Instruction for use
ROOTT Dental Implant System
Implants ROOTT K

1. Description

ROOTT Dental Implant System is a system of endosseous dental implants with corresponding abutments, healing abutments, covering and fixing screws, other prosthetic parts and surgical instruments.

Implants ROOTT K are one-piece implants made from Commercially Pure Titanium.

For Implants ROOTT K the HA/TCP is used as a blasting media with later etching for surface cleaning and reaching the surface microtopography on the part of the implant which is intended to be placed to the bone.

Implants ROOTT K delivered in a sterile package with a multifunctional carrier and a two-component holder. Secondary package has peel-off stickers for clinical documentation.

Implants ROOTT K are single-use medical devices, can only be used in sterile conditions and are not intended to be resterilized.

ROOTT K

REF No.: Cxxxxk, where is C - Compressive type of implant, xxxx - dimensions (diameter and length of implant), k - subtype of implant

To the Implants ROOTT K assigned Related Superstructures - healing abutments and abutments.

Healing abutment is screwed onto the top of the implant during surgical procedure to guide the healing of soft tissue to replicate the contours and dimensions of the natural tooth that is being replaced by the implant and to ensure access to the implant restorative platforms for impression and definitive abutment placement.

Dental abutments are connecting elements between the dental implant and the crown, they are connectors, placed on, or built into, the top of the implants to fix the crown.

Related Superstructures are made from Titanium Alloy (Ti 6-Al 4-V ELI) and are supplied in non-sterile conditions.

For detailed information about Related Superstructures see *Instruction for use for Healing abutments* and *Instruction for use for Abutments*.

Basic UDI-DI information

System	**Basic UDI-DI**
ROOTT Dental Implant System	76300538ROOTTSystemRC

Product	**Basic UDI-DI**
Dental Implant, ROOTT K	76300538ROOTTKTH

ROOTT K Dental Implants, sizes available:

Diameter: 3.0 mm, 3.5 mm, 4.0 mm, 4.5 mm, 5.0 mm, 5.5 mm, 6.5 mm, 7.5 mm, 8.5 mm
Length: 4 mm, 6 mm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm

Delivery set:

Combined single unit package - every implant is packed into the pre-formed blisters with a die-cut lid with a two-component holder. Blister packed in a protective package.

2. Intended Purpose

Dental implants are intended to replace missing or corrupted teeth:

- that can not be repaired, replaced or compensated by other means;
- where other solutions have an undesired impact on sound teeth, or
- where implants are desired for obtaining an optimal cosmetic result.

ROOTT Dental Implants are intended for surgical placement in the upper or lower jaw to provide anchorage for prosthetic superstructures for teeth restorations.

3. Indications

The medical indications for the use of ROOTT Dental implants and related to their superstructures are:

- loss of teeth / missing teeth,
- replacement of damaged or ill teeth.

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

Surgical protocols, position in mouth, single or multiple tooth replacement and bone type are not part of the indication of the dental implants. The choice of the right implant is incumbent to the implantologist and the manufacturer does not limit the range of indications for specific implant types, unless contraindications are met.

Range of Application for ROOTT K

ROOTT K implant is a one-piece implant with compressive threads with widening cutting strands of an implant for additional fixation of the implant to lateral alveolar walls during the implantation. It is used for single and multiple restorations with immediate loading in the upper and lower jaws with adequate bone tissue. Implant can be placed by flap or flapless approach with subcrestal position of the implant. Implant placement is also possible immediately following tooth extraction, if sufficient bone tissue is available. It can be used in combination with other types of ROOTT implants. Abutment direction can be adjusted up to 15° relative to the implant axis. Abutment designed for conometric fixation, means the crown consists of two parts: one is fixed on the implant abutment (cap) and the crown itself which is glued on this cap. This is a conditionally removable denture, which is periodically removed for a more thorough care and hygiene.

Limitations for ROOTT K

1. For cement-retained and telescopic restorations only,
2. Abutment direction cannot be adjusted for implant with diameter 5.0 mm, 5.5 mm, 6.5 mm, 7.5 mm, 8.5 mm,
3. Not for use in red-white aesthetic zones.

Duration of use:

ROOTT dental implants are intended for long term continuous use for more than 30 days.

Successfully osseointegrated dental implant is a long-term, permanent teeth replacement, which is expected to perform as intended during the lifetime of the patient if proper oral hygiene and regular check-ups are maintained.

In case if there is no occurrence of conditions determined as contraindications TRATE AG highly recommend not to explant the implant after 5 years and its preferable to make prolongation of the implant lifetime based on the observation results.

4. 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 possibility of healing of the bone and surrounding soft tissues.

Absolute contraindications: myocardial infarction (within six months of an attack), cerebral infarction and cerebral apoplexy (in cases where the condition of the disease is serious and the patient is concurrently taking anticoagulants), severe immunodeficiency, patients who are undergoing strong chemotherapy, severe neuropsychiatric disease, mental disability, patients who are concurrently taking bisphosphonates, youths under the age of 18, allergies or hypersensitivities to chemical ingredients of material used (Titanium and its alloy).

Relative contraindications: 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, the quantity of radiation, localization of the cancerous lesion etc.), certain auto-immunes diseases, drug / narcotic / alcohol dependency, pregnancy, certain diseases of the mucous membranes of the mouth, bruxism, periodontal diseases (loosening of the teeth); it is necessary to clean up the gums and stabilize the disease

first, an unbalanced relationship between the upper and lower teeth, poor hygiene of the mouth and teeth, an insufficient quantity of bone, infections in the neighbouring teeth (pockets, cysts, granulomas), major sinusitis.

In case, if implantation was performed in conditions of absolute contraindications, the manufacturer does not accept any warranty requirements.

5. Patient population

There is no convincing evidence to suggest that age or gender affect the outcome of osseointegration in the short or the long term. This is somewhat a surprising finding, given that, a sudden decline in bone volume and bone mass occurs as a result of ageing and particularly in postmenopausal women.

Dental implants are effectively ankylosed to the bone, for this reason implants are not placed until the facial skeleton has stopped growing; this being usually about 18 years of age. If this rule is not observed, integrated implants could soon become “submerged” similar to retained deciduous teeth as the permanent dentition continues to erupt.

Intended part of the body or type of tissue applied to interacted with

The upper and lower jaws in all types of bone tissue.

6. Intended users

For use only by dental professionals within the dental clinic.

7. Summary of clinical benefit

As a clinical benefit of the Dental Implant treatment, patients can expect to have their missing / lost tooth or teeth to be replaced. Dental Implant treatment may lead to restored masticatory function, bite force, enabled natural speech, enhanced comfort, and restored aesthetics. Dental Implant treatment may also prevent bone loss, prevent facial sagging, and keep adjacent teeth stable and leave them intact.

8. Summary of safety and clinical performance

When the European Database on Medical Devices comes online, the Summary of Safety and Clinical performance reports by Basic UDI-DI will be available at https://ec.europa.eu/tools/eudamed.

To request a copy of the Summary of Safety and Clinical Performance for ROOTT Dental implants and Related dental superstructures, please send an email specifying the Basic UDI-DI and/or REF number(s) to info@trate.com or Summary of safety and clinical performance reports for ROOTT Dental Implant System products can be found in: https://trate.com/sscp/.

9. Sterility

All ROOTT dental implants are supplied in sterile conditions. Sterilized using irradiation. All ROOTT Dental implants are single-use medical devices, can only be used in sterile conditions and not intended to be resterilized.

Can be used only in dental clinics during implantation surgery.

Cleaning and disinfection

ROOTT Dental Implants are delivered sterile and for single use only prior to the labelled expiration date.

TRATE AG does not accept any responsibility for re-sterilized implants, regardless of who has carried out the re-sterilization or by what method.

Sterilization

ROOTT Dental Implants are delivered sterile. The intact sterile packaging protects the sterilized implant from external influences and if stored correctly, the packaging ensures sterility up to the expiration date. The sterile packaging must be opened immediately prior to insertion of the implant. When removing the implant from sterile packaging, rules of asepsis must be observed.

10. Aseptic presentation requirements

The sterile packaging must be opened immediately prior to insertion of the implant within conditions of the surgery room. When removing the implant from sterile packaging, rules of asepsis must be observed.

Opening of implant packages shall be performed by personnel involved in the surgery with usage of protective equipment, such as sterile gloves and gowns.

Sterile packaging should be aseptically removed from the sterile barrier system by the *Instruction for opening boxes and blisters of sterile products*. And placed in a way as to eliminate or to reduce as far as possible the risk of infection to patients and users, allow easy and safe handling, reduce as far as possible any microbial leakage from the device and/or

microbial exposure during use according to *Placement protocols*.

11. Storage

The product must be stored in a dry place in the original packaging and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Do not reuse ROOTT Dental Implants. Do not use ROOTT Dental Implants after the expiry date indicated on the packaging.

12. Operating principles

Before surgery:

The implant diameter, implant type, position and number of implants should be selected individually taking the anatomy and spatial circumstances into account.

Implant treatments various tests should be done: Blood test, Mouth examination, X-ray examination, CT examination.

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

Special attention has to be given to patients who have localised 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 neighbourhood tooth or bone, patients passed bisphosphonate therapy).

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

ROOTT Dental Implant System must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use devices in accordance with these instructions and determine if the device fits the individual patient situation.

At surgery:

All instruments and toollings used during procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

After the implant insertion, the surgeon’s evaluation of bone quality and primary stability shall decide if required immediate or delayed loading protocol.

Implant bed preparation

Under local anaesthesia the implant bed is created with the use of implant drills. For the preparation of the appropriate bed for the implant it is recommended to use ROOTT Implant drills and observe the technology of preparation of the bone bed. Regarding the rotations per minute, intermittent drilling techniques and adequate cooling, the IFU of the drilling procedure provided in the *Drilling protocol* should be reviewed prior to attempting placement.

Insertion of the implant

The implant shall be removed from the sterile packaging immediately prior to the insertion and stably inserted in the bone bed. Be sure to install it securely immediately. ROOTT Implant can be placed either manually with the ratchet or with the aid of the handpiece, according *Placement protocol*.

After surgery:

To secure the long term treatment outcome, it is recommended to provide comprehensive regular patient follow up after implant treatment and inform about necessary or appropriate oral hygiene.

After implantation the patient record must include the types of the used implants and lot number (separate stickers located inside the box with the implant).

13. Residual risks

One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure.

Inappropriate use of the products leads to badly executed work and increased risks.

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 mouth.

Reuse of single-use devices increase risk of contamination, cross-contamination and the whole implantation failure.

Treatment by means of implants may lead to loss of bone, biologic and mechanical failures, including fatigue fracture of implants. Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.

Mechanical failure could occur in case of torque force violated, the device is used in unintended way or with not ROOTT system instruments.

If the treatment is performed to the contraindicated patient, the failure of the whole implantation is possible. In case, if implantation was performed in conditions of absolute contraindications, the manufacturer does not accept any warranty requirements.

Occurrence of temporary discomfort after the invasive treatment such as typical side effects are common.

The risk of swallowed or aspirated small devices by patients is possible. Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield).

Infection can inhibit implant osseointegration and lead to implant failure, however it can be avoided if sterility assured during the whole implant surgery and if proper maintenance, medication and oral hygiene is taken upon after the treatment.

14. Side effects, complications with implants

Immediately after the insertion of a dental implant, activities that demand considerable physical exertion should be avoided. Possible complications following the insertion of dental implants are temporary symptoms: pain, swelling, phonetic difficulty and gingival inflammation.

More persistent symptoms: chronic pain in connection with implants, permanent paraesthesia, dysesthesia, loss of maxillary / mandibular ridge bone, localized or systemic infection, oroantral or oronasal fistula, unfavourably affected adjacent teeth, fracture of implant, jaw, bone or prosthesis, aesthetic problems, nerve damage, exfoliation, hyperplasia.

14.1. Medical emergencies in dental practice

Medical emergencies can occur in the dental practice. The emergencies that potentially could happen during the general dental treatment are listed in below:

- Bleeding, Adrenal crisis, Anaphylaxis asthma, Cardiac emergencies, Epileptic seizures, Hypoglycaemia, Red flag sepsis, Stroke, Syncope, Allergy.

Members of the dental team have a duty of care to ensure they provide an effective and safe service to their patients. A patient could collapse on any premises at any time, whether they have received treatment or not. It is therefore essential that all registrants must be trained in dealing with medical emergencies, including resuscitation, and possess up to date evidence of capability.

Planning ahead, there should be at least two people available within the working environment to deal with medical emergencies when treatment is scheduled to take place (in exceptional circumstances, the second person could be a receptionist or a person accompanying the patient.

Thus, this instruction does not contain the description of sighs, symptoms and management of medical emergency situations. Please, follow the recommendations to have trained members of the team and publicly available poster of the General Dental Council related to the Medical emergencies in dental practice.

15. Requirements for specific training and facilities for users

For use only by dental professionals within the dental clinic. Recommended that clinicians, new as well as experienced users, always go through special training before using a new product or treatment method. TRATE offers a wide range of different courses. For more information, please visit www.trate.com.

16. Instructions in the event of the sterile packaging being damaged or unintentionally opened before use

If the primary package has been damaged or unintentionally opened before use DO NOT USE IT and contact local representative of TRATE AG for exchange via web page: www.trate.com.

17. Compatibility information

ROOTT Dental Implants are compatible with ROOTT Dental implant system components due to their technical characteristics.

For detailed information about ROOTT Dental Implants and related to them system components compatibility see *Compatibility book.*

For instruments use see *Placement protocol.*

Restrictions to combinations

All what is not mentioned in the *Compatibility book* is restricted to use in combination with the devices.

18. Performance characteristics and changes in performance

To achieve the expected performance, the ROOTT Implants shall only be used with products described in this instruction for use, and in accordance with the intended use for each product. To confirm the compatibility of products which are intended to be used in combination with ROOTT Dental Implants, please check the *Compatibility book, Product catalogue* and dimensions on the product labelling.

It is responsibility of the clinicians to instruct the patient on all related contraindications, precautions and side effects, as well as the need to seek the services of a trained dental professional if there is any changes in performance of the implant (infection, pain, any other unusual symptoms that the patient has not been told to expect).

19. Warnings

Implants ROOTT K must be used in combination with immediate loading only. No delayed loading option possible.

Do not use a device if the primary package has been damaged or previously opened. Do not resterilize ROOTT Dental Implants. If the primary package has been damaged or unintentionally opened before use DO NOT USE IT and contact local representative of TRATE AG for exchange via web page: www.trate.com.

Do not use ROOTT Dental Implants after the expiry date indicated on the packaging.

Do not reuse ROOTT Dental Implants. Do not reprocess implants. Reprocessing may cause infection and implant failure.

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

Avoid any contact of the implant with foreign substances prior to their use. Do not touch the endoseal part of the implant.

ROOTT Dental implants are delivered in a sterile package with two-component plastic holders. The holder is only for handing the implant inside the blister. The plastic implant holder is not intended to be used as an implant driver. It is prohibited to apply torque to the plastic implant holder to screw in the implant. Only the designated instruments may be used for implant insertion. If implants are not assembled any more with a holder and just moving into the blister, DO NOT USE this implant because the surface is already contaminated by plastic particles. Contact the local representative of TRATE AG for exchange via web page: www.trate.com.

Do not exceed recommended insertion torque (see section “Insertion of the implant”), as it might cause bone necrosis or system components fracture.

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield).

Beside the mandatory precautions for any surgery such as asepsis, during drilling in the jaw bone, one must avoid damage to the nerves and vessels by referring to anatomical knowledge and preoperative medical imaging (e.g. radiographs).

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 mouth.

Do not use damaged or blunt instruments for implantation.

20. Cautions / Precautions

One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure. Treatment by means of implants may lead to loss of bone, biologic and mechanical failures, including fatigue fracture of implants. Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.

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

It is strongly recommended that clinicians, new as well as experienced users, always go through special training before using a new product or treatment method. TRATE offers a wide range of different courses. For more information, please visit www.trate.com.

Radiation therapy for patients with dental implants should be planned and prescribed with extreme caution by the health care professionals to avoid possible complications. Thus, informing the patient about possible risks considering radiation therapy after implant treatment.

Notice regarding serious incidents

For a patient, user and / or third party in the European Union and in countries with an identical regulatory requirements (EU Regulation 2017 / 745 on medical devices) if, during the use of this device or as a result of its use, a serious incident has occured, please report in to the manufacturer TRATE AG and to your national authority. The contact information for the manufacturer of this devices to report a serious incident is as follows:

TRATE AG
https://trate.com/warranty-and-return-form/

21. Magnetic Resonance Imaging (MRI) compatibility

Please note that ROOTT K Implants have not been tested for safety in the MR environment. The safety and compatibility of ROOTT K Implants evaluated in subject of ROOTT R Dental implant and abutment configuration which have been tested for RF Heating and Image Artifacts. For further information refer to TRATE MRI Safety Information, at www.trate.com.

Patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 3 T;
- Recommended maximum MR System reported whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode). Maximum MR system reported whole body averaged specific absorption rate (SAR) of 3,5 W/kg of scanning (i.e., per pulse sequence) in the Normal Operating Mode showed a maximum temperature increase of 6.5 ℃ in implants from the ROOTT Dental Implant System after 15 minutes of continuous scanning. SAR should be kept as low as possible for medical diagnosis in order to minimise any risks for the patient. The temperature rise is under consideration of a static phantom without cooling processes like for example blood flow.
- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the implant/device. The image artefact caused by the ROOTT dental implant and abutment may extend maximum up to 19,7±4,2 mm (SE) or 19,3±4,1 mm (GRE) from the devices when imaged at 3 T MR system.

ROOTT Dental implants are fabricated from a material that can be affected by exposure to MRI energy and is MR Conditional. The emergence of image artefacts is expected and should be considered when necessary the analysis of images. Image artefacts pose no risk to the patient.

Denture and crowns can be fabricated from a metal material which can be affected by MRI energy. Patient shall be informed. Removable restorations should be taken out prior to scanning.

22. Material

ROOTT K Dental Implants:

Commercially Pure Titanium Grade 4 according to ASTM F67 and ISO 5832-2:	
Chemical components	Composition % (mass/mass)
Iron, max	0.50
Oxygen, max	0.40
Titanium	balance

23. Implant removal

In cases, when circumstances require to remove an implant, the implant removal procedure provided in the *Instruction for Implant Removal* should be followed.

24. Disposal

Removed and/or disposed of the implant and/or its superstructures should be handled as potentially contaminated products unless conclusive evidence exists to the contrary. Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account. The general waste management procedures for dental offices are in *Biohazardous Implant-related Waste Disposal Instruction for the Dental Offices.*

According to the Warranty and return policy, disposed TRATE AG medical devices under specified conditions which are failed, fractured or damaged, after removal, together with the accompanying documents, can be returned to TRATE AG under a feedback procedure. Potentially biologically contaminated product for TRATE AG determined as a returned product

that was in use.

All other products, which were in use, but not returned to TRATE AG must be handled in line with waste regulations of the country in which they were used.

Used devices under *Warranty and return policy,* returned to a TRATE AG should have been cleaned and decontaminated by the user before shipment and labelled as such. Decontamination of used devices should be performed by *Instruction for Product Return*.

25. Implant passport

The information to be supplied to the patient with an implanted device must be provided to patients by the dental clinic. For an implant passport please contact the local representative of TRATE AG via web page: www.trate.com.

26. Information for patients

Surgeons shall provide to patients information about specified Dental implant(s). And shall inform the patient about side effects, complications for implants, contraindications, residual risks, what patients shall do or shall not do after the implantation, e.g.:

- Follow good oral hygiene: clean teeth at least 2 times a day, use dental floss;
- Avoid very hard, hot, spicy food during the healing stage;
- Avoid high physical exertion during the healing stage;
- Quit smoking because it is extremely damaging to the health of teeth and gums and slows down healing processes;
- Regularly visit the dentist and do not delay scheduled visits for observation purposes;
- The patient must contact his surgeon immediately and do not remove and dispose of any parts of superstructures of the implants themselves.

Surgeons also shall inform the patient about possible risks considering MRI treatment**.** Radiation therapy for patients with dental implants should be planned and prescribed with extreme caution by the health care professionals to avoid possible complications.

27. Validity

Upon publication of these instructions for use, 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.

28. Manufacturer and Authorized Representative information

TRATE AG
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29. Symbols explanation

Available in *Instruction for explanation of symbols on ROOTT product labelling.*

CE 2797

Change history:

Ver	Date	Change description	Responsible
1	2022-06-01	Printing date	V. Shulezhko D. Karpavicius
2	2022-12-05	Manufacturer address changed from “Seestrasse 58 8806 Bäch Switzerland” to “Bahnhofstrasse 16 6037 Root Switzerland”. Minor corrections have been made to the text.	V. Shulezhko D. Karpavicius