



Designation: F 763 – 99 (Reapproved 2003)

Standard Practice for Short-Term Screening of Implant Materials¹

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1. Scope

1.1 This practice provides guidelines for short-term testing or screening of candidate materials, both porous and dense, as to the effects of the material on animal tissue in which it is implanted. This is a rapid screening procedure for determining acceptability of candidate materials.

1.2 This practice, along with other appropriate biological tests (including other appropriate ASTM tests) may be used in the biocompatibility assessment of the candidate materials for use in the fabrication of devices for clinical application.

1.3 This experimental protocol is not designed to provide a comprehensive assessment of the systemic toxicity, carcinogenicity, teratogenicity, or mutagenicity of the material since other standards deal with these issues.

1.4 This practice is one of several developed for the assessment of the biocompatibility of materials. Practice F 748 provides guidance for the selection of appropriate methods for testing materials for a specific application.

2. Referenced Documents

2.1 ASTM Standards:²

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 Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

F 136 Specification for Wrought Titanium-6Aluminum-4Vanadium 4V 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 562 Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)

F 563 Specification for Wrought Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563)

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 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

3. Terminology

3.1 Description of a Term Specific to this Standard:

3.1.1 *biocompatibility assay*—a comparison of the tissue response produced through the close association of the implanted candidate material to its implant site within the host animal to that tissue response recognized and established as suitable with control materials.

4. Summary of Practice

4.1 Under aseptic conditions, test specimens of the candidate material and of controls are inserted into a muscle or group of muscles of the animal host. After a period of time the animals are euthanized. The tissue reactions to implants of the candidate material during the acute to subchronic time period of healing are compared with tissue reactions to control materials which have a well characterized response. The implants are not subject to major stress while *in situ*.

5. Significance and Use

5.1 The use of *in vivo* implantation techniques for characterizing the biocompatibility of materials to be utilized in various medical applications provides a unique assessment of such materials not achieved by other procedures. Physical characteristics (that is, form, density, hardness, surface finish) can influence the character of the tissue response to the test materials.

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.