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Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Protection contre les blessures par perforants — Exigences et méthodes d'essai — Dispositifs de protection des aiguilles hypodermiques, des introducteurs pour cathéters et des aiguilles utilisées pour les prélèvements sanguins, non réutilisables

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Contents

Page

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.

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 23908 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

Introduction

This International Standard addresses sharps injury protection systems designed to protect users of medical devices. These sharps injury protection features are intended to prevent, or reduce the potential for, disease transmission which could result from accidental, post-use sharps injuries.

This International Standard is aimed at addressing devices primarily intended for human use, of a wide range of product types, including, among others, hollow-bore needles for injection or infusion of therapeutics into the body, or sampling of fluids from the body, and hollow bore or solid-core needles used for blood sampling (e.g. lancing devices). It addresses sharps injury protection systems which are either active or passive in their activation after the medical device's intended use. It does not cover solid-core needles used for surgery (e.g. suture needles).

Given the broad variation in product design and sharps protection technology, the variety of different types of devices, and in order to avoid unnecessarily restricting innovation, this International Standard has been developed as “horizontal” in nature, which means it provides for general design, testing and labelling requirements, rather than specific physical and prescriptive design requirements. It therefore differs from more “vertical” standards, which list specific maximum forces, detailed test fixture designs, test systems to be used or detailed test measures, as such prescriptive details cannot cover the variety of designs and devices, and may impede continuing innovation in new products, features and/or protection mechanisms that lead to future improvements in healthcare.

This International Standard presumes that the product developer would use a risk-based approach (consistent with ISO 14971) to determine the device design that best meets the needs of a target user population and expected use settings. Through this risk-based approach, the sharps injury protection system would have performance requirements appropriate to the foreseeable risks associated with the intended use of the device, expected user interfaces, and the settings in which these safety features are expected to be used.

This International Standard provides guidelines to enable the manufacturer to verify that the design of the sharps injury protection systems complies with the design intent spelled out in the design specification. As part of this verification, the manufacturer is expected to demonstrate that the performance of the sharps injury protection system is appropriate to the intended users and settings through the use of appropriate simulated or clinical use studies. These simulated or clinical use studies allow the manufacturer to demonstrate that, when used in accordance with the instructions for use, in settings representative of real-life intended use and by intended or foreseeable users, the device functions as intended.

Existing products and those currently under development may not fulfil some of the requirements given by this International Standard. However, manufacturers would be well advised to follow its provisions when improving existing products or developing new products to obtain an even higher level of quality.

Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

1 Scope

This International Standard gives requirements and test methods for evaluating the performance parameters of sharps injury protection features, whether active or passive in design, for medical devices containing (sharp) hypodermic needles for single use, introducers for catheters and lancets, and other needles used in blood sampling. The sharps injury protection devices it covers may be provided integral to the device or combined with the device prior to use to achieve the sharps injury protection.

It does not give requirements for the storage and handling of the sharps protection before its intended use, or for the medical device itself.

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 2859 (all parts), *Sampling procedures for inspection by attributes*

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

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

ISO 16269-6, *Statistical interpretation of data — Part 6: Determination of statistical tolerance intervals*

3 Terms and definitions

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

3.1
activation
deployment of the sharps protection mechanism

3.2
active safety feature
sharps protection feature that requires an additional step by the user to activate, separate from any action needed to perform the primary intended function of the device

3.3
accidental sharps injury
unintentional penetration into human tissue by the sharp after the intended use

3.4
passive safety feature
sharps protection feature that does not require an additional step by the user to activate, separate from any action needed to perform the primary intended function of the device

3.5
safe mode
state of the device after activation of the safety feature

3.6
sharp
part of the device that can penetrate human tissue

3.7
sharps injury protection feature
feature that prevents accidental sharps injury

4 Requirements

4.1 General

4.1.1 Where the requirements do not specify forces for activation of the safety feature, the appropriate force shall be determined by using a risk-based approach in accordance with ISO 14971, supported by simulated user studies that mimic actual clinical use by using patient substitutes (e.g. instructional models) rather than actual patients. The study design should be based on statistical considerations and should have clear acceptance criteria. Guidance on conducting simulated user studies is outlined in Annex A.

4.1.2 Once in safe mode, the safety feature(s) of the device shall provide protection against accidental sharps injury until safe disposal of the sharp under expected conditions of use.

4.1.3 It shall be apparent to the user as to when the device is in safe mode.

Activation/safe mode shall be communicated to the user in a clear and unmistakeable manner by either visual, tactile and/or audible means. If the manufacturer determines that the user environment requires a permanent indication of safe mode, then a visual indication shall be included.

4.1.4 Activation of the sharps protection feature shall permit the user's hand(s) to remain behind the exposed contaminated sharp.

Safety features may be operated either actively or passively. If active operation is required, one-handed operation is recommended.

4.1.5 The safety result shall

- not negatively affect the intended performance characteristics or proper disposal of the device,
- not impede or adversely affect the intended clinical performance of the device,
- resist inadvertent activation under expected conditions of use.

4.1.6 The performance of the safety feature as described in 4.1.2 to 4.1.5 shall be demonstrated through appropriate simulated or clinical use studies for the specified conditions indicated under the conditions of use.

NOTE 1 Appropriate simulated or clinical use studies may be helpful in establishing specifications to meet the requirements of Clause 5.

NOTE 2 Annex A contains guidance for simulated or clinical use studies.

NOTE 3 IEC 62366 covers the application of usability engineering to medical devices.

4.2 Activation of the sharps injury protection feature

Active sharps injury protection features shall be able to be activated immediately after intended use.

Passive sharps injury protection features shall enter safe mode immediately after intended use.

The sharps injury protection feature shall be able to be activated by a force appropriate for the intended users of the device (e.g. patients, health care professionals or family members). An appropriate force shall be selected that eases actuation and avoids unintended actuation.

The appropriate activation forces shall be determined using a risk-based approach in accordance with ISO 14971. The manufacturer shall confirm that these force values are the values at which the sharps injury protection feature can be activated. These force values shall be obtained using the methodology outlined in Clause 5.

4.3 Security of safe mode protection

Once in safe mode, the safety feature shall

a) resist forces so as to prevent unintended exposure to the sharps, when tested in accordance with 5.3, and

b) minimize the risk of accidental access to the sharp, when tested in accordance with 5.4.

Using a risk-based approach in accordance with ISO 14971, the manufacturer shall determine appropriate minimum overriding forces. These force values shall be obtained using the methodology outlined in Clause 5.

5 Test methods

5.1 General

Unless otherwise specified in the relevant device standard(s), all tests and test evaluations shall be performed at the following standard atmosphere conditions:

— temperature: (23 ± 5) °C;

— relative humidity: (50 ± 25) %.

The device with integrated sharps injury protection or stand-alone sharps injury protection device that is tested shall have been subjected to storage for at least 4 h under these conditions immediately prior to testing/evaluation.

The repeatability and reproducibility of the test apparatus shall be no greater than 20 % of the allowed tolerance band for any given set of measurements.

When a sharps protection means is integral to a device covered by any other standard, or when combined with such a device prior to use, it shall be subjected to the same preconditioning requirements set out for the device by that other standard.

5.2 Testing activation of a sharps injury protection feature

5.2.1 Principle

Test pieces shall be chosen to test the intended means of activation by either tensile, compressive or torsional force applied directly (but smoothly) to the safety mechanism. The resulting activation forces/torques shall be recorded as specified in 5.6.