# Instruction for use
# ROOTT Dental Implant System
# Instruments for handpiece

## 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.

Instruments for handpiece are tools related to the implantation procedure for placement of the ROOTT Dental Implants and Related superstructures, with connection to handpiece (active device) and manual handles and which are intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.

The shank of Instruments for handpiece is designed according to type 1 of ISO 1797 to provide full compatibility with all types of standardized drill handles.

Instruments for the handpiece can only be used in sterile conditions.

Instruments for the handpiece are made from Stainless steel Ergste® 1.4108 (X30CrMoN15-1) and supplied in non-sterile conditions.

**Instruments for handpieces:**

- Implant drivers (ITzHyx) - tools with internal or external platform for use with ROOTT Dental Implants, for implant insertion with handpiece equipment. Implant drivers are various by types of ROOTT Dental implant types;
- Screwdrivers (SDHx) - tools are used to turn the attachment or abutment screws that secure different components to implant fixtures with handpiece equipment;
- Drill extension (ET) - tool intended for extending (prolongation) of the dill.


**REF No.:**

ITzHyx, where is IT - insertion tool, z - type of platform (e.g. E- external), H - handpiece, y - stands for type of Dental implant, x - length of shank for instrument (sizes S, L).

SDHx, where is SD - Screwdriver; H - handpiece, x - length of shank for instruments (sizes S, L).

ET - extension tool

**Basic UDI-DI information**

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

| Products | Basic UDI-DI |
|---|---|
| Implant drivers R | 76300538ImplantdriverHN6 |
| Implant drivers C, CS, B, BS | |
| Implant drivers K | |
| Screwdrivers U | 76300538ScrewdriverHF9 |
| Drill extensions U | 76300538DrillExtension6W |

**Delivery set:**

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

**2. Intended Purpose/ intended function**

Instruments for handpieces intended for the placement of the ROOTT Dental Implants and fixation related to them dental superstructures only. Intended use is related to that of the corresponding implants.

**Range of Application**

| | |
|---|---|
| Implant drivers R | Shall be used for ROOTT R Implants insertion |
| Implant drivers C, CS, B, BS | Shall be used for ROOTT C, ROOTT CS, ROOTT B, ROOTT BS Implants insertion |
| Implant drivers K | Shall be used for ROOTT K Implants insertion |
| Screwdrivers U | Shall be used with all types of ROOTT Dental Implants related superstructures |
| Drill extensions U | Shall be used with all types of ROOTT Implant Drills |

**3. Indications**

There is no stand-alone indication for the application of the Instrument for the handpiece. The different variants of the Instrument for handpiece are assigned to an implant type. The indications for the use of Instrument for handpieces are strongly connected to the indications of the corresponding ROOTT Dental Implant.

All Instruments for handpieces produced by TRATE have the only one indication - support implant placement surgical procedure.

**4. Contraindications**

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 Instruments for handpieces are made:

- Stainless steel Ergste® 1.4108 (X30CrMoN15-1)

**5. Patient population**

Instruments for handpieces used during ROOTT Dental implant placement procedure and fixation of ROOTT Related superstructures, so all requirements to the patient population and selection criteria used for instruments as well.

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

**8. Summary of safety and clinical performance**

Summary of safety and clinical performance for ROOTT Dental Implant System products can be found in: https://trate.com/sscp/.

**9. Sterility**

Instruments for handpieces are multiple use medical devices, can only be used in sterile conditions and intended to be resterilized.

Instruments for handpieces are supplied in non-sterile conditions.

Can be used only in dental clinics during implantation surgery.

**Cleaning, disinfection and sterilization**

Instruments for handpieces are determined as multiple use devices. Before and after usage they must be cleaned, disinfected and sterilized properly.

Instruments for handpieces are supplied in non-sterile conditions. For initial use and for all next uses Instruments for handpieces 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:**

Instruments for handpieces should be selected individually taking the anatomy and spatial circumstances into account and what 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 the procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

**Use of pressure**

Users of the instruments should at all times avoid applying excessive pressure. This can damage the working part of the instruments and cause the cutting edges to break off. At the same time, it generates excessive heat.

**After surgery:**

Instruments for handpieces 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.

Failure to recognize actual lengths of instruments relative to radiographic measurements can result in permanent injury to nerves and other vital structures.

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.

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.

**13. Side effects, complications with Instruments for handpieces**

Instruments for handpieces are only used if a dental implant placed, so all side effects and complications that appear during the use of a dental implant can appear in the use of Instruments for handpieces as well.

Complications may occur if Instruments for handpieces 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 local representative of TRATE AG for exchange via web page: www.trate.com.

**16. Compatibility information**

Instruments for handpieces 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.*

The course and sequence for Instruments for handpieces established in *Placement protocols.*

**Restrictions to combinations**

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

**Limitations**

For Instruments for handpieces there are no limitations.

**17. Warnings**

The ROOTT Instruments for handpieces are only compatible with ROOTT Dental implants and Related Dental superstructures.

This product must be sterile.

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.

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.

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.

Instruments for handpieces 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**

Instruments for handpieces can not be used during any radiographic examinations and MRI scanning.

**20. Materials**

| **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 a 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**
Bahnhofstrasse 16
6037 Root
Switzerland
SRN: CH-MF-000019071
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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<br>D. Karpavicius |
| 2 | 2022-12-05 | Manufacturer address changed from “Seestrasse 58 8806 Bäch Switzerland” to “Bahnhofstrasse 16 6037 Root Switzerland”.<br>Minor corrections have been made to the text. | V. Shulezhko<br>D. Karpavicius |