

## Instructions for TBR® Universal Homologue Implants



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Contents (non-sterile): TBR® Universal homologue (in titanium).

### Warning

1. The TBR® dental implant system must only be used by dental surgeons, stomatologists, maxillofacial surgeons, specially trained surgeons or dental technicians for the prosthetic part only.
2. The TBR® laboratory parts require the use of specific instrumentation to implement the TBR® range of implants and TBR® prosthetics, as well as strict observance of user protocols.
3. Any adjustment will be considered as an alteration to the characteristics and performance of the TBR® products which may compromise patient safety. In this instance, all guarantees and the responsibility of the manufacturer would be nullified.
4. In the event of any malfunction or failure, please contact the manufacturer.
5. The user must take into account the applicable regulatory requirements in force.

**The manufacturer accepts no responsibility if these conditions are not met.**

### INSTRUCTIONS

The universal homologue is a part intended to be used in the laboratory to faithfully reproduce the positioning of an implant in the plaster or resin model. This will allow the laboratory to work on the crown or the bridge on a replica of the mouth's condition. This universal homologue is not intended to be put in the mouth.

### CONTRAINDICATIONS

These are the same as those for implant placement (see User instruction manual for the TBR® implants, available as a hard copy free of charge on request within a maximum of 7 days, or electronically from the website: <http://ifu.tbr.dental>).

### RISKS - SPECIAL PRECAUTIONS - CAUTION

There are no special risks associated with the use of the universal homologue except that it is not intended to be used in the mouth.

### USAGE PROTOCOL FOR THE TBR® UNIVERSAL HOMOLOGUE

The TBR® universal homologue can be used as:

- a traditional method with the manufacture of a plaster model which faithfully reproduces the positioning of the implant in the oral cavity;
- a digital method with an impression of a resin model which faithfully reproduces the positioning of the implant in the oral cavity.

#### I. Traditional method with the plaster model design

Once you receive the impression made by the practitioner:

- 1 Check the transfer technique carried out by the practitioner:
  - a. Laboratory transfer Indirect Technique Pop-in
    - ➔ Screw the Pop-in transfer onto the universal homologue using the screw supplied and a TBR® hexagonal screwdriver then insert the whole thing into the intended cavity in the impression. Repeat this process as often as necessary if you have several cavities in this impression.
  - b. Laboratory transfer Direct Technique Pick-up
    - ➔ Connect the Pick-up transfer maintained in the impression to the universal homologue using the screw supplied and a TBR® hexagonal screwdriver. Repeat this process as often as necessary if you have several transfers in this impression.
  - c. Laboratory transfer Swissclip Technique
    - ➔ Insert the Swissclip transfer maintained in the impression into the homologue. Repeat this process as often as necessary if you have several transfers in this impression.
- 2 Add the silicone to reproduce the gingival margins (following the silicone manufacturer's instructions).
- 3 Prepare and add the plaster to create the model (following the plaster manufacturer's instructions).
- 4 Carry out the prosthetic restoration desired on the universal homologue(s).

#### II. Digital method with the resin model design

Note: Before planning your prosthetic work, make sure you have installed the correct elements in your CAO software.

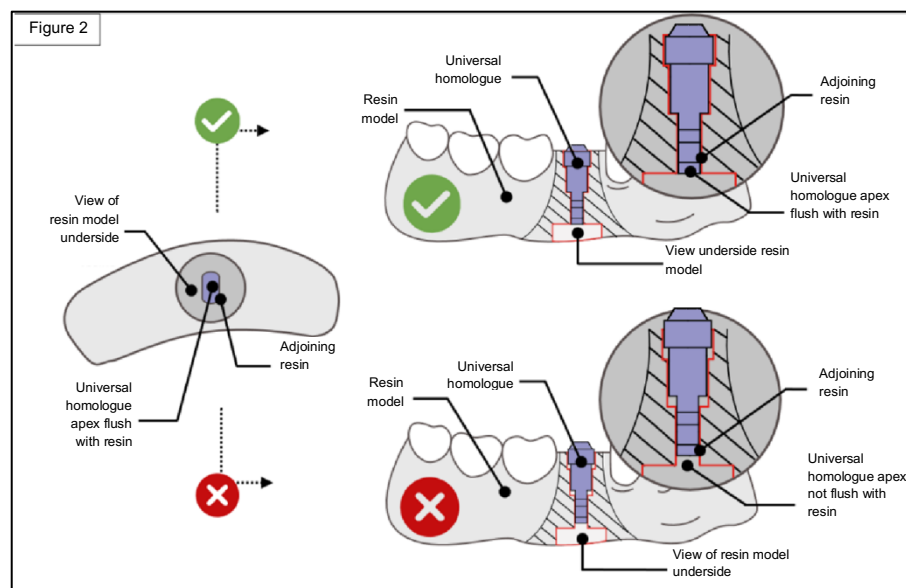
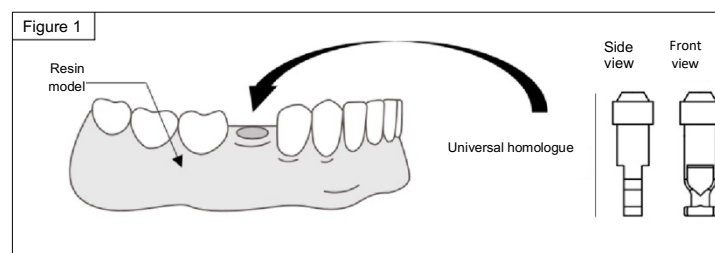
The digital impression is carried out directly in the patient's mouth by the dentist using an intra-oral camera. This impression is composed of 3 separate \*.stl files (maxilla, mandible and occlusion).

Once you have the digital impression:

- 1 Open the digital impression with your CAO software.
- 2 Design the virtual model by adding the virtual homologue(s) to it.
- 3 Generate the articulator interface and define the gingival margins on the area to be treated.
- 4 Validate the virtual model.
- 5 Print out the virtual model as a hard copy (in resin) according to the design carried out (following your 3D printer's instructions).

Note: For all 3D print-outs of the resin model, we recommend the following 3D printers: Varseo (Bego), Formlabs 2 (Formlabs) and XFAB 2500 pd (DWS).

- 6 Insert the universal homologue(s) into the slots provided (Figure 1).
- 7 Make sure that the homologue is positioned correctly in the resin model. To do this, you must check the position of the universal homologue apex using the viewpoint which is accessible from the underside of the model. The homologue is positioned correctly when the homologue universal apex is flush with the adjacent resin (Figure 2).
- 8 Carry out the prosthetic restoration on the universal homologue(s).



## STORAGE - DISPOSAL

Store the TBR® products in their original packaging or in a clean container, in a dry environment, at room temperature (from 10 to 30°C), and protected against any risk of deterioration.

There are no special restrictions with regard to disposal of this product.

## TRACEABILITY

To ensure patient safety, it is the responsibility of the health care professional to **retain the reference and batch number of all the items fitted and used**. These instructions are on the detachable labels adhered to or in the packaging of the TBR® parts. We advise against using a TBR® product with damaged packaging or where the label is illegible.

## TRAINING

The TBR® group offers regular training on implantology and the use of the TBR® product range.