BIODUR® 108 STAINLESS

Applicable specifications: AMS 2630, ASTM F2229

Associated specifications: UNS S29108

Type analysis

Wt.%. Single figures are nominal except where noted.

Iron	Balance	**Manganese**	21.00–24.00 %	**Chromium**	19.00–23.00 %
Nitrogen	Min 0.90 %	**Silicon**	Max 0.75 %	**Molybdenum**	0.50–1.50 %
Copper	Max 0.25 %	**Nickel**	Max 0.10 %[1]	**Carbon**	Max 0.080 %
Phosphorus	Max 0.030 %	**Sulfur**	Max 0.010 %		

[1] *0.050 max nickel available upon request.*

Forms manufactured

Bar-Rounds	**Billet**	**Strip**	**Wire**	**Wire-Rod**

Description

BioDur 108 is an essentially nickel-free austenitic stainless alloy that contains a high nitrogen content to maintain its austenitic structure. As a result, BioDur 108 stainless has improved levels of tensile and fatigue strength, as compared 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. BioDur 108 is produced by the electro-slag remelting (ESR) process to ensure its microstructural integrity and cleanness. The alloy is non-magnetic and essentially free of ferrite phase.

The chemistry of BioDur 108 meets the recently implemented **EU MDR** regulatory labeling threshold of less than 0.10% cobalt by weight. Devices made from this alloy should not need to be labeled as containing a potential CMR (carcinogenic, mutagenic, and reprotoxin) element.

Key Properties:

- Nitrogen-strengthened, austenitic stainless steel
- Improved tensile and fatigue strength
- Crevice and pitting corrosion resistance
- Non-magnetic and essentially ferrite-free

Markets:

- Medical

Applications:

- Bone plates and screws
- Spinal fixation components
- Hip and knee components
- Orthodontic appliances
- Forged and machined medical components
- Hypoallergenic jewelry

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Biocompatibility summary

Cytotoxicity	A study was conducted based on the procedure described in ANSI/AAMI/ISO 10993-5, 1993; Biological evaluation of medical devices - Part 5: Tests for Cytotoxicity. The BioDur 108 test article was concluded to be non-cytotoxic and meeting the requirements of the Elution Test, ISO 10993.
Irritation	Testing was based upon ISO Biological Testing of Medical Devices Part 10: Irritation and Sensitization Tests, ISO 10993-10, 1995. Extraction procedures were based upon ISO 10993-12, 1996. The test sites did not exhibit any signs of erythema, edema, or necrosis, and the BioDur 108 test article was concluded to be a negligible irritant.
Acute Systemic Toxicity	Testing was based on ISO Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity, ISO 10993-11, 1993. Extraction procedures were based upon ISO 10993-12, 1996. No signs of toxicity were observed and the test article was concluded to meet the requirements of ISO 10993-11, Systemic Injection Test.
Pyrogenicity	Testing was based on ISO Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity, ISO 10993-11, 1993, and upon the standards set by the current version of the United States Pharmacopia. Extraction procedures were based upon ISO 10993-12, 1996. The BioDur 108 test article was concluded to meet the requirements of ISO 10993-11 for the absence of pyrogens as specified for the Pyrogen Test.
Mutagenicity	Testing was based on ISO Biological Evaluation of Medical Devices, Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity; IS010993-3, 1992, and revised methods for the Salmonella Mutagenicity Test, Maron, D.M. Ames, B.N., Mutation Research, 113: 173-215, (1993). Extraction procedures were based upon ISO 10993-12, 1996. The BioDur 108 test article was concluded to be non-mutagenic based on the methods employed.
Implantation With Histopathology	Testing was based on ANSI/AAMI/ISO 10993-6, 1995; Biological Testing of Medical Devices, Part 6: Tests for Local Effects After Implantation; and ASTM Standards Section 13, Volume 13.01, Medical Devices, Designation: F 981-93 (1996). No signs of toxicity were exhibited after 14- and 28-day implantation test periods, and the BioDur 108 test article was concluded to be non-toxic.
Hemocompatibility	Testing was based on the following references: DHEW publication # (NIH) 77-1294, 9.213, 1977; ISO Biological Evaluation of Medical Devices, Part 4, Selection of Tests for Interactions with Blood, ISO 10993-4, 1992; Extraction Procedures were based on ISO 10993-12, 1996; Autian Method described in ATTP-I, University of Tennessee Center for the Health Sciences, Memphis, TN, 18-Apr-77; Veterinary Hematology, Schalm O.W., pp 51-53 ,1965, Lea & Feviger, Philadelphia. The BioDur 108 test article was concluded to be non-hemolytic based on the methods employed. Testing was conducted and reported by Toxikon Corporation, 15 Wiggins Avenue, Bedford, MA 01730, USA, on behalf of Carpenter Technology Corporation.

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Corrosion resistance

BioDur 108 stainless possesses a high resistance to corrosion due to its high levels of chromium and nitrogen and its molybdenum content. The alloy exhibits excellent resistance to pitting and crevice corrosion. BioDur 108 was designed to have corrosion resistance equivalent to or greater than the nickel-containing alloys 22Cr-13Ni-5Mn (ASTM F1314) and 734 (ASTM F1586). The corrosion resistance levels of these alloys are superior to Type 316L (ASTM F138).

Critical crevice temperatures of 50°F (10°C) were measured (per ASTM G48, Method D) in BioDur 108 specimens. Critical temperatures of 41°F (5°C) were measured in identically prepared specimens of 22Cr-13Ni-5Mn. Under these test conditions, the critical temperature of Type 316L would be below 32°F (0°C). The relative corrosion resistances of BioDur 108 and the comparative alloys were confirmed with anodic polarization testing in Ringer's solution at 98.6°F (37°C).

BioDur 108 stainless specimens tested passed the intergranular corrosion requirements of ASTM A262, Practice A.

IMPORTANT NOTE:
The following 4-level rating scale is intended for comparative purposes only. Corrosion testing is recommended; factors that affect corrosion resistance include temperature, concentration, pH, impurities, aeration, velocity, crevices, deposits, metallurgical condition, stress, surface finish and dissimilar metal contact.

Nitric Acid	Good	**Salt Spray (NaCl)**	Excellent
Sea Water	Moderate	**Humidity**	Excellent

Physical properties

DENSITY	0.2760 lb/in^3
POISSON'S RATIO	0.300
MODULUS OF ELASTICITY (E)	29.0 x 10^3 ksi

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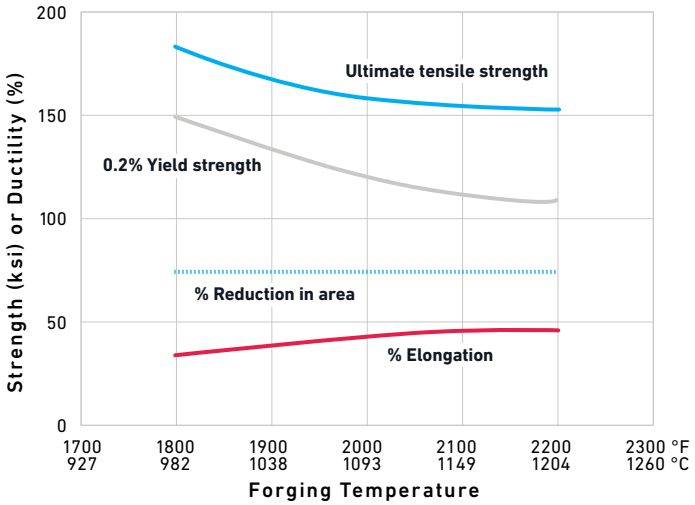
Magnetic properties

MAGNETIC PERMEABILITY	1.0100 Mu

Typical mechanical properties

STRENGTH AND DUCTILITY VS. FORGING TEMPERATURE



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Tensile properties

BioDur 108 possesses high strength levels and a high work hardening rate due to its high nitrogen content.

0.1 IN. (2.5MM) DIAMETER WIRE

CONDITION	COLD WORK	0.2% YIELD STRENGTH		ULTIMATE TENSILE STRENGTH		ELONGATION	REDUCTION OF AREA
	%	ksi	MPa	ksi	MPa	%	%
Annealed	—	88	607	135	931	49	70
Cold worked	10	140	965	165	1138	33	69
Cold worked	20	175	1207	195	1345	23	68
Cold worked	30	205	1413	225	1551	16	64
Cold worked	40	230	1586	245	1689	12	60
Cold worked	50	245	1689	270	1862	7	53
Cold worked	60	260	1793	292	2013	5	45
Cold worked	70	268	1848	308	2124	4	35
Cold worked	80	270	1862	320	2206	3	23

Data represent wire cold drawn various amounts from a starting diameter of 0.1 in. (2.55 mm). Tests represent full wire section. Elongation values represent a gauge length of 2 in. (50 mm).

1.0 IN. (25 MM) DIAMETER BAR

CONDITION	COLD WORK	0.2% YIELD STRENGTH		ULTIMATE TENSILE STRENGTH		ELONGATION	REDUCTION OF AREA
	%	ksi	MPa	ksi	MPa	%	%
Annealed	—	85	586	135	931	52	75
Cold worked	10	114	786	154	1062	37	73
Cold worked	20	138	952	183	1262	25	69
Cold worked	30	178	1227	217	1496	19	63
Cold worked	40	225	1551	251	1731	12	59

Data represent bar cold drawn various amounts from a starting diameter of 1.0 in. (25 mm). Tests represent 0.505 in. (12.8 mm) diameter specimens machined from the bar center.

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PARTS FORGED FROM VARIOUS TEMPERATURES AND WATER QUENCHED							
FORGING TEMPERATURE		0.2% YIELD STRENGTH		ULTIMATE TENSILE STRENGTH		ELONGATION IN 4D	REDUCTION OF AREA
°F	°C	ksi	MPa	ksi	MPa	%	%
2200	1204	107	741	157	1083	45	75
2200	1204	120	827	165	1138	43	74
2100	1149	110	759	156	1078	44	74
2000	1093	115	792	154	1061	45	73
1900	1038	147	1014	172	1185	34	73
1900	1038	131	905	172	1188	39	74
1800	962	150	1036	182	1253	33	73

Data represent hip implant parts forged from 0.625 in. (16 mm) diameter bar and water quenched. Tests represent 0.150 in. (3.8 mm) diameter specimens machined from the distal end of the forgings and tested in the as-forged condition.

Toughness

Like most austenitic alloys, BioDur 108 stainless possesses very high toughness levels. In the annealed condition, room temperature impact energy levels for standard 10 mm x 10 mm Charpy V-Notch specimens would exceed the capacity of common testing machines. High-nitrogen austenitic alloys exhibit a "ductile-to-brittle" transition behavior that is similar to ferritic alloys. In BioDur 108, this transition is suppressed to temperatures below 32°F (0°C). The CVN impact test data below represent tests of annealed BioDur 108 sub-size specimens at various temperatures. Note the transition from ductile to brittle behavior as the temperature is lowered below -4°F (-20°C).

The fatigue resistance of BioDur 108 benefits from its high strength levels, since, in austenitic alloys, fatigue limit is closely related to the tensile strength. The RR Moore rotating-beam fatigue test data below represent annealed BioDur 108 specimens with a grain size of ASTM #5 and an ultimate tensile strength of 135 ksi (930 MPa). The fatigue limit is approximately 41% of the tensile strength.

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CVN IMPACT TEST — 5 MM X 10 MM SUB-SIZE SPECIMENS, PER ASTM E23				
TEST TEMPERATURE		IMPACT ENERGY		FRACTURE MODE
°F	°C	ft-lb	J	
100	38	100	136	Ductile Rupture
72	22	90	122	Ductile Rupture
32	0	86	117	Ductile Rupture
5	-15	78	106	Ductile Rupture
-4	-20	79	107	Ductile Rupture
-13	-25	24	33	Mixed
-22	-30	6.5	8.8	Cleavage
-40	-40	5.5	7.5	Cleavage

RR MOORE ROTATING-BEAM FATIGUE TEST AT ROOM TEMPERATURE			
TEST STRESS		ULTIMATE TENSILE STRENGTH	CYCLES TO FRACTURE
ksi	MPa	%	
75	517	56	40,000
65	448	48	37,000
60	414	44	224,000
57.5	396	43	612,000
55	379	41	23,512,000 (NF)

% of Ultimate Tensile Strength values represents the test stress divided by the UTS 135 ksi (931 MPa).
"NF" indicates test was terminated without the specimen fracturing.

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Heat treatment

Annealing	Annealing is accomplished in the range 1900 to 2100°F (1040 to 1150°C). Typically, the alloy is annealed in the lower part of this range to preserve a fine grain size. The alloy should be rapidly cooled from the annealing temperature. This is because slow cooling through the range from 1800 to 1500°F (980 to 810°C) under some circumstances can cause precipitation of a chromium nitride phase (Cr2N), which could adversely affect corrosion resistance and toughness. Annealing at 1950°F (1065°C) for one hour, followed by a water quench, may be used in most cases. Heat treating BioDur 108 in non-argon atmospheres results in the formation of a thin magnetic (ferritic) surface layer on the heat treated product that must be removed from the finished product.
Hardening	BioDur 108 cannot be hardened by heat treatment. It must be hardened by cold working.

Workability

Forging	BioDur 108 may be hot worked by procedures simulating those used for 22Cr-13Ni-5Mn (ASTM F1314) and 734 (ASTM F1586) alloys. Heat the alloy uniformly to a temperature in the range of 1900°F to 2200°F (1040°C to 1200°C) for forging. Do not forge at temperatures below 1800°F (980°C). Forgings may be air cooled or water quenched. Parts should be annealed after forging. In some cases, water quenching after forging may circumvent the need for annealing. The effect of forging temperature on mechanical properties can be found in the Typical Mechanical Properties and Tensile Properties sections of this datasheet.
Machinability	BioDur 108 may be machined by procedures similar to those used for 22Cr-13Ni-5Mn (ASTM F1314) and 734 (ASTM F1586) alloys. A continuous positive cutting action should be maintained to avoid work hardening. Slow to moderate speeds, moderate feeds, and rigid tools should be considered. Tools must be kept sharp. Use a sulfurized cutting fluid, preferably of the chlorinated type. The feeds and speeds in the table below may be considered as starting points when developing machining parameters for a specific job.
Weldability	BioDur 108 alloy should not be welded using fusion welding processes.

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Typical feeds and speeds

The feeds and speeds in the following charts are conservative recommendations for initial setup. Higher feeds and speeds may be attainable depending on machining environment. See the additional machinability notes above.

TURNING — HIGH-SPEED TOOLS

OPERATION	SPEED		FEED	
	SFM	M/MIN	IN/REV	MM/REV
Single point and box tools[1]	55–70	17–21	0.015–0.007	0.38–0.18
Cut-off tools: 3 mm (0.125 in.)	40–65	12–20	0.001	0.025
Form tools: 25 mm (1 in.)	40–65	12–20	0.001	0.025

TURNING — CARBIDE TOOLS

OPERATION	SPEED		FEED	
	SFM	M/MIN	IN/REV	MM/REV
Single point and box tools[1]	225	70	0.015–0.007	0.38–0.18
Cut-off tools: 3 mm (0.125 in.)	150	45	0.005	0.13
Form tools: 25 mm (1 in.)	150	45	0.003	0.08

DRILLING — HIGH-SPEED TOOLS

OPERATION	SPEED		FEED	
	SFM	M/MIN	IN/REV	MM/REV
6 mm (0.25 in.) diameter	45–50	14–15	0.004	0.10
20 mm (0.75 in.) diameter	45–50	14–15	0.010	0.25

REAMING — HIGH-SPEED TOOLS

OPERATION	SPEED		FEED	
	SFM	M/MIN	IN/REV	MM/REV
6 mm (0.25 in.) diameter	65	20	0.005	0.13
20 mm (0.75 in.) diameter	65	20	0.010	0.25

REAMING — CARBIDE TOOLS

OPERATION	SPEED		FEED	
	SFM	M/MIN	IN/REV	MM/REV
6 mm (0.25 in.) diameter	200	60	0.005	0.13
20 mm (0.75 in.) diameter	200	60	0.010	0.25

[1] *Depth of cut = 3.8–0.6 mm (0.150–0.025 in.)*

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Metallurgical requirements

BioDur 108 heats evaluated have met the matallurgical requirements pertaining to 22Cr-13Ni-5Mn, which are listed in section 7 of ASTM F1314. These requirements are as follows:

1. The material shall exhibit no free ferrite phase when examined metallographically at 100X magnification.
2. The microcleanness, as determined by ASTM E45, Method A, except using Plate III and Plate I, on representative billet or bar samples shall not exceed the following:

INCLUSION TYPE	A (SULFIDE)	B (ALUMINA)	C (SILICATE)	D (GLOBULAR OXIDE)
Thin	1.5	2.5	2.5	2.5
Heavy	1.5	1.5	1.5	1.5

For additional information, please contact your nearest sales office:
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