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Sharps injury protection — Requirements and test methods —

Part 2: Reusable sharps containers

Protection contre les blessures par perforants — Exigences et méthodes d'essai —

Partie 2: Conteneurs réutilisables pour perforants

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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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).

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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

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.

Sharps injury protection — Requirements and test methods —

Part 2: Reusable sharps containers

1 Scope

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

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

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

3.18
processing
validated methods used to render a reusable sharps container, which has been previously used, safe for handling and a subsequent use

3.19
reusable sharps container
container designed or intended by the manufacturer to be suitable for use, emptying, *processing* (3.18) and subsequent reuse

3.20
secondary stabilizer
attachment or design feature intended to provide extra stability and prevent the device from toppling over

3.21
sharps
objects capable of cutting or penetrating skin

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

3.22
sharps containment area
surface that directly encloses *sharps* (3.21) for the purposes of container puncture protection while in use and in the final closed configuration

3.23
lifespan simulation
conditioning of the reusable container by repeated exposure to cycles of representative transport and *decontamination* (3.4) process conditions to represent the *lifespan* (3.10) of the container, as specified by the manufacturer

3.24
temporary closure
closure feature (3.3) *integrally attached* (3.8) to the container which, once activated for closure, can be re-opened, without being damaged

3.25
test specimen
portion of the container obtained

Note 1 to entry: Refer to 6.3.2.1.

3.26
total volume of the container
entire air space in the closed container

4 Requirements and recommendations

4.1 General

The principles of risk assessment, as well as human factors to avoid any inappropriate use such as incorrect assembly and overfilling, shall be considered in the design process of sharps containers.

NOTE ISO 14971 is relevant where containers are classified as a medical device.

The base dominant colour should be yellow unless local regulations state otherwise.

Fill level visibility shall be a design requirement for the containers.

When evaluated in accordance with Clause 6, the container shall show no rupture, leakage, or deterioration that could adversely affect its safe use or functionality.

4.2 Design and construction

4.2.1 General

The materials used in the construction of reusable sharps containers shall be designed and manufactured in a manner that enables full function, safety, and preservation of aesthetics for the expected lifespan of the product.

4.2.2 Container stability

The container shall not topple over when tested in accordance with 6.1.

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 the secondary stabilizer.

Sharps containers equipped with a needle disconnection feature shall have a means whereby the disconnection procedure is achieved with one hand.

Pocket collectors are not required to have needle disconnection feature.

4.2.3 Strength of handles

All sharps containers shall be provided with one or several handles. Where handle(s) is/are included in the design, it shall meet the requirements of 4.2.3.

Pocket collectors are not required to have handle(s).

When tested in accordance with 6.2, 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.

4.2.4 Aperture and closure

4.2.4.1 General

Reusable sharps containers shall be provided with closure features that are integrally attached. The aperture shall be designed to minimize the potential for accidental sharps injuries during placement of sharps into the container. There shall be an indicator or mechanism (preferably visual) to clearly differentiate the permanent and temporary closure engagements.

Requirements regarding the attachment of the closure device do not apply to pocket collectors intended for a single device

4.2.4.2 Requirements and recommendations 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.

The aperture should be designed to prevent the risk of overfilling.

4.2.4.3 Requirements and recommendations 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. All containers, including pocket collectors, shall be equipped with a temporary closure and a permanent closure.

The temporary closure, once activated for closure, shall be capable of being re-opened with one hand without risk and without the need to grasp the body of the container.

Re-opening the temporary closure may require the use of a secondary stabilizer to reduce risk.

4.2.5 Resistance to penetration

When tested in accordance with 6.3, the force needed to penetrate test specimens shall be a minimum of 20 N or greater.

4.2.6 Resistance to damage or leakage after dropping

When tested in accordance with 6.4, there shall be no evidence of leakage and no breach of the sharps containment area.

Minimum five minutes after every drop, the following points shall be visually checked:

— there shall be no damage compromising safe use;

— the container's permanent closure shall remain intact;

— handles, if present, shall remain functional.

4.2.7 Resistance to damage or leakage after toppling

When tested in accordance with 6.5, there shall be no evidence of breach of the sharps containment area.

Minimum five minutes after every topple, the following points shall be visually checked:

— there shall be no evidence that the performance or function of the container has been compromised;

— the container's temporary closure shall remain intact.

4.2.8 Fill line

The fill line 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 volume of the container.