

FSI72-TSM-002 B (TIPORE™ Specifications for US market)

	Service/Nom	Date	Visa
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U.S. GENERAL SPECIFICATIONS
Titanium powders and coatings
APS - VPS - Tipore™

	POWDER	V.P.S.	A.P.S.	REFERENCE DOCUMENTS
		Tipore™ TSU	Tipore™ TIU	
GENERAL REQUIREMENTS	The compliance of Tipore™ TSU and Tipore™ TIU coating to FDA guidance is documented in a Device Master File			FDA - Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements (February 2, 2000) PR001-MOD-002
A) Chemical requirements, % mass/mass				ASTM F1580-07 (powder) FSI74-TSM-003 (powder)
N	≤0.05	≤0.50	≤5.00	
O	≤0.40	≤1.00	≤10.00	
H	≤0.05	≤0.20	≤0.20	
C	≤0.08	≤0.08	≤0.08	
Fe	≤0.50	≤0.50	≤0.50	
Ti	Balance	Balance	Balance	
B) Density (image analysis) *	Does not apply	3.83 +/- 0.67 g/cm3	3.83 +/- 0.67 g/cm3	PT82-TLBP-003
C) Porosity (image analysis) *		0-30%	0-30%	PT82-TLBP-003
D) Roughness (average)				ISO4287 (1998) ISO4288 (1998) NF S94-071 (08/93) FSI82-TLBP-029 PT82-TLBP-003
- Substrate (Roughness meter with a sampling length of 5x0.8 mm) *		Ra = 5 µm +/- 1µm	Rt = 35,5 µm +/- 10 µm	
- Coating (Optical microscope : mean value on 10 pictures 890 µm in width) *		Rt = 150 +/- 50 µm	Rt = 150 +/- 50 µm	
E) Thickness		50 - 500 µm Homogeneity : +/- 30%	50 - 400 µm Homogeneity : +/- 30%	ASTM F1854-01 PT82-TLBP-003 SE3392
F) Static tensile strength		≥ 30 MPa	≥ 22 MPa	ASTM F1147-05 PT82-TLBP-005 SE3364
G) Static shear strength		≥ 30 MPa	≥ 20 MPa	ASTM F1044-05 PT82-TLBP-005 SE3459
H) Fatigue shear strength		≥ 15 MPa for 10 ⁷ cycles	≥ 15 MPa for 10 ⁷ cycles	ASTM F1160-05 SE3363
I) Taber abrasion resistance		≤ 65 mg	≤ 65 mg	ASTM F1978-00 SE3365
J) Authorized and validated substrates		ISO 5832-1 ISO 5832-2 ISO 5832-3 ISO 5832-4 ISO 5832-9 ISO 5832-12	SE2210 SE2511 SE2512 SE3361	
K) Compatible cleaning solvents		Acetone - Ethanol		
L) Compatible sterilization method		Gamma sterilization		

Product referring to this specification shall be notified to MEDICAL COATING

* Roughness, density and porosity specifications are calculated with k=1