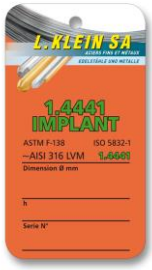

1.4441 IMPLANT

1.4441/AISI 316L – Austenitic stainless steel for implants

Features and Particularities

This steel is the classical austenitic stainless steel for medical applications. It has been specifically developed and originally optimized for internal fixation devices. Its American equivalent is the VAR remelted, ASTM F 138, 316LVM steel. The 1.4441 IMPLANT steel is ESR remelted to a particularly low S content. Its composition ensures that it is ∂ (Delta) Ferrite free, and not forming ferromagnetic α (Alpha) martensite up to the highest required cold worked strengths. It can be easily cold worked to high strength levels. This steel has a good corrosion resistance, especially against pitting corrosion. And exhibits fair high fatigue endurance limit at 10^7 cycles.

Uses

This 1.4441 IMPLANT steel is well adapted for numerous applications in the medical field and more particularly for bone surgery, like implants for joint replacement, internal fixation devices, high strength guide wires and Kirschner wires for internal and external fixations. It is also well indicated for non-medical applications with similar requirements, such as components of the watch exterior. It can be fairly easily machined.

Standards

Material number	1.4441
ISO	5832-1
EN 10088-3 09/05	X2CrNiMo18-15-3
DIN / AFNOR	X2CrNiMo18-15-3
AISI/SAE	316 LVM
ASTM	F 138
UNS	S31673

Chemical composition (%wt)

C	Si	Mn	P	S	Cr	Ni	Mo	N	Cu	Fe
max.	max.	max.	max.	max.	17.0	13.0	2.70	max.	max.	Balance
0.030	0.75	2.00	0.025	0.003	19.0	15.0	3.00	0.10	0.50	

Dimensions and Tolerances and

Standard: Bars 3 m (+50/0 mm), coils for Escomatic

- Bars Ø < 0.8-18 mm: ISO h8
- Bars Ø ≥ 2.00 mm: ISO h6 (h7)
- Wires Ø 0.80 - 3.00 mm: ISO fg7, coils for Escomatic
- Out of roundness max: ½ Diameter tolerance

Executions

- Bars Ø ≥ 2.00 mm: cold drawn, ground, polished, Ra ≤ 0.4 µm (N5)
  Crack test EN 10277-1 Tab1: Ø <6.0 Kl. 2, ≤6.0 Kl. 3
  Bar ends: pointed, chamfered
- Bars < 2.00 mm: Surface condition: cold drawn
- Bars ≥ 6.00 mm: SWISSLINE execution
- Wires Ø < 3.00 mm: Surface condition: cold drawn, coils for Es comatic

Other executions and tolerances on request

Strength

- Bars Ø ≥ 3.0 - 22 mm: Strength UTS: for screws: 930-1100 MPa
- Bars Ø ≥ 0.80 - 13 mm: extra-hard: ≥ 1'400 MPa

Availability

Standard dimensions on stock, see: Delivery program

Cutting conditions

Machinability: relatively difficult, best in the cold worked condition
Cutting speed: V_c ≈ 30 - 40 m/min.
Lubricant-coolant: individual choice

- The optimal cutting conditions depend on the machine tool, the cutting tools, the chip dimensions, the lubricant-cooling fluid, as well as the tolerances and surface the roughness to be achieved.

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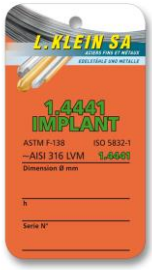

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Cleanliness

According to: EN 50602: K0.5 < 1 (K1 < 0.5)
ASTM 45 (E 1122): < 1 A, B, C and D type of inclusions

Grain size

According to: ASTM E47:
- Hot rolled bars: ASTM Nr. ≥ 6-7
- Cold drawn bars and wires: ASTM Nr. ≥ 8

δ (Delta) Ferrite

According to the Schaeffler-DeLong diagram as revised by Outokumpu, this steel does not form or contain any δ (Delta) ferrite. It is non-ferromagnetic.
- Cr_{eq} = 1.5Si + Cr + Mo + 2Ti + 0.5Nb
- Ni_{eq} = 30(C + N) + 0.5Mn + Ni + 0.5(Cu + Co)
- $\%_{vol}$ Ferrite δ or Ferrite Number FN
  FN = ([{1.375 (Cr_{eq} – 16} + 10] - Ni_{eq}) 2.586
- Calculated FN key values: min. -3.4 / max. -2.3
  Negative values indicate the absence of δ (Delta) ferrite

PREN

- PREN = %Cr + 3.3%Mo + 18%N
- Computed basic parameters: min./ max. 25.9/30.7

Forming

Warm, forging: 970 – 1100°C, quenching, rapid cooling
- In case the working temperature should fall below 960°C, it is advisable to submit the parts to a solution anneal

Cold: no limitations, See also p. 3, cold working strengthening

Solution anneal

1050-1080°C/quenching or rapid cooling
- A minimum cold reduction of ≥ 10 – 15% is recommended to reduce the risk of a too fast and strong grain growth
- Temperature below 960°C should be avoided to eliminate the risk of precipitating the undesirable σ (Sigma) phase.
- The formation of σ (Sigma) phase leads to brittleness, reduction of the ductility and corrosion resistance.
  In such cases a solution anneal at 1050-1080°C is recommended.

Hardening

The 1.4441 IMPLANT steel cannot be thermally hardened.

Strengthening

This steel can only be strengthened by cold deformation. See Figure 1, page 3.

Microstructures

Delivery condition, hot rolled: Austenite, annealed
For machining and polishing: Austenite, annealed or cold worked

Polishing

Mirror polishing: adapted
Electro-polishing: adapted
- The1.4441 IMPLANT steel being free of ∂ (Delta) Ferrite.
- In case the undesirable σ Sigma) or ψ (Chi) Phases have been formed, a 1050-1080°C solution anneal can be necessary to restore in order to not impair the polishing and hinder the later development of intercristaline corrosion.

Welding

Feasible

Laser marking

A normal HAZ (Heat Affected Zone) due to the heating of the laser marking should not significantly affect the microstructure and its properties. More info

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Strengthening

The 1.4441 IMPLANT steel can be strengthened by cold deformation only. Figure 1 shows the strength levels of UTS, $Y_{0.2\%}$ and the fatigue endurance limit at 10^7 cycles, which can be achieved by cold deformation.
Figure 2 shows the Wöhler curve in rotating bending fatigue of this steel.

Figure 1
Strength:
UTS and $Y_{0.2\%}$
Fatigue endurance limit at:
10^7 cycles

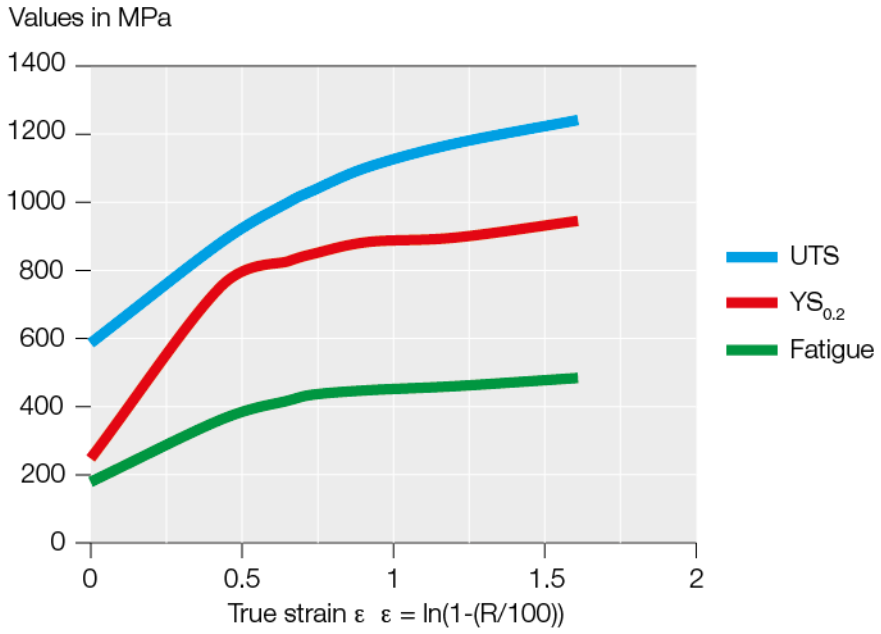
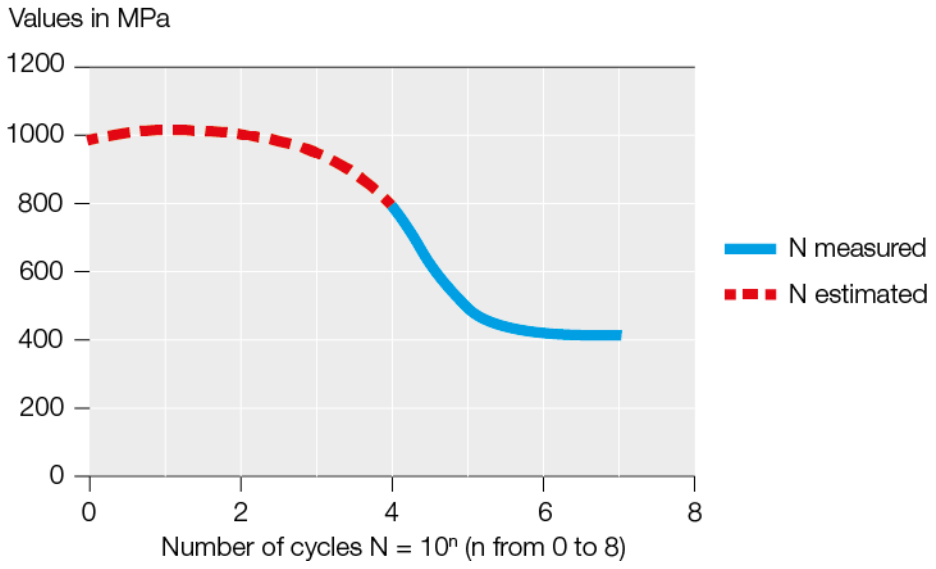
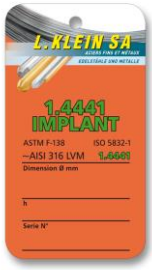


Figure 2
Endurance fatigue limit
Wöhler-Kurve



Referenz: Daten der Abbildungen 1 und 2
John Disegi, Implant Material, 3. Auflage, Synthes (USA), 2009



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Surface oxidation

The oxides formed by thermal oxidation must be eliminated either mechanically or chemically.

- The presence of colored oxides or oxide scales on the surface can strongly reduce the corrosion resistance.

Pickling - Passivation

The procedures and products used to pickle and passivize this steel should be adapted to the requirements of austenitic stainless steels. More info

- Potential “Flash back“ reactions can be avoided if the processed products are pickled before passivation.
- A passivation treatment is not necessary after eletro-polishing.

Corrosion resistance

- Optimal surface condition: clean, polished and passivized.
- The various corrosion resistances of the 1.4441 IMPLANT steel in the mediums prevailing for components for the watch exterior, are given in Table 1.

Table 1 Corrosion resistance Components for the watch exterior

Corrosion type	Condition	Corrosion susceptibility
Pitting corrosion	all	Unaltered
Spray salt	all	Unaltered
Sea water	all	Unaltered
Stress corrosion cracking	Annealed	Not susceptible
	Cold worked ≤ 63% ε=1	Generally not susceptible
	In some circumstances a low temperature 250-300°C/1h stress relief treatment can be made preventively.	

Galvanic corrosion

- The 1.4441 IMPLANT steel is more noble than many metals including current 18/8 stainless steels.
- The electrolyte and the metals of an assembly may form a galvanic corrosion cell, which ultimately could lead to galvanic corrosion. More info.

Elementary precautions

- The simplest and easiest precautions are always to keep the parts clean, free of working residues, polished, and correctly dried.
- Use only chloride free disinfection solutions, cleaning and washing solutions and products.

Magnetism

The 1.4441 IMPLANT steel steel grade is not ferromagnetic.
Relative permeability: max 1.003

- No evidence of the presence of ∂ (Delta) ferrite by „Ferritoscope“ check or metallographic examination at 100X.
- A strong plastic deformation i.e. à ε = 1 (≈ 63% cold reduction) does not lead to the formation of ferromagnetic α (Alpha) martensite.

Magnetism: More info.

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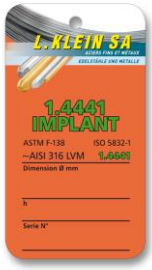

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Physical properties

Properties	Unit	Temperature (°C)				
		20	200	300	400	500
Density	g cm^{-3}	8.00				
Young modulus E	GPa	200	186	179	172	165
Poisson Coefficient		0.29				
Electrical resistance	$\Omega.mm^2.m^{-1}$	0.75				
Thermal expansion	10^{-6} m m^{-1} K^{-1}	16.0	16.5	17.0	17.5	18.0
Thermal conductivity	$W.m^{-1}.K^{-1}$	15			15.2	
Specific heat	$J.kg^{-1}.K^{-1}$	500				
Melting range	°C	1370-1400				
Relative Permeability	µr	max. 1.003				
Magnetism	non-ferromagnetic					

Disclaimer: The information and data of this informative “Data sheet“ are indicative only. They are not use instructions. The users must define and endorse them in each case.

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