
**Sharps injury protection — Requirements
and test methods — Sharps containers**

*Protection contre les blessures par perforants — Exigences et méthodes
d'essai — Conteneurs pour objets coupants, tranchants et perforants*

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 23907 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

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Introduction

Single-use 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 International Standard 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 International Standard covers single-use sharps containers. The test methods included in this International Standard might be applicable when developing a reusable sharp container standard.

This International Standard includes informative annexes with rationales on several subjects, which have undergone profound debate in ISO/TC 84. These rationales have been elaborated to provide further explanation on the present requirements. In future editions of this International Standard, these rationales will also clarify the justification of the current requirements.

National regulations exist in some countries; their requirements might supersede or complement this International Standard.

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Sharps injury protection — Requirements and test methods — Sharps containers

1 Scope

This International Standard specifies requirements for single-use 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 reusable sharps containers or the outer containers used in the transportation of filled single-use sharps containers.

2 Normative references

The following referenced documents are indispensable for the application 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*

3 Terms and definitions

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

3.1

aperture

opening of the sharps container in which sharps are inserted for disposal

3.2

closure feature

flap, plug, lid or slide that is intended to close the aperture

3.3

permanent closure

condition when the closure feature is locked/sealed in preparation for final disposal

3.4

total volume of the container

entire air space in a closed container

3.5

fill volume of the container

usable volume determined by the manufacturer and indicated by the fill line on the container

3.6

fill line indicator

mark or indicator on the container that represents the fill volume

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-resistant

ability of a container to prevent escape of fluid under the conditions specified in this International Standard

3.10

penetration

movement of a needle through the test specimen until the point of the needle exits on the side opposite the point of entry

3.11

penetration force

amount of force applied to a hypodermic needle to achieve penetration under the conditions specified in this International Standard

NOTE The penetration force is expressed in Newtons.

3.12

pocket collectors

sharps container that has a total capacity equal to or less than 0,75 l, intended to contain a limited number of sharps

NOTE The primary design considerations for pocket collectors is to prevent penetration of the sharp(s) through the container while providing a compact size that can be easily carried on the person of the user, 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 International Standard.

3.13

sharps

objects capable of cutting or penetrating skin

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EXAMPLES Needles of various types, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, exposed ends of dental wires.

3.14

sharps containment area

surface intended to directly enclose sharps for the purposes of container puncture protection in use and in the final closed configuration

3.15

single-use sharps container

container designated or intended by the manufacturer for a one-time filling of the container

3.16

secondary stabilizer

attachment or design feature intended to provide extra stability and prevent the device from toppling over when placed on a horizontal surface

4 Requirements

4.1 General

The principles of risk assessment, as well as human factors, should be considered in the design process of sharps containers, e.g. by applying the relevant requirements of ISO 14971.

4.2 Construction

4.2.1 Container stability

The container shall not topple over when tested in accordance with 5.1. Containers recommended for use with a wall mount and pocket collectors are excluded from the requirement specified in 5.1. The requirement applies to containers intended for use on a horizontal surface. Sharps containers intended to be used with a secondary stabilizer shall be tested in conjunction with that device.

4.2.2 Strength of handles

All sharps containers excluding pocket collectors shall be provided with one or several handles.

When tested in accordance with 5.2, the handle/carrying feature shall not break or detach during testing. The position of the handle(s), finger recesses, protrusions or flanges shall not interfere with the normal use of the container.

Finger recesses, if present, shall be sited above the fill line. This requirement does not apply to pocket collectors.

4.2.3 Aperture and closure

4.2.3.1 General

Single-use sharps containers shall be provided with a closure feature that is integrally attached. Pocket collectors intended for single devices are excluded from the requirements regarding attachment of the closure device. The aperture shall be designed to minimize the potential for accidental sharps injuries during placement of sharps into the container.

4.2.3.2 Requirements for the aperture

It shall be possible to place sharps into the sharps container without using a second hand to manipulate the aperture.

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.

NOTE A risk assessment should address the risk of overfilling.

4.2.3.3 Requirements for the closure feature

Closure features shall be capable of being closed without the risk of sharps injury to the user.

The permanent closure, once activated, shall be resistant to manual opening. Pocket collectors should be provided with a permanent closure.

4.2.4 Resistance to penetration

When tested in accordance with 5.3, the force needed to penetrate test specimens shall be not less than 15 N.

4.2.5 Resistance to damage or leakage after dropping

When tested in accordance with 5.4, there shall be no evidence of leakage and no breach of the sharps containment area.

4.2.6 Fill line indicator

The fill line indicator shall be determined by the design of the container, taking into account the risk of sharps extending above the fill line, and shall be at a level no greater than 85 % of the total capacity of the container. A fill line indicator is not mandatory for pocket collectors.

5 Test methods

5.1 Container stability

5.1.1 Fill the container to the fill line with material of a density of $(0,20 \pm 0,01)$ kg/l. Do not lock or close the aperture closure.

5.1.2 Place the container in the most adverse position for toppling on a surface with a minimum inclination angle of 15° . Ensure that the container does not slide before toppling.

Check for compliance with 4.2.1.

5.2 Strength of handle(s)

5.2.1 Fill the container with a mass equivalent to 150 % of the manufacturer's maximum allowable gross mass.

5.2.2 Fit the aperture closure and close or lock it as if the sharps container is ready for final disposal.

5.2.3 Suspend the container by its handle(s) at the intended carrying point(s) from a rigid support for 1 h at a temperature of (23 ± 5) °C.

If the container has more than one intended carrying point, at least two of the worst-case carrying points shall be tested.

5.2.4 Remove the container from the support and inspect the handle(s) for integrity and for any evidence of detachment of the handle(s) from the container.

Check for compliance with the requirements in 4.2.2.

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5.3 Resistance to penetration

5.3.1 Apparatus

5.3.1.1 Tensometer, having a load cell capable of measuring the force applied to a needle penetrating a test specimen and means to record the force necessary to just penetrate one surface of the test specimen when the needle is pressed into the other surface.

NOTE A suitable means of sensing penetration is to place a piece of aluminium foil in intimate contact with the test specimen, wired so that an event marker will indicate, on a chart recorder that records the force being applied, when the needle penetrates the test specimen and touches the foil.

5.3.1.2 Hypodermic needles, of nominal size 0,8 mm × 25 mm, that comply with the requirements of ISO 7864.

5.3.1.3 Test specimen support, with a 6 mm diameter hole in its centre and a depth that permits needle emergence.

5.3.1.4 Needle holder that accepts a hypodermic needle (5.3.1.2) so that it points vertically downwards.

NOTE See Annex A for a rationale for gauge size and puncture value.

5.3.2 Procedure

5.3.2.1 Determine the worst-case area for needle penetration of the sharps containment surface in the final closure configuration. Determine the number of test specimens for testing. Cut test specimens of approximately 12 mm × 12 mm from this area.

NOTE See Annex B for guidance on sample testing and finding the worst-case area for needle penetration testing.

5.3.2.2 Condition the test specimens at (23 ± 5) °C for at least 2 h and carry out the test under the same conditions.

5.3.2.3 Fix a hypodermic needle (5.3.1.2) in the needle holder (5.3.1.4). Place the test specimen centrally on the test specimen support with the inside container surface facing upwards (5.3.1.3). Do not distort the test specimens by attempting to flatten any curves.

5.3.2.4 Lower the needle vertically towards the test specimen at a rate of 100 mm/min. Allow the needle to pass through the test specimen and record the penetration force.

5.3.2.5 Repeat the procedure described in 5.3.2.3 and 5.3.2.4 for each of the remaining test specimens, using a new hypodermic needle to penetrate each test specimen.

Check for compliance with the requirements in 4.2.4.

5.4 Resistance to damage and leakage after dropping

5.4.1 Apparatus

5.4.1.1 Means of holding the sharps container, prior to release in its intended orientation prior to the drop.

5.4.1.2 Means of releasing the sharps container, such that its fall is not obstructed by any part of the apparatus before striking the impact surface.

5.4.1.3 Impact surface, which is horizontal and flat, heavy enough to be immovable, and rigid enough to be non-elastic under the test conditions. The impact surface shall be:

- a) flat, so that no two points on its surface differ in level by more than 2 mm;
- b) rigid, so that it is not deformed by more than 0,1 mm when an area of 100 mm² is loaded statically with 10 kg anywhere on the surface;
- c) sufficiently large to ensure that the sharps container falls entirely upon the surface.

EXAMPLE A concrete floor at least 150 mm thick is suitable provided that it complies with the above requirements.

5.4.2 Procedure

5.4.2.1 Condition the sharps container at (23 ± 5) °C for at least 2 h and carry out the test at the same temperature.

NOTE 1 Where transport of containers at low temperature conditions/exposure is of concern, additional test/conditioning temperatures as required by international, national or regional standards should be used.

NOTE 2 Single-use sharps containers are commonly placed in secondary transport containers for disposal; these are designed to comply with specific shipping and transportation requirements, such as UN regulations and ADR regulations.

5.4.2.2 Fill the sharps container with a volume of water at (23 ± 5) °C equal to 1 % of the volume at the fill line indicator of the container. Fill the container to the fill line with representative sharps or a substance of density $(0,2 \pm 0,02)$ kg/l. If a substance with a different density is used, the target mass should be equivalent to that of the container filled to the fill line with representative sharps. Sharps containers that are commercially available with