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 reproccessing. Staff working in the central sterilisation department (CSD) 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 CSD cannot reproccess 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 reproccessing these after use, for example, after surgery. When developing the reproccessing techniques, the manufacturer must give due consideration to the practices and techniques available in the country where a device is marketed (see above 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 and tear, abundance of oxides, etc.).

The standard identifies the following steps in the reproccessing procedure:

1. preparation at the point of use
2. preparation before cleaning
3. cleaning, disinfection and drying
4. inspection, maintenance and testing

Where applicable for the medical device, the manufacturer must give detailed instructions for each of these steps. For example, when cleaning is concerned, the manufacturer is required to specify both a manual method and at least one automatic method using a washer disinfecter. 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 '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 reproccessed, 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.

Moreover, 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 reproccess 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...
lected instructions, the completed check- lists and the results were sent to the RVIM. We verified the filled-in checklists to see whether the answers given by the assessors were in agree- ment with the intention of the checklist. The comments received and the dis- crepancies between the answers given by the assessors and our own promoted us to prepare a new checklist. For the eval- uation of the new checklist we selected three instructions for reuse that we had re- ceived from the sterilization experts and sent these together with the revised check- list 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 check- list 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 instruc- tions 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. Sev- eral members of the panel stated that al- though there was not enough information supplied by the manufacturer, they were nevertheless able to reprocess the par- ticular 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 check- list, consisting of only six questions and fo- cusing on whether the user is able, given the available facilities, to reprocess the medical device. For each question, a num- ber 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 sec- ond 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).

Although this study was not primarily aimed at gaining insight into the quality of the instructions for reuse currently pro- vided with reusable medical devices, the results were disappointing. Unfortunate- ly, the instructions did not provide all the relevant information and/or the recom- mended processes and procedures were not available in the hospital. It should be noted, however, that only a limited num- ber of instructions were evaluated and the instructions were not chosen at ran- dom. 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-dis- placement steam-stereilisation processes. None of these sterilisation cycles were available in the Dutch hospitals. Appar- ently 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 clean- ing and sterilisation processes at all, but instead referred back to the user for se- lecting the right sterilisation process for the product. It is doubtful that the user is ca-
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 sterilization 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.nvm.nl/preventie/hospideln/Hergebruik/Instructies_voor__Reinigingen.jsp](http://www.nvm.nl/preventie/hospideln/Hergebruik/Instructies_voor__Reinigingen.jsp) (in Dutch only).