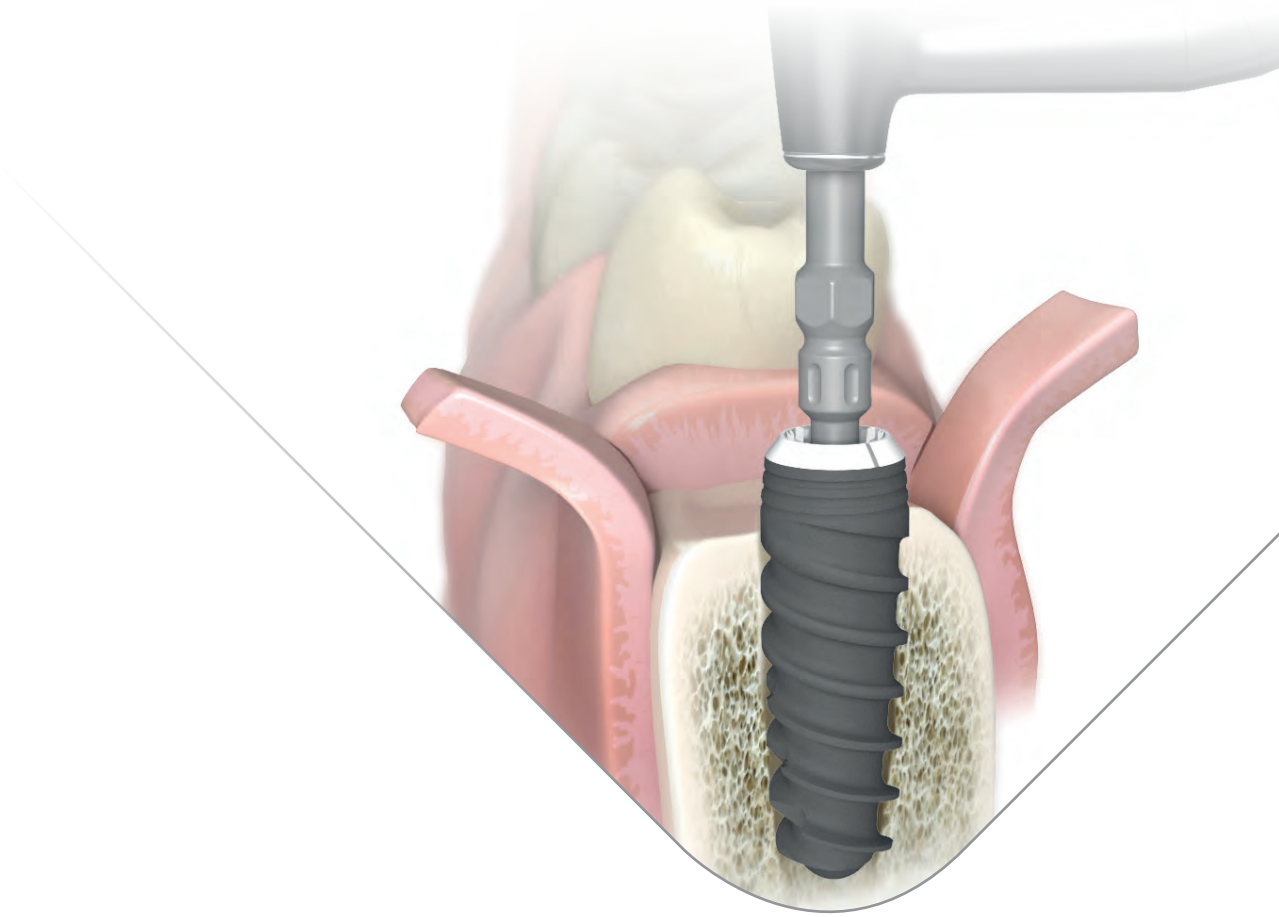
SURGICAL
MANUAL

btk Implanting Trust, Smile Again!

GENERAL SURGICAL GUIDELINES



GUIDELINES FOR EMPLOYMENT OF BTK DEVICE AND SURGICAL RECOMMENDATIONS

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IMPORTANT NOTE

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This manual provides dental practitioners and related specialists
with general surgical information regarding the use of BTK dental implant systems.

For detailed information on other specific implant lines and their restorative procedures,
please refer to the corresponding manuals, specific literature or refer to the BTK website.

Consider to regularly visit practical courses for updates and professional exchange
with dedicated colleagues in order to ensure your long-term success with implant-borne
dental restorations.

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GENERAL SURGICAL GUIDELINES

GUIDELINES FOR EMPLOYMENT OF BTK DEVICE AND SURGICAL RECOMMENDATIONS

INDEX

600 B.C.

Mayan Mandible with shell fragments as tooth replacements.

SHORT HISTORY OF OSSEOINTEGRATION

As early as the 7th century BC, Etruscans in northern Italy made partial dentures out of human or animal teeth fastened together with gold bands. In the late 1950's, new concepts and implants designed for immediate load were fueled by Stefano M. Tramonte, a known Italian pioneer of implant dentistry.

In the early 1960's, Per-Ingvar Branemark and coworkers at the University of Gothenburg in Sweden started a systematic development of a dental implant concept that for clinical function depends on direct bone anchorage named 'osseointegration'.

Even though Branemark's team was the first to suggest a direct bone anchorage (1969, 1977), the scientific community at the time remained unconvinced. The first investigator to clearly demonstrate osseointegration was Andre Schroeder from University of Berne, Switzerland.
He worked from the mid 1970's, with research on direct bone anchored implants.
In histologic illustrations, a direct bone-to-implant contact was proven (1976, 1978, 1981).
In the past 25 years, the use of osseointegrated implants have become the standard of care for the rehabilitation of fully and partially edentulous patients, leading to a rapid expansion of implant therapy in dental offices around the globe.

Prospective clinical studies have demonstrated survival and success rates clearly exceeding 90% after up to 10 years follow-up.
Several factors and trends have influenced this development such as greater acceptance among patients and dentists, progress in bone-augmentation procedures and last but not least, the standardization of implant therapy by the development of precise, prefabricated systems.

CORPORATE BACKGROUND

Privately held BTK BIOTEC was founded in 1998 in order to improve the quality of life of people with missing teeth.

BTK is a dedicated supporter of the genuine "100% Made in Italy" label, because with this it is guaranteed that BTK products are of unmatcheable Italian craftsmanship and premium quality materials offering dedicated specialization and ample differentiation.

BTK Headquarters - NORTH ITALY

Implanting Trust, Smile again!

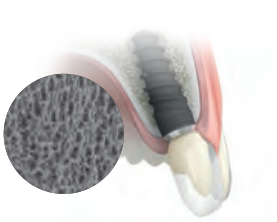
By combining cutting-edge technologies and biology, BTK's mission is to offer affordable and personalized implant-borne solutions thereby sustainably improving the daily life of dental patients.

Together with leading professionals, BTK strives to become a reference in replacing missing teeth with trusted implant solutions in order to improve oral health around the globe.

PREMIUM QUALITY MATERIALS

Grade 4 commercially pure titanium (ASTM F 67 / ISO 5832-2) is BTK's material of choice for dental implants. Grade 4 is slightly harder to work, but it provides the highest strength and durability characteristics among the commercially pure titanium grades, making it the natural choice for BTK dental implants.

Grade 5 titanium (ASTM F 136 / ISO 5832-3) is used for BTK's prosthetic components, as these are subject to certain levels of stress and in the MINI line implants. This high-strength version, also known as Ti-6Al-4V, is widely used in orthopedics and shows excellent long-term physical and mechanical properties.



ENDOSSEOUS SURFACE DAE

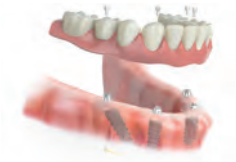
Clinical trials confirm that roughened endosseous surfaces perform better than machined surfaces concerning endosseous wound healing, "de novo" bone formation and reduced time-to-loading.

Our DAE (dual- acid-etched) process aims to obtain a moderately rough surface with a controlled micro-roughness.

IMPLANT-ABUTMENT CONNECTION

The precision of the connection between implant and abutment creating a tight seal may be beneficial in preventing inflammatory bacteria propagating in the interface between different components.

Apart from that, extremely tight tolerances as applied by BTK help to avoid micromovements.
Providing precision in every part produced is one of our key contributions ensuring longterm restorative success.



RESTORATIVE OPTIONS

The purpose of dental implant therapy, now widely used in dentistry, is to replace lost dental elements with biocompatible titanium implants, in order to obtain a new and correct occlusion, using prostheses on implants.

In order to achieve this goal, BTK offers a focused portfolio of restorative solutions backed-up by comprehensive clinical experience. BTK offers a variety of prostheses components to satisfy the clinical preferences and needs of the patients.

CE

MADE IN ITALY, USED GLOBALLY

We constantly ensure that the quality of our products and services meet the high expectations of our customers and their patients. Specialized professionals are taking care to offer comprehensive solutions in applied research, engineering, education and related activities.

Our brand is a solid promise of quality, we are certified UNI EN ISO 9001, UNI EN ISO 13485 and MDD 93/42/EEC Annex II and subsequent amendements and additions, and is therefore authorized to apply the CE Mark on its products.

INDICATIONS AND CONTRAINDICATIONS OF THE IMPLANTOLOGY THERAPY

The purpose of dental implant therapy, now widely used in dentistry, is to replace lost dental elements with biocompatible titanium implants, in order to obtain a new and correct mastication, using prostheses on implants.

To plan the treatment, to position the implant and to restore it correctly, it is necessary to be aware of the required surgical techniques and to have an adequate specialized training.

Before proceeding with implant therapy, consider the following contraindications and risk factors:

GENERAL CONTRAINDICATIONS

- insufficient bone quantity or poor bone quality endangering the primary stability of the implant
- acute or chronic infections
- subacute chronic osteitis of the jaws
- impairment of microvascular circulation
- systemic disease
- poor general health condition
- recent myocardial infarction
- immunosuppression
- active treatment of malignancy
- not completed maxillary or mandibular growth
- allergies or hypersensitivity to chemical ingredients of materials used

RELATIVE CONTRAINDICATIONS

- addictions (alcohol, tobacco, drugs)
- inadequate oral hygiene, lack of motivation, lack of cooperation
- diabetes mellitus
- head and neck radiation
- postmenopausal and hormone replacement therapy
- osteoporosis, e.g. intravenous bisphosphonate use
- psychiatric illness
- use of anticoagulation drugs / hemorrhagic diathesis
- pregnancy

LOCAL CONTRAINDICATIONS

- uncontrolled parafunctional habits
- insufficient height and/or width of bone
- insufficient inter-arch space
- intraoral infection
- local root remnants

Both surgical and prosthodontic phases of treatment require careful pre-treatment diagnosis, evaluation and planning. Preservation of remaining natural structures, improved functional and aesthetic outcomes and patient satisfaction are the goals of dental implant therapy.

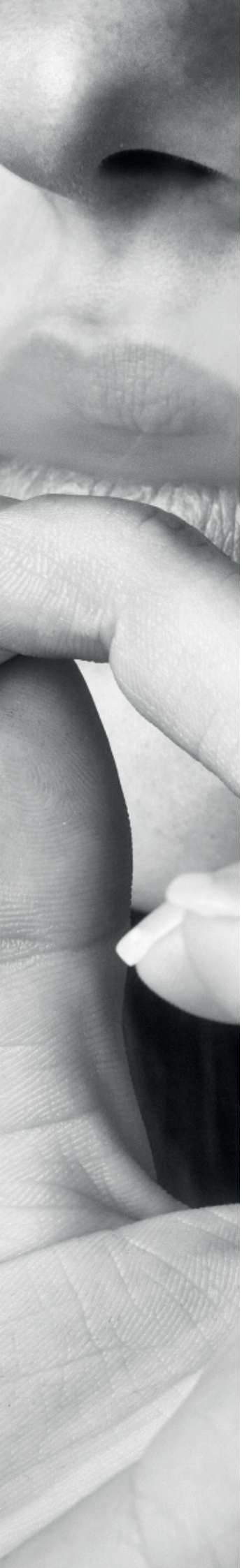
Careful case planning requires intense communication between the patient and the medical team.

RISK PATIENTS

"A risk patient is a patient in whom the strict application of the standard protocol does not offer the expected results"
(Renouard, 1999)

Successful, predictable implant treatment - especially in sites of aesthetic relevance - requires advance detection of specific risk factors that potentially may lead to complications and failure.

For some patients, identification of specific risk factors lead to modification of the treatment plan (e.g. prolonging the healing time, placing more / less implants, reducing prosthetic extensions), while others may contraindicate implant treatment altogether.
The aesthetic risk profile helps to minimize potential restorative pitfalls that may ultimately be associated with unacceptable restorative outcomes.



AESTHETIC RISK ASSESSMENT

The table below summarizes the various aesthetic risk factors. The individual risk profile of each patient is defined on the basis of a careful preoperative analysis.

AESTHETIC RISK FACTORS	LOW	MEDIUM	HIGH
MEDICAL STATUS	Healthy patient intact immune system	-	Reduced immune system
SMOKING HABIT	Non-smoker	Light smoker (< 10 cig/d)	Heavy smoker (> 10 cig/d)
PATIENT'S AESTHETIC EXPECTATION	Low	Medium	High
LIP LINE	Low	Medium	High
GINGIVAL BIOTYPE	Low-scalloped, thick	Medium-scalloped, medium-thick	High-scalloped, thin
SHAPE OF TOOTH CROWNS	Rectangular	-	Triangular
INFECTION AT IMPLANT SITE	None	Chronic	Acute
BONE LEVEL AT ADJACENT TEETH	≤ 5mm to contact point	5.5 – 6.5mm to contact point	≥ 7mm to contact point
RESTORATIVE STATUS OF NEIGHBOURING TEETH	Virgin	-	Restored
WIDTH OF EDENTULOUS SPAN	1 tooth (≥ 7mm)	1 tooth (< 7mm)	2 teeth or more
SOFT-TISSUE ANATOMY	Intact soft tissue	-	Soft-tissue defects
BONE ANATOMY OF ALVEOLAR CREST	Without bone deficiency	Horizontal bone deficiency	Vertical bone deficiency

MECHANICAL & TECHNICAL RISKS

Apart from a patient aesthetic risk assessment, mechanical / technical risks must also be considered. These risks play an important role in implant dentistry as they may lead to increase the probability of failure of the case, resulting in waste of time and financial resources for both the doctor and the patient.

During treatment planning, choices that lead to unsafe or potential conditions of excessive loading of implants and / or prosthetic components, must be avoided such as:

- Inadequate number of installations
- Implants with inadequate length and / or diameter
- Long lever arm
- Incorrect positioning of the prosthesis
- Occlusal interferences that cause excessive lateral forces
- Patient parafunctions
- Inadequate dental function procedures in the laboratory
- Inadequate adaptation of the prosthesis
- Trauma resulting from accidents or from patient habits

As a general rule, always use the implant with the largest possible diameter.

Due to the reduced mechanical stability, small diameter implants (< 3.7 mm) should only be used in cases with low mechanical load.

PREOPERATIVE PLANNING

To plan the treatment and to position the implant correctly it is necessary to be aware of the required surgical techniques and to have an adequate specialized training.

Before any implant surgery the patient's medical records should be accurately examined (clinical and radiographic analysis are necessary) and all possible risks must be assessed.
Patient expectations must also be well defined. Close communication between the patient, dentist, surgeon and dental technician is imperative for achieving the desired prosthetic result.

To establish the topographical situation, the axial orientation and the choice of implants, we recommend the following:

- Make a wax-up/set-up on the previously prepared study cast.
- Define the type of superstructure

This is particularly indicated for the anterior region of the maxilla, where the aesthetic result is even more relevant. The wax-up can also be used to show the patient the result of the proposed treatment and, subsequently, to make a surgical guide or a temporary restoration.

The implant diameter, implant type, position and number of implants should be selected individually, taking into account the anatomy and spatial circumstances of the desired prosthesis. Only when the minimum distances are observed it is possible to design the restoration so that the necessary oral hygiene measures can be carried out. An inappropriate choice of implant sizes can lead to complications in the hard and soft tissue, until the failure of implant surgery.

The implant position can be viewed in three dimensions: Mesiodistal, Orofacial and Coronoapical.

In order for the intervention to be successful, sufficient horizontal and vertical bone volume and the stability of the soft tissue is required. If there are any deficits, it will be necessary to perform appropriate hard and / or soft tissue augmentation procedures.

A well done surgical protocol, which is based on preoperative exams and on treatment planning, is the prerequisite for future successful result.

If the anatomical situation allows it, the implant should preferably be placed in the position of the replaced tooth, both in the mesio-distal direction and in the vestibular-lingual one.

The distance between two implant sites should not be less than 7 mm, measured from center to center, otherwise there may be problems with the use of the instruments, or, subsequently, with oral hygiene of the abutments.

In case of partially edentulous sites, it is advisable to mark the first site starting from about 4 mm from the prominence of the nearest tooth. The subsequent implant positions will then have to be marked in the distal direction until reaching the area of the minimum bone volume available for the implant.

As a general rule, more the bone is soft, more closer should be inserted the implants. As an alternative to a reduction in the distance between the implants and, consequently, to a higher number, it is sometimes possible to insert larger diameter implants.

Related to anatomic conditions, it is advisable to insert implants of greater size and length, in order to optimize primary stability, the level of osseointegration and to have properly sized implants according to the load they will have to support.

When choosing the number of implants to be inserted, it must be taken into account not to overload the implants too much, to avoid risks of fractures.

If the bone volume allows the insertion of at least three implants, it is recommended not to place them in a straight line. This allows to attenuate the transmission of the bending forces, acting on each individual system.

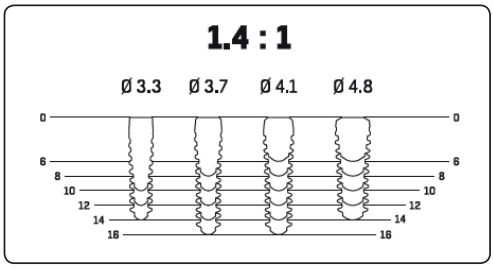
A suitable implant must be used for the edentulous site to be restored and correctly sized according to the single crown to be supported.

It is advisable to avoid the combination of implants and natural teeth in order to support a fixed bridge. This solution leads to an excessive overload of the implant and a consequent failure of the case.

To avoid aesthetic failures, do not place implants at the midline of the mandible or maxilla.
To avoid clinical damage, do not place implants on important structures such as nerves, dental roots or jaw and maxilla cavity.

X-RAY REFERENCE TEMPLATE

To support thorough case planning, BTK provides x-ray reference template with various different scales of magnification for each implant family. X-ray reference template are used for measurement and comparison and assist in selecting the suitable implant type, diameter and length.



COMPUTER-GUIDED SURGERY

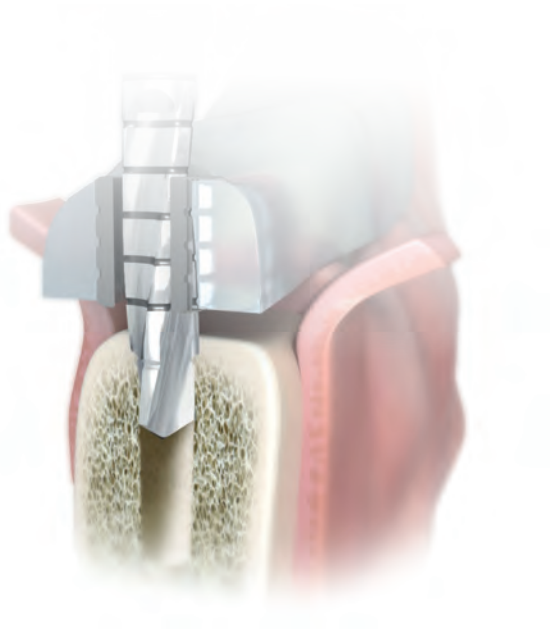
Computer guided surgery allows the clinician to make an even more accurate diagnosis of the case and an implant planning in line with the prosthetic needs.

To do this, a radiographic template, that the patient must wear during the CT / CBCT examination, is required.

The software of the computer- guided allows to integrate the information of the bone tissue, the soft tissue and the prosthetic part.

The combination of these aspects guarantees a better analysis of the case and treatment planning as:

- highlights any critical issues in a three-dimensional way
- allows an accurate choice of position and orientation of the implants
- offers the possibility to choose in advance the most suitable prosthetic solution



NOTE

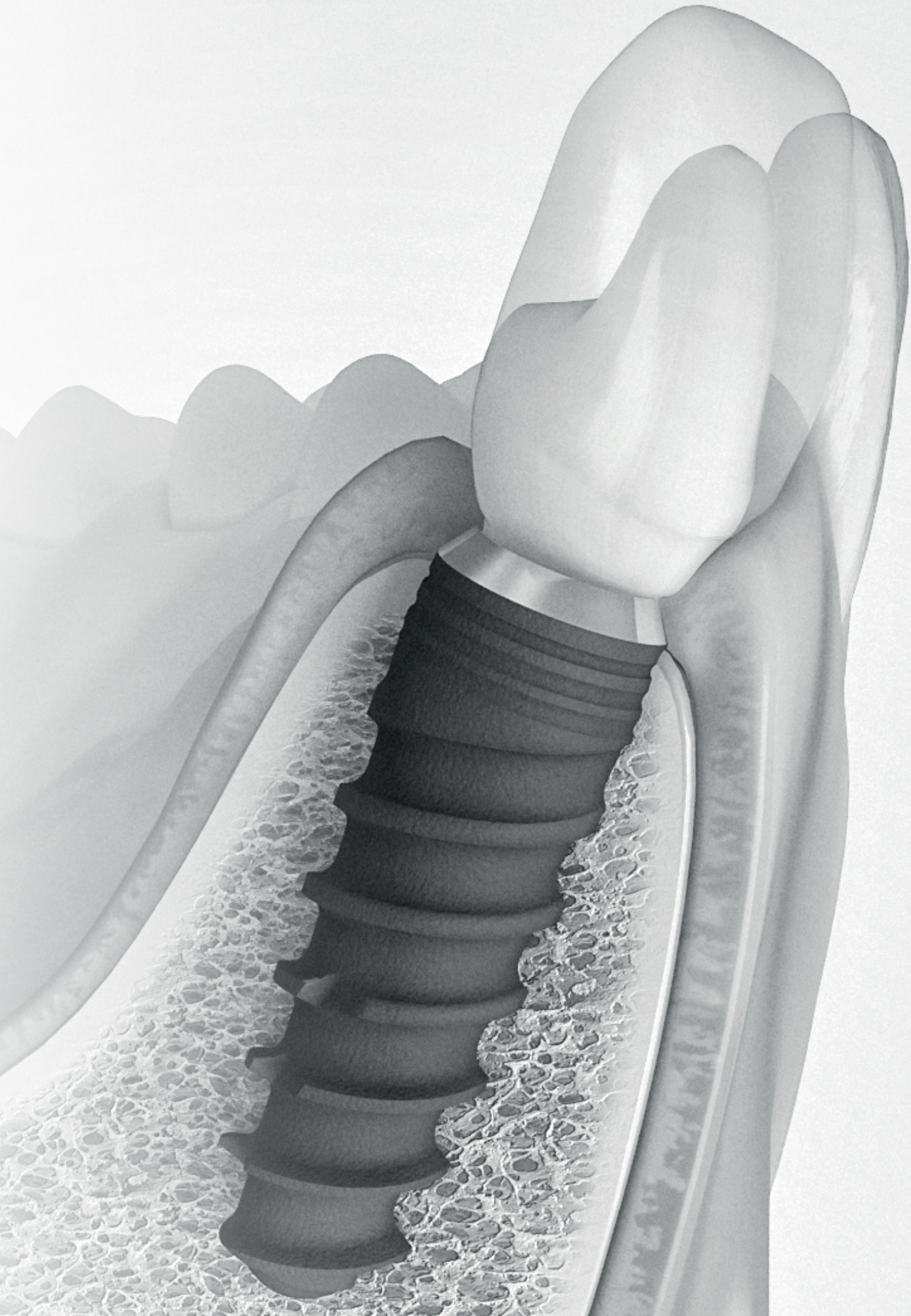
Due to reported mean deviations, at least (an additional) 2.0 mm should be taken into consideration when planning implant position with relation to vital structures and adjacent implants in all directions. In borderline cases, an intraoperative periapical radiograph should be made as a safety measure.

Surgical guides are an indispensable tool for the preparation of the implant site, according to the computer-guided surgery procedure, and can be customized according to the different surgical requirements: for dental support, with a mucous support or for approaches with flap opening.

For improved accuracy, implants should be inserted in a fully guided manner (vs. guided implant site preparation alone) whenever possible.

The computer-guided surgery may be applied with different loading protocols, in partially and fully edentulous cases.

BTK offers 3D-PILOT / "OPERA" as a complete digital workflow and related services for conventional and implant-borne dental rehabilitations. For detailed information, refer to the respective documentation on the website or contact Biotec company.



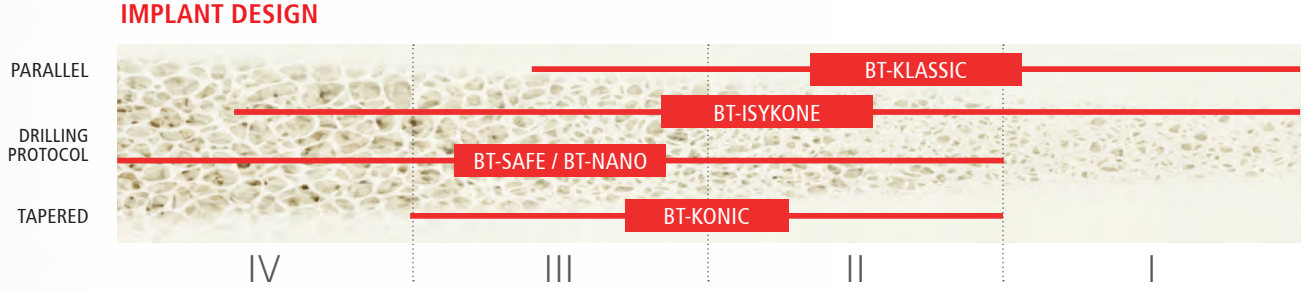
IMPLANT PORTFOLIO

BTK is dedicated to offer comprehensive implant solutions to meet the requirements of individual clinical situations, user preferences and economic constraints.

Different designs, sizes, diameters, surfaces and abutment connections are available, while at the same time BTK strives to maintain a small number of precision-instruments thus simplifying procedures and limiting investments needed.

SELECTION OF THE IMPLANTS ON THE BASIS OF BONE DENSITY AND OF THE DRILLING PROTOCOL

IMPLANT DESIGN



OVERVIEW OF THE PORTFOLIO OF BTK STANDARD IMPLANTS

BTK dental implants are made of commercially pure, cold-worked titanium Grade 4 and feature the DAE (dual acid-etched) surface.

BTK offers four standard implant lines all of which are bone-level designs with diverse body, neck and abutment connection designs.

All implants, for surgical placement, require the use of precision instruments. Depending on the implant family, BTK provides specific surgical kits.

Standard BTK dental implants are mainly available in different endosseous diameters ranging from Ø 3.25 mm up to Ø 6.00 mm, and lengths ranging from 5 mm up to 16 mm. However, BTK also offers other implant lines for particular clinical situations.

For more information on the complete portfolio of implants and related codes, refer to the BTK documentation of the respective implant lines.
A single color coding simplifies the identification of the implant diameters.

STANDARD INDICATIONS		IMPLANT-ABUTMENT CONNECTION		
TYPE	**CHARACTERISTICS**	**EXTERNAL HEX**	**INTERNAL HEX**	**MORSE-TAPER**
BT-KLASSIC 	• cylindrical shape • fine V-thread • self-tapping, flat apex	✓	✓	–
BT-KONIC 	• conical shape • single-lead thread • rounded-off apex	✓	✓	–
BT-ISYKONE 	• cylindro-conical shape • single-lead square thread • rounded-off apex	✓	✓	✓
BT-SAFE, BT-NANO 	• conical core shape • cylindrical double-lead square thread • self-tapping, rounded-off apex	–	–	✓

In addition to standard systems with a bone level connection, BTK also provides systems with a tissue level connection.

CHARACTERIZATION OF BTK IMPLANT-ABUTMENT CONNECTIONS

MORSE-TAPER (MTH)

BTK's morse-taper hexagon connection comprises a 2.6 mm conical portion at 11° above a hexagon configuration combined with a M1.6 (KR) or M1.8 (KW) abutment screw to deliver adequate pre-load with a minimum of tightening.

Implants with a tapered interface can resist larger axial and transversal forces than implants with a flat interface.
The design guides the abutment into a predictable location with a precise fit with the inner portion of the implant.

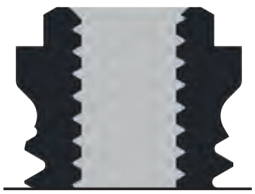
The precision of the conical connection with its tight seal may be beneficial in preventing inflammatory bacteria from propagating in the interface between implant and abutment and it helps to avoid micro-movements.

INTERNAL HEXAGON (INT)

BTK's internal hexagon connection comprises a parallel hexagon of 2 mm length opening with a small conical portion combined with a M1.8 abutment screw to deliver adequate pre-load with a minimum of tightening.

The internal hexagon has two functions: to transfer the torque momentum during implant placement and as an indexing system to transfer the precise 3D-position of the implant to the master cast.

Internal indexing systems have some advantages over external indexing systems since they allow longer engaging surfaces while reducing the platform height of the implant. This offers somewhat more flexibility in designing the emergence profile of the final restoration.



EXTERNAL HEXAGON (EXT)

BTK's external hexagon connection comprises a parallel hexagon at 0.7 mm height and a 90° shoulder to allow a flat-to-flat margin fit to the implant. Abutments are connected to the implant using a M1.8 (EN) or M2.0 (ER/EW) abutment screw.

The abutment screw plays a central role for the mechanical, long-term strength and fatigue resistance of the implant abutment connection. The requirements for such a screw are many, such as no loosening, long-term fatigue resistance, overload protection and safe pick-up and handling ability.

Due to the fact that the abutment screw is exposed to heavy dynamic loads, the precise application of tightening torque force is essential.

MORSE-TAPER (MTH)	INTERNAL HEXAGON (INT)	EXTERNAL HEXAGON (EXT)
		EN = EXTERNAL NARROW
KR = KONIC REGULAR	**IR** = INTERNAL REGULAR	**ER** = EXTERNAL REGULAR
	IM = INTERNAL MEDIUM	
KW = KONIC WIDE	**IW** = INTERNAL WIDE	**EW** = EXTERNAL WIDE

NOTE that different BTK implants require different types of prosthetic platforms using corresponding abbreviations according to their sizes. For more details, refer to the corresponding BTK implant lines documentation.

CHARACTERIZATION OF BTK STANDARD IMPLANT LINES

BT-KLASSIC

BT-KLASSIC INT

This bone-level, cylindrical, traditional-type implant offers a parallel smooth neck portion between 0.7 mm-1.5 mm (depending on diameter / type) and is especially suitable for classic two-stage procedures, where the implant is placed at bone level and covered with surrounding soft tissue during the healing phase (two-stage healing).

BT-KLASSIC employs either an internal (INT) or external (EXT) hexagon connection. The fine V-shaped thread pitch on the BT-KLASSIC measures 0.6 mm for endosseous Ø 3.25 mm / Ø 3.75 mm / Ø 4.00 mm and 0.9 mm for endosseous Ø 4.25 and Ø 5.00 mm.

BT-KLASSIC EXT

BT-KONIC

BT-KONIC INT

This bone-level, root-shaped type implant offers a parallel smooth neck portion of 1.0 mm (INT) - 1.2 mm (EXT) and is especially suitable for classic two-stage procedures, where the implant is placed at bone level and covered with surrounding soft tissue during the healing phase (two-stage healing).

BT-KONIC employs either an internal (INT) or external (EXT) hexagon connection. The single-lead thread pitch on BT-KONIC measures 0.8 mm - 0.9 mm depending on the diameter/connection.

BT-KONIC EXT

The color codes applied for different implant diameter are indicated below:

3.25 / 3.3	3.7 / 3.75	4.0 / 4.1	4.2 / 4.7	4.8 / 5.0	4.8 KW	6.0
PURPLE	WHITE	BLUE	GREY	YELLOW	ORANGE	GREEN

BT-ISYKONE

BT-ISYKONE MTH / INT

This bone-level implant, which replicates the root of the natural tooth and has self-tapping characteristics, has a back-tapered, micro-threaded neck with a smooth portion between 0.8 and 1.0 mm and it is suitable for most indication.

BT-ISYKONE is positioned at the bone level and allows both ways of healing. The BT-ISYKONE single square thread pitch fits 0.9 mm for all diameters, Ø 3.3 mm / Ø 3.7 mm / Ø 4.1 mm / Ø 4.8 mm.
BT-ISYKONE is a highly versatile type of implant line because it offers three different abutment connections: with internal hexagon (INT) or external (EXT) and, as a third option, with the 11° morse-taper hexagon (MTH), widely tested, with corresponding regular prosthetic components (KR).
The surgical kit is the same as BT-SAFE and BT-NANO.

BT-ISYKONE EXT

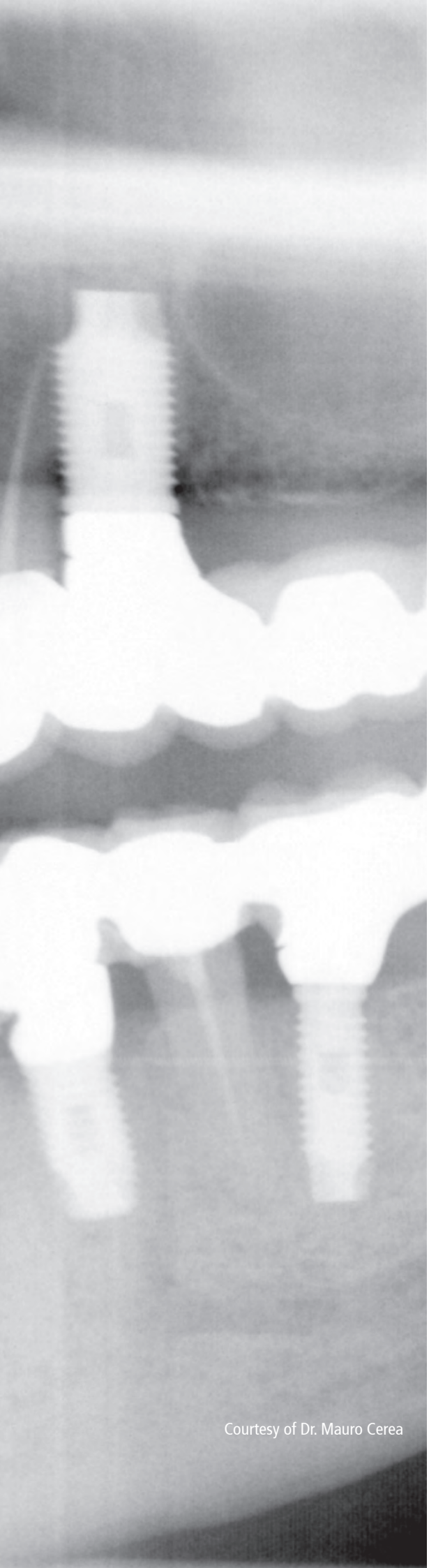
BT-SAFE & BT-NANO

BT-SAFE

This bone-level implant, which replicates the root of the natural tooth and has self-tapping characteristics, offers a back-tapered, micro-threaded neck with a smooth portion of 0.7 mm. BT-SAFE is particularly suitable for early or immediate placement after extraction or loss of natural teeth and/or immediate loading applications in edentulous jaws, as it guarantees excellent primary stability.

BT-SAFE is positioned at the bone level and offers both healing modes. Implant threading evolves from a triangular shape in the apical part to a squared shape in the coronal portion. The BT-SAFE double thread pitch measures 2.4 mm for all diameters, Ø 3.3 mm / Ø 3.7 mm / Ø 4.1 mm / Ø 4.8 mm / Ø 6 mm. The BT-SAFE implant line has an abutment connection based on the 11° mxorse-taper hexagon, widely tested, with corresponding prosthetic components regular (KR) or wide (KW). The implant line is completed by the highly compact **BT-NANO** (KW) implant (length 5 mm and 6 mm) for severely atrophic jaws.
The surgical kit is the same as BT-SAFE and BT-ISYKONE.

BT-NANO



Courtesy of Dr. Mauro Cerea

SOLUTIONS FOR NOT STANDARD INDICATIONS

In addition to the "standard" implant lines, BTK has developed the PTERIGO and MINI implant lines.

The PTERIGO implant is the alternative to maxillary sinus-lift augmentation in the rehabilitation of post-superior atrophic saddles.
The MINI implant is the solution for stabilizing mobile prostheses.

For more details, refer to the documentation of the relative implant lines.

TYPE	CHARACTERISTICS
PTERIGO 	• gradual conical shape • self-tapping, flat apex • alternative to maxillary sinus-lifts
MINI 	• self-tapping, Ø 2.5mm / 1.9mm • monotype, ball anchor • for economic denture fixation

IMPLANT SELECTION

HANDLING OF STERILE IMPLANT PACKAGING

CAUTION

The sealed package of the medical device (MD) must be opened in a surgically suitable environment.
The removal of the implant and of the cover screw, if provided, must be carried out using sterilized instruments, avoiding any contact with non-sterile surfaces.
The sterility of the medical device is only guaranteed if the following conditions are met:
the expiry date stated on the packaging is still valid; there is a red dot on the sterile vial that signals the successful operation of gamma ray irradiation; the sealed package has not been opened and does not show damage or perforations.If only one of the aforementioned conditions is not respected, the device must not be used.
The device is disposable; the reuse can compromise the safety features of the device making it inappropriate for its intended use. BIOTEC explicitly declares that the MD is for single use and assumes no responsibility for any re-use by users.

1

BTK dental implants are supplied sterile in a double-vial package. The implant diameter, length and lot are shown on the label located in the vial containing the implant and in the outer label on the back of the packaging.

2

Open the blister from the back by breaking the outer label, and take out the vial.

3

The top lid of the vial is protected by the seal label. The color of the seal label identifies the diameter of the implant. To facilitate compliance with the traceability requirement of the medical device, there are two detachable patient-labels in the vial. One must be stuck onto the patient's medical record and one onto the patient's implant passport.

4

Open the external vial and withdraw the internal vial containing the implant in a surgically suitable environment. The internal vial must be handled with sterile gloves.

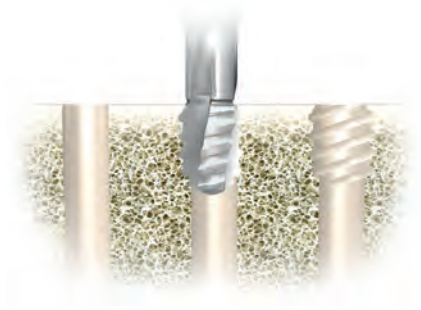
5

Remove the safety cap of the sterile inner vial, which always includes the sterile closure screw.
WARNING The internal vial consists of 3 parts.
The cover screw (locking screw), if provided, is placed in the vial cap.
Hold the vial upright to prevent the devices from leaking out.
Unscrew the central part of the vial, to access the implant.

6

Some implant lines are supplied with mounting device connected to the implant, other lines are supplied without.
Depending on the different configuration, use the appropriate instrument for the implant withdrawal from the vial and for the insertion of the same in the previously prepared implant site. For further details, please refer to the documentation of the relative implant lines.
The BTK dental implants can be positioned manually with the Reversible Torque Wrench or they can be inserted using the contra-angle handpiece. A range of 15 - 25 rpm is recommended for implant insertion and not to exceed the maximum torque indicated by BTK.

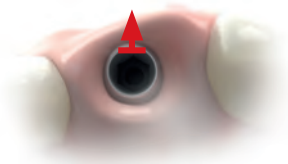
IMPLANT INSERTION



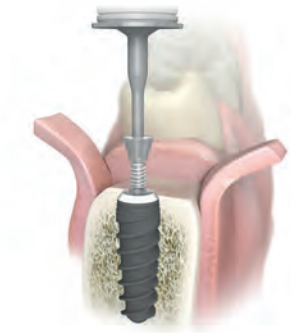
If a (partial / complete) tapping has been performed before implant insertion, the implant should be placed carefully on the implant site by performing a counterclockwise half rotation to engage the implant with the prepared thread.
After inserting into the thread, the implant can be guided in its final position clockwise, making sure that the implant is inserted at the desired depth and that the connection is intact.
WARNING The "implant driver" insertion drivers for the Morse-taper hexagon implant connection must be removed with delicate off-axis movements before removing them.

Insert the implant slowly in the previously prepared site.
A range of 15-25 rpm is recommended. During insertion, do not exceed the maximum torque values indicated below:

- **implant ≤ Ø 3,7 mm:**
  Insertion torque max. 35 - 45 Ncm
- **implant > Ø 3,7 mm:**
  Insertion torque max. 45 - 65 Ncm



In the cap of the internal vial there is, for each implant family, the corresponding cover screw (locking screw), sterile and ready for use.
Use sterile saline solution to carefully clean the implant connection from any organic residues. Therefore, make sure that it is clean and dry, before placing the cover screw (locking screw) or any prosthetic components that have been decided to be connect to the implant.
The cover screw is the chosen solution for the closed healing mode. To remove it more easily at the end of the healing period, a small amount of sterile vaseline or sterile chlorhexidine gel can be applied to the thread of the cover screw or healing cap before tightening it manually (5-8 Ncm) on the BTK implant, using a driver with a hex connection.



It is advisable to perform a postoperative x-ray check.

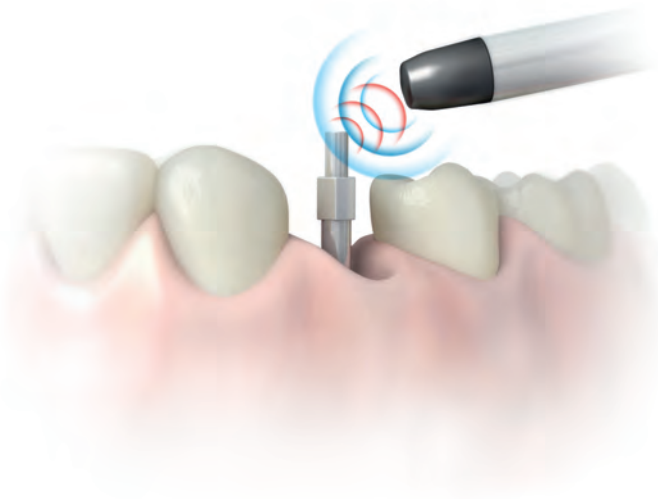
HEALING AND LOADING

POST-OPERATIVE CARE

It is necessary to instruct the patient on the need for regular oral hygiene.
It is important that regular check-up are carried out in order to complete in the best way the planned implant-prosthetic treatment.

MEASURING IMPLANT STABILITY

The stability of the implant is essential for a successful implant procedure. The achievement of primary stability (absence of mobility of the device in the bone site after implant insertion) and of the secondary one (bone formation and remodeling at the bone-implant interface) is fundamental. Resonance frequency analysis (RFA) is the preferred method for measuring implant stability. After the healing phase and before starting the prosthetic rehabilitation, an X-ray is also recommended.



HEALING PHASE DURATION

The healing period for osseointegration is variable and depends on several factors such as:

a) Primary implant stability

b) Bone quality

c) If methods of bone augmentation have been undertaken

d) Overall patient health

e) Expected masticatory forces

f) The design of the temporary and eventually the final restoration

Healing phase duration must be defined according to the individual case and considered according to the most critical bone site, i.e. where bone density is lower.

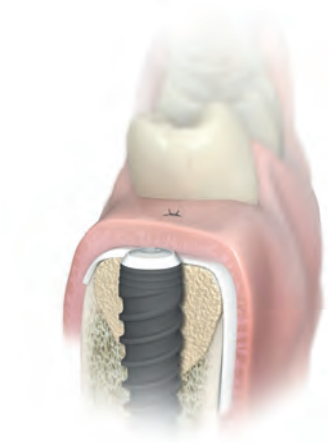
In situations of good bone quality and quantity, the conventional healing time is at least 2-3 months in the jaw, and minimum 4-5 months in the maxilla.

In the presence of less bone quantity and quality, it is advisable to extend the indicated healing times by a few months.

If methods of bone augmentation (GBR) have been undertaken, the healing phase must be adapted to the specific clinical case.

HEALING MODES: CLOSED (SUBMUCOSAL) OR OPEN (TRANSMUCOSAL)

BTK dental implants can be used in both healing modalities, both closed and open, depending on the clinical situation. Concerning the healing modality, numerous studies have demonstrated that both the closed and open approach offer predictable tissue integration of endosseous implants.



CLOSED MODE

With this modality the healing occurs below the closed mucoperiosteal flap. The submucosal approach is recommended for all implants inserted:

a) In aesthetic areas

b) In combination with guided bone regeneration (GBR) or membrane technique

With this method, a second surgical procedure is required to uncover the implant and insert the desired abutment after removing the closer screw.

- Check that the implant connection is clean and free of organic material.
- Connect the screw to the implant, respecting the torques recommended by BTK.
- Carefully adjust the mucoperiosteal flaps and suture them together with continuous sutures. Minimizing suture tensions.
- Verify that the implant has formed a secure sealing.

In the second operation, a small crestal incision must be made to the closure screw. Slightly open the flaps and remove the screw by unscrewing it with the appropriate driver. Make sure the connection is clean and free of organic material. Insert the selected secondary component. Adapt the soft tissue and suture it around the abutment, avoiding tension in the tissues.

OPEN MODE

BTK provides a wide selection of healing abutments suitable for soft tissue modeling during transmucosal healing.

The transmucosal approach is preferable in all standard sites without specific aesthetic needs.

- Check that the system connection is clean and free of organic material.
- Connect the healing screw / abutment to the implant, respecting the torques recommended by BTK.
- Adapt the soft tissue and suture around the healing screw / abutment, avoiding tension in the tissues.

After the soft tissue-healing phase, the healing screw / abutment must be replaced with the appropriate temporary or permanent restoration.

NOTE

Only the cover screw supplied in the vial with the implant is sterile. All the prosthesis and the BTK instrumental are not sterile and must be properly cleaned and sterilized before use, respecting the BTK indications.

LOADING PHASE

The healing phase and the implant-loading phase can be managed in different ways.

The most appropriate approach must be evaluated appropriately for each individual case.

The possible types of loads are summarized below:

LOADING CONCEPT	DEFINITION
IMMEDIATE LOADING	A restoration placed in occlusion with the opposing dentition within 1 week of implant placement.
EARLY LOADING	A restoration placed in occlusion with the opposing dentition at least 1 week after implant placement but not later than 2 months afterwards.
CONVENTIONAL LOADING	A restoration placed in occlusion with the opposing dentition after a healing period of more than 2 months.

PROSTHETIC SOLUTION

The purpose of implant therapy is to replace lost dental elements with biocompatible titanium implants, in order to obtain a new and correct mastication, using prostheses on implants.

In order to achieve this objective, BTK offers a targeted portfolio of reconstructive solutions based on a vast clinical experience. BTK provides a variety of medical devices that meet the preferences of clinicians and the needs of patients. BTK has a solution for every case and can also provide customized products, designed and manufactured specifically for each patient.

Biotec offers a complete portfolio of devices for anchoring overdentures.

For more information on the complete portfolio of prosthetic solutions offered by Biotec and related codes, refer to the BTK documentation.

The restorative connection to the implant or abutment can either be screw-retained or cement-retained.

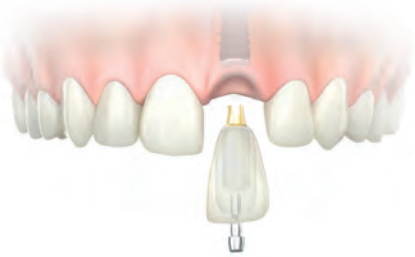
With screw-retained restorations, an abutment or meso-structure is combined as part of the fabrication procedure of the restoration (one piece) and secured to implant with screws.

With cement-retained restorations, an abutment or meso-structure is separate from the restoration (two pieces); the abutment or meso-structure is attached to implant with screws, and the restoration is then cemented to the abutment or meso-structure.

CEMENT-RETAINED (CR)

IS INDICATED:

- for short span prosthesis with margins at or above tissue level;
- to simplify fabrication procedures;
- to enhance aesthetics when the screw access passes transocclusally or in cases of malposition of implant(s);
- when an intact occlusal plan is desirable;
- to reduce initial treatment costs.



SCREW-RETAINED (SR)

IS INDICATED:

- In situations with minimal interarch space;
- To avoid cement margin and thus the possibility of cement residues – especially in cases where the prosthetic margins are submucosally. It is extremely difficult to remove cement residues from margins placed < 1.5 mm submucosally;
- When retrievability is required;
- In the zone of aesthetic importance, to facilitate tissue contouring and conditioning in the transition zone (emergence profile).

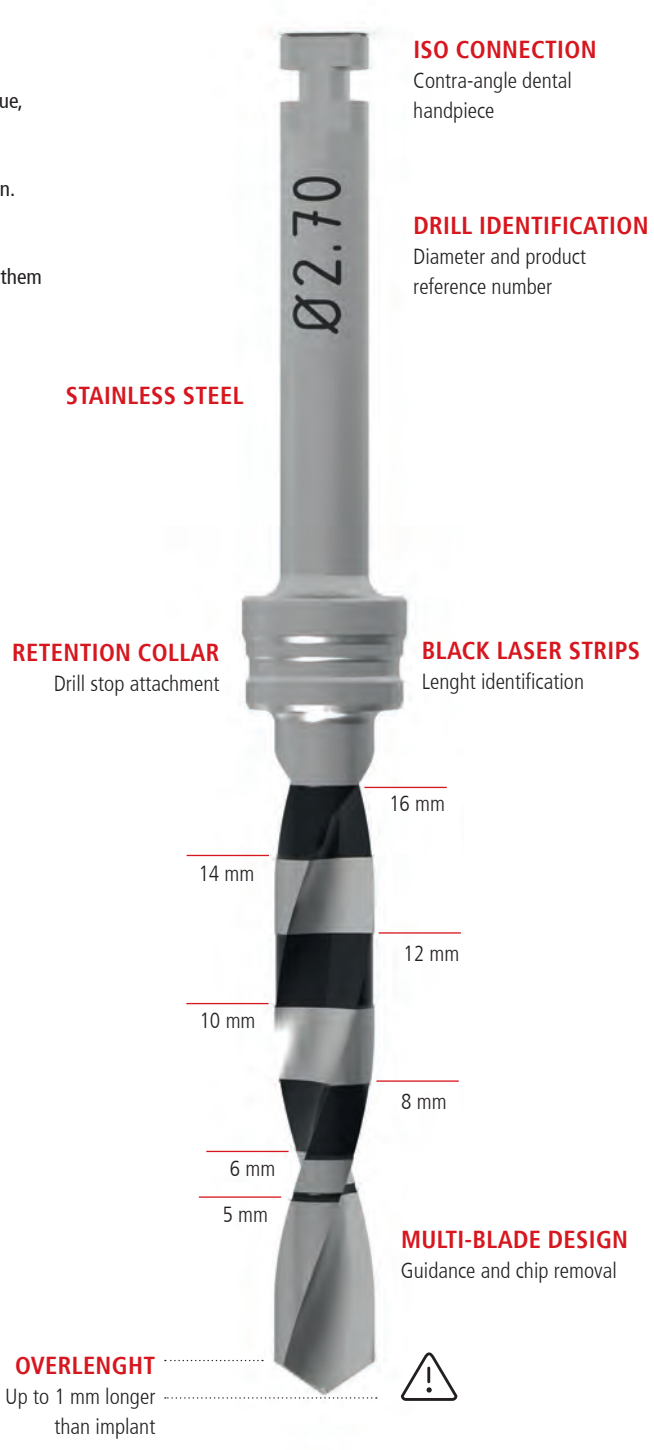
THE SEMPLICITY OF BTK KITS

BTK supplies specific surgical kits, depending on the implant family.
The surgical kits are used to store and sterilize the surgical and auxiliary instruments of the BTK dental implant systems.

The surgical trays are used for the secure storage and sterilization of the surgical and auxiliary instruments of the BTK dental implant systems. They are made of a highly shock-proof thermoplastic, which is well established in medical applications and the material is suitable for frequent sterilizations cycles in the autoclave.
It is recommended to follow the general cleaning guidelines and sterilization, shown below.

CHARACTERISTICS OF SURGICAL DRILLS

- All drills and screw taps are made of stainless steel.
- All drills and screw taps are supplied in non-sterile single packs or in kit not sterile. Please refer to the recommendations on cleansing and sterilization indicated by BTK.
- Drills and screw taps must be replaced after a maximum of 20 uses. The effectiveness decreases after 5/6 applications already.
- All drills and screw taps have depth markings made with laser technique.
- The length relative to the corresponding black strip, realized with laser technique, it is always the lower or upper end of the strip.
- The black strips correspond to the length of the selected implant. However, to increase security, the drill stops can be used during site preparation.
- All drills report their diameter and the relevant reference code on the stem.
- All final drills allow you to apply suitable drill stops.
- In case the length of the drills is insufficient, there is the possibility to connect them to the "Drill Extension" tool.



SURGICAL STANDARDS

For successful osseointegration, a precise, not traumatic surgical technique is required, which safeguards the soft tissues and accurately prepares the implant site without overheating the bone.

Before starting the surgical procedure and during the same procedure the following points must be taken into account:

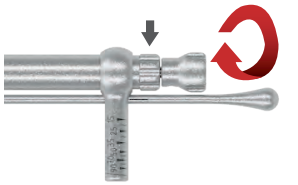
- Check that all the necessary tools are available and fully functional. It is recommended to always keep an adequate supply of sterile implants and instruments.
- Do not use cutting tools more than 20 times. Make sure that the drills are sharp before each use. The effectiveness of a drill already decreases after 5/6 applications.
- Drilling must be carried out with sharp drills, intermittently at 500 - 600 rpm, always with abundant external irrigation with pre-cooled sterile saline solution and avoiding excessive pressures.
- Do not exceed the speeds indicated by BTK for drills.
- Use the drills with diameters in ascending order.
- The drills can be placed in distilled / deionized water but should not be placed in saline or Ringer's solution during surgery if they are used for more than one preparation.

REVERSIBLE TORQUE WRENCH

The Reversible Torque Wrench is a dismantable, multiple-use instrument that provides means of tightening implants, abutments and screws. The lever arm integrated in the Reversible Torque Wrench is pushed away from the main body to the desired torque value. A torque value indicator is mounted at 90° in relation to the lever arm and indicates different value marks.

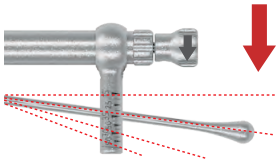
NOTE

Before the first and each following use, the Reversible Torque Wrench should be dismantled, cleaned, disinfected and sterilized in accordance with the instructions for use, please refer to **ifu.btk.dental**.



To dismantle the torque wrench for cleaning procedure, unscrew the wheel and then remove the inner bar where the spring is assembled.

APPLYING THE CORRECT TORQUE VALUE

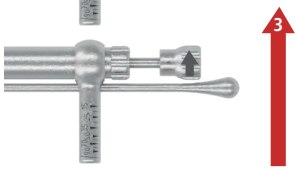


In order to achieve the desired torque value, apply the force only to the lever-arm to the desired value mark. **The following marks are indicated: 15, 25, 35, 50, 70 and 90 Ncm.** Make sure that the arrow of the inversion device is matching to the lever-arm direction.

HOW TO CHANGE DIRECTIONS

With this type of Reversible Torque Wrench, one is able to change directions by simply pulling (1) and turning (2) the inversion device 180° in the desired direction.

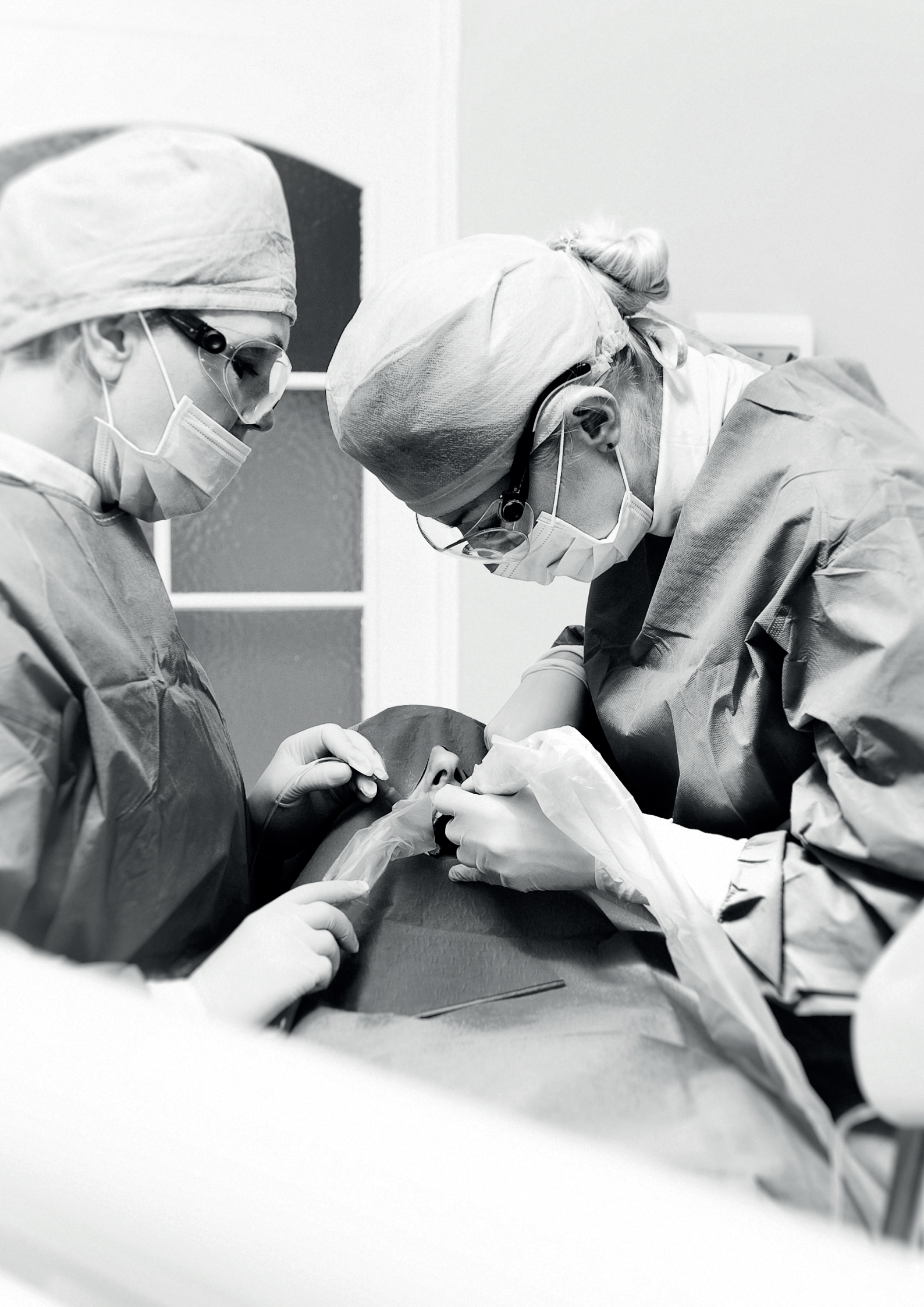
This is done without removing the Reversible Torque Wrench from the attached driver in order to avoid additional manipulations and to save time.



The grey arrow on the inversion device always indicates in which direction the force is applied (3). This design was chosen to avoid additional manipulation, reduce potential sources of error while helping to save time.

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)	BP, BT, BU	Titanium GR5	from 10 to 15 Ncm
	AB, CB, CC, EA, KR, FA, IE, IF, IG, IH, CA, IA, IB, IC, ID, KB, QA, QB	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)	BP, BT, BU	Titanium GR5	from 10 to 15 Ncm
	CA, IA, IB, IC, ID, KB, QA, QB	Titanium GR5	from 20 to 25 Ncm
	AB, CB, CC, EA, KR, FA, IE, IF, IG, IH	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%



INSTRUMENTS CLEANING AND THE STERILIZATION GUIDELINES

An adequate and careful process of cleaning and sterilization is necessary to ensure health and safety of patients and professional who are involved in dental implant treatment. If these processes are carried out correctly, of the quality of the instruments will be preserved as well as their effectiveness over time will be prolonged. The sterility of the instruments is under user's responsibility as well as the use of approved methods and sterilization devices, which must be regularly submitted to service and control.

Please find below a general indication, for cleaning and sterilization of the instruments, which are not intended to substitute the current national regulations and the hygiene rules applied in dental clinics.

For a correct sterilization procedure, follow the steps below:

1. Decontamination and cleaning
2. Rinsing and drying
3. Packaging and Sterilization

Each instrument must be disinfected, cleaned and sterilized before each use, **also at its first usage** and before its disposal.

1. DECONTAMINATION AND CLEANING

Immediately after usage and before sterilization, the device must be properly decontaminated and cleaned of all coarse components (blood and organic material), in all its parts, within 2 hours.

In the first phase, it is advisable to immerse the instruments immediately after use and before any manipulation in a biocide solution of recognized effectiveness, following the manufacturer's instructions. The solution must be virucidal, tuberculocidal and mustn't damage the instrument. The goal of this phase is the decontamination of potentially infected instruments and the protection of the professional from possible infections.

WARNING do not use aldehyde-based solutions, which could fix the blood residues.

Once decontaminated, the instrument can be disassembled and washed.
Cleaning is normally carried out with water, mechanical action and use of specific detergents. Washing can be done manually or in ultrasonic.
For manual washing it is necessary to wear protective gloves, avoiding contact with wounds or skin lesions; immerse the instrument in the container with the detergent/ disinfectant product and wash the instrument with special sponges, brushes in its various components (do not use abrasive products or metal brushes).
For mechanical cleaning it is possible to insert the cleaning agents prepared in an ultrasonic bath. Completely immerse the device in the washing solution and sonicate according to the manufacturer's instructions.

WARNING the immersed instruments must not be in contact with each other.

WARNING disinfectants or detergents that have the following characteristics can not be used:

- strong bases (> pH 9)
- strong acids (< pH 4)
- phenols or iodophors
- halogenated hydrocarbons
- strong oxidizers / peroxides
- organic diluents

These compounds can damage the surface protection layer (passivation) of the steel, making it oxidizable.

2. RINSING AND DRYING

After manual cleaning or ultrasonic treatment, it is necessary to carefully rinse (even up to 5 times) the instruments with water to completely eliminate both the residues of washing solution and the biological ones, detached after cleaning.

WARNING We recommend using only distilled or completely deionized water, as the high content of chlorine or other minerals present in normal drinking water can cause corrosion and the appearance of spots in the devices.

Drying is an essential phase in order to allow the correct exposure of the material to the sterilizing agent. In order to guarantee the internal drying of hollow objects or pipes, insufflation can be adopted with compressed air or forced passage of air.
Remove excess of humidity from the instrument with a clean cloth, absorbent, lint-free, or with disposable paper towel to prevent the rise of oxidation traces.

WARNING Instruments which have not been dried can incur in danger of corrosion.

3. PACKAGING AND STERILIZATION

Instruments are now ready for packing and sterilization.
Envelopes / rolls for sterilization in polymeric paper / film is suggested for packaging.

As a method of sterilization*, we recommend autoclaving / steam: standard time is 20 minutes at 121°C (about 250°F) and 1.1 bar pressure, or 7 minutes at 134 °C (about 273 ° F) and 2.1 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 choice of the most suitable cycle depends on the type of material to be treated.

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.

MATERIAL SPECIFICATIONS

TITANIUM GRADE 4 IMPLANTS

CHEMICAL COMPOSITION:	MAXIMUM VALUES (%)	TOLERANCE
Nitrogen (N)	0.05	+/- 0.02
Carbon (C)	0.08	+/- 0.02
Hydrogen (H)	0.015	+/- 0.002
Iron (Fe)	0.50	+/- 0.10 (%<0.25) +/- 0.15 (%>0.25)
Oxygen (O)	0.40	+/- 0.02 (%<0.20) +/- 0.03 (%>0.20)
Titanium (Ti)	balance	-

MECHANICAL PROPERTIES:	MINIMUM VALUES
Tensile stress:	550 MPa
Yield strength (0.2%):	483 MPa
Elongation at yield:	15 %
Section reduction:	25 %

This technical information complies with the express specification of the regulations in force for the use of grade 4 titanium in implantology:

- ASTM F67: Standard Specification for unalloyed titanium, for surgical implant applications.
- ISO 5832-2: Implant for surgery – Metallic Materials – Part 2: Unalloyed titanium.

TITANIUM GRADE 5 PROSTHETICS AND MINI IMPLANTS

CHEMICAL COMPOSITION:	MAXIMUM VALUES (%)	TOLERANCE
Nitrogen (N)	0.05	+/- 0.02
Carbon (C)	0.08	+/- 0.02
Hydrogen (H)	0.012	+/- 0.002
Iron (Fe)	0.25	+/- 0.10
Oxygen (O)	0.13	+/- 0.02
Aluminium (Al)	5.50-6.50	+/- 0.40
Vanadium (V)	3.50-4.50	+/- 0.15
Titanium (Ti)	balance	-

MECHANICAL PROPERTIES:	MINIMUM VALUES
Tensile stress:	860 MPa
Yield strength (0.2%):	795 MPa
Elongation at yield:	10 %
Section reduction:	25 %

This technical information complies with the express specification of the regulations in force for the use of grade 5 titanium in implantology:

- ASTM F136: Standard Specification for wrought Titanium-6Aluminium-4Vanadium ELI (Extra low Interstitial) Alloy for surgical implant applications;
- ISO 5832-3: Implant for surgery – Metallic Materials – Part 3: Wrought titanium 6-alumium 4-vanadium alloy.

COBALT CHROME COBALT CCM®

CHEMICAL COMPOSITION: (%)	
Carbon (C)	max. 0.14
Silicon (Si)	max. 1.00
Manganese (Mn)	max. 1.00
Chromium (Cr)	26.00-30.00
Molybdenum (Mo)	5.00-7.00
Nickel (Ni)	max. 1.0
Iron (Fe)	max. 0.75
Nitrogen (N)	max. 0.25
Cobalt (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)	$13.2 \bullet 10^{-6}\ °C^{-1}$
Melting range	1340-1440°C
Yield strength (R0.2)	up to 1115 MPa
Young Modulus E	241 GPa
Hardness	up to 46 HRC

PRECIOUS ALLOY FOR ABUTMENTS

COMPOSITION:	
Gold (Au)	60.0 %
Platinum (Pt)	24.9 %
Palladium (Pd)	15.0 %
Iridium (Ir)	0.1 %

PHYSICAL AND MECHANICAL PROPERTIES:	
Density:	18.1 g/cm³
Melting range:	1350 – 1460 °C
Coefficient of Expansion (CTE) 25-500°C – 25-600°C:	$12.7 \bullet 10^{-6}$ °C^{-1} – $12.9 \bullet 10^{-6}$ °C^{-1}
Modulus of elasticity (tensile test):	110 GPa
Elongation at yield:	18 – 12 %
Breaking load:	580 – 810 MPa
Yield strength (0.2%):	450 – 720 MPa
Vickers Hardness HV5/30:	150 – 205 – 230

PRECIOUS ALLOY FOR GOLD RETENTIVE SCREWS

COMPOSITION:	MAXIMUM VALUES (%)	TOLERANCE
Gold (Au)	0,5	+/- 0.2
Gallium (Ga)	2	+/- 0.2
Copper (Cu)	10	+/- 0.5
Iridium (Ir)	7	+/- 0.5
Ruthenium (Ru)	0.03	+/- 0.02
Rutenio (Ru)	0.1	+/- 0.09
Palladium (Pd)	balance	

MECHANICAL PROPERTIES:	MINIMUM VALUES (%)
Tensile stress:	586 - 862 MPa
Yield strength (0.2%):	483 - 690 MPa
Elongation:	5 - 20 %
Young's Modulus:	138 GPa

PHYSICAL PROPERTIES:	
Melting Range	1450 – 1500 °C
Coefficient of Expansion (CTE) 25-500°C – 25-600°C:	$12.3 \bullet 10^{-6}$ °C^{-1}

The temporary abutments in PEEK and the SCAN ABUTMENT are made of PEEK / TECAPEEK CLASSIC (chemical name Polietereterketone). This material is suitable to stay in contact with tissue for up to 180 days.

Depending on the intended use, the Biotec instrumental is made of specific types of stainless steel.

SYMBOLS USED ON LABELS

Legal manufacturer

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

0426
Number of the notification body

Consult instructions for use

Electronic instructions for use available online ifu.btk.dental

Caution; see instructions for use

Catalogue number

Lot/batch number

Use-by date: indicates the date after which this device is not to be used

Do not use if packaging is damaged

Do not reuse

Keep away from sunlight

Sterile by gamma irradiation

DELIVERY TERMS & CONDITIONS

RESPONSABILITY

The use of BTK medical devices is reserved exclusively for personnel with the necessary qualifications for the exercise. An improper or incorrect use of the devices can cause the failure or worse, injury to the patient or the user. BTK implant systems should only be used with original BTK components and instruments and in accordance with the specific BTK instructions. Combining with different devices may cause a failure. Biotec must not and can not control the procedures for using the product for implant-prosthetic treatment. Therefore, Biotec assumes no responsibility for the application of the device and its processing nor for any incongruous use of the device under the surgical or prosthetic profile, nor in any case for failure, adverse reactions or damage to the patient or dentist as a result of application of the product.

STERILITY OF WARRANTY AND DISPOSABLE

Dental implants are supplied STERILE (gamma ray sterilization).
The sterility of the medical implant is guaranteed only according to the following conditions: the expiry date stated on the packaging is still valid; there is a red dot on the sterile vial which demonstrates that it has undergone gamma ray irradiation; the sealed package has not been opened and does not show any signs of damage. Compliance with all these conditions must be ensured; alternatively do not use the device.

Surgical components, laboratory accessories and instruments are not supplied in sterile packs, therefore before use they must be properly CLEANED and STERILIZED, as shown in the instructions for use. Biotec dental implants, prosthetics and laboratory accessories are designed for SINGLE USE. In fact, reuse is a potential risk and could damage the construction of the device, making it inappropriate for its intended use. Biotec explicitly declares the single-use of MD and assumes no responsibility for any re-use by users.

STORAGE

Biotec products must be stored at room temperature and protected from direct heat or sunlight and dust.

INSTRUCTIONS FOR USE

The information in this manual is not intended to be exhaustive for BTK implant systems. It is recommended that new customers follow the training courses that Biotec makes available with trained personnel and clinicians who are experts in implantology and in the use of BTK devices. The complete and updated user manuals, which allow the correct use of the product, are available online (www.btk.dental) or at BTK and / or the local distributor.

AVAILABILITY

Not all products described here are available in ExtraEU countries. For more information, please contact BTK and / or your local distributor.

RETURNS

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

GUARANTEE

We constantly guarantee that the quality of our products and services meets the high expectations of our customers and their patients. Specialized professionals are committed to offering complete solutions in applied research, engineering, training and related activities. Biotec is available to customers in the event that a defect in the product or its use is found.

VALIDITY

The contents are updated at the date of publication. This manual replaces all previous editions.

CASE DOCUMENTATION AND TRACEABILITY

BTK absolutely recommends documenting implant cases comprehensively at the clinical, radiographic, photographic and statistical levels. The clinician must guarantee the traceability of the devices used. It is advisable to use the adhesive labels included in the packaging of the BTK devices, which show the code and lot of the device used, for the purpose of documentation on the medical records and on the relative implant passport of the patient.

TRAINING

Comprehensive and regular training ensures long-term implant success.
Be advised that we strongly recommend regular education events in order to update your know-how and clinical expertise.

DELIVERY TERMS

BTK delivery terms are 1 working day for order received before 12.00 p.m. of the previous day in Italy; except for islands where delivery is evaluated to be 2 working days. For export deliveries contact Biotec offices.

QUALITY STANDARD

Owing to extensive research, development and to a strict quality standard, we guarantee premium quality materials and products. Our products meet the requirements of directive 93/42 /EEC and subsequent amendments and additions, and therefore have the CE mark, in accordance with the corresponding law. BTK has a quality system certified UNI EN ISO 9001 and UNI EN ISO 13485.

CAUTION

In addition to the instructions for use, warnings and risks reported both in this document and in the instructions for use, it must always be ensured that the devices used in the oral cavity are not aspirated or swallowed by the patient.

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SURGICAL
MANUAL

Implanting Trust,
Smile Again!

BTK PERSONAL TUTOR

A program for individual case planning and execution supported by experienced professionals in order to leverage know-how and maximize clinical experience with the aim to achieve sustainable high patient satisfaction rates.

BTK is always at your disposal for any request for further follow-up or information, promoting periodic and ad-hoc training course.

CERTIFIED QUALITY SYSTEM

BIOTEC is certified UNI EN ISO 9001 and UNI EN ISO 13485.

CE

CE marked product, in accordance with Directive 93/42/EEC and subsequent modifications and additions.

MADE IN ITALY USED GLOBALLY

We constantly ensure that the quality of our products and services meet the high expectations of our customers and their patients.
Specialized professionals are taking care to offer comprehensive solutions in applied research, engineering, education and related activities.

the smile system®

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