1. General Information

1.1 Manufacturer

Legal Manufacturer

HumanTech Dental GmbH

Gewerbestraße 5

71144 Steinenbronn

Germany

SRN: DE-MF-000010597

1.2 Scope of these Instructions for Use

These Instructions for Use apply to the **RatioPlant® Dental Implant System** manufactured by HumanTech Dental GmbH.

The RatioPlant® Dental Implant System comprises dental implants and associated components, instruments and accessories used for surgical, prosthetic, impression, digital and laboratory procedures within the RatioPlant® system.

Depending on the respective device, products covered by these Instructions for Use may be supplied sterile or non-sterile, may be intended for single use or reuse, and may have direct, indirect or no patient contact. The specific characteristics of the respective device, including sterility, single-use or reusable status and other product-specific information, are indicated on the product label and/or packaging, as applicable.

These Instructions for Use shall be read before using any device of the RatioPlant® Dental Implant System. The instructions applicable to the respective device and procedure shall be observed.

1.3 Device Identification and Product Groups

The RatioPlant® Dental Implant System includes the following principal product groups:

- Dental Implants
- Cover Screws
- Prosthetic Components, including Prosthetic Abutments, Multi-Unit Abutments, Healing Components, Prosthetic Screws, Prosthetic Caps and Provisional PEEK Abutments
- Rotary Surgical Instruments
- Reusable Surgical Instruments and Sterilization Accessories
- Impression and Digital Transfer Components
- Laboratory and other Non-invasive Components

Individual devices are identified by the information provided on the respective product label and/or packaging, including the applicable article number and UDI information.

1.4 Symbols and Abbreviations

Symbols used on the product labels, packaging and in these Instructions for Use shall be interpreted in accordance with the applicable regulatory requirements and standards.
A complete explanation of the symbols used is provided in Chapter 20 – Symbols of these Instructions for Use.

Relevant abbreviations used in this document include:
eIFU – Electronic Instructions for Use
IFU – Instructions for Use
MDR – Regulation (EU) 2017/745 on medical devices
SSCP – Summary of Safety and Clinical Performance
UDI – Unique Device Identification

1.5 Electronic Instructions for Use (eIFU)

These Instructions for Use are provided in electronic form in accordance with the applicable requirements for electronic instructions for use of medical devices.
The current version of the eIFU is available electronically at the website indicated on the product label and/or packaging.
Users shall ensure that they consult the current version of the eIFU applicable to the respective device before use.
A paper copy of these Instructions for Use may be requested from HumanTech Dental GmbH and will be provided free of charge within the timeframe required by the applicable regulatory requirements.
The electronic Instructions for Use shall be accessible throughout the period required by the applicable regulatory requirements.

2. Intended Purpose

The RatioPlant® Dental Implant System is intended for the replacement of missing teeth by means of endosseous dental implants placed in the maxillary and/or mandibular bone and the subsequent support of prosthetic restorations following successful osseointegration.
The associated prosthetic components, surgical and prosthetic instruments, impression and digital transfer components, laboratory components and accessories are intended to support the surgical, prosthetic and laboratory procedures required for treatment with the RatioPlant® Dental Implant System.

3. Indications

The RatioPlant® Dental Implant System is indicated for the replacement of one or more missing teeth in the maxilla and/or mandible.

RatioPlant® dental implants may be used to support fixed or removable prosthetic restorations, including single-tooth restorations, bridges and implant-supported removable restorations, depending on the individual clinical situation and treatment plan.

Implant treatment requires adequate bone quantity and quality, or the possibility of establishing an adequate implant site by appropriate clinical procedures.

The selection of the implant, prosthetic components and treatment procedure shall be based on the individual anatomical and clinical conditions of the patient and shall be performed by an appropriately qualified dental professional.

4. Intended Patient Population

The RatioPlant® Dental Implant System is intended for adult patients with completed jaw growth requiring replacement of one or more missing teeth.

Treatment with RatioPlant® dental implants is not intended for children or adolescents with incomplete jaw growth.

Suitability for implant treatment shall be determined by the treating dental professional based on the individual clinical condition, medical and dental history, anatomical conditions and the planned prosthetic restoration.

5. Intended Users

The RatioPlant® Dental Implant System is intended for use by appropriately qualified dental professionals who have the necessary knowledge, training and experience in implant dentistry and in the respective surgical and/or prosthetic procedures.

The selection, surgical placement and prosthetic restoration of RatioPlant® dental implants shall be performed in accordance with the individual treatment plan and the applicable clinical procedures.

Devices and instruments intended for laboratory procedures shall be used by appropriately trained dental professionals or dental laboratory personnel, as applicable.

6. Contraindications

Contraindications may be absolute or relative and shall be assessed individually by the treating dental professional before implant treatment.

The RatioPlant® Dental Implant System shall not be used, or implant treatment shall be deferred, where the individual clinical condition does not permit safe implant placement and successful healing.

Contraindications and conditions that may adversely affect implant treatment include:

- incomplete jaw growth;
- insufficient bone quantity or quality and/or insufficient soft-tissue conditions where adequate implant support cannot be achieved;
- local acute or chronic infection, inflammation or other pathological conditions at the intended implant site or in the oral cavity;
- diseases, disorders or medical treatments that significantly impair bone healing, wound healing, osseointegration or blood microcirculation;
- coagulation disorders or an increased tendency to bleeding;
- severe or uncontrolled systemic disease;
- immunocompromised conditions or long-term immunosuppressive therapy;
- radiotherapy in the craniofacial region;
- chemotherapy during the implantation period;
- uncontrolled parafunctional or destructive habits that may compromise implant treatment;
- poor oral hygiene where adequate plaque control cannot be achieved;
- known hypersensitivity or allergy to materials used in the respective device;
- pregnancy and breastfeeding.

Patient-specific medical conditions, medication, smoking, alcohol or drug abuse and other factors that may impair healing or increase the risk of complications shall be carefully assessed before treatment.

7. Clinical Benefits and Performance

The intended clinical benefit of the RatioPlant® Dental Implant System is the restoration of oral function through the replacement of one or more missing teeth by means of implant-supported prosthetic restorations.

Following successful osseointegration, RatioPlant® dental implants provide stable anchorage for fixed or removable prosthetic restorations.

Successful treatment depends on appropriate patient selection, adequate bone and soft-tissue conditions, correct treatment planning, appropriate surgical and prosthetic procedures, successful osseointegration, good oral hygiene and regular professional follow-up.

Clinical outcome and long-term implant function may vary between patients and cannot be guaranteed for an individual patient.

8. Warnings and Precautions

The RatioPlant® Dental Implant System shall only be used by appropriately qualified and trained professionals. Improper patient selection, treatment planning, surgical or prosthetic procedures may result in treatment failure, device damage or injury to the patient.

The following warnings and precautions shall be observed:

- Perform a comprehensive clinical and radiographic assessment and treatment planning before implant placement.
- Use only compatible RatioPlant® components and instruments intended for the respective device and procedure. Incorrect selection or combination of components may result in mechanical failure, tissue injury or an unsatisfactory clinical outcome.
- Select implant dimensions and position according to the available bone, anatomical structures and planned prosthetic restoration.
- Protect surrounding tissues and anatomical structures during surgical preparation. Avoid excessive surgical trauma and overheating of the bone.
- Rotary instruments shall be used correctly and securely connected to the intended drive or adapter. Verify correct engagement before use.
- Take appropriate precautions to prevent swallowing or aspiration of small components during intraoral use.
- Maintain aseptic conditions when handling sterile devices. Sterile packaging shall only be opened immediately before use.
- Do not use a sterile device if the packaging is opened or damaged, if sterility may have been compromised, or if the labelled expiry date has passed.
- Devices labelled for single use shall not be reused or reprocessed for reuse. Reuse may result in contamination, infection, loss of performance or mechanical failure.
- Devices supplied non-sterile shall be cleaned, disinfected and, where applicable, sterilized before clinical use in accordance with the applicable reprocessing instructions in these Instructions for Use.
- Reusable devices shall be inspected before each use. Do not use devices showing damage, deformation, corrosion, excessive wear or impaired function.
- Do not use any device if its identity, integrity or compatibility cannot be clearly established.
- Observe the product-specific information provided on the label and packaging.

8.1 Magnetic Resonance (MR) Safety Information

RatioPlant® implants and prosthetic components are MR Conditional.

A patient with a RatioPlant® dental implant and associated prosthetic components may undergo an MR examination under the following conditions:

- Static magnetic field strength: 1.5 T or 3 T
- Maximum spatial field gradient: 11.0 T/m (1,100 G/cm) at 1.5 T and 7.0 T/m (700 G/cm) at 3 T
- MR system operated in Normal Operating Mode
- Whole-body averaged SAR reported by the MR system: maximum 2 W/kg
- Maximum continuous scanning time: 15 minutes

Under these conditions, no relevant magnetically induced displacement or torque was observed. The maximum additional temperature rise attributable to the tested RatioPlant® configuration was 0.9 °C at 1.5 T and 0.4 °C at 3 T.

The presence of other electrically conductive devices in the vicinity of the implant may affect RF-induced heating and shall be considered before MR examination.

9. Residual Risks and Undesirable Side Effects

Dental implant treatment is a surgical procedure. Despite appropriate patient selection, treatment planning and correct use of the RatioPlant® Dental Implant System, residual risks and undesirable side effects may occur.

Possible risks, complications and undesirable side effects include:

- pain, swelling, bleeding or hematoma;
- infection or inflammation;
- delayed or impaired wound healing;
- failure of osseointegration;
- loosening, migration or loss of the implant;
- peri-implant mucositis and peri-implantitis;
- bone loss around the implant;
- injury to adjacent teeth, bone, soft tissue, nerves, blood vessels or other anatomical structures;
- temporary or persistent sensory disturbances;
- mechanical complications, including loosening, wear, deformation or fracture of components;
- prosthetic complications or loss of prosthetic function;
- allergic or hypersensitivity reactions to device materials;
- swallowing or aspiration of small components;

- aesthetic or functional impairment;
- the need for additional treatment, revision or removal of the implant.

The occurrence and severity of complications may depend on the individual patient, anatomical conditions, general and oral health, healing response, oral hygiene, functional loading and compliance with professional follow-up and maintenance.

Patients shall be informed about relevant risks, possible complications and the importance of appropriate oral hygiene and regular professional follow-up before treatment.

10. Device Description and Materials

The RatioPlant® Dental Implant System comprises dental implants and associated prosthetic components, instruments, transfer components, laboratory components and accessories. The design, material and intended function depend on the respective device and product group.

10.1 Dental Implants

RatioPlant® dental implants are endosseous implants intended for placement in the maxillary or mandibular bone and for supporting prosthetic restorations following successful osseointegration.

The implants are manufactured from titanium alloy Ti6Al4V in accordance with ISO 5832-3 and have a treated surface intended to support osseointegration.

Implants are available in different designs and dimensions to allow selection according to the individual anatomical and clinical situation.

10.2 Prosthetic Components

Prosthetic components include prosthetic abutments, multi-unit abutments, healing components, prosthetic screws, prosthetic caps and provisional PEEK abutments.

Depending on the respective component and intended use, components are manufactured from suitable materials, including titanium alloy and PEEK.

The appropriate component shall be selected according to the implant configuration, clinical situation and planned prosthetic restoration.

10.3 Surgical and Prosthetic Instruments

The RatioPlant® Dental Implant System includes rotary surgical instruments and reusable surgical and prosthetic instruments used during surgical preparation, implant placement and prosthetic procedures.

Depending on the respective instrument and its intended function, instruments are manufactured from suitable metallic materials, including stainless steel.

10.4 Impression and Digital Transfer Components

Impression and digital transfer components are used to transfer the implant position and/or prosthetic situation for conventional or digital restorative workflows.

Depending on the respective device and intended use, these components may be manufactured from metallic or polymeric materials.

10.5 Laboratory and Other Non-invasive Components

Laboratory and other non-invasive components support laboratory and prosthetic workflows and are not intended for permanent implantation.

Depending on their intended function, these components may be manufactured from metallic or polymeric materials.

The specific device identification and product-specific characteristics shall be determined from the applicable product information, label and/or packaging.

11. Compatibility and Selection of Components

Only components and instruments intended for use within the RatioPlant® Dental Implant System shall be used together.

The selection of implants, prosthetic components, instruments and accessories shall be based on the respective implant configuration, component dimensions, intended clinical procedure and planned prosthetic restoration.

Before use, verify that all components intended to be connected or used together are compatible and correctly matched.

Do not combine incompatible components or use components for purposes for which they are not intended. Incorrect component selection or combination may result in improper fit, mechanical failure, damage to the implant or components, or an unsatisfactory clinical outcome.

Product-specific identification and compatibility information shall be observed when selecting the components required for the respective procedure.

12. Before Use

Before using any device of the RatioPlant® Dental Implant System, verify the device identification, intended use and compatibility with the planned procedure.

12.1 Inspection of Device and Packaging

Before use, inspect the device and, where applicable, its packaging for damage, contamination or other visible defects.

Verify the product identification and expiry date, where applicable.

Do not use a device if the device or packaging is damaged, if the product identity cannot be clearly established, or if there is any indication that the device may no longer be suitable for its intended use.

12.2 Sterile Devices

Devices labelled as sterile shall be considered sterile only if the packaging is unopened, undamaged and within the labelled expiry date.

Do not use a sterile device if the sterile barrier system is damaged or has been opened before use.

Open sterile packaging immediately before use and handle the device using appropriate aseptic technique.

12.3 Non-sterile Devices

Devices supplied non-sterile shall be cleaned, disinfected and, where applicable, sterilized before clinical use in accordance with Chapter 14 of these Instructions for Use.

12.4 Single-use Devices

Devices labelled for single use are intended for one use only.

Do not reuse or reprocess single-use devices for reuse. Reuse may result in contamination, infection, impaired performance or mechanical failure.

12.5 Reusable Devices

Reusable devices shall be cleaned, disinfected and sterilized, where applicable, in accordance with Chapter 14 of these Instructions for Use.

Before each use, reusable devices shall be inspected for cleanliness, damage, deformation, corrosion, wear and proper function.

Do not use a reusable device if its safe and proper function can no longer be ensured.

13. Clinical Procedure

13.1 Treatment Planning and Patient Selection

Before treatment, assess the patient's medical and dental history, oral condition, anatomical situation and suitability for implant treatment.

Appropriate clinical and radiographic examination shall be performed to determine the available bone, relevant anatomical structures, implant position and dimensions, and the planned prosthetic restoration.

Select the appropriate RatioPlant® implant and associated components according to the individual clinical situation and treatment plan.

13.2 Surgical Preparation

Implant site preparation shall be performed using appropriate RatioPlant® surgical instruments and according to the planned implant dimensions and position.

During preparation, protect adjacent anatomical structures and avoid excessive surgical trauma and overheating of the bone.

Rotary instruments shall be correctly connected and securely engaged before use. Appropriate irrigation shall be used during surgical preparation where required.

13.3 Implant Placement

The implant shall be placed into the prepared implant site using the appropriate RatioPlant® instruments. Implant position, orientation and primary stability shall be assessed clinically. Excessive insertion forces shall be avoided.

Following implant placement, select the appropriate healing or prosthetic component according to the planned treatment protocol.

13.4 Healing and Osseointegration

Adequate healing and osseointegration shall be allowed before definitive functional loading, taking into account the individual clinical situation, implant stability, bone quality and treatment protocol.

The implant site shall be monitored during healing for signs of infection, inflammation, impaired healing or other complications.

13.5 Prosthetic Restoration

Prosthetic restoration shall be performed using compatible RatioPlant® components selected according to the implant configuration and planned restoration.

Ensure correct seating and connection of the prosthetic components. Applicable product-specific tightening requirements shall be observed.

Occlusal conditions and functional loading shall be assessed and adjusted as clinically appropriate.

13.6 Follow-up and Maintenance

Regular professional follow-up is required to monitor the implant, peri-implant tissues and prosthetic restoration.

Patients shall be instructed in appropriate oral hygiene and maintenance of the implant-supported restoration.

Clinical findings such as pain, mobility, persistent inflammation, bleeding, suppuration, progressive bone loss or other signs of complications shall be evaluated and treated as clinically appropriate.

14. Cleaning, Disinfection and Sterilization

14.1 General Requirements

The reprocessing requirements depend on the respective device and its labelled condition of supply.

The information provided on the product label and packaging regarding sterility, single-use or reusable status shall be observed.

Devices supplied sterile shall not be reprocessed before first use.

Devices supplied non-sterile and intended for clinical use shall be cleaned, disinfected and sterilized before use as specified below.

14.2 Non-sterile Devices Before First Use

Non-sterile devices intended for clinical use shall be cleaned and disinfected before sterilization.
Cleaning and disinfection shall be performed using appropriate validated procedures and equipment suitable for the respective device and material.
After cleaning and disinfection, devices shall be thoroughly rinsed, dried and visually inspected for cleanliness and integrity.
Devices shall only proceed to sterilization when visibly clean and free from damage.

14.3 Reusable Instruments

Reusable instruments shall be cleaned and disinfected after each use and sterilized before subsequent clinical use.
Visible contamination shall be removed before further reprocessing. Particular attention shall be paid to areas that may be difficult to clean.
After cleaning and disinfection, reusable instruments shall be inspected for cleanliness, damage, deformation, corrosion, wear and proper function.
Damaged, worn or otherwise impaired devices shall not be reused.
Following cleaning and disinfection, reusable instruments intended for sterile use shall be appropriately packaged for steam sterilization.

14.4 Steam Sterilization

Non-sterile devices intended for sterile clinical use shall be sterilized by steam sterilization using a validated pre-vacuum cycle.

The following validated sterilization parameters shall be applied:

- Sterilization temperature: 132 °C
- Holding time: 5 minutes
- Cycle: Pre-vacuum steam sterilization

After sterilization, the devices shall be allowed to dry adequately before use or storage.
Sterilized devices shall be stored under conditions that maintain the integrity of the sterile barrier until use.

14.5 Limitations on Reprocessing

Devices labelled for single use shall not be reused or reprocessed for reuse.
Repeated reprocessing may affect the condition and performance of reusable devices.

Reusable devices shall therefore be inspected before each use. Devices showing damage, corrosion, deformation, excessive wear, impaired cutting performance or any other deterioration that may affect safe and proper function shall be removed from service.
Product-specific limitations and information provided on the label and packaging shall be observed.

15. Storage, Handling and Shelf Life

RatioPlant® devices shall be stored in their original packaging under dry and clean conditions and protected from direct sunlight, excessive heat, moisture and contamination.
Devices shall be handled with care to prevent damage to the device, its surface, packaging or sterile barrier system.
Sterile devices shall remain in their original sterile packaging until immediately before use. Do not use a sterile device if the packaging is opened or damaged or if sterility may otherwise have been compromised.
Where an expiry date is indicated on the product label or packaging, the device shall not be used after this date.
Non-sterile devices and reusable instruments shall be stored under conditions that protect them from contamination, damage and deterioration.
The product-specific storage conditions and information provided on the label and packaging shall be observed.

16. Disposal

Used devices, components and instruments shall be handled and disposed of in accordance with the applicable local regulations and the healthcare facility's procedures.
Devices that have been in contact with blood, tissue or other potentially infectious material shall be considered potentially contaminated and shall be handled accordingly.
Single-use devices shall be disposed of after use and shall not be reused.
Reusable devices that are damaged, worn or otherwise no longer suitable for safe use shall be removed from service and disposed of appropriately.
Care shall be taken when handling and disposing of sharp or pointed devices to prevent injury and contamination.

17. Information to be Provided to the Patient

The treating dental professional shall provide the patient with the information necessary for the safe and appropriate use and long-term care of the implant-supported restoration.

The patient shall be informed in particular about:

- the implanted device and the treatment performed;

- the importance of maintaining good oral hygiene;
- the need for regular dental examinations and professional follow-up;
- signs or symptoms that may indicate a complication, including pain, swelling, bleeding, mobility, persistent inflammation or persistent bad breath;
- the need to contact a dental professional if unusual or persistent symptoms occur;
- relevant precautions and information concerning future medical or dental treatment.

For implantable devices, the patient shall receive the applicable implant card and patient information in accordance with the requirements of Regulation (EU) 2017/745.
The patient should be advised to retain the implant card and present it to healthcare professionals where information about the implanted device may be relevant.

18. Serious Incident Reporting

Any serious incident that has occurred in relation to a device of the RatioPlant® Dental Implant System shall be reported to **HumanTech Dental GmbH** and to the competent authority of the Member State in which the user and/or patient is established.
When reporting an incident, the device should be identified as clearly as possible using the available product information, such as the product name, article number, UDI and lot or batch number.
Where possible, the affected device and relevant packaging should be retained to support investigation of the incident.

19. Summary of Safety and Clinical Performance (SSCP)

A Summary of Safety and Clinical Performance (SSCP) is available for the applicable implantable and Class III devices of the RatioPlant® Dental Implant System in accordance with Regulation (EU) 2017/745.
The SSCP provides information on the safety and clinical performance of the devices and is made publicly available through the **European Database on Medical Devices (EUDAMED)** following validation by the Notified Body.
The applicable SSCP can be identified using the device information and Basic UDI-DI provided for the respective device.

20. Symbols

The symbols used on the product labels, packaging and in these Instructions for Use are based on the applicable regulatory requirements and standards.
Depending on the respective device and its configuration, the following symbols may be used:
Only symbols applicable to the respective device are displayed on its label and/or packaging.

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Unique device identifier
	Medical device
	Sterilized using irradiation
	Do not resterilize
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Consult electronic instructions for use: https://docs.humantech-dental.de/
	Caution
	Keep dry
	Keep away from sunlight
	Non-sterile
	Single sterile barrier system
	CE marking of conformity

21. Document Information / Revision

Document: IFU-001 – Instructions for Use – RatioPlant® Dental Implant System

Revision: Rev01

Legal Manufacturer: HumanTech Dental GmbH

Language: English

Format: Electronic Instructions for Use (eIFU)

Revision	Date	Description of Change
Rev01	23.09.2026	Initial release of the consolidated Instructions for Use for the RatioPlant® Dental Implant System under Regulation (EU) 2017/745.

The current version of these Instructions for Use is available electronically at the website indicated on the product label and/or packaging.