voestalpine
High Performance Metals

Politecnico di Milano

Nov. 2024

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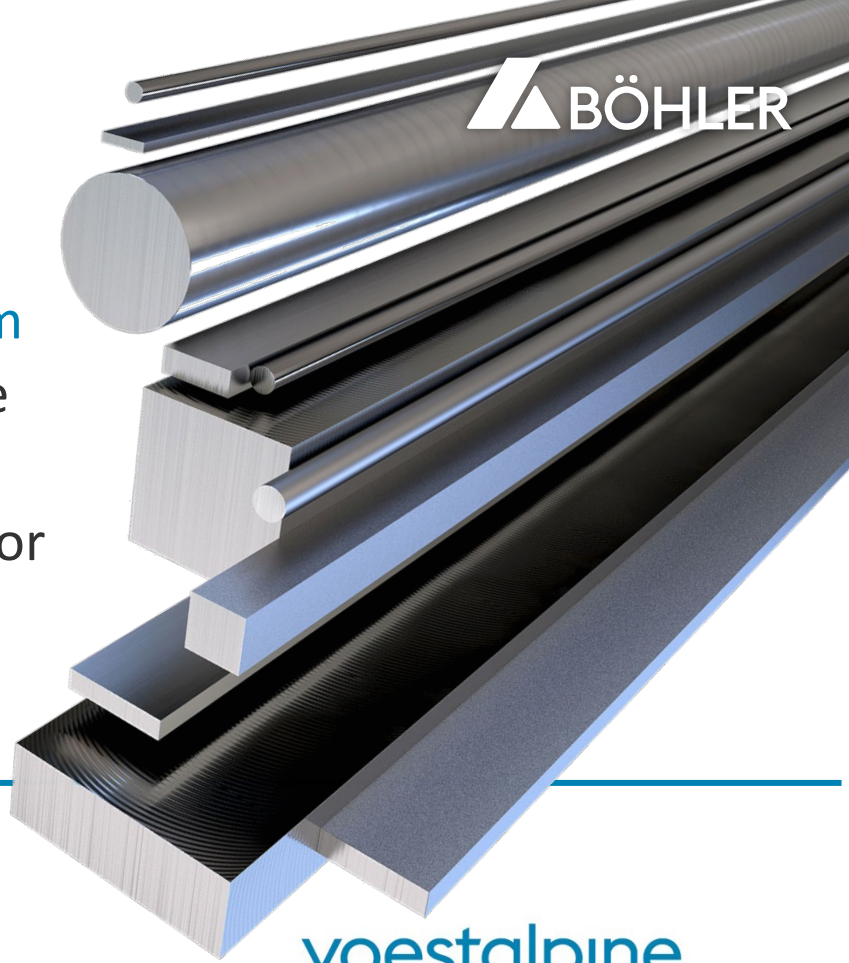
With the know-how and experience from 150 years of special steel production, we develop, produce and sell high-speed steels, tool steels and special materials for the highest demands worldwide.



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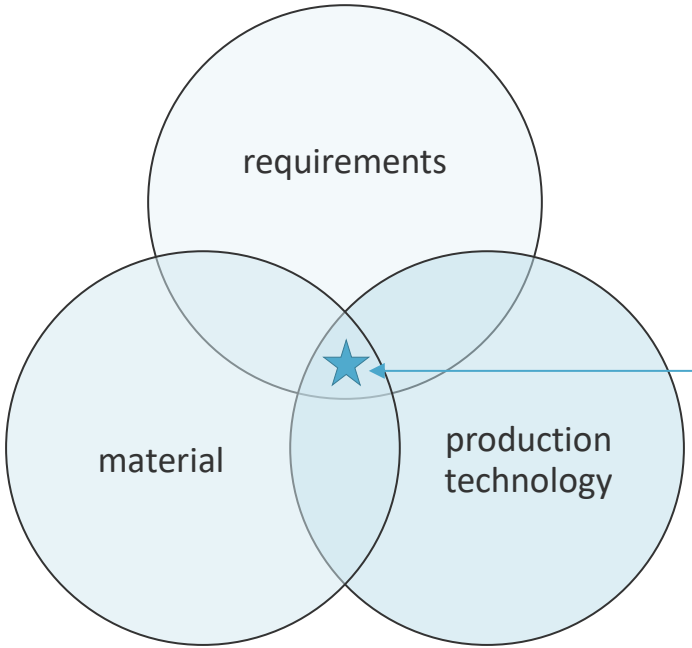
WORLD'S MOST MODERN STEEL MILL
ESW2020+

- Largest single investment ever made by voestalpine in Europe
- Secures global technology leadership in the long term
- Highest environmental standards through the most modern process technology
- Conservation of resources through automated processes

MEDICAL TECHNOLOGY
Böhler Position



BÖHLER

High performing products and customized solutions for medical instruments

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REQUIREMENTS

Material Requirements

- **High corrosion resistance (in use and/or cleaning)**
- **Mechanical properties**
- High cleanliness and homogeneity
- Polishability
- Machinability
- **Biocompatibility**
- Traceability
- Sustainability

REQUIREMENTS

ASTM INTERNATIONAL

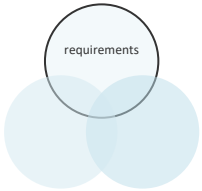
ASTM F138 This is the standard for **316L grade stainless steel**, which is commonly used in medical implants. It regulates the chemical composition, mechanical properties, and corrosion resistance of stainless steel for surgical implants.
ASTM F75 Standard for cast **cobalt-chromium-molybdenum alloys** for implants. This does not apply to Böhler stainless steel but is relevant as **AMPO powder**.
ASTM F1537 For **CoCr material for implants**.

ISO 10993

ISO 10993-1 Evaluation and testing within a risk management process.
ISO 10993-5 Tests for cytotoxicity.
ISO 10993-10 Tests for irritation and sensitization potential.
ISO 10993-11 Tests for systemic toxicity.

These standards apply to all materials that come into **contact with the human body**, including **stainless steel and cobalt-chromium alloys**.

REQUIREMENTS



ISO 5832 – Surgical implant metals

ISO 5832-1 **Stainless steel** for surgical implants (316L).
ISO 5832-4 Forged parts made from **cobalt-chromium-molybdenum alloys**.
ISO 5832-12 Forged parts made from a **nickel-cobalt-chromium-molybdenum alloy**.

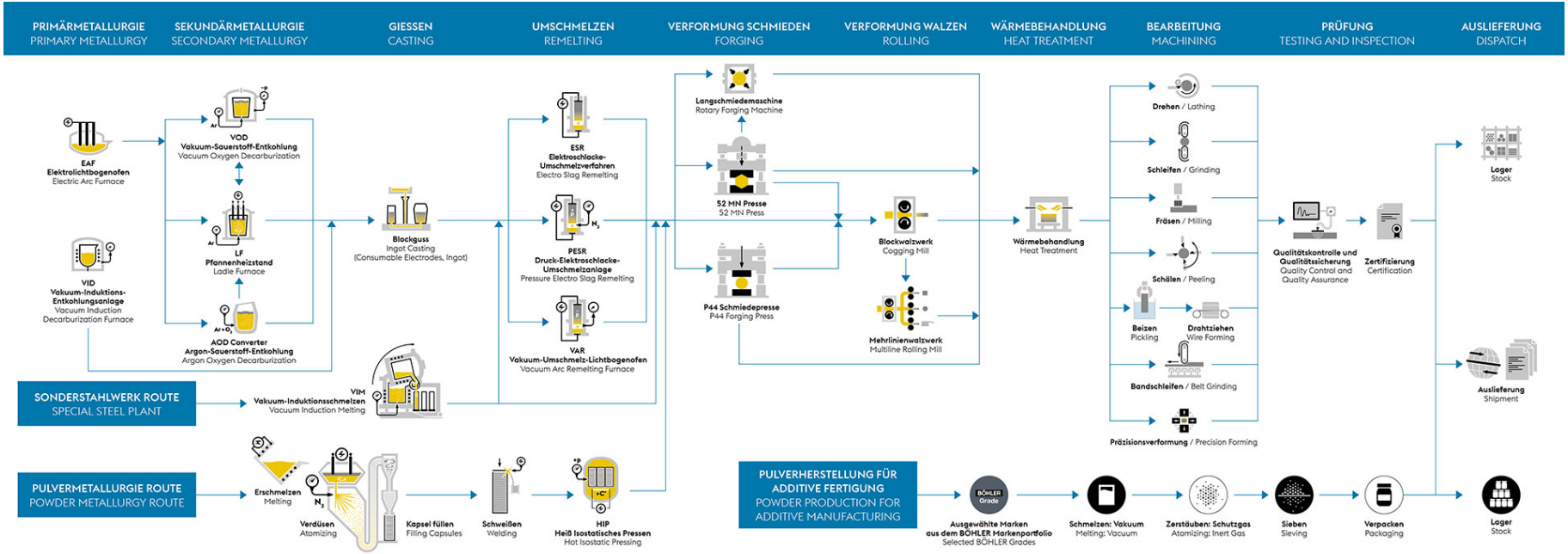
These standards define the chemical composition, mechanical properties, and corrosion resistance of metal alloys to ensure their suitability for medical applications.

EN ISO 7153-1 – Materials for surgical instruments

This standard specifies requirements for metals used in surgical instruments, including **stainless steels** (e.g., 316L).
It also considers aspects such as **corrosion resistance and biocompatibility.**

PRODUCTION TECHNOLOGY

production technology



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MATERIAL

material

BÖHLER Brand	Material code		Melting route	Standards / International Designation				
	DIN	UNS		DIN/EN	ASTM	ISO	AISI	Others
Austenitic								
A220SC	1.4441	S31673	airmelt + ESR	-	F138	5832-1	316L	-
P504	1.4472	S31675	airmelt + ESR	-	F1586	5832-9	-	REX 734
P558	1.3808	S29225	airmelt + ESR	-	F2581	-	-	-
P511	-	S20910	airmelt	-	F1314	-	-	XM19 Nitronic 50
Martensitic								
N324	1.4197	-	airmelt		F899		420Fmod	-
N360	1.4108	S42027	airmelt + ESR	-	F899	-	-	SEW400
N664	-	S44002	airmelt	-	F899	-	440A	-
N685	1.4112	-	airmelt	EN10088-3	F899	-	440B	-
N695	1.4125	S44004	airmelt	EN10088-3	F899	-	440C	-

- Austenitic
- Martensitic
- PH-Grades
- NiCo-Alloy/Co-Alloy

Link to Böhler Homepage for material datasheets:

https://www.bohler-edelstahl.com/de/applications/medizintechnik/

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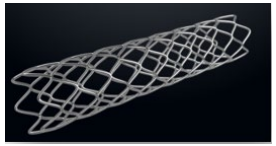
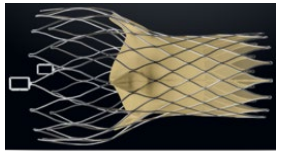
MATERIAL

material

BÖHLER Brand	Material code		Melting route	Standards / International Designation				
	DIN	UNS		DIN/EN	ASTM	ISO	AISI	Others
PH-Grades								
N700	1.4542	S17400	airmelt + ESR	EN10088-3	F899 A564	-	630	17-4PH
N700SA	1.4542	S17400	airmelt	EN10088-3	F899 A564	-	630	17-4PH
N709	1.4534	S13800	VIM+VAR	-	F899 A564	-	-	XM13 13-8Mo
N713	1.4543	S45500	airmelt + ESR	-	F899 A564	-	-	XM16 Custom 455
N765	1.4614	S46500	VIM+VAR	-	F899 A564	-	-	Custom 465
NiCo-Alloy / Co-Alloy								
L035	2.4999	R30035	VIM+VAR	-	F562	5832-6	-	MP35N
L605	2.4964	R30605	airmelt + ESR	-	F90	5832-5	-	-
L135	-	R31537	airmelt + ESR	-	F1537	5832-4 5832-12	-	-

✓ Böhler Product Portfolio - procurable product types

- Austenitic
- Martensitic
- PH-Grades
- NiCo-Alloy/Co-Alloy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MATERIAL

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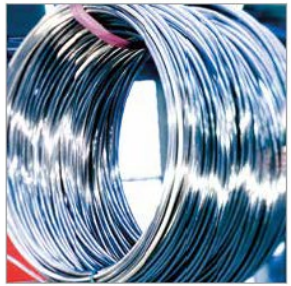
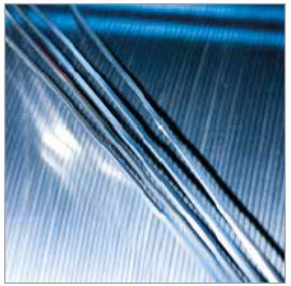


WIRE

- Pickled
- Blasted and pickled
- Unfinished

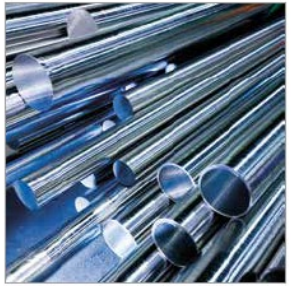


HIGH-PRECISION WIRE

- Cold-drawn
- Ground

AM POWDER

- Particle size 15 – 90 µm



ROUND ROD

- Peeled and polished
- Peeled and ground

FLAT ROD

- Unfinished
- Blasted
- Pickled
- Surfaces ground
  Edges unground

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FOCUS ON – KNEE IMPLANTS

Knee implants must meet a variety of requirements to ensure safety and effectiveness

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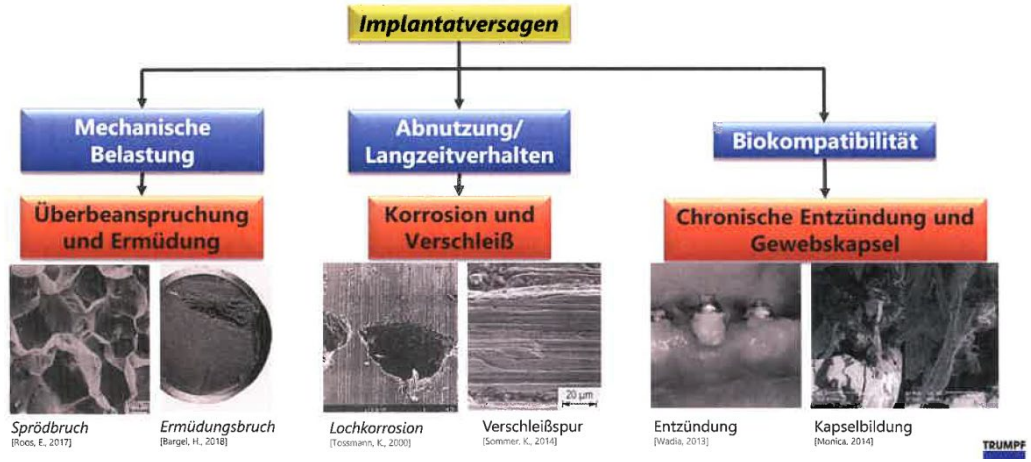
IMPLANT FAILURES



Brittle fracture | Fatigue Fracture | Pitting Corrosion | Wear Track | Inflammation | Capsule Formation

Most implant failures come from:

- **Mechanical load** overload and fatigue
- **Wear and long-term behavior** Corrosion and wear
- **Biocompatibility** Chronic inflammation and capsule formation

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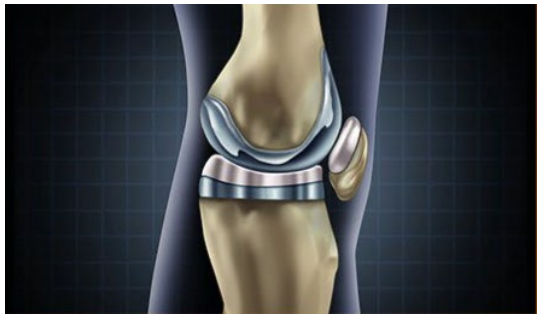
KNEE LOADING

» Biocompatibility

Knee loading plays an important role in the biocompatibility of knee replacement materials for several reasons.



» Loads

Activity	Hip		Knee	
	Load (N)	Moment (Nm1)	Load (N)	Moment (Nm2)
Climbing stairs	3606	2.00	4572	10.5
Climbing stairs (downwards)	3875	2.73	4348	18.5
Sit down	2935	2.09	4036	10.8
Stand up	3839	2.77	3870	11.4
Walking	2880	1.76	3581	12.0
Jogging	4839	1.60	5551	13.7

1) Specification of resulting frictional torques in the femoral head

2)Specification of torsional moments occurring as a result of inward and outward rotation of the knee joint

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ESSENTIAL FACTORS IN MATERIAL SELECTION

Mechanical demands

High mechanical stress
Material must withstand the stresses during movement as well as the **compressive and tensile forces during walking or running**.

Material fatigue

Materials must have a **high fatigue resistance** to withstand repeated stresses over many years
Weakening due to mechanical stress can compromise the integrity of the implant.

Wear of the implant

High loads can lead to increased wear of the implant. This can promote the formation of abrasion particles, which can lead to inflammation and a negative immune reaction, which impairs biocompatibility.

Compatibility with surrounding tissue

Materials that cannot withstand high loads can damage the surrounding tissue and cause inflammatory reactions.
Good biocompatibility ensures that the **implant interacts well with the surrounding tissue** and does not cause any undesirable reactions.

Adaptation to dynamic loads

The materials must be able to adapt to the dynamic loads and movements of the knee.
Non-optimal material selection can lead to complications such as implant failure or loosening.

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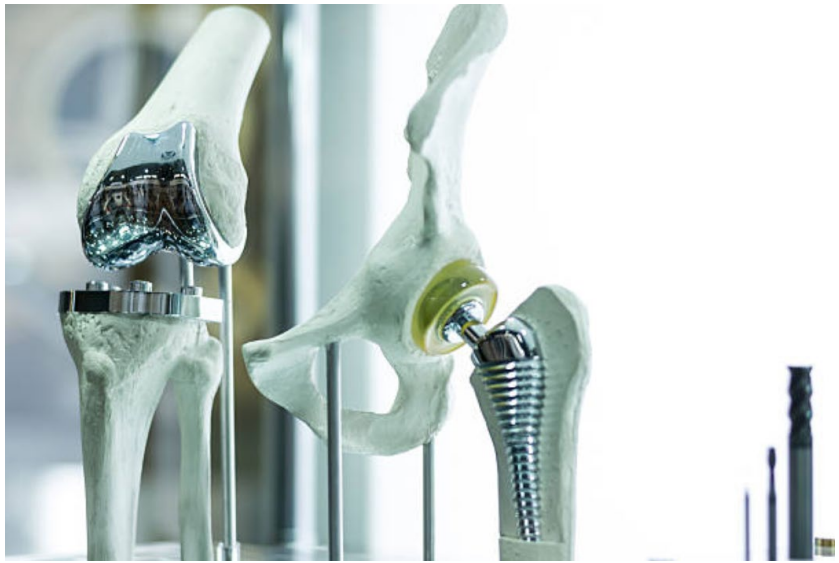
ADVANCED MATERIALS FOR LONG-LASTING ORTHOPEDIC IMPLANTS



» Joint Reconstruction (Hip, Knee, Extremities)

Orthopedic implants require not only biocompatibility, but also exceptional **mechanical properties and corrosion resistance** in intense physiological conditions over a long service life, **requiring materials with exceptionally high abrasion (wear) and fatigue resistance**.

» Used Grades

P504, L135, L035, L605, Ti-6AL-4V-ELI Grade 5 and 5ELI (Gr. 23)

The manufacturing of medical implants and devices from **stainless steel and cobalt-chromium alloys emphasizes biocompatibility.** To ensure that these materials can be safely used in the body, they must meet a **range of standards and regulations.**

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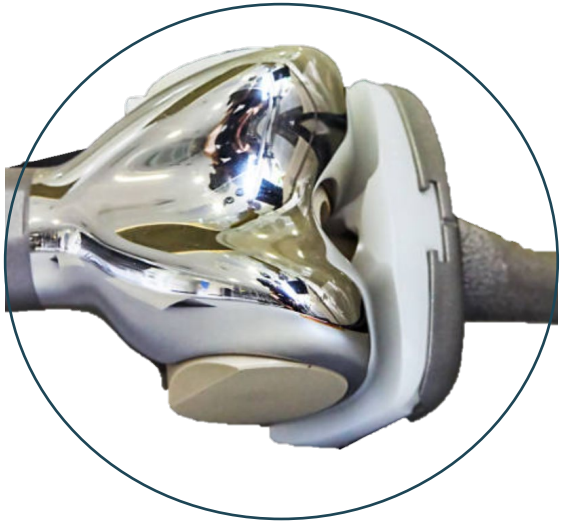
3 ESSENTIAL STEPS WE CAN GUIDE YOU



1 **Support with MATERIAL SELECTION**
Choosing the right material for your application!

e.g. Böhler A220SC / 316LVM (DIN 1.4441) according to ASTM F138
low carbon content (L for "low carbon")
highly suitable due to its corrosion resistance and strength.

2 **Confirm Medical STANDARDS**
We certify medical standards according to ASTM or ISO. This may confirm **biocompatibility**.

3 **Offer FURTHER PRODUCTION steps**
e.g. Surface treatment (coating PVD & DLC)
e.g. Additive Manufacturing (from design to print 3D)

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