

Instructions for Use

radix Implants & Biomaterials GmbH – Implant Systems

SCOPE OF THE INSTRUCTIONS FOR USE

radix Implant System (Bone Level, Tissue Level)

Implants, abutments, surgical, restorative and dental components/accessories

MANUFACTURING AND FABRICATION

Manufacturer
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PRODUCT INFORMATION

General product description

Implant

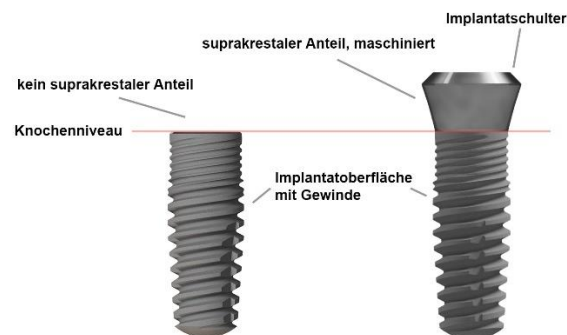
The radix implant system serves as a tooth root replacement and can be inserted in free jaw sections or in edentulous jaws. The implants of the radix implant system are made of Grade 4 pure titanium and the prosthetics are made of Grade 5 titanium. The surface in the endosseous part is micro-structured, the implant shoulder is machined and the Tissue Level Implant is height optimised for long-term irritation-free mucosal attachment. The prosthetic connection is provided via an inner cone with additional hexagonal rotation lock. The radix Tissue Level Implant is designed for the transgingival healing mode and the radix Bone Level Implant for closed healing, closed healing, preferably in subepithelial mode (e.g. with simultaneous alveolar ridge augmentation), is possible.

Bone Level Implant

A Bone Level Implant is an implant without supracrestal parts which is inserted into the bone level. The biological width is formed by the horizontal shift from implant to implant abutment (platform switching).

Tissue Level Implant

The Tissue Level Implant is an implant in which the implant shoulder protrudes a few millimetres above the bone level and thus contributes to soft tissue formation. The biological width is classically achieved vertically over the implant shoulder.



Implant abutments

Various abutment parts which can be individually selected by the user for the purpose of prosthetic restoration depending on the indication and anatomical requirements. The connection to the implant is via a titanium screw.

Surgical instruments

Various surgical instruments which are used to insert the implant and implant abutment parts. These include various drills, screwdrivers and a torque wrench. The use of the surgical instruments is described in the corresponding instructions for use.

Intended use and indication

The radix implant system can be used in professional health care facilities such as medical practices, hospitals, clinic centres and other medical facilities. The radix implant system and abutments may only be used by surgeons, dentists, physicians and dental technicians familiar with and trained in implant dentistry. The radix implant system can be used in patients with a tooth set where all remaining teeth are visible.

Restorative measures may only be performed after successful osseointegration of the inserted implant. radix implant systems can be used for all indications of oral, endosseous implants in the maxilla and mandible, for functional and aesthetic oral rehabilitation of edentulous and partially edentulous patients. The prosthetic restoration can be provided by single crowns, bridges, partial or full dentures, which are connected to the radix implants by appropriate elements.

The diameter-reduced implants (\varnothing 3.3 mm) and the short implants (6 mm and 8 mm) are intended for use in conjunction with at least one further implant.

Contraindications

General medical and local, absolute and relative contraindications for dental surgery must be taken into account when selecting implant patients.

The radix implant systems must not be used in the following diseases:

- severe internal diseases;
- bleeding disorders / blood coagulation disorders;
- metabolic disorders;
- (bone) metabolic disorders (i.e. osteoporosis);
- impaired immune defence;
- psychiatric disorders;
- medication, drug, alcohol and tobacco abuse.

Local contraindications include an insufficient supply of bone and inadequate bone quality as well as poor oral hygiene and a residual unrestored tooth. If the bone supply is insufficient, we refer to the common augmentation procedures and the corresponding literature.

The diameter-reduced implants (\varnothing 3.3 mm) and the short implants (6 mm and 8 mm) may not be used for single tooth restorations.

Insufficient length or number of implants, as well as incorrect positioning of the implants, can lead to a biomechanical overload re-

sulting in implant loss, fatigue fractures of implants, implant abutments or prosthetic screws. This should be taken into account particularly for prosthetic restorations with ball head anchors, as an unfavourable distribution of forces can lead to a fracture of the prosthetic components.

The success of the implant largely depends on the prosthetics. Intensive communication between the dentist and the dental technician, careful preoperative planning and the involvement of the patient are important prerequisites for a successful implant restoration.

Risks and side effects

The risks, complications and side effects can be divided into intraoperative and postoperative risks, complications and side effects.

Intraoperative risks, side effects and complications

Injury to important structures:

- mandibular nerve (Nervus alveolaris inferior);
- tongue nerve (Nervus lingualis);
- adjacent teeth;
- soft tissue:
- maxillary sinus;
- bleeding (vessels).

Postoperative risks, side effects and complications

Early complications:

- post-operative bleeding / haematoma;
- swelling;
- infection;
- wound healing disorders.

Late complications:

- peri-implantitis;
- loss of implant.

SAFETY

General

Read these instructions for use completely. Keep the instructions for use for future reference. If the instructions for use are not observed, injuries or damage to the product cannot be ruled out.

radix implant systems and abutments may only be used by surgeons, dentists, physicians and dental technicians familiar with and trained in implant dentistry. The individual dentist is solely responsible for deciding on the concrete application and the respective design of the implant system and the corresponding prosthetic restoration, and thus on the detailed application of the product, according to the respective situation (indication). Methodical errors in application may result in the loss of implants as well as substantial damage to the peri-implant bone substance as a consequence.



radix offers appropriate information and training opportunities for doctors, dentists and dental technicians.



During intraoral use, care must be taken to ensure that the products are protected against aspiration or falling off.

Structure of safety instructions

NOTE



Notes are general precautions which, if ignored, may result in impairment or short-term inconvenience.

CAUTION



The signal word CAUTION indicates hazards which, if ignored, can lead to minor to moderate injuries or impairment of therapy.

WARNING



The signal word WARNING indicates hazards which, if ignored, can lead to serious injuries or severe impairment of therapy.

General safety instructions, liability and guarantee



CAUTION

The use of non-system components can impair the function of the radix implant system and excludes any guarantee or compensatory service by radix.

This applies in particular to other application methods that are not recommended. The processing and application of radix products is beyond our control and is the sole responsibility of the user. Any liability for damages thus caused is excluded.



CAUTION

Document the frequency of use or sterilisation of the reusable cutting instruments to ensure that they are used only within their intended service life.



CAUTION

Store the radix implant system in a dry place at room temperature and preferably without direct incidence of light.



WARNING

Before use, check whether the product is suitable for the intended use and indication. Check the colour coding and labelling to avoid mix-ups of tools and implants.



WARNING

The implants are single-use products supplied sterile. Re-use or re-sterilisation of the implants is not permitted.

When single-use products are re-used, there is an increased risk of infection and risk-free functional reliability (e.g. in terms of stability or accuracy of fit) cannot be guaranteed.

**WARNING**

Avoid thermal damage in the jawbone caused by rotary instruments. The rotary instruments are to be used at low speed. Ensure adequate cooling.

**WARNING**

Before each treatment, take a medical history and inform the patient about contraindications and possible side effects.

**WARNING**

Check the products and the inner packaging for damage before use. Damaged products or products with damaged packaging must not be used. Sterility is no longer guaranteed if the packaging is damaged or has already been opened.

APPLICATION**General preparation****WARNING**

Check the product for integrity before use. Damage can lead to injuries and impair the effectiveness of the therapy.

The implant abutment parts and surgical instruments are supplied non-sterile and must therefore be cleaned, disinfected and sterilised beforehand. Please refer to the section "Processing".

Treatment planning**WARNING**

Shortcomings in the patient history, in preoperative diagnostics and in therapy planning can lead to a premature implant loss.

Before each treatment, take a comprehensive patient history. Inform the patient about the purpose, the procedure for treatment and the risks and side effects.

Conduct the preoperative diagnostics with care and document the therapy planning.

Procedure for implant insertion**CAUTION**

Inserted implants must demonstrate primary stability. Instruments and tools must be secured to prevent accidental aspiration by the patient.

The protective treatment of hard and soft tissue must be strictly observed to create optimal conditions for the healing phase of the radix implant system. The procedure should be performed as atraumatically as possible and requires a high degree of precision and care. Parallel drilling with suitably sharp drills should be performed at max. 800 rpm, ensuring sufficient cooling of the drill tip to avoid thermal trauma which may prevent successful osseointegration of the implant. We recommend using physiological, sterile saline solution as cooling liquid. The implant should be inserted at a torque of max. 40 Ncm, irrespective of mechanical or manual insertion.

Performing surgery**CAUTION**

Any contamination of the implant must be avoided.

1. Exposure: the gingiva is cut open with a scalpel. A mucoperiosteal flap is then prepared to display the osseous structures.
2. Implant positioning – triangular drill: the implantation site is determined at the prosthetically optimal location.

3. Ø 2.0 mm spiral drill: the pilot hole is drilled at the centre punch as specified and under checking of the implant axis.
4. Ø 2.5 mm spiral drill: expansion of the implant bed from 2.0 mm to 2.5 mm under checking of the implant axis.
5. Ø 2.8 mm spiral drill: preparation of the implant bed to 2.8 mm – if necessary.
6. Ø 3.2 mm spiral drill: preparation of the implant bed to 3.2 mm – if necessary.
7. Ø 3.65 mm spiral drill: preparation of the implant bed to 3.65 mm – if necessary.
8. Ø 4.5 mm spiral drill: preparation of the implant bed to 4.5 mm – if necessary.
9. Insertion: the sterile packaging is only opened in the treatment room immediately prior to implantation. The implant is provided in a titanium sleeve, removed from this sleeve with the insertion tool and gently inserted directly into the prepared implant bed. The label with the information on the radix implant and the LOT number is transferred to the patient file. A torque of 40 Ncm should not be exceeded during insertion, otherwise bone damage may occur, which increases the risk of implant loss. After insertion of the implant, the internal thread is closed with the cover screw.
10. Wound closure: the radix Tissue Level is designed for the transgingival and the radix Bone Level Implant for the closed healing mode. In the case of the radix Tissue Level Implant, the wound margins are sutured atraumatically and tightly around the implant neck. In the case of Bone Level Implants, the wound margins are sutured atraumatically closely above the implant. The closure of the suture must not impair the supply of blood vessels to the margins of the mucous membrane. Closed healing requires a second procedure to shape the gingiva, during which the cover screw is replaced with a gingiva former.

11. Prosthetic restoration: an impression can now be taken with the aid of the screw-retainable impression post, and a model with laboratory implant analogues can be fabricated. The restoration can be fabricated and be screw-retained to the implant or bonded, depending on the case. A maximum torque of 30 Ncm is recommended for connection with the screw. For more detailed information please contact radix Implants & Bio-materials GmbH.

Healing phase

The healing phase in the mandible is usually three months and six months in the maxilla. Depending on the bone quality and anatomy, this can both be shorter or longer. Once the healing phase has been completed and the gingiva has been formed, prosthetic restoration can commence.

Follow-up / final discussion

Inform the patient in detail about the necessary oral hygiene measures. Recommend to the patient to attend follow-ups regularly.

PROCESSING

The implants of the radix Hexagon implant system are delivered sterile. They may not be reprocessed. Of the products listed at the end of this manual, the Healing Abutments and Center Screw must be reprocessed before use as they are supplied non-sterile.

The following workflow description provides a first overview. For a detailed description of reprocessing, please refer to the *reprocessing instructions*.

Pretreatment

After application to the patient, all components designed for re-use must be placed in a container containing physiological saline solution and the coarse contamination is to be removed.

In preparation for disinfection, the re-usable components must be removed from the mentioned container and wiped with a lint-free

disposable cloth. The components are then placed in another container containing unused physiological saline solution. Once all components have been treated in this manner, they are placed in the sterilisation basket.

Cleaning and disinfection



CAUTION

Blood and tissue residues must not dry out on the sterilisation baskets.

Remove coarse contamination from the sterilisation baskets immediately. Thermal disinfection must be started within 2 hours after surgery. For this purpose, the template must be removed from the sterilisation basket and placed separately in the thermal disinfectant.

Sterilisation

Permissible sterilisation processes are fractionated vacuum processes exclusively (with sufficient product drying). The sterilisation hold time is at least 4 minutes at 132 °C. The maximum sterilisation temperature must not exceed 138 °C.

We recommend keeping to a drying time of at least 30 minutes.

The steam sterilisers used must have a valid CE marking and meet the requirements of EN 13060 or EN 285. The processes used must be validated for the specific equipment and products and comply with the requirements of ISO 17665. The sterilisers used must be serviced and checked regularly. The validated parameters must be maintained during each cycle

Storage

Store all components in a dry, dust-free, contamination-protected location in their sterile packaging until they are used. If the packaging is damaged, complete re-processing is required including a functional check.

ADDITIONAL INFORMATION

Material information and packaging

Product	Material
Implant	Pure titanium Grade 4 Surface blasted with aluminium oxide (> 99 % Al ₂ O ₃) and acid-etched
Abutments/Healing Abutments/Screws	Titanium Grade 5

The implant is contained in a special titanium sleeve and is held in place in the sleeve by the Tyvek foil. After removing the Tyvek foil, the implant moves freely in the titanium sleeve and can be removed with the insertion tool. The titanium sleeve is fixated in the plastic blister. The sleeve with the implant is double packed in a double blister pack. A label can be removed and is used to transfer the implant data to the patient file (LOT no.).

Durability / service life

Product	Service life
Implant	20 years
Implant abutments	20 years

Spare parts and order numbers

Implants

Art. No.	Product designation
R-BL02	Bone Level Implant Ø 3.3 mm / L 8.0 mm
R-BL03	Bone Level Implant Ø 3.3 mm / L 10.0 mm
R-BL04	Bone Level Implant Ø 3.3 mm / L 11.5 mm
R-BL05	Bone Level Implant Ø 3.3 mm / L 13.0 mm
R-BL06	Bone Level Implant Ø 3.3 mm / L 16.0 mm
R-BL08	Bone Level Implant Ø 3.75 mm / L 8.0 mm
R-BL09	Bone Level Implant Ø 3.75 mm / L 10.0 mm
R-BL10	Bone Level Implant Ø 3.75 mm / L 11.5 mm
R-BL11	Bone Level Implant Ø 3.75 mm / L 13.0 mm
R-BL12	Bone Level Implant Ø 3.75 mm / L 16.0 mm
R-BL13	Bone Level Implant Ø 4.2 mm / L 6.0 mm
R-BL14	Bone Level Implant Ø 4.2 mm / L 8.0 mm
R-BL15	Bone Level Implant Ø 4.2 mm / L 10.0 mm
R-BL16	Bone Level Implant Ø 4.2 mm / L 11.5 mm
R-BL17	Bone Level Implant Ø 4.2 mm / L 13.0 mm
R-BL18	Bone Level Implant Ø 4.2 mm / L 16.0 mm
R-BL19	Bone Level Implant Ø 5.0 mm / L 6.0 mm
R-BL20	Bone Level Implant Ø 5.0 mm / L 8.0 mm

Art. No.	Product designation
R-BL21	Bone Level Implant Ø 5.0 mm / L 10.0 mm
R-BL22	Bone Level Implant Ø 5.0 mm / L 11.5 mm
R-BL23	Bone Level Implant Ø 5.0 mm / L 13.0 mm
R-BL24	Bone Level Implant Ø 5.0 mm / L 16.0 mm
R-TL01	Tissue Level Implant Ø 3.3 mm / L 6.0 mm
R-TL02	Tissue Level Implant Ø 3.3 mm / L 8.0 mm
R-TL03	Tissue Level Implant Ø 3.3 mm / L 10.0 mm
R-TL04	Tissue Level Implant Ø 3.3 mm / L 11.5 mm
R-TL05	Tissue Level Implant Ø 3.3 mm / L 13.0 mm
R-TL06	Tissue Level Implant Ø 3.3 mm / L 16.0 mm
R-TL07	Tissue Level Implant Ø 3.75 mm / L 6.0 mm
R-TL08	Tissue Level Implant Ø 3.75 mm / L 8.0 mm
R-TL09	Tissue Level Implant Ø 3.75 mm / L 10.0 mm
R-TL10	Tissue Level Implant Ø 3.75 mm / L 11.5 mm
R-TL11	Tissue Level Implant Ø 3.75 mm / L 13.0 mm
R-TL12	Tissue Level Implant Ø 3.75 mm / L 16.0 mm
R-TL13	Tissue Level Implant Ø 4.2 mm / L 6.0 mm
R-TL14	Tissue Level Implant Ø 4.2 mm / L 8.0 mm
R-TL15	Tissue Level Implant Ø 4.2 mm / L 10.0 mm
R-TL16	Tissue Level Implant Ø 4.2 mm / L 11.5 mm
R-TL17	Tissue Level Implant Ø 4.2 mm / L 13.0 mm
R-TL18	Tissue Level Implant Ø 4.2 mm / L 16.0 mm
R-TL19	Tissue Level Implant Ø 5.0 mm / L 6.0 mm
R-TL20	Tissue Level Implant Ø 5.0 mm / L 8.0 mm
R-TL21	Tissue Level Implant Ø 5.0 mm / L 10.0 mm
R-TL22	Tissue Level Implant Ø 5.0 mm / L 11.5 mm
R-TL23	Tissue Level Implant Ø 5.0 mm / L 13.0 mm
R-TL24	Tissue Level Implant Ø 5.0 mm / L 16.0 mm

Accessories

For further spare parts and order numbers, e.g. for prosthetics, you can find the current information on the company's homepage. You can find this at <http://www.radix-implants.com>

Disposal

Dispose of all used products in accordance with the disposal guidelines for medical practices and hospitals.

MANUFACTURER



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KEY TO SYMBOLS



Manufacturer



Use by



Observe instructions for use



Article number



Batch designation



Radiation-sterilised



Do not re-use



Do not re-sterilise



Do not use if packaging is damaged



Attention



Not sterile



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