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# 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.

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<br>Type B—30 MPa<br>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.

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.

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.

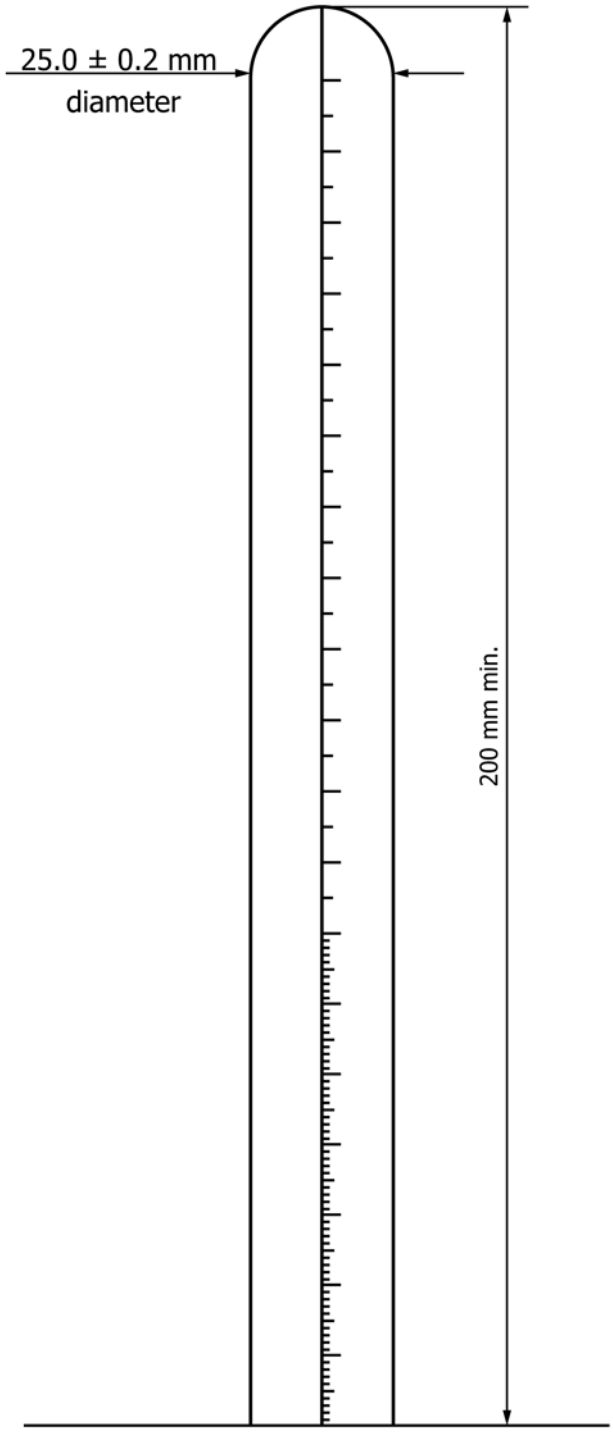


**FIG. A1.1 Mandrel for Determining Length of Condom**

## A2. TEST METHOD FOR TENSILE PROPERTIES OF POLYURETHANE CONDOMS BY THE DUMBBELL METHOD

### A2.1 Scope

A2.1.1 This annex covers the dumbbell test method for determining the tensile properties of polyurethane condoms. Specimen elongation may be measured by extension indicators or displacement of gauge marks.

### A2.2. Significance and Use

A2.2.1 Tensile properties determined by this test method are of value for the identification and characterization of materials for control and specification purposes.

### A2.3. Apparatus

A2.3.1 *Tensile Tester,* with a constant rate of grip separation, and capable of measuring the applied load to an accuracy of within ±2 %. The maximum force is to be recorded.

A2.3.2 *ASTM Die,* D-412, Type "C", DIN 53 504, S3A, or ISO 37: 1994(E) Type 3.

A2.3.3 *Gripping System,* which will exert uniform pressure to minimize slippage and prevent uneven stress.

A2.3.4 *Thickness Measuring Device,* reading to 0.001 mm and in accordance with Test Methods D374 or a method of equivalent accuracy.

A2.3.5 *Stereo Microscope* (recommended).

A2.3.6 *Conditioning Apparatus*—Condition the test specimens in their primary packages at 23 ± 2°C (73.4 ± 3.6°F) and 50 ± 5 % relative humidity for not less than 16 h prior to testing in accordance with Procedure A of Practice D618. Conduct the tests in a standard laboratory atmosphere of 23 ± 2°C (73.4 ± 3.6°F) and 50 ± 5 % relative humidity.

### A2.4 Speed of Testing

A2.4.1 The crosshead speed shall be determined in accordance with Test Method D882.

A2.4.2 The gauge length shall be 45 mm for Die D-412, "Type C" or 10 mm if Die 53 504, S3A, or ISO 37: 1994(E) Type 3 is used.

### A2.5. Procedure

A2.5.1 Remove the closed end of the condom by making a cut perpendicular to the length, followed by a lengthwise cut of the side. Open the condom into a flat sheet and lay it on a smooth, flat surface suitable for cutting thin films. Cut the specimens with a single impact of the die. The cutting edges of the die shall be free of nicks. After cutting, the specimens should be visually examined, preferably using a stereo microscope to look for flaws. Record the direction orientation of the specimens. Report separately data from specimens cut at different orientations.

A2.5.2 If dressing materials are present, remove by carefully wiping the sample with a clean dry cloth or tissue before measuring the thickness.

A2.5.3 Measure the thickness of each specimen at three points; one at the center and one at each end of the reduced section of the specimen to the nearest 0.001 mm.

A2.5.4 With the sample laying on a flat, smooth surface, mark a 25-mm (1-in.) segment in the reduced section of the sample equidistant from its center and perpendicular to its longitudinal axis, using an extra-fine felt tip pen. Exercise care to ensure that the sample is not under tension and to prevent scratching, which could cause premature failure during testing.

A2.5.5 Place the test sample in the grips, taking care to align the long axis of the sample with an imaginary line between the points where the grips attach to the instrument. Start the instrument, initiating grip separation, and record the peak load.

A2.5.6 To record the sample elongation, it is recommended that a non-contacting extensiometer be used to limit the potential of damage to the sample and an inaccurate determination.

A2.5.7 Discard specimens that fail at an obvious flaw or that fail outside the gauge length and retest.

### A2.6. Calculation

A2.6.1 *Tensile Strength*—Tensile strength equals force at break per cross-sectional area of the unstretched specimen. Report the results in force per unit area (megapascals or pound-force per square inch).

A2.6.2 *Percent Elongation*—Percent elongation equals 100 (distance between bench marks at break minus the original distance between bench marks) per original distance between bench marks.

### A2.7. Report

A2.7.1 Report the following information:

A2.7.1.1 Sample identification,

A2.7.1.2 Orientation of sample,

A2.7.1.3 Average thickness of each test specimen and the average thickness of all test specimens,

A2.7.1.4 Force at break and the calculated tensile strength of each specimen,

A2.7.1.5 Calculated elongation for each specimen,

A2.7.1.6 The standard deviation from the values,

A2.7.1.7 Laboratory conditions at the time of testing: temperature and humidity,

A2.7.1.8 Initial gauge length,

A2.7.1.9 Speed of grip separation,

A2.7.1.10 Load range, and

A2.7.1.11 Die used.

## A3. PREPARATION AND TESTING OF RING-STYLE TEST SPECIMENS FOR THE TENSILE TESTING OF CONDOMS

### A3.1 Purpose

A3.1.1 The purpose of Annex A3 is to provide information on the preparation of the ring-type tensile specimens supplementary to that provided in Test Methods D412. Experience with the tensile testing of condoms has resulted in several refinements to the methods of specimen preparation described in Test Methods D412. It has been demonstrated during inter-laboratory studies of this test procedure that the hand or mallet cutting of specimens, as allowed by Test Methods D412, results in consistently lower tensile strength values and considerably greater experimental variability.

### A3.2 General

A3.2.1 The importance of cutting properly prepared ring-type test specimens for the tensile testing of condoms cannot be overemphasized. Every effort must be made in the training of personnel and the selection of equipment to ensure that the test specimen is clean cut and that the cut across the width of the condom is made at a right angle to the condom's length. The use of guides for the selected sample cutting equipment to ensure the condom is placed at right angles to the cutting die is recommended. In addition, the region selected for cutting should be inspected carefully prior to cutting to ensure that the resulting ring specimen is free of film flaws.

### A3.3 Equipment

A3.3.1 *Die*—A device having parallel cutting edges spaced 20 ± 0.1 mm apart and having a length of at least 70 mm designed so that the cutting edges may be replaced or honed periodically to maintain the die's sharpness.

A3.3.2 *Cutter*—A mechanical press or other apparatus that ensures that the die's cutting edges will move in a straight vertical direction to the anvil (cutting surface).

NOTE A3.1—Experience has shown that a mechanical press operating at a minimum vertical cutting speed of not less than 500 mm/s (20 in./s) and constructed so that the die may be attached to the arbor will result in more uniform specimens. As an alternative, a mallet and die can be used for sample cutting. However, this method is not recommended since the quality of the sample produced is greatly affected by the skill of the technician and the technique used.

A3.3.3 *Anvil (Replaceable Cutting Surface)*—The anvil must be a flat surface large enough to support a replaceable backing material that will permit the die to cut cleanly through the test specimen with minimal damage to the die's cutting edge. The cutting die shall not cut over previous cutting scars in the backing material.

NOTE A3.2—Experience has shown that 3 mm (0.125 in.) thick high density polyethylene (HDPE), polyvinylchloride (PVC), rubber, and polyethylene-coated cardboard are acceptable backing materials. Hard-pressed cardboard also has been used successfully, but care must be taken to ensure that the die cutting edge is not damaged. A wide variety of materials produce good results if they meet the basic requirements of being smooth, flat, and firm. When cutting specimens, excessive penetration of the cutting surface should be avoided. If considerable penetration is required to cut the sample, the cutting surface is not sufficiently firm or the die is not sufficiently sharp.

A3.3.4 *Unrolling Mandrel*—A device made of suitable material (smooth and cleanable) that will permit the condom to be unrolled, if necessary, and sized so that the condom is not stretched during its removal.

A3.3.5 *Towel*—A soft laboratory grade absorbent material to be used to remove lubricant, if required.

A3.3.6 *Dressing Material*—Virgin talc, corn starch or silica, or both, (fragrance-free) to be used to assist drying and avoid stickiness during handling and cutting.

### A3.4 Method

A3.4.1 *Condom Preparation:*

A3.4.1.1 Carefully remove the condom from the package, being sure to hold the condom while still inside the package in such a manner that during the opening of the package, the packing material does not damage or cut the condom.

A3.4.1.2 Carefully unroll the condom to its full length.

A3.4.1.3 Cut off the reservoir portion at the shoulder area. For round end condoms, cut just below the round end.

A3.4.1.4 If dressing materials are present, remove by carefully wiping the sample with a clean dry cloth or tissue before measuring the thickness.

A3.4.1.5 Lay the condoms flat on a bench top surface covered with towels and allow to air dry at ambient temperature for a minimum of 16 h. The condoms must be covered in some manner during this period.

A3.4.2 *Ring Specimen Preparation*—Lay the condom on the replaceable cutting surface, making sure that it is flat and free of folds and wrinkles.

NOTE A3.3—The cutting die shall not cut over the previous cutting scars in the backing material.

A3.4.2.1 *Smooth Surface Condoms*—Cut the ring specimen in the region approximately 80 mm from the open end of the condom. Care should be taken to ensure that the cutting edges of the die are parallel to the "width" of the condom and perpendicular to the "length" of the condom.

A3.4.2.2 *Textured Surface Condoms*—Cut the ring specimen in a region free of texture and at least 5 mm from the nearest texture or the rim. Care should be taken to ensure that the cutting edges of the die are parallel to the "width" of the condom and perpendicular to the "length" of the condom.

A3.4.2.3 *Form-Fitting Condoms*—Cut the ring specimen in a region free of shaping, that is, in a region in which the edges of the condom are parallel to and at least 5 mm from the end of the shaping or the rim. Care should be taken to ensure that the cutting edges of the die are parallel to the "width" of the condom and perpendicular to the "length" of the condom.

A3.4.2.4 *Other Styles of Condoms*—Cut the ring specimen in the region approximately 80 mm from the open end of the condoms, if free of texture or shaping, or in any other region consistent with the intent of forming a ring specimen that, when tested, will yield information consistent with assessing product quality.

A3.4.3 *Inspection:*

A3.4.3.1 Examine the ring specimens for evidence of damage, for example, nicks, or tears along the cut edges, or flaws in the film. Discard any ring specimen determined to be unsuitable and replace with a newly cut specimen from a freshly opened condom prepared as described in A3.4.1.

A3.4.3.2 Condition all tensile test specimens, if not already conditioned, for not less than 3 h at 25 ± 5°C and at 50 ± 5 % relative humidity. Test at 25 ± 5°C.

A3.4.4 *Dimensions of Tensile Specimen:*

A3.4.4.1 For each specimen, measure the thickness to the nearest 0.01 mm. Discard any specimen if the three measurements differ by more than 0.02 mm. Record the mean for the thickness.

A3.4.4.2 Lay the specimen flat. For each specimen, measure the distance between the two folded edges to the nearest 0.5 mm. Multiply the measurement by 2 to obtain the circumference of the ring specimen.

A3.4.5 *Tensile Tester*—Use a tensile tester with a range of approximately 100 N and a speed of 8.5 ± 0.8 mm/s (500 mm/min). Use roller grips at least 20 mm in length and 15 ± 1 mm in diameter that rotate on low friction bearings. If desired, rotate one roller grip mechanically at a rate of approximately one revolution in 6 to 10 s.

A3.4.6 *Procedure*—If necessary, lubricate the roller surface with a lubricant or powder that does not affect the material. Place the specimen over the rollers and start the tester. Record the force and separation of roller centers at break.

A3.4.7 *Calculations:*

A3.4.7.1 Calculate the tensile strength as follows:

$$T = \frac{F}{2WD} = 0.025\,\frac{F}{D} \qquad \text{(A3.1)}$$

where:

$T$ = tensile strength, MPa,
$F$ = breaking force, N,
$W$ = width of ring, 20 mm, and
$D$ = mean single wall thickness, mm.

A3.4.7.2 Calculate the elongation at break as follows:

$$E = 100\,\frac{(2D + G - C)}{C} \qquad \text{(A3.2)}$$

where:

$E$ = elongation at break, %,
$D$ = distance between centers of rollers at break, mm,
$G$ = circumference of one roller, mm, and
$C$ = circumference of the specimen, mm.

A3.4.8 *Test Report*—Report the following information:

A3.4.8.1 Identification of the sample,

A3.4.8.2 Breaking force, ultimate tensile strength, and elongation for each tested condom, and

A3.4.8.3 Date of testing.

## A4. DETERMINATION OF WIDTH

### A4.1 Scope

A4.1.1 This annex covers the method for determining the width of polyurethane male condoms.

### A4.2 Principles

A4.2.1 *Width*—Free hanging of an unrolled condom over the edge of a ruler and measurement of its width.

### A4.3. Apparatus

A4.3.1 *Ruler,* with a scale divided into 0.5-mm readings.

### A4.4. Procedure

A4.4.1 Move the condom inside the package such that it is away from the area where the package is torn. Tear the package and remove the condom. In no circumstances use scissors or sharp instruments to open the package.

A4.4.2 Unroll the condom and stretch it lightly twice but no more than 20 mm to smooth out any wrinkles.

NOTE A4.1—These may be the same condoms used in the length evaluations.

A4.4.3 *Width*—Lay the condom flat over the edge of the ruler at a distance less than 30 mm from the open end allowing it to hang freely. Measure, to the nearest 0.5 mm, the width of the condom.

### A4.5. Report

A4.5.1 Report the following information:

A4.5.1.1 Identification of the sample, for example, batch number,

A4.5.1.2 The width measured in accordance with A4.4.3,

A4.5.1.3 Where the width measurement was taken, and

A4.5.1.4 The date of the test.

## A5. LEAKAGE TEST

### A5.1 Scope

A5.1.1 Experience has shown that the water leakage test is most sensitive when the condom is filled while hanging vertically, its top is closed off, and the condom is placed in a horizontal position while it is examined for leaks. With this technique, the internal pressure over the entire condom surface is approximately uniform.

### A5.2. Apparatus

A5.2.1 *Filling Apparatus,* with suitability smooth-finished funnel fixture whose design permits the condom under test to hang unsupported, that is, with the closed end not touching the surface below while being filled with water, should be used. If the condom is not removed from the device for inspection, the apparatus must also seal the end of the condom against water overflow without the introduction of an air headspace as the condom is positioned horizontally as in A5.3.5.

### A5.3. Procedure

A5.3.1 Carefully remove the condom from the package, being sure to hold the condom while it is still inside the package in such a manner that during the opening of the package, the packaging material does not damage or cut the condom. In no circumstances use scissors or a sharp instrument to open the package. Remove the condom, and, if rolled, unroll the condom to its fullest length.

A5.3.2 Carefully stretch the condom's rim and affix it on the filling apparatus.

A5.3.3 Fill each condom to be tested with 300 ± 25 $cm^3$ of water whose temperature is not less than 20°C nor greater than 40°C. Allow the condom to hang freely for not less than 1 min. Inspect the entire surface of the water-filled area of the condom for evidence of leakage.

A5.3.4 Close off the top of the condom. If the condom is not removed from the device for inspection, the apparatus must also seal or permit manual sealing of the open end of the condom against water overflow without the introduction of an air headspace as the condom is positioned horizontally as in A5.3.5.

NOTE A5.1—Surveys of the marketplace have found products within the scope of this specification that will not readily contain the 300 $cm^3$ of water as required for this test. To evaluate these products for leakage, manual extension of the condom to allow filling with the 300 $cm^3$ or pressurization of the condom to a uniform pressure of 1.6 kPa is allowed.

A5.3.5 Manually raise the closed end of the freely hanging condom (for example, in the cupped palm of one hand) through an angle of 90 ± 10°, that is, until it is horizontal. Inspect the entire surface of the condom for evidence of leakage.

A5.3.6 If leakage is noted in the upper region of the condom near the rim, mark the spot. Remove the condom from the funnel fixture. Empty the water. Measure the distance from the marked spot of the leak to the rim.

### A5.4 Interpretation of Results

A5.4.1 See 5.5.1.

### A5.5. Report

A5.5.1 Report the following information:
A5.5.1.1 Identification of the sample,
A5.5.1.2 Date of testing,
A5.5.1.3 Number of samples tested, and
A5.5.1.4 Number of samples not meeting the criteria of 5.5.1.

## A6. DETERMINATION OF CONDOM THICKNESS

### A6.1 Scope

A6.1.1 This annex covers the methods for determining the thickness of polyurethane male condoms.

### A6.2 Principles

A6.2.1 *Thickness*—Free hanging of the unrolled condom over the foot of a dial or digital gauge mircometer and measurement of its thickness.

### A6.3. Apparatus

A6.3.1 *Micrometer Dial or Digital Gauge*—The gauge shall preferably be graduated in divisions of 0.001 mm and be in accordance with Practice D3767, Procedure A.

### A6.4. Procedure

A6.4.1 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.

A6.4.2 Unroll the condom, stretch it slightly twice but by no more than 20 mm to smooth out any wrinkles.

NOTE A6.1—Lubricants may be removed carefully with absorbent paper and suitable powders may be added to avoid sticking. The condoms should be dried at room temperature for a minimum of 16 h after any dressing materials have been removed.

A6.4.3 *Thickness*—Measure the wall thickness at three points, 30 ± 5 mm, 90 ± 5 mm, and 150 ± 5 mm from the closed end. The thickness measuring device shall conform to that specified in Practice D3767, Test Method A with the pressure of the foot thickness gage at 22 ± 5 kPa. When a condom is textured, measure the thickness in the non-textured area. Report the measurements to the nearest 0.01 mm.

### A6.5. Report

A6.5.1 Report the following information:

A6.5.1.1 Identification of the sample, e.g., batch number,

A6.5.1.2 The thickness measured in accordance with A6.4,

A6.5.1.3 Note if a powder was used and type of powder, and

A6.5.1.4 The date of test.

### A6.6 Condom Disposal

A6.6.1 Condoms subjected to this test shall be destroyed after testing.

## A7. AIR BURST TESTING OF POLYURETHANE CONDOMS

### A7.1 Scope

A7.1.1 This annex outlines a test method for determining the bursting volume and bursting pressure of polyurethane condoms. This test method is patterned after standard methods typically used in determining the air inflation properties of latex condoms.

A7.1.2 The specification for air burst volume and pressure minimums will be derived from the material validation exercise in Annex A9.

### A7.2 Principle

A7.2.1 A constant length of the condom is inflated with air at a prescribed flow rate, with the volume and pressure at the moment of bursting recorded.

### A7.3. Apparatus

A7.3.1 Apparatus capable of inflating the condom with clean, oil-free air at a specified rate and provided with equipment for measuring volume inside the condom to the accuracy of ±0.2 $dm^3$ and pressure inside the condom to an accuracy of ±0.05 kPa, and capable of delivering the air without visible condensation in the lines or the condom.

A7.3.2 Mount suitable for clamping the condom to the apparatus without damaging or stretching the condom. The mount shall be equipped with a rod of sufficient length and diameter to ensure that the test length of the condom, excluding reservoir (if any), is 150 ± 3 mm. The rod shall terminate in a smooth sphere of an appropriate diameter for hanging the unrolled condom when fixed to the apparatus.

NOTE A7.1—Various mounting systems may be needed to accommodate different shapes and sizes.

### A7.4. Procedure

A7.4.1 Unroll the condom onto the rod without stretching but ensuring that any wrinkles and folds are removed. Properly place the condom to the testing apparatus and ensure that air cannot leak through the seal or from the system during inflation.

NOTE A7.2—All products may not be rolled. If the sample is in the unrolled state, proper care should be taken in draping the sample over the testrod.

A7.4.2 Inflate the condom with air at a rate of 400 to 500 $cm^3$/s (24 to 30 $dm^3$/min). The optimal flow rate may be dependent upon the physical proportions of the material and design.

NOTE A7.3—The flow rate referred to is that under pressure and temperature conditions prevailing at the opening that leads into the condom.

A7.4.3 If the condom is observed to leak, discontinue the test. In the analysis of the test results, such as behavior does not constitute a sample tested.

A7.4.4 If the condom does not leak, measure and record the bursting volume, in cubic decimetres rounded to the nearest 1.0 $dm^3$, and the bursting pressure, in kilopascals rounded to the nearest 0.1 kPa.

### A7.5. Report

A7.5.1 Report at least the following particulars:

A7.5.1.1 Identification of the sample,

A7.5.1.2 Bursting volume and bursting pressure for each condom tested,

A7.5.1.3 Date of testing, and

A7.5.1.4 Standard deviation, range, means, median, and histograms (optional) for both pressure and volume values.

## A8. EXPIRATION DATE TESTING

A8.1 Only products that are found to conform to the requirements of Section 5 of this standard shall be entered into the expiration date testing of this Annex.

A8.2 The expiration date must be supported by data demonstrating physical and mechanical integrity of the product after three discrete and representative lots of the product have been subjected to each of the following conditions:

A8.2.1 Storage of unpackaged bulk product at ambient room temperature under the manufacturer's typical factory conditions for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at 70° C ± 2° C for 7 days (followed by room temperature equilibration for 24 hours);

A8.2.2 Storage of unpackaged bulk product at ambient room temperature under the manufacturer's typical factory conditions for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the primary-packaged product at a selected temperature between 40° and 50° C ± 2° C for 90 days; and

A8.2.3 Storage of unpackaged bulk product at ambient room temperature under the manufacturer's typical factory conditions for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the primary-packaged product at a monitored or controlled temperature of 30 -2/+5 °C for the lifetime of the product (real time storage).

A8.3 If all of the products tested after storage at temperatures as described in paragraphs A8.2.2 and A8.2.3 of this Annex pass the manufacturer's physical and mechanical integrity tests, the manufacturer may label the product with an expiration date of up to 5 years from the date of product packaging.

A8.4 If the extrapolated expiration date under paragraphs A8.2.1 and A8.2.2 of this Annex is used, the labeled expiration date must be confirmed by physical and mechanical integrity tests performed at least annually and at the end of the stated expiration period as described in paragraph A8.2.3.

A8.5 If any of the testing performed at least annually and at the end of the stated expiration period following real time storage described in paragraph A8.2.3 of this Annex fails to confirm the extrapolated expiration date, the manufacturer must, at that time, re-label subsequently produced product to reflect the actual shelf life.

A8.6 Initial testing of finished packaged final product shall conform to the sample plan.

## A9. CONDOM MATERIAL AND CLINICAL VALIDATION

### A9.1 Slippage and Breakage User Study

A9.1.1 The slippage and breakage user study shall be a crossover design comparing the test polyurethane condom with a commercially marketed latex condom. Guidance for the clinical study can be found in the Food and Drug Administration's Guide,[4] World Health Organization's Guide, ISO 29943 Guidance on condom break/slip studies or other scientifically sound sources.

### A9.2 Shelf Stability Studies

A9.2.1 A scientifically sound stability study shall be conducted to provide evidence that the product life is adequate for the purposes of the polyurethane condom.

A9.2.2 An on-going monitoring shelf-life study shall be performed on one lot of condoms per year to ensure that the condoms have the life that has been predicted by the stability study.

### A9.3 Permeability

A9.3.1 To ensure that the polyurethane material is an adequate barrier to small particles, including viruses, a permeability study shall be undertaken. The guidelines for permeability study can be found in the U.S. Food and Drug Administration's Guide.

NOTE A9.1—This material characterization will be undertaken using analytical techniques such as, but not limited to, gel permeation chromatography (GPC) for molecular weight data, differential scanning calorimetry (DSC) for thermal transitions or 100 % relaxed modulus to determine cross-link density, HPLC for residual solvents or starting materials or contaminants, etc. These tests are intended to support condom material validation of performance in use and the consistency of material supply.

[4] Testing Guidance for Male Condoms Made from New Material, Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857.

# APPENDIXES

## X1. TEST METHOD FOR WELD STRENGTH OF POLYURETHANE CONDOMS

### X1.1 Scope

X1.1.1 This appendix covers the test method for determining the strength of welded seams of polyurethane condoms.

### X1.2. Apparatus

X1.2.1 *Tensile Tester,* with a constant rate of grip separation and capable of measuring the applied load to an accuracy of within ±2 %. The maximum force is to be recorded.

X1.2.2 *Die,* 20 by 70 mm.

X1.2.3 *Roller Grips,* at least 20 mm in length and 15 ± 1 mm in diameter, which are free to rotate on low friction bearings.

X1.2.4 *Stereo Microscope* (recommended).

X1.2.5 *Conditioning Apparatus*—Condition the test specimens at 23 ± 2°C (73.4 ± 3.6°F) and 50 ± 5 % relative humidity for not less than 40 h prior to testing in accordance with Procedure A of Practice D618. Conduct the tests in a standard laboratory atmosphere of 23 ± 2°C (73.4 ± 3.6°F) and 50 ± 5 % relative humidity.

### X1.3 Speed of Testing

X1.3.1 The crosshead speed shall be determined in accordance with Test Method D638.

### X1.4. Procedure

X1.4.1 Cut a ring specimen perpendicular to the length direction of the condom with a die having cutting edges 20 ± 0.1 mm apart and at least 70 mm long. Cut the specimens in the region of the condom approximately 80 mm from the rim. Use only specimens cut by a single impression of the die. After cutting, the specimens should be visually examined, preferably using a stereo microscope to look for flaws.

X1.4.2 *Tensile Tester*—Use a tensile tester with a range of approximately 100 N and a speed that is to be determined in accordance with Test Method D638. Use roller grips at least 20 mm in length and 15 ± 1 mm in diameter, which are free to rotate on low friction bearings. If desired, rotate one roller grip mechanically at a rate of approximately one revolution in 6 to 10 s.

X1.4.3 *Procedure*—Lubricate the roller surface with a lubricant or powder that does not affect the material. Place the specimen over the rollers and start the tester. Record the force and separation of rollers centers at break.

X1.4.4 *Calculation*—Record the force at break.

### X1.5. Report

X1.5.1 Report the following information:
X1.5.1.1 Sample identification,
X1.5.1.2 Force at break,
X1.5.1.3 Location of break (weld or material),
X1.5.1.4 Laboratory conditions at the time of testing: temperature and humidity,
X1.5.1.5 Speed of grip separation,
X1.5.1.6 Load range, and
X1.5.1.7 % Elongation at break.

## X2. CONDOM MATERIALS VALIDATION—STATISTICAL ANALYSIS TO SET SPECIFICATIONS

### X2.1 Scope

X2.1.1 This appendix covers setting minimum specification limits for air burst and tensile strength testing data.

### X2.2 Distribution of Data

X2.2.1 Common distributions, such as the Normal distribution, have been extensively studied and it is relatively straightforward to predict their behavior. For that reason, if the sample data can be shown to follow a common distribution then the known properties of that distribution can be used to identify the specification limits. However, if the sample data does not conform to a common distribution then nonparametric methods will be required to identify the specification limits. (For example, it is known that airburst pressure and volume data for NRL male condoms do not follow a common distribution.)

X2.2.2 For products already in production, sufficient data may exist to construct an empirical distribution which explains both short term (within-lot) and long term (between lots) variation and identifies appropriate specification limits. An example of a nonparametric method utilizing order statistics and designed for use with limited data can be found in ISO standard 23409. An example designed for use with limited data shown to follow a Normal distribution is provided in section X2.3.

X2.2.3 Regardless of what method is utilized to identify the specification limits, a statistical report demonstrating the stability of the process and justifying the chosen limits should be made available to relevant regulatory bodies. Further, the limits should be identified prior to the slippage and breakage study required by section 8.6, and the condoms used for that study should reflect the range of "good quality" condoms defined by the limits. (If a gap exists between the minimum physical properties of the condoms used in the slippage and breakage study and the specification limits, then the statistical report should contain a section explaining why this gap is not clinically significant.)

### X2.3 Example for Normal Distribution of Data

X2.3.1 The AQL of 1.5 % for physical properties conforms to a 2.17 sigma level, meaning that 1.5 % of condoms should have physical property measurements which are more than

2.17 standard deviations below the mean. This estimate, however, assumes no difference between short-term variation and long-term variation. For typical manufacturing processes following a Normal distribution, the long-term variation can be estimated by allowing for a 1.5 standard deviation drift in the mean. Thus by setting the specification limit 3.67 standard deviations below the mean we can expect 1.5 % of condoms will be rejected long-term. Sample from a minimum of three production lots and test to ensure that the means of the three samples are not significantly different. Pool the data and compute the mean and standard deviation. Lower specification limits should be set 3.67 standard deviations below the mean.

### X2.4 Long-Term Variability Determination

X2.4.1 If limited data is utilized to identify the specification limits, then these limits will only estimate the long term variation. Therefore, after a minimum of 30 production lots have been produced, or when sufficient data exists to estimate long-term variability directly, the specification limits should be recalculated. (It is recommended that a minimum of three manufacturers lots of resin be used to establish a strong statistical basis for the long-term variation of the manufacturing system.) If this recalculation lowers the specification limits, then either a follow-up slippage and breakage study should be conducted for condoms with physical properties below the original limits and above the new limits, or a statistical report should be made available to the relevant regulatory bodies explaining why the change in specification limits is not clinically significant.

## X3. CLINICAL METHODS FOR THE EVALUATION OF A NEW CONDOM SHAPE

### X3.1 Scope and Objective

X3.1.1 This outline, taken from methodology provided in part by California Family Health Council, is for conducting a user study of a new condom shape that is considered to be significantly different than the product that has completed a material validation as described in Section 8. The objective of this study is to provide assurance that the change to the shape of the condom does not affect performance.

### X3.2 Study Design

X3.2.1 $n$ = 40 couples, typically need to recruit 45 to 50 couples to finish with 40;

X3.2.2 Each couple to use 3 condoms of the test product and the control;

X3.2.3 Double blinded randomized cross-over design;

X3.2.4 Each couple should be given two consecutive weeks to complete each evaluation (one type of condom);

X3.2.5 Each couple shall complete a diary of each coital event when one of the samples is used, including the sexual position used;

X3.2.6 At the end of the use of each product the couple should be interviewed either by phone, internet or by clinic visit, the later being preferred;

X3.2.7 Clinical end points determined should be limited to slippage and breakage.

### X3.3 Inclusion Criteria

X3.3.1 Couples not at risk of pregnancy (using alternate contraception);

X3.3.2 Monogamous heterosexual couples who agree to practice vaginal sex only during the study;

X3.3.3 Couples should be experienced condom users, minimum 10 male condoms used in the last 12 months;

X3.3.4 Age of couple between 18 to 45 years.

### X3.4 Exclusion Criteria

X3.4.1 Couples should not be recruited who work for the clinical testing laboratory or who are relatives of staff of the clinical test laboratory;

X3.4.2 Couples where one knowingly has a sexually transmitted infection.

### X3.5 Informed Consent (recommend following FDA 21 CFR Part 50)

### X3.6 Adverse Event Report Form

### X3.7 Statistical Analysis

X3.7.1 The total clinical failure rate for both the test and control condoms should be reported, along with a 95 % confidence interval for each estimate. Data should be reported and retained for review by relevant regulatory body.

X3.7.2 Confounding factors to be noted are couples who cluster break or experience slippage on either the test or control product, and if more than 20 % of the recruited couples fail to complete the study.