User's instruction for the TBR® kit for surgical guide

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The protocols and user's instructions can be:

- **Provided in printed paper form at no additional cost within 7 days of request.**
- **Downloaded on the website http://ifu.tbr.dental.**

Content (non sterile, to be sterilized before use): TBR® instruments for surgical guide 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 surgeons, stomatologists, maxillofacial surgeons, especially trained surgeons or dental technicians.
3. The TBR® surgical guide kit requires the use of specific instruments and TBR® implants as well as a strict respect of the user's instructions. The use of the surgical kit is essential, the use of the kit of removable stop drills corresponding to the implants to be set is also essential unless the kit for surgical guide is only used for pilot drilling.
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. The validation and the manufacturing of the guide remain under the responsibility of the practitioner, his or her prosthesis laboratory and his or her planning and manufacturing partners, but in any case under the responsibility of TBR®.
6. Every cutting tool (circular surgical knife, drill, etc.) has a lifetime of about ten drillings.
7. The practitioner must consider the current applicable regulatory requirements.
8. Conditions of perfect asepsis and material sterility are also essential in order to perform the surgery.
9. In case of malfunction, inform the manufacturer.

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

INDICATIONS

The surgical guide is manufactured by the practitioner, the dental laboratory or a specialized partner based on a guided implant treatment done previously by a planning software or a plaster model and/or a radiological guide validated by the practitioner. The surgical guide can be either for one implant or several implants.
The indication of the others instruments from the kit (such as sleeves, sleeve holders) is to materialize the axes of the TBR® implants to be set, inside the surgical guide to be realized. The surgical guide kit ensures that the drilling sequence respects precisely the axes defined by the guide.

CONTRAINDICATIONS

The surgical guide kit is used to set TBR® implants and does not generate more contraindications than those listed in the user's instructions provided with the implant (see User's instructions for TBR® implants). 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.

Caution

The implant choice (diameter and length) will be done thanks to the TBR® X-Ray template or thanks to a planning software 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 1.0 for the drill #5. For the 1-stage implants, the practitioner must consider the transgingival ring bulk.

Warning

Patients must be informed that:

1. **In 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 surgery.**
3. **A rigorous and non-traumatic hygiene of the patient is recommended as well as regular dental consultations.**
4. **Drug prescriptions that are eventually implemented but the practitioner must be respected.**

PROTOCOL FOR THE ASSEMBLY OF THE SLEEVES INTO THE GUIDE (SEE ILLUSTRATIONS AT THE END OF THE USER'S INSTRUCTIONS):

a) For a guide manufactured from a planning software, the digital libraries of implants and sleeves files must be used by following the instructions of the software manufacturer. When the guide is realized, the sleeves must be forced into the guide by inserting the sleeve by the end with the bevelled edge that helps their insertion. Every sleeve has a diameter and color specific to the matching implant diameter.

b) For a guide manufactured from a plaster model, the implants analogs (matching with the implant system and diameter to be set) must be placed where the implants are intended to be set. The sleeve holders are screwed on the implant analogs and will hold in place the sleeve during the finalization of the surgical guide.
- There is a specific sleeve holder in order to fix the guide on the patient thanks to osseosynthesis screws. The minimal length must be 9 mm beside the gingival thickness and the maximal diameter is 1.5 mm.
- In order to guide the rotary instruments before the use of the stops through the guide sleeves, longer sleeves exist and they can be altered if needed (example: limited available occlusal height) with a crown-saw bur as follows: no alteration for an implant with a 15 or 15.5 mm length, cut at the first mark for an implant with a 13 or 11.5 mm length and cut at the second mark for an implant with a 8, 10 or 10.5 mm length.

SURGICAL PROTOCOL FOR A TBR® IMPLANT SETTING WITH A SURGICAL GUIDE (SEE ILLUSTRATIONS AT THE END OF THE USER'S INSTRUCTIONS):

(See User's instructions for TBR® implants and the general surgical protocol for further information regarding the implant setting):

After a perfect and uninterrupted asepsis, local anesthesia, the guide will be placed in the patient's mouth on the remaining teeth or the gingiva. It possible to secure the guide with the use of sleeves for osseosynthesis screws: they will be preferably placed in the mandibular symphysis or on the vestibular surfaces of the maxilla by avoiding any anatomical obstacle and by respecting the user's instructions from the screws manufacturer. When the guide is placed, set the implantology control unit at a torque of 45 N.cm, mount the contra-angle with the green ring and under irrigation. The surgical technique must consider the following steps:

Caution

The instruments must only rotate when they reach the gingiva (for the circular surgical knife) or the bone crest inside the sleeve. All the instruments from this protocol can go through the sleeve adapted to the diameter. However, the guide can be taken out at any step during the implantary surgery.

1. Punch the gingiva with the circular surgical knife adapted to the diameter of the implant to be set at 300 to 500 rpm.

2. Respect the rotary instruments sequence adapted to the diameter of the implant to be set as indicated in the user's instructions for TBR® implants. Please note that the pilot drill and the drills to be used are the one from the surgical guide kit except that the final drill will be the one from the kit for drills with a removable stop.

Implant diameter	**Drilling sequence**		
	Drills from the kit for surgical guide to be used		**Terminal drill from the kit removable stop drills**
	Without stop	With the stop matching the length of the implant to be set	
Pilot drilling for all diameters	Pilot drill (1200 rpm) #1	Then drill#1 of the surgical kit (1200 rpm)	NA
Ø3.5 & 3.2	Pilot drill (1200 rpm) #3	Then drill#1 (1200 rpm) Then drill#2 (1000 rpm)	Drill #3 (800 rpm)
Ø3.5 Z1-Connect (use sleeve Ø4)	Pilot drill (1200 rpm) #4	Then drill#1 (1200 rpm) implant Ø4 Then drill#2 (1000 rpm) implant Ø4 Then drill#3 (800 rpm) implant Ø4	NA
Ø4 & 3.9	Pilot drill (1200 rpm) #4	Then drill#1 (1200 rpm) Then drill#2 (1000 rpm) Then drill#3 (800 rpm)	Drill #4 (600 rpm)
Ø5 & 4.7	Pilot drill (1200 rpm) #5	Then drill#1 (1200 rpm) Then drill#2 (1000 rpm) Then drill#3 (800 rpm) Then drill#4 (600 rpm)	Drill #5 (500 rpm)

3. Use the screwtap matching with the diameter and shape of the implant until reaching the bottom of the dental alveolus.

4. Set the TBR® implant by following the surgical protocol the setting of TBR® implants.
Note 1: If an obstacle prevents the passage of the contra-angle head, use the drill extension from the surgical guide kit.
Note 2: If the guide is still in use during the implant setting, the setting will only be done with the use of the screwtool for contra-angle. At the end of the implant setting, remove the guide.

DISINFECTION, CLEANING AND STERILIZATION

The instruments from the surgical guide kit are sold non sterile and must be disinfected, cleaned and sterilized before use (see User's instructions for TBR® Prosthetic Products).

Warning

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

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.

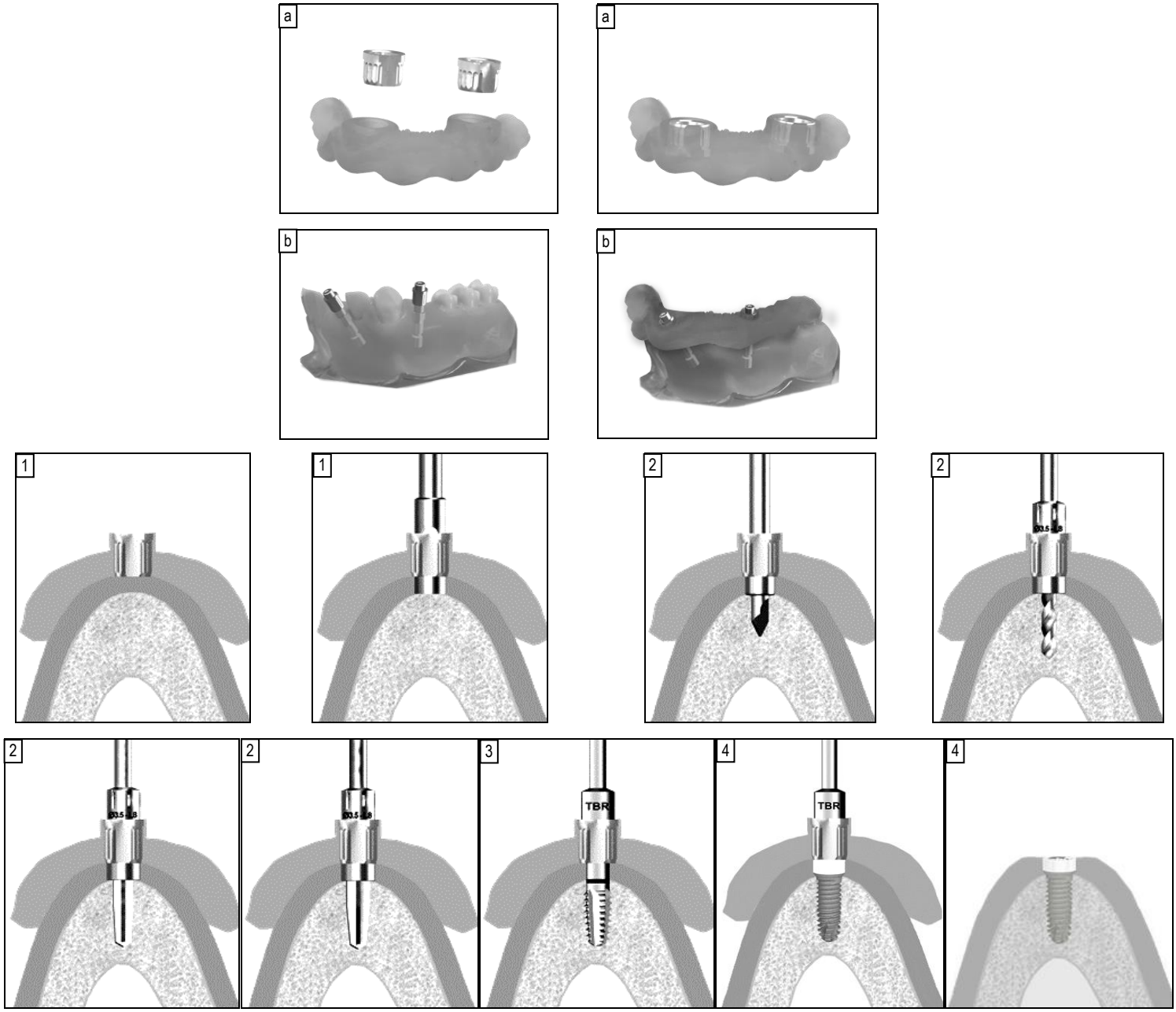
TRACEABILITY

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.

ILLUSTRATIONS OF THE USER'S INSTRUCTIONS



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