Designation: D3579 – 77 (Reapproved 2016)

Standard Specification for Rubber Surgical Drainage Tubes, Penrose-Type[1]

This standard is issued under the fixed designation D3579; 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 Penrose-type rubber tubes used in performing certain surgical drainage procedures.

1.2 The specification provides for packaged sterile rubber tubes and packaged or bulk nonsterile rubber tubes.

1.3 *This standard does not purport to address all of the safety problems, 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:*[2]

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D573 Test Method for Rubber—Deterioration in an Air Oven

2.2 *Other Documents:*[3]

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes

3. Significance and Use

3.1 This specification is intended as a reference to the performance and safety of rubber surgical drainage tubes. The safe and proper use of rubber surgical drainage tubes is beyond the scope of this standard.

4. Materials and Manufacture

4.1 Any rubber polymer compound that permits the tube to meet the requirements of this standard.

4.2 Absorbable dusting powder that meets the current requirements of the U.S. Pharmacopoeia may be applied to the tube.

4.3 X-ray opaque materials that permit the tube to meet the requirements of this specification may be added to the rubber polymer compound.

5. Sampling

5.1 For referee purposes, tubes 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.

6. Performance

6.1 As necessary, tubes sampled according to Section 5 shall be subject to inspection and tests to meet the following referee performance requirements:

6.1.1 Comply with requirements for sterility when tested in accordance with 7.2.

6.1.2 Comply with requirements for safety when tested in accordance with 7.3.

6.1.3 Be X-ray opaque when tested in accordance with 7.4.

6.1.4 Have consistent physical dimensions in accordance with 7.5.

6.1.5 Have acceptable physical property characteristics in accordance with 7.6.

7. Referee Test Methods

7.1 The following tests shall be conducted to assure the necessary requirements of Section 6 as specified in Table 1.

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

7.3 *Safety Test*—Testing for safety shall be conducted in accordance with the latest revision of the U.S. Pharmacopoeia, for transfusion and infusion assemblies.

7.4 *X-ray Opaque Test*—Select at least two tubes from each lot and radiograph as follows: Place a small foreign body of not less than 0.5-mm thick sheet lead under each tube. Superimpose 240 ± 10 mm of USP paraffin over the tubes. Use a standard make of cassette with screens, films, and processing solutions. Expose at a setting of 85 kV, 10 mA·s and from a

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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.

TABLE 1 Performance Requirements

Characteristic	Related Defects	Inspection Level	AQL
Sterility	fails sterility	[A]	N/A
Safety	toxic	[A]	N/A
X-ray opaque	not opaque	two units per lot	N/A
Dimensions	length, width, and thickness	S-2	2.5
Physical properties	before aging, after accelerated aging	S-2	4.0

[A] See U.S. Pharmacopoeia, latest edition, Mack Publishing Co., Easton, PA 19175.

distance of 640 ± 10 mm. The tubes shall show a definite, uniform shadow, and the degree of opaqueness shall show the shadow of the foreign body.

7.5 *Physical Dimensions Test:*

7.5.1 The tubes shall comply with the dimension requirements specified in Table 2.

7.5.2 The length shall be expressed in millimetres as measured from end to end and parallel to the axis of the tube.

7.5.3 The flat width of the tube shall be expressed in millimetres as measured at a right angle to the axis of the tube. Three random measurements shall be taken and averaged. The average dimension shall be within the tolerance requirements specified in Table 2.

7.5.4 The minimum wall thickness shall be expressed in millimetres as specified in Table 2 when using a dial micrometer described in Test Methods D412. Three random measurements shall be taken along the axis of the tube. Each measurement shall be calculated for single thickness and shall meet the minimum dimension requirement. For referee tests, cutting the tube along the axis is necessary to obtain single-thickness measurements.

7.6 *Physical Requirements Test:*

7.6.1 Before and after accelerated aging, the tubes shall conform to the physical requirements specified in Table 3. Tests shall be conducted as specified in Test Methods D412.

7.6.2 Accelerated aging tests shall be conducted in accordance with Test Method D573. Test the tubes by either one of the following methods:

7.6.2.1 After being subjected to a temperature of 70 ± 2°C for 166 ± 2 h, the tensile strength and elongation shall not be less than the values specified in Table 3. This method shall be the condition for referee tests.

7.6.2.2 After being subjected to a temperature of 100 ± 2°C for 22 ± 0.3 h, the tensile strength and elongation shall not be less than the values specified in Table 3.

8. Acceptance

8.1 Tubes will be considered to meet the referee performance requirements when test results do not exceed the AQL prescribed in Table 1.

TABLE 2 Dimensions and Tolerances

Description	All Sizes	Tolerance, mm
Length	as labeled	±10
Width	as labeled	±1.0
Single-wall thickness, mm	0.15	min

TABLE 3 Physical Requirements

Before Aging		After Accelerated Aging	
Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation
21 MPa min	700 % min	16 MPa min	500 % min

8.2 Retests or reinspections are permissible under the provisions of the U.S. Pharmacopoeia and ISO 2859.

9. Packaging and Marking

9.1 *Sterile Packaging:*

9.1.1 The unit of packaging shall normally be one tube per package.

9.1.2 The tube shall be totally enclosed in an outer package that will allow sterilization of the product.

9.1.3 The outer package shall have a method of closure sufficient to assure the sterility of the product until opened or damaged.

9.1.4 The outer package shall have sufficient strength and integrity to withstand normal transportation and storage within the intermediate or shipping cartons, or both.

9.1.5 The method of closure of the outer package shall be such that prior opening will be detectable by the user.

9.1.6 None of the packaging material shall contain any material likely to impair the quality and use of the tubes.

9.1.7 Intermediate cartons and shipping cases shall be of sufficient strength to maintain the quality and sterility of the product during normal transportation and storage.

9.2 *Nonsterile and Bulk Packaging:*

9.2.1 The unit of packaging shall normally be more than one tube and of a specific amount.

9.2.2 The tubes shall be enclosed in an outer package that has sufficient strength to withstand normal transportation and storage within the cartons or shipping cases, or both.

9.2.3 None of the packaging material shall contain any material likely to impair the quality and use of the tubes.

9.2.4 Cartons and shipping cases shall be of sufficient strength to maintain the quality of the product during normal transportation and storage.

9.3 *Marking:*

9.3.1 Sterile packages shall bear markings for the contents to include the tube size, instructions for opening, the legend “sterile,” and a manufacturing lot number.

9.3.2 Nonsterile and bulk packages shall bear markings for the contents to include the tube size and a manufacturing lot number.

9.3.3 The outermost case shall be labeled on one or more end panels with the tube size and a manufacturing lot number. Sterile product cases shall also be marked with the legend “sterile.”

9.3.4 All levels of packaging shall conform to all appropriate government labeling regulations.

10. Keywords

10.1 drainage tubes; penrose; surgical