



Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air¹

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1. Scope

1.1 It is the intent of this practice to permit an investigator to evaluate the oxidative stability of UHMWPE materials as a function of processing and sterilization method. This practice describes a laboratory procedure for accelerated aging of ultra-high molecular weight polyethylene (UHMWPE) specimens and components for total joint prostheses. The UHMWPE is aged at elevated temperature and at elevated oxygen pressure, 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 method described by this practice will permit an investigator to compare the oxidative stability of different UHMWPE materials, it is recognized that this method may not precisely simulate the degradative mechanisms for an implant during real-time shelf aging and implantation.

1.3 The accelerated aging method specified herein has been validated based on oxidation levels exhibited by certain shelf-aged UHMWPE components packaged in air and sterilized with gamma radiation. The method has not been shown to be representative of shelf aging when the UHMWPE is packaged in an environment other than air. For example, this practice has not been directly correlated with the shelf life of components that have been sealed in a low-oxygen package, such as nitrogen. This practice is not intended to simulate any change that may occur in UHMWPE following implantation.

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 Plastics²

F 648 Specification of Ultra-High Molecular-Weight Polyethylene Powder and Fabricated Form Surgical Implants³
F 1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices³
F 1715 Guide for Gravimetric Wear Assessment of Prosthetic Knee-Designs in Simulator Devices³

2.2 ISO Standards:

ISO 5834 Implants for surgery—Ultra-high molecular weight polyethylene⁴
ISO 14242 Implants for surgery—Wear of total hip joint prostheses⁴
ISO 14243 Implants for surgery—Wear of total knee joint prostheses⁴

3. Terminology

3.1 *Definitions*—For definitions of terms in this practice relating to plastics, refer to Terminology D 883. For definitions of terms in this practice 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 reaction, resulting in the formation of a chemical covalent bond.

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

4. Significance and Use

4.1 This practice summarizes a method that may be used to accelerate the oxidation of UHMWPE components using elevated temperature and elevated oxygen pressure. 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

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 F04.15 on Material Test 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 (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.