Instruction for use
ROOTT Dental Implant System
Reusable surgical instruments

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.

Reusable surgical instruments are 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.

Reusable surgical instruments can only be used in sterile conditions.

These devices are designed and labelled 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.

Reusable surgical instruments are made from Stainless steel Ergste® 1.4108 (X30CrMoN15-1) or Titanium Alloy (Ti 6Al-4V ELI) and supplied in non-sterile conditions.

Reusable surgical instruments there are:

Taps:

Taps used for preparation of drilled cavities for insertion of a dental implant and bone collecting for use in surgical operation. Less force needed for implantation. Very useful for D1 bone, to prepare threads before implantation.

Taps are made from Titanium Alloy (Ti 6-Al 4-V ELI) and supplied in non-sterile conditions.

REF No.:

TRxxxx, where is TR - tap for ROOTT R Type Implant; xxxx - dimensions (diameter and length of implant).

CSxxxx, where is CS - tap for ROOTT C/CS/M/S Type Implant; xxxx - dimensions (diameter and length of implant).

CSxxxxF, where is CS - tap for ROOTT C/CS/B/BS Type Implant, xxxx - dimensions (diameter and length of implant), F - FILO universal

Sizes available:

	Taps for ROOTT R Dental Implants	Taps for ROOTT C/CS/M/S Dental Implants	Taps
Ø	3.0 mm, 3.5 mm, 3.8 mm, 4.2 mm, 4.8 mm, 5.5 mm	3.0 mm, 3.5 mm, 4.0 mm, 4.5 mm, 5.0 mm, 5.5 mm	2.5 mm, 3.0 mm, 4.0 mm
Length:	10 mm, 12 mm, 14 mm, 16 mm	6 mm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm	18 mm, 16 mm

Note: *The marks on the taps are used for the visualisation of the insertion depth of the tap, and are not intended to be used for measurement purposes.*

Gauges:

Implant depth gauge - surgical instrument for intra-oral checkings during implant treatment procedure.

Gauges are made from Stainless steel and supplied in non-sterile conditions.

REF No.: DPG

Alignment pin - metal tool for manual applications during the bed preparation for the implant insertion. Alignment pins are made from Titanium Alloy (Ti 6-Al 4-V ELI) and supplied in non-sterile conditions.

REF No.: P2

Note: *The marks on the pin are used for the visualisation of the insertion depth of the pin, and are not intended to be used for measurement purposes.*

Basic UDI-DI information

System	**Basic UDI-DI**
ROOTT Dental Implant System	76300538ROOTTSystemRC

Product	**Basic UDI-DI**
Tap for Rxxxx	76300538Tap3M
Tap for Cxxxx	
Tap	
Implant depth gauge	76300538DepthgaugeL4
Alignment pin	76300538Pin3M

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

Reusable surgical instruments 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. Reusable surgical instruments have no stand-alone intended use, because the different variants of the Reusable surgical instruments are assigned to an implant type.

3. Range of Application

Taps for Rxxxx	Condense the bone for insertion of ROOTT R implants
Tap for Cxxxx	Condense the bone for insertion of ROOTT C, CS, M, S, P implants
Tap (FILO universal)	Condense the bone for flapless ROOTT C, CS, B, BS implantation
Implant depth gauge	Intended for use for intra-oral checkings during implant treatment procedure. The thin side is intended to be used for checking the relative deepness prepared implant bed after pilot drilling to identify the length for the implant to be inserted. The wide side intended to be used for checking the depth gap between the implant end and the

	soft tissue to know exactly what abutment or a healing need to be selected.
Alignment pin	Intended to check the direction and relative deepness of the prepared implant bed after pilot drilling.

4. Indications

There is no stand-alone indication for the application of the Reusable surgical instruments. The different variants of the Reusable surgical instruments are assigned to an implant type.

Reusable surgical instruments produced by TRATE have the only one indication - support implant placement surgical procedure.

Note: surgical protocols and determination of the bone type are not part of the indication of the Reusable surgical instruments.

5. Contraindications

Reusable surgical instruments 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 Reusable surgical instruments as well. The contraindications of the Reusable surgical instruments 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 Reusable surgical Instruments are made:

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

6. Patient population

Reusable surgical instruments 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.

7. Intended users

For use only by dental professionals within the dental clinic

8. 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

Reusable surgical instruments are multiple use medical devices, can only be used in sterile conditions and intended to be resterilized.

Reusable surgical instruments are supplied in non-sterile conditions.

Can be used only in dental clinics during implantation surgery.

Cleaning, disinfection and sterilization

Reusable surgical instruments are determined as multiple use devices. Before and after usage they must be cleaned, disinfected and sterilized properly.

Reusable surgical instruments are supplied in non-sterile conditions. For initial use and for all next uses Reusable surgical instruments 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:

Reusable surgical instruments 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:

Reusable surgical instruments 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.rootts.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 Reusable surgical instruments

Reusable surgical instruments 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 Reusable surgical instruments as well.

Complications may occur if ROOTT Reusable surgical instruments 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

Reusable surgical instruments are compatible with ROOTT Dental implants due to their technical characteristics.

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

Restrictions to combinations

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

Limitations

Taps can only be used with D1 type of bone.

The recommended torque limitations are:

Taps R and Taps C from diameter 3.0 mm, via direct insertion	Never exceed 117 Ncm
Taps R and Taps C from diameter 3.5 mm - 3.8 mm, via direct insertion	Never exceed 133 Ncm
Taps R from diameter 4.2 mm - 4.8 mm and Taps C 4.5 mm - 5.0 mm, via direct insertion	Never exceed 238 Ncm
Taps R and Taps C from diameter 5.5 mm, via direct insertion	Never exceed 298 Ncm

For Gauges there are no limitations.

17. Warnings

Reusable surgical instruments are only compatible for bone bed preparation for installation of ROOTT Implants

The tap should not be resharpened.

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 surgical 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.

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.

Reusable surgical instruments can not be used during any radiographic examinations (e.g. MRI and others).

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

Reusable surgical instruments can not be used during any radiographic examinations and MRI scanning.

20. Materials

For Taps and Alignment pin:

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

For Implant depth gauge:

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

TRATE AG
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www.trate.com, www.rootт.ch
e-mail: info@trate.com

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Lithuania
SRN: LT-AR-000002509 (EC Rep)
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24. Symbols explanation

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

CE 2797

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