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## Metal Composition

Smith & Nephew uses one of four alloys in most metallic implant components. These materials are: Cobalt-Chromium-Molybdenum Alloy (Co-Cr-Mo; ASTM F-1537), Titanium Alloy (Ti-6Al-4V; ASTM F-1472), 316L Stainless Steel (ASTM F-138), and Zirconium Alloy (Zr-2.5Nb; ASTM F-2384). Elemental compositions for these alloys meet industrial standard limits (in weight percent), as follows:

| Cobalt-Chromium-Molybdenum Alloy | |
|---|---|
| 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 |

| Titanium Alloy | |
|---|---|
| Nitrogen | 0.05 max. |
| Carbon | 0.08 max. |
| Hydrogen | 0.015 max. |
| Iron | 0.30 max. |
| Oxygen | 0.20 max. |
| Aluminum | 5.5 – 6.75 |
| Vanadium | 3.5 – 4.5 |
| Yttrium | 0.005 max. |
| Titanium | Balance |

| 316L Stainless Steel | |
|---|---|
| Carbon | 0.030 max. |
| Manganese | 2.00 max. |
| Phosphorus | 0.025 max. |
| Sulfur | 0.010 max. |
| Silicon | 0.75 max. |
| Chromium | 17.00 – 19.00 |
| Nickel | 13.00 – 15.00 |
| Molybdenum | 2.25 – 3.00 |
| Nitrogen | 0.10 max. |
| Copper | 0.50 max. |
| Iron | Balance |

| Zirconium Alloy | |
|---|---|
| Niobium | 2.40 – 2.80 |
| Oxygen | 0.09 – 0.13 |
| Carbon | 0.027 max. |
| Chromium | 0.020 max. |
| Hafnium | 0.010 max. |
| Hydrogen | 0.0025 max. |
| Iron | 0.15 max. |
| Nitrogen | 0.0080 max. |
| Tin | 0.0050 max. |
| Zirconium | Balance |

The measured content of elements specified above with a maximum limit are typically about half of that maximum limit. Some elements are controlled more tightly by Smith & Nephew specification than are listed above for the industry standards. For example, Smith & Nephew Zirconium Alloy has a maximum limit for Nickel content of 0.0035% (it is difficult to measure Nickel content if it is lower than this).

Some level of "tramp element" content is present in any alloy. Elements not listed above for an alloy are not absent, they are just not specified. For Titanium Alloy, the limit in the aerospace industry for each of these “unspecified” elements, including Nickel, is 0.10% maximum. The aerospace industry requires so much more Titanium Alloy than the medical industry that the metal suppliers also make the medical alloy to this limit (to minimize inventory).

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## UHMWPE Composition

Chemical compositions of the ultra-high-molecular-weight polyethylene (UHMWPE) materials used by Smith & Nephew in the manufacturing of orthopaedic implants are defined in ASTM F648 and ISO 5834-1. The material is a homopolymer of ethylene (i.e., pure polyethylene) with a generic formula of $(C_2H_4)_n$. No stabilizers, antioxidants or processing aids are added to the virgin polymer powder during processing or fabrication of the final implant.

However, several trace impurities that are residuals from the production process or are picked-up during storage and handling could be present in UHMWPE. These common trace impurities are controlled by the same standards (ASTM F648 and ISO 5834-1) with the limits shown in the Table 1 below. For other trace elements not listed in the table, the content for each of those elements shall not exceed 10 mg/kg (10 ppm or 0.001 wt.%). These requirements apply to the Smith & Nephew UHMWPE materials both in the virgin (conventional) and highly crosslinked conditions.

**Table 1:** Allowable limits of trace impurities allowed in UHMWPE according to ASTM F648 and ISO 5834-1. Ash refers to an inorganic substance.

| | Max. (mg/kg, ppm) | Max. (wt.%) |
|---|---|---|
| Ash | 125 | 0.012 |
| Titanium | 40 | 0.004 |
| Aluminium | 20 | 0.002 |
| Calcium | 5 | 0.0005 |
| Chlorine | 30 | 0.003 |

If you have any further questions, please contact Smith & Nephew Customer Service by email at CustomerServiceDomestic@smith-nephew.com or by phone at 800-238-7538.