Instruction for use
ROOTT Dental Implant System
Implant Drills

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.

Implant drills are reusable invasive devices that are intended for surgical use, 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 Implant drills is designed according to type 1 of ISO 1797 to provide full compatibility with all types of standardised drill handles.

Implant drills can only be used in sterile conditions.

Implant drills are made from Stainless steel Ergste® 1.4108 (X30CrMoN15-1) and supplied in non-sterile conditions.

Implant drills

Implant drills are instruments and intended only for the preparation of the cavities in the maxillary and / or mandibular bone for the placement of the ROOTT Dental Implants.

Types of Implant drills:

- Lance Drills ,
- Twist Drills,
- Drills R,
- Drills C, CS, M, S, K
- Drills B, BS,
- Tapered drills,
- Flat drills,
- Punches.

REF No.: DYxxxx , where is D - drill, xxxx - dimensions: diameter and length of working part of the instrument (the dimensions correspond to the thickness and length to the root of Dental implants), Y - stands for type of Dental implant.

Sizes available:

	Lance drills	**Twist drills**	**Tapered drills**
Ø	1.5 mm	2 mm	2.5 mm, 2.8 mm, 3.2 mm, 3.6 mm, 4.0 mm, 4.3 mm, 4.6 mm, 5.0 mm, 5.3 mm
Length:	8 mm	6 mm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 26 mm	16 mm
	Drills R	**Drills C, CS, M, S, K**	**Drills B, BS**

Ø	3 mm, 3.5 mm, 38 mm, 4.2 mm, 4.8 mm, 5.5 mm	3 mm, 3.5 mm, 4 mm, 4.5 mm, 5 mm, 5.5 mm	2 mm, 2.3 mm
Length:	6 mm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm,	6 mmm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm	10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 22 mm, 24 mm, 26 mm
	Flat drills	**Punches**	
Ø	2.8 mm, 3.5 mm, 4.1 mm	3 mm, 4 mm, 5 mm	
Length:	24 mm, 29 mm, 34 mm	24 mm, 29 mm	

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

Basic UDI-DI information

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

Products	**Basic UDI-DI**
Lance drills	76300538DrillLanceDM
Twist drills	76300538DrillTwistNU
Drills R	76300538DrillR9Z
Drills C, CS, M, S, P, K	76300538DrillC93
Drills B, BS	76300538DrillB8Z
Tapered drills	76300538DrillTaperedNV
Punches	76300538Punch6C
Flat drills	76300538DrillFlatAT

Delivery set:

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

2. Intended Purpose/ intended function

Implant drill is an instrument intended only for the preparation of the cavities in the maxillary and / or mandibular bone for the placement of the ROOTT Dental Implants. Implant drills have no stand-alone intended use, because their intended use is related to that of the corresponding implants.

Range of applications

Lance drills	intended to penetrate the cortical bone in order to mark the site and to guide the subsequent drills
Twist drills	intended to be used to develop an osteotomy to its full depth at the implant site
Drills R	intended only for the preparation of the cavities in the maxillary and / or mandibular bone for the placement of the ROOTT R Implants

Drills C, CS, M, P, S, K	intended only for the preparation of the cavities in the maxillary and / or mandibular bone for the placement of the ROOTT C, CS, M, P, S, K Implants
Drills B, BS	intended only for the preparation of the cavities in the maxillary and / or mandibular bone for the placement of the ROOTT B, BS Implants
Tapered drills	intended for the drilling of bone tissue during the preparation of the surgical socket prior to the installation of tapered implants
Punches	intended for punching out a section of mucosa, usually circular, for exposing an implant.
Flat drills	intended to be used to prepare cavities in cases when bone surface is not flat

3. Indications

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

All Instruments for handpieces produced by TRATE have 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 drills. The choice of the right drill is incumbent to the implantologist.

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 hypersensitivity to materials from which the Implant drills are made:

- Stainless steel Ergste® 1.4108 (X30CrMoN15-1)

5. Patient population

Implant Drills are only used for the preparation of holes for insertion of a ROOTT dental implant used during ROOTT Dental implant placement procedure, so all requirements for the patient population and selection criteria are used for drills 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, 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

Implant drills are multiple use medical devices, can only be used in sterile conditions and intended to be resterilized.

Implant drills are supplied in non-sterile conditions.

Can be used only in dental clinics during implantation surgery.

Cleaning, disinfection and sterilization

Implant drills are determined as multiple-use devices. Before and after usage they must be cleaned, disinfected and sterilized properly.

Implant drills are supplied in non-sterile conditions. For initial use and for all next uses Implant drills must be cleaned, disinfected and sterilized prior to use.

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

If possible, automated methods 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:

Implant drills 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.

During the operation it is necessary to follow the course and sequence established in the *Drilling protocols.*

Speed recommendations for rotary instruments

Following the instrument-specific speed recommendations produces the best results.

Exceeding the maximum admissible speed (rev/min) when using long and pointed instruments tends to produce vibrations that can lead to the destruction of the instrument.

When using working parts with diameters exceeding the thickness of the shaft, excessive speed can release great centrifugal forces that may cause the shaft to bend and/or the instrument to break. Therefore, the maximum admissible rev/min must not be exceeded.

Recommended speeds:

- Initiating drilling (speed 1.200-1.500 rev/min).
- Pilot drilling (speed 900-1.200 rev/min). For twist drills the optimal speed is 1.200 rev/min.
- Form drilling for ROOTT R Dental Implants (speed 200 - 800 rev/min), for ROOTT B/BS and ROOTT C/CS/M/P/S/K Implant (speed 1.200-1.500 rev/min) with drills of increasing diameter.

Generally, the following rules apply:

The larger the working part of an instrument the lower the speed,

The larger the working part of an instrument, the greater the force of pressure.

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.

Cooling

In order to avoid excessive heat generation during preparation, a sterile water/sodium chloride solution supplied via a permanent feeding device should be used to ensure sufficient cooling during use of the instruments. Insufficient cooling will lead to irreversible damage to the bone and/or the adjacent tissue.

General Operation Procedure

Under local anaesthesia the implant bed is created with the use of Implant drills. For the preparation of the appropriate bed for the implant it is recommended to use drills of dental implant system ROOTT and observe the technology of preparation of the bone bed:

During the whole drilling procedure, the drills should be cooled with sterile saline.

1. Initiating drilling (speed 1.200-1.500 rev/min).
2. Pilot drilling (speed 900-1.200 rev/min). For twist drills the optimal speed is 1.200 rev/min.
3. Check the depth and direction.
4. Form drilling for the ROOTT R type of Implant (speed 200 - 800 rev/min), for the ROOTT B and ROOTT C type of Implant (speed 1.200-1.500 rev/min) with drills of increasing diameter. In cases of insufficient bone density it is recommended to use the previous diameter of the forming drill or even installation after the pilot drilling.

During the preparation of the bone bed attention should be given to the need of substantial cooling of the implant bed and fraises (e.g. using chilled (degree-sterile), normal saline). Continuing to use only sharp burs. Use intermittent drilling technique.

5. Implant placement.

Bleeding can be stopped with implant placement.

After surgery:

Implant drills 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.rootт.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.

Exceeding of 20 times of use can lead to increased risk of overheating the tissues or drill mechanical failure. Note that in case of inappropriate usage the drill can be useful less than 20 times.

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.

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.

13. Side effects, complications with Implant drills

Implant drills are only used in the subject of dental implants, so all side effects and complications that appear during

the use of a dental implant can appear in the use of Implant drills as well.

Complications may occur if Implant drills and 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 practise

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 practise.

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

The shank of Implant drills is designed according to type 1 of ISO 1797 and fully compatible with all types of standardised drill handles.

Implant drills are compatible with ROOTT Dental implants due to their technical characteristics.

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

The course and sequence for Implant drills established in *Drilling protocols*.

Restrictions to combinations

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

17. Warnings

The ROOTT drills are only compatible for bone bed preparation for installation of ROOTT Implants.

The drill should not be resharpened.

This product must be sterile.

Failure to replace the drill as recommended by the manufacturer can result in improper bone heating, jeopardizing the success of the procedure.

Due to reduced mouth opening in the posterior region, it is not recommended to use long drills in the regions of premolars and molars.

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.

Do not exceed 20 times of uses for ROOTT Implant Drills.

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.

Implant drills 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 these defects are visible (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.

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.

TRATE defines the maximum 20 time of use appropriate for ROOTT Implant Drills. In case of inappropriate usage the drill can be useful less than 20 times.

Product life time will be preserved and extended (up to 20 times of usage) 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 are 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

Implant drills 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 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*

CE 2797

Change history:

Ver	Date	Change description	Responsible
1	2013-02-26	Printing date	V. Shulezhko D. Karpavicius
2	2013-06-17	Reprocessing parameters added	V. Shulezhko D. Karpavicius
3	2013-10-01	Added information on detergents and cleaning precaution and warnings	V. Shulezhko D. Karpavicius
4	2017-04-24	Symbol “Manufacturer” placed near by manufacturer address	V. Shulezhko D. Karpavicius
5	2019-02-18	NB number was changed from 0086 to 2797	V. Shulezhko D. Karpavicius
6	2019-04-19	Was added link of “Instruction for cleaning, disinfection and sterilization of non sterile and reusable medical devices Dental Implant System ROOTT” and information about residual risks, side effects warnings	V. Shulezhko D. Karpavicius
7	2022-06-01	Updated information under MDR requirements Added requirement to use ROOTT Implant Drills up to 20 times . Added SRN number for manufacturer TRATE AG To the Clause 16 added information about compatibility with standardized drill handles. Added recommendation to the twist drilling speed with 1200 rev/min. Updated information with full material composition Updated, Added Section 13.1. Medical emergencies in dental practise	V. Shulezhko D. Karpavicius