

## **iSLA** – Steiger Surface treatments for dental implants

The power of innovation

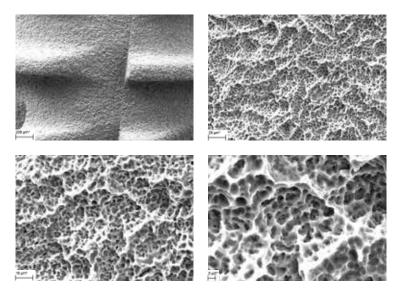




## iSLA – Steiger Surface treatments for dental implants

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Acid etch is a worldwide accepted surface treatment for dental implants. It consists of the buildup of two roughness levels. The macro level is obtained with sand blasting and the micro level by chemical etching. Typical roughness values lie between Ra 1.2 and 2 μm.



SEM Pictures showing topographical details of a gr 4 cpTi implant

#### Scope of iSLA process

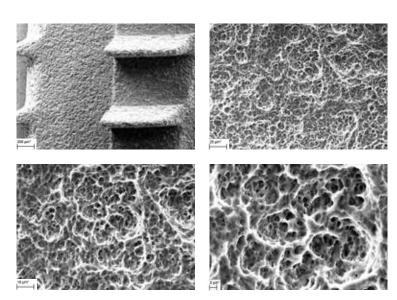
Rough-surfaced implants encourage both bone anchoring and biomechanical stability. The clinical success of oral implants is related to their early osseointegration. Geometry and surface topography are crucial for the short and long term success of dental implants. Typical clinical efficacy of SLA is >95% over 5 years.

Most dental implants are made from grade 4 cpTi. However, for small diameters, Titanium alloys, as for instance grade 5 Ti6Al4V, are used for their greater yield strength and better fatigue properties than pure titanium. For grade 5 Ti implants, the standard SLA process is not well adapted and the process has been optimized at Steiger in order to suit grade 5 Ti and other Ti alloys. The family of processes which has been developed for pure cpTi and different titanium alloys including grade 5 Ti6Al4V as well as Ti-Nb, Ti-Zr and Ti-Nb-Zr alloys is designated by **iSLA**, the **«innovative-SLA»** which produces surfaces with controlled and standardized topography.

#### Macro level roughness

The sand blasting consists of projecting ceramic particles at high velocity on the titanium implant. The macro level roughness resulting from the sand blasting is defined for topographical features as being in the range of tens of microns. The blasting material is chemically stable, biocompatible and does not hamper the osseointegration. A major risk with high surface roughness may be an increase in peri-implantitis as well as an increase in ionic leakage. A moderate roughness of 1–2  $\mu$ m as in **iSLA**, limits these occurrences.

The sand blasting is operated on a programmable fully automatic multi nozzle equipment where all parameters are monitored and documented in order to provide perfect lot reproducibility and traceability. Our engineering team develops custom made masking devices, protecting the top of the implant to keep it shiny according to customer specifications. After sand blasting, the implants are submitted to a 100% visual inspection under binocular for checking the masking selectivity as well as the topography conformity. Thorough subsequent cleaning steps eliminate blasting residues.



SEM Pictures showing topographical details of a gr 5 Ti6Al4V implant

# The validation is based on the following measurement report

- Visual test 100%: uniformity of color, no stains, conformity of masking area
- Roughness measurement Ra (1.2 2 μm)
- SEM control of morphology
- Organic carbon residue analysis (< 5 μg/implant)</li>
- Detergent residue analysis (< 10 µg/implant)
- Chloride residue analysis (< 1 µg/implant)
- Cytotoxicity measurement
- Bioburden measurement

#### Biocer®

Steiger Galvanotechnique SA also offers in house developed biomimetic surfaces based on calcium, phosphorous and magnesium containing anodic microarc coatings. This surface treatment is commercialized under the designation Biocer®

#### Micro level roughness

Dual acid-etching at high temperature produces micro pits on titanium surfaces with sizes ranging from 1 to 10  $\mu$ m in diameter. This microporous surface is characterized by higher bone-to-implant contact, enhancing osseointegration, resulting in bone formation directly on the surface of the implant.

The dual acid-etching is operated on in house developed equipment according to the high safety and environmental requirements. Close control of process parameters and of chemical bath compositions guarantee the reproducibility and traceability of the produced lots. Appropriate masking techniques allow to satisfy customer's specifications, for example to protect the upper edge of the implant, when required.

#### Final cleaning and inspection

Further manufacturing steps include final ultrasonic cleaning of external and internal parts of the implants, in biological controlled water. Final inspection occurs in a clean room ISO 7 environment; 100% of parts are visually inspected under binocular for masking selectivity, absence of stains and scratches, color homogeneity and quantity. The implants are packaged in double pouches or blisters. Conditioning in customer's designed packaging is also offered.





### **High-tech from Switzerland.**

Welcome to Steiger Galvanotechnique SA.

Steiger Galvanotechnique SA

in Châtel-St-Denis (CH) is a member of the Estoppey-Reber group which was founded in 1885. Today, the group employees 150 people. The other members of the group are located in Aegerten, Switzerland including Estoppey-Reber SA, Akrom SA and Galvametal SA. The four companies are international leaders in electrochemical and chemical surface treatments.



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# Steiger Galvanotechnique SA skills mainly focus on:

- Titanium and stainless steel surface treatment for medical applications: implants for traumatology, spine, dental as well as medical instruments. Clean & pack in clean room belongs to the complete service package.
- Coating on Aluminum: silver, electroless nickel, Ni-PTFE and different types of anodizing
- UV-LIGA Microelectroforming for watches, precision mechanics, optics, HF connectors, biomedical devices, permanent magnet microdevices
- Coating Systems, combining PVD layers and Electroplating

Steiger Galvanotechnique SA is certified ISO 9001 and ISO 13485



