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Sharps injury protection — Requirements and test methods — Sharps containers

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National foreword

This British Standard is the UK implementation of EN ISO 23907:2012. It supersedes BS 7320:1990, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Schutz vor Stich- und Schnittverletzung - Anforderungen und Prüfverfahren - Behälter für spitze und scharfe Abfälle (ISO 23907:2012)

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Foreword

This document (EN ISO 23907:2012) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and intravascular catheters" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2013, and conflicting national standards shall be withdrawn at the latest by March 2013.

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Foreword

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

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.

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

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 ± 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.

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 mm^2 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 ± 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

an absorbent material (i.e. absorbent pad/sachet) to assist leak resistance, shall be tested with this material in the container. Close and permanently secure the aperture for final disposal. Leave the container to stand for 1 h.

NOTE When using sharps for testing, safety engineered devices shall be used with the safety feature deployed in an effort to protect the sharp and minimize any risk of exposure during both setup and testing.

5.4.2.3 Test to be performed from a height of (1 ± 0,02) m, as measured by the distance between the lowest point on the sharps container and the nearest point on the impact surface (5.4.1.3).

5.4.2.4 The procedure for all sharps disposal containers with a capacity above 12 l of total volume is as follows.

Follow steps a) to d) for each of the following orientations: base, side wall and adjacent side wall.

a) Position the container at the proper height and in the desired orientation for the impact fall.

b) Release the container. Do not obstruct its fall or restrict movement of the container after it has struck the impact surface.

c) Examine the sharps container for integrity and evidence of leakage/wetting of the outer surface of the container and/or wetting of the impact surface.

d) Repeat the procedure in a different orientation (as described above) using a new container for each test.

5.4.2.5 The procedure for all single-use sharps containers with a capacity of or below 12 l of total volume is as follows.

Follow steps a) to d) for each of the following orientations: base, side wall, adjacent side wall and top.

a) Position the container at the proper height and in the desired orientation for the impact fall.

b) Release the container. Do not obstruct its fall or restrict movement of the container after it has struck the impact surface.

c) Examine the sharps container for integrity and evidence of leakage/wetting of the outer surface of the container and/or wetting of the impact surface.

d) Repeat the procedure in a different orientation (as described above) using a new container for each test.

Check for compliance with the requirements in 4.2.5.

6 Labelling and marking

Any marking or labelling on the container that is essential for safe use shall be visible and easily legible.

Marking or labelling shall comply with local, national or regional requirements. Marking or labelling on the container should include the following information.

— A clear indication of the fill line (see 4.2.6).

— Appropriate hazard symbols.

— The word “DANGER” or the equivalent wording in the language of the country where the container is used.

— Identification of the specific use (where applicable) of the container (e.g. chemotherapy, biohazard).

— An indication that the container is not re-usable.

— Identification of the total and/or fill volume of the container.

— Name and address of the manufacturer. Where national legislation allows, a trademark, logo or website address may be sufficient to identify the manufacturer, provided that traceability can be established. The

actual corporate name, which can be preceded or followed by the name of the particular division of the corporation, may be sufficient.

— Lot or batch identification.

— Commercial reference for the container (e.g. product code, re-order number, model number).

NOTE For pocket collectors, due to space limitations, this labelling information may be present on the secondary packaging information.

7 Instructions for use

Instructions for use, required for the safe assembly, use, closure, handling and storage of the container, shall be made available by the manufacturer.

The instructions for use should minimize the potential for accidental sharps injury. Drawings, pictograms or other graphical aids may be used where applicable.

Instructions for use shall include the following, as applicable:

— instructions for proper and secure assembly of the container before use, and any required stabilizing accessories;

— correct method for placement of the sharp in the container;

— correct filling of the container to the fill line, including specific instructions not to overfill;

— correct, verifiable closure of the container when the contents have reached the fill line;

— correct procedure for lifting or handling the container when it has been filled (to fill line only) and closed as per manufacturer's instructions;

— any other warnings or precautions that the manufacturer deems appropriate to assist the user in the safe use of the container.

NOTE In certain countries, national regulations may require that containers (body and lid) be supplied in a specific colour or combination of colours.

Annex A
(informative)

Rationale for gauge size and puncture value

ISO/TC 84, when reviewing comments to the draft circulated in October 2009, investigated the proposal to change the current needle gauge size that is used to conduct the needle penetration testing from a 0,8 mm × 25 mm (21 gauge) hypodermic needle complying with ISO 7864 to a 0,6 mm × 25 mm (23 gauge) hypodermic needle complying with ISO 7864.

After significant investigation, ISO/TC 84 was not able to find evidence that changing the gauge size used in the resistance to penetration testing would be more relevant than potentially amending the force value requirement. Review of the EPINET data, as well as review of the internal customer complaints for a cross-section of the participant manufacturers, did not highlight a clear correlation between needlestick injuries that resulted from a needle puncturing the container at a higher rate on thinner gauge sizes. The information was limited due to the fact that the current process for capturing injuries does not typically identify the specific gauge size involved in the injury. It was also determined that the situation is not likely to change in the future given the fact that the injured customer will likely not be able to visually tell what gauge size caused the injury.

In relation to the prevalence and volume share of needles sold per gauge size, although the market in general has increased for the smaller gauge sizes, data presented at the meeting in London did not support the change in gauge size purely on a volume share perspective. Data supplied by the NHS supply chain representing needle usage by UK hospitals in 2009 demonstrated that, combining all gauge volume across standard syringe needles, insulin syringes, insulin syringes with attached needles, insulin pens and BD Vacutainer needles, the 21 gauge needle still represents 50 % of the share, while the 22 gauge needle is only 14 % of the share. The two manufacturers that supply the majority of US needles confirmed that internal market data are consistent with UK volume. In addition to this, 2008 Global Healthcare Exchange (GHX) data of the 343 million IV catheters placed on the US market was presented, confirming again that only 13 % of the IV catheters used were gauge size 22 and above.

All current sharps disposal standards specify testing with a 21 gauge needle. A new test method would have to be developed and proven out with a 23 gauge needle and data collected over time to ensure reliability. ISO/TC 84 agreed by consensus that the information available does not support the need for a change in the method as the most appropriate method to address the risk of needle penetration injuries.

Annex B
(informative)

Guidance on selection of test specimens for resistance to penetration test

The test method for resistance to penetration defined in Clause 5 is intended to provide assurance that the container will achieve certain minimum performance levels relative to the primary intended use. The determination of how to select the test specimens includes where to test, as well as how many data points are required. This informative annex is intended to address containers composed of moulded plastic; testing for other types of containers should follow the same principles.

Since the intent is to define the minimum performance level, it is appropriate to test the worst-case point of the container. Determination of worst case is a function of risk analysis and should address the inherent likelihood of puncture (i.e. the sharps containment areas) as well as the mechanical resistance to puncture. For containers made of moulded plastics, the puncture resistance will normally be a function of the specific plastic used and the thickness. Moulded containers are made up of one or more moulded components, each representing a continuous piece of plastic (regardless of shape). Within each moulded component, the composition of the plastic will be essentially consistent but thickness may vary. The thinnest area within that moulded component can be expected to exhibit the point of lowest resistance to penetration for that component. Multiple components of identical plastic are expected to behave in a similar manner, but components made of different plastics will need to be evaluated individually. In the absence of a precise knowledge of the composition, each discrete moulded component should be evaluated at the worst-case point of that section (excluding any areas that are not part of the sharps containment area).

Having determined the worst-case points for a container design, the number of containers to be sampled will be determined based on how the data are to be analysed. If, because of the container design, multiple moulded sections have to be tested to ensure that the worst case has been addressed, the data from separate test points should not be comingled. The minimum puncture resistance should be determined separately for each test point identified as a potential “worst case”. Analysis of each chosen test specimen location should result in a conclusion of conformance to achieve an overall passing result.

Regardless of the sampling method employed, the statistical confidence required should be no less than 95 %, and the potential fraction non-conforming should be no higher than 5 %.

Guidance on sampling plans can be found in References [1] and [2].

Bibliography

[1] ISO 3951 (all parts), *Sampling procedures for inspection by variables*

[2] ISO 2859-10, *Sampling procedures for inspection by attributes — Part 10: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes*[1)]

[3] ISO 14971, *Medical devices — Application of risk management to medical devices*

[4] BS 7320, *Specification for sharps containers*

[5] OSHA 1910.1030, *Occupational Safety and Health Standards, Subpart; Toxic and Hazardous Substances, Bloodborne Pathogens*

[6] NIOSH Publication No. 97-111, *Selecting, Evaluating, and Using Sharps Disposal Containers*, January 1998

[7] NF X30-500, *Packaging for medicinal care waste — Boxes and small collectors for perforating waste — Specifications and tests*

[8] NF X30-505, *Packaging for medical care waste — Health care waste — Draft standard relative to plastic barrels and jerrycans for health care waste and infection risks*

1) Replaces ISO 2859-0:1995.

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