

TRATE	Technical Documentation	Instruction	No. INS-RF_IM.02
	Subject: Instruction for use for Root Form Dental Implants		
Developed by:	Director of Quality V. Shulezhko	Approved by:	Member S, Shulezhka 2019-02-18

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

Description

Dental Implant System ROOTT is a system of endosseous dental implants with corresponding abutments, gingiva formers, covering and fixing screws, and surgical and prosthetic parts of instrument.

Root Form implants are made from Titanium Alloy Ti-6Al-4V (titanium, aluminum, vanadium). The implant is delivered in a sterile package with a multifunctional carrier, a two-component holder and a covering screw. A primary box has one peel-off stickers: for clinical documentation and / or implant passport. Rootform implant has a variety of prosthetic solutions for cemented fixation and multi-unit components with screw fixation to be used. The cone connection between Root Form implant and the abutment creates possibility for all prosthetic solutions. HA/TCP is used as a sandblasting media with later etching for surface cleaning and reaching the optimum surface micro-topography. Rootform has a combination of M, U and microthread.

Intended Use / Intended Function

Dental implants are intended to replace missing or corrupted teeth,

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

In general, ROOTT implants are intended for surgical placement in the upper or lower jaw to provide an anchorage for prosthetic superstructures for tooth restorations or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

Indications

The medical indications for the use of a ROOTT implant 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.

Contraindications

The contraindication to place implants will be evaluated by professionals on a case-by-case basis, with the greatest caution.

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.

Contraindications can be separated into absolute and relative contraindications:

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, and narcotic drug addicts,
- Patients who are concurrently taking bisphosphonates,
- Youths under the age of 15,
- Allergies or hypersensitivities to chemical ingredients of material used: titanium alloy (Ti6Al4V).

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, quantity of radiation, localization of the cancerous lesion etc.).

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- 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); 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 neighboring teeth (pockets, cysts, granulomas), major sinusitis,

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

Side effects, complications with Root Form implants

Immediately after the insertion of dental implants, 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.

Warning

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, use rubber dam!

Do not exceed recommended insertion torque, as it might cause bone necrosis or system components fracture.

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).

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.

Do not use damaged or blunt instruments for implantation.

The plastic implant holder are not intended to be used as insertion tool. 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.

Cautions / Precautions

General:

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.

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

Do not resterilize ROOTT Dental Implants.

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

Implants should be used according to their expiration date.

If implants not assembled any more with holder and just moving into the blister, DO NOT USE this implant because surface already contaminated by plastic particles. Contact local representative of TRATE AG for exchange via web page: www.trate.com

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

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components, 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

All implants delivered with Multifunctional holder and Plastic holder. The Multifunctional holder is used with insertion tool for external platform ITE. Multifunctional holder can be used as a temporary abutment, as a transfer for open / closed tray or as a healing abutment. Surface is polished and anodized. The plastic holder is only for handing the implant over and first placement into the cavity.

Magnetic Resonance Imaging (MRI). Safety information: these products are fabricated from a metal material what can be affected by MRI energy. For further information refer to *MRI Safety Information* at www.ifu.roott.ch

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.

At surgery:

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

After the implant installation, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded.

After surgery:

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

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.

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

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.

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

Root Form is compatible with ROOTT system components due to the same platform. For all diameters of Root Form implants one-platform has been especially developed. No matter which diameter of implant is used, it will have the same platform. It is helpful to eliminate stock and simplify practice.

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- **Compatibility matrix: Implant / Prosthetic parts**

	Abutment	Analogs	Transfers	Gingiva Formers	CAD/CAM	M / MS Abutment	Burnout	Locators
Root Form	Ax, AxAxx, ATx, ATRx, AxN, Bx	AN	TO, TOS, TOD, TR+TC,	GFx, GFNx	SPCO, SPCOIO, PCOx, PCOxS, PMAB, PMABP	Mx, MSx	BP, AB, ABR, ABM	BCW, BCP, BCY, HBC, PD

- **Compatibility matrix: Implant / Instrument**

	Initial drills	Pilot drills	Form drills	Insertion tool manual insertion	Insertion tool handpiece insertion	Screwdriver manual insertion	Screwdriver handpiece insertion	Wrenches	General surgical instruments
Root Form	D15xx	D20xx	Dxxxx	IT, ITL	ITH, ITHL	SD, SDL	SDH, SDHL	TW50, RW	SR, P2, ET, DPG

Cleaning and disinfection

ROOTT Dental Implants are delivered sterile and for single use only prior to the labeled expiration date. They must not be cleaned and sterilized.

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 expiration date. The sterile packaging must not be opened until immediately prior to insertion of the implant. When removing the implant from sterile packaging, aseptic techniques must be applied. The sterile packaging must not be opened until immediately prior to insertion of the implant.

Preoperative planning

The implant diameter, implant type, position and number of implants should be selected individually taking the anatomy and spatial circumstances into account. Before implant treatments various tests should be done: Blood test, Mouth examination, X-ray examination, CT examination.

Implant bed preparation

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. Regarding the rotations per minute, intermittent drilling techniques and adequate cooling, the IFU of the drilling procedure should be reviewed prior to attempting placement.

Insertion of the implant

The implant is removed from the sterile packaging immediately prior to the introduction and shall be stably installed in the implant bed prepared. Be sure to install it securely immediately. ROOTT Implant can be placed either manually with the ratchet or with the aid of the handpiece. There is recommended torque limitations provided:

Implant insertion via carrier CRE part	Never exceed 50 Ncm
Implant insertion via direct insertion with insertion tool	Never exceed 100 Ncm

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Wound treatment

Prior to wound treatment covering screw or appropriate gingiva former is selected and placed in the implant. For more information about available wound healing products refer to the website www.roott.ch

Healing phase

Root form implants are suitable for immediate and early restorations in single tooth gaps and in an edentulous or partly edentulous jaw. In case of immediate restoration in partly edentulous jaw, two or more adjacent implants should be prosthetically connected. In edentulous jaw at least 4 implants must be connected together. Radiographic scan is recommended after a healing phase before starting the prosthetic restoration.

After treatment:

- After implantation the patient record must include the types of the used implants and lot number (put inside of card special label what located into the box with implant).
- ROOTT Products must be used in according with the instructions for use provided by manufacturer. It is the practitioner responsibility to use device in accordance with these instructions and determine if the device fits to the individual patient situation.

Validity






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






Please note

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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.

Signs explanation

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

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



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

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