

## CONFORMIS STANCE ON POTENTIAL METAL SENSITIVITY / ALLERGY

### Information for physicians who believe their patient may have sensitivity to metal

The most common metallic sensitizers 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. ConforMIS implants are composed of Cobalt Chrome Molybdenum Alloy (Co-Cr-Mo) and can be supplied in two different specific composition types, information for both can be found below.

ConforMIS does not recommend external metal disc skin testing for allergic reaction and as a result our policy is to not offer test samples of various implant alloys that could be used for this purpose. We follow this policy for the following reasons:

- Standard sensitivity testing has not proven to be an accurate predictor of the likelihood of a reaction to a metallic implant. Clinical results have 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.
- 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.
- 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.

ConforMIS recommends that a patient with a potential metal sensitivity be seen by a dermatologist or allergist and undergo appropriate testing before having surgery. 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 access the website of the American Contact Dermatitis Society at [www.contactderm.org](http://www.contactderm.org), which provides a physician locator service to identify doctors in your area offering allergy testing. If more information is needed, please email Customer Service at [customer-service@conformis.com](mailto:customer-service@conformis.com) or call 781-345-9001 and select option 3.

#### Material Composition of ConforMIS Metal Implants

**Material Description:** Cobalt Chrome Molybdenum Alloy (Co-Cr-Mo) – Cast Method

**Standards:** ISO 5832-4 / ASTM F-75

**Composition - weight percent:** See Table A.

Table A.		
Chromium - 27.0 to 30.0%	Silicon - 1.0 max	Nitrogen - 0.25 max
Molybdenum - 5.0 to 7.0	Manganese - 1.0 max	Aluminum - 0.10 max
Nickel – 0.50 max	Tungsten - 0.20 max	Boron - 0.01 max
Titanium – 0.10 max	Iron - 0.75 max	Phosphorous - 0.020 max
Carbon - 0.35 max	Sulfur - 0.010 max	Cobalt - Balance

**Material Description:** Cobalt Chrome Molybdenum Alloy (Co-Cr-Mo) – Wrought Method

**Standards:** ISO 5832-12 / ASTM F-1537

**Composition - weight percent:** See table below

Table B.		
Chromium - 26.0 to 30.0%	Silicon - 1.0 max	Nitrogen - 0.25 max
Molybdenum - 5.0 to 7.0	Manganese - 1.0 max	Nickel - 1.0 max
Iron - 0.75 max	Carbon - 0.35 max	Cobalt - Balance