PRODUCT BY:

btk Implanting Trust, Smile Again!

BIOTEC S.r.l.
Via Industria, 53 - 36031 Povolaro di Dueville
VICENZA - ITALY
Infoline +39 0444 361251 - Fax +39 0444 361249
info@btk.dental

ifu.btk.dental

IFU - Instructions for use

ENG - LABORATORY **PROSTHETIC** AND ACCESSORIES

The following instruction for use is for Biotec prosthetic and accessories. Read carefully before use. Paragraphs that do not mention the product are to be considered valid for all types of BTK prostheses, unless otherwise specified (ex. Locator® Attacks).

1.1 APPLICATION FIELD

Biotec prosthetic products are designed to be used for the fitting to implants, whereas the laboratory accessories are suitable for the taking of dental imprints and the reconstruction in the laboratory of the impressions of the mouth area involved in prosthetic implant reconstruction. These devices can be used only with Biotec items listed in the general catalogue and on the web site www.btk.dental. Any combination with different devices may lead to failure.

1.2 WARNINGS AND RISKS OF USING THE MEDICAL DEVICE

The medical device should only be used by suitably trained personnel, highly qualified, with the required qualifications and after reading this instructions leaflet. Improper use or misuse of the devices can cause damage to the components or injury to the patient. Before any surgery the patient's medical history should be accurately examined (clinical and radiographic analysis are necessary).
Do not use if the packaging is damaged. The device must not come in contact with any possible contaminants. 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 MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Biotec devices in the MR environment are unknown. Scanning a patient who has this device may result in patient injury.
The LOCATOR® Implant Attachment System, it is not appropriate where a totally rigid connection is required. Use of a single implant with divergence of greater than 20 degrees from vertical is not recommended.

1.3 INFORMATION FOR THE PATIENT

Doctors shall fully inform the patient about all the characteristics of prosthetic implants. The patient should also be instructed to carry out regular checkups in case of unexpected problems with his prosthesis. During the post-operative period, the patient must be informed about the need to avoid mechanical loads in the implant area.

For LOCATOR® Attachment Systems, the patients should be made aware of the following:
• The LOCATOR® Attachments must be thoroughly cleaned each day to prevent plaque build-up and they should use a soft nylon bristle or end-tufted toothbrush, and non-abrasive toothpaste to clean the Abutments and Inserts and floss to polish the Abutments
• The coarse particles in abrasive toothpaste may scratch the surfaces of the denture and cause plaque accumulation.
• An irrigation system is recommended to flush out debris from the inside of the LOCATOR® Inserts.
• The Inserts are made of a soft plastic material (nylon) to allow the dentures to be removed/replaced regularly. Plastic materials are subject to wear as part of normal use and may require replacement.

1.4 CONTRAINDICATIONS AND RISKS

The device must not be used 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

Implantology and bone regeneration procedures are however not recommended in the following cases:
- 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

Biotec prosthetic products are not supplied in sterile packs, therefore before use it must be properly cleansed and sterilized. Cleaning and sterilization processes are necessary to ensure health and safety for patients and all persons who work in the laboratory.

Cleaning
Cleaning can be done manually with hot water and a suitable detergent, using plastic or nylon brushes (never steel wool or metal brushes). Always follow the manufacturer's specific recommendations for all the cleaning products used. Ultrasound equipment can also be used for cleaning. Be sure to check each device after the wash cycle to ensure that any organic residues are removed efficiently.
Do not leave wet parts after rinsing to avoid the formation of oxide stains

Sterilization
The recommended sterilization method depends on the type of device. Below there are different methods.

Sterilization method for medical devices in plastic material
Do not sterilise and do not expose the plastic material to direct heat, to avoid deformation or loss of elasticity
The males or the components that are made in plastic material or nylon, may be sterilized/disinfected using a liquid chemical sterilant.
In order to ensure that these products are sterilized/disinfected (all microorganisms including Clostridium sporogenes and Bacillus subtilis spores are eliminated), they must be soaked for a minimum of 3 hours in the liquid sterilant at room temperature.
The plastic cap of the device "transfer-abutment" is provided non-sterile. DO NOT STERILISE AND DO NOT EXPOSE THE PLASTIC CAP TO DIRECT HEAT OVER 80°C (about 176 °F), TO AVOID DEFORMATION OR LOSS OF ELASTICITY.
The plastic cap must be disinfected before the use with common disinfectants for plastic products (observe the manufacturer's instructions).
Only the devices for which it is expressly indicated to be made of PEEK material, can be sterilized in autoclave, see section "Sterilization method in autoclave for devices in metal and PEEK".

Sterilization method for medical devices LOCATOR® in metal
LOCATOR® devices are manufactured by Zest Anchors, LLC. Below is the information provided by Zest Anchors LLC regarding the sterilization of these devices.
Gravity autoclave: Temperature 132 °C, Exposure Time 15 Minutes, Dry time 30 Minutes.
Pre-vacoom autoclave: Temperature 132 °C, Exposure Time 4 Minutes, Dry time 20 Minutes.

Sterilization method in autoclave for devices in metal and PEEK
As a method of sterilization, we recommend autoclaving/steam: standard time recommend* is 20 minutes at 121 °C (about 250 °F) and 1.1 bar pressure.
** 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.
Biotec prosthetics and accessories are designed for SINGLE USE. In reuse there is the risk that potential mechanical damage, due to previous uses, could compromise their insertion and use.

SINGLE USE means that each single device must be used exclusively for one patient and only in the scope of the surgical intervention for which it was designed. It's possible for the clinician to have the necessity to try the device in situe in the patient's mouth before final installation. This trial fitting is permitted and does not alter the concept of disposable device, provided that the same device is used only ever on the same patient and in the context of the same surgical operation. Reuse of the medical device must be considered off-label use and in such cases Biotec s.r.l. declines any responsibility.

Screw the prosthesis and the accessories according to the torque indicated below.
For more details, refer to the catalogue or to the web site www.btk.dental.
The screwing of the prosthetic part and the laboratory accessories must be carried out with the help of the appropriate screwdrivers.

DEVICE	IMPLANT CONNECTION	MATERIAL	TIGHTENING TORQUE
Cover screw	–	Titanium GR5	from 5 to 8 Ncm ("hand tight")
Healing abutment	–	Titanium GR5	from 5 to 8 Ncm ("hand tight")
Impression Post screw, tightening to implant or implant replica	–	Titanium GR5	from 5 to 8 Ncm ("hand tight")
Retentive screw, tightening Scan Abutment	–	Titanium GR5	from 5 to 8 Ncm ("hand tight")
Retentive screw, temporary tightening (abutment to implant)	CA, IA, IB, IC, ID, KB, QA, QB, AB, CB, CC, EA, KR, FA	Titanium GR5	from 15 to 20 Ncm
	AC, DA, DB, EC, EN, ER, EW, IR, IM, IW, KA, KC, KW, SE, SR, TN, TR, TW	Titanium GR5	from 20 to 25 Ncm
Retentive screw, final tightening (abutment to implant)	CA, IA, IB, IC, ID, KB, QA, QB	Titanium GR5	from 20 to 25 Ncm
	AB, CB, CC, EA, KR, FA	Titanium GR5	from 25 to 30 Ncm
	AC, DA, DB, EC, EN, ER, EW, IR, IM, IW, KA, KC, KW, SE, SR, TN, TR, TW	Titanium GR5	from 30 to 35 Ncm
	EN, ER, EW, IR, IM, IW, TN, TR, TW	Pd-based Alloy*	from 30 to 35 Ncm
Straight abutment M.U.A.	KR	Titanium GR5	from 25 to 30 Ncm
	EN, ER, IR, KW	Titanium GR5	from 30 to 35 Ncm
Abutment SOLID and OCTA	SR	Titanium GR5	from 30 to 35 Ncm
Retentive screw, tightening angled abutment M.U.A.	KR	Titanium GR5	from 20 to 25 Ncm
	EN, ER, IR, KW	Titanium GR5	from 25 to 30 Ncm
Retentive screw, prosthesis to abutment M.U.A. - suprastructures	BT, BU, BP	Titanium GR5	from 10 to 15 Ncm
Locator® abutment to implant	–	Titanium GR5	from 20 to 25 Ncm
Lingual screw	–	Titanium GR5	10 Ncm
Retentive screw, tightening installation device to implant	–	Titanium GR5	12 Ncm
Implant installation with installation device. Implant Ø ≤ Ø 3,7 mm	–	–	from 35 to 45 Ncm
Implant installation with installation device. Implant Ø > 3,7 mm	–	–	from 45 to 65 Ncm

* Composition: (%wt.): Pd bal., Ga 10%, Cu 7%, Au 2%, Zn 0.5%, Ir 0.3%, Ru 0.1%

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Torque values greater than the recommended values may result in failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.
It is always advisable to fix the permanent prosthetic to the implant using a new screw, to avoid damage to the implant / prosthesis connection, which can be done using, for example, screws used in the laboratory. It is recommended to check the final position of the prosthetic structure by radiographic analysis.

1.6 RETURNS

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

1.7 STORAGE INSTRUCTIONS

Store in a dry place and do not expose to direct heat or sunlight.

1.8 SURGICAL PROCEDURE

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
Procedural recommendations and the full list of all Biotec codes are set-out in the brochure and on the Biotec www.btk.dental website.
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.

Screwing of the prosthetic part and accessories must be carried out with the help of the appropriate screwdrivers. Do not exceed the recommended tightening torques declared by Biotec.
It is always advisable to make sure that the screwdriver and the device are properly connected to avoid lever movements and thus increase the risk of breakage.

Here are some ways to use the main components:

- **IMPRESSION POST PICK UP (risk class I)**

Place transfer to the implant and lock it with his screw. Take an impression with a separate perforated spoon for each implant. When the impression material has completely cured, unscrew the screw first and then the spoon with the impression transfer.

- **IMPRESSION POST WITH CUP**

Place the transfer in the implant and lock it with his screw. Place the cup on the transfer and than impregnated it with adhesive. Take an impression with an individual close spoon. When the impression material has completely cured, remove the spoon with the cups and place the transfer back in position. Send the complete assembly to the laboratory.

- **IMPRESSION POST ABUTMENT**

1 - Position the abutment to the implant and secure the screw. Position the plastic cap over the abutment and and then wet it with adhesive. Make a impression with a single closed tray. When the impression is pulled, the cap will disengage from the abutment and will remain in the impression. Remove the abutment from the implant and send the impression and the removed abutment to the dental laboratory. The laboratory will then prepare the appropriate abutment and the prosthesis.
2 - Once the prosthesis is prepared, fix the abutment to the implant using a new retention screw.

- **IMPRESSION POST SCREW (risk class I)**

It is used to secure the transfer to the implant during the impression.

- **SR POSITION CYLINDER (risk class I)**

It is for impression. Two versions available: Octa and Solid.

OCTA version. Before taking the impression, place and push the impression tray on the implant's emergency until it engages the shoulder (initial countersink 90° of the SR connection). The correct positioning of the tray can be tested with a slight rotating movement: if it rotates on the system, it has been correctly positioned. Important: In order to avoid mistakes in the impression, the shoulder of the implant and the closure of the tray need to be perfectly intact.
The octagon of the octa positioning cylinder have to be aligned with the octagon of the implant and the cylinder have to be inserted into the tray until it stops.

SOLID version. Place the tray and imbed it in the implant shoulder (initial countersinks 90° SR connection). Turn slightly the cap and make sure it has properly been positioned. Push the positioning cylinder across the tray, paying attention to align the inner flat side of the positioning cylinder with the flat side of the secondary component. Push it until it is flush with the tray.

Both techniques involve the use of a closed spoon for taking the impression. Take the impression, allow it to solidify and then remove it gently with the incorporated cylinder, trying to extract it with a vertical movement. Remove the basket from the implant and send it all to the laboratory.

- **SR IMPRESSION BASKET (class risk I)**

It must be used together with the SR positioning cylinder. The doctor must place the basket on the positioning cylinder and attach it to the shoulder of the implant for interference (Solid version), or attach it directly to the shoulder of the implant for interference (Octa version).

- **IMPLANT REPLICA (risk class I)**

Insert the replica on the transfer and lock it with the relevant screw. Prepare the cast containing the replica, remove the screw and the transfer and replace it with the abutment to be prepared or with the base for the prosthesis or prosthesis manufactured using CAD-CAM techniques.

- **EXTRA-ORAL SCAN ABUTMENT AND INTRA-ORAL SCAN ABUTMENT**

They are used in the manufacture of prosthetic components using CAD-CAM technique and must be fixed, using a screw, to the analogue (when using table scanners) or to the implant (when using intra-oral scanners).
These devices are used to detect, with the help of scanners, the exact position of the endosseous implant that the practitioner has placed on the patient. The end is to reconstruct, physically or virtually, the exact reproduction of the oral cavity, that will need to receive the denture. After detecting the position of the implant, proceed to the construction of the prosthesis in electronic format using modeling software.

- **HEALING ABUTMENT**

When osseointegration of the implant has occured, replace the cover screw with a healing screw of suitable length for the thickness of the mucosa, with a small gingival incision.

- **ABUTMENT**

Replace the healing screw with a suitable abutment and fix it on the implant using the retention screw provided. Then, fix the prosthesis to the abutment. For the preparation of the prosthesis and the final shaping of the abutment it is absolutely necessary to take some impressions and accurately process them in the laboratory. There are many versions of abutments (temporary, straight, angled, aesthetic, M.U.A. (BT-4, BT-4 SLIM), millable ...). Refer to Biotec catalog or website for a list of all codes and for more information on their use.

- **PEEK Temporary Abutments**

They are made in PEEK, plastic material. Tighten the abutment in Peek to the implant, using retention screw.
PEEK Temporary Abutments can stay in contact with tissue for up 180 days. Use them for non-occlusal loading of single or multiple unit provisional restorations at mandible or maxilla for periods of up to 180 days during the endosseous and gingival healing process.
The prostheses can be cement-retained to the abutment. These Temporary Abutment can support a maximum angulation of 15°. In the case of already integrated systems, the abutments allow the occlusal load of single or multiple reconstructions for soft tissue guided healing up to 180 days.

- **TWO CEMENTABLE ABUTMENT**

Replace the healing screw with a cementable abutment, secure it with cement and fix the prosthesis (previously prepared in the laboratory) to the abutment.

- **RETENTIVE SCREW, Pd-BASED ALLOY SCREW AND M.U.A. SCREW (BT-4)**

They are used to tighten the prosthesis on the analogue or on the implant. In the case of the M.U.A (BT-4) system, they are used to fasten the BT-4 cylinder to the angled abutment BT-4.
The composition of Pd-based alloy screw is (%wt.): Pd bal., Ga 10%, Cu 7%, Au 2%, Zn 0.5%, Ir 0.3%, Ru 0.1%

- **LINGUAL SCREW**

It is used to fix the prosthesis to aesthetic abutments.

- **CASTABLE PLASTIC ABUTMENT**

It is used to create customized prosthetic devices by casting. It is made of a particularly plastic, easy to workable, that leaves minimal residues when melted. Make the appropriate modeling, working in the laboratory with the help of the molds made according to the impressions taken on the patient. Proceed to the melting of the calcinable and finishing the obtained structure, which will be fixed to the implant using the retaining screws.

- **TITANIUM BASE**

They are used to create prosthetic artifacts, using various techniques, such as fusion (where the calcinable is available), bonding, CAD-CAM techniques. The titanium base allows for a good finish and a precise implant-prosthetic connection. Make the proper molding and finishing of the abutment. Secure the obtained abutment on the system, using the provided retaining screw. Finally, fix the prosthesis on the abutment.

- **M.U.A. COVERING CAP**

Provisional component useful to cover the M.U.A. (BT-4 straight or angled and BT-4 SLIM bushing), during the healing of the implants to avoid contamination at the implant site. The cap must be screwed to the implant by retentive screw.

- **M.U.A. TITANIUM ABUTMENT (BT-4 and BT-4 SLIM)**

After adjusting it in the laboratory, screw the cylinder on M.U.A. abutment (BT-4 straight or angled BT-4 SLIM). The cylinder is the link to the prosthesis.

- **MOUNTING DEVICE (risk class I)**

It is used to remove the implant from the phial and insert the implant into the created envelope. The connection between the device and the implant is made by retention screw (the mounting device and its screw are usually supplied in the phial with sterile implant). When it is sold individually it is supplied in non-sterile packaging and it must be properly cleaned and sterilized before use.

- **RETENTIVE CAP (MINI IMPLANT)**

The retentive cap should be embedded in the removable prosthesis in correspondence with the spheres of the previously inserted MINI implants. This device connected to the MINI implants is intended to stabilize the removable prostheses.

- **LOCATOR® SYSTEM**

The LOCATOR® System is designed for use with overdentures or partial dentures, anchored in their entirety or in part, by endosseous implants in the mandible or maxilla.
These medical devices are manufactured by Zest Anchors. The procedural advice to be followed during prosthetic insertion and dental impression and the complete list of all codes are listed in the Biotec catalog and on the Biotec www.btk.dental website. For more information on the LOCATOR® system, refer also to the Zest Anchors manufacturer website at www.zestanchors.com.
LOCATOR® Abutment: remove the healing screw and screw the abutment to the implant. To select the correct abutment remember to account for the thickness of the patient's gum. Using a calibrated torque wrench, tighten the Locator Abutment to the torque recommended.
Impression Post LOCATOR® (risk class I): Place the Impression Post onto the abutment and push down to snap into place. Syringe impression material around the Impression Post, fill the impression tray and place it into the mouth. When the impression material has completely cured, remove the spoon with the Impression Post.
Abutment replica LOCATOR® (risk class I): Press the locator Abutment Replica into the Impression Post in the impression. Pour plaster cast into the impression to create the cast. Place the Block-Out Spacer over the replica. Press the Metal Caps with the Black Male onto the replica. Process and finish the overdenture on the cast around the Metal Cap.
LOCATOR® Replacement males: When the overdenture is finished, remove the Black Males from each Denture Metal Cap (using the Locator® Core Tool) and place the Locator® Replacement Male selected for each abutment into the Denture Metal Cap (using the Locator® Core Tool).

- **BT-LINK and RELATIVE CASTABLE PLASTIC ABUTMENT**

These medical devices have been designed in order to facilitate the fabrication of custom designed screw retained gold, titanium and ceramic abutments or frameworks which are utilised in the production of cement or screw retained implant prosthesis. The fabrication of abutments/frameworks can be done through CAD-CAM machinery or through conventional cast-on techniques. For this option, it is recommended to use the castable abutment supplied in the packaging. The titanium base of BT LINK have to be linked to the final prosthesis using a suitable cement. To fix the prosthesis on the implant, tighten the retentive screw.

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IFU - Instructions for use

- **CAST-ON ABUTMENTS**

CoCr Cast-On Abutments and Gold Cast-On Abutments are designed for casting-on with metal alloys in order to manufacture a framework which is consequently veneered with suitable materials.

COBALT CCM® (% in weight) Austenitic Cobalt-Chromium-Molybdenum Alloy		**PLATINOR N (% in weight) Gold-Palladium-Platinum-Iridium Alloy**	
REFERENCE ANALYSIS			
C	max. 0.14	Au	60
Si	max. 1.00	Pd	15
Mn	max. 1.00	Pt	24.9
Cr	26.00-30.00	Ir	0.1
Mo	5.00-7.00	Au&PGM	100
Ni	max. 1.00		
Fe	max. 0.75		
N	max. 0.25		
Co	balance		
MATERIAL NO. AND NORMS			
DIN	CoCr28Mo		
ISO	5832-12		
AFNOR	CoCr28Mo		
ASTM	F1537 alloy 1		
UNS	R31537		
MECHANICAL PROPERTIES			
Coefficient of Expansion (CTE)	13.2•10^{-6} C^{-1}	Coefficient of Expansion (CTE)	12.9• 10^{-6} C^{-1}
Melting range	1340-1440°C	Melting range	1350-1460°C
Yield strength (R0.2)	Up to 1115 MPa	Yield strength (R0.2)	450-720 MPa
Young Modulus E	241000 MPa	Young Modulus E	110000 MPa
Hardness	Up to 46 HRC	Hardness	Up to 230HV

Cast-On Abutments provide support and retention for single-unit or multi-unit, screw-retained restorations in the mandible or maxilla. CoCr Cast-On Abutments and Gold Cast-On Abutments are intended for use in conjunction with BTK dental implants in partially or fully edentulous mandibles and maxillae, to support single-unit or multi-unit, screw-retained restorations. CoCr and Gold alloy Cast-On Abutments are made of a metal alloy base, as indicated above, and combined with a combustible plastic sleeve that burns-out without any residue. The plastic sleeve can be shortened prior to waxing-up, depending on individual cases.

Waxing-up and Investment

Waxing-up of framework is done applying standard techniques. The minimum wall thickness of 0.4 mm must be obeyed in order to ensure a proper casting result. The connection geometry and platform of the corresponding implant must be thoroughly clean to ensure that there is no casting in this area.
The configuration must be carefully cleaned before investment. Only phosphate-bonded (gypsum-free) investment compounds are recommended for basic metal casting. Ensure to avoid air entrapment in the investment compound. Observe the instructions for use for the casting equipment. Observe exactly the recommended mixing, the times and the heating temperatures.

Fusion, casting and cooling

Gold Cast-On Abutments are designed for casting-on with noble metal alloy. CoCr Cast-On Abutments are designed for casting-on with CoCr alloys. Observe the instructions for use for the casting equipment. Vacuum induction casting is recommended for CoCr alloy. Follow the instructions given by the manufacturer of the alloy for overcasting. To prevent the cast object from being subject to stress, allow the casting cylinder to cool down to room temperature.

Investment removal, finishing and possible welding

Proceed to remove the investment compound with max 2 bar pressure with glass polishing beads to ensure that the dimensions of the connection remain undamaged. The cast framework can be finished with ceramic bonded discs / stones or with crosscut tungsten carbide burs. Connecting the cast framework to a lab analogue during finishing is recommended. Using CoCr alloy it is possible to weld the cylinders to the framework at the marginal region, using a laser weld. This procedure is to be considered optional. Welding is not required for noble alloy frameworks and bases.

Try-in

Ensure the framework achieves a passive fit on the master cast. If necessary, confirm intraorally, before cleaning and sterilization processes.

Veneering

Before veneering, check the compatibility between CTE value of the ceramic compound to be applied to the framework and CTE value of base metal. A primary opaque layer is recommended prior to sculpting with ceramics.
Once the prosthesis is made, fix it to the implant using its screw, following the tightening torques indicated by Biotec.

- **WINGS ABUTMENTS**

Wings Abutments are intended for the production of prosthetic structures by intraoral welding.
It is recommend the use of intraoral welding devices, specially designed for this purpose and equipped with the necessary certifications.
The use of protective glasses is recommended, for both the physician and the patient.
Wings Abutments provide support and retention for multi-unit, screw-retained restorations in the mandible or maxilla.
Each abutment is provided with two wings available in different height and angulation. The framework can be realized by welding the wings together.

Surgical Procedure

First choose the correct abutment in order to obtain the best overlap of adjacent wings and follow the patient anatomy. Shape the Wings Abutments in order to put in contact the wings each other and minimizing the space between them.
Next, shaping and modelling the wings, using nippers, in order to secure the support between them. If the wings are too long, they may be trim with appropriate nippers or mill. Before welding it is recommended to check the adherence between wings; it is important that both wings are supported as adjacent abutments, in order to avoid tensions in the final structure.
The structure can now be weld; making sure that the wings and the electrodes are in contact each other in order to avoid sparks or electrical discharges. It is suggested to set weld energy at 280J.
In case of full arch restoration it is recommended to start the welding from the front section so as to discharge any tension along the end of the prosthesis.
In case of overly spaced systems, an extension can be applied between the wings of the two abutments.
The retention screws, dedicated to this method, are made with a long head which protrudes from the abutments. Once the final prosthesis is made, it is possible to shorten the retention screws: once cut off part of the head with appropriate tools, it is necessary to obtain a slot. The screw can then be tightened with the flat-blade screwdriver made by Biotec for this purpose.
If you do not want to modify the screw, you will be able to use a normal retention screw, compatible with your implant connection. The screw will have to tighten respecting the torque indicated by Biotec.

- **BWB SYSTEM**

The devices described below are intended for the fabbrication of prosthetic structures by means of intraoral welding. The use of specifically made devices for intraoral welding, with the necessary certifications, is recommended.
The use of protective glasses is recommended, for both the physician and the patient.
Biotec prosthetic products are designed to be used for anchorage to dental implants to support dental restorations.
BWB system, with standard components, supports a minimum spacing between cylinders of 15 mm. The distance is considered within the cylinder surfaces and with parallel implants.
In the presence of closer implants (down to 7 mm) the use of special component is recommended. The Cylindrical Abutments have been designed in order to be applied on implants or on MUAs and to sustain the prosthetic structure. It is strictly recommended to choose a correct cylinder, compatible with the implant or MUA connection. The cylindrical abutment must be coupled by the use of the appropriate retention screw. After being welded the cylindrical abutment could be cut and/or modelled to fit with the prosthesis.
Rings are components designed to connect the cylinder abutments to the threaded joints. They are made in two different configuration in according to the insertion direction on the cylindrical abutment. They have to be inserted on the cylindrical abutment and positioned at the appropriate height. The threaded joints have to be fully inserted in the spherical housing.
The rings have to be chosen in order to facilitate the insertion and eventual extraction of the threaded joints.
Threaded joints are made in two different types, with male thread and female thread.
The joints with female tread are made in two length. A male and a female joints coupled together form a connection bar between two adjacent cylindrical abutment.
The bar length can be adjusted screwing and unscrewing the threaded joints. It is recommended not to unscrew more than 2 mm the joints from the position of maximum insertion. Use a longer threaded joint or an extension if a longer bar is needed.
The Short Joints for close implant are designed to connect implant in cases where the threaded joints are too long to be places between the implants. Like for threaded joints they are available in male and female version.
The bar length can be adjusted varying components inclination.

Welding Procedure

The welds must be executed in the sequence shown below in order not to generate residual stresses that could affect the passivity on the implants.
Pay attention to the placement of the clamp on the medical device making sure that the electrodes and the components are in contact each other. It is suggested to exert a compression force of approximately 200N between the two electrodes of the clamp. To achieve a better result, it is suggested to use dual pulse mode.
Joints for close implants, if present, have to be welded using an energy of 180 J. These components must be welded in opera. Also be execute outside the mouth removing carefully the bar paying attention not to alter its length. The spherical joints have to be welded with an energy of 255 J. This operation have to be execute in the patient mouth with all the component correctly assembled. The rings must be weld with the cylindrical abutment individually. The pliers must only be in contact with the ring to be welded. Use an energy of 210 J. If the two rings are in contact each other, it is suggested to perform an additional welding by placing the clamp on both rings and using an energy equal to 300 J. These components must be welded in opera.
In the following table we report a summary of the welding sequence, percentage values refer to DAVINCI welding machine, made by Swiss&Wegman.

WELDING ORDER	ELEMENT TO BE WELDED	ENERGY [J]	ENERGY FOR DAVINCI WELDER [J]
1	Joints for close implant	180	60%
	Threaded segment	270	90%
2	Spherical joints	255	85%
3	Single rings and abutments	210	70%
4*	Coupled rings and abutments	300	100%

* only in case of need and after the welding of the single rings

PRODUCT BY:

Implanting Trust,
Smile Again!

BIOTEC S.r.l.
Via Industria, 53 - 36031 Povolaro di Dueville
VICENZA - ITALY
Infoline +39 0444 361251 - Fax +39 0444 361249
info@btk.dental

ifu.btk.dental

IFU - Instructions for use

1.9 POST-OPERATIVE CARE

The patient must be informed about the importance of regular oral hygiene. During the post-operative period avoid mechanical loads in the implant area.
It is important that the patient carries out periodic checks, including specific examinations, such as radiological evaluation.

1.10 DISPOSAL

After removal of the medical device, if required, 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. The components designed to remain in the mouth of the patient for long periods are supplied with two labels containing information regarding the construction and traceability of the product. These tags could be attached to the patient's medical records, kept in file by the dentist, and to the "Implant Passport" released 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.

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

Risk Class I

Consult instructions for use

Do not reuse

LOT Batch code

REF Catalogue number

Keep away from sunlight

Do not use if package is damaged

Manufacturer

01500065 REV2 del 7/05/2018

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