



Standard Specification for Ureteral Stents¹

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INTRODUCTION

The objective of this specification is to describe the test methods used to evaluate the safety and effectiveness of an indwelling ureteral stent, having retention means at the kidney and bladder ends, used for urinary drainage of the kidney to the bladder via the ureter.

This specification includes referee test methods that can be used to evaluate the performance characteristics of ureteral stents. 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 ASTM task group to be pertinent to the product.

1. Scope

1.1 This specification covers the referee test methods for evaluating the performance characteristics of a single-use ureteral stent with retaining means at both ends, during short term use for drainage of urine from the kidney to the bladder. These stents are typically available in diameters of 3.7 Fr to 14.0 Fr, and lengths of 8 cm to 30 cm, and are made of silicone, polyurethane, and other polymers. They are provided non-sterile for sterilization and sterile for single-use.

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 ureteral stents for non-ureteral applications such as nephrostomy and ileostomy is excluded from the scope of this specification. Non-sterile ureteral stents are also excluded due to the variability of hospital sterilization equipment and processes and the resulting effects on ureteral stent characteristics.

1.3 The following precautionary statement pertains only to the test method portion, Section 5, of this specification:

1.4 *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 and health practices and determine the applicability of regulatory limitations prior to use.*

¹ This 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. Referenced Documents

2.1 ASTM Standards:²

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

F640 Test Methods for Determining Radiopacity for Medical Use

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

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *artificial urine*—a solution of organic and inorganic compounds that closely simulates the chemical and physical properties of normal human urine. Artificial urine will be used as a substitute for human urine to simulate the effects of human urine on ureteral stents.

3.1.2 *bladder retention means*—physical feature of bladder end of stent that prevents movement of stent out of bladder.

3.1.3 *break strength*—peak tensile load required to break stent.

3.1.4 *cross section*—view of stent tube when cut in a plane perpendicular to length of stent.

3.1.5 *distal*—situated away from the point of origin. The distal end of a stent is the end that resides in the bladder, also known as the bladder end.

3.1.6 *drainage holes*—holes in wall of stent tubing that allow flow of urine into and out of lumen of stent.

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.