Instructions for use for TBR® implants

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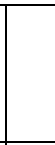
CE 0459

The protocols and user's instructions can also:

- Be provided in printed version at no charge, upon simple request and within a maximum of 7 days.
- Be downloaded on the website http://ifu.tbr.dental

1. Description of TBR® implants

The medical device you have just received is a TBR® endosseous dental implant delivered with its cover screw, both in sterile condition.
The table hereunder describes all the variants of TBR® dental implants and their composition:

	Tissue Level Z1									Bone Level												
Connection	8						M			8								M				
Representation																							
Range	Z1-Infinity			Z1-Connect			Z1-M			Infinity			Connect			Baby 8		M			Baby M	
Color code																						
Ø body emergence (mm)	3,5	4	5	3,5	4	5	3,2	3,9	4,7	3,5	4	5	3,5	4	5	4	5	3,2	3,9	4,7	3,9	4,7
Body length (mm)	8 – 10,5 – 11,5 – 13 – 15,5			8 – 10,5 –13 – 15,5			8 – 10 – 11,5 – 13 – 15			8 – 10,5 – 11,5 – 13 – 15,5			8 – 10,5 – 11,5 – 13 – 15,5			6		8 – 10 – 11,5 – 13 – 15			6	
Collar height (mm)	1,5 – 2,5			1,5 – 2,5			1,5 – 2,5			Non applicable			Non applicable			Non applicable		Non applicable			Non applicable	
Composition of the implant body and screw	Titanium T60 grade 4 commercially pure according to EN ISO 5832-2:2018 (percentage by mass): N≤0.05, C≤0.08, H≤0.0125, Fe≤0.50, O≤0.40, Ti: balance.																					
Composition of the transgingival collar	Zirconia Y-TZP according to EN ISO 13356:2015 (percentage by mass): $ZrO_2+HfO_2+Y_2O_3 \geq 99.0$, $Y_2O_3 > 4.5$ to ≤6, $HfO_2 \leq 5$, $Al_2O_3 \leq 0.5$, Other oxides≤0.5.									Non applicable												

2. Purpose and indication of TBR® implants

The TBR® endosseous dental implants are designed to be placed in the bone of the upper or lower jaw arches of partially or totally edentulous adult patients of any gender in order to provide support for prosthetic devices in the following cases: single-tooth edentulism, edentulous spaces, terminal edentulism, total edentulism, stabilisation of an overdenture. The bone volume and quality must be sufficient to support TBR® dental implants. TBR® implants have a lifespan of 15 years under normal conditions of use.
TBR® implants are indicated to physically replace one or more missing teeth and to restore the patient's masticatory function and smile aesthetics.
They must be used by dental practitioners specially trained in implantology to ensure that they are used safely and appropriately, in accordance with these instructions for use. The TBR® range of implants requires the specific use of TBR® surgical instrumentation, TBR® prosthetic parts and TBR® laboratory items corresponding to the range of implants used, as well as the strict respect of the protocols for use.

3. Clinical benefits

TBR® implants restore the function of one or several missing teeth: they osseointegrate into the jawbone, are biocompatible, resist masticatory forces and provide support for prosthetic components.
Thus, the clinical benefits of the restoration of the function of the missing teeth, thanks to the implementation of the whole TBR® implant system are:

- the improvement of the quality of life associated with the whole procedure,
- the improvement of the masticatory function associated with the whole procedure.

4. Contraindications

General contraindications:

- Absolute and definitive:
  - Cardiovascular disorders, coronary insufficiency, bacterial endocarditis, high blood pressure, blood abnormalities: patient on anticoagulants, patient who suffered a stroke,
  - Immunodeficency, viral infection (H.I.V. seropositivity, A.I.D.S., hepatitis B, C, etc.), hypersensitivity to Titanium (rare),
  - Bone disorders, unfavourable bone anatomy; cancers, radiotherapy of the cervico-facial region,
  - Smoking, alcoholism, drug abuse, mild psychological disorders, psychological problems,
  - Insulin-dependent diabetes, uncontrolled mature-onset diabetes, on biphosphonate medication (past or ongoing),
  - Parafunction, bruxism, periodontal disease.

- Absolute and temporary:
  - Pregnancy, breastfeeding, patient must have reached bone maturity,
  - Situations subject to pressure variations (E.g.: plane, mountains, scuba diving, etc.) after an implant setting near the maxillary sinuses.

Local contraindications:

- Insufficient bone volume or residual roots,
- Benign or malignant tumor close to or at the implant site,
- Poor oral hygiene, residual infection or cyst,
- Prosthetic difficulties (axis, emergence, insufficient or inadequate prosthetic space available, an unfavorable crown / implant clinical ratio),
- Non-stabilised periodontal problems,
- Low motivation of the patient or unrealistic patient expectations.

This list of contraindications cannot be exhaustive. Before any implant treatment, the patient's general health must be clearly established in coordination with the general practitioner.

5. Warning and precautions

Pre-operatively

- To minimize the risk of infection, it is highly recommended to perform surgical procedures in a suitable room, complying with strict hygiene standards. Although absolute sterility is not essential for successful implant osseointegration, it is imperative that the patient is covered with sterile fields and that the surgeon and dental assistant wear sterile garments.
- Perfect conditions of asepsis and sterility of the equipment are also essential for carrying out this surgery successfully.
- Antibiotic therapy should be prescribed 24 hours before surgery and continued for 6 days after surgery. This may be combined with a prescription of anti-inflammatories and painkillers; oedema and haematomas should be expected after any implantation. The use of ice packs may offer relief. The antiseptic mouthwash rinse should only be used 24 hours after the surgical procedure (and for limited duration).
- Preoperative examinations:
  - General and local anamnesis, patient information,
  - Clinical assessment: hygiene, periodontium, occlusion, dental arches, soft tissue,
  - Biological (CBC, ...) and radiological assessments: panoramic radiograph, cone beam, retroalveolar, 3D X-ray, etc.

- The user must ensure there are no abnormal biological constants. The radiological check-up must clearly indicate the anatomical structures that must be imperatively respected (mandibular nerve and its mental foramen, chin emergence, lingual nerve, maxillary sinuses, nasal fossa, posterior palatal foramen, etc.), assess the quality of the residual bone and detect any bone defect visible on X-rays. If in doubt, the practitioner should contact the patient's GP to ensure that the patient's treatment (medication, biological disorders, medical history, etc.) or general condition are not incompatible with implant surgery.
- The choice of the implant (in terms of its dimensions) can also be made using the TBR® X-Ray template corresponding to the implant to be placed by the dental practitioner.
- TBR® Tissue Level Z1 implants are recommended for 1-stage surgery. TBR® Bone Level implants are recommended for 2-stage surgery.
- We advise you not to use a TBR® product if the packaging is damaged, previously opened or if the label is unreadable.
- The practitioner must take into account the applicable regulatory requirements in force in the country in which they practice.

During the operation

- Inhalation or ingestion of products can lead to infection or unexpected physical injury.
- The practitioner must check radiologically that the TBR® dental implant has been correctly inserted.
- If the packaging is damaged or soiled, the implant will not be returned or exchanged by the manufacturer.
- In the event of a malfunction, contact the manufacturer.

Post-operatively

- Safety information on magnetic resonance imaging (MRI):
  The products in the TBR® range have not been assessed for safety and compatibility in a magnetic resonance environment.
- For patient safety, it is the responsibility of the healthcare professional to keep the reference and batch number of all components fitted or used. This information can be found on the detachable labels attached to or present in the packaging of the TBR® components. TBR® implants are delivered with a certificate of authenticity on which the implant traceability label can be stuck in order to provide traceability to the patient.

Additional

- Any alteration will be considered as an alteration of the characteristics and performance of TBR® products which may compromise patient safety. As a result, all warranty and liability on the part of the manufacturer will be void.
- Any serious incident involving the device must be reported to the manufacturer and to the competent authority of the Member State in which the serious incident occurred.
- Under Article 32 of the European Medical Device Regulation (MDR) 2017/745, the summary of safety and performance can be accessed on the European database EUDAMED (as soon as available): https://ec.europa.eu/tools/eudamed/ or written request (see at the beginning of these instructions for our contact details).

6. Warning

The patient must be informed that:

- In the event of complications, consult your practitioner immediately.
- Physical activities requiring considerable effort should be avoided for at least 4 weeks after the operation.
- Metallic implants and prostheses can impair the diagnostic capabilities of high-field magnetic resonance imaging.
- Rigorous, non-traumatic hygiene of the patient's oral cavity is recommended, as are regular check-ups.
- Any medication prescribed by the practitioner must be complied with.
- A certificate of authenticity enables the implanted devices to be traced.

7. Residual risks and adverse effects

Undesirable effects may include the following:

- The risks associated with implant surgery (risks associated with local or general anaesthesia, haemorrhage, infection, bone loss, etc.),
- Paresthesia, contact with anatomical obstacles,
- Tissue resorption, fracture of bone tables,
- The fracture of the medical device,
- Bucco-sinusal and bucco-nasal communication,

- Unusual exposure of medical devices to the oral cavity,
- Allergic reaction (or hypersensitivity) to the materials that constitute the implant,
- Peri-implantitis.

Failure to osseointegrate can occur as a result of specific factors such as infection, inadequate osteotomy, disease or systemic problems, lack of or inadequate irrigation, use of non-specific instruments, occlusal trauma, non-compliance with contraindications or lack of specific training. This failure of osseointegration leads to the loss or removal of the implant.

8. Sterilisation

The TBR® dental implant is sterilised by gamma rays at a minimum dose of 25 kGy. Sterility is only guaranteed if the packaging is intact. The packaging should only be opened at the very moment of the implant procedure. The implant must not be used after the stated expiry date.
To ensure the sterility and cleanliness of the products, TBR® implants are for single use only. Reusing dental implants, even if they have been resterilised, can lead to their rejection and bio-incompatibility, irreversible tissue damage and it can greatly increase the risk of infection (conventional and non-conventional).

9. Storage – Handling – Disposal

TBR® dental implants must be stored in their original storage packaging, in a dry environment, at room temperature (10 to 30°C) and protected from any risk of damage.
Packaging and products must be disposed of in accordance with the applicable national regulations. Waste resulting from the surgical procedure (packaging, extracted parts, etc.) must be treated as medical waste under the responsibility of the user.

10. Instruction for use for TBR® implants

The main steps in placing TBR® implants are as follows:

- Planning of the treatment stages (including the choice of implant dimensions),
- Preparation of the implant site with the surgical sequence,
- The implant is inserted using a contra-angle handpiece or manually,
- Bone healing time of 4 to 6 months (longer in case of pre- or per-operative tissue management, poor primary stability, etc.) but this decision is left to the sole appreciation of the dental practitioner.

Detailed instructions for the use of TBR® dental implants, in particular for preparing the implant site and placing the implant, are described for each of our dental ranges in surgical protocols available on our website: http://ifu.tbr.dental tab « Protocols ».

		Reference	Designation
Implants Tissue Level Z1	Z1-Infinity	P-EN500ZI	Surgical protocol for Z1-Infinity Implant
	Z1-Connect	P-EN500ZC	Surgical protocol for Z1-Connect Implant
	Z1-M	P-EN500ZM	Surgical protocol for Z1-M Implant
Implants Bone Level	Infinity	P-EN500I	Surgical protocol for Infinity Implant
	Connect	P-EN500C	Surgical protocol for Connect Implant
	Baby 8	P-EN500B8	Surgical protocol for Baby 8 Implant
	M	P-EN500M	Surgical protocol for M Implant
	Baby M	P-EN500BM	Surgical protocol for Baby M Implant
All implants		P-EN500DI	Implant Removal Protocol

11. Products compatibility

The range of TBR® implants and prosthetic parts offers a wide variety of configurations to meet different clinical needs. It is essential to note that only TBR® components, specifically designed to be compatible with the chosen implant connection, should be used. This ensures optimum integration and safe operation of the implant system. This compatibility ensures optimum integration and safe operation of the implant system.

Implant Range	Type of Connection	Compatible components	Compatible ancillary instruments
Tissue Level Z1 Range	Internal octagon	Tissue Level Z1 8 Range	Ancillary instruments for the TBR® Tissue Level Z1 and Bone Level implants setting
		LOCATOR® (abutment manufactured by ZEST ANCHORS)	
	Internal hexagon	Tissue Level Z1 M Range	
		LOCATOR® (abutment manufactured by ZEST ANCHORS)	

Implant Range	Type of Connection	Compatible components	Compatible ancillary instruments
Bone Level Range	Internal octagon	Range Bone Level ⑧	Ancillary instruments for the TBR® Tissue Level Z1 and Bone Level implants loading
		LOCATOR® (abutment manufactured by ZEST ANCHORS)	
	Internal hexagon	Bone Level Ⓜ Range	
		LOCATOR® (abutment manufactured by ZEST ANCHORS)	

For further information on product compatibility, please consult the documents listed below:

- Tissue Level Z1 Range – *Products Catalog, Tissue Level implants with a Zirconia collar (Reference: Z-AZ1)*
- Bone Level Z1 Range – *Products Catalog, Bone Level implants (Reference: Z-ABONELEVEL)*

12. Symbols

The following symbols may appear on the device label or in the information accompanying the device:

Symbol	Symbol description	Origin of the symbol
	Manufacturer	EN ISO 15223-1:2021
REF	Catalogue number.	EN ISO 15223-1:2021
LOT	Batch code.	EN ISO 15223-1:2021
YYYY-MM-DD	Use-by date (in Year-Month-Day format).	EN ISO 15223-1:2021
YYYY-MM-DD	Date of manufacture (in Year-Month-Day format).	EN ISO 15223-1:2021
UDI	Unique Device Identifier.	EN ISO 15223-1:2021
CE	CE marking.	MDR 2017/745
http://ifu.tbr.dental	Consult electronic instructions for use (with the electronic instructions for use (eIFU) indicator).	EN ISO 15223-1:2021
STERILE R	Sterilized using irradiation.	EN ISO 15223-1:2021
	Double sterile barrier system.	EN ISO 15223-1:2021
	Caution.	EN ISO 15223-1:2021
	Do not re-use.	EN ISO 15223-1:2021
	Do not resterilize.	EN ISO 15223-1:2021
	Do not use if package is damaged and consult instructions for use.	EN ISO 15223-1:2021
°C 30° 10°	Temperature limit (min 10°C/ max 30°C).	EN ISO 15223-1:2021
	Keep dry.	EN ISO 15223-1:2021
	Keep away from sunlight	EN ISO 15223-1:2021
MD	Medical device.	EN ISO 15223-1:2021