



Designation: F623 – 19

Standard Performance Specification for Foley Catheter¹

This standard is issued under the fixed designation F623; 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 reappraisal. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reappraisal.

INTRODUCTION

The objective of this specification is to describe those product requirements and associated test methods that will assess the safety and effectiveness of a disposable, 5-cm³ (mL) balloon, retention-type catheter used in urinary bladder drainage.

This specification includes *referee test* methods that can be used to determine compliance with the stated performance requirements. Note that the test methods are not to be construed as production methods, quality control techniques, or manufacturer's lot release criteria.

This specification represents the state of the art at this time and is a minimum performance specification. It is recognized that the document must remain dynamic; suggestions for revision are encouraged, and should be directed to ASTM, 100 Barr Harbor Dr., PO Box C700, West Conshohocken, PA 19428–2959.

1. Scope

1.1 This performance specification establishes performance requirements for the short-term utilization of a single-use, balloon-retention catheter, French sizes 12 through 26 inclusive, used by the medical professions for providing a means of bladder drainage by means of the urethra. The product is manufactured in various sizes and materials such as latex, silicone, rubber, and various polymers (as well as combinations of these) and is provided non-sterile for sterilization and sterile for single use only. Catheters whose surface has been chemically treated to effect biocompatibility or microbial properties may be tested to this specification.

1.2 Catheters whose surface has been chemically treated to enhance their lubricity with a coating may be tested to this specification.

1.3 The annexes in this specification include detailed information, such as apparatus or materials for this specification.

¹ This performance specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.34 on Urological Materials and Devices.

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1.4 The appendixes in this specification contain information intended to provide guidance only and are not a mandatory part of the specification.

1.5 Regulatory bodies may require additional information, such as clinical data, to support different design features.

1.6 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

1.7 *Exclusions*—Long-term indwelling usage (over 30 days) is encountered with this product, but not commonly, and is therefore considered an exception to this specification. Similarly, the use of such catheters for nonurethral catheterization (such as for nephrostomy, suprapubic cystostomy, ureterostomy, gastrostomy, enemas, and so forth) is excluded from the scope of this specification. Likewise, three lumen catheters, 30-cm³ balloon and pediatric catheters, and catheters whose surface has been enhanced for lubricity using liquids or gels.

1.8 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

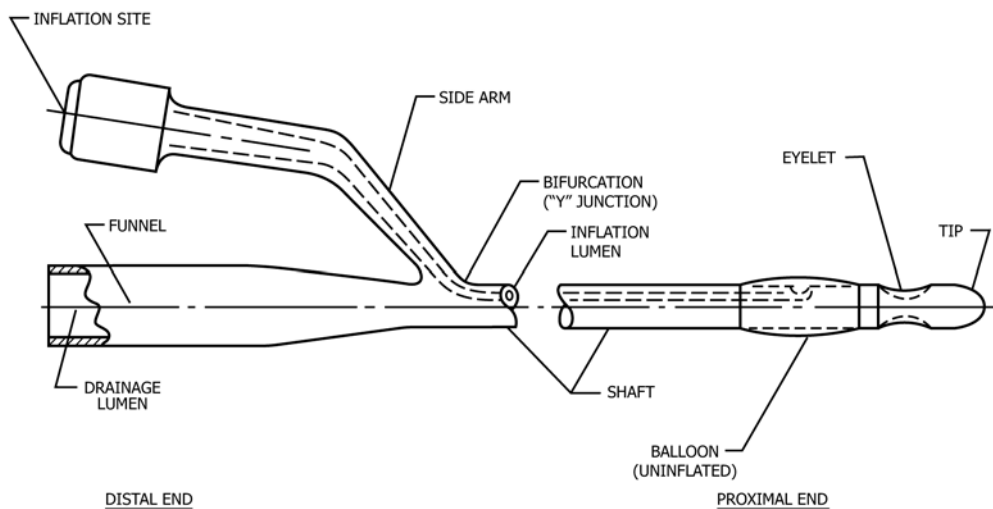


FIG. 1 Balloon Retention (Foley) Type Catheter

1.9 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:²

- D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- D573 Test Method for Rubber—Deterioration in an Air Oven
- D1076 Specification for Rubber—Concentrated, Ammonia Preserved, Creamed, and Centrifuged Natural Latex
- D3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- D3767 Practice for Rubber—Measurement of Dimensions
- D4483 Practice for Evaluating Precision for Test Method Standards in the Rubber and Carbon Black Manufacturing Industries
- E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method
- F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 ISO Standard:³

ISO 10993 Biological Evaluations of Medical Devices

2.3 Other Documents:

ISO/AAMI/ANSI 10993-1 Biological Testing of Medical and Dental Material and Devices — Part 1: Guidance on Selection of Tests

U.S. Pharmacopeia⁴

3. Terminology

3.1 Definitions:

3.1.1 **Balloon (Foley) catheter**—an indwelling catheter retained in the bladder by a balloon that is inflated with liquid.

3.1.1.1 **Discussion**—A two-way balloon catheter has a drainage lumen and inflation lumen (see Fig. 1). Common balloon inflation sizes are 5 cm³ with the 5-cm³ balloon being used to hold the catheter in place for normal usage, and 30 cm³ where so designated when a larger balloon is used. A three-way balloon catheter is used for continuous bladder irrigation and features both a drainage lumen and an irrigation lumen (but as noted above is excluded from consideration in this specification).

3.1.2 **French size**—a scale used for denoting the size of other tubular instruments and devices, each unit being roughly equivalent to 0.33 mm in diameter. Label French sizes are as follows:

French Size	Outside Diameter, in. (mm)
12	0.157 (4.0)
13	0.171 (4.3)
14	0.184 (4.7)
15	0.197 (5.0)
16	0.210 (5.3)
17	0.223 (5.7)
18	0.236 (6.0)
19	0.249 (6.3)
20	0.262 (6.7)
21	0.276 (7.0)
22	0.289 (7.3)
23	0.302 (7.7)
24	0.315 (8.0)
25	0.328 (8.3)
26	0.341 (8.7)

3.1.3 **lumen**—the channel within a tube.

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), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, <http://www.iso.org>.

⁴ Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, <http://www.usp.org>.

3.1.4 *proximal*—refers to the balloon end of the catheter, since when in position for clinical use, the balloon end is proximal or closest to the patient.

3.1.5 *referee test method*—the method cited in the published specification for the device. This method and the corresponding requirements will be invoked when the performance of the medical device will be questioned. The manufacturer need not use this referee test method in his usual inspection and quality control.

3.1.6 *sterility*—generally, the state of being free of microorganisms. For purposes of this specification, sterility is defined as freedom from microorganisms when tested according to the methodology defined by the USP for non-parenteral devices.

3.1.7 *tolerances*—the allowable deviation from a standard size. In usual engineering practice, the maximum permitted size is denoted by a plus sign followed by the tolerance and the minimum permitted size denoted by a minus sign followed by the tolerance. In this standard, the label French size has tolerances given for several dimensions. For example, +3, −1 means that a nominal 14 label French size can be permitted to go as high as 17, but not below 13. Another way of writing tolerance, when both tolerances are equal, is: ± 2 , meaning the 14 label French size must be between 12 French and 16 French.

3.1.8 *USP*—U.S. Pharmacopeia.

4. Requirements⁵

4.1 *Flow Rate through Drainage Lumen*—Label French size catheters 14 through 26 inclusive shall have a minimum average flow rate of 100 cm³/min, and a label French size 12 catheter shall have a flow rate of 70 cm³/min. Tests shall be conducted in accordance with [Annex A1](#).

4.2 *Balloon Integrity (Resistance to Rupture)*—The inflation balloon must be inflated easily with distilled or deionized water to labeled volume without showing any evidence of breakage throughout the test period. Leakage and failure to deflate are dealt with in 4.4 and 4.6. Tests shall be conducted in accordance with [Annex A2](#).

4.3 *Inflated Balloon Response to Traction*—The entire balloon of catheters label French size 14 through 26 shall not pass into or through the funnel barrel ([Fig. 2](#)). Tests shall be conducted in accordance with [Annex A3](#).

4.4 *Balloon Volume Maintenance*—The catheter shall maintain its volume throughout the test. Tests shall be conducted in accordance with [Annex A4](#).

4.5 *Balloon Size and Shaft Size*—The base dimension for the requirement on sizes and tolerances on the diameter of the catheter tip, the size of the balloon, and the diameter of the shaft is the “label French size.” The proximal catheter tip, the balloon, and the shaft, for 10 in. distal to the balloon, shall meet

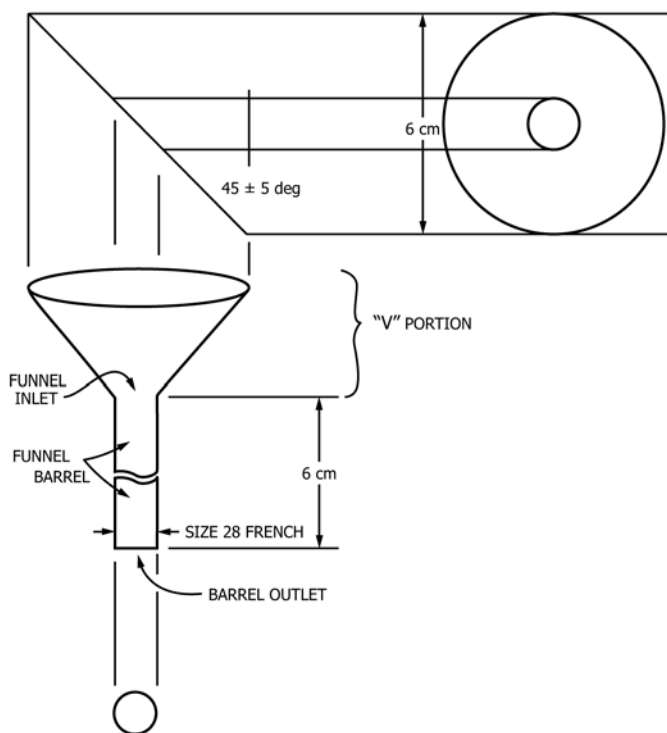


FIG. 2 Test Funnel

the requirements on size and tolerances on diameter shown in [Table 1](#). Tests shall be conducted in accordance with [Annex A5](#).

4.6 *Deflation Reliability (Failure to Deflate)*—The balloon shall deflate to within four French sizes of the label French size within 15 min or be otherwise manipulated to effect drainage within this time period. Tests shall be conducted in accordance with [Annex A6](#).

4.7 *Biocompatibility*—Foley catheters are considered to be prolonged term (24 h to 30 days) surface devices contacting mucosal membranes and shall pass the appropriate biological tests conducted using the specification in ASTM Practice [F748](#) or similar guidance established by the U.S. Food and Drug Administration⁶ or the International Organization for Standardization (ISO).³

4.7.1 The grading of any positive reaction that might be observed should reflect the degree of erythema or edema, or both, on the test sites. The pass or fail conclusion is based on the mild or severe nature of the reactions, respectively.

4.7.2 Criteria as to the microscopical evaluation of tissue reaction to the methods are included in this document. The question of pass or fail should be dealt with by reliable, competent scientists or pathologists and should be based on the degree of histological findings as compared with the response to the recommended USP polyethylene as “negative controls.”

4.7.3 *Packaging and Labeling*—Packaged and individual items shall be properly labeled and conform to (1) legal requirements, (2) the needs of medical usage (such as size

⁵ Supporting data for this specification, which provides a rationale of the performance requirements and test methods, have been filed at ASTM International Headquarters and may be obtained by requesting Research Report RR:F04-1003.

⁶ Available from Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, <http://www.fda.gov>