A guide to using a single barrier layer
Objective

• To provide guidance on using a transportation layer alongside a standard certified barrier wrap.

• To emphasise that, if presented aseptically, this combination satisfies the requirements of ISO 11607.

(including:
Point 3.22: a scientifically proven “sterile barrier system”
Point 3.1 for “aseptic presentation”)
Current Standards

• 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

- Two barrier bonded
- Two barrier interleaved
- Crepe
- Two barrier interleaved with a transportation layer
- SMS/Crpe/TWrap
- Crepe/Linen/SMS
- Single layers
- One barrier with a transportation layer
- Linen/paper
- Crepe single layer
Why so many combinations?

- Is it a historical thing?
- Inherited from a previous manager?
- Does it stem from user issues?
- Is it to accommodate certain user requests? (what they used before?)
- Is it because of on site "process equipment" issues?
- Is it because of ripping & tearing issues?
Wrapping methodologies in practice

- One step wrapping
- One step methodology wrapping with two layers
- Parcel fold
- Envelope method
- Combined parcel and envelope on same tray
- Individual layers wrapped
- Interleaved one step
Process Change

• Any change to a fundamental part of the decontamination process must be based upon risk evaluation

• 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...

• An addition to the number of layers of wrap

• The removal of layers

• A change to wrapping methodologies which may impact on "Theatre Aseptic Presentation"

• A change to the strength of wrap

• A change of manufacturer
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.

• 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

- 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.
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
Compliance

• 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 sets 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.
Assurance

• 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”.
Any Questions?

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