



Standard Guide for *in vivo* Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage¹

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1. Scope

1.1 This guide covers general guidelines for the *in vivo* assessment of implantable devices intended to repair or regenerate articular cartilage. Devices included in this guide may be composed of natural or synthetic biomaterials (biocompatible and biodegradable) or composites thereof and may contain cells or biologically active agents such as growth factors, synthetic peptides, plasmids, or cDNA.

1.2 Guidelines include a description and rationale of various animal models utilizing a range of species such as rabbit (lupine), dog (canine), pig (porcine), goat (caprine), sheep (ovine), and horse (equine). Outcome measures based on histologic, biochemical, and mechanical analyses are briefly described and referenced. The user should refer to specific test methods for additional detail.

1.3 This guide is not intended to include the testing of raw materials, preparation of biomaterials, sterilization, or packaging of product. ASTM standards for these steps are available in Reference Documents.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *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 requirements prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

F561 Practice for Retrieval and Analysis of Medical

Devices, and Associated Tissues and Fluids

F565 Practice for Care and Handling of Orthopedic Implants and Instruments

F895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

F1983 Practice for Assessment of Compatibility of Absorbable/Resorbable Biomaterials for Implant Applications

F2150 Guide for Characterization and Testing of Biomaterial Scaffolds Used in Tissue-Engineered Medical Products

2.2 Other Documents:

ISO-10993 Biological Evaluation of Medical Devices—Part 5: Tests for *in vitro* Cytotoxicity³

21 CFR Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies⁴

3. Terminology

3.1 Definitions:

3.1.1 *cartilage regeneration*—the formation of articular-like cartilage that has histologic, biochemical, and mechanical properties similar to that of native articular cartilage (**1**, **2**).⁵

3.1.2 *cartilage repair*—the process of healing injured cartilage or its replacement through cell proliferation and synthesis of new extracellular matrix (**1**, **2**).

3.1.3 *compact bone*—classification of ossified bony connective tissue characterized by the presence of osteons containing lamellar bone.

3.1.4 *femoral condyles*—the anatomic site corresponding to the distal end of the femur characterized by medial and lateral convex surfaces that are lined by cartilage and articulate with the proximal tibia and medial and lateral menisci.

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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.

⁴ Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.

⁵ The boldface numbers in parentheses refer to the list of references at the end of this standard.