acumed®

Metal Sensitivity Statement

Physician Information Regarding Metal Sensitivity in Patients

Although rare, metal sensitivities and allergic reactions to foreign materials have been reported for orthopaedic implant patients. The most common sensitivities, in order of their frequency, are to nickel, cobalt, and chromium.[1] Implant sensitivity reactions to titanium and titanium alloy are much less common. Information on the composition of metals in Acumed implants is included with this statement (see following page). All implant materials used by Acumed are specified for surgical implants, and many are associated with American Society for Testing and Materials (ASTM) specifications.

Preoperative screening for metal sensitivity may help identify patients predisposed to symptomatic metal sensitivity. Acumed recommends that a patient with potential metal sensitivity be seen by a dermatologist or allergist and undergo appropriate testing prior to material selection or implant surgery. Dermatologists and allergists should have access to information and products for metal sensitivity testing.

Examples of information that dermatologists and allergists use as reference include:

- The T.R.U.E. TEST® is a patch test for diagnosis of allergic contact dermatitis, with details at www.truetest.com
- MELISA® is a medical test that may detect hypersensitivity to metals, with details at www.melisa.org
- The American Contact Dermatitis Society provides information on testing for metal allergens at www.contactderm.org

Modern metal alloys have been used successfully in orthopaedic and dental implants for almost 100 years. Many of the metals used today were initially used for experimentation in the early 1900s in order to determine which metals were strong, corrosion-resistant, and biocompatible. The widespread use of titanium for implants, however, did not begin until after the 1960s due to difficulty in its processing.

Companies that use metals in their implants today typically choose materials that meet ASTM or ISO specifications for implant-grade material. These specifications have evolved over time and help ensure that the materials used have the proper chemical composition, strength, and structure.

Implant materials that comply with standardized specifications may still contain trace amounts of elements that are unintended and possibly harmful. For example, in addition to the elements shown above, it is possible to have impurities such as nickel present in a standard-compliant material.[2] When present, these impurities are in extremely small quantities, typically measured in parts per million. Surgeons and patients alike should be aware that there is a risk associated with any implantable material due to possible impurities.

Titanium is available in many forms, including both alloyed and commercially pure versions. An alloyed titanium material will contain elements that affect material characteristics of the overall material, such as strength. One of the most commonly used implant-grade titanium alloys is Ti-6Al-4V (titanium-6aluminum-4vanadium). This material, specified in ASTM F136, is known for being lightweight, corrosion resistant, high strength and biocompatible.

Many people have demonstrated sensitivity to nickel and materials containing nickel. While titanium is considered to be “nickel free,” and titanium alloy is commonly used as an alternative to stainless steel alloys for patients who may have nickel sensitivity, it is possible that trace amounts of impurities including nickel could be contained within these materials. Nickel impurities in titanium implants, even in very small amounts, could lead to a patient reaction.

Chemical Composition of Acumed Metal Implants

The metals described below are commonly used in Acumed implants. The ASTM-specified composition is provided.

Metal	Standard	Composition %	
Titanium Alloy (Ti-6Al-4V ELI)	ASTM F136-13	Nitrogen—0.05 max Carbon—0.08 max Aluminum—5.5–6.50 Iron—0.25 max	Oxygen—0.13 max Vanadium—3.5–4.5 Hydrogen—0.012 max Titanium—balance
Titanium Unalloyed (Commercially Pure) Grade 2	ASTM F67-13	Nitrogen—0.03 max Carbon—0.08 max Hydrogen—0.015 max	Iron—0.30 max Oxygen—0.25 max Titanium—balance
Titanium Unalloyed (Commercially Pure) Grade 4	ASTM F67-13	Nitrogen—0.05 max Carbon—0.08 max Hydrogen—0.015 max	Iron—0.50 max Oxygen—0.40 max Titanium—balance
Stainless Steel (SS 316L or 316LVM)	ASTM F138-13	Carbon—0.03 max Manganese—2.0 max Chromium—17.0–19.0 Sulfur—0.010 max Silicon—0.750 max Nitrogen—0.10 max	Nickel—13.0–15.0 Molybdenum—2.25–3.0 Copper—0.50 max Phosphorous—0.025 max Iron—balance
Cobalt Chrome (Co–Cr–Mo)	ASTM F799-11 & ASTM F1537-11	Carbon—0.14 max Chromium—26.0–30.0 Molybdenum—5.0–7.0 Nickel—1.0 max Iron—0.75 max	Silicon—1.0 max Manganese—1.0 max Nitrogen—0.25 max Cobalt—balance
Cobalt Chrome (Co–Cr–W–Ni)	ASTM F90-14	Carbon—0.05–0.15 Silicon—0.40 max Phosphorous—0.04 max Sulfur—0.030 max Chromium—19.0–21.0	Iron—3.0 max Nickel—9.0–11.0 Tungsten—14.0–16.0 Manganese—1.00–2.00 Cobalt—balance

References

1. Hallab N, et al. Metal sensitivity in patients with orthopaedic implants. *J Bone Joint Surg.* 2001;3(83-A):428-435.
2. Harloff T, et al. Titanium allergy or not? Impurity of titanium implant materials. *Health.* 2010;4(2):306-310.

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