Facet Screw Systems – Performance Criteria for Safety and Performance Based Pathway

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions about this document, contact the OHT6: Office of Orthopedic Devices/DHT6B: Division of Spinal Devices at 301-796-5650.

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

Preface

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I. Introduction

This draft guidance provides performance criteria for facet screw systems in support of the Safety and Performance Based Pathway.[1] Under this framework, submitters (you)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Performance Based Pathway for facet screw systems will have the option to use the performance criteria proposed in this draft guidance to support substantial equivalence, rather than a direct comparison of the performance of the subject device to that of a predicate device.

For the current edition of the FDA-recognized consensus 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]

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended

[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

only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are 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 facet screw systems that are the subject of this guidance consist of metallic bone screws and optional washer components. These devices are unclassified and are identified with the product code MRW (system, facet screw spinal device).

Intended Use/Indications for Use:
The facet screw systems that fall within the scope of this guidance document are intended for bilateral immobilization of facet joints to stabilize the spine as an aid to fusion. The optional washer components are intended for use with the facet screw to aid in load distribution at the screw head/bone interface.

Device Design Characteristics:
The facet screw systems that fall within the scope of this guidance document consist of solid or cannulated screws with fully or partially threaded screw shafts, and optional washer components, constructed solely from the following material in conformance with the associated FDA-recognized consensus standard:

- ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*

A dimensional comparison of the subject device should be performed, and the dimensions should fall within the dimensional ranges listed in Table 1. Washer components should have an inner diameter that is larger than the thread diameter (major diameter) of the compatible screw and less than the diameter of the screw head.

Note: Based on review of historical submissions, screws below 4.5 mm in diameter and screws 4.5 mm and above were often indicated for different anatomical regions and have different design characteristics and different performance characteristics. Therefore, screw design characteristics and performance criteria are stratified in this document based on these diameter ranges.

Table 1 – Dimensional ranges for facet screws*

Facet Screws Parameters	< 4.5 mm Diameter	≥ 4.5 mm Diameter
Nominal Major Diameter Range	3.5-4.3 mm	4.5-6.0 mm
Minimum Total Screw Length**	6.0 mm	15 mm
Minimum Threaded Length	6.0 mm	12 mm

* The dimensional ranges listed were derived from historical data submitted to FDA in 510(k) submissions for devices previously found substantially equivalent.
** The maximum facet screw length reported in the historical data was 60 mm. However, maximum screw length can be justified based on the anatomic region into which the subject facet screws are intended to be implanted.

Facet screw systems that fall within the following categories are not eligible for the Safety and Performance Based Pathway via this guidance:

- Combination products
- Resorbable devices
- Device with coatings
- Additively manufactured devices
- Devices that utilize surgical techniques or associated instruments outside the standard of care
- Devices with complex geometries, or unique technological characteristics (e.g., unique screw thread, modularity, fenestrations)

FDA may determine, on a case-by-case basis, that additional data are necessary to evaluate whether 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[4] 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 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 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. 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

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

guidance: Safety and Performance Based Pathway.[5] 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.[6]

Mechanical Testing

To assess mechanical strength of the worst-case facet screw(s) in the system, static cantilever bending testing should be performed on your final, finished device in conformance with the FDA currently-recognized version of ASTM F2193 *Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System*-Annex 4: *Test Method for Measuring the static and fatigue bending strength of metallic spinal screws*. To assess screw fixation, axial pullout strength should be evaluated using the engineering analysis method described below.[7] Mechanical testing and engineering analyses should be performed on devices that represent the worst-case (e.g., most likely to loosen or fail). You should also provide a rationale identifying how you identified the worst-case design for each test/evaluation. All mechanical testing should be performed on the final, finished versions of the devices unless certain processes (e.g., sterilization) can be rationalized to have no impact on the mechanical strength of the device. Acceptance criteria are listed below for each test.

For the mechanical test below, you should provide a report as specified in the relevant reporting section of ASTM F2193, in addition to a Declaration of Conformity (DoC) to the consensus standard. Any protocol deviations should be thoroughly described and justified; however, note that certain protocol deviations may invalidate comparison to the performance criteria listed below, resulting in the need for submission of a Traditional, Special, or Abbreviated 510(k), as appropriate.

1. **Test name:** Static Cantilever Bending
   Methodology: ASTM F2193 *Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System*-Annex 4: *Test Method for Measuring the static and fatigue bending strength of metallic spinal screws*
   Performance Criteria:

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

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

[7] It should be noted that although ASTM F2193 is FDA-recognized in full, FDA believes that for the purposes of the Safety and Performance Based Pathway, the testing, methods and criteria identified in this section on mechanical bench testing represent the least burdensome approach to demonstrating substantial equivalence for this pathway, although alternative or additional methods or acceptance criteria are identified in the recognized consensus standard for some tests.

Table 2 – Static cantilever bending acceptance criteria for facet screw systems

Test Parameter	< 4.5 mm diameter (Cervical)	≥ 4.5 mm diameter (Lower Thoracic/Lumbar)
Static Cantilever Bending Yield Moment (Nm)	2.6	3.7

Performance Criteria Source: Criteria are based on aggregated mechanical testing data submitted to FDA in 510(k) submissions for facet screw systems previously found to be substantially equivalent. It should be noted that the values in the table above were rounded to be the most inclusive and accurate based on the final data.
Additional Considerations: As specified in ASTM F2193, a minimum of five samples should be tested. In order to be considered a successful result, either: (1) all samples should meet or exceed the acceptance criteria listed above, or (2) the average of all samples should meet or exceed the criteria above and the standard deviation should be ≤ 10% of the calculated average.
Submission Information: Results summary and DoC

2. **Test name:** Axial Pullout Strength
Methodology: An engineering analysis is recommended to assess axial pullout strength using the equation described by Chapman et al., 1996.[8] Note that for this analysis to be appropriate, the instrumentation identified in the associated surgical technique manual should allow for close to idealized thread engagement. If this assumption is not accurate for your scenario, then the identified engineering analysis may not be appropriate for the assessment of the proposed device as identified in this guidance.

For all facet screw sizes, extract the relevant dimensions below (i.e., screw major diameter, screw minor diameter, screw pitch, and axial thread length). These dimensions will be used to calculate theoretical pullout strengths for the worst-case screws in the device system using the following equation:

$$Fs = S * A = \{S * L * \pi * Dmajor * TSF\}$$

Fs = predicted shear failure force (N)
S = material ultimate shear stress (MPa)
A = thread shear area (mm^2)

[8] Chapman, J. R. (1996). Factors Affecting the Pullout Strength of Cancellous Bone Screws. Journal of Biomechanical Engineering,118(3), 391. doi:10.1115/1.2796022

L = axial thread length (mm) including only threads that have the nominal major diameter where complete purchase is expected (e.g., excluding the screw tip) of thread engagement in material
Dmajor = major diameter (mm)
TSF = Thread Shape Factor (dimensionless) = (0.5 + 0.57735 d/p)
d = thread depth (mm) = (Dmajor – Dminor)/2
Dminor = minor (root) diameter (mm)
p = thread pitch (mm)

Use a material ultimate shear stress (S) value of 3.395 MPa, which is representative of Grade 20 polyurethane foam material (per FDA currently-recognized version of ASTM F1839 *Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments*). The resulting theoretical pullout strength value obtained for the device should be equivalent or greater to the following values depending on the nominal major diameter of the worst-case screws. A justification should be provided to support why the evaluated facet screws selected are worst-case. Axial pullout performance is heavily influenced by amount of interface. Factors such as decreasing outer diameter and decreasing axial thread length may help identify the worst-case.

Dimensions used for calculations should be clearly listed for each theoretical outcome. Dimensional values used in this calculation should be consistent with the values listed on the screw engineering drawings.

Performance Criteria: The resulting theoretical pullout strength values obtained for your worst-case devices should meet or exceed to the values listed in Table 3 depending on the major diameter of the screw being evaluated.

Table 3 – Axial pullout strength acceptance criteria for facet screw systems

Nominal Major Diameter (mm)	Theoretical Pullout Strength in Grade 20 Foam (N)
< 4.5 mm	190
≥ 4.5 mm	390

Performance Criteria Source: Criteria are based on aggregated mechanical testing data and device description information submitted to FDA in 510(k) submissions for facet screws previously found to be substantial equivalent.
Submission Information: Results summary and engineering analysis

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

3. **Test name:** Sterilization (devices labeled as sterile) and Reprocessing (end-user sterilized)
Methodology: FDA currently-recognized versions 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 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 guidance:
    - Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile[9]
    - Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling[10]

    Submission Information: If using an Established Category A sterilization method, you should provide the information described in Section V.A. as specified in the FDA guidance Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile[11]; 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 the Center for Devices and Radiological Health's (CDRH) guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices –

[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled
[10] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling
[11] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled

Part 1: Evaluation and testing within a risk management process,[12] 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 Implanted Devices in contact with tissue/bone with a "permanent" contact duration of > 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
- Chronic Toxicity
- Carcinogenicity

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: In rare cases, if you determined that testing is needed to address some or all of the identified biocompatibility 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, resulting in the need for submission of a Traditional, Special, or Abbreviated 510(k).

4. **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

[12] 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

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