Health Canada / Santé Canada

June 1, 2011

Notice

Our file number: 11-109075-568

Re: Guidance Document: Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices

Health Canada is pleased to announce the release of the final version of the *Guidance Document: Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices*. A draft version of this guidance document was first published and released for consultation in 2006. Comments from stakeholders and the Scientific Advisory Panel on Reprocessing of Medical Devices have been considered in producing this final version.

To reduce the risks associated with the use of reprocessed reusable medical devices, Health Canada has developed this guidance document to aid manufacturers of Class I, II, III and IV reusable medical devices in the preparation of reprocessing and sterilization information to be provided with these devices.

The guidance document is intended to assist manufacturers in understanding and complying with the regulatory requirements of section 21(1)(i) of the *Medical Devices Regulations* as they pertain to the directions for use for reusable medical devices. This guidance document should be used in conjunction with the *Guidance Document on Recognition and Use of Standards under the Medical Devices Regulations*.

In order to provide industry with sufficient time to meet the specifications of the guidance document, Health Canada will allow a six-month transition period commencing on the date of implementation, June 1, 2011. Following the transition period, Health Canada will expect manufacturers to meet the specifications listed in the guidance document.

Further information on this guidance document, and a summary of comments received and Health Canada's responses to them, may be obtained by contacting:

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GUIDANCE DOCUMENT

Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices

Published by authority of the
Minister of Health

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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

Également disponible en français sous le titre : Ligne directrice - Renseignements devant être fournis par les fabricants pour le retraitement et la stérilisation des matériels médicaux réutilisables

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

TABLE OF CONTENTS

1 INTRODUCTION

1.1 Policy Objectives

To reduce the risks associated with the use of reprocessed reusable medical devices by assisting manufacturers in providing detailed instructions to users for the effective disinfection, cleaning and sterilization of these devices, as required by paragraph 21(1)(i) of the *Medical Devices Regulations*. (See Appendix 1 for the text of section 21).

The reprocessing procedure should also maintain the functionality of the device and the manufacturer should provide the user with instructions for testing its functionality when required.

1.2 Policy Statements

All manufacturers of reusable medical devices must include with their products appropriate reprocessing information that details the instructions for effective disinfection, cleaning and sterilization. This reprocessing information should meet requirements of the International Organization for Standardization (ISO) 17664:2004 (Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices) or the equivalent National Standard of Canada, CAN/CSA-ISO 17664:2004.

Alternately, as described in the guidance document titled, *Recognition and Use of Standards under the Medical Devices Regulations*, the manufacturer may provide Health Canada with evidence showing that the instructions for reprocessing comply with another equivalent or better standard, or provide evidence that the instructions contain an equivalent level of detail to enable the user to effectively clean, disinfect and sterilize the product.

Manufacturers are also expected to meet the Additional Expectations (section 2.3) of this guidance document.

1.3 Scope and Application

This guidance document applies to all manufacturers of Class I, II, III or IV reusable medical devices that are intended to be cleaned, disinfected or sterilized by the user.

This guidance document should be used in conjunction with the guidance document titled, *Recognition and Use of Standards under the Medical Devices Regulations*.

The use of the term “reprocessing” in this guidance document includes disinfection, cleaning and sterilization.

1.4 Background

Reusable medical devices are becoming increasingly complex and sophisticated as new technologies are developed. This increasing complexity often demands more challenging and arduous reprocessing of the devices prior to their reuse. Medical procedures involving inadequately reprocessed reusable medical devices carry the risk of exposing patients to pathogenic microbes which could lead to disease transmission from person to person.

Canadian health care facilities have expressed concerns that instructions provided with some reusable medical devices are not sufficiently detailed to enable users to reprocess these products effectively. Paragraph 21(1)(i) of the *Medical Devices Regulations* contain requirements for the labelling of products including directions for use. However, the *Medical Devices Regulations* do not specify any explicit requirements for the directions for use, such as their content and comprehensiveness.

In 2005, Health Canada referred this issue to the Health Canada Scientific Advisory Panel on Reprocessing of Medical Devices (SAP-RMD), composed of external experts in hospital infection control, reprocessing, sterilization, microbiology and standards development. The SAP-RMD reviewed the manufacturers' instructions provided with a variety of reusable medical devices and found that the quality and quantity of information provided was often inadequate. For example, some manufacturers had developed the practice of instructing users to follow routine hospital reprocessing procedures for the medical device rather than providing specific instructions for their products.

Following the review, the SAP-RMD recommended that Health Canada develop a guidance document to identify the reprocessing information that manufacturers should include in the instructions provided with their products, and that this information should comply with ISO 17664:2004, Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. The SAP-RMD also made some additional recommendations to help strengthen the quality of the instructions in an effort to further reduce the risks associated with the use of reprocessed reusable medical devices. Several of these recommendations have been included in this guidance document.

2 GUIDANCE FOR IMPLEMENTATION

2.1 Guidance Document Application to Class I, II, III and IV Medical Devices

This Guidance will be applied to Class I, II, III and IV reusable medical devices as described below.

2.1.1 Class I Medical Devices

Class I medical devices must meet the general requirements of the *Medical Devices Regulations* including the labelling requirements described in section 21. It is expected that manufacturers of Class I reusable medical devices will follow this guidance document in order to meet the labelling requirements, and will provide Health Canada with the necessary evidence to show compliance upon request.

2.1.2 Class II Medical Devices

Under paragraph 32(2)(d) of the *Medical Devices Regulations*, a manufacturer applying for a licence for a Class II medical device must include an attestation by a senior official of the manufacturer that the device meets the applicable labelling requirements of the *Medical Devices Regulations*. It is expected that manufacturers of Class II reusable medical devices will follow this guidance document in order to meet the labelling requirements, and will provide Health Canada with the necessary evidence to show compliance upon request.

2.1.3 Class III and IV Medical Devices

Under paragraph 32(3)(g) and 32(4)(o) of the *Medical Devices Regulations*, a manufacturer applying for a licence for a Class III or IV medical device must include with the application a copy of the medical device label and the directions for use. In complying with these regulatory requirements, manufacturers should submit to Health Canada evidence that the directions for use provided with the reusable medical device meet the specifications of this guidance document. Health Canada also requests manufacturers to provide validation information demonstrating that the recommended reprocessing procedures will be effective when carried out in a hospital's reprocessing department using equipment and supplies typically available in such a facility.

If a manufacturer elects to demonstrate conformance with ISO 17664:2004 or CAN/CSA-ISO 17664:2004, a Declaration of Conformity is expected to be submitted in accordance with section 2.1.2 of the guidance document, *Recognition and Use of Standards under the Medical Devices Regulations*. If a manufacturer elects to either:

- comply with an equivalent or better standard; or
- provide alternate evidence that the instructions contain an equivalent level of detail to enable the user to effectively reprocess the product;

the manufacturer must provide Health Canada with detailed information with the medical device licence application. If the manufacturer does none of the above, a licence will not be issued.

2.2 ISO 17664:2004

ISO 17664:2004, developed by the International Organization for Standardization (ISO), specifies the information to be provided by a medical device manufacturer on the reprocessing of

medical devices claimed to be resterilizable and medical devices intended to be sterilized by the processor. The purpose of ISO 17664:2004 is to ensure that the reprocessing instructions included with the device provide sufficient clear information so that the medical device can be reprocessed safely and will continue to meet its performance specification. The standard includes requirements for reprocessing, including:

- preparation at point of use;
- preparation, cleaning, disinfection;
- drying;
- inspection, maintenance and testing;
- packaging;
- sterilization; and
- storage.

The standard also provides templates for the presentation of this information. Appendix 2 of this guidance document gives a more detailed example of the kind of information a manufacturer should provide.

2.3 Additional Expectations

2.3.1 General

All information provided to the purchaser of the medical device, either by the manufacturer, importer or authorised dealer, should be endorsed by the manufacturer.

2.3.2 Information to be provided upon request by the purchaser

The *Medical Devices Regulations* (subsection 23(2)) require that, where the directions for use are supplied in only one official language at the time of sale, the manufacturer must provide them in the other official language as soon as possible at the request of the purchaser (see Appendix 1).

Upon request by the purchaser of the medical device, the manufacturer or importer should provide the following information:

a. The names of suppliers of equipment and tools, and the trade name of at least one example of each cleaning agent, disinfectant, sterilant or other product that is necessary for reprocessing and testing the medical device and has been validated by the manufacturer to be acceptable.

b. A summary of the validation procedures carried out by the manufacturer to confirm that the specific medical device in question will be clean and sterile when reprocessed as directed. Groups of similar devices may share the same validation, provided that the reprocessing procedures are the same for all the devices included in that group.

c. A summary of the validation for sterilizing the medical device while in its container, if the medical device is sold in a container in which it is to be sterilized.

2.3.3 Instructions

Instructions for disassembly and reassembly of the medical device should include photographs or schematic diagrams and a list of the components of the medical device.

Instructions should be specific to the medical device in question. An identifier, such as a catalogue number, should be provided in the instructions and marked on the medical device if possible. Groups of similar devices may share the same instructions, provided that the reprocessing procedures are the same for all the devices included in that group.

Sterilization instructions should specify the reprocessing method, process temperatures and times, and drying or aeration times to be used.

Reprocessing instructions should take into account the reprocessing equipment usually available in a health care facility and the times and temperatures commonly used in North America.

2.3.4 Limited Use Devices

A reusable medical device designated by the manufacturer as intended for a specific number of reprocessing cycles should, where feasible, be marked with an identifier unique to that individual medical device which enables the user to:

a. track the number of times the medical device has been reprocessed; or

b. identify when the medical device will no longer safely fulfil its intended use.

3 APPENDICES

APPENDIX 1: Labelling Requirements of the *Medical Devices Regulations*

21. (1) No person shall import or sell a medical device unless the device has a label that sets out the following information:

(a) the name of the device;
(b) the name and address of the manufacturer;
(c) the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
(d) in the case of a Class III or IV device, the control number;
(e) if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units;
(f) the word "Sterile", if the manufacturer intends the device to be sold in a sterile condition;
(g) the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life;
(h) unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use;
(i) the directions for use, unless directions are not required for the device to be used safely and effectively; and
(j) any special storage conditions applicable to the device.

(2) The information required pursuant to subsection (1) shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.

22. (1) Subject to subsection (2), if a medical device is intended to be sold to the general public, the information required by subsection 21(1) shall

(a) be set out on the outside of the package that contains the device; and
(b) be visible under normal conditions of sale.

(2) Where a package that contains a medical device is too small to display all the information in accordance with section 21, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sale.

23. (1) Subject to subsection (3), the information required by subsection 21(1) shall, as a minimum, be in either English or French.

(2) Subject to subsection (3), where the directions for use are supplied in only one official language at the time of sale, directions for use in the other official language shall be made available by the manufacturer as soon as possible at the request of the purchaser.

(3) In respect of a medical device to be sold to the general public, the information required by paragraphs 21(1)(a) and (e) to (j) shall, as a minimum, be in both English and French.

APPENDIX 2: TABLE OF REPROCESSING INSTRUCTIONS FOR REUSABLE MEDICAL DEVICES

Details of reprocessing instructions as recommended in CAN/CSA/ISO 17664

Note: This table is intended to serve as a checklist for the manufacturer and should be made available to users in addition to, or in conjunction with, the detailed instructions for use and reprocessing. Manufacturers should indicate whether each of these processes and steps is recommended or not recommended. Attach a copy of the validated, detailed reprocessing instructions where applicable.

Product Name:
Manufacturer:
Product Number (optional):
Contact (Name, telephone number, email address):

Specify the intended use of device and method of reprocessing required by checking the appropriate box or boxes:

- ☐ Non-critical contact (contacts intact skin only); requires low level disinfection
- ☐ Semi-critical contact (contacts mucosal surface but does not enter sterile body site); requires high level disinfection
- ☐ Critical contact (enters sterile body site or is exposed to blood); requires sterilization

If more than one box is checked, separate forms and processes are needed.

PROCESS	PROCESS STAGE	PROCESS STEP	RECOM'D	NOT RECOM'D	Specific information to be provided by manufacturer (attach details)
PREPARATION AT POINT OF USE	SOAKING AFTER USE				Specify type of detergent or agent to use for soak (for example [e.g.] alkaline, acidic, neutral pH, enzymatic solution, enzymatic foam, or water).
					Specify maximum soak time and volume of rinse solution.
DECONTAMINATION	PREPARATION	DISASSEMBLY			Device specific disassembly instructions with pictures.
	CLEANING (INCLUDES RINSING)	MANUAL CLEANING			Specify any special cleaning brushes or tools needed.
					Specify water quality needed. Specify type of agent to use for cleaning (e.g. alkaline, acidic, neutral pH, enzymatic solution, enzymatic foam, or water). Specify minimum volume of water needed for rinsing.
		AUTOMATED (MACHINE) CLEANING			Specify type of detergent to use for cleaning (e.g. alkaline, acidic, neutral pH).
					Specify water quality needed and maximum temperature (if applicable) that medical device can withstand.
		ULTRASONIC CLEANING			Specify whether cleaning solution is to be used and if so, specify type (e.g., low sudsing).
					Specify (if applicable) duration of exposure of instrument to ultrasonic cleaning.
					Specify sonication conditions that medical device can withstand for cleaning.

DISINFECTION	LIQUID CHEMICAL	AUTOMATED OR MANUAL			Specify compatible liquid chemicals that can be used.
					Specify validated exposure time to liquid chemical.
					Specify water quality for rinse and minimum volume for rinsing.
	THERMAL	AUTOMATED ONLY			Specify maximum time and temperature that medical device can withstand.
					Specify water quality.
DRYING					Specify how device should be dried (e.g. pressurized air at recommended maximum air pressure, manual wiping, heat, etc.).
					Specify maximum temperature the medical device can withstand
PREPARATION and PACKING	REASSEMBLY				Provide device-specific reassembly instructions with pictures
					Specify whether device is not to be reassembled (or only partially reassembled) prior to sterilization.
MAINTENANCE					Specify any requirements for ensuring functionality, e.g., sharpening, lubrication, testing device function, testing sheath integrity.
STEAM STERILIZATION	DYNAMIC AIR REMOVAL				Specify time and temperature for which sterilization of device has been validated.
					Where possible, specify time and temperature cycles used in North American health care facilities, that is (i.e.), 132°C for 4 minutes or 135°C for 3 minutes. (See CSA Z314.3 and AAMI ST 79). If extended cycles are required, use 132 - 135°C for 10 or 20 minutes.
	GRAVITY DISPLACEMENT				Specify time and temperature for which medical device has been validated

					Where possible, specify time and temperature cycles used in North American health care facilities, i.e., 132°C for 4 minutes or 135°C for 3 minutes. (See CSA Z314.3 and AAMI ST 79.) If extended cycles are required, use 121°C for 40 or 60 minutes.
ETO STERILIZATION					Validate that EtO residues are acceptable after standard aeration time of 12 hours.
OTHER STERILIZATION PROCESSES					Specify sterilization process including cycle and conditions for which device has been validated.
DEVICE TO BE STERILIZED IN CONTAINER PROVIDED BY MANUFACTURER					Provide attestation that validation of the recommended sterilization process has been performed in the specified containment system.