

## 別表

## 脊椎内固定器具として使用が確認された規格材料

原材料	原材料規格
チタン	<ul style="list-style-type: none"> <li>• JIS H4600 チタン及びチタン合金の板及び条</li> <li>• JIS H4650 チタン及びチタン合金の棒</li> <li>• ISO 5832-2 Implants for surgery -- Metallic materials -- Part 2: Unalloyed titanium</li> <li>• ASTM F67 Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)</li> </ul>
チタン合金	<ul style="list-style-type: none"> <li>• ISO 5832-3 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy</li> <li>• ISO 5832-11 Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy</li> <li>• ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)</li> <li>• ASTM F1108 Standard Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants (UNS R56406)</li> <li>• ASTM F1472 Standard Specification for Wrought Titanium -6Aluminum -4Vanadium Alloy for Surgical Implant Applications (UNS R56400)</li> </ul>
鉄基合金	<ul style="list-style-type: none"> <li>• JIS G4303 ステンレス鋼棒</li> <li>• JIS G4305 冷間圧延ステンレス鋼板及び鋼帯</li> <li>• ISO 5832-1 Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel</li> <li>• ISO 5832-9 Implants for surgery -- Metallic materials -- Part 9: Wrought high nitrogen stainless steel</li> <li>• ASTM F138 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)</li> <li>• ASTM F1314 Standard Specification for Wrought Nitrogen Strengthened 22 Chromium - 13 Nickel - 5 Manganese - 2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)</li> </ul>
コバルトクロム合金	<ul style="list-style-type: none"> <li>• ASTM F562 Standard Specification for Wrought 35 Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications (UNS R30035)</li> </ul>