Metal Injection Molding

material: implantable Grade Titanium and its alloys
company overview

• founded in December 2003

• certified according to DIN EN ISO 13485 : 2003

• currently the main focus is medical industry

• facility is dedicated to Titanium and its alloys

• several products have CE mark and are being implanted

• started high volume production this year

• activities include development of actual implants

• portfolio includes IPG cases made of Ti6Al4V, Super Plastic Formed
Ti MIM development overview

- the development for the MIM of Titanium started in 1997
- first parts implanted in 2005
- largest challenge was the feedstock composition and manufacturing
- development of this technology resulted in several additional Ti powder technologies
- creation of ASTM F standards for MIM Ti implants

the following materials are currently offered:

1. Commercially Pure Titanium
2. Titanium/Aluminum/Vanadium alloy Ti 6Al/4V
3. Titanium/Aluminum/Niobium alloy Ti 6Al/7Nb

other alloys like Nitinol (Ti/Ni) are possible as well

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MIM process flow

1 Metal Powder + 2 Binder = 3 Feedstock

4 Green Part 5 Removing Binder 6 Solid Component

• feedstock developed and manufactured by TiJet

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MIM design overview

- MIM-typical http://mimaweb.org/
- 3-Dimensional free form planes
- weight reduction through design
- very long and small holes
- inner and outer threads
- structured surfaces
- no or only minimal finishing treatment necessary
- minimal material loss in fabrication
- engravings, threads, inner contours, non-symmetric parts can be achieved
- optimization of part geometry through experienced applications engineers

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Titanium powder

**EIGA - Electrode Induction-melting Gas Atomization**

- powder particles are spherical and tailored to our MIM process
- particles usually have diameters smaller than 45 µm
- particle sizes can be adjusted to the product design

- currently use EIGA powder, but develop method for alternative powder
mechanical properties

Commercially Pure (CP) MIM Titanium, as sintered

- reference standards are ASTM B348, ASTM F67
- new ASTM F standard being written
- the material properties can be adjusted

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<th>( R_{p0.2} )</th>
<th>( R_m )</th>
<th>A</th>
<th>density</th>
<th>( O_2 )</th>
<th>( N_2 )</th>
<th>C</th>
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<tr>
<td>Ti CP 1</td>
<td>&gt; 350 MPa</td>
<td>&gt; 440 MPa</td>
<td>&gt;22%</td>
<td>&gt;96%</td>
<td>&lt;0.25%</td>
<td>&lt;0.03%</td>
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<td>Ti CP 2</td>
<td>&gt; 430 MPa</td>
<td>&gt; 510 MPa</td>
<td>&gt;15%</td>
<td>&gt;96%</td>
<td>&lt;0.25%</td>
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### Mechanical Properties

**MIM Titanium 6Al4V**

- Ti 6Al/4V #1: as sintered (no densifying)
- Ti 6Al/4V #2: as densified (HIP)

- Reference standards are ASTM B348, ASTM F136, F1472
- New ASTM F standard being written
- The material properties can be adjusted

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<th>Rp_{0.2}</th>
<th>Rm</th>
<th>A</th>
<th>Density</th>
<th>O_2</th>
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<td><strong>Ti 6Al/4V #1</strong></td>
<td>&gt; 750 MPa</td>
<td>&gt; 850 MPa</td>
<td>&gt;12%</td>
<td>&gt;96%</td>
<td>&lt;0.25%</td>
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<tr>
<td><strong>Ti 6Al/4V #2</strong></td>
<td>&gt; 860 MPa</td>
<td>&gt; 930 MPa</td>
<td>&gt;12%</td>
<td>&gt;99.5%</td>
<td>&lt;0.25%</td>
<td>&lt;0.05%</td>
<td>&lt;0.08%</td>
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<td>&gt;125k PSI</td>
<td>&gt;135k PSI</td>
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microstructure

- homogeneous microstructure
- grain size approx. 100 µm
- fine lamellar microstructure with $\alpha\beta$ – mixed structures

Cross section, polished & etched

BSE picture: light = $\beta$, dark = $\alpha$
material properties

well over 1,000 tensile tests performed on MIM samples

- fracture surface of a MIM-tensile test sample
- honeycomb structure is shown
- typical sign for a ductile break

SEM picture of fracture area

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surface finish & porosity

the typical surface finish after the sintering process is slightly textures smooth finish:

- $Ra = 3$ to $5 \, \mu m$
- $Rz = 20$ to $30 \, \mu m$

surface - top view

cross-section of surface
biocompatibility tests to ISO standards

all tests proved the anticipated very good biocompatibility of MIM Titanium

consducted studies:

- Cytotoxicity
- Implantation / short – 7 days
- Implantation / long – 90 days
- Hemocompatibility
- Irritation, Sensitisation(LLNA), Reverse Mutation Assay, Acute Systemic Toxicity, Mammalian Cell Gene Mutation Assay

Implantation of the Portsystem titus

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surface finish

polished surface

polished and anodized surface

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surface finish

bead blasted and anodized

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example: port system titus®

no 2nd operation needed

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example: compression screw

- **two self-cutting threads**
- **longitudinal hole with 3 mm hexagon socket throughout the part**
example: aortic-valve-prosthesis
example: aortic-valve-prosthesis

heart valve with three movable closing wings
• 3D-free-form surfaces
• wall thicknesses down to 0.4mm (.016")

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example: mini screw

hexagonal screw head
- Ø1,8 mm (Ø 0.071”)
- length: 18mm (0.709”)

CAD

Real sintered part

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example: base plate / implantable pump

- weight: approx. 50 grams
- dia. 78 mm (approx. 3”)
- cylindrical bore Ø 0,5 mm (0.020”)
- conical boring starting with Ø 0,8mm (.031”) down to Ø 0,4mm (0.16”)

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example: diffuser nozzle

cross-section of the finished part with undercut
example: housing for implant

- many design options available
- mat’l thickn. down to 0,3mm (0.012”)
- any Ti alloy possible
- Helium leak tested=>hermetically tight
- HIP optional
- excellent mechanical properties
porous coating

usage in medical industry:
- fixation of implant
- increased surface area (impedance)
- enhance bone growth
porous structure

- many different applications
- porosity level is controllable

porous structure made of spherical powder  

porous structure made of irregular powder
Thank you!

Please feel free to contact Matthias Scharvogel at TiJet Medizintechnik GmbH

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