This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: D6324 – 11 (Reapproved 2017)

Standard Specification for Male Condoms Made from Polyurethane[1]

This standard is issued under the fixed designation D6324; 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 This specification covers the minimum requirements for individually packaged male condoms made from polyurethane. This specification also describes 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 polyurethane condom manufacturing operations.

1.2 This specification is intended to assist buyers in obtaining male polyurethane condoms of consistent quality. The safe and proper use of male polyurethane condoms is excluded from the scope of these test methods.

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

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

1.5 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

1.6 It shall be the responsibility of the manufacturer for any condom design that falls outside the specifications of this standard to determine testing methodology and substantiate the appropriateness of that methodology to assure the quality of the condoms to the purchaser and to the government regulatory authority having jurisdiction.

1.7 *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.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D374 Test Methods for Thickness of Solid Electrical Insulation (Metric) D0374_D0374M

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D618 Practice for Conditioning Plastics for Testing

D638 Test Method for Tensile Properties of Plastics

D882 Test Method for Tensile Properties of Thin Plastic Sheeting

D3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission

D3492 Specification for Rubber Contraceptives (Male Condoms)

D3767 Practice for Rubber—Measurement of Dimensions

2.2 *Other Documents:*

ANSI/ASQC Z1.4–2003 Sampling Procedures and Tables for Inspection by Attributes[3]

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[3]

ISO 10993 Biological Evaluation of Medical Devices, Part 2[3]

ISO 23409 Synthetic Condom Standard[3]

3. Significance and Use

3.1 New polymer materials for male condoms are being developed. Several products have been developed and are currently marketed in international commerce. This standard is intended to provide specifications to adequately describe the design and the quality of condoms made of polyurethane material.

[1] This specification is under the jurisdiction of Committee D11 on Rubber and Rubber-like Materials and is 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] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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3.2 This standard is not intended to be design restrictive. The condom design shall be validated prior to use.

3.3 This standard will provide test methods to validate the material of construction for a polyurethane condom characterizing this material and then confirm the material as suitable for a male condom with a performance in-use test.

3.4 Current products in international commerce at the time of publication shall be considered in compliance with this standard. The use of a polyurethane condom material validation for line extension will still need to be undertaken or alternately individual performance user studies will need to be undertaken.

4. Materials and Manufacture

4.1 Condoms shall be manufactured from polyurethane 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 a spermicide, 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 polyurethane condom in order to minimize the possibility of damage during the testing procedure.

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

TABLE 1 Quality Inspection Requirements[A]

Characteristic	Inspection Level	AQL	Specification Minimum
Polyurethane 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
Air Burst Properties	GI	1.5	Defined by material validation protocol
Strength[B]	S2	Mean	Type A—15 MPa Type B—30 MPa Type C—50 MPa
Strength (ring or dumbbell testing)	S2	2.5	Defined by material validation protocol
Package:			
Package integrity	S-3	2.5	not applicable

[A] ANSI/ASQC Z1.4-2003.
[B] Requirement is the minimum level based on an "as-manufactured" basis with dumbbell testing only and without the completion of a material validation protocol.

5.1.4 *Lot*—A collection of condoms of the same design, color, shape, size, and formulation manufactured continuously, and at essentially the same time using the same process, raw materials, or the same specification, common equipment, and packaged with the same lubricant and any other additives or dressing in the same type of individual container. The maximum lot size shall be 500 000 condoms.

5.1.5 *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 polyurethane condom. The inspection level, AQL, and a minimum length are given in Table 1.

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

5.2.2 Precision and bias for measuring the length can be found in Specification D3492.

5.3 *Width*—This part of the standard specifies a method for measuring the width of a polyurethane 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 A4.

5.3.2 Precision and bias for measuring the width can be found in Specification D3492.

5.4 *Thickness*—Measure the thickness of condoms after being dried at room temperature for a minimum of 16 h. Any dressing materials (lubricant) should be removed carefully with absorbent paper.

5.4.1 *Procedure for Thickness Evaluation*—Measure the wall thickness at three points, 30 ± 5 mm, 90 ± 5 mm, and 150 ± 5 mm from the closed end of the condom, excluding reservoir tip. The thickness measuring device shall conform to that specified in Practice D3767. Use the test method in Annex A6. When a condom is textured, measure the thickness in the nontextured area. Report the measurements to the nearest 0.01 mm.

5.4.2 Precision and bias for measuring the thickness can be found in Specification D3492.

5.5 *Leakage:*

5.5.1 *Criteria*—Polyurethane condoms that burst during the test or show any evidence of leakage in the test area, including seepage, micro-droplets, 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 A5 with the quality inspection level and AQL given in Table 1.

5.5.2 *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.

5.6 *Strength Requirements for Polyurethane Condoms:*

5.6.1 The strength of the condom can be determined using either ring or dumbbell test pieces. If the condom is manufactured with a welded seam, then it is required that the weld of the condom be in the test area.

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5.6.2 *Procedure for Tensile Properties: Breaking Force, Tensile Strength, and Ultimate Elongation*—Test methods are presented in Annex A2 (dumbbell testing) and Annex A3 (ring testing).

5.6.3 Precision and bias for the tensile properties can be found in Test Methods D412.

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

5.6.5 *Procedure for Measuring Weld Strength*—A test method for determining the strength of a welded seam is presented in Appendix X1.

5.6.6 Precision and bias for the weld strength can be found in Test Methods D412.

5.6.7 To maintain this standard as a basis for currently marketed products after the type dumbbell test for the ultimate elongation for the synthetic condom has been determined, the condom can be classified into either Type A, Type B, or Type C.

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

5.6.7.2 *Type B*—This condom shall have an ultimate elongation of no more than 675 % and no less than 400 %.

5.6.7.3 *Type C*—This condom shall have an ultimate elongation of less than 400 %.

5.6.8 The tensile strength specifications in Table 1 for Types A, B, and C can then be utilized without the need for completion of a material validation protocol but only for that product—defined by the specific shape, thickness and lubricant system. A slippage and breakage user study could be necessary to achieve local regulatory approval.

5.7 *Packaging:*

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

5.7.2 Packaging shall be tested in accordance with Test Method D3078 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.

5.8 *Design Requirements*—While the rapid proliferation of new materials and development in polyurethane condoms make standardization difficult, the design tests included in this standard shall be used as a guide in the development or assessment, or both, of polyurethane condoms. Rather than describe a list of requirements and tests that might be soon outdated, Annex A9 consists of what is required to validate the design of polyurethane condoms.

5.9 *Air Burst Properties*—This part of the standard specifies a test method for determining the volume and pressure at break for polyurethane condoms. The specifications for the airburst testing of volume and pressure will be derived from the material validation exercise in Section 8 and Annex A9.

5.9.1 *Procedures for Air Burst Properties: Volume and Pressure*—A test method is presented in Annex A7.

5.9.2 Precision and bias for the air burst testing can be found in Specification D3492.

6. Labeling

6.1 Each condom package (individual primary package and retail package) shall be legibly marked.

6.1.1 The name or trademark of the product shall be included on each condom package (individual primary package and retail package).

6.2 The expiration date, which shall be marked as such, for example, "Exp.," shall be displayed on the condom primary package (a.k.a. "wrapper" or "foil") and the retail package.

6.2.1 The expiration date, which shall be interpreted as the last day of the month indicated, shall be displayed as the month and year of expiry using either a numeric or alphabetic month, preceded or followed by the numeric year designation, for example: 01/2010 or Jan 2010 or 2010/01 or 2010 Jan.

6.2.2 The expiration date shall be determined as specified in Annex A8.

6.3 Each condom primary package and retail package shall also include the name and place of business of manufacturer, packer or distributor; statement of identity ("polyurethane condom"); lot number and expiration date; the intended uses; appropriate warning statements; and declaration of net quantity of contents.

6.4 The retail package label shall, if appropriate, indicate the country of origin (for example, "Made in -----") and may also contain information regarding the description of the condom (for example, nominal width, length, texture, shape, etc.).

6.5 Appropriate directions for use shall be included on the retail package or separately in a package insert.

6.6 For packaged condoms intended for export from the USA, each condom package (individual and retail) shall accord to the specifications of the foreign purchaser and not be in conflict with the laws of the country to which it is intended for export.

7. Storage

7.1 During production, processing, and packaging, condoms shall not be allowed to come into contact with materials that will degrade the condom.

7.2 In-process bulk unpackaged condoms should be stored in appropriate closed containers in dry areas at a temperature below 40°C (104°F). Storage for short periods of time above this temperature will not be harmful to product. They should be kept away from direct sources of heat and ultraviolet light.

8. Condom Material and Clinical Validation

8.1 The manufacturing process used to make the condom lots will have completed a documented validation process.

8.2 Full production lots will be sampled to complete the condom material validation.

8.3 A material characterization protocol shall be undertaken. Examples of useful testing techniques are outlined in Annex A9, Note A9.1. Airburst testing and tensile strength testing shall be the minimum physical testing required.

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8.4 Once the validated process used for the manufacture of the condom has been determined to be in control, i.e. producing condoms with stable and predictable physical properties, three production lots should be sampled using statistically valid sample sizes to produce a baseline distribution of the airburst and tensile strength properties. The three lots chosen must reflect the long-term variation expected in the process, for example, different manufacturers lots of the polymer resin being expected to be a critical factor.

8.5 Methods for the development of specifications for air burst and tensile strength testing can be found in Appendix X2.

8.6 The material will be validated for use as a condom using a slippage and breakage user study.

8.7 Completion of the material validation and local regulatory approval for commercialization of the product will be justification for product line extensions, such as, a change in shape, addition of texturing or a change of lubricant. These are considered to be minor changes and do not require the full material validation and an associated slippage and breakage user study, but will require qualification for product safety and stability. For completeness in the development process the clinical performance of a change in shape of the product should be evaluated. Appendix X3 is an example of acceptable methods.

8.8 An additional material validation study and associated clinical slip/break study will be required for a change in the condom airburst or tensile, or both, specification beyond the tolerances of the original specification. This additional work will require samples from the stable and predictable process to be used to make condoms at the new airburst or tensile specification, or both. A slippage and breakage user study shall be completed.

ANNEXES

(Mandatory Information)

A1. DETERMINATION OF LENGTH

A1.1 Scope

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

A1.2 Principles

A1.2.1 *Length*—Frees 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. Under no circumstances should scissors or other sharp instruments be used 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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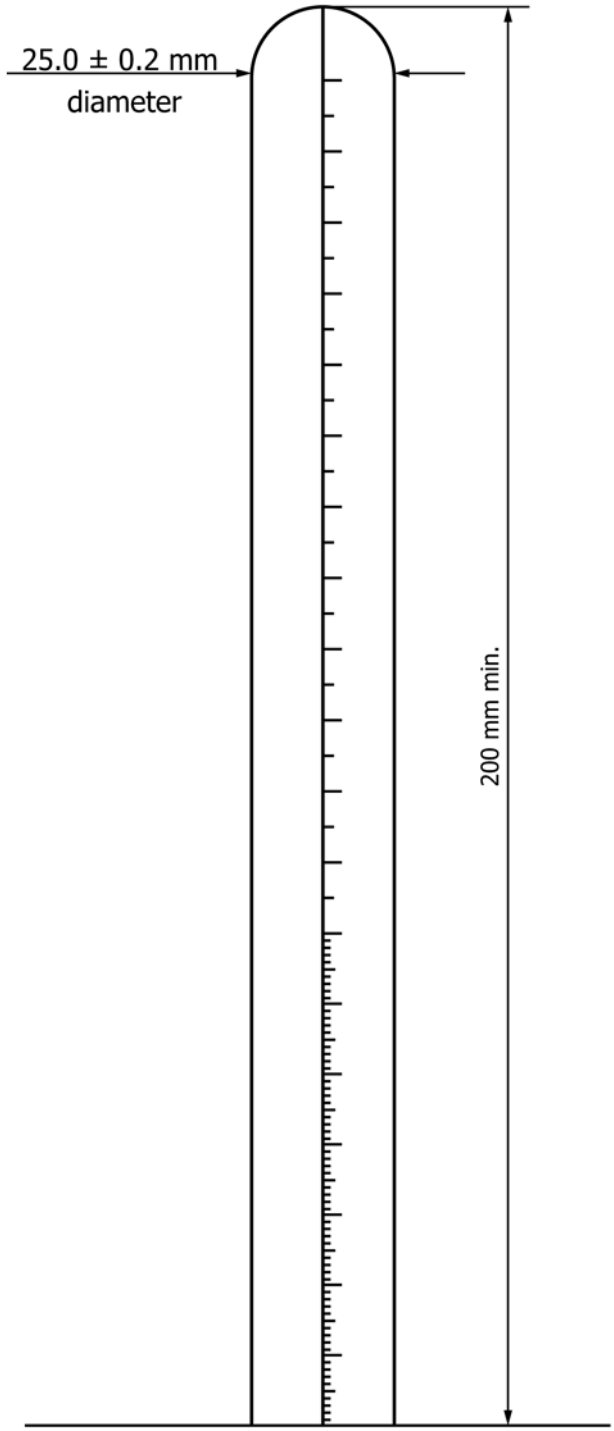

FIG. A1.1 Mandrel for Determining Length of Condom

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