



Summary of Safety and Clinical Performance

ROOTT Dental Implant System

One-piece implants (ROOTT S)

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 S) 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.

1. Device identification and general information

1.1.	Device trade name(s)	ROOTT S dental implants
1.2.	Manufacturer's name and address	Name: TRATE AG Address: Bahnhofstrasse 16, 6037 Root, Switzerland Homepage: https://www.trate.com
1.3.	Manufacturer's single registration number (SRN)	SRN: CH-MF-000019071
1.4.	Basic UDI-DI	76300538ROOTTSTZ
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	2017
1.8.	Authorised representative if applicable; name and the SRN	Name: TRATE UAB Address: Kauno m. sav. Kauno m. Jonavos g. 254 Kaunas, 44110, Lithuania SRN: LT-AR-000002509
1.9.	Notified Bodies (NB) name (the NB that will validate the SSCP) and the NB's single identification number	BSI Group The Netherlands B.V. (2797)

2. Intended use of the device

2.1. Intended purpose

- 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

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- 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 stabilise the disease first, an unbalanced relationship

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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.

Limitations are provided in the table below.

Device	Limitations
ROOTT S	For placement in a narrow ridge area only. For multiple restorations only. For screw-retained restoration 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 S is a one-piece tissue-level dental implant with compressive threads with a narrow head of abutment (Ø 4.0 mm). It is used for multiple restorations with immediate or delayed loading in the upper and lower jaws with adequate bone tissue. Implants can be placed by flap or flapless approach with subcrestal position of the implants. Implant placement is also possible immediately following tooth extraction, if sufficient bone tissue is available. It can be used in combination with ROOTT M / P implants. Abutment of implants designed just for screw-retained prosthesis in aesthetically important areas (anterior teeth) and narrow ridge area.

ROOTT S Dental Implants are made from titanium alloy (Ti 6-Al 4-V ELI) and are delivered in a sterile package with 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.

ROOTT S implants are available in different size configurations (diameter and length):


Material: Titanium alloy
REF: Cxxxxms, where is C - compressive type of implant; xxxx - dimensions (diameter and length of implant), ms - subtype of implant
Models: C3008ms, C3010ms, C3012ms, C3014ms, C3016ms, C3506ms, C3508ms, C3510ms,

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C3512ms, C3514ms, C3516ms

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

ROOTT S 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 S 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.

Inappropriate use of the products leads to badly executed work and increased risks.

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 haemorrhage in the floor of the mouth.

Reuse of single-use devices increases risk of contamination, cross-contamination and the whole implantation failure.

Treatment by means of implants may lead to loss of bone, biologic and mechanical failures, including fatigue fracture of implants. Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.



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Mechanical failure could occur in case of torque force violated, the device is used in unintended way or with not ROOTT system instruments.

If the treatment is performed to the contraindicated patient, the failure of the whole implantation is possible. In case, if implantation was performed in conditions of absolute contraindications, the manufacturer does not accept any warranty requirements.

Occurrence of temporary discomfort after the invasive treatment such as typical side effects are common.

The risk of swallowed or aspirated small devices by patients is possible. Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield).

Infection can inhibit implant osseointegration and lead to implant failure, however it can be avoided if sterility is assured during the whole implant surgery and if proper maintenance, medication and oral hygiene is taken upon after the 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, localised or systemic infection, oroantral or oronasal fistula, unfavourably affected adjacent teeth, fracture of implant, jaw, bone or prosthesis, aesthetic problems, nerve damage, exfoliation, hyperplasia.

Probability of occurrence of residual risks

Probability to experience residual risks depends on many factors, including patients health, surgery planning etc. and can be extremely increased in case of violation of the instructions. The typical side effects are probable and common, while more persistent and undesirable side effects are rare. Only 9.5% of all patients in the PMCF study experienced early postoperative complications and recorded such side-effects as infection, loss of ridge bone, and paraesthesia. No adverse events have been observed and reported during the 5-year follow-up of the PMCF study. For people with no contraindications implantation success is excellent. Thus close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.

Lifetime

The proven lifetime of the sterile package is 5 years.

The proven lifetime of the implant is not less than 7 years in accordance with available own clinical data. Reduction of the lifetime could happen depending on clinical conditions where implant does not have influence on it - the occurrence of conditions determined as contraindications during the life of the patient after the placement of dental implants (severe bone resorption around the implant, mechanical fracture of the implant body, strong chemotherapy, poor oral hygiene, severe periodontal diseases).

Successfully osseointegrated dental implant is a long-term, permanent teeth replacement, which is expected to perform as intended during the lifetime of the patient if proper oral hygiene and regular check-ups are maintained.

In case if there is no occurrence of conditions determined as contraindications TRATE AG highly recommends not to explant the implant after 5 years and it is preferable to make prolongation of the implant lifetime based on the clinical observation results.



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Based on information provided in the scientific literature, the expected lifetime for ROOTT dental implants is 30 years.

4.2. Warnings and precautions

Warnings

Implants ROOTT M / P / S shall be used for multiple restorations only.

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, 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 haemorrhage 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



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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.

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

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

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

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

Depending on the details of the study and the materials used, the typical implant survival rate after 5 years is determined to be over 95.6 %. The survival rate over 95% after 5 years is an excellent result and an indication that implant-supported restorations are an excellent treatment modality. While complications are mainly infections, the rates average around 10 % of the implants and 20 % of the patients. Given these results, the extent for improving either the materials or the clinical procedures is limited. For this reason, the two well-established titanium alloys continue to be used for the overwhelming majority of implants used in dentistry, and this use seems likely to continue for the foreseeable future. The results in the reviewed studies are comparable and show similar tendencies, thus titanium dental implants, regardless of the implant



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material, design, surgical procedure and/or patient characteristics and potential complications, can be described as having predictable outcomes.

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

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

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 424 ROOTT S implants were placed in a total of 100 patients (43 male/57 female; mean age 51 years (range 27-81)) during the period of 2017-2018. Average number of implants placed in one patient: 1-4 (max. 16). All 424 ROOTT S implants passed a 3-year follow-up.

The collected data so far showed excellent clinical results - a cumulative survival rate of ROOTT S Implants is 98.77%. After the implantation only 1 patient had an infection (1%) and 1 patient failed to maintain oral hygiene (1%). No adverse events, unanticipated side-effects or complications have been reported during the study.

5.4. An 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 3 years, a cumulative survival rate of 98.77% of ROOTT S implants was achieved with 424 implants in 100 patients, despite the fact that 39 patients (39.0%) 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



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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 S Implants can be considered of the highest clinical safety. The only registered side-effects after the implant treatment procedure experienced by the patient population (100 patients) were temporary and not severe, including infection (1%) and failure to maintain oral hygiene (1%). Significantly low rates of infections - only 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

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

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

1. What is the cumulative survival rate of all implants?
2. What is the cumulative survival rate of each implant type (ROOTT R, ROOTT B, ROOTT C)? Is there a statistically significant difference between the survival rates of the implant types?
3. What is the distribution of early stage complications?
4. What is the impact of immediate vs. delayed loading on the success of the treatment (applicable only to ROOTT R implants)?
5. Is there a statistically significant difference in implant failure of single tooth implants vs. multiple tooth replacements?
6. Is there a statistically significant difference in implant failure between implantation in the upper and lower jaw?

The PMCF Evaluation Report has been prepared after collecting 5-year follow-up data. Overall 3271 implants were included in the study. Such sample size is considered adequate to sufficiently describe a

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wide-range context and prevailing global tendencies. 3271 ROOTT Implants were placed in 1108 patients by 10 different experienced implantologists. To achieve a heterogeneous patient population, implants were placed in the following countries: France, Luxemburg, Spain, Hungary, Slovakia, Greece, Lithuania, Russia, India, and Israel.

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

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 stabilise 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

For use only by dental professionals within the dental clinic. Recommended that clinicians, new as well as experienced users, always go through special training before using a new product or treatment method. TRATE offers a wide range of different courses. For more information, please visit www.trate.com

8. Reference to any harmonised standards and Common Specifications (SC) applied

Common specification(s)

N/A



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Harmonised 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; harmonized 2020 03 24, A1:2021 (amendment)
- EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018). EN ISO 11737-1:2018/A1:2021;
- EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilisation process (ISO 11737-2:2019);
- 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;
- EN ISO 14971:2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021.

State of the art standards:

- EN 1642:2011 Dentistry - Medical devices for dentistry - Dental implants;
- EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018);
- EN 556-1:2024 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; Amd 1:2023
- EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems; Amendment A11:2022 + Amd 1:2023
- EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes; Amendment A11:2022+Amd 1:2023
- ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer.



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9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1	2022-03-21	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)
2	2022-04-04	Section 8 was managed to be in compliance with the list of applicable regulatory requirements	<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)
3	2022-12-05	Section 1.2 updated: Manufacturer address changed. Section 8 updated	<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)
4	2023-08-08	Minor changes made to the text	<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)
5	2024-10-07	Content have been reviewed: - updated State of the art standards and Harmonised standard(s) under MDR to the section 8;	X Yes (T0074241/ 30319186) Validation language: English <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)
Revision	2025-03-21	In section 1 updated format of address for Authorised representative according the certificate and EUDAMED; In section 9 updated latest validation by NB and added validation language: English	-