



Practice for Retrieval and Analysis of Implanted Medical Devices, and Associated Tissues¹

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1. Scope

1.1 This practice covers recommendations for the retrieval, handling, and analysis of implantable medical devices and associated specimens which are removed from patients, during revision surgery, at postmortem, or as part of animal studies. The aim is to provide guidance in preventing damage to the associated specimens which could obscure the investigational results, and in gathering data at the proper time and circumstance to validate the study.

1.2 This practice offers guidelines for the analysis of retrieved implants to limit damage to them, and to allow comparisons between investigational results from different studies. The protocols are divided into three stages, where Stage I is the minimum non-destructive analysis, Stage II is more complete non-destructive analysis, and Stage III is destructive analysis. Standard protocols for the examination and collection of data are provided for specific types of materials in relation to their typical applications. For particular investigational programs, additional, more specific, protocols may be required. If special analytical techniques are employed, the appropriate handling procedures must be specified.

1.3 This practice recommendation should be applied in accordance with national regulations or legal requirements regarding the handling and analysis of retrieved implants and excised tissues, especially with regard to handling devices which may become involved in litigation, as per Practice E 860.

1.4 A significant portion of the information associated with a retrieved implant device is often at the device-tissue interface or in the tissues associated with the implant and related organ systems. Attention should be given to the handling of adjacent tissues, so as not to interfere with study of the particles in the adjacent tissue, a chemical analysis for the byproducts of degradation of the implant, or a study of the cellular response to the implant.

1.5 *This standard may involve hazardous materials, operations, and equipment. As a precautionary measure, removed implants should be sterilized or minimally disinfected by an*

appropriate means that does not adversely affect the implant or the associated tissue that may be subject to subsequent analysis. 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:

- A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels²
- A 751 Test Methods, Practices and Terminology for Chemical Analysis of Steel Products²
- C 20 Test Methods for Apparent Porosity, Water Absorption, Apparent Specific Gravity and Bulk Density of Burned Refractory Brick and Shapes by Boiling Water³
- C 158 Test Methods for Strength of Glass (Determination of Modulus of Rupture)⁴
- C 169 Test Methods for Chemical Analysis of Soda-Lime and Borosilicate Glass⁴
- C 573 Test Methods for Chemical Analysis of Fireclay and High-Alumina Refractories⁵
- C 623 Test Method for Young's Modulus, Shear Modulus, and Poisson's ratio for Glass and Glass-Ceramics by Resonance⁴
- C 633 Test Method for Adhesion or Cohesive Strength of Flame-Sprayed Coatings⁶
- C 674 Test Methods for Flexural Properties of Ceramic White Ware Materials⁴
- C 730 Test Method for Knoop Indentation Hardness of Glass⁴
- C 849 Test Method for Knoop Indentation Hardness of Ceramic Whitewares⁴
- C 1069 Test Method for Specific Surface Area of Alumina or Quartz by Nitrogen Adsorption⁴
- C 1161 Test Method for Flexural Strength—Advanced Ceramics at Ambient Temperatures³
- C 1198 Test Method for Dynamic Young's Modulus, Shear

¹ This practice is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices, and is the direct responsibility of Subcommittee F04.18 on Device Retrieval Analysis.

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² *Annual Book of ASTM Standards*, Vol 01.03.

³ *Annual Book of ASTM Standards*, Vol 15.01.

⁴ *Annual Book of ASTM Standards*, Vol 15.02.

⁵ Discontinued—See 1994 *Annual Book of ASTM Standards*, Vol 03.05.

⁶ *Annual Book of ASTM Standards*, Vol 02.05.