

	<p>Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)¹ 用于外科植入物应用的锻造钛-6Al-4V ELI (超低间隙) 合金的标准规格 (UNS R56401) ¹ 见注脚1</p> <p>外科植入用 Ti-6Al-4V ELI 加工材(美国)</p>	<p>ASTM F 136 -2008</p>
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This standard is issued under the fixed designation F 136; 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.

本标准以固定名称F 136发布; 紧接在指定之后的数字表示原始采用的年份, 或者在修订的情况下, 指最后修订的年份。括号中的数字表示上次重新核准的年份。上标 ϵ (ϵ) 表示自上次修订或重新核准后的编辑变更

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.

注脚1: 本规范在ASTM F04关于医疗和外科材料和设备委员会的管辖范围内, 是F04.12金属冶金材料小组委员会的直接责任。

1. Scope 范围

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought annealed titanium-6aluminum-4vanadium ELI (extra low interstitial) alloy 01) to be used in the manufacture of surgical implants.

1.1本规范涵盖用于外科植入物制造的锻造退火钛-6铝-4钒ELI (超低间隙) 合金01) 的化学, 机械和冶金要求。

1.2 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

1.2以英寸 - 磅单位表示的值应视为标准值。括号中给出的值是SI单位的数学倒置, 其提供的信息仅被认为是标准。

2. Referenced Documents 参考文件

2.1 *ASTM Standards*:² ASTM标准:²

²For 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.

注脚2: 于参考的ASTM标准, 请访问ASTM网站, www.astm.org或主要ASTM客户服务service@astm.org。有关ASTM标准卷年表的信息, 请参阅ASTM网站上标准的文件摘要页。

E 8/E 8M Test Methods for Tension Testing of Metallic Materials E 8/E 8M金属材料拉伸试验测试方法

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications E 29使用测试数据中的重要数字确定符合规范的做法

E 290 Test Methods for Bend Testing of Material for Ductility E 290材料的延展性弯曲试验方法

E 539 Test Method for X-Ray Fluorescence Spectrometric Analysis of 6Al-4V Titanium Alloy

E 539 6Al-4V钛合金的X射线荧光光谱分析的测试方法

E 1409 Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique

E 1409通过惰性气体融合技术测定钛和钛合金中的氧和氮的测试方法

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity/Infrared Detection Method

E 1447通过惰性气体熔融热导率/红外检测法测定钛和钛合金中的氢的试验方法
 E 1941 Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys
 E 1941测定耐火和反应性金属及其合金中碳的试验方法
 E 2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry E 2371通过原子发射等离子体光谱法分析钛和钛合金的测试方法
 F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone
 F 981外科植入物生物材料与材料对肌肉和骨骼的影响的兼容性评估实践

2.2 ISO Standards: ISO标准: 3

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

注脚3: 可从美国国家标准学会 (ANSI), 25W 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>。

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 6892金属材料环境温度下的拉伸试验

ISO 9001 Quality Management Systems Requirements

ISO 9001质量管理体系要求

2.3 ASQ Standard: ASQ标准:

ASQ C1 Specifications of General Requirements for a Quality Control Program⁴

ASQ C1质量控制计划的一般要求规范⁴

⁴ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

注脚4: 可从美国质量协会 (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>。

2.4 Aerospace Material Specifications: 航天材料规格:

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 2249化学检查分析限值, 钛和钛合金⁵

⁵ Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, <http://www.sae.org>.

注脚5: 可从汽车工程师协会 (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, <http://www.sae.org>。

3. Terminology术语

3.1 Definitions of Terms Specific to This Standard:

3.1本标准特定术语的定义:

3.1.1 *beta transus, n*—the minimum temperature at which the alpha plus beta phase can transform to 100 % beta phase.

3.1.1 β转变, n-α和β相可以转化为100%β相的最低温度。

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

3.1.2批次, n-在相同条件下基本上同时从一次加热生产的碾磨产物的总数。

4. Product Classification产品分类

4.1 *Strip*—Any product under 0.1875 in. (4.76 mm) in thickness and under 24 in. (610 mm) wide.

4.1剥离 - 任何厚度小于0.1875英寸 (4.76毫米), 宽度小于24英寸 (610毫米) 的产品。

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

4.2片材 - 厚度为0.1875英寸 (4.76毫米), 宽度为24英寸 (610毫米) 或以上的任何产品。

4.3 *Plate*—Any product 0.1875 in. (4.76 mm) thick and over and 10 in. (254 mm) wide and over, with widths greater than five times thickness. Plate up to 4.00 in. (101.60 mm), thick inclusive is covered by this specification.

4.3板 - 任何产品0.1875英寸（4.76毫米）厚和10英寸（254毫米）宽及以上，宽度大于厚度的五倍。本规范涵盖高达4.00英寸（101.60毫米），包括厚度的板。

4.4 *Bar*—Round bars and flats from 0.1875 in. (4.76 mm) to 4.00 in. (101.60 mm) in diameter or thickness (other sizes and shapes by special order).

4.4棒 - 直径或厚度从0.1875英寸（4.76毫米）到4.00英寸（101.60毫米）的圆棒和平面（特殊顺序的其它尺寸和形状）。

4.5 *Forging Bar*—Bar as described in 4.4, used for production of forgings, may be furnished in the hot worked condition.

4.5如4.4所述的锻造棒材，用于锻件的生产，可以在热加工条件下提供。

4.6 *Wire*—Rounds, flats, or other shapes less than 0.1875 in. (4.76 mm) in diameter.

4.6线 - 圆，平面或其他直径小于0.1875英寸（4.76毫米）的形状。

5. Ordering Information 订购信息

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

5.1包括对本规范下材料的查询和订单的以下信息：

5.1.1 Quantity, 数量,

5.1.2 ASTM designation and date of issue,

5.1.2 ASTM标准和发布日期,

5.1.3 Form (sheet, strip, plate, bar, forging bar, or wire),

5.1.3形式（板材，带材，板材，棒材，锻造棒材或线材），

5.1.4 Condition (See Section 3 and 6.3),

5.1.4条件（见第3和6.3节），

5.1.5 Mechanical properties (if applicable, for special conditions),

5.1.5机械性能（适用于特殊条件）

5.1.6 Finish (See 6.2),

5.1.6完成（见6.2），

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

5.1.7适用尺寸包括尺寸，厚度，宽度，长度或图号，

5.1.8 Special tests, if any, and

5.1.8特殊试验（如有）和

5.1.9 Other requirements.

5.1.9其他要求。

6. Materials and Manufacture 材料和制造

6.1 The various titanium mill products covered in this specification normally are formed with the conventional forging and rolling equipment found in primary ferrous and nonferrous plants. The alloy is usually multiple melted in arc furnaces (including furnaces such as plasma arc and electron beam) of a type conventionally used for reactive metals.

6.1本规范涵盖的各种钛轧机产品通常使用常规的锻造和轧制设备在原始黑色和有色植物中发现。该合金通常在常规用于活性金属的类型的电弧炉（包括诸如等离子体电弧和电子束的炉）中多重熔融。

6.2 *Finish*—The mill product may be furnished to the implant manufacturer as mechanically descaled or pickled, abrasively blasted, 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 if the resultant area meets the dimensional and

surface finish requirements of this specification.

6.2 抛光 - 抛光产品可以通过机械除锈或酸洗, 磨料喷砂, 化学研磨, 研磨, 机加工, 剥离, 抛光, 这些操作的组合, 或按照采购方的规定, 提供给种植体制造商。在坯料, 棒, 板和锻件上, 如果所得区域满足本规范的尺寸和表面光洁度要求, 则允许通过研磨除去较小的表面缺陷。

6.3 *Condition*—Material shall be furnished in the annealed or cold-worked condition. Mechanical properties for conditions other than those listed in Table 1 and Table 2 may be established by agreement between the supplier and the purchaser.

6.3 条件 - 材料应在退火或冷加工条件下提供。除表1和表2所列条件外的其他条件的机械性能可通过供应商和采购方之间的协议确定。

TABLE 1 Annealed Mechanical Properties of Bar, Wire, and Forgings

表1: 棒, 线和锻件的退火机械性能

Nominal Diameter or Distance Between Parallel Sides 公称直径或距离, 英寸 (mm)	Tensile Strength min, 拉伸强度psi (MPa)	Yield Strength(0.2 % offset) min, 屈服强度psi (MPa)	Elongation <i>A</i> in 4D or 4W min 伸长率, %			Reduction of Area <i>B</i> min 断面收缩率, %		
			L	LT	ST	L	LT	ST
			--	--	--	--	--	--
<0.187英寸 (4.75mm)	125000 (860)	115000 (795)	10	--	--	--	--	--
≥0.187 (4.75) ~1.75 (44.45)	125000 (860)	115000 (795)	10	--	--	25	--	--
≥1.75 (44.45) ~2.50 (63.50)	120000 (825)	110000 (760)	8	--	--	25	--	--
≥2.50 (63.50) ~4.00 (101.60)	120000 (825)	110000 (760)	8	8 <i>C</i>	8 <i>C</i>	15	15 <i>C</i>	15 <i>C</i>

^A Elongation of material 0.063 in. (1.6 mm) or greater in diameter (D) or width (W) shall be measured using a gage length of 2 in. or 4 D or 4 W. The gage length must be reported with the test results. The method for determining elongation of material under 0.063 in. (1.6 mm) in diameter or thickness may be negotiated. Alternatively, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser. (5.65 times the square root of So, where So is the original cross sectional area.) Gage length shall be reported with the elongation value. L = longitudinal; LT = long transverse; ST = short transverse.

注脚A: 材料直径 (D) 或宽度 (W) 为0.063英寸 (1.6毫米) 或更大的材料的伸长率应使用2英寸或4英寸或4英寸的计量长度测量。计量长度必须用测试报告结果。可以协商确定直径或厚度在0.063英寸 (1.6mm) 以下的材料的伸长率的方法。或者, 当在供应商和购买者之间达成一致时, 可以使用对应于ISO 6892的计量长度。(是So的平方根的5.65倍, 其中So是原始横截面积)。应该用伸长率值报告量具长度。 L =纵向; LT =长横向; ST =短横向。

^B Applies to bar and forgings only. L = longitudinal; LT = long transverse; ST = short transverse. For round bar, the long and short transverse are identical tests, therefore only one transverse is required.

注脚B: 仅适用于条和锻件。 L =纵向; LT =长横向; ST =短横向。对于圆棒, 长短横向是相同的试验, 因此只需要一个横向。

^C Transverse requirements in Table 1 apply only to product from which a tensile specimen not less than 2.50 in. (63.5 mm) in length can be obtained.

注脚C: 表1中的横向要求仅适用于可获得长度不小于2.50英寸 (63.5毫米) 的拉伸试样的产品。

7. Chemical Requirements 化学需求

7.1 The heat analysis shall conform to the chemical composition specified in Table 3. Ingot analysis may be used for reporting all chemical requirements, except hydrogen. Samples for hydrogen shall be taken from the finished mill product. The supplier shall not ship material with chemistry outside the requirements specified in Table 3.

7.1 热分析应符合表3中规定的化学成分。锭料分析可用于报告除氢以外的所有化学品要求。氢气样品应取自成品磨产品。供应商不得运输具有超出表3规定要求的化学品。

TABLE 2 Annealed Mechanical Properties of Sheet, Strip, and Plate

表2, 板, 带和板的退火机械性能

Nominal Diameter or Distance Between Parallel Sides 公称直径或距离, 英寸 (mm)	Tensile Strength min, 拉伸强度psi (MPa)	Yield Strength min, 屈服强度psi (MPa)	Elongation A in 4D or 4W min 伸长率, %			Reduction of Area B min 断面收缩率, %			Bend Test Mandrel Diameter C, D 弯曲试验心轴直径 <i>c, D</i>	
			L	LT	ST	L	LT	ST	<0.070 (1.78 mm)	0.070~0.1875 (1.78 ~4.75)
			--	--	--	--	--	--	--	--
<0.187英寸 (4.75mm)	125000 (860)	115000 (795)	10	--	--	--	--	--	9T	10T
≥0.187 (4.75) ~1.75 (44.45)	125000 (860)	115000 (795)	10	--	--	25	--	--	--	--
≥1.75 (44.45) ~2.50 (63.50)	120000 (825)	110000 (760)	8	--	--	20	--	--	--	--
≥2.50 (63.50) ~4.00 (101.60)	120000 (825)	110000 (760)	8	8 <i>E</i>	8 <i>E</i>	15	15 <i>E</i>	15 <i>E</i>	--	--

A Elongation of material 0.063 in. (1.6 mm) or greater width (W) shall be measured using a gage length of 2 in. or 4 W. The gage length must be reported with the test results. The method for determining elongation of material less than 0.063 in. (1.6 mm) in thickness may be negotiated. Alternatively, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser. (5.65 times the square root of S_0 , where S_0 is the original cross sectional area.) Gage length shall be reported with the elongation value. L = longitudinal; LT = long transverse; ST = short transverse.

注脚A: 材料0.063英寸(1.6毫米)或更大宽度(W)的伸长率应使用2英寸或4英寸的计量长度测量。计量长度必须与测试结果一起报告。可以协商确定厚度小于0.063英寸(1.6mm)的材料的伸长率的方法。或者,当在供应商和购买者之间达成一致时,可以使用对应于ISO 6892的计量长度。(是 S_0 的平方根的5.65倍,其中 S_0 是原始横截面积)。应该用伸长率值报告量具长度。L = 纵向; LT = 长横向; ST = 短横向。

B Applies to plate only. L = longitudinal; LT = long transverse; ST = short transverse.

注脚B: 仅适用于板。L = 纵向; LT = 长横向; ST = 短横向。

C The bend test is applicable to sheet and strip products

注脚C: 弯曲试验适用于板材和带材产品

D T equals the thickness of the bend test specimen. Refer to Test Methods E 290. Bend tests are not applicable to material over 0.187 in. (4.75 mm) in thickness.

注脚D: T等于弯曲试样的厚度。参见测试方法E 290。弯曲试验不适用于厚度超过0.187英寸(4.75毫米)的材料。

E Transverse requirements in Table 2 apply only to product from which a tensile specimen not less than 2.50 in. (63.5 mm) in length can be obtained.

注脚E: 表2中的横向要求仅适用于可获得长度不小于2.50英寸(63.5毫米)的拉伸试样的产品。

TABLE 3 Chemical Requirements 表3化学需求

Element	元素	Composition, (mass/mass)% 组成, % (质量/质量)
Nitrogen, max	N	≤0.05
Carbon, max	C	≤0.08
Hydrogen, max	H	≤0.012 <i>A</i>
Iron, max	Fe	≤0.25
Oxygen, max	O	≤0.13
Aluminum	Al	≤5.5 ~ 6.50
Vanadium	V	≤3.5 ~ 4.5
Titanium B	Ti	基

A Material 0.032 in. (0.813 mm) and under may have hydrogen content up to 0.0150 %.

注脚A: 材料0.032英寸(0.813mm)及以下可具有高达0.0150%的氢含量。

B The percentage of titanium is determined by difference and need not be determined or certified.

注脚B: 钛的百分比由差异确定, 不需要确定或证明。

TABLE 4 Product Analysis Tolerance A 表4产品分析公差 A

Element	元素	Tolerance Under the Minimum or Over the Maximum Limit B 最小或超过最大限制的公差, % (质量/质量)
Nitrogen	N	≤0.02
Carbon	C	≤0.02
Hydrogen	H	≤0.0020
Iron	Fe	≤0.10
Oxygen	O	≤0.02
Aluminum	Al	≤0.40
Vanadium	V	≤0.15

^ASee AMS 2249.

注脚A: 见AMS 2249。。

^BUnder minimum limit not applicable for elements where only a minimum percentage is indicated.

注脚B: 最低限度不适用于仅指示最低百分比的要素。。

7.1.1 Requirements for the major and minor elemental constituents are listed in Table 3. Also listed are important residual elements. Analysis for elements not listed in Table 3 is not required to verify compliance with this specification.

7.1.1主要和次要元素组分的要求列于表3中。还列出了重要的残余元素。不需要对表3中未列出的元件进行分析, 以验证是否符合本规范。

7.2 Product Analysis: 产品分析:

7.2.1 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. The product analysis tolerances shall conform to the product tolerances in Table 4.

7.2.1产品分析公差不扩大指定的热分析要求, 但涵盖了化学含量测量中实验室之间的差异。产品分析公差应符合表4中的产品公差。

7.2.2 The product analysis is either for the purpose of verifying the composition of a heat or manufacturing lot or determining variations in the composition within the heat.

7.2.2产品分析是为了验证热或制造批次的组成或确定热量内组成的变化。

7.2.3 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product analysis. Product analysis outside the tolerance limits allowed in Table 4 is cause for rejection of the product. A referee analysis may be used if agreed upon by the supplier and purchaser.

7.2.3购买者在产品分析的基础上可以接受或拒绝热或制造批次的材料。产品分析超出表4中允许的公差范围是产品拒收的原因。如果供应商和购买者同意, 可以使用裁判分析。

7.2.4 For referee purposes, use Test Methods E 539, E 1409, E 1447, E 1941, and E 2371 or other analytical methods agreed upon between the purchaser and the supplier.

7.2.4为了参考, 使用测试方法E 539, E 1409, E 1447, E 1941和E 2371或买方与供应商之间商定的其他分析方法。

7.3 Samples for chemical analysis shall be representative of the material being tested. The utmost care must be used in sampling titanium 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. Cutting tools should be clean and sharp.

Samples for analysis should be stored in suitable containers.

7.3用于化学分析的样品应代表被测试的材料。在对钛进行化学分析时，必须非常小心，因为其对氧，氮和氢等元素具有亲和性。因此，在切割用于分析的样品中，应该在无尘的气氛中尽可能地进行操作。切削工具应清洁，锋利。用于分析的样品应储存在合适的容器中。

8. Mechanical Requirements机械要求

8.1 The material supplied under this specification shall conform to the mechanical property requirements in Table 1 and Table 2.

8.1本规范提供的材料应符合表1和表2中的机械性能要求。

8.2 Specimens for tension tests shall be machined and tested in accordance with Test Methods E 8/E 8M. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in./min (mm/mm/min) through yield and then the crosshead speed may be increased so as to produce fracture in approximately one additional minute.

8.2拉伸试验样品应按E 8 / E 8M试验方法进行加工和试验。拉伸性能应使用0.003至0.007in./in./min (mm / mm / min) 的应变速率通过屈服来确定，然后可以增加十字头速度以在大约另外一分钟内产生断裂。

8.2.1 *Bar, Forging Bar, Shapes, and Wire*—Test according to Test Methods E 8/E 8M. Should any test specimen 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.

8.2.1根据测试方法E 8 / E 8M的棒，锻造棒，形状和线材试验。如果任何试样不满足规定的要求，则对于每个失效的试样，以相同的方式测试代表相同批次的两个附加试样。只有所有额外的试件符合规定的要求，该批才会被认为合格。

8.2.2 Tensile tests results for which any specimen fractures outside the gage 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 E 8/E 8M. If either the 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.

8.2.2拉伸试验结果，如果断裂伸长率和断面收缩率均符合规定的最低要求，那么任何试样断裂外的试样断裂应被认为是可接受的。参见测试方法E 8 / E 8M的第7.11.4和7.12.5小节。如果面积的伸长或减小小于最小要求，则丢弃测试并重新测试。对不满足最低要求的每个样品重新测试一个样品。

8.3 For sheet and strip, the bend test specimen shall withstand being bent cold through an angle of 105° without fracture in the outside surface of the bent portion. The bend shall be made around a mandrel which has a diameter equal to that shown in Table 2. Test conditions shall conform to Test Method E 290.

8.3对于板材和带材，弯曲试样应经受105° 弯曲的冷弯，在弯曲部分的外表面上不断裂。弯曲应在直径等于表2所示直径的心轴周围进行。测试条件应符合测试方法E 290。

8.3.1 *Sheet, Strip, and Plate*—Test according to Test Methods E 8/E 8M. Perform at least one bend test from each lot in both the longitudinal and transverse directions. Tests in the transverse direction need be made only on product from which a specimen not less than 8.0 in. (200 mm) in length for sheet and 2.50 in. (64 mm) in length for plate can be taken. 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.

8.3.1根据测试方法E 8 / E 8M的板材，带材和板材试验。每个批次在纵向和横向上进行至少一次弯曲试验。在横向上的测试仅需要对产品进行测试，从其中可以取得片材长度不小于8.0英寸（200mm）和板材长度为2.50英寸（64mm）的样品。如果这些测试样本中的任何一个不满足规定的要求，则对于每个失败的测试样本，以相同的方式测试代表相同批次的两个额外的测试样本。只有所有额外的试件符合规定的要求，该批才会被认为合格。

9. Special Requirements特殊要求

9.1 The microstructure shall be a fine dispersion of the alpha and beta phases resulting from processing in the alpha plus beta field. There shall be no continuous alpha network at prior beta grain boundaries. There shall be no coarse, elongated alpha platelets.

9.1微观结构应是 α 和 β 相中产生的 α 和 β 相的精细分散体。在先前的 β 晶粒边界处不存在连续的 α 网络。不应有粗的，伸长的 α 血小板。

9.2 Determine the beta transus temperature for each heat by a suitable method and report on the material certification if required by the purchaser.

9.2通过合适的方法确定每个热量的 β 转变温度，如果买方要求，报告材料认证。

9.3 Alpha case is not permitted for products supplied with a machined, ground, or chemically milled surface finish. For other products, there shall be no continuous layer of alpha case ≥ 0.001 in. when examined at $100\times$ magnification.

9.3对于采用机加工，磨削或化学铣削的表面处理的产品，不允许使用 α 情况。对于其他产品，在 $100\times$ 放大倍数下检查时，不应有连续的 α 情况层 ≥ 0.001 英寸。

10. Significance of Numerical Limits数值限制的意义

10.1 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 E 29.

10.1以下内容适用于本规范中的所有指定数字限值。为了确定符合这些限值，根据实践E29的舍入方法，观察值或计算值应四舍五入到用于表示规格限值的最后右手数字中最接近的单位。

11. Certification认证

11.1 The supplier shall provide a certification that the material was tested in accordance with this specification. A report of the test results shall be furnished to the purchaser at the time of shipment.

11.1供应商应提供材料按照本规范进行测试的认证。测试结果的报告应在装运时提供给买方。

12. Quality Program Requirements质量计划要求

12.1 The producer shall maintain a quality program as defined in ASQ C1, ISO 9001, or similar quality program.

12.1生产者应保持ASQ C1, ISO 9001或类似质量计划中定义的质量计划。

13. Keywords关键字

13.1 metals (for surgical implants); orthopedic medical devices; titanium alloys; titanium alloys (for surgical implants)

13.1金属（用于手术植入物）；矫形医疗器械；钛合金；钛合金（用于手术植入物）**APPENDIXES附录****(Nonmandatory Information)（非强制性信息）****X1. RATIONALE理由**

X1.1 The purpose of this specification is to characterize the chemical, physical, mechanical, and metallurgical properties of wrought annealed titanium-6aluminum-4vanadium ELI (extra low interstitial) alloy to be used in the manufacture of surgical implants.

X1.1本规范的目的是表征用于制造外科植入物的锻造退火的钛-6铝-4钒ELI（超低间隙）合金的化学，物理，机械和冶金性能。

X1.2 The microstructural requirements contained in this specification represent the current general consensus of opinion with respect to optimization of mechanical properties for implant applications.

X1.2本规范中包含的微观结构要求代表了目前对植入体应用的机械性能优化的一般观点。

X1.3 The minimum mechanical properties specified ensure a baseline of strength and ductility for the highly stressed devices for which this alloy is typically used.

X1.3规定的最小机械性能确保了通常使用该合金的高应力设备的强度和延展性的基线。

X2. BIOCOMPATIBILITY生物兼容性

X2.1 The alloy composition covered by this specification has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the well-characterized level of biological response exhibited by this alloy, it has been used as a control material in Practice F 981.

X2.1本规范涵盖的合金组合物已经成功地用于与软组织和骨接触的人类植入物应用中超过十年。由于该合金表现出的良好表征的生物响应水平，它已被用作实践F 981中的对照材料。

X2.2 No known surgical implant material has ever been shown to be completely free from adverse reactions in the human body. Long-term clinical experience of the use of the material referred to in this specification, however, has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

X2.2从未显示出任何已知的外科植入材料在人体内完全没有不良反应。然而，使用本说明书中提及的材料的长期临床经验表明，如果材料用于适当的应用中，则可以预期可接受的生物反应水平。

SUMMARY OF CHANGES变更摘要

Committee F04 has identified the location of selected changes to this standard since the last issue (F 136 – 02a) that may impact the use of this standard. (Approved Nov. 1, 2008.)

F04委员会已确定自上次发行（F 136 - 02a）以来可能影响本标准的使用的本标准的选定变更的位置。（2008年11月1日批准）

(1) Section 2, Referenced Documents, was updated.

(1) 第2节，参考文件已更新。

(2) Section 6 and subsections 6.1, 6.2, and 6.3 were updated.

(2) 第6节和第6.1,6.2和6.3节已更新。

(3) Test Methods E 539, E 1941, and E 2371 were added to 7.2.4.

(3) 将试验方法E 539, E 1941和E 2371加入到7.2.4中。

(4) Section 8.4 was deleted, and relevant information was moved to subsections 8.2 and 8.3.

(4) 删除了第8.4节，相关信息移至第8.2和8.3小节。

(5) Mechanical Properties have been split into Table 1 for Bar, Wire, and Forgings and Table 2 for Sheet, Strip, and Plate.

(5) 机械性能分为棒材，线材和锻件的表1，片材，带材和板材的表2。

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