Designation: F 2132 – 01

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 F 2132; 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.

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 will be considered "puncture resistant." This specification will 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 (beyond the clinical environment, 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:*

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method[2]

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]

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

[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.

Current edition approved Aug. 10, 2001. Published September 2001.

[2] *Annual Book of ASTM Standards*, Vol 14.02.

[3] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

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

[5] Available from British Standards Institute, 2 Park St., London, England W1A2B5.

[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.

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 compared to 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 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 is to 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 process used to represent the sharps container. These plaques will not be from the container itself, but will be used to correlate the measured thickness of an actual container to the puncture resistance value of plaques having the same characteristics.

5.1.2.2 Produce a minimum of nine test plaques to represent a minimum of four different thicknesses that span the range of thicknesses expected for each region of uniform material and thickness of the representative container. Select 9 test plaques from a minimum of 4 thickness ranges for a minimum of 36 specimens. The size of each prepared plaque is to be determined by 5.1.1.2.

5.1.2.3 Measure and record the thickness at the center of each selected test plaque, using the same thickness measuring device as in 5.1.1.5, and identify the plaque as to material and

thickness represented.

5.1.2.4 Proceed to Section 6.

6. Puncture Test Procedure

6.1 *Conditioning*:

6.1.1 Condition all test specimens at 23 ± 2°C for 24 h before testing, unless the material is hydrophilic, requiring, in addition, a 50 ± 5 % relative humidity.

6.1.2 Conduct tests under the same standard laboratory conditions as that used for conditioning.

6.2 *Apparatus Requirements*:

6.2.1 *Testing Machine*—any force-generating device capable of operating a movable member at a constant rate of motion. The testing machine shall be calibrated according to the manufacturer's instructions.

6.2.2 *Crosshead Speed Control*—a drive mechanism for imparting to the movable member of the testing machine a uniform, controlled velocity of 4 in./min (100 mm/min) with respect to the fixed member.

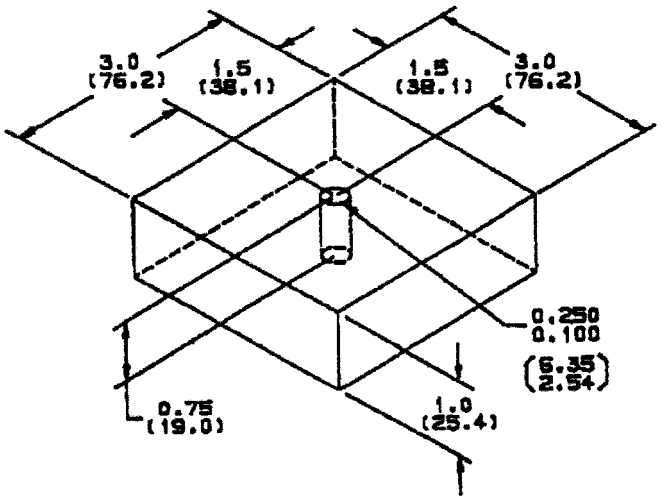
6.2.3 *Load Indicator*—a load-indicating mechanism shall be capable of measuring and recording force with an accuracy of ±1 % of the measured test force.

6.2.4 *Representative Sharp Object*—regular wall and bevel, Luer-type hypodermic needle, 21 gage by 1 in. (0.8 by 25.4 mm) that meets ISO Standards 7864 and 594.

6.2.5 *Needle Holder*—any Luer-type fitting or other suitable holder that will attach the needle securely to the testing machine or load indicator at an angle of 90 ± 5° with respect to the test specimen.

6.2.6 *Specimen Support*—a block of any suitably rigid material (aluminum, steel, wood, and so forth) conforming to the dimensions of the block shown in Fig. 1.

6.2.7 *Puncture Sensing Device*—any device capable of sensing when the needle tip just penetrates (exits) the opposite side of the test specimen from the side which it enters, and, when used in conjunction with the load indicator, records the force applied to the needle as its tip just penetrates (exits) the specimen. Any mechanism or materials used to sense puncture shall not influence the test results.



NOTE 1—in. (mm)—minimum dimensions, unless noted.

FIG. 1 Specimen Support

NOTE 1—A suitable means of sensing puncture is to place a piece of thin metal foil secured with suitable adhesive on the side of the test specimen corresponding to the outside of the container. The foil is wired such that an event marker will indicate, on the load indicator, the force being applied to the needle when it just penetrates the sample and touches the metal foil. The foil must be in intimate contact with the test specimen (that is, no air bubbles). Suggested foil is 0.001-in.-thick aluminum food wrap; suggested adhesive is household glue stick.

6.3 *Puncture Test*:

6.3.1 Prepare the testing machine and specimen support and set the crosshead speed velocity to 4 in./min (100 mm/min).

6.3.2 Affix a new needle to the needle holder. Zero the load indicator to account for the weight of the holder and the needle.

6.3.3 Secure the test specimen on the specimen support so that the surface of the specimen corresponding to the inside surface of the container (if applicable) is facing toward, and is perpendicular to, the needle. Any securing mechanism used to affix the specimen to the support shall not influence the test results. The test specimen, as identified in 5.1.1.5, shall be placed over the hole of the specimen support, with the area to be punctured directly under the needle. Do not alter or distort the configuration of the specimen. If the material is layered or a liner, refer to 4.2.

6.3.4 Allow sufficient space between the needle and the test specimen so that the movable member can attain the specified crosshead velocity before the needle penetrates the test specimen. Start the drive mechanism.

6.3.5 Stop the test after the cannula of the needle has penetrated the sensing material on the side of the puncture specimen opposite that side which it entered. If the needle cannot exit the puncture specimen, record that the needle did not puncture.

6.3.6 Record the puncture force of each puncture specimen, as defined in 3.1.3 of this specification, to the nearest 0.1 lbf.

6.3.7 Record the identity of the puncture specimen and the measured thickness of the specimen.

6.3.8 Repeat 6.3.1-6.3.7 for each test specimen.

7. Puncture Resistance Measurement

7.1 *Direct Method Data Analysis*:

7.1.1 Determine the average puncture force value for all puncture specimen measurements from each region of uniform material and thickness recorded in 6.3.6 (one average for each region).

7.1.2 Determine the minimum puncture force value from all puncture specimen measurements from each region of uniform material and thickness recorded in 6.3.6 (one minimum for each region).

7.1.3 Record the average and minimum puncture force values along with the previously recorded container information of material, location, and thickness for each region.

7.1.4 Compare the average and minimum puncture force values of each region with the performance requirements in Section 4. If the puncture force values meet the puncture force requirements of Section 4, the container material(s) representing each region may be deemed puncture resistant using the direct method.

7.2 *Indirect Method Data Analysis*:

7.2.1 This method can be used ONLY if it can be correlated using the following puncture force (*Fp*) versus thickness (*t*)

relationship, as determined for the material and thickness being evaluated.

7.2.2 Using the recorded thickness of each test plaque (see 5.1.2.3) and the recorded puncture force of each puncture plaque (see 6.3.6), determine the puncture force (*Fp*) versus thickness (*t*) relationship of the test plaques and fit a regression curve/equation to the data. Use all data points to develop the relationship. Then calculate the lower 95 % confidence level of the mean for the data and plot a regression curve or calculate a regression equation for these values.

NOTE 2—Choose a regression curve that provides the best correlation coefficient (*r*) value. If an *r* value of 0.8 or greater cannot be achieved, new test data must be obtained, or the direct method shall be used (see 5.1.1).

7.2.3 Determine the average and minimum thickness for each region of uniform material and thickness of test plaques representing the material(s) being evaluated.

NOTE 3—The thickness of the representative container region(s) may be obtained using the procedure defined in Section 5 or by other similar methods that will obtain the thickness of the container region(s) by evaluating at least 10 % of the surface area (see 5.1.1.4). For example, the use of a Hall Effect sensor thickness gage will allow the evaluation of a large percentage of the surface of the container without the need to cut measurement samples from the container.

7.2.4 Compare the average and minimum thickness of the representative container region being evaluated (see 7.2.3), to the lower 95 % confidence interval *Fp* versus *t* regression curve/equation of the test plaques (see 7.2.2). Record the thickness and corresponding puncture force value for both the minimum and average thickness of the test plaque that corresponds to each region of the actual container material thickness being measured.

NOTE 4—The relationship of the *Fp* versus *t* regression curve/equation and the puncture resistance of the regions representing actual containers must be correlated if test specimens other than from actual containers are used to create the *Fp* versus *t* relationship. If test plaques are produced for the indirect method, they must be from the same material and range of thickness, and made under equivalent manufacturing conditions, as the actual container used in the direct method analysis (see 5.1.1).

7.2.5 Compare the average and minimum puncture force values obtained from 7.2.4 to the performance requirements in Section 4. If the test plaques meet the puncture force requirements of Section 4 and have been properly correlated, the representative container material(s) may be deemed puncture resistant using the indirect method.

8. Precision and Bias

8.1 *Precision Statement for Test Method*:

8.1.1 Precision is based on round-robin testing at five different laboratories, conducted on five different thicknesses of test plaques, molded from the same material. The number of participating laboratories (five) does not meet the minimum of six required for determining precision, as described in Practice E 691.

8.1.2 Precision, characterized by repeatability (*Sr* and *r*) and reproducibility (*SR* and *R*) has been determined by round-robin testing by five (5) laboratories to be:

Thickness, in.	Average, lbf	*Sr*	*SR*	*r*	*R*
0.03	1.92	0.10	0.14	0.27	0.40
0.04	2.90	0.13	0.16	0.36	0.44
0.05	3.82	0.20	0.21	0.55	0.59
0.06	5.00	0.12	0.14	0.35	0.40
0.07	5.96	0.11	0.19	0.30	0.53

8.1.3 This precision statement is provisional. The task group intends to conduct another round-robin within five years when additional data will be obtained and processed that does meet the requirements of Practice E 691.

8.2 *Bias Statement for Test Method*:

8.2.1 No reference material exists for this test method, therefore, no bias statement is being made.

9. Keywords

9.1 material puncture resistance; needle disposal; puncture resistance; puncture-resistance testing; safety devices; sharps container; sharps disposal

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 This specification and test procedure are intended to provide guidelines for the puncture resistance evaluation of materials used in the construction of containers for the collection and disposal of discarded medical needles and other sharps. It is not the intention of this specification to limit or restrict the design or processing of reliable and functionally performing puncture resistant containers.

X1.2 Gaps between movable parts or locking flaps, and small openings for autoclave vents, are *not* to be evaluated for puncture resistance in this specification, as they have no puncture resistance. It is recommended, however, that these features be minimized or protected to prevent the protrusion of sharps.

X1.3 Materials meeting the minimum puncture resistance requirements of this specification provide one of many basic criteria for user safety. The specific application of each sharps container should be evaluated carefully following published guidelines, such as DHHS (NIOSH) Publication No. 97-111, for the selection and use of sharps containers.

X1.4 The puncture force requirements of 4.1 were adapted in part from the existing BSI 7320:1990, Appendix C. These performance values were validated by the ASTM Task Force

through puncture testing a variety of commercially available sharps containers during the early development of this standard, in addition to round-robin testing of molded plaques in various thicknesses. The British Standard guideline has also influenced Canadian (see CSA Z316.6-95) and Australian (see AS 4031:1992) sharps-container standards, which use the same performance criteria.