Instruction for use
Dental Implant System ROOTT
Rootform 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.

Rootform implants are two-piece implants. Rootform implants are made from Titanium Alloy Ti-6Al-4V ELI. HA/TCP is used as a sandblasting 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.

The implants are delivered in a sterile package with a two-component holder and multifunctional carrier. A secondary box has peel-off stickers for clinical documentation and delivered an implant passport. Rootform implants are supplying **in sterile conditions**. Sterilized using irradiation.

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

REF No.: Rxxxx, where is R - Rootform; xxxx - dimensions: diameter and length of implant.

Rootform implants sizes available:
Diameter: 3.0 mm, 3.5 mm, 3.8 mm, 4.2 mm, 4.8 mm, 5.5 mm, 6.5 mm, 7.5 mm, 8.5 mm
Length: 6 mm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm

Delivery set:
One Rootform implant unit packed into the sterile blister with a multifunctional carrier and two component holder.

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.

Range of Application

Rootform implant with combined thread and tapered connection can be used for single and multiple restorations with immediate and delayed loading in the upper and lower jaws in all types of bone tissue. Implant can be placed by flap or flapless approach with subcrestal position of the implants. Implant placement is also possible immediately following tooth extraction, if sufficient bone tissue is available

Limitations:

- Rootform Implant 3.0 mm diameter are intended to be used to replace a central incisor only for single tooth restorations. In other cases Rootform Implant 3.0 mm diameter can be also used in combination with other implants for multiple unit restorations for placement in the area of central incisors with a minimum 6 implants.
- Can be used with caution to create single restorations in situations where good primary stability is achieved on placement (35 N/cm)

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, the 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 clinics use only and for use only by dental professionals.

Use environment

All ROOTT dental implants are supplying in sterile conditions. Sterilized using irradiation. All ROOTT dental

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.

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.

Sterile barrier system/sterile packaging should be aseptically removed from the sterile barrier system by the *Instruction for opening boxes and blisters of sterile products* in accordance with ISO 11607.

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 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 and shall decide if required immediate or delayed 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 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. There is recommended torque limitation provided:

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

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 (separate stickers put inside into the box with implant).

Wound treatment

Implant shall be used in combination with immediate and delayed loading.

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 (35 N/cm) 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:

Rootform implants are made from Titanium Alloy Ti-6Al-4V ELI.

Compatibility information

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

Compatibility matrix: Implant / Prosthetic parts

	Abutments	**Analogs**	**Transfers**	**Gingiva Formers**	**Abutments (CAD/CAM)**	**Abutments (caps)**	**Burn-outs**	**Locators**	**Scan posts**	**Covering screw**	**Screws**			
											for abutments	**for gingiva formers**	**for abutments (CAD\CAM)**	**for transfers**
Root form	Ax, AxAxx, AxN, ATx, ATRx, AxK, AxAxxK, Bx, PMAB, PMABP, Mx, MxAxx, MSx, ABM	AN, AND	TO, TOS, TOD, TOA, TRD, TR, TC	GFx, GFNx, GFPx, GFASx, GFAMx, GFALx, GFPSx, GFPMx, GFPLx, GFMSSx, GFMSMx,	PCO, PCOR, PCOx, PCORS, PCOxS,	TCREx, TCKx, TCKSx, TCKXSx, PCKx, PCKSx, PCKXSx	BP, AB, ABR, A1NP	BCW, BCP, BCY, HBC, PD	SPCO, SPCOIO, SPCOSIR	SC	S8, SL8, SBx, SBLx, SFMx, SLFMx	SGFx	SFPCOx, SFPCOxL, SFPCOxS, SFPCOxSL	ST, STOD, STS

				GFMSLx, GFMESx, GFMEMx, GFMELx, GFI, GFKx										

Compatibility matrix: Implant / Instrument

Root form	Initial drills	Pilot drills	Form drills	Accessories for drills D2020; DB2020; D2516; D2816; D3216; D3616; D4016; D4316; D4616; D5016; D5316			Insertion tools			Wrenches	Tapering tools	General surgical instruments	Screw drivers		
				Stoppers	Sleeves	Handles	for manual insertion	for handpiece insertion	for AO connection				for manual insertion	for handpiece insertion	for AO connection
	D15xx	D20xx, DB20xx	Dxxxx Dxx16 (D2516; D2816; D3216; D3616; D4016; D4316; D4616; D5016; D5316)	S1Lxx, S2Lxx, S3Lxx	SL02, SLSx	A02SLx, A1SL2, A1SL3, A2SL3	ITx	ITHx	ITAO	TW50, RW	TRxxxx	ETH, SRx, P2, ET, ETAO, ETEAO, DIR, DPG, DW, IF, PRT, PRS	SDx, SDxB	SDHx	SDAO

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.

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 a 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.

Cautions / Precautions

Covering screws for the Root form 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 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 are not assembled any more with holder and just moving into the blister, DO NOT USE this implant because the surface is 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 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 ROOTT implants are delivered in a sterile package with two-component holder. The two-component holde is only for handing 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.

Implant removal:

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

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

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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

CE 2797

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

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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	2018-06-21	IFU content was revised to be in compliance with indications, 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
14	2020-06-25	Added information to the related documents: *Instruction for opening boxes and blisters of sterile products, Drilling protocol* and *Instruction for Implant Removal,* Supplemented Gingiva formers and Abutments (caps) to the table “Compatibility matrix: Implant/ Prosthetic part” , Supplemented General surgical instruments to the table “Compatibility matrix: Implant/ Instrument”	V. Shulezhko D. Karpavicius