EN - Instruction for use RatioPlant® Implant System

HumanTech Medical Devices

Advice:

The following descriptions are not sufficient for the immediate application of the RatioPlant® Implant System. We recommend the briefing into the handling of the RatioPlant® Implant System by an experienced surgeon. Fundamentally the RatioPlant® Implant System only should be used by trained dentists, implantologists and dental technicians.

1. Product Description

RatioPlant® implants are endosseous implants, available in different lengths and shapes. They are surgically placed in the bone of maxillary and/ or mandibular arch to provide support for functional and aesthetic oral fixtures in partially or fully edentulous patients. The restoration may consist of single crowns, bridges, partial or full dentures which are fastened to RatioPlant® implants with suitable attachments. The RatioPlant® Implant System contains surgical, prosthetic, and dental laboratory components and instruments. Basically there are no preferred indications of application for the different implant configurations.

2. Indications

RatioPlant® implants are used in indications for oral enosseous implants in the maxilla and/or mandible as part of a functional and aesthetic oral rehabilitation in partial or fully edentulous patients. The RatioPlant® surgical procedure contains suggestions for specific applications with the different implant types and sizes.

3. Contraindications

Insufficient bone volume and soft tissue coverage and/or inadequate bone quality, local root remnants, bone and wound healing disorders, local infection at the implantation site, severe refractory functional disorders, uncontrolled diabetes mellitus, long-term immunosuppressant drug therapy, disease of connective tissue/collagen diseases, hematological diseases (e. g. leukemia, hemophilia), intra oral infection or malignancies, uncontrolled para-functional habits, untreatable occlusal or articulation disorders, severe psychological disorder, xerostomy, and sensitivity to titanium.

3.1 Precautions

It is important to obtain a thorough medical history from the patient and if necessary from the general practitioner prior to conducting implant surgery in order to determine if conditions exist that will 1) make implant placement difficult because of anatomical conditions, 2) create a signifi cant surgical or general risk, 3) impair healing capacity and/or osseointegration, or 4) lessen the likelihood of proper hygiene and/or maintenance of the implant, abutments and fi xtures. Following are examples of conditions in each category that should be considered. Some of these conditions may be relevant to more than one category. If any of the these conditions or combination of conditions are severe or uncontrolled, dental implants should not be used.

3.2 Anatomical Conditions

Incomplete jaw development, diffi cult anatomical bone relationships, previously irradiated bone, temporomandibular joint disease and treatable jaw conditions.

3.3 Surgical and General Risks

Severe systemic diseases, reduced immune response and leukocytic disorders that increase the risk of infection, endocrine diseases, anticoagulation therapy/hemorrhagic diathesis, arteriosclerosis and CVA, Hypertension, cardiac infarct, diseases requiring periodic uses of steroids, hepatitis, diabetes mellitus, and pregnancy.

3.4 Impaired Healing Capacity

Bone metabolism disorders, any disease that affects bone regeneration or micro-circulation of the blood, rheumatic diseases, and abuse drugs including alcohol and tobacco.

3.5 Maintenance

Inadequate patient compliance, inadequate oral hygiene, periodontitis, bruxism, loss of proper
functionality, and oral mucosal changes.

4. Side Effects, Complications and Adverse Reactions

In some cases, osseointegration fails to occur. In such an event, consult your local representative. Immediately after dental implant insertion, activities that expose the body to high physical stress should be avoided. Possible complications after dental implant insertion may include:

Temporary symptoms

Pain, swelling, speech diffi culties, gingival infl ammation.

Prolonged symptoms

Chronic pain associated with the dental implant, permanent paresthesia, dysesthesia, nerve damage, exfoliation, hyperplasia, localized or systemic infection, oroantral or oronasal fi stulas, loss of maxillary/mandibular ridge bone, negative impact on adjacent teeth, irreversible damage to adjacent teeth, fractures of the implant, jaw, bone, or restoration, aesthetic problems.

5. General Safety Instructions and Warnings

• An improper approach with regard to surgery and prosthetics can lead to damage to the implant or to bone loss. The RatioPlant® implant system should only be used by dentists, doctors and surgeons who have undergone training on the system.

• The application of the implant system requires special knowledge and skills regarding implantology. Every patient must be examined thoroughly and assessed based on their radiographical, mental and physical status, including the teeth and associated hard and soft tissue deficits that could have a bearing on the end result.

• A close collaboration between the surgeon, prosthodontist and dental technician is essential for success. The RatioPlant® implant system and the corresponding procedures have been developed and clinically proven by experts.

• More detailed information on choosing the right implants, elements of treatment planning and the application of dental implants is contained in the surgical procedure for RatioPlant® implants.

6. Preparation of the Implants and Instruments

6.1 Preparation of the Patient

The prerequisites for a successful implant procedure are as follows: Local and systemic requisite

Normal wound healing capacity, efficient oral hygiene, remaining healthy dentition, maxillary and mandibular development complete, good general health, adequate volume of healthy bone in the arch. Local examination Anatomy of the alveolar ridge, interarch relationships, such as deep overbite, quality and thickness of themucosa, study models and bite registration in the articulator, radiographs. Deficiencies in patient evaluation, preoperative diagnostics or treatment planning can cause loss of an implant. The surgical component of implant treatment must be

preceded by a comprehensive patient evaluation, preoperative diagnostics and treatment planning. You must evaluate the implant diameter and implant length in such a way that sufficient bone (at least 1 mm) is present around the implant. Maintain a minimum distance of 1.5 mm to an adjacent natural tooth and 3 mm to an adjacent implant.

6.2 Preparation of the Instruments

The instruments of the RatioPlant® Implant System are supplied non-sterile unless they are explicitly marked as sterile. They must be cleaned, disinfected, and sterilized before first use and every further use thereafter (see Section 8.2 Preparation of Instruments and Prosthetic Components).

6.3 Preparation of the Implants and Cover Screws

RatioPlant® implants and cover screws are provided in sterile packaging and must be stored dry at room temperature and away from direct sunlight. The packaging must be checked for damage and its expiry date before opening and may only be opened immediately before the products are used. Implants and cover screws may not be used when:

• the expiration date (see label) has passed
• the packaging is damaged before use or is already open

7. Application

7.1 Surgery

To create optimal conditions for successful healing of the implants, the hard and soft tissue must be treated very gently. The implant bed must be prepared with the utmost care. The diagnostic documentation and the previously prepared surgical guides must be made available for the surgical intervention. The implantation can be performed transgingivally in a single step or with a cover screw in a 2-step procedure. In the case of a transgingival single-step implantation, a second surgical intervention is unnecessary. In the case of a 2-step implantation procedure with cover screw, a healing screw for soft tissue conditioning must be screwed into the implant three weeks before the impression. Make sure that the cutting instruments matching the implant type are arranged in the correct location in the matching surgery set.

7.1.1 Preparation of the Implant Bed

The use of a drilling guide is recommended because the long-term prognosis for the implant and the aesthetic outcome increase with optimal positioning. Thermal trauma can prevent healing of the dental implants. Because of this, excessive temperature elevation must be minimized to the extent possible. Take note of the maximum rotational speeds for drills and taps as follows:

Rose-head bur all Ø800 U/min

Twist drill Ø 1.5 – 2.8 mm	600 U/min
Twist drill Ø 3.0 – 3,2 mm	550 U/min
Twist drill Ø 3.5 – 3.8 mm	500 U/min
Twist drill Ø 4.5 mm	400 U/min
Twist drill Ø 5.0 mm	350 U/min
Twist drill Ø 5,5 mm	300 U/min
Final drill all Ø	300 U/min
Thread cutter all Ø	15 U/min
Countersink all Ø	300 U/min

Only use sharp drill bits and taps (no more than 10 to 20 applications). Use an intermittent drilling technique. Provide sufficient cooling using pre-cooled (5°C) sterile, physiological saline solution. Use drill bits with an ascending diameter. The surgeon must possess precise knowledge of the measuring system used when planning the procedure and maintain a sufficient safety distance from the teeth and vital structures. If the actual drilling depth is not correctly determined in relation to the X-ray and drilling goes beyond the intended depth, this can cause permanent injury to nerves and other vital structures. A safety distance of 1.5 mm from the mandibular nerve or inferior alveolar nerve must be observed. Every drill bit has depth markings that you must observe, or a stop must be used. If the coronal bone margin is smoothed, the available bone height is less. It is essential that the length of the implant is verified. If the maxillary sinus in the upper jaw is perforated when making the pilot hole, the implantation must be halted. Augmentation techniques are required during further treatment.

• Incision
• Optional: Trimming/levelling of the alveolar ridge at the desired implant position with the round burr.
• Attach an appropriate depth stop to the drill, in order to prevent the implant bed from being drilled too deep. If a drilling template is used, the depth stops can be attached after the marking bores.
• Intermittent drilling technique for pilot drills, pre-drills and form drills: Drill into bone for 2-3 seconds. Then pull the drill out of the top of the bone without stopping the hand motor. Repeat procedure until the desired depth has been achieved.
• If necessary, when making the pilot hole or pre-drilled holes, check the depth and axial direction with a gauge and/or a paralleling pin.
• Use drill bits with ascending diameters until the desired diameter is achieved for the implant bed.
• For bone qualities D1 and D2, under certain circumstances pre-cutting of the thread with the tap may be necessary, if it is seen during the implant bed preparation that the cortex is very compact. Screw in the tap at the maximum up to the upper edge of the cutting work element and expand the inlet opening for the area of the implant neck with the countersink.

7.1.2 Implant Insertion

The primary packaging of the implants is given a label with the batch number, which must be entered into or adhered to the patient documentation. Each implant can thus be tracked if required.

• Open the sterile packaging of the implant.
• Only remove the implant from the packaging with the corresponding adapter (hand instrument).
• Insert the implant by hand into the implant bed and screw in place until the first stop.
• Pull off the hand instrument.
• Screw in further with the motor adapter (slowest setting). Always perform the final positioning by hand. Otherwise, the external thread of the implant could be overwound in the bone.
• Screw the implant in finally by hand using an insertion device and the ratchet.
• Clean the inner thread of the implant.
• Insert the cover screw with the hexagonal hand screwdriver.
• Check the cover screw for its tight fit.

The wound edges are closed tightly with atraumatic suture material. Do not tie the sutures too tightly. They must be placed in such a way that the wound edges lie without tension over the cover screw. Instead of the cover screw, a healing screw can be used with the corresponding soft tissue height. This enables transgingival 1-phase healing. The healing screw must fit the implant diameter and is screwed in by hand. Ensure the healing screw is positioned precisely. The mucous membrane must lie tight against the healing screw.

7.1.3 Post-implantation Care

Proper oral hygiene by the patient is an important prerequisite for long-term implant success.

The surgical field must be kept as free as possible from mechanical stresses immediately after the implantation. Use the ice pack method to prevent swelling.

• The patient should report any health abnormalities occurring after the operation to the dentist immediately.

7.1.4 Temporary Restoration

A temporary restoration may be inserted only after controlling that no mechanical friction occurs against the implant or the suture. If a temporary restoration is used, take care that it does not load the implant during the healing phase. Functionally and statically there must not be any contact with the nearest teeth and antagonists.

7.1.5 Healing Phase

The healing phase should take at least 3 months with good bone quality, or a minimum of 6 months with spongy bone quality. The values apply to both the upper and lower jaw. The healing time is always dependent on the respective patient situation and is subject to the healthcare provider's assessment.

7.1.6 Postoperative Follow-up

Follow-up examinations should be performed on the following day up to a week postoperatively. Attention should be given to the tightness of the suture and signs of incipient infection. Sutures may be removed after 7–10 days.

7.1.7 Implant Exposure and Soft Tissue Management

All healing screws are packed unsterile and are to be sterilised with the instruments before use!

• Expose implant.
• Remove cover screw.
• Clean the inside of the implant.
• Screw the healing screw in by hand. The healing screw must fit the implant diameter and the soft tissue thickness of the patient.
• Ensure the healing screw is positioned precisely. The mucous membrane must lie tight against the healing screw. The temporary abutments made of PEEK may only be in place for a maximum of 180 days.

7.2 Prosthetics

Definitive prosthetic implant treatment should only take place when the soft tissue has healed completely without irritation. Before prosthetic treatment begins, an X-ray check-up is required after 6-12 weeks of healing. Suitable casting materials are silicone and polyether.

When selecting the abutment, the diameter and the angulation of the implant and the height of the gingiva must be taken into consideration. No angulation corrections of more than 25° can be performed. No cantilever bridge is to be attached to a freestanding individual implant. Caution! The contact surfaces of abutments or structural parts to the implant must neither be blasted or processed. The following points are to be noted when providing prosthetic treatment:

• The geometric processing of abutments can have a negative influence on the stability of the abutment and the overall system. For CAD/CAM abutments, it should be ensured that the produced geometry exhibits sufficient stability.
• In the processing of abutments, it should be ensured that the connection geometry to the implant and the fitting of the prosthetic screw are not changed, as otherwise a secure fitting cannot be guaranteed.
• Favourable load distribution
• Tension-free seat of the prosthetic on the abutment
• Correct occlusion

When making a frame, only materials intended for this purpose should be used. RatioPlant® implant system prosthetic components are supplied non-sterile if not explicitly labelled as sterile. They may only be used once. They must be cleaned, disinfected and, where required, sterilised before being used on the patient (see section 8.2 Preparation of the instruments and prosthetic components). Exception: Plastic parts for taking impressions, including bites, do not have to be sterilised. The RatioPlant® system allows the telescopic crown technique to be used in combination with electroforming of secondary parts.

7.2.1 Opening and Transfer

The transfer of the oral situation to the master cast is performed via the original RatioPlant® impression posts, screws and transfer caps. To take the impression, you may choose between the open tray and closed tray method. Appropriate impression posts are available for both techniques. Impression post for the closed tray technique will be used with the tranfer cap. All components are adapted to the particular implant diameter.

Closed Tray Impression

Standard trays may be used for this impression method.

• Remove the healing cap or cover screw.
• Insert the impression post for the closed tray in the implant
• Fasten the impression post tightly by hand with the prosthetic screw.
• Mount the impression cap on the impression post; note the correct final position.
• Syringe impression material around the impression post and the mounted impression cap.
• Fill the tray with impression material and insert it.
• Let the impression material set.
• Remove the impression, leaving the impression cap in the impression.
• Remove the impression post.
• Cover the implant again with the healing cap or cover screw.
• Prior to repositioning in the impression, mount the impression post to the laboratory analog with the laboratory screw. The tranfer cap must snap in noticeable on the analog
• Use preferably a soft gingiva mask material in the gingival area around the analog and pour the impression with model material.
• Let the model material set.
• Remove the impression post and replace it with the appropriate abutment.

Open Tray Impression

Custom trays must be prepared using this impression method. The impression post and the shaft of the long-head screw must not touch the tray or the opening.

• Remove the healing cap or cover screw.
• Insert the impression post for the open tray in the implant. Tighten the long-head screw for impression by hand.
• Syringe impression material around the impression post.
• Fill the tray with impression material and insert it.

• Let the impression material set.
• Loosen the long-head screw and withdraw it about the length of the guide tube from the impression post. Caution! Do not completely remove the screw.
• Remove the impression including the impression post.
• Cover the implant again with the healing cap or cover screw.
• Mount the lab analog by hand to the impression post with the long-head screw.
• Use preferably a soft gingiva mask material in the gingival area around the analog and pour the impression with model material.
• Let the model material set.
• Remove the impression post and replace it with the appropriate abutment.

7.2.2 Restoration Fabrication

The fabrication of single crowns and bridges as well as fi xed and removable dentures is performed in the dental laboratory according to the protocols given in the RatioPlant® Prosthetics Instruction.

7.2.3 Restoration Insertion

• Remove the healing cap or coverscrew.
• Clean the inside of the implant.
• Insert the selected abutment in the implant. Caution! The abutment must be seated correctly in the implant. Make sure there is no soft tissue trapped between the implant and abutment.
• Tighten the abutment screw to the specified torque (see Product Catalog). Herefore an individual centering key made in the dental laboratory is recommended.
• After 5 minutes retighten to the same torque.

8. Maintenance and Care

8.1 Implant Care

All implants are provided in sterile packaging are to be used before the noted expiration date. The sterile implants are to be used while noting the sterility measures. Never implant unsterile implants. Implants may under no circumstances be resterilised by users and must be destroyed. In the event that the original packaging is damaged, no returns are to be made to the manufacturer! No resterilisation is possible by the manufacturer either.

8.2 Preparation of Instruments and Prosthetic Components

Instruments

The instruments of the RatioPlant® Implant System are supplied non-sterile unless they are explicitly marked as sterile. They must be cleaned, disinfected, and sterilized before fi rst use and every further use thereafter.

Prosthetic components

RatioPlant® implant system prosthetic components are supplied non-sterile if not explicitly labelled as sterile. They may only be used once. They must be cleaned, disinfected and sterilised before use on patients.
Exception: Plastic parts for taking impressions, including bites, do not have to be sterilised. The instructions for the RatioPlant® implant system on preparing instruments and prosthetic components of the RatioPlant® implant system must be observed. They can be found at www.HumanTech-solutions.de or requested from your local distributor.

8.3 Sterilisation

RatioPlant's reusable instruments must be sterilised or re-sterilised in autoclaves prior to use using a validated steam sterilisation process. Refer to the autoclave manufacturer's instructions to determine the correct sterilisation temperature and cycle time. The sterilisation must be performed using steam in accordance with the provisions of EN ISO 17665-1. The use of flash sterilisation is not recommended. The minimum recommended sterilisation parameters are as follows:
• Pre-vacuum steam 132°C ≥ 5 minutes
• Pre-vacuum steam 121°C ≥ 30 minutes
Then allow the case with the instruments to dry for at least 40 minutes.
Record the sterilisation date (and sterile batch/LOT) on the packaging. Processes that are not recommended may be performed but these must be checked thoroughly by the user. Exception: Plastic parts for taking impressions, including bites, do not have to be sterilised. Please refer to www.HumanTech-solutions.de or your local distributor for further information on preparing instruments and prosthetic components from the RatioPlant® implant system.

9 Technical Data

RatioPlant® implants are manufactured with Ti6Al4V in accordance with ISO 5832-3. The abutments and components consist of the titanium alloy Ti6Al4V, ZiO^2, gold alloys and polymers. All RatioPlant® Classic, Avantgarde and Single implants possess a sandblasted and acid-etched surface.

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10. Zeichenerklärung; Explanation of Symbols; Explicación de símbolos; Explication des symboles; Spiegazione dei simboli; Explicação dos símbolos; Çerçevesinde Simgelerin Anlamları; Расшифровка символов в соответствии со стандартом; 符号说明; - DIN EN 980:2008-08

	Herstellerinformation; Manufacturer; Fabricante; Fabricant; Produttore; Fabricante; Üretici; Производитель; 生产厂家;
	Herstellungsdatum; Manufacturing date; Fecha de fabricación; Date de fabrication; Data di produzione; Data de fabricação; Üretim tarihi; Дата изготовления;
	Verwendbar bis; Date of expiry; Fecha de caducidad; Respecter la date de péremption; Data di scadenza; Data de validade; Son kullanma tarihi; Годен до; 制造日期;
	Bestellnummer; Reference number; Numero de referencia; Code de commande; Numero di codice; Número de referência; Referans numarası; Номер по каталогу; 参考号码;
	Chargennummer; Lot number; Numero de lote; Désignation du lot; Numero di lotto; Número de lote; Parti numarası; Номер партии; 批号;
	Sterilisation durch Bestrahlung; Sterilization using irradiation; Esterilización por irradiación; Stérilisation par irradiation; Sterilizzazione mediante irradiazione; Esterilização por radiação; İrradiyasyon yoluyla sterilizasyon; Стерилизовано облучением; 使用辐射消毒;
	Nicht Steril; Non steril; Sin esterilizar; Non stérile; Non sterile; Não estéril; Steril değil; Нестерильно; 非灭菌;
	Einmalige Verwendung; Do not reuse; No reusar; Ne pas réutiliser; Non riutilizzare; Não reutilizar; Tekrar kullanılmaz; Повторное использование запрещено; 不要重复使用;
	Bei beschädigter Verpackung nicht verwenden; Do not use with damaged packaging; No usarse en caso de que el empaque este dañado; Ne pas utiliser si l'emballage est endommagé; Non utilizzare se la confezione è danneggiata; Não utilizar se a embalagem estiver danificada; Hasarlı paketlerden çıkan ürünleri kullanmayınız; Не использовать, если упаковка повреждена; 不要使用包装破损;
	Trocken aufbewahren; Store in a dry place; Almacenar en un lugar seco; Conserver au sec; Conservare in luogo asciutto; Armazenar em lugar seco; Kuru ortamda muhafaza ediniz; Хранить в сухом месте; 储存在干燥的地方;
	Nicht erneut sterilisieren; Do not resterilize; No re-esterilizar; Ne pas restériliser; Non risterilizzare; Não re-esterilizar; İkinci kez sterilize edilmez; Повторная стерилизация запрещена; 不要再灭菌;
	Gebrauchsanweisung beachten; Attention, see instruction for use; Atención, ver instrucciones de uso; Attention, lire le mode d'emploi; Attenzione, leggere le istruzioni per l'uso; Atenção, 0bservar as instruções de utilização; Dikkat! Kullanmadan önce kılavuzu okuyunuz; Внимание! См. инструкцию по использованию; 注意，请参阅使用说明书;
	Achtung; Attention; Atención; Attention; Attenzione; Atenção; Dikkat; Внимание; 注意;

Stand der Gebrauchsanweisung; State of the instruction for use; Estado de las instrucciones de uso; L'état de l'instruction pour l'utilisation; Stato delle istruzioni per l'uso; Estado da instrução para uso; Kullanmak için talimat devlet; Состояние инструкцией по применению; 国的使用的指令;
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