



Standard Guide for Mechanical and Functional Characterization of Nucleus Devices¹

This standard is issued under the fixed designation F2789; 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 guide describes various forms of nucleus replacement and nucleus augmentation devices. It further outlines the types of testing that are recommended in evaluating the performance of these devices.

1.2 Biocompatibility of the materials used in a nucleus replacement device is not addressed in this guide. However, users should investigate the biocompatibility of their device separately (see [X1.1](#)).

1.3 While it is understood that expulsion and endplate fractures represent documented clinical failures, this guide does not specifically address them, although some of the factors that relate to expulsion have been included (see [X1.3](#)).

1.4 Multiple tests are described in this guide; however, the user need not use them all. It is the responsibility of the user of this guide to determine which tests are appropriate for the devices being tested and their potential application. Some tests may not be applicable for all types of devices. Moreover, some nucleus devices may not be stable in all test configurations. However, this does not necessarily mean that the test methods described are unsuitable.

1.5 The science of nucleus device design is still very young and includes technology that is changing more quickly than this guide can be modified. Therefore, the user must carefully consider the applicability of this guide to the user's particular device; the guide may not be appropriate for every device. For example, at the time of publication, this guide does not address the nucleus replacement and nucleus augmentation devices that are designed to be partially or completely resorbable in the body. However, some of the test recommended in this guide may be applicable to evaluate such devices. It has not been demonstrated that mechanical failure of nucleus devices is related to adverse clinical results. Therefore this standard should be used with care in evaluating proposed nucleus devices.

1.6 This guide is not intended to be a performance standard. It is the responsibility of the user of this guide to characterize the safety and effectiveness of the nucleus device under evaluation.

1.7 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard. Angular measurements may be reported in either degrees or radians.

1.8 *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.*

2. Referenced Documents

2.1 ASTM Standards:²

- [D2990](#) Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics
- [D6204](#) Test Method for Rubber—Measurement of Unvulcanized Rheological Properties Using Rotorless Shear Rheometers
- [E6](#) Terminology Relating to Methods of Mechanical Testing
- [E111](#) Test Method for Young's Modulus, Tangent Modulus, and Chord Modulus
- [E132](#) Test Method for Poisson's Ratio at Room Temperature
- [E328](#) Test Methods for Stress Relaxation for Materials and Structures
- [E1823](#) Terminology Relating to Fatigue and Fracture Testing
- [F561](#) Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids
- [F1582](#) Terminology Relating to Spinal Implants
- [F1714](#) Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices
- [F1877](#) Practice for Characterization of Particles
- [F1980](#) Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- [F2267](#) Test Method for Measuring Load Induced Subsidence

¹ This test method is under the jurisdiction of ASTM Committee [F04](#) on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee [F04.25](#) on Spinal Devices.

Current edition approved May 1, 2015. Published July 2015. Originally approved in 2010. Last previous edition approved in 2010 as F2789 – 10. DOI: 10.1520/F2789-10R15.

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.