



Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

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 Dental abutments.

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.

Following this information there is a summary for patients.

1. Device identification and general information

1.1.	Device trade name(s)	ROOTT Dental Implant System Dental abutments
1.2.	Manufacturer's name and address	Name: TRATE AG Address: Seestrasse 58, 8806 Bäch (Switzerland) Homepage: https://www.trate.com
1.3.	Manufacturer's Actor ID/SRN	SRN: CH-MF-000019071
1.4.	Basic UDI-DI	76300538ROOTTSystemRC
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	2012
1.8.	Authorised representative if applicable; name and the SRN	TRATE UAB, Lithuania, Jonavos g. 254, 44110 Kaunas 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

Dental implants are intended to replace missing or corrupted teeth,

- that cannot be repaired, replaced or compensated by other means;
- where other solutions have an undesired impact on sound teeth, or
- where implants are desired for obtaining an optimal cosmetic result.

Dental Implants are assigned Related Superstructures - dental abutments.

Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

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

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

The medical indications for the use of a ROOTT Dental Implants and related to them superstructure are:

- 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.

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.

Due to the dental abutments are intended to be used as an aid of prosthetic rehabilitation after implant treatment, the patient target group is adults with jaws when the skeleton has stopped growing to whom none of the contraindications that are related to the dental implantation.

2.3. Contraindications and/or limitations

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).

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.

Related Superstructures do not have stand-alone contraindications, so all contraindications that prohibit the use of a dental implant prohibit the use of the superstructures as well. The contraindications of the Related superstructures are always connected to that of the dental implants.

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



Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

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 dental abutments.

Related Superstructures, i.e. dental abutments, are produced from Titanium Alloy (Ti 6-Al 4-V ELI Grade 23) and PEEK (polyetheretherketone) plastic.

ROOTT Dental abutments are delivered in non-sterile conditions. All ROOTT Dental Implants and Related Superstructures are single use devices. Dental abutments are directly connected to the endosseous implant intended for use as an aid in prosthetic rehabilitation.

The Basic UDI-DI for each device group is provided in the table below.

Device groups	Basic UDI-DI
Abutments R	76300538AbutmentsRNG 76300538PabutmentsRCW
Abutments C/CS/B/BS	76300538AbutmentsCMJ 76300538CabutmentsCXA
Abutments M/P	76300538AbutmentsMN6 76300538ProstheticSVC
Abutments S	76300538AbutmentsSNJ 76300538ProstheticSVC
Abutments K	76300538AbutmentsKN2 76300538ProstheticSVC

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

ROOTT Dental abutments 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 abutments 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

ROOTT Dental abutments are intended to be used with ROOTT Dental Implants: ROOTT R, ROOTT C / CS / B / BS, ROOTT M / P, ROOTT S, ROOTT K

Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

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. insertion tools and auxiliary tools).

4. Risks and warnings

4.1. Residual risks and undesirable side-effects

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.

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.

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.

4.2. Warnings and precautions

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).

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



Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

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.

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

No other additional information related to the device safety, including any field safety corrective actions, is available. The devices have not been subject to any field safety corrective actions.

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

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

N/A - The demonstration of equivalence is not applicable. Equivalence is not claimed.

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

N/A - No clinical investigations were conducted for the devices before 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 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.

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).

2229 ROOTT R, ROOTT C/CS, and ROOTT B/BS implants passed a 5-year follow-up. The remaining 1042 ROOTT M, ROOTT S, ROOTT P, and ROOTT K implants passed a 3-year follow-up.



Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

Overall, a total of 1695 ROOTT Dental abutments were implanted in a total of 556 patients on ROOTT R / S / M / P / K implants. No abutments were placed on ROOTT C / CS / B / BS implants, since crowns or other prosthetic devices can be cemented directly on these implants. During the follow-up years of the PMCF study no adverse events directly related to abutments, such as abutment rupture, breaking or other mechanical failures have been observed and reported. None of the patients experienced unanticipated or unexpected side-effects or complications.

5.4. As overall summary of the clinical performance and safety

TRATE started its clinical register at the end of 2012 as part of the PMCF. During the PMCF study the safety and performance of the device is closely monitored. The clinical data collected so far shows excellent clinical results. In 5 years, a cumulative survival rate of 97.86% of ROOTT R / C / CS / S / M / P / K / B / BS implants was achieved with 3271 implants in 1108 patients, despite the fact that 458 patients (41.3%) had contraindications. Overall 1695 ROOTT Dental abutments were placed on ROOTT R / S / M / P / K implants.

Medical device performance is described as the ability to achieve its intended purpose as claimed by the manufacturer. Dental implants achieve their intended purpose by replacing missing teeth.

Accordingly, dental abutment performance is described as their ability to perform as intended by connecting the implant and the required prosthetic device. As the clinical findings are considered for the final device configuration, i.e. implant and abutment, implant survival rate data can be considered as the main performance indicator. Implant survival is determined simply as an implant still in the required position. This is based on the scientific literature where dental implant performance is primarily based on survival rate data. If the implant survived, this means the implantation procedure was successful, implant has osseointegrated. Another 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 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 dental 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 implant abutments. Since no severe side-effects were reported during the years of the PMCF study follow-up, ROOTT Dental abutments can be considered of the highest clinical safety. No side-effects were reported to be specifically caused by abutments. The only registered side-effects after the implant treatment procedure experienced by the patient population (556 patients) were temporary and not severe, including pain (9.35%), infection (1.8%), alveolar ridge height (0.54%), failure to maintain oral hygiene (1.26%), paresthesia (0.36%). Significantly low rates of infections - only 1.8% of patients - is a confirmation that the abutment surface is of the highest quality and cleanliness, providing safe and desirable bone to implant connection and secure osseointegration.

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

The current PMCF study is still on-going in order to obtain long-term results. The extended goal of the study is to achieve a cumulative implant survival rate of at least 90% after ten years of follow-up.

The following questions will be answered with further clinical data:

- Will the goal of a survival rate over 90% after 10 years be achieved?
- What is the long-term stability of the implants in time after 10 years?

Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

6. Possible diagnostic or therapeutic alternatives

Since Dental 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 stabilize 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

ROOTT Dental Implant System is intended for dental clinics use only and for use only by dental professionals with knowledge of oral and/or maxillofacial dentistry and surgery. The intended users, i.e. the implantologists, are highly recommended to get acquainted with the devices IFUs before use and always go through special training before undertaking a new treatment method. The manufacturer provides special courses, as well as, clear and easy to follow instructions for implant placement, and removal if necessary, using various instruments, instructions for cleaning, disinfection and sterilization of non-sterile and reusable medical devices, instructions for assemble and disassemble of the products, and examples of inspection of the defects.

ROOTT Dental Implant System devices are not intended to be handled directly by the patients. Surgeons shall provide to the patient information about dental implant(s) and shall inform the patient about side-effects, complications of implants, contraindications, residual risks, what patients shall do or 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.

Summary of Safety and Clinical Performance ROOTT Dental Implant System Dental abutments

8. Reference to any harmonised standards and CS applied

Common specification(s)

N/A

Harmonized 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;

State of the art standards:

- EN 1642:2011 Dentistry - Medical devices for dentistry - Dental implants;
- EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01);
- EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009). EN ISO 10993-1:2009/AC:2010
- EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices;
- 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	2022-02-22	Printing date	<input type="checkbox"/> Yes Validation language: <input type="checkbox"/> No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2 nd paragraph) for which the SSCP is not yet validated by the NB)

A summary of the safety and clinical performance of the device, intended for patients, is given below.



Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

Summary of safety and clinical performance

Document revision: v1

Data issued: 2022-02-22

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of the device safety and clinical performance prepared for healthcare professionals can be found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card of the Instructions For Use to provide information on the safe use of the device.

The following information is intended for patients

1. Device identification and general information

Device trade name

ROOTT Dental Implant System Dental abutments

Manufacturer; name and address

Name: TRATE AG

Address: Seestrasse 58, 8806 Bäch (Switzerland)

Homepage: <https://www.trate.com>

Basic UDI-DI

The Basic UDI-DI of ROOTT Dental Implant System: 76300538ROOTTSystemRC

The Basic UDI-DI for each device group is provided in the table below.

Device groups	Basic UDI-DI
Abutments R	76300538AbutmentsRNG 76300538PabutmentsRCW
Abutments C/CS/B/BS	76300538AbutmentsCMJ 76300538CabutmentsCXA
Abutments M/P	76300538AbutmentsMN6 76300538ProstheticSVC
Abutments S	76300538AbutmentsSNJ 76300538ProstheticSVC
Abutments K	76300538AbutmentsKN2 76300538ProstheticSVC

Year when the device was first CE-marked

2012

Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

2. Intended use of the device

Intended purpose

Dental implants are intended to replace missing or corrupted teeth,

- a) that cannot be repaired, replaced or compensated by other means;
- b) where other solutions have an undesired impact on sound teeth, or
- c) where implants are desired for obtaining an optimal cosmetic result.

Dental Implants are assigned Related Superstructures - dental abutments.

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

Indications and intended patient groups

The medical indications for the use of a ROOTT Dental Implants and related to them superstructure are:

- 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.

Dental abutments do not have stand-alone indications and are intended to be used in combination with placed ROOTT Dental Implants.

Dental implants and dental abutments are intended to be used in adult patients' jaws when the skeleton has stopped growing and to whom none of the contraindications that are related to the dental implantation apply.

Contraindications

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).

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 neighbouring 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.

Dental abutments do not have stand-alone contraindications, so all contraindications that prohibit the use of a dental implant prohibit the use of the dental abutments as well. The contraindications of the



Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

dental abutments are always connected to that of the dental implants.

3. Device description

Device description and material/substances in contact with patient tissues

ROOTT Dental Implant System consists of ROOTT Dental Implants and Related Superstructures, i.e. healing abutments and abutments. Dental implant is a surgical fixture that is placed into the jawbone that acts as a replacement for the root of the missing tooth. Dental implant consists of two parts - the threaded part that is intended to fuse with the bone to replace the root of the missing tooth and the upper part, i.e. dental abutment that is intended to fix the tooth crown, bridge or dentures.

ROOTT Dental abutments are produced from Titanium Alloy and PEEK plastic.

Information about medicinal substances in the device, if any

ROOTT Dental Implants and Related Superstructures do not contain any medical substances.

Description of how the device is achieving its intended mode of action

Dental Implant achieves its mode of action by fusing with the bone and replacing the tooth root. Dental abutments achieve their mode of action by enabling the fixation of required prosthesis on the implant.

Description of accessories, if any

N/A; ROOTT Dental Implants and Related Superstructures do not have any accessories.

4. Risks and warnings

Contact your healthcare professional if you believe you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

How potential risks have been controlled and managed

Any potential risks are controlled by the manufacturer by implementing and maintaining high quality risk control measures such as inherently safe design, protective measures and detailed information for safe use. Occurrence of side-effects is constantly monitored by the implemented continuous Post-market Clinical Follow-up study and close cooperation with the implantologists.

Remaining risks and undesirable effects

One hundred percent implant success cannot be guaranteed. 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.

Implant surgery, as any other surgery is an invasive procedure in which side-effects are inevitable. Side-effects are a natural response to the alterations that take place during the dental implant procedure, and are a normal result of dental implant treatment. The most common side-effects of the implant treatment are only temporary and are typically not considered severe. These include: pain, discomfort, bleeding, swelling, bruising (hematomas), phonetic difficulty, flap dehiscence, gingival inflammation. Temporary side-effects usually pass away naturally or can be easily treated. Rare but longer-term side-effects include: chronic pain in connection with the implant, nerve damage resulting in permanent

Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

paraesthesia or dysesthesia, loss of maxillary/mandibular ridge bone, oroantral or oronasal fistula, unfavourably affected adjacent teeth, fracture of the jawbone, aesthetic problems, exfoliation, hyperplasia, localized or systemic infection.

Warnings and precautions

Warnings:

- 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;
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Cautions/Precautions:

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

Treatment by means of implants may lead to loss of bone, biologic and mechanical failures, including fatigue fracture of implants.

Magnetic Resonance Imaging (MRI): TRATE considers their dental implants to be compatible to be used in MRI procedure. Due to the large variety of MRI scanners available on the market, TRATE cannot make any predictions regarding the safety or behaviour of implants and related superstructures in any specific MRI system.

Radiation therapy for patients with dental implants should be planned and prescribed with extreme caution by the health care professionals to avoid possible complications. Dentures and crowns may also be fabricated from a metal material which can be affected by MRI energy. Informing the patient about possible risks considering MRI procedure is included in the manufacturer's Instructions For Use.

Summary of any field safety corrective action, (FSCA including FSN) if applicable

N/A; The devices have not been subject to any field safety corrective actions.

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

Clinical background of the device

Dental implants have been introduced in the 1960s and are used ever since as a treatment option in dentistry. Despite the large variety of different sizes (e.g. diameter, length, shape), thread design and/or surface topography, dental implant mode of action (osseointegration, i.e. the ability to fuse with the bone), ensuring a fixture in the jaw bone, and intended purpose stayed nearly identical over the years. A similar assumption can be made for the surgical procedure for the implantation, therefore dental implants can be considered the state-of-the-art treatment for patients missing teeth. More than 50 years of proven clinical safety and performance of dental implants and related superstructures is widely available in the scientific literature.

ROOTT Dental Implant System has been on the market since 2012 and uses the same materials and similar designs as other dental implant systems available on the market.



Summary of Safety and Clinical Performance

ROOTT Dental Implant System

Dental abutments

The clinical evidence for the initial CE-marking

ROOTT Dental Implant System has well-established safety and clinical performance, which is based on the biocompatibility of used materials, established and validated cleanliness and shelf-life stability, and real-life clinical data, stating the 97.86% implant survival rate after a 5-year follow-up.

Safety

Treatment by dental implants has an evidently positive benefit-risk profile. 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. 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 Dental Abutments can be considered safe for their intended use.

The manufacturer continuously collects clinical data and information on the device safety and clinical performance by conducting an on-going Post-market clinical follow-up study. During the study, careful observation of the implant survival, short and long-term side-effects is carried out.

6. Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

General description of therapeutic alternatives

Since Dental 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 stabilize 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.



Summary of Safety and Clinical Performance
ROOTT Dental Implant System
Dental abutments

7. Suggested training for users

The devices, i.e. ROOTT Dental Implant System Dental abutments are not intended to be used and handled by the patient directly, therefore no training is required.

Nonetheless, patients must follow the recommendations and instructions provided by their healthcare professionals and maintain adequate oral hygiene.