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Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications¹

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1. Scope

1.1 This specification covers ultra-high molecular weight polyethylene (UHMWPE) powder blended with alpha-tocopherol (vitamin E) intended for use in surgical implants.

1.2 The requirements of this specification apply to alpha-tocopherol-containing UHMWPE in two forms. One is virgin polymer powder blended with alpha-tocopherol prior to consolidation (Section 4). The second is any form fabricated from this blended, alpha-tocopherol-containing powder from which a finished product is subsequently produced (Section 5). This specification does not apply to finished or semi-finished products that are doped with vitamin E after consolidation.

1.3 Aside from blending with alpha-tocopherol, the provisions of Specifications F648 and D4020 apply. Special requirements detailed in this specification are added to describe powders containing alpha-tocopherol that will be used in surgical implants. This specification addresses material characteristics and does not apply to the packaged and sterilized finished implant. This specification also does not apply to UHMWPE materials extensively crosslinked by gamma and electron beam sources of ionizing radiation.

1.4 The following precautionary caveat pertains only to the fabricated forms portion, Section 5, of this specification. *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:²

D648 Test Method for Deflection Temperature of Plastics Under Flexural Load in the Edgewise Position

D790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials

D1898 Practice for Sampling of Plastics

D4020 Specification for Ultra-High-Molecular-Weight Polyethylene Molding and Extrusion Materials ~~astm-f2695-12~~

F619 Practice for Extraction of Medical Plastics

F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F749 Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit

F756 Practice for Assessment of Hemolytic Properties of Materials

F763 Practice for Short-Term Screening of Implant Materials

F813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices

F895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

2.2 ISO Standards:

ISO 3451-1/ISO 3451-1 Plastics—Determination of Ash, Part 1: General Methods³

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

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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.

³ Withdrawn.

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *crosslinking*—the process by which ionizing irradiation produces chemical bonds between two UHMWPE molecules.

3.1.2 *extensively crosslinked UHMWPE*—UHMWPE material that has been subjected to total doses of gamma and/or electron beam ionizing irradiation greater than 40 kGy.

3.1.3 *fabricated form*—any bulk shape of UHMWPE, fabricated from the virgin polymer powder, used during the process of fabricating surgical implants prior to crosslinking, packaging, and sterilization. A fabricated form includes a semi-finished rod or sheet as well as a direct compression molded component.

3.1.4 *generic property*—that property which is determined solely by the chemical composition and structure of the virgin polymer.

3.1.5 *ionizing irradiation*—gamma ray or high energy electron irradiation sources.

3.1.6 *virgin polymer powder*—~~the form of UHMWPE as obtained from the powder manufacturer and prior to fabrication into a bulk shape.~~—the initially delivered form of the polymer as synthesized from its monomers prior to any processing or fabrication into a medical device. The provided resin is typically in the form of pellets, granules, or powder and is the material from which fibers, tubes, rods, slabs, sheets, films, or specific parts and devices are fabricated. Specifically, it is the form of UHMWPE as obtained from the powder manufacturer and prior to blending and fabrication into a bulk shape.

4. Alpha-Tocopherol-Blended UHMWPE Powder Requirements

4.1 Generic Properties:

4.1.1 The virgin polymer shall be a homopolymer of ethylene in accordance with Specification D4020.

4.1.2 The resin type and solution viscosity number requirements are listed in Table 1 of Specification F648.

4.1.3 To promote uniformity between different lots of the virgin polymer powder, concentration limits for trace elements have been established and are listed in Table 1 of Specification F648.

4.1.4 When determined as described in ISO 3451–1, the mean ash of duplicate samples shall not exceed the limits established in Table 1 of Specification F648.

4.2 Nongeneric Properties:

4.2.1 ~~When a 300 g sample is prepared and viewed in accordance with section 7.1.2 of Specification F648, there shall be no more particles of extraneous matter than that specified in Table 1 of Specification F648.~~

4.2.2 ~~To promote uniformity between different lots of polymer powder, concentration limits for trace elements have been established and are listed in Table 1 of Specification~~

4.2.1 When a 300 g sample is prepared and viewed in accordance with section 7.1.2 of Specification F648:

4.2.3 ~~When determined as described in ISO 3451-1, the mean ash of duplicate samples shall not exceed the limits established in Table 1 of Specification~~, there shall be no more particles of extraneous matter than that specified in Table 1 of Specification F648.

4.3 Compositional Requirements :

4.3.1 Only alpha-tocopherol (certified pharmaceutical grade) is to be blended with the virgin polymer powder.

4.3.1.1 The alpha-tocopherol content in the blended powder may be based on agreement between the vendor and purchaser.

4.3.1.2 When measured based on agreement between the vendor and purchaser, the alpha-tocopherol content added to the powder shall be reported in units of ppm and percent mass.

4.3.1.3 Uniformity of the alpha-tocopherol in the blended powder will be measured based on agreement between the vendor and the purchaser.

4.3.1.4 No other stabilizers or processing aids are to be added to the virgin polymer powder.

5. Alpha-Tocopherol-Blended UHMWPE Fabricated Form Requirements

5.1 Compositional Requirements :

5.1.1 Only alpha-tocopherol-blended powder, specified in Section 4, is to be used to produce the fabricated form.

5.1.1.1 The alpha-tocopherol content in the fabricated form may be based on agreement between the vendor and purchaser.

5.1.1.2 When measured based on agreement between the vendor and purchaser, the alpha-tocopherol content used to produce the fabricated form shall be reported in units of ppm and percent mass.

5.1.2 Uniformity of the alpha-tocopherol in the fabricated form shall be measured based on agreement between the vendor and the purchaser.

5.1.3 No other stabilizers or processing aids are to be added to the alpha-tocopherol-blended polymer powder during manufacture of the fabricated form.

5.2 Physical Requirements:

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.