

Material Composition of Centinel Spine[®] Implantable Devices

Centinel Spine products and their composition are listed below in order to clarify the materials of fabrication used in these products. Nickel may account for about 90% of the metal sensitivity reactions that occur in approximately 2-3% the patient population. Women are more likely to experience metal allergies. All listed alloys with greater than 10% nickel are more likely to cause nickel allergy reactions in a small percentage of the patient population. Highly sensitized patients may experience nickel allergy reactions at lower nickel levels and an allergist should be consulted under these circumstances.

Other metal sensitizers include chromium in stainless steels (18-22% Cr) and cobalt-base alloys (20-28% Cr). Cobalt is also considered a metal sensitizer and is present in cobalt-base alloys Co-28Cr-6Mo, L-605, Elgiloy, and MP35N in the range of 30-65% Co. Chromium and cobalt allergy reactions are relatively rare when compared to nickel. The nickel content of titanium implants is extremely low because nickel is not intentionally added to titanium compositions. Titanium implants are recommended for patients who have a known allergic response to metals. Centinel Spine recommends that patients with metal allergies consult an allergist.

Centinel Spine does not provide samples for allergy testing. If allergy testing is needed, patients should consult an allergist.

<u>ACTILIF[™] C interbody spinal fusion device, and STALIF C[®], STALIF[®] M (MIDLINE II[™]), and STALIF L[®] Integrated Interbody[™] spinal fusion devices:</u>

- Implant: Manufactured from polyetheretherketone (PEEK) to ASTM F2026. X-Ray marker rods and spheres are manufactured from unalloyed Tantalum (Ta) per ASTM F-560.
- Screws: Manufactured from Titanium Alloy (Ti-6Al-4V) to ASTM F-136.

STALIF C-Ti[®] and STALIF[®] M-Ti (MIDLINE II-Ti[™]) Integrated Interbody[™] spinal fusion devices:

- Implant: Manufactured from polyetheretherketone (PEEK) to ASTM F2026 with optional commercially pure titanium (CP-Ti) coating to ASTM F1580. X-Ray marker rods and spheres are manufactured from unalloyed Tantalum (Ta) per ASTM F-560.
- Screws: Manufactured from Titanium Alloy (Ti-6Al-4V ELI) to ASTM F-136.

<u>ACTILIF™ C FLX interbody spinal fusion device, and STALIF C[®] FLX, STALIF[®] M FLX, and STALIF L[®]</u> <u>FLX Integrated Interbody™ spinal fusion devices:</u>

- Implant: Manufactured from Titanium Alloy (Ti-6Al-4V ELI) per ASTM F3001.
- Screws: Manufactured from Titanium Alloy (Ti-6Al-4V ELI) to ASTM F-136.

ALTOS[™] Posterior Cervical Thoracic System:

• Implants (rods, hooks, polyaxial screws, and connecting components): Manufactured from Titanium Alloy (Ti-6AI-4V ELI) according to ASTM F-136 or ISO 5832-3.

FORTOS-C[™] Anterior Cervical Plate System:

 Implants (plates and screws): Manufactured from Titanium Alloy (Ti-6Al-4V ELI) to ASTM F-136.

Prodisc C US (Legacy), Nova, SK and Vivo devices:

- Superior and Inferior Endplate Material: Manufactured from Cobalt Chrome (low carbon composition) to ISO 5832-12 and ASTM F1537-11.
- Superior and Inferior Endplate Coating: Manufactured from commercially pure titanium (CP-Ti) powder form per ASTM F1580.
- Inlay: Manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) to ISO 5834-1 and ASTM F648.

Prodisc C International (Legacy), Nova and Vivo devices:

- Superior and Inferior Endplate Material: Manufactured from Titanium Alloy (Ti-6Al-4V) to ASTM F-136 & ISO 5832 Part 3 and BS 7252 Part 3.
- Insert Material: Manufactured from Cobalt Chrome (low carbon composition) to ISO 5832-12 and ASTM F1537.
- Superior and Inferior Endplate Coating: Manufactured from commercially pure titanium (CP-Ti) powder form per ASTM F1580.
- Inlay: Manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) to ISO 5834-1 and ASTM F648.

Prodisc L US and International devices:

- Superior and Inferior Endplate Material: Manufactured from Cobalt Chrome (hot worked) to ISO 5832-12 and ASTM F1537-11.
- Superior and Inferior Endplate Coating: Manufactured from commercially pure titanium (CP-Ti) powder form per ASTM F1580.
- Inlay: Manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) to ISO 5834-1 and ASTM F648.
- Prodisc L US inlays have a tantalum marker per ASTM F560.

The following tables are excerpts from the appropriate international standards that specify the material chemistry for each of the material components:

Ti-6Al-4V ELI material per ASTM F-136

TABLE 3 Chemical Requirements		
Element	Composition, % (mass/mass)	
Nitrogen, max	0.05	
Carbon, max	0.08	
Hydrogen, max	0.012 ^A	
Iron, max	0.25	
Oxygen, max	0.13	
Aluminum	5.5-6.50	
Vanadium	3.5-4.5	
Titanium ^B	balance	

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

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

Floment	Compositions, max % mass/mass		
Element	R05200 ⁴	R05400 ^B	
Carbon	0.010	0.010	
Oxygen	0.015	0.03	
Nitrogen	0.010	0.010	
Hydrogen	0.0015	0.0015	
Niobium	0.10	0.10	
Iron	0.010	0.010	
Titanium	0.010	0.010	
Tungsten	0.050	0.050	
Molybdenum	0.020	0.020	
Silicon	0.005	0.005	
Nickel	0.010	0.010	
Tantalum	balance ^C	balance ^C	

Tantalum (Ta) per ASTM F-560 TABLE 1 Chemical Requirements

^A Electron-beam or vacuum-arc cast tantalum.

^B Sintered tantalum.

^C The percentage of tantalum is determined by difference and need not be determined or certified.

TABLE 1 Chemical Requirements						
Element	Unalloyed Ti Sponge Ti Powder ^A Powder ^B % (mass/mass) % (mass/mass)		oonge der ^B s/mass)	Ti-6Al-4V Powder ^C % (mass/mass)		
	Min	Max	Min	Max	Min	Max
Al				0.05	5.50	6.75
V					3.50	4.50
0		0.40		0.40 ^D		0.20
Fe		0.50		0.15		0.30
С		0.08		0.03		0.08
Н		0.05		0.03		0.015
N		0.05		0.02		0.05
Cu						0.10
Sn						0.10
Si				0.04		
CI				0.20 ^E		
Na				F		
Y						0.005 ^C
Ti	bala	nce ^G	bala	nce ^G	bala	ance ^G

Commercially Pure Titanium (CP-Ti) powder to ASTM F-1580

^A Chemistry per Specification F67 except hydrogen.

^B Chemistry per Specification B299, general purpose grade.

^c Chemistry per Specification F1472.

^{*D*} Oxygen per Specification B299 is 0.15 %. This level is reasonable for sponge product but not for powder because of the increased surface area of small particle powder product.

^E Lower maximum chlorine content may be agreed upon between buyer purchaser and seller supplier.

^F Sodium or magnesium, 0.50 maximum.

^G The percentage of titanium is determined by difference and need not be measured.

Cobalt Chrome ISO 5832-12 (Alloy 1)

Table 1 — Chemical composition

-	Mass fraction %		
Element	Alloy 1 Low carbon	Alloy 2 High carbon	
Chromium	26,0 to 30,0	26,0 to 30,0	
Molybdenum	5,0 to 7,0	5,0 to 7,0	
Iron	0,75 max.	0,75 max.	
Manganese	1,0 max.	1,0 max.	
Silicon	1,0 max.	1,0 max.	
Carbon	0,14 max.	0,15 to 0,35	
Nickel	1,0 max.	1,0 max.	
Nitrogen	0,25 max.	0,25 max.	
Cobalt	Balance	Balance	

Ultra High Molecular Weight Polyethylene (UHWMPE) to ISO 5834-1

Element	Мах	Test method according		
	Type 1	Type 2	Type 3 ^a	to subclause
Ash	125	125	300	8.3
Titanium	40	40	150	8.4
Calcium	5	5	50	8.4
Chlorine	30	30	90	8.4
Aluminium	20	20	100	8.4
a Type 3 polymer is no	longer manufactured. He	wever in order to cover	existing supplies held in	stocknile, this Type 3 material is

Table 2 — Maximum ash and trace element content

^a Type 3 polymer is no longer manufactured. However, in order to cover existing supplies held in stockpile, this Type 3 material is retained in this part of ISO 5834 until the next revision.

Polyetheretherketone (PEEK) to ASTM F2026

Parameter	Method	Requirement	
Glass transition temperature, T_g (°C)	DSC, ^A 20°K/min, sealed sample, T _g taken on second reheat, D3418	125 - 165	
Melt temperature, T _m (°C)	DSC, 20°K/min, sealed sample, T _m taken as max point on reheat endotherm, D3418	320 - 360	
Recrystallization temperature, T_{σ} (°C)	DSC, 20°K/min, sealed sample, T _c taken as max point on cooling exotherm, D3418	260 - 320	
Viscosity	As agreed per 5.4	As agreed per 5.4	
Infrared spectrum	As agreed per 5.2	As agreed per 5.2	
Total heavy metals as lead, max, %	US Pharmacopeia, Test 231	<0.1	