EN - Instructions for the RatioPlant® SMART implant system

Note:

The following descriptions are not sufficient for the immediate application of the RatioPlant® SMART implant system. We recommend training from an experienced surgeon in how to use the RatioPlant® SMART implant system. As a rule, the RatioPlant® SMART implant system should only be used by trained dentists, implantologists and dental technicians.

1. Product description

RatioPlant® SMART implants are enossal implants, available in various lengths and shapes. They are surgically inserted into the bone of the upper and/or lower jaw to anchor functional and aesthetic rehabilitations in partially and fully edentulous patients. The prosthetic treatment takes place with individual crowns, bridges, partial or total prostheses, which are joined to the corresponding elements with RatioPlant® SMART implants. The RatioPlant® SMART implant system includes surgical, prosthetic and laboratory components and instruments. As a rule, there is no preferred area of application for the RatioPlant® SMART implant system.

2. Indications

RatioPlant® SMART implants can be used for indications for oral enossal implants in the lower and upper jaw for the functional and/or aesthetic oral treatment of edentulous and partially edentulous patients. Suggestions for specific applications of the various implant types and sizes can be found in the surgical procedure for RatioPlant® SMART implants.

3. Contraindications

Insufficient bone and soft tissue available and/or insufficient bone quality, local root remnants, bone disorders and wound-healing disorders, local infection of the implant location, serious treatment-resistant dysfunctions, uncontrolled diabetes mellitus, long-term immunosuppressive treatment, connective tissue disorder/collagenosis, blood disorders (e.g. leukaemia, haemophilia), intraoral infection or malignant tumours, uncontrolled parafunctional habits, untreatable occlusal or articulation disorders, serious mental illnesses, xerostomia and titanium allergy.

3.1 Precautionary measures

It is important to collect a careful patient medical history and, where required, a third-party medical history from the GP before surgical implantation to clarify whether there is the possibility of 1) hindered implantation due to the anatomical situation, 2) a serious surgical problem or a general risk, 3) impaired wound healing and/or osseointegration, or 4) an impairment to the proper hygiene and/or care of the implant, abutment and prosthesis. Examples are listed below from each category and should be taken into account. Some may relate to more than one category. If any of these cases or a combination of these cases is serious or uncontrolled, a jaw implant should be avoided.

3.2 Anatomical conditions

Incomplete jaw growth, unfavourable anatomic bone conditions, pre-irradiated bone, temporomandibular joint disorders and treatable pathological jaw disorders.

3.3 Surgical and general risks

Serious systematic disorders, reduced immune defence mechanism and leukocyte dysfunctions that increase the risk of infection, endocrine illnesses, medicamentous anticoagulation/bleeding diathesis, arteriosclerosis and stroke, hypertension, heart attack, disorders from the periodic consumption of steroids, hepatitis, diabetes mellitus and pregnancy.

3.4 Impaired wound-healing abilities

Bone metabolism disorders, all illnesses that influence bone regeneration or the microcirculation of the blood, rheumatic illnesses and drug, alcohol or tobacco addiction.

3.5 Care

Rejected patient compliance, insufficient oral hygiene, periodontitis, bruxism, parafunctional habits and oral mucosal changes.

4. Side effects

In individual cases, no osseointegration occurs. Please contact your local representative in this case. Immediately after dental implants are inserted, activities during which the body is exposed to high physical stress should be avoided. Possible complications following insertion of dental implants include:

Temporary ailments pain, swelling, difficulties speaking, gum inflammation.

Longer-lasting ailments:

Chronic pain in conjunction with the dental implant, permanent paraesthesia, dysaesthesia, nerve damage, exfoliation, hyperplasia, localised or systemic infection, oroantral or oronasal fistulas, loss of upper jaw/lower jaw ridge bone, unfavourably influenced neighbouring teeth, irreversible damage to neighbouring teeth, implant, jaw, bone or dental prosthesis fractures, aesthetic problems.

5. General safety and warning notes

• An improper approach with regard to surgery and prosthetics can lead to damage to the implant or to bone loss. The RatioPlant® SMART 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. 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® SMART implants.

• As safe application requires special knowledge, our products are only provided to doctors/dentists and dental technical laboratories or on their behalf. Not all parts are available in all countries.

• The use of components and instruments that are not part of the system can impair the function and safety of the RatioPlant® SMART implant system. HumanTech assumes no guarantee or compensation for the use of components that are not part of the system. You should thus exclusively use surgical, prosthetic and laboratory components and instruments from RatioPlant® SMART. All components of the RatioPlant® SMART implant system are ideally coordinated with each other and form part of the overall system.

• The drill, instruments and system components are designed for this range of implants.

Use for other implant ranges or diameters can lead to the mechanical failure of system component, tissue damage or to unsatisfactory aesthetic results. As a result, there is a special surgical set with the suitable instruments for RatioPlant® SMART implants.

• Due to its small size, a RatioPlant® SMART product may be swallowed or inhaled. Inhalation can lead to shortness of breath and, in the worst case, asphyxia. As a result, particular care is required when using the products in intraoral applications and suitable measures should be taken.

6. Preparation of the implants and instruments

6.1 Preparation of the patient

Prerequisites for successful implantation are: local and systemic requirements, normal wound healing capacity, efficient oral hygiene, cleaned residual dentition, completed upper and lower jaw growth, good general health, and sufficient availability of healthy jaw bone. Local findings, anatomy of the jaw ridge, intermaxillary relations such as deep overbite, quality and thickness of the mucosa, study models and bite registration in the articulator, X-ray findings. Deficiencies in the patient evaluation, preoperative diagnosis and treatment planning can cause implant loss. A comprehensive patient evaluation, preoperative diagnosis and treatment planning must precede the surgical part of implant treatment. The RatioPlant® SMART implant system should then only be chosen when sufficient bone (at least 1 mm) is available around the implant bed. A minimum spacing of 1.5 mm from a neighbouring natural tooth and 3 mm from a neighbouring implant is to be observed.

6.2 Preparation of the instruments

The instruments of the RatioPlant® SMART implant system are not supplied in a sterile state if not explicitly labelled as sterile. They must be cleaned, disinfected and sterilised before the first and every further application on patients (see section 8.2 Preparation of the instruments and prosthetic components).

6.3 Preparation of the implants and cover screws

RatioPlant® SMART implants and cover screws are provided in double 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 expiry date has elapsed (see label).

• The packaging is damaged before use or has already been opened.

7. Application

7.1 Surgery

To create the ideal conditions for the successful healing of the implant, it is essential that the hard and soft tissue are handled gently. The implant bed must be prepared with the utmost care. The implantation is a covered 2-phase procedure.

7.1.1 Preparation of the implant bed

Thermal trauma can prevent the healing of the dental implant. Excessive temperature development should thus be kept as low as possible. Note the speed of drills bits and taps. 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 instruments 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. If the coronal bone margin is smoothed, the available bone height is less. It is essential that the depth 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 bur.

• Intermittent drilling technique for the twist drill bit and form cutter: 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.

• Optionally, when making the pilot hole or pre-drilled holes, check the depth and axial direction with a suitable gauge and/or a paralleling pin.

• Use drill bits with ascending diameters until the desired diameter is achieved for the implant bed.

7.1.2 Insertion of the implant

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.

The implant is used as per the protocol when it sits a maximum of 10.5 or a minimum of 8.5 mm below the bone level. The corresponding body is to be selected following the healing phase and according to the available bone situation.

Length of the 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 subsequent implant in mm	13.5	14.5	15.5
Bone height above the implant in mm	1.9	2.9	3.9

7.1.3 Insertion of the spacer

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

• Open the sterile packaging of the spacer.

• Only remove the spacer from the packaging with the corresponding adapter (hand instrument).

• Insert the spacer by hand into the implant and screw in place until the first stop.

• Pull off the hand instrument.

• Finally screw in the spacer by hand using the insertion device.

• Adjust the spacer to the bone level using the tool provided so that the spacer is in a subcrestal or subgingival position. The spacer can be shortened accordingly by simply turning the predetermined breaking point using an instrument supplied in the surgical set as part of the RatioPlant® SMART implant system.

• Screw the healing screw into the spacer by hand with the hexagonal hand screwdriver.

• Check the cover screw is firmly seated.

RatioPlant® SMART implant system offers the possibility of easily stabilising the spacer in the alveole with autologous bone material or with bone

replacement material and thus to reconstruct the e.g. cavities created through extraction with augmentation material.
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.

7.1.4 Care after implantation

The impeccable oral hygiene of the patient is a major prerequisite for the long-term success of dental implants. Immediately after implantation, the operation site must be kept free of mechanical influences as far as possible. Swelling prophylaxis can be provided through cooling.

• The patient should contact your practice immediately in the event of any condition that is abnormal for him.

7.1.5 Temporary treatment

Temporary prosthetic treatment can only take place to the extent that it can be ensured that no mechanical irritation takes place to the implant or the sutures. If temporary treatment is provided, it should be ensured that the dental implants are not put under stress during the healing phase. This should not come into contact, functionally or statically, with neighbouring teeth or antagonists.

7.1.6 Healing phase

The healing phase should take at least 3 months with good bone quality, or 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.

7.1.7 Postoperative follow-ups

Follow-ups should take place on the next day and up to one week postoperatively. Attention is to be paid to the tightness of the suture and any early signs of inflammation. The sutures can be removed after 7-10 days.

7.1.8 Exposure of the implant and soft tissue management

All healing screws are packed unsterile and are to be sterilised with the instruments before use! Unsterile healing screws that have not been used in the oral cavity can be resterilised.

• 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.

7.1.9 Insertion of the body

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

• Locate the spacer and open the mucous membrane
• Remove healing screw
• Screw out the spacer with the associated tool.
• Manually roughen the bone in the implant channel with the bone rasp from the surgical set. This step is intended to reactivate the bone growth that has already taken place once the body is attached.
• Open the sterile packaging of the body.
• Only remove the body from the packaging with the corresponding adapter (hand instrument).
• Insert the body by hand into the implant bed and screw in place until the first stop.
• Screw in the body with the torque ratchet until a maximum torque of 50Ncm has been achieved. It must be ensured that no higher torque is used to attach the body.

The healing cap is to be attached and secured with the cover screw. A healing time of a further 8 weeks is to be ensured. Care should be taken to prevent exerting mechanical stress on the implant.

7.2 Prosthetic

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.
The body also represents the abutment.
No angulation corrections of more than 25° can be performed. No cantilever bridge is to be attached to a freestanding individual implant.
The following points are to be noted when providing prosthetic treatment:

• 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. The prosthetic components of the RatioPlant® SMART implant system are not supplied in a sterile state 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.

7.2.1 Opening and casting

The oral situation is transferred to the master model using the original RatioPlant® SMART impression caps. Casting takes place with a closed tray. Standard trays can be used for this casting method. An individual tray can be an advantage, as the layer thickness of the impression material is even and thus greater precision is ensured.

• Remove healing screw and healing cap.
• Apply impression caps from the body while noting the correct end position.
• Coat the body and applied impression cap with impression material.
• Fill and use the impression tray with impression material.
• Allow the impression material to set.
• Remove impression, the transfer cap remains in the impression material.
• Close the implant again with the healing cap and cover screw.
• For a reposition in the impression, the laboratory analogue is used in the impression cap. The impression cap must be noticeably locked in place in the laboratory analogue.
• Preferably coat the gingiva area on the model analogue with soft gingiva material and cast the impression with model material.
• Allow model material to set.
• Remove impression tray with impression cap.

Oral digital casting with the Scanbody
The Smart Scanbodies are used for this casting method.
Place Scanbody on the body. Then fix the included screw tight by hand. A digital impression can now be taken using an oral scanner.
• Loosen retaining screw and remove with the Scanbody.
• Close the implant again with the healing cap.
• The laboratory analogue is fixed in place by hand with the impression post using the retaining screw.

7.2.2 Prosthetic manufacture

The manufacture of individual crowns and bridges as well as permanent and removable prostheses takes place in a dental technical laboratory in accordance with the RatioPlant® SMART prosthetics instructions.

7.2.3 Integration of prosthetic treatment

• Remove healing screw and healing cap.
• Clean and dry the supragingival part of the body.
• Cement the selected prosthetic part after cleaning and conditioning or fix to the body with occlusal screws with 25 Ncm torque.

Caution! The prosthetic part must sit correctly on the body. No soft tissue may be trapped. Functional and fault-free occlusion is to be ensured for long-term treatment success.

8. Care and maintenance

8.1 Care of the implants

All implants are provided in double 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 Preparing instruments and prosthetic components

Instruments

The instruments of the RatioPlant® SMART implant system are not supplied in a sterile state if not explicitly labelled as sterile. They must be cleaned, disinfected and sterilised before the first use and before each subsequent use on patients.

Prosthetic components

The prosthetic components of the RatioPlant® SMART implant system are not supplied in a sterile state if not explicitly labelled as sterile. They may only be used once. They must be cleaned, disinfected and sterilised before use on patients.

8.2.1 Sterilisation

The reusable RatioPlant® instruments must be sterilised or re-sterilised prior to use by means of validated steam sterilisation in an autoclave. Consult the autoclave manufacturer's instruction manual for details of the correct sterilisation temperature and cycle time. Steam sterilisation should be performed in accordance with 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. More information on preparing the instruments and prosthetic components of the RatioPlant® SMART implant system can be found at www.HumanTech-solutions.de or from your local distributor.

9. Technical data

RatioPlant® SMART implants are manufactured from pure titanium in accordance with ISO 5832-3. The bodies and components are composed of the titanium alloy Ti6Al4V and PEEK. All RatioPlant® SMART implants possess a sandblasted and acid-etched surface. The RatioPlant® SMART implants are available with a shoulder diameter of 3.8 mm.
The RatioPlant® SMART implants are two-part screw implants with a sandblasted and acid-etched surface.
• The RatioPlant® SMART implants enable a bony fusion and are thus inserted ideally and securely into the bone structure.
• Prosthetic aids are accommodated via a hexagonal connection on the body, which can be optionally secured via a prosthetic screw.
• The implants have an atraumatic self-cutting thread with two cutting slots to collect bone chips and as a double antirotational mechanism.

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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