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Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps[1]

This standard is issued under the fixed designation F2132; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε[1] NOTE—Editorial changes were made throughout in June 2008.

1. Scope

1.1 The purpose of this specification is to provide a test procedure and performance requirement for the puncture resistance of materials used in the construction of containers for discarded medical needles and other sharps. This test specification will establish (*1*) the average puncture force and (*2*) a minimum value of puncture force that container material(s) must withstand when following the test procedure described in Section 6. This specification shall be applicable to regions of uniform material and thickness, and needle contact areas as defined in 3.1.7 and 3.1.9. Materials meeting the performance requirements of Section 4 shall be considered "puncture-resistant." This specification does not evaluate the construction of, or provide pass/fail criteria for, a sharps container.

1.2 This specification provides a test procedure to determine if all regions of one container meet the material puncture resistance requirements. It does not define the number of additional test containers required to achieve a statistically valid sample of a manufacturing lot or process. An appropriate sampling plan shall be determined by the test requester, as this depends upon the manufacturing process variability, manufacturing lot size, and other factors, such as end-user requirements.

1.3 This specification is intended to evaluate the performance of materials used in the construction or manufacture of sharps containers under controlled laboratory conditions, and at normal room temperature (see 6.1). (**Warning**—This specification only characterizes material puncture resistance at normal room temperatures. Applications of sharps containers outside the range of 23 ± 2°C (such as usage in emergency vehicles) require further material characterization by the product specifier to determine suitable use.)

1.4 The values stated in inch/pound are to be regarded as the standard. The SI values given in parentheses are for information only.

1.5 The following hazard caveat pertains only to the test procedure portion, Section 6, of this specification.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

2.2 *ISO Standards:*

ISO 7864 Sterile Hypodermic Needles for Single Use[3]

ISO 594 Luer Fittings[3]

2.3 *Other Standards:*

AS 4031:1992 Non-reusable Containers for the Collection of Sharp Medical Items Used in Health Care Areas[4]

BSI 7320:1990 Specification for Sharps Containers[5]

CSA Z316.6-95 Evaluation of Single Use Medical Sharps Containers for Biohazardous and Cytotoxic Waste[6]

DHHS (NIOSH) Publication No. 97-111 Selecting, Evaluating, and Using Sharps Disposal Containers[7]

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.33 on Medical/Surgical Instruments.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from Standards Australia International Ltd., 286 Sussex St., Sydney, Australia NSW 2000.

[5] Available from British Standards Institute (BSI), 389 Chiswick High Rd., London W4 4AL, U.K., http://www.bsi-global.com.

[6] Available from Canadian Standards Association, Andre Wisaksana, 178 Rexdale Blvd., Etobicoke, ON Canada M9W 1R3.

[7] Available from Publications Dissemination, EID National Institute for Occupational Safety and Health, 4676 Columbus Pkwy., Cincinnati, OH 45226-1998.

3. Terminology

3.1 *Definitions:*

3.1.1 *container*—a product used for the containment of discarded medical needles and other sharps.

3.1.2 *material*—the substance(s) used in the construction of a sharps container.

3.1.3 *puncture force*—the minimum force applied to the representative sharp object that causes its tip to penetrate (exit) the opposite side of the test specimen from the side that it entered when tested in accordance with the test procedure portion, Section 6, of this specification.

3.1.4 *puncture resistant*—a region of uniform material and thickness is defined as puncture resistant if it meets Section 4 of this specification when tested in accordance with Section 6 of this specification.

3.1.5 *test specimen*—a sample of material being evaluated for puncture resistance that is taken from the actual container (direct method) or a representative example of the material and thickness having the same characteristics as the actual container (indirect method). Refer to Section 5.

3.1.6 *puncture test specimen*—a test specimen that has been punctured using the puncture test described in 6.3, and subsequently evaluated using the direct or indirect methods described in 7.1 and 7.2 of this specification.

3.1.7 *region of uniform material and thickness*—sharps-contact areas of the container, in aggregate, that are made of the same homogeneous, composite, or laminated material, and, as a consequence of fabrication or design or both, are expected to have the same material and thickness as other areas of the container. For example, in molded containers, the corners could be expected to be of different thickness than the sides and bottom, resulting in different regions of uniform material and thickness. Labels, tabs, membranes, or thin films covering openings in the container are considered separate regions of uniform material and thickness.

3.1.8 *sharps*—items used in medical treatment, diagnoses, or research that may cause puncture wounds, cuts, or tears in skin or mucous membranes, including, but not limited to: hypodermic, surgical, suture, and IV needles; Pasteur pipets, lancets, razors, scalpels, and other blades and sharp objects.

3.1.9 *sharps-contact areas*—the material of a container that represents those surfaces that enclose sharps within the container, when in its final closure configuration (that is, disposal) configuration.

4. Performance Requirements

4.1 *Puncture Resistance Specification*—When tested in accordance with Section 6, the average puncture force to penetrate material test specimens representing any regions of uniform material and thickness and sharps-contact areas, as defined in Section 3, shall not be less than 3.4 lbf (15 N), with no one value from any region of material tested less than 2.8 lbf (12.5 N).

4.2 *Layered Materials and Liners*—If a container is designed to use nonlaminated layers of material in sharps-contact areas, the combination of these layered materials must be tested as configured in actual use and shall meet the puncture resistance specification of this standard to be deemed puncture-resistant. If a container is designed to use a removable liner enclosed by the container, the material used in the removable liner must meet the puncture resistance specification of this standard to be deemed puncture-resistant.

For example, layered materials must be tested with the same spacing as configured in the actual application.

5. Sampling and Specimen Preparation

5.1 *Direct Versus Indirect Method*—Either of two testing procedures may be used to demonstrate that the material is puncture-resistant under this specification. The direct method shall be used if the material being evaluated has unknown characteristics. The indirect method may be used only if the material being evaluated has been previously characterized by a puncture force versus thickness relationship (see 7.2.2).

5.1.1 *Direct Method Specimen Preparation:*

5.1.1.1 One sharps container shall be selected at random to represent the material(s) to be tested. If it is not possible to obtain the required number of test specimens from one container, additional randomly selected containers shall be sampled until the required number of test specimens is obtained.

5.1.1.2 Identify each region of uniform material and thickness (see 3.1.7 and 3.1.9). Mark each region with a grid of 1-in. (25.4-mm) squares until the entire region has been covered. If it is not possible to fit a 1-in. grid over certain areas of the container, a smaller grid may be used; however, it shall be no less than 0.5 in. (12.7 mm) on a side.

5.1.1.3 Number every square of the grid so that each region of uniform material and thickness has consecutive numbers, starting with No. 1 in each region.

5.1.1.4 Using a random-number generator or table, select a quantity of 1-in. (or 0.5-in.) square specimens equal to 10 % of the surface area of each region of the container as defined in 3.1.7 or no less than twelve specimens from each region. If at least twelve specimens cannot be obtained from one container, refer to 5.1.1.1. Remove the specimens identified by the random number selection from each region of the test container. Mark the test specimen as it is removed to identify the inside of the container, as the puncture is required from the inside of the container outward.

5.1.1.5 Measure, mark, and record the thickness at the center of each selected test specimen using a thickness-measuring device capable of measuring in 0.001-in. (0.025-mm) increments, with an accuracy of 2 % of the thickness measured, for example, a ball micrometer with a ball diameter of 0.06 to 0.125 in. (1.6 to 3.2 mm). If the test specimen includes a radius, corner, edge, or other design feature, find the minimum thickness and mark the location, if not in the center of the specimen. Identify the specimen as to material and thickness represented.

5.1.1.6 Proceed to Section 6.

5.1.2 *Indirect Method Specimen Preparation:*

5.1.2.1 Obtain fabricated or molded test specimens (referred to as plaques within the indirect section) representing each material, range of thickness, and equivalent manufacturing