

**TRATE****Technical Documentation**

Instruction

**No.** INS-AB.01**Subject:** Instruction for use for ROOTT Superstructures**Developed by:** Director of Quality Vladlena Shulezhko**Approved by:**

Member Siarhei Shulezhka

04. Feb. 2013

**Instructions for use  
for ROOTT Superstructures**

<b>Document Status:</b>	<i>Original document</i>
<b>Approved by:</b>	<i>Director of Quality</i>
	<i>Vladlena Shulezhko</i>
<b>Date:</b>	<i>2013.02.04</i>
<b>Place:</b>	<i>Bach</i>
<b>Signature / Stamp</b>	

**Prepared by:** Director of Quality Vladlena Shulezhko**Updating Date:** 04.02.2013

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**Device's description and expected performances:**

ROOTT Dental Implant Abutments and Gingiva Formers are manufactured from biocompatible material (titanium alloy). ROOTT Implant Abutments and Gingiva Formers may have various treatments such as titanium anodized surfaces. For specific product descriptions and net quantities, please refer to individual product labels

**Intended use:**

ROOTT Dental Implant Gingiva formers are management of soft tissue after treatment before Dental Abutment installation.

ROOTT Dental Implant Abutments are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially edentulous or edentulous patient. These are intended for use to support single- and multiple-tooth prostheses in the jaws.

**Precautions:**

- S8 it is clinical fixing screw (colour: grey). S8 you have to use into the mouth of patient. SL8 it is laboratory fixing screw (colour: green). SL8 you have to use in dental technician laboratory only!
- Covering screw for the implant are delivered sterile and ready for use. All other ROOTT screws are delivered non-sterile and must be sterilized prior to use
- Gingiva formers and abutments are delivered non-sterile and must be sterilized prior to use

**Contraindications:**

Do not use these components if the patient has a known hypersensitivity to titanium alloy.

**Sterilization before Use:**

Products provided non-sterile must be sterilized prior to use. Use a steam gravity sterilization method - minimum fifteen (15) minutes at a temperature of 270-275°F (132-135°C) or pre-vacuum sterilization method - minimum four (4) minutes (four pulses) at a temperature of 270-275°F (132-135°C). Drying times may vary according to load size.

**Safety and Warranty:**

ROOTT Superstructures are manufactured according to CE rules concerning medical devices' use. No undesired side effects have been lately known or reported. Basic warranty rules are current.

**Storage, transportation and cleaning:**

The components should be stored at room temperature. Store in a dry and clean place possibly into original boxes.

**Attention:** do not damage packaging during shipping. Product does not expire. The products are NOT STERILE, it's suggested perform a cold sterilization on caps/clips with benzalcyanhydrin before to place in the patient's mouth.

**Technical Support:**

For technical support you can call at our phone numbers + 41 79 848 19 18 or e-mail to: [info@trate.com](mailto:info@trate.com) order to consult a Certified Dental Technician or qualified dental professionals who can address you properly. You can also have more detailed info on Caps by consulting our Catalogue.

**Patient's Guidelines:**

Patients are suggested to follow carefully their Dentists' advices and get proper periodical checkups. A good hygiene needs to be performed daily as per Dentist' directions.

**Technical Aspects:**

Abutments (straight and angled)

Gingiva formers (narrow and normal)

**Instructions for use:**

Insertion of the Gingiva Former: After complete insertion of the Implant in his final vertical and rotational position and after releasing the transfer post by using the wrench, position the Gingiva Former on the Screw driver and screw it into the internal thread of the Implant manually. Tighten it with 15 Ncm. Gingiva Former remain in place for approx. 30 days. Note: Where the gingiva is stiff gradually stretch it to the desired diameter. Switch to larger diameters after 5 – 7 days.

Insertion of the Abutment: after complete soft tissue management, remove Gingiva former and in the same way screw related abutment into the internal thread of the Implant manually. Tighten it with 15 Ncm.

**Courses and training:**

Continuing education ensures long-term success. Please, ask your ROOTT representative directly for information on the ROOTT Dental Implant System courses and training. Further information at [www.roott.ch](http://www.roott.ch)

**Form of delivery:**

Delivery set for the customer:

**ROOTT Superstructures**

Transportation box (for 20, 40, 80, 160, 240, 320 pcs)\*

Group Box B20\* with group label

Individual box B5\* with individual label

Blister with lid and product label on blister

Product itself

Set of screw (clinical and laboratory)

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This medical product is CE marked in accordance with Directive 93/42/EEC on medical devices

**Notes!**

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- *Some products may not be available in all markets. Please contact your local TRATE representative to review the product range available.*

**Manufacturer**

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