

別表 1

体内固定用コンプレッションヒッププレート及びその他の構成品として使用が確認された規格材料
(平成 21 年 8 月現在、使用が確認された原材料規格)

原材料	原材料規格
チタン	<ul style="list-style-type: none">• ASTM F67, Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)• ISO 5832-2, Implants for surgery -- Metallic materials -- Part 2: Unalloyed titanium• JIS H4670, チタン及びチタン合金－線
チタン合金	<ul style="list-style-type: none">• ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)• ASTM F1472, Standard Specification for Wrought Titanium -6 Aluminum -4 Vanadium Alloy for Surgical Implant Applications (UNS R56400)• ISO 5832-3, Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy• ISO 5832-11, Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy
鉄基合金	<ul style="list-style-type: none">• ASTM A276, Standard Specification for Stainless Steel Bars and Shapes• ASTM F138, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)• ASTM F139, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)• ASTM F621, Standard Specification for Stainless Steel Forgings for Surgical Implants• 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)• ISO 5832-1, Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel• JIS G4303, ステンレス鋼棒