Conventional Foley Catheters – Performance Criteria for Safety and Performance Based Pathway

---

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on September 20, 2019.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the DHT3B: Division of Reproductive, Gynecology and Urology Devices at 301-796-7030 or Glenn Bell at Glenn.Bell@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 19010 and complete title of the guidance in the request.

Conventional Foley Catheters – Performance Criteria for Safety and Performance Based Pathway

---

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance provides performance criteria for conventional Foley catheters in support of the Safety and Performance Based Pathway.[1] Under this framework, submitters planning to submit a 510(k) using the Safety and Performance Based Pathway for Foley catheters will have the option to use the performance criteria proposed in this draft guidance to support substantial equivalence, rather than a direct comparison of performance of the subject device to that of a predicate device.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[2] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.[3]

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Scope/Device Description

The Foley catheters that are the subject of this guidance are intended for the drainage and/or irrigation of the urinary tract. These devices are Class II and are regulated under 21 CFR 876.5130 with the product code EZL (Catheter, Retention Type, Balloon).

Intended Use/Indications for Use:
Drainage is accomplished by inserting the catheter through the urethra into the bladder. The catheter is retained by use of a balloon inflated in the bladder, which is attached to the distal end of the catheter. The devices are single-use and indwelling time should be 30 days or less.

Device Design Characteristics:
The French sizes within the scope of this guidance include sizes 12 through 26 with a retention balloon volume no greater than 30 cm^3. Two lumen catheters are included within the scope of this guidance. Three lumen catheters, catheters treated to enhance their lubricity, suprapubic catheters, and antimicrobial catheters are outside the scope of this guidance.

General guidance that is beyond the scope of this safety and performance guidance document (e.g., labeling recommendations) regarding submission of a 510(k) for Foley catheters can be found in FDA's guidance document Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters.[4]

Where FDA determines that additional data are necessary to make these determinations, the Agency may, on a case-by-case basis, review that data before determining whether or not the device is appropriate for the Safety and Performance Based Pathway. In situations, where you determine that additional testing outside of those identified in this guidance are necessary to make a determination regarding eligibility into the Safety and Performance Based Pathway, we would encourage sponsors to submit a Pre-Submission[5] to engage in discussion with FDA prior to submission of the 510(k).

III. Testing Performance Criteria

If your device is appropriate for submission through the Safety and Performance Based Pathway, and you choose to use that option, you do not need to provide direct comparison testing against a legally marketed predicate device to demonstrate substantially equivalent performance characteristics. To ensure that the performance criteria outlined in this guidance remain contemporary and take into account relevant data from recent clearances, FDA recommends that

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-notifications-conventional-and-antimicrobial-foley-catheters

[5] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

you provide a results summary for all tests evaluated in addition to the other submission information (e.g. Declaration of Conformity (DoC)) identified for each test or evaluation below. Unless otherwise identified in the submission information sections below, test information such as results summary, test protocols, or complete test reports should be submitted as part of the 510(k) as described in FDA's guidance Safety and Performance Based Pathway.[6] For additional information regarding the submission of non-clinical bench testing information, please see FDA's guidance Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.[7]

Mechanical Testing

1. **Test name:** Dimensional Analysis
   Methodology: FDA currently-recognized version of American Society for Testing and Materials (ASTM) F623 *Standard Performance Specifications for Foley Catheters*
   Performance Criteria: The "label French size" should correspond with the following actual diameters of the catheter tip, shaft, and balloon within tolerances as identified in test #6, "Balloon Size and Shaft Size."

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)

   Performance Criteria Source: For French sizes - ASTM F623: *Standard Performance Specifications for Foley Catheters*
   Additional Considerations: Conventional Foley catheters typically have an even numbered French size.
   Submission Information: DoC

[6] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway
[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

2. **Test name:** Flow Rate
   Methodology: ASTM F623 *Standard Performance Specifications for Foley Catheters*
   Performance Criteria: Catheters with French size 14-26 should have a minimum average flow rate of 100 cm^3/min. French size 12 catheters should have a minimum average flow rate of 70 cm^3/min.
   Performance Criteria Source: ASTM F623 *Standard Performance Specifications for Foley Catheters*
   Additional Considerations: ASTM F623 does not provide a criterion for French size 13 catheters as conventional Foley catheters typically have an even numbered French size.
   Submission Information: DoC

3. **Test name:** Balloon Integrity (Resistance to Rupture)
   Methodology: ASTM F623 *Standard Performance Specifications for Foley Catheters*
   Performance Criteria: The inflated balloon must inflate easily with distilled or deionized water to the labeled volume without showing any evidence of breakage throughout the test period. Any catheter whose balloon has burst during or after filling up to the time of examination of the balloon, are considered to have failed the test. Any catheter whose balloon does not burst but which deflates during the test because of some form of leakage should be considered an invalid test item.
   Performance Criteria Source: ASTM F623 *Standard Performance Specifications for Foley Catheters*
   Submission Information: DoC

4. **Test name:** Inflated Balloon Response to Traction
   Methodology: ASTM F623 *Standard Performance Specifications for Foley Catheters*.
   Performance Criteria: The entire balloon of the catheters with a labeled French size 14 through 26 should not pass into or through the funnel barrel with a size of 28Fr.
   Performance Criteria Source: ASTM F623 *Standard Performance Specifications for Foley Catheters*
   Additional Considerations: Labeled French size 12 catheters are not expected to pass this testing.
   Submission Information: DoC

5. **Test name:** Balloon Volume Maintenance
   Methodology: ASTM F623 *Standard Performance Specifications for Foley Catheters*.
   Performance Criteria: The catheter should maintain its volume throughout the test.
   Performance Criteria Source: ASTM F623 *Standard Performance Specifications for Foley Catheters*
   Submission Information: DoC

6. **Test name:** Balloon Size and Shaft Size
   Methodology: ASTM F623 *Standard Performance Specifications for Foley Catheters*.

Performance Criteria: The proximal catheter tip, the balloon, and the shaft should measure within the tolerances on diameter shown below in comparison to the labeled French size:

Material Type	Tip Tolerance	Shaft Tolerance	Balloon Size, Maximum	
			As Received, Uninflated	Deflated, After Immersion
Latex and coated latex	±1	+2,-1	±3	±4
All silicone	±1	±1	±4	±4
Others	±1	±1	±3	±4

Performance Criteria Source: ASTM F623 *Standard Performance Specifications for Foley Catheters*
Submission Information: DoC

7. **Test name:** Deflation Reliability (Failure to Deflate)
Methodology: ASTM F623 *Standard Performance Specifications for Foley Catheters*
Performance Criteria: The balloon should deflate to no less than four French sizes of the labeled French size within 15 minutes or be otherwise manipulated to effect drainage within this time-period.
Performance Criteria Source: ASTM F623 *Standard Performance Specifications for Foley Catheters*
Submission Information: DoC

Sterilization (devices labeled as sterile) and Reprocessing (end-user sterilized) Validation

8. **Test name:** Sterilization (devices labeled as sterile) and Reprocessing (end-user sterilized)
Methodology: FDA currently-recognized version of the following consensus standards (as applicable):
   - International Organization for Standardization (ISO) 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*
   - ISO 11135-1 *Sterilization of health care products – Ethylene oxide- Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*
   - ISO 11137-1 *Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*
   - ISO 20857 *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

- ISO 11607-1 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- ISO 11607-2 *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*

Performance Criteria: Validation testing should demonstrate the cleanliness and sterility of, or the ability to clean and sterilize to a sterility assurance level of 10^{-6}, the device and device-specific instruments. You should provide a description of the packaging (sterile barrier system) and how it will maintain the device's sterility, and a description of the package test methods, but not package test data.

Performance Criteria Source: FDA's guidance:

- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile[8]
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling[9]

Submission Information: If using an Established Category A sterilization method, you should provide the information described in Section V.A. of the FDA guidance Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile; the validation data itself is not needed to demonstrate substantial equivalence.

Biocompatibility Evaluation

To identify the biocompatibility endpoints to include as part of your biocompatibility evaluation you should use Attachment A of CDRH's guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,[10] referred to in the rest of this document as the CDRH Biocompatibility Guidance for brevity. FDA considers the devices covered by this guidance to be categorized as "External Communicating Devices" with a "prolonged" tissue contact duration of >24 hours to 30 days and you should assess the endpoints below per Attachment A of the CDRH Biocompatibility Guidance.

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Sub-acute/Sub-chronic Toxicity
- Genotoxicity
- Implantation

[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled

[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling

[10] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and

Rationale in Lieu of Testing: If the subject device is manufactured from the identical raw materials using identical manufacturing processes as a predicate device with the same type and duration of tissue contact, and any changes in geometry are not expected to impact the biological response, this is typically sufficient to establish substantially equivalent biocompatibility, if documentation such as that outlined in Attachment F of the CDRH Biocompatibility Guidance is also provided.

Testing: If you determined that testing is needed to address some or all of the identified endpoints, FDA recommends that complete test reports be provided for all tests performed unless a declaration of conformity without supplemental information can be appropriately provided, per Attachment E of the CDRH Biocompatibility Guidance. Any test-specific positive, negative, and/or reagent controls should perform as expected, and protocol deviations should be thoroughly described and justified; however, note that certain protocol deviations may invalidate comparison to the performance criteria listed below and require submission of a Traditional, Special, or Abbreviated 510(k).

9. **Test name:** Biocompatibility endpoints (identified from CDRH Biocompatibility Guidance)
   Methodology: FDA currently-recognized versions of biocompatibility consensus standards
   Performance Criteria: All direct or indirect tissue contacting components of the device and device-specific instruments should be determined to have an acceptable biological response.
   Performance Criteria Source: The CDRH Biocompatibility Guidance
   Additional Considerations: For any biocompatibility test samples with an adverse biological response, the biocompatibility evaluation should explain why the level of toxicity seen is acceptable. Some comparison testing against a legally marketed predicate may be necessary (and is considered acceptable under the Safety and Performance Based Pathway) to support such a rationale as explained in the CDRH Biocompatibility Guidance. For standard biocompatibility test methods that include comparison device control samples, the legally marketed comparison device control samples should perform as expected, as specified above for the subject device samples.
   Submission Information: Refer to CDRH Biocompatibility Guidance