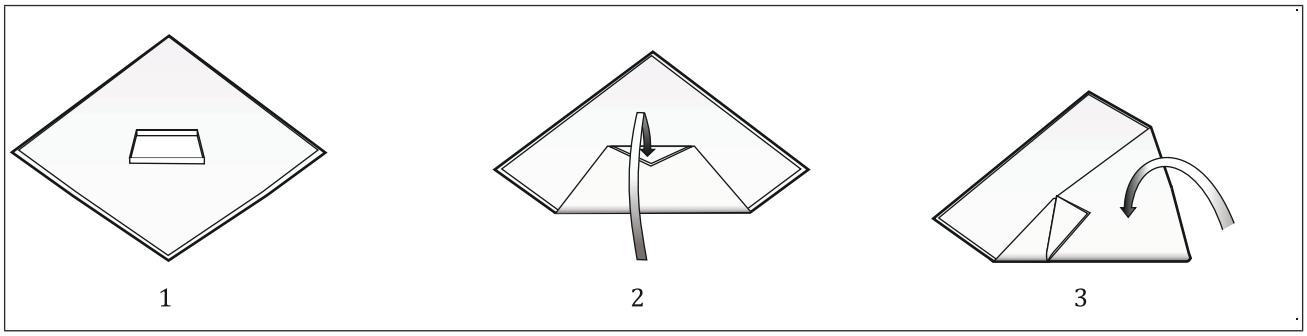


Figure B.1 — Simultaneous double envelope method steps 1 to 3

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.

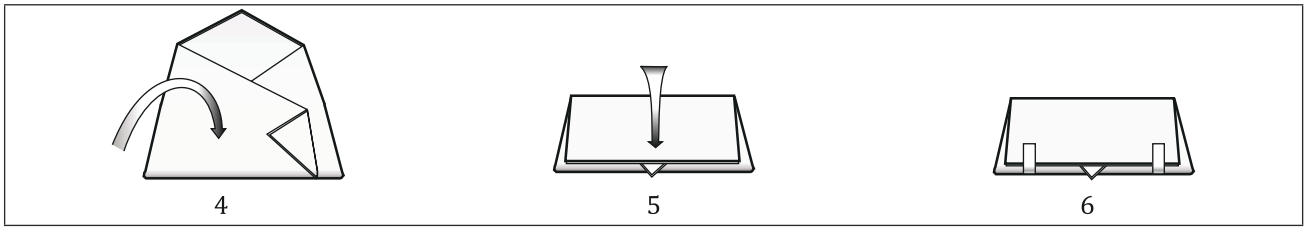


Figure B.2 — Simultaneous double envelope method steps 4 to 6

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.

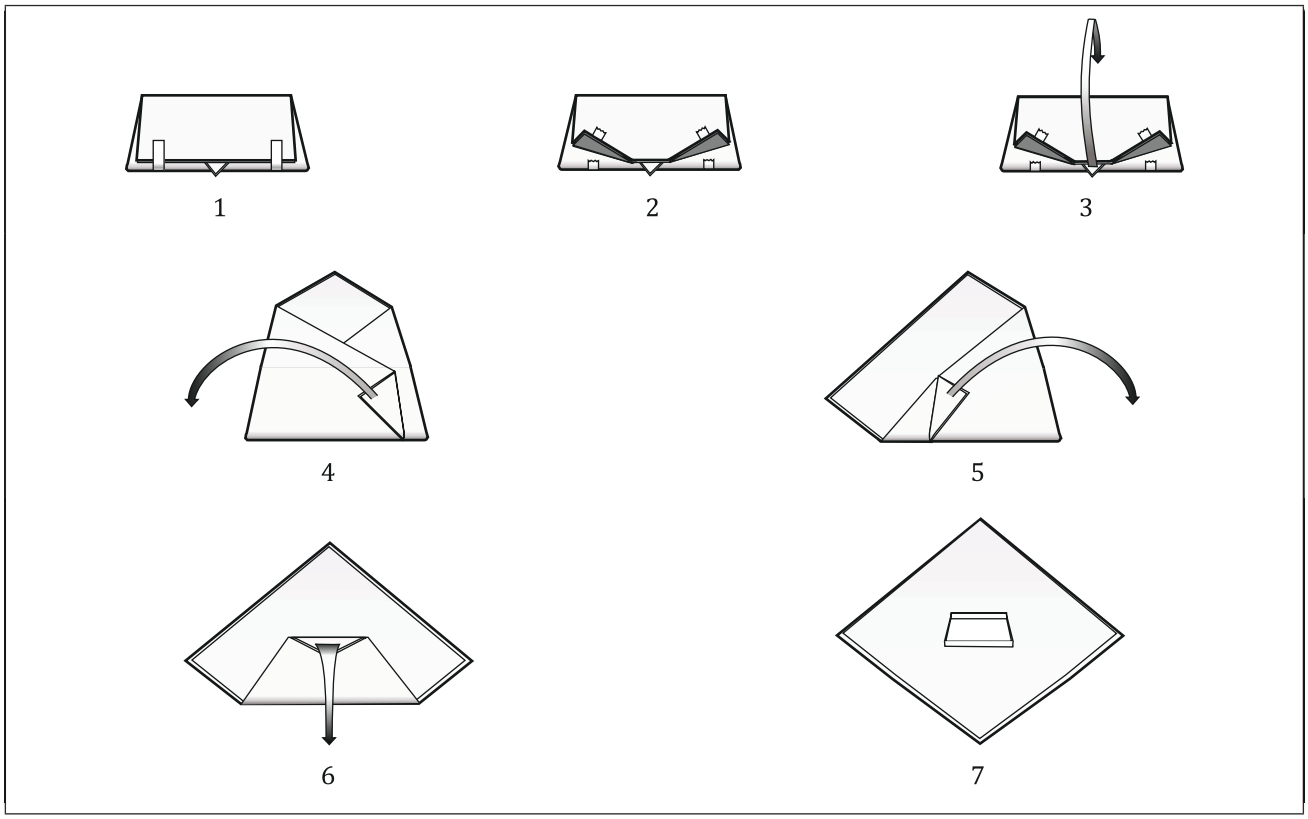
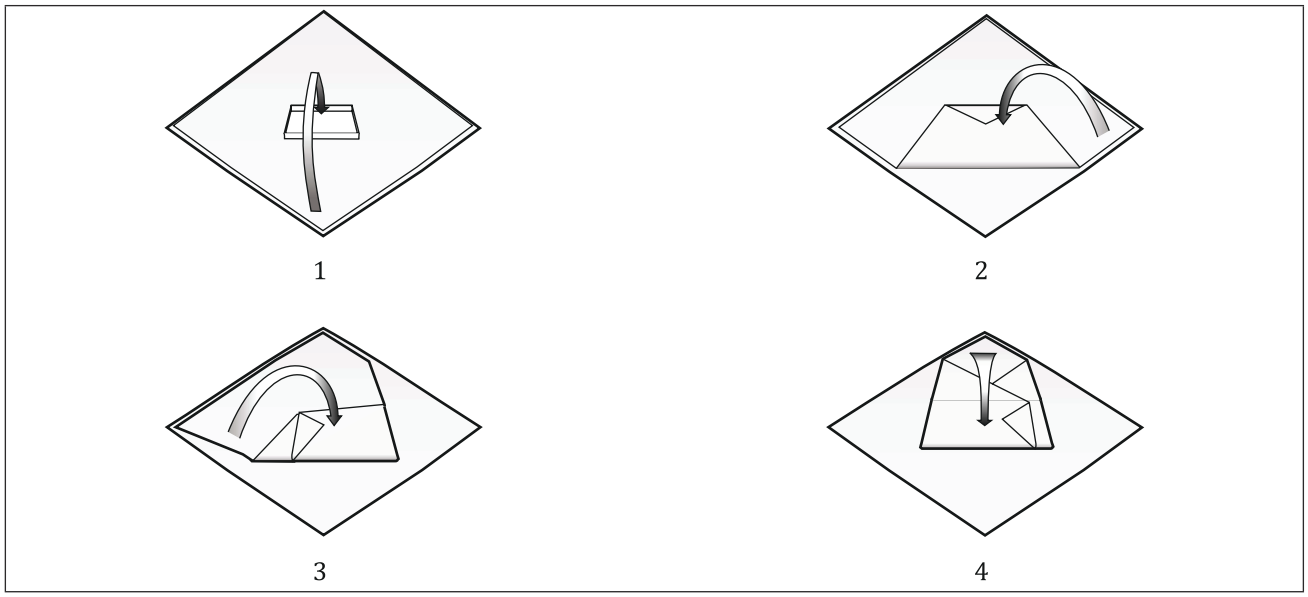


Figure B.3 — Aseptic opening of simultaneous double envelop wrapping

B.4.3.3.2 Sequential double envelope method

Figure B.4 illustrates the sequential double envelope method.



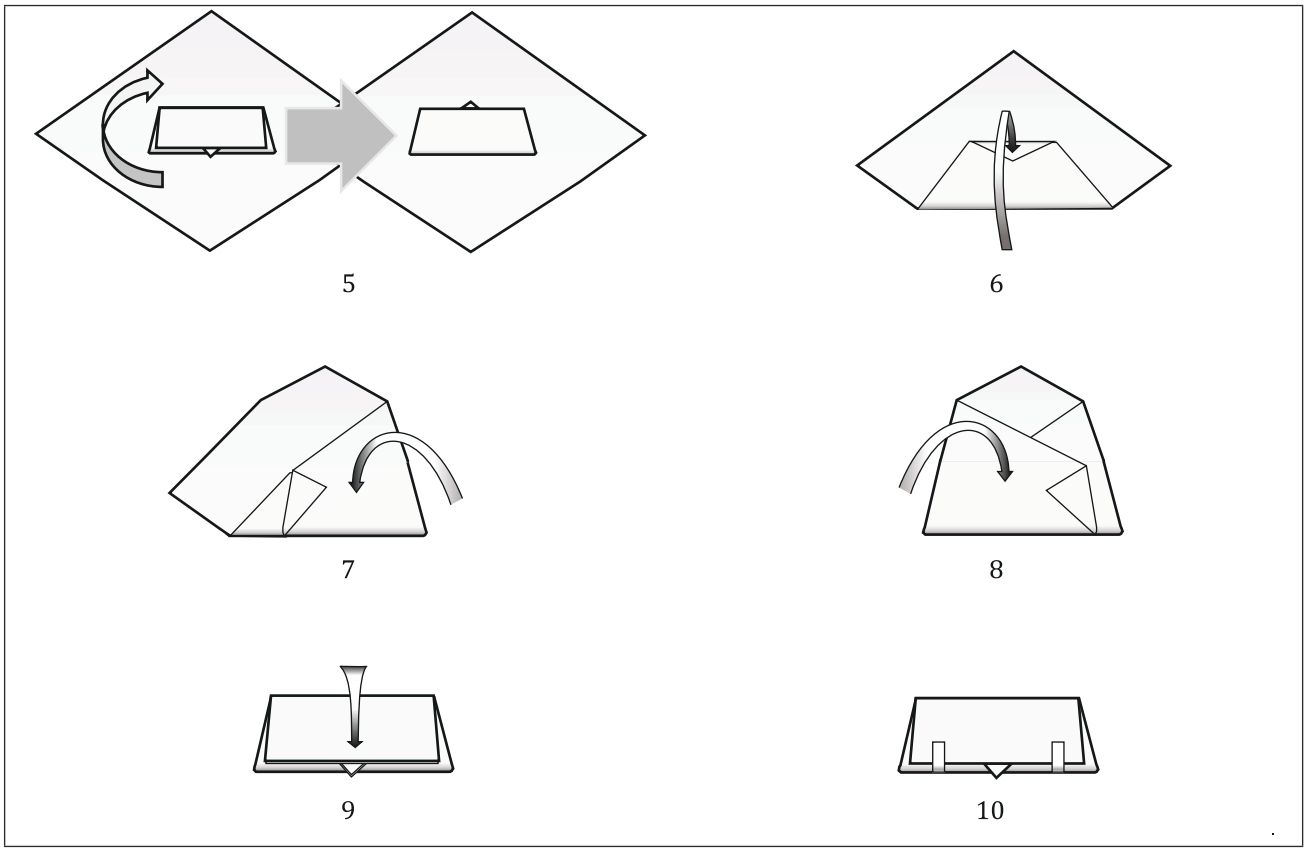


Figure B.4 — Sequential double wrapping envelope method

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.

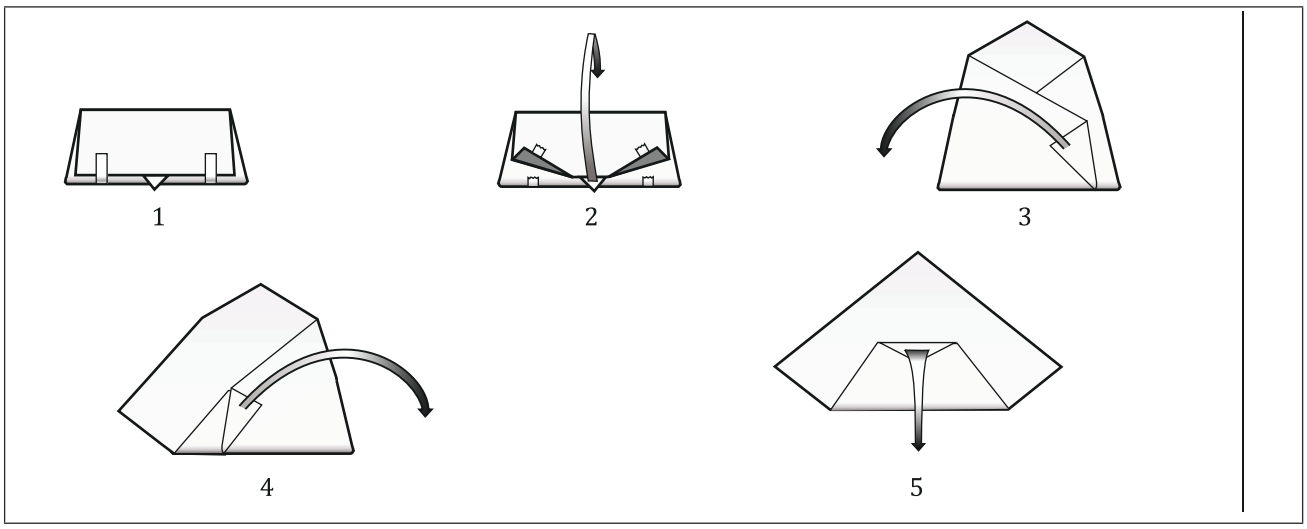


Figure B.5 — Aseptic opening of sequential double envelope wrapping by the non-sterile nurse

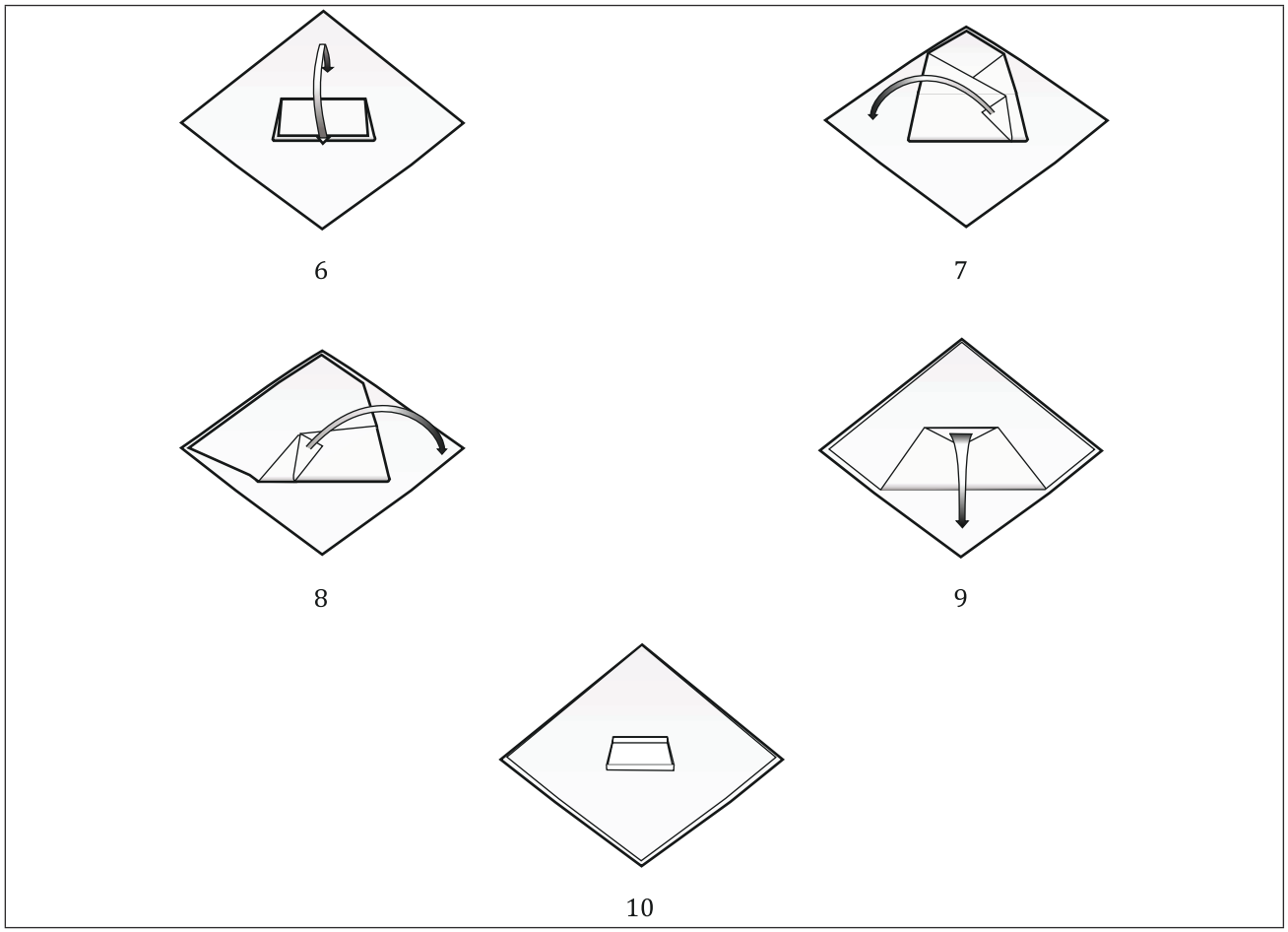


Figure B.6 — Aseptic opening of simultaneous double envelop wrapping by the sterile scrub nurse

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.

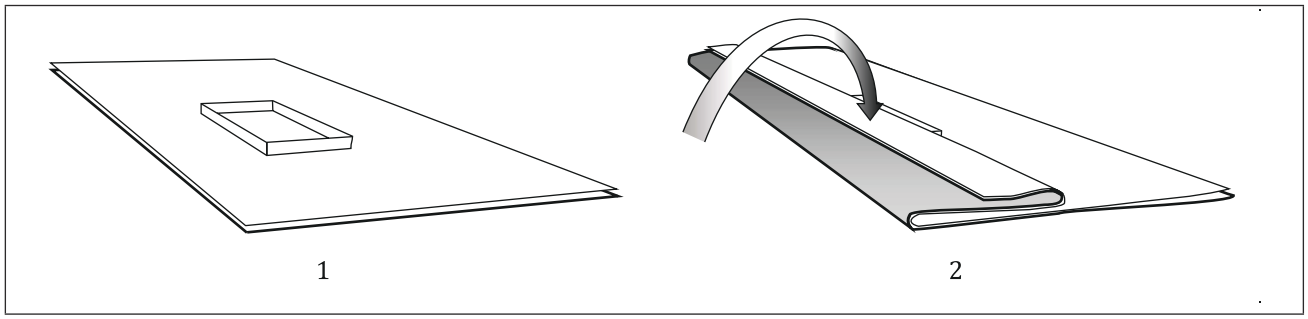


Figure B.7 — Simultaneous square fold / parallel wrapping steps 1 to 2

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).

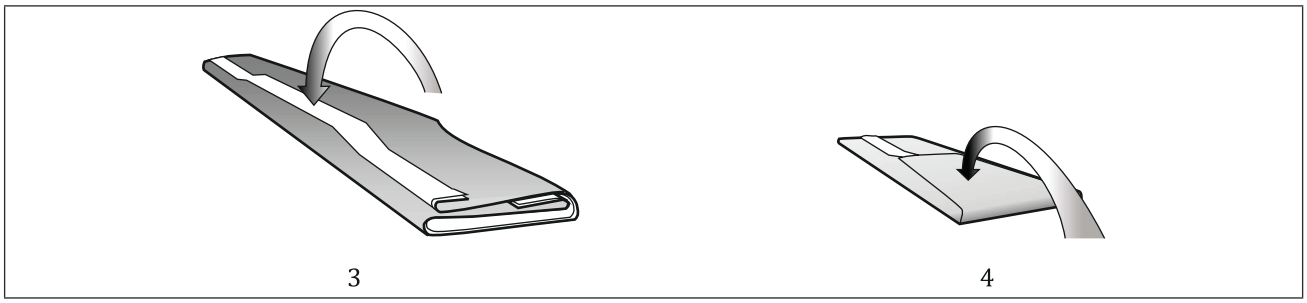


Figure B.8 — Simultaneous square fold / parallel wrapping steps 3 to 4

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.

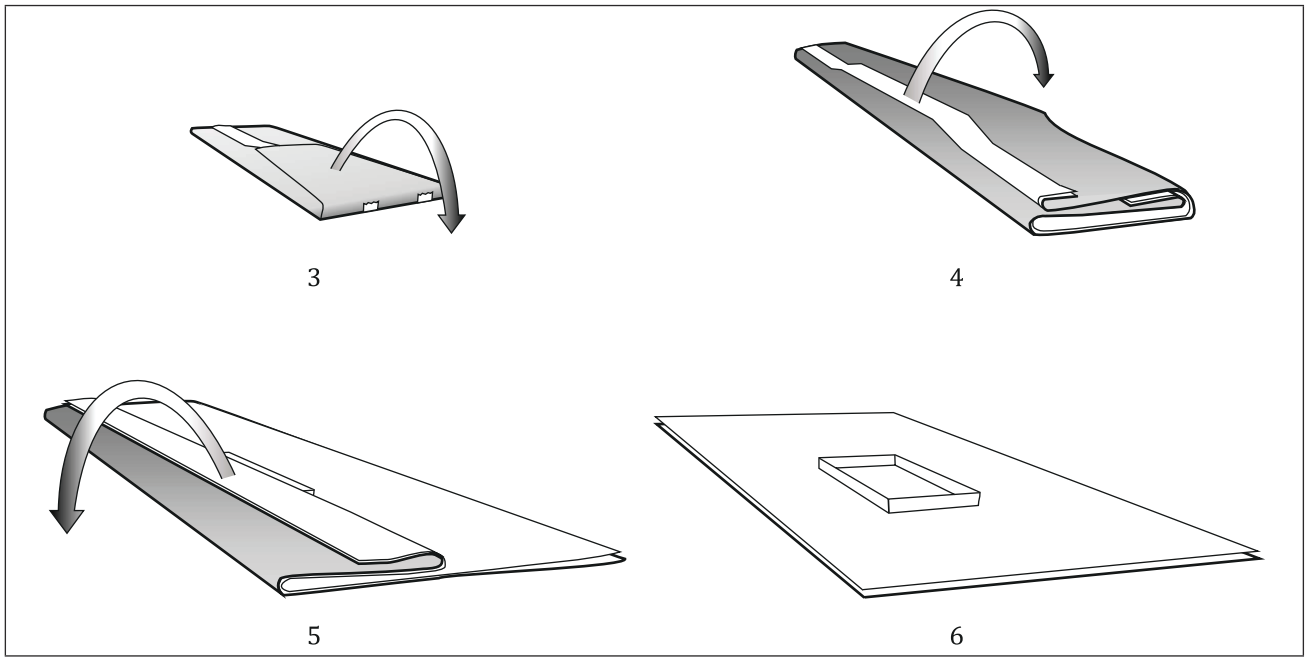


Figure B.10 — Aseptic opening of square fold simultaneous double wrapping by the non-sterile nurse

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.

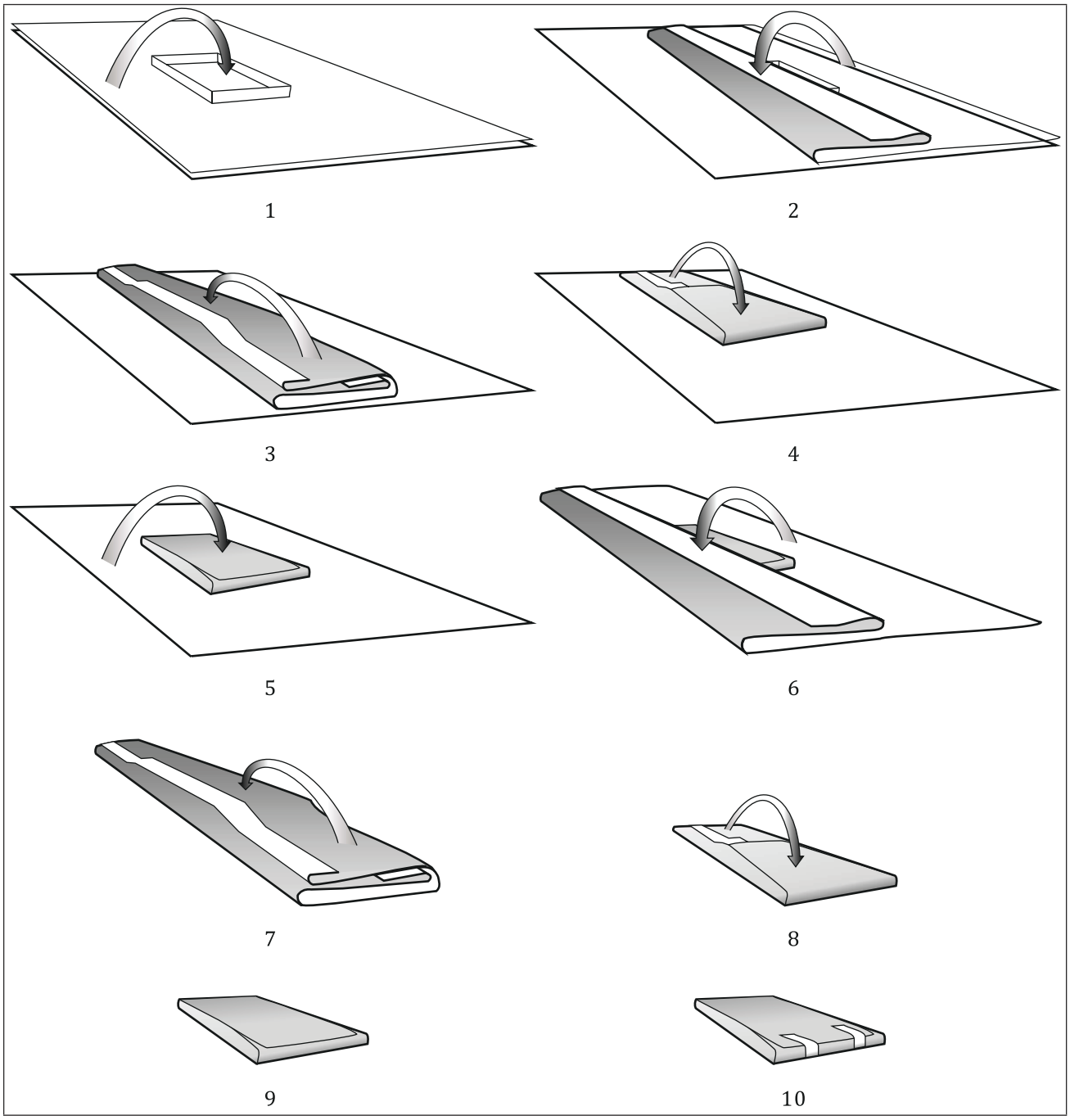


Figure B.11 — Square fold sequential double wrapping

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.

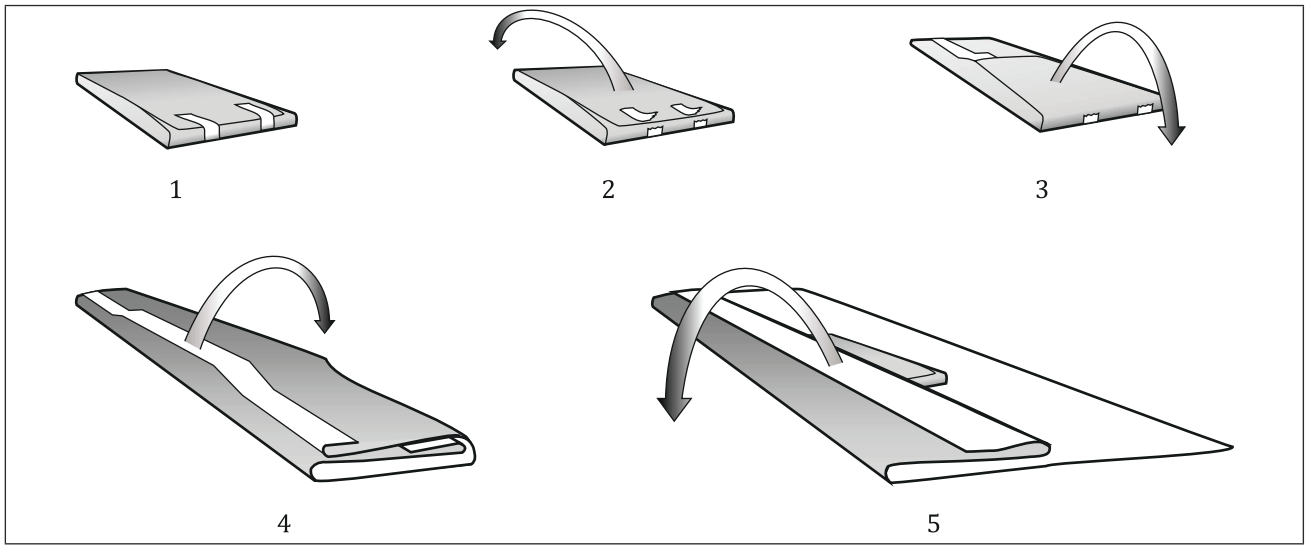


Figure B.12 — Aseptic opening of square fold sequential double wrapping by non-sterile nurse

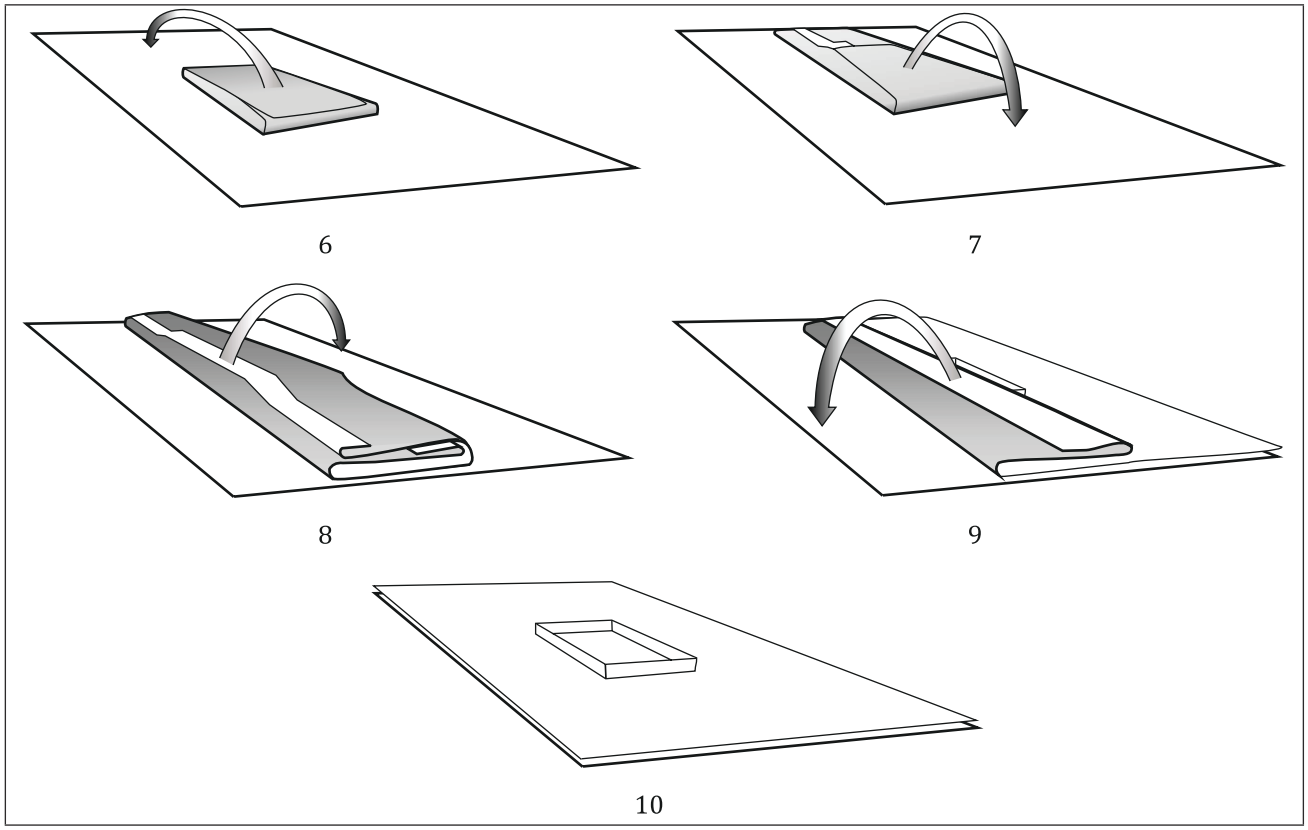


Figure B.13 — Aseptic opening of square fold sequential double wrapping by sterile scrub nurse

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).