ASTM F136 - The Definitive Specification for Surgical Implant Grade Titanium Alloy (Ti-6Al-4V ELI / Grade 23)

Our main products include titanium tubes, titanium plates, titanium rods, titanium wires, titanium foils, and CNC machined titanium parts.

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1. Standard Identification

1.1 Formal Designation

ASTM Designation: F136
Title: Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
UNS Number: R56401
Common Industry Name: Grade 23, Ti-6Al-4V ELI
ISO Equivalent: ISO 5832-3:2018

1.2 Regulatory Recognition

FDA: Recognized consensus standard (CFR Title 21)
EU MDR: Harmonized standard for implantable devices
Health Canada: Recognized standard
PMDA (Japan): Accepted standard for orthopedic implants

1.3 Scope and Application

This specification establishes requirements for wrought titanium alloy material that has been specifically processed and tested for use in manufacturing permanent surgical implants. The material is intended for applications including but not limited

to:
Orthopedic implants (hips, knees, shoulders)
Spinal implants (rods, screws, cages)
Trauma implants (plates, screws, nails)
Dental implants (root-form, plate-form)
Cranial/maxillofacial implants

2. Material Definition and Classification

2.1 Alloy System

Alloy Type: Alpha-Beta titanium alloy
Primary Alloying Elements: 6% Aluminum (alpha stabilizer), 4% Vanadium (beta stabilizer)
ELI Designation: Extra Low Interstitial elements (O, N, C, H)

2.2 Comparison with Related Grades

Parameter	ASTM F136 (Grade 23)	ASTM F1472 (Grade 5)	ASTM B348 (Grade 23)	ASTM F67 (Grade 4)
Primary Use	Medical implants	Medical implants	Industrial	Medical implants
UNS Number	R56401	R56400	R56401	R50700
O_2 Max (%)	0.13	0.20	0.13	0.40
Fe Max (%)	0.25	0.30	0.25	0.50
Required Melting	Double/Triple VAR	Single/Double VAR	VAR	VAR
Fatigue Testing	Mandatory	Optional	Not required	Not required
Microcleanliness	ASTM F1440 required	Optional	Not specified	Not specified

3. Detailed Chemical Composition Requirements

3.1 Elemental Composition Limits (Weight Percent)

Element	Minimum	Maximum	Critical Control Point	Analytical Method
Aluminum (Al)	5.50	6.50	±0.15% from target	ICP-OES, AAS
Vanadium (V)	3.50	4.50	±0.15% from target	ICP-OES, AAS
Oxygen (O)	-	0.13	Critical - ELI defining	Inert gas fusion
Nitrogen (N)	-	0.05	Critical - ELI defining	Inert gas fusion
Carbon (C)	-	0.08	Critical - ELI defining	Combustion analysis
Hydrogen (H)	-	0.0125	Critical - 125 ppm max	Inert gas fusion
Iron (Fe)	-	0.25	Lower than industrial Grade 23	ICP-OES
Yttrium (Y)	-	0.005	-	ICP-MS
Other Elements (each)	-	0.10	Sum must not exceed 0.40%	ICP-OES
Other Elements (total)	-	0.40	-	-

Element	Minimum	Maximum	Critical Control Point	Analytical Method
Titanium (Ti)	Balance	-	-	-

3.2 Interstitial Element Control Rationale

Element	Effect on Properties	Medical Implication	Control Method
Oxygen	Increases strength, reduces ductility and fracture toughness	Critical for fatigue life and crack propagation	VAR melting, strict melt control
Hydrogen	Causes hydrogen embrittlement	Premature implant failure	Vacuum annealing, controlled cooling
Nitrogen	Strong alpha stabilizer, causes severe embrittlement	Risk of brittle fracture	Protective atmosphere processing
Carbon	Forms carbides, reduces ductility	Affects implant flexibility	Raw material selection

4. Manufacturing Requirements

4.1 Melting and Primary Processing

Melting Method: Double or Triple Vacuum Arc Remelting (VAR) mandatory
First melt: Consumable electrode vacuum arc melting
Second melt: VAR of first melt electrode
Third melt: Optional for highest quality (triple VAR)
Alternative Melting: Electron Beam Cold Hearth Melting (EBCHM) or Plasma Arc Melting (PAM) permitted with equivalent qualification
Ingot Quality: Must be free from segregation, pipe, and excessive porosity
Hot Working: Forging or rolling above beta transus temperature (typically 995°C ±15°C)
Condition: Supplied in annealed condition

4.2 Thermal Processing

Annealing Temperature: 700-800°C (1292-1472°F)
Annealing Time: 1-2 hours per inch of cross-section
Cooling Rate: Air cool or faster
Alpha Case Removal: Mandatory acid pickling after heat treatment to remove oxygen-enriched surface layer

4.3 Microstructural Requirements

Structure Type: Equiaxed or transformed beta structure
Alpha Platelet Thickness: Maximum 20 µm
Grain Boundary Alpha: Not continuous
Macrostructure: Uniform grain flow, no abnormalities in macroetch evaluation
Phase Distribution: Alpha phase in beta matrix, approximately 60-90% alpha

5. Mechanical Property Specifications

5.1 Tensile Properties (Longitudinal Direction, Room Temperature)

Property	Test Method	Minimum Requirement	Typical Value	Test Specimen Requirements
Tensile Strength	ASTM E8/E8M	860 MPa (125 ksi)	900-1000 MPa	Gage length: 4D, Diameter: 6.35±0.13 mm
Yield Strength (0.2% offset)	ASTM E8/E8M	795 MPa (115 ksi)	830-900 MPa	Surface finish: 0.8 µm Ra max
Elongation	ASTM E8/E8M	10% in 4D	12-18%	Must be chemically cleaned to remove alpha case
Reduction of Area	ASTM E8/E8M	25%	28-45%	Test speed: 0.005-0.015 mm/mm/min

5.2 Fatigue Properties (Mandatory Requirement)

Test Method: ASTM E466 (Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests)
Test Condition: Rotating beam, R = -1 (fully reversed stress)
Frequency: 30-100 Hz (typical)

Test Environment: Laboratory air, room temperature
Number of Specimens: Minimum 8 per lot/heat
Run-out Condition: 10^7 cycles
Minimum Fatigue Strength: 550 MPa (80 ksi) at 10^7 cycles
Data Reporting: S-N curve must be provided
Specimen Preparation: Electropolished surface, Ra ≤ 0.2 µm

5.3 Additional Mechanical Tests

Young's Modulus: 110-114 GPa (16-16.5 Msi)
Shear Modulus: 40-45 GPa (5.8-6.5 Msi)
Poisson's Ratio: 0.31-0.34
Hardness: 30-36 HRC (typical annealed condition)
Fracture Toughness (KIC): 70-90 MPa√m (typical)

6. Surface and Dimensional Requirements

6.1 Surface Condition

Finish: Descaled and pickled or turned/ground
Surface Defects: No seams, laps, cracks, or forging defects
Depth of Defects: Maximum 0.076 mm (0.003 in) or 5% of section thickness (whichever is less)
Decarburization: Not applicable (titanium alloy)
Alpha Case: Must be completely removed by pickling

6.2 Dimensional Tolerances

Product Form	Diameter/Thickness Tolerance	Straightness Tolerance	Length Tolerance
Bar Stock	±0.1 mm (±0.004 in) for diameters ≤25 mm ±0.15 mm (±0.006 in) for diameters >25 mm	0.5 mm per 300 mm (0.02 in per ft)	+10 mm, -0 mm (+0.4 in, -0 in)
Wire	±0.025 mm (±0.001 in) for diameters ≤1 mm ±0.05 mm (±0.002 in) for diameters 1-5 mm	-	As specified on coil
Forgings	As per drawing specifications	-	-

7. Applications and Design Considerations

7.1 Typical Medical Applications

Orthopedic: Hip stems, femoral components, acetabular shells
Spinal: Interbody fusion devices, pedicle screws, rods
Trauma: Bone plates, intramedullary nails, screws
Dental: Implant bodies, abutments
Craniomaxillofacial: Reconstruction plates, mesh

7.2 Design Factors

Fatigue Life: Primary design consideration
Notch Sensitivity: Moderate ($K_t \approx 2$-3)
Wear Resistance: Poor (requires surface treatments for articulating surfaces)
Modulus Mismatch: 110 GPa vs. 10-20 GPa for bone
CTE: 8.6×10^{-6}/°C

8. Packaging and Storage

8.1 Packaging Requirements

Cleanliness: Clean room packaging (ISO Class 7 or better)
Materials: Non-shedding, non-reactive materials
Identification: Clear labeling with all traceability information
Protection: Protection from mechanical damage and contamination

8.2 Storage Conditions

Environment: Clean, dry, temperature controlled
Shelf Life: Indefinite if properly stored
Handling: Clean gloves, no direct skin contact
Segregation: By heat/lot number