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Standard Test Methods for Male Condoms Made from Synthetic Materials[1]

This standard is issued under the fixed designation D 6324; 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 These test methods cover and shall be used to evaluate male condoms made of various synthetic materials. These test methods also describe the minimum inspection and quality levels that shall be utilized in referee tests. It is not intended to be a routine quality control specification for synthetic condom manufacturing operations.

1.2 These test methods are intended to assist buyers in obtaining synthetic condoms of consistent quality. The safe and proper use of synthetic condoms is excluded from the scope of these test methods.

1.3 The system of units for these test methods is a combination of systems. When the SI units are not utilized, they will be provided in parentheses.

1.4 The annexes in these test methods include important information, such as that on apparatus or materials, that is a mandatory part of these test methods but too detailed for inclusion in the main text.

1.5 The appendixes in these test methods contain information intended to provide guidance.

2. Referenced Documents

2.1 *ASTM Standards:* [2]

D 374 Test Methods for Thickness of Solid Electrical Insulation

D 618 Practice for Conditioning Plastics for Testing

D 638M Test Method for Tensile Properties of Plastics [Metric][3]

D 882 Test Method for Tensile Properties of Thin Plastic Sheeting

D 3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission

D 3767 Practice for Rubber—Measurement of Dimensions

2.2 *Other Documents:*

ANSI/ASQC Z1.4–2003 Sampling Procedures and Tables for Inspection by Attributes[4]

ISO 37 Rubber, Vulcanized or Thermoplastic—Determination of Tensile Stress-Stain Properties Preclinical and Clinical Requirements for Approval to Market Non-latex Condoms, World Health Organization, 1997[4]

ISO 10993 Biological Evaluation of Medical Devices, Part 2[4]

Testing Guidance for Male Condoms Made from New Material; Center for Devices and Radiological Health, Food and Drug Administration, Draft June 29, 1995[5]

3. Significance and Use

3.1 New polymer materials for male condoms are being developed. This standard is intended to describe the test methods whose results shall adequately describe the design and the quality of the condoms.

3.2 These test methods are not intended to be design or material restrictive. The design requirements for each material are unique to that material and shall be validated prior to use.

4. Materials and Manufacture

4.1 Condoms shall be manufactured from synthetic materials.

4.2 The biocompatibility of the finished product, including any dressing materials, shall be assessed in accordance with ISO 10993 or its equivalent.

NOTE 1—Condom lubricants that contain spermicides, such as Nonoxynol 9, cause irritation in a small proportion of the user population.

5. Requirements

5.1 *General*:

5.1.1 *Sampling*—Samples will be selected randomly from the defined lot. The sampling plan must conform to the requirements listed in Table 1.

5.1.2 *Sample Handling*—To avoid inadvertent damage, operators must wear gloves, finger cots, or other suitable hand/finger covers and exercise reasonable caution in handling the packet or synthetic condom in order to minimize the possibility of damage during the testing procedure.

[1] These test methods are under the jurisdiction of Committee D11 on Rubber and are the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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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] Withdrawn.

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

[5] Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857.

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TABLE 1 Quality Inspection Requirements[A]

Characteristic	Inspection Level	AQL	Specification Minimum
Synthetic Condom:			
Length	S-2	4.0	160 mm
Width	S-2	4.0	±2 mm nominal width per manufacturer
Leakage	GI	0.25	not applicable
Strength (see Note 2)	S2	Mean	Type A—15 MPa Type B—35 MPa Type C—50 MPa
Package:			
Package integrity	S-3	2.5	not applicable

[A] ANSI/ASQC Z1.4 - 2003.

5.1.3 *Process Controls*—Manufacturers may use process control tests to determine synthetic condom properties. Finished synthetic condoms shall be used for qualifications and referee tests.

5.1.4 *Training*—Properly trained and qualified operators are required for each test method.

5.2 *Length*—This part of the standard specifies a method for measuring the length of a synthetic condom. The inspection level, AQL, and a minimum length are given in Table 1.

5.2.1 *Procedure for Length Evaluation*:

5.2.1.1 *Length*—Measure the length of the condom, to the nearest 1 mm, using the test method described in Annex A1.

5.3 *Width*—This part of the standard specifies a method for measuring the width of a synthetic condom. The inspection level, AQL, and a width requirement are given in Table 1.

5.3.1 *Procedure for Width Evaluation*—Measure, to the nearest 0.5 mm, the width of the condom laid flat at a distance less than 30 mm from the open end using the test method described in Annex A2.

5.4 *Leakage*:

5.4.1 *Criteria*—Synthetic condoms that burst during the test or show any evidence of leakage in the test area, including seepage, microdroplets, squirters, and so forth, not including leakage at a distance of 25 mm (1 in.) or less from the open end, will be considered failures. The test method is described in Annex A4 with the quality inspection level and AQL given in Table 1.

5.4.2 *Precision and Bias*—No statement is made concerning the precision or bias of determining leakage in condoms since the result states merely whether there is conformance to the criteria specified.

5.5 *Strength Requirements for Synthetic Condoms*:

5.5.1 For the strength requirement to be determined and validated, the condom shall be type tested for its ultimate elongation to determine its minimum equivalent strength parameters. The method for sample preparation for this test is found in Annex A2. The dumbbell specimen for this test shall include the weld of the condom in the test area, if any is present.

5.5.2 Once the type test for the ultimate elongation for the synthetic condom has been determined, the condom will be classified into either Type A, Type B, or Type C.

5.5.2.1 *Type A*—This condom shall have an ultimate elongation of greater than 675 %

5.5.2.2 *Type B*—This condom shall have an ultimate elongation of no more than 675 % and no less than 500 %.

5.5.2.3 *Type C*—This condom shall have an ultimate elongation of less than 500 %.

NOTE 2—Requirement is the minimum level based on an "as-manufactured" basis.

5.6 *Packaging*:

5.6.1 Unless otherwise specified, packaging shall be in accordance with the manufacturer's commercial practice.

5.6.2 Packaging shall be tested in accordance with Test Method D 3078 with the pressure reduced to 50 kPa (380 mm Hg or 15 in. Hg) below atmospheric pressure. The inspection level and AQL are given in Table 1.

6. Additional Test Methods

6.1 *Dimensions–Thickness*—This part of the standard specifies a test method for measuring the thickness of a synthetic condom. There are no thickness requirements given in this standard.

6.1.1 *Procedures for Measuring the Thickness*:

6.1.1.1 *Thickness*—Measure the thickness of condoms dried at room temperature for a minimum of 16 h after any lubricant dressing materials have been removed, if applicable. Measure the wall thickness at the following three points: 30 ± 5 mm, 90 ± 5 mm, and 150 ± 5 mm, all from the closed end of the synthetic condom, excluding reservoir tip, using the method described in Appendix X1.

6.1.1.2 Precision and bias for measuring the thickness of a synthetic condom have not been determined.

6.2 *Air Burst Properties*—This part of the standard specifies a test method for determining the volume and pressure at break for synthetic condoms. There are no volume or pressure requirements for a synthetic condom in this standard.

6.2.1 *Procedures for Air Burst Properties: Volume and Pressure*—A test method is presented in Appendix X2.

6.2.2 Precision and bias for the air burst testing of a synthetic condom have not been determined.

6.3 *Tensile Properties*—This part of the standard specifies a method for determining the breaking force, tensile strength, and ultimate elongation of synthetic condoms. There are no breaking force, tensile strength, or elongation requirements for synthetic condoms in this standard.

6.3.1 *Procedure for Tensile Properties: Breaking Force, Tensile Strength, and Ultimate Elongation*—A test method is presented in Annex A2.

6.3.2 Precision and bias for the tensile properties of synthetic materials have not been determined.

6.4 *Weld Strength Property*—This part of the standard specifies a test method for measuring the weld strength of a synthetic condom. There is no weld strength requirement for synthetic condoms given in this standard.

6.4.1 *Procedure for Measuring Weld Strength*—A test method for determining the strength of a welded seam is presented in Appendix X3.

6.4.2 Precision and bias for the weld strength of synthetic condoms have not been determined.

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6.5 *Design Validation*—While the rapid proliferation of new materials and development in synthetic condoms make standardization difficult, the design tests included in this standard should be used as a guide in the development or assessment, or both, of synthetic condoms. Rather than describe a list of requirements and tests that might be soon outdated, Appendix X4 consists of recommendations to validate the design of synthetic condoms.

7. Labeling

7.1 *Condom Identification*—Each condom individual package or retail package shall be marked legibly to include the name or trademark of the marketer, and the condom type as defined in 5.5.2.

7.2 The retail package and the individual package shall contain a lot number and an expiration date, which shall be marked as such.

7.3 Storage information and directions for use shall be contained in the labeling.

8. Storage

8.1 Condoms shall not be allowed to come into contact with materials that will degrade the condom.

8.2 Condoms shall be protected from exposure to excessive heat and light in storage.

ANNEXES

(Mandatory Information)

A1. DETERMINATION OF LENGTH

A1.1 Scope

A1.1.1 This annex covers the method for determining the length of synthetic male condoms.

A1.2 Principles

A1.2.1 *Length*—Free hanging of the unrolled condom over a graduated mandrel (Fig. A1.1) and measurement of its length, the reservoir excluded, if one exists.

A1.3 Apparatus

A1.3.1 *Mandrel*, with a scale divided into millimetres and having the dimensions shown in Fig. A1.1 with the zero beginning at the rounded end.

A1.4 Procedure

A1.4.1 Move the condom inside the package such that it is away from the area where the package is to be torn. Tear the package and remove the condom. In no circumstances use scissors or other sharp instruments to open the package.

A1.4.2 Unroll the condom and stretch is slightly twice but by no more than 20 mm to smooth out any wrinkles.

NOTE A1.1—Lubricants may be removed and suitable powders may be added to avoid sticking.

A1.4.3 *Length*—Put the condom over the mandrel and let it hang freely, stretched only by the force of gravity. Record, to the nearest millimetre, the smallest value of the length of the condom that can be read on the scale outside the open end of the condom.

A1.5 Report

A1.5.1 Report the following information:

A1.5.1.1 Identification of the sample, for example, batch number,

A1.5.1.2 The length measured in accordance with A1.4.3, and

A1.5.1.3 The date of the test.

A1.6 Condom Disposal

A1.6.1 Condoms subjected to this test may also be used for determination of width and thickness but shall be destroyed after testing.

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