

TRATE	Technical Documentation	Instruction	Version 13
	Subject: Instruction for use for BASAL Dental Implants		
Developed by:	Director of Quality V. Shulezhko	Approved by:	Member S. Shulezhka 2019-04-19

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

Description

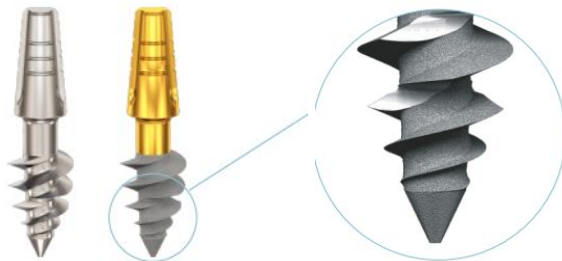
Dental Implant System ROOTT is a system of endosseous dental implants with corresponding abutments, gingiva formers, covering and fixing screws, other prosthetic parts and surgical instruments.

The BASAL implants are one-piece implants “Basal” and “Basal SS”. They are made from Titanium Alloy Ti-6Al-4V ELI. The implants are delivered in a sterile package with a two-component holder. A secondary box has peel-off stickers for clinical documentation and delivered implant passport. BASAL implants are supplying **in sterile conditions**. Sterilized using irradiation.

BASAL implants are **single use** medical devices, **can only be used in sterile conditions** are **not intended to be resterilized**.

Delivery set: one “Basal” or “Basal SS” implant unit packed into the sterile blister with a two-component holder.

Different surfaces
Polished, sandblasted and anodized



“Basal” implants delivered polished, without any surface treatment. “Basal SS” delivered sandblasted, HA/TCP is used as a sandblasting media with later etching for surface cleaning and reaching the surface microtopography on the part of implant which is intended to be placed to the bone.

REF No.: Bxxxx or Bxxxxss, where is B - “Basal”; BxxxxSS - “Basal SS”; xxxx - dimensions: diameter and length of implant.

“Basal” implants sizes available:

Diameter: 3.5 mm, 4.5 mm, 5.5 mm, 6.5 mm, 8.5 mm, 10.5 mm

Length: 6 mm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 22 mm, 24 mm, 26 mm

“Basal SS” implants sizes available:

Diameter: 3.5 mm, 4.5 mm

Length: 6 mm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm

User specification:

Medical 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.

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.

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Range of Application

BASAL implant is a one-piece implant. It is used mainly to create multiple unit restorations with immediate loading in the upper and lower jaws in resorbed ridges. 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. Implant can be placed by flap or flapless approach and bicortical engagement shall be 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.

Limitations

- Bicortical engagement shall be achieved in case of placement “Basal” implants. This is not relevant to the “Basal SS” implants.
- “Basal” and “Basal SS” implants for multiple restorations only
- “Basal” and “Basal SS” for cement-retained restoration only.

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.

There is no upper age limit providing the patient is capable of undergoing the surgical phase and the subsequent self maintenance. In contrast implant treatment should be delayed in young individuals until growth is complete. Patients should be at least 15 years of age with sufficient bone volume and maturity to prevent any related post operative complications linked to further bone growth. Clinicians should be aware that facial growth continues after 15 years of age and that this can cause complications.

The general health of the patients should be good enough to undergo surgical and restorative treatment.

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.

Contraindications can be separated into absolute and relative contraindications. Contraindications of the implants have been taken mainly on the basis of the scientific literature. They are known to have a negative impact to the mere implantation process or to the stability of the implant over time. The following contraindications are in line with standard textbooks [Renouard et al., 1999]:

- 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 ELI)
- 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 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.

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

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

Intended user profile

For dental clinic use only and for use only by dental professionals.

Use environment

All BASAL implants are supplying in sterile conditions. Sterilized using irradiation. All BASAL implants there are single use medical devices, can only be used in sterile conditions and not intended to be resterilized.

Can be used only in clinic during implantation surgery.

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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.

Aseptic presentation requirements

The sterile packaging must not be opened until immediately prior to insertion of the implant within conditions of surgery room. 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.

Opening of implant package shall be performed by personal involved to the surgery with usage of protective equipment, such as sterile gloves and gowns.

Operating principles

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.

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 patients 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.

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

At surgery:

All instruments and toolings 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 and using immediate loading protocol.

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 ROOTT 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 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. 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

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BASAL implant from diameter 5.5 mm, via direct insertion	Never exceed 298 Ncm
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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.

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).

Wound treatment

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

Healing phase

The healing time required for osseointegration is very individual and treatment depended. It is the sole responsibility of the surgeon to decide when the implant can be loaded. ROOTT implants are suitable, within the scope of indications, for immediate and delayed loading. Good primary stability and an appropriate occlusal load are essential.

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.

Material for implants:

Titanium alloy Ti-6Al-4V ELI.

Compatibility information

BASAL implants are compatible with ROOTT system components due to their technical characteristics.

Compatibility matrix: Implant / Prosthetic parts

Basal; Basal SS	Burnouts	Analogs	Transfers	Gingiva formers	Abutments	Scan posts	Screws (for caps)
	BOP, A0, A15, A25	ANA, ANE, ANED	TRA, TOE, TOEA, TOES	GFE _x	TCE _x , TCES _x , TCEXS _x , PCE _x , PCES _x , PCEXS _x	SPCOIOE	STK _x

Compatibility matrix: Implant / Instrument

Basal; Basal SS	Initial drills	Pilot drills	Form drills	Accessories for drills D2020; DB2020; D2516; D2816; D3216; D3616; D4016; D4316			Insertion tools			Wren-ches	General surgical instruments	Screw drivers		
				Stoppers	Sleeves	Handles	for manual insertion	for hand-piece insertion	for AO connection			for manual insertion	for handpiece insertion	for AO connection
				D15 _{xx}	D20 _{xx} , DB20 _{xx}	DB _{xxxx} , D _{xx} 16* (D2516; D2816; D3216; D3616; D4016; D4316)	S1L _{xx} , S2L _{xx}	SL02, SLS1, SLS2	A02SL1, A02SL2, A1SL2			ITEx	ITEH _x	ITEAO

*Except for: B3522, B3524, B3526, B4522, B4524, B4526, B3524ss, B3526ss

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Side effects, complications with implants

Immediately after the insertion of 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.

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.

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.

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.

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 (see section "Insertion of the implant"), 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 mouth.

Do not use device 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.

"Basal" and "Basal SS" Implant shall be used in combination with immediate loading only. No delayed loading option available.

Cautions / Precautions

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

Do not resterilize ROOTT 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 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

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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

All BASAL implants are delivered in a sterile package with two-component holder. The two-component holder is only for handling the implant inside the blister.

Magnetic Resonance Imaging (MRI). Denture and crowns can be fabricated from a metal material which can be affected by MRI energy. Patient shall be informed.

Information for patients:

Surgeon shall inform patient about side effects, complications for implants, residual risks and what patients shall do or shall not do after the implantation:

- 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.

Validity











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

Please note

For the purpose of legibility, TRATE does not use TM 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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Change history:

Ver	Date	Change description	Responsible
01	2012-10-22	Printing date	V. Shulezhko D. Karpavicius
02	2013-03-17	Was added max speed to the drilling protocol	V. Shulezhko D. Karpavicius
03	2013-04-11	Was added reprocessing process	V. Shulezhko D. Karpavicius
04	2014-03-27	Was added materials of product	V. Shulezhko D. Karpavicius
05	2014-05-07	Was added symbols table	V. Shulezhko D. Karpavicius
06	2014-06-06	Was added warnings	V. Shulezhko D. Karpavicius
07	2015-03-18	Was changed delivery set to the customer	V. Shulezhko D. Karpavicius
08	2015-11-18	Was added note never resterilize implants	V. Shulezhko D. Karpavicius
09	2017-04-24	Symbol “Manufacturer” placed near by manufacturer address	V. Shulezhko D. Karpavicius
10	2017-07-13	Instructions for implants and instruments were separated, instruction for each type of implant was separated	V. Shulezhko D. Karpavicius
11	2018-06-12	IFU content was revised to be in compliance with indication, contraindications and intended use with CER	V. Shulezhko D. Karpavicius
12	2019-02-18	NB number was changed from 0086 to 2797	V. Shulezhko D. Karpavicius
13	2019-04-19	Added aseptic presentation requirements, residual risks description	V. Shulezhko D. Karpavicius