

Instruction for use ROOTT Dental Implant System Healing 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.

Healing abutments are pre-manufactured dental implant abutments which can be directly connected to the endosseous dental implant to support healing of the surrounding soft tissues.



REF No.: GFYx, where is GF - healing abutment; Y - type, X - collar height
Healing abutments made from Titanium Alloy (Ti 6-Al 4-V ELI) are supplied in non-sterile conditions.

Healing abutments available:

- For ROOTT R Implants (regular, narrow),
- For ROOTT ROOTT C / CS / B / BS Implants (regular, narrow),
- For ROOTT M / P (regular, narrow),
- For ROOTT S (regular, narrow),
- For ROOTT K (regular, narrow).

Basic UDI-DI information

System	Basic UDI-DI
ROOTT Dental Implant System	76300538ROOTTSystemRC

Product	Basic UDI-DI
Healing abutments, for ROOTT R	76300538HabutmentRL5
Healing abutments for ROOTT C / CS / B / BS	76300538HabutmentCK7
Healing abutments for ROOTT M / P	76300538HabutmentMKT
Healing abutments for ROOTT S	76300538HabutmentSL7
Healing abutments for ROOTT K	76300538HabutmentKKP

Delivery set:

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

2. Intended Purpose

ROOTT Healing abutments are available as a one-piece or a two-piece temporary abutments with intended purpose to protect inner configuration of the implant from contamination by soft tissues and form the soft tissues during the healing process.

3. Indications

Healing abutments are indicated for use with endosseous dental implants or implant abutments in the maxilla or mandible for supporting single tooth or full arch denture procedures.

Healing abutment is screwed onto the top of the implant during surgical procedure to guide the healing of soft

tissue to replicate the contours and dimensions of the natural tooth that is being replaced by the implant and to ensure access to the implant restorative platforms for impression and definitive abutment placement.

Duration of use:

ROOTT Healing Abutments are intended for temporary use up to 180 days as an aid in prosthetic rehabilitation.

4. Range of applications

Healing abutments (for ROOTT R, C, CS, B, BS), regular	Shall be used to guide the healing of the soft tissues with sufficient space between placed implants
Healing abutments (for ROOTT R, C, CS, B, BS), narrow	Shall be used to guide the healing of the soft tissues where insufficient space to place an anatomical abutment and in cases with narrow ridge and in aesthetically important area
Healing abutments (for ROOTT M / P / S), regular	Shall be used to guide the healing of the soft tissues with sufficient space between placed implants with multi-unit
Healing abutments (for ROOTT M / P / S), narrow	Shall be used to guide the healing of the soft tissues where insufficient space between placed implants with multi-unit and in cases with narrow ridge and in aesthetically important area
Healing abutments (for ROOTT K), regular	Shall be used to guide the healing of the soft tissues with sufficient space between placed implants.
Healing abutments (for ROOTT K), narrow	Shall be used to guide the healing of the soft tissues with insufficient space between placed implants.

5. Contraindications

Healing abutments are only used if dental implants are placed, so all contraindications that prohibit the use of dental implants prohibit the use of the healing abutments as well. The contraindications of the healing 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

Healing 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

Healing 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 and/or 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

Healing 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}

Healing 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

Anatomical healing abutments

1. Select appropriate abutment and check the occlusal clearance.
2. Connect the abutment to implant and hand-tighten using a dedicated screwdriver. Check the Compatibility book for information regarding the screwdriver. It is highly recommended to verify the final abutment seating using the radiographic imaging. Never exceed recommended tightening torque in 15 N/cm for the screw. Overtightening of abutment may lead to a screw fracture.
3. If removal of the abutment is needed, untighten it using a dedicated screwdriver.

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 Healing Abutments REF No. GFNM(S)x.

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.

Healing 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, ulcers, 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 signs, 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, healing 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 Healing 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 catalogue* 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

Healing 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 Healing 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 neighbourhood 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.

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 occurred, 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

Please note that Healing abutments have not been tested for safety in the MR environment. The safety and compatibility of Healing abutments evaluated in the subject of ROOTT R Dental implant and abutment configuration which have been tested for RF Heating and Image Artifacts. For further information refer to TRATE MRI Safety Information, at www.trate.com.

Patient with Healing 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. Materials

Healing abutments (REF No. GFNM(S)x):

TiN coating:	
Chemical components	Composition; at%
Titanium	50
Nitrogen	50

All other Healing Abutments (except GFNM(S)x):

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

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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25. Symbols explanation

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

CE 2797

Change history:

Ver	Date	Change description	Responsible
1	2022-07-11	Printing date	V. Shulezhko D. Karpavicius
2	2022-12-05	Manufacturer address changed from "Seestrasse 58 8806 Bäch Switzerland" to "Bahnhofstrasse 16 6037 Root Switzerland". Minor corrections have been made to the text.	V. Shulezhko D. Karpavicius
3	2023-04-28	Added information to the device description Clause 1 about TiN coated Healing Abutments. Updated Clause 13 with residual risk for TiN coated devices Updated Clause 21 with information about TiN coating chemical composition	V. Shulezhko D. Karpavicius