HALYARD

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STERILISATION WRAP AND BACK TABLE COVERS
THE CRITICAL DIFFERENCE TO MINIMISE THE RISK OF INFECTION IN THE OPERATING THEATRE

INTRODUCTION

In recent years a key priority for hospitals has been to reduce the level of healthcare associated infections (HAI). In targeting areas considered to be 'higher risk', initiatives have focused on specific types of HAI, such as surgical site infections (SSI).

Driven by both a desire to ensure patient safety as well as save money in the NHS, a combination of legislation, regulation and best practice guidance, together with the introduction of new techniques and the adoption of innovative technology, have combined to lower infection rates.

An important part of this ongoing process is the examination and evaluation of long-established processes and procedures and it is vital that this development is continuous to reflect changing circumstances. But because change is constant and, at times not easy to interpret or understand, it can lead to confusion and the continuation of practices which do not accurately reflect current standards.

This is the case with the continued use of sterilisation wrap as a back table cover in some hospitals.

The European Norms (EN) for Sterilisation Packaging have been revised and harmonised but practice in some operating theatres has not kept pace. Sterilisation wrap does not provide the necessary level of protection required of a back table cover in the sterile area of the operating theatre according to European standards. Continued use of sterilisation wrap as a back table cover, therefore, increases the risk of the surgical instruments becoming contaminated which, in turn, increases the risk of SSI.

THE CASE FOR MINIMISING THE RISK OF HAI

HAIs are a tremendous financial burden for society and considerable misery for patients and their families. A report by the Public Health Laboratory Service (PHLS) on HAI (Plowman et al, 1999) suggested that it may be costing the NHS in England £1 billion a year, with potential avoidable costs of approximately £150 million annually[1].

Surgical site infection is a type of healthcare-associated infection in which a surgical incision site becomes infected after a surgical procedure. It can cause significant morbidity and mortality if left untreated. Surgical site infections have been shown to account for up to 16% of all healthcare-associated infections[2].

Key to helping prevent SSI in the operating theatre is the maintenance of sterile area around the patient; the 'critical' area. This is achieved through the use of surgical drapes which 'serve as a barrier to endogenous and exogenous sources of contamination'. Draping not only contributes to protecting the surgical site but expands the sterile field allowing members of the sterile surgical team to place sterile instrumentation and supplies on the drape[3]. As such a back table cover is part of the sterile field.

Therefore back table covers, along with drapes and gowns, fall under EN 13795 completed in 2006[4] which clearly defines the performance requirements, levels and threshold values ***(Table 1)***. A matrix divides the products into 'standard' and 'high performance' and within each group thresholds for 'critical' and 'less critical' areas are indicated.

According to EN13795, resistance to liquid penetration must be ≥ 100cm H_2O for critical areas; the back table covers are part of the critical area and so must adhere to the norm. Sterilisation wrap is designed for a different function and does not meet this norm.

			Requirement			
			Standard Performance		High Performance	
Characteristic	Test Method	Unit	Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration – Dry	EN ISO 22612	CFU	Not required	≤ 300	Not required	≤ 300
Resistance to microbial penetration – Wet	EN ISO 22610	I_B	≥ 2.8	Not required	6.0	Not required
Cleanliness – Microbial	EN ISO 11737-1	CFU / 100 cm^2	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness – Particulate Matter	EN ISO 9073-10	IPM	≤ 3.5	≤ 3.5	≤ 3.5	≤ 3.5
Linting	EN ISO 9073-10	$\log_{10}$ (lint count)	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0
Resistance to liquid penetration	EN 20811	Cm H_2O	≥ 30	≥ 10	≥ 100	≥ 10
Bursting strength – Dry	EN ISO 13938-1	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength – Wet	EN ISO 13938-1	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength – Dry	EN 29073-3	N	≥ 15	≥ 15	≥ 20	≥ 20
Tensile strength – Wet	EN 29073-3	N	≥ 15	Not required	≥ 20	Not required

Table 1: Requirements EN 13795

STERILISATION PACKAGING; HARMONISING THE EUROPEAN NORMS

Sterilisation wrap is used to package surgical instruments and trays during the steam sterilisation process and other sterilisation processes (e.g. gas plasma, ethylene oxide). As such it needs to be permeable to steam and sterilant gases.

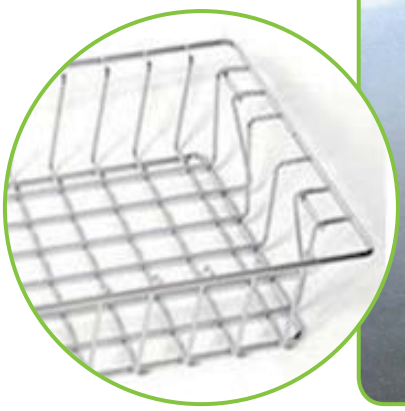
For optimal safety, sterilisation packaging must meet EN ISO 11607-1:2006 (Packaging for terminally sterilised medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems).

ISO 11607 is a harmonised standard and it replaces EN 868-1. It refers to a microbial barrier as the property of the sterile barrier system which ensures that it prevents the ingress of microorganisms, demonstrated under test conditions which consider sterilisation process, handling, distribution, transport and storage.

The standard describes:

- **Sterile Barrier System:** minimum package that prevents ingress of micro-organisms and allows aseptic presentation of the product at the point of use
- **Protective Packaging:** configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of assembly until the point of use
- **Packaging system:** combination of the sterile barrier system and protective packaging

As well as the barrier definition, EN ISO 11607 also covers a number of general requirements for sterilisation packaging including temperature, microbial barrier and shelf life.



EN 868; THE SOURCE OF CONFUSION

It would appear that confusion has arisen about the suitability of sterilisation wrap as a back cover as a result of an outdated version of EN 868-2.

The previous version of the EN 868-2 stated 'for materials where the intended use, as specified by the manufacturer, includes its use, as a sterile field where contact with low surface tension liquids can occur, the repellency to low surface tension liquids shall be tested in accordance with the requirements of Annex A.'

The standard test method for alcohol repellency requires putting a drop of 0.05ml or 5mm diameter of a well-defined alcohol containing solution, at three different locations on the test specimen. If after five minutes no penetration is observed the next level up of alcohol solution can be tested.

This test is not representative of the situation in an operating theatre where sterile trays exert an amount of pressure on table covers that become soiled with low surface tension liquid. This combination may lead to penetration if the table cover is not impervious, hence the requirement of EN 13795 to have a resistance to liquid penetration which is $\geq$ 100cm H_2O.

Indeed EN 868-2 2009, which replaces EN 868-2 1999, no longer mentions low surface tension liquids; it states: 'If the intended purpose according to the manufacturer of the material for sterile barrier system specifies the use as sterile field, then the additional requirements of the EN 13795 series apply.' So in the case of back table covers, their use is intended as a sterile field and fall under the scope of EN 13795 while sterilisation wrap does not.

ISO TS 16775; THE LATEST GUIDANCE

Recently new guidance was published that further emphasises the need to focus on the appropriate norm for sterilisation wrap. ISO TS 16775 states that if packaging material is used for another purpose than merely packaging the appropriate norm should be used.

ISO TS 16775 'does not provide guidance for applications of packaging materials and systems after their opening. In the use of packaging for other purposes such as a "sterile field" or transport of contaminated items, other regulatory standards will apply'.

CONCLUSION

Keeping up with European Norms in the healthcare setting requires constant monitoring and evaluation of changes to ensure that practices reflect current standards. In the case of sterilisation wrap being used as a back table cover, it would appear that some hospitals have not kept pace with the updated standards and so not benefiting from the guidance aimed at minimising the risks of HAI. An audit of practices, and an evaluation of products used in the sterile field of the operating theatre, would ensure that best practice according to EN 13795 – the appropriate standards for the critical area – are being met.

References **1.** British Journal of infection control: Healthcare governance and the modernisation of the NHS: infection prevention and control, OCTOBER 2002 VOL. 3 NO. 5. **2.** Surgical site infection, NICE (National Institute for Health and Care Excellence) October 2013 NICE Quality Standard 49. **3.** AST (Association of Surgical Technologists), recommendations 2008. **4.** EN 13795 can be purchased and downloaded from the BSI Shop at http://shop.bsigroup.com.

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