Summary of Safety and Clinical Performance

ROOTT Dental Implant System
One-piece implants (ROOTT C / CS / S / M / P / K / B / BS)

Preface

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 ROOTT Dental Implant System One-piece (ROOTT C / CS / S / M / P / K / B / BS) dental 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.

Following this information there is a summary for patients.

1. Device identification and general information

1.1.	**Device trade name(s)**	ROOTT C / CS / S / M / P / K / B / BS dental implants
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 single registration number (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 can not 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.

ROOTT Dental Implants are intended for surgical placement in the upper or lower jaw to provide anchorage for prosthetic superstructures for teeth restorations or as a terminal, intermediary abutment for fixed or removable bridgework, and to retain overdentures.

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

Indication

The medical indications for the use of a ROOTT Dental Implants 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.

Surgical protocols, position in mouth, single or multiple tooth replacement and bone type are not part of the indication of the dental implants. The choice of the right implant is incumbent to the implantologist and the manufacturer does not limit the range of indications for specific implant types, unless contraindications are met.

Patient population

There is no convincing evidence to suggest that age or gender affect the outcome of osseointegration in the short or the long term. This is somewhat a surprising finding, given that, a sudden decline in bone volume and bone mass occurs as a result of ageing and particularly in postmenopausal women.

Dental implants are effectively ankylosed to the bone, for this reason implants are not placed until the facial skeleton has stopped growing; this being usually about 18 years of age. If this rule is not observed, integrated implants could soon become “submerged” similar to retained deciduous teeth as the permanent dentition continues to erupt.

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.

Limitations are provided in the table below.

Device	Limitations
ROOTT C	Can be used with caution to create single restorations in situations where good primary stability is achieved on placement (35 Ncm). For cement-retained restoration only.
ROOTT CS	Abutment direction cannot be adjusted. Can be used with caution to create single restorations in situations where good primary stability is achieved on placement (35 N/cm). For cement-retained restoration only
ROOTT M	For screw-retained restoration only. For multiple restorations only.
ROOTT P	For placement in pterygoid area only. For screw-retained restoration only. For multiple restorations only.
ROOTT S	For placement in a narrow ridge area only. For multiple restorations only. For screw-retained restoration only.
ROOTT K	For conometric restoration only. Abutment direction cannot be adjusted for implants with diameter 5.0 mm, 5.5 mm, 6.5 mm, 7.5 mm, 8.5 mm. Not for use in red-white aesthetic zones.
ROOTT B/BS	Bicortical engagement shall be achieved in case of placement of ROOTT B implants. For multiple restorations only. For cement-retained and telescopic restorations only.

3. Device description

3.1. Description of the device

ROOTT Dental Implant System is a system of endosseous dental implants with corresponding abutments, healing abutments, covering and fixing screws, other prosthetic parts and surgical instruments.

ROOTT C / CS / S / M / P / K / B / BS Dental Implants can be used for single and multiple restorations with immediate loading in the upper and lower jaws in all types of bone tissue. Implants can be placed by flap or flapless approach with subcrestal and crestal level. Implant placement is also possible immediately following tooth extraction, if sufficient bone tissue is available.

ROOTT C / CS / S / M / P / B / BS Dental Implants are made from Titanium Alloy (Ti 6-Al 4-V ELI) and ROOTT K Dental implants are made of Commercially Pure Titanium (Titanium Grade 4). All ROOTT implants are delivered in a sterile package with a multifunctional carrier and a two-component holder. Secondary package has peel-off stickers for clinical documentation.

ROOTT Dental Implants are single use medical devices, can only be used in sterile conditions and are not intended to be resterilized.

To the ROOTT Dental implants are assigned Related Superstructures - healing abutments and abutments.

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

Device group	Basic UDI-DI
ROOTT C	76300538ROOTTCSZ
ROOTT CS	76300538ROOTTCS2J
ROOTT B	76300538ROOTTBSX
ROOTT BS	76300538ROOTTBS2F
ROOTT M	76300538ROOTTMTM
ROOTT P	76300538ROOTTPTT
ROOTT S	76300538ROOTTSTZ
ROOTT K	76300538ROOTTKTH

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

ROOTT C / CS / S / M / P / K / B / BS Dental Implants 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 the 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 C / CS / S / M / P / K / B / BS Dental Implants 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 Implant system consists of other medical devices intended to be used in combination with it that are not covered by this report, such as:

- Healing abutments, dental abutments;
- Related Superstructures, class I medical devices (transfers, implant analogs, scan posts and burn out parts);

- Associated instruments (Implant drills and instruments for handpiece, reusable surgical instruments 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

Immediately after the insertion of a dental implant, activities that demand considerable physical exertion should be avoided. Possible complications following the insertion of dental implants are temporary symptoms: pain, swelling, phonetic difficulty and gingival inflammation.

More persistent symptoms: chronic pain in connection with implants, permanent paraesthesia, dysesthesia, loss of maxillary / mandibular ridge bone, localized or systemic infection, oroantral or oronasal fistula, unfavourably affected adjacent teeth, fracture of implant, jaw, bone or prosthesis, aesthetic problems, nerve damage, exfoliation, hyperplasia.

4.2. Warnings and precautions

Warnings

Do not use a device if the primary package has been damaged or previously opened. Do not resterilize ROOTT Dental Implants. 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

Do not use ROOTT Dental Implants after the expiry date indicated on the packaging.

Do not reuse ROOTT Dental Implants. Do not reprocess implants. Reprocessing may cause infection and implant failure.

Sterile handling is essential. Never use potentially contaminated components. Contamination may lead to infection.

Avoid any contact of the implant with foreign substances prior to their use. Do not touch the endoseal part of the implant.

ROOTT Dental implants are delivered in a sterile package with two-component plastic holders. The holder is only for handing the implant inside the blister. The plastic implant holder is not intended to be used as an implant driver. It is prohibited to apply torque to the plastic implant holder to screw in the implant. Only the designated instruments may be used for implant insertion. If implants are not assembled any more with a holder and just moving into the blister, DO NOT USE this implant because the surface is already contaminated by plastic particles. Contact local representative of TRATE AG for exchange via web page: www.trate.com

Do not exceed recommended insertion torque (see section “Insertion of the implant”), as it might

cause bone necrosis or system components fracture.

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).

Beside the mandatory precautions for any surgery such as asepsis, during drilling in the jaw bone, one must avoid damage to the nerves and vessels by referring to anatomical knowledge and preoperative medical imaging (e.g. radiographs).

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.

Do not use damaged or blunt instruments for implantation.

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

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.

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

Radiation therapy for patients with dental implants should be planned and prescribed with extreme caution by the health care professionals to avoid possible complications. Thus, informing the patient about possible risks considering radiation therapy after implant treatment.

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 2618 ROOTT C / CS / S / M / P / K / B / BS implants were placed in a total of 857 patients (320 male/537 female; mean age 56.5 years (range 18-93)) in the period from 2013 to 2018. Average number of implants placed in one patient: 1-6 (max. 18). 1576 ROOTT C / CS / B / BS implants passed a 5-year follow-up. The remaining 1042 ROOTT M / S / P / K implants passed a 3-year follow-up.

The collected data so far showed excellent clinical results - a cumulative survival rate of ROOTT C / CS / S / M / P / K / B / BS Implants is 98.17%. All individual ROOTT Implant type success rate is above 95%; the highest success rate was achieved with the ROOTT M implants - 99.2%, the lowest success rate was of ROOTT B/BS implants - 95.5%. Only 9.3% of all patients experienced early postoperative complications that were temporary and are not considered severe, including mild ones, such as pain after the surgery. No serious adverse events, such as implant rupture, breaking or other mechanical failure has been observed during the years of the follow-up, and none of the patients experienced unanticipated or unexpected side-effects.

	ROOTT B/BS	ROOTT C/CS	ROOTT M	ROOTT S	ROOTT P	ROOTT K	Total
Patients (M/F)	301 (105/196)	251 (88/163)	55 (22/33)	100 (43/57)	50 (24/26)	100 (38/62)	857
Mean age, years	55	52	60	51	62	59	56.5
Implants	645	931	253	424	80	285	2618
Survival rate	95.48%	98.24%	99.21%	98.77%	98.75%	98.59%	98.17%

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 98.17% of ROOTT C / CS / S / M / P / K / B / BS implants was achieved with 2618 implants in 857 patients, despite the fact that 370 patients (43.2%) had contraindications.

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, implant survival rate data can be considered as the main implant 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 superstructure 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 implants are mainly related to complication rates (side-effects) and risks associated with implant loading procedures. The non-occurrence of severe side-effects is an indicator for the clinical safety of the implants. Since no severe side-effects were reported during the years of the PMCF study follow-up, ROOTT C / CS / S / M / P / K / B / BS Implants can be considered of the highest clinical safety. The only registered side-effects after the implant treatment procedure experienced by the patient population (857 patients) were temporary and not severe, including pain (4.9%), infection (2.1%), alveolar ridge height (0.35%), failure to maintain oral hygiene (1.52%), paresthesia (0.47%). Significantly low rates of infections - only 2.1% of patients - is a confirmation that the implant 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 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

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:

a) 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.
b) Prosthesis without anchorage: this type of 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.
c) 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.
d) Crowns / Bridges: intact teeth are required in proximity of the edentulous site.
e) 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, as well as 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 Common Specifications (SC) applied

Common specification(s)

N/A

Harmonized standard(s) under MDR

- EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013). EN ISO 11137-1:2015/A2:2019;
- 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 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices. EN 556-1:2001/AC:2006;
- EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013);
- EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006);

- EN ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006).

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1	2022-02-21	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
One-piece implants (ROOTT C / CS / S / M / P / K / B / BS)

Summary of safety and clinical performance

Document revision: v1
Data issued: 2022-02-21

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 or 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 One-piece (ROOTT C / CS / S / M / P / K / B / BS) Implants

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 the device group is provided in the table below.

Device groups	Basic UDI-DI
ROOTT C	76300538ROOTTCSZ
ROOTT CS	76300538ROOTTCS2J
ROOTT B	76300538ROOTTBSX
ROOTT BS	76300538ROOTTBS2F
ROOTT M	76300538ROOTTMTM
ROOTT P	76300538ROOTTPTT
ROOTT S	76300538ROOTTSTZ
ROOTT K	76300538ROOTTKTH

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:

- that can not 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.

ROOTT Dental Implants are intended for surgical placement in the upper or lower jaw to provide anchorage for prosthetic superstructures for teeth restorations or as a terminal, intermediary abutment for fixed or removable bridgework, and to retain overdentures.

Indications and intended patient groups

The medical indications for the use of a ROOTT Dental Implants 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.

ROOTT C / CS / S / M / P / K / B / BS dental implants 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.

3. Device description

Device description and material/substances in contact with patient tissues

ROOTT C / CS / S / M / P / K / B / BS 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. ROOTT C / CS / S / M / P / B / BS implants are made of titanium alloy; ROOTT K implants are made from titanium.

Information about medicinal substances in the device, if any
ROOTT Dental Implants 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.

Description of accessories, if any
N/A; ROOTT C / CS / S / M / P / K / B / BS Dental Implants 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 properties, 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 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 98.17% implant survival rate of ROOTT C / CS / S / M / P / K / B / BS dental implants after a 5-year patient 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 of the implant treatment outweigh the residual risks by far. Additional risk control measures are not applicable and the medical device, i.e. ROOTT C / CS / S / M / P / K / B / BS Dental Implants 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

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 C / CS / S / M / P / K / B / BS Dental Implants 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.