

User's instructions for the TBR® osteotomy and bone expansion kit



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The protocols and user's instructions can also be provided:

- In printed paper form at no additional cost within 7 days of request.
- In a pdf form on the website <http://ifu.tbr.dental>.

Content (non sterile, to be sterilized prior to use): stainless steel TBR® ancillary instruments for osteotomy and bone expansion.

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.
3. The TBR® osteotomy and bone expansion kit requires the use of specific TBR® 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. Every cutting tool (circular knife, drill ...) has a lifetime of about ten drillings.
6. The practitioner must consider the current applicable regulatory requirements.
7. In case of malfunction, inform the manufacturer.

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

INDICATIONS

The TBR® kit for osteotomy with a crestal access on the upper jaw (unmodified Summer's Technique) and for bone expansion of the jaws is based on surgical instruments that condense, expand and push the bone in order to set one or several TBR® dental implants during the same surgical procedure. Following a bone loss that prevents a direct setting of a dental implant, their action creates an increase of the alveolus bone volume, vertically for the upper jaw but at the expense of the sinus for the osteotomy, in a lateral direction when expanding the bone crest, when condensing the bone for the compaction of the spongy bone.

The indications of the TBR® kit for osteotomy and bone expansion are:

- condensation of a spongy bone from type III or IV;
- local expansion of thin or deformed crest,
- sinus lift by using the crestal access;
- sinus floor elevation with bone filling;
- preparation of the future implantary area.

CONTRAINDICATIONS

In addition to those mentioned in the user's instructions provided with the implant (see User's instructions for TBR® implants), it is not recommended to use the osteotomy method when there is a sinus infection or an history a chronic sinusitis, and the use of the crest expansion method if there is a risk of bone table fracture. 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

In addition to the two risks mentioned in the user's instructions provided with the implant (see User's instructions for TBR® implants), the failure risk of the implant is higher than the standard implantation rates. It will depend:

- on the anchorage quality (height, quality and quantity of the residual bone);
- on the type of filling used or of the graft;
- on the used surgical technique;
- on the healing period;
- on the development a post-surgery sinusitis. It is recommended to prescribe a nasal decongestant besides the normally prescribed antibiotic therapy.

Perfect conditions of asepsis and sterility of the material are also essential to see through this operation.

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 and the situations submitted to pressure variation (such as plane, mountains, scuba diving, etc.) must be avoided for at least 4 weeks after the 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 by the practitioner must be respected.

5. The following post-surgery recommendations must be respected by the patient after an osteotomy surgery: do not blow his/her nose, drink with a straw during two weeks after the surgery, avoid the use of prosthesis with mucous support and prefer soft food for at least three weeks.

PROTOCOL FOR THE ASSEMBLY OF THE TIPS AND HANDLES:

- Every tip must be mounted on the straight or curved handle depending on the surgical area.
- The chosen stop (universal or matching the implant length) should be slightly screw before the insertion of the tip. **You must absolutely not screw with strength a stop without the tip, it will deteriorate the winglets of the handle.**
- The tip has a flat side that must be inserted until reaching the bottom of the handle opening. In order to be sure, the tip rotation should not be possible and the circular laser mark (or the mark) on the cylindrical shank should not be visible. Otherwise rotate the tip until you are able to insert it deeper and the mark is not visible anymore.
- Then the tip will be screwed until a resistance is reached.

SURGICAL PROTOCOL OF AN OSTEOTOMY OR BONE EXPANSION WITH THE TBR® IMPLANTS SETTING:

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

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.

1. OSTEOTOMY (SEE ILLUSTRATIONS AT THE END OF THE USER'S INSTRUCTIONS):

After a perfect and uninterrupted asepsis, local anesthesia, the setting of the implantology control unit at a torque of 45 N.cm (green ring) and under irrigation, the surgical technique must consider the following steps:

1. Punch the gingiva with the circular surgical knife adapted to the diameter of the implant to be set at 300 to 500 rpm or make a crestal incision with a surgical knife (by avoiding the anatomical obstacles: sinus, nerves and pedicles) and then detach the flaps.
2. Two methods are possible:
 - a) Manual trepanation: Use the manual pointer mounted on the osteotomy handle and screwed with the chosen stop (universal or matching the length of the implant) and impact with a Teflon mallet. Do the same with the intermediate osteotomes if needed.
 - b) Mechanical trepanation: Use the pilot drill for the surgical contra-angle at 1200 rpm on 1 to 3 mm and then trepan the implantary area with a speed from 800 to 1000 rpm thanks to the trephine matching the diameter of the implant to be set.

Warning

Regardless of the used technique, the pilot drilling and the trepanation must leave at least a bone height of 1 to 2 mm before reaching the septum of the sinus.

3. Mount on the chosen osteotome handle the concave tip for osteotomy matching the diameter of the implant to be set thanks to the chosen stop.
4. By using the Teflon mallet, impact the tip mounted on the handle until it reaches the adapted stop or until it reaches the laser marking matching the length of the implant in case of using the universal stop. This technique uses the fractured sinus floor as an osteotome.

Implant diameter	Manual osteotomy sequence	Mechanical osteotomy sequence
Implant Ø3.5 & 3.2	Manual pointer then osteotome #3	Contra-angle pilot drill, trephine #3 then osteotome #3
Implant Ø4 & 3.9	Manual pointer, osteotomes #3 then #4	Contra-angle pilot drill, trephine #4 then osteotome #4
Implant Ø5 & 4.7	Manual pointer, osteotomes #3, #4 then #5	Contra-angle pilot drill, trephine #5 then osteotome #5

5. Fill eventually with autograft bone or a bone substitute (Graftek® or similar substitute by referring to the user's instructions from the manufacturer), through the hole by pushing the bone filling material inside the cavity created by the last tip that has been used.
6. There are two specific cases depending on the residual bone height:
 - a) The residual bone height is at least 4 mm: It is enough to obtain a primary anchorage. Set the TBR® implant by following the surgical protocol for the setting of TBR® implants. Wait for the osseointegration during 6 months without loading the implant.
 - b) The residual bone height is less than 4 mm: The protocol stays the same except that the implant setting will be delay for 6 months.

2. BONE EXPANSION:

2.1 Bone condensation (See illustrations at the end of the user's instructions)

After a perfect and uninterrupted asepsis, local anesthesia, the surgical technique must consider the following steps

1. Punch the gingiva with the circular surgical knife adapted to the diameter of the implant to be set at 300 to 500 rpm or make a crestal incision with a surgical knife (by avoiding the anatomical obstacles: sinus, nerves and pedicles) and then detach the flaps.
2. Respect the rotary instrument sequence adapted to the diameter of the implant to be set as it is described in the user's instructions for the implant, except that the final drill will be switched with the bone expansion tip matching the implant diameter.
3. Mount on the chosen osteotome handle the convex tip for expansion matching the diameter of the implant to be set thanks to the chosen stop.

Implant diameter	Drilling sequence and convex tips to be used
Implant Ø3.5 & 3.2	Pilot drill (1200 rpm) then drill #1 (1200 rpm) then drill #2 (1000 rpm) then convex tip for expansion #3
Implant Ø4 & 3.9	Pilot drill (1200 rpm) then drill #1 (1200 rpm) then drill #2 (1000 rpm), then drill #3 (800 rpm) then convex tip for expansion #4

Implant Ø5 & 4.7	Pilot drill (1200 rpm) then drill #1 (1200 rpm) then drill #2 (1000 rpm), then drill #3 (800 rpm) then drill #4 (600 rpm) then convex tip for expansion #5
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- By using the Teflon mallet, impact the tip mounted on the handle until it reaches the stop matching the implant length or until the laser marking matching the implant length when using the universal stop.
- Set the TBR® implant by following the surgical protocol for the setting of TBR® implants.

2.2 Lateral bone expansion (or bone-splitting) (See illustrations at the end of the user's instructions)

After a perfect and uninterrupted asepsis, local anesthesia, the surgical technique must consider the following steps

- Make a crestal incision with a surgical knife (by avoiding the anatomical obstacles: sinus, nerves and pedicles) and then detach the flaps.
- Make a span of the crestal bone with an insert for bone surgery or crown-saw. (Sometimes, it will be essential to flatten the ridge of the crest if it is too thin).
- Respect the rotary instrument sequence adapted to the diameter 3.2/3.5 mm of the implant to be set as it is described in the user's instructions for the implant, except that the final drill will be switched with the bone expansion tip #3. If you would like to more expand the crest, expansion tips 3.9/4 and 4.7/5 are available in the kit but make sure to preserve a sufficient thickness for the crestal walls.
- Mount on the chosen osteotome handle the convex tip for expansion matching the diameter of the implant to be set thanks to the chosen stop.

Implant diameter	Drilling sequence and convex tips to be used
Implant Ø3.5 & 3.2	Crown-saw (1000 rpm) then pilot drill (1200 rpm) then drill #1 (1000 rpm) then drill #2 (800 rpm) then convex tip for expansion #3
Implant Ø4 & 3.9	Identical to implant Ø3.5 & 3.2 then convex tip for expansion #4
Implant Ø5 & 4.7	Identical to implant Ø3.5 & 3.2 then convex tip for expansion #4 then #5

- By using the Teflon mallet, impact the tip mounted on the handle until it reaches the stop matching the implant length or until the laser marking matching the implant length when using the universal stop.
- Set the TBR® implant by following the surgical protocol for the setting of TBR® implants.
- Fill eventually the span with autograft bone or a bone substitute (Graftek® or similar substitute by referring to the user's instructions from the manufacturer). If need, the use of a membrane is also possible (Neomem® or equivalent membrane).

DISINFECTION, CLEANING AND STERILIZATION

The instruments from the osteotomy and bone expansion 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.

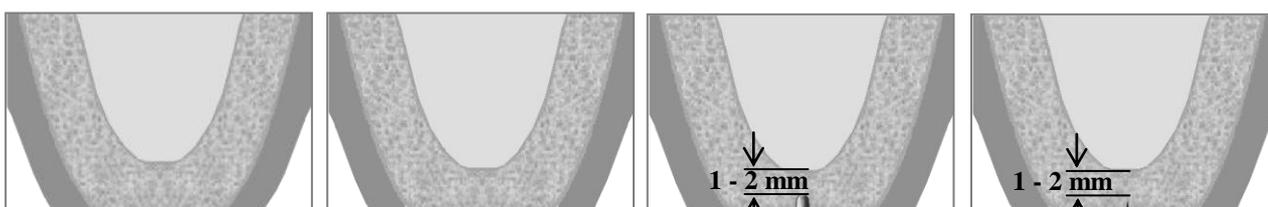
We advise to not use any TBR® products when the packaging is damaged or when the label is unreadable.

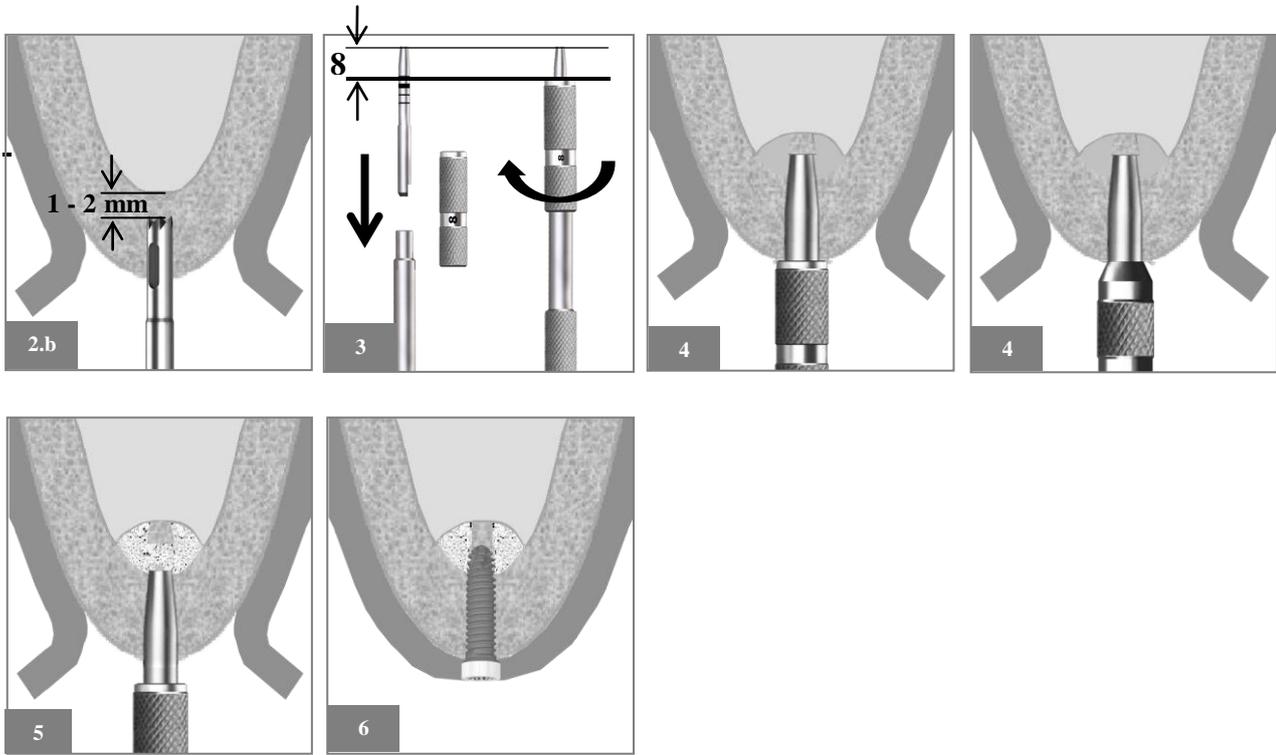
FORMATION

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

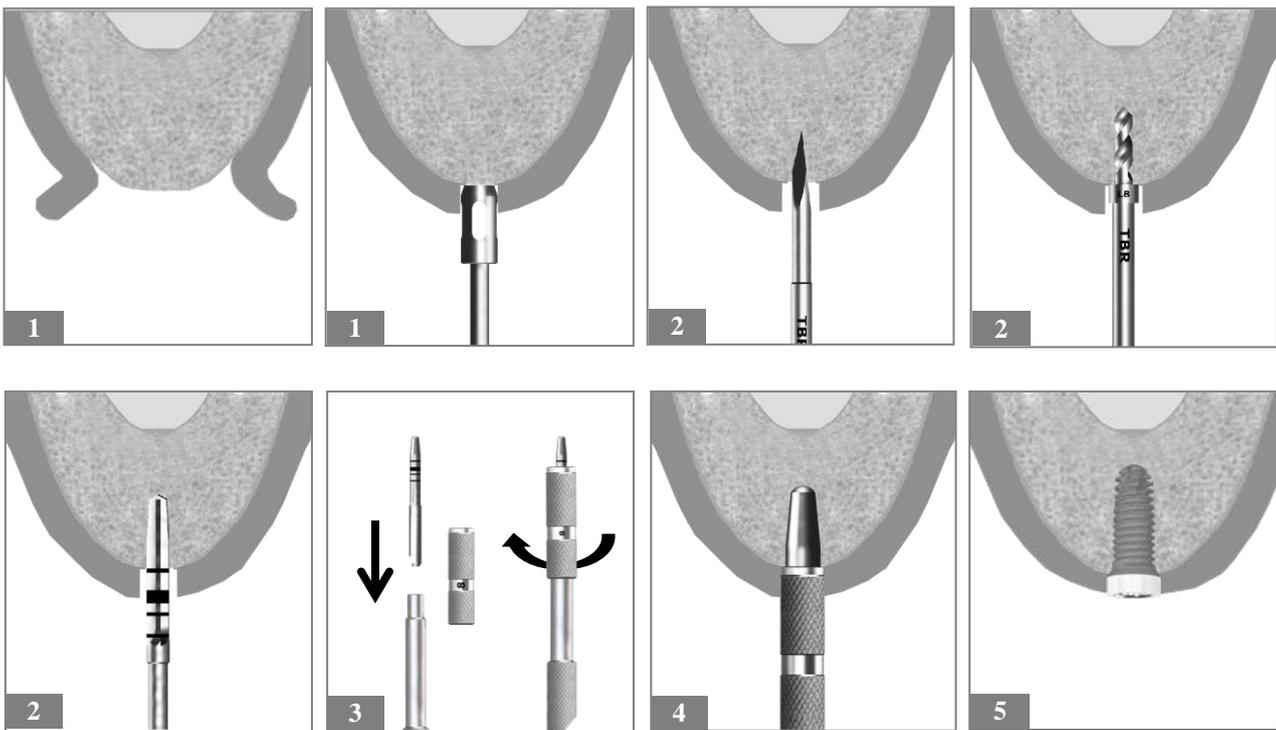
ILLUSTRATIONS OF THE USER'S INSTRUCTIONS

OSTEOTOMY:





BONE CONDENSATION:



LATERAL BONE EXPANSION:

