



Standard Specification for Rubber Contraceptives—Vaginal Diaphragms¹

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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 Use⁴

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 Varembe, 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