Instructions for Scanbodies - TBR® Digital Transfers

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Contents (non-sterile): TBR® Scanbody (monobloc PEEK) with titanium screw.

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® scanbodies require the use of specific instrumentation for their implementation on TBR® medical devices only, as well as strict observance of usage 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. TBR® Scanbodies are disposable. Reusing these parts, even when sterilised, compromises the performance and usability of these medical devices.
5. In the event of any malfunction or failure, please contact the manufacturer.
6. 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 scanbody is a part intended to be used at the dentist's practice or at the laboratory to digitally transfer the three-dimensional position of the implant in the mouth or the position of the implant replica (homologue) into a plaster model using an intra-oral camera or desk-top scanner.

CONTRAINDICATIONS

These are the same as those for the other laboratory parts (see Instructions for TBR® Prosthetic Parts, 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 scanbody, if it is only screwed into the mouth.

USAGE PROTOCOL FOR THE TBR® SCANBODY

The scanbody can be used in the mouth by the practitioner or on a plaster model in the laboratory.

Note: An intra-oral camera (at the practice) or a desk-top scanner (at the laboratory) is required to use the scanbody.

Using the scanbody at the practice

Once the implant is installed in the mouth and after the necessary healing time (see Instructions for using TBR® implants):

1/Check that the scanbody is adapted to the range of implant used.
2/Unscrew the healing screw (in the case of Bone Level implants) or the cover screw (in the case of Tissue Level implants) using the TBR® hexagonal screwdriver intended for this use.
3/Screw the scanbody on the implant in the mouth using the screw supplied and a TBR® hexagonal screwdriver whilst ensuring that the scanbody is correctly aligned with the implant connection.
4/Start the digital acquisition using your intra-oral camera in accordance with the manufacturer's protocol.

Important
In the event of restoration of several implants, it is necessary to place one scanbody per item.

Using the scanbody at the laboratory

Once you receive the conventional impression made by the practitioner:

1/Check that the scanbody is adapted to the range of implant used.
2/Make up the plaster model with the homologue(s) in place faithfully reproducing the position of the implant(s).
3/Screw the scanbody(ies) on the TBR® homologue using the screw supplied and a TBR® hexagonal screwdriver whilst ensuring that the scanbody is correctly aligned with the implant connection.
4/Start the digital acquisition using the desk-top scanner in accordance with the manufacturer's protocol.

Important
In the event of restoration of several homologues, it is necessary to place one scanbody per item.

DISINFECTION, CLEANING, STERILISATION

TBR® scanbodies are sold non-sterile. When they are used in the mouth, they must be sterilised beforehand.

Warning

In the event of damage or soiling of the packaging, the parts will not be taken back or exchanged by the manufacturer.

Warnings and recommendations for disinfection, cleaning and sterilisation

Scanbodies must be disinfected, cleaned and sterilised by competent and qualified personnel. Check the content, cleanliness, working order and qualification (calibration, maintenance etc.) of all the necessary equipment before starting the cleaning and sterilisation cycle. Contaminated devices must be handled with personal protective equipment (gloves, lab coat, safety glasses, mask, etc.). The drying, packaging and sterilisation processes must be carried out in a clean, orderly and uncluttered environment.

Attention:

All the parts which are to be sterilised require certain recommendations to maintain their quality. Not adhering to these requirements can alter the devices (degradations of the marking, etc.) and compromise the safety of the operators and that of the patients (contamination):

Point A: Use cleaning/disinfection products specific for surgical instruments and the equipment involved. Do not use chlorine, iodine, phenol, or strong acid or alkaline based products (do not use sodium hypochlorite (bleach), oxalic acid, sodium hydroxide, hydrogen peroxide, or 9‰ physiological fluid, beware of running water that is too heavily chlorinated). Avoid any product which contains an aldehyde as they fix proteins.

Point B: For the washer disinfector: Only use agents recommended by the manufacturer, preferably mildly alkaline products (PH between 7 and 10.5).

Point C: For all products and equipment (for cleaning/disinfection, washer disinfector, ultrasonic tank, sterilisation sachet, autoclave etc.) you must strictly observe the manufacturer's instructions (dosage, immersion time, temperature etc.) and the expiry dates.

Point D: Avoid as much as possible, all bumping and contact with other instruments (deterioration of the surface quality, laser marking and/or cutting power).

Point E: Clean parts which are of the same material in the same tank.

1. Before use, the devices are placed in a suitable clean container and totally immersed in a freshly made disinfectant solution, with no bubbles (using an ultrasound system is also recommended) (see Points A, C, D & E). Rinse thoroughly in running water until there are no chemical residues on the device.

2. Manual cleaning: Immediately after cleaning, carefully rub dry all the parts' surfaces with clean lint-free absorbent paper or with compressed air for medical use (see Point C).

Washer disinfector: Immediately after cleaning, place the devices in the washer disinfector, avoiding all contact between them, and start the cycle according to the manufacturer's instructions (see Points B, C & D).

3. Visually inspect the devices for cleanliness, and absence of moisture and stains and make sure there is no deterioration which could compromise their safety, integrity or proper functioning. Place the part(s) in sterilisation sachets which are large enough to prevent tension on the seal (see Point C).

4. Ensure that there are no corroded parts inside the type B pressurised steam steriliser (autoclave). Sterilise the autoclave at 134°C, 18 minutes (see Points C & E).

5. Check the cycle is running correctly, the integrity of the sachets as well as the physicochemical sterilisation indicator (if necessary, re-start the operation at point 4). Mark the sterilisation date on each sachet (and any necessary traceability information) which will then be stored in conditions which will preserve the safety and sterility of the products (a clean, dry, safe place, without constraints, at room temperature and away from direct sunlight).

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.