



## Standard Performance Specification for Foley Catheter<sup>1</sup>

This standard is issued under the fixed designation F 623; 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.

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

### INTRODUCTION

The objective of this specification is to describe those product requirements and associated test methods that will assure the safety and effectiveness of a disposable, 5-cm<sup>3</sup> (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. The product parameters addressed by the standard include those determined by the FDA Panel on Review of Gastroenterological-Urological Devices to be pertinent to the proposed classification of the Foley catheter to FDA Class II standards, plus other parameters determined by the ASTM task force to be pertinent to the product.

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 Committee F04 Staff Manager, ASTM, 100 Barr Harbor Dr., PO Box C700, West Conshohocken, PA 19428-2959.

### 1. Scope

1.1 This 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 nonsterile 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 *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, etc.) is excluded from the scope of this specification. Likewise, three lumen catheters, 30-cm<sup>3</sup> balloon and pediatric catheters, and catheters whose surface has been chemically treated to enhance their lubricity have not been tested to this specification and excluded from the

scope of this specification and will require separate standard development.

1.3 *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety concerns 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:

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices<sup>2</sup>

#### 2.2 Other Documents:

ISO/AAMI/ANSI 10993-1 Biological Testing of Medical and Dental Material and Devices — Part 1: Guidance on Selection of Tests<sup>3</sup>

U.S. Pharmacopeia<sup>4</sup>

### 3. Terminology

#### 3.1 Definitions of Terms:

<sup>1</sup> 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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<sup>2</sup> *Annual Book of ASTM Standards*, Vol 13.01.

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

<sup>4</sup> Available from U.S. Pharmacopeia, 12601 Twinbrook Pkwy., Rockville, MD 20852.

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 cm<sup>3</sup> with the 5-cm<sup>3</sup> balloon being used to hold the catheter in place for normal usage, and 30 cm<sup>3</sup> 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 *FDA*—the abbreviation for the Food and Drug Administration, the Federal agency under Health, Education, and Welfare responsible for the regulation of medical device products.

3.1.3 *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)

3.1.4 *lumen*—the channel within a tube.

3.1.5 *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.

3.1.6 *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.

3.1.7 *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 nonparenteral devices.

3.1.8 *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.

3.1.9 *USP*—U.S. Pharmacopeia

#### 4. Requirements<sup>5</sup>

4.1 *Flow Rate through Drainage Lumen*—Label French size catheters 14 through 24 inclusive shall have a minimum average flow rate of 100 cm<sup>3</sup>/min, and a label French size 12 catheter shall have a flow rate of 70 cm<sup>3</sup>/min. Tests shall be conducted in accordance with 6.1.

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 6.2.

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 6.3.

<sup>5</sup> Supporting data for this specification, which provides a rationale of the performance requirements and test methods, is available on loan from ASTM Headquarters, 100 Barr Harbor Dr., PO Box C700, West Conshohocken, PA 19428-2959. Request Research Report F04-1003.

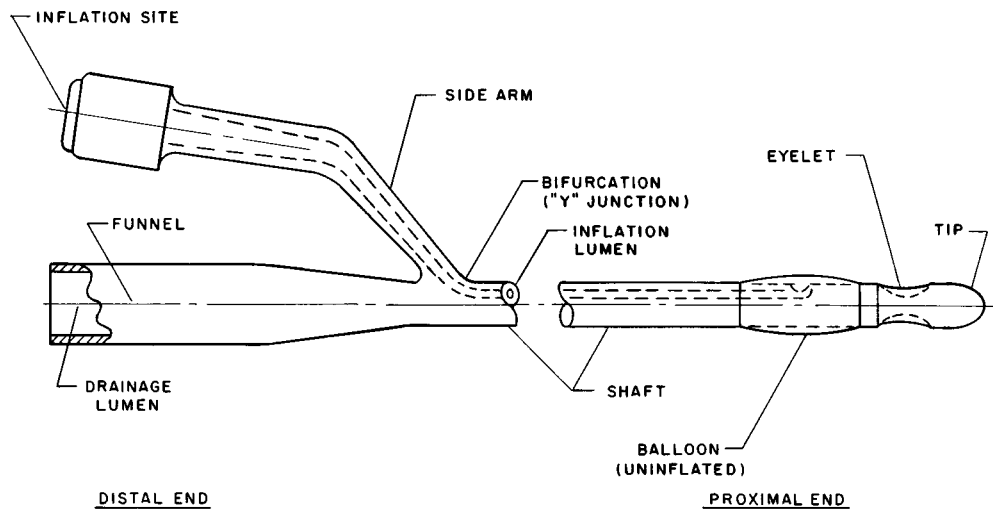


FIG. 1 Balloon Retention (Foley) Type Catheter

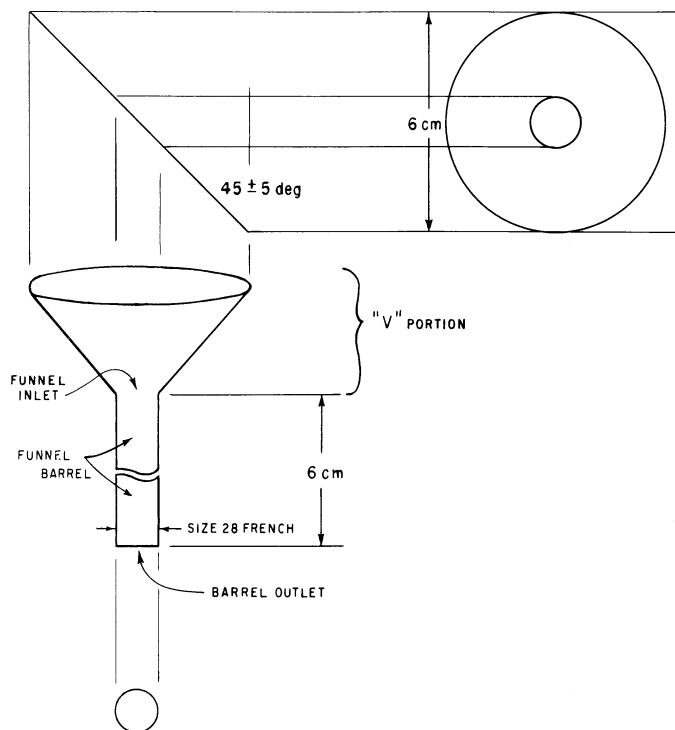


FIG. 2 Test Funnel

4.4 *Balloon Volume Maintenance*—The catheter shall maintain its volume throughout the test. Tests shall be conducted in accordance with 6.4.

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 the requirements on size and tolerances on diameter shown in Table 1. Tests shall be conducted in accordance with 6.5.

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 6.6.

4.7 *Biocompatibility*—Foley Catheters are considered to be prolonged term (24 h to 30 d) surface devices contacting mucosal membranes and shall pass the appropriate biological

TABLE 1 Requirements for Dimensions, Label French Size

Material Type	Tip, tolerance (3.5 and 5.5)	Shaft, tolerance (3.5 and 5.5)	Balloon size, maximum	
			As Received, Uninflated (3.5 and 5.5)	Deflated, after Immersion (3.6 and 5.6)
Latex and coated latex	±1	+2, -1 <sup>A</sup>	+3	+4
All-silicone	±1	±1	+4	+4
Others	±1	±1	+3	+4

<sup>A</sup> During the development of this standard, there was much discussion of the tolerance on the dimension of the shaft of the “latex and coated latex” type catheter. The industry recognizes that ±1 label French size is the desired value. The tolerance in this table is representative of the present state-of-the-art in manufacturing Foley catheters; however it is argued that this value can be improved.

tests conducted using the specification in ASTM Practice F 748 or similar guidance established by the U.S. Food and Drug Administration<sup>6</sup> or the International Organization for Standardization (ISO).<sup>3</sup>

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 identification), (3) requirements for traceability and identification in event of failure, and (4) requirements for precautions in usage. In the majority of situations current GMP (good manufacturing practice) will provide guidelines for proper labeling.

### 5. Special Precautions

5.1 The following cautionary comments recognize the sensitivity of the materials of construction to potential environmental conditions. These are outlined here to point out potential situations that could adversely affect the performance of the catheter during referee testing.

5.1.1 Care shall be taken during testing and use to prevent damage to the catheters. Such damage can be caused by abrasion and contact with sharp objects or chemical products. Contact shall be avoided with any of the following substances: vegetable oils, mineral oils or petrolatum, cleaning solvents, phenol, ether, cresols, oxidizing agents, copper, and manganese.

5.1.2 In addition, catheters should be kept away from the vicinity of generators, electric motors, diathermy machines, fluorescent lights, etc., because the ozone produced attacks rubber. This applies to both storage and handling.

5.1.3 To help avoid contamination of the catheters, proper handling precautions shall be observed.

### 6. Test Methods<sup>5</sup>

#### 6.1 Flow Rate Through Drainage Lumen:

6.1.1 *Scope*—This method covers the determination of flow rates through the drainage lumen of the balloon retention catheters.

6.1.2 *Significance and Use*—The flow rate is measured in reverse flow for ease in testing, since differences in the flow rate due to flow direction are theoretically insignificant.

6.1.3 *Summary of Test Method*—The apparatus is set up as shown in Fig. 3. The flow rate is adjusted through the water inlet to a rate sufficient to maintain flow through the overflow outlet while each catheter is tested. A head pressure of 20 ± 1.0 cm of water (196 ± 10 kPa) above the tank bottom shall be

<sup>6</sup> Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

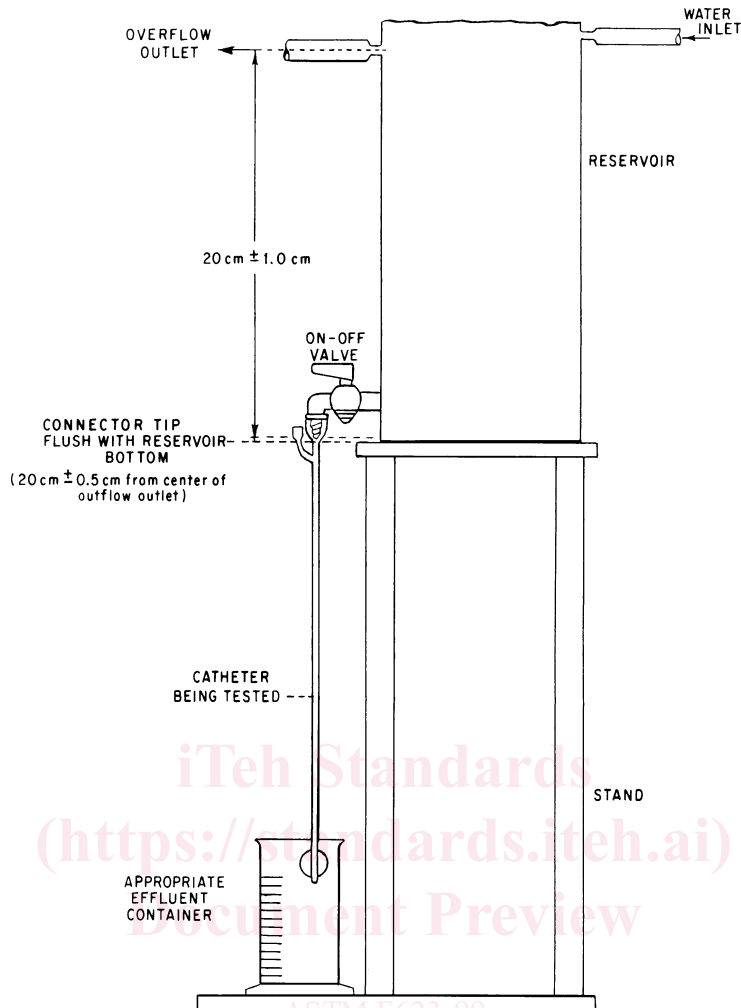


FIG. 3 Flow Rate Apparatus for Reverse Flow Technique

maintained throughout the test to approximate actual physiologic conditions. The overflow outlet should not be covered by water.

6.1.4 Apparatus:

6.1.4.1 *Water Reservoir*, capable of maintaining  $20 \pm 1.0$  cm ( $7.9 \pm 0.4$  in.) of water ( $196 \pm 10$  kPa) above the tip of the catheter connection throughout the test as shown in Fig. 3.

6.1.4.2 *Graduated Cylinder*, calibrated for suitable measurement of the effluent.

6.1.4.3 *Syringe*, with appropriate tip for inflation of catheter balloon.

6.1.5 Precautions:

6.1.5.1 Overflow should not be covered. Head pressure must be kept constant; water should always be exiting through the overflow outlet.

6.1.5.2 Establish equilibrium prior to testing.

6.1.5.3 Flow rates through all fittings must exceed that of the catheter being tested.

6.1.6 *Test Specimen*—The test specimen shall consist of the manufacturer's new, finished, untested product; at least statistically valid samples of the smallest and the largest diameter catheters shall be tested.

6.1.7 Procedure:

6.1.7.1 Test at  $23 \pm 4^\circ\text{C}$  ( $73.4 \pm 7^\circ\text{F}$ ).

6.1.7.2 Inflate the retention balloon of the test specimen with distilled or deionized water to labeled volume. For example, a  $5\text{-cm}^3$  balloon should be inflated with  $5 + 2, -0$   $\text{cm}^3$  of distilled or deionized water (or as recommended by the individual manufacturer on the label).

6.1.7.3 Connect the catheter to catheter connector and open the stopcock. The tip of the catheter connection at the junction of catheter on-off valve should be level with the bottom of the tank  $\pm 1$  cm and it should deliver fluid at  $20 \pm 1$  cm ( $196 \pm 10$  kPa) head pressure at that junction.

6.1.7.4 Establish the inflow and outflow equilibrium prior to test measurements.

6.1.7.5 Record the amount of water flowing through the catheter drainage lumen in 1 min. Express results in cubic centimetres per minute as flow rate. Test each catheter three times and calculate the average flow rate for each catheter.

6.1.8 *Interpretation of Results*—Flow rates for catheters tested must meet or exceed those established in the criteria section.

6.2 *Balloon Integrity (Resistance to Rupture)*:

6.2.1 *Scope*—This method covers the determination of balloon integrity of Foley-type, balloon-retention, urinary drainage catheters.

6.2.2 *Significance and Use*—This method is designed to