Technical Information Report

AAMI TIR12: 2010

Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

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Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

Abstract: This technical information report (TIR) covers design considerations that medical device manufacturers should take into account to help ensure that their products can be safely and effectively reprocessed. It also provides information on decontamination, cleaning, disinfection, and sterilization processes commonly used in health care facilities so that manufacturers can validate reprocessing procedures that can be recommended to and performed adequately in health care facilities. Labeling recommendations and information on applicable regulations are also provided in the TIR, as well as a bibliography and other informative annexes.

Keywords: cleaning, decontamination, disinfection, instructions for use, medical device design, sterilization
AAMI Technical Information Report

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

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### Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. **NOTE:** Documents are sorted by international designation. The code in the US column, "(R)20xx" indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

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Committee representation

Association for the Advancement of Medical Instrumentation

Instructions for Reusable Device Reprocessing Working Group

This technical information report (TIR) was developed by the AAMI Instructions for Reusable Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the TIR does not necessarily mean that all working group members voted for its approval.

At the time this document was published, the AAMI Instructions for Reusable Device Reprocessing Working Group had the following members:

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

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Foreword

This AAMI Technical Information Report (TIR) was developed by the AAMI Instructions for Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee.

The first edition of this TIR was published in 1994 and a second edition in 2004. The current edition, the third, provides up-to-date information on cleaning processes, cleaning verification, and currently available sterilization technologies. Also, the text and reference material have been generally updated for currency.

As used within the context of this document, “should” indicates that among several possibilities one is recommended as particularly suitable without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the TIR. “Can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulations. See also the NOTE on Page 1.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of AAMI TIR12:2010, Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, but it does provide important information about the development and intended use of the document.
Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities:
A guide for device manufacturers

Introduction

Scientific advances in diagnostic and therapeutic medicine have led to the development of new and sophisticated reusable medical devices and instruments for use by health care professionals. These devices vary in size, complexity, fragility, and immersibility, as well as in sensitivity to cleaning, disinfecting, and sterilizing agents and processes used. Manufacturers of reusable medical devices have the responsibility to support product label claims of reusability by providing complete and comprehensive written instructions for the handling, cleaning, disinfection, testing, packaging, sterilization, and, if applicable, aeration of their products. Manufacturers also have the responsibility to conduct and document any testing necessary to validate the suitability of these instructions. Manufacturers have these obligations under U.S. Food and Drug Administration (FDA) labeling regulations (21 CFR 801). Detailed FDA recommendations are provided in the FDA guidance document, Labeling reusable medical devices for reprocessing in health care facilities: FDA reviewer guidance (FDA, 1996).

Health care personnel have the responsibility to obtain and review manufacturers’ data and recommendations and to ensure that they have the necessary resources to follow manufacturers’ instructions thoroughly.

This TIR is intended to assist medical device manufacturers in the design, testing, and labeling of devices intended for reuse and reprocessing in health care facilities. Device manufacturers might wish to reassess the labeling of existing products in light of the recommendations of this TIR.

In addition, this TIR can serve as a resource for identifying the questions health care professionals should ask manufacturers when considering a product for purchase or when devising a reprocessing protocol for a product already being used. See also ANSI/AAMI ST40, ANSI/AAMI ST41, ANSI/AAMI ST58, and ANSI/AAMI ST79.

NOTE—This technical information report is not a standard, and the material contained herein is not normative in nature. The committee has used the term "shall" in a few instances, based on their knowledge of requirements contained in relevant standards and regulatory requirements.

1 Scope

1.1 Inclusions

The scope of this TIR includes the following topics:

a) Design considerations: Assurance that a device can be safely and effectively reprocessed begins with the design of the device. Section 3 of the TIR describes categories of medical devices and the materials and other design characteristics that affect the ability of health care personnel to clean, disinfect, and/or sterilize devices adequately.

b) Decontamination: A device cannot be disinfected adequately or sterilized to an adequate sterility assurance level (SAL) if it cannot be cleaned thoroughly. Section 4 addresses variables associated with cleaning and other decontamination processes used in health care facilities, as well as the minimum information that the device manufacturer should supply to health care personnel.

c) Disinfection: Section 5 describes the levels of disinfection, the criteria for selecting chemical disinfectants, and the testing that device manufacturers should perform to establish the effectiveness of the disinfection processes recommended for their products.

d) Sterilization: Section 6 describes the sterilization processes commonly used in health care facilities, the minimum information that device manufacturers should provide with their products, and the procedures that device manufacturers should use to qualify the sterilization parameters that they recommend for their products.
This TIR also includes definitions of terms, a list of references, and annexes providing supplementary information.

1.2 Exclusions

This TIR does not cover the following topics:

   a) the design, testing, and labeling of reusable textiles (see ANSI/AAMI PB70),
   b) the design, testing, and labeling of devices intended and labeled for single use, or
   c) the design, testing, and labeling of containment devices for reusable medical devices (see ANSI/AAMI ST77).

Although this TIR refers to water quality for cleaning and other elements of reprocessing, it does not address methods of producing or ensuring adequate water quality (see AAMI TIR34).