Summary of Safety and Clinical Performance
ROOTT Dental Implant System
Healing abutments N-Line (Regular)

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 N-Line (Regular).

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

The following information is intended for users/healthcare professionals.

1. Device identification and general information

1.1.	**Device trade name(s)**	**Healing abutments N-Line:** Regular (REF: NGFMx, x - height)
1.2.	**Manufacturer's name and address**	Name: **ROOTT AG** Address: Bahnhofstrasse 16, 6037 Root, Switzerland Homepage: https://www.trate.com
1.3.	**Manufacturer's Actor ID/SRN**	**SRN:** CH-MF-000019071
1.4.	**Basic UDI-DI**	76300538NLinehealingabuH2
1.5.	**Medical device nomenclature description / text**	P010201, category "DENTAL IMPLANTS AND ACCESSORIES"
1.6.	**Class of device**	IIb
1.7.	**Year when the first certificate (CE) was issued covering the device (available on the EU market)**	2026
1.8.	**Authorised representative if applicable; name and the SRN**	Name: **ROOTT UAB** Address: Kauno m. sav. Kauno m. Jonavos g. 254 Kaunas, 44110, Lithuania **SRN:** LT-AR-000002509
1.9.	**Notified Bodies (NB) name (the NB that will validate the SSCP) and the NB's single identification number**	BSI Group The Netherlands B.V. (2797)

2. Intended use of the device

2.1. Intended purpose

ROOTT Healing abutments are available as a one-piece or a two-piece temporary abutments with intended purpose to protect inner configuration of the implant from contamination by soft tissues and form the soft tissues during the healing process.

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

Indication

Healing abutments are indicated for use with endosseous dental implants or implant abutments in the maxilla or mandible for supporting single tooth or full arch denture procedures.

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Healing abutment is screwed onto the top of the implant during surgical procedure to guide the healing of soft tissue to replicate the contours and dimensions of the natural tooth that is being replaced by the implant and to ensure access to the implant restorative platforms for impression and definitive abutment placement.

Patient population

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

2.3. Contraindications and/or limitations

Healing abutments are only used if dental implants are placed, so all contraindications that prohibit the use of dental implants prohibit the use of the healing abutments as well. The contraindications of the healing abutments are always connected to that of the dental implants.

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

Absolute contraindications: myocardial infarction (within six months of an attack), cerebral infarction and cerebral apoplexy (in cases where the condition of the disease is serious and the patient is concurrently taking anticoagulants), severe immunodeficiency, patients who are undergoing strong chemotherapy, severe neuropsychiatric disease, mental disability, patients who are concurrently taking bisphosphonates, youths under the age of 18, allergies or hypersensitivities to chemical ingredients of material used (Titanium and its alloy, TiN coating).

Relative contraindications: diabetes (particularly insulin-dependent), angina pectoris (angina), seropositivity (absolute contraindication for clinical AIDS), significant consumption of tobacco, certain mental diseases, radiotherapy to the neck or face (depending on the zone, the quantity of radiation, localization of the cancerous lesion etc.), certain auto-immunes diseases, drug / narcotic / alcohol dependency, pregnancy, certain diseases of the mucous membranes of the mouth, bruxism, periodontal diseases (loosening of the teeth); it is necessary to clean up the gums and stabilize the disease first, an unbalanced relationship between the upper and lower teeth, poor hygiene of the mouth and teeth, an insufficient quantity of bone, infections in the neighboring teeth (pockets, cysts, granulomas), major sinusitis.

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

Limitations

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

3.1. Description of the device

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

Healing abutment is fixed onto the top of the implant during surgical procedure to guide the healing of soft tissue to replicate the contours and dimensions of the natural tooth that is being replaced by the implant and to ensure access to the implant restorative platforms for impression and definitive abutment placement.

N-Line Regular healing abutments for ROOTT M / P Implants are produced from titanium alloy (Ti 6-Al 4-V ELI Grade 23).

N-Line Regular healing abutments for ROOTT M / P Implants are delivered in non-sterile conditions. All ROOTT Dental Implants and Related Superstructures are single use devices.

Healing abutment is screwed onto the top of the implant during surgical procedure to guide the healing of soft tissue to replicate the contours and dimensions of the natural tooth that is being replaced by the implant and to ensure access to the implant restorative platforms for impression and definitive abutment placement.

N-Line Regular healing abutments for ROOTT M / P Implants are available in different size:

	Regular
	Material: Titanium Alloy
	REF: NGFMx (x - height)

	Models: NGFM0, NGFM2, NGFM4
	Range of applications: Shall be used to guide the healing of the soft tissues with sufficient space between placed implants with multi-unit

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

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

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

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

N-Line Regular Healing abutments for ROOTT M / P 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

N-Line Regular healing abutments are intended to be used with ROOTT M / P dental implants.

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

4. Risks and warnings

4.1. Residual risks and undesirable side-effects

Residual risks

Healing abutments and dental abutments are an integral part of the dental implant means treatment of implant, so residual risks are directly related to the dental implant and the whole implantation success.

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

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

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

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

Mechanical failure could occur in case of torque force violated, the device is used in an unintended way or with no ROOTT system instruments.

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

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

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

Inappropriate cleaning, disinfection and sterilisation procedures before the first use of dental superstructures can lead to whole implantation failure.

Infection can inhibit implant osseointegration and lead to implant failure, however it can be avoided if sterility is maintained and assured during the whole implant surgery and if proper maintenance, medication and oral hygiene is taken upon after the treatment.

Side effects

The placement of these devices is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain and swelling. During abutment placement or removal the pharyngeal reflex (gag reflex) may be triggered in patients with a sensitive gag reflex.

Healing abutments are part of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to these associated with teeth, such as retained cement, calculus, mucositis, ulcers, soft tissue hyperplasia, soft and / or hard tissues recessions. Some patients may experience discoloration in the mucosal area such as graying.

Probability of occurrence of residual risks

Probability to experience residual risks depends on many factors, including patients health, surgery planning, etc. and can be extremely increased in case of violation of the instructions. The typical side effects are probable and common, while more persistent and undesirable side effects are rare. Only 9.5% of all patients in the PMCF study experienced early postoperative complications and recorded such side-effects as pain, infection, loss of ridge bone, and paraesthesia.

Lifetime

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

Warnings

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

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

Cautions/Precautions

It is recommended that ROOTT Dental implants are used only with dedicated surgical instruments and prosthetic components, as violation of this recommendation may lead to mechanical instrumental failure or unsatisfactory treatment results.

Never exceed recommended tightening torque for the screw. Overtightening of abutment may lead to a screw fracture.

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

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

ROOTT Dental Implant System must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use devices in accordance with these instructions and determine if the device fits the individual patient situation.

Special attention has to be given to patients who have localised or systemic factors that could interfere with the healing process of bone, or soft tissue, or the osseointegration process (e.g. smoking, poor oral hygiene, uncontrolled diabetes, facial radiotherapy, infections in neighbourhood tooth or bone, patients passed bisphosphonate therapy).

Preoperative hard tissue and soft tissue deficit may yield a compromised aesthetic result.

All components, instruments and tooling used during the clinical and laboratory procedures must be

maintained in good conditions and care must be taken that instrumentation does not damage implants or other components.

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

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

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

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

The N-line is restorative platform represents a widely established prosthetic platform for Multi-Unit Abutments and is used by several internationally recognized dental implant manufacturers such as Nobel Biocare (the classic Multi-Unit concept), Zimmer Biomet, Implant Direct, Straumann, MegaGen, Alpha-Bio Tec. Various compatible prosthetic manufacturers, including DESS and Osteon Medical, supply a standardized Multi-Unit platform for several implant connections, such as Nobel, Straumann Bone Level, Astra Tech, Zimmer, MIS and others.

It enables standardization of the restorative workflow across different implant-level connections. The abutment-to-prosthesis restorative platform is standardized at Ø4.8 mm. The submitted design follows the same general clinical and technological concept and is recognized as WET (Well-established technology).

The modern Multi-Unit restorative platform has been known and clinically used for approximately 25–26 years (design dates from approximately 2000).

The manufacturer has established and is actively conducting its own Post-Market Clinical Follow-up (PMCF) studies to generate direct clinical evidence. These ongoing investigations are designed to confirm the long-term safety and performance of the devices within real-world clinical use.

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

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

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

foreseeable future. The results in the reviewed studies are comparable and show similar tendencies, thus titanium dental implants, regardless of the implant material, design, surgical procedure and/or patient characteristics and potential complications, can be described as having predictable outcomes.

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

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

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

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

Healing abutments are usually used on two-piece implants with delayed loading protocol. One-piece implants, however, are usually implanted with immediate loading indicating that the prosthesis is provided immediately after implant placement. This means that no healing abutments are used and the intended purpose of the healing abutments is fulfilled by the dental abutments or the crown itself. The decision whether to use a healing abutment or not solely depends on the implantologist treatment plan and specific patient case.

5.4. An overall summary of the clinical performance and safety

At the time of preparation of this SSCP, no device-specific clinical data from post-market clinical follow-up (PMCF) studies are yet available for the N-line abutments. A PMCF Plan has been established, and appropriate PMCF activities are planned to prospectively collect and evaluate clinical data relating to the safety, clinical performance and long-term performance of the devices under routine conditions of use. The results will be assessed as they become available and incorporated into the Clinical Evaluation Report, PMCF Evaluation Report and future updates of this SSCP.

The current evaluation of clinical performance and safety is based on the classification of the underlying design concept as well-established technology (WET). The N-line incorporates a Ø4.8 mm and Ø3.5 mm abutment-to-prosthesis restorative platforms corresponding to the widely established Multi-Unit Abutment concept. This restorative platform has been used clinically for approximately 25–26 years, with its introduction dating to around 2000.

This Multi-Unit restorative platform is used by several internationally recognised dental implant manufacturers, including Nobel Biocare, Zimmer Biomet, Implant Direct, Straumann, MegaGen and Alpha-Bio Tec. Compatible prosthetic components based on the same general platform concept are also supplied by manufacturers such as DESS and Osteon Medical for various implant-level connections, including Nobel Biocare, Straumann Bone Level, Astra Tech, Zimmer and MIS systems.

The standardised restorative interface enables the use of an established prosthetic workflow across different implant-level connections. The N-line follows the same general clinical, functional and technological principles as this widely used restorative concept. Therefore, pending the availability of device-specific PMCF results, the assessment of its clinical performance and safety relies on the available clinical and scientific evidence concerning the well-established Multi-Unit restorative platform, together with applicable verification and validation data, risk-management documentation, post-market surveillance information and the overall clinical evaluation.

Based on the evidence currently available, no new or device-specific safety concerns have been identified, and the anticipated clinical performance and safety profile of the N-line is considered consistent with the established state of the art for Multi-Unit Abutment systems. This conclusion will be continuously reviewed and confirmed through the planned PMCF activities and ongoing post-market surveillance.

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

A PMCF Plan has been established, and appropriate PMCF activities are planned to prospectively collect and evaluate clinical data relating to the safety, clinical performance and long-term performance of the devices under

routine conditions of use. The results will be assessed as they become available and incorporated into the Clinical Evaluation Report, PMCF Evaluation Report and future updates of this SSCP.

Primary endpoints of the PMCF study.

The primary objective of the PMCF study is to confirm the clinical safety and performance of the N-line Multi-Unit Abutment system when used according to its intended purpose and instructions for use by determining the clinical success rate of the N-line abutments 12 months after definitive prosthetic loading

1. N-line clinical success at 12 months:

Proportion of N-line abutments remaining in functional use 12 months after definitive prosthetic loading without:

- fracture or permanent deformation of the abutment;
- abutment or prosthetic screw fracture;
- recurrent screw loosening requiring replacement or unscheduled clinical intervention;
- loss of prosthetic function attributable to the N-line component;
- serious adverse device effect attributable to the N-line.

2. N-line abutment survival at 12 months:

- Removal or replacement of the abutment for any N-line-related reason should be considered a failure.

Secondary endpoints of the PMCF study.

The secondary objectives are to determine the incidence of device-related adverse events, device deficiencies and mechanical or prosthetic complications

Endpoint	Objective
Prosthetic restoration survival	Restoration remains functional without complete replacement
Prosthetic complications	Chipping, framework fracture, loss of retention or other restoration complications
Seating and connection problems	Incomplete seating, connection mismatch or inability to achieve the intended position

6. Possible diagnostic or therapeutic alternatives

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

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

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

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

7. Suggested profile and training for users

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

8. Reference to any harmonised standards and CS applied

Common specification(s)

Not applied

Harmonised standard(s) under MDR

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

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

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

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

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

State of the art standard(s)

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

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

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1	2026-09-11	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)