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Standard Guide for Accelerated Aging of Ultra-High Molecular Weight Polyethylene[1]

This standard is issued under the fixed designation F 2003; 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 It is the intent of this guide to permit an investigator to investigate the oxidative stability of ultra-high molecular weight polyethylene (UHMWPE) materials as a function of processing and sterilization method. This guide describes a laboratory test method for accelerated aging of UHMWPE specimens and components for total joint prostheses. The UHMWPE is aged at elevated temperatures and, alternatively, at elevated partial pressures of oxygen, to accelerate oxidation of the material and thereby allow for the evaluation of its long-term chemical and mechanical stability.

1.2 Although the accelerated-aging test methods described by this guide will permit an investigator to compare the oxidative stability of UHMWPE, it is recognized that these test methods may not precisely simulate the degradative mechanisms for an implant during real-time shelf aging and implantation. However, these accelerated oxidation methods have been successfully used to rank UHMWPE materials for their long-term oxidative stability.

1.3 The accelerated aging test methods specified herein have been validated based on oxidation levels exhibited by certain shelf-aged UHMWPE components packaged in air and sterilized with gamma radiation. The methods have not been shown to be representative of shelf aging when the UHMWPE is packaged in an environment other than air. For example, these test methods have not been directly correlated with the shelf life of components that have been sealed in a low-oxygen package, such as nitrogen.

1.4 *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:*

D 883 Terminology Relating to Plastics[2]

F 648 Specification of Ultra-High Molecular-Weight Polyethylene Powder and Fabricated Form Surgical Implants[3]

F 1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices[3]

F 1715 Guide for Gravimetric Wear Assessment of Prosthetic Knee-Designs in Simulator Devices[3]

2.2 *ISO Standards:*

ISO 5834 Implants for surgery—Ultra-high molecular weight polyethylene[4]

ISO 14242 Implants for surgery—Wear of total hip joint prostheses[4]

ISO 14243 Implants for surgery—Wear of total knee joint prostheses[4]

3. Terminology

3.1 *Definitions*—For definitions of terms in this guide relating to plastics, refer to Terminology D 883. For definitions of terms in this guide relating to UHMWPE, refer to Specification F 648 and ISO 5834.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *oxidation, n*—the incorporation of oxygen into another molecule (for example, UHMWPE) by means of a chemical covalent bond.

3.2.2 *oxygen bomb, n*—a pressure vessel suitable for preconditioning of UHMWPE at an elevated temperature and partial pressure of oxygen.

4. Significance and Use

4.1 This guide summarizes test methods that may be used to accelerate the oxidation of UHMWPE components using elevated temperatures and, alternatively, elevated partial pressures of oxygen. Under real-time conditions, such as shelf aging and implantation, oxidative changes to UHMWPE after sterilization using high energy radiation may take months or years to produce changes that may result in deleterious mechanical performance. The test methods outlined in this guide permit the evaluation of oxidative stability in a relatively short period of time (for example, weeks).

4.2 This guide may also be used to precondition UHMWPE test specimens and joint replacement components prior to characterization of their physical, chemical, and mechanical

[1] This guide is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Test Material Methods.

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[2] *Annual Book of ASTM Standards*, Vol 08.01.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

[4] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.