

TMJ Concepts Patient-Fitted TMJ Implants: Material Composition Information

TMJ Concepts implants are made from implant-grade materials that are certified to conform to various ASTM (American Society for Testing and Materials) Standards. These standards are identified below along with the elemental composition limits for each material.

The actual amount of each element present can vary between material lots as long as it meets the percentage requirements listed. The elements for which maximum percentages are given are considered to be trace elements that are allowable in very small quantities.

Fossa Component Mesh Backing: ASTM F67-13 Grade 1, Unalloyed Titanium

ELEMENT	AMOUNT
Titanium	Balance
Iron	0.20% max
Oxygen	0.18% max
Carbon	0.08% max
Nitrogen	0.03% max
Hydrogen	0.015% max

Fossa Component Articular Bearing: ASTM F648-14 Type 2, Ultra-High-Molecular-Weight Polyethylene (UHMWPE)

ELEMENT	AMOUNT
Homopolymer of ethylene in accordance with D4020	Balance
Ash	125 mg/kg max
Titanium	40 mg/kg max
Chlorine	30 mg/kg max
Aluminum	20 mg/kg max
Calcium	5 mg/kg max

Mandibular Component Condylar Head: ASTM F1537-11 Alloy 1, Wrought Co -28Cr-6Mo Low Carbon Alloy

ELEMENT	AMOUNT
Cobalt	Balance
Chromium	26.0% - 30.0%
Molybdenum	5.0% - 7.0%
Manganese	1.0% max
Nickel	1.0% max
Silicon	1.0% max
Iron	0.75% max
Nitrogen	0.25% max
Carbon	0.14% max

Mandibular Component Body and Fixation Bone Screws: ASTM F136-13, Wrought Ti-6Al-4V ELI* Alloy

ELEMENT	AMOUNT
Titanium	Balance
Aluminum	5.5 - 6.5%
Vanadium	3.5 - 4.5%
Iron	0.25% max
Oxygen	0.13% max
Carbon	0.08% max
Nitrogen	0.05% max
Hydrogen	0.012% max

* Extra Low Interstitial