



BIODUR® 108

Carpenter Technology's proposed cobalt-free alternative to CoCrMo alloys for articulating orthopedic implants

SUMMARY

Carpenter Technology is proposing BioDur 108, a cobalt-free alloy, as a potential alternative to cobalt-chromium-molybdenum (CoCrMo) for articulating orthopedic implants. This alloy, combined with Carpenter Technology's newly patented process, offers biocompatibility, strength, and wear resistance comparable to CoCrMo.

Without intentional additions of cobalt, BioDur 108 supports new device compliance with recent regulatory changes on medical devices in Europe.

These attributes position BioDur 108 as a strong candidate for next-generation implant materials, potentially enhancing patient safety, regulatory compliance, and manufacturing flexibility.



APPLICATION HISTORY

Metallic components in joint replacements

Joint components in total hip arthroplasty (THA) come in four main types based on the materials used for the ball and socket: metal-on-polyethylene (MoP), metal-on-metal (MoM), ceramic-on-ceramic (CoC), and ceramic-on-polyethylene (CoP). Ceramic counterparts tend to be made with alumina, zirconia, or zirconia toughened alumina (ZTA). In MoM replacements, both the ball and socket are made of metallic alloys, usually a CoCrMo, stainless steel, high-nitrogen stainless steel, or titanium alloy.

In contrast, MoP replacements feature a metal ball and a polyethylene (PE) socket. Wear and damage of the PE have long been the cause of osteolysis and the main factor limiting the longevity of hip replacement components.¹ The development of ultra-high molecular weight polyethylene (UHMWPE) and highly crosslinked UHMWPE with improved wear resistance have addressed most of these issues, making them no longer a significant medical concern.² This shift has redirected the conversation towards wear damage on the metallic components of the articulation.



Cobalt-based alloy innovations

A significant share of metallic components in hip replacements are based on cobalt and its derivatives. Cobalt-chromium (CoCr) and later CoCrMo alloys were developed in the early 20th century and initially utilized in aerospace applications requiring high wear resistance. These alloys quickly found their way into biomedical applications due to their exceptional corrosion resistance and biocompatibility. Originally used in dental applications, CoCrMo alloys rapidly gained popularity in orthopedic implants. By the 1960s and 1970s, they were approved by the Food and Drug Administration (FDA) and became favored materials for articulating metal-on-metal components in load-bearing orthopedic applications such as knee and hip replacements. This resulted in a significant improvement in the quality of life for many patients suffering from hip joint issues.

Other conventional alloys, such as 304 or 316L stainless steel, are more cost-effective than CoCrMo and are suitable for implantation. However, they have lower wear resistance, and the presence of elements such as nickel can lead to allergic reactions and medical complications. In comparison, CoCrMo alloys offer superior performance in high-stress, long-term applications, making them the preferred choice for many medical implants.

Changing regulatory landscape for cobalt-containing devices

The presence of cobalt in metallic alloys used in hip replacement components has long been a concern because of the potential release of cobalt ions into the bloodstream due to wear damage. Although quite rare, this condition is known as metallosis. Specifically, the accumulation of metallic debris and particles in the soft tissue surrounding the articulation can potentially lead to severe health issues, such as inflammation and damage to the cardiovascular and nervous systems. The only long-term solution was revision surgery to remove the implant, which further increased the risk of complications and negatively impacted patient outcomes.

Under intense pressure from the public, regulatory bodies in the United States and Europe began scrutinizing medical devices and issuing stricter guidelines. In particular, the EU Medical Device Regulation (MDR 2017/745) was created in 2017 to replace the 1993 Medical Devices Directive, driving more scrutiny, testing and control on medical devices.

The EU MDR now classifies cobalt as a carcinogenic, mutagenic, and reproductive toxin (CMR) substance.

Original equipment manufacturers marketing devices containing 0.1 wt.% cobalt or more must justify their use through a risk assessment and explore alternative material options. The implications for the industry are substantial. Manufacturers must either reduce cobalt content in their products or provide strong justifications for its continued use. This has led to the development of low-cobalt biomedical alloys and renewed interest in cobalt-free alternative solutions. Compliance with these regulations ensures more control on medical devices but may increase production costs and require significant R&D investments and regulatory approval costs.



MATERIAL SOLUTION

BioDur 108 as an alternative to CoCrMo

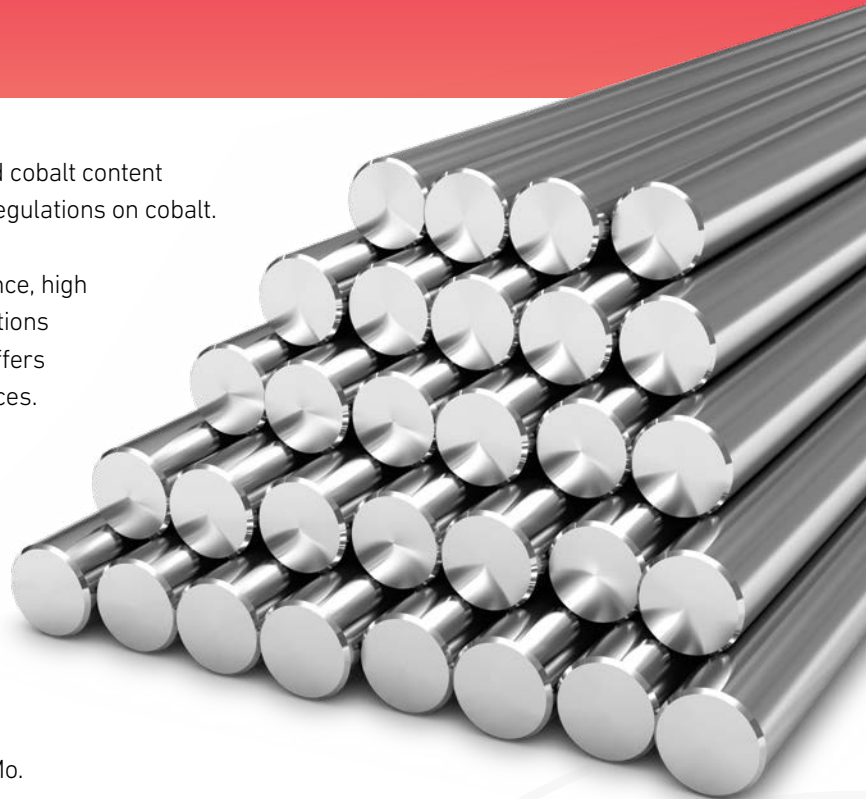
Alternatives to CoCrMo naturally include 316 derivatives (316L, 316 LVM) and nitrogen-strengthened stainless steels (22Cr-13Ni-5Mn) for applications that require a higher modulus and yield strength. BioDur 108 (UNS #S29108) contains up to 1.1 wt.% nitrogen and is approved by the FDA for implantable medical devices. Developed by Carpenter Technology as a nickel-free alloy, its use minimizes allergic reactions in metal-sensitive patients. It is manufactured with a guaranteed cobalt content below 0.1 wt.%, rendering it fully compliant with the EU MDR regulations on cobalt.

The benefits of BioDur 108 include excellent corrosion resistance, high strength, and biocompatibility. Its prior use in medical applications includes orthopedic, dental, and spinal implants. BioDur 108 offers a promising solution for safer and more durable medical devices.

However, like most stainless steels, BioDur 108 cannot be hardened through heat treatment and requires further processing to develop its mechanical properties. It is often used after cold working, but for more critical load-bearing applications, such as articulating joints. Carpenter Technology developed a new patented process (US 12,188,112 B2³) that combines cold working and surface treatment. This process gives BioDur 108 tension and wear resistance properties similar to those of warm-worked CoCrMo.

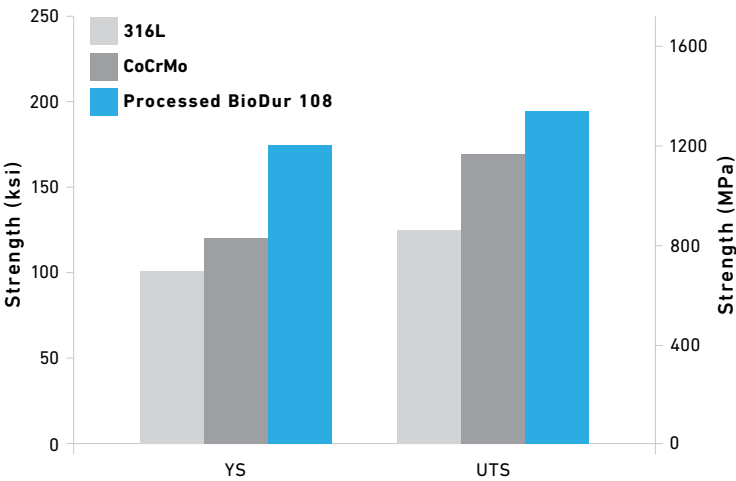
BioDur 108 is cobalt-free, and:

- Biocompatible and corrosion-resistant
- Essentially nickel-free
- Ideal for medical device applications



Typical tension properties of CoCrMo used in articulating orthopedic implants are 120 ksi (827 MPa) yield strength (YS) and 170 ksi (1172 MPa) ultimate tensile strength (UTS) (ASTM F1537). Carpenter Technology's patented process gives BioDur 108 bulk mechanical properties of 175 ksi (1207 MPa) YS and 195 ksi (1344 MPa) UTS, which are comparable to, if not better than, those of CoCrMo and significantly superior to those of 316L surgical steel (Figure 1).

FIGURE 1— TENSION PROPERTIES



Pin-on-disc, the gold standard for measuring wear resistance

The bio-tribological behavior of metallic articulating implants is vital for patient safety. In metal-on-polyethylene artificial hip components, the surface roughness of the metallic counterpart can significantly increase damage to the UHMWPE acetabular cup. To simulate wear damage, it is common to perform pin-on-disc tribology experiments by sliding a UHMWPE pin on a metallic disc, measuring both the surface roughness of the disc and the mass loss of the disc and the pin.

In our investigation, a one-million cycle (1 MC) pin-on-disc wear damage experiment was performed according to the ASTM F732 standard⁴ to benchmark a new material, BioDur 108, against the incumbent CoCrMo. All tests were carried out in bovine serum with a total protein concentration of 20 g/L. After 1 MC, the surface roughness of the disc and the mass loss of the pin were measured. Data from a published study on medical-grade 316L tested under similar conditions⁵ were used as an industry benchmark.

After 1 MC, the surface roughness measured was 0.122 μm for the CoCrMo disc, 0.022 μm for the BioDur 108 disc, and over 0.500 μm for the 316L disc (Figure 2). These results indicate that BioDur 108 is significantly more resistant to wear damage compared to both alloys.

The mass loss of the UHMWPE pin was 0.6 mg when sliding against the CoCrMo disc and 0.7 mg when sliding against the BioDur 108 disc (Figure 3). In both cases, the pins exhibited similar microabrasive damage modes, including microscratching and polishing in the contact region. For reference, the mass loss of the pin sliding against a 316L disc was 4.3 mg, indicating substantially greater wear damage.

FIGURE 2 — SURFACE ROUGHNESS RZ AFTER 1 MC

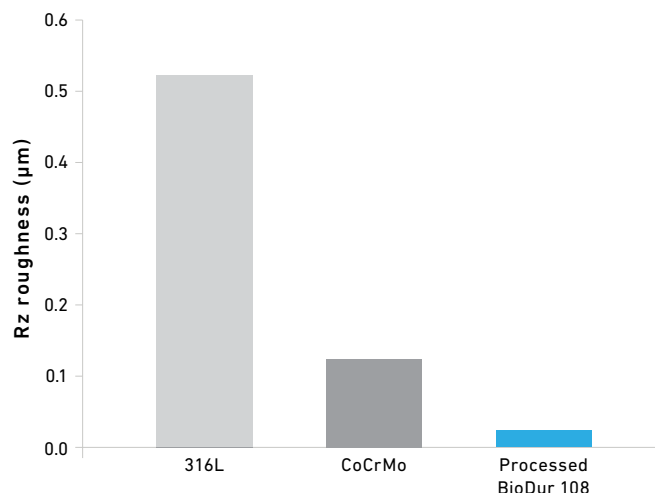
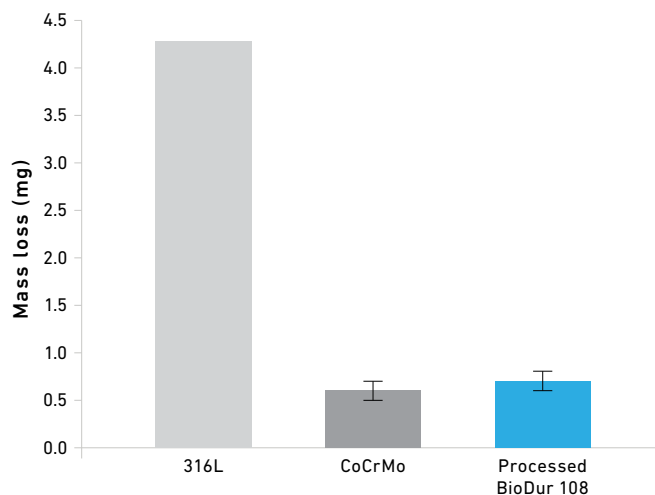


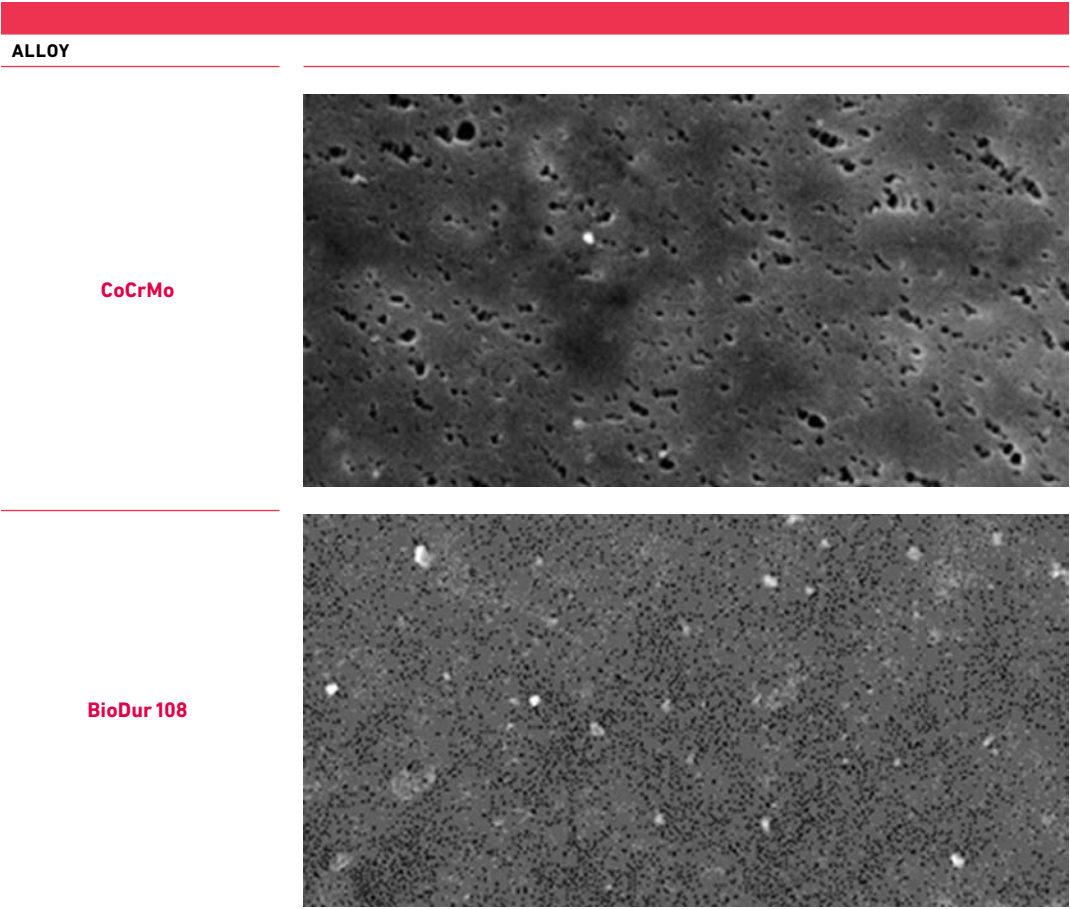
FIGURE 3 — PIN GRAVIMETRIC ANALYSIS AFTER 1 MC



Following the completion of the test, and in accordance with FDA recommendations, over 400 polymeric debris particles were analyzed. The wear particles were predominantly spheroidal or granular in shape, consistent with expectations for *in vitro* wear-tested UHMWPE. No significant differences were observed between the polyethylene debris generated by the CoCrMo disc and the BioDur 108 disc (Figure 4).

FIGURE 4—POLYETHYLENE DEBRIS

Representative high-magnification (10,000x) micrographs of UHMWPE particles (white phase) after pin-on-disc test against a CoCrMo (top) and a BioDur 108 (bottom) disc.



CONCLUSION

Advancing technology and improving patient outcomes

The biomedical industry faces increasing pressure to remove cobalt from medical device metallic components due to increasing regulatory restrictions in Europe. Carpenter Technology proposes cobalt-free (and nickel-free) BioDur 108, an FDA-approved biomedical stainless steel, and a novel proprietary process (US 12,188,112 B2) to create a cobalt-free alternative to CoCrMo for load-bearing orthopedic applications.

The new highly processed BioDur 108 exhibits mechanical and wear resistance properties comparable to CoCrMo. In a one-million-cycle pin-on-disc wear test, BioDur 108 demonstrated performance on par with CoCrMo, showing consistent surface integrity, comparable wear rates, and similar debris morphology, key indicators of long-term durability in biomedical applications.

BioDur 108 is a strong candidate for next-generation cobalt-free implant materials, offering potential benefits in patient safety, regulatory compliance, and manufacturing flexibility.



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For additional information on BioDur 108 or other specialty alloys engineered for medical devices, visit CarpenterTechnology.com/Ask-An-Expert or contact your nearest sales office:

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