# User's instructions for TBR® implants

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**This document can also be downloaded on the website http://ifu.tbr.dental.**
**Content (sterile):** 1 implant **TBR®** with its cover screw (material: Titanium + Zirconia only for the 1-stage Soft Tissue Level implants).
The following pictogram means: « Do not use if package is damaged».

**CAUTION**

**1. For USA: US Federal law restricts this device to sale by or on the order of a dentist or a physician.**
**2. The TBR® dental implants must only be used by dental surgeon, stomatologists, maxillofacial surgeons or especially trained surgeons.**
**3. The TBR® implant systems require the specific use of TBR® surgical instruments and prosthetic elements that are adapted to the implant range to be set as well as a strict respect of the user's instructions.**
**4. Any adjustment shall be considered as an alteration of the characteristics and the perfomances of the TBR® products that may compromise the patients' safety. Therefore, it may void the guarantee and cancel the responsibility of the manufacturer.**
**5. In order to guarantee the sterility and the cleanliness of the products, the TBR® implants are single-use. The re-use of dental implants, even if resterilized, can generate implant loss, bioincompatibility, permanent tissular lesions and can strongly increase infectious risks (conventional and unconventional).**
**6. In case of malfunction, inform the manufacturer.**
**7. If there is any doubt, the practitioner must contact the patient's general practitioner to make sure that the treatment followed by the patient (drug use, biological disorders, anamnesis, …) and his general state are not incompatible with the dental implant surgery.**

**The manufacturer assumes no responsibility if these conditions are not respected.**

## INDICATIONS

The TBR® endosseous dental implants are designed to be placed in the bone of the upper or lower jaw arches of partially or totally edentate patients in order to provide support for prosthetic devices in the following cases: unitary edentulousness, insert edentulousness, terminal edentulousness, total edentulousness, stabilization of an overdenture. The bone volume and quality must be sufficient to bear dental implants.

## CONTRAINDICATIONS

***General contraindications,***

**Absolute and definitive:**

- cardiovascular disorders, coronary insufficiency, bacterial endocarditis, high blood pressure, blood abnormalities: patient on anticoagulants, patient who had a vascular accident,
- immunodeficiency, viral infection (H.I.V seropositivity, A.I.D.S., hepatitis B, C, etc. ), hypersensitivity to Titanium (rare),
- bone disorders, unfavorable 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, breast feeding, children must have reached bone maturity,
- situations subjected to pressure variations (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, usable prosthetic space insufficent or incompatible),
- unstabilized 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 agreement with the general practitioner.

## RISKS - SPECIAL PRECAUTIONS - WARNING

Risks are associated with oral surgery in general (local or general anaesthetic risks, hemorrhage, infection, endocarditis, etc.). Perfect conditions of asepsis and sterility of the material are also essential to see this operation through.

Antibiotic therapy may be prescribed 24 hours before the operation and continued for 6 days. Analgesic and anti-inflammatory medication may also be prescribed. Swelling or bruising may 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 assessments:
- General and local anamnesis, patient information,
- clinical assessment: hygiene, periodontium, occlusion, teeth, mucous membranes,
- biological (complete blood count) and radiological assessment: panoramic radiograph, cone beam, retroalveolar, 3D X-ray, etc.

The user must confirm the absence of abnormal biological constants. The radiological check-up must clearly indicate the anatomical structures that must be imperatively respected (mandibular nerve and its mental foramen, lingual nerve, maxillary sinus, nasal fossa, posterior palatal foramen) and assess the quality of the residual bone and detect any radiovisible bone defect.
Other possible complications:
- chronic pain associated with the implant, parasthesia,
- bone loss of the maxillary or mandibular ridge crest, fractures: bone, implant, prosthesis
- oral-antral or oral-nasal communication,
- consequences on adjacent or opposing teeth, aesthetic problems.

**Warning**

**Patients must be informed that:**

1. **In the case of complication, the dentist or oral surgeon must be contacted immediately.**
2. **Physical activity requiring great effort should be avoided for at least 4 weeks after the surgery.**
3. **Metal implants and prostheses may alter the potential diagnostic of a magnetic resonance imagery examination.**
4. **A rigorous and non-traumatic hygiene of the patient is recommended as well as regular dental consultations.**
5. **Drug prescriptions that are eventually implemented by the practitioner must be respected.**

## OPERATIVE PROTOCOL OF THE TBR® IMPLANTS:

(See the general surgical protocol for further information):

### 1. SURGICAL SETTING OF THE IMPLANT:

After a perfect and uninterrupted asepsis, local anesthesia, crestal incision (the incision must avoid anatomical obstacles: sinus, nerves and pedicles), flesh strips detachment, the surgical technique must consider:

**CAUTION**

**The implant choice (diameter and length) will be done thanks to the TBR® X-Ray template matching the implant to be set. The practician must imperatively respect a safety margin of 2 mm with regard to any anatomical obstacle or to the available bone height and by taking into consideration the drilling tip that measures from 0.6 mm for the drill #1 to 1.5 mm for the drill #5. For 1-stage implants, the practitionner must consider the transgingival ring bulk. The protocol excludes any alteration of the zirconia ring.**

### 1.1. ROTARY INSTRUMENT SEQUENCE

Individual drills will complete about 10 procedures (essentially depending on the quality and hardness of the bone). Drilling must be progressive using an intermittent pumping motion. Abundant irrigation (external or/and internal irrigation) is necessary when drilling into bone as well as a respect of the chronology in the drills use with progressive diameter. Thermal trauma, which has a major influence on bone healing, will be reduced if these rules are observed.
The drilling guide enables to determine the minimal distance between two side-by-side sites and to parallelize osteotomies. The graduated gauges enable to control the depth of the drilling and to parallelize the implant with an adjacent root or implant. It is advised to use a surgical guide during the drilling process.

| Drilling sequence | TBR® |
|---|---|
| Pilot drill – 1200 rpm | |
| Straight stop drill #1 – TBR 1 – 1200 rpm | |
| Drill #2 adapted to the shape of the implant to be set – TBR 2 – 1000 rpm | |
| Drill #3 adapted to the shape of the implant to be set – TBR 3 – 800 rpm | → Ø 3.2 and 3.5 mm implants |
| Drill #4 adapted to the shape of the implant to be set – TBR 4 – 600 rpm | → Ø 3.9 and 4 mm implants |
| Drill #5 adapted to the shape of the implant to be set – TBR 5 – 500 rpm | → Ø 4.7 and 5 mm implants |

1. Initiate crestal bone penetration with the pilot drill in order to make it easier to use the drill #1.
2. Use stop drill # 1 corresponding to the implant length. In the case of two side-by-side implants, use the drilling guide to determine the minimum distance and to parallelize the implants. Perform a radiological check with the graduated drilling gauge (on the side matching the implant range to be set) in order to eventually correct the drilling axis.
3. Use the drill # 2 up to the required laser mark corresponding to the implant length or to the corresponding stop.
4. Stop to the drill # 3 for Ø 3.2 and 3.5 mm implants at the required laser mark corresponding to the implant length or at the corresponding stop.
5. Stop to the drill # 4 for Ø 3.9 and 4 mm implants at the required laser mark corresponding to the implant length or at the corresponding stop.
6. Stop to the drill # 5 for Ø 4.7 and 5 mm implants at the required laser mark corresponding to the implant length or at the corresponding stop.
7. Use screw tap corresponding to the implant diameter and shape until the laser mark corresponding to the implant length (highest rotation speed 15-20 rpm).
8. In dense bone cases (except for cylindrical implants), use the countersink corresponding to the implant diameter up to the laser marking for 1-stage implant or to the top of the cylindrical part for 2-stage implants.

### 1.2. TBR® IMPLANT SETTING

1. Take off the two successive covers of the packaging in order to expose the implant and the cover screw.
2. With the help of a screwtool for ratchet wrench, or for contra-angle, take the implant out of its housing. Make sure that the connections perfectly fit together before taking the implant out. Turn the screwtool upside down with the implant up in order to prevent any accidental fall.
3. Screw the implant in the beforehand prepared site (with a speed of 15 to 20 rpm for the setting with a contra-angle). The implant is submerged in the bone. For 1-stage implants, the Zirconia ring above the bone has a trans-gingival course. Make sure that the implant has a good primary stability in the bone.
***Note:*** *If the screwing is not complete with the contra-angle, finalize it with the ratchet wrench or the torque ratchet and its screwtool.*
4. Pull the screwtool vertically to remove (if it is needed, reverse the ratchet wrench or the torque ratchet to take the screwtool out).
5. Take the cover screw out of its housing, and maintain it pointing up in the hexagonal tip (screwtool or screwdriver) in order to prevent any accidental fall.
6. Close the implant with the cover-screw. Suture the ginviga (on either side of the implant for the non-submerged technique).
7. Perform a radiological check to verify the perfect placement of the implant in the bone.

**Warning**
**The set implant is stable. However, a too much important insertion torque (superior to 45 N.cm) in order to overcome the bone resistance can cause an implant damaging, a fracture or a necrosis of the bone area.**

**2. IMPLANT LOADING**

**2.1. FOR THE 2-STAGE IMPLANTS:**

After the necessary waiting period for bone healing in order to obtain the osseointegration (about 4 to 6 months) and after asepsis, anesthesia, incision and implant exposure, the cover screw is taken out with the hexagonal tip (screwtool or screwdriver). The healing screw is thus set. Suture. The implant, if osseointegrated, will show clinical rigidity and produce a clear sound if tapped slightly. After soft tissue healing, the corresponding TBR® prosthodontic element may be fitted in order to make the implant functional respecting the appropriate prosthodontic and occlusal principles (see the prosthetic protocol).

**2.2. FOR THE 1-STAGE IMPLANTS:**

After the necessary waiting period for bone healing in order to obtain the osseointegration (about 4 to 6 months), the cover screw is taken out and the corresponding TBR® prosthodontic element may be fitted in order to make the implant functional respecting the appropriate prosthodontic and occlusal principles (see the prosthetic protocol).
***Note****: Perform a radiological check to verify if the abutment perfectly fit in the implant. We recommend the use of an implant supported prosthesis and not splinted to natural teeth and to avoid cantilevers.*

**Warning**
**The practitioner must choose the torque when screwing the abutments with the help of the torque wrench: we recommand a 20 to 30 N.cm torque depending on the implant diameter and length, on the bone quality and on the healing period.**

**STERILITY**

The TBR® implant is sterilized by gamma radiation at a minimal dose of 25 kGy. The sterility is only guaranteed if the packaging is intact. The implant must not be used after the indicated expiration date. This package must only be opened during the implantary act.

**Warning**
**If the packaging is damaged or soiled, the implant cannot be returned or exchanged by the manufacturer.**

**STORAGE – ELIMINATION**

Store the implants in their original storage pack, at room temperature, in a dry area (from 10 to 30°C) and protected from any deterioration risk.
The products that have to be eliminated are thrown away in sharp disposal containers.

**TRACEABILITY**

In order to guarantee the security of patients, the practitioner must keep the reference and batch number for all the products that has been set or used. These specifications are stipulated on the adhesive detachable labels which are sticked on or inside the blister pack of TBR® pieces.
We advise to not use any TBR® products when the packaging is damaged or when the label is unreadable.

**TRAINING**

SUDIMPLANT offers on a regular basis trainings about implantology and about the use of TBR® products.