



Designation: D8389 – 21

Standard Performance Specification for Urinary Intermittent Catheters¹

This standard is issued under the fixed designation D8389; 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 performance specification establishes performance requirements for the short-term utilization of a single-use, non-balloon- urinary catheter, French sizes 12 through 30 inclusive, used by the medical professions for providing a method of bladder drainage through 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 and sterile for single use only. The non-sterile catheters should be sterilized.

1.2 Catheters whose surface has been chemically treated to effect biocompatibility or microbial properties may be tested to this specification. The safety and effectiveness of antimicrobial coatings or their incorporation into device polymer materials are not within the scope of this specification.

1.3 Catheters whose surface has been chemically treated to enhance their lubricity may be tested to this specification.

1.4 Regulatory bodies may require additional information, such as clinical data, to support the subject products of this standard.

1.5 *Exclusions*—Catheters for non-urethral catheterization, such as for nephrostomy, suprapubic cystostomy, ureterostomy, gastrostomy, enemas, and so forth, are excluded from the scope of this specification.

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 *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.*

¹ 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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1.8 *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

D1894 Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheet

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

F1980 Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

2.2 ISO Standards:³

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

ISO 20696 (2018) Sterile Urethral Catheters for Single Use

3. Terminology

3.1 Definitions:

3.1.1 *distal, n*—refers to the funnel end of the catheter, since when in position for clinical use, the funnel is distal or farthest from the patient.

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

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>.

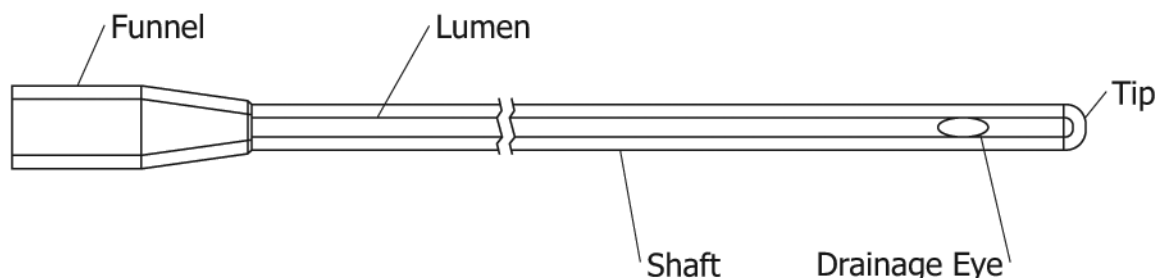


FIG. 1 Non-Balloon Urinary or Intermittent Type Catheter

TABLE 1 Requirements for Dimensions, Label French Size

Manufacturing Type	French Size, Tolerance (3.5 and 5.5)
Dipped products: e.g. NR Latex, synthetic polyisoprene and coated products	+ 2, - 1
All -silicone extrusion	±1
Others	±1

3.1.2.1 Discussion—Label French sizes are as follows:

French Size	Outside Diameter, in. (mm)
6	0.078 (2.0)
8	0.104 (2.6)
10	0.130 (3.3)
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)
28	0.354 (9.0)
30	0.367 (9.3)

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

3.1.4 *non-balloon urinary catheter, n*—a catheter inserted into the bladder via the urethra for short-term drainage (equal to or less than 24 h).

3.1.4.1 *Discussion*—A non-balloon urinary or intermittent type catheter has a drainage lumen, drainage eye and shaft (see Fig. 1). No specifications for minimum dimensions of the drainage eye and lumen are needed since they must achieve minimum flow rate requirements.

3.1.5 *proximal, n*—refers to the tip end of the catheter, since when in position for clinical use, tip end is proximal to the point of entry.

3.1.6 *referee test method, n*—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, n*—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.

3.1.8 *tolerances, n*—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, *n*—U.S. Pharmacopeia.

4. Requirements⁴

4.1 *Flow Rate through Drainage Lumen*—Label French size catheters 14 through 30 inclusive shall have a minimum average flow rate of 100 cm³/min, a label French size 12 catheter shall have a minimum average flow rate of 70 cm³/min, a Label French size 10 catheter shall have a minimum average flow rate of 30 cm³/min and Label French size catheters 6 through 8 shall have a minimum average of 10 cm³/min. Tests shall be conducted in accordance with Annex A1.

4.2 *Shaft Size*—The base dimension for the requirement on sizes and tolerances on the diameter of the catheter tip and the diameter of the shaft is the “label French size.” The Fr gauge shall meet the requirements on size and tolerances on diameter shown in Table 1. Tests shall be conducted in accordance with Annex A2.

4.3 *Biocompatibility*—Intermittent catheters shall pass the appropriate biological tests conducted using the specification in Practice F748 or similar standard recognized by the U.S. Food and Drug Administration or relevant regulatory body on biocompatibility for medical devices or the International Organization for Standardization (ISO), such as ISO 10993.

4.4 *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

⁴ 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 R14400.