



Information for Physicians Who Believe They May Have a Patient With a Sensitivity to Metal

The most common metallic sensitizers that are used in orthopaedic alloys are nickel, cobalt, and chromium. Orthopaedic grades of stainless steel and cobalt-chromium alloys both contain these materials while titanium and titanium alloys do not. Information is attached concerning the composition of Zimmer cobalt-chromium, tantalum, stainless steel and titanium alloys. The excellent biocompatibility of titanium and its alloys, such as Ti-6Al-4V alloy, is well documented. Persons with a history of allergies, including sensitivities to cobalt, chromium, or nickel, generally do not exhibit or develop sensitivity to titanium or other constituents of Ti-6Al-4V alloy.

Standard sensitivity testing has not proven to be an accurate predictor of the likelihood of a reaction to a metallic implant. Clinical experience has shown that patients who have tested positive for metal sensitivity generally do not exhibit a reaction when the sensitizing material is implanted as an orthopaedic device.

In the past Zimmer recommended external metal disc skin testing for allergic reaction and provided test samples of various implant alloys to be used for this purpose. We no longer follow this policy for the following reasons:

1. Taping dry metal disks to a patient's skin is not considered the optimal method for metal sensitivity testing. In order to challenge a patient's response to an implant constituent, the metal should be in water-soluble ion form.
2. Solid test specimens may irritate the underlying skin by rubbing and pressing against it. This nonspecific irritation may be mistaken for a positive reaction to the components of the metal.

Currently, Zimmer recommends that a patient with a potential metal sensitivity be seen by a dermatologist or allergist and undergo appropriate testing before having surgery. Most dermatologists and allergists have access to products that can be used for metal sensitivity testing (nickel sulfate, cobalt chloride, potassium dichromate, etc.). Physicians consulted by Zimmer stated that the T.R.U.E. TEST^{TM*} Patch Test may be obtained exclusively from:

- SmartPractice^{®**} through their Allerderm division (telephone number 800-365-6868, www.truetest.com or www.allerderm.com)

* Trademark of Allerderm Laboratories

** Trademark of SmartHealth, Inc.

There may be other sources for metal sensitivity testing of which we are not aware. If you are located in an area where there is no access to a dermatologist or allergist who is familiar with patch testing for metal allergens, we suggest you call the American Academy of Dermatology's American Contact Dermatitis Society subgroup for a reference (telephone number 847-330-0230).

Other methods of metal sensitivity testing, such as Lymphocyte Transformation Testing (LTT), have been used to assess metal sensitivity. Physicians consulted by Zimmer stated that Metal-LTT can be obtained from:

- Orthopedic Analysis/Department of Orthopedic Surgery, Rush University Medical Center (Chicago, IL, telephone number 312-942-5000, Ext. 29723).

If more information is needed, please call Rebecca Davis 800-613-6131, Ext. 14108, 574-372-4922 or e-mail at rebecca.davis@zimmer.com.

Chemical Composition of Zimmer Implant Metals

Biodur® 108 Alloy*

Zimmer Trade Names: None
Standards: None

Composition (weight percent):

Carbon - 0.08 max	Silicon - 0.75 max	Nitrogen - 0.85 to 1.10
Manganese - 21.00 to 24.00	Chromium - 19.00 to 23.00	Copper - 0.25 max
Phosphorous - 0.03 max	Nickel - 0.05 max	Iron - balance
Sulfur - 0.01 max	Molybdenum - 0.50 to 1.50	

* Trademark of Carpenter Technology Corp.

Commercially Pure Titanium - Grade 1

Zimmer Trade Names: *Protasul*® - Ti Metal Alloy
Standards: ISO 5832-2 / ASTM F-67

Composition (weight percent):

Nitrogen - 0.03 max	Hydrogen - 0.015 max	Oxygen - 0.18 max
Carbon - 0.08 max	Iron - 0.20 max	Titanium - balance

Ti-6Al-4V Alloy - Wrought ELI Grade

Zimmer Trade Names: *Protasul*® - 64WF Metal Alloy / *Tivanium*® Ti-6Al-4V Alloy
Standards: ISO 5832-3 / ASTM F-136

Composition (weight percent):

Aluminum - 5.50 to 6.50	Nitrogen - 0.05 max	Iron - 0.25 max
Vanadium - 3.50 to 4.50	Oxygen - 0.13 max	Titanium - balance
Carbon - 0.08 max	Hydrogen - 0.012 max	

Ti-6Al-4V Alloy - Cast

Zimmer Trade Names: *Tivanium*® Ti-6Al-4V Alloy
Standards: ASTM F-1108

Composition (weight percent):

Aluminum - 5.50 to 6.75	Nitrogen - 0.05 max	Iron - 0.30 max
Vanadium - 3.50 to 4.50	Oxygen - 0.20 max	Titanium - balance
Carbon - 0.10 max	Hydrogen - 0.015 max	

Ti-6Al-7Nb Alloy - Wrought or Forged

Zimmer Trade Names: *Protasul*® - 100 Metal Alloy
Standards: ISO 5832-11 / ASTM F-1295

Composition (weight percent):

Aluminum - 5.50 to 6.50	Nitrogen - 0.05 max	Iron - 0.25 max
Niobium - 6.50 to 7.50	Oxygen - 0.20 max	Tantalum - 0.50 max
Carbon - 0.08 max	Hydrogen - 0.009 max	Titanium - balance

Co-Cr-Mo Alloy - Cast

Zimmer Trade Names: *Protasul*[®] - 1 Metal Alloy / *Zimaloy*[®] Cobalt-Chromium-Molybdenum Alloy

Standards: ISO 5832-4 / ASTM F-75

Composition (weight percent):

Chromium - 27.0 to 30.0	Silicon - 1.00 max	Nitrogen - 0.25 max
Molybdenum - 5.0 to 7.0	Manganese - 1.00 max	Aluminum - 0.30 max
Nickel - 1.00 max	Tungsten - 0.20 max	Boron - 0.01 max
Iron - 0.75 max	Phosphorous - 0.020 max	Cobalt - balance
Carbon - 0.35 max	Sulfur - 0.010 max	

Co-Cr-Mo Alloy - Wrought

Zimmer Trade Names: *Protasul*[®] - 21WF Metal Alloy

Standards: ISO 5832-12 / ASTM F-1537

Composition (weight percent):

Chromium - 26.0 to 30.0	Silicon - 1.00 max
Molybdenum - 5.0 to 7.0	Manganese - 1.00 max
Nickel - 1.00 max	Nitrogen - 0.25 max
Iron - 0.75 max	Cobalt - balance
Carbon - 0.35 max	

316L Stainless Steel - Cast or Wrought

Zimmer Trade Names: None

Standards: ISO 5832-9 / ASTM F-138 or F-139

Composition (weight percent):

Carbon - 0.030 max	Silicon - 0.75 max	Nitrogen - 0.10 max
Manganese - 2.0 max	Chromium - 17.00 to 19.00	Copper - 0.50 max
Phosphorous - 0.025 max	Nickel - 13.00 to 15.00	Iron - balance
Sulfur - 0.010 max	Molybdenum - 2.25 to 3.00	

Tantalum Trabecular Metal - Cast or Wrought

Zimmer Trade Names: *Trabecular Metal*[™] Technology

Standards: None

Composition (weight percent):

Oxygen - 0.20 max	Iron - 0.50 max	Silicon - 0.040 max
Nitrogen - 0.20 max	Tungsten - 0.20 max	Nickel - 0.050 max
Hydrogen - 0.050 max	Molybdenum - 1.00 max	Tantalum - balance

Carbon - Typically 1% by weight of the material. The carbon is encased within the tantalum structure. For all practical purposes the composition of the material in contact with human tissue is pure tantalum metal.