



Designation: F 2003 – 002

Standard Guide 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 guide practice to permit an investigator to ~~investigate~~ evaluate the oxidative stability of ~~ultra-high molecular weight polyethylene (UHMWPE)~~ UHMWPE materials as a function of processing and sterilization method. This ~~guide practice~~ describes a laboratory ~~test method~~ procedure for accelerated aging of ultra-high molecular weight polyethylene (UHMWPE) specimens and components for total joint prostheses. The UHMWPE is aged at elevated ~~temperatures and, alternatively, temperature and at elevated partial pressures of oxygen, 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 ~~test methods~~ method described by this guide practice will permit an investigator to compare the oxidative stability of different UHMWPE materials, it is recognized that ~~these test methods~~ this method 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.~~ implantation.

1.3 The accelerated aging ~~test methods~~ method specified herein ~~have~~ has been validated based on oxidation levels exhibited by certain shelf-aged UHMWPE components packaged in air and sterilized with gamma radiation. ~~The methods have~~ method has 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~~ 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

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

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