EN – Instructions for use for the RatioPlant® implant system

GENERAL INFORMATION:

Components of the RatioPlant® implant system may not be replaced by components/products from other systems of another source or manufacturer, except these have been expressly approved by HumanTech Dental GmbH. Furthermore, no direct connection of components of the Ratioplant® implant system to components of other systems, not expressly approved by HumanTech Dental GmbH, may be established. If this is not complied with or if the products are otherwise used or used improperly, HumanTech Dental GmbH assumes no responsibility. Our application-technical recommendations, whether verbally, in writing or by means of practical instructions, are based on clinical and own experience as well as on trials.

The following descriptions are not sufficient for the immediate application of the RatioPlant® implant system. The instruction in the handling of the RatioPlant® implant system by an experienced surgeon is required. In principle, the RatioPlant® implant system may only be used by trained dentists, implantologists and dental technicians. It is the responsibility of the dentist to use the product in accordance with this instructions for use and to determine whether it is suitable for the individual patient situation.

The user of HumanTech Dental GmbH products must determine whether the product is suitable for a specific patient under the given conditions. HumanTech Dental GmbH assumes no liability, neither expressly nor conclusively, for direct or indirect damages, penalties including compensationor other damages that occur due to or in connection with errors in the professional assessment or practice in the context of the use of HumanTech Dental GmbH products. In this case, the warranty or other express or implied assurances of HumanTech Dental GmbH expire.

In order to ensure a long-term optimal treatment outcome, comprehensive follow-up appointments should be agreed with the patient on a regular basis and the patient should be informed about optimal oral hygiene.

This instructions for use must be read carefully and must be adhered to.

1. SCOPE

The instructions for use apply to the products delivered STERILE:

- RatioPlant® ConeCept, Avantgarde, Classic, Single Implants (including C*over Screw*)

as well as products of the RatioPlant® implant system delivered UNSTERILE:

- RatioPlant® *Prosthetic components* including *Screws*
- RatioPlant® *Screws (Prosthetic Screw, Lab Screw, Impression Screw, MU Screw)*
- RatioPlant® *Healing Caps*
- RatioPlant® *Countersinks*
- RatioPlant® C*utter*
- RatioPlant® *Drills*
- RatioPlant® *Instruments*

2. PRODUCT DESCRIPTION

RatioPlant® implants are endosseous implants for long-term use and serve as dentures in partially dental and toothless patients. They are available in different lengths and shapes. The implants are placed surgically in the bones of the upper and/or lower jaw to anchor functional and aesthetic oral rehabilitations. The prosthetic supply is carried out with single crowns, bridges, partial or total prostheses, which are connected to the implants by prosthetic components and screws of the RatioPlant® system. The RatioPlant® implant system contains surgical, prosthetic, laboratory components and related instruments. Basically, there are no preferred areas of application for the different implant geometries.

3. PURPOSE AND MATERIAL

RatioPlant® implants are implantable products for long-term use (oral endosseous implants) which are placed surgically and invasively into the bones of the upper and/or lower jaw in partially toothless and toothless patients who have completed jaw growth. They are available in different lengths and diameters. RatioPlant® implants are made of titanium alloy Ti6Al4V. All RatioPlant® implants have a blasted and etched surface.

RatioPlant® C*over Screw* and *Healing Caps* are invasive medical devices for long-term use in the oral cavity. Both are used during the healing phase of the implant and are removed after some time. *Healing Caps* form a desired emergence profile of the gingiva. Both cannot be absorbed by the mucous membrane. The *Cover Screws* and *Healing Caps* are available in different sizes and are made of titanium alloy (Ti6Al4V). *Healing Caps* made of titanium alloy are anodised and not anodised available. The *Healing Cap Individual* consists of polyetheretherketone (PEEK material).

The prosthetic components of the RatioPlant® system are divided into:

- Invasive medical devices for long-term use in the oral cavity
- Medical devices remaining in the oral cavity for short-term use
- Medical devices that do not have an application in the oral cavity but are needed for dental work

Prosthetic components of the RatioPlant® system, which are associated with invasive medical devices for long-term applications, include:

- RatioPlant® A*butments*, these are attached to the implant with the help of the *Prosthetic Screw* and serve the construction of prosthetic cares. They are available in various sizes and are made of titanium alloy (Ti6Al4V), PEEK material or zirconium oxide.
- *MU Prosthetic Cap TI* is used for the connection of occlusal screw-on prostheses to *Multiunit (MU) Abutments.* They are made of titanium alloy (Ti6Al4V).

Prosthetic components of the RatioPlant® system, which are associated with invasive medical devices for short-term applications, include:

- The prosthetic components of the RatioPlant® system, which remain in the oral cavity for short-term use, include: RatioPlant® *Impression Posts*, these are required to create an open or closed imprint of the implantation area. They are available in various sizes and are made of titanium alloy (Ti6Al4V).
- RatioPlant® T*ransfer Cap,* this is needed to create a closed print. The *Transfer Cap* is placed on an *Impression Post Closed* which is fixed in the implant and remains stuck in the imprint spoon after hardening of the imprint material. It is available in three different sizes and consists of polyoxymethylene (POM).
- RatioPlant® *Scan Connector,* which is screwed in with the help of a *Lab* Screw into the master model, or for an intraoral scan with a

Prosthetic Screw, into the implant. In this way, a scan of the present oral situation can then be made and the prosthetic supply with CAD/CAM techniques can be made individually. The *Scan Connector* is made of PEEK material.

Prosthetic components of the RatioPlant® system, which do not have an application in the oral cavity, but which are required for dental engineering work include:

- RatioPlant® *Lab Analog,* these are required to reflect the position and orientation of the implant in the master model. These are made of titanium alloy (Ti6Al4V).
- RatioPlant® *Plastic Abutments, Quick Plastic Cap* and *Prosthetic Cap Plastic.* They are used to make the basic construction in the laboratory and are made of polyoxymethylene (POM).
- RatioPlant® *Prosthetic* Screw *Normal, Prosthetic Screw ZiO and Prosthetic Screw Short* are invasive medical devices for long-term use in the oral cavity, which serve as a link between the implant and the prosthesis (e.g. bridges).The *Prosthetic Screws* cannot be absorbed by the mucous membrane. They are made of titanium alloy (Ti6Al4V). The *Prosthetic Screw ZiO* is golden anodised.
- The RatioPlant® *Lab Screw* has no application in the oral cavity and serves to attach prosthetic components in the master model. It is made of titanium alloy (Ti6Al4V) and is red anodised.
- The RatioPlant® *Impression Screw* is an invasive medical device for short-term use in the oral cavity, which is screwed into an *Impression Post* when performing an open impression. After hardening the moulding mass, the *Impression Screw* is removed and the impression tray, together with the embedded *Impression Post* and the *Impression Screw* still in it, is removed from the oral cavity.
- The *Impression Screw* is made of titanium alloy (Ti6Al4V).
- RatioPlant® *MU Prosthetic Screw* is an invasive medical device for long-term use in the oral cavity, which serves as a link between abutment and the prosthesis (e.g. occlusally screwed total prosthesis).The *MU Prosthetic Screw* cannot be absorbed by the mucous membrane. It is made of titanium alloy (Ti6Al4V) and is green anodised.
- RatioPlant® Drills *(Final Drills*, *Twist Drills, Rose-Head Burs, Pilot Drill*, *Triangle Drill*) *and Countersinks* are medical devices for temporary use intended for surgically invasive drilling of bones of the upper and/or lower jaw in partially toothless and toothless patients in order to place implants. *Rose-Head Burs* have a carbide head and a shaft made of surgical stainless steel. All other drills are made of surgical stainless steel.
- RatioPlant® *Cutter (Thread Cutter*, *Gingiva Cutter)* are medical devices for temporary use. *Thread Cutters* are used for surgically invasive drilling of bones of the upper and/or lower jaw in partially toothless and toothless patients to be able to place implants. *Gingiva Cutters* serve the previous surgical-invasive opening of the gingiva. RatioPlant® *Cutters* are made of surgical stainless steel.
- RatioPlant® *Instruments (Adapter Hex, Screwdriver Hex, Drill Extender, Parallel Post, MU Abutment Inserter, MU 0 Insert, Ratchet, Equator Inserter, Ball Attachment Inserter, Inserter CC, Connector Handpiece, Depth Gauge, Drilling Stop, Insert Square, ISO Insert, Measuring Post, Mulitplex Handle, Osteotom)* are invasive medical devices for temporary use in the oral cavity. They serve as aids for inserting and fixing the implants and *prosthetic components*. The *instruments* are made of surgical stainless steel.

4. INDICATIONS

RatioPlant® system components are intended for use in the lower and upper jaw in functional and/or aesthetic oral implantological and prosthetic care as well as for the rehabilitation of missing or lost dental structures in toothless or partially dental patients. The procedure for using the different types of implants is included within the RatioPlant® implant brochure (https: //www.humantech-dental.de/394-de-Catalogues.html) and in chapters 10-13 of this instruction for use.

5. CONTRAINDICATIONS

Contraindications may be either relative or absolute. The selection of a particular implant must be weighed carefully against the overall assessment of the patient. The following conditions can have an adverse impact on the chances of successful surgery:

- Insufficient bone and soft tissue supply and/or insufficient bone quality
- Necessary size and number of implants for the expected functional loads cannot be included
- Unfinished jaw growth
- Difficult occlusion and bone conditions
- Dysgnathia
- Local root residues
- Medical conditions or behaviour that are in conflict with bone and/or wound healing
- Discomfort (symptoms of disease)
- Bone disease and wound healing disorders
- Local infection of the implant site
- Severe therapy-resistant dysfunction
- Pregnancy and lactation
- Coagulation disorders
- Crohn's disease
- Diabetes Mellitus
- Long-term immunosuppressive therapy
- Immunocompromised patients
- Corticosteroid therapy
- Radiotherapy in the craniofacial area (head, skull, neck, jaw)
- Chemotherapy during the implantation period
- Intraoral acute or chronic infection or malignancies
- Intake of cytotoxic medicines
- Intake of anticoagulants
- Increased tendency to haemorrhage

- Drug abuse (alcohol, tobacco abuse)
- Connective tissue disease/collagenosis
- Blood diseases (e.g. leukaemia, haemophilia)
- Cardiovascular problems
- Kidney and/or liver disease
- Inflammation of the oral cavity (chewing apparatus and mouth cavity)
- Autoimmune diseases
- Acute or chronic infectious diseases
- Oral mucosa disease
- Poor oral hygiene
- Masticatory muscle hypertrophy
- Heart valve surgery
- Acute abscess or chronic sinuses
- Chronic disease and/or medicines that affect osseointegration/regeneration and wound healing as well as blood microcirculation
- Uncontrolled parafunctional or destructive habits (e.g.: Bruxism, jaw presses)
- Incapable of treating occlusal or articulation disorders
- Serious mental illnesses
- Xerostomia
- Allergy or hypersensitivity to titanium alloy, surgical steel, ZrO2, gold alloys and polymers; in case of suspected intolerance, this product may only be used after prior allergological clarification and proof of non-existence of an allergy
- Poor general condition of the patient
- Medical history in which any surgical intervention would be contraindicated
- Any other medical, physical or psychological factor that could affect the operation and hence the subsequent treatment
- All diseases in which oral surgery is normally contraindicated
- Any patient who, due to his mental or neurological condition, is not willing or able to follow the follow-up instructions.

6. PRECAUTIONS

It is important to establish a careful patient history prior to surgical implantation and, if necessary, to establish a third-party anamnesis by the general practitioner in order to determine whether:
1. difficult implantation due to the anatomical situation,
2. a serious surgical problem or a general risk,
3. impaired wound healing and/or osseointegration or
4. a deterioration of proper hygiene and/or care of implant, abutment and prosthesis

could occur.

7. SIDE EFFECTS / COMPLICATIONS

No osseointegration takes place in individual cases. In addition, as a result of implantation, crestal bone loss, injury of anatomical structures, functional limitations and mental and social impairments may occur. Immediately after insertion of dental implants, activities where the body is exposed to high physical stress should be avoided. Possible complications after insertion of dental implants may include:

7.1 Temporary complaints

- Pain
- Swelling
- Speaking difficulties
- Infections of gingiva
- Inflammation of teeth
- Infections
- Redness
- Edema
- Ulcers
- Lack of primary stability
- Foreign body sensation

7.2 Long lasting complaints:

- Chronic pain associated with the dental implant
- Permanent paraesthesia
- Dysesthesia
- Neuropathy
- Esthetic failure
- Exfoliation
- Hyperplasia
- Necrosis
- Thermal damage
- Bone resorption

- Localized or systemic infections
- Oroantral or oronasal fistulas
- Loss of upper/ lower jawbone
- Unfavourably influenced adjacent teeth
- Irreversible damage to adjacent teeth
- Injury of anatomical structures (nerve-vascular bundles) and resulting pathological consequences
- Implant, jaw, bone or dental prosthesis fractures
- Electrochemical reactions leading to dysgeusia and/ or pain
- Restriction of mobility
- Implant mobility
- Functional limitations
- Misalignment
- Mucositis or other chronic inflammatory diseases
- Foreign body sensation
- Atypical facial pain
- Instabilities/ fractures/ damage or loosening of mechanical and prosthetic components
- Repulsion of the implant
- Occlusal overload
- Allergic/toxic reaction
- Microgap
- Colour change
- Cheek and lip biting
- Mental and/or social complaints and/or impairments
- Esthetic problems
- Disorder of the temporomandibular joint
- Problems with biting and chewing
- Speaking difficulties
- Tinnitus

8. GENERAL SECURITY AND WARNINGS

- An improper procedure in surgery and prosthetics can lead to damage to the product or to negative effects on the patient. The RatioPlant® implant system may only be used by dentists, doctors and surgeons trained with the system. The application of the implant system requires special knowledge and skills about implantology. Each patient must be thoroughly examined and assessed for his or her radiological, mental and physical status, including teeth and associated hard and soft tissue deficits that may affect the end result (see also chapter 4 INDICATION and chapter 5 CONTRAINDICATION). Detailed information on the use of dental implants is described in the surgical technique for RatioPlant® implants (chapter 12) and the respective product brochures (https: //www.humantech-dental.de/394-de-Catalogues.html).
- When using X-ray for diagnosis or control, the national limits for radiation dose must be observed.
- Since the safe application requires special knowledge, our products are only handed over to doctors/dentists, authorised dealers and dental laboratories or on their order. Not all parts are available in all countries.
- Use only surgical, prosthetic laboratory components and instruments from RatioPlant®. All components of the RatioPlant® implant system are compatible with each other and part of the overall system.
- Drills, instruments and system components are intended for specific implant lines and implant diameters. Use for other implant lines or diameters can lead to mechanical failure of system components, damage to the patient or unsatisfactory aesthetic results. For this reason, RatioPlant® implants have their own surgical instrument kit with instruments suitable for the system. Note the colour markings and labels to select the instruments for the required implant diameters. The drill length must be matched with the planned implantological care and anatomical conditions before use.
- Incorrect use of rotating instruments can lead to injuries.
- Due to the small size, it can lead to swallowing and aspiration of components of the RatioPlant® implant system. Aspiration can lead to shortness of breath and, in the worst case, suffocation. For this reason, special caution should be exercised and appropriate measures should be taken for the products in intraoral use. All parts used in the mouth must be protected against swallowing and aspiration.
- In principle, correct locking of the drills, instruments and other components on the intended adapter must be ensured. Care must also be taken to fully connect the components. A careful pull or shake test is recommended. Incorrectly locked items can cause damage to components or loss of the component, which may cause complications during or after surgery in case of doubt.
- If comparatively high loads are to be expected, particular attention must be paid to ensure an exact implant alignment. Avoid corrections to the vertical position by rotating the implant counter clockwise. This could lead to reduced primary stability. Diameter-reduced implants, diameter < Ø3.8 mm, are not recommended for the lateral tooth area.
- Sterile handling is absolutely necessary. Never use potentially contaminated components. Contamination can lead to infections and foreign body spreads.
- The safety and compatibility of the implants were not assessed with regard to the influences of magnetic resonance (imaging). No thermal tests or migration tests have been performed under these influences.
- When the implant is removed from the sterile packaging, the rules of asepsis must be observed. The sterile packaging may only be opened immediately before insertion of the implant. It is recommended to always keep a replacement implant available. The implant must be removed from the packaging using appropriate aseptic provisos.
- It is essential to protect the surrounding tissue, in particular to avoid overheating, surgical trauma, impurities and sources of infection.
- The implants must not be used or reused under any circumstances if they have had contact with body fluids or tissues of a third person.

9. PACKAGING, LABELING, TRANSPORT AND STORAGE

- The handling, transport and storage of the implant components must be carried out with care. Damage to the product packaging or damage to the product itself can significantly reduce the performance, strength and durability of the implant system.
- The products should be stored at room temperature. Environmental influences such as salty air, humidity, direct sunlight, chemicals, etc. must not affect the implants.
- A careful inspection of the components of the RatioPlant® implant system to be used must be carried out before surgery to prevent damage caused by storage, transport or prior procedures.

Products of the RatioPlant® implant system are delivered in STERILE as well as in UNSTERILE packed form.

STERILE delivered RatioPlant® products:
STERILE packaged RatioPlant® implants including *Cover Screw* are delivered. These are sterilised by validated gamma sterilisation and marked as STERILE. Cleaning, processing and sterilisation before use doesn't need to be performed. The products are intended for single use only.
STERILE products of the RatioPlant® implant system are packed in a blister-tube combination and delivered protected by a carton.
These may only be used if the label of the outer packaging as well as the inner packaging is intact. If the packaging is damaged or opened, the sterility of the product is not guaranteed and must not be used.
The products must not be used if the indicated expiration date has passed.
Preparation, reprocessing, sterilisation or re-sterilisation of the products after opening the STERILE packaging or in case of a damaged STERILE packaging is not intended.
HumanTech Dental GmbH assumes no responsibility for the use of re-sterilised implants regardless of the person who carried out the re-sterilisation or the method used.

UNSTERILE delivered RatioPlant® products:
UNSTERIL packaged are *Prosthetic Components* of the RatioPlant® system like *abutments*, *Screws*, *Healing Caps, Countersinks, Cutters, Drills* and *Instruments.* These are marked as UNSTERILE and must be cleaned, disinfected and sterilised prior to use (see chapter 11, DESINFECTION AND STERILISATION).
RatioPlant® *Cutters*, *Drills* and *Instruments* are delivered in equipped RatioPlant® containers with internal RatioPlant® Tray as instrument kits or individually packaged. All other UNSTERILE delivered RatioPlant® products are delivered individually packaged. The original packaging must be intact at the time of delivery. Sterilisation in the original packaging is not permitted.

10. PREPARATIONS

10.1 Preparation of the patient

The prerequisites for successful implantation are local and systemic requirements:

- Normal wound healing capacity
- Efficient oral hygiene
- Refurbished residual teeth
- Completed upper and lower jaw growth
- Good general health condition
- Adequate supply of healthy jawbone
- Local findings
- Anatomy of the jaw crest
- Intermaxillary relationships such as deep bite, quality and thickness of mucosa, study models and bite registration in the articulator, X-ray findings

Deficiencies in patient evaluation, preoperative diagnosis and therapy planning can cause implant loss. The surgical part of the implant care must be preceded by comprehensive patient evaluation, preoperative diagnostics and therapy planning. Implant diameter and implant length shall be determined in such a way that sufficient bones (at least 1 mm) are present around the implant. A minimum distance of 1.5mm to an adjacent natural tooth and 3 mm to an adjacent implant shall be observed. Further requirements can be found in the indications (chapter 4) and contraindications (chapter 5).

10.2 Preparation, review and maintenance of instruments

- Check the ratchet and joint instruments for smooth running and, if necessary, carry out maintenance (see https://www.humantech-dental.de/379-de-Gebrauchsanweisungen-RatioPlant.html — Use and Maintenance Instructions for Torque Ratchet)
- Products delivered UNSTERILE and reusable products must be prepared, tested and maintained before and after use in accordance with the instructions "Reprocessing instructions" for RatioPlant® products (https://www.humantech-dental.de/379-de-Gebrauchsanweisungen-RatioPlant.html).

11. CLEANING, DISINFECTION AND STERILISTATION

UNSTERILE packed and unsterilized RatioPlant® products must be cleaned, disinfected and sterilised prior to use. All necessary steps of cleaning, disinfection, care and sterilisation are described in the instructions "Preparation instructions" for RatioPlant® products. You will always receive the latest edition status on our homepage, https://www.humantech-dental.de/379-de-Gebrauchsanweisungen-RatioPlant.html, as well as on request from HumanTech Dental GmbH.

12. APPLICATION

12.1 Surgery

In order to create optimal conditions for the successful healing of the implant, hard and soft tissue must be treated carefully. The implant bed must be prepared with utmost care. For the surgical procedure, the diagnostic documentation and, where appropriate, the stencils prepared in advance shall be available. The implantation can be performed transgingival 1-phase or covered 2-phase. For the 2-phase implantation, the *Cover Screw* must be replaced by a *Healing Cap* in the implant for soft tissue conditioning at least three weeks before the impression. Please make sure that the cutting instruments are placed in the right place in the instrument kit according to the implant type.

12.2 Preparation of the implant bed

Since the long-term prognosis of an implant and the aesthetic result increase with optimal positioning, the use of a drilling template is recommended. A thermal trauma can inhibit the healing of the dental implant. Therefore, excessive temperature development must be kept as low as possible. The required speed for Drills, *Countersinks* and *Thread Cutters* must be complied with:

Rose-head bur all Ø	800 rpm
Triangle drills	800 rpm
Countersink all Ø	350 rpm
Thread cutter all Ø	15 rpm

All other drills:

Drill Ø 1.5	1000 rpm
Drill Ø 2.4	700 rpm
Drill Ø 2.8	650 rpm
Drill Ø 3.0	600 rpm
Drill Ø 3.2/3.3/3.5	500 rpm
Drill Ø 3.8	450 rpm
Drill Ø 4.5	400 rpm
Drill Ø 5.0	350 rpm
Drill Ø 5.5/6.0	300 rpm

Drill Extender	Use up to max.20 Ncm. Intended exclusively for use with HumanTech implant drills. It is important to ensure that the Drill is inserted into the *Drill Extender* until it hits, so that the Drill locks correctly. A pull control is recommended for this purpose.

For the optimal preparation of the implant bed and for the inhibition of unwanted heat development, use only sharp Drills, *Countersinks* and *Thread Cutters* (not more than 20 applications), use intermittent drilling technique and ensure sufficient cooling by pre-cooled (5 °C) sterile, physiological saline solution. Also use Drills in ascending diameter and keep the pressure on the Drill low.
During planning, the surgeon must have accurate knowledge of the measuring system used and maintain an appropriate safety distance between the Drills and *Thread Cutters* to the teeth and vital structures. If the actual drilling depth is not correctly determined in relation to the X-ray image and drilled beyond the intended depth, this can cause permanent injuries to nerves or other vital structures. A safety distance of at least 1.5mm from the drill tip to the mandibularis nerve or alveolaris inferior nerve must be observed. In the upper jaw a sufficient distance from the sinus membrane should be ensured.
The drill must be selected according to the size of the implant. The names of the drills depend on the implant lengths and diameters and do not represent an exact metric specification.
Drills with and without stop are offered. Drills without stops have depth markings that must be taken into account. For Drills with stops, care must be taken to completely sink the drill to the stop in order to allow an optimal implant seat. When using Drills with stops, attention must also be paid to a flat impact surface, the highest point of the impact surface affects the insertion depth of the implant. The correct locking of the ISO-adapter must be checked before using the Drills. A pull control is recommended for this purpose.
The length and diameter of the implant as well as the length and diameter of the Drill must be checked.
The steps for correct implant bed preparation can be found in the current drilling protocol of the corresponding implant line (https://www.humantech-dental.de/379-de-Gebrauchsanweisungen-RatioPlant.html). HumanTech Dental GmbH reserves the right to publish country- and index-specific drilling protocols.
In the bone qualities D1, D2 and D3 (bone qualities *acc. Misch*) a pre-cutting of the thread may be indicated by a thread cutter or the use of *Countersinks* or *Final Drills HB*.

12.3 Insertion of the implant

The primary packaging of the implants contains a label with the batch number, which must be entered or sticked in the patient documentation. Each implant can be traced if necessary. In addition to the designation, each implant packaging is marked by a colour point, which corresponds to the colour encoding of the Drills. This is to prevent unnecessary opening and mixing of the implant and drill sizes. The adhesion points for size determination are as follows:


white: Ø 6.0, blue: Ø 5.0, green: Ø 4.2, red: Ø3.8, yellow: Ø3.2

The following procedure is recommended:

- Open the sterile packaging of the implant.
- Take the implant only with the *Adapter Hex Ratchet* from the packaging.
- Insert the implant by hand into the implant bed and screw in until the first hold.

- Remove *Adapter Hex Ratchet*.
- As an alternative to the ratchet, the *Adapter Hex Motor* can be rotated further with about 15 rpm. Always perform the final positioning manually. Otherwise, the external implant thread could be overturned inside the bone.
- Finally screw in the implant with an *Adapter Hex Ratchet* and the *Ratchet*. Implants of the line "Avantgarde" and "Classic" should be placed with the occlusal connection geometry at the level of the present bone level. "Single" implants should be rotated until the blasted thread is completely lowered. For implants of the "ConeCept" line it is recommended to place these 0.5-1.0 mm below the bone levels. This must be taken into account when planning the supply and handling of the instruments.

Attention: A torque of 40 Ncm must not be exceeded when inserting the implant. Otherwise, the implant or instrument could be damaged.

- Clean the internal thread of the implant.
- The Cover Screw must fit to the implant diameter and is rotated by hand. Insert a *Cover Screw* with the *Screwdriver Hex Hand.* Since the *Cover S*crew must be removed after the healing phase, it must only be hand-tightened.
- The wound edges are tightly sealed with atraumatic seam material. Do not overtighten the seams .They must be placed in such a way that the wound edges above the *Cover Screw* are stressless. Instead of a *Cover Screw*, a *Healing Cap* with the corresponding soft tissue height can be used. This allows transgingival 1-phase healing. Pay attention to the exact seat of the *Healing Cap.* The mucous membrane must fit tightly to the *Healing C*ap.

12.4 Care after implantation

Impeccable oral hygiene of the patient is an essential prerequisite for the long-term success of dental implants. Immediately after implantation, the surgical area must be kept free of mechanical influences. A swelling prophylaxis must be operated by cooling. The patient should be advised to contact his practice immediately in any abnormal condition after surgery.

12.5 Provisional care

Temporary prosthetic care can only be carried out as far as it can be ensured that there is no mechanical stimulus on the implant or on the seam. If temporary care is taken, care must be taken to ensure that the dental implants are not strained during the healing phase. Temporary care must not be functionally and statically in contact with neighbouring teeth or antagonists.

12.6 Healing phase

The healing phase should be at least three months for hard bone quality (D1-D2 after *acc. Misch*), for cancellous bone (D3-D4 *acc. Misch*) and/or augmentation for at least six months. The values are valid for both the upper and lower jaws. The healing time is always dependent on the respective patient situation and is the responsibility of the attending physician. Too short selected healing times, as well as shortfalling of the previously mentioned experience may endanger the success of a treatment.

12.7 Postoperative controls

Controls should be carried out within one week after surgery. Pay particular attention to the tightness of the seam and signs of a possible beginning inflammation. Suture removal depends on the patient's individual healing process and is subject to the medical judgmentof the attending physician.

12.8 Uncovering the implant and soft tissue management

All *Healing Caps* and *Instruments* are packagedUNSTERILE and must be sterilised before use. The procedure for uncovering the implant and soft tissue management shall be as follows:

- Uncover the implant.
- Remove the *Cover Screw* with *Screwdriver Hex Hand.*
- Clean the inside of the implant.
- Turn in *Healing Cap* with *Screwdriver Hex Hand*. The *Healing Cap* must match the occlusal implant connection geometry and the patient's soft tissue thickness.
- Pay attention to the exact seat of the *Healing Cap*. The mucous membrane must be close to the healing cap. Temporary abutments made of PEEK may stay in situ for a maximum of 180 days.

13. PROSTHETICS

The definite prosthetic supply of the implant is only allowed to be carried out after the soft tissue has healed without irritation. X-ray control is required before the prosthetic supply begins. The impression shall be carried out exclusively with materials intended and approved for dental impression.

When selecting the abutments, attention must be paid to the diameter and angulation of the implant and the height of the gingiva. Angulation corrections of more than 25° (30° for multi-unit abutments) must not be performed. A free-standing single implant must not have a cantilever pontic attached to it.

Attention: The contact surfaces of abutments or body parts to the implant or thread shall not be blasted or processed.

The following points must be observed when fabricating the prosthetic restoration:

- The geometrical processing of abutments can have a negative impact on the stability of the abutment and the overall system.
- For CAD/CAM abutments, the geometry produced must have sufficient stability. Find out more about this in our separate CAD/CAM user manual (https://www.humantech-dental.de/379-de-Gebrauchsanweisungen-RatioPlant.html).
- When processing prosthetic components, the connection geometry to the implant as well as the seat or the *Prosthetic Screw* itself must not be changed, otherwise a fixed and secure connection cannot be guaranteed. An anodised *Lab Screw* is intended for processing in the laboratory instead of the *Prosthetic Screw.* The *Lab Screw* should only be hand-tightened.

The following points must also be taken into account in the production of the prosthetic supply:

- Favorable load distribution

- Tension-free seat of the prosthetic supply on the abutments
- Correct occlusion
- Only materials intended for this purpose may be used for fabrication of the basic structure.

13.1 Opening and impression

The oral situation is transferred to the master model with the original RatioPlant® *Impression Posts, Screws, Transfer Caps* and *Scan Connectors.* The impression can be accomplished either with closed tray, open tray and/or digital. Corresponding *Impression Posts* are available for the above mentioned procedures. *Impression Post Closed* are used with a *Transfer Cap* for a closed print. An open impression takes place with the *Impression Post Open.* A digital impression with the RatioPlant® *Scan Connector* takes place with a dental scanner and associated software, via intraoral scan or on the previous master model. All components are matched to the appropriate implant diameter.

13.1.1 Impression with closed impression tray

Standard impression trays can be used for this impression method. The procedure for this is as follows:

- Remove *Healing Cap, Abutment* or *Cover Screw* with *Screwdriver Hex Hand.*
- Insert *Impression Post Closed* into the implant.
- Screw a *Prosthetic Screw* into the *Impression Post* with the *Screwdriver Hex Hand.*
- Place *Transfer Cap* on the *Impression Post*, the correct end position must be observed.
- Overmolding the *Impression Post Closed* with attached *Transfer Cap* with impression material.
- Fill and insert impression trays with impression material.
- Allow the impression material to harden.
- Remove the impression, the *Transfer Cap* remains in the impression.
- Remove *Impression Post Closed* with the *Screwdriver Hex Hand.*
- Seal implant again with *Healing Cap, Abutment or Cover Screw.*
- Before repositioning in the imprint, the *Impression Post Closed* is directly connected by the *Lab Screw* to a laboratory analogue *(Lab Analog).*When repositioning in the imprint, the *Transfer Cap* must be noticeably snapped into the *Impression Post*.
- Preferably overmould gingiva area at the *Lab Analog* with softened gingiva model material and pour out impression with model material.
- Allow the model material to harden.
- Remove *Impression Post Closed* and replace them with *Healing Cap, Abutment or Cover Screw.*

13.1.2 Impression with open impression tray

For this impression method individual impression trays or impression trays with occlusal opening should be used. The *Impression Posts* including the shaft of the holding screw shall not touch the tray or its opening. The sequence of the print shall be as follows:

- Remove *Healing Cap, Abutment* or *Cover Screw* with Screwdriver *Hex Hand.*
- Insert *Impression Post Open* into the implant. Then fasten by hand with the *Impression Screw Long.*
- The *Impression Post Open* is overmolded with impression material.
- Fill and insert impression trays with impression material.
- Allow the impression material to harden.
- Remove *Impression Screw Long* and pull it out as far as corresponding to the length of the guide.

Attention: Do not remove the screw completely!

- Remove impression including the *Impression Post Open*.
- Seal the implant again with the *Healing Cap, Abutment or Cover Screw*.
- The laboratory analogue *(Lab Analog)* with the *Impression Post* is screwed in with the *Impression Screw Long* and is hand-tightened.
- Preferably overmould gingiva area at the *Lab Analog* with softened gingiva model material and pour out impression with model material.
- Allow the model material to harden.

13.1.3 Digital impression

The RatioPlant® *Scan Connectors* are used for the optical, 3-dimensional localisation of RatioPlant® implants in the mouth or laboratory analogues in the master model. RatioPlant® *Scan Connectors* are available with different connection geometries according to RatioPlant® implants or with a *MulitUnit Abutment* connection geometry. It is imperative to use RatioPlant® *Scan Connectors* matching the respective connection geometry to avoid offsetting. The digital impression can be done with suitable dental scanners. Afterwards, the digital form can be paired with RatioPlant® components in a suitable CAD/CAM software to create the prosthetic supply following the CAD/CAM techniques. It is important to ensure that the required RatioPlant® components are stored in the software library used and that they are up to date. The current state of the compatible software libraries must be checked on the following link "https://www.humantech-dental.de/428-de-CAD-CAM-Support.html" and in the respective software used. When using CAD/CAM techniques for planning and creating the prosthetic supply, the instructions for use and instructions of the systems used must be taken into account.

The process of digital imaging in the master model is as follows:

- Create master model according to the above-mentioned analogous methods (see 13.1.1 Form with closed tray and 13.1.2 impression with open tray).
- Connect a *Scan Connector* to an embedded *Lab Analog* with a *Lab Screw* or *Prosthetic Screw* with the *Screwdriver Hex Hand.*
- Perform a scan with a suitable dental scanner.
- Import digital model into CAD/CAM software and plan dentures digitally.

The process of digital expression in the mouth is as follows:

- Remove *Healing Cap, Abutment* or *Cover Screw* with *Screwdriver Hex Hand.*

- Intraoral scan of soft tissue with dental scanner.
- Insert the RatioPlant® *Scan Connector* with *Prosthetic Screw* into the implant and hand-tightening with the *Screwdriver Hex Hand.*
- Intraoral scan of the present situation with RatioPlant® *Scan Connector* with dental scanner.
- Remove *Prosthetic Screw* and remove RatioPlant® *Scan Connector* and replace it with *Healing Cap, Abutment* or *Cover Screw.*
- Import digital model into CAD/CAM software and plan dentures digitally.

13.2 Manufacturing of the prosthetics

The production of single crowns and bridges as well as fixed and removable prostheses takes place in the dental laboratory in accordance with the specifications in the respective RatioPlant® brochures (https://www.humantech-dental.de/394-de-Catalogues.html) or common CAD/CAM techniques, according to the instructions for use and instructions of the CAD/CAM systems used (see also 13.1.3 Digital impression). When using RatioPlant® CAD/CAM titanium blanks, please refer to the instructions for use of CAD/CAM titanium blanks for individualisation of the abutments (https://www.humantech-dental.de/379-de-Gebrauchsanweisungen-RatioPlant.html).

13.3 Integration of prosthetic care

- Remove *Healing Cap, Abutment* or *Cover Screw* with *Screwdriver Hex Hand.*
- Clean the inside of the implant.
- Insert prosthetic supply into the implant.

Attention: The prosthetic care must sit properly in the implant. No clamping of any soft tissue between implant and prosthetic supply.

- Tighten the *Prosthetic Screw* with the specified torque of 25 Ncm. For this purpose a laboratory-made centering key is recommended.
- Tighten with the same torque after at least five minutes.

14. DISPOSAL

The product must be disposed of in accordance with local regulations and environmental regulations, taking into account the degree of contamination.

15. PRODUCT COMPLAINTS

Any person working in the healthcare sector (e.g. customer or user of this product system), who has complaints of any kind or who is dissatisfied with the handling of the product, should notify the relevant HumanTech representative about quality, identity, shelf life, durability, safety, effectiveness, and function.

If a product of the RatioPlant® implant system ever has a “malfunction” (i.e. does not meet the performance specifications or does not work as planned), or if it is suspected that this will occur, the HumanTech representative should be notified immediately.

If a HumanTech product ever has a malfunction that has caused or contributed to the death or serious injury of a patient, the representative must be notified immediately by telephone, fax or in writing.

If you have any complaints, we ask you to send us the name, article number and lot number of the component as well as your name and address together with a description of errors as detaild as possible in written form.

FURTHER INFORMATION
In the case of complaints, suggestions or notes on the content of this instruction manual or the use of the product, please contact the address listed on the last page.

VALIDITY
With the publication of this instruction for use, all previous versions lose their validity.

	Manufacturer information
	Date of manufacture
	Date of expiry
	Order number
	Lot number
	sterilized by irradiation
	Not sterile
	For single use only
	Do not use if packaging has been damaged
	Store in dry place
	Follow instructions for use
	Attention
	Do not resterilize

State of the instructions for use
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HumanTech Dental GmbH
Gewerbestr.5
D-71144 Steinenbronn
Germany
Tel.:+ 49 (0) 7157/5246-71
Fax: + 49 (0) 7157/5246-33
info@humantech-dental.de
www.humantech-dental.de

CE 0297