Designation: F623 – 99 (Reapproved 2013)

Standard Performance Specification for Foley Catheter[1]

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 reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

The objective of this specification is to describe those product requirements and associated test methods that will ensure the safety and effectiveness of a disposable, 5-cm^3 (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 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 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, and so forth) is excluded from the scope of this specification. Likewise, three lumen catheters, 30-cm^3 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:*[2]

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

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[3]

[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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[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, http://www.ansi.org.

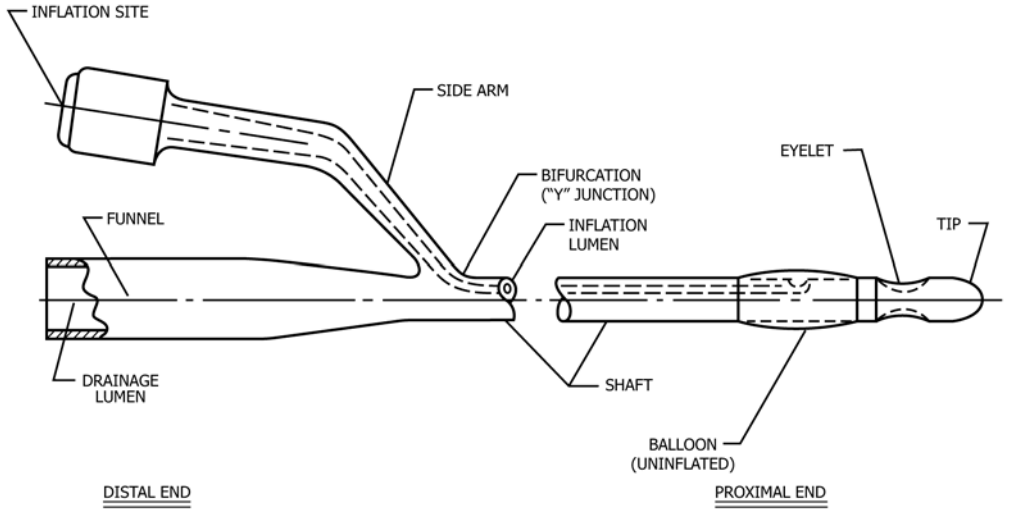

FIG. 1 Balloon Retention (Foley) Type Catheter

U.S. Pharmacopeia[4]

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 cm^3 with the 5-cm^3 balloon being used to hold the catheter in place for normal usage, and 30 cm^3 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[5]

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^3/min, and a label French size 12 catheter shall have a flow rate of 70 cm^3/min. Tests shall be conducted in accordance with 6.1.

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

[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.

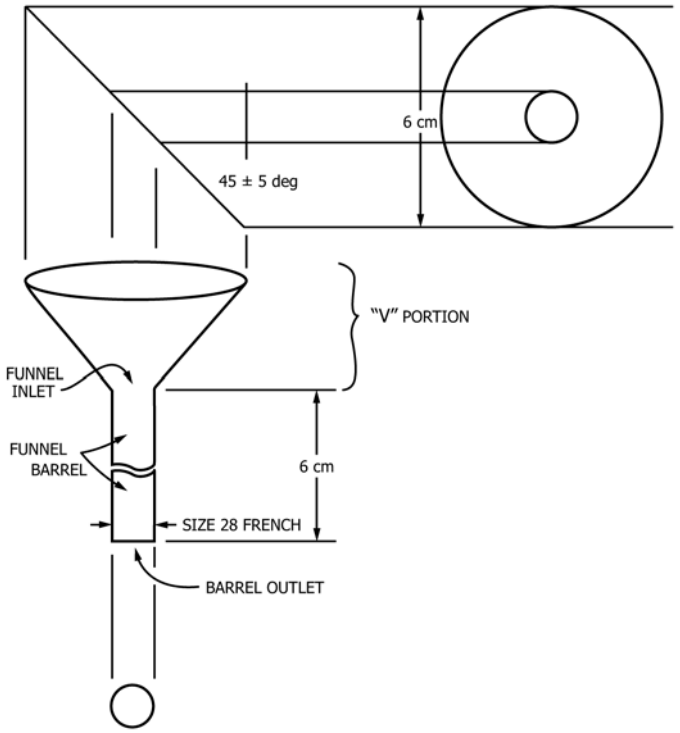

FIG. 2 Test Funnel

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.

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 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 Administration[6] or the International Organization for Standardization (ISO).[3]

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[A]	+ 3	+ 4
All-silicone	±1	±1	+ 4	+ 4
Others	±1	±1	+ 3	+ 4

[A] 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.

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, and so forth, because the ozone produced attacks rubber. This applies to both storage and handling.

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

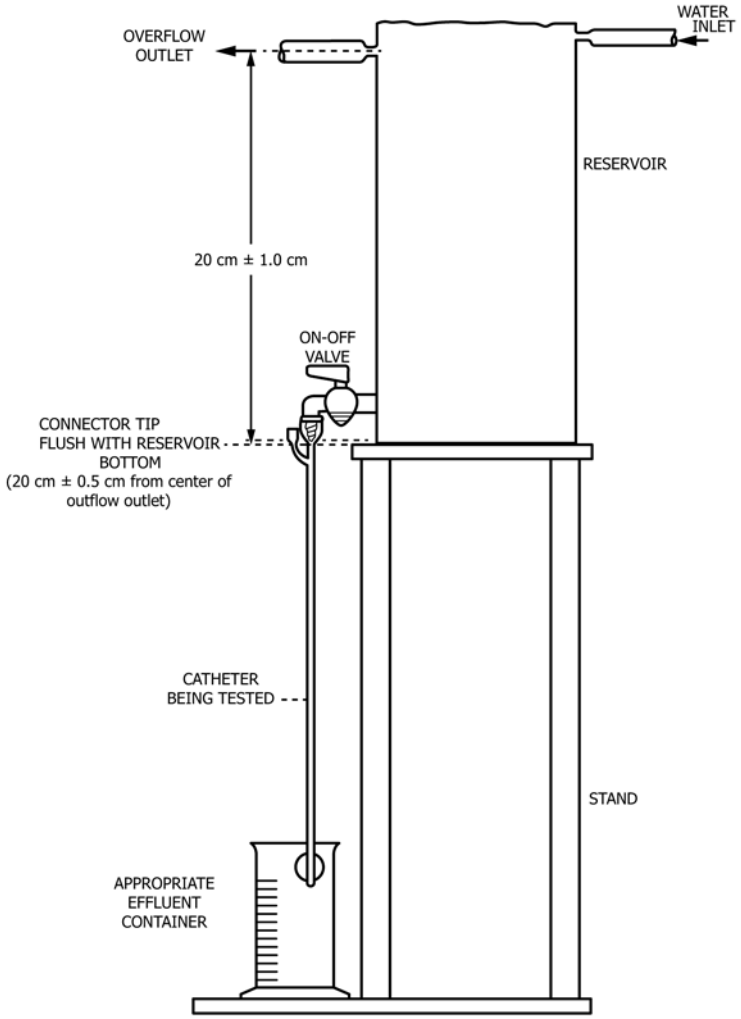

FIG. 3 Flow Rate Apparatus for Reverse Flow Technique

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

6. Test Methods[5]

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 as a result of 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 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 ± 1.0 cm (7.9 ± 0.4 in.) of water (196 ± 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 *Warnings:*

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 before 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 ± 4°C (73.4 ± 7°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-cm^3 balloon should be inflated with 5 + 2, – 0 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 ±1 cm and it should deliver fluid at 20 ± 1 cm (196 ± 10 kPa) head pressure at that junction.

6.1.7.4 Establish the inflow and outflow equilibrium before 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 simulate the actual intended use of the catheter, by exposing the balloon to body temperature for a period of seven days. The balloon survival under effects of moisture can be determined during the usual life expectancy of the catheter.

6.2.3 *Summary of Test Method*—The catheter balloons are inflated with distilled distilled or deionized water and submerged in artifical urine at 37.8 ± 3° C (100 ± 5°F) for seven days. The catheters are then examined for burst balloons.

6.2.4 *Apparatus:*

6.2.4.1 *Corrosion-Resistant Tanks*—The tanks should contain no exposed iron, copper, or brass elements and include mixing and heating units of suitable capacity with flow-through water and a thermostatically controlled heating element.

6.2.4.2 *Device,* suitable for filling the balloons to labeled volume.

6.2.4.3 *Distilled or Deionized Water.*

6.2.4.4 *Artificial Urine.*

6.2.5 *Warnings:*

6.2.5.1 No materials destructive to latex, such as copper, manganese, or iron may contact the catheters during test. Copper content in the bath water of more than 50 ppm could seriously damage the balloons (see Section 5).

6.2.5.2 Catheters must be exposed to fresh artificila urine for each test period, a procedure that is required to prevent accumulation of bacteria, scum, and leached chemicals that could damage the catheter or balloon. It must be realized that bacteria or bacteriological inhibitors could also damage the balloons and should not be used in test baths.

6.2.6 *Test Specimens*—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.

6.2.7 *Procedure:*

6.2.7.1 Fill the tanks with artificial urine and raise the temperature to 37.8 ± 3°C.

6.2.7.2 Fill the balloons with distilled or deionized water to the labeled volume.

6.2.7.3 Fully submerge at least the entire balloon of the catheter in the tank.

6.2.7.4 After seven days, inspect the catheters for ruptured balloons.

6.2.8 *Interpretation of Results:*

6.2.8.1 Any catheter whose balloon has burst during or after filling, up to the time of examination of the balloon, shall have failed the test.

6.2.8.2 Any catheter whose balloon does not burst but which deflates during the test because of some form of leakage shall be an invalid test item.

6.3 *Inflated Balloon Response to Pullout:*

6.3.1 Scope—This method assesses the catheter's response to forces occurring during clinical use. Label French size 12 catheters shall be excluded from conforming to this test.

6.3.2 *Significance and Use*—The catheter, when subjected to reasonable traction forces, shall not be distorted and pulled through the bladder outlet of static and impact forces.

6.3.3 *Summary of Test Method:*

6.3.3.1 A funnel-like apparatus, with a size 28 French lumen, represents the bladder outlet and urethra. An inflated catheter balloon rests in the V-shaped portion of the funnel with the distal end of the catheter extended through the funnel barrel and hanging downward. A specified load hangs from the distal end of the catheter. (See Fig. 2 and Fig. 4.)

6.3.3.2 *Static Load Test*—A 0.45-kg (1-lb) weight is attached to the catheter suspended through the funnel. The load is applied for 2 min.

6.3.3.3 *Impact Load Test*—A 0.45-kg (1-lb) weight is suspended from the distal end of the catheter passing through the funnel. The load is then lifted vertically 0.6 m (2 ft) from its original hanging position and released.

6.3.4 *Apparatus:*

6.3.4.1 *Funnel,* mounted on a ring stand (see Fig. 2 and Fig. 4).

6.3.4.2 *Weight,* 0.45 kg (1 lb).

6.3.4.3 *Ring Stand.*

6.3.5 *Warnings:*

6.3.5.1 Use proper balloon inflation volume.

6.3.5.2 Be sure of proper balloon position before testing.

6.3.5.3 Be sure to have the natural suspension point of the weight marked and lift the weight vertically 0.6 m (2 ft) above the mark before releasing.

6.3.6 *Test Specimens*—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.

6.3.7 *Procedure:*

6.3.7.1 Pass the proximal tip of the catheter through the funnel barrel, advancing the balloon past the funnel inlet.

6.3.7.2 Inflate the balloon with 5 cm^3 of distilled or deionized water.

6.3.7.3 Pull the balloon back slowly until it fits snugly against the funnel inlet.

6.3.7.4 Hang a 0.45-kg (1-lb) weight from the distal end of the catheter.

(1) Static Load Test—Observe the catheter balloon for 2 min.

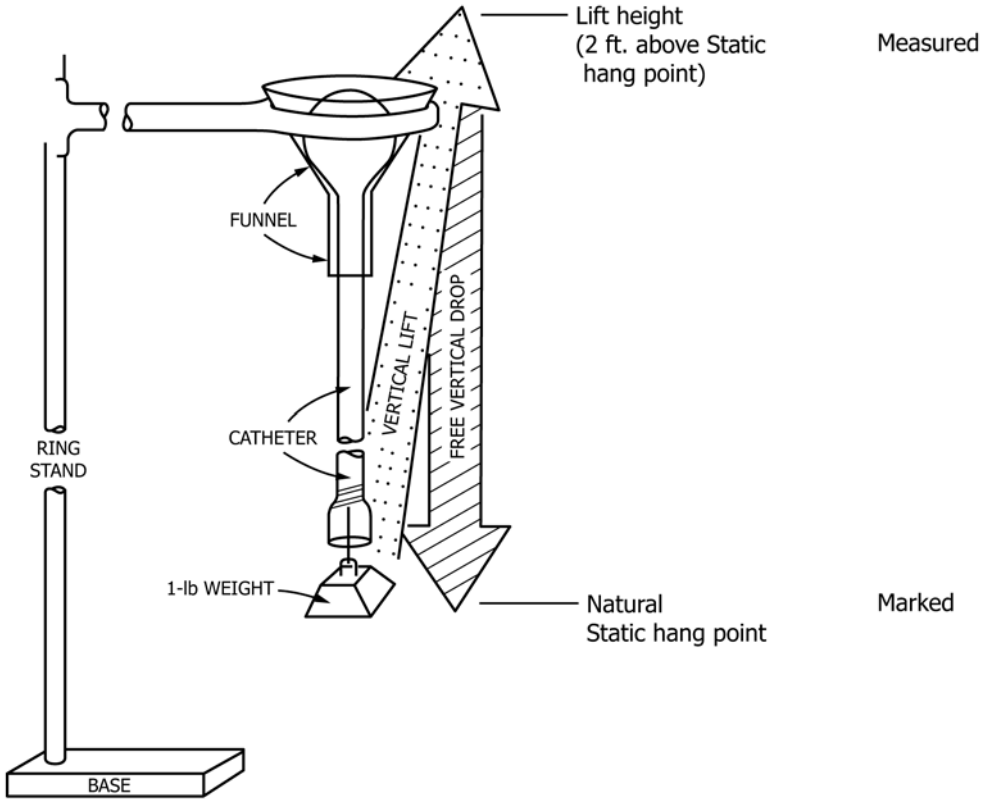

FIG. 4 Inflated Balloon Response to Pullout Test

(2) Impact Load Test—There should be no obstruction to the free fall of the weight from a height of 305 mm (1 ft) above the base of the ring stand during its natural suspension.

6.3.7.5 Lift the weight 0.6 m (2 ft) from the point of its natural suspension and then release.

6.3.7.6 Observe the balloon position in the funnel inlet after the drop.

6.3.8 *Interpretation of Results:*

6.3.8.1 Passage of the entire balloon into or through the funnel barrel shall constitute a test failure.

6.3.8.2 Rupture (or other deflation) of the balloon shall constitute a test failure, regardless of catheter slippage.

6.4 *Balloon Volume Maintenance:*

6.4.1 Scope—This method may be applied to balloon-retention-type catheters to test their ability to retain injected balloon volume.

6.4.2 *Significance and Use:*

6.4.2.1 This method establishes a standard test method for determining the functional integrity of the inflation system of the balloon-retention catheter.

6.4.2.2 Since it is the function of the inflation balloon to keep the urinary catheter tip within the bladder and to permit drainage, it is imperative that the balloon inflate, retain inflation volume, and release that volume only when called upon to do so. The catheter balloon, therefore, is expected to maintain its volume throughout the test.

6.4.3 *Summary of Test Method*—The method is performed to identify inflation failure and immediate retention failure irrespective of cause. A balloon is inflated to a labeled volume using colored solution from a device such as a syringe. The filled balloon catheter is then placed on a surface suitable for detecting color and leakage from the inflation system (such as a paper towel). The balloon remains filled for a 24-h period. After this time, the balloon is examined for leakage.

6.4.4 *Apparatus:*

6.4.4.1 *Syringe,* or other suitable inflation device.

6.4.4.2 *Distilled or Deionized Water,* for use as the inflation solution.

6.4.4.3 *Methylene Blue Crystal Solution or Equivalent*—Prepare 1 g of methylene crystals and dilute in 2000 cm^3 of water, to be detectable in the described retention test.

6.4.4.4 *Background Material,* suitable for detection of any leakage.

6.4.5 *Warnings:*

6.4.5.1 Assure that the syringe is properly seated in the valve.

6.4.6 *Test Specimens*—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.

6.4.7 *Procedure:*

6.4.7.1 Inflate the balloon with the methylene blue solution to the labeled volume.

6.4.7.2 Place on a surface suitable for detection of color leakage for a 24-h period. Cover or otherwise protect the catheters from light or ozone for the duration of the test.

6.4.7.3 After the test time has elapsed, observe the surfaces for any discoloration caused by content leakage from the catheter balloon-inflation system.

6.4.8 *Interpretation of Results:*

6.4.8.1 Failure to inflate is a failure of the liquid from the filling device (syringe) to enter the retention balloon.

6.4.8.2 Failure of retention is a discoloration of or leakage on the clean surface beneath the catheter.

6.5 *Balloon Size and Shaft Size:*

6.5.1 *Scope*—This method covers the determination of the Foley catheter balloon and shaft size.

6.5.2 *Significance and Use*—The overall outside diameter of the catheter during passage should conform to the expected urethral size.

6.5.3 *Summary of Test Method*—Using a French size gage, the proximal catheter tip is measured in holes close to the label French size. The balloon size is measured in larger holes. The catheter is then cut distal to the balloon and the shaft size is measured. The requirements are in Table 1.

6.5.4 *Apparatus:*

6.5.4.1 *French Size Calibration Gage,* having a tolerance of ±0.13 mm (±0.005 in.).

6.5.4.2 *Metric Scale Rule.*

6.5.5 *Warnings:*

6.5.5.1 No lubrication or undue force shall be applied to the catheter.

6.5.5.2 The edges of each hole should be smooth to avoid interference to the passage of the test catheter.

6.5.6 *Test Specimens*—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.

6.5.7 *Procedure:*

6.5.7.1 Without lubrication, push or otherwise thread the proximal end of the uninflated catheter through the various holes of the calibrated French-size gage, advancing it to the uninflated balloon.

6.5.7.2 Repeat 6.5.7.1, using the uninflated balloon.

6.5.7.3 After recording the measurements, cut the catheter just distal to the uninflated balloon. Then pass the proximal end of the remaining catheter (the cut surface) through the French scale to a point 254 mm (10 in.) distal to the cut end.

6.5.8 *Interpretation of Results:*

6.5.8.1 *Label French Size*—The balloon section may wrinkle but shall not tear or distort, and the catheter shaft or tip may offer resistance but if distortion or stretching occurs it is considered a failure. To pass this test, the catheter shaft and balloon measurements must meet all three test requirements as shown in Table 1. Catheters not meeting these criteria will be judged failures.

6.6 *Deflation Reliability (Failure to Deflate):*

6.6.1 *Scope*—This method covers the determination of deflation failure risk of the balloon and deflation channel of the catheters.

6.6.2 *Significance and Use*—This test is designed to detect, in a wet medium, failures of the balloon and shaft lumen to deflate properly at the time of withdrawal. Proper deflation is critical to removal of the catheter from the patient following its use. Conditions of use are simulated.

6.6.3 *Summary of Test Method*—Inflated catheters that have been submerged for seven days are deflated using a syringe (and "cut-off" method, if necessary).

6.6.4 *Apparatus:*

6.6.4.1 *Holding Bath*—A vessel of any suitable material (stainless steel, glass, fiberglass, or polyethylene) that will not deteriorate or discolor the material that the catheter is made of (see 6.2.4.1 and Section 5). The capacity of the vessel should be based on a minimum of 10 gal of liquid to 150 catheters. The liquid shall be kept at 37.8 ± 3°C (100± 5°F) by means of a suitable heating apparatus and thermostat.

6.6.4.2 *Calibrated Devices,* suitable for inflating the balloons.

6.6.4.3 *Scissors or Scalpel.*

6.6.4.4 *Distilled or Deionized Water.*

6.6.5 *Warnings:*

6.6.5.1 Tests shall be performed on separate sampling lots of catheters rather than attempting to perform three or four tests on the same group of catheters.

6.6.5.2 Catheters must be securely bundled and clearly marked to ensure identification.

6.6.6 *Test Specimens*—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.

6.6.7 *Procedure:*

6.6.7.1 Fill the catheter with a volume of distilled or deionized water according to the stated capacity of the balloon and manufacturer labeling.

6.6.7.2 Place the filled catheters in an immersion bath for a period of seven days at 37.8 ± 3°C (100 ± 5°F).

6.6.7.3 After catheters are placed in bath, cover them to ensure complete immersion and to prevent evaporation and light damage.

6.6.7.4 After seven days immersion, remove the catheters, place on clean surface and empty in accordance with the manufacturer's recommended technique or by use of the appropriate syringe or by the "cut-off" technique. Post-deflation shape of the balloon portion of the catheter shall pass through a calibrated French-size hole (or ring) no greater than four French sizes larger than the label French size. A force of no greater than 4.5 N (1 lbf) may be used to pull the catheter through.

6.6.7.5 Any catheter that fails to deflate using the syringe shall be cut off approximately 12.7 mm (½ in.) proximal to the bifurcation of the inflation lumen and drainage lumen.

6.6.8 *Interpretation of Results*—Any cut-off catheter balloon that does not drain within 15 min shall be reported as a failure if it cannot be withdrawn through the appropriate French-size scale (not greater than four sizes larger than the label French size).

7. Keywords

7.1 balloon catheter; bladder drainage; urology

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 Foley catheters exhibit a range of physical properties that affect their clinical performance. These properties are affected by materials, manufacturing processes, and catheter geometry. This specification is intended to describe standard test methods to be used to measure the important functional characteristics of Foley catheters such as flow rate and balloon integrity, resistance to traction, volume maintenance, and deflation reliability.

X1.2 The objective of this specification is to describe the laboratory tests methods used to evaluate the safety and efficacy of disposable, 5-mL balloon, retention–type catheters used for urinary bladder drainage. The minimum performance requirements presented include those determined by the FDS Panel of Review of Gastroenterologiacal-Urological Devices to be appropriate for a Class II medical device, as well as those determined by the ASTM subcommittee to be relevant to Foley catheters.

X1.3 This specification includes referee test methods that are not to be construed as production methods, quality control techniques, or manufacturers' lot release criteria.

X2. CHEMICAL COMPOSITION OF ARTIFICIAL URINE

X2.1 This formulation artificial urine is based on the formulation propose by B. Finlayson (**1**) modified to include certain salts known to be present in human urine. The pH is adjusted to 5.5 to 7.0 range by adding a 1 normal (N) solution of NH4OH or NH4Cl to a 1000-mL volumetric flask.

Salt	Mass, g
NaCl	6.17
NaH2PO4	4.59
Na3Citrate	0.944
MgSO4	0.463
Na2SO4	2.41
KCl	4.75
CaCl2	0.64
Na2Oxalate	0.043
Distilled water	1000

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