



## A guide to using a single barrier layer

**JOY MARKEY**

Clinical Lead, Clinipak Limited.

**THE** purpose of this editorial is to provide Guidance on using a transportation layer alongside a Standard Certified Barrier wrap highlighting that if presented aseptically, this combination satisfies the requirements of ISO 11607 (including points 3.22 as a scientifically proven “Sterile Barrier System” and 3.1 for “Aseptic Presentation”).

At present, standards do not clearly define the number of wrap layers that must be used when tray sets are prepared for sterilisation. Current practices consequently vary among hospitals and wrap choices are often based on how each hospital has wrapped trays in the past. Combinations of wrapped sets may include the following combinations. Two barrier bonded, Two barrier interleaved, Crepe, Two barrier interleaved with a transportation layer, SMS/Crepe/TWrap, Crepe/Linen/SMS, Single layers, One barrier with a transportation layer, Linen/paper and Crepe single layer. One might ask the question how we have ended up with so many combinations of wrap to ensure the same outcome.

It may be a historical thing, or inherited from a previous **Manger**, might it be to accommodate certain user requests or help combat past user issues. Is it as a result of process equipment faults on site, or because of the old age “ripping and tearing or reprocessed sets of instruments? So how do we set about rationalising the number of wraps, the combinations and the methodologies wrapping in our Decontamination Units. By Developing and rolling out a Process Change plan we ensure that the product, mythology and combination is suitable for use in our Decontamination Unit and meets our User requirements.

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However, any change to a fundamental part of the decontamination process must be based upon risk evaluation this should reflect the following:

- Rationale for change as per local policy  
Evaluated and, in some cases, validated (if presenting a greater challenge to the steriliser than the commissioning load)

- Live trialled

- Sterility assured as fit for purpose

This includes the addition to the number of layers of wrap, the removal of layers, and change to wrapping methodologies which may impact on “Theatre Aseptic Presentation”, a change to the strength of wrap and a change of manufacturer.

We must also examine how/if our wrapping materials are used when they are received by the end user e.g. Wrap vs Aseptic Field Trolley Cover.

The purpose of wrapping materials/barriers is to ensure that the medical devices within a set are exposed to the steam sterilisation process. That the integrity of the contents thereafter are maintained/preserved until the point of use – and not to act as an aseptic field for procedures.

Aseptic Presentation: at present standards do not clearly state whether a processed barrier wrap is appropriate to use as a “trolley cover”, acting as the aseptic barrier to maintain the aseptic field during preparation of instruments and subsequent surgical procedures. A trolley cover/surgical draping system should be used to ensure that the sterile field is maintained and remains intact. That said, there is a rationale for use of sterile barrier wraps in the minor procedure field. Theatres should conduct a risk evaluation based on the materials they choose to act as and maintain the aseptic field for both major and minor procedures.





## USING A “ONE BARRIER LAYER”

There is no scientific proof of greater sterility assurance or legislation that states that both layers need to be germ-proof barrier layers. Today various products are used as part of a 2-layer system, the specific requirements being that one layer must be a wet and dry bacterial barrier in order to create a sterile barrier system, **If used correctly in combination with a standard certified barrier wrap and aseptically presented, this combination satisfies the requirements of ISO 11607 including point 3.22 -acting as scientifically proven “sterile barrier system” and 3.1 -aseptic presentation.** There is clinical evidence to support a 2-layer wrapping system, stating only one germ-proof barrier is required to ensure that the set contents are reprocessed appropriately and ensure they are fit for patient use. Provided the barrier layer is protected by a tear-resistant strong outer layer, a single barrier layer is perfectly adequate in preventing germs from entering an instrument set after sterilisation.

## COMPLIANCE CHECKLIST

To ensure compliance to standard, the following steps should be followed before converting to the combination of barrier wrap, to ensure the product is suited to local reprocessing practice and protocols:

1. Ensure that all relevant hospital stakeholders are aware and have an understanding of this approach to wrapping solutions.
2. Conduct a local risk evaluation for process change (changing to a single barrier layer system with a transportation wrap). The evaluation should be based around current equipment and procedures and should ensure that the movement of instrument trays and related equipment is compatible with Clinipak wrap.
3. Commence a “dummy” trial -reprocessing/sterilizing some challenging instrument sets that are not required for theatres/clinics. If there are then some initial non-conforming issues this will not impact on theatre lists etc.
4. If the “dummy trial” is deemed successful it is recommended that one of the reprocessed/sterilised instrument set is sent for sterility integrity/sterility assurance testing. This is usually carried out at an external licensed laboratory through the hospital authorising engineer.

5. Move forward to “Live Trials”. It is advisable that staff are trained in the change-over.
6. Thereafter, make the necessary changes to local protocol and commence with the use of new wrap combination in the decontamination process.

**Note:** *It is critical that the hospital theatre staff, as well as the decontamination unit are trained in “Aseptic Presentation” when using this combination. **Where a single barrier layer is used, the instrument set must be opened by a circulating nurse down to tray level to preserve the aseptic field and prevent “desterilisation”.***

**Joy** has expertise within Decontamination Standard Development and operational management risk evaluation and training of decontamination staff.

She provides clinical/technical consultation on Decontamination Standard elements, supporting Clinipak users/customers in the appropriate use of the Clinipak portfolio.

Joy advises distributors/users/customers on development of operational policy for the introduction and use of Clinipak Products.

She assists/supports distributors and decontamination units in the local testing/verification and subsequent evaluation process to support the business case to introduce new and existing Clinipak products.

Joy develops training tools and provides on site bespoke training for Clinipak distributors/users/customers.

