



## Designation: D3579 – 77 (Reapproved 2023)

# Standard Specification for Rubber Surgical Drainage Tubes, Penrose-Type<sup>1</sup>

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 ( $\epsilon$ ) 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

## 2. Referenced Documents

### 2.1 ASTM Standards:<sup>2</sup>

**D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension**

**D573 Test Method for Rubber—Deterioration in an Air Oven**

### 2.2 Other Documents:<sup>3</sup>

**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.

<sup>1</sup> This specification is under the jurisdiction of ASTM Committee D11 on Rubber and Rubber-like Materials and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

<sup>3</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

## 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