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StandardSpecification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns[1]

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1. Scope

1.1 This specification covers ultra-high molecular weight polyethylene (UHMWPE) yarns intended for use in medical devices or components of medical devices, such as sutures and ligament fixations.

1.2 This standard is intended to describe the required properties and the procedures to be followed for testing UHMWPE yarns as raw materials for medical devices. This specification does not purport to address the testing that is needed for medical devices or components of medical devices that are fabricated from the raw materials specified herein.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 The following precautionary caveat pertains only to the test method portion, Section 6, 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]

D792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement

D885 Test Methods for Tire Cords, Tire Cord Fabrics, and Industrial Filament Yarns Made from Manufactured Organic-Base Fibers

D1907 Test Method for Linear Density of Yarn (Yarn Number) by the Skein Method

D2256 Test Method for Tensile Properties of Yarns by the Single-Strand Method

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

2.2 *ISO Standards:*[3]

ISO 1628-3 Plastics—Determination of the Viscosity of Polymers in Dilute Solution Using Capillary Viscometers—Part 3: Polyethylenes and Polypropylenes

ISO 2062 Textiles—Yarns from Packages—Determination of Single-end Breaking Force and Elongation at Break

ISO 10993 Biological Evaluation of Medical Devices

2.3 *Other Documents:*

ICH Q3C(R3) International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Quality Guideline: Impurities: Residual Solvents[4]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *UHMWPE filament*—molecularly oriented highly crystalline fiber spun from virgin UHMWPE polymer powder.

3.1.2 *UHMWPE yarn*—a continuous strand of more than one UHMWPE filaments in a form suitable for operations such as weaving, knitting, etc., prior to packaging and sterilization.

3.1.3 *linear density*—mass per length, expressed in dtex (mass in grams per 10 000 metres).

3.1.3.1 *Discussion*—Tex is a unit of measure for the linear mass density of yarns and is defined as the mass in g/1000 m. Because of the low mass of yarns used in medical applications, decitex (abbreviated as dtex) is more commonly used, and is mass in g/10 000 m. Another related unit of measure for the linear mass density is denier, which is defined as g/9000 m.

[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] Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland, http://www.iso.ch.

[4] Available from International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), ICH Secretariat, c/o IFPMA, 15 ch. Louis-Dunant, P.O. Box 195, 1211 Geneva 20, Switzerland, http://www.ich.org.

3.1.4 *production liquid*—any liquid(s) used in the production of the filaments and yarns, such as solvents and extraction solutions.

4. UHMWPE Filament and Yarn Requirements

4.1 *Compositional Requirements:*

4.1.1 Current yarns used for medical application with clinical history are produced with decalin as solvent. The maximum decalin residual level is 100 mg/kg (see 6.1).

4.1.2 In case other production liquids are used, the acceptable residual levels of these particular production liquid(s) shall be reflective of toxicity, with a maximum acceptable limit consistent with ICH Q3C(R3). If no ICH concentration guideline has been established for a utilized production liquid, proof of biocompatibility has to be given.

4.1.3 To promote consistency in production and pureness of the yarn, concentration limits for trace elements have been established and are listed in Table 1.

4.2 *Physical Requirements:*

4.2.1 The density of the yarn shall comply with the requirement listed in Table 1.

4.2.2 The linear density requirement of single filaments is listed in Table 1.

4.2.3 The intrinsic viscosity requirement for the UHMWPE yarn is listed in Table 1.

4.3 *Mechanical Requirements:*

4.3.1 UHMWPE yarns shall meet the tensile requirements on strength, modulus and elongation-at-break as listed in Table 1. Note that tensile properties of the final medical device depend on the construction of yarns used therein.

4.4 *Biocompatibility Requirements:*

4.4.1 The UHMWPE yarn shall be biocompatible. While the biocompatibility of UHMWPE powder and fibers has been characterized **(1-8)**,[5] this data cannot be assumed to be appropriate for all uses of UHMWPE. When new applications of the material, or modification to the material or physical forms of the materials are being contemplated, biological testing shall be selected and conducted in accordance with Practice F748 or ISO 10993, depending on the available published biocompatibility data and the end-use application.

[5] The boldface numbers in parentheses refer to a list of references at the end of this standard.

5. Sampling

5.1 Compliance with this specification shall be determined by sampling sizes and procedures as agreed upon between the purchaser and seller.

6. Test Methods

6.1 Residual production liquids shall be determined by gas chromatography or other suitable, validated analytical methods for the specific materials used to produce the yarn.

6.2 Determine the trace element concentrations of titanium, sodium, chromium, iron, and calcium by a validated analytical method, such as neutron activation analysis (NAA), inductively coupled plasma spectroscopy (ICP), atomic absorption (AA), or X-ray fluorescence (XRF).

6.3 Determine filament linear density by dividing the yarn linear density, measured according to Test Method D1907, by the number of filaments in the yarn.

6.4 The intrinsic viscosity shall be measured according to ISO 1628-3, but in the case of incomplete dissolution of the polymer, longer dissolution times and/or lower dissolution temperatures can be applied.

6.5 Determine tensile strength, tensile modulus and elongation-at-break as the average of 15 samples tested according to the following test conditions, derived from Test Methods D885, Test Method D2256, and ISO 2062, and optimized for UHMWPE yarns:

6.5.1 *Test Conditions:*

6.5.1.1 Temperature shall be 21 ± 1°C, at a relative humidity between 40 and 75 %.

6.5.1.2 Twisting level shall be according to product specifications, and any change in twist shall be avoided.

6.5.1.3 Touching of the test specimen with bare hands shall be avoided.

6.5.1.4 Special care shall be taken to avoid slippage of the yarn in the clamps (see Appendix X2).

6.5.1.5 A load cell with an accuracy of at least ±1 % at the anticipated breaking force of the yarn shall be used.

6.5.1.6 Gauge length shall be 500 mm.

6.5.1.7 A pre-tension (in Newton) of 0.2 % of the yarn linear density (in dtex) shall be applied at a speed of 50 mm/min to remove any slack from the yarn. The initial yarn length that is used in strain calculations, shall be adjusted

TABLE 1 Requirements for UHMWPE Yarns

Property	Test Method	Requirement
Trace Elements		
Titanium, mg/kg (Maximum)	6.2	25
Sodium, mg/kg (Maximum)	6.2	50
Chromium, mg/kg (Maximum)	6.2	10
Iron, mg/kg (Maximum)	6.2	100
Calcium, mg/kg (Maximum)	6.2	100
Density, g/cm^3	Test Methods D792	0.95–0.98
Filament Linear Density, dtex (Maximum)	6.3	2.7
Intrinsic Viscosity, dl/g (Minimum)	6.4	12.5
Tensile Strength, cN/dtex (Minimum)	6.5	28.0
Tensile Modulus, cN/dtex (Minimum)	6.5	750
Elongation-at-break, %	6.5	2.9–4.3