



Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone¹

This standard is issued under the fixed designation F 981; 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 practice provides a series of experimental protocols for biological assays of tissue reaction to nonabsorbable biomaterials for surgical implants. It assesses the effects of the material on animal tissue in which it is implanted. The experimental protocol is not designed to provide a comprehensive assessment of the systemic toxicity, immune response, carcinogenicity, teratogenicity, or mutagenicity of the material since other standards deal with these issues. It applies only to materials with projected applications in humans where the materials will reside in bone or soft tissue in excess of 30 days and will remain unabsorbed. It is recommended that short-term assays, according to Practice F 763, first be performed. Applications in other organ systems or tissues may be inappropriate and are therefore excluded. Control materials will consist of any one of the metal alloys in Specifications F 67, F 75, F 90, F 136, F 138, or F 562, high purity dense aluminum oxide as described in Specification F 603, ultra high molecular weight polyethylene as stated in Specification F 648 or USP polyethylene negative control.

1.2 This practice is a combination of Practice F 361 – 80 and Practice F 469 – 78. The purpose, basic procedure, and method of evaluation of each type of material are similar; therefore, they have been combined.

1.3 *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

F 67 Specification for Unalloyed Titanium for Surgical

Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F 75 Specification for Cobalt-28Chromium-6Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F 90 Specification for Wrought Cobalt20-Chromium15-Tungsten10-Nickel Alloy for Surgical Implant Applications (UNS R30605)

F 136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

F 138 Specification for Wrought-18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F 361 Practice for Assessment of Compatibility of Metallic Materials for Surgical Implants with Respect to Effect of Materials on Tissue³

F 469 Practice for Assessment of Compatibility of Nonporous Polymeric Materials for Surgical Implants with Regard to Effect of Materials on Tissue³

F 562 Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)

F 603 Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

F 763 Practice for Short-Term Screening of Implant Materials

3. Summary of Practice

3.1 This practice describes the preparation of implants, the number of implants and test hosts, test sites, exposure schedule, implant sterilization techniques, and methods of implant retrieval and tissue examination of each test site. Histological criteria for evaluating tissue reaction are provided.

¹ This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.16 on Biocompatibility Test Methods.

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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 Withdrawn.