CENDRES+ MÉTAUX

Material Data Sheet

for: Esteticor Implant® 58

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

1. Composition

Au + Pt group-metals	87.50%
Au	58.50%
Pd	28.85%
Ag	8.00%
Sn	4.50%
Ru	0.10%
Ir	0.05%

2. Physical Properties

Melting range	1215-1305°C
Density	15.1 g/cm^3
Young's Modulus	120 GPa
Linear Coeff. of thermal expansion (25-500°C)	13.9 x10^{-6} K^{-1}
Linear Coeff. of thermal expansion (25-600°C)	14.0 x10^{-6} K^{-1}
Colour	white

3. Mechanical Properties

	as cast	after firing
Condition		ISO 960°C/15' air
Hardness HV5	240	260
Tensile strength (Rm)	745 MPa	820 MPa
0.2% Proof stress (Rp 0.2%)	495 MPa	610 MPa
Elongation	12 %.	13 %.
Schwickerath crack initiation test		52 MPa

4. Biological tests

Cytotoxicity test according to ISO 10993-5:

The cytotoxic effect of the alloy was tested with the extract test.
(Project, 052016C, 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 052017C, 06.09.2005, 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 072424, 23.08.2007, 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 0.0 $\mu g/cm^2 7d$ was released (limit: $200 \mu g/cm^2 x 7d$).

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

Cendres+Métaux SA

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