



1. INTRODUCTION

Medical device manufacturers wish to ensure that there is sufficient clarity on how devices need to be treated before and during the process of product returns. This document is issued in order to establish a consensus between hospitals, health care professionals as well as manufacturers and distributors of medical devices, on how products should be returned. The premise for this best practice standard is the protection and preservation of health and safety for health care, transport and industry personnel who may handle these devices at any stage of the return process.

This document describes the standard requirements for the return of explanted and/or contaminated medical devices for inspection, analysis, investigation or disposal by the original device manufacturer or their distributor or agent. The standard requirements apply to preparation, packaging, labeling and shipping of medical devices and components that have been exposed to tissues, body fluids, known or suspected pathogens, or that have been in contact with materials exposed to any of the aforementioned contaminants.

2. SCOPE

This document applies to health care facilities and other institutions that may handle explanted and/or contaminated medical devices (e.g. funeral homes, coroners).

The content of this document applies to the return of explanted and/or contaminated medical devices and components for inspection, analysis, investigation or disposal by the original device manufacturer, distributor, or their agent. The scope of the requirements specified within this document apply to such devices whether or not the device is returned with its original packaging.

This document does not apply to the inter-institutional transfer of reusable medical devices or the return of reusable medical devices to the original manufacturer, distributor or agent for the purpose of reprocessing. For these purposes, refer to the current version of Canadian Standard CSA Z314.22-10 *Management of loaned, reusable medical devices*.

This document does not provide guidance for the preparation or shipment of radiation emitting contaminated medical devices. For such devices, senders should contact the manufacturer for specific return packaging and transportation instructions.

Within Scope of this Standard	Outside of Scope of this Standard
<ul style="list-style-type: none"> • Health care facilities and other institutions that may handle explanted and/or contaminated medical devices • Explanted and/or contaminated medical devices and components returned to the manufacturer or distributor for inspection, analysis, investigation, repair or disposal • Reusable medical devices returned to the manufacturer or distributor for investigation due to an alleged adverse event, or product failure. 	<ul style="list-style-type: none"> • New (in original packaging with all seals intact) or unsealed but unused medical devices that have not been exposed to biological contaminants • Reusable medical devices shipped to the original manufacturer, distributor or agent for the purpose of reprocessing • Radiation emitting medical devices



3. RELATED DOCUMENTS

- *Canada Labour Code* (R.S.C., 1985, c. L-2) Part II Occupational Health and Safety
- *Transportation of Dangerous Goods Act*, 1992 (S.C. 1992, c. 34)
- *Transportation of Dangerous Goods Regulations* (SOR/2001-286) have been consolidated to include SOR/2014-159 (Part 4, Dangerous Goods Safety Marks) and SOR/2014-152 (Update of Standards).
- *Canada Occupational Health and Safety Regulations* SOR/86-304
- *Occupational Health and Safety Act*, Alberta (RSA 2000 Chapter 0-2)
- *Occupational Health and Safety Regulation*, Alberta (Alberta Reg. 62/2003)
- *Occupational Health and Safety (OHS) Regulation*, British Columbia (B.C. Reg. 296/97)
- *The Workplace Safety and Health Act*, Manitoba, (C.C.S.M c. W210)
- *Workplace Safety and Health Regulation*, Manitoba (*Manitoba Reg. 217/206*)
- *Occupational Health and Safety Act*, New Brunswick (Chapter O-0.2)
- *Occupational Health and Safety Act*, Newfoundland and Labrador (RSNL1990 CHAPTER O-3)
- *Occupational Health and Safety Regulations*, Newfoundland and Labrador (5/12)
- *Occupational Health and Safety Act*, Nova Scotia (S.N.S. 1996, c.7, s.1)
- *Occupational Safety General Regulations*, Nova Scotia (N.S. Reg. 44/99)
- *Occupational Health and Safety Act*, Ontario, (R.S.O 1990 Chapter O.1)
- *An Act Respecting Occupational Health and Safety*, Quebec, (R.S.Q., c. S-2.1)
- *Regulation respecting occupational health and safety*, Quebec (S-2.1, r. 13)
- *The Occupational Health and Safety Act*, 1993 which was repealed by Chapter S-15.1 of the Statutes of Saskatchewan, 2013 (effective April 29, 2014). The Saskatchewan Regulations continue in force under The Saskatchewan Employment Act (S-15.1).
- *The Occupational Health and Safety Regulations*, Saskatchewan (1996, Chapter O-1.1 Reg 1)
- *Occupational Health and Safety Act*, Yukon (RSY 2002, c.159; amended by SY 2005, c.4; SY 2009, c.21; SY 2010, c.12)

Note: *Occupational Health and Safety Regulations* for Nunavut and Northwest Territories remained in draft at the time of publication of this best practices standard.

4. DEFINITIONS

Contamination	Direct or indirect exposure to tissues, body fluids, known or suspected pathogens, including contact with materials previously exposed to any of the aforementioned contaminants.
Decontamination	Cleaning, followed by inactivation of pathogenic micro-organisms, to render an object safe for handling.
Explanted Medical Device	A device that was previously implanted and is subsequently removed from a surgically or naturally formed cavity in the human body.
Health care facility	A facility where people are accommodated on the basis of medical and/or nursing need.
Implant	A device that is placed into a surgically or naturally formed cavity of the



	human body and is intended to remain there for 30 days or more.
Infectious substance	A substance known or reasonably believed to contain viable micro-organisms such as bacteria, viruses, rickettsia, parasites, fungi and other agents such as prions that are known or reasonably believed to cause disease in humans or animals.
Loaned reusable medical device	Medical device that is not labeled for single-use only and is provided on loan by the manufacturer, distributor or their agent to an institution.
Medical device (including medical device sets and accessories)	Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of <ol style="list-style-type: none">diagnosis, prevention, monitoring, treatment, or alleviation of disease;diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap;investigation, replacement, or modification of the anatomy or a physiological process; orcontrol of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but can be assisted in its function by such means.
Organization	A business, company, or facility that is involved in manufacturing, distributing, transporting, reprocessing, or using a medical device. This includes health care facilities, manufacturers and their agents and distributors.
Pathogen	An infectious substance.
Recipient	An organization that is receiving a medical device from another organization.
Reprocessing	The steps performed to prepare a used medical device for reuse.
Reusable medical device	Medical device that is not labeled for single-use only.
Sender	An organization from which a device is being transferred.
Sterilization	The validated process used to render a product free from viable micro-organisms.
Transfer	Preparing and moving a device from one organization to another. It includes sending, transporting, and receiving.
Transportation	Movement of medical devices between geographically separate organizations.

5. PURPOSE

In accordance with Part II of the Canada Labour Code, the purpose of this document is to avoid preventable injury to health arising out of, linked with, or occurring to persons who handle or are otherwise exposed to contaminated medical devices in the course of their employment.



Conformance with the guidance issued herein is intended to promote compliance with provincial occupational health and safety acts, regulations and codes; infection control standards and policies, and the Federal Transportation Regulations;

6. DOCUMENTATION

It is recommended that each institution that purchases or makes use of medical devices that are subject to contamination, as described above, shall have written procedures in place for the preparation of any explanted, or otherwise contaminated medical device, for transfer to the manufacturer, distributor or their agent, for the purpose of inspection, analysis, investigation or disposal. Such procedures should specify the necessary documentation for this activity. Where such written procedures are not established de novo, for any institution, this document, in its entirety, when completed and signed by an authorized representative of the institution (see Section 7), may represent the written procedures referred to in this section.

Procedures shall include

- A. specifications for the handling and packaging of contaminated medical devices (CMDs) destined for return to the manufacturer.
- B. specifications for the documentation to be sent with the returned device.
- C. provisions to follow separate and specific instructions provided by the manufacturer for the preparation, packaging, labeling and shipping of medical devices, when those instructions are not in accordance with this document.

7. PROCEDURE

The following instructions apply to contaminated medical devices that are neither known nor reasonably believed to have been exposed to any infectious substance.

For any contaminated medical device that is known or believed to have been exposed to infectious material, the sender should contact the manufacturer or intended recipient, prior to preparing the device for return.

A. GUIDING PRINCIPALS

- i. The sender should contact the recipient and obtain a return authorization and/or specific return instructions, prior to returning the device. This will enable traceability and timely processing upon receipt.
- ii. The chain of custody of the device must be traceable. The sender should retain a record of how the device was handled, to whom it was sent and when it was shipped.
- iii. Any cleaning or decontamination necessary for transfer should be performed in a manner that impacts the condition and structural integrity of the device as little as



possible (for example, the device should not be disassembled if that can be avoided, a partially broken component should not be pulled off in the cleaning process, etc.)

- iv. Containment and packaging should attempt to minimize the chance that the condition and structural integrity of the device will be affected in transit (for example, the device should not be loose in an oversized box without adequate packing material, any broken pieces should be stabilized if possible, etc.).

B. RETURN PROCESS

For contaminated medical devices NOT exposed to infectious substance(s):

- i. The device must be cleaned of all visible blood, tissue and body fluids.
- ii. Carefully wipe the external surfaces of the device and all integral accessories/components with a concentrated germicide or detergent.
- iii. DO NOT subject the device to sterilization or immersion in a decontamination agent unless expressly instructed to do so by the intended recipient of the returned device.
- iv. Ensure that all essential components of the device are present. The sender shall communicate any deviation from these requirements on the documentation accompanying the device.
- v. Contaminated medical devices shall be carefully prepared for transportation in accordance with the manufacturer's instructions and the health care facility's protocols for the transport of dangerous goods.
- vi. Determine the appropriate containment and packaging for the device to be returned (See Sub-section 7.viii., below). Manufacturer-supplied and/or device-specific return shipping containers should be used whenever possible.
- vii. Complete an *Explanted / Contaminated Medical Device Return Form* (Appendix A) or other institutional or manufacturer-supplied document. The minimum information to be recorded includes the device identification (e.g. model and serial number), date of explant/removal (if applicable) and the reason for explant and/or return of the device. Unless the device has been sterilized or decontaminated according to the manufacturer's instructions, return documentation must specify that the "Device is contaminated".
- viii. The device must be sealed within two (2) impermeable containers (internal and external) such as sealable specimen bags of sufficient size, or other containment devices. Containers must be clearly labeled: "Biohazard". For devices that contain liquid or include liquid contaminants, an absorbent material shall be placed in the external containment device.



- ix. The double-contained device must be placed in a rigid transportation container (e.g. specimen container or shipping carton) with a copy of the device return form. If the device does not fit in a standard specimen bag, it should be placed in a suitably sized, labeled specimen container or other impermeable containment device specified by the manufacturer or intended recipient, with a copy of the device return form or similar document securely affixed to the container.

8. ENFORCEMENT

To ensure the safety of all returned device handling personnel, any explanted and/or potentially contaminated medical device that is shipped to a manufacturer, distributor or agent, and that is not packaged in accordance with this Best Practices Standard may be disposed of immediately, by the recipient, using appropriate biohazard containment and disposal practices. Any such device(s) will not be subjected to inspection, analysis, investigation or evaluation by the recipient. Whether to dispose of an improperly packaged device will ultimately be the decision of the manufacturer, distributor or agent in question, having regard to their own internal product analysis processes and applicable legal obligations.