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Standard Specification for Rubber Contraceptives—Vaginal Diaphragms[1]

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1. Scope

1.1 This specification covers requirements for contraceptive vaginal diaphragms, hereafter called diaphragms.

1.2 Vaginal barrier devices known as cervical caps, vaginal sponges and female condoms are not included in this specification.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D573 Test Method for Rubber—Deterioration in an Air Oven

D3767 Practice for Rubber—Measurement of Dimensions

2.2 *ISO Standards:*[3]

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes

ISO 10993 Biological Evaluation of Medical Devices

2.3 *Federal Regulations:*

U.S. Code of Federal Regulations, Title 21, Food and Drug Administration, Section 177.2600, Rubber Articles Intended for Repeated Use[4]

3. Classification

3.1 The following types of diaphragms are covered by this specification:

3.1.1 *Type 1*—Coil spring diaphragm.

3.1.2 *Type 2*—Flat spring diaphragm (also called watch spring or Mensinga diaphragm).

3.1.3 *Type 3*—Arching or bow-bend diaphragm.

4. Materials and Manufacture

4.1 Diaphragms shall be made of an elastic polymer with a rim reinforced with metal or other suitable material. The diaphragm dressing material, compounding materials, and rim reinforcing material shall not have a deleterious effect on the rubber or be harmful to the user under normal conditions of use. Manufacturers should evaluate the cytotoxicity, sensitization, irritation, and acute systemic toxicity potential of the diaphragm per ISO 10993. Materials used should be permitted by the Code of Federal Regulations, Title 21, Section 177.2600.

4.2 *Construction:*

4.2.1 The diaphragm shall consist of a dome and an integral peripheral rim. The dome and rubber portion of the rim shall be one continuous film.

4.2.2 The rim of the diaphragm may be reinforced with a spring, either helically wound or flat leaf construction, which shall be sufficiently rigid to hold the rim in a flat, circular position.

4.2.3 The reinforcing spring shall be encapsulated completely and located centrally within the rim so that the spring shall not be exposed under normal conditions of use.

4.2.4 The ends of any spring shall be joined so that they will not project through the surface of the rim when encapsulated.

5. Physical Requirements

5.1 *Rim and Spring Compression:*

5.1.1 When the sides of the diaphragm are compressed across the diameter of the rim as described in Annex A1, the rim shall be substantially in the same plane and shall not have a deviation greater than 20°.

NOTE 1—Tests 5.1.1 and 5.1.2 are only applicable to diaphragms with springs of coil construction (Type 1) or flat leaf construction (Type 2) and are not applicable to diaphragms with springs designed to form an arc when compressed (Type 3).

5.1.2 When the sides of a diaphragm are compressed across the diameter of the rim by a suspended mass of 280 g, as described in Annex A2, the diameter shall be between 55 and 78 % of the original diameter.

5.1.3 When the diaphragms are repeatedly compressed to 25 % of their original diameter and released after the 1000th compression, the compression resistance and degree of twist measurements are repeated. The diameter along the axis of

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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 International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland.

[4] Available from Standardization Documents Order Desk, DODSSP, Bldg. 4, Section D, 700 Robbins Ave., Philadelphia, PA 19111-5098

compression shall be at least 90 % of the original value and the degree of twist shall not be greater than 20°.

NOTE 2—Manufacturers of diaphragms who are certified to a quality management system, ISO 9000 or equivalent, whose suppliers are similarly certified may use the repeated compression testing part of this method as a qualification or type test. In that case, lot by lot testing shall consist of a single compression and the measurement of the compression resistance.

5.1.4 *Precision and Bias*—A precision and bias statement is not applicable since the results merely indicate whether there is conformance to the criteria specified in the procedure.

5.2 *Tensile Strength and Elongation at Break of Rubber:*

5.2.1 The rubber in the dome shall comply with the following requirements when tested in accordance with 5.2.1.1:

Tensile strength, min, 15 MPa	
Elongation at break, min, 650 %	

5.2.1.1 A ring specimen having a mean circumference of 100.0 ± 0.5 mm and a radial width of 2.00 ± 0.02 mm shall be cut with a die from each diaphragm. The specimens shall be tested in accordance with Test Methods D412. The internal circumference shall be used for calculation of elongation at break.

5.2.2 After accelerated aging under the conditions specified in 5.2.2.1, the tensile strength and elongation at break shall be at least 75 % of the value before aging.

5.2.2.1 Condition the diaphragms at 70 ± 2°C for 166 ± 2 h in accordance with Test Method D573. Do not age diaphragms of different compositions simultaneously in the same oven. After aging, condition the diaphragms at 23 ± 2°C for not less than 16 h, and prepare and test the specimens within 96 h in accordance with Test Methods D412. Manufacturers may use process control tests to determine suitable shelf life but accelerated aging at 70°C and 166 h shall be used for qualification tests and referee tests.

5.2.3 *Precision and Bias*—The precision and bias of determining tensile strength and ultimate elongation of diaphragm dome rubber are as specified in Test Methods D412.

6. Dimensions, Requirements, and Permissible Variations

6.1 *Diameter:*

6.1.1 The following diameters are standard sizes: 55, 60, 65, 70, 75, 80, 85, 90, 95, and 100 mm.

6.1.2 The size of the diaphragm shall be the nominal external diameter of the rim in accordance with 6.1.1. The actual diameter shall conform to the standard size within ±2 mm.

6.1.3 The actual diameter shall be determined by measurement of the external diameter at two positions perpendicular to each other. The difference between these two measurements shall not exceed 2 mm. Alternatively, go-no-go devices may be used to determine compliance with 6.1.2.

6.2 *Thickness:*

6.2.1 The thickness of the dome shall not be less than 0.2 mm.

6.2.2 Measure the thickness of the dome at five locations using a dial micrometer in accordance with Practice D3767 and accurate to 0.01 mm.

6.2.3 *Precision and Bias*—The precision and bias of measuring diaphragm dimensions are as specified in Practice D3767.

7. Workmanship, Finish, and Appearance

7.1 The diaphragm dome shall have a uniform, smooth finish and be free of holes, thin spots, air bubbles, embedded particles, and other defects likely to affect serviceability. Inspection shall be made under bright lumination in accordance with Annex A3. The dome shall not be sticky when touched.

7.2 The diaphragm rim shall have a smooth surface, and the reinforcing material shall be encapsulated completely. The surface of the rim shall not be sticky when touched.

8. Sampling and Inspection

8.1 Follow the sampling procedure in ISO 2859 using General Inspection Level I and an acceptable quality level (AQL) of 1.5 for inspection for dimensions, rim and spring compression, tensile strength and elongation at break, and workmanship (Sections 5, 6, and 7). The compliance level shall be an AQL of 0.4 for the following major defects, (*a*) hole in the dome, (*b*) exposed spring, (*c*) broken spring, (*d*) illegible marking on the diaphragm, and (*e*) illegible labeling.

9. Product Marking

9.1 *Diaphragm Identification*—Each diaphragm shall be marked legibly with the manufacturers' name or recognized trademark and its size in accordance with 6.1.1.

9.2 *Package Identification*—Each packaged diaphragm shall be marked legibly with the following information:

9.2.1 Name or trademark of manufacturer,

9.2.2 Identifying code of manufacturer,

9.2.3 Size of diaphragm, and

9.2.4 Date of manufacture or of expiration per results of testing completed per 5.2.2.1.

10. Packaging and Package Marking

10.1 *Individual Diaphragm:*

10.1.1 Each diaphragm shall be packaged individually in a container that protects the contents from mechanical damage during normal handling, transit, and storage.

10.1.2 Each diaphragm package shall contain instructions for the use, care, and storage of the diaphragm.

10.2 *Outer Container(s)*—A convenient number of individual packages shall be packaged in one or more outer containers, which shall be sufficiently strong to protect the contents during transit and storage.

11. Report

11.1 Report the following information for the tests described in 5.1, 5.2, 6.1, and 6.2:

11.1.1 Sample identification.

11.1.2 Date of testing.

11.1.3 Name and address of test laboratory.

11.1.4 Reference to relevant standards.

11.1.5 Test results.

11.1.6 Precision and bias per 5.2.3 and 6.2.3.

11.1.7 Date of test report.

12. Keywords

12.1 contraceptives; diaphragms; rubber; vaginal

ANNEXES

(Mandatory Information)

A1. METHOD OF OPERATION FOR FIGURE EIGHT TEST

A1.1 Compress the diaphragm between two metal rods, each provided with a cavity to fit the rim (see Fig. A1.1). One rod, A, is movable along its axis, but cannot rotate. The other rod, B, is not movable along its axis, but can rotate freely.

A1.2 Compress the diaphragm by pushing it forward using Handle C to a fixed distance between Rods A and B, depending upon the size of the diaphragm (see Table A1.1). In this position, measure the possible turn of Rod B by using the pointer, D, affixed to it.

A1.3 Spindle E is provided for permanent setting of the distance between Rods A and B for each size diaphragm.

TABLE A1.1 Rod Separation

Size of Diaphragm, mm	Distance Between Rods, mm
55	21.5
60	22.5
65	23.5
70	24.5
75	25.5
80	26.5
85	27.5
90	28.5
95	29.5
100	30.5

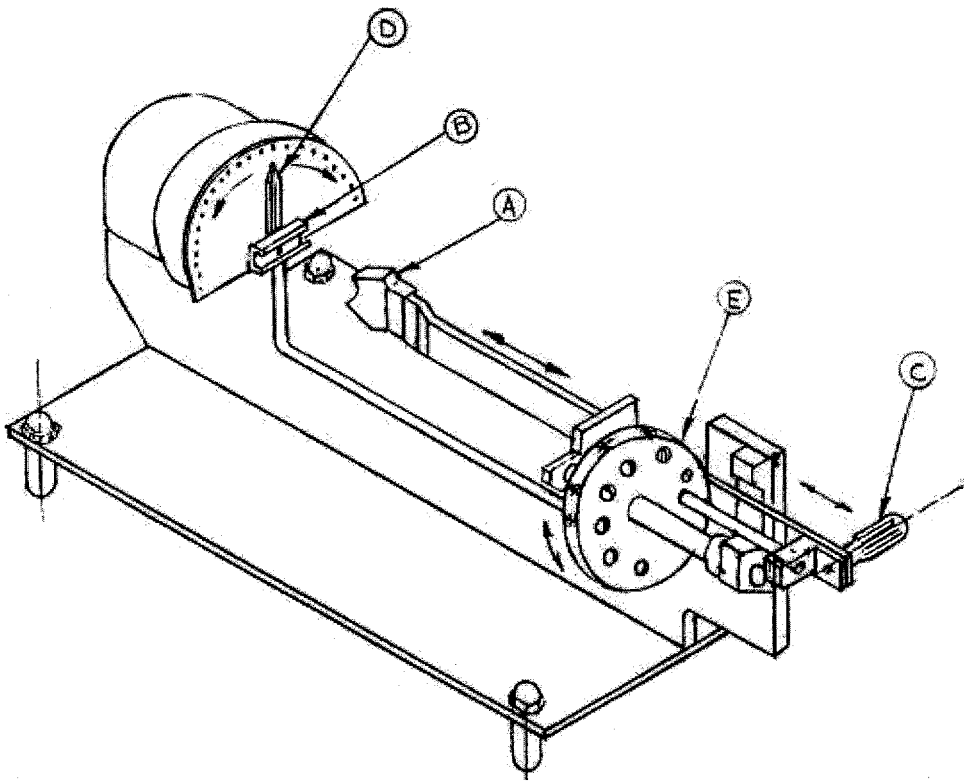

FIG. A1.1 Figure Eight Diaphragm Tester

A2. METHOD OF OPERATION FOR COMPRESSION TESTER

A2.1 Place the diaphragm, A, on top of Rods E and F as noted in Fig. A2.1. Hook Rod B over the diaphragm. When Rod B is released, the diaphragm will compress across its diameter, between the top of Rod B and Rods E and F.

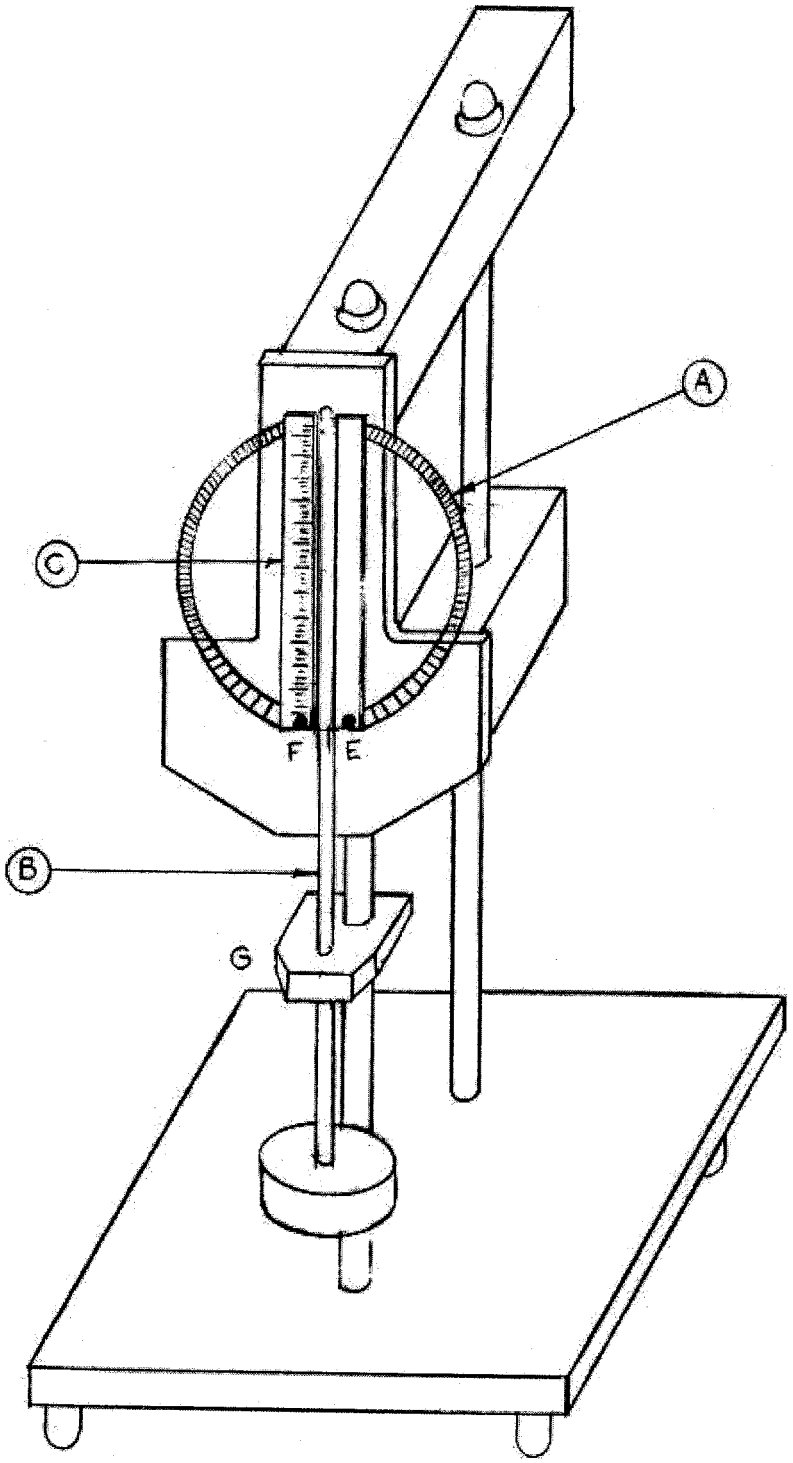

FIG. A2.1 Compression Test

A2.2 Note the dimensional change on the attached scale, C.

NOTE A2.1—Slotted Guide G is affixed to the testing device and holds Rod B in a vertical position.

A3. METHOD OF OPERATION FOR DIAPHRAGM INSPECTION

A3.1 Hold the diaphragm in the hand, and pull the dome of the diaphragm over the glass cylinder with the light source underneath the glass (see Fig. A3.1).

A3.2 Move the diaphragm around and inspect it for objectionable defects.

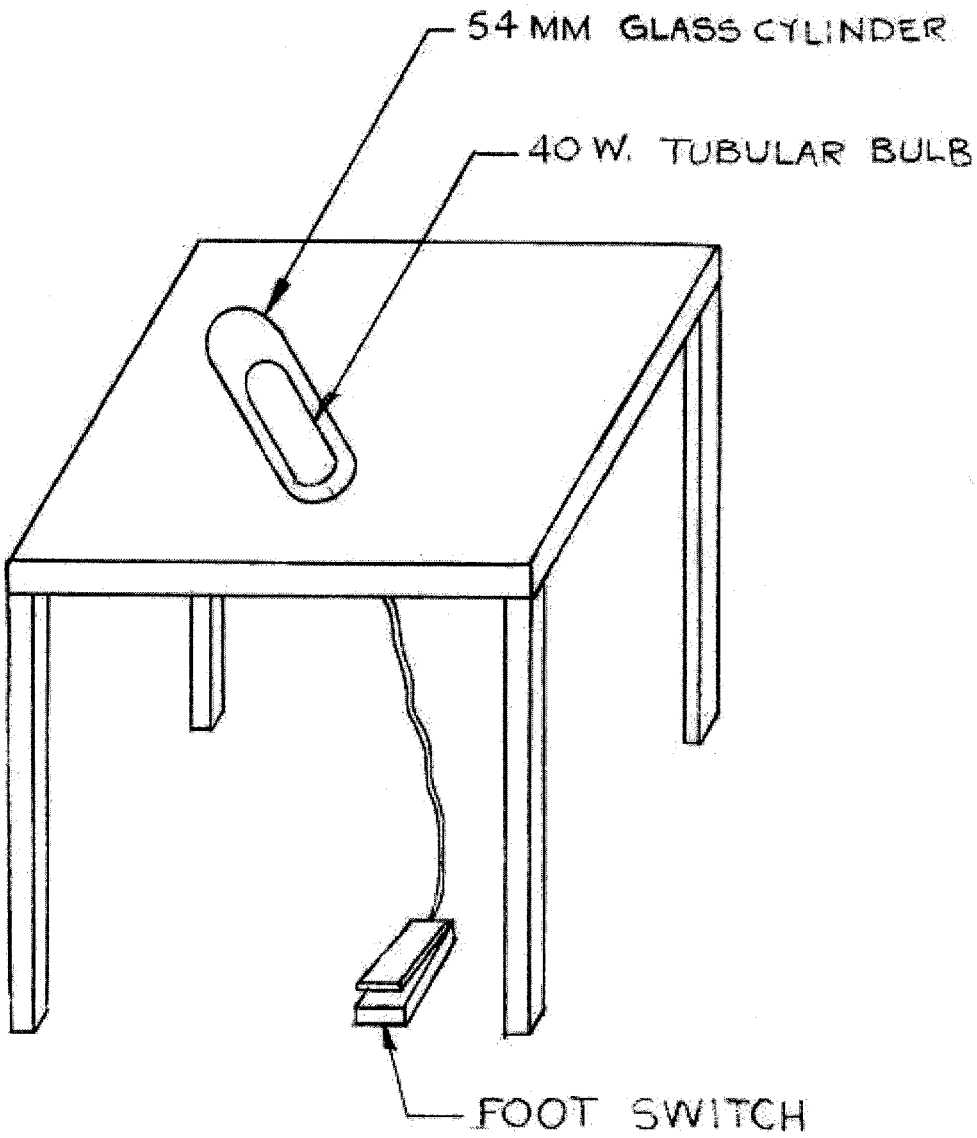

FIG. A3.1 Diaphragm Inspection Lamp