

<b>TRATE</b>	<b>Technical Documentation</b>	Instruction	No. INS-RE-D.02
	<b>Subject:</b> Instruction for use for drills for Dental Implant System ROOTT		
<b>Developed by:</b>	Director of Quality V. Shulezhko	<b>Approved by:</b>	Member S. Shulezhka 2019-02-18

**Instruction for use  
Drills for  
Dental Implant System ROOTT**

**Description**

TRATE drills are intended only for the preparation of the cavities in the maxillary and / or mandibular arch for the placement of the ROOTT dental implant system. This procedure has to be performed by an trained implantologist who is familiar with the placement of dental implants. They are reusables devices. (Max. 10 Applications).

TRATE drills are made from Stainless Steel 1.4197. The drills are supplied in non sterile condition either in single blister packaging or as part of a starter-kit tray.

These instructions are valid for all implantological dental drills manufactured by TRATE AG:

- Initial Drills,
- Pilot Drills,
- Form Drills:
  - Rootform,
  - Basal Form,
  - Compressive Form.

**Intended purpose**

TRATE drills are intended only for the preparation of the cavities in the maxillary and / or mandibular arch for the placement of the ROOTT dental implant system.

**Intended use**

Drilling procedure must be performed by Oral and Maxillofacial Surgeons and Periodontists with knowledges of dental implantology. Practitioners must have knowledge of instruction for using of TRATE drills. Dental drills must be used in accordance with their instruction for use provided by the manufacturer.

**Indications**

The medical indications of the drills are used for implant site preparation, hence the indications and contraindications are the same as the indications of ROOTT implants:

- Loss of teeth / missing teeth,
- replacement of damaged or ill teeth,

The concrete disease, injury or physiological condition or traumatic event leading to the loss of teeth or to the necessity of tooth removal are manifold and do not matter, as long they are not explicitly listed in the contraindications.

**Contraindications**

Preoperative diagnosis is necessary to identify threats to the patient, related to the procedure of the implant placement, as well as factors that may affect the possibilities of healing of the bone and surrounding soft tissues. Dental implants should not be set for patients with medical contraindications related to oral and maxillofacial surgery.

Contraindications can be separated into absolute and relative contraindications:

Absolute contraindications are myocardial infarction: within six months of an attack, cerebral infarction and cerebral apoplexy, severe immunodeficiency, patients who are undergoing strong chemotherapy, severe neuropsychiatric disease, mental disability, and narcotic drug addicts, patients who are concurrently taking bisphosphonates, youths under the age of 15.

Relative contraindications are diabetes (particularly insulin-dependent), angina pectoris (angina), seropositivity (absolute contraindication for clinical AIDS), significant consumption of tobacco, certain mental diseases, radiotherapy to the neck or face (depending on the zone, quantity of radiation, localization of the cancerous lesion etc.), certain auto-immunes diseases, drug and alcohol dependency, pregnancy, certain diseases of the mucous membranes of the mouth, bruxism, periodontal diseases (loosening of the teeth), severe grinding or clenching of the teeth, an unbalanced relationship between the upper and lower teeth, poor hygiene of the mouth and teeth, an insufficient quantity of bone, infections in the neighboring teeth (pockets, cysts, granulomas), major sinusitis, allergies or hypersensitivities to chemical ingredients of material used: Stainless Steel 1.4197.

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**Side effects, complications with ROOTT Dental drills**

Temporary symptoms: pain, swelling, phonetic difficulty and gingival inflammation.

**Warnings:**

- Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury. If you want to protect it, to use rubber dam! For the case, an implant or an instrument was swallowed or aspirated, immediately call a doctor.
- Do not exceed recommended drilling speeds, as it might cause bone necrosis or system components fracture.
- Drills are provided in non-sterile conditions and have to be reprocessed and sterilized prior to first use.
- The transport blister is not intended to be used as container for the steam sterilization of the drills. They have to be unpacked prior to first reprocessing.
- Beside the mandatory precautions for any surgery such as of asepsis, during drilling in the jaw bone, one must avoid damage the nerves and vessels by referring to anatomical knowledge and preoperative medical imaging (e.g. radiographs).
- Do not use damaged or blunt instruments for drilling. Dispose a drill after 10 applications.
- Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to hemorrhage in the floor of the mouths.
- Do not use devise if the primary package has been damaged or previously opened.

**Cautions / Precautions**

**General:**

Sterile handling is essential. Never use potentially contaminated components. Contamination may lead to infection.

Avoid any contact of the drill with foreign substances prior to their use.

Drills should be used according to their expiration date, if applicable.

It is recommended that ROOTT Dental Implants are used only with dedicated surgical instruments, as violation of this recommendation may lead to mechanical instrumental failure or unsatisfactory treatment result.

It is strongly recommended that clinicians, new as well as experienced users, always go through special training before to use a new product or treatment method. TRATE offers a wide range of different courses. For more information, please visit [www.trate.com](http://www.trate.com).

If appropriately cared for, and provided they are undamaged and not contaminated, the cutting instruments can be reused up to a maximum of 10 times (1 time use = placement of 1 implant); any further use extending beyond this number or the use of damaged and/or contaminated instruments is not allowed.

All surgical residues that stick to and dry on the instruments (incrustations) lead to corrosion. Exposing instruments to moisture for large amounts of time also leads to damage! Possible initial and further damages and their causes:

<b>Cause:</b>	<b>Damage occurring</b>
Blood, pus, secretion, tissue residues, bone residues	Corrosion, rusting
Saline solution, iodine tinctures, unsuitable water, unsuitable and/or incorrectly used cleaning agents and disinfectants	Pitting, discoloration
Steel wool, steel brushes	Contact corrosion, destruction of the material surface, removal of oxide layer p increased susceptibility to corrosion
Contact between instruments of different metallic materials	Contact corrosion

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Overloading the instruments	Cutting surfaces become blunt, are damaged p increased susceptibility to corrosion
Mutual contact of the instruments	Damage of the instruments, especially of cutting surfaces p increased susceptibility to corrosion
Impurities in the sterilizer, e.g. due to already corroded instruments, or improper maintenance of the sterilizer	Initial rust: contaminating intact instruments with rust
Insufficient drying of the instruments	Corrosion, rust

### 7 measures that help to avoid greater problems:

1. Use each instrument only for its intended purpose.
2. Never let surgical residues (blood, secretion, tissue residues) dry on an instrument; clean immediately after surgery.
3. Thoroughly clean off incrustations with soft brushes only. Disassemble instruments, clean cavities especially well.
4. Never disinfect, clean (also ultrasound) or sterilize instruments made of different materials together.
5. Use only cleaning agents and disinfectants intended for the material and follow the instructions for use of the manufacturers.
6. Rinse disinfectants and cleaning agents very thoroughly with water.
7. Never leave or store instruments moist or wet.

### Before surgery:

Clinical and radiological examination of the patient has to be performed prior to surgery to determine psychological and physical status of the patient.

Special attention has to be given to patient who have localized or systemic factors that could interfere with the healing process of bone, or soft tissue, or the osseointegration process (e.g. smoking, poor oral hygiene, uncontrolled diabetes, facial radiotherapy, infections in neighborhood tooth or bone, patients passed bisphosphonate therapy).

Preoperative hard tissue and soft tissue deficit may yield to compromised aesthetic result.

### General Operation Procedure

Under local anaesthesia for the implant bed is created with the use of drills. For the preparation of the appropriate bed for the implant it is recommended to use drills of dental implant system ROOTT and observe the technology of preparation of the bone bed:

During the whole drilling procedure, the drills should be cooled with sterile saline.

1. Initiating drilling (1200-1500 rev/min).
2. Pilot drilling (900-1200 rev/min).
3. Check of the depth and direction.
4. Form drilling for Rootform type of Implant (200-800 rev/min), for Basal and Compressive type of Implant (1200-1500 rev/min) with drills of increasing diameter. In cases of insufficient bone density it is recommended to use the previous diameter of the forming drill or even installation after the pilot drilling.

During the preparation of the bone bed attention should be given to the need of substantial cooling of the implant bed and fraises (eg using chilled (degree-sterile), normal saline). Continuing to use only sharp burs (max. 10 uses). Use intermittent drilling technique.

5. Implant placement.

Bleeding can be stopped with implant placement.

### Storage

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure. If drill seems to have a transport damage, do not use the drill.

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### Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

### Materials

ROOTT Dental Implants and abutments: titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).

Covering and fixing screws: titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).

Caps: PEEK plastic and titanium alloy Ti-6Al-4V

Burnout parts: POM-C plastic

Drills, insertion tools, screwdrivers, ratchets: stainless steel

Handless, screw removals, compressive screws: titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).

### Compatibility information

#### Compatibility matrix- drill/ implants

	Compressive / S / Basal / Basal SS	Root form	Compressive M / MP	Compressive MS	Compressive K
<b>Initial drill</b>	D15xx	D15xx	D15xx	D15xx	D15xx
<b>Pilot drill</b>	D20xx	D20xx	D20xx	D20xx	D20xx
<b>Form drill</b>	DCxxxx	Dxxxx	DCxxxx	DCxxxx	DCxxxx

### 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)

### Reprocessing Instructions

Drills are determined as reusable devices. Before and after usage they must be cleaned, disinfected and sterilized properly!. Please, follow the Instruction for use reusable devices from Dental Implant System ROOTT No. INS-RE-D which you can download on <http://ifu.roott.ch/>

### Validity






Upon publication of these instructions for use (IFU), all previous versions are superseded.

### Please note







For the purpose of legibility, TRATE does not use ™ or ® in the text. This does not affect TRATE's rights with regards to registered trademarks.

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

### Signs explanation

	Consult instructions for use
	Catalogue number
	Batch code
	Use by
	Sterilized using irradiation

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	Non-sterile
	Do not use if package is damaged
	Do not reuse
	Keep away from sunlight
	Keep away from water
	Manufacturer

**CE 2797**

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

Manufacturer  
 TRATE AG  
 Seestrasse, 58  
 8806 Bäch,  
 Switzerland.  
[www.trate.com](http://www.trate.com), [www.roott.ch](http://www.roott.ch)  
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