

## **Material Data Sheet**

# for: Esteticor Implant® 76

This metal-ceramic alloy corresponds to the standards ISO 22674/Type 4 and ISO 9693.

### 1. Composition

Au + Pt	group-metals	7.5	96.90%
Au			76.80%
Pd	5		18.60%
Sn			2.90%
Pt			- 1.35%
Zn			0.20%
lr			0.15%

### 2. Physical Properties

Melting range	1165-1290℃
Density	16.9 g/cm <sup>3</sup>
Young's Modulus	115 GPa
Linear Coeff. of thermal expansion (25-500°C)	13.7 x10 <sup>-6</sup> K <sup>-1</sup>
Linear Coeff. of thermal expansion (25-600°C)	13.9 x 10 <sup>-6</sup> K <sup>-1</sup>
Colour	white

#### 3 Mechanical Properties

3. Mechanical Properties	as cast		after firing
Condition			ISO 960°C/15' air
Hardness HV5	205		235
Tensile strength (Rm)	670 MPa		785 MPa
0.2% Proof stress (Rp 0.2%)	455 MPa	12	630 MPa
Elongation	13 %.		10 %.
Schwickerath crack initiation test			47 MPa

### 4. Biological tests

### Cytotoxicity test according to ISO 10993-5:

The cytotoxic effect of the alloy was tested with the extract test. (Project, 052016A, 03.08.2005, BSL Bioservice, DE-82152 Planegg, FRG)

### Sensitization test according to ISO 10993-10:

The allergic sensitization of the alloy was tested with the maximization test. (Project 050647, 17.05.2005, BSL Bioservice, DE-82152 Planegg, FRG)

### Mutagenicity test (AMES) according to ISO 10993-3:

The mutagenicity was tested with the «Reverse Mutation Assay» using bacteria Salmonella typhimurium. (Project 072425, 28.08.2007, BSL Bioservice, DE-82152 Planegg, FRG)

#### Results:

The alloy showed neither a cytotoxic nor a munagenic potential nor did it cause any allergic sensitization.

### 5. Certification

This metal-ceramic alloy corresponds to the standards ISO 22674/Type 4 and ISO 9693.

Corrosion testing according to standard ISO 10271 showed that a total of 0.1  $\mu$ g/cm<sup>2</sup>x7d was released (limit:  $200\mu g/cm^2x7d$ ).

Manufacture, packing and delivery are constantly monitored according to the quality management system standards according to ISO 9001 and ISO 13485.

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