1. About this Patient Information

This information is intended for patients who have received one or more implants from the RatioPlant® Dental Implant System .

It provides important information about your dental implant, including its intended purpose, materials, expected benefits, possible risks and complications, precautions, recommended care and follow-up, expected lifetime and information concerning magnetic resonance imaging (MRI).

Please read this information carefully and keep your Implant Card for future reference.

Your Implant Card contains information identifying the implant(s) placed in your body. Show the Implant Card to dentists, physicians and other healthcare professionals when this information may be relevant to your treatment or examination.

If you have questions about your implant, your treatment or your individual medical situation, please contact your dentist or treating healthcare professional.

2. Your RatioPlant® Dental Implant

The RatioPlant® Dental Implant System is a dental implant system used to replace missing teeth.

A dental implant is placed into the bone of the upper or lower jaw. After successful healing and integration of the implant into the surrounding bone (osseointegration), it can support a dental restoration such as a crown, bridge or other implant-supported prosthetic restoration.

The implant itself acts as an artificial tooth root. Depending on your individual treatment, additional RatioPlant® components may be used to connect the implant with the dental restoration.

Your individual Implant Card contains the product and traceability information for the implant(s) placed in your body.

The exact treatment and type of dental restoration depend on your individual clinical situation and are determined by your treating dentist or healthcare professional.

3. What is the implant intended for?

The RatioPlant® Dental Implant System is intended to replace missing teeth.

The dental implants are placed in the bone of the upper and/or lower jaw and, following successful osseointegration, are used to support prosthetic restorations.

The aim of the treatment is to restore oral function by providing support for the replacement of missing teeth.

Whether dental implant treatment is suitable for you depends on your individual oral and general health, the condition of your jawbone and other clinical factors. This is assessed by your treating dentist or healthcare professional before treatment.

4. What materials are used?

RatioPlant® dental implants and the principal implant components intended to remain in the body are made of titanium alloy (Ti6Al4V, material specification 3.7165 according to ISO 5832-3).

Depending on the individual treatment, additional components made of other materials may be used as part of the RatioPlant® Dental Implant System . These components may have different functions and different types or durations of patient contact.

The materials used have been selected and evaluated for their intended medical use and for their respective contact with the human body.

If you have a known or suspected allergy or sensitivity to metals or other materials, inform your dentist. Information about the specific implant placed in your body can be identified using your Implant Card and the corresponding product information.

5. Expected benefits

The expected clinical benefit of treatment with the RatioPlant® Dental Implant System is the restoration of oral function by replacing missing teeth with implant-supported prosthetic restorations.

Following successful healing and osseointegration, the implant provides stable support for the dental restoration and can contribute to restoring chewing function.

The individual outcome of implant treatment depends on several factors, including the clinical situation, successful osseointegration, oral hygiene, regular follow-up care and compliance with the recommendations of your treating dentist.

6. Possible risks and complications

As with any dental implant treatment, complications may occur during or after treatment. These may be temporary or, in some cases, may require additional treatment or removal of the implant.

Possible risks and complications include:

- pain, swelling, bleeding or inflammation;
- infection at or around the implant site;
- delayed or insufficient healing;
- failure of the implant to integrate successfully with the surrounding bone;
- loss or loosening of the implant;
- inflammation of the tissues surrounding the implant (peri-implant mucositis or peri-implantitis);
- bone loss around the implant;
- loosening, wear, fracture or failure of implant or prosthetic components;
- damage or irritation to surrounding structures, including nerves, teeth or soft tissues;
- temporary or persistent changes in sensation;
- adverse reactions or sensitivity to materials;
- aesthetic or functional complications that may require additional treatment.

Good oral hygiene, regular professional follow-up and early treatment of inflammation or other problems can help reduce the risk of complications.

If you experience persistent pain, swelling, bleeding, loosening of the implant or restoration, persistent bad breath or other unusual symptoms around the implant, contact your dentist or healthcare professional.

7. Warnings and precautions

To support the long-term function of your dental implant, follow the instructions and recommendations of your dentist.

Please observe the following precautions:

- Maintain good oral hygiene and clean your teeth and implant-supported restoration as instructed by your dentist or dental professional.
- Attend the recommended regular dental examinations and professional cleaning appointments.
- Do not ignore pain, swelling, bleeding, inflammation, loosening or other unusual changes around the implant.
- Avoid excessive forces on the implant and restoration. If you grind or clench your teeth, discuss this with your dentist.
- Smoking may adversely affect healing and the long-term outcome of implant treatment.
- Inform dentists, physicians and other healthcare professionals that you have a dental implant when this may be relevant to an examination or treatment.
- Keep your Implant Card and present it to healthcare professionals when relevant.

If you are unsure whether a dental treatment or procedure may affect your implant, consult your dentist. For medical examinations or treatments, inform the relevant healthcare professional that you have a dental implant.

8. Care, oral hygiene and follow-up

Good oral hygiene and regular dental care are important for the long-term health and function of your dental implant.

- Clean your teeth and implant-supported restoration carefully every day as instructed by your dentist or dental professional.
- Use suitable oral hygiene aids recommended for your individual situation.
- Attend regular dental examinations and professional cleaning appointments at the intervals recommended by your dentist.
- Your dentist should regularly check the implant, the surrounding gums and bone, and the implant-supported restoration.
- Follow any specific instructions provided after implant placement or prosthetic treatment.

Plaque and bacteria around the implant can cause inflammation of the surrounding tissues. If left untreated, inflammation may progress and contribute to bone loss and possible implant failure.

Regular follow-up allows potential problems to be detected and treated at an early stage.

9. When should you contact your dentist?

Contact your dentist if you notice any unusual or persistent changes around your dental implant or implant-supported restoration.

In particular, seek dental advice if you experience:

- persistent or increasing pain;
- swelling, redness or tenderness around the implant;
- bleeding around the implant;
- discharge or signs of infection;
- persistent bad breath or an unpleasant taste;
- loosening or movement of the implant or implant-supported restoration;
- changes in your bite or difficulty chewing;
- numbness, tingling or other changes in sensation;
- any other persistent or unusual symptoms around the implant.

Persistent bad breath may be a sign of inflammation around the implant and should be assessed by your dentist.

Early examination and treatment can help prevent a problem from becoming more serious.

10. Expected lifetime of the implant

Dental implants are intended for long-term use. However, a specific lifetime cannot be guaranteed for an individual implant.

The lifetime of your dental implant depends on several factors, including:

- successful healing and osseointegration;
- your oral and general health;
- good oral hygiene;
- regular dental examinations and professional care;
- the condition of the surrounding bone and soft tissues;
- the forces acting on the implant and restoration;
- habits such as smoking, grinding or clenching of the teeth;
- the condition and maintenance of the implant-supported restoration.

Regular dental follow-up is important throughout the lifetime of the implant.

Your dentist will assess the condition and function of the implant and restoration during follow-up examinations and recommend appropriate care or treatment if necessary.

11. MRI and other medical examinations

Your RatioPlant® dental implant contains metallic components and is MR Conditional. This means that magnetic resonance imaging (MRI) can be performed safely under specific conditions.

Before undergoing an MRI examination, always inform the physician or MRI staff that you have a dental implant and show them your **Implant Card**.

The RatioPlant® Dental Implant System has been evaluated for use in MRI environments under defined conditions. The detailed MRI conditions, including permitted magnetic field strength and scanning parameters, are provided in the current RatioPlant® product information.

MRI may cause image artefacts in the area around the implant. This may affect the quality of diagnostic images close to the implant.

For other medical examinations or treatments, inform the relevant healthcare professional that you have a dental implant if this information may be relevant to the planned procedure.

Do not make decisions about the suitability of an MRI examination yourself. The physician or MRI professional is responsible for determining whether the examination can be performed under the specified conditions.

12. Information for other healthcare professionals

Keep your Implant Card and show it to dentists, physicians and other healthcare professionals whenever information about your dental implant may be relevant to an examination or treatment.

The Implant Card contains information that allows the implanted device to be identified.

For detailed information about the RatioPlant® Dental Implant System , including MRI conditions and other safety information, healthcare professionals should refer to the current RatioPlant® product information available from the manufacturer.

If you receive dental treatment from a different dentist, inform them that you have a dental implant and provide your Implant Card where relevant.

13. Serious incidents

If you experience a serious health problem that you believe may be related to your RatioPlant® dental implant, contact your dentist or physician as appropriate.

Any serious incident related to the implant should also be reported to:

- HumanTech Dental GmbH, as the manufacturer of the RatioPlant® Dental Implant System ; and
- the competent authority in the country where you are located.

Your dentist or another healthcare professional can assist you with reporting if necessary.

When reporting an incident, provide the information from your Implant Card, if available, to help identify the affected implant.

14. Further information

Further information about the RatioPlant® Dental Implant System is available from the manufacturer.

The Summary of Safety and Clinical Performance (SSCP) provides additional information about the safety and clinical performance of the RatioPlant® Dental Implant System . Following validation by the Notified Body, the SSCP is made publicly available through the European Database on Medical Devices (EUDAMED).

The current Patient Information and further product information are available via the manufacturer's website.

The QR code and website address on your Implant Card provide access to the current Patient Information.

If you require further information about your individual implant or treatment, please contact your dentist.

15. Manufacturer and document information

Legal Manufacturer

HumanTech Dental GmbH
Gewerbestraße 5
71144 Steinenbronn
Germany
www.humantech-dental.de

Device: RatioPlant® Dental Implant System

The current version of this Patient Information is available electronically via the website address and QR code provided on the Implant Card.