Reprocessing Recommendations

Comparing AAMI Standards With the 'Red Book'

Holger Biering

About the Author

Holger Biering, PhD, is a consultant specializing in the cleaning and disinfection of reusable medical devices. He is a member of various standards organizations and guideline committees in the United States and in Europe. E-mail: Holger.biering@web.de

Recommendations about the reprocessing of reusable medical devices are made by AAMI standards, such as ANSI/AAMI ST79,[1] which covers steam sterilization, and AAMI technical information reports, such as TIR12,[2] TIR30,[3] and TIR34.[4] The focus of each document differs, but the maintenance of devices, their cleaning, and workers' safety are covered, in varying degrees, by all of them. Although mainly used in the United States, AAMI documents are also considered by authorities in other countries and scientific organizations in the drafting of their own standards or guidelines.

The brochure *Proper Maintenance of Instruments,* also known by its nickname, the *Red Book* (or brochure),[5] is a collection of recommendations about the reprocessing of medical instruments. This brochure, in its ninth edition, is prepared and updated by various medical industry experts who make up what's called Instrument Preparation Working Group, which was established 35 years ago in Germany. The objective of this document is the compilation and publication of practical information on the proper reprocessing of reusable medical devices, with a special focus on the maintenance of medical instruments. It is available in 19 languages and is commonly used in many countries in Europe, Asia, and Latin America.

The brochure *Proper Maintenance of Instruments,* also known by its nickname, the *Red Book* (or brochure), is a collection of recommendations about the reprocessing of medical instruments.

The recommendations in AAMI documents and the *Red Book* are not always identical, leading to conflicting guidance. For that reason, members of the Instrument Preparation Working Group, assisted by the working group's junior expert team, compared recommendations for each reprocessing step in the AAMI documents ST79, TIR12, TIR30, and TIR34 to the steps in the *Red Book,* and highlighted differences relevant to the maintenance of instruments.

Comparison Procedure

The stages for medical device reprocessing were divided into the following groups:

- Preparation for cleaning and disinfection
- Manual and automated cleaning and disinfection
- Inspection and care
- Packaging
- Sterilization
- Storage

Additional groups covered recommendations related to:

- Treatment of new and repaired instruments
- Treatment for returned goods
- Surface changes on instruments

Recommendations for each step in the four AAMI documents and the *Red Book* were compared by the subgroups. The complete team evaluated the findings in the next working stage, and ranked them as major and minor deviations, or as opportunities for improvement to the *Red Book* or to the AAMI documents.

Results

The comparisons show that the majority of recommendations in the four AAMI documents and the *Red Book* are the same or similar with respect to the maintenance of medical devices. Some examples of the differences and the group's evaluation can be seen in Table 1. In some cases, procedures are described in more detail in the AAMI documents. On the other hand, the *Red Book* recommends careful placement and handling of instruments after use, whereas AAMI documents do not mention this. The *Red Book* also contains a more detailed chapter covering surface changes on instruments, describing types of changes, origin and causes, treatment recommendation, preventive measurements, and risk analyses.

Other minor deviations are linked in most cases with local requirements i.e., efficacy range of disinfectants, preferred cleaner, or parameters for steam sterilization.

Major deviations were identified in two areas:

- Transport of contaminated items from the point of use to the decontamination area
- Lubrication of surgical instruments with moving parts, hinges, and box locks

Red, white, and blue: While they have different covers, a comparison of standards documents related to reprocessing in the United States and abroad finds many similarities.

Subject	Recommendation				Evaluation
	Red Book	TIR12	TIR30	ST79	
Treatment Immediately After Use	Coarse contamination should be removed immediately.	Soil is wiped from the device.	Some devices with lumens should be suctioned or flushed.	Gross soil should be removed if immediate cleaning is not possible.	Slight modifications, but no deviation.
Interval Between Use and Cleaning	Long intervals should be avoided. Timeframe up to 6 hours poses no problem.	Cleaning should begin as soon as possible.	Cleaning should take place as soon as possible.	Cleaning should take place as soon as possible.	Major deviation with respect to acceptable interval.
Transport	Dry disposal is preferred.	Moist disposal is recommended.	Moist disposal is recommended.	Moist disposal is recommended.	Major deviation.
Contact With Saline	Avoid contact with saline.	Don't moisten the towel with saline.	Don't moisten the towel with saline.	Don't moisten the towel with saline.	Same recommendation.
Device Placement	Careless dropping can damage instruments.	No advice.	No advice.	No advice.	Advice in U.S. standards could be helpful.
Transport Equipment	Use closed systems.	Use closed containment devices.	Items should be contained.	Items should be contained.	Same recommendation.
Cleaning Supplies	Soft, lint-free cloths or towels, plastic brushes or cleaning guns.	Surgical scrub brush, chenille pipe cleaners, cotton-tip applicators, several sizes and length of brushes, soft cloth, syringes.	Device manufacturer should specify the correct brush dimension (length and diameter) for lumen-containing instruments.	Lint-free clothes or towels, bushes with appropriate size and bristle type, daily disinfection or sterilization of reusable brushes	Equal recommendations Advice in Red Book with respect to size and bristle type of brushes, and disinfection or sterilization of reusable brushes could be helpful.

Table 1. Examples of Varying AAMI and Red Book Reprocessing Recommendations

Transport of Contaminated Items

AAMI documents recommend what the *Red Book* defines as "moist disposal": Contaminated items "should be kept moist in the transport container by adding a towel moistened with water (not saline) or foam, spray, or gel product specifically intended for this use. Transporting contaminated items in liquid is not recommended."[3]

The preferred transport option in the *Red Book* is the so-called "dry disposal." If "wet disposal" is applied, the *Red Book* and AAMI documents advise the immersion of contaminated items in a combined etergent-disinfectant solution with no protein-fixing effect. For this reason, detergent-disinfectants containing aldehyde should be avoided.

"Because of the corrosion risk and cleaning factors, long intervals between instrument use and processing for reuse (e.g., overnight or over the weekend) should be avoided, irrespective of the disposal method used (i.e., wet or dry). Experience has shown that in the case of dry disposal, in practice intervals of up to six hours pose no problem."[5,6] (It is worth noting that device manufacturers recommend that reprocessing begin as soon as possible.)

Lubrication of Surgical Instruments

AAMI documents recommend immersing "instruments for a few moments in a water-soluble lubricant solution or spraying them with a water soluble lubricant solution."[3] Additionally, "Silicone- or oil-based lubricants are not recommended."[3]

Preferred treatment in the *Red Book* is the "targeted application of instrument lubricant to the joints, hinges, locks, threads or friction surfaces of instruments such as clamps, scissors or punches…."[5] Furthermore, the *Red Book* describes the requirements for care agents as follows:

- Paraffin/white oil basis
- Biocompatible in accordance with the current European or United States Pharmacopoeia
- Suitable for steam sterilization and vapour-permeable[5]

Discussion

It is no surprise that most of the recommendations in AAMI documents and in the *Red Book* are the same or similar. All of these documents are prepared by teams of experts with much experience in the reprocessing of reusable medical devices. Nevertheless, some minor and two major deviations were identified in this comparison.

The findings with respect to the more detailed and precise procedures and appendices of the AAMI documents will be used to improve the next issue of the *Red Book*.

Likewise, those who draft AAMI standards and technical information reports might consider integrating the advice for careful placement and handling of medical instruments. "Careless dropping can damage instruments. For example, the hardened (tungsten carbide) tips of scissors may come off, or small clamps may be bent."[5]

Minor deviations related to the preferred use of chemicals or steam sterilization conditions are mainly caused by different requirements in local markets. This is not the case with respect to the two major deviations related to the transport of contaminated medical devices and the care of surgical instruments.

Wet, Moist, or Dry Disposal

"Wet disposal" was once the preferred transport option of contaminated instruments in some European countries. In most cases, detergent-disinfectants are used. The advantage of this option is the combination of precleaning effects with the reduction of viable microorganism on the contaminated items. This procedure reduces the occupational risk to personnel during manual cleaning. The precondition for applying this procedure is the use of waterproof containers. Disadvantages are the handling and transport of heavy containers, the amount of waste water, and the risk for carry-over of foaming cleaner into the washer-disinfector.

"Dry disposal" has been the preferred option in most of Europe for the past 15 years. Dry transport causes no problem with respect to cleaning ability and material compatibility when the transport time is less than six hours. Hospitals with integrated sterilization departments are able to manage this interval.

Sterilization departments have been increasingly outsourced in some European countries in the past couple of years. External sterilization departments offer the service for multiple hospitals with long transport distances, which may result in transport times exceeding six hours. The "moist disposal" option is the most

frequently used procedure in those cases. Investigations about material compatibility of stainless steel and anodized aluminium with foam sprays for moist disposal showed that for most of the products, no material damage/corrosion occurred at exposure times longer than six hours.[7] One product caused pitting corrosion at a contact time longer than six hours. The cleaning ability of these foams at longer storage time was not the objective of this study. Some side observations lead to the conclusion that the moisturizing and rinsing behaviors of foam cleaners at contact time longer than six hours should be investigated in further studies.

Wet, moist, and dry transportation of contaminated items have advantages and disadvantages, and should be mentioned in the standards/guidelines. Depending on the circumstances at point of use the preferred option should be selected by the hospital. The moist disposal option will be considered in the next issue of the *Red Book*. Nevertheless the Instrument Preparation Working Group will continue to recommend the dry disposal as the preferred option when transportation times are less than six hours. Furthermore, it is suggested that AAMI document integrate descriptions for dry and wet disposal options.

Instrument Lubrication

The compared five documents described three procedures for lubrication of surgical instruments with moving parts, joints, hinges, locks, and threads:

- Immersion of instruments in lubricant solution
- Spray instruments with lubricant solution manually or automated, i.e., in washer-disinfectors
- Targeted application of lubricant solution

Targeted application is the preferred procedure in the *Red Book*. It is most effective in the lubrication of moving parts, enhancing cleaning ability,[8] and has fewer side effects.

Immersion and spray of instruments, i.e., in the final rinse stage of automated washers are not recommended by the Instrument Preparation Working Group for the following reasons:

- The amount of lubrication agent on the moving parts is not high enough, especially in the case of very effective cleaning procedures.

Wet, moist, and dry transportation of contaminated items have advantages and disadvantages, and should be mentioned in the standards/guidelines.

- Lubricant agents on open instrument surfaces can cause colored deposits in the steam sterilization process.
- Lubricant agents can cause damages on plastic and rubber parts of washer-disinfectors.

Behaviors of lubricant agent are described more precisely in the *Red Book*. The term "water-soluble lubricant solution" and the discussion of oil-based lubricants sometimes leads to confusion for non-native speakers. Most of the lubricant solutions are based on paraffin-oil combined with surfactants and corrosion inhibitors. They are available as lubricant solutions or sprays.

It is suggested that AAMI expert groups consider the more detailed description of lubricant agent and consider changing the preferred procedure to targeted application.

Summary

The comparison of four AAMI documents and the *Red Book* shows a high level of consistency with respect to the maintenance of reusable medical devices and in their reprocessing procedures. The Instrument Preparation Working Group will consider the findings related to a more detailed and precise description of some procedures in the next issue of the *Red Book*. AAMI working groups should consider modification of the recommendations for transportation of contaminated items and for the care of surgical instruments. ■

The comparison of four AAMI documents and the *Red Book* shows a high level of consistency with respect to the maintenance of reusable medical devices and in their reprocessing procedures.

Acknowledgement

The comparison of the four documents was performed by the following senior and junior experts of the Instrument Preparation Working Group:

Klaus-Peter Becker (Ecolab), Holger Biering (Consultant), Christian Bullmann (Miele), Hans-Jörg Drouin (MMM), Robert Eibl (MMM), Wolfgang Fuchs (Aesculap), Rudolf Glasmacher (Ecolab), Ina Haacke (Dr.Weigert), Helmi Henn (Richard Wolf Endoskope), Ulrich Junghans (Fachhochschule Köthen), Karl Leibinger (KLS Martin Group), Winfried Michels (Miele), Sebastian Niebuhr (Ecolab), Ursel Oelrich (Aescu-

lap), Verona Schmidt (Dr.Weigert), Matthias Schöttler (Ecolab), Michael Sedlag (Miele), Jürgen Staffeldt (Dr.Weigert), Bernd Tangel (Richard Wolf Endoskope), Matthias Tschörner (Dr.Weigert), and Matthias Warken (Aesculap).

References

1. **ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 (Consolidated Text),** *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* Association for the Advancement of Medical Instrumentation. Arlington, VA.
2. **AAMI TIR12:2010,** *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.* Association for the Advancement of Medical Instrumentation. Arlington, VA.
3. **AAMI TIR30:2011,** *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.* Association for the Advancement of Medical Instrumentation; 2011. Arlington, VA.
4. **AAMI TIR34:2007,** *Water for the reprocessing of medical devices.* Association for the Advancement of Medical Instrumentation. Arlington, VA.
5. **Instrument Preparation Working Group.** *Proper Maintenance of instruments.* 9th revised ed. Morfelden-Walldorf (Germany): Arbeitskreis Instrumenten-Aufbereitung, 2009. Available at: www.a-k-i.org/index.php?id=11&L=1. Accessed April 11, 2012.
6. **Sonntag HG, Werner HP.** Arbeitstagung Hygiene in der zahnaerztlichen Praxis. *Hyg Med.* 1980;5:487-494.
7. **Biering H, Fuchs W, Staffeldt J.** Analysis of Stainless Steel and Anodized Aluminium Material Compatibility with Foam Sprays Used for Keeping Used Surgical Instruments Moist. *Zentr Steril.* 2010;18:240-243.
8. **Project Group Cleaning, Kirmse G.** Investigations About Reproducible Cleaning of Instruments Based on a Worst-Case Model. *Zentr Steril* 2011;19:26-36.