

TRATE	Technical Documentation	Instruction	Version 3
	Subject: Instruction for use for abutments and gingiva formers for Dental Implant System ROOTT		
Developed by:	Director of Quality V. Shulezhko	Approved by:	Member S. Shulezhka 2019-04-19

**Instruction for use
Dental Implant System ROOTT
Abutments and Gingiva formers**

Description

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

Gingiva former 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 natural tooth that is being replaced by implant and to ensure access to the implant restorative platforms for impression and definitive abutment placement.

Dental Abutment are connecting element between the dental implant and the crown, they are connectors, placed on, or built into, the top of the implants to be able to fix the crown.

User specification for Gingiva Formers

Medical indications

ROOTT Gingiva formers are intended to use with ROOTT Dental Implants to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.

Intended Use / Intended Function

Intended to guide the healing of soft tissue to replicate the contours and dimensions of natural tooth that is being replaced by implant and to ensure access to the implant restorative platforms for impression and definitive abutment placement in different clinical cases (with sufficient space between placed implants, with insufficient space between placed implants, for anterior teeth, for premolar teeth in narrow and large ridge, for molar teeth with squared and elongated shape in narrow and large ridge)

Range of applications of gingiva formers

Anatomical gingiva formers, regular, shall be used to guide the healing of the soft tissues with sufficient space between placed implants

Anatomical gingiva formers, narrow, shall be used to guide the healing of the soft tissues where insufficient space to place an anatomical abutment and in cases with narrow ridge and in aesthetically important area

Gingiva formers for regular multi-unit abutments, regular, shall be used to guide the healing of the soft tissues with sufficient space between placed implants with regular multi-unit

Gingiva formers for regular multi-unit abutments, narrow, shall be used to guide the healing of the soft tissues with sufficient space between placed implants with regular multi-unit where insufficient space to place an anatomical abutment and in cases with narrow ridge and in aesthetically important area

Gingiva formers for small multi-unit abutments, regular, shall be used to guide the healing of the soft tissues with sufficient space between placed implants with small multi-unit

Gingiva formers for small multi-unit abutments, narrow, shall be used to guide the healing of the soft tissues with sufficient space between placed implants with small multi-unit where insufficient space to place an anatomical abutment and in cases with narrow ridge and in aesthetically important area

Gingiva formers for anterior teeth, small, shall be used to guide the healing of the soft tissues when implants placed to anterior teeth in case of narrow ridge

Gingiva formers for anterior teeth, medium, shall be used to guide the healing of the soft tissues when implants placed to anterior teeth in case when small or large gingiva formers cannot be placed

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Gingiva formers for anterior teeth, large, shall be used to guide the healing of the soft tissues when implants placed to anterior teeth in case of large ridge

Gingiva formers for premolar teeth, small, shall be used to guide the healing of the soft tissues when implants placed to premolar in case of narrow ridge

Gingiva formers for premolar teeth, medium, shall be used to guide the healing of the soft tissues when implants placed to premolar in case when small or large gingiva formers cannot be placed

Gingiva formers for premolar teeth, large, shall be used to guide the healing of the soft tissues when implants placed to premolar in case of large ridge

Gingiva formers for squared shape molar teeth, small, shall be used to guide the healing of the soft tissues when implants placed to molar teeth with squared shape in case of narrow ridge

Gingiva formers for squared shape molar teeth, medium, shall be used to guide the healing of the soft tissues when implants placed to molar teeth with squared shape in case when small or large gingiva formers cannot be placed

Gingiva formers for squared shape molar teeth, large, shall be used to guide the healing of the soft tissues when implants placed to molar teeth with squared shape in case of large ridge

Gingiva formers for elongated shape molar teeth, small, shall be used to guide the healing of the soft tissues when implants placed to molar teeth with elongated shape in case of narrow ridge

Gingiva formers for elongated shape molar teeth, medium, shall be used to guide the healing of the soft tissues when implants placed to molar teeth with elongated shape in case when small or large gingiva formers cannot be placed

Gingiva formers for elongated shape molar teeth, large, shall be used to guide the healing of the soft tissues when implants placed to molar teeth with elongated shape in case of large ridge

Gingiva formers, individual, shall be used to guide the healing of the soft tissues when required individual creation of the form of gingiva former depend on gingiva

User specification for abutments

Medical indications

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

Intended Use / Intended Function

Dental Abutment are connecting element between the dental implant and the crown, they are connectors, placed on, or built into, the top of the implants to be able to fix the crown.

Range of applications of abutments

Anatomical abutments for regular prosthesis, straight, shall be used to create cement-retained restoration with sufficient space between placed implants

Anatomical abutments for regular prosthesis, angled, shall be used to create cement-retained restoration with sufficient space between placed implants in cases where implants are placed not in parallel to improve implant angulation

Anatomical abutments for regular prosthesis, narrow, shall be used to create cement-retained restoration where insufficient space to place an anatomical abutment and in cases with narrow ridge and in aesthetically important area

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Multi-unit abutments, regular straight, shall be used to create screw-retained restorations

Multi-unit abutments, regular angled, shall be used to create screw-retained restorations in cases where implants are placed not in parallel to improve implant angulation

Multi-unit abutments, small straight, shall be used to create screw-retained restorations in cases with narrow ridge and in aesthetically important area

Anatomical abutments for conometric prosthesis, straight, shall be used to create single and multiple conditionally removable denture

Anatomical abutments for conometric prosthesis, angled, shall be used to create single and multiple conditionally removable denture in cases where implants are placed not in parallel to improve implant angulation

Transgingival abutments, with transfer function, shall be used to create single cement-retained restorations with adjustable height only

Transgingival abutments, without transfer function, shall be used to create single cement-retained restorations with adjustable height only and provide possibility to take impression directly from the abutment

Attachments, Shall be used for fixation of removable overdentures supported by the implants

Castable custom abutment, from titanium, shall be used for creation of screw-retained single crown based on individually taken impression

Castable custom abutment, from PEEK, shall be used for creation of screw-retained single crown in aesthetically important area based on individually taken impression

Abutment for restoration with digital workflow, standard, shall be used to create screw-retained and cement-retained restorations in cases where required fabrication of individual abutments

Abutment for restoration with digital workflow, for Sirona CAD-CAM, shall be used to create screw-retained and cement-retained restorations in cases where required fabrication of individual abutments on Sirona CAD-CAM machine

Titanium caps, regular, shall be used to create single and multiple conditionally removable denture

Titanium caps, short, shall be used to create single and multiple conditionally removable denture in cases where insufficient space to place regular cap

Titanium caps, extra short, shall be used to create single and multiple conditionally removable denture in cases where insufficient space to place regular and short cap

PEEK caps, regular, shall be used to create single and multiple conditionally removable denture in aesthetically important area

PEEK caps, short, shall be used to create single and multiple conditionally removable denture in aesthetically important area in cases where insufficient space to place regular cap

PEEK caps, extra short, shall be used to create single and multiple conditionally removable denture in aesthetically important area in cases where insufficient space to place regular and short cap

Contraindications

ROOTT Gingiva formers and abutments are only used if dental implant placed, so all contraindications that

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prohibit the use of a dental implant prohibit the use of the superstructures as well. The contraindications of the Related dental superstructures are always connected to that of the dental implants. Refer to the instructions for use for ROOTT Dental Implants

Intended user profile

For dental clinic use only and for use only by dental professionals.

Use environment

ROOTT gingiva formers and abutments are supplying in non-sterile conditions and must be sterilized prior to use. All ROOTT gingiva formers and abutments are single use medical devices, can only be used in sterile conditions and not intended to be resterilized.

Can be used only in clinic during or after implantation surgery, depending on the treatment plan.

Preoperative planning

Before implant treatments various tests should be done: Blood test, Mouth examination, X-ray examination, CT examination.

The abutments and gingiva formers should be selected individually taking the anatomy and spatial circumstances into account, according to implant type, space between implants, position and tissues.

Warning

Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury. If you want to protect it, use rubber dam!

An implant is only to be restored with the corresponding original abutment and gingiva formers compatible with the specific implant.

Provisional restorations must always be placed out of occlusion.

Always ensure that surfaces of threads and screw heads are clean and that a green screw is used for the final restoration. Insert the screw straight to the implant axis.

Place implant-bone restorations only when the implant is fully osseointegrated.

Do not grind, polish, sandblast any part of the abutment and gingiva formers.

Do not exceed recommended insertion torque 15 Ncm, as it might cause failure of the abutment or gingiva formers. Torque levels less than recommended values may result in loosening of the abutment.

Angled abutments should not be used in areas of high mechanical loads on small diameter implants.

The implant connection and the screw channel of the ROOTT abutments must not be sandblasted or polished. Sandblasting, grinding or polishing of the implant connection may cause the product to fail. Any mechanical finishing - e.g. sandblasting, polishing or grinding - of the abutment is not permitted.

The handling and use of the product are not within the control of TRATE AG and is the responsibility of the user. All liability for loss or damage is excluded.

Failure to follow the procedures listed in these instructions may harm the patient and/or lead to any or all of the following complications, as swallowing or aspiration of components; infection; damage to the abutment, implant, components or tooling; loosening of the abutment or other components; improper final restoration or malfunction of the bridge, crown or other final prosthetic; impairment of patient's chewing function; failure of implant; removal of implant.

Cautions/Precautions

The inner connection of the implant must be clean with an adequate brush before restoration.

Dental System ROOTT abutments and gingiva formers are delivered non-sterile and must be sterilized prior to use.

Never use potentially contaminated or non sterile components. Contamination may lead to infection.

Provisional cement, cement or any other material used for attaching prosthetic components to others must be processed as specified by the manufacturer.

Dental system ROOTT abutments and gingiva formers are for single use only.

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

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

It is recommended that ROOTT Dental abutments and gingiva formers 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

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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.

Magnetic Resonance Imaging (MRI). Denture and crowns can be fabricated from a metal material which can be affected by MRI energy. Patient shall be informed.

Cleaning, disinfection and sterilization

ROOTT gingiva formers and abutments are delivered in non-sterile conditions. Prior to use, the gingiva formers and abutments must be cleaned, disinfected and sterilized. TRATE recommend following procedure for the cleaning, disinfection and sterilization prior to use:

For cleaning can be used both methods manual (with ultrasonic) and automated mechanical cleaning.

If possible, a mechanical method should be used for cleaning and disinfection. A manual method should be used only if a mechanical method is not available, because of its clearly lower effectiveness and reproducibility. This also applies when using an ultrasonic bath.

Perform pre-treatment both in manual and in mechanical cleaning! Cleaning procedure shall be used witch valid within the cleaning.

The products can be sterilized in the autoclave at 132 °C in one standard sterilization cycle with a dwell time of 3 minutes to achieve a SAL of 10⁻⁶

For cleaning, disinfection and sterilization must be followed requirements in “Instruction for cleaning, disinfection and sterilization of non sterile and reusable medical devices From Dental Implant System ROOTT”.

Side effects, complications

ROOTT Gingiva formers and abutments are only used if dental implant placed, so all side effects and complications that appear during the use of a dental implant appear the use of the superstructures as well

May harm the patient and/or lead to any or all of the following complications, as swallowing or aspiration of components; infection; damage to the abutment, components; loosening of the abutment or other components; improper final restoration or malfunction of the bridge, crown or other final prosthetic; impairment of patient’s chewing function; failure of implant; removal of abutment.

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.

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 treatment.

Storage

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Do not reuse ROOTT gingiva formers and abutments.

Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

Material for implants:

Gingiva formers (except individual) and abutments are made from Titanium Alloy Ti-6Al-4V ELI.

Gingiva formers individual, caps and Castable custom abutment are made from PEEK plastic.

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Compatibility information

Abutments and gingiva formers are compatible with ROOTT system components due to their technical characteristics.

Abutments	Gingiva formers	Implants	Associated surgical instrument
Ax, AxAxx, AxN, ATx, ATRx, AxK, AxAxxK, Bx, PMAB, PMABP, Mx, MxAxx, MSx, PCO, PCOR, PCOx, PCORS, PCOxS, ABM	GFx, GFNx, GFPx, GFASx, GFAMx, GFALx, GFPSx, GFPMx, GFPLx, GFMSx, GFMSMx, GFMSLx, GFMESx, GFMEMx, GFMEIx, GFI	Root form implants (Rxxxx)	Screw drivers SDx, SDxB, SDHx, SDAO Screw for removing of superstructures SR
TCEx, TCESx, TCEXSx, PCEx, PCESx, PCEXSx	GFEx	Compressive, Compressive S, Basal, Basal SS (Cxxxx, CxxxxS, Bxxxx, BxxxxSS)	Screw drivers SDx, SDxB, SDHx, SDAO
AM, PCOM	GFMx, GFNMx,	Compressive M/MP (CxxxxM, CSxxxxMP)	Screw drivers SDx, SDxB, SDHx, SDAO
AMS, PCOMS	GFMSx, GFNMSx	Compressive MS (CxxxxMS)	Screw drivers SDx, SDxB, SDHx, SDAO
TCKx, TCKSx, TCKXSx, PCKx, PCKSx, PCKXSx	GFKx	Compressive K (CxxxxK)	Screw drivers SDx, SDxB, SDHx, SDAO Screw for removing of superstructures SR Cap removing tool PRT and screw PRS

Storage

Do not store sterilized abutments and gingiva formers. Use devices immediately after sterilization.

Prior to the first use of the device, products should be stored in its original packaging at room temperature in dust free and humidity free conditions and not exposed to direct sunlight.

Warning

Always ensure that surfaces of threads and screw heads are clean and that a green screw is used for the final restoration. Insert the screw straight to the implant axis (do not insert tilted). Ensure correct handling of the torque control device. Greater torque may result in a failure of the screw, gingiva former or abutment and/or implant. Torque values less than the recommended values may result in loosening of the gingiva former or abutment, which may lead to screw, abutment and/or implant failure.

Device type	Tightening torque
Gingiva formers	15 Ncm
Abutments (permanent)	15 Ncm
Components on implant analogs	Hand-tight

Closure of the screw channel

Before cementing the crown or bridge, the screw openings are sealed with wax or gutta-percha. This makes it possible to release the screw again if required. The final cementing of the crown to the mesostructure can take place.

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Information for patients:

Surgeon shall inform patient about side effects, complications for implants, residual risks and what patients shall do or shall not do after the implantation:

- 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.

Validity










Upon publication of these instructions for use, all previous versions are superseded.

Please note

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Some products may not be available in all markets. Please contact your local TRATE representative to review the product range available.

Signs explanation

	Consult instructions for use
	Catalogue number
	Batch code
	Do not use if package is damaged
	Non-sterile
	Do not reuse
	Keep away from sunlight
	Keep away from water
	Manufacturer

CE 2797

This medical product is CE marked in accordance with Directive 93/42/EEC on medical devices

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Ver	Date	Change description	Responsible
01	2017-07-13	Printing date	V. Shulezhko

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			D. Karpavicius
02	2019-02-18	NB number was changed from 0086 to 2797	V. Shulezhko D. Karpavicius
03	2019-04-19	Added residual risks description	V. Shulezhko D. Karpavicius