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>Prodisc C US (Legacy), Nova, SK and Vivo devices:</u>

- 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.

<u>Prodisc C International (Legacy), Nova and Vivo devices:</u>

- 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.

Tantalum (Ta) per ASTM F-560

TABLE 1 Chemical Requirements

Element	Compositions, max % mass/mass	
	R05200[A]	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]

[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.

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

TABLE 1 Chemical Requirements

Element	Unalloyed Ti Powder[A] % (mass/mass)		Ti Sponge Powder[B] % (mass/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
O		0.40		0.40[D]		0.20
Fe		0.50		0.15		0.30
C		0.08		0.03		0.08
H		0.05		0.03		0.015
N		0.05		0.02		0.05
Cu						0.10
Sn						0.10
Si				0.04		
Cl				0.20[E]		
Na				[F]		
Y						0.005[C]
Ti	balance[G]		balance[G]		balance[G]	

[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

Element	Mass fraction %	
	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

Table 2 — Maximum ash and trace element content

Element	Maximum quantity permitted mg/kg			Test method according to subclause
	Type 1	Type 2	Type 3[a]	
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. 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

TABLE 1 Required Properties of Virgin Resin

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_c (°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

[A] Differential Scanning Calorimetry (DSC).