Stainless Steel for Medical

The high level of nitrogen in BioDur 108 stainless steel provides enhanced mechanical and physical properties for medical implants.

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Higher strength, better corrosion resistance, and improved biocompatibility compared with other BioDur alloys have been demonstrated by BioDur 108, an essentially nickel-free stainless steel alloy designed for medical implants. As Table 1 shows, nitrogen is present at levels >0.90%, compared with 0.10 to 0.50% for the other Biodur alloys, and nickel levels are no higher than 0.05%, compared with 9 to 15%. The alloy also includes manganese in the range of 21 to 24%, much higher than the 2 to 6% manganese levels of the other BioDur alloys. The higher manganese content is required to maintain austenite stability in high-nitrogen strengthened alloys such as Biodur 108.

In tests meeting ASTM standards, BioDur 108 has exhibited significantly higher strength than any of the common nickel-containing stainless alloys for medical applications, in both the annealed and cold worked conditions. It has demonstrated corrosion resistance equivalent to that of BioDur 734 and BioDur 22Cr-13Ni-5Mn, and significantly greater than that of the widely applied BioDur 316LS alloy.

This article describes a study in which strength, corrosion resistance, and biocompatibility were evaluated for BioDur 108, 734, 22Cr-13Ni-5, and 316LS.

Table 1 — Comparative chemistries of four BioDur alloys

Element	BioDur® 108	BioDur 316LS	BioDur 22-13-5	BioDur 734
C	0.08 max.	0.03 max.	0.03 max.	0.08 max.
Mn	21.0-24.0	2.00 max.	4.00-6.00	2.00-4.75
Si	0.75 max.	0.75 max.	1.00 max.	0.75 max.
P	0.03 max.	0.025 max.	0.040 max.	0.025 max.
S	0.01 max.	0.010 max.	0.030 max.	0.01 max.
Cr	19.00-23.00	17.00-19.00	20.50-23.50	19.50-22.00
Ni	0.05 max.	13.00-15.50	11.50-13.50	9.00-11.00
Mo	0.50-1.50	2.25-3.50	1.50-3.00	2.00-3.00
Cu	0.25 max.	0.50 max.	—	0.25 max.
N	>0.90	0.10 max.	0.20-0.40	0.25-0.50
Nb	—	—	0.10-0.30	0.25-0.80
V	—	—	0.10-0.30	—

Table 2— Comparative yield strength in ksi

		Cold work				
Alloy	Anl	35%	50%	60%	70%	80%
BioDur 316LS	35	115	120	128	130	137
22Cr-13Ni-5Mn*	65	170	190	215	230	—
BioDur 108	88	197	243	260	268	270

** BioDur 734 essentially equivalent*

Table 3 — Comparative tensile strength in ksi

		Cold work				
Alloy	Anl	35%	50%	60%	70%	80%
BioDur 316LS	85	125	145	160	170	180
22Cr-13Ni-5Mn*	120	190	215	230	245	—
BioDur 108	135	230	270	292	308	320

** BioDur 734 essentially equivalent*

Testing procedure

Conventionally cast electro-slag remelted (ESR) ingots of BioDur 108 were converted into billet for subsequent processing into finished bar and wire of various sizes. BioDur alloys 108, 316LS, 22-13-5, and 734 were then tested in the annealed and various cold-worked conditions.

Specimens were machined and tested in accordance with ASTM standards to measure yield strength, tensile strength, impact toughness, and fatigue resistance.

Corrosion resistance was determined by three methods:

- **Critical crevice corrosion** temperature was calculated and measured by ASTM G48, Method D.
- **Pitting resistance equivalent number (PREN)** was calculated.
- **Pitting** tests were carried out per ASTM G48 Method A.

Specimens were evaluated for biocompatibility in accordance with ISO and industry standards. Cytotoxicity, irritation, acute systemic toxicity, pyrogenicity, mutagenicity, implantation with histopathology, and hemocompatibility were assessed.

Effects of nitrogen

BioDur 108 alloy depends primarily on its high nitrogen content of approximately one percent to maintain its austenitic structure. The high nitrogen also contributes to its high levels of strength, ductility, and corrosion resistance.

The typical yield strength of BioDur 108 alloy is approximately 606 MPa (88 ksi) in the annealed condition. This compares with typical yield strength for

Implants

BioDur 316LS of approximately 241 MPa (35 ksi), which is typical of austenitic stainless steels with low nitrogen content.

The nitrogen-strengthened BioDur 734 and 22Cr-13Ni-5Mn alloys contain more nitrogen than BioDur Type 316LS alloy but less than BioDur 108 alloy. They typically exhibit approximately 448 MPa (65 ksi) yield strength in the annealed condition.

The high nitrogen content of BioDur 108 also enhances the effect of cold work to increase strength levels. This effect can be seen in Tables 2 and 3, which show yield strength and tensile strength achieved with varying amounts of cold work.

Effects of cold reduction

A graphical representation of the effect of cold reduction on yield strength for BioDur 108 compared with BioDur 734, 22Cr-13Ni-5Mn and BioDur 316LS is presented in Fig. 1. BioDur 108 exhibits yield strength approximately 20% higher than 22Cr-13Ni-5Mn and over double that of BioDur 316LS at 69% cold reduction. Figures 2 and 3 summarize yield strength, tensile strength, elongation, and reduction of area versus percent cold work reduction.

Toughness levels

Like most austenitic alloys, BioDur 108 has very high toughness. In fact, in the annealed condition, room-temperature impact energy levels for standard 10 mm x 10 mm Charpy V-notch specimens exceed the capacity of common testing machines. For this reason, sub-size 10 mm x 5 mm Charpy V-notch impact specimens are suggested when testing for impact energy.

High-nitrogen austenitic alloys tend to exhibit "ductile-to-brittle" transition behavior, which is similar to that of ferritic alloys. In BioDur 108, the ductile-to-brittle transition response is suppressed to below 0ºC, and takes place at approximately –20ºC. Therefore, it can be considered for applications above –20ºC.

BioDur Type 316LS alloy was not tested for impact resistance in this study, because its impact energy behavior is well known.

In addition to very high levels of strength, high nitrogen also provides BioDur 108 with very high levels of fatigue resistance. Rotating-beam fatigue tests were conducted on specimens of the alloy from annealed bar stock having an ASTM #5 grain size and an ultimate tensile strength of 930 MPa (135 ksi). The fatigue limit observed was approximately 380 MPa (55 ksi), or about 41% of the ultimate strength. This fatigue limit is essentially equivalent to that of 22Cr-13Ni-5Mn, and higher than that of BioDur 316LS.

Corrosion resistance

Corrosion resistance in austenitic alloys is strongly related to levels of chromium, molybdenum, and nitrogen. Because these levels are high in BioDur 108, it offers excellent resistance to pitting and crevice corrosion, resistance that is critical for materials in medical devices.

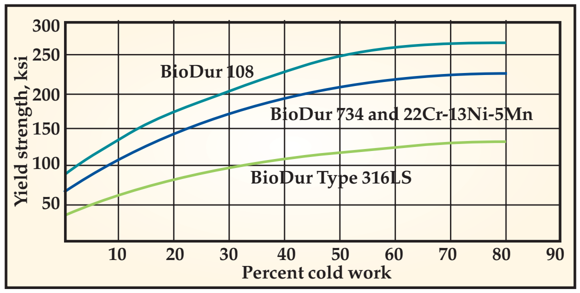

Fig. 1 — Comparative yield strength for four BioDur Alloys. This graph shows yield strength versus cold work for wire.

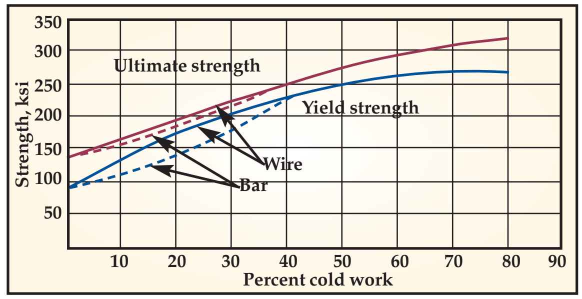

Fig. 2 — BioDur 108 yield and tensile strength with increasing cold work. This graph shows strength versus cold work for bar and wire.

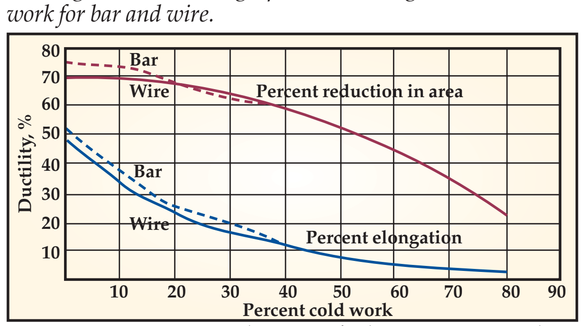

Fig. 3 — BioDur 108 elongation/reduction in area with increasing cold work for bar and wire.

Tests in the study included Pitting Resistance Equivalent Number (PREN), measured weight loss in ferric chloride pitting tests (ASTM G48 Method A), and calculated and measured critical crevice corrosion temperature (CCT) tests (ASTM G48 Method D).

Compared with 22Cr-13Ni-5Mn and BioDur 316LS, the BioDur 108 alloy had a higher calculated PREN, the least amount of weight loss in pitting tests, and the highest calculated and measured CCT. See Table 4 for detailed results.

Testing for corrosion fatigue limits in distilled water solution and a standard Ringer's solution at 37°C (98°F) have confirmed the relative corrosion resistance of the alloys. In addition, BioDur 108, passed the ASTM A262 Practice A requirements for resistance to intergranular corrosion.

Biocompatibility evaluation

BioDur 108 was subjected to a series of biocompatibility tests to further evaluate its potential for biomaterial applications, and to compare it with the conventional nickel-bearing austenitic

Table 4 — Comparative corrosion properties

Alloy	PREN[1]	Pitting weight loss,[2] 25°C/72 hr	CCT[3], calculated, °C	CCT, measured, °C
BioDur 108	31	0.0 mg	9	10
22Cr-13Ni-5Mn*	30.3	0.2 mg	6.3	5
BioDur 316LS	27.4	na	–7.6	–5

** BioDur 734 essentially equivalent*
1-Pitting Resistance Equivalent (PREN) = Cr + 3.2Mo + 8N
2-Test completed in 6%$FeCl_3$ per ASTM G48 Method A
3-Critical Crevice Corrosion Temperature completed in 6% $FeCl_3$ + 1%HCL (ASTM G48 Method D)

stainless steels. Extensive biocompatibility tests were conducted by Toxikon Corp., Bedford, Mass., on behalf of Carpenter. BioDur 108 alloy met all the requirements of the test standards. Briefly defined here are highlights of the findings; more specific details about test procedures and standards met (such as ISO numbers) are available from Carpenter.

• **Cytotoxicity:** The alloy was found to be noncytotoxic and meets the requirements of the Elution test, ISO 10993.

• **Irritation:** Test samples did not exhibit any signs of erythema, edema, or necrosis. Alloy was concluded to be a negligible irritant.

• **Acute Systemic Toxicity:** No signs of toxicity were observed. Test samples met the requirements of ISO 10993-11, Systemic Injection Test.

• **Pyrogenicity:** Test samples met the requirements of ISO 10993-11 for the absence of pyrogens.

• **Mutagenicity:** Alloy specimens were shown to be non-mutagenic based on the test methods.

• **Implantation with Histopathology:** No signs of toxicity were exhibited after 14-day and 28-day implantation test periods. Alloy was concluded to be nontoxic.

• **Hemocompatibility:** Alloy samples were concluded to be non-hemolytic based on test methods.

In summary, the essentially nickel-free BioDur 108 alloy has demonstrated higher levels of strength, impact toughness, and fatigue and corrosion resistance than BioDur 22Cr-13Ni-5Mn/BioDur 734 and BioDur 316LS. For these reasons it can be considered as a possible material upgrade for biomedical implant and instrument applications. **MPMD**

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