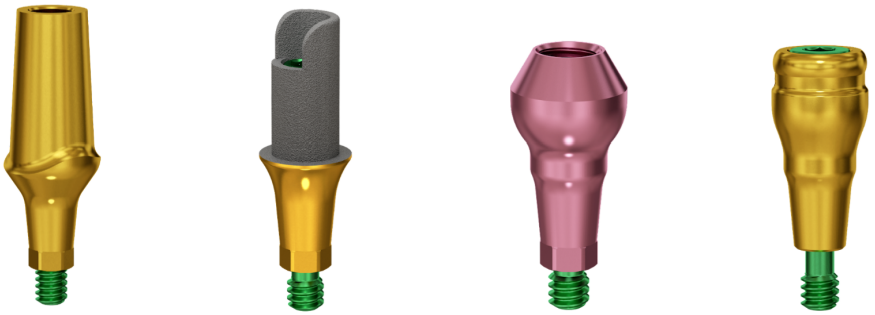
Instruction for use
ROOTT Dental Implant System
Abutments

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.

A pre-manufactured dental implant abutment directly connected to the endosseous implant intended for use as an aid in prosthetic rehabilitation.



REF No.: AYX, where is A - abutment, Y - type, X - collar height

Abutments are made from Titanium Alloy (Ti 6-Al 4-V ELI).

Abutments (attachments REF No.: Bx) are coated with TiN coating which forms a versatile wear protection that provides effective reduction of abrasive and adhesive wear in dental applications.

No bioactive or antimicrobial coating applied.

All abutments are supplied in non-sterile conditions.

Abutments available:

- Anatomical abutments (two-piece and one-piece), for ROOTT R,
- Transgingival abutments, for ROOTT R,
- Narrow abutments, for ROOTT R,
- Abutments, titanium base, for ROOTT R,
- Abutments, blank, for ROOTT R,
- Abutments, multi-unit, for ROOTT R,
- Abutments, attachment, for ROOTT R,
- Abutments for ROOTT C / CS / B / BS,
- Abutments, multi-unit, for ROOTT M / P / S,
- Abutments, titanium base, for ROOTT M / P / S,
- Abutments for ROOTT K.

Basic UDI-DI information

System	Basic UDI-DI
ROOTT Dental Implant System	76300538ROOTTSystemRC

Device type	Models	Basic-UDI
to ROOTT R	A1, A2, A3, A4, A1A15, A2A15, A3A15, A4A15, A1A25, A2A25, A3A25, A4A25, AT1, AT2, AT3, AT4, A05K, A1K, A2K, A3K, A4K, A1N, A1A15K, A2A15K, A3A15K, A4A15K, PCO1, PCO2, PCO3, PCOR, PCO1S, PCO2S, PCO3S, PCORS, PCO, ATR1, ATR2, ATR3, ATR4, PMAB, ABM, M1, M2, M3, M4, M1A15, M2A15, M3A15, M4A15, M1A30, M2A30, M3A30, M4A30,	76300538AbutmentsRNG

	M1A45, M2A45, M3A45, M4A45, MS1, MS2, MS3, MS4, B1, B2, B3, B4, B5	
to ROOTT C, CS, B, BS	TCE0, TCE1, TCE2, TCE3, TCES0, TCES1, TCES2, TCEXS1, TCEXS2	76300538AbutmentsCMJ
to ROOTT M, P	AM, PCOM	76300538AbutmentsMN6
	SFPCOM	76300538ProsthethicSVC
to ROOTT S	AMS, PCOMS	76300538AbutmentsSNJ
	SFPCOMS	76300538ProsthethicSVC
to ROOTT K	TCK0, TCK1, TCK2, TCK3, TCKS0, TCKS1, TCKS2, TCKXS1, ESK, TTCK, TTCKS, TTCKXS	76300538AbutmentsKN2
	FSK, FSKL	76300538ProsthethicSVC
	ESK, TTCK , TTCKS , TTCKXS	76300538AbutmentsKN2

Delivery set:

Five units of one type of abutment packed into the preformed 5-cells blisters with a die-cut lid. Blister packed in a protective package.

2. Intended Purpose

Prosthetic components connected to the implant are intended for use as an aid in prosthetic rehabilitation.

3. Indications

Dental Abutment is the connecting element between the dental implant and the crown, they are connectors, placed on, or built into, the top of the implants to be able to fix the crown.

Duration of use:

ROOTT Dental abutments may be placed into occlusion for implants with sufficient primary stability or for implants that are fully osseointegrated and duration of use are unlimited.

For Abutments type attachments:

Abutments type attachment REF No.: Bx can be safely used for 3 years. After 3 years of usage, it is recommended to evaluate if retention is sufficient. In case of retention loss, abutment should be changed.

4. Range of applications

Anatomical abutments (two-piece and one-piece), for ROOTT R	Straight abutment shall be used to create cement-retained restoration with sufficient space between placed implants Angled abutment shall be used to create cement-retained restoration with sufficient space between placed implants in cases where implants are placed not in parallel to improve implant angulation.
Transgingival abutments, for ROOTT R	Shall be used to create single cement-retained restorations with adjustable height only
Narrow Abutments, for ROOTT R	Narrow abutment shall be used to create cement-retained restoration with insufficient space between placed implants.
Abutments, titanium base, for ROOTT R	Shall be used to create screw-retained and cement-retained restorations with CAD-CAM technology for more precise individual abutments.

Abutments, blank, for ROOTT R	Shall be used to create screw-retained and cement-retained restorations in cases where required fabrication of individual abutments.
Abutments, multi-unit, for ROOTT R	Straight regular multi-unit abutment shall be used to create screw-retained restorations Angled regular multi-unit abutment shall be used to create screw-retained restorations in cases where implants are placed not in parallel to improve implant angulation Straight small multi-unit abutment shall be used to create screw-retained restorations in aesthetically important area and narrow ridge areas.
Abutments, attachment, for ROOTT R	Shall be used for fixation of removable overdentures supported by the implants
Abutments for ROOTT C / CS / B / BS	Regular abutments shall be used to create telescopic single and multiple restorations. Short abutments shall be used to create single and multiple restorations with insufficient space for occlusion.
Abutments, multi-unit, for ROOTT M / P / S	Straight regular multi-unit abutment shall be used to create screw-retained restorations. Straight small multi-unit abutment shall be used to create screw-retained restorations in aesthetically important area and narrow ridge areas.
Abutments, titanium base, for ROOTT M / P / S	Regular abutments shall be used to create screw-retained multiple restorations with CAD-CAM technology for more precise individual abutments. Small abutments shall be used to create screw-retained multiple restorations with CAD-CAM technology for more precise individual abutments in aesthetically important area and narrow ridge areas.
Abutments for ROOTT K	Regular abutments shall be used to create telescopic single and multiple restorations. Narrow abutments shall be used to create telescopic single and multiple restorations with insufficient space between implants.

5. Contraindications

Abutments are only used if dental implants are placed, so all contraindications that prohibit the use of dental implants prohibit the use of the abutments as well. The contraindications of the abutments are always connected to that of the dental implants. Refer to the instructions for use for relevant type of ROOTT Dental Implants.

6. Patient population

Abutments are to be used in patients subject to dental implant treatment.

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

Abutments are a component of treatment with a dental implant system and / or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and / or crown restored.

9. Summary of safety and clinical performance

When the European Database on Medical Devices comes online, the Summary of Safety and Clinical performance reports by Basic UDI-DI will be available at https://ec.europa.eu/tools/eudamed.

To request a copy of the Summary of Safety and Clinical Performance for ROOTT Dental implants and Related

dental superstructures, please send an email specifying the Basic UDI-DI or/and REF number(s) to info@trate.com or Summary of safety and clinical performance reports for ROOTT Dental Implant System products can be found in: https://trate.com/sscp/.

10. Sterility

Abutments are delivered in non-sterile conditions. Prior to use, they must be cleaned, disinfected and sterilized.

Cleaning and disinfection

TRATE recommend following procedure for the cleaning, disinfection and sterilization prior to use:

For cleaning, both methods can be used: 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 pre-treatment both in manual and in mechanical cleaning!

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*.

Sterilization

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}

Abutments are single use devices and must not be reprocessed. Reprocessing could cause mechanical, chemical and / or biological characteristics. Reuse could cause local or systemic infection.

11. Storage, handling and transportation

The product must be stored and transported in dry conditions in the original packaging and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

12. Operating principles

Clinical procedures

1. Remove healing abutment or temporary abutment.
2. Connect the abutment to implant and hand-tighten using a dedicated screwdriver. Check the Compatibility book for information regarding the screwdriver. Never exceed recommended tightening torque in 15 Ncm for the screw. Overtightening of abutment may lead to a screw fracture.
3. Cover hole.

Laboratory procedures

1. Select appropriate abutment, modify if needed.
2. Manually screw abutment to analog.
3. Fabricate prosthesis.
4. Cement prosthesis to abutment.

13. Residual risks

Healing abutments and Implant abutments are an integral part of the dental implant means treatment of implant, so residual risks are directly related to the dental implant and the whole implantation success.

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 risks.

Reuse of single-use devices increase risk of contamination, cross-contamination and the whole implantation 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.

Mechanical failure could occur in case of torque force violated, the device is used in unintended way or with not ROOTT system instruments.

If the treatment is performed to the contraindicated patient, the failure of the whole implantation is possible. In case, if implantation was performed in conditions of absolute contraindications, the manufacturer does not accept any warranty requirements.

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

The risk of swallowed or aspirated small devices by patients is possible. 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 procedure before the first use of dental superstructures can lead to whole implantation failure.

Infection can inhibit implant osseointegration and lead to implant failure, however it can be avoided if sterility is maintained and assured during the whole implant surgery and if proper maintenance, medication and oral hygiene is taken upon after the treatment.

A risk of hypersensitivity reaction to TiN coating material occurrence is possible for patients who use Abutments type attachment (REF No. Bx).

14. Side effects, complications with implants

The placement of these devices is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain and swelling. During abutment placement or removal the pharyngeal reflex (gag reflex) may be triggered in patients with a sensitive gag reflex.

Abutments are part of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to these associated with teeth, such as retained cement, calculus, mucositis, ulcera, soft tissue hyperplasia, soft and / or hard tissues recessions. Some patients may experience discoloration in the mucosal area such as graying.

14.1. 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.

15. 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.

16. Performance requirements and limitations

To achieve the desired performance, abutments only be used with the products described in the Compatibility book and in accordance with the intended use for each product.

Performance characteristics and changes in performance

To achieve the expected performance, the ROOTT abutments shall only be used with products described in this instruction for use, and in accordance with the intended use for each product. To confirm the compatibility of products which are intended to be used in combination with ROOTT Dental Implants, please check the *Compatibility book*, product catalog and dimensions on the product labelling.

It is responsibility of the clinicians to instruct the patient on all related contraindications, precautions and side effects, as well as the need to seek the services of a trained dental professional if there is any changes in performance of the implant (infection, pain, any other unusual symptoms that the patient has not been told to expect).

17. Compatibility information

Abutments 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.*

For further management of the ROOTT abutments and subsequent placement of definitive abutment/crown/prosthesis see *Prosthetic protocols.*

Restrictions to combinations

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

18. Warnings

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

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).

19. Cautions / Precautions

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.

Never exceed recommended tightening torque for the screw. Overtightening of abutment may lead to a screw fracture.

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.

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.

ROOTT Dental Implant System must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use devices in accordance with these instructions and determine if the device fits the individual patient situation.

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 a compromised aesthetic result.

All components, instruments and tooling used during the clinical and laboratory procedures must be maintained in good conditions and care must be taken that instrumentation does not damage implants or other components.

For Abutments type attachments (REF No. Bx)

Retention force could be decreased in time of usage of removable dentures. Retention insert must be changed annually.

Abutments type attachments (REF No. Bx) can be safely used for 3 years. After 3 years of usage, it is recommended to evaluate if retention is sufficient. In case of insufficient retention, abutment should be changed.

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/

20. Magnetic Resonance Imaging (MRI) compatibility

ROOTT R Dental implant and abutment configuration have been tested for RF Heating and Image Artifacts. For further information refer to TRATE MRI Safety Information, at www.trate.com.

Patient with abutment can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 3 T;
- Recommended maximum MR System reported whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode). Maximum MR system reported whole body averaged specific absorption

rate (SAR) of 3,5 W/kg of scanning (i.e., per pulse sequence) in the Normal Operating Mode showed a maximum temperature increase of 6,5°C in implants from the ROOTT Dental Implant System after 15 minutes of continuous scanning. SAR should be kept as low as possible for medical diagnosis in order to minimise any risks for the patient. The temperature rise is under consideration of a static phantom without cooling processes like for example blood flow.

- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the implant/device. The image artefact caused by the ROOTT dental implant and abutment may extend maximum up to 19,7±4,2 mm (SE) or 19,3±4,1 mm (GRE) from the devices when imaged at 3 T MR system.

ROOTT Dental devices are fabricated from a material that can be affected by exposure to MRI energy and is MR Conditional. The emergence of image artefacts is expected and should be considered when necessary the analysis of images. Image artefacts pose no risk to the patient.

Denture and crowns can be fabricated from a metal material which can be affected by MRI energy. Patient shall be informed. Removable restorations should be taken out prior to scanning.

21. Material

Abutments (except abutments *type attachments (REF No. Bx)*:

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	3.5–4.50
Titanium	balance

Attachments *(REF No. Bx)*:

TiN coating:	
Chemical components	Composition %
Titanium	50
Nitrogen	50

22. Disposal

Safety discards potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, recycling or disposal of packaging materials shall follow local country and government legislation on packaging and packaging waste, where applicable.

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.

Used devices under *Warranty and return policy,* returned to a TRATE AG should have been cleaned and decontaminated by the user before shipment and labelled as such. Decontamination of used devices should be performed by *Instruction for Product Return*.

23. Information for patients

Surgeons shall provide to patients information about specified Dental implant(s). And shall inform the patient about side effects, complications for implants, contraindications, residual risks, what patients shall do or shall not do after the implantation, e.g.:

- Follow good oral hygiene: clean teeth at least 2 times a day, use dental floss;
- Avoid very hard, hot, spicy food during the healing stage;
- Avoid high physical exertion during the healing stage;
- Quit smoking because it is extremely damaging to the health of teeth and gums and slows down healing processes;
- Regularly visit the dentist and do not delay scheduled visits for observation purposes;

- The patient must contact his surgeon immediately and do not remove and dispose of any parts of superstructures of the implants themselves.

Surgeons also shall inform the patient about possible risks considering MRI treatment**.** Radiation therapy for patients with dental implants should be planned and prescribed with extreme caution by the health care professionals to avoid possible complications.

24. 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.

25. Manufacturer and Authorised Representative information

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26. Symbols explanation

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

CE 2797

Change history:

Ver	Date	Change description	Responsible
01	2017-07-13	Printing date	V. Shulezhko D. Karpavicius
02	2019-02-18	NB number was changed from 0086 to 2797	V. Shulezhko D. Karpavicius
03	2019-04-19	Added residual risks description	V. Shulezhko D. Karpavicius
04	2020-06-25	Supplemented abutments, gingiva former and associated surgical instruments to the Rootform implants in the table provided in the clause ”Compatibility information”	V. Shulezhko D. Karpavicius
05	2022-07-11	Instruction separated from healing abutments, added all information required by MDR 2017/745 Updated MRI safety information, more detailed Material composition. Added SRN number for manufacturer, Duration of use, links to Prosthetic protocol, Performance characteristics and changes in performance	V. Shulezhko D. Karpavicius

		Updated information of residual risks Added information in section:9: information should state the value of the Basic UDI-DI to find the intended SSCP in Eudamed. Added Section 14.1. Medical emergencies in dental practice	
06	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
07	2023-04-28	Added information to the device description Clause 1 about TiN coated abutments attachment type Bx. Updated Duration of use to the Clause 3 with information about attachment type abutments service life. Updated Clause 13 with residual risk for TiN coated devices Updated Clause 19 with cautions for usage of attachment type implant abutments, added information about retention insert change interval Updated Clause 21 with information about TiN coating chemical composition	V. Shulezhko D. Karpavicius