Physician Information for 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 frequencies, are nickel, cobalt and chromium.1 Titanium-alloy implant sensitivity reactions are much less common. Information on the composition of materials in Acumed’s implants is included with this statement. All materials used by Acumed are specified for surgical implants, with the American Society for Testing and Materials (ASTM) specifications provided for each.

When material sensitivity is suspected, appropriate tests should be performed prior to material selection or implantation. Historically, testing for delayed-type hypersensitivity has been conducted in vivo by skin testing, and in vitro by lymphocyte transformation testing (LTT) and leukocyte migration inhibition (LIF or MIF) testing.1 However, patch or skin testing is not representative of sensitization of deep immunoresponsive tissue.2 Preoperative screening for metal sensitivity, particularly for constituent metals present in greater quantities, can be performed to identify patients predisposed to symptomatic metal sensitivity.3

Acumed recommends that a patient with potential metal sensitivity be seen by a dermatologist or allergist and undergo appropriate testing before having implant surgery. Dermatologists and allergists should have access to products for metal sensitivity testing. Here are examples of information that may be helpful:

- 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.

Acumed has not validated the information provided by these organizations. Additional information on metal sensitivity and sensitivity testing continues to become available, so physicians should not consider this information to be completely comprehensive.
Chemical Composition of Acumed Metal Implants*

Titanium Alloy (Ti 6Al 4V ELI)
Standard – ASTM F 136-08
Composition %: Nitrogen – .05 max  Carbon – .08 max  Hydrogen – .012 max
               Iron – 0.25 max  Oxygen – 0.13 max  Aluminum – 5.5-6.5
               Vanadium – 3.5-4.5  Titanium – balance

Titanium Unalloyed (Commercially Pure) Grade 2
Standard – ASTM F 67-06
Composition %: Nitrogen – .03 max  Carbon – .08 max  Hydrogen – .015 max
               Iron – 0.30 max  Oxygen – 0.25 max  Titanium – balance

Stainless Steel (SS 316L or 316LVM)
Standard – ASTM 138-08
Composition %: Carbon – .03 max  Manganese – 2.0 (max)  Phosphorous – .025 max
               Sulfur – .010 max  Silicon – 0.750 max  Chromium – 17.0-19.0
               Nickel – 13.0-15.0  Molybdenum – 2.25-3.00  Iron – balance
               Nitrogen – 0.10 max  Copper – 0.50 max  Cobalt – balance

Cobalt Chrome (Co – Cr – Mo) Alloy # 1
Standards – ASTM F 799-11 and ASTM F 1537-11
Composition %: 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)
Standards – ASTM F 90-01
Composition %: Carbon – 0.15 max  Manganese – 2.0 max  Silicon – 0.40 max
               Sulfur – .03 max  Chromium – 19.0-21.0  Phosphorous – 0.04 max
               Nickel – 9.0 – 11.0  Tungsten – 14.0-16.0  Iron – 3.0 max
               Cobalt – balance

*Note the following regarding possible impurities in metallic implants.

The Composition of Implant Grade Materials

Implant materials which are made to the highest international standards may still contain trace amounts of elements that are unintended and possibly harmful. One example of this is the possible inclusion of minute amounts of nickel in titanium and titanium alloys. While it is unclear if these trace amounts are harmful, surgeons and patients should understand that there is a risk associated with any implantable material.

Modern metal alloys have been used successfully for orthopaedic and dental implants for almost 100 years. Many of the metals that we use today began with experimentation in the early 1900s in order to determine which metals were strong, corrosion resistant and biocompatible. Titanium due to its difficulty in processing is one exception and its widespread use in medicine did not occur until after the 1960s.

Metals used for orthopaedic surgery are well proven having been used successfully in millions of procedures. Companies today that use metals for their products will choose materials that are processed to meet one of the
appropriate ASTM or ISO specifications for implant grade material. These specifications have evolved over time and ensure that the materials which are delivered from a materials manufacturer have the proper chemical composition, strength and structure. When submitting to the FDA or for CE Mark approval for most products both the ASTM and the ISO specifications are recognized as being the standard for use in orthopaedic implants.

Titanium can come in many forms including both alloyed and commercially pure versions. An alloyed material will contain titanium and other elements that in most cases are added to change the strength of a particular material. One of the most commonly used alloys for both medical and aerospace applications is described in ASTM F 136 and is known as Ti 6Al 4V. This material is light weight, corrosion resistant, high strength and biocompatible.

The composition for Ti 6Al 4V is primarily as follows:

90% Titanium
6% Aluminum
4% Vanadium

While the elements shown above represent the primary materials used to create this alloy, other small amounts of the following materials are allowed to be present according to the ASTM specification.

<table>
<thead>
<tr>
<th>Element</th>
<th>Allowable %</th>
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<tbody>
<tr>
<td>Nitrogen</td>
<td>0.05</td>
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<tr>
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<tr>
<td>Hydrogen</td>
<td>0.012</td>
</tr>
<tr>
<td>Iron</td>
<td>0.25</td>
</tr>
<tr>
<td>Oxygen</td>
<td>0.13</td>
</tr>
</tbody>
</table>

In addition to the elements shown above it is also possible to have impurities such as nickel. These impurities are present in extremely small quantities typically measured in the parts per million. Many people have demonstrated sensitivity to nickel and materials containing nickel. While titanium is considered to be nickel free it is possible that minute amounts of impurities could be contained within these materials.

Titanium alloy is commonly used as a substitute for stainless steel alloys for patients who may have nickel sensitivity but there is some evidence that impurities in titanium metallic implants, even in very small amounts, could lead to a reaction by a patient. We are not aware at this time of a clinical study which shows a link between these impurities and the rejection of an implant; however we believe that it may be possible.

While implant grade materials are made to the highest possible standards, surgeons and patients alike should be aware that very small amounts of impurities could be present and impact the performance of a metallic medical device.
Cited Sources


Other Sources