PRODUCT BY:

btk Implanting Trust, Smile Again!

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IFU - Instructions for use

EN - INSTRUMENTS

1.1 APPLICATION FIELD

Stainless steel manual tools and/or micro-powered are necessary for: preparing the surgical area where the implant and the cortical screw, BT SCREW, are to be placed; make tapping; tightening or removing the prosthesis or implant; measuring the depth and direction of surgical pockets by applying the practice of implant dentistry and bone regeneration techniques. These instruments should only be used with Biotec devices from the general catalogue/manual and on the web site www.btk.dental. Any combination with different devices may bring to failure of the clinical case.

1.2 WARNINGS AND RISKS IN THE USE OF THE INSTRUMENTATION

All instruments must be exclusively used by qualified staff and trained personnel, with the necessary operating qualifications and having read this instruction for use. Improper use or misuse of the instruments can cause damages to the components or injuries to the patient. Before any implant surgery the patient's history should be accurately noted (clinical and radiographic analysis are necessary).
Do not use if the packaging is damaged. Before using it, the device must be sterilized in according to the "INSTRUCTION FOR USE" section of the instructions leaflet.
Biotec devices have not been evaluated for safety and compatibility in the MRI environment. It has not been tested for heating, migration, or image artifact in the MRI environment. The safety of Biotec devices in the MRI environment are unknown. Scanning a patient who has this device may result in patient injury.

1.3 INFORMATION FOR THE PATIENT

Dentists shall inform the patient on all the on all aspects related to surgery. The patient should also be instructed to maintain proper oral hygiene and to carry out regular check-ups in case of unexpected problems related to surgery and post-surgery.
During the post-operative period, when appropriate, the patient must be informed about the need to avoid mechanical loads in the implant area.

1.4 CONTRAINDICATIONS AND RISKS

Implantology and bone regeneration procedures are however not recommended in the following cases:
- in non-bone site
- in necrotic or infected sites
- in case of bone degenerative disease
- demonstrated or suspected allergy of titanium or metals
- Poor bone quality
- suspected site infection
- inadequate oral hygiene
- poor patient cooperation
- Heavy smoking
- general pathological conditions (AIDS, cancer, diabetes, osteoporosis, etc.).

In the case of treatment with medicines that act on phospho-calcium metabolism, the use of the device must be carefully evaluated.
Various alloy types in the same oral cavity may lead to galvanic reactions! Caution must be exercised if mixing metal types.
The prosthetic devices must be secured to prevent aspiration and swallowing of a component.

1.5 INSTRUCTIONS FOR USE

Instruments are NOT SUPPLIED IN STERILE PACKS, therefore they must be properly cleaned and sterilized before use, also at first use. The processes of cleaning and sterilization are necessary to ensure the health of patients and of all persons who work and study in the laboratory.
On the Biotec website it is possible to consult the manual with general surgical guidelines, where information on the cleaning and sterilization process, recommended by Biotec Srl, are reported in detail.

Cleaning
Cleaning can be done manually with hot water and a suitable detergent, non-aggressive, using plastic or nylon brushes, (never use steel wool or metal brushes), to remove any organic residues. Always follow the manufacturer's specific recommendations for all cleaning products used. To facilitate cleaning, some instruments are easy to mount and dismount (remove metal stops from the drills, unscrew the torque ratchet etc...). Ultrasound equipment can also be used for cleaning.
It is recommended to check each individual device after the wash cycle to check that any residues have been completely removed.
During washing, take care not to rub the various products together to avoid any damage to the sharp parts of the devices. Do not leave wet parts after rinsing, in order to avoid oxidation

Sterilization
As a method of sterilization, we recommend autoclaving / steam: the recommended* standard time is 20 minutes at 121 °C (about 250 ° F) and 1.1 bar pressure. Failure to follow these instructions may lead to cross-infection and failed surgery.
**Sterilization time and temperatures may vary depending on the type of machine and the load. Always follow the instructions provided by the manufacturer. Make sure to pack each component separately. The sterilized bags should be stored in a dry place, protected from dust and not exposed to direct heat or sunlight. Once the maximum storage time is exceeded (30 to 60 days depending on the type of packaging used), the devices must be sterilized again.*
Clean and sterilize the product before final disposal.

1.6 RETURNS

Biotec does not accept returned goods if the packaging seals are open, broken or not conforming to the sale specifications of the company.

1.7 STORAGE INSTRUCTIONS

Store in a dry and clean place, protected from dust. Do not expose to direct heat or sunlight.

1.8 SURGICAL PROCEDURES

Preliminary checks:
- Check that the packaging is intact and not damaged
- Proceed to the cleaning and the sterilization as indicated in the section "INSTRUCTION FOR USE"
- Check that the device has been properly sterilized before use
- Make sure everything that can be in contact with the device is also clean and sterile.

Surgical Indications
Detailed instructions for the use of the various instruments, procedure's recommendations and the full list of all Biotec codes are reported in the brochure and on the Biotec www.btk.dental website or it can be requested to Biotec Srl.
Use of the device must be carried out in a suitable surgical environment and the handling, during surgical intervention, should be carried out using gloves, or appropriate tools, which must also be sterile. A specific treatment plan should be studied, based on the patient's state of health and on the surgery. For the success of the procedure, soft tissue management is a critical factor. It is necessary to study the more appropriate technique of surgery and tissue preservation, according to the patient's needs and his clinical profile. The use of protective glasses is recommended.
The manufacturer accepts no liability for customers' own modifications without his prior approval. If in doubt about the cutting capacity or the correct functioning of the instrument, replace the instrument.
For instruments powered by the micro-motor it is important to ensure that the instrument is firmly mounted on the motor before starting, and that there is a large flow of saline solution to the surgical pocket during surgery. Make sure not to exceed the maximum torque or maximum force as recommended in the general catalogue/manual and on the website.
Torques higher than those recommended may cause the breakage of the devices and consequently complications in surgery.
Below is a brief summary of some general indications concerning the main devices.
Mucotome: used to cut the mucose to the bone crest (recommended speed 40rpm). Mucotome can be manually used by hooking it to the appropriate digital wrench or ratchet.
Drill and drill stop: used to make the implant site. In order to avoid any damage to the bone it is very important not to heat it. For this reason, you should use drills in a sequence of decreasing diameters, and always have a steady flow of saline. The maximum speed must not exceed the values reported in the surgical procedures in the Biotec catalog / manual.
Do not exert a constant pressure on the hand piece when reaching maximum depth, but perform the drilling rotating strokes back and forth, a few millimetres at a time, in order to allow the inflow of the pre-cooled physiological solution and allow the evacuation of the residues derived from drilling of the bone. If necessary, pause at intervals to enable the bone and the drill to cool. The required depth is indicated by the notches on the drills and corresponds to the end of the sharp cutter part. The drills have a stop provision to help you determine the exact depth to avoid damaging the maxillary sinus and the alveolar nerve. The effectiveness of a drill decreases after about 5-6 applications, and we recommend replacement after about 20 utilization. However, the life of an instrument depends on the actual conditions of use and if used incorrectly, the durability will be less. Some drills are used to prepare the surgical site for the insertion of cortical screws.
Flat Drill: the Flat drill is used to level irregularities of the bone crest, favoring the subsequent operations of preparing the surgical site. This drill is used in the guided surgery method and this instrument is guided by the surgical guide and by appropriate stops / sleeves. Its use is defined in the design phase of the case, in which eventual irregularities of the bone crest are also evaluated. Consult the Biotec brochure dedicated to this guided surgery method, downloading it online or requesting it from Biotec Srl.
Guide-Stop Drill: they are particular stops that must be connected to the drills and that are used in the guided surgery method. Consult the Biotec brochure dedicated to this guided surgery method, downloading it online or requesting it from Biotec Srl.
Sleeve For Surgical Guide: They must be applied to the surgical guide for guided surgery and are intended to guide the instrumental during surgery. The sleeves must be inserted on the appropriate seats with the correct interference.
Pit Countersink and Pit Drill: This instrumental was designed for the preparation of the surgical site to place an IUXTA-3D subperiosteal implant (Custom Medical Device). Use the "Pit Countersink " to prepare the site that will house the subperiosteal implant. The procedure involves making a Ø2 diameter hole with the pilot drill and then preparing the site with the countersink. Pit Drill's pin must be inserted in the prepared hole. This allows you to have a guide when using the preparer.
The Pit Drill, with cutting edges on the sides, is suitable for eliminating any undercuts on bony ridges and / or for smoothing the support pit of subperiosteal implant or in any case to refine the seat, created with the Pit Countersink. This drill cuts only laterally. With regard to this procedure, consult the Biotec information material. Biotec provides specialists on this method and organizes specific training courses.
Drill extension: used to extend the shank of the drills.
Countersink: used to form the base of the neck where the implant has to be inserted. (recommended speed 300-400rpm)
Screw Tap: used for tapping the previously prepared surgical site. (Tapping with max speed of 15rpm). If it becomes too hard, do not force it. Stop and check the conditions of the screw tap and make sure that the diameter of the implant site is correct. The depth to be reached is indicated by the reference marks at the end of the cutter or marked on the tap. If you use the manual tap, hook it to the digital wrench or ratchet.
It is recommended to use the screw tap only if required by the Biotec Srl procedure, reported in the relative manual / brochure of the specific implant line.
Tapping Kit (to restore thread): used to restore the internal thread of the implant, in case of damage.
Trephine Drill: used to cut the bone cavity for bone grafting or pathological investigations or for the removal of failed implants (recommended speed 800-1200rpm). Also in this case it is important not to overheat the bone, so we recommend a perforation with plunger rotation and an abundant irrigation with pre-cooled physiological solution. To avoid lateral deviation during the first stage, the drill must be firmly held.
Depth Gauge: it is used to check the depth of the alveolus, referring to the notches on the instrument itself, and / or to visually verify the parallelism between several alveoli.
Parallelism Pin: is used to visually verify the parallelism between the alveoli.
Wrenches / drivers: there are different types for different functions. Used to tighten or loosen the screws, take out, place and screw implants or cortical screws; engage instruments. The drivers are used: manually or connected to the dynamometric reversible Torque Wrench or connected to the micromotor. Some tools are used for taking and inserting the pin.
Angled Wrench: It is used to lock the mounting device while loosening its retention screw.
Guide Shaft: it is used to facilitate the driving of the digital driver or manual wrench during the screwing or unscrewing phase.
Torque Wrench JD, reversible: It is used for the correct tightening of the screws, for the measurement of the force applied during the insertion of the implants and during the use of manual screw taps. The maximum force applicable to the instrument is 90N. Various types of connections can be applied to this instrument: by hooking them together make sure that they are inserted well. The device is equipped with an inversion me-

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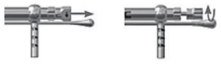
chanism that allows a screwing in both directions. The connections can be inserted from both sides to allow the use of the dynamometric lever both in screwing and in unscrewing. To tighten to the desired force value, bring the movable lever up to the notch indicating the force you want to reach.

To reverse the direction of rotation of the instrument, remove the device located at the end of the wrench and rotate it 180°.



Wrench: it allows the inversion of the rotation without having to turn the instrument, acting on the device placed at the end of the ratchet. It is equipped with a double connection, on one side 3x3 square and on the other Ex. 3.1.
Adapter Connection: They are used manually or connected to the reversible torque wrench for the following instruments: driver for inserting implants; screw tap, for tapping manually. In addition, the implants provided with a mounting device can be screwed manually or with a reversible dynamometric wrench.
Surgical Guide BT4: after any decontamination of the oral cavity and neck flap, make a median osteotomy using a 2 mm diameter drill. Insert the surgical guide into the osteotomy and shape it so that it follows the occlusal line of the opposite arch.
Bone Profiler and Bone Profiler Guide for BT4: The Bone Profiler is used to shape the bone profile around the collar, in the case of using angled BT4 abutments. Bone profiler for the osteologist.
Locator intruments: used to remove a retentive nylon cap from the titanium cap, first unscrew the tip of the instrument, turning 3 times anti-clockwise. Then just insert the tip of the instrument in the nylon cap and push directly into the bottom of the cap itself. Then tilt the tool so that the sharp edge of the tip cuts the cap and then extract from the titanium cap. To remove the nylon cap from the tip of the instrument, point the instrument directly down and away from itself and unscrew the instrument, turning clockwise, again three times. This will activate the removal pin and dislodge the nylon cap from the tip of the instrument. Separate the removed tip from the tool and use the end of the remaining instrument to place a new nylon cap in the empty titanium housing.
Drilling Tool for Pins: use this instrument connected to the manual wrench. This device is used to prepare the site for the pinn, using light hammer blows on the end of the manual wrench.
Insertion Device for Pins: use this instrument connected to the manual wrench. This device is used to pick up the pin and insert it into the site by light hammer strokes on the end of the manual wrench.
Retractor: It serves to keep the flaps open for surgical access
X-Ray Reference Sphere: Ø5 diameter sphere - It is placed inside a vacuum-packed mask, in the position of the implant to be inserted. It is used to determine the magnification scale of the radiograph thanks to a comparison with the selectors, to measure the thickness of the mucosa, the quantity of vertical bone available and to select the length and type of implant to be used.
Implant Removal Device: allows you to remove the implant if the procedure has not been performed correctly and if the connection has been ruined.
Extractor D-Block+Driver JD: they allow the D-Block abutments to be removed after their final tightening. They are used manually or connected to the dynamometric wrench.

1.9 POSSIBLE SURGICAL COMPLICATIONS AND POST-OPERATIVE CARE

After surgical implants or bone regeneration some complications are possible such as dehiscence of the gingival area around the implant, localized or diffuse oedema, hematoma or post-surgical hemorrhage. Paraesthesia of the lower lip and chin region are possible in the event of injuries to the inferior alveolar nerve and chin area. These paraesthesias are usually reversible, but in rare cases permanent. The inflammation and ulceration of the gingival area around the implant respond well to local and general therapy. It's important to inform the patient about the importance of regular oral hygiene for the first 7-10 days after surgery. During the post-operative period avoid mechanical loads in the implant area. It is important that the patient carry out regular check-up, that include specific tests, such as radiological evaluation.

1.10 DISPOSAL

Proceed with disposal in accordance with the local law concerning the disposal of special medical waste with contamination risk. Biotec recommends cleaning and sterilization of device before disposal.

1.11 PRODUCT TRACEABILITY

All Biotec medical devices are identified by a code and a batch number; this information is necessary to ensure product traceability. In the case of the purchase of the devices with the kit configuration, the traceability of the device is guaranteed by the kit identification lot, shown on the external label of the kit received and in the order / shipping documents. For devices intended to remain in the patient's mouth for a long time, the package contain, in addition to the external label, an internal label with detachable parts containing traceability information. These labels must be applied by the doctor, one on the patient's medical record and one on the "Implant Passport", which is recommended to be delivered to the patient.

1.12 LIMITATIONS OF LIABILITY

The devices are developed and designed to be used according to the above-described instructions. No part of Biotec product should be replaced with a part of a different manufacturer from Biotec, neither if it was visually and dimensionally comparable to the original product. The use of products from other manufacturers with Biotec products, could lead to unacceptable and / or non-predictable adverse reactions, endangering the patient, the user, or a third party.
Unprompted use of non-original products or unplanned products during the planning phase, in combination with Biotec products, will make no warranty and any other Biotec obligation, expressed or implied. The doctor, Biotec product user, has the duty to determine whether a product is suitable for the specific patient and to particular circumstances. Biotec declines any liability, express or implied, concerning direct, indirect, punitive or other damages, arising from, or related to, any errors of assessment or professional practice carried out in the use of Biotec products. The user has also the obligation to be regularly update on the latest developments regarding this Biotec product and its applications. In case of doubt, the user must contact Biotec. Because the use of the product is under the control of the prescriber doctor, he assumes full responsibility. Biotec declines every responsibility for any resulting damages.

Biotec S.r.l.

CE 0426 CE — Products with the CE mark in accordance with Directive 93/42/EEC and following modifications/integrations

Consult instructions for use

LOT — Batch code

REF — Catalogue number

Keep away from sunlight

Do not use if package is damaged

Manufacturer

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