

Instructions for Use

radix Implants & Biomaterials GmbH – Implant Systems

SCOPE OF THE INSTRUCTIONS FOR USE

radix Implant System (Bendable One piece)

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

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. The surface in the endosseous part is micro-structured, the implant shoulder is machined and the Tissue Level One piece Implant is height optimised for long-term irritation-free mucosal attachment. The radix One piece Implant is designed for the transgingival healing mode and the radix Bone Level Implant for closed healing.

One piece Implant

The One piece 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.

One piece Implant is suitable for immediate loading, at least 3 implants should be splinted together when cementing the prosthetic part.

Not recommended as single implant in the posterior region.

Implant abutments

The abutment of the One piece implant can be bent after insertion in the bone up to 30 degrees with the bending tool provided in the surgical kit.

There are grooves in the abutment each 1 mm as indicator for height reduction.

In case implant's abutments fracture during bending there is a square below the abutment's neck for easy removal of the implant using the same insertion tool.

Bending is allowed one and in one direction otherwise the implant neck may fracture due to high tension.



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 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 (Ø 2.8 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 (Ø 2.8 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 resulting 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).
- Fracture of bone while bending if too much force is used.
- Fracture of implant neck.

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.

Due to the different bone qualities, the radix implant system provides a variety of drills for preparing the implant bed.

To ensure the greatest possible safety in terms of drilling depth, radix Implants & Biomaterials GmbH provides drill stops in addition

to the depth markings on the actual drills. The drill stops are mounted on the drill and prevent the drill from penetrating too deeply into the bone. Drill stops are provided for the depths 8mm, 10mm, 11.5mm and 13mm. The drill stops are designed such that one drill stop fits all drills.

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. 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 or fracture.

8. Wound closure: the radix One piece is designed for the transgingival healing. The wound margins are sutured atraumatically and tightly around the implant neck. The closure of the suture must not impair the supply of blood vessels to the margins of the mucous membrane.

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.

Follow-up / final discussion

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



Prior to the final prosthetic restoration, the connecting screw should be re-tightened again. Ideally, the connecting screw of the prosthetic restoration should be re-tightened - if possible - after 3 months.

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 disinfecter.

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 |

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 |

Spare parts and order numbers

Implants

| Art. No. | Product designation |
|----------|--|
| R-OP-18 | One Piece Implant Ø 2.8 mm / L 10.0 mm |
| R-OP-19 | One Piece Implant Ø 2.8 mm / L 11.5 mm |
| R-OP-20 | One Piece Implant Ø 2.8 mm / L 13.0 mm |
| R-OP-21 | One Piece Implant Ø 3.3 mm / L 8.0 mm |
| R-OP-22 | One Piece Implant Ø 3.3 mm / L 10.0 mm |
| R-OP-23 | One Piece Implant Ø 3.3 mm / L 11.5 mm |
| R-OP-24 | One Piece Implant Ø 3.3 mm / L 13.0 mm |
| R-OP-25 | One Piece Implant Ø 3.8 mm / L 8.0 mm |
| R-OP-26 | One Piece Implant Ø 3.8 mm / L 10.0 mm |
| R-OP-27 | One Piece Implant Ø 3.8 mm / L 11.5 mm |
| R-OP-28 | One Piece Implant Ø 3.8 mm / L 13.0 mm |

Accessories

For further spare parts and order numbers, 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

CE 0483

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