User's instruction for the TBR® kit for prosthetic spacing guides

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This document can be provided in printed paper form at no additional cost within 7 days of request.
Content (non sterile): TBR® prosthetic spacing guides made from titanium and pilot drills for prosthetic spacing made from stainless steel.

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 implant system must only be used by dental surgeon, stomatologists, maxillofacial surgeons, especially trained surgeons or dental technicians for the prosthetic part only.
3. The TBR® dental implant and prosthetic elements require the specific use of instruments 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 performances 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 case of malfunction, inform the manufacturer.

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

INDICATIONS

The kit for prosthetic spacing guides contains templates and pilot drills with a predefined prosthetic bulk that will guide the practitioner during the preparation of the implant site. It will also ensure the practitioner that there is enough prosthetic space, in the mesio-distal direction, for the treatment plan.

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 bisphosphonate 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 insufficient 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 FOR THE USE OF THE PROSTHETIC SPACING GUIDES:

(See the general surgical protocol for further information):
The use of the kit for prosthetic spacing guides will be complementary to the use of the surgical kit for the TBR® implants. The pilot drill for prosthetic spacing will indeed be used instead of the classical pilot drill contained in the surgical kit. The interest in using these pilot drills is to help the practitioner with the perforation of the cortical bone by knowing the mesio-distal prosthetic spacing needed for the treatment plan.
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 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.
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 practitioner 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 practitioner must consider the transgingival ring bulk. The protocol excludes any alteration of the zirconia ring.

1. IN CASE OF A SINGLE IMPLANT

1. Perforate the cortical bone with the pilot drill for prosthetic spacing (with a speed of 1200 rpm) until the stop. The pilot drill must have been chosen beforehand with the adequate diameter according to the volume of the future crown (among the 5 diameters that are available).
2. Keep on with the rotary instrument sequence in order to set the TBR® implant according to the User's instructions for TBR® implants.

2. IN CASE OF MULTIPLE CONSECUTIVE IMPLANTS

1. Perforate the cortical bone with the pilot drill for prosthetic spacing (with a speed of 1200 rpm) until the stop. The pilot drill must have been chosen beforehand with the adequate diameter according to the volume of the future crown (among the 5 diameters that are available).
2. Place in this bone housing that has just been created a prosthetic spacing guide with the same diameter as the last used pilot drill. It will help to simulate the prosthetic volume used on the first implant next to the second one.
3. Perforate the cortical bone of the juxtaposed implant with the pilot drill for prosthetic spacing (with a speed of 1200 rpm) until the stop. The pilot drill must have been chosen beforehand with the adequate diameter according to the volume of the future prosthetic rehabilitation (among the 5 diameters that are available).
4. If there is only two implants to be set, keep on with the rotary instrument sequence in order to set the TBR® implant according to the User's instructions for TBR® implants.
5. Otherwise place again a prosthetic spacing guide with the same diameter as the used pilot drill's one. When all the implant sites have been prepared, keep on with the rotary instrument sequence in order to set the TBR® implant according to the User's instructions for TBR® implants.

DISINFECTION, CLEANING AND STERILIZATION

The ancillary instruments contained in the kit for prosthetic spacing guides are sold non sterile.

Warning

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

Warnings and recommendations for disinfection, cleaning and sterilization

Ancillary instruments must be disinfected, cleaned, sterilized by trained and qualified staff. Check for the presence, the cleanliness, the operational state and the qualification (calibration, maintenance, etc.) of all the necessary material before starting the cleaning and sterilization cycle. The handling of contaminated devices must be done by using personal protective equipment (gloves, gowns, glasses, mask, etc. ...). The drying, packaging and sterilization process must be performed in a clean, orderly and clear environment.

Caution:

All the parts to be sterilized require some recommendations for the preservation of their quality. The non-respect of these instructions can alter the lifetime of the devices (corrosion, coloring, deterioration of the marking, premature wear, etc.) and the users and patients safety (contamination):

Point A: Use cleaning / disinfection products adapted to surgical instrumentation and materials they are made of. Do not use products containing chlorine, iodine, phenols, strong acids or alkaline (do not use sodium hypochlorite (bleach), oxalic acid, sodium hydroxide or hydrogen peroxide, or normal saline, beware of the too strongly chlorinated tap water). Avoid any product containing aldehyde because of their ability to bind proteins.

Point B: For the washer-disinfector: Only use agents recommended by the manufacturer and prefer the use of slightly alkaline products (pH between 7 and 10.5).

Point C: For all products and materials (for cleaning / disinfection, washer-disinfector, ultrasound vat, sterilization pouch, autoclave etc.), follow carefully all manufacturer's instructions (dosage, soaking time, temperature etc ...) and expiration dates.

Point D: Avoid as far as possible shocks and contacts with other instruments (deterioration of the surface state, the marking laser and/or the cutting power).

Point E: Please clean products made from the same material in the same container.

Point F: Do not leave contaminated instruments to dry before the cleaning / sterilization cycle.

Before each intervention:

1. As soon as possible after their use (if more than 30 minutes, do not forget to wrap them in a damp cloth to prevent the soiling from drying), the dirty instruments are carried in a suitable container, avoiding shocks, to the area dedicated for the cleaning. They are arranged in a clean and adapted packaging, dismantled if necessary (in the case of the torque wrench) and completely soaked in a freshly prepared disinfecting solution, without any bubble (the use of a system with ultrasounds is also appropriate) (see points A,C, D & E). Rinse thoroughly under running water until the absence of chemical residues on the device.

2. Remove carefully all the post-operative residues (blood, bones ...) on the instruments (use a nylon brush), or inside for products with an internal irrigation or hollow products (thanks to a syringe, e.g. drills, cannula, etc.) by using an alkaline detergent (but not a strong one) or neutral one (see points A, C & E). Rinse thoroughly (preferably use using deionized water for the final rinse).

3. In case of a manual cleaning: Immediately after cleaning, dry all the instruments surfaces with a lint-free clean absorbing paper by scrubbing carefully or with compressed air for medical use (see points C).

In case of a washer-disinfector: Immediately after cleaning, put the instruments in the washer-disinfector avoiding contacts between the devices and start the cycle following the manufacturer's instructions (see points B, C & D).

4. Visually inspect the cleanliness and the absence of humidity or stains on the components and make sure that no deterioration may affect their safety, integrity or functioning. If necessary, repeat the cleaning cycle from the point 2. Reassemble the instruments when needed. Put one or several products in a sterilization pouch, big enough so that no tension is applied on the closure (see point C).

5. Make sure that no corroded elements are inside the type B pressurized steam sterilizer. Sterilize in the autoclave at 134 °C, 18 minutes (see points C & E).

6. Verify the good progress of the cycle, the integrity of the pouches as well as the physico-chemical indicator of sterilization (if necessary, start again the operation from the point 4). Indicate the sterilization date on every pouch (and any information necessary for the traceability) which will then be stored in conditions preserving the products safety and sterility (a clean, dry, safe and stress-free place, at room temperature and out of direct sunlight).

STORAGE – ELIMINATION

Store the TBR® products 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 on the TBR® products.

We advise to not use any TBR® products when the packaging is damaged or when the label is unreadable.

FORMATION

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

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