

<b>TRATE</b>	<b>Technical Documentation</b>	Instruction	No. INS-B IM.02
	<b>Subject:</b> Instruction for use for Basal Dental Implants		
<b>Developed by:</b>	Director of Quality V. Shulezhko	<b>Approved by:</b>	Member S. Shulezhka 2019-02-18

**Instruction for use  
Dental Implant System ROOTT  
BASAL and BASAL SS implants**

**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.

BASAL 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 primary box has one peel-off stickers: for clinical documentation and / or implant passport. Depending on the length of the implant the abutment can be bent up to 15° as long as the implant is placed in sound bone. Polished surface protects from the accumulation of bacteria at the cervical part of the implant. Sandblasted surface available as Basal SS.

**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.

**Range of Application**

Basal implants are used mainly to create multiple unit restorations in the upper and lower jaws. They can be placed in extraction sockets and in healed bone. The structural characteristics allow placement in bone that is deficient in height and width. They can be placed with flap or flapless technique. A good understanding of the maxillofacial anatomy is recommended so that bi-cortical engagement is achieved. Can be used to bypass the mandibular nerve, and for engagement of the cortical bone at the fusion of the pterygoid with the maxilla. Can be used in combination with compressive implants. Abutment direction can be adjusted up to 15° relative to the implant axis.

**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),

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- 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); 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.

BASAL implants are intended to be used for placement in resorbed ridges and for placement in the socket of an extracted tooth. In other cases BASAL implants can be also used in combination with COMPRESSIVE implants.

#### **Side effects, complications with BASAL 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](http://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.

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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 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)

All BASAL implants are delivered in a sterile package with multifunctional carrier. The multifunctional carrier 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](http://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 toolings 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).

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**

One-piece BASAL implants are compatible with ROOTT system components due to the same abutment diameter. For all lengths of BASAL implants one-platform has been especially developed. No matter which length 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**

1. Compatibility matrix: Implant / Prosthetic parts				
Basal; Basal SS	Burnout	Analogs	Transfers	Conometric (telescopic) caps
		BOP, A0, A15, A25	ANA, ANE	TRA, TOE, TOEA, TOES

- **Compatibility matrix: Implant / Instrument**

Basal; Basal SS	Initial drills	Pilot drills	Form drills	Insertion tools (for manual insertion)	Insertion tools (for handpiece insertion)	Implant Insertion tool	Wrenches	General surgical instruments
		D15 <sub>xx</sub>	D20 <sub>xx</sub>	DB <sub>xxxx</sub>	ITES, ITE, ITEL, ITEXL	ITEH, ITEHL	ITEAO	RW, TW50

**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, rules of asepsis must be observed. 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 stably installed 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. There is recommended torque limitation provided:

Basal implant from diameter 3.0 mm, via direct insertion	Never exceed 117 Ncm
Basal implant from diameter 4.5 mm - 5.0 mm, via direct insertion	Never exceed 238 Ncm
Basal implant from diameter 5.5 mm, via direct insertion	Never exceed 298 Ncm

For more information on the use of a dental implant ROOTT refer to the clinical guidance available on the website [www.roott.ch](http://www.roott.ch)

**Wound treatment**

Implant shall be used in combination with immediate loading only. No delayed loading option available.

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### Healing phase

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### 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

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
	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

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