Material Composition of the iFuse Implants™

Composition of iFuse Implants

iFuse Implants are constructed from a core of titanium alloy (Ti-6Al-4V ELI) and are coated with commercially pure (CP) titanium. The iFuse-3D Implants are additively manufactured from titanium alloy (Ti-6Al-4V ELI) powder. The alloyed titanium of both Implants has additional elements (see chart below) added to it while the CP titanium in the coating of the iFuse Implant doesn't have other metals/elements added to it. While no additional elements have been added to the CP titanium, there may be trace amounts of other elements present in the metal.

The CP titanium and titanium alloys are manufactured according to American Society for Testing and Materials (ASTM) International specifications.

The core of Ti-6Al-4V ELI titanium alloy is manufactured according to the specifications found in ASTM F136.[1] The iFuse coating is manufactured to the specifications found in ASTM F1580.[2] The powder used to manufacture the iFuse-3D Implant conforms to the specifications of ASTM F3001.[3] The metal products are routinely tested by the manufacturers to confirm that the products conform to these standards. However, there may be trace amounts of other materials[4,5] within the metal samples and the samples will still conform to the given ASTM standards.

Titanium and titanium alloys are commonly used in medical devices. **Medical implants manufactured from alloy compositions covered by ASTM F136, F1580 and F3001 have a long history of successful clinical application in soft tissue and bone in humans**.[2] Titanium alloys demonstrate favorable material properties compared to other metals. In addition, titanium is significantly less likely to stimulate an immune response compared to other metals such as nickel, cobalt, and chromium.[6] However, it has been documented that, while uncommon, individuals may develop sensitivity to titanium and other metal ions such as beryllium, tantalum and vanadium.[6-8]

SI-BONE recently had testing performed by an independent third-party laboratory to identify and quantify the amount of trace metals present in the iFuse and iFuse-3D Implants. The materials of both implants contain trace amounts of nickel, cobalt, and chromium as well as trace amounts of other elements. This independent testing also confirmed that the iFuse and iFuse-3D Implant compositions adhere to the ASTM standards (see Table 1).

If a patient is suspected of having sensitivity to metal, the physician may consider having the patient tested for metal allergies with a test such as a MELISA test (Memory Lymphocyte Immunostimulation Assay, http://www.melisa.org)[9,10] or the LTT (Lymphocyte transformation test, https://www.orthopedicanalysis.com/)[11,12] prior to implanting the iFuse or iFuse-3D Implants. Both of the MELISA and the LTT are blood tests that measure metal hypersensitivity – type IV allergy to metals and other low-molecular weight allergens.

Table 1. Material Composition of the iFuse Implants (Includes ASTM Specifications and Comprehensive Analysis by an Independent Laboratory) *All values in percent by weight*						
	iFuse				**iFuse-3D**	
	Ti-6Al-4V Titanium Alloy Core		**CP Titanium Powder Coating**		**Ti-6Al-4V Titanium Alloy Powder**	
Element	**ASTM F136 Specifications** (including tolerances)	**Test Results Percent Weight** (300213)	**ASTM F1580 Specifications** (including tolerances)	**Test Results Percent Weight** (300213)	**ASTM F3001 Specifications** (including tolerances)	**Test Results Percent Weight** (300652)
Nitrogen	0.07 (max)	0.0013	0.04 (max)	0.028	0.05 (max)	0.013
Carbon	0.10 (max)	0.03	0.05 (max)	0.3[a]	0.08 (max)	0.02
Hydrogen	0.014 (max)	0.0027	0.032 (max)	0.026	0.012 (max)	0.0067
Iron	0.35 (max)	~0.2	0.25 (max)	0.0073	0.25 (max)	0.16
Oxygen	0.15 (max)	0.15	0.40 (max)	0.33	0.13 (max)	0.13
Aluminum	5.1 - 6.9	5.98	0.09 (max)	0.002	5.50 – 6.50	6.38
Vanadium	3.35 - 4.65	4.15	*not required*	0.0037	3.50 – 4.50	4.02
Yttrium	*not required*	<0.02	*not required*	<0.02	0.005 (max)	<0.02[c]
Silicon	*not required*	0.021	0.06 (max)	0.0081	*not required*	0.013
Chlorine	*not required*	~0.0002	0.20 (max)	~0.3[b]	*not required*	0.000051
Sodium	*not required*	0.000061	0.50 (max)	0.033	*not required*	0.000014
Nickel	*not required*	0.0052	*not required*	0.00022	*not required*	0.0084
Chromium	*not required*	0.0041	*not required*	0.00017	*not required*	0.014
Cobalt	*not required*	0.000091	*not required*	0.00052	*not required*	0.00099
Copper	*not required*	0.0014	*not required*	0.003	*not required*	0.00047
Molybdenum	*not required*	0.0031	*not required*	0.00064	*not required*	0.0023
Titanium	Balance	Balance	Balance	Balance	Balance	Balance

a Not confirmed with additional testing. Material Certification for Carbon verified at 0.006% by weight.
b Not confirmed with additional testing. Material Certification for Chlorine verified at 0.02% by weight.
c Not confirmed with additional testing. Test Report 300533 includes <0.005 Yttrium.

Sources cited

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