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100 Barr Harbor Dr., West Conshohocken, PA 19428
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Standard Specification for Rubber Contraceptives—Vaginal Diaphragms¹

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^{†1} NOTE—Note 2 was added editorially in March 1997.

1. Scope

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

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

2. Referenced Documents

2.1 ASTM Standards:

D 412 Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension²

D 573 Test Method for Rubber—Deterioration in an Air Oven²

D 3040 Practice for Preparing Precision Statements for Standards Related to Rubber and Rubber Testing³

D 3767 Practice for Rubber—Measurement of Dimensions²

2.2 ISO Standard:

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes⁴

2.3 Federal Regulations:

U.S. Code of Federal Regulations, Title 21, Food and Drug Administration, Section 177.2600, Rubber Articles Intended for Repeated Use⁵

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. Materials used should be permitted by the Code of Federal Regulations, Title 21, Section 177.2600.

5. Construction

5.1 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.

5.2 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.

5.3 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.

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

6. Physical Requirements

6.1 Rim and Spring Compression:

6.1.1 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—This test is only applicable to diaphragms with springs of flat leaf construction (Type 2).

6.1.2 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. See Note 2.

NOTE 2—This test is not applicable to diaphragms with springs designed to form an arc when compressed.

6.1.3 *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.

6.2 Tensile Strength and Elongation at Break of Rubber:

6.2.1 The rubber in the dome shall comply with the following requirements when tested in accordance with 6.2.1.1:

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

6.2.1.1 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 D 412. The

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² Annual Book of ASTM Standards, Vol 09.01.

³ Discontinued—see 1986 Annual Book of ASTM Standards, Vols 09.01 and 09.02.

⁴ Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

⁵ Available from the Superintendent of Documents, U. S. Government Printing Office, Washington, DC 20402.