

ISO 23907-2 Sharps Injury Protection

REQUIREMENTS AND TEST METHODS

PART 2: REUSABLE SHARPS CONTAINERS

SHARPSMART STUDY GUIDE



Sharpsmart

ACADEMY



A brief overview of the scope and requirements for the first ISO Reusable Sharps Container Standard and a comparison of differences between Part 1: for Single use containers



SINGLE USE CONTAINER

Vs.



REUSABLE SHARPS CONTAINER



Introduction

This study Guide briefly describes the requirements and test methods for Reusable Sharps Containers and will reference the differences between ISO 23907 Part 1 and Part 2.

The introduction of Reusable Sharps Containers is being widely accepted within the healthcare industry due to the inherent benefits which include a reduction in plastics manufacture and disposal, a significant decrease in CO2e (when compared with the use of single use containers) and in many cases, a reduction in sharps injuries as a result of inherent engineered safety features that can be incorporated into reusable sharps containers.

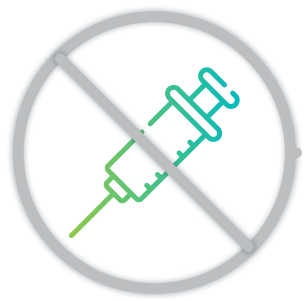
INTENDED LEARNER AUDIENCE

This is a self-learning programme intended for the use by healthcare professionals involved in the procurement and disposal of healthcare generated sharps and manufacturers/distributors of Reusable Sharps Containers



Learning Objectives

At the end of this lesson, the learner should be able to:



Understand the standards associated with Sharps Injury Protection as they relate to Reusable Sharps Containers



Understand the main differences between ISO 23907 part 1 (single use Sharps Containers) and Part 2 (Reusable Sharps Containers)



Have a basic understanding of the specification requirements and test methods associated with Reusable Sharps Containers



Glossary of Terms

- ▶ **SHARPS:** Objects capable of cutting the skin including sharps medical waste with or without sharps protection features, e.g. scalpel blades, trocars, hypodermic needles and syringes
- ▶ **REUSABLE SHARPS CONTAINER:** A Sharps Container designed or intended by the manufacturer to be suitable for use, emptying, processing and subsequent reuse
- ▶ **SINGLE-USE SHARPS CONTAINER:** A Sharps Container designated to be filled and used only once
- ▶ **BSI:** British Standards Institution
- ▶ **ISO STANDARD:** International Standard, published by the International Standards Organisation (ISO)
- ▶ **CONTAINER APERTURE:** opening of the sharps container through which sharps are deposited for disposal
- ▶ **CLOSURE:** flap, plug, lid or slide that is intended to close the aperture
- ▶ **CONTAINER FILL LINE:** Mark, indicator or feature on the container that represents the maximum fill volume
- ▶ **TEST METHODS:** The conditions to which the containers are subjected to ensure minimum attainment of test results in order to meet the standards testing regime



ISO 23907-2: 2019

ISO 23907-2: 2019 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.

It 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.



History of Reusable Sharps Containers

Reusable Sharps containers were introduced into the UK in 2002 as an alternative to the single use sharps containers.

It has been proven that the reusable sharps container will reduce the overall sharps waste disposal by a minimum of 32% and will reduce the CO2e by 92%.



PR Study: Waste Reduction >



PR Study: Carbon Emission Reduction >



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Standards & Recent Changes

At the time of introduction of Reusable Sharps Containers into the UK, the technical requirements and test methods for single use sharps containers was outlined in BSI Standard 7320 which was released in 1990.

The BSI standard was not applicable to reusable sharps containers at the time of launch, so it was typical for reusable container suppliers to mirror the tests performed within BSI 7320-1990 as a 'claim of safety'. Whilst this was deemed acceptable by some procurement professionals, it did not go as far as other international standards (ie Canadian, Australian and New Zealand) where additional performance testing was required to prove that reusable containers would meet the performance criteria of a single use container throughout the reuse lifespan.



Standards & Recent Changes

One UK provider of reusable sharps containers (Sharpsmart Ltd) also mirrored the test methods outlined in the more stringent international standards to provide comfort to NHS procuring authorities that the containers were safe to use throughout the expected life of the reusable container.

The lack of standards control related to reusable sharps containers has however enabled some providers to supply containers which have not routinely undertaken lifecycle and cleaning validation tests under the claim that 'single use or international standards do not apply to UK Reusable containers'. This vacuum in standards availability has, in some instances, allowed non-compliant and poor quality reusable containers to enter the global market. The introduction of ISO 23907 Part 2 was developed to ensure that safety and quality was incorporated into the global healthcare market where healthcare worker and patient safety is an absolute priority.



ISO 23907 Part 1 | For Single Use Containers

In 2012 a new single use sharps container standard was launched and adopted by BSI which superseded the old BSI 7329-1990. EN ISO 23907 Part 1 was introduced and adopted by BSI and included globally harmonised, modernised and more stringent design criteria and test methods that what was in the 1990 British Standard.

Again, this standard did not include reference to the requirements for reusable sharps containers. This standard was updated again in 2019 and the new standard reference for Single Use Sharps Containers is now BS ISO 23907-1:2019



ISO 23907 Part 2 | For Reusable Containers

During the production of the ISO single use container standard, it was agreed by the ISO working group that a completely new standard for reusable sharps containers was required. In 2019 the BS ISO 23907-2:2019 was launched.

This new standard not only covered the design functionality for user safety outlined in ISO 23907 Part 1 (single use containers) but it also included **requirements for lifespan simulation, cleaning & decontamination, microbial validation, quality monitoring and performance testing for reusable standards.**

The goal of the new standard to ensure cleanliness and quality was inherent each time the container was reused and also to **ensure that the container performed 'as designed' and compliantly after each use.**



Engineered Safety Features of Reusable Containers



**GRAVITY BALANCED
SAFETY TRAY**



**MAXIMUM STRENGTH
HARDENED PLASTIC**



CHECK CONTENT LEVELS



**TEMPORARY
FRONT LOCK**



Engineered Safety Features of Reusable Containers



WIDE OPENING



ELIMINATES OVERFILLING



NO-LEAK SEAL



TAMPER-PROOF



Who are the new ISO Standards aimed at?



These Reusable Sharps Container Standards are aimed at container manufacturers and distributors as a minimum baseline for container specification, cleaning and quality monitoring throughout the intended lifespan of the container.

In addition, the standard provides a reference for all NHS procurement professionals and group purchasing organisations who can now control the quality and safety of reusable sharps containers without the ambiguity previously associated with having to reference other international standards or standards which applied only to single use containers.



It is important to remember...

All healthcare institutions and their senior healthcare workers should be made aware of **“the standard to which their containers are manufactured and managed”** to provide security for their workers and to ensure that they have the correct risk management processes in place **to comply with the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013.**



Key Points and Differences

Part 1 vs Part 2

REQUIREMENT OF STANDARD	PART 1	PART 2
Refers to Design & Testing of Single Use Containers	✓	✗
Refers to Design & Testing of Reusable Containers	✗	✓
States that the aperture shall be designed to minimize the potential for accidental sharps injury	✓	✓
States that there will be an indicator or mechanism, preferably visible, required to clearly differentiate the permanent and temporary closure engagements	✓	✓
States that aperture of containers 'intended to be placed in public access areas' should be designed to restrict hand entry and removal of contents from the container	✓	✓



Key Points and Differences

Part 1 vs Part 2

REQUIREMENT OF STANDARD	PART 1	PART 2
States that the aperture should be designed to prevent the risk of overfilling	✓	✓
States that closure features shall be closed without risk of sharps injury to the user	✓	✓
States that the permanent closure, once activated, shall be resistant to manual opening	✓	✓
States that it shall be possible (for user) to ensure (visibly or mechanically) that the sharps are not above the fill line	✓	✓
Testing of container stability	✓	✓



Key Points and Differences

Part 1 vs Part 2

REQUIREMENT OF STANDARD	PART 1	PART 2
Testing of handle Strength	✓	✓
Labelling, Marking and Instructions for use	✓	✓
The Container will have a unique product identifier as a means of Monitoring the number of reuses e.g. a batch number, bar code or UPC serial number	✗	✓
Testing for Resistance to penetration	✓	✓
Penetration Force - Minimum Test Requirement	16N	20N



Key Points and Differences

Part 1 vs Part 2

REQUIREMENT OF STANDARD	PART 1	PART 2
Penetration Force – Average Test Requirement	18N	20N
Testing for Resistance to damage and leakage after dropping	✓	✓
Containers under 12 litre (of total volume): Testing for resistance to damage and leakage after dropping on all orientations (i.base, ii.side wall, iii. adjacent side wall, iv. top, v. a lower corner or bottom edge and vi. an upper corner)	✓	✓
Containers over 12 litre (of total volume): Testing for resistance to damage and leakage after dropping on all orientations (i.base, ii.side wall, iii. adjacent side wall, iv. top, v. a lower corner or bottom edge and vi. an upper corner) *Note: single use containers over 12 litres only require testing i, ii, iii due to economic/commercial design cost restrictions	✗	✓



Key Points and Differences

Part 1 vs Part 2

REQUIREMENT OF STANDARD	PART 1	PART 2
Test for resistance to spillage by toppling	✓	✓
Lifespan simulation regime for Transport & Processing prior to testing	✗	✓
Cleaning & Decontamination Process Overview	✗	✓
Process overview for Microbial Validation	✗	✓
Post Decontamination quality assurance monitoring	✗	✓



Explanation of **Additional Testing** *for reusable containers*

Overview of unique testing requirements for Reusable Sharps Containers

As reusable sharps container manufacturers have validated their containers for many hundreds of uses, the reusable sharps standard outlines the pre-conditioning processes that should be carried out to ensure that when the tests are performed to validate that the resistance to penetration, stability, handle strength and resistance to damage/leakage would pass following the expected lifecycle use expiration of the container. Detailed below is an overview of the simulation testing and additional requirement included within the ISO 23907 Part 2 standard.

Test procedures for Lifespan Transport & Processing Simulation Testing

Section 5 of ISO 23907 Part 2 outlines the rigorous conditioning that the reusable sharps containers will undergo before the standard sharps container testing (as outlined in ISO 23907 Part 1) will take place.

The Part 2 standard outlines the procedures for temperature conditioning, tumbling with representative sharps simulation, transportation and processing (opening, decanting decontamination and closing).



Explanation of Additional Testing for reusable containers

Test procedures for Cleaning & Decontamination

Section 4.5 of ISO 23907 Part 2 outlines the stringent requirements of the cleaning and validation process that must be achieved to render the containers clean i.e. aesthetic and visibly free of soil, debris and organic matter, and decontaminated to a level that renders them safe for handling and reuse.

This section goes on to point out that cleaning can be achieved by multiple methods but that the process must be automated, microbiologically validated prior to commissioning (by a competent third party) and that the process must be continually monitored to confirm that each container has been subjected to the decontamination parameters stipulated by the validation processes

Request example copy of third party validation report from Sharpsmart Ltd if required

THE SHARPSMART WASH PROCESS



Explanation of **Additional Testing** *for reusable containers*

Test procedures for Microbial Validation

Annex A within ISO 23907 Part 2 shows an example of a process suitable for the validation of the microbiological efficacy of the decontamination process and for establishing the validation parameters during automated processing and shows an example of a and example test report

[Download a full copy of BS ISO 23907-2 >](#)



How can Reusable Sharps Containers be purchased



reusable sharps containers can be purchased through competitive tendering processes and procurement frameworks. The reusable sharps container service can include the supply and collection of the containers including or excluding the sharps disposal element of the service. The reusable sharps container service can be procured on a 'per turn' basis (where the supplier charges by the number of containers delivered/collected) or as a fixed monthly service fee which is calculated based on the prior year sharps disposal weights and single use bin procurement volumes.

For details on Reusable Sharps Container frameworks contact Sharpsmart Ltd



Test your knowledge



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Questions

- ① Which of the following statements is true related to the standard; BS ISO 23907-Part 2:2019 sharps injury protection. Requirements and test methods?
- a. The standard outlines sharps injury protection requirements and test methods for single use sharps containers only
 - b. The standard outlines sharps injury protection requirements and test methods for reusable sharps containers only
 - c. The standard outlines sharps injury protection requirements and test methods for both single use and reusable sharps containers
- ② Lifespan simulation regime for Transport and Processing prior to testing of containers, must be carried out on which of the following?
- a. Reusable sharps containers only
 - b. Single use sharps containers only
 - c. Both reusable and single use sharps containers



Questions

- ③ **For sharps containers under 12 litre (of total volume): Testing for resistance to damage and leakage must be performed after on all orientations (i.base, ii.side wall, iii. adjacent side wall, iv. top, v. a lower corner or bottom edge and vi. an upper corner) for which of the following container Types:**
- a. Reusable sharps containers only
 - b. Single use sharps containers only
 - c. Both reusable and single use sharps containers
- ④ **When were reusable sharps containers first introduced into the UK?**
- a. 2001
 - b. 2002
 - c. 2000



Questions

- ⑤ Which Standards states that the Aperture of containers 'intended to be placed in public access areas' should be designed to restrict hand entry and removal of contents from the container?
- a. Reusable sharps containers only
 - b. Single use sharps containers only
 - c. Both reusable and single use sharps containers
- ⑥ Which Standards states that there will be an indicator or mechanism, preferably visible, required to clearly differentiate the permanent and temporary closure engagements?
- a. Reusable sharps containers only
 - b. Single use sharps containers only
 - c. Both reusable and single use sharps containers

Answers: 1b; 2a; 3a; 4b; 5c; 6c



References & Further Reading

- ▶ **HSE Information Sheet:** Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 Guidance for employers and employees

[Access here >](#)

- ▶ **Research Study:** Sharpsmart - 86% Carbon Emissions Reduction

[Access here >](#)

- ▶ **Peer Review Study:** 28% Waste Reduction

[Access here >](#)



Get In Touch!



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