

Material Information

cara Titan (Ti-6Al-4V)

Titanium alloy for producing individual one piece cara I-Butments
(spec. ASTM F136-13 and EN ISO 22674)

Manufacturer: Kulzer GmbH

Chemical composition (in mass %):

| cara Titan | | | | | | | |
|------------|-----------|-----------|-------|-------|-------|-------|--------|
| Ti | Al | V | Fe | O | N | C | H |
| bal | 5.50–6.50 | 3.50–4.50 | ≤0.25 | ≤0.13 | ≤0.05 | ≤0.08 | ≤0.012 |



Biocompatibility

We confirm that the product was evaluated in accordance to the internationally valid standards EN ISO 7405; "Evaluation of biocompatibility of medical devices used in dentistry" and EN ISO 10993-1; "Biological evaluation of medical devices". The assessment includes possible risks of cytotoxicity, sensitization, irritation and genotoxicity.

The testing was carried out in accordance with the specifications of the OECD guidelines and satisfies the requirements of GLP (Good Laboratory Practice). The assessment verifies the biocompatibility of this dental alloy.

Chemical solubility

The test of chemical solubility was conducted in accordance with the standard EN ISO 22674; "Dentistry – Alloy materials for fixed and removable restorations and appliances". The standard specifies that the total release of the alloy materials over a period of 7 days at 37°C should not exceed 200 µg/cm². The testing showed that the ion release of the alloys tested fulfilled the requirements of EN ISO 22674. Therefore it is given that the alloy has an excellent corrosion resistance.

Evaluation

On the basis of the above tests and assessments this alloy is classified as biologically tolerated when used as specified. A clinical assessment showed that the specified requirements for characteristics and performance are fulfilled.

This Material Information is subject to an internal approval process. It was created electronically and is therefore valid without a signature.

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Giving a hand to oral health.



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