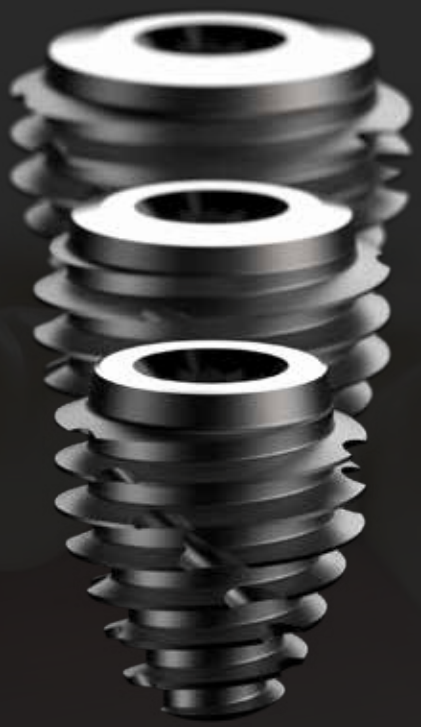
ULTRA
MANUAL

btk Implanting Trust, Smile Again!

ULTRA

THE POST EXTRACTIVE IMPLANT OF LARGE DIAMETER
FOR MOLAR EXTRACTION SOCKETS



visit **btk.dental**

NATURAL

IT FITS PERFECTLY TO THE IMPLANT SITE

CONSERVATION

MAXIMUM PRESERVATION OF RESIDUAL BONE

IMMEDIATE

IMPLANT POSITIONING IN THE SAME TIME OF MOLAR EXTRACTION

THE LARGE DIAMETER POST EXTRACTIVE IMPLANT F

ULTRA

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STABLE

THANKS TO THE SPECIFIC IMPLANT DESIGN

SIMPLE

COMPACT SURGICAL KIT: FAST AND INTUITIVE PROCEDURE

ANATOMICAL

EMERGENCY PROFILE AS EQUAL TO NATURAL TOOTH,
THANKS TO THE DEDICATED PEEK HEALING ABUTMENTS

OR POSTERIOR SECTORS

SYSTEM

SEE IT IN ACTION

IMPORTANT NOTE

For the latest updates and information, **visit www.btk.dental**

This manual provides dental practitioners and related specialists with general information regarding the use of ULTRA dental implant system.

For detailed information about 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.

btk Implanting Trust, Smile Again!

ULTRA

THE POST EXTRACTIVE IMPLANT OF LARGE DIAMETER
FOR MOLAR EXTRACTION SOCKETS

INDEX

WHY A LARGE DIAMETER IMPLANT

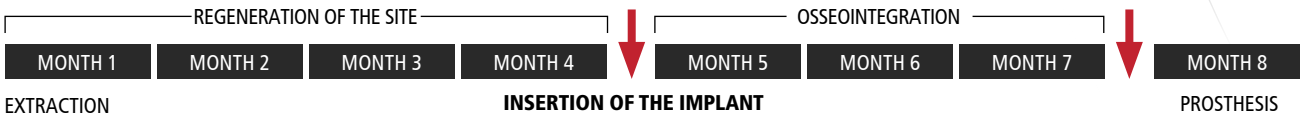
The main difficulty due to the use of standard implants is their insertion in the wide post-extractive alveolus, resulting too narrow in the majority of cases.
In effect, if we wait for the complete recovery of the post-extractive site, we notice an important contraction of the alveolar bone volume, which can suffer from a resorption up to 40% *.

In order to restore the missing element, standard implants must be employed, which, from the biomechanical point of view do not represent the best choice.
By following this therapeutical approach, the patient must undergo two surgeries: the extraction and, after 4 / 5 months, the insertion of an implant.

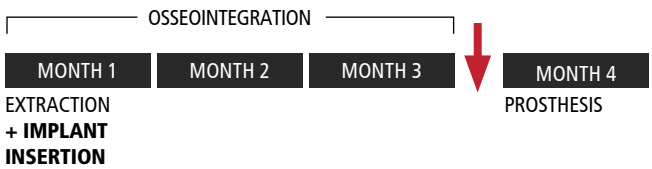
The consequences of an approach of this kind are prosthetic rehabilitations which do not satisfy the biomechanical and anatomical needs of the implantology site.

With the ULTRA post-extractive approach is possible to treat the patient with a single surgery, during which the extraction and the insertion of the ultra implant are performed, and, after 4 months, there is the finalization of the case.

TRADITIONAL APPROACH



ULTRA: POST-EXTRACTIVE APPROACH



* BIBLIOGRAPHY page 30

PRIMARY STABILITY

The large diameter and the threads minimize the anatomical discrepancies with the post-extractive alveolus increasing the surface of bone-implant contact (BIC).

BIOMECHANICS

The increase of the diameter of the implant results in a significant improvement of the distribution of the occlusal loads on the bone-implant interface, much more than what the length does.

* BIBLIOGRAPHY pag 30

BIO-DESIGN

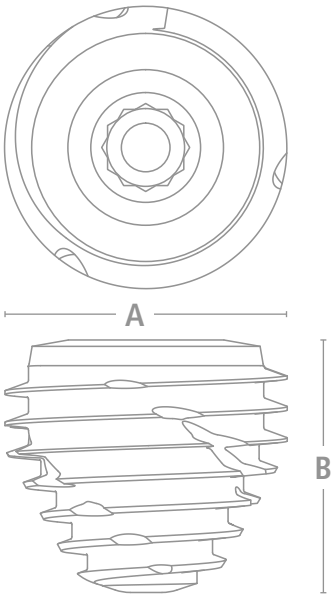
ULTRA dental implants are characterized by a body with a larger diameter than those of standard implants.

This performs two main tasks:

1 – To obtain, thanks to its particular design, an optimal primary stability.
2 – Functioning as a "filler" of the alveolus, thus accelerating the recovery.

ULTRA very aggressive thread permits to have an optimal primary stability and a very high torque.

So, ULTRA is the perfect implant for the rehabilitation of a post-extractive site in the upper and lower area of the molars respecting and favouring the natural biological answer of the patient's organism with a **single surgery**.



DODECAGONAL INTERNAL CONNECTION

B - Implant length in mm			
A - ∅ mm	6	8	10
7	145LW70G	145LW70J	145LW70L
8	145LW80G	145LW80J	145LW80L
9	145LW90G	145LW90J	145LW90L

ANATOMICAL HEALING ABUTMENTS

In conventional post-extractive implant rehabilitation of the posterior sectors, solutions with a deferred prosthetic load are often chosen.
Whether it is a 2 stage surgery or if the recovery is conditioned by a rounded transmucosal healing abutment, there is a complete loss of the morphology of the papillae of the emergence profile with an evident buccolingual and apical collapse of the tissues.

A possible therapeutical alternative which, on par with an immediate provisional prosthetic element, allows us to condition the tissues of the post-extractive alveolus is the new line of ULTRA healing screws in PEEK. Conceived to preserve the volumes of the gingival tissues after the extraction.

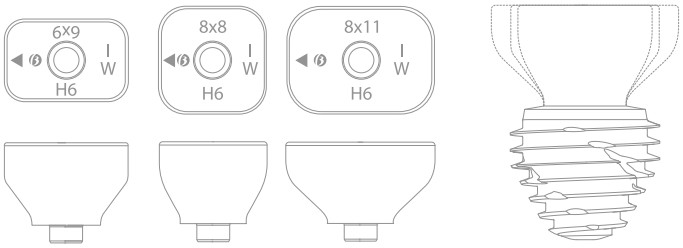
These ANATOMICAL SCREWS are realized in Peek, material that has shown optimal characteristics in the biomedical use starting from a long-term compatibility and from a total absence of residual solvents.

Other advantageous characteristics of this material are the high resistance to abrasion and corrosion even if it owns a degree of hardness and elasticity similar to those of the bone tissue.

Finally, this material is compatible with the sterilization in autoclave thus allowing the re-use.

Revolutionary ULTRA anatomical healing screws in PEEK are customizable, they preserve and maintain the natural emergence profile of the molar, thus limiting the contraction.

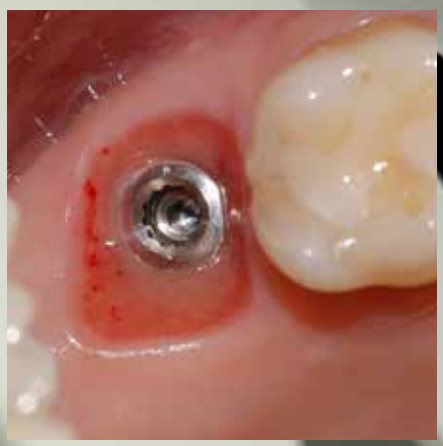
Three different measures have been realized to be used in the upper maxilla (8x11) or in the mandible (8x8) or in less space situations (6x9).



KIT FOR MILLING AND POLISHING
PEEK HEALING ABUTMENTS

INSTRUCTIONS FOR KIT:

1. Select the most suitable peek healing abutment.
   The height can be adjusted using the tungsten carbide drill.
2. The axial contours of the healing abutment can be modified to achieve the desired shape.
   Once this modification has been made, polishing with the shape instrument is recommended.
3. Place the healing abutment on the implant and tighten it manually.



EMERGENCE PROFILE

The use of large diameter implants combined with ULTRA healing screws in PEEK allow us:

- the possibility to maintain an emergence profile almost analogous to the one of the natural tooth with an optimal management of the papillary volumes.

- thanks to its design, the screw completely closes the post-extractive alveolus, thus providing a "clogging" effect which facilitates the retention of the regenerative material.

KIT AND DEDICATED SURGICAL PROCEDURE

The KIT and the surgical protocol have been improved and simplified for a rapid and intuitive use.

The exclusive round drill has been conceived to operate in the centre of the interosseous septum, thus providing a rapid and safe preparation.

Then, a set of progressive shaped drills is available to recreate the space of the implant inside the alveolus.

The Kit is completed by parallelism and positioning Pins in order to check the depth of insertion thanks to an intraoperative Rx.

The set of taps in the kit can be used to finish the preparation depending on the bone quality.

ULTRA SURGICAL KIT

The screen-printed lines and the colour codes make it intuitive the surgical sequence and the sequence of the instruments at each step. Once opened, it remains inclined to render it easier the access to the instruments. Realised in a highly shock-proof material which is suitable for frequent sterilization in the autoclave.

COD 627NA001

	6	8	10
7	145LW70G	145LW70J	145LW70L
8	145LW80G	145LW80J	145LW80L
9	145LW90G	145LW90J	145LW90L

TORQUE WRENCH JD, REVERSIBLE

90 Ncm Ref. **501JD003**

HANDPIECE DRIVER

HEX1.20 L30mm Ref. **530HS005**

SCREWDRIVERS JD

HEX0.90 L15mm Ref. **530JD012**

HEX1.20 L15mm Ref. **530JD005**

MANUAL WRENCH JD

ISO/HEX3.10 L10mm Ref. **530JD033**

ROUND DRILL

Ref.**401HL500**

SHARP LANCE DRILL

Ø2mm L32.8mm Ref. **401HR202**

DRILLS HS

Ø2mm L36.5mm Ref. **426HR200**

Ø3.85mm L36.5mm Ref. **426HR385**

Ø4.55mm L36.8mm Ref. **426HR455**

DRILLS EXTENSION

Ø2.8mm L31mm Ref. **520HS004**

MOUNTING DEVICE

LR-LW ISO L11mm Ref. **530HS026**

LR-LW ISO L21mm Ref. **530HL007**

SHAPED DRILLS ISO HR

Ø6.00mm L6mm Ref. **445HR600**

Ø6.00mm L8mm Ref. **445HR601**

Ø6.00mm L10mm Ref. **445HR602**

Ø7.00mm L6mm Ref. **445HR700**

Ø7.00mm L8mm Ref. **445HR701**

Ø7.00mm L10mm Ref. **445HR702**

Ø8.00mm L6mm Ref. **445HR800**

Ø8.00mm L8mm Ref. **445HR801**

Ø8.00mm L10mm Ref. **445HR802**

TAPS

Ø6.8mm L6mm Ref. **479HR680**

Ø6.8mm L8mm Ref. **479HR681**

Ø6.8mm L10mm Ref. **479HR682**

Ø7.8mm L6mm Ref. **479HR780**

Ø7.8mm L8mm Ref. **479HR781**

Ø7.8mm L10mm Ref. **479HR782**

Ø8.8mm L6mm Ref. **479HR880**

Ø8.8mm L8mm Ref. **479HR881**

Ø8.8mm L10mm Ref. **479HR882**

PARALLELISM PIN

Ø7.0mm L6mm Ref. **540MA028**

Ø7.0mm L8mm Ref. **540MA029**

Ø7.0mm L10mm Ref. **540MA030**

Ø8.0mm L6mm Ref. **540MA031**

Ø8.0mm L8mm Ref. **540MA032**

Ø8.0mm L10mm Ref. **540MA033**

Ø9.0mm L6mm Ref. **540MA034**

Ø9.0mm L8mm Ref. **540MA035**

Ø9.0mm L10mm Ref. **540MA036**

SURGICAL PROCEDURE

The molar has to be extracted separating the roots which must be removed with attention to avoid the fracture of the buccal wall.

1 TOOTH EXTRACTION

By paying attention to the preservation of the buccal wall

2 PREPARATION WITH ROUND DRILL

Flattening of the inter-radicular crest

3 PREPARATION WITH SHARP LANCE DRILL

Positioned at the centre of the alveolus

4 PREPARATION WITH PILOT DRILLS

Direction and depth

5 PROGRESSIVE PREPARATION OF THE OSTEOTOMY

6 TAPPING

According to the bone quality (D1/D2/D3)

7 INSERTION OF THE PARALLELISM PIN

Position and depth

8 IMPLANT PLACEMENT

9 PLACEMENT OF THE HEALING ABUTMENT

NOTE

Shaped drills have been designed with a longer stem to guarantee a better view during the preparation without the need of an extension.

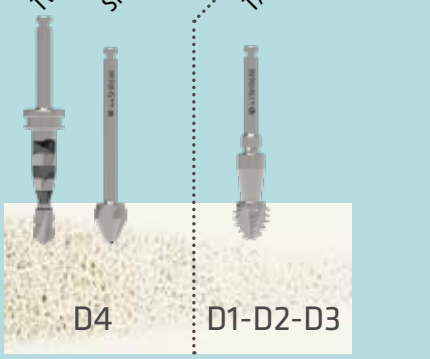
PREPARATION OF THE IMPLANT SITE

TAPPING SEQUENCE

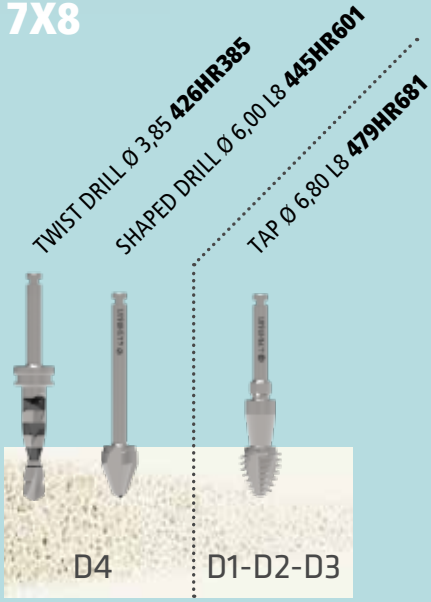
	PILOT DRILLS			TWIST DRILLS		SHAPED DRILLS							TAPS							
	ROUND DRILL Ø 5,00 **401HL500**	SHARP LANCE DRILL **401HR202**	FRESA PILOTA Ø 2,00 **426HR200**	TWIST DRILL Ø 3,85 **426HR385**	TWIST DRILL Ø 4,55 **426HR455**	SHAPED DRILL Ø 6,00 L6 **445HR600**	SHAPED DRILL Ø 6,00 L8 **445HR601**	SHAPED DRILL Ø 6,00 L10 **445HR602**	SHAPED DRILL Ø 7,00 L6 **445HR700**	SHAPED DRILL Ø 7,00 L8 **445HR6701**	SHAPED DRILL Ø 7,00 L10 **445HR702**	SHAPED DRILL Ø 8,00 L6 **445HR800**	SHAPED DRILL Ø 8,00 L8 **445HR801**	SHAPED DRILL Ø 8,00 L10 **445HR802**	TAP Ø 6,80 L6 **479HR680**	TAP Ø 6,80 L8 **479HR681**	TAP Ø 6,80 L10 **479HR682**	TAP Ø 7,80 L6 **479HR780**	TAP Ø 7,80 L8 **479HR781**	TAP Ø 7,80 L10 **479HR782**	TAP Ø 8,80 L6 **479HR880**	TAP Ø 8,80 L8 **479HR881**	TAP Ø 8,80 L10 **479HR882**
7x6	□	□	□	●		●									○					
7x8	□	□	□	●			●									○				
7x10	□	□	□	●				●									○			
8x6	□	□	□	●	●	●			●									○		
8 x8	□	□	□	●	●		●			●									○	
8x10	□	□	□	●	●			●			●									○
9x6	□	□	□	●	●	●			●			●							○	
9x8	□	□	□	●	●		●			●			●							○
9x10	□	□	□	●	●			●			●			●						○

□ At the discretion of the dentist according to the anatomy.

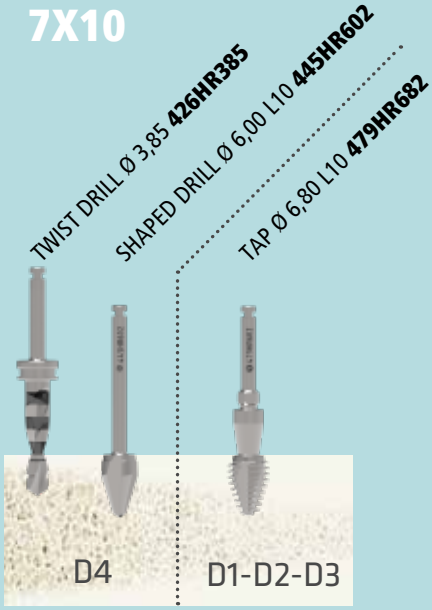
7X6



7X8



7X10



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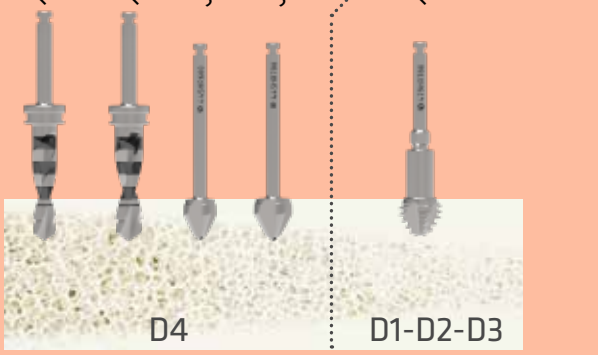

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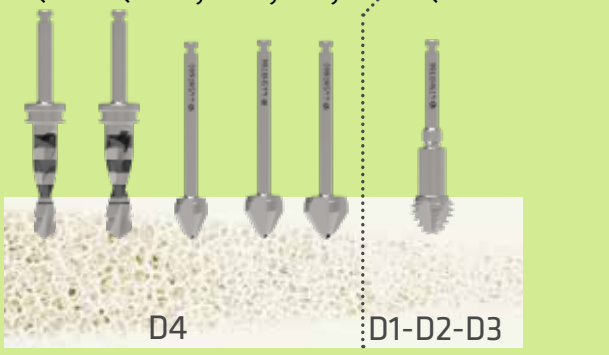

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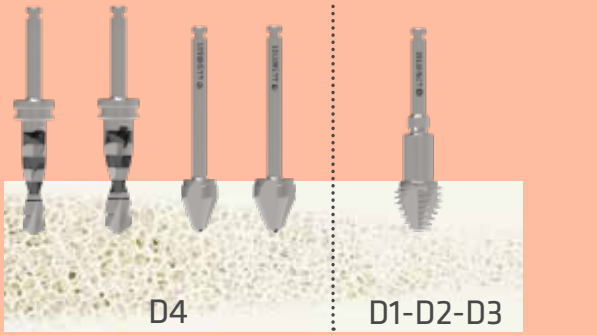

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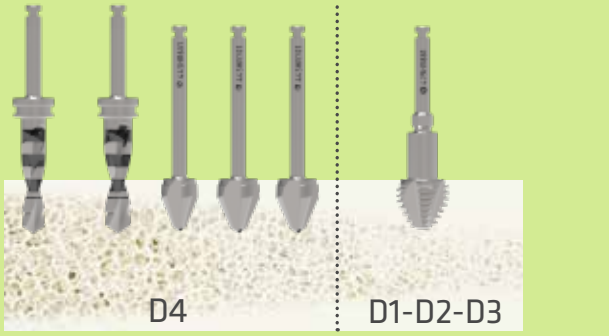

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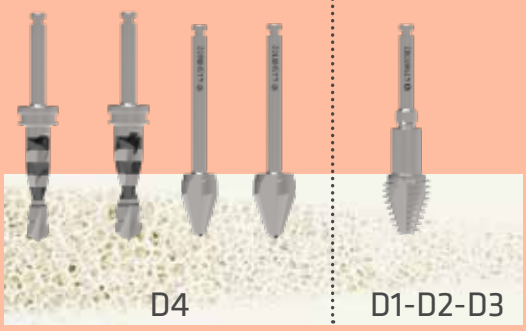

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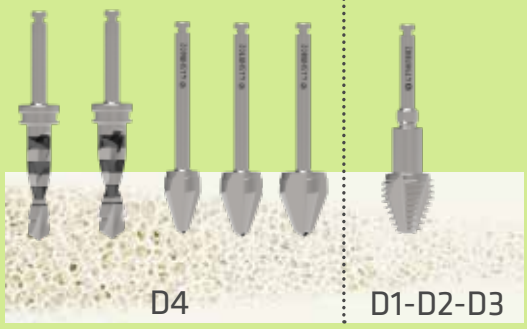

HANDLING AND POSITIONING OF THE STERILE IMPLANT

CAUTION: The sealed package of the medical device 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.

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 colour 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, the internal metallic vial is suspended from the lid. Withdraw carefully the vial from the lid keeping it vertical as shown in the picture. The operation must be performed in a surgically suitable environment. The internal vial must be handled with sterile gloves.

5

By means of the implant driver is possible to withdraw the implant from the vial and to insert it in the previously prepared implant site. 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

Insert the implant slowly into the previously prepared site. A range of 15 -25 rpm is recommended.
During the insertion, do not exceed the maximum torque values indicated below: insertion torque max. 60 – 70 Ncm.

The cover screw is separately supplied, it is not inside the vial.
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 chlorheixidine 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.

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PROSTHETIC

	REF	PRODUCT NAME	SPECIFICATION
HEALING ABUTMENTS			
	200IW0A0	Locking screw	M1.8 HEX 1.20
	208IW6A2	Millable Healing Abutments Peek	6X9mm h 6mm
	208IW6A0	Millable Healing Abutments Peek	8X8mm h 6mm Lower molar
	208IW6A1	Millable Healing Abutments Peek	8X11mm h 6mm Upper molar
	690NA012	Retentive screw	M1.8 HEX 1.20 TITANIUM

PEEK HEALING SCREW MILLING AND POLISHING KIT (Ref. 690NA357)

IMPRESSION TAKING

IR - PLATFORM SWITCHING	IW	IMAGES	REF	PRODUCT NAME	SPECIFICATION
IMPRESSION POST					
●			320IR0A1	Impression Post IR	Aluminium cap
	●		320IW0A1	Impression Post IW	Aluminium cap
●	●		690NA029	Cap	Aluminium Kit 3 pcs
●			325IR0A0	Impression Post Pro IR	Plastic cap
	●		325IW0A1	Impression Post Pro IW	Plastic cap
●	●		690NA091.10	Caps kit Pro	Ø5.1mm Kit 10pcs
●	●		690NA068	Impression Post Screw	M1.8 HEX1.20 H7.9mm
TRANSFER PROPICK-UP					
●			323IR0A0	Transfer Propick-Up IR	HUseful21.5mm Long Screw
			323IR0A1	Transfer Propick-Up IR	HUseful16.5mm Short Screw

IMPLANT REPLICA

IR - PLATFORM SWITCHING	IW	IMAGES	REF	PRODUCT NAME	SPECIFICATION
●			301IR0A1	Implant Replica IR	
	●		301IW0A1	Implant Replica IW	

INTERIM RESTORATIONS

IR - PLATFORM SWITCHING	IW	IMAGES	REF	PRODUCT NAME	SPECIFICATION
TEMPORARY ABUTMENT					
●			210IR2A0	Temporary Abutment IR	
●			215IR2A0	Temporary Abutment IR	Peek
	●		210IW2A0	Temporary Abutment IW	
	●		215IW2A0	Temporary Abutment IW	Peek
●	●		690NA012	Retentive Screw	M1.8 HEX1.20

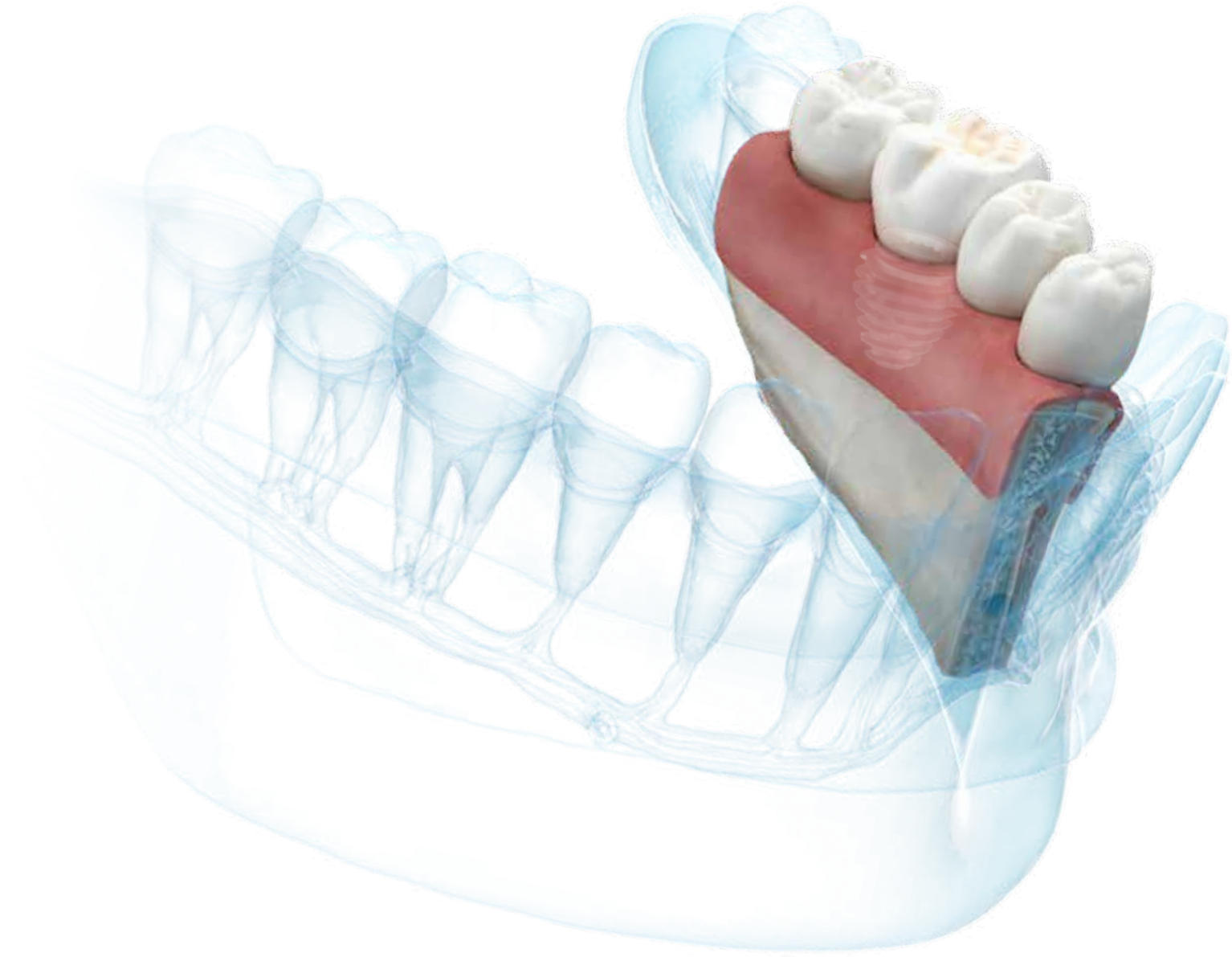
PROTESI CEMENTATA

IR - PLATFORM SWITCHING	IW	IMAGES	REF	PRODUCT NAME	SPECIFICATION
STRAIGHT ABUTMENTS Ø 4.5 MM					
●			220IR0A0	Straight Abutment IR	H0mm Ø4.5mm
			220IR2A1	Straight Abutment IR	H2mm Ø4.5mm
			220IR3A0	Straight Abutment IR	H3mm Ø4.5mm
			220IR4A0	Straight Abutment IR	H4mm Ø4.5mm
			220IR5A0	Straight Abutment IR	H5mm Ø4.5mm
STRAIGHT ABUTMENTS Ø 5.5 MM					
	●		220IW0A0	Straight Abutment IW	H0mm Ø5.5mm
			220IW2A0	Straight Abutment IW	H2mm Ø5.5mm
			220IW3A0	Straight Abutment IW	H3mm Ø5.5mm
			220IW5A0	Straight Abutment IW	H5mm Ø5.5mm
STRAIGHT ABUTMENTS Ø 6 MM					
	●		220IW4A0	Straight Abutment IW	H4mm Ø6mm
ESTHETIC ABUTMENTS					
●			219IR0A0	Esthetic Abutment IR	
	●		219IW0A0	Esthetic Abutment IW	
●	●		690NA012	Retentive Screw	M1.8 HEX1.20

SCREW-RETAINED / CEMENT-RETAINED PROSTHESIS

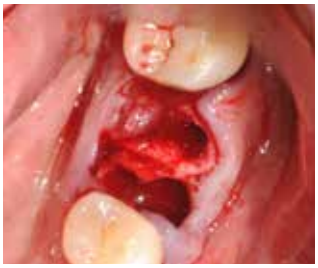
IR - PLATFORM SWITCHING	IW	IMAGES	REF	PRODUCT NAME	SPECIFICATION
BT LINK - PLATFORM SWITCHING					
●			246IR1A0	BT Link IR	H1mm Ø4.1mm
●			247IR1A0	Base BT Link IR	H1mm Ø4.1mm no Cap.
●			205NA001.05	Castable BT Link	H1mm Ø4.7mm Kit 5pcs
●			244IR0A0	SIR Link IR	H0.8mm Ø4.1mm
	●		246IW1A0	BT Link IW	H1mm Ø5.6mm
	●		247IW1A0	Base BT Link IW	H1mm Ø5.6mm no Cap.
	●		205NA005.05	Castable BT Link	H1mm Ø5.6mm Kit 5pcs
●	●		690NA077	Retentive Screw	M1.8 HEX1.20 H7.8mm TP
BT GRIP					
●			530JD036	Screwdriver JD BT GRIP	HEX1.50 L15 mm (Short)
			530JD037	Screwdriver JD BT GRIP	HEX1.50 L30 mm (Long)
●			248IR1A0	X3 Link IR	H1mm Ø4.1mm Multi High
●			690NA237	Retentive Screw BT GRIP	M1.8 HEX 1.50
CAST-ON TECHNIQUE					
●			245IR1A0	Base Gold IR	H1mm
●			240IR1A0	Base CoCr IR	H1.5mm
	●		245IW1A0	Base Gold IW	H1mm
	●		240IW1A0	Base CoCr IW	H1.5mm
●	●		690NA012	Retentive Screw	M1.8 HEX1.20
CASTABLES					
●			205IR1A0	Castable IR	
			205IR1A0.10	Castable IR	Kit 10pcs
	●		205IW1A0	Castable IW	
			205IW1A0.10	Castable IW	Kit 10pcs
●	●		690NA012	Retentive Screw	M1.8 HEX1.20
SCAN ABUTMENT					
●			351IR1A0	Scan Abutment Extra-oral IR	
			352IR1A0	Scan Abutment Intra-oral IR	
	●		351IW1A0	Scan Abutment Extra-oral IW	
			352IW1A0	Scan Abutment Intra-oral IW	
●	●		690NA077	Retentive Screw	M1.8 HEX1.20 H7.8mm TP

CLINICAL APPLICATIONS

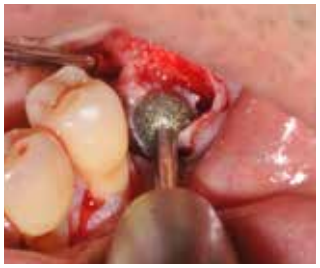


CASO CLINICO

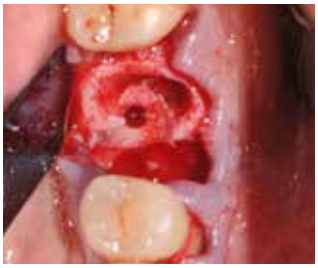
Paziente: MASCHIO, 56 ANNI, NON FUMATORE
Situazione: FRATTURA RADICE MESIALE DEL 36



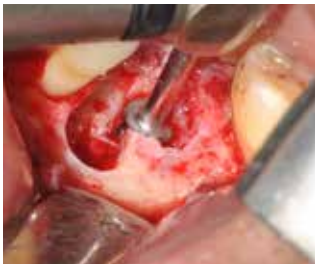
1 ALVEOLUS IMMEDIATELY AFTER THE EXTRACTION



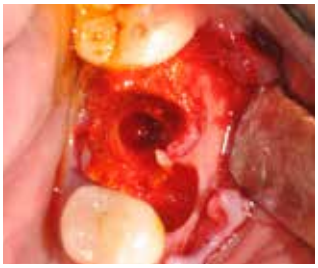
2 PREPARATION WITH ROUND DRILL



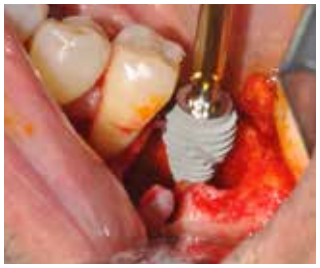
3 PREPARED SITE WITH SHARP DRILL



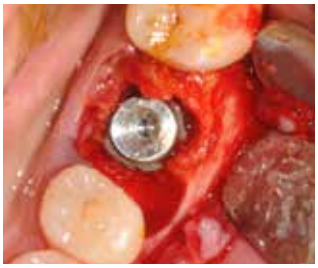
4 FINAL SHAPED DRILL



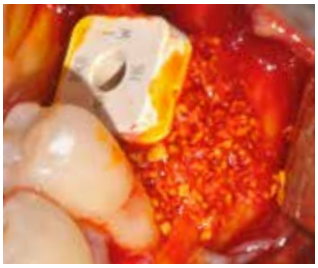
5 PREPARED ALVEOLUS



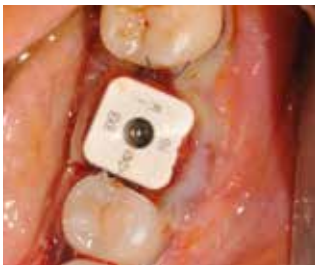
6 INSERTION OF THE ULTRA IMPLANT



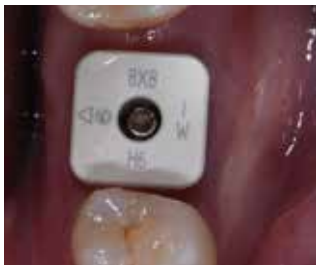
7 VIEW OF THE ALVEOLUS WITH INSERTED IMPLANT



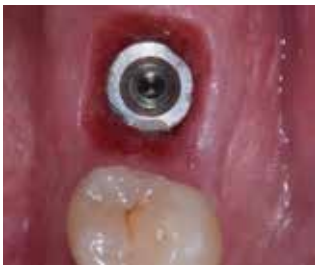
8 POSITIONING OF THE ANATOMICAL SCREW AND BONE REGENERATION WITH RIGENERA GRAINS



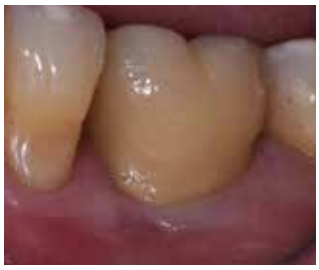
9 SUTURE



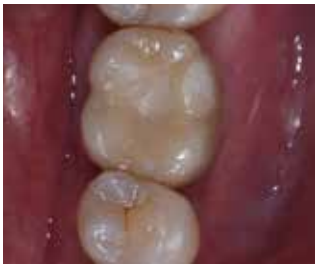
10 RECOVERY WITH PEEK ABUTMENT



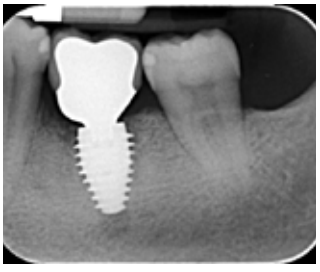
11 RECOVERY



12 VESTIBULAR VIEW



13 OCCLUSAL VIEW

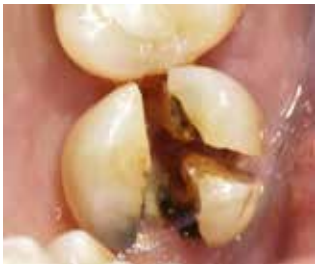


14 RX WITH DEFINITIVE PROSTHETIC AFTER 3 MONTHS

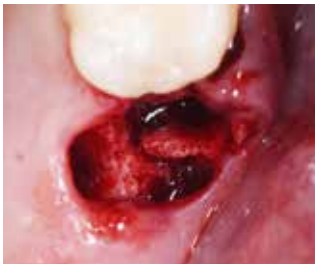
Courtesy of Dr. Antonio Olivo.

CLINICAL CASE

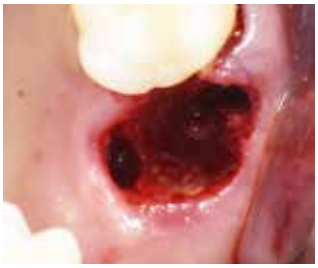
Patient: MALE, 68 YEARS OLD, NON-SMOKER
Situation: VERTICAL FRACTURE, TOOTH 27



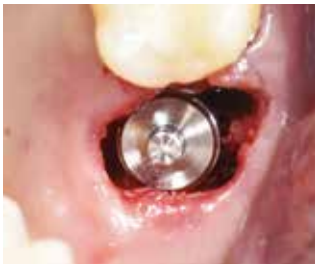
1 ROOTS SEPARATION



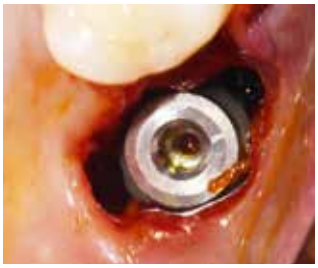
2 EXTRACTION OF THE ROOTS SEPARATELY



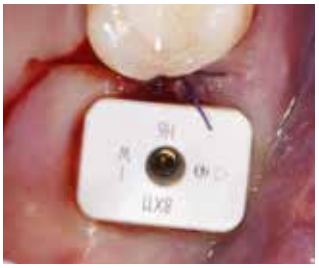
3 PREPARED SITE



4 POSITIONING AND DEPTH PIN

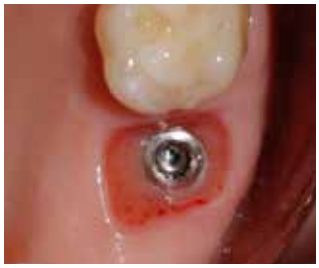


5 INSERTED IMPLANT

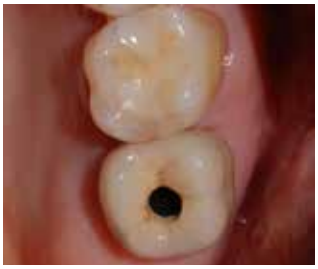


6 SUTURE

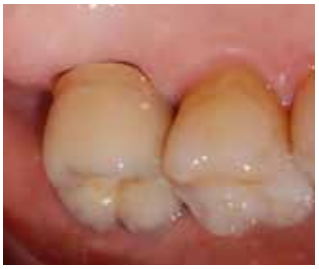
7 RECOVERY AFTER 4 MONTHS



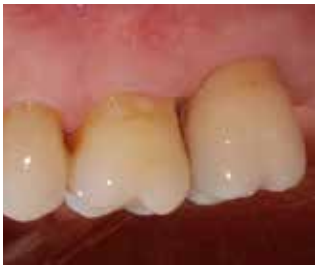
8 RECOVERY AFTER 3 MONTHS



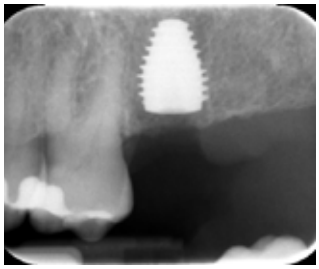
9 OCCLUSAL VIEW



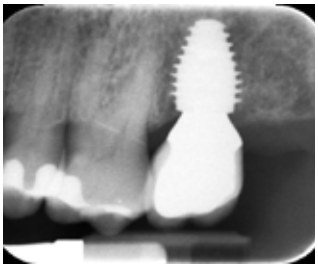
10 PALATAL VIEW



11 BUCCAL VIEW



12 RX IMMEDIATE INSERTION



13 RX WITH DEFINITIVE PROSTHETIC AFTER 3 MONTHS

Courtesy of Dr. Antonio Olivo.

btk Implanting Trust, Smile 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)
Oxigen (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
Oxigen (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 strenght (R0.2)	up to 1115 MPa
Young Modulus E	241 GPa
Hardness	up to 46 HRC

PRECIOUS ALLOY FOR BASE/GOLD ABUTMENTS	
CHEMICAL COMPOSITION:	**MAXIMUM VALUES (%)**
Gold (Au)	60.0 %
Platinum (Pt)	24.9 %
Palladium (Pd)	15.0 %
Iridium (Ir)	0.1 %
Oxigen (O)	0.40

MECHANICAL PROPERTIES:	MINIMUM VALUES
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 WITH PALLADIUM FOR GOLD RETENTIVE SCREWS		
CHEMICAL COMPOSITION:	**MAXIMUM VALUES (%)**	**TOLERANCE**
Zinco (Zn)	0,5	+/- 0.2
Gold (Au)	2	+/- 0.2
Gallium (Ga)	10	+/- 0.5
Copper (Cu)	7	+/- 0.5
Iridium (Ir)	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:	MINIMUM VALUES
Melting range	1450 – 1500 °C
Coefficient of Expansion (CTE)	$12.3 \bullet 10^{-6}$ °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

Implanting Trust, Smile Again!

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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BIBLIOGRAPHY

1. Müller F, Naharro M, Carlsson GE. What are the prevalence and incidence of tooth loss in the adult and elderly population in Europe? Clin Oral Implants Res. 2007 Jun;18 Suppl 3:2-14.

2. Cardaropoli G, Araújo M, Lindhe J. Dynamics of bone tissue formation in tooth extraction sites. An experimental study in dogs. J Clin Periodontol. 2003 Sep;30(9):809-18.

3. Schropp L, Wenzel A, Kostopoulos L, Karring T. Bone healing and soft tissue contour changes following single-tooth extraction: a clinical and radiographic 12-month prospective study. Int J Periodontics Restorative Dent. 2003 Aug;23(4):313-23.

4. Bartee BK. Extraction site reconstruction for alveolar ridge preservation. Part 1: rationale and materials selection. J Oral Implantol. 2001;27(4): 187-93.

5. Denissen HW, Kalk W, Veldhuis HA, van Waas MA. Anatomic consideration for preventive implantation. Int J Oral Maxillofac Implants. 1993;8(2):191-6.

6. Kopp CD. Brånemark osseointegration. Prognosis and treatment rationale. Dent Clin North Am. 1989 Oct;33(4): 701-31.

7. Jaffin RA, Berman CL. The excessive loss of Branemark fixtures in type IV bone: a 5-year analysis. J Periodontol. 1991 Jan;62(1):2-4.

8. Bahat O, Handelsman M. Use of wide implants and double implants in the and double implants in the posterior jaw: a clinical report. Int J Oral Maxillofac Implants. 1996 May-Jun;11(3):379-86.

9. Balshi TJ. First molar replacement with an osseointegrated implant. Quintessence Int. 1990 Jan;21(1):61-5.

10. Huang HL, Huang JS, Ko CC, Hsu JT, Chang CH, Chen MY. Effects of splinted prosthesis supported a wide implant or two implants: a three-dimensional finite element analysis. Clin Oral Implants Res. 2005 Aug;16(4):466-72.

11. Qian L, Todo M, Matsushita Y, Koyano K. Effects of implant diameter, insertion depth, and loading angle on stress/strain fields in implant/jawbone systems: finite element analysis. Int J Oral Maxillofac Implants. 2009 Sep- Oct;24(5):877-86.

12. Petrie CS, Williams JL. Comparative evaluation of implant designs: influence of diameter, length, and taper on strains in the alveolar crest. A three-dimensional finite-element analysis. Clin Oral Implants Res. 2005 Aug;16(4):486-94.

13. Hoshaw SJ, Brunski JB, Cochran GVB. Mechanical loading of Branemark implants affects interfacial bone modeling and remodeling. Int J Oral Maxillofac Implants. 1994;9:345–360.

14. Pierrisnard L, Renouard F, Renault P, Barquins M. Influence of implant length and bicortical anchorage on implant stress distribution. Clin Implant Dent Relat Res. 2003;5(4):254-62.

15. Peñarrocha-Diago M, Carrillo-Garcîa C, Boronat-Lopez A, García-Mira B. Comparative study of wide-diameter implants placed after dental extraction and implants positioned in mature bone for molar replacement. Int J Oral Maxillofac Implants. 2008 May-Jun;23(3):497-501.

16. Vandeweghe S, Ackermann A, Bronner J, Hattingh A, Tschakaloff A, De Bruyn H. A retrospective, multicenter study on a novo wide-body implant for posterior regions. Clin Implant Dent Relat Res. 2012 Apr;14(2):281-92.

17. Rickne C. Scheid. Woelfel's Dental Anatomy, Lippincott Williams & Wilkins, 2012.

NOTE

ULTRA
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.

btk the smile system®

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mail: info@btk.dental

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