

Care without Compromise

The safe processing of multiple use surgical instruments

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Abstract
 This article explores some of the problems surrounding the decontamination of multiple use medical devices/surgical instruments and seeks to raise awareness of the most recent standard to be introduced.

2003 will herald the introduction of ISO 17664 – a European Standard that is specific to for multiple devices, which are intended for medical use.

It specifies that the information provided by the manufacturer will ensure that the medical device can be processed safely and so 'continue' to meet its performance specification.

It also states that the manufacturer must provide the customer with evidence of the validation and verification of the recommended cleaning, decontamination and sterilisation processes.

Introduction
 The life cycle of a re-useable surgical instrument has become a matter of public scrutiny, primarily because there is a serious issue of public safety.

The introduction of current guidelines and information from Hospital Technical Memorandums (appendix 1) placed the onus of responsibility on sterile services departments (SSDs) to provide evidence of validation of all parts of the cleaning, decontamination and sterilisation processes. The HTMs are far reaching and there are severe penalties for non-compliance.

The government also released Process Assessment Tool forms which have had a major impact on decontamination/sterilisation processes.

These guidelines and PAT Forms have changed the purchasing criteria for theatre/SSD managers, who are now including in their business case proposals, the methods and costs of reprocessing multiple use devices.

Investment in, and upgrading of SSDs throughout the country was long overdue and the changes have been welcomed by all those involved in the processing of contaminated devices.

we can even provide a signature to say that all parts of the system / process has been observed and completed but, sadly, it will not remove the proteins or bio-burden which adheres to the inside of a narrow lumen or the coiled spring of a flexible intra medullary reamer.

Indeed the use of incorrect chemical enzymes on a medical device may seriously compromise the product.

The writer of this article recently asked a UK manufacturer for cleaning, decontamination and sterilisation instructions for an instrument the company was promoting. After three requests the instructions were finally faxed, alas in French! Too often, instructions are ambiguous and may, for example, recommend US standards for temperatures and times which may not be relevant to the UK market and hospitals.

fit for purpose - re-defined

A surgical instrument may be excellent in function, ergonomically superb, and the surgeon convinced of the economic benefit to the trust. However, if it cannot be 'cleaned' it is a danger to the next patient it is used on.

'Fit for purpose' for a surgical instrument must be urgently re-defined to include decontamination, which must be seen as an

integral part of the 'purpose' of a re-useable instrument.

This article does not attempt to argue the benefits of 'single use' instrumentation but where this is not possible manufactures of surgical devices should provide the customer/users with clear instructions which, when implemented, result in sterility.

ISO17664

Theatre and Sterile Supply Managers will welcome the introduction of this new standard in 2003.

The standard specifies requirements for information to be provided, by the manufacturers, so that the device can be processed safely and will continue to meet its performance specifications. The standard also includes requirements for the verification and validation to be performed by the manufacturer.

It is interesting to note that under Section 6: Risk Analysis: the medical device manufacturer must perform a risk analysis to determine the content and detail of the information to be provided, and the manufacturer shall take into account the nature and intended use of the device, the likely training and knowledge of the processor and most importantly the equipment likely to

be available to the processor.

The requirement for risk analysis by the manufacturers will bring them into line with the requirements for managing risk within hospitals and SSDs.

We look forward to receiving the reprocessing instructions, in the correct language, which will assist the purchasers and all the users, to choose instruments/devices which have a validated decontamination / sterilisation process.

Only then should decisions be made about purchase.

Conclusion

We do not underestimate the challenges that compliance with the new standards present and manufacturers may have to return to the 'drawing board' as surgical instrument design is re-assessed.

Redefining 'fit for purpose' and providing validated instructions to the processors assists in our shared journey towards compliance.

The partnership between the product specialist and theatre staff has intensified over the past few years and extending your support and expertise to Sterile Supplies Departments must surely benefit all involved

in the process of providing the surgeon with a reusable instrument which is indeed - fit for purpose!

Appendix 1

Current guidance and information:

- Hospital Technical Memorandum (HTM) 2010 Sterilization
- Part 1 - Management Policy
- Part 2 - Design Considerations
- Part 3 - Validation and Verification
- Part 4 & 6 - Operational Management (testing and validation protocols)
- Part 5 - Good Practice Guide

Hospital Technical Memorandum (HTM) 2030 Washer Disinfectors

- Part 1 - Operational management
- Part 2 - Design considerations
- Part 3 - Validation and Verification

Hospital Technical Memorandum (HTM) 2031 Clean Steam for Sterilization

Hospital Building Note (HBN) 13 Sterile Services Department

- Supplement 1 - Ethylene Oxide Sterilization section
- Sterilization, Disinfection & Cleaning of Medical Equipment Guidance on Decontamination from the Microbiology Advisory Committee to the Department of Health. (MAC Manual)

Guidance produced by the Advisory Committee on Dangerous Pathogens, Sporeform, Encephalopathy Advisory Committee (SEAC)



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