Instruction for use
ROOTT Dental Implant System
Tools related to the implantation procedure

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.

Tools related to the implantation procedure there are reusable devices that intended for surgical use, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out for the placement of the different types of the ROOTT Dental Implants.

Tools related to the implantation procedure can only be used in sterile conditions.

These devices are designed and labeled for multiple uses and are reprocessed by thorough cleaning followed by high-level disinfection or sterilization between patients. They are made of materials that can withstand repeated reprocessing, including manual brushing and the use of chemicals.

Tools related to the implantation procedure are made from Stainless steel Ergste® 1.4108 (X30CrMoN15-1) or Titanium Alloy (Ti 6Al-4V ELI) and supplied in non-sterile conditions.

Tools related to the implantation procedure there are:

Implant drivers - tools with internal or external platforms for use with ROOTT Dental Implants, for manual implant insertion.

Abutment extractors - tool for manual removal of the dental superstructure from the implant.

Abutment benders - tools for manual application with the neck of ROOTT dental Implant during the surgical procedure in cases where such applications are applicable.

Alignment bar - tool intended for intra-oral checkings during implant treatment procedure for visual comparing directions between implants.

Screwdrivers - tools are used to turn the attachment or abutment screws that secure different components to implant fixtures.

Drill extensions - tool intended for extending (prolongation) of handpiece instrument which need to be fixed to the handle with AO connection

Handles - tool for different manual applications during the ROOTT Dental Implant placement procedure.

Wrenches - tools for supporting implant insertion during the surgery.

Drill stops - tools to provide precise control over the drilling depth during implant bed preparation for the placement of ROOTT Dental Implants.

Sleeves - tools used for reference templates, planning and surgical templates and fully guided planning or surgical templates. Sleeves are indicated for planning and surgical drilling templates and for use in the first drilling steps (e. g. pilot drill) during implant surgery.

Drill handles - tools used for reducing a diameter of sleeve for smaller diameter of the drill. The cylinder of the drill handle is inserted into the sleeve fixed to the surgical template.

Samples of Tools related to the implantation procedure: 1- Implant drivers, 2- Screwdriver, 3- Handle for handpiece instruments, 4 - Abutment extractor, 5 - Abutment bender, 6 - Alignment bar, 7 - Ratchet, wrench, 8 -Drill Stop

Basic UDI-DI information

System	Basic UDI-DI
ROOTT Dental Implant System	76300538ROOTTSystemRC

Device type	Models	Basic UDI-DI
Instruments R		
Implant drivers R	IT, ITL, ITAO	76300538ImplantdriverRNS
Abutment extractors R	SR, SRL	76300538ExtractorsRR6
Instruments C / CS / B / BS		
Implant drivers C / CS / B / BS	ITES, ITE, ITEL, ITEXL, ITEAO	76300538ImplantdriverCMU
Abutment bender C / B / BS	BT	76300538BendersC7J
Instruments M		
Implant drivers M / P	ITM0, ITM10, ITM, ITML, ITMXL	76300538ImplantdriverMNG
Implant drivers HE M / P	ITHES, ITHE, ITHEL, ITHEXL ITHEAO	76300538ImplantdriverHE7S
Instruments S		
Implant drivers S	ITMS, ITMSL, ITMSXL, ITMS0, ITMS10	76300538ImplantdriverSNU
Instruments K		
Implant drivers K	ITEKS, ITEK, ITEKL, ITEKXL, ITEAOK	76300538ImplantdriverKNC
Abutment benders K	BTK, BTKL	76300538BenderKHL
Abutment extractors K	PRT, PRS	76300538ExtractorsKQQ
Universal instruments		

Gauges	DIR	76300538DIRVP
Screwdrivers U	SD, SDL, SDXL, SDLB, SDXLB, SDAO, SDM, SDML	76300538ScrewdriverMFK
Drill extensions U	ETEAO	76300538DextentionAO7P
Handles U	ETH, ETR, DW	76300538HandlesM8
Wrenches U	RW, RWS	76300538RWrenchesFD
	TW70	76300538TWrenchesGT
Drill stops	S1L02, S1L04, S1L06, S1L08, S1L10, S1L12, S1L14, S1L16, S2L02, S2L04, S2L06, S2L08, S2L10, S2L12, S2L14, S2L16, S3L02, S3L04, S3L06, S3L08, S3L10, S3L12, S3L14, S3L16	76300538DrillstopMV
Sleeves	SL02, SLS1, SLS2, SLS3	76300538SleevesW8
Drill handles	A02SL3, A1SL3, A2SL3, A02SL2, A1SL2, A02SL1	76300538DrillhandlesVX

Initial delivery set:

5 units of instruments packed into the rigid thermoformed 5-cells blister used in combination with die-cut lids.

2. Intended Purpose/ intended function

Tools related to the implantation procedure are intended for surgical use, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out for the placement of the different types of the ROOTT Dental Implants. Tools related to the implantation procedure have no stand-alone intended use, because the different variants of the Reusable surgical instruments are assigned to an implant type.

Range of Application

Implant drivers	intended for manual insertion of the implant to the cavity prepared in the mouth.
Abutment extractors	intended to lift off the dental superstructure from the implant to remove it from conical connection
Abutment benders	intended to make a bending of the neck of Dental implant, if required and applicable
Screwdrivers	intended for screwing the components to the ROOTT Dental Implants and related dental superstructures
Handles	a) handle for the connection with handpiece instruments intended for manual manipulation while preparing the implant bed, also for manual implant insertion or screw tightening. Very useful for manipulations in the maxilla. b) handle with AO connection intended for manual implant insertion or screw tightening in the maxilla. c) handle for implant driver intended to be used for preventing axial oscillations during implant insertion via insertion tool for ratchet.
Gauge	intended for intra-oral checkings during implant treatment procedure for visual comparing directions between implants
Wrenches	Ratchet intended to be used to apply a torque to dental implants, fastener screws for fixation of an abutment, dentures or prosthetics on a dental implant.
Drill extension	intended for extending (prolongation) of handpiece instrument which need to be fixed to the handle with AO connection
Drill stops	used to determine the depth of the hole drilled in the patient's jaw bone.
Sleeves	for guiding drill stoppers through the surgical template to reduce friction between drill stopper and surgical template material

Drill handles	used for reducing a diameter of sleeve for smaller diameter of the drill to avoid free movements between drill and bigger diameter of the sleeve

3. Indications

There is no stand-alone indication for the application of the tools related to the implantation procedure. The different variants of the tools related to the implantation procedure are assigned to an implant type. The indications for the use of tools related to the implantation procedure are strongly connected to the indications of the corresponding ROOTT Dental Implant and related dental superstructures.

All tools related to the implantation procedure produced by TRATE have indications - to support implant placement and related dental superstructures procedures.

4. Contraindications

Tools related to the implantation procedure are only used for placement of a ROOTT Dental Implant so all contraindications that prohibit the use of a dental implant prohibit the use of Tools related to the implantation procedure as well. The contraindications of the Tools related to the implantation procedure are always connected to that of the dental implants.

Patients who are contraindicated for treatment with ROOTT Dental implants.

Allergy or hypersensitive to materials from which the Tools related to the implantation procedure are made:

- Stainless steel Ergste® 1.4108 (X30CrMoN15-1),
- or Titanium Alloy (Ti 6Al-4V ELI).

5. Patient population

Tools related to the implantation procedure are used for the placement of a ROOTT Dental Implant, so all requirements to the patient population and selection criteria are always connected to that of the dental implants.

The patient population and selection criteria are always connected to that of the dental implants.

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, restored aesthetics. Dental Implant treatment may also prevent bone loss, prevent facial sagging, and keep adjacent teeth stable and leave them intact.

9. Sterility

Tools related to the implantation procedure are multiple use medical devices, can only be used in sterile conditions and intended to be resterilized.

Tools related to the implantation procedure are supplied in non-sterile conditions.

Can be used only in dental clinics during implantation surgery.

Cleaning, disinfection and sterilization

Tools related to the implantation procedure are determined as multiple use devices. Before and after usage they must be cleaned, disinfected and sterilized properly.

Tools related to the implantation procedure are supplied in non-sterile conditions. For initial use and for all next uses Tools related to the implantation procedure must be cleaned, disinfected and sterilized prior to use.

For cleaning can be used both methods: manual and automated cleaning.

If possible, automated method should be used for cleaning and disinfection. A manual method should be used only if an automated method is not available, because of its clearly lower effectiveness and reproducibility. This also applies when using an ultrasonic bath.

Perform pretreatment both in manual and in automated cleaning! Cleaning procedure shall be used which is valid within the cleaning.

The products can be sterilized in the autoclave at 132 °C in one standard sterilization cycle with a dwell time of 3 minutes to achieve a SAL of 10^{-6}.

For cleaning, disinfection and sterilization must be followed requirements of *"Instruction for cleaning, disinfection and sterilization of non sterile and reusable medical devices from Dental Implant System ROOTT*".

10. Storage

Prior to the first use of the device, products should be stored in its original packaging at room temperature in dust free and humidity free conditions and not exposed to direct sunlight.

Subsequently, the products should be stored in appropriate hygienically maintained containers (protected from dust, humidity and recontamination).

After sterilization, the products need to be stored in sterilization wrapping in a dry and dust free place and not exposed to direct sunlight. Follow the expiration date marked in the sterilization label.

11. Operating principles

Before surgery:

Tools related to the implantation procedure should be selected individually taking the anatomy and spatial circumstances into account and what implant diameter, implant type, position and number of implants.

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

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 surgery:

Tools related to the implantation procedure must be reprocessed (cleaned, disinfected, inspected and sterilized) immediately.

For cleaning, disinfection and sterilization must be followed requirements of "*Instruction for cleaning, disinfection and sterilization of non sterile and reusable medical devices from Dental Implant System ROOTT* (available on the internet at http://ifu.rootT.ch/).

12. 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 risk.

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.

TRATE medical devices do not have risks of fire or explosion during normal use and in single fault condition and its intended use does not include use in association with flammable or explosive substances or substances which could cause combustion.

Swallowed or aspirated small devices by patients.

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).

Inappropriate cleaning, disinfection and sterilization procedures of reusable instruments can lead to whole implantation failure. Effective decontamination is essential in reducing the potential risk of cross-contamination. Also, risk of infection develops from improperly processed devices which allow for accumulation of microbial biofilms.

Risk of injury related with sharpness of instruments can not be reduced as it represents intended use of instrument and it is clinician responsibility to be attentive, use forceps and protectors for sharp points.

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

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.

13. Side effects, complications with tools for implantation procedure

Tools related to the implantation procedure are only used if dental implant placed, so all side effects and complications that appear during the use of a dental implant can appear in the use of Tools related to the implantation procedure as well.

Complications may occur if ROOTT Tools related to the implantation procedure are used for non-ROOTT implants and superstructures treatment.

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 jaw, bone, aesthetic problems, nerve damage, exfoliation, hyperplasia.

13.1. 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.

14. 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

15. Instructions in the event of the packaging being damaged

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

16. Compatibility information

Tools related to the implantation procedure are compatible with ROOTT Dental implants and Related superstructures due to their technical characteristics.

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

For tools used for implant placement see *Placement protocols.* For Related Dental superstructures fixation see *Prosthetic protocols.*

Restrictions to combinations

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

Limitations:

Use of pressure

Users of the Tools related to implantation procedure should at all times avoid applying excessive pressure. This can damage the working part of the instruments and cause the working edges to break off.

Limitations for torque for implants placement:

Dental products	Insertion	Torque
ROOTT R Dental implants	Implant insertion via carrier CRE part	Never exceed 50 Ncm
	Implant insertion via direct insertion with insertion tool	Never exceed 100 Ncm
ROOTT C/ CS/ M/ P/ S/ K Dental implants	from diameter 3.0 mm, via direct insertion	Never exceed 117 Ncm
	from diameter 3.5 mm - 3.8 mm, via direct insertion	Never exceed 133 Ncm
	from diameter 4.2 mm - 5.0 mm, via direct insertion	Never exceed 238 Ncm

	from diameter 5.5 mm, via direct insertion	Never exceed 298 Ncm
ROOTT B/BS Dental implants	from diameter 3.0 mm, via direct insertion	Never exceed 117 Ncm
	from diameter 4.5 mm - 5.0 mm, via direct insertion	Never exceed 238 Ncm
	from diameter 5.5 mm, via direct insertion	Never exceed 298 Ncm

Limitations for fixation of Related Dental Superstructures:

Device type	**Tightening torque**
Healing abutments	15 Ncm
Abutments	15 Ncm
Components on implant analogs	Hand-tight

17. Warnings

Tools related to the implantation procedure are only compatible to use with ROOTT Dental Implants and Related Dental superstructures.

These products must be used in sterile conditions.

Inadequate planning may compromise the performance of the implant resulting in system failure, such as loss or fracture of the implant.

Be aware in cases of patients that show signs of allergy or hypersensitivity to chemical components of the material: surgical stainless steel or Titanium Alloy.

Do not use the product if the packaging is broken.

Before each procedure, make sure the pieces are properly seated.

Ensure that the parts are not swallowed or aspirated by the patient.

Make sure you have all the necessary instruments for the surgery according to surgical planning.

Before each procedure, check the conditions of the ROOTT instruments, always respecting their useful life. Replace the instruments if there is damage, markings deleted, sharpening jeopardized, deformation and wear.

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

Do not use damaged or blunt instruments for implantation.

Tools related to the implantation procedure consisting of several parts or components must be disassembled prior reprocessing. The information of assembling and disassembling of the instruments is provided in the *Assemble and disassemble of the products.*

Do not bend instruments.

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

Always use the ROOTT product sequence. The use of prosthetic components and/or instruments of other manufacturers does not ensure the perfect function of the ROOTT Implant System and exempts any product warranty.

It is the professional's responsibility to use the ROOTT products according to the instructions for use, and to determine whether it suits the individual situation of each patient.

Tools related to the implantation procedure can not be used during any radiographic examinations (e.g. MRI and others).

Users of the Tools related to implantation procedure should at all times avoid applying excessive pressure. This can damage the working part of the instruments and cause the working edges to break off.

18. 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

Products should not be used if are visible these defects (see: *Examples of inspection of the defects*):

- Corrosion, rusting;
- Pitting, discoloration;
- Cutting surfaces become blunt, are damaged, increased susceptibility to corrosion;
- Destruction of the material surface, removal of oxide layer increased susceptibility to corrosion;
- Damage of the instruments, especially of cutting surfaces increased susceptibility to corrosion.

Causes of defects:

- Unsuitable and/or incorrectly used cleaning agents and disinfectants, saline solution, iodine tinctures, unsuitable water;
- Cleaning with steel wool, steel brushes;
- Contact between instruments of different metallic materials;
- Overloading the instruments;
- Mutual contact of the instruments;
- Impurities in the sterilizer, e.g. due to already corroded instruments, or improper maintenance of the sterilizer;
- Insufficient drying of the instruments.

TRATE does not define the maximum number of uses appropriate for reusable devices. The useful life of these devices depends on a number of factors including the methods and duration of each use and the handling between uses.

Product life time will be preserved and extended if:

- Use each instrument only for its intended purpose.
- Never let surgical residues (blood, secretion, tissue residues) dry on an instrument; clean immediately after surgery.
- Thoroughly clean off incrustations with soft brushes only. Disassemble instruments, clean cavities especially well.
- Never disinfect, clean (also ultrasound) or sterilize instruments made of different materials together.
- Only use cleaning agents and disinfectants intended for the material and follow the instructions for use of the manufacturers.
- Rinse disinfectants and cleaning agents very thoroughly with water.
- Never leave or store instruments moist or wet.

The user must at all times avoid touching the instruments and parts without protection (protective sterile gloves and gowns should be worn).

During intraoral application attention has to be made to the fact that the products are protected against aspiration or falling on the floor.

Instruments that are bent and/or do not run true should be discarded forthwith. The general waste management procedures for dental offices see in *Biohazardous Implant-related Waste Disposal Instruction for the Dental Offices*.

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/

19. Magnetic Resonance Imaging (MRI) compatibility

Tools related to the implantation procedure can not be used during any radiographic examinations and MRI scanning.

20. Materials

For Handles, Abutment extractors, Alignment bar, Wrenches, Drill stops, Sleeves and Drill handles:

Titanium Alloy according to ASTM F136 and ISO 5832-3:	
Chemical components	Composition % (mass/mass)
Iron, max	0.25
Oxygen, max	0.13

Aluminium	5.5–6.50
Vanadium	3.5–4.5
Titanium	balance

Implant drivers, Screwdrivers, Drill extension and Abutment benders:

Stainless steel according to ASTM F899:	
Chemical components	Composition % (mass/mass)
Carbon	0.28–0.34
Manganese, max	0.3–0.6
Silicon, max	0.3–0.8
Chromium	14.5–16.0
Molybdenum	0.95–1.10
Nickel	0.3 max

21. Disposal

Disposed Reusable surgical instruments 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 see 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 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 labeled as such. Decontamination of used devices should be performed by *Instruction for Product Return*.

22. 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.

23. Manufacturer and Authorized Representative information

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24. Symbols explanation

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

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
3	2024-06-03	Added new instruments to the type Implant drivers S: ITMS0, ITMS10	V. Shulezhko D. Karpavicius
	Revision 2025-03-21	Updated format of address for EU REP according the certificate and EUDAMED	V. Shulezhko