Summary of Safety and Clinical Performance

ROOTT Dental Implant System
Healing abutments for ROOTT R Implants

Preface

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an up-to-date summary of the main aspects of the safety and clinical performance of the ROOTT Dental Implant System Healing abutments (Regular, two piece) Basic UDI-DI 76300538HabutmentRL5 for ROOTT R Implants.

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the device, nor it is intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1. Device identification and general information

1.1.	**Device trade name(s)**	**Healing abutments for ROOTT R Implants:** Regular, two-piece (REF: GF0, GFx, x - height)
1.2.	**Manufacturer's name and address**	Name: **ROOTT AG** Address: Bahnhofstrasse 16, 6037 Root, Switzerland Homepage: https://www.trate.com
1.3.	**Manufacturer's Actor ID/SRN**	**SRN:** CH-MF-000019071
1.4.	**Basic UDI-DI**	76300538HabutmentRL5
1.5.	**Medical device nomenclature description / text**	P010201, category "DENTAL IMPLANTS AND ACCESSORIES"
1.6.	**Class of device**	IIb
1.7.	**Year when the first certificate (CE) was issued covering the device (available on the EU market)**	2012
1.8.	**Authorised representative if applicable; name and the SRN**	Name: **ROOTT UAB** Address: Kauno m. sav. Kauno m. Jonavos g. 254 Kaunas, 44110, Lithuania **SRN:** LT-AR-000002509
1.9.	**Notified Bodies (NB) name (the NB that will validate the SSCP) and the NB's single identification number**	BSI Group The Netherlands B.V. (2797)

2. Intended use of the device

2.1. 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.

2.2. Indication(s) and target population(s)

Indication

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.

Patient population

Healing abutments are to be used in patients subject to dental implant treatment.

2.3. Contraindications and/or limitations

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.

Preoperative diagnosis is necessary to identify threats to the patient, related to the procedure of the implant placement, as well as factors that may affect the possibility of healing of the bone and surrounding soft tissues.

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, patients who are concurrently taking bisphosphonates, youths under the age of 18, allergies or hypersensitivities to chemical ingredients of material used (Titanium and its alloy, TiN coating).

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 / narcotic / 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.

In case, if implantation was performed in conditions of absolute contraindications, the manufacturer does not accept any warranty requirements.

Limitations

To ensure the desired performance, healing abutments shall be used exclusively with ROOTT system components as specified in the Compatibility Book, and strictly in accordance with the intended use defined for each product.

3. Device description

3.1. Description of the device

ROOTT Dental Implant System consists of ROOTT Dental Implants and Related Superstructures, i.e. healing abutments and abutments.

Healing abutment is fixed 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.

Regular, two-piece healing abutments for ROOTT R Implants are produced from Titanium Alloy (Ti 6-Al 4-V ELI Grade 23).

Regular, two-piece healing abutments for ROOTT R Implants are delivered in non-sterile conditions. All ROOTT Dental Implants and Related Superstructures are single use devices.

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.

Regular, two-piece healing abutments for ROOTT R implants available in different sizes:

	Regular, two-piece
	Material: Titanium Alloy
	REF: GFx (x - height)
	Models: GF1, GF2, GF3, GF4, GF5, GF6, GF7
	Range of applications: Shall be used to guide the healing of the soft tissues with sufficient space between placed implants

3.2. A reference to previous generation(s) or variants if such exist, and a description of the differences

ROOTT Dental Implants and Related Superstructures do not have any novel features in comparison with the current state of the art similar products. Constructions of all products do not have any principal and critical innovations or modifications and are generally accepted at the moment as state of the art construction (current level of technique). No clinically relevant changes to any of the devices were made.

3.3. Description of any accessories which are intended to be used in combination with the device

Based on the definition provided by Article 2 (2) of MDR 2017 / 745, "Accessory" means an article which whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specially enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose.

ROOTT Dental Implants and Related Superstructures do not have accessories which fall under the definition.

3.4. Description of any other devices and products which are intended to be used in combination with the device

Regular, two-piece healing abutments are intended to be used with ROOTT R dental implants.

ROOTT Dental Implant System consists of other medical devices intended to be used in combination with it that are not covered by this report, such as: Associated surgical instruments (e.g. screwdrivers and auxiliary tools).

4. Risks and warnings

4.1. Residual risks and undesirable side-effects

Residual risks

Healing abutments and dental 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 increases 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 sterilisation procedures 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.

Side effects

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.

Probability of occurrence of residual risks

Probability to experience residual risks depends on many factors, including patients health, surgery planning, etc. and can be extremely increased in case of violation of the instructions. The typical side effects are probable and common, while more persistent and undesirable side effects are rare. Only 9.5% of all patients in the PMCF study experienced early postoperative complications and recorded such side-effects as pain, infection, loss of ridge bone, and paraesthesia. No adverse events have been observed and reported during the 10-years follow-up of the PMCF study. For people with no contraindications implantation success is excellent. Thus close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.

Lifetime

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

4.2. Warnings and precautions

Warnings

ROOTT Dental Implant System has warnings related particularly to the usage of the healing abutments.

- Do not use a device if the primary package has been damaged or previously opened.
- Do not reprocess devices. Reprocessing may cause infection and failure.
- Do not exceed recommended insertion torque, as it might cause system components fracture.
- Due to the small size of the devices, care must be taken to ensure that they are not accidentally swallowed or aspirated by the patient. The use of appropriate protective measures - such as a throat shield or other suitable supporting tools - is recommended to prevent aspiration of loose components during clinical procedures.

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.

Clinicians—both new and experienced users—are strongly advised to complete specific product and procedural training prior to using a new device or treatment method. ROOTT provides a variety of professional training courses; further information is available at 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 localised 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.

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

No additional safety-related information is available. The devices have not been subject to any Field Safety Corrective Actions (FSCA) or Field Safety Notices (FSN).

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device, if applicable

In general, ROOTT does not claim full clinical equivalence to other manufacturers' devices. However, for certain product groups within the same product family, supporting data from comparable devices are utilized to demonstrate equivalent design characteristics, materials, and intended use.

Such data provide sufficient justification to reasonably conclude that the clinical performance and safety profile of the subject device are consistent with those of the comparator devices, until manufacturer-specific clinical data are fully collected, analysed, and integrated into the clinical evaluation.

For the majority of ROOTT devices, equivalence has not been claimed, as the manufacturer has established and is actively conducting its own Post-Market Clinical Follow-up (PMCF) studies to generate direct clinical evidence. These ongoing investigations are designed to confirm the long-term safety and performance of the devices within real-world clinical use.

As the manufacturer continues to collect and analyze its own clinical data within the planned 10-year PMCF program, reliance on equivalent device data will gradually be phased out. The final clinical evaluation will therefore be primarily supported by manufacturer-generated clinical evidence.

While specific clinical data for the subject device is not available, comprehensive supporting data from similar devices within the same product family - demonstrating equivalent design, materials, and intended use - has been assessed. This data provides sufficient evidence to reasonably conclude that the clinical performance and safety profile of the subject device is consistent with the comparator devices.

A Post-Market Clinical Follow-Up (PMCF) study was conducted between December 2013 and May 2015 to evaluate the clinical performance of abutments used in conjunction with ROOTT R implants. The study involved a total of 653 abutments placed in 251 patients.

The observation period focused on the short- to long-term (10 full years) clinical outcomes following implantation. All cases demonstrated successful integration and function, with no reports of abutment fracture, mechanical complications, or any adverse biological response.

Based on the available data, the clinical outcomes indicate a high level of safety and performance of the abutments when used with ROOTT R implants in the studied population. The results support the continued use of the device with no identified risks or negative impact on patient health.

Nonetheless, regular scientific literature review is conducted to collect and analyse clinical data related to similar devices available on the market. According to the reviewed literature, the following titanium (commercially pure and titanium alloy) dental implant manufacturer devices can be established as similar benchmark devices for ROOTT Dental Implant system: Neoss; Dentsply Sirona Implants (OsseoSpeed, Astra Tech, Ankylos); Nobel Biocare (TiUnite, Nobel-Speedy), Biomet 3i (NanoTite, Osseotite); Intra-Lock International; Southern Implants; Sweden&Martina; Straumann (Standard Plus, Tapered effect).

In summary, literature data from similar devices demonstrated the ubiquity of design, lack of novelty, and a

known safety and performance profile of the whole generic device group. Various studies have shown that failure rates over considerable time periods are extremely low, while most of the studies considering complications are published in case reports or case series, which can not be considered for a large scale estimation and are highly patient specific.

The following complications, side-effects and risks of the overall implant treatment were identified from the reviewed literature:

- Technical: loosening of abutment of prosthesis screw; fatigue fracture of implant, abutment or prosthesis screw; micro-motion between abutment and implant leading to bacterial leakage; gingival discoloration due to abutment colour; implant micromovement (mobility); wear debris;
- Biological: corrosion; metal ion/particle release; allergic reactions; hypersensitivity; mild facial erythema; hyperplastic tissues; cytotoxicity; inflammatory directions (mucositis, peri-implantitis);
- Clinical: marginal bone loss; peri-implant radiolucency; mechanical and/or thermal damage to the tissue during implant site preparation; tissue necrosis; suppuration and bleeding due bacterial colonisation; swelling; haematomas; pain; wound dehiscence; fistula.

Since the healing abutments can only be used in combination with dental implants, they are usually not singled-out in the clinical literature data. Implant survival is always directly related to the final and overall device configuration, i.e. dental implant plus abutment/healing abutment.

Depending on the details of the study and the materials used, the typical implant survival rate after 10 years is determined to be over 95.6 %. The survival rate over 95% after 10 years is an excellent result and an indication that implant-supported restorations are an excellent treatment modality. While complications are mainly infections, the rates average around 10 % of the patients and 20 % of the patients. Given these results, the extent for improving either the materials or the clinical procedures is limited. For this reason, the two well-established titanium alloys continue to be used for the overwhelming majority of implants used in dentistry, and this use seems likely to continue for the foreseeable future. The results in the reviewed studies are comparable and show similar tendencies, thus titanium dental implants, regardless of the implant material, design, surgical procedure and/or patient characteristics and potential complications, can be described as having predictable outcomes.

Ultimately, an evidently positive benefit-risk ratio of implant therapy can be derived, considering the significantly low reported implant failures and complication cases compared with highly beneficial patient satisfaction rates, restored masticatory function, increased aesthetic requirements and patients overall physical and mental health. Therefore titanium dental implants can be confidently determined to be a state-of-the-art treatment option for patients missing teeth.

5.2. Summary of clinical data from conducted investigations of the device before CE-marking, if applicable

No clinical investigations were conducted for the devices prior to CE marking.

5.3. Summary of clinical data from other sources, if applicable

Clinical data of the devices in question is collected through an implant register conducting a multicenter, open-label Post market clinical follow-up (PMCF) study of the CE-marked ROOTT Dental Implant System. The study plan was initiated with the objective to validate the ROOTT Dental Implant System by its practical daily use and application as state of the art with regards to its use and usability as intended. All devices belonging to the ROOTT Implant System were included in the study, without exceptions.

The primary endpoint of the study was the implant survival rate after five years postoperatively. The secondary endpoints were: the determination and evaluation of short-term complications related to the implantation procedure and/or implants; determination and evaluation of mid-term and long-term complications related to the implants; and the determination and evaluation of potential causes of implant loss.

Since the healing abutments can only be used in combination with dental implants, they are usually not singled-out in the clinical data. Implant survival is always directly related to the final and overall device configuration, i.e. dental implant plus abutment/healing abutment. Therefore the implant survival rate data is always applicable to the overall devices configuration, including healing abutments, if relevant.

In order to avoid manufacturer's bias as much as possible no patient inclusion or exclusion criteria were set. No specific selection of patients was made, therefore the inclusion/exclusion criteria were those of the common and daily practice.

Overall, a total of 3271 ROOTT Implants were implanted in a total of 1108 patients (424 males/684 females; mean age 54 years (range 18-93)) in the period from 2013 to 2018. Average number of implants placed in one patient: 1-6 (max. 18). 653 ROOTT R implants passed a 10-years follow-up.

Healing abutments are usually used on two-piece implants with delayed loading protocol. According to the obtained PMCF study data, 474 out of the 653 of two-piece ROOTT R implants were implanted with the delayed protocol, indicating that 474 healing abutments were used. Out of 474 delayed implants, 9 (1.9%) implants failed. None of the 9 failures were reported to be directly related to the healing abutments. Statistical analysis showed no statistical significance between delayed and immediate loading indicating that the use of healing abutments does not have an effect on implant survival.

5.4. An overall summary of the clinical performance and safety

ROOTT initiated its clinical registry at the end of 2012 as part of its Post-Market Clinical Follow-up (PMCF) activities. During the initial PMCF study, the safety and performance of the devices were systematically monitored. The clinical data collected to date demonstrate excellent clinical outcomes.

Over a 10-year observation period, a cumulative implant survival rate of 98.15% was achieved for 653 ROOTT R implants and corresponding 653 dental abutments in 251 patients, despite the fact that 35% of the patients presented clinically significant risk factors or contraindications. These results are consistent with data available in the scientific literature, confirming that ROOTT dental implant devices are not inferior to comparable devices within the same generic group currently available on the market.

The performance of a medical device is defined as its ability to achieve the intended purpose as claimed by the manufacturer. Dental implants fulfil their intended purpose by replacing missing teeth; accordingly, dental abutments are evaluated based on their ability to support prosthetic rehabilitation. Accordingly, healing abutment performance is described as their ability to protect the implant from soft-tissue contamination ingress into the implant and ability to form the soft-tissues. No reports indicating that the devices failed to perform as intended have been received. All documented clinical cases demonstrated successful healing and soft-tissue formation, and no implant failures related to infection or soft-tissue contamination were reported.

Another device performance indicator is the absence of mechanical failures, i.e. implant or superstructure fatigue fracture. In accordance with the PMCF study data no adverse events, including implant and/or healing abutment failure due to mechanical fatigue fracture have been observed and recorded.

Medical device safety is described as the acceptability of risks as weighed against benefits, when using the medical device according to the manufacturer's labelling. Safety concerns related to healing abutments are mainly related to complication rates (side-effects). The non-occurrence of severe side-effects is an indicator for the clinical safety of the healing abutments.

Since no severe side-effects were reported during the years of the PMCF study follow-up, ROOTT Healing abutments R can be considered of the highest clinical safety. No side-effects were reported to be specifically caused by the healing abutments. The only registered side-effects after the implant treatment procedure experienced by the patient population (251 patients) were temporary and not severe, including pain (14.3%), infection (1.6%), alveolar ridge height (1.2%), failure to maintain oral hygiene (0.8%), paresthesia (0.4%). Significantly low rates of infections - only 1.6% of patients - is a confirmation that the healing abutment is of the highest quality and cleanliness, providing protection of contamination ingress into the implant and desirable bone to implant connection and secure osseointegration.

Clinical benefits to the patient should be experienced immediately after the implant treatment and the healing process is over and should last as long as the implant is in place and retains its function. The primary intended clinical benefits to the patient are restored previous dental and masticatory function, bite force, restored esthetics, which relates to patient satisfaction and increased physical and mental health and general, health related quality of life. These benefits should be achieved and last as long as the implant is in place and no severe complications occur. Considering the results obtained from the PMCF study and data obtained from the literature, evidently positive benefit-risk ratio of implant therapy can be derived, considering the significantly low reported implant failures and complication cases compared with highly beneficial patient satisfaction rates, restored masticatory function, increased aesthetic requirements and patients overall physical and mental health. Patients treated with implants have higher levels of satisfaction, quality of life, function and bite force than patients treated conventionally, despite the possible risks associated with the implant therapy. According to the conducted benefit-risk analysis, the following conclusion was reached:

The manufacturer has considered the totality of the evidence regarding the extent of probable benefits and the extent of probable risks of a device in the benefit-risk information. All residual risks were mitigated as far as it is possible to reduce until additional risk controls are not practicable. Those implemented risk control measures are verified and considered as effective based on the issued annual PMS report which contains evidence of no incidents,

recalls, adverse events, evidence of product cleanliness based on test reports, and evidence of product performance based on continuous PMCF study. All identified hazardous situations have been evaluated and all risks have been reduced to an acceptable level based upon a benefit-risk analysis. Each residual risk is acceptable, the benefits outweigh the risks by far. No additional side-effects arising from the residual risks were identified. Based on the benefits and risks it can be concluded that the multiple benefits outweigh the residual risks by far. Additional risk control measures are not applicable and the medical device, i.e. ROOTT Healing abutments R can be considered safe for their intended use.

5.5. Ongoing or planned post-market clinical follow-up

Post-market clinical follow-up plan is established to proactively collect and evaluate clinical data from the use in or on humans of a device which bears a CE marking and is placed on the market or put into service within its intended purpose, with the aim of confirming the safety and performance throughout the expected lifetime of the devices, of ensuring continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

The only activity that is undertaken under the post-market clinical follow-up of the ROOTT Dental Implant System devices is a PMCF study. PMCF study is planned as a prospective, multicentric, non-controlled, non-randomized, open label study to evaluate the CE-labelled ROOTT Dental Implant System under routine conditions. The primary objective of the PMCF study is to validate the ROOTT Dental Implant System by its practical daily use and application as state-of-the-art with regard to its use and usability, as intended. Clinical data is collected and evaluated in order to: confirm the safety and performance of the device throughout its expected lifetime; identify previously unknown side-effects and monitor the identified side-effects and contraindications; identify and analyse emergent risks; ensure the continued acceptability of the benefit-risk ratio; identify possible systematic misuse or off-label use of the device, with a view to verify that the intended purpose is correct. The primary endpoint of the PMCF study is the survival rate of ROOTT Dental Implants after a 5-year follow-up of at least 95%. The secondary endpoints are mainly attributed to the postoperative outcomes, such as determination and evaluation of short-term complications related to the implantation procedure and/or implants; determination and evaluation of mid-term and long-term complications related to the implants; and determination and evaluation of potential causes for implant loss. The following questions were raised regarding the safety and performance of the healing abutments:

1. Do healing abutments perform as intended by forming the gingiva as required during the healing stage?
2. Do healing abutments adequately protect the implant from soft tissue contamination during the healing stage?
3. Have healing abutments or abutments caused an inflammation reaction due to selected material?
4. Have healing abutments or abutments caused implant failure due to the state of cleanliness and proposed sterilisation procedure?

The PMCF Evaluation Report has been prepared after collecting 10-year follow-up data. Overall 3271 implants were included in the study. Such sample size is considered adequate to sufficiently describe a wide-range context and prevailing global tendencies. 3271 ROOTT Implants were placed in 1108 patients by 10 different experienced implantologists. To achieve a heterogeneous patient population, implants were placed in the following countries: France, Luxemburg, Spain, Hungary, Slovakia, Greece, Lithuania, Russia, India, and Israel.

The mean age of the patients was 54.17 years, with a standard deviation of 14.63 years. The youngest patient was 18 years old, the oldest patient was 93 years old. No patient drop-outs of the PMCF study have been reported so far. The population contained patients with relative contraindications, such as smokers, patients with diabetes, patients with chronic or aggressive periodontitis, patients with poor oral hygiene, patients experiencing bruxism, hypertension, hypotension or osteoporosis. This is a ratio of 41% of risk patients, while more than one contraindication in one patient was also possible.

According to the obtained PMCF study results, 474 out of the 653 of two-piece ROOTT R implants were implanted with the delayed protocol, indicating that 474 healing abutments were used. Out of 474 delayed implants, 9 (1.9%) implants failed. None of the 9 failures were reported to be directly related to the healing abutments. Also, no healing abutment failures, or adverse events related to healing abutments were observed during the years of the study follow-up.

Since the healing abutments are only intended to be used for up to 180 days, a period after which the devices are removed from the patient, no further follow-up of these devices is possible and applicable.

6. Possible diagnostic or therapeutic alternatives

Since Healing abutments do not have stand-alone indications and are intended to be used in combination with placed ROOTT Dental Implants, therefore when considering alternatives the indication of implants shall be taken into account.

When a lack in the dentition has an impact on the ability to chew, there are several alternative possibilities to implants, depending on the severity of teeth defects:

- Conservative Treatment: efforts to save the teeth of a patient (possible only in mild cases). When the natural teeth can be saved, this might be the best option for the patient, but is no longer an option for patients who already lost teeth.
- Prosthesis without anchorage: this prosthesis is the most painless for the patient, but such patients are commonly restricted to soft food that is easy to chew and are not protected from bone loss.
- Endodontic implants: endodontic implants are artificial metallic extensions, which can extend out through the apex of the tooth into sound bone. Endodontic implants increase the root to the crown ratio and stabilise a tooth with weakened support. It serves the patient and avoids replacement of the tooth for several years.
- Crowns / Bridges: intact teeth required in proximity of the edentulous site.
- Alternative implants from other manufacturers (there are currently more than 200 different types available on the EU market).

Dental implants are the last resort in the spectrum of possibilities of a dentist to restore the ability to chew and is commonly used when teeth conservation is no longer an option. In cases where even dental implant treatment is not possible (e.g. with too poor bone quality), a dental plate or prosthesis without anchorage is commonly still an option.

7. Suggested profile and training for users

For professional use only. ROOTT dental devices are intended to be used exclusively by qualified dental professionals within a clinical setting. It is strongly recommended that both new and experienced clinicians complete dedicated training before using any new product or treatment method. ROOTT provides a wide range of professional training courses. For further information, please visit www.trate.com.

8. Reference to any harmonised standards and CS applied

Common specification(s)

Not applied

Harmonised standard(s) under MDR

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016). EN ISO 13485:2016/A11:2021;

EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements; EN ISO 15223-1:2021/A1:2025;

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021;

EN ISO 10993-1:2025 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process;

EN ISO 17665:2024 Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices.

State of the art standard(s)

EN 1642:2011 Dentistry - Medical devices for dentistry - Dental implants;

ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer.

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body

1	2022-03-30	Printing date	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
2	2022-04-04	Section 8 was managed to be in compliance with the list of applicable regulatory requirements	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
3	2022-12-05	Section 1.2 updated: Manufacturer address changed. Section 8 updated	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
4	2024-10-07	Content have been reviewed: - updated State of the art standards to the section 8;	X Yes (T0074241/ 30319186) Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
Revision	2025-03-21	In section 1 updated format of address for Authorised representative according the certificate and EUDAMED; In section 9 updated latest validation by NB and added validation language: English	-
5	2026-09-11	In section 1 updated: - Legal manufacturer name of TRATE AG have been renamed to ROOTT AG, - EU rep name of TRATE UAB have been renamed to ROOTT UAB - Separate BUDI-DI designations have been assigned to the other types of ROOTT R healing abutments, and separate SSCPs have been prepared for them. In section 5 updated PMCF data. In section 8 updated actual versions of harmonized and state of the art standards	☐ Yes Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)