



Standard Performance Specification for Foley Catheter¹

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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-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. 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-cm³ 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 Tests³

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>.