

AS 23907:2023



STANDARDS
Australia



Sharps injury protection — Requirements and test methods — Sharps containers (ISO 23907-2:2019, MOD)



AS 23907:2023

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The following are represented on Committee HE-011:

- Australasian College for Infection Prevention and Control
- Australian College of Perioperative Nurses
- Australian Dental Association
- Australian Funeral Directors Association
- Australian Healthcare and Hospitals Association
- Australian Medical Association
- Australian Nursing and Midwifery Federation
- Australian Private Hospitals Association
- Australian Society for Microbiology
- Consumers Federation of Australia
- Department of Environment and Science (QLD)
- HealthShare Victoria
- Medical Technology Association of Australia
- NSW Health
- Queensland Health
- Royal Australian College of General Practitioners
- Royal College of Pathologists of Australasia
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- Waste Contractors and Recyclers Association of NSW
- Waste Management and Resource Recovery Association of Australia

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Sharps injury protection — Requirements and test methods — Sharps containers (ISO 23907-2:2019, MOD)

Originated in part as AS 4031—1992.
Originated in part as AS/NZS 4261—1994.
Revised, amalgamated and redesignated in Australia as AS 23907:2023.

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Preface

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-011, Safe Management of Sharps and Related Wastes, to supersede AS 4031:1992, *Non-reusable containers for the collection of sharp medical items used in health care areas* and its Amendment 1 (1996) and AS/NZS 4261:1994 *Reusable containers for the collection of sharp items used in human and animal medical applications* and its Amendment 1 (1997).

AS 4031:1992 and AS/NZS 4261:1994 will remain current for 12 months after the date of publication of this document and after this time they will be superseded by AS 23907:2023. Regulatory authorities that reference this document in regulation may apply these requirements at a different time. Users of this document should consult with these authorities to confirm their requirements.

The objective of this document is to specify requirements for single-use and reusable sharps containers intended to hold potentially hazardous sharps medical waste with or without sharps protection features, e.g. scalpel blades, trocars, hypodermic needles and syringes.

This document is applicable to sharps containers supplied as assembled units by the manufacturer and to those supplied as components intended to be assembled by the user.

This document includes design functionality and performance testing for user/handler safety for single-use and reusable sharps containers, and in addition, lifespan simulation, cleaning and decontamination, microbiological validation and quality monitoring for reusable sharps containers.

This document is an adoption with national modifications, and has been reproduced from ISO 23907-2:2019, *Sharps injury protection —Requirements and test methods—Part 2: Reusable sharps containers*.

The inclusion of national variations in boxed text above the relevant clauses in this modified adoption, was approved by the Standards Australia Production Management Group (PMG) on 21 January 2022, as a one-off exemption to the directives of [Clause A.3](#) in Standardization Guide 007: Adoption of International Standards.

In this edition, the design and testing requirements for single-use and reusable sharps containers for use in Australia have been updated and combined in one document.

To meet these requirements in an efficient manner, the requirements of the most recent ISO sharps container standard (ISO 23907-2:2019) have been adopted and specific clauses modified or added for application in Australia.

The major changes from AS 4031:1992 and AS/NZS 4261:1994 to this document are as follows:

- (a) Design:
 - (i) Increasing the number of definitions.
 - (ii) Increasing the safety requirements for apertures and closures.
 - (iii) Updating the colours required for sharps containers.
 - (iv) Recommending that needle-removal devices in sharps containers be prohibited.
 - (v) Requiring all sharps containers to have a temporary and permanent closure.
 - (vi) Requiring single-use sharps containers to have penetration requirement of 20N.
 - (vii) Redefining fill line capacity to allow greater flexibility in aperture design
 - (viii) Including cleaning, decontamination and process-validation for reusable sharps containers.

- (ix) Increasing the requirements for pre-test lifespan simulation for reusable sharps containers.
- (b) Testing:
 - (i) Decreasing the mass required in the strength of handle test.
 - (ii) Increasing the number of samples required in penetration test.
 - (iii) Decreasing the fluid volume and mass in the drop test.
 - (iv) Including a new spillage by toppling test.

The reasons for national modification are to —

- (i) enable single-use and reusable sharps containers to be included in one document;
- (ii) depict which clauses specifically apply to reusable sharps containers; and
- (iii) include changes required by Australia as follows:
 - (A) Include AS 3816:2018, *Management of clinical and related wastes*, in normative references.
 - (B) Definition of “manufacturers maximum allowable gross mass”.
 - (C) Recommendation that needle-removal devices in sharps containers be prohibited.
 - (D) Specify the colours of sharps containers according to their contents.
 - (E) Single-use containers to meet requirements of this document, as follows:
 - (1) 20 N penetration requirement.
 - (2) Six orientation drop test.
 - (F) Clarify grammar or sentence structure.

As this document has been reproduced from an international standard, a full point substitutes for a comma when referring to a decimal marker.

Australian or Australian/New Zealand standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific standards.

The terms “normative” and “informative” are used in standards to define the application of the appendices or annexes to which they apply. A “normative” appendix or annex is an integral part of a standard, whereas an “informative” appendix or annex is only for information and guidance.

Contents

Preface	ii
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements and recommendations	4
4.1 General.....	4
4.2 Design and construction.....	5
4.2.1 General.....	5
4.2.2 Container stability.....	5
4.2.3 Strength of handles.....	6
4.2.4 Aperture and closure.....	6
4.2.5 Resistance to penetration.....	7
4.2.6 Resistance to damage or leakage after dropping.....	7
4.2.7 Resistance to damage or leakage after toppling.....	8
4.2.8 Fill line.....	8
4.3 Closure device.....	8
4.4 Monitoring of reuses.....	8
4.5 Cleaning and decontamination.....	9
4.5.1 Cleaning and decontamination process.....	9
4.5.2 Microbiological validation.....	9
5 Lifespan simulation prior to testing	10
5.1 General.....	10
5.2 Conditioning.....	10
5.3 Tumbling with sharps simulation.....	10
5.4 Transport simulations.....	11
5.5 Processing simulations.....	11
6 Test methods	12
6.1 Container stability.....	12
6.2 Strength of handle(s).....	12
6.3 Resistance to penetration.....	13
6.3.1 Apparatus.....	13
6.3.2 Procedure.....	13
6.4 Resistance to damage and leakage after dropping.....	13
6.4.1 Apparatus.....	13
6.4.2 Procedure.....	14
6.5 Resistance to spillage by toppling.....	15
6.5.1 Apparatus.....	15
6.5.2 Procedure.....	15
7 Quality monitoring: Post decontamination quality assurance	15
8 Labelling and marking and instructions for use	16
8.1 Labelling and marking.....	16
8.2 Instructions for use.....	17
Appendix A (informative) Microbiological validation	19
Bibliography	23

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

A list of all parts in the ISO 23907 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

NATIONAL VARIATIONS

1. First paragraph, first sentence, *delete* “Reusable”.
2. *Delete* second paragraph.

Reusable sharps containers are designed for the containment and disposal of sharps such as scalpel blades, trocars, hypodermic needles and syringes. They are supplied in a wide range of sizes and can be manufactured from a variety of materials. This document does not specify the size range of the containers or the materials selected to manufacture the containers.

Sharps containers can be either single-use or reusable. This document covers reusable sharps containers.

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Sharps injury protection — Requirements and test methods — Sharps containers (ISO 23907-2:2019, MOD)

1 Scope

NATIONAL VARIATIONS

1. First paragraph, first sentence, *delete* “reusable”.

2. *Delete* third paragraph and *replace* with the following:

This document covers single-use and reusable sharps containers. Sharps containers meeting the requirements of this document are considered safe for the purposes of:

- a) use, handling and disposal, in the case of single-use sharps containers; and
- b) use, handling, decontamination and reuse, in the case of reusable sharps containers.

3. *Delete* fourth paragraph and *replace* with the following:

This document includes design and functionality requirements and performance testing for single-use and reusable sharps containers, and lifespan simulation, cleaning and decontamination, microbiological validation, and quality monitoring for reusable sharps containers.

This document specifies requirements for reusable sharps containers intended to hold potentially hazardous sharps medical waste with or without sharps protection features, e.g. scalpel blades, trocars, hypodermic needles and syringes.

This document is applicable to sharps containers that are supplied complete by the manufacturer and to those that are supplied as components intended to be assembled by the user.

It is not applicable to single use sharps containers (refer to ISO 23907-1 for such containers).

This document includes design functionality for user safety, lifespan simulation, cleaning and decontamination, microbiological validation, quality monitoring and performance testing.

2 Normative references

NATIONAL VARIATIONS

After the second paragraph, *add* the following:

AS 3816:2018, *Management of clinical and related wastes*

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

3 Terms and definitions

NATIONAL VARIATIONS

(continued)

1. In **3.15 permanent closure**, at the end of the definition, *add* “i.e. without the use of a tool”.
2. In **3.17 representative sharps**, *delete* definition and *replace* with the following:
unused equal quantities of 3 ml and 10 ml luer-lock 21G syringes-needles in the ratio of 35 % safety devices with safety mechanism activated and 65 % syringe-needles with no safety device
3. After [Clause 3.26](#), *add* the following:
3.27
shall
indicates that a statement is mandatory
3.28
should
indicates a recommendation
3.29
single-use sharps container
container designated by the manufacturer to be filled only once

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1
aperture
opening of the sharps container through which *sharps* ([3.21](#)) are deposited for disposal

3.2
clean
visually free of soil, debris and organic matter

3.3
closure feature
flap, plug, lid or slide that is intended to close the *aperture* ([3.1](#))

3.4
decontamination
use of physical, chemical or thermal means to remove, soiling, and inactivate or destroy pathogens where to the point they are no longer capable of transmitting infectious disease and the container is rendered safe for handling and use

Note 1 to entry: Refer to [4.5](#).

3.5
fill line
mark, indicator or feature on the container that represents the *fill volume* ([3.6](#))

3.6
fill volume
usable volume determined by the manufacturer and indicated by the *fill line* ([3.5](#)) on the container

3.7**handle**

appendage, protrusion, flange or recess intended for lifting the container

3.8**integrally attached**

tethered or joined to the container by a permanent means

3.9**leak-resistance**

ability of a container to prevent escape of fluid

Note 1 to entry: Refer to [6.4.2.2](#).

3.10**lifespan**

maximum number of uses and/or processing cycles as validated by the manufacturer

3.11**manufacturer's allowable gross mass**

maximum mass of the container and contents as recommended by the manufacturer for safe handling and operation

Note 1 to entry: Mass shall be measured in kilograms (kg).

3.12**needle disconnection feature**

feature allowing single-handed *sharps* ([3.21](#)) disconnection

3.13**penetration**

movement of a needle through the *test specimen* ([3.25](#)) until the point of the needle exits on the side opposite the point of entry

3.14**penetration force**

amount of force applied to a hypodermic needle to achieve *penetration* ([3.13](#))

Note 1 to entry: The penetration force is expressed in Newtons.

3.15**permanent closure**

closure feature ([3.3](#)), *integrally attached* ([3.8](#)) to the container, which once activated cannot be re-opened manually

3.16**pocket collectors**

sharps container that has a *fill volume* ([3.6](#)) equal to or less than 0,6 l

Note 1 to entry: The primary design considerations for pocket collectors are to prevent penetration of the sharp(s) through the container while providing a compact size that can be carried on the person, such as in the user's pocket. In order to achieve portability and a low profile, these devices have been excluded from certain aspects of the requirements of this document.

3.17**representative sharps**

representative quantities of unused 1 ml to 60 ml syringes-needles in the ratio of 70 % safety devices with safety mechanism activated and 30 % syringe-needles with no safety device