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Standard Specification for Wrought Molybdenum-47.5 Rhenium Alloy for Surgical Implants (UNS R03700)[1]

This standard is issued under the fixed designation F3273; 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.

ε1 NOTE—Appendix X2 was updated editorially in November 2021.

1. Scope

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought molybdenum-47.5 rhenium alloy to be used in the manufacture of surgical implants.

1.2 The SI units in this standard are the primary units. The values stated in either primary SI units or secondary inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance with the standard.

1.3 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *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]

B193 Test Method for Resistivity of Electrical Conductor Materials

B311 Test Method for Density of Powder Metallurgy (PM) Materials Containing Less Than Two Percent Porosity

B774/B774M Specification for Low Melting Point Alloys and Solders

C1113/C1113M Test Method for Thermal Conductivity of Refractories by Hot Wire (Platinum Resistance Thermometer Technique)

E8/E8M Test Methods for Tension Testing of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E228 Test Method for Linear Thermal Expansion of Solid Materials With a Push-Rod Dilatometer

E290 Test Methods for Bend Testing of Material for Ductility

E1621 Guide for Elemental Analysis by Wavelength Dispersive X-Ray Fluorescence Spectrometry

E1941 Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis

E2626 Guide for Spectrometric Analysis of Reactive and Refractory Metals (Withdrawn 2017)[3]

IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 *Aerospace Material Specifications:*[4]

AMS 2630 Inspection, Ultrasonic Product 0ver 0.5 inch (12.7 mm) Thick

AMS 2632 Ultrasonic Inspection of Thin Materials

2.3 *ISO Standards:*[5]

ISO 6892-1 Metallic materials—Part 1: Method of test at room temperature

ISO 9001 Quality management systems requirements

ISO 10993-5 Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity

ISO 10993-6 Biological evaluation of medical devices—Part 6: Tests for local effects after implantation

ISO 10993-10 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization

[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 F04.12 on Metallurgical 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] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from Aerospace Industries Association (AIA), 1000 Wilson Blvd., Suite 1700, Arlington, VA 22209, http://www.aia-aerospace.org.

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

ISO 10993-11 Biological evaluation of medical devices—Part 11: Tests for systemic toxicity

3. Terminology

3.1 *Definitions:*

3.1.1 *cold work, n*—any mechanical deformation process performed below the recrystallization temperature which results in strain hardening of the material.

3.1.2 *lot, n*—the total number of mill products produced from the same melt heat under the same conditions at essentially the same time.

4. Product Classification

4.1 *Bar*—Round bars and flats from 1.00 mm (0.0394 in.) to 101.60 mm (4.00 in.) in diameter or thickness (other sizes and shapes by special order).

4.2 *Sheet*—Any product under 4.76 mm (0.1875 in.) in thickness and 610 mm (24 in.) or more in width.

4.3 *Other*—Other forms and shapes may be provided by agreement between the purchaser and supplier.

5. Ordering Information

5.1 Include with inquiries and orders for material under this specification the following information:

5.1.1 Quantity;

5.1.2 ASTM designation and date of issue;

5.1.3 Form (bar, sheet);

5.1.4 Condition (see 6.3);

5.1.5 Mechanical properties (if applicable, for special conditions), Table 2;

5.1.6 Finish (see 6.2);

5.1.7 Applicable dimensions including size, thickness, width, length, or drawing number;

5.1.8 Special tests (see 9.1); and

5.1.9 Other requirements.

TABLE 1 Chemical Requirements

Element	Composition, % (mass/mass)
Nitrogen, max	0.010
Carbon, max	0.050
Hydrogen, max	0.010
Iron, max	0.010
Oxygen max	0.010
Sulfur, max	0.010
Phosphorous, max	0.010
Silicon, max	0.010
Boron, max	0.010
Copper, max	0.010
Titanium., max	0.010
Tungsten, max	0.050
Manganese, max	0.010
Tin, max	0.010
Rhenium	46.0–49.0
Molybdenum	Balance[A]

[A] Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage molybdenum content by difference is not required to be reported.

6. Materials and Manufacture

6.1 The alloy consists of nominal 47.5 mass % rhenium balance molybdenum of approximately 99.79 % purity and residual plus trace elements.

6.2 *Finish*—The product may be furnished to the implant manufacturer as mechanically or chemically descaled by pickling, abrasively blasting, chemically milled, ground, machined, peeled, polished, combinations of these operations, or as specified by the purchaser. On billets, bars, plates, and forgings, it is permissible to remove minor surface imperfections by grinding or machining if the resultant area meets the dimensional and surface finish requirements of this specification.

6.3 *Condition*—Material shall be furnished in the annealed, cold-worked, or extra hard conditions that result from thermal or work-hardening operations. Conditions other than those listed in Table 2 may be established between the supplier and purchaser.

7. Chemical Requirements

7.1 The heat analysis shall conform to the chemical composition specified in Table 1. The supplier shall not ship material with chemistry outside the requirements specified in Table 1.

7.1.1 Requirements for the major and minor elemental constituents are listed in Table 1. Also listed are important residual elements. Analysis for elements not listed in Table 1 is not required to verify compliance with this specification.

7.2 For referee purposes use Guides E1621 and E2626 and Test Method E1941, or other analytical method agreed upon between the purchaser and the supplier.

7.3 Samples for chemical analysis shall be representative of the material being tested. The utmost care must be used in sampling for chemical analysis because of its affinity for elements such as oxygen, nitrogen, and hydrogen. In cutting samples for analysis, therefore, the operation should be carried out insofar as possible in a dust-free atmosphere. If cutting tools are to be used they should be clean and sharp; however, laser cutting is preferred. Samples for analysis should be stored in suitable containers.

8. Mechanical Requirements

8.1 The material supplied under this specification shall conform to the mechanical properties given in Table 2. Alternate properties may be agreed upon between the purchaser and supplier.

8.2 Specimens for tension tests shall be prepared and tested in accordance with Test Methods E8/E8M. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 mm/mm/min (in./in./min) through yield and then the crosshead speed may be increased to produce fracture in approximately one additional minute.

8.2.1 *Bar and Sheet*—Test according to Test Methods E8/E8M. If one test specimen does not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner for each test specimen. The

TABLE 2 Mechanical Properties for Bar and Sheet

Condition	Form	Ultimate Tensile Strength, min, MPa (psi)	Yield Strength (0.2 % offset), min, MPa (psi)	Elongation[A] min, %	Reduction of Area, min, %
Annealed	Bar	760 (110 000)	480 (70 000)	10	12
Cold-Worked	Bar	1240 (180 000)	1100 (160 000)	12	40
Extra Hard	Bar	1380 (200 000)	1310 (190 000)	10	45
Annealed	Sheet[B]	860 (125 000)	610 (85 000)	10	—

[A] Elongation of material 1.6 mm (0.063 in.) or greater in diameter (D) or thickness (T) shall be measured using a gauge length of 50 mm, 4D or 4W. The gauge length must be reported with the test results. The method for determining elongation of material under 1.6 mm (0.063 in.) in diameter or thickness may be negotiated. Alternatively, a gauge length of 5.65 times the square root of So, where So is the original cross-sectional area corresponding to ISO 6892-1, may be used when agreed upon between the supplier and purchaser.
[B] Minimum values apply to tests taken both longitudinal and transverse to the direction of rolling.

lot will be considered in compliance only if all additional test pieces meet the specified requirements.

8.2.2 Tensile tests results for which any specimen fractures outside the gauge length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to subsections 7.11.4 and 7.12.5 of Test Methods E8/E8M. If either elongation or reduction of area is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements. If either elongation or reduction of area is less than the minimum requirements for each lot then the lot should be rejected. If either elongation or reduction of area is less than the minimum requirement the entire lot should be rejected.

8.2.3 *Sheet*—Test according to Test Methods E8/E8M. Perform at least one tensile test from each lot of sheet in both the longitudinal and transverse directions. Tests in the transverse direction need be made only on product from a specimen not less than 200 mm (8.0 in.) in length for sheet. Should any of these test specimens not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test specimen. The lot will be considered in compliance only if all additional test pieces meet the specified requirements.

8.2.4 For sheet, bend test specimen shall withstand being bent cold through an angle of 105° without fracture in the outside surface of the bent portion. Test conditions shall conform to Test Methods E290.

8.2.4.1 Bend test mandrel diameter shall be agreed to by the supplier and purchaser.

9. Ultrasonic Inspection

9.1 All centerless ground or peeled and polished bar ≥9.5 mm (0.375 in.) in nominal diameter shall be ultrasonically inspected at final diameter according to AMS 2630, Class A1. Equivalent test methods may be submitted when agreed upon by the purchaser and supplier.

NOTE 1—AMS 2630 specifies a minimum size limit of 12.7 mm (0.50 in). Subcommittee F04.12 has intentionally specified the use of AMS 2630 below 12.7 mm (0.50 in.) based on the experience of users and producers on the committee. There is disagreement in the industry as to whether AMS 2632, which does apply to sizes under 12.7 mm (0.50 in.), applies to solid round bar.

9.2 Other sizes and product forms may be ultrasonically inspected according to inspection criteria that shall be agreed upon between the purchaser and supplier.

10. Dimensions and Permissible Variations

10.1 *Units of Measure:*

10.1.1 *Selection*—This specification requires that the purchaser selects the units (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

10.1.1.1 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

10.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's purchase order (PO), specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification

10.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.

10.1.2 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A of IEEE/ASTM SI 10 provides conversion tables and Annex B of IEEE/ASTM SI 10 provides rules for conversion and significant digits.

11. Significance of Numerical Limits

11.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right-hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E29.

12. Certification

12.1 The supplier shall provide a certification that the material was tested in accordance with this specification and met all requirements. A report of the test results including the gauge length shall be furnished to the purchaser at the time of shipment.