



Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps¹

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^{ε1} 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 $23 \pm 2^\circ\text{C}$ (such as usage in emergency vehicles) require further material characterization by the product specifier to determine suitable use.)

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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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 Use³

ISO 594 Luer Fittings³

2.3 Other Standards:

AS 4031:1992 Non-reusable Containers for the Collection of Sharp Medical Items Used in Health Care Areas⁴

BSI 7320:1990 Specification for Sharps Containers⁵

CSA Z316.6-95 Evaluation of Single Use Medical Sharps Containers for Biohazardous and Cytotoxic Waste⁶

DHHS (NIOSH) Publication No. 97-111 Selecting, Evaluating, and Using Sharps Disposal Containers⁷

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.