EN – Instructions for use for RatioPlant® SMART implant system

GENERAL INFORMATION:

Components of the RatioPlant® *SMART* implant system may not be replaced by components/products from other systems of another source or manufacturer, as these have been expressly approved by HumanTech Dental GmbH. Furthermore, no direct connection of components of the RatioPlant® *SMART* implant system to components of other systems, not be 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® *SMART* implant system. The instruction in the handling of the RatioPlant® *SMART* implant system by an experienced surgeon is required. In principle, the RatioPlant® *SMART* 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 damages or 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. Here, 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 STERILE delivered products of the following product groups:

- RatioPlant® *SMART Implants*
- RatioPlant® *SMART Cover Screw*
- RatioPlant® *SMART Body*
- RatioPlant® *SMART Spacer*
- RatioPlant® *SMART Healing Cap*

as well as for UNSTERILE products of the following product groups of the RatioPlant® *SMART* implant system:

- RatioPlant® *SMART Prosthetic Screw*
- RatioPlant® *SMART Final Drill*
- RatioPlant® *SMART Bar Connector*
- RatioPlant® *SMART Instruments*
- RatioPlant® *SMART Drills*
- RatioPlant® SMART *Countersink*

2. PRODUCT DESCRIPTION

RatioPlant® *SMART* implants are endosseous implants for long-term use and serve as dentures in partially toothed 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 by prosthetic components and screws of the RatioPlant® *SMART* system to the *SMART* body, which was previously inserted into the implant. The RatioPlant® *SMART* implant system includes 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® *SMART 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 a universal size and made of pure titanium. All RatioPlant® *SMART* implants have a blasted and etched surface.

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

RatioPlant® *SMART Body* is an implantable product for long-term use, which is used as a connection between *SMART* implants and prosthesis *(e.g.*Crown) to serve. These are available in different sizes and made of titanium alloy (Ti6Al4V).

RatioPlant® *SMART Spacer* is an invasive medical device for long-term use in the oral cavity. This is used to heal the RatioPlant® *SMART Implant* and is removed after some time. The RatioPlant® *SMART Spacer* is available in various sizes and is made of polyetheretherketone (PEEK material).

RatioPlant® *SMART Bar Connector* RatioPlant® *SMART Ti* and the *Prosthetic Screw* are invasive medical devices for long-term use in the oral cavity, which are used as a link between *SMART* implant with the *body* and the *prosthesis (e.g.*Bridges).Both cannot be absorbed by the mucous membrane. These are available in different sizes and made of titanium alloy (Ti6Al4V).

RatioPlant® *SMART* Instruments *(Implant* Inserter, *Body Inserter, Depth Gauge SMART, Rasper)* 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.

RatioPlant® *SMART Drills* (*Twist Drill*, *Triangle Drill*) and *Countersink* are medical devices for temporary use intended for surgically invasive drilling of bones of the upper and/or lower jaws in partially dental and toothless patients in order to be able to place implants. These products are made of surgical stainless steel.

RatioPlant® *SMART Final Drill* is a medical device for temporary use intended for surgically invasive drilling of bones of the upper and/or mandible in partially toothless and toothless patients in order to be able to place implants. The drill is made of surgical stainless steel.

4. INDICATIONS FOR USE

RatioPlant® system components are intended for use in the lower and upper jaw in functional and/or aesthetic oral implantological and prosthetic treatment as well as for the rehabilitation of missing or lost dental structures in toothless or partially dental patients. The procedure for using the RatioPlant® *SMART* implant system is included within the RatioPlant® *SMART* product brochure (https://www.humantech-dental.de/394-de-Catalogues.html) and in chapters 10-14 of this instruction manual.

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 disorder
- 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 medical history of the patient prior to surgical implantation and, if necessary, to establish a foreign 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

In some cases osseointegration doesn't take place. 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 Longer-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 jaw/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 fractures
- Electrochemical misconceptions
- Restriction of mobility
- Implant mobility
- Functional restrictions
- Misalignment
- Muscositis 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
- Aesthetic 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 negative effects on the patient. The RatioPlant® *SMART* 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 chapters 4 INDICATIONS FOR USE5CONTRAINDICATIONST and chapter 5 CONTRAINDICATIONS). Detailed information on the use of dental implants is described in the surgical procedure for RatioPlant® *SMART* implants (chapter 12) and in the RatioPlant® *SMART* product brochure (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 safe use requires special knowledge, our products are only handed over to or on behalf of doctors/dentists, authorised dealers and dental laboratories. Not all parts are available in all countries.
- Use only surgical, prosthetic laboratory components and instruments from RatioPlant® *SMART*. All components of the RatioPlant® *SMART* implant system are coordinated and part of the overall system.
- Drills, instruments and system components are intended for specific implant lines and implant diameters. The Usage 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® *SMART* 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 treatment and anatomical conditions before use.
- Incorrect use of rotating instruments can lead to injuries.
- Due to its small size, it can lead to swallowing and aspiration of components of the RatioPlant® *SMART* 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 recordings must be ensured. Care must also be taken to fully connect the components. A 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 ensuring an exact implant alignment. Avoid corrections to the vertical position by rotating the implant counter clockwise. This could lead to reduced primary stability.

- 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 in terms of 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, MARKING, 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 implants and instruments should be stored at room temperature. Environmental influences such as salty air, moisture, direct sunlight, chemicals, etc. must not affect the implants.
- A careful inspection of the components of the RatioPlant® *SMART* 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® *SMART* implant system are delivered in STERILE as well as in UNSTERILE packed form.

STERILE delivered RatioPlant® *SMART* products:

STERILE packaged RatioPlant® *SMART Implants including Cover Screw, Body, Spacer* and *Healing Cap* are delivered. These are sterilised by validated gammasterilisation process and marked as STERILE. Cleaning, re-sterilisation and sterilisation before use does not need to be performed. The products are intended for single use only.

Sterile products of the RatioPlant® *SMART* 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 may not be used if the stated shelf-life date is exceeded.

Preparation, reprocessing, sterilisation or re-sterilisation of the products after opening the STERILE packaging or in case of 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® *SMART* products:

UNSTERILE packaged RatioPlant® *SMART Drills*, Bar *Connector, Prosthetic Screw* and *Instruments* are supplied. These are marked as unsterile and must be cleaned, disinfected and sterilised before use (see *chapter* 11 CLEANING, DISINFECTION AND STERILISATION).

These RatioPlant® *SMART Drills* and *Instruments* are delivered in equipped RatioPlant® containers with internal RatioPlant® *Tray* as instrument kits or individually packaged. All other UNSTERILE delivered RatioPlant® *SMART* 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 bite
- Completed upper and lower jaw growth
- Good general health status
- Sufficient range of healthy jaw bones
- Local findings
- Anatomy of the jaw crest
- Intermaxillary connections such as deep bite, quality and thickness of mucosa, study models and bite registration in the articulator, radiological 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 1.5 mm to an adjacent

natural tooth and 3 mm to an adjacent implant shall be observed. Further requirements are given in the indications for use (*chapter* 4) and contraindications (chapter 5)

10.2 Preparation, inspection and maintenance of the products

- Check the ratchet and hinged 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 STERILISATION

UNSTERILE packed and unsterilized RatioPlant® *SMART* 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®". 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 extreme care. For the surgical procedure, the diagnostic documentation and, where appropriate, the stencils prepared in advance shall be available. The implantation is performed transgingival 2-phase covered. For implantation, a healing period of at least three months is required for the RatioPlant® *SMART* implant to heal. After this healing period, the RatioPlant® *SMART Spacer* is removed after the opening of the gingiva and replaced by *the* RatioPlant® *SMART Body,* followed by the RatioPlant® *SMART Healing Cap.* 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 prevent the healing of the dental implant. Therefore, the excessive temperature development must be kept as low as possible. The required touring numbers for the *SMART Final Dill,* Triangel *drill, Spiral* drill (Twist drill) and *Countersink must* be adhered to:

Triangle drill	900-1200 rpm
Spiral drill Ø2.8	400-700 rpm
Spiral drill Ø3.5	400-700 rpm
Final Drill	400-600 rpm
Countersink	200-500 rpm

Drill Extender	Use up to max. 20 Ncm. Exclusively for use with HumanTech implant drills. It is important to ensure that the Drill is inserted into the *Drill Extender* until stop, so that the Drill locks correctly. It is recommended to perform a pull control to verify the correct locking.

For the optimal preparation of the implant bed and for the inhibition of unwanted heat development, use only sharp Drills and Countersinks (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 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 1.5 mm 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. When using drills with stops, care must be taken to completely lower the Drill to the stop in order to provide 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.
If only hard cortical bone is present, the use of a *Countersink* may be indicated.

12.3 Insertion of the implant

The primary packaging of the implants contains a label with the batch number, which must be filled out or sticked in the patient documentation. Each implant can be traced if necessary.

The following procedure is recommended:

- Open sterile packaging of the implant.
- Remove implant only with the appropriate *Implant Inserter Ratchet* from the packaging.
- Insert implant by hand into the implant bed and screw in until the first hold.
- Remove the *Implant Inserter Ratchet.*
- Alternatively to the ratchet, the *Implant Inserter Motor* can be turned with about 15 rpm. Always perform the final positioning manually. Otherwise, the external implant thread in the bone could be overturned inside the bone.
- Finally screw in the implant with *Implant Inserter Ratchet* and the *Ratchet*.
- The implant is used according to protocol if it is up to 10.5 mm or at least 8.5 mm below bone level. The implant is enclosed with sterile RatioPlant® *SMART Spacers* in two lengths for the later RatioPlant® *SMART Bodies* to be used.

The corresponding RatioPlant® *SMART Body* must be selected after the healing phase and the existing bone situation.

Length of RatioPlant® *SMART Body* in mm	8,5	9,5	10,5
Depth of the implant bed in mm	8,5	9,5	10,5
Total length of the later implant in mm	13,5	14,5	15,5
Bone height above the implant in mm	1,9	2,9	3,9

12.4 Insertion of the RatioPlant® *SMART Spacer*

The primary packaging of the RatioPlant® *SMART Spacer* contains a label with the batch number, which must be recorded or sticked in the patient documentation. Each RatioPlant® *SMART Spacer* can be traced if necessary.

- Open the STERILE packaging of the RatioPlant® *SMART Spacer*.
- Take the RatioPlant® *SMART Spacer* out of the packaging with the RatioPlant® *SMART Body Inserter Ratchet* only.
- Insert the RatioPlant® *SMART Spacer* into the implant by hand and rotate until the first hold.
- Remove the RatioPlant® *SMART Body Inserter Ratchet.*
- No RatioPlant® *SMART Cover Screw* is necessary.

The RatioPlant® *SMART* implant system offers the possibility to stabilise the spacer with autologous bone material or with bone replacement material in the alveole and thus rebuild the cavities, e.g. resulting from extraction, with augmentate.
The wound edges are tightly sealed with atraumatic seam material. Do not tighten the seams. They must be placed in such a way that the wound edges on/or above the RatioPlant® *SMART Spacer* are stressless.

12.5 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.

12.6 Temporary treatment

Temporary prosthetic treatment 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 a temporary restoration is made, it is important to ensure that the dental implants are not loaded during the healing phase. Temporary care must not be functionally and statically in contact with neighbouring teeth or antagonists.

13. 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 the previously mentioned experience may endanger the success of implantation treatment.

13.1 Postoperative controls

Controls should be carried out within one week after surgery. Note above all the tightness of the seam and signs of an inflammation that may begin. Suture removal depends on the patient's individual healing process and is subject to the medical judgment of the attending physician.

13.2 Insertion of the RatioPlant® *SMART Body*

The RatioPlant® *SMART Body's* primary packaging contains a label with the batch number, which must be entered or sticked in the patient documentation. Each RatioPlant® *SMART Body* can be traced if necessary.

- Finding the RatioPlant® *SMART Spacer* and opening the mucous membrane
- Turn the RatioPlant® *SMART Spacer* out with the RatioPlant® *SMART Body Inserter Ratchet.*
- Manual roughing of the bone in the implant channel with the RatioPlant® *SMART Rasper* from the surgical set. This step serves to reactivate the bone growth that has already taken place after inserting the RatioPlant® *SMART Body.*
- Open sterile packaging of the RatioPlant® *SMART Body.*
- Take RatioPlant® *SMART Body* only with the appropriate RatioPlant® *SMART Body Inserter Ratchet* from the packaging.
- Insert RatioPlant® *SMART Body* by hand into the implant bed and screw in until the first hold.
- Turn in RatioPlant® *SMART Body* with the RatioPlant® *SMART Torque Ratchet* and RatioPlant® *SMART Body Inserter Ratchet (*or with the motor and RatioPlant® *SMART Body Inserter Motor) until a* maximum torque of 40 Ncm is achieved. Care must be taken that no higher torques are used to insert the RatioPlant® *SMART Body.*

The *SMART Healing Cap* must be applied and secured with the RatioPlant® *SMART Cover Screw*, with the help of the RatioPlant® *SMART Screw Driver Hex Ratchet.* A healing period of another 8 weeks must be ensured. Care must be taken to avoid mechanical stress on the implant.

14. 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.

The RatioPlant® *SMART Body* represents the abutment at the same time.

Angulation corrections can influence the stability of prosthetics and should be avoided. A free-standing single implant must not have a cantilever pontic attached to it.

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

- Favourable load distribution
- Stressless seat of the prosthetic supply on the RatioPlant® *SMART Body*
- Correct occlusion
- Only materials intended for this purpose may be used for fabrication of the basic structure.

14.1 Opening and impression

The transfer of the oral situation to the master model takes place with the original RatioPlant® *SMART Transfer Cap*. The impression is done with a closed spoon. Standard spoons can be used for this impression method. An individual spoon can be an advantage, as the layer thickness of the impression compound is uniform and thus a higher precision is guaranteed.

- Remove RatioPlant® *SMART Cover Screw* and RatioPlant® *SMART Healing Cap* with *Screw Driver Hex Ratchet*.
- Place the RatioPlant® *SMART Transfer Cap* on the RatioPlant® *SMART Body* and observe the correct position.
- Coat the RatioPlant® *SMART Body* with attached impression cap with impression material.
- Fill and insert the impression spoon with impression material.
- Let the impression material to be hardened.
- Remove impression, the RatioPlant® *SMART Transfer Cap* remains in the impression mass.
- Lock the implant again with the RatioPlant® *SMART Healing Cap* and RatioPlant® *SMART Cover Screw*, with the help of the *Screw Driver Hex Ratchet.*
- For repositioning in the imprint, the *Lab Analog SMART* must be connected with the RatioPlant® *SMART Transfer Cap*. The RatioPlant® *SMART Transfer Cap* must be noticeably snapped in.
- Preferably overmould gingiva area at the Lab Analog *SMART* with softened gingiva model material and pour out impression with model material.
- Let the model material to be hardened.
- Remove impression spoon with RatioPlant® *SMART Transfer Cap.*

14.2 Manufacturing of individualised abutments

Individualized abutments can be manufactured with the aid of RatioPlant® SMART Plastic Abutment SMART S and Plastic Abutment SMART S hex. They are fixed to the RatioPlant® SMART Body using RatioPlant® SMART Prosthetic Screw SMART prior to impression taking. After curing, the Prosthetic Screw SMART is released and the Plastic Abutment SMART remains in the impression. Subsequently, the Plastic Abutment SMART can be used to cast an individual abutment, e.g. made of gold. It is burned out afterwards.

14.3 Prosthetic production

The production of single crowns and bridges as well as fixed and removable prostheses is carried out in the dental laboratory in accordance with the specifications in the RatioPlant® *SMART* brochure (https://www.humantech-dental.de/394-de-Catalogues.html).

14.4 Integration of prosthetic treatment

- Remove RatioPlant® *SMART Cover Screw* and RatioPlant® *SMART Healing Cap* with *Screw Driver Hex Ratchet*.

- Clean and dry the supragingival part of the RatioPlant® *SMART Body*.
- Cement the selected prosthetic treatment after cleaning and conditioning or fix it occlusally onto the RatioPlant® *SMART Body* with use of the ratchet *(*or *Screw Driver Hex Motor* and the motor*)* with 25 Ncm of torque with the RatioPlant® *SMART Prosthetic Screw*, *Screw Driver Hex Ratchet* and *Screw Driver Hex Motor.*

Attention! The prosthetic treatment must be properly mounted on the RatioPlant® *SMART Body*. No clamping of any soft tissue between implant and prosthetic treatment. A long-term successful treatment requires a functional and trouble-free occlusion.

15. DISPOSAL

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

16. 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® *SMART* 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 the patient, the HumanTech representative must be notified immediately by telephone, fax or in writing.

If you have any complaint, 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 detailed 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 the present instructions for use, all previous editions will become invalid.

	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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