

別表 1

体内固定用ケーブル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"> ・ JIS H 4600, チタン及びチタン合金の板及び条 ・ JIS H 4670, チタン及びチタン合金線 ・ ASTM F67, Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)
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 F620, Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants ・ ASTM F1472, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications (UNS R56400)
鉄基合金	<ul style="list-style-type: none"> ・ JIS G 4303, ステンレス鋼棒 ・ JIS G 4305, 冷間圧延ステンレス鋼板及び鋼帯 ・ 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 Sheet and Strip for Surgical Implants (UNS S31673) ・ 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)
コバルトクロム合金	<ul style="list-style-type: none"> ・ ASTM F90, Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605) ・ ASTM F799, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539) ・ ASTM F1091, Standard Specification for Wrought Cobalt-20 Chromium-15 tungsten-10 Nickel Alloy Surgical Fixation Wire (UNS R30605)
超高分子量ポリエチレン	<ul style="list-style-type: none"> ・ ASTM F648, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants