Designation: ~~F2848 – 10~~ F2848 – 16

Standard Specification 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. This specification covers natural (non-colored) and pigmented (colored) yarns.

1.2 This standard is intended to describe the ~~required properties~~ requirements and the procedures to be followed for testing UHMWPE yarns as ~~raw materials for medical devices.~~ a component for medical devices prior to manufacturing processes of the medical device such as fabric formation, assembling and sterilization. This specification does not purport to address the requirements for the finished medical devices or the testing that is needed for medical devices ~~or components of medical devices~~ that are fabricated from the ~~raw materials~~ components 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~~D885/D885M Test Methods for Tire Cords, Tire Cord Fabrics, and Industrial Filament Yarns Made from Manufactured Organic-Base Fibers

D1505 Test Method for Density of Plastics by the Density-Gradient Technique

D1601 Test Method for Dilute Solution Viscosity of Ethylene Polymers

~~D1907~~D1907/D1907M Test Method for Linear Density of Yarn (Yarn Number) by the Skein Method

~~D2256~~D2256/D2256M 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

F756 Practice for Assessment of Hemolytic Properties of Materials

F2625 Test Method for Measurement of Enthalpy of Fusion, Percent Crystallinity, and Melting Point of Ultra-High-Molecular Weight Polyethylene by Means of Differential Scanning Calorimetry

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~~10993-1 Biological Evaluation of Medical Devices Part 1 – Evaluation and testing within a risk management processs

ISO 10993-4 Biological Evaluation of Medical Devices Part 4 – Selection of tests for interactions with blood

[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.

ISO 10993-5 Biological Evaluation of Medical Devices Part 5 – Tests for in vitro cytotoxicity
ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-17 Biological Evaluation of Medical Devices Part 17 – Establishment for allowable limits for leachable substances
ISO 10993-18 Biological Evaluation of Medical Devices Part 18 – Chemical characterization of materials
ISO 13485 Medical Devices – Quality Management Systems – Requirements for regulatory purposes
ISO 14971 Medical Devices – Application of risk management to 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]
US Code of Federal Regulations—CFR section 21 Parts 70, 71, 73, 74 and 80 on color additives for medical devices[5]

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.~~etc.

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

[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.

[5] U.S. Government Publishing Office, 710 North Capitol Street N.W., Washington, DC (corner of North Capitol and H Streets), www.gpo.gov/about/bookstore.htm

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.

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~~Maximum acceptable limits for residual constituents shall be determined based on prevention of adverse effects when used in a medical application (see also 4.4~~history are produced with decalin as solvent. The maximum decalin residual level is 100 mg/kg (see~~). Residual constituents can be residues from the used production liquids, processing aids, or residual elements 6.1~~).~~from raw materials.

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~~ Residual production liquids shall be assessed with regard to toxicity hazards, 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~~ a toxicity assessment and corresponding potential leaching characteristics for the identified potential toxic ingredients should be performed in accordance with 4.4 to ~~be given.~~establish a maximum residual level.

4.1.3 Potential effects of residual production liquid(s) on mechanical or physical yarn properties should be considered as well for establishing maximum limits.

4.1.4 For decalin as solvent, the residual level has been established in accordance with 4.4 and 4.1.3 and shall be less than 100 mg/kg (see 6.1).

4.1.5 ~~To promote consistency in production and pureness of the yarn, concentration limits for trace elements have been established and are listed~~ In case a color additive or pigment is added to the yarn, this should be compliant to the FDA regulation as published in ~~Table 1.~~the US Code of Federal Regulations - CFR section 21, parts 70, 71, 73, 74 and 80 on color additives for medical devices.

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 Tensile testing shall be conducted after sufficient conditioning to the laboratory conditions, with a minimum of 2 h to achieve uniform temperatures within the yarn package.

TABLE 1 Requirements for UHMWPE Yarns

Property	Test Method	Requirement
~~Trace Elements~~		
Density, g/cm^3	Test Methods D792 or D1505	0.95 - 1.00
~~Titanium, mg/kg (Maximum)~~	~~6.2~~	~~25~~
~~Sodium, mg/kg (Maximum)~~	~~6.2~~	~~50~~
~~Chromium, mg/kg (Maximum)~~	~~6.2~~	~~10~~
Melting temperature – peak, °C	Test Method F2625	140 - 150
~~Iron, mg/kg (Maximum)~~	~~6.2~~	~~100~~
Filament Linear Density, dtex (Maximum)	6.3	2.7
~~Calcium, mg/kg (Maximum)~~	~~6.2~~	~~100~~
Intrinsic Viscosity, dl/g (Minimum)	6.4	15
~~Density, g/cm^3~~	~~Test Methods D792~~	~~0.95–0.98~~
Tensile Strength, cN/dtex (Minimum)	6.5	26
~~Filament Linear Density, dtex (Maximum)~~	~~6.3~~	~~2.7~~
~~Intrinsic Viscosity, dl/g (Minimum)~~	~~6.4~~	~~12.5~~
Tensile Modulus, cN/dtex (Minimum)	6.5	750
~~Tensile Strength, cN/dtex (Minimum)~~	~~6.5~~	~~28.0~~
Elongation-at-break, %	6.5	2 - 5
~~*Tensile Modulus, cN/dtex (Minimum)*~~	~~6.5~~	~~750~~
Additional requirement for colored yarn:		
~~Elongation-at-break, %~~	~~6.5~~	~~2.9–4.3~~
Pigment content, wt.% (Maximum)	6.2	2
Chromium-cobalt-aluminum oxide		

4.3.2 UHMWPE yarns shall meet the tensile requirements on strength, modulus, and elongation-at-break as listed for individual data 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 and Biosafety Risk Assessment Requirements:*

4.4.1 The ~~UHMWPE yarn shall be biocompatible. While the biocompatibility of UHMWPE powder and fibers has been characterized~~ first principle of ISO 10993-1 states that biological evaluation ~~(1-8), 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~~ of any material or medical device intended for use in humans shall form part of a structured biological evaluation program within a risk management process in accordance with ~~Practice F748 or ISO 10993, depending on the available published biocompatibility data and the end-use application.~~ ISO 14971. This should be addressed through chemical characterization of the material, following ISO 10993-18, and toxicological assessment based on ISO 10993-17. See the following for more specific specifications for this medical-grade UHMWPE yarn:

4.4.1.1 The full quantitative composition of the yarn as component supplied should be established, including residual processing aids and relevant impurities or trace elements; hereinafter referred to as ingredients.

4.4.1.2 For each ingredient, a toxicological assessment should be performed based on ISO 10993-17, which means that Tolerable Intake (TI) values in mg/kg bw/day are derived based on collected information on known critical adverse effects.

4.4.1.3 A worst-case assessment should be performed for each ingredient. Determine whether the quantity established in 4.4.1.1 is below the TI as defined in 4.4.1.2 for the application under consideration or, if the application is unknown, for 1 g of yarn (see Appendix X1.3), assuming a body weight of 50 kg and full bio-availability of the ingredients within 1 day.

4.4.1.4 If the worst case assessment indicates that the TI can be exceeded, perform extraction and/or leaching studies in accordance with ISO 10993 and determine whether the extracted/leached amount is below the TI for the application under consideration or, if the application is unknown, for 1 g of yarn, assuming a body weight of 50 kg and bio-availability of the extracted components/leachables within 1 day.

4.4.1.5 Based on the outcome of previous steps, maximum residual levels should be set for the critical ingredients (refer to 4.1).

4.4.2 For a proper biosafety analysis, chemical and biological testing should always be combined, especially since not all potential adverse effects can be derived from toxicological evaluation of individual ingredients only. As a minimum, the following biological tests should be conducted for medical-grade UHMWPE yarn:

4.4.2.1 *Cytotoxicity,* in accordance with ISO 10993-5.

4.4.2.2 *Hemolysis,* in accordance with Practice F756 and following ISO 10993-4.

4.4.2.3 *Acute Irritation,* in accordance with ISO 10993-10, with a preference for *in vitro* methods.[6]

4.4.2.4 *Sensitization,* in accordance with ISO 10993-10, with a preference for the Guinea Pig Maximization test.

4.4.3 The biosafety assessment described above should be made available in a material master file. General results should be made available on a certification document for a specific product yarn design and corresponding yarn manufacturing process.

[6] ~~*The boldface*~~*In vitro* ~~numbers~~ methods are preferred above *in* ~~*parentheses*~~*vivo* ~~refer to a list of references at the end of this standard.~~methods to limit animal testing, also since the medical-grade UHMWPE yarn component is not a final finished device.