Instruction for use
Drills for
Dental Implant System ROOTT

Description

Dental Implant System ROOTT is a system of endosseous dental implants with corresponding abutments, gingiva formers, covering and fixing screws, other prosthetic parts and surgical instruments.

ROOTT drills there are reusable surgical instruments. ROOTT 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.

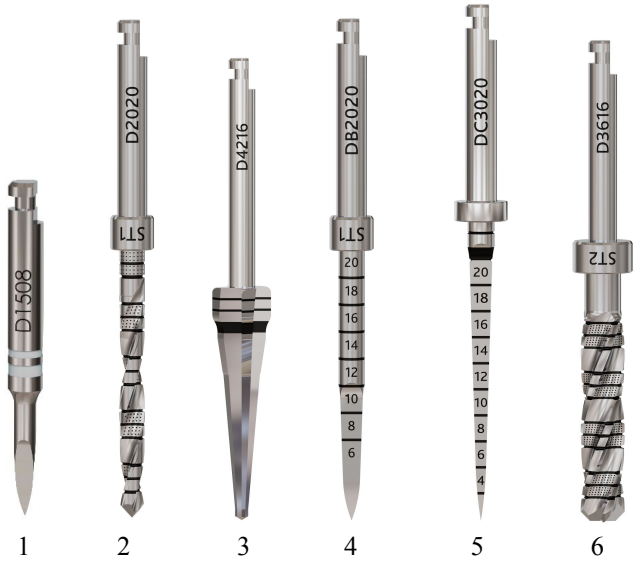
This procedure has to be performed just for dental clinic use only and dental professionals, by a trained implantologist who is familiar with the placement of dental implants.

Drills are intended to be used for drilling holes in the interior part of mandibula or maxilla bone to create a cavity for the insertion of a dental implant. The drills have no stand-alone intended use, because their intended use is related to that of the corresponding implants.

This instruction is valid for all implantological drills manufactured by TRATE AG:

- Initial Drills (D15xx),
- Pilot Drills (D20xx),
- Form Drills:
  - for „Rootform" implants (Dxxxx),
  - for BASAL form implants (DBxxxx),
  - for COMPRESSIVE form implants (DCxxxx),
  - Universal (Dxxxx).

xxxx - dimensions: diameter (from 3,0 mm till 5,5 mm) and length of working part of instrument (from 6 mm till 20 mm), the dimensions correspond to the thickness and length to the root of implants.



Samples of drills: 1- initial drill, 2- pilot drill, 3- Rootform drill,4 - BASAL form drill, 5- COMPRESSIVE form drill, 6- Universal drill

ROOTT drills are made from Stainless Steel 1.4197 (X20CrNiMoS13-1).

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

ROOTT drills are supplied in non sterile conditions either in single blister packaging or as part of an instrument kit.

Reusable instruments must be sterilized before use. For cleaning, disinfection and sterilization must be followed requirements in "Instruction for cleaning, disinfection and sterilization of non sterile and reusable medical devices from Dental Implant System ROOTT".

TRATE AG does not define the maximum number of uses appropriate for reusable 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. For details see Instruction for cleaning, disinfection and sterilization of non sterile and reusable medical devices from Dental Implant System ROOTT.

Products should not be used if are visible these defects:

- Corrosion, rusting;
- Pitting, discoloration;
- Cutting surfaces become blunt, are damaged p 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.

All TRATE AG instructions for use are provided with devices and are available on web page http://ifu.rootT.ch/, or you can apply directly for a copy of the paper instruction to TRATE AG.

User specification:

Medical indication

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

The indications for the use of the drills are strongly connected to the indications of the corresponding ROOTT Dental Implant:

- loss of teeth / missing teeth,
- replacement of damaged or ill teeth.

The concrete disease, injury, physiological condition or traumatic event leading to the loss of a tooth or to the necessity of tooth removal are manifold and do not matter, as long they are not explicitly listed in the contraindications.

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.

Intended use/Intended function

ROOTT 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.

Patient population

ROOTT Drills only used for the preparation of hole for insertion of a ROOTT dental implant, so all requirements to the patient population and selection criteria used for drills as well. The patient population and selection criteria are always connected to that of the dental implants.

There is no convincing evidence to suggest that age or gender affect the outcome of osseointegration in the short or the long term.

There is no upper age limit providing the patient is capable of undergoing the surgical phase and the subsequent self maintenance. In contrast implant treatment should be delayed in young individuals until growth is complete. Patients should be at least 15 years of age with sufficient bone volume and maturity to prevent any related post operative complications linked to further bone growth. Clinicians should be aware that facial growth continues after 15 years of age and that this can cause complications.

The general health of the patients should be good enough to undergo surgical and restorative treatment.

Contraindications

ROOTT Drills only used for the preparation of hole for insertion of a ROOTT dental implant, so all contraindications that prohibit the use of a dental implant prohibit the use of drills as well. The contraindications of the drills are always connected to that of the dental implants.

Contraindications can be separated into absolute and relative contraindications. Contraindications of the implants have been taken mainly on the basis of the scientific literature. They are known to have a negative impact to the mere implantation process or to the stability of the implant over time. The following contraindications are in line with standard textbooks [Renouard et al., 1999]:

- Absolute contraindications: myocardial infarction (within six months of an attack), cerebral infarction and cerebral apoplexy (in cases where the condition of the disease is serious and the patient is concurrently taking anticoagulants), severe immunodeficiency, patients who are undergoing strong chemotherapy, severe

neuropsychiatric disease, mental disability, and narcotic drug addicts, patients who are concurrently taking bisphosphonates, youths under the age of 15, allergies or hypersensitivities to chemical ingredients of material used (titanium alloy Ti6Al4V ELI).

- Relative contraindications: diabetes (particularly insulin-dependent), angina pectoris (angina), seropositivity (absolute contraindication for clinical AIDS), significant consumption of tobacco, certain mental diseases, radiotherapy to the neck or face (depending on the zone, the quantity of radiation, localization of the cancerous lesion etc.), certain auto-immunes diseases, drug and alcohol dependency, pregnancy, certain diseases of the mucous membranes of the mouth, bruxism, periodontal diseases (loosening of the teeth); it is necessary to clean up the gums and stabilize the disease first, an unbalanced relationship between the upper and lower teeth, poor hygiene of the mouth and teeth, an insufficient quantity of bone, infections in the neighboring teeth (pockets, cysts, granulomas), major sinusitis.

Related to the ROOTT Implants Dental Superstructures only used if dental implant placed, so all contraindications that prohibit the use of a dental implant prohibit the use of the superstructures as well. The contraindications of the Related dental superstructures are always connected to that of the dental implants.

Intended part of the body or type of tissue applied to interacted

The upper and lower jaws in all types of bone tissue.

Intended user profile

Dental Implant System ROOTT products for dental clinic use only and for use only by dental professionals.

Use environment

Drills can be used only in clinic during implantation surgery.

Reprocessing Instructions

Drills are determined as reusable devices. Before and after usage they must be cleaned, disinfected and sterilized properly.

Reusable instruments are supplying in non sterile conditions in transport packaging. Before placing the restoration in the patient's mouth, reusable instruments after removal of transport packaging must be cleaned, disinfected and sterilized prior to use.

For cleaning can be used both methods manual (with ultrasonic) and automated mechanical cleaning.

If possible, a mechanical method should be used for cleaning and disinfection. A manual method should be used only if a mechanical 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 mechanical 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”.

Operating principles

Before surgery

Clinical and radiological examination of the patient has to be performed prior to surgery to determine psychological and physical status of the patient.

Special attention has to be given to patients who have localized or systemic factors that could interfere with the healing process of bone, or soft tissue, or the osseointegration process (e.g. smoking, poor oral hygiene, uncontrolled diabetes, facial radiotherapy, infections in neighborhood tooth or bone, patients passed bisphosphonate therapy).

Preoperative hard tissue and soft tissue deficit may yield to compromised aesthetic result.

The planning of the exact drilling procedure, the succession of drill sizes may differ from case to case, depending on the drilling site, bone quality and other individual factors, and is under the responsibility of the implantologist.

So, the following simplified description is not intended to be taken as strict clinical operation manual but as typical example for illustration:

First step: Positioning. The site of the implant is “marked with a small first drilling that forms a small deepening to mark the position for pilot drilling in the bone.

Second step: Pilot drilling. With a twisted drill, a cylindrical cavity is created. This one serves as a guidance for the following form drills. It nearly has the depth of the final cavity.

Third step: Form drilling. Starting with a small form drill, the size of the drills get increased stepwise until the cavity has the desired form for the implant.

For detailed implants sizes, drill size and bone types see “Drilling protocol”.

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.

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.

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 for the implant bed is created with the use of drills. For the preparation of the appropriate bed for the implant it is recommended to use 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).
3. Check of the depth and direction.
4. Form drilling for Rootform type of Implant (speed 200 - 800 rev/min), for BASAL and COMPRESSIVE 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 (eg 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.

Storage

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

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).

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.rootte.ch/).

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.

Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

Materials

Stainless Steel 1.4197 (X20CrNiMoS13-1).

Compatibility information

Compatibility matrix- drill/implants

		ROOTT Dental Implants						
		Basal / Basal SS	Compressive / S	Rootform	Compressive M	Compressive MP	Compressive MS	Compressive K
Drills	Initial drill	x	x	x	x	x	x	x
	Pilot drill	x	x	x	x	x	x	x
	COMPRESSIVE form drill		x					
	BASAL form drill	x	x	x	x	x	x	x
	Rootform drill			x				
	Universal form drill*	x**	x	x	x	x**	x	x

* Must be used in combination with pilot or BASAL form drills.
**Except for: B3522, B3524, B3526, B4522, B4524, B4526, B3524ss, B3526ss, C3522mp, C3524mp, C3526mp, C4522mp, C4524mp, C4526mp.

For detailed implants sizes and drill types see "Drilling protocol".

Drills and accessories for drills

Table 1

Drills	Stoppers	Sleeves
D2020	S1L02, S1L04, S1L06, S1L08, S1L10, S1L12, S1L14, S1L16	SLS1
DB2020		
D2516		
D2816		
D3216	S2L02, S2L04, S2L06, S2L08, S2L10, S2L12, S2L14, S2L16	SLS2
D3616		
D4016		
D4316		
D4616	S3L02, S3L04, S3L06, S3L08, S3L10, S3L12, S3L14, S3L16	SLS3
D5016		
D5316		

In cases, when space is limited to use two or more regular sleeves (SLSx) near to each other, then use sleeve for pilot drills SL02 instead of one of these sleeves (see information below). Further drill protocol may be executed without sleeves and handles. Form drills can be used with stoppers according to Table 2.

Drills	Stoppers	Sleeves
D2020	n/a	SL02
DB2020		

Table 2

Form drills	Stoppers
D2516	S1Lxx
D2816	
D3216	S2Lxx
D3616	
D4016	
D4316	
D4616	S3Lxx
D5016	
D5316	

Table 3

Sleeves	Handles for pilot drills	Handles
SLS1	A02SL1	n/a
SLS2	A02SL2	A1SL2
SLS3	A02SL3	A1SL3, A2SL3
SL02	n/a	n/a

Courses and training

Continuing education ensures long-term success. Please, ask your ROOTT representative directly for information on the ROOTT Dental Implant System courses and training. Further information at www.root.ch

Side effects, complications with Drills

ROOTT drills are only used if dental implant placed, so all side effects and complications that appear during the use of a dental implant appear the use of drills as well.

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.

Residual risks

One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure.

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to hemorrhage in the floor of the mouth.

Treatment by means of implants may lead to loss of bone, biologic and mechanical failures, including fatigue fracture of implants. Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.

Warnings:

Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury. If you want to protect it, to use rubber dam! For the case, an implant or an instrument was swallowed or aspirated, immediately call a doctor.

Beside the mandatory precautions for any surgery such as of asepsis, during drilling in the jaw bone, one must avoid damage the nerves and vessels by referring to anatomical knowledge and preoperative medical imaging (e.g. radiographs).

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to hemorrhage in the floor of the mouth.

Inappropriate use of the products leads to badly executed work and increased risk.

In particular, users of hand tools should take care to use them gently and with consideration.

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

Thermal bone damage caused by rotating and oscillating tools must at all times be avoided (user training, working at low speed and with sufficient cooling (see section “Cooling”).

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

Rotating instruments need to be clamped as far down as possible with their speed set before applying them on the object are used with the rotary instruments. Do not exceed recommended drilling speeds as it might cause bone necrosis or system components fracture.

Drills are provided in non-sterile conditions and have to be reprocessed and sterilized prior to first use. Prior to their first use on the patient and immediately after each use, all products need to be disinfected and sterilized. Inappropriate cleaning and sterilizing of the instruments can result in the patient being infected with harmful bacteria.

In order to avoid damaging the instruments, they must be removed from the blister pack individually.

The transport blister is not intended to be used as a container for the steam sterilization of the drills. They have to be unpacked prior to first reprocessing.

It is essential to only use turbines as well as hand and angle pieces that are technically and hygienically faultless, maintained and cleaned.

Do not use device if the primary package has been damaged or previously opened.

Do not use damaged or blunt instruments for drilling.

Broken off cutting edges of instruments cause vibrations and great forces of pressure, which, in turn, leads to broken preparation corners and rough surfaces.

Instruments that are bent and/or do not run true should be discarded forthwith.

Damaged, corroded or worn devices should not come into contact with intact instruments to avoid contact corrosion.

Cautions / Precautions:

Sterile handling is essential. Never use potentially contaminated components. Contamination may lead to infection.

Do not use damaged or blunt instruments for drilling.

TRATE AG 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 allow instruments to land on their tips.
- 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.

Avoid any contact of the drill with foreign substances prior to their use.

It is recommended that ROOTT Dental Implants are used only with dedicated surgical instruments, as violation of this recommendation may lead to mechanical instrumental failure or unsatisfactory treatment result.

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.

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.

Signs explanation

	Consult instructions for use
	Catalogue number
	Batch code
	Non-sterile
	Do not use if package is damaged
	Keep away from sunlight
	Keep away from water
	Manufacturer

CE 2797

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

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Ver	Date	Change description	Responsible
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