Summary of Safety and Clinical Performance
ROOTT Dental Implant System
Healing 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 Healing 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 Healing 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,

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 - healing abutments.

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 abutments from PEEK are intended to be also adjustable.

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.

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.

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

Due to the healing 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, healing abutments are only to be used with the

products described in the Compatibility book and in accordance with the intended use 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.

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

ROOTT Related Superstructures are delivered in non-sterile conditions. All ROOTT Dental Implants and Related Superstructures are single use devices.

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

Device groups	Basic UDI-DI
Healing abutments R	76300538HabutmentRL5 76300538GFIVB
Healing abutments C/CS/B/BS	76300538HabutmentCK7
Healing abutments M/P	76300538HabutmentMKT
Healing abutments S	76300538HabutmentSL7
Healing abutments K	76300538HabutmentKKP

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.

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 specialy 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

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

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.

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, ulcera, 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 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 (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.

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.

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 mandatorily 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. No healing abutments were placed on ROOTT C/CS, ROOTT B/BS, ROOTT S, ROOTT M, ROOTT P, ROOTT K implants during the study.

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 devices are closely observed. The clinical data collected so far shows excellent clinical results. In 5 years, a cumulative survival rate of 97.86% of all ROOTT Implant types was achieved with 3271 implants and 474 healing abutments in 1108 patients, despite the fact that 41% of the patients involved in the study showed clinically increased risk factors, i.e. had contraindications. Implant survival, as a simple measure, is the ultimate long-term performance criterion. The obtained PMCF study results are in line with the clinical data available in the literature showing that ROOTT Dental Implant devices are not inferior to similar devices belonging to the generic device group available on the market.

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 Dental Implants and Related Superstructures can be considered safe for their intended use.

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?

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 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 acquitted 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.

8. Reference to any harmonised standards and CS applied

Common specification(s)

N/A

State of the art standards:

- EN 1642:2011 Dentistry - Medical devices for dentistry - Dental implants;
- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016). EN ISO 13485:2016/AC:2018;
- 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	2022-02-10	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)

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
Healing abutments

Summary of safety and clinical performance
Document revision: v1
Data issued: 2022-02-10

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 Healing 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
Healing abutments R	76300538HabutmentRL5 76300538GFIVB
Healing abutments C/CS/B/BS	76300538HabutmentCK7
Healing abutments M/P	76300538HabutmentMKT
Healing abutments S	76300538HabutmentSL7
Healing abutments K	76300538HabutmentKKP

Year when the device was first CE-marked
2012

2. Intended use of the device

Intended purpose
Dental implants are intended to replace missing or corrupted teeth,
d) that cannot be repaired, replaced or compensated by other means;
e) where other solutions have an undesired impact on sound teeth, or

f) where implants are desired for obtaining an optimal cosmetic result.

Dental Implants are assigned Related Superstructures - healing abutments.

Healing abutments are indicated for use with endosseous dental implants or implant abutments in the upper and lower jaw 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 (gums) 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.

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.

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

Dental implants and healing 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.

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

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

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. abutment that is intended to fix the tooth crown, bridge or dentures. Healing abutments are temporary fixtures intended to guide the healing and forming of the gums. After the healing stage is over, the healing abutment is replaced by the permanent abutment.

ROOTT Dental Implant healing 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. Healing abutments achieve their mode of action by guiding the healing and forming of the gums.

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 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.

The clinical evidence for the 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 Implant System can be considered safe for its 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 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 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 training for users

The devices, i.e. ROOTT Dental Implant System healing 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.