

# Instrument set wrapping: when less is more

The correct packaging of surgical instrument sets before sterilisation is vital to reduce the risk of surgical site infections. However, because there is no standard to define the number of layers of wrap that should be used, practice varies. **Suzanne Callander** reports.

A key strategy for reducing the risk of surgical site infections (SSIs) is the provision of surgical instruments and other devices used during the surgical procedure that are free from contamination at the time of use.

Medical devices used in surgical procedures are classified as 'critical' patient care items, according to the Spaulding classification system which was devised in 1968 and is still in use today. Critical items are considered to be those that enter normally sterile tissue or the vascular system or through which blood flows and these items should be sterilised, which is defined as the destruction of all microbial life.

An important element of the sterilisation of these critical devices is that they are appropriately packaged before sterilisation. This packaging is necessary to provide an effective barrier to microbial penetration as well as to protect the packaged items from contamination during handling, and to maintain sterility up to the delivery of the contents to the sterile field.

There are several methods used to package critical instruments including rigid containers, peel pouches of plastic and/or paper, and the use of sterilisation wrapping materials. Most hospitals and sterile services providers, will use a variety of these packaging choices, but the most commonly used method today is sterilisation wraps.

Current practice relating to the number of wrap layers required when surgical instrument tray sets are prepared for sterilisation varies among hospitals, due to the fact that there are no standards in place today to define practice. This has resulted in wrapping choices often being based on how each



**Transportation Wrap** is manufactured from a material that is designed specifically to perform as a protective outer wrap to protect instrument sets throughout the decontamination journey.

hospital has, traditionally, wrapped trays.

When tray wraps were initially developed, the most commonly used combination was waxed paper (the sterile field) and crepe paper. A second outer wrap was later identified as providing an effective way to provide a protective layer. Traditionally, linen was the preferred choice for the outer wrap, even though it exhibits poor barrier properties, particularly against dust.

In today's healthcare environment any new wrapping method being considered needs to be able to offer both cost and time saving benefits without compromising aseptic technique.

The goal of any packaging system should be to enable penetration of the sterilant while protecting the instruments in the tray from contact contamination during handling and



to provide an effective barrier against microbial penetration, as well as ensuring the sterility of the contents inside.

Materials for wrapping sterile items continue to evolve, but evaluation of such products under clinical conditions has been rare. One exception is Webster *et al*<sup>1</sup> who set out to test a new product before introducing it to a sterilising processing unit. The study involved 400 instrument sets being wrapped in either in a compliant sterile wrap and a linen wrap, or a one-step sterile wrap. The wrapped sets were stored in a variety of conditions and periodically tested. The study found no difference in bacterial contamination between the single layer and the multi-layer wrapping techniques. However the single wrap method did offer time savings for the sterile service staff and consumable savings.

## Satisfying ISO 11607

According to Clinipak the use of its Transportation Wrap, alongside a standard certified barrier wrap and presented aseptically, satisfies the requirements of ISO 11607. ISO 11607 specifies the requirements and test methods for materials, preformed sterile ►

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barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilised medical devices until the point of use.

“ISO 11607 does not state how many layers of wrapping should be used,” said Joy Markey, clinical lead at Clinipak. “What it is clear about, however, is the aseptic presentation of the contents of the set of instruments. Clinipak works with clients to ensure that they ‘aseptically’ present the instrument set contents when using a single layer of compliant wrap, with a layer of Transportation Wrap. The difference in presentation with this solution is that the internal surface of the Transportation Wrap and the external surface of the barrier layer are not considered ‘sterile’. However, the internal surface of the microbial barrier layer is, and this therefore is the septic field. Within a theatre this means that the circulation nurse should open the set down to tray content and thereafter only the scrub nurse should handle it to maintain the barrier.”

The ideal wrap combination should enable penetration of the sterilant, protect against contact contamination during handling, provide an effective barrier to microbial penetration, and maintain the

## ISO 11607: the importance of the correct terminology

One area of confusion that was rectified by the introduction of ISO 11607 in 2006 was that of the terminology being used to describe the different types of packaging. Terms such as primary package, secondary package, sterile package, barrier package, shipping package, and others were found to have been used indiscriminately in the older standards and that these descriptions meant different things to different people. The standard, therefore included four key definitions –used consistently. These are:

- Sterile barrier system (SBS): The minimum packaging that prevents

ingress of microorganisms and allows aseptic presentation at the point of use.

- Preformed sterile barrier system: The sterile barrier system that is supplied partially assembled for filling and final closure or sealing. For example, pouches, bags, and open reusable containers.
- Protective packaging: The packaging configuration designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use.
- Packaging system: The combination of the sterile barrier system and protective packaging.

sterility of the processed item after sterilisation. Clinipak’s Transportation Wrap is manufactured from a latex free, non-woven polypropylene layered material which is designed to perform as a protective outer wrap. The physical properties of the material ensure stream permeability. It also offers high

tensile strength to protect from tears and punctures and also provides an effective barrier to microbial penetration.

### Ensuring compliance

To ensure compliance to ISO 11607 prior to changing an existing wrap combination, it is necessary to review the steps taken to ensure that the product is suited to local reprocessing practice and protocols. Sterile service providers and hospitals are advised to conduct a risk evaluation and also to determine suitability of any packaging system change for both the processes and the procedures already in place at the establishment.

One Dublin based university hospital undertook a pack integrity research study in its sterile services department to evaluate Clinipak’s two-layer wrap solution, using a single compliant tray wrap layer with a Transportation Wrap outside layer. Standard hospital protocols and good practices were followed during the trial, which consisted of four tray packs containing a range of surgical instruments presented in steel surgical trays. The trays, instruments and bio-indicators were wrapped in a single layer of compliant wrap before being placed in a layer of Transportation Wrap prior to sterilisation at 134°C for four minutes.

On completion of the sterilisation process the packs were stored on shelves in a designated storage room under controlled conditions and handled regularly to simulate normal storage patterns and rotation. At 4, 8, 10 and 13 months, single packs were removed from storage and the microbiological content assessed by an independent microbiological laboratory.

Although viable bacterial were found on the outer surface of the Transportation Wrap, no organisms were found on the inner surface. Under the study conditions the inner surface of the Transportation Wrap, the compliance wrap layer, instrument tray or surgical instruments indicated that there was no ingress of viable bacteria during a



**There was no ingress of viable bacteria during a 13 month period of storage following sterilisation.**

13 month period of storage following sterilisation.

Clinipak has identified a growing number of sterile service providers – commercial decontamination providers in particular – who are successfully utilising this wrap combination which, according to the company, means that a second layer of compliant wrap is not needed.

Joy Markey explains: “A second compliant wrap layer has, traditionally, been used to counter the risk of ripping, tearing or punctures occurring while the instrument set is reprocessed and transported back to theatre.” Sometimes, however, adding this additional layer can result in wet pack issues which compromises instrument set sterility. The use of a single transportation layer provides protection for the sterilised sets without the need for additional layers of compliant wrap. “We are suggesting a two barrier system,” continued Joy Markey. “One microbial layer and one transportation layer. When compared to the use of a packaging system that uses two or three microbial layers, this can offer cost savings. Also, if the instrument sets need to be transported from the sterile services unit to another site, the use of Transportation Wrap ensures a reduction in the number of instrument sets being damaged and returned to sterile services.

“It is essential, when choosing a wrapping method, that consideration is given to how the instrument set will be aseptically

opened for use,” continued Joy Markey.

Before converting to such a combination, the following actions are recommended to ensure that the solution works as part of local reprocessing practice and protocols:

- Ensure that all relevant hospital stakeholders are aware and have an understanding of this approach to wrapping solutions.
- Conduct a local risk evaluation for process change (changing to a single barrier system with a transportation wrap). The evaluation should be based around all current equipment and procedures, ensuring the movement of instrument trays and all related equipment is compatible with the new wrap.
- Commence a ‘dummy’ trial to both reprocess and sterilise challenging instrument sets that are not required for theatres or clinics. This shall enable users to identify nonconforming issues in the initial phases and not impact on theatre lists.
- If the ‘dummy’ trial has been considered successful, it is recommended that one reprocessed and sterilised set with the new combination is sent for sterility integrity/ sterility assurance testing. This is most normally carried out at an external licensed laboratory through the hospital authorising engineer.
- Move forward to ‘live trials’. Prior to any live trial, Clinipak recommends a one-to-one consultation at the unit to

train and support staff with the changeover.

- Introduce changes to local protocol thereafter and commence with the use of the new wrap combination in the decontamination process.

**Conclusion**

Selecting and using the most appropriate sterilisation packaging is a challenging responsibility for healthcare professionals responsible for sterile services provision. Wrapping solutions available today can offer the cost and time savings that are being demanded across the NHS. However, before changing an existing wrapping method it is always important to ensure that it corresponds with existing practices and protocols. A risk assessment and testing should be conducted before considering a change in procedure and packaging system. CSJ

**Reference**

1 Webster J, Radke E, George N, Faoagali J, Harris M. Barrier properties and cost implications of a single versus a double wrap for storing sterile instrument packs. *American Journal of Infection Control*. 01 August 2005, vol./is. 33/6(348-352)

Share your views with other readers on the use of this approach to instrument set wrapping, as well as other key issues in sterile services, by emailing the Editor at: [louiseframpton@stepcomms.com](mailto:louiseframpton@stepcomms.com)

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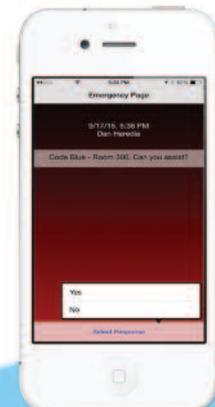
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