CARPENTER TECHNOLOGY

WHITE PAPER

MEDICAL DEVICE INSTRUMENTATION

Materials solutions for strength, corrosion resistance, and performance

SUMMARY

Stainless steels have been used for decades in the medical industry, for both medical device instrumentation and implants. It is generally understood that corrosion resistance is required for medical implants and their instrumentation, coupled with good levels of strength. However, how such corrosion resistance and strength are derived, or what is currently available to the field is not entirely clear. This paper outlines recent advancements of current materials used in medical instrumentation and introduces new materials and processes available to the medical device industry.

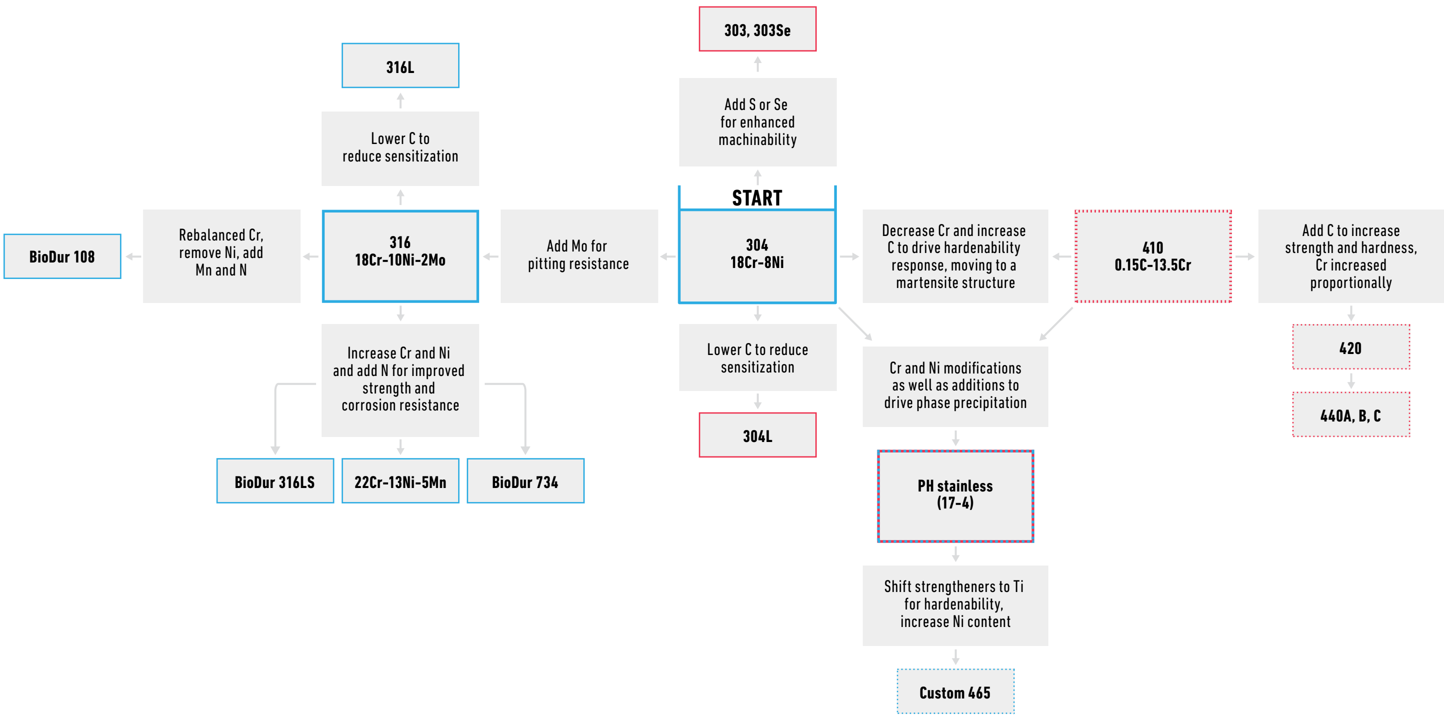
Carpenter Technology has developed numerous alloys to support the ever-evolving needs of the medical industry, driving toward alloys with improved performance and processes that further harness the capabilities of flagship materials.

The essentially nickel-free BioDur® 108 shows improved corrosion resistance, fatigue strength, and impact toughness over its vacuum melted 316L counterpart. Additionally, Custom 465® has shown fantastic performance in numerous medical applications, such as surgical drivers, needle wires, and dental instruments. Cold worked Custom 465® stainless, aged at 900°F, can provide further improvement, with maximum achievable tensile strengths approaching 300 ksi (2070 MPa). For these reasons, next-generation materials are finding success in more and more applications and could be considered for the next innovations in minimally invasive surgery, in which strong, tough, corrosion-resistant materials will be a must.

STAINLESS STEEL ALLOYS

The alloys presented in this paper relate to one another and have a clear evolutionary development path, as shown in Figure 1.

FIGURE 1—COMPRESSED COMPOSITIONAL MAP OF MEDICAL INSTRUMENTATION ALLOYS.



Stainless steel is a term that describes numerous iron-based alloys that contain approximately 10.5% or greater concentrations of chromium (Cr). Depending on the other constituents within the material's overall chemistry, the minimum chromium content to sustain corrosion resistance may be higher. Stainless steels consist of several "families" of materials, each of which have their own set of defining attributes. These families are the austenitic, ferritic, martensitic, and duplex alloys. This paper covers a selection of martensitic and austenitic alloys well suited for medical applications.

Martensitic stainless

Martensitic stainless steels are defined by their ability to be hardened by heat treating and, to some degree, cold working (see the definition of cold working below). Typically, they have moderate to low corrosion resistance, but obtain high levels of strength and hardness. Everyday examples of these materials are pocketknives and kitchen cutlery. Following are blends within the martensitic stainless steel family of alloys.

410 stainless (UNS S41000) is the basic hardenable martensitic stainless steel suitable for highly stressed parts where corrosion resistance, good strength, and ductility are needed. This alloy can be used up to 1200°F (649°C) where resistance to scaling and oxidation is required.

420 stainless (UNS S42000) is a hardenable 12% chrome steel with higher strength and hardness and better wear resistance than 410. It is corrosion-resistant and offers high strength at room and moderately elevated temperatures, accuracy in heat treatment, and mirror-like finishes without chrome plating.

440 stainless (UNS S44002 / S44003 / S44004) is a high-carbon, high-chromium martensitic stainless steel designed to provide stainless properties with excellent hardness. The alloy has a good combination of strength, ductility, toughness, corrosion resistance, and fabricability. It attains a hardness of Rockwell C 56 and maximum toughness when heat treated, and has good toughness at cryogenic temperatures and relatively high tensile and yield strengths at moderately high elevated temperatures. There are three common blends of 440: 440A, 440B, and 440C, with increasing carbon content respectively. This, in turn, increases the materials' hardness capability from 56 to 60 HRC.

Austenitic stainless

Austenitic stainless steels are defined as the most corrosion-resistant of the stainless steel families. They cannot be heat treated to increase their strength or hardness, but instead are hardenable only by cold working. Everyday examples of austenitic stainless steels are cookware, stainless steel water bottles, sinks, and most silverware (not the sharp cutlery). Following are blends within the austenitic stainless steel family of alloys.

304/304L stainless (UNS S31600 / S31603) has excellent fabricability and weldability characteristics and is the most widely used chromium-nickel austenitic stainless steel. It is nonmagnetic in the annealed condition and becomes slightly magnetic when cold worked. Nonhardenable by heat treating, 304L provides a tightly controlled carbon content to minimize carbide precipitation during welding operations. Project 70®+ 304/304L is a dual-certified, enhanced machinability variant of the 304 stainless alloy.

316/316L stainless (UNS S31600 / S31603) is a molybdenum-bearing austenitic stainless offering improved corrosion resistance in chlorides and many other environments over 304 stainless. It also has higher tensile and creep strength at elevated temperatures than the conventional 18% chromium-8% nickel alloys. Similar to 304, it is nonmagnetic in the annealed condition, becomes slightly magnetic when cold worked, and is nonhardenable by heat treating. Also similar to 304, there is a controlled carbon content variant known as 316L to minimize carbide precipitation during welding operations. Project 70+ 316/316L is a dual-certified, enhanced machinability variant of the 316 stainless alloy.

22Cr-13Ni-5Mn stainless (UNS S201910) is a nitrogen-strengthened austenitic stainless steel that provides very good corrosion resistance in combination with high strength. It has better corrosion resistance than 316 with approximately twice the yield strength. It can be welded, machined, and cold worked using the same equipment and methods used for the conventional 300 series stainless steels and remains nonmagnetic after severe cold work.

BioDur® 316LS stainless (UNS S31673) is an electroslag remelted (ESR) or vacuum arc remelted (VAR), low carbon, high nickel and molybdenum version of 316 stainless. The secondary premium melting step (ESR or VAR) imparts improved cleanliness, with chemistry modifications designed to maximize the corrosion resistance of this alloy and provide a ferrite-free microstructure. The alloy is nonmagnetic even after severe cold forming operations, but provides higher strength capability even in the annealed condition as compared to its 316 stainless counterpart. Furthermore, the chemistry meets the less than 0.1% cobalt restrictions set forth by EU MDR regulatory labeling.

BioDur® 734 stainless is a nitrogen-strengthened, austenitic stainless steel. The alloy exhibits improved tensile strength, impact strength, fatigue strength, and crevice and putting corrosion resistance over BioDur 316LS. The microstructural integrity and cleanness of this alloy is ensured through electroslag remelting (ESR). The alloy is nonmagnetic and essentially free of ferrite. And the chemistry meets the less than 0.1% cobalt restrictions set forth by EU MDR regulatory labeling.

BioDur® 108 stainless is an essentially nickel-free austenitic stainless alloy with a high nitrogen content to maintain its austenitic structure. As a result, it has superior tensile and fatigue strength to nickel-containing alloys such as 316L (ASTM F138), 22Cr-13Ni-5Mn (ASTM F1314), and 734 (ASTM F1586). The resistance of Biodur 108 to pitting and crevice corrosion is superior to 316L and equivalent to 22Cr-13Ni-5Mn and 734. It is produced by the electroslag remelting (ESR) process to ensure its microstructural integrity and cleanness, is nonmagnetic, and is essentially free of ferrite phase. And the chemistry meets the less than 0.1% cobalt restrictions set forth by EU MDR regulatory labeling.

Precipitation hardenable (PH) stainless steel

The precipitation hardenable stainless steels can be classified as austenitic, martensitic, or semi-austenitic. For the purposes of this paper, we will focus on the martensitic PH stainless materials, which are the most commonly used PH stainless steels in the medical market — known to provide high levels of corrosion resistance, while also providing an ability to strengthen through heat treatment and cold working. Following are blends within the martensitic PH stainless steel sub-family of alloys.

Custom 630 / 17Cr-4Ni stainless (UNS S17400) is a martensitic precipitation/age-hardening stainless steel offering high strength and hardness along with excellent corrosion resistance. It has good fabricating characteristics and can be age hardened by a single-step, low temperature treatment. The alloy has withstood corrosive attack better than any of the 400 series hardenable stainless steels (ex., 420 and 440A/C), and in most environments, the corrosion resistance approaches that of 304 stainless. Available in a Project 70+ modified version for improved machinability for applications that call for extensive machining.

Custom 450® stainless (UNS S45000) is a martensitic age-hardenable stainless steel that exhibits very good corrosion resistance (similar to 304) with moderate strength (similar to 410). The alloy has a yield strength somewhat greater than 100 ksi (689 MPa) in the annealed condition but is easily fabricated. A single-step aging treatment develops higher strength with good ductility and toughness. This stainless can be machined, hot worked, and cold formed in the same manner as other martensitic age-hardenable stainless steels with mechanical properties that depend on the aging temperature selected. Custom 450 stainless is similar to Custom 630 (17Cr-4Ni) but contains additional molybdenum for pitting resistance and utilizes niobium as a strengthener.

Custom 455® stainless (UNS S45500) is a martensitic age-hardenable stainless steel with a single-step aging treatment that develops exceptionally high yield strength, good ductility, good toughness, and a hardness capability of approximately HRC 50. This stainless can be machined in the annealed condition and welded in much the same manner as other precipitation hardenable stainless steels. Because of its low work-hardening rate, it can be extensively cold formed and has minimal dimensional change during hardening to permit close-tolerance finish machining in the annealed state. It should be considered where simplicity of heat treatment, ease of fabrication, high strength, and corrosion resistance are required in combination. Custom 450 stainless provides even higher strength capability, utilizing titanium as a strengthener.

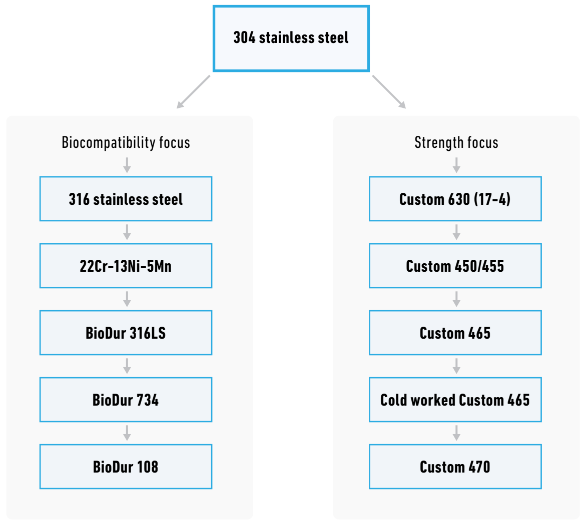
Custom 465® stainless (UNS S46500) is a premium melted, martensitic, age-hardenable alloy capable of ultimate tensile strength in excess of 250 ksi in the overaged (H 950) condition. This alloy was designed to have excellent notch tensile strength and fracture toughness in this condition. It can provide the best combination of strength, corrosion resistance, and toughness of any stainless steel. Custom 465 can be cold worked prior to heat treating to attain strengths near 300 ksi ultimate tensile. A Micro-Melt® variant of Custom 465 is available for enhanced machinability and finds application in various components where fine internal features, such as fine drilling, are required.

EVOLUTION OF MEDICAL MATERIALS

304 stainless steel can be thought of as the “starting point” for medical device instrumentation. As requirements in materials evolved throughout the industry (i.e., smaller form factors, more complex designs, general biocompatibility, longer lasting implants, etc.), performance expectations for the workpiece material increased. Most notably, the performance requirements increased in two distinct categories: those requiring an improved corrosion resistance over 304 stainless, and those requiring similar corrosion resistance but improved strength.

From these requirements were born the organic split we saw in Figure 1, further illustrated in Figure 2. Several alloys were omitted from the two compositional maps for brevity and to visually conceptualize how medical instrumentation/implant alloys are interrelated.

FIGURE 2—TYPICAL DESIGN-CRITERIA MEDICAL STAINLESS BREAKDOWN.



Straight martensitic alloys (ex., 420, 440s, etc.) are not shown.

304 stainless, albeit not the first stainless steel, is now considered the baseline alloy for its corrosion resistance properties, balanced chemistry, and performance in most ambient environments and temperatures. Unfortunately, the human body is anything but ambient. As such, improvements in corrosion resistance for implant materials were necessary, leading to expectations and requirements for improved biocompatibility. Alloys like 22Cr-13Ni-5Mn, BioDur 316LS, BioDur 734, and BioDur 108 were created in response. The latest materials not only focused on improving strength and corrosion resistance, but also tackled cobalt content concerns and nickel sensitivities, addressing additional market drivers.

Martensitic stainless

Martensitic stainless steels provide an amazing advantage over their carbon steel counterparts—namely, corrosion resistance! As mentioned earlier, only about 10.5% chromium is necessary for pure iron to become corrosion resistant. However, in the case of martensitic stainless steels, a bit more chromium is required to maintain stainless properties. This is due to the formation of carbides, the main strengthener of martensitic stainless steels. Carbon tends to combine with chromium and form chrome-carbides, disallowing the chromium to be available to form the protective oxide layer that makes stainless steel stainless. As such, additional chromium is necessary to maintain corrosion resistance. Martensitic stainless steels are fantastic materials for cutting blades, wear components, and other applications where hardness, strength, and good corrosion resistance capability is a must. However, for many medical applications, the community was looking for further improved corrosion resistance and performance.

Austenitic stainless

Once again, stainless steel is known for its corrosion-resistant properties, deriving its corrosion resistance from an adherent chromium oxide layer that forms on the surface of the material, regenerating in most environments if temporarily scratched away. Specific to austenitic stainless steels, this chromium oxide layer is further boosted by nickel content, which provides pitting resistance and stabilizes the microstructure in the austenitic phase. In some austenitic alloys, nickel is replaced by additions of manganese and nitrogen, providing similar benefits and often improved strength and wear characteristics. One interesting thing about austenitic stainless steels is their high level of ductility, affording most of the alloys within this family the ability to be severely cold worked, boosting strength tremendously. The one area lacking for austenitic stainless steels is their wear characteristics. As they are not hardened by precipitates of high hardness, they typically do not exhibit good wear resistance.

Cold working

Cold working is a process where material is subjected to a permanent shape or size change due to squashing or forming a constant volume of material. Typically, the term "cold" in cold working is meant to refer to room temperature or near room temperature and as the complement to "hot working," which is done at temperatures circa 2000°F for most stainless steels. Cold working, also known as strain hardening, work strengthening, or plastic deformation, is used to create dislocations within the material, driving a "resistance" to further change. This "resistance" is perceived on the macro-scale as "strength."

Precipitation hardenable stainless

Answering the call for high strength, improved wear resistance, high toughness, and corrosion resistance were (and still are) precipitation hardenable stainless steels. PH stainless materials have built a strong foundation in the medical community, finding applications in numerous types of surgical tooling, from pry tools to cutting tools, reamers to hammers, trays to drill guides. Most surgical tools used today are of the martensitic precipitation hardenable variety. Currently, we see further shifts in the medical community to design in requirements for cold worked, precipitation hardenable stainless steels to further push the performance of the tooling and drive towards small form factor surgeries, micro-surgeries, and minimally invasive procedures.

TABLE 1 — TYPICAL YIELD STRENGTH (KSI) VS. CONDITIONS.

ALLOY	COLD WORK (%)			HEAT TREATED					
							60%+ CW AND AGED		
	ANNEAL	35	60	H900	H950	H1000	H900	H950	H1000
BioDur 316LS	35	115	128+	—					
22Cr-13Ni-5Mn	65	170	215+						
BioDur 108	88	197	260+						
Custom 630 / 17Cr-4Ni	—			183	—	—	—	—	—
Custom 465[1]				247[1]	240	217	285	280	250

[1]The use of Custom 465 H900 condition should be reviewed for acceptability, due to its reduced toughness tradeoff and near peak-age properties.

FIGURE 3—YIELD STRENGTH VS. COLD WORK FOR SELECTED ALLOYS.

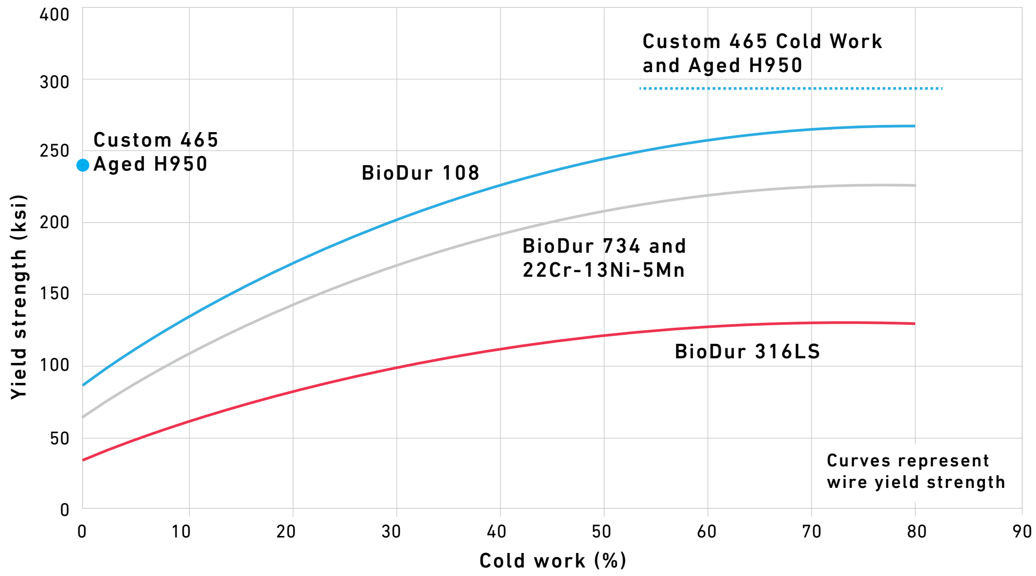


FIGURE 4—ENHANCED SELECTALOY DIAGRAM

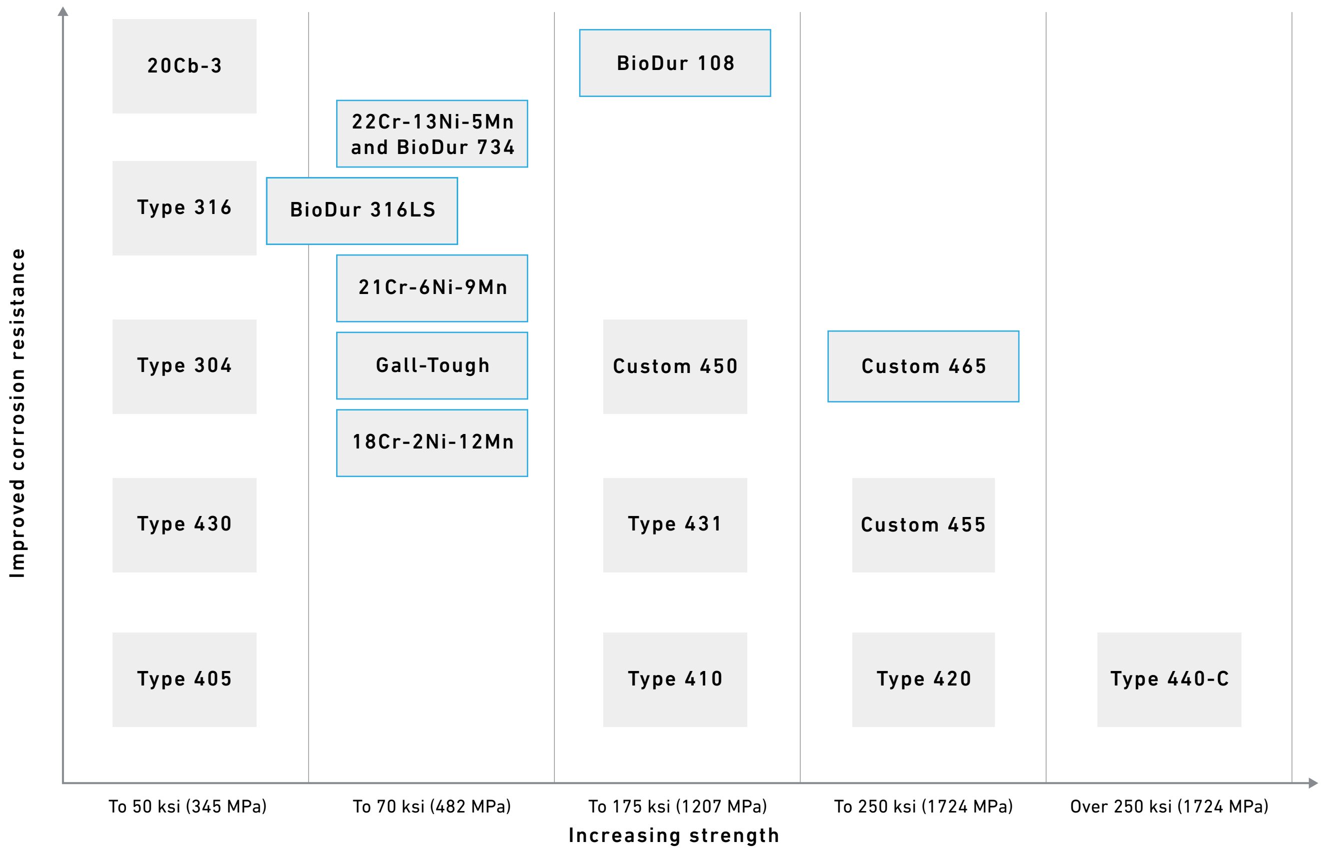
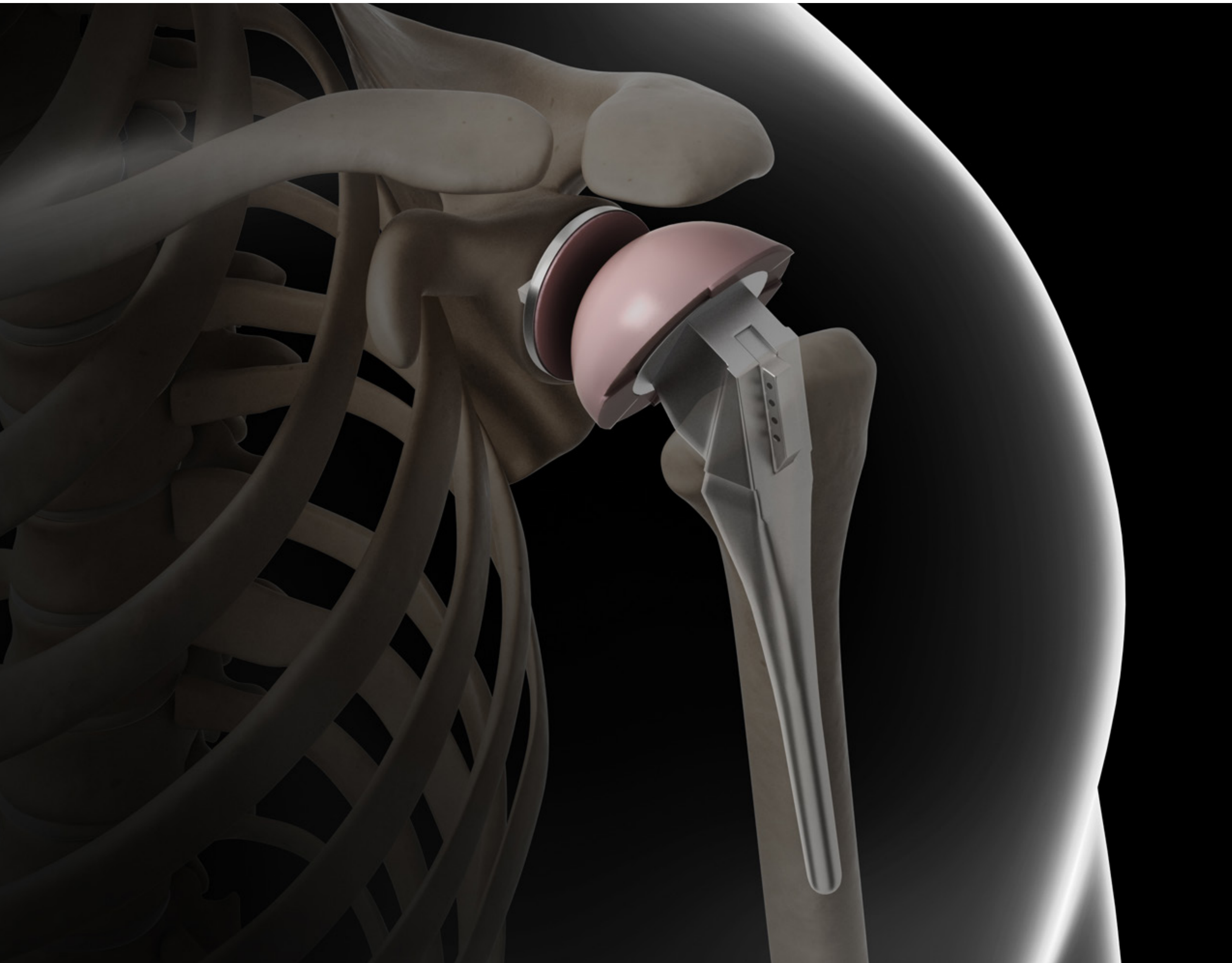


TABLE 2 — NOMINAL TYPE ANALYSIS FOR SELECTED ALLOYS.

	AUSTENITIC				PH STAINLESS	
	BIODUR 316LS	**BIODUR 22-13-5**	**BIODUR 734**	**BIODUR 108**	**CUSTOM 630 (17-4)**	**CUSTOM 465**
C	Max 0.03 %	Max 0.03 %	Max 0.08 %	Max 0.08 %	Max 0.07 %	Max 0.02 %
Mn	Max 2.00 %	4.00–6.00 %	2.00–4.75 %	21.00–24.00 %	Max 1.00 %	Max 0.25 %
Si	Max 0.75 %	Max 1.00 %	Max 0.75 %	Max 0.75 %	Max 1.00 %	Max 0.25 %
P	Max 0.025 %	Max 0.040 %	Max 0.025 %	Max 0.03 %	Max 0.040 %	Max 0.015 %
S	Max 0.10 %	Max 0.030 %	Max 0.01 %	Max 0.01 %	Max 0.030 %	0.010 %
Cr	17.00–19.00 %	20.50–23.50 %	19.50–22.00 %	19.00–23.00 %	15.00–17.00 %	11.00–12.50 %
Ni	13.00–15.50 %	11.50–13.50 %	9.00–11.00 %	Max 0.05 %	3.00–5.00 %	10.75–11.25 %
Mo	2.25–3.50 %	1.50–3.00 %	2.00–3.00 %	0.50–1.50 %	—	0.75–1.25 %
Cu	Max 0.50 %	—	Max 0.25 %	Max 0.25 %	3.00–5.00 %	—
N	Max 0.10 %	0.20–0.40 %	0.25–0.50 %	> 0.90 %	—	—
Nb	—	0.10–0.30 %	0.25–0.80 %	—	+Ta: 0.15–0.45 %	—
Ti	—	—	—	—	—	1.50–1.80 %
Other	—	0.10–0.30 % V	—	—	—	—



APPLICATIONS

Stainless steels are used in a variety of medical applications, spanning the range of simple tools to highly complex, patient-specific tooling and/or implants. Various surgical procedures, such as joint replacement, spinal fixation, fracture fixation, and many others, require both implantable materials and the surgical instruments to perform or install the implant itself. Stainless steels are the materials of choice when it comes to trauma implants or surgical instrumentation.

As mentioned above, surgical procedures have evolved over the years, driving additional performance needs from the material itself. Robotic assisted surgical procedures and microsurgeries require smaller form factors for both the implant and the installation tools. This trend magnifies the stresses experienced on the metallic component and/or installation tool, and as such requires improved performance. As a result, static properties for materials, such as ultimate tensile strength, yield strength, and impact properties, have become increasingly important to consider. This has culminated into the use of precipitation hardening stainless steels, with Custom 465 being the leader for the best combination of strength, toughness, and corrosion resistance of the PH family. Strengthening this alloy even further with cold work can provide a unique opportunity for manufacturers and OEMs alike to obtain a material with nearly 300 ksi ultimate tensile strength and similar corrosion resistance to 304 stainless.

European Union regulations

European Union Medical Device Regulation 2017/745 (EU MDR) requires devices containing 0.10% or greater cobalt content to indicate the presence of cobalt as a potential carcinogenic, mutagenic, reproductive toxin substance.

Changes to EU MDR 2017/745 will require devices containing more than 0.10 wt% cobalt content to indicate the presence of cobalt as a potential carcinogenic, mutagenic, reproductive toxin substance. To address increasing regulatory scrutiny and up-classification of cobalt as a Class II RMR substance, we offer a range of stainless steel alloys in low-cobalt variations.

Carpenter Technology is one of the first to officially introduce low-cobalt stainless steel products to the market. The company continues to participate in public forums, including ASTM, and work closely on material standards impacted by the new regulations. Carpenter Technology is also innovating alternative materials for regulation compliance, increased quality, and improved patient outcomes.

Our low-cobalt stainless steels meet EU MDR standards and lead the industry in performance.

Nickel sensitivities

You may have noticed how common it is to get rashes from certain types of jewelry. This is called contact dermatitis and is likely caused by a nickel sensitivity. Approximately 10–20% of the public is affected by a nickel sensitivity. Certainly, if an individual experiences a rash with jewelry, it would be terrible for an implant containing nickel to be used in their surgical implant. Carpenter Technology has material alternatives to address this need, including as titanium and the essentially nickel-free stainless steel BioDur 108.

Patient-specific needs

Carpenter Technology has been at the forefront of additive manufacturing, innovating powder production of many of its alloys. With the ability to customize melts and test materials in various additive manufacturing equipment platforms in-house, Carpenter Technology can support patient-specific implants or tooling. A great example of this is our BioDur 108 powder, which provides a significant boost in properties over vacuum melted 316L stainless in the as-printed condition and supports nickel sensitivities with an essentially nickel-free chemistry.

Adjacent alloy systems

Carpenter Technology continues to innovate, responding to market demand for next-generation alloys, as well as staffing a full research and development center for the development of new-to-world materials and processes.

- Investigating next-generation additive manufacturing in BioDur 108.
- Challenging what's possible in stainless performance in quench and temperature martensitic materials.
- Engineering numerous variants of popular alloys, from enhanced machinability variants, to custom chemistries, to variants that provide enhanced weldability or dispersion strengthening. A perfect example of this is our 420 stainless offerings. While this alloy has an extensive history in the medical industry, Carpenter Technology offers 12 different variants/sub-variants, tweaking the performance for the specific application or method of manufacturing.
- It is important to note the high strength, high corrosion resistance alloys such as Custom 465, most notably used for the most demanding instrumentation applications. Not only does this alloy provide incredible levels of strength, wear resistance, and corrosion resistance, but Carpenter Technology is working on the next generation of this product for "tomorrow's performance" needs.

Product forms and finishing

Carpenter Technology provides metallic materials in cut-to-length bar, coiled wire, cut-to-length sheet, coiled strip, forged bar products, and consolidated powders of Fe, Co, Ni, and Ti-based alloys. We own the recipes, from melt to finish, producing material in the United States.

Carpenter Technology can also thermally treat many of its alloys, including precision grinding, polishing, and drawing products to tight tolerances. See the Product Line Card for a complete listing of products.

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