Co-20Cr-15W-10Ni

Tradenames
Haynes 25, L605, L-605

Standards
AMS 5537, AMS 5759, ASTM F90, ISO 5832-5

Alternate Names
Co-20Cr-10Ni-15W, UNS R30605

Compositions
See Table 1

Cardiovascular Device Applications
Bare Metal Stent, Drug-Eluting Arterial Stent

Other Medical Device Applications
Radial-Hemi Elbow, Semiconstrained Shoulder Devices

Material Description

Co-20Cr-15W-10Ni is more ductile than most other alloys used for cardiovascular applications. It has excellent in vivo corrosion resistance. Ductility makes this material suitable to fabricate among other things, wire suitable for sutures or cerclage for securing bone fragments (F. Reinlander applications). Also suitable for cardiovascular applications such as stents and eyelet markers in porcine bioprosthesis (Gibbons 2008).

Physical and Mechanical Properties

See Table 2 for physical properties and Table 3 for mechanical properties. Stress-strain curves are shown in Fig. 1.

ISO 10993 Biological Evaluation Tests

See Table 4 for a list of ISO 10993 subparts assessed and passed for devices containing this material.

Degradation in Body Fluid

Degradation Rate

In experiments by Espevik (1978 from Kuhn 1981), the Co-20Cr-10Ni-15W alloy was placed in a beaker of aqueous fluid at 37 °C for two months. After the immersion period, the levels of cobalt and chromium ions present in the solution are described as being undetectable by any means other than atomic adsorption spectroscopy. According to the data sheet (Porvair Metal Foam Properties), L605 is extremely corrosion resistant; however, there is no specific application stated. The corrosion of wrought Haynes Stellite alloy 25 was determined in two different corrosive media. The alloy was observed to degrade at a rate of 0.02 mg/cm^2/day in gasketed tests in 10% HCl and 1% $FeCl_3$ at a temperature of 37 °C; in the corresponding nongasketed test, the alloy was observed to degrade at a rate factor of ten times less (0.002) (Kuhn 1981). In tests in which the alloy was immersed in 20% HCl in a nongasketed test for a duration of ten days, the alloy was observed to degrade at a rate of 0.03 mg/cm^2/day (Kuhn 1981).

Degradation Properties/Mechanisms

According to the Summary of Safety and Effectiveness Data for the Multi-Link Vision Stent, the corrosion resistance of the L-605 CoCr alloy tubing used to fabricate the stent is governed by the presence of a passive oxide film, which results in a decrease in corrosion by isolating the alloy from the corrosive environment. According to the reference, the metal is succeptible to pitting corrosion in the event of film breakdown or discontinuity. In high-chloride solutions such as blood and body fluid, the alloy is unable to repassivate. As part of the studies conducted for the Summary of Safety and Effectiveness Data for the Multi-Link Vision Stent, the corrosion resistance of the material was evaluated in three separate studies, which indicated that the material had good resistance to corrosion. In experiments by Gruen and Amstutz (1975), the simultaneous use of both the Co-28Cr-6Mo alloy and the Co-20Cr-15W-10Ni alloy in an orthopaedic application was observed to result in the accelerated corrosion of the Co-20Cr-15W-10Ni alloy. Other similar studies were conducted as part of the aforementioned Summary of Safety and Effectiveness Data submission for the Multi-Link Vision Stent, which is composed of the L-605

Table 1 Compositions of Co-20Cr-15W-10Ni specific grades

	Composition, %									
Specific Grade	C	Cr	Co	Fe (max)	Mn	Ni	P (max)	Si (max)	S (max)	W
ASTM F90	0.05–0.15	19–21	…	3	1–2	9–11	0.04	0.4	0.03	14–16
Carpenter L-605(a)	0.05–0.15	19–21	…	3	1–2	9–11	0.03	0.4	0.03	14–16
Haynes 25(b)	0.1	20	51	3	1.5	10	…	0.4	…	15
Udimet L-605	0.05–0.15	19–21	…	3	1–2	9–11	0.04	0.4	0.03	14–16

Base element, Co; (a) Type analysis; (b) Balance cobalt (Co)

Excerpted and adapted from Materials for Medical Devices Database, Cardiovascular Module, ASM International, 2009. Refer to the database for the latest updates, details on device applications, and information on manufacturer-specific material grades.

Table 2 Physical properties of Co-20Cr-15W-10Ni

Property	Minimum to maximum value	
	Metric	US
Density	9120–9240 kg/m^3	0.33–0.334 lb/in^3
Melting point	1340–1430 °C	2450–2610 °F
Specific heat capacity	375–384 J/kg·K	0.0897–0.0917 BTU/lb·F
Thermal conductivity	8.8–12.2 W/m·K	5.08–7.05 BTU·ft/h·ft^2·F
Thermal expansion coefficient	12.2–13.8 µstrain/°C	6.77–7.67 µstrain/°F
Electrical resistivity	88.6 µohm·cm	88.6 µohm·cm

Physical properties for Co-20Cr-15W-10Ni have been summarized from the following manufacturers specific grades: ASTM F9, Carpenter L-605, Haynes 25, MMPDS L-605, Udimet L-605

Table 3 Mechanical properties of Co-20Cr-15W-10Ni

Property	Minimum to maximum value	
	Metric	US
Compressive strength	283–313 Mpa	41–45.4 ksi
Tensile strength	773–1180 MPa	112–172 ksi
Bulk modulus	178–188 Gpa	25.9–27.2 10^6 psi
Young's modulus	222–240 GPa	32.1–34.9 10^6 psi
Shear modulus	86.9–87 Gpa	12.6 10^6 psi
Flexural strength (modulus of rupture)	310–427 Mpa	45–61.9 ksi
Elongation	23.6–49.2 %	23.6–49.2 %
Hardness - Vickers	220–300 HV	220–300 HV
Rockwell C Hardness	19.2–51.8	19.2–51.8
Mechanical loss coefficient (tan delta)	0.0004–0.0008	0.0004–0.0008
Poisson's ratio	0.29	0.29
Yield strength (elastic limit)	254–819 Mpa	36.9–119 ksi
Fatigue strength at 10^7 cycles	438 Mpa	63.5 ksi
Fracture toughness	120–150 MPa·m$^{1/2}$	109–137 ksi·in$^{1/2}$

Mechanical properties for Co-20Cr-15W-10Ni have been summarized from the following manufacturers specific grades: ASTM F9, Carpenter L-605, Haynes 25, MMPDS L-605, Udimet L-605

CoCr alloy. The stent material demonstrated acceptable corrosion resistance in contact with stainless steel or other Co-20Cr-15W-10Ni alloy stents.

Corrosion Crevice. In experiments by Levine and Staehle (1997), Haynes alloy 25 was observed to have a very good resistance to crevice corrosion. In experiments by Sutow et al. (1985), tests were conducted on the Co-20Cr-10Ni-15W alloy immersed in deaerated Ringer's solution, maintained at pH 7 and a temperature of 37 °C. Anodic polarization was conducted potentiostatically, and the resultant currents were measured at 600 mV relative to a standard calomel electrode for 1000 min. The Co-20Cr-10Ni-15W alloy was observed to be resistant to crevice corrosion.

Corrosion Pitting. Cohen and Wulff (1972) measured the rest potentials of Haynes Stellite 25 alloy fitted to a collar to stimulate pitting corrosion. Rapid potential fluctuations were observed, which the authors state are indicative of pitting corrosion.

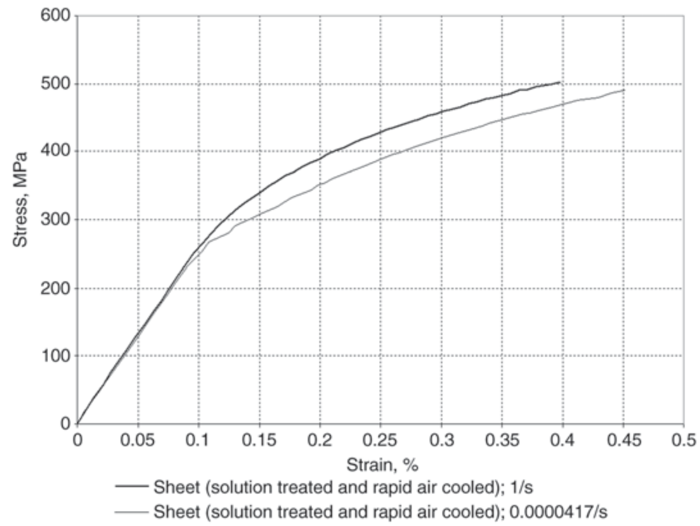

Fig. 1 Stress-strain curve for Co-20Cr-15W-10Ni, 2.77 mm (0.109 in.) sheet, solution treated at 1200 °C (2200 °F) and rapid air cooled. Source: ASM International 2002

Table 4 ISO 10993 subparts passed by devices containing Co-20Cr-15W-10Ni

ISO No.	Title
10993/3	Genotoxicity, carcinogenicity, and reproductive toxicity
10993/4	Interactions with blood
10993/5	In vitro cytotoxicity
10993/6	Local effects after implantation
10993/10	Irritation and delayed-type hypersensitivity
10993/11	Systemic toxicity

Degradation Products or Leachate

In experiments by Espevik (1978 from Kuhn 1981), the Co-20Cr-10Ni-15W alloy was placed in a beaker of aqueous fluid at 37 °C for two months. After the immersion period, the levels of cobalt and chromium ions present in the solution are described as being undetectable by any means other than atomic adsorption spectroscopy, which is indicative of a low level of ion release.

Systemic Toxicity of Degradation Products

In experiments by Girsdansky and Newman (1941), Co-20Cr-10Ni-15W was used as an implant in a soft tissue site. The authors report that postoperatively they saw no evidence of systemic toxicity. Although the authors did not report whether the material had been observed to corrode, Co-20Cr-10Ni-15W has been observed to corrode in aqueous solution in experiments by Espevik (1978 from Kuhn 1981), resulting in the release of low levels of chromium and cobalt ions. The lack of systemic toxicity observed by Girsdansky and Newman (1941) is supported by testing that was conducted on the Multi-Link Vision Stent. The Multi-Link Vision Stent is composed of the L605 cobalt-chromium tubing. The Summary of Safety and Effectiveness Data for the device states that the stent material was not observed to result in systemic toxicity when tested according to the relevant ISO 10993 standard.

Blood Compatibility

Hemolysis

The Multi-Link Vision Stent is composed of the Co-20Cr-10Ni-15W cobalt-chromium alloy. According to the Summary of Safety and Effectiveness Data for the Multi-Link Vision Stent, the stent was tested according to the relevant ISO 10993 standard and was found to be nonhemolytic.

Thrombogenicity

According to the Summary of Safety and Effectiveness Data for the Multi-Link Vision Stent, stents fabricated from Co-20Cr-10Ni-15W have been shown to be nonthrombogenic, using coagulation prothrombin time and unactivated partial thromboplastin time (UPTT) assays. However, thrombus formation has been reported on the struts of Bjork-Shiley leaflet and Monostrut valves and the Sorin Allcarbon tilting-disc valves, all of which were made of Haynes alloy 25 (Butany et al. 2003). In experiments by Yang et al. (1996), discs of Haynes alloy 25 placed in the intrathoracic vena cavae of sheep were observed to result in less thrombus formation, as evaluated by close-up photography and scanning electron microscopy (SEM), than pyrolytic-carbon-coated discs.

Soft Tissue Response

Response to Material (Direct Contact)

In experiments by Messer et al. (2005), the CoCrNi alloy was placed in direct contact with human microvascular endothelial cells for a duration of 72 hours at a variety of surface roughnesses. Cytotoxicity was determined by measuring succinate dehydrogenase activity; no evidence of cytotoxicity was observed.

Response of Contacting Tissues (In vivo)

Studies have been conducted comparing the response to stents fabricated from 316L stainless steel or Co-20Cr-10Ni-15W when implanted in porcine coronary arteries for 28 days, 3 months, and 6 months (USFDA-SSED for Multi-Link Vision Stent). It was observed that the stents precipitated a vascular response comparable to that elicited to 316L stainless steel, and it was concluded that the stent material and design could be deployed safely in coronary arteries. In experiments by Glantz et al. (1975), fibrous encapsulation with a lack of acute inflammatory response was observed following the implantation of Co-20Cr-10Ni-15W testpieces in rat soft tissues.

Other Biological Responses

Allergenicity/ Sensitization

According to Marti et al. (2000), despite a low nickel content (10%) relative to materials such as 316L stainless steel, nickel sensitivity reactions are still possible.

Mutagenicity in Nonhumans

According to the Summary and Safety Effectiveness Data for the Multi-Link Vision Stent, stents fabricated from Co-20Cr-10Ni-15W have been shown to be nonmutagenic, using the Ames test. In experiments by Gaechter et al. (1977), Co-20Cr-10Ni-15W alloy rods were implanted in Sprague-Dawley rats between 20 and 30 days old for a duration of 24 months. No benign or malignant tumors were observed in proximity to the implant site, nor was there an increased incidence in malignant tumor formation at distant sites.

Pyrogenicity

According to the Summary of Safety and Effectiveness Data for the Multi-Link Vision Stent, stents fabricated from Co-20Cr-10Ni-15W have been shown to be nonpyrogenic, using the rabbit and LAL pyrogen tests.

Sterilization Treatments

Gamma Irradiation/Electron Beam

According to the Summary of Safety and Effectiveness Data for the Multi-Link Vision Stent, stents fabricated from Co-20Cr-10Ni-15W are suitable for sterilization using gamma irradiation.

Ethylene Oxide

The Palmaz Blue Transhepatic Biliary Stent is composed of the Co-20Cr-10Ni-15W alloy and is sterilized using ethylene oxide. The stent functions well enough to have received FDA approval, which suggests that this sterilization methodology is suitable for this material.

Optical/Acoustical Properties

Radiopacity

The Co-20Cr-10Ni-15W alloy is used to make the cage of Bjork-Shiley aortic tilting-disc heart valves, which are radiopaque (Cedars-Sinai Medical Center Prosthetic Heart Valve Information). According to the cobalt-chromium data sheet, it is the tungsten content of the alloy that renders it radioopaque.

MRI Properties

According to the Summary of Safety and Effectiveness Data for the Multi-Link Vision Stent, artifacts were observed while viewing stents fabricated from Co-20Cr-10Ni-15W, which may negatively influence their visibility.

Failure Analyses

In experiments by Marrey et al. (2006) on stents fabricated from L-605, it was observed that premature fatigue failure as a result of radially pulsatile loading by the coronary artery was unlikely to occur, provided all flaws greater than approximately 90 microns were detected prior to deployment in vivo.

General Notes

Warnings

In experiments by Gruen and Amstutz et al. (1975), the simultaneous use of both the Co-28Cr-6Mo alloy and the Co-20Cr-15W-10Ni alloy in an orthopaedic application was observed to result in the accelerated corrosion of the Co-20Cr-15W-10Ni alloy. Other similar studies were conducted as part of the Summary of Safety and Effectiveness Data submission for the Multi-Link Vision Stent, which is composed of the L-605 CoCr alloy. The stent material demonstrated acceptable corrosion resistance in contact with stainless steel or other Co-20Cr-15W-10Ni alloy stents.

Notes

According to Marrey et al. (2006), the use of the Co-20Cr-15W-10Ni alloy allows a reduction in stent thickness relative to stainless steel stents as a result of the superior properties of the Co-20Cr-15W-10Ni alloy relative to stainless steel. According to “Skeletal Replacement and Repairs,” tungsten and nickel are included in the Co-20Cr-10Ni-15W alloy to improve the machinability and workability of the alloy. In the annealed state, the alloy has similar properties to ASTM F75, the Co-Cr-Mo alloy; however, cold working at 44 percent results in a twofold increase in mechanical performance.

Processing and Treatment

See Table 5 for discussion of suitable and unsuitable processing methods for use with this material.

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Table 5 Processing methods

Suitable processing methodologies	
Arc Spot - MIG	Haynes alloy 25 can be welded using gas metal arc. The reference recommends that the weld area be clean and contaminant-free. Spot and seam welding are reported to be suitable for products in sheet or strip form. The reference also recommends that the filler metal electrodes be of the same composition as Haynes alloy 25 and states that preheating and postweld heat treatments are not usually required (Material Property Data Sheet Alloy 25 Super Alloys).
Arc Spot - TIG	Haynes alloy 25 can be welded using gas tungsten arc. The reference recommends that the weld area be clean and contaminant-free. Spot and seam welding are reported to be suitable for products in sheet or strip form. The reference also recommends that the filler metal electrodes be of the same composition as Haynes alloy 25 and states that preheating and postweld heat treatments are not usually required (Material Property Data Sheet Alloy 25 Super Alloys).
Gas Metal Arc (MIG)	Haynes alloy 25 can be welded using shielded metal arc, gas tungsten arc, and gas metal arc methodologies. The reference states that the material is not suitable for submerged arc welding and recommends that the weld area be clean and contaminant-free. Spot and seam welding are reported to be suitable for products in sheet or strip form. The reference also recommends that the filler metal electrodes be of the same composition as Haynes alloy 25 and states that preheating and postweld heat treatments are not usually required (Material Property Data Sheet Alloys 25 Super Alloys).
Gas Tungsten Arc (TIG)	Haynes alloy 25 can be welded using shielded metal arc, gas tungsten arc, and gas metal arc methodologies. The reference states that the material is not suitable for submerged arc welding and recommends that the weld area be clean and contaminant-free. Spot and seam welding are reported to be suitable for products in sheet or strip form. The reference also recommends that the filler metal electrodes be of the same composition as Haynes alloy 25 and states that preheating and postweld heat treatments are not usually required (Material Property Data Sheet Alloy 25 Super Alloys).
Forging	The reference states that hot forging can be done at temperatures between 1850 and 2250 F (Material Property Data Sheet Alloy 25 Super Alloys).
Machining Processes	Haynes alloy 25 can be machined using conventional methods and high-speed steel tools or carbide tools (Material Property Data Sheet Alloy 25 Super Alloys).
Rolling	Co-20Cr-10Ni-15W can be cold rolled or hot rolled (Haynes 25 Alloy 2004). Co-20Cr-10Ni-15W can also be wire rolled in a process refined by the Cross Engineering Company.
Unsuitable processing methodologies	
Arc Spot - MIG	
Submerged Arc	The reference states that the material is not suitable for submerged arc welding (Material Property Data Sheet Alloy 25 Super Alloys).

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