



Designation: D 3577 – 00

Standard Specification for Rubber Surgical Gloves¹

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This standard has been approved for use by agencies of the Department of Defense.

1. Scope

1.1 This specification describes certain requirements for packaged sterile rubber surgical gloves used in conducting surgical procedures.

1.2 The following safety hazards caveat pertains only to the test method portion, Section 8, of this specification: *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.*

2. Referenced Documents

2.1 ASTM Standards:

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

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

D 3767 Practice for Rubber—Measurement of Dimensions²

D 5151 Test Method for Detection of Holes in Medical Gloves³

D 5712 Test Method for the Analysis of Protein In Natural Rubber and its Products³

D 6124 Test Method for Residual Powder on Medical Gloves³

2.2 Other Documents:

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes⁴

U.S. Pharmacopeia⁵

3. Classification

3.1 *Type 1*—Gloves compounded primarily from natural rubber latex.

3.2 *Type 2*—Gloves compounded from a rubber cement or from synthetic rubber latex.

4. Materials and Manufacture

4.1 Any rubber polymer compound that permits the glove to meet the requirements of this specification.

4.2 A lubricant that meets the current requirements of the U.S. Pharmacopeia for Absorbable Dusting Powder may be applied to the glove. Other lubricants may be used if their safety and efficacy have been previously established.

4.3 The inside and outside surface of the rubber surgical gloves shall be free of talc.

5. Significance and Use

5.1 The specification is intended as a reference to the performance and safety of rubber surgical gloves. The safe and proper use of rubber surgical gloves is beyond the scope of this specification.

6. Sampling

6.1 For referee purposes, gloves shall be sampled and inspected in accordance with ISO 2859. The inspection levels and acceptable quality levels (AQL) shall conform to those specified in Table 1, or as agreed between the purchaser and the seller, if the latter is more comprehensive.

7. Performance

7.1 Gloves, sampled in accordance with Section 6, shall meet the following requirements:

7.1.1 Comply with requirements for sterility when tested in accordance with 8.2.

7.1.2 Be free from holes when tested in accordance with 8.3.

7.1.3 Have consistent physical dimensions in accordance with 8.4.

7.1.4 Have acceptable physical property characteristics in accordance with 8.5.

7.1.5 Have a powder residue limit in accordance with 8.6.

7.1.6 Have a recommended aqueous soluble protein content limit of 200 $\mu\text{g}/\text{dm}^2$ in accordance with 8.7 and Annex A2.

7.1.7 Have a recommended maximum powder limit in accordance with 8.8.

8. Referee Test Methods

8.1 The following tests shall be conducted to assure the requirements of Section 7 as prescribed in Table 1:

8.2 *Sterility Test*—Testing for sterility shall be conducted in accordance with the latest edition of the U.S. Pharmacopeia.

¹ This specification is under the jurisdiction of ASTM Committee D-11 on Rubber and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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² *Annual Book of ASTM Standards*, Vol 09.01.

³ *Annual Book of ASTM Standards*, Vol 09.02.

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

⁵ U.S. Pharmacopeia, latest edition, Mack Publishing Co., Easton, PA 19175.