Designation: F2848 – 17

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

This standard is issued under the fixed designation F2848; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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 requirements and the procedures to be followed for testing UHMWPE yarns as 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 that are fabricated from the 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 *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.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

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

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

D2256/D2256M Test Method for Tensile Properties of Yarns by the Single-Strand Method

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 10993-1 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

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

[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.

TABLE 1 Requirements for UHMWPE Yarns

Property	Test Method	Requirement
Density, g/cm^3	Test Methods D792 or D1505	0.95 - 1.00
Melting temperature – peak, °C	Test Method F2625	140 - 150
Filament Linear Density, dtex (Maximum)	6.3	2.7
Intrinsic Viscosity, dl/g (Minimum)	6.4	15
Tensile Strength, cN/dtex (Minimum)	6.5	26
Tensile Modulus, cN/dtex (Minimum)	6.5	750
Elongation-at-break, %	6.5	2 - 5
Additional requirement for colored yarn:		
Pigment content, wt.% (Maximum) Chromium-cobalt-aluminum oxide	6.2	2

ISO 8 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.

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.

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 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). Residual constituents can be residues from the used production liquids, processing aids, or residual elements from raw materials.

4.1.2 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, a toxicity assessment and corresponding potential leaching characteristics for the identified potential toxic ingredients should be performed in accordance with 4.4 to 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 In case a color additive or pigment is added to the yarn, this should be compliant to the FDA regulation as published in 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.

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 first principle of ISO 10993-1 states that biological evaluation 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 ISO 14971. This should be addressed through chemical characterization of the material, following ISO

[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

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 70 kg and full bioavailability of the ingredients within 1 day. The 70 kg body weight is not appropriate for pediatric and/or neonate applications. A lower body weight is required for calculations for these applications.

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 10993–18 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 70 kg and bioavailability of the extracted components/leachables within 1 day. The 70 kg body weight is not appropriate for pediatric and/or neonate applications. A lower body weight is required for calculations for these applications.

4.4.1.5 Based on the outcome of previous steps, maximum residual levels should be set for toxicologically critical ingredients (see 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 only individual ingredients. 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.

4.4.2.5 Results of above biological tests for the yarns cannot replace biological evaluation and testing in accordance with ISO 10993-1 for the final medical device. Additional endpoints may be necessary; therefore the final medical device manufacturer should evaluate the finished component or medical device for the intended use in accordance with ISO 10993-1.

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.

4.4.4 It is important to note that biological safety evaluation is a continuous process. In case of any change in yarn design or its manufacturing process, the yarn manufacturer should evaluate the consequences on biological safety and the material master file should be updated accordingly. The user or final medical device manufacturer should evaluate the consequences on biological safety of any additional processes (such as, for example, from cleaning and sterilization) and shall qualify the finished component or medical device for the intended use.

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 liquids used to produce the yarn to a sufficient accuracy in relation to the specified value.

6.2 If applicable, determine concentrations of color pigment or specified trace element in accordance with 4.1 by a validated analytical method, such as neutron activation analysis (NAA), inductively coupled plasma spectroscopy (ICP), atomic absorption (AA), or X-ray fluorescence (XRF) to a sufficient accuracy in relation to the specified value.

6.3 Determine the filament linear density by dividing the yarn linear density, measured in accordance with Test Method D1907/D1907M, by the number of filaments in the yarn.

6.4 The intrinsic viscosity shall be measured in accordance with ISO 1628-3 or ASTM D1601, but in the case of incomplete dissolution of the polymer, longer dissolution times and lower dissolution temperatures may be used.

6.5 Determine tensile strength, tensile modulus, and elongation-at-break in accordance with the following test conditions, derived from Test Methods D885/D885M, Test Method D2256/D2256M, and ISO 2062, and optimized for UHMWPE yarns:

6.5.1 *Test Conditions:*

6.5.1.1 Temperature shall be 21 ± 3°C.

6.5.1.2 Twisting level shall be in accordance with 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 of 0.2 cN/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

[6] *In vitro* methods are preferred above *in vivo* methods to limit animal testing, also since the medical-grade UHMWPE yarn component is not a final finished device.

adjusted accordingly; that is, the value for the initial yarn length shall be the actual initial yarn length after pre-tensioning.

6.5.1.8 The test speed shall be constant and half the gauge length per minute.

6.5.1.9 Force and elongation shall be recorded until yarn breakage.

6.5.2 For tensile strength (in cN/dtex), divide the maximum force-at-break (in cN) by the yarn linear density (in dtex) as determined in accordance with Test Method D1907/D1907M.

6.5.3 Tensile modulus (in cN/dtex) shall be determined as the slope of the regression line to the part of the force-elongation curve corresponding to strains between 0.3 % and 1.0 %, consisting of at least 45 data points. The slope (in cN) shall be divided by yarn linear density (in dtex) as determined by Test Method D1907/D1907M.

6.5.4 Elongation-at-break (in %) shall be determined by dividing the increase in length after pre-tensioning until break, by the initial yarn length, and multiplying by 100.

7. Inspection and Certification

7.1 The manufacturer shall certify that the yarn is manufactured according to validated processes in accordance with a recognized quality system like CFR 820 or ISO 13485, and meets the specified requirements of this standard.

7.2 The certification shall also state the colorant chemistry, when present, and the specified maximum trace amount of manufacturing residues.

7.3 Biosafety and biocompatibility test results and type of testing shall be provided in the certification or in the material master file on record with the FDA or notified body.

8. Packaging, Labeling and Storage

8.1 UHWMPE yarn for use in medical applications shall be supplied, shipped, and stored in proper packaging to prevent contamination during typical conditions of shipment and storage.

8.2 All packages shall be labeled so as to identify the manufacturer, specific product name, lot or batch number, and date of manufacturing.

8.3 The material supplier shall provide information regarding recommended yarn storage conditions and shelf life of the yarn.

9. Quality Control Provisions and Risk Management

9.1 UHMWPE yarn as described in the scope of this specification shall be produced in accordance with a CFR 820 or ISO 13485-certified quality management system.

9.2 Design and manufacturing risks of UHMWPE yarn shall be managed in accordance with ISO 14971.

10. Keywords

10.1 fiber; high-modulus polyethylene (HMPE); high-performance polyethylene (HPPE); medical; surgical implants; ultra-high molecular weight polyethylene (UHMW-PE, UHMWPE); yarn

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 This specification is intended to describe the properties required and procedures to be followed in testing medical-grade UHMWPE yarns. This is different from Specification F648, (**1**) which addresses UHMWPE powder and bulk shapes fabricated from this powder for surgical implants.

X1.2 While the biological response to medical-grade UHMWPE in soft tissue and bone has been well characterized by a history of clinical use (**2-4**) and by laboratory studies (**5-9**), the data cannot necessarily be assumed to be applicable to modified forms, including UHMWPE yarns, or applications of the material. The material user should carefully analyze the published biocompatibility data and then decide whether additional testing may be necessary as a result of the changes which may have been made.

X1.3 The quantity of 1 g of yarn in 4.4.1 is based on the rationale that most applications do not contain more than 1 g of yarn. For example, 1 g corresponds to over 4 m of braided USP 2 suture size or 12 m of USP 2-0 suture size and is in fact a worst case scenario amount.

X1.4 The requirements of Table 1 are also based on historical data from yarn products with a history of clinical use. The listed physical requirements also assure UHMWPE yarn component identification and batch-to-batch consistency.

X1.5 The relationship between these mechanical properties and the *in-vivo* performance of a fabricated form has not been determined. While trends are apparent, specific property-polymer structure relationships are not well understood. These mechanical tests are frequently used to evaluate the reproducibility of a fabrication procedure and are applicable as quality control tests to determine lot-to-lot repeatability for a process of converting virgin polymer powder into a fabricated form. The mechanical properties are subject to variation as the fabrication process variables (such as temperature, pressure and time) are changed.

X1.6 All properties are based on non-sterilized material, because this standard describes a component. The recommended method of sterilization is ethylene oxide sterilization. High-energy sterilization methods such as, for example, gamma-irradiation or e-beam irradiation are not recommended since they may result in a loss of properties.

X2. SUGGESTED GUIDELINE FOR CLAMPING IN TENSILE TESTING

X2.1 This guideline is intended to minimize slip of the yarn in the clamps during tensile testing. It is recommended to use pneumatic yarn grips especially designed to overcome the problem of sample failure by incorporating a lever design which evenly distributes the gripping force over the surface. An example of such a pneumatic yarn clamping system is the Instron type CP103684 with Instron 1498K stainless steel faces.

REFERENCES

(1) ASTM F648, "Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants," ASTM International.

(2) Charnley, J., Cupiz, A., "The Nine and Ten Year Results of the Low Friction Arthroplasty of the Hip," *Clinical Orthopaedics*, Vol 95, No. 9, 1973.

(3) Cimbrelo, E. G., Munera, L., "Early and Late Loosening of the Acetabular Cup After Low-Friction Arthroplasty", *The Journal of Bone and Joint Surgery*, Vol 74-A, No. 8, 1992.

(4) Mirra, J., Amstutz, H., Matos, M., Gold, R., "The Pathology of the Joint Tissues and Its Clinical Relevance in Prosthesis Failure," *Clinical Orthopaedics*, No. 117, 1976.

(5) Turner, J., Lawrence, W., Autian, J., "Subacute Toxicity Testing of Biomaterials Using Histopathologic Evaluation of Rabbit Muscle Tissue," *Journal of Biomedical Materials Research*, Vol 7, 1973.

(6) Laing, P., " Compatibility of Biomaterials," *Orthopedic Clinics of North America*, Vol 4, No. 2, 1973.

(7) Escalas, F., Galante, J., Rostoker, W., "Biocompatibility of Materials for Total Joint Replacement," *Journal of Biomedical Materials Research*, Vol 10, No. 2, 1976.

(8) Traoré, A. S., Guidoin, M. F., Marois, Y., Zhang, Z., Douville, Y., Guidoin, R., King, M. W., Legrand, A. P., "Newly developed hybrid suture with lubricant: noninvasive *in vivo* assessment of biocompatibility with multiparametric MR imaging," *Journal of Investigative Surgery*, Vol 20, No. 2, 2007.

(9) Kurtz, S. M., *The UHMWPE Biomaterials Handbook: Ultra-High Molecular Weight Polyethylene in Total Joint Replacement and Medical Devices* (2nd edition). Burlington, MA: Academic Press, 2009.