ZENTRAL STERILISATION 1

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- reuse
- manufacturers' instructions
- processing

Instructions for Reuse: Beware when Buying!

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Introduction

Manufacturers' instructions for cleaning and sterilisation do not receive adequate attention during a hospital's purchase of reusable medical devices. Manuals often do not provide the necessary instructions for reprocessing. Staff working in the central sterilisation department (CSSD) come across uncommon cleaning and sterilisation processes. Unfortunately, in many of these cases the sterilisation department is confronted with a fait accompli in which a medical device has been purchased that the CSSD cannot reprocess adequately.

The acknowledgement by CEN and ISO of the necessity for a standard to include requirements for instructions for reuse prompted joint cooperation on this issue nearly ten years ago. The result of this work, the international standard, EN ISO 17664, was published in 2004. This standard requires the manufacturers of resterilisable medical devices to specify validated methods for reprocessing these after use, for example, after surgery. When developing the reprocessing techniques, the manufacturer must give due consideration to the practices and techniques available in the country where a device is marketed (see scope of ISO 17664). The instructions must also include the limitations placed on the reuse of the device, e.g. maximum number of reuses or clear indications for determining the moment of decommission (visible wear, backlash on hinges, etc.).

The standard identifies the following steps in the reprocessing procedure:

- preparation at the point of use
- preparation before cleaning
- cleaning, disinfection and drying
- inspection, maintenance and testing
- packaging
- sterilisation
- storage

Where applicable for the medical device, the manufacturer must give detailed instructions for each of these steps. For example, where cleaning is concerned, the manufacturer is required to specify both a manual method and at least one automated method using a washer disinfector. The manufacturer is to indicate the required accessories for cleaning, the type and concentration of process chemicals, the water quality, the temperature, the exposure time and the limits on these process parameters.

For sterilisation, the standard requires the sterilising agent to be specified in detail. Only stating that "ethylene oxide gas shall be used" is not sufficient; the composition of the gas mixture must also be stated. The sterilisation time and the post-treatment techniques, e.g. aeration of the sterilised products, are also to be specified.

To avoid the purchase of instruments that cannot be adequately reprocessed, the instructions for reuse should be evaluated during purchase. Inadequate instructions should be a reason for not purchasing the device. The concrete guidelines and requirements taken up in EN ISO 17664 may be useful in the assessment of the instructions for reuse. The Dutch Healthcare Inspectorate has requested the National Institute for Public Health and the Environment (RIVM) to develop a checklist to facilitate such an assessment by the sterilisation experts in the hospitals. Besides the development of the checklist, this study could also serve to provide some indication about the quality of the selected instructions for reuse.

Method

A comprehensive checklist was developed on the basis of the requirements in EN ISO 17664. In this fairly long checklist (96 questions), the user was asked to verify whether the instructions contained all the detailed information required by EN ISO 17664. At several positions in the checklist, the user had to verify whether the method (e.g. cleaning or sterilisation), as specified in the manual, was available in the hospital. The final questions in the checklist were enquiries about whether the sterilisation department of the particular hospital would be able to reprocess the device on the basis of the information provided.

The checklist was sent to ten Dutch sterilisation experts who had shown interest in the topic in personal communications. Most of them were managers of hospital sterilisation departments. Each of these experts was asked to select, according to their own experience and opinion, one instruction for reuse of insufficient quality, one of moderate quality and one of high quality; they were to evaluate these instructions using the checklist. The experts were asked specifically to comment on the checklist itself. Finally, they were requested to send a copy of the se-

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lected instructions, the completed checklists and their comments on the checklist to the RIVM. We verified the filled-in checklists to see whether the answers given by the assessors were in agreement with the intention of the checklist.

The comments received and the discrepancies between the answers given by the assessors and our own prompted us to prepare a new checklist. For the evaluation of the new checklist we selected three instructions for reuse that we had received from the sterilisation experts and sent these together with the revised checklist to the experts, requesting them to use it for checking the instructions and then comment on it once again.

Results

According to the experts, the first checklist did not place sufficient emphasis on ability of the hospitals to reprocess the device. It seemed that the experts were not really interested whether the instructions for reprocessing met all the EN ISO 17664 requirements. They expected to get information from the instructions for reuse, sufficient for them to decide whether or not the medical device could be reprocessed within their hospitals. Several members of the panel stated that although there was not enough information supplied by the manufacturer, they were nevertheless able to reprocess the particular medical device. Apparently they do not stick to the literal requirements in the instructions, but interpret this information using their know-how and experience in reprocessing similar devices. Furthermore, the checklist was too long and not to-the-point.

To resolve the problem of the experts we wrote a second version of the checklist, consisting of only six questions and focusing on whether the user is able, given the available facilities, to reprocess the medical device. For each question, a number of guidance questions were added to aid the user in determining whether there was sufficient information to perform each stage of the reprocessing procedure.

In general, the experts found this second version of the checklist suitable to their needs. The few comments they gave were mainly on the supporting questions. Incorporation of these comments into the checklist led to the final version (see Text box 1).

The checklist consists of six questions with accompanying supporting texts

Can the medical device be cleaned in an automated washer disinfector?
Can be disassembled to clean the component parts
Must be manually pre-cleaned
Inside component cleaned using an accessory to the washer disinfector (e.g. connector for MIC instruments)
Can be cleaned in an ultrasonic bath
Can withstand alkaline detergent / acid neutraliser
Can withstand temperatures up to 95 °C
Can withstand the drying temperature in the washer disinfector

Is an acceptable alternative method for manual cleaning and disinfection given?
Can be performed safely and within a reasonable time
Medical device may be submersed in detergent or disinfectant solutions
Necessary materials (e.g. detergent, disinfectant, brush) available
Internal parts of hollow instruments can be brushed and flushed with water

Are you convinced that the medical device can be adequately cleaned and disinfected?
Can be processed in an automated washer disinfector
Can be disassembled and the internal parts flushed in the washer disinfector
Adequate cleaning can be established visually or otherwise
Sterilisation department experienced in reprocessing similar types of medical devices

Can you check the proper functioning of the device after cleaning?
Visual check, performance check, measurements, tests, insulation test of electrosurgical instruments
Replacement of parts, adjustment, lubrication

Can you package the medical device?
Can be packed in normal instrument trays, containers, pouches, wrapping materials
Dedicated packaging material and/or system provided with the medical device and fits into the logistic system; does not conflict with standard operating procedures

Can you sterilise the medical device?
Device can withstand a temperature of 121 ± 3 °C or 134 ± 3 °C
No limits with regard to vacuum pressure, rate of pressure change and/or rate of temperature change
Where applicable, sterilisation process validated for sterilisation of hollow devices
Another sterilisation method, other than steam, available or outsourcing possible

Text Box 1: Final Checklist

Although this study was not primarily aimed at gaining insight into the quality of the instructions for reuse currently provided with reusable medical devices, the results were disappointing. Unfortunately, the instructions did not provide all the relevant information and/or the recommended processes and procedures were not available in the hospital. It should be noted, however, that only a limited number of instructions were evaluated and the instructions were not chosen at random. Therefore the results should not be generalised.

It was clear that many products were supplied by non-European companies, since a sterilisation process of 132 °C was often mentioned, as well as gravity-displacement steam-sterilisation processes. None of these sterilisation cycles were available in the Dutch hospitals. Apparently the manufacturers were not aware of the Dutch situation.

Specifications of the processes and their parameters were usually absent. For the washer disinfectors, there was often no temperature specified and even the type of detergent to be used was not usually given. Some manufacturers did not give any specific information on the cleaning and sterilisation processes at all, but instead referred back to the user for selecting the right sterilisation process for the product. It is doubtful that the user is ca-

A collection of examples showing inadequate, incomplete or inappropriate sterilisation instructions

- Steam sterilisation according to DIN standard
- Cold sterilisation or gas sterilisation
- 10–20 min at sterilisation temperature (134 °C)
- 4 min at 132–135 °C according to the ANSI/AAMI guidelines
- Sterilisation according to one's own protocol
- "The choices and validation of specific cycle and aeration parameters are the responsibility of the Health Care Institution."

Text Box 2

pable of doing this, regardless of the fact that the manufacturers neglected their own responsibility, as stated in the medical device directive.

See Text box 2 for a collection of inadequate sterilisation protocols in the instructions for reuse.

Discussion and conclusions

EN ISO 17664 is a comprehensive standard specifying proper instructions for reuse of medical devices. This standard is intended for manufacturers preparing their instructions for reuse rather than for users checking the instructions supplied with a product. This was the general opinion of the experts using our first extensive checklist. However, this standard does contain the necessary background information for users to assess the instructions for reuse. The revised checklist, consisting of only six questions, was considered to be a valuable tool for systematic assessment of instructions for reuse.

The quality of the instructions assessed during this study was disappointing. Quite a number of the instructions studied did not contain the necessary information for an adequate reprocessing procedure. Although the users will be able to reprocess most of these devices based on their professional knowledge and experience, the quality of the instructions needs to improve. To put pressure on the manufacturers to supply adequate instructions, hospitals should demand instructions for reuse according to EN ISO 17664. A sterilisation expert should evaluate the appropriateness of the instructions for reuse before the hospital purchases it. Inadequate instructions should be a reason for not purchasing that device.

The latest version of the checklist is available at http://www.rivm.nl/preventie/hulpmiddelen/Hergebruik/Instructies_voor_het_reinigen.jsp (in Dutch only). ✦