GENERAL INFORMATION

RatioPlant® *CAD/CAM-Titanium Blanks*, *-Adhesive Abutments* and *–Lab Analogs* may not be replaced by components/products from other systems of another source or manufacturers, except these have been expressly approved by HumanTech Dental GmbH. Furthermore, no direct connection of components of RatioPlant® *CAD/CAM-Titanium Blanks*, *-Adhesive Abutments* and *–Lab Analogs* 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 orally, 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 RatioPlant® *CAD/CAM-Titanium Blanks*, *-Adhesive Abutments* and *–Lab Analogs* because knowledge of dental laboratory technology is mandatory. Basically, RatioPlant® *CAD/CAM-Titanium Blanks*, *-Adhesive Abutments* and *–Lab Analogs* may only be used by persons who have completed professional training in dental technology. It is the responsibility of the user to apply the product in accordance with these instructions for use and to decide whether it is suitable for the individual patient situation.
The user of HumanTech Dental GmbH products has to determine whether the product is suitable for a certain patient in the given conditions. HumanTech Dental GmbH assumes no responsibility, neither express nor implied, for any direct or indirect damages, penalties including compensatory damages or any other damages arising out of or in connection with errors in professional judgment or practice in the use of HumanTech Dental GmbH products. In this connection, the warranty or other express or implied warranties of HumanTech Dental GmbH expire.
To ensure optimal long-term treatment results, comprehensive follow-up examinations should be scheduled with the patient on a regular basis and the patient should be informed about optimal oral hygiene.
These instructions for use must be read carefully and must be complied with.

1 SCOPE

These instructions for use apply for UNSTERILE products of the following product groups:

- RatioPlant® *CAD/CAM-Titanium Blanks*
- RatioPlant® *Adhesive Abutments*
- RatioPlant® *Lab Analogs*

2 PRODUCT DESCRIPTION

RatioPlant® *CAD/CAM-Titanium Blanks* (*Abutment Ti CAD CAM*, *Abutment Ti ConeCept CAD CAM*) are prefabricated components for the machined fabrication of customized, one-piece abutments using CAD/CAM technology.
RatioPlant® *Adhesive Abutments* (*Ti Adhesive Abutment, Ti Adhesive Abutment ConeCept, Ti Adhesive Abutment Base, Ti Adhesive Abutment ConeCept Base)* can be used as conventional Abutments for manually manufactured cemented restauration or serve as an adhesive base for CAD/CAM customized implant-supported dental replacements made of suitable materials.
RatioPlant® *Lab Analogs* are laboratory products. They represent RatioPlant® implants within a master model for marking their orientation and position. RatioPlant® *Lab Analogs* may be applied either manually or by means of CAD/CAM technologies in combination with a dental scanner.

3 INTENDED PURPOSE AND MATERIAL

3.1 RatioPlant® *CAD/CAM-Titanium Blanks*

RatioPlant® *CAD/CAM-Titanium Blanks* (*Abutment Ti CAD CAM*, *Abutment Ti ConeCept CAD CAM*) are applied for fabrication of customized one-piece abutments by means of CAD/CAM technologies. RatioPlant® *CAD/CAM-Titanium Blanks* are available with the respective connection geometries of the implants of the RatioPlant® *Classic*, *Avantgarde* and *ConeCept* system.
For both RatioPlant® *Classic* and *Avantgarde* it is possible to apply the *Abutment Ti CAD CAM* because the interface geometry between implant and abutment is identical. The interface connection geometry of RatioPlant® *Classic* and *Avantgarde* vary within the implant diameters like described below. For the RatioPlant® *ConeCept* implant system there is a separate RatioPlant® *CAD/CAM-Titanium Blank* available. The *Abutment Ti ConeCept CAD CAM* is compatible with all implant diameters of RatioPlant® *ConeCept* like described below. The cylinder located above the occlusal connection geometry is processed into customized abutment using computer-assisted machining techniques (CAD/CAM techniques).
RatioPlant® *CAD/CAM-Titanium Blanks* are intended for single-use and are made of titanium alloy Ti6Al4V.

Abutment Ti Mini CAD CAM: The implant diameters Ø3.2 and Ø3.3 are supplied with the same blanks for RatioPlant® *Classic* and *Avantgarde* implant system.

Abutment Ti S CAD CAM: The implant diameters Ø3.8 and Ø4.2 are supplied with the same blanks for RatioPlant® *Classic* and *Avantgarde* implant system.

Abutment Ti L CAD CAM: The implant diameters Ø5.0 and Ø6.0 are supplied with the same blanks for RatioPlant® *Classic* and *Avantgarde* implant system.

Abutment Ti ConeCept CAD CAM: The *CAD/CAM-Titanium Blank* for the RatioPlant® *ConeCept* implant system is applied for all implant diameters (Ø3.3; Ø3.8; Ø4.2; Ø5.0).

3.2 RatioPlant® *Adhesive Abutment*

RatioPlant® *Adhesive Abutments* are inserted in RatioPlant® implants for prosthetic reconstruction, e.g. single-tooth crowns. Both manual and CAD/CAM technologies may be used for this purpose. *Adhesive Abutments* are intended for single-use and are made of titanium alloy Ti6Al4V.

3.3 RatioPlant® *Lab Analog*

RatioPlant® *Lab Analogs* are inserted into a master model (physical or digital) and represent a RatioPlant® implant. They show the orientation and position of the implant in the master model. They are made of titanium alloy Ti6Al4V. The description of the application can be found in the instruction for use for the RatioPlant® implant system in chapter 13 (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html).

4 INDICATIONS

4.1 RatioPlant® *CAD/CAM-Titanium Blanks*

RatioPlant® *CAD/CAM-Titanium Blanks* are semifinished parts for the fabrication of customized one-piece abutments on RatioPlant® *Classic*, *Avantgarde* and *ConeCept* implants for use in the upper and lower jaws. RatioPlant® *CAD/CAM-Titanium Blanks* are combined with RatioPlant® implant system and therefore share its indications. General indications for the use of RatioPlant® implant system can be found in chapter 4 of the instructions for use for the RatioPlant® implant system (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html).

4.2 RatioPlant® *Adhesive Abutment*

RatioPlant® *Adhesive Abutments* are directly or indirectly connected with the endosseous dental implant and serve as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented onto the *Adhesive Abutment*. Prior to the insertion of the final components it is possible to apply a temporary restoration in order to maintain, stabilize and shape the soft tissue during the healing phase; they must not be placed in occlusion. Final abutments and restorations can be placed in occlusion after the implant is fully osseointegrated.

5 CONTRAINDICATIONS

RatioPlant® *CAD/CAM-Titanium Blanks* and *Adhesive Abutments* must not be used in case of:

- Single-tooth restoration without free-end pontic
- Extension attachments to abutment
- Direct laser welding
- Casting technique
- Ceramic facing
- Known allergies or hypersensitivities to the chemical components of the titanium alloy Ti6Al4V
- Clinical situations that do not allow compliance with the specifications mentioned in the following chapters or where the stability of the customized abutment cannot be ensured

RatioPlant® *CAD/CAM-Titanium Blanks* and *Adhesive Abutments* are used with RatioPlant® implant system and therefore share its contraindications. General contraindications for the use of RatioPlant® implant system can be found in chapter 5 of the instructions for use for the RatioPlant® implant system (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html).

6 SIDE EFFECTS / COMPLICATIONS

RatioPlant® *CAD/CAM-Titanium Blanks* and *Adhesive Abutments* are used together with the RatioPlant® implant system. Side effects and complications that may occur during use are described in chapter 7 of the instructions for use for the RatioPlant® implant system (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html).

7 GENERAL SECURITY AND WARNING INSTRUCTIONS

Improper use of the RatioPlant® *CAD/CAM-Titanium Blanks*, *Adhesive Abutments* and *Lab Analogs* may result in damage to the product or negative effects on the patient. Relevant safety instructions and warnings are described in the instruction for use for RatioPlant® implant system (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html)

8 ACCESSORIES

Each RatioPlant® *CAD/CAM-Titanium Blank, Adhesive Abutment and Lab Analogs* is supplied with a corresponding *Prosthetic Screw* for final fixation of the prosthetics in the implant. The *Lab Screw* which is applied for laboratory usage is available separately.

8.1 *Prosthetic Screw*

The tightening torque of the customized abutments manufactured from the RatioPlant® *CAD/CAM-Titanium Blanks* on the implants by means of the *Prosthetic Screw* is 25 Ncm. Fixation is performed using the *Screwdriver Hex Ratchet* and the *Ratchet Torque*. The *Prosthetic Screw* is used for final fixation of the abutment in the implant. Screwing by torque must be repeated five minutes after tightening with 25 Ncm. It is made of titanium alloy Ti6Al4V. The detailed purpose is described in the instructions for use for the RatioPlant® implant system (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html).

8.2 *Lab Screw*

The *Lab Screw* is used by the laboratory technician for fixation of the customized abutment on the *Lab Analog* in the working cast. To avoid confusion with the *Prosthetic Screw* the *Lab Screw* is anodized in color. It should only be tightened by hand. The *Lab Screw* is made of titanium alloy Ti6Al4V. The detailed intended purpose is described in the instructions for use for the RatioPlant® implant system (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html).

9 PACKAGING, TRANSPORT AND STORAGE

- Handling, transport and storage of the implant components has to be carried out carefully. Damage to the packaging or damage to the product itself may significantly reduce performance, stability and fatigue strength of the product.
- The products should be stored at room temperature. Environmental influences like salty air, humidity, direct sunlight, chemicals, etc. must not affect the implants.
- RatioPlant® *CAD/CAM-Titanium Blanks*, *Adhesive Abutments* and *Lab Analogs* are supplied in UNSTERILE packaging. They are labeled as UNSTERILE and therefore they must be cleaned, disinfected and sterilized before use. The same procedure has to be chosen for this as is described for RatioPlant® abutments in the instructions for use for RatioPlant® implant system (see chapter 11 CLEANING, DISINFECTION AND STERILIZATION). The latest version is available on our homepage (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html) and on request from HumanTech Dental GmbH.

10 CLEANING, DISINFECTION AND STERILIZATION

RatioPlant® products delivered in UNSTERILE packaging must be cleaned, disinfected and sterilized before use. All necessary steps for cleaning, disinfection, maintenance and sterilization are described in the "Processing Instructions" for RatioPlant® products. The latest version is available on our homepage (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html) and on request from HumanTech Dental GmbH. The same Processing Instructions apply for RatioPlant® *CAD/CAM-Titanium Blanks*, *Adhesive Abutments* and *Lab Analogs* as to RatioPlant® abutments.

11 APPLICATION

RatioPlant® *CAD/CAM-Titanium Blanks*, *Adhesive Abutments* and *Lab Analogs* are applied with the RatioPlant® implant system. For more information on the use of RatioPlant® implant system, refer to chapter 12 of the instructions for use for the RatioPlant® implant system (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html).

12 PROSTHETICS

12.1 Responsibilities for manufacturing of customized abutments

The CAD/CAM customized abutments and supra-structures are being manufactured by dental laboratories or CAD/CAM mill centers on milling machines designed for this purpose. Humantech Dental GmbH only offers RatioPlant® *CAD/CAM-Titanium Blanks* and **does not** manufacture of customized abutments or supra-structures.

12.2 Digital impression

For planning a customized CAD/CAM abutment a digital impression is necessary. For more information refer to chapter 13.1.3 in the instructions for use for RatioPlant® implant system (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html).

12.3 Dimensioning of customized abutments

- The dimensioning and manufacturing of a prosthetic restauration as well as the processing of the system components used for this purpose can have an influence on its performance. Please refer to chapter 13 of the instructions for use for RatioPlant® implant system for this (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html).
- Customized RatioPlant® *CAD/CAM-Titanium Blanks* and supra-structures on *Adhesive Abutments* must provide sufficient stability and comply with design specifications. For this purpose, the limit specifications of the respective processing software and by the material manufacturer as well as the specifications listed below must be complied with during the design of the customized abutment (see chapter 12.4).

12.4 Limit specifications

The machining of the RatioPlant® *CAD/CAM-Titanium Blanks* is limited as follows:

- The customized angulation of the abutments must not exceed 25°.
- The minimum wall thickness of the screw channel after machining must be greater than 0.25 mm.
- The length of the customized abutment must not exceed 12.5 mm for implants of the RatioPlant® *Avantgarde* implant system.
- The length of the customized abutment must not exceed 13.2 mm for implants of the RatioPlant® *ConeCept* implant system.
- Machining of the interface geometry, which connects implant and abutment, is generally excluded.
- The customized abutments should be occlusally rounded and not pointed. Sharpe edges should be avoided.

The CAD/CAM softwares Exocad and 3Shape allow the design of customized supra-structures, e.g. occlusal screw-retained hybrid ceramic crowns on RatioPlant® *Adhesive Abutments*. The following basic rules should be complied with:

- The RatioPlant® *Adhesive Abutment* must not be machined, changed or modified in the CAD/CAM system or during any phase of the processing. This can cause subsequent misalignment of digitally planned parts or instability.
- In order to ensure correct functioning, no modifications may be made to the RatioPlant® *Adehesive Abutment* with regard to angle, wall thickness or height. Preparation for the bonding process by means of blasting is permitted.
- The adhesive surface of the RatioPlant® *Adhesive Abutment* can be blasted with Al_2O_3 blasting material with 50 µm and max. 2 bar and subsequently cleaned thoroughly (free of grease and dust). Care must be taken to ensure that the wall thickness (screw hole to outer abutment surface) is not less than 0.25 mm.
- The connection geometry to the implants must not be machined.
- The emergence profile should be designed gently and based on biological aspects, taking into account the soft tissue. A larger expansion of the gingiva than has been shaped by healing caps should always be carried out with the consultation of the treating physician. The gingiva can also be successively expanded with customized fabricated temporary abutments made of plastic.
- In general, the circular step should be placed slightly below the gingiva in the vestibular region and orally on the gingival line. In this way, the transition is not visible vestibularly. Excess cement must be removed.
- The necessary wall thickness and oversize for a customized prosthetic superstructure on a RatioPlant® *Adehesive Abutment* must be taken from the manufacturer's instructions for the materials used.
- The abutments should be occlusally rounded and not pointed. Sharpe edges should be avoided.

- The customization must be performed by professionals with knowledge of CAD/CAM.
- The customized design and manufacturing of the prosthetics must be in accordance with the current state-of-the-art of science and technology and include a medical benefit.

12.5 Check of the dataset

Checking the dataset of the computer-aided design (CAD-file) for compliance with the prerequisites according to the limit specifications is mandatory before customizing the RatioPlant® *CAD/CAM-Titanium Blank*, planning of a customized prosthetic abutment and digitally designed master model. If the prerequisites are not complied with the geometry has to be adjusted accordingly.
This data is provided without any express or implied warranty. Due to the variety of conditions and hardware under which this data may be used, no warranty of suitability for any particular purpose is given. The user is advised to test the data thoroughly before relying on it. The user must assume all risk of use of this data and accepts it "with all its faults". The user must assume the entire risk of using the program. Supplied CAD / CAM dataset must not be changed. Errors shall be reported to supplier.

12.6 Machining of RatioPlant® *CAD/CAM-Titanium Blanks*

With RatioPlant® *CAD/CAM-Titanium Blanks*, clamping during customization takes place on a cylindrical section opposite to implant connection geometry. As machine specific clamping device the Preface® abutment holders from the manufacturer Medentika® can be used.
After setting the axial alignment, including the correct positioning of the rotation lock of the RatioPlant® *CAD/CAM-Titanium Blank* in the machine, the RatioPlant® *CAD/CAM-Titanium Blank* is customized according to the specified dataset and by machining techniques. The correct position of the origin as well as the correct rotational alignment of the connection geometry must be ensured before machining the blank. The connection geometry of the abutment must not be machined. During machining, the stability must not be impaired, in particular in load-bearing areas (e.g. low wall thickness). Sufficient cooling lubrication during machine must be ensured. In order to prevent notch effects and the associated risk of breakage, sharp transitions at the customized abutment must be avoided. If necessary, the customized abutment must be discarded or notch-effect shapes eliminated by polishing during microscopic examination. Contact surfaces of the customized abutment to the implant must not be machined.

12.7 Reworking and cleaning

Machining can result in sharp edges and protruding elevations on the customized abutment. These must subsequently be removed. When manually reworking the customized abutments, it is to be ensured that the connection geometry of the abutment is neither sandblasted nor machined. Through reworking the stability must not be impaired in particular in load-bearing areas (e.g. low wall thickness). Furthermore, it must be ensured that the bore of the abutment is free to move after machining and that the *Prosthetic Screw* may be inserted without any problems. The customized abutment must be cleaned of production residues and processing media used after completion of the machining.

12.8 Processing

The products are delivered in UNSTERILE packaging. The products must be cleaned and disinfected before use on the patient. We recommend a serilization of the manufactured abutments. All necessary steps for cleaning and disinfection are described in the "Processing Instructions" for RatioPlant® products (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html). RatioPlant® *CAD/CAM-Titanium Blanks and Adhesive Abutments* must be treated in the same way as RatioPlant® abutments.

12.9 Prosthetics manufacturing

Single-tooth crowns and bridges as well as fixed and removable dentures are manufactured in a dental laboratory according to the specifications in the respective RatioPlant® broschure (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html) or common CAD/CAM techniques in accordance with the instructions for use and notes of the CAD/CAM system in use.

12.10 Insertion of the prosthetic supply

The insertion of the customized prosthetic supply is described in chapter 13.3 of the instructions for use for RatioPlant® implant system (https://www.humantech-dental.de/379-en-Gebrauchsanweisungen-RatioPlant.html).

13 DISPOSAL

The disposal of the product must be carried out in accordance with the local applicable and environmental regulations, taking into account the respective degree of contamination.

14 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 detailed as possible in written form.

FURTHER INFORMATION

In case of any 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
	Manufacturing date
	Date of Expiry
	Reference number
	Lot number
	Sterilized by irradiation
	Non sterile
	Do not reuse
	Do not use if packaging is damaged
	Store in a dry place
	Follow instructions for use
	Attention
	Do not resterilize

State of the instruction for use

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