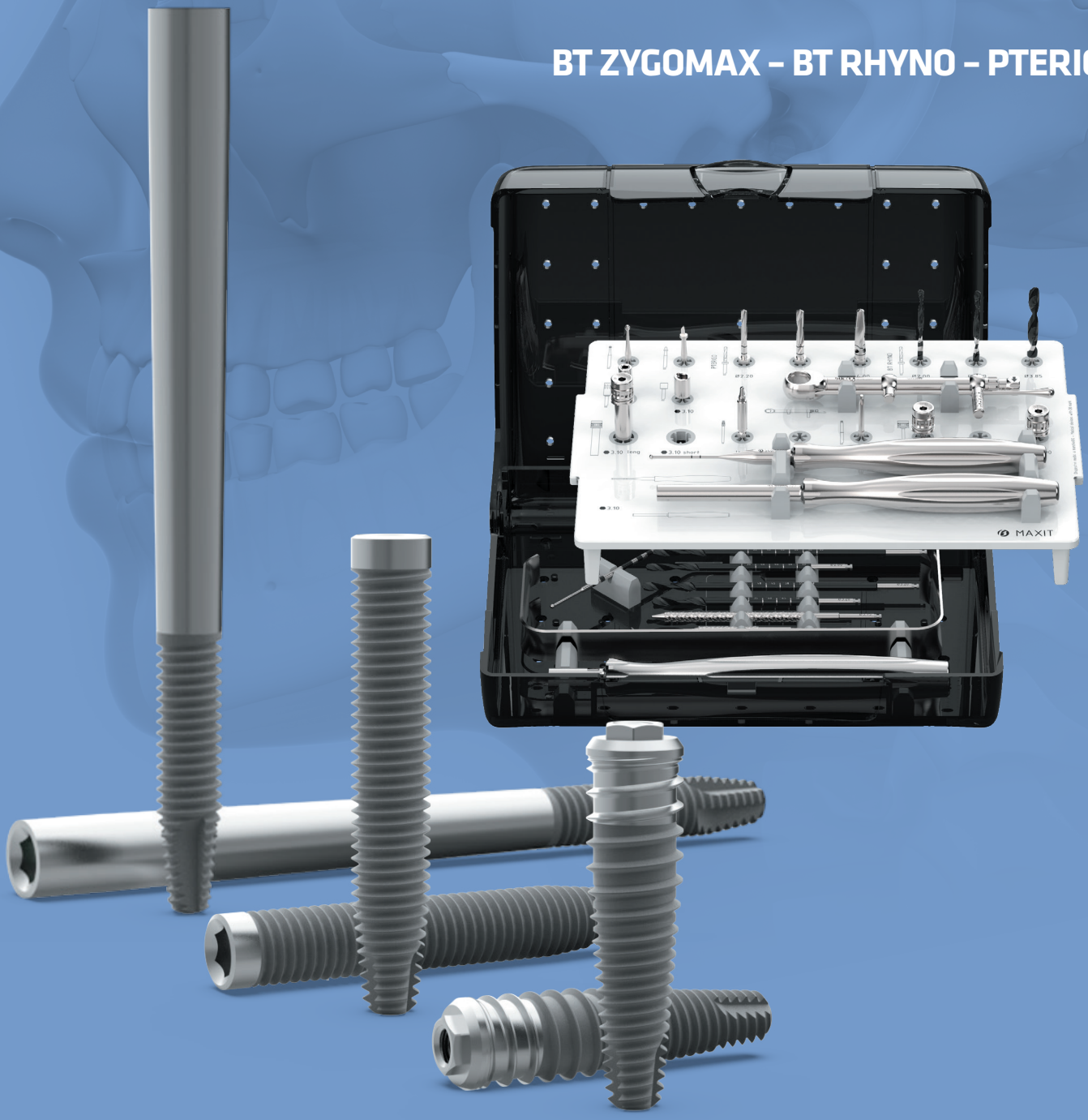
MAXIT
MANUAL

btk Implanting Trust, Smile Again!

MAXIT LINE

Graftless solutions for severe atrophies of the upper jaw in a single surgical kit

BT ZYGOMAX – BT RHYNO – PTERIGO



visit **btk.dental**

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IMPORTANT NOTE

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

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

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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MAXIT LINE

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INDEX

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!

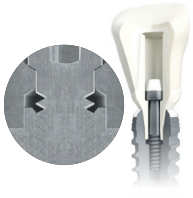
By combining cutting-edge technologies and biology, BTK's mission is to offer affordable and personalized implant-borne solutions thereby sustainably improving the daily life of dental patients.

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.

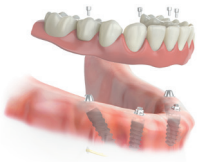
Grade 5 titanium (ASTM F 136 / ISO 5832-3) is used for BTK's prosthetic components, as these are subject to certain levels of stress and in the MINI line implants. This high-strength version, also known as Ti-6Al-4V, is widely used in orthopedics and shows excellent long-term physical and mechanical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



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.

MAXIT

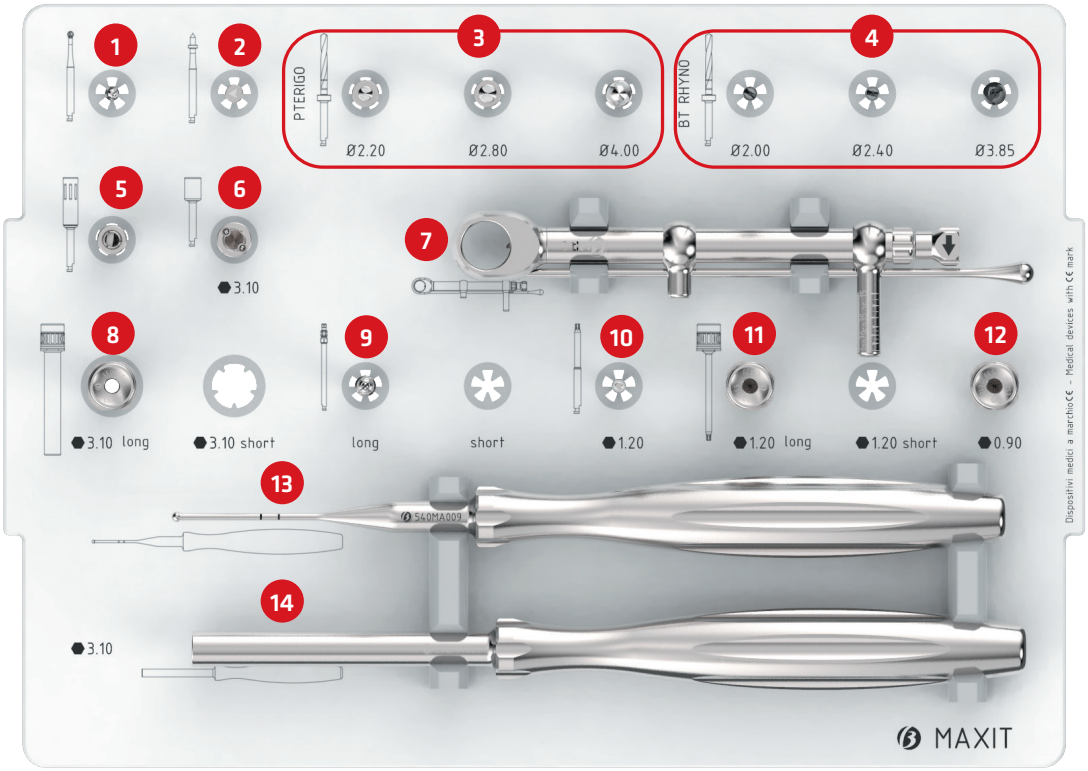
THE SURGICAL KIT FOR THE RESOLUTION OF BIG ATROPHIES

The Surgical KIT MAXIT (Ref.651NA001)
contains all the tools necessary for the application of the ZIGOMATIC, NASAL AND PTERIGOYD IMPLANTS.

SURGICAL KIT MAXIT

BTK has developed this surgical kit for the placement of three implant lines: BT ZYGOMAX, BT RHYNO AND PTERIGO.

The surgical tray is made of a highly shock-proof thermoplastic, which is well established in medical applications and the material is suitable for frequent sterilization in the autoclave.
General guidelines for the cleaning and sterilization are given in the corresponding SURGICAL MANUAL.



1 ROUND DRILL HS

401HS200 | Ø 2mm L30mm

2 LANCE DRILL HS

401HS201 | Ø 2mm L30mm

3 TWIST PRODRILL HR

412HR220 | Ø 2.2mm L37mm

412HR280 | Ø 2.8mm L37mm

412HR400 | Ø 4mm L37mm

4 TWIST DRILL HR

429HL200 | Ø2.0mm L44.8mm

429HL240 | Ø2.4mm L44.8mm

429HL385 | Ø3.85mm L44.8mm

5 DRILL EXTENSION HS

520HS003 | L28mm

6 RETENTIVE WRENCH

530HS017 | HEX 3.10

7 TORQUE WRENCH JD, REVERSIBLE

501JD003 | 90Ncm

8 ADAPTER CONNECTION

530JD031 | ISO/HEX3.10 JD-L35mm

9 IMPLANT DRIVER HANDPIECE IR-IW

530HL005 | L35mm

10 HANDPIECE DRIVER

530HS005 | HEX 1.20 L30mm

11 SCREWDRIVER JD

530JD007 | HEX1.20 L30mm

12 SCREWDRIVER JD

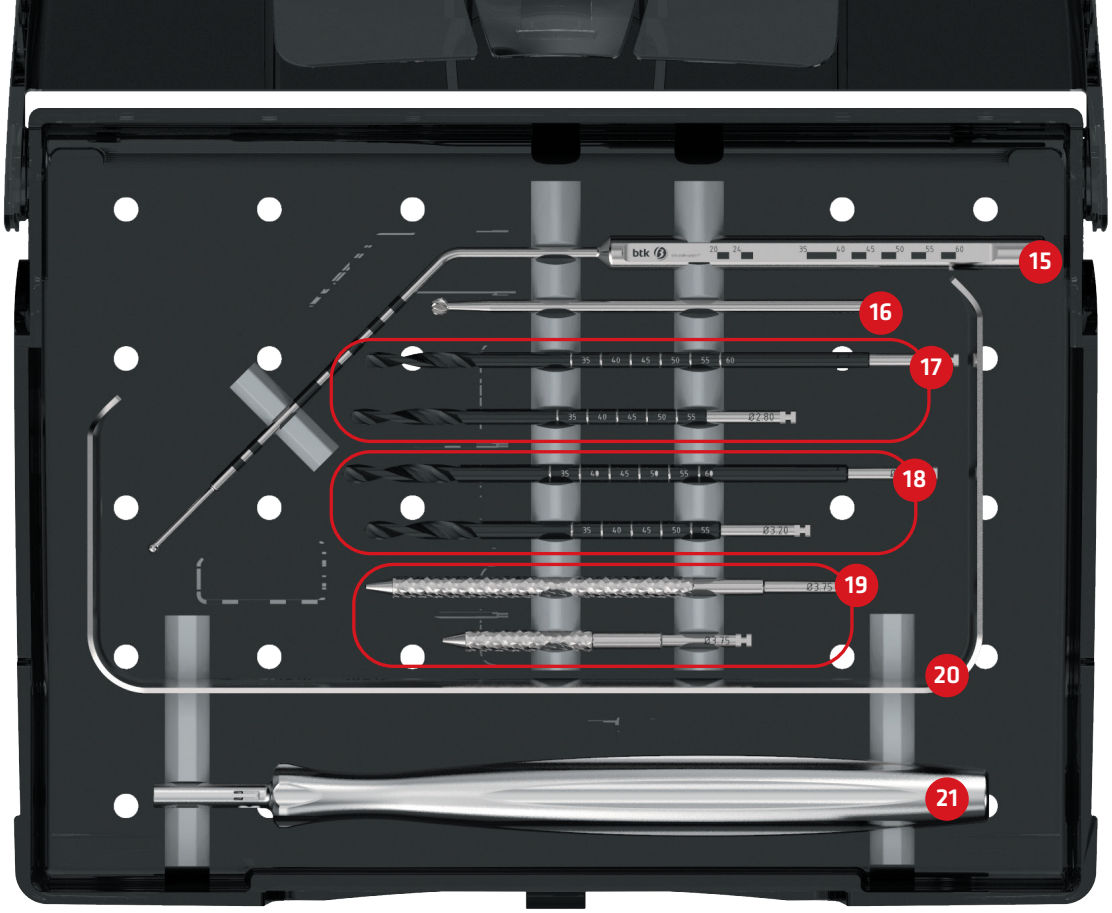
530JD012 | HEX0.90 L15mm

13 DEPTH GAUGE

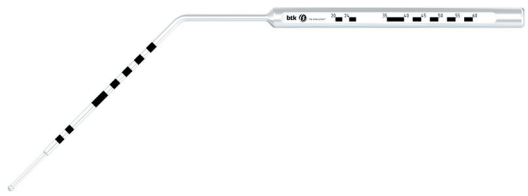
540MA009 | Ø 1.8mm L140mm

14 MANUAL WRENCH

502MA020 | HEX 3.10 L140mm



15
DEPTH GAUGE



540MA021 | Ø1.8mm L175mm 45°

16
ROUND DRILL HL

401HL300 | Ø3mm L75mm

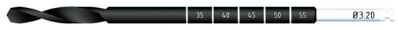
17
HELICAL DRILL HL DLC Ø2.8

428HL280 | Ø2.8mm L99.8mm

428HL281 | Ø2.8mm L74.8mm SHORT

18
HELICAL DRILL HL DLC Ø3.2

428HL320 | Ø3.2mm L99.8mm



428HL321 | Ø3.2mm L74.8mm SHORT

19
ABRASIVE DRILL HL

441HL370 | Ø3.75mm L82mm

441HL371 | Ø3.75mm L52mm SHORT

20
SURGICAL RETRACTOR

SURGICAL RETRACTOR
Notched to have greater grip on the mucosa

502MA008 | 70x16mm / 50x12mm

21
MANUAL WRENCH

520MA002 | L140mm

PRE-OPERATIONAL PLANNING AND CONTRAINDICATIONS

There are many factors that must be taken into consideration in the therapeutic planning phase. These should be based on a thorough evaluation of the patient's clinical and radiological examination results.

The following problems must be taken into consideration in the clinical examination:
- Lack of teeth, bone, gum.
- Type of bone defects.
- Smile line and its impact on reconstruction.
- Interdental relations.
- Para functional habits.

In order for the doctor to exclude any pathology and plan the number and positions of the implants, the radiological examination must be performed on radiographs and CT scans that include all the relevant information.

CONTRAINDICATIONS

- Acute infections of the maxillary sinus.
- Disorders of the jaw or zygomatic bone.
- Disorders that represent contraindications for the insertion of the dental implant.

RELATIVE CONTRAINDICATIONS

- Chronic infections of the maxillary sinus.
- Bisphosphonate therapies.
- Smoking.

POST OPERATIVE INSTRUCTIONS

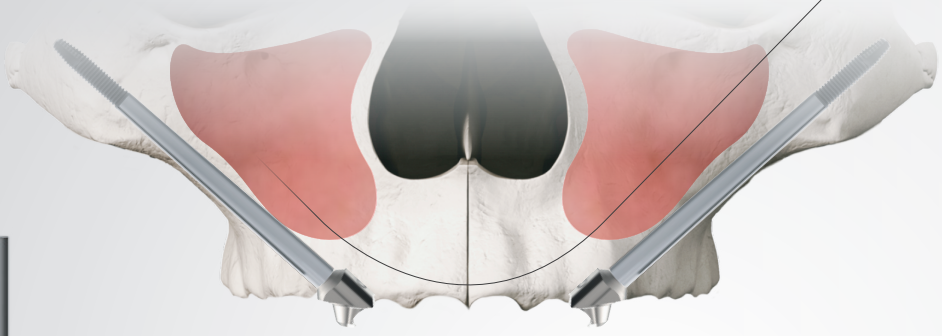
- Diet based on soft foods and medical support therapy.
  The post-operative indications are similar to those of the maxillary sinus lift operation.
- Periodical oral hygiene and check-ups.
- After six months from the surgery, it is possible to do the final restoration.

POSSIBLE COMPLICATIONS

- Sinusitis.
- Oro-antral fistulas.
- Loss of osseointegration of the implant.

BT ZYGOMAX

The implant for severe resorption in maxillary bone



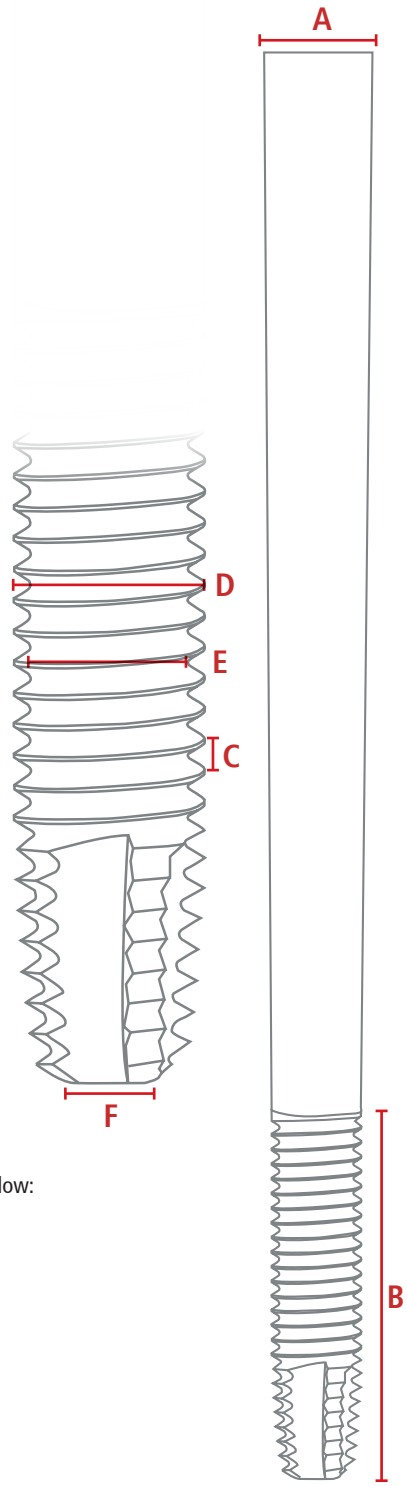
The **BT ZYGOMAX** implant is used in cases of partial or total maxillary edentulism and therefore placed in a multi-implant system (for example all-on-4) in which the loads are distributed.

The **BT ZYGOMAX** implant is extrasinusal and does not require perforation of the sinus membrane. In the extrasinusal approach, the implant is positioned on the external side of the maxilla, trying not to tear the sinus membrane itself.

Before the surgery, it is suggested to do a pre-operative study with radiographic images, CT images and any stereolithographic model of the maxilla.

IMPLANT PORTFOLIO
BT ZYGOMAX

INTERNAL HEXAGON CONNECTION **IR**					
3,5	**IR (INTERNAL REGULAR)** M1.8 Occlusal thread Ø 4.30 mm Prosthetic platform Etched part height 15.1 mm				
A PLATFORM Ø					
Ø 4.30 mm					
B ETCHED PART HEIGHT					
15.1 mm					
C THREAD PITCH					
0.60 mm					
D DIAMETER Ø					
Ø 3.5 mm					
E CORE DIAMETER					
Ø 2.85 mm					
F APEX TIP					
Ø 2.5 mm					
TOTAL LENGTH					
35 mm	**37.50 mm**	**40 mm**	**42.50 mm**	**45 mm**	**47.50 mm**
133IR37A	**133IR37B**	**133IR37C**	**133IR37D**	**133IR37F**	**133IR37G**
50 mm	**52.50 mm**	**55 mm**	**57.50 mm**	**60 mm**	
133IR37H	**133IR37I**	**133IR37K**	**133IR37L**	**133IR37M**	



The color codes applied for different implant diameters and prosthetic platforms are indicated below:

	WHITE
IMPLANT DIAMETER Ø	3,5
PROSTHETIC PLATFORM **INT**	**IR**

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 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 sterilization; 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.

BT ZYGOMAX

BT Zygomax dental implants are supplied sterile. The external packaging is made up of a cardboard box. The implant is inserted into the vial placed inside a sealed blister. The diameter, length and production lot of the implant are shown on the device identification label.

Open the cardboard box and remove the blister containing the vial with 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. Inside the box there are also dedicated instructions for use, which must be consulted before using the device.

Open the blister and remove the vial.

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

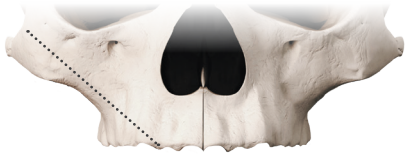
Keep the vial in vertical position to prevent the device from leaking out.

The BT Zygomax system is supplied without the mounting device. Use the IR-IW implant driver (530HL005) and possibly extended with the drill extension (520HS003 torque wrench) for the removal of the implant from the vial and for its insertion into the previously prepared implant site. BTK dental implants can be positioned manually with the reversible dynamometric ratchet or can be inserted using the micromotor. Insert the implant into the bone at the required depth by screwing it with appropriate instruments (max speed 15-25 rpm), not exceeding the torque values indicated below in order not to damage the implant connection and the instruments:

• Implants> Ø 3.7 mm
Max insertion torque 45-65 Ncm
Upon completion of the insertion, the doctor will have to evaluate the quality of the bone and the initial stability, which are decisive elements to load the prosthesis.

SURGICAL PROCEDURE

FLAP OPENING AND SITE PREPARATION:



1
Proceed with an incision on the crest of the edentulous maxilla with a distal vertical incision of release.

Proceed with the lifting of a full thickness mucoperiosteal flap, exposing the lateral side of the maxilla.

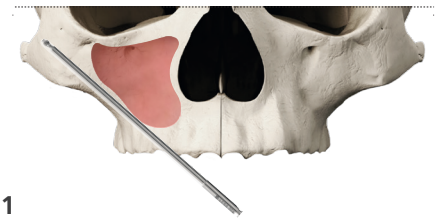
The alveolar ridge is exposed, including the palatal side, so dissect up to the level of the infraorbital foramen to facilitate anatomical orientation.

2
Identification of the alveolar support point and where possible try to safeguard the bone structure of the alveolar region for greater stability of the future implant.

3
It is possible to subsequently mill a space of about 10 mm x 5 mm on the lateral side of the maxilla until to clearly highlight and detach the sinus mucosa in the area in which the implants will be inserted.

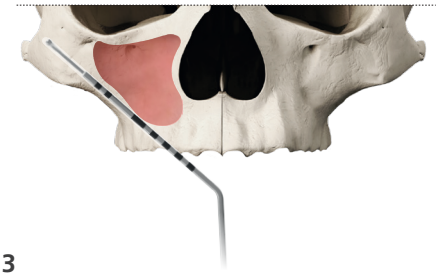
4
The possible trajectory of the implant is identified by positioning the ball drill over the lateral wall of the jaw. The implant must rest on the lateral wall of the maxilla, from the alveolar region and inserting itself into the zygomatic bone until it reaches the external cortex.

IMPLANT SITE CREATION:

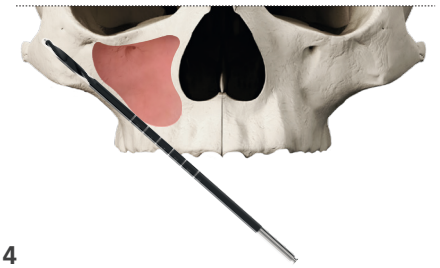


1
Mark the entrance of the implant in the cheekbone region with the stainless steel ball bur **(401HL300 Round Drill)** and create an invitation to enter the posterior-upper side of the maxillary sinus to allow insertion of the abrasive drill. **Maximum recommended speed: 800 RPM**

2
Use the abrasive drill **(441HL370)** to prepare the intermediate passage between the alveolar position and the zygomatic region (preparation of the lateral bone wall of the maxillary sinus).
Maximum recommended speed: 500 RPM



3
Use the depth gauge **(540MA021)** to determine the ideal implant length.



4
Proceed to enlarge the bone passage with the helical drill with **DLC** coating **(428HL280 o 428HL320)**.
Maximum recommended speed: 600 RPM.

Once the osteotomy is completed, we recommend irrigating the sinus with pre-cooled physiological solution before inserting the implant.

INSERTION OF THE IMPLANT

1

Open the package and insert the implant with the implant driver for handpiece IR-IW **(530HL005)** and possibly extended with the drill extension **(520HS003)** and insert the implant in the bone site, prepared with a **setting of 65 Ncm maximum and a maximum speed of 25 RPM.**

2

To complete the insertion of the implant, it is also possible to insert it with the connection adapter **(530JD031)** and reversible dynamometric ratchet **JD (501JD003 torque wrench)** to check the final insertion torque of the implant.

3

Proceed with the immediate loading technique by inserting the **angled BT4 IR abutment (45 ° 266IR3J0 and 55 ° 266IR3M0)** in combination with the **BT4 prosthetic cylinder (267NA0A0)** and the respective screws, then creating the dedicated prosthetic.

The final tightening of the retention screw of the angled abutment with the implant must be **maximum 30Ncm;** while the tightening of the connection screw of the BT4 prosthetic cylinder must be a **maximum of 15Ncm.**

BT ZYGOMAX IMPLANT	Round Drill HL 401HL300	Abrasive Drill HL Ø 3.75 441HL370	Helical Drill HL DLC Ø2.8 428HL280	Helical Drill HL DLC Ø3.2 428HL320
				
Ø 3,75 X **35**	●	○	●	○
Ø 3,75 X **37,5**	●	○	●	○
Ø 3,75 X **40**	●	○	●	○
Ø 3,75 X **42,5**	●	○	●	○
Ø 3,75 X **45**	●	○	●	○
Ø 3,75 X **47,5**	●	○	●	○
Ø 3,75 X **50**	●	○	●	○
Ø 3,75 X **52,5**	●	○	●	○
Ø 3,75 X **60**	●	○	●	○

● Always

○ It depends on the appearance of the maxillary sinus and the direction of the implant in situ, so it is a choice that must be evaluated by the doctor after the appropriate analyzes.

○ Helical drill HL Ø 3.20 = Should be used if the helical drill HL Ø 2.80 is not sufficient to fully insert the implant without exceeding the maximum recommended torque (max 30 Ncm) and it is a choice that must be evaluated by the doctor after appropriate analysis.

To preserve the alveolar bone, at the beginning of the procedure the clinician can use the Helical Drill HL ref. 426HR455

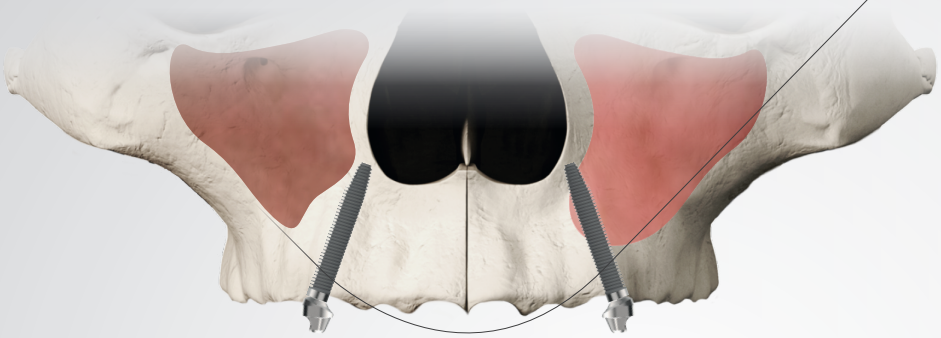
PROSTHETIC OPTIONS

INTERNAL HEXAGON PROSTHETICS IR

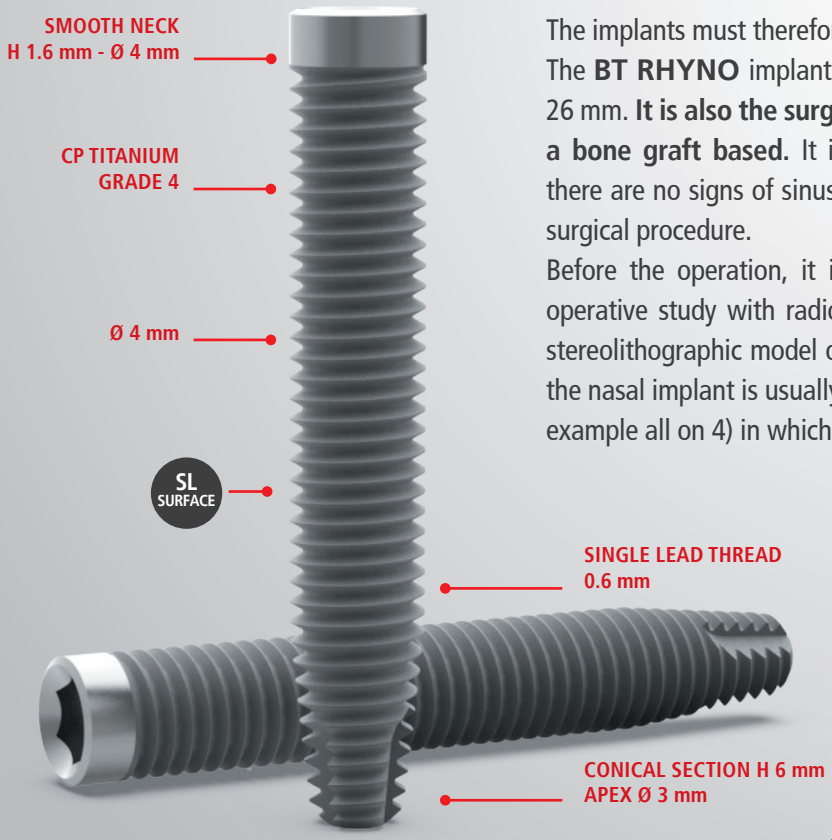
PICTURE	REF	PRODUCT NAME	SPECIFICATION
HEALING & SOFT TISSUE CONDITIONING			
	201IR2A0	Healing Abutment IR	H2mm Ø4.5mm
	201IR3A0	Healing Abutment IR	H3mm Ø4.5mm
	201IR4A0	Healing Abutment IR	H4mm Ø4.5mm
	201IR4A1	Healing Abutment IR	H4mm Ø5.5mm
	201IR5A0	Healing Abutment IR	H5mm Ø4.5mm
	201IR5A1	Healing Abutment IR	H5mm Ø1.8mm
	201IR7A0	Healing Abutment IR	H7mm Ø1.8mm
	200IR0A0	Cover Screw IR	HEX1.20
SCREW-RETAINED PROSTHESIS			
	266IR3M0	Abutment IR	45° H3.5 SV5.7
	266IR3J0	Abutment IR	55° H3.5 SV6.2
	690NA066	Retentive Screw BT4	M1.8 Angled abutment IR-EN
	330NA0A0.04	Covering Caps BT4	H5 Kit 4pcs
	690NA024	Retentive Screw	M1.4 HEX1.20 10N
	267NA0A0	BT4 Titanium Abutment	
	207NA0A0	Castable Plastic Abutment BT4	
	207NA0A1	Castable Plastic Abutment BT4	No Screw
	351BT1A1	Scan Abutment Extra-oral BT	Rotating
	352BT1A1	Scan Abutment Intra-oral BT	Rotating
	246BT1A1	BT Link BT	H1mm Ø4.8mm Rotating
	247BT1A1	Base BT Link BT	H1mm Ø4.8mm no Cap. Rot
	205NA003.05	Castable Plastic Abut. BT Link	H1mm Ø5.4mm Kit 5pcs
	240BT1R0	CoCr Abutment BT	H1.5mm Rotating
	311NA0A0	Impression Post Pick-up BT4	with long Screw
	690NA031	Impression Post Pick-Up Screw	M1.4 HEX1.20 H17mm
	303NA0A0	Abutment Replica BT4	

BT RHYNO

GRAFTLESS SOLUTIONS FOR SEVERE ATROPHIES WITH NASAL ANCHORAGE

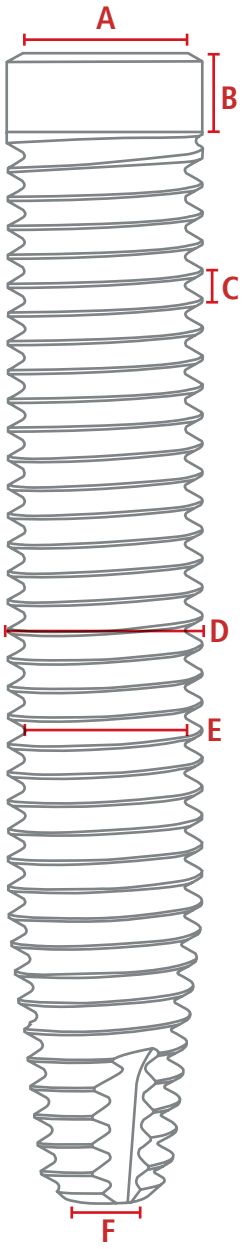


In the case of partial or total maxillary edentulism, **BT RHYNO** implants can be used to exploit the maxillary bone surrounding the nose. The relative implant site begins in the alveolar bone (which must be at least 3mm) in the premolar area and ends in the bone between the maxillary sinus and the nasal cavity.
The implants must therefore be long enough to cross the sinus.
The **BT RHYNO** implant is available in lengths 20, 22, 24 and 26 mm. **It is also the surgeon's choice whether or not to add a bone graft based.** It is always mandatory to monitor that there are no signs of sinus infection before proceeding with the surgical procedure.
Before the operation, it is recommended to carry out a pre-operative study with radiographic images, CT images and any stereolithographic model of the maxilla. It should be noted that the nasal implant is usually placed in a multi-implant system (for example all on 4) in which the loads are distributed.



IMPLANT PORTFOLIO
BT RHYNO

INTERNAL HEXAGON CONNECTION **IR**			
4,0	**IR (INTERNAL REGULAR)** M1.8 Occlusal thread Ø 4.0 mm Prosthetic platform 1.6 mm Smooth neck portion		
A PLATFORM Ø			
Ø 4 mm			
B SMOOTH NECK HEIGHT			
1.6 mm			
C THREAD PITCH			
0.60 mm			
D DIAMETER Ø			
Ø 4 mm			
E CORE DIAMETER			
Ø 3.25 mm			
F APEX TIP			
Ø 2.0 mm			
TOTAL LENGTH			
20 mm	**22 mm**	**24 mm**	**26 mm**
134IR41U	**134IR41V**	**134IR41W**	**134IR41X**



The color codes applied for different implant diameters and prosthetic platforms are indicated below:

	BLUE
IMPLANT DIAMETER Ø	4,0
PROSTHETIC PLATFORM **INT**	IR

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 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 sterilization; 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.

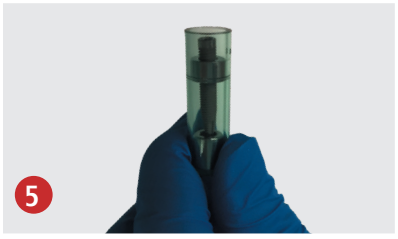
BT RHYNO

BT Rhyno dental implants are supplied sterile. The external packaging is made up of a cardboard box. The implant is inserted into the vial placed inside a sealed ampoule. The diameter, length and production lot of the implant are shown on the device identification label.

Open the cardboard box and remove the ampoule containing the vial with 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. Inside the box there are also dedicated instructions for use, which must be consulted before using the device.

Open the ampoule and remove the vial.

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

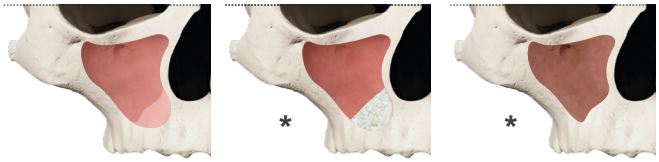


Keep the vial in vertical position to prevent the device from leaking out.

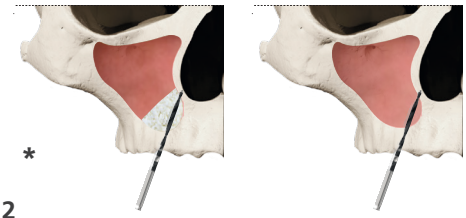
The BT Rhyno system is supplied without the mounting device. Use the IR-IW implant driver (530HL005) and possibly extended with the drill extension (520HS003) for the removal of the implant from the vial and for its insertion into the previously prepared implant site. BTK dental implants can be positioned manually with the reversible dynamometric ratchet or can be inserted using the micromotor. Insert the implant into the bone at the required depth by screwing it with appropriate instruments (max speed 15-25 rpm), not exceeding the torques indicated below in order not to damage the implant connection and the instruments:

• Implants> Ø 3.7 mm
Max insertion torque 45-65 Ncm
Upon completion of the insertion, the doctor will have to evaluate the quality of the bone and the initial stability, which are decisive elements to load the prosthesis.

SURGICAL PROCEDURE

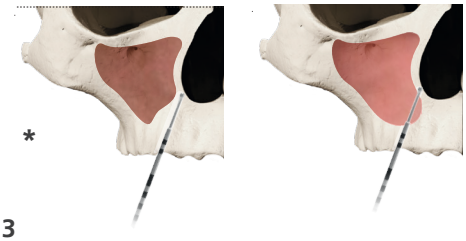


1
It is advised to open a window in the lateral sinus wall, gently reflecting the Schneiderian membrane without perforating it.
The site preparation begins with the identification of the access in the alveolar bone.



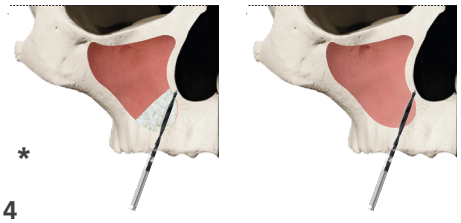
2
If the alveolar has more than 3mm of good bone, use the twist drill **DLC 429HL200 Ø2 mm** to cross through the sinus, engaging the lateral nasal wall.
Max. Speed: 600 RPM

It is optional the reflect of the Schneiderian membrane of the sinus, but it is advisable.
It is a surgeon's choice how to proceed.

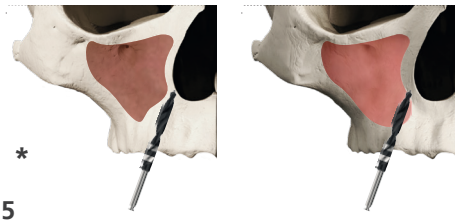


3
The depth probe **540MA021** can be used to verify the depth of the osteotomy and for the implant selection.

*
NB: The surgeon can choose to open a window in the lateral sinus wall, gently reflecting the Schneiderian membrane, then insert the bone graft.



4
Use the twist drill **429HL240 Ø2.4 mm** to enlarge the implant site.
Max. Speed: 600 RPM



5
If is necessary to enlarge the hole to obtain optimal torques (maximum 45 Ncm) use the drill **429HL385**.
Maximum recommended speed: 500 RPM.
It is always a clinician's choice.

6
Place the implant, with the IR implant driver **530HL005** or with the extension drill **520HS003**, until reaching the final position with setting **45-65 Ncm maximum and a maximum speed of 15-25 RPM**.

INSERTION OF THE IMPLANT

It is possible to proceed with the immediate loading technique by inserting the angled BT4 IR abutment **(45 ° 266IR3J0 and 55 ° 266IR3M0)** in combination with the BT4 prosthetic cylinder (**267NA0A0**) and the respective screws, then creating the dedicated prosthetic.

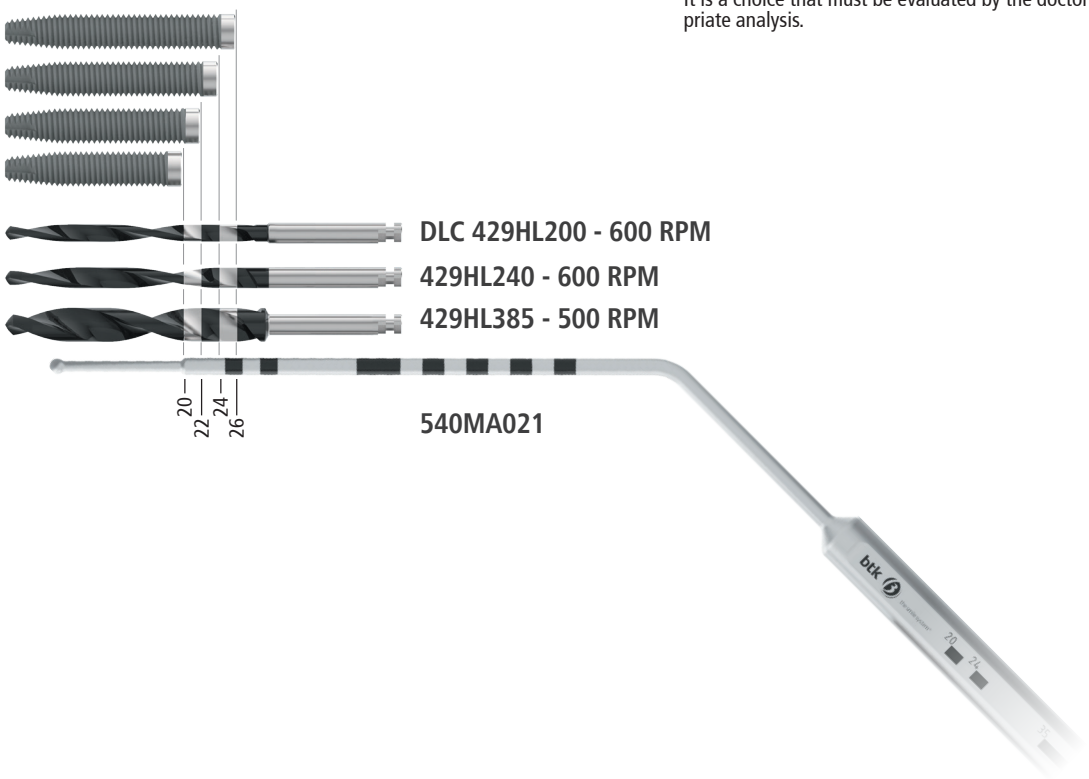
The final tightening of the retention screw of the angled abutment with the implant must be **maximum 30Ncm;** while the tightening of the connection screw of the BT4 prosthetic cylinder must be a **maximum of 15Ncm.**

BT RHYNO IMPLANT	Twist Drill HL DLC 429HL200	Twist Drill HL DLC 429HL240	Twist Drill HL DLC 429HL385
			
Ø 4 X 20	●	●	○
Ø 4 X 22	●	●	○
Ø 4 X 24	●	●	○
Ø 4 X 26	●	●	○

● Always

○ It is recommended to place BT Rhyno implant if there are at least 3 mm of residual bone crest.

Sometimes it may be necessary to use the twist drill 429HL385 to drill more the alveolar bone and get the right torque.
It is a choice that must be evaluated by the doctor after the appropriate analysis.



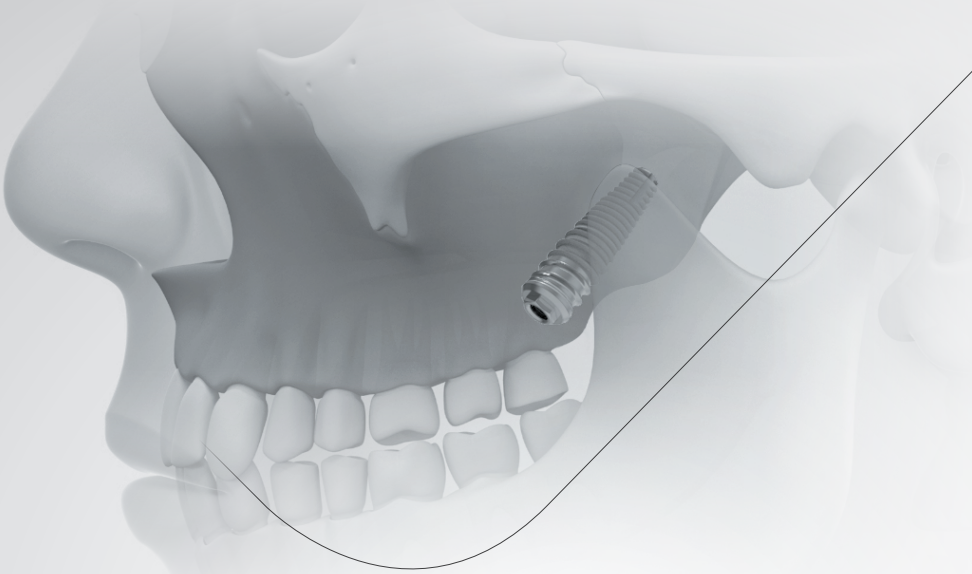
PROSTHETIC OPTIONS

INTERNAL HEXAGON PROSTHETICS IR

PICTURE	REF	PRODUCT NAME	SPECIFICATION
HEALING & SOFT TISSUE CONDITIONING			
	201IR2A0	Healing Abutment IR	H2mm Ø4.5mm
	201IR3A0	Healing Abutment IR	H3mm Ø4.5mm
	201IR4A0	Healing Abutment IR	H4mm Ø4.5mm
	201IR4A1	Healing Abutment IR	H4mm Ø5.5mm
	201IR5A0	Healing Abutment IR	H5mm Ø4.5mm
	201IR5A1	Healing Abutment IR	H5mm Ø1.8mm
	201IR7A0	Healing Abutment IR	H7mm Ø1.8mm
	200IR0A0	Cover Screw IR	HEX1.20
SCREW-RETAINED PROSTHESIS			
	266IR3M0	Abutment IR	45° H3.5mm Ø5.7mm
	266IR3J0	Abutment IR	55° H3.5mm Ø6.2mm
	266IR2L0	Angled Abutment BT4 IR	17° H2mm Ø4.8mm
	266IR3L0	Angled Abutment BT4 IR	17° H3mm Ø4.8mm
	266IR3G0	Angled Abutment BT4 IR	30° H3mm Ø4.8mm
	690NA066	Retentive Screw BT4	M1.8 Angled abutment IR-EN
	330NA0A0.04	Covering Caps BT4	H5 Kit 4pcs
	267NA0A0	BT4 Titanium Abutment	
	207NA0A0	Castable Plastic Abutment BT4	
	207NA0A1	Castable Plastic Abutment BT4	No Screw
	351BT1A1	Scan Abutment Extra-oral BT	Rotating
	352BT1A1	Scan Abutment Intra-oral BT	Rotating
	246BT1A1	BT Link BT	H1mm Ø4.8mm Rotating
	247BT1A1	Base BT Link BT	H1mm Ø4.8mm no Cap. Rot
	205NA003.05	Castable Plastic Abut. BT Link	H1mm Ø5.4mm Kit 5pcs
	240BT1R0	CoCr Abutment BT	H1.5mm Rotating
	690NA024	Retentive Screw	M1.4 HEX1.20 10N
	311NA0A0	Impression Post Pick-up BT4	with long Screw
	690NA031	Impression Post Pick-Up Screw	M1.4 HEX1.20 H17mm
	303NA0A0	Abutment Replica BT4	

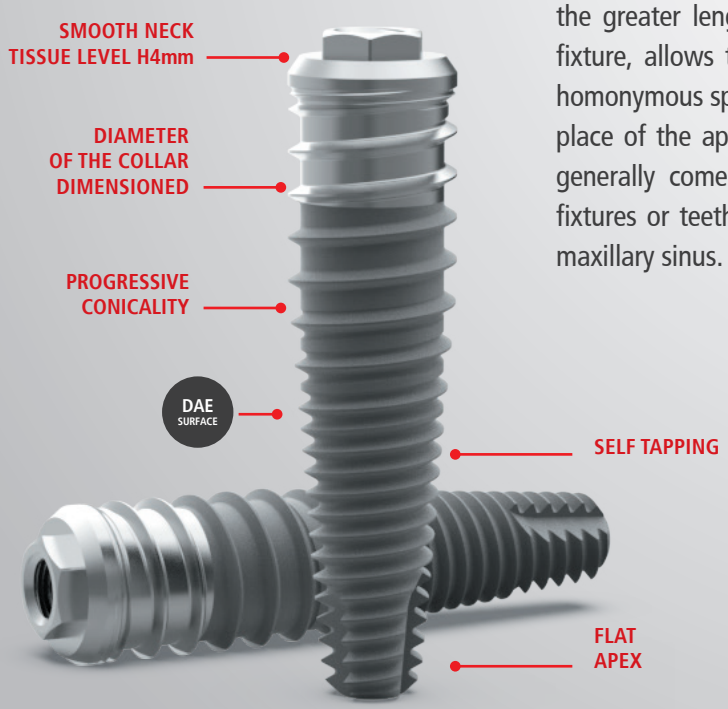
PTERIGO

THE PTERIGOID SOLUTION



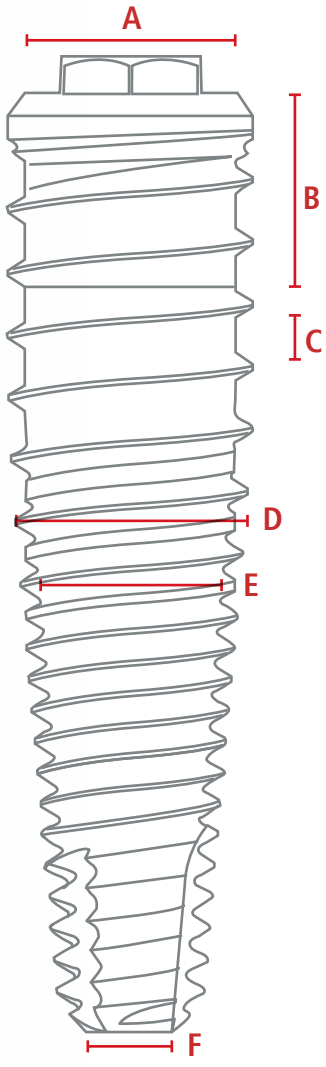
The posterior area of the maxillary tuberosity is closely connected at the bone level with the pterygoid process of the sphenoid and with the wall of pyramidal process of the palatine, thus representing an appropriate anatomical structure, characterized by dense bone, suitable to support dental implants.

The pterygoid implant is an endosseous fixture, of 15-18 mm in length, positioned in the region of the superior maxillary tuber; the greater length of the implant, if compared to a standard fixture, allows to reach the pterygoid fossa and therefore the homonymous sphenoid abutment on which the anchoring takes place of the apical part of the implant. The pterygoid implant generally comes used together with the placement of other fixtures or teeth placed in the mesial area with respect to the maxillary sinus.



IMPLANT PORTFOLIO
PTERIGO

CONNECTION EXTERNAL HEXAGON **ER**	
4,7	**ER (EXTERNAL REGULAR)** Occlusal thread M2.0 Prosthetic Platform Ø 4.1 mm Smooth Neck Portion 4.0 mm
A PLATFORM Ø	
Ø 4.1 mm	
B SMOOTH NECK HEIGHT	
4 mm	
C THREAD PITCH	
1.2 mm	
D DIAMETER Ø	
Ø 4.7 mm	
E CORE DIAMETER	
Ø 4.0 mm	
F APEX DIAMETER	
Ø 2.0 mm	
TOTAL LENGTH	
15 mm	**18 mm**
150ER47R	**150ER47T**



The color codes applied for different implant diameters and prosthetic platforms are indicated below:

	GREY
IMPLANT DIAMETER Ø	4,7
PROSTHETIC PLATFORM **EXT**	ER

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 sterilization; 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.

PTERIGO

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

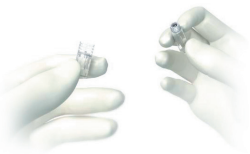
Open the blister from the back by breaking the outer label, and take out the vial.

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.

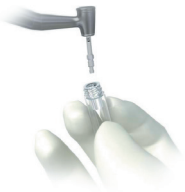
4

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

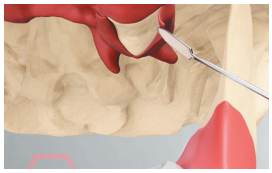
Remove the safety cap of the sterile inner vial, which always includes the sterile closure screw. Warning The internal vial consists of 3 parts. The cover screw (locking screw), if provided, is placed in the vial cap.
Hold the vial upright to prevent the devices from leaking out.
Unscrew the central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

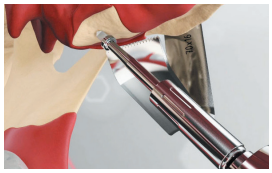


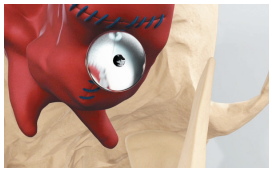
6

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.

SURGICAL AND PROSTHETIC GUIDELINES







OPENING OF THE FLAP AND SITE PREPARATION

Make an incision of the maxilla tuber in the ridge at all thickness and subsequently vestibular release incisions and palatal. Proceed with the skeletonization of the maxilla
superior posterity and the identification of anatomical landmarks clinical and radiological.

CREATING THE IMPLANT SITE

Use the **lance drill (401HS201) or ball drill (401HS200)** to create an invitation on the cortical bone useful for the placement of the depth drill.
• Recommended maximum speed: **700 RPM**.

Use the Ø 2.20mm depth drill (412HR220) to create the depth pilot hole, up to the pterygoid fossa.
• Recommended maximum speed: **300 RPM**.

Use the **depth gauge (540MA009)** to verify the clinical length of the pterygoid implant. Proceed to enlarge the hole with the **twist drill Ø 2.80mm (412HR280)** and subsequently with the **twist drill Ø 4mm (412HR400)**.
• Recommended maximum speed: **150 RPM**.

We recommend connecting all rotating instruments to the drill extension for easier access to the surgical area.
Abundant irrigation by means of physiological pre-cooled solution is recommended.

INSERTION OF THE IMPLANT

Insert the implant with the **retentive wrench and the drill extension tool (530HS017 + 520HS003)**. Apply a maximum torque of 50 Ncm with a maximum speed of 25 RPM.

To complete the insertion it is possible to place the implant also with the manual mounter and **the reversible torque wrench (501JD003)**, in order to evaluate the final torque of insertion for the implant. Insert the cap screw and tighten using **the HEX 0.90 mm screwdriver (530JD012)**.

In the case of immediate loading, once taken the impression, insert the healing screw.

Close the surgical area by suture.

In the case of insertion of a deferred load implant, it is necessary a surgical re-entry, to remove the cap screw and place the healing screw, finally proceed again with the suture.

INSTRUMENTS

The drill extension (520HS003) must be used for extend rotary tools, such as **the HEX 1.20 mm handpiece driver.**

The HEX 1.20 mm handpiece driver (530HS005), must be used to INSERT AND REMOVE the healing screw.

The HEX 0.90 mm (manual) screwdriver JD (530JD012), must be used to REMOVE THE SCREW CAP.

The HEX 3.10 L140 mm manual wrench (502MA020) must be used for manual insertion of the implant.

The HEX 1.20 L30 mm (manual) screwdriver (530JD007), must be used connected to **the 90Ncm reversible torque wrench**, included in the kit, for the final tightening of the abutment screws.
• We recommend using a torque of 30-35Ncm.

IMPRESSION TAKING

25° angled transfer with cap.
This transfer allows to correct the disparallelism of the implant compared to other implants or natural elements.
The transfer is equipped with hexagonal base and guarantees to transfer the position of the hexagon in relation to the implant such as the three-dimensional position of the implant itself in comparison to the maxillary bone.
The plastic cap is a single-use device and is supplied NOT-STERILE. It is not auto-clavable. It must be disinfected before use with a common disinfectants for plastic products.
The impression process use a closed tray and the repositioning of the system transfer + analogous with the cap, which remains in the impression, is done manually. The master model thus obtained, allows the design of both the temporary prosthesis and the definitive one done in collaboration with the dental laboratory technician.

Temporary prosthesis:
We recommend the execution of a temporary resin prosthesis, CEMENTED to the pterygoid implant by means of the temporary titanium abutments, or a SCREWED prosthesis to not-rotating peek abutment.

Definitive prosthesis:
In collaboration with the dental laboratory it is performed the design of the final restoration, choosing between a screwed or cemented approach; the final restoration can be realized also by means of CAD-CAM technology.

Anyway, the choice is subjective and it can condition the clinical case in question. The final tightening of the abutment screw must take place at 30-35 Ncm using the torque wrench.

PROSTHETIC OPTIONS

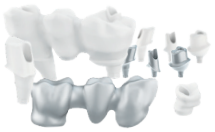
EXTERNAL HEXAGON PROSTHETICS ER

PICTURE	REF	PRODUCT NAME	SPECIFICATION
HEALING & SOFT TISSUE CONDITIONING			
	201ER6A3	Healing Abutment ER	H6mm Ø7mm
IMPRESSION TAKING			
	325ER0F0	Transfer Cappetta PRO ER	25° Cappetta Plastica
	301ER0A1	Implant Replica	–
TEMPORARY ABUTMENTS			
	210ER2A0	Temporary Abutment ER	
	210ER2A1	Temporary Abutment ER	Rotating
	215ER2A0	Temporary Abutment ER	Peek
CEMENT-RETAINED PROSTHESIS			
	220ER2A1	Straight Abutment ER	H2mm Ø5mm
	220ER2A3	Straight Abutment ER	H2mm Ø6mm
	220ER2A2	Straight Abutment ER	H2mm Ø7.5mm
	220ER4A0	Straight Abutment ER	H4mm Ø5mm
	220ER4A1	Straight Abutment ER	H4mm Ø6mm
	220ER4A2	Straight Abutment ER	H4mm Ø7.5mm
	220ER2D0	Angled Abutment ER	15° H2mm
	220ER4D0	Angled Abutment ER	15° H4mm
	220ER2F0	Angled Abutment ER	25° H2mm
	220ER4F0	Angled Abutment ER	25° H4mm
SCREW-RETAINED / CEMENT-RETAINED PROSTHESIS			
	246ER1A0	BT Link ER	H1mm Ø4.6mm
	247ER1A0	Base BT Link ER	H1mm Ø4.6mm no Cap.
	248ER1A0	Base BT Link ER	H1mm Ø4.6mm Multi Lenght
	205NA002.05	Castable Plastic Abut BT Link	H1mm Ø5.2mm Kit 5pcs
	240ER1A0	CoCr Abutment ER	H1.5mm
	245ER1A0	Gold Abutment ER	H1mm
	205ER2A0	Castable Plastic Abutment ER	–
	205ER2A0.10		Kit 10pcs
	246ER1A1	BT Link ER	H1mm Ø4.6mm Rotating
	247ER1A1	Base BT Link ER	H1mm Ø4.6mm no Cap. Rot.
	240ER1R0	CoCr Abutment ER	H1.5mm Rotating
	245ER1R0	Gold Abutment ER	H1mm Rotating
	205ER2A1	Castable Plastic Abutment ER	Rotating
	205ER2A1.10		Rotating Kit 10pcs

ACCESSORIES

PICTURE	REF	PRODUCT NAME	SPECIFICATION
	690NA013	Retentive Screw	M2.0 HEX1.20
	690NA019	Retentive Screw Gold	M2.0 HEX1.20
	690NA067	Impression Post Screw	M2.0 HEX1.20 H8.1mm
	690NA091.10	Caps Kit Pro	Ø5.1mm Kit 10pcs

CAD-CAM

PICTURE	PRODUCT	SPECIFICATION
	351ER1A0	Scan Abutment Extra-oral ER
	Prosthesis Options (Titanium)	• Customized abutments • Screw-retained single crowns • Bridges on implants • Anatomically reduced Toronto bridges • Toronto bridges for commercial teeth
	Prosthesis Options (Cobalt Chrome)	
	Prosthesis Options (Zirconia)	

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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MAXIT
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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SURGICAL KIT
BT SCREW

BTK's BT SCREW kit contains the tools suitable for the correct management of surgical procedure for the fixation of bone grafts, meshes and membranes on the mandible or maxilla.
The kit contains a set of fixation screws and pins, with several diameters and length, in order to cover all the surgical needs.

OVERVIEW

COMPLETE
With drills, screwdrivers, manual and micromotor wrenches, torque wrench, etc.

VERSATILE
Screw fixation by means of handipiece or manual driver

FREE SLOTS
For additional tools and spare parts

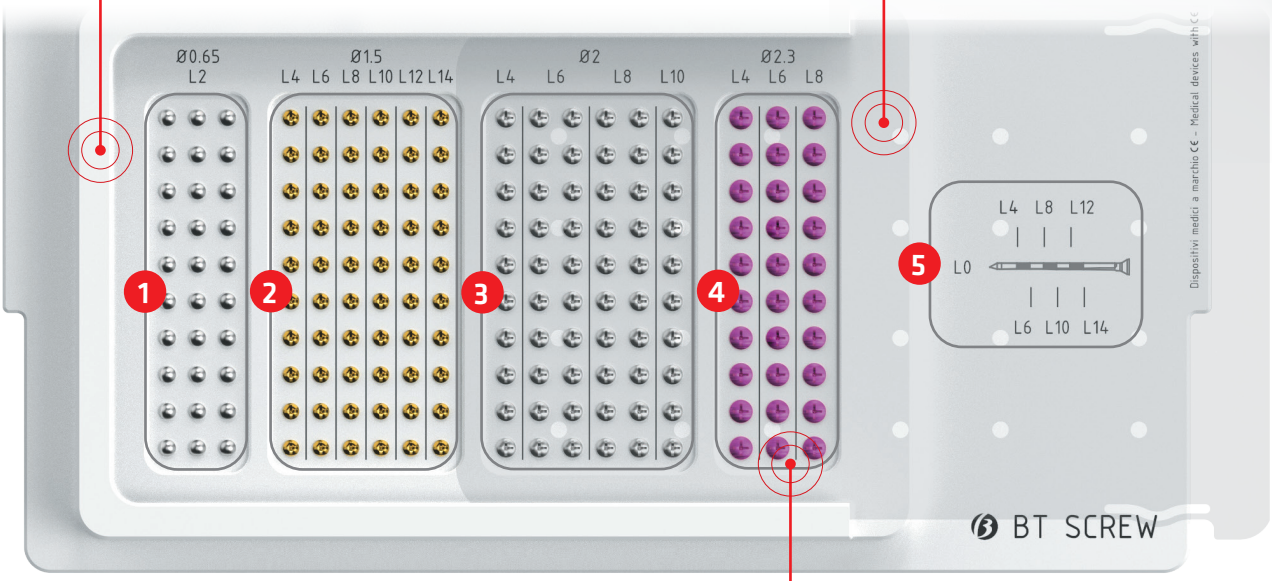
SMALL DIMENSION
19.0 x 13.8 x 6.0 cm

AUTO-CLAVABLE
Materials are compliant with sterilization regulations

PORTFOLIO SCREWS
MANUFACTURED IN BIOMEDICAL TITANIUM

EASY ORGANIZATION
up-to 150 fixation screws e 30 pins

INNOVATIVE & SAFE
Detachable screw holder with removable cover



1 PIN Ø 0.65
L=4

2 SCREW Ø 1.5
L=4, 6, 8, 10, 12 e 14 mm

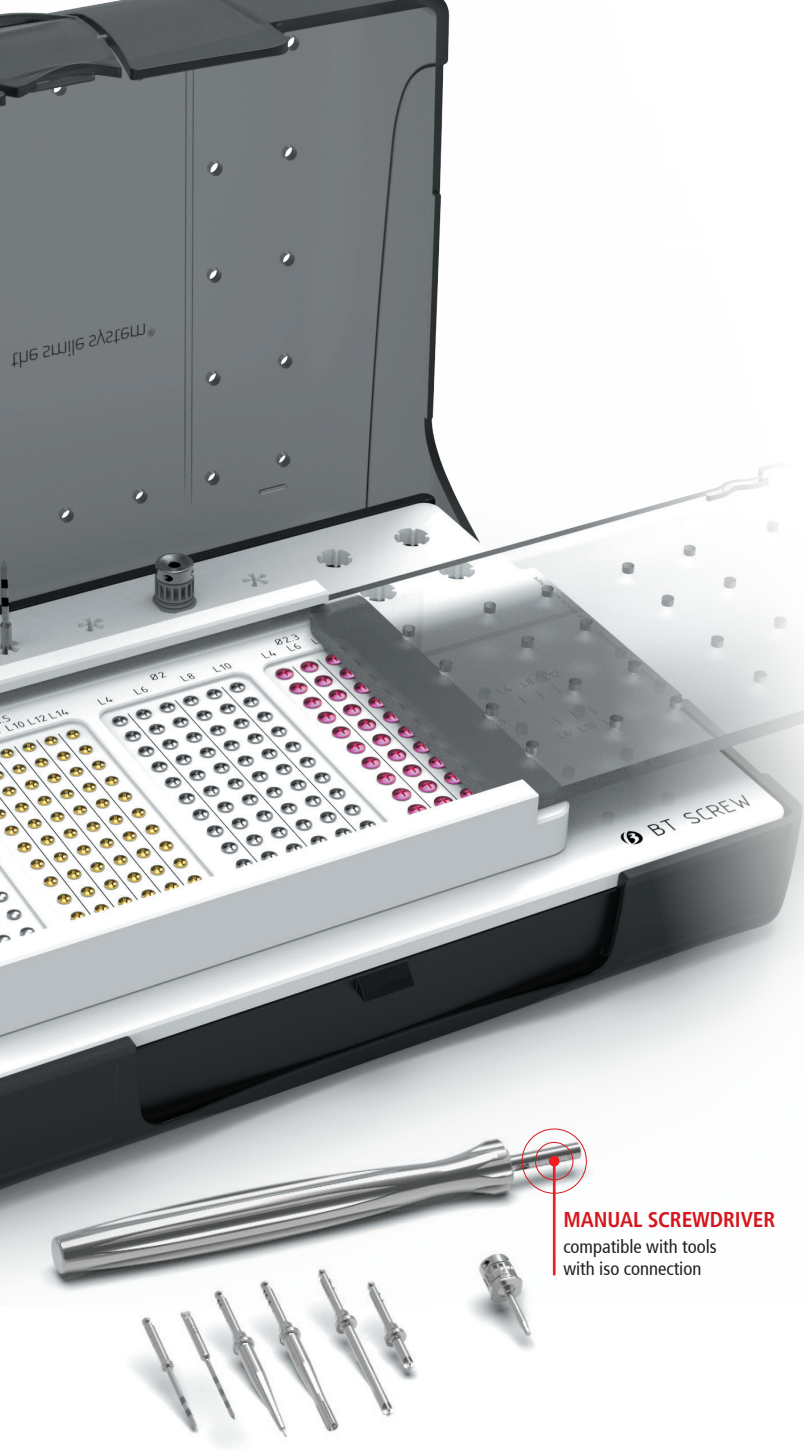
3 SCREW Ø 2.0
L= 4, 6, 8 e 10 mm

4 SCREW Ø 2.3
L= 4, 6, e 8 mm

CROSS-HEADED SCREWS
the screw are designed for use with a cross-headed screwdriver

5 1:1 SCALE SKETCH
Ruler for checking the dimensions of the screws and the drill

visit **btk.dental**



MANUAL SCREWDRIVER
compatible with tools
with iso connection

INSTRUMENTS INCLUDED IN THE KIT

DRILLING TOOL FOR PINS		
	Ø0.5mm L49mm	415HR050
LANCE DRILLS		
	Ø1mm L33.5mm	415HL100
	Ø1mm L29.5mm	415HS100
	Ø1.5mm L29.5mm	415HS150
INSERTION DEVICE FOR PINS		
	L49mm	530HS020
HANDPIECE DRIVER		
	CR0.41 L29mm	530HS021
	CR0.41 L49mm	530HL004
MANUAL SCREWDRIVER		
	L140 mm	520MA002
SCREWDRIVER JD		
	HEX1.20 L15mm	530JD005

OPTIONAL INSTRUMENTS

TORQUE WRENCH JD		
	Reversible 90 Ncm	501JD003
SCREWDRIVER JD		
	HEX0.90 L15mm	530JD012
DRILL EXTENSION HS		
	L28 mm	520HS004
SURGICAL RETRACTOR		
	70x16mm / 50x12mm	502MA008
ADAPTER CONNECTION		
	ISO/HEX3.10-JD L10mm	530JD033

SCREW PORTFOLIO

PIN AND CORTICAL SCREW AVAILABLE WITH THE KIT BT SCREW

	Ø0.65mm L2mm	10 pcs	167NA65A.10
	Ø1.2mm L4mm CR0.41	5 pcs	167NA12C.05*
	Ø1.2mm L6mm CR0.41	5 pcs	167NA12G.05*
	Ø1.2mm L8mm CR0.41	5 pcs	167NA12J.05*
	Ø1.2mm L10mm CR0.41	5 pcs	167NA12L.05*
	Ø1.2mm L12mm CR0.41	5 pcs	167NA12N.05*
	Ø1.2mm L14mm CR0.41	5 pcs	167NA12Q.05*
	Ø1.5mm L4mm CR0.41	5 pcs	167NA15C.05
	Ø1.5mm L6mm CR0.41	5 pcs	167NA15G.05
	Ø1.5mm L8mm CR0.41	5 pcs	167NA15J.05
	Ø1.5mm L10mm CR0.41	5 pcs	167NA15L.05
	Ø1.5mm L12mm CR0.41	5 pcs	167NA15N.05
	Ø1.5mm L14mm CR0.41	5 pcs	167NA15Q.05
	Ø2mm L4mm CR0.41	5 pcs	167NA20C.05
	Ø2mm L6mm CR0.41	5 pcs	167NA20G.05
	Ø2mm L8mm CR0.41	5 pcs	167NA20J.05
	Ø2mm L10mm CR0.41	5 pcs	167NA20L.05
	Ø2.3mm L4mm CR0.41	5 pcs	167NA23C.05
	Ø2.3mm L6mm CR0.41	5 pcs	167NA23G.05
	Ø2.3mm L8mm CR0.41	5 pcs	167NA23J.05

NOTE

The pins and fixation screws can be ordered separately in packs of 10pcs and 5pcs respectively (the codes are indicated in the table). The fixation screws are also available, upon request, with surface treated by double etching (codes 168NA ..). For more information, contact your BTK'S Distributor.

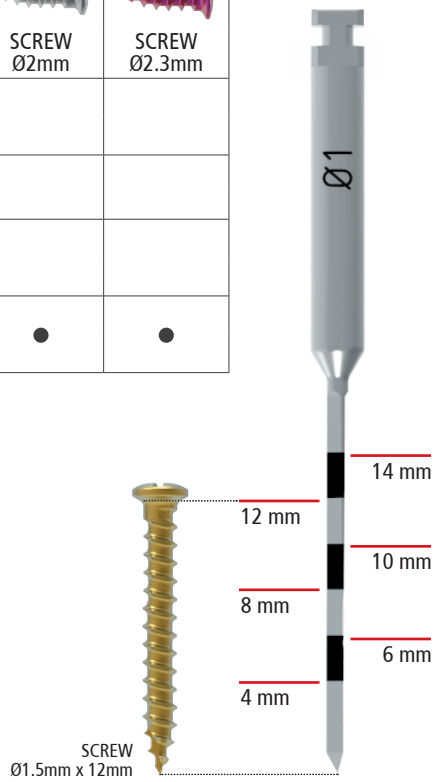
* SCREWS NOT INCLUDED IN THE KIT

SURGICAL PROCEDURE

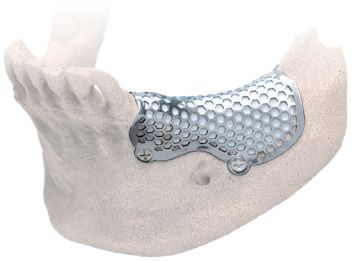
DRILLS	PIN / SCREW				
	PIN Ø0.65mm	SCREW Ø1.2mm	SCREW Ø1.5mm	SCREW Ø2mm	SCREW Ø2.3mm
Drilling Tool for Pins Ø0.5 L49mm 415HR050	●				
Lance Drill HR Ø1 L33.5mm 415HL100		●	●		
Lance Drill HS Ø1 L29.5mm 415HS100		●	●		
Lance Drill HS Ø1.5 L29.5mm 415HS150				●	●

In order to achieve a successful fixation of the screw within the bone site, a precise and low-trauma surgical technique is required. BTK suggests to prepare the fixation site using the adequate lance drills combined with a proper drilling process (suggested speed 800 rpm). The direction and depth of the drill preparation must be carefully and clinically evaluated.Following the procedure indicated in the table, the screws are inserted at a maximum value of 25Ncm.

In cases of insertion of L4mm screws or insertion in D3 and D4 density bone, the surgeon must take care during the final tightening, because there is a risk that, due to the few threads engaged or the inconsistent bone density, the site will be damaged. For this reason, the screw must be tightened until the contact point between the under-head of the screw and the medical device, without an over tightening of the screw. The indicated lengths of the screws correspond to the threaded part (excluding the head size which is 0.9mm).



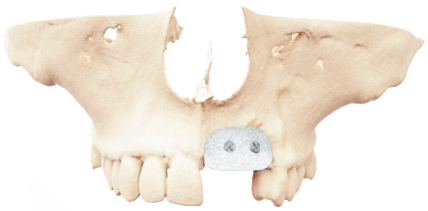
INDICATIONS OF USE: APPLICATION EXAMPLES



GUIDED BONE REGENERATION (GBR) 3D-MESH

The 3D-MESH bone regeneration mesh is an implantable medical device made to measure for each single patient. It is made of biomedical titanium using the innovative Selective Laser Melting technology.

3D-MESH is developed based on the dentist's plan and it is made in compliance with the specific treatment needs of each individual patient.



3D-BONE CUSTOMIZED BONE GRAFTS

The "3D-BONE" service offers clinicians an innovative, synthetic bone grafts made to measure, modelled with utmost precision based on the patient's bone defect. Based on the patient's CBCT, the bone graft is produced using CAD-CAM technology. It can be used for small and medium sized bone reconstructions and to prepare the site for receiving one or several dental implants needed to replace missing teeth.

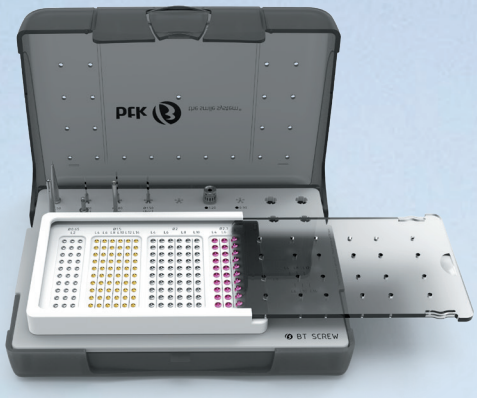
IUXTA-3D SUB-PERIOSTEAL IMPLANTS

The IUXTA-3D service allows to solve cases of extreme atrophy of the upper and lower jaw when the bone is not sufficient for conventional endosseous titanium implants. The juxta-osseous implant is designed based on the patient's examination, it is customized following the patient's anatomical features and prosthetic needs and it is made of biocompatible, certified titanium.

IMPLANTABLE DEVICES FOR CRANIO-MAXILLO-FACIAL SURGERY

BTK can produce implantable medical devices for patients who need advanced surgical rehabilitation.

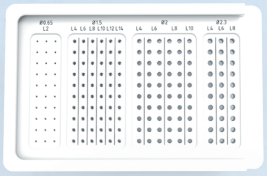
These devices are developed following the request of practitioner, based on the examination and needs of individual patients. They are made of biomedical titanium and are prepared by means of a a verified and traced production process.



Complete Kit BT-SCREW

(with tools and full screw-rack)

Cod. 667NA001

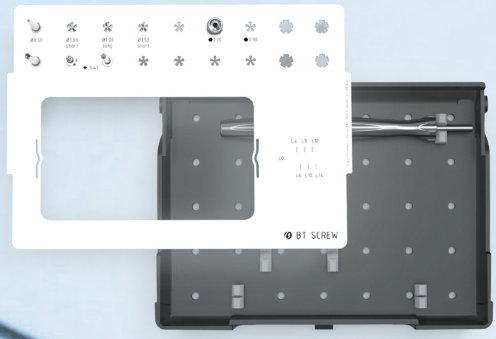


Empty Screw-Rack

Cod. 667NA002

Compact Screw-Rack

Cod. 667NA003



Kit BT-SCREW

without screw-rack, with tools

Cod. 667NA004

SURGICAL KIT
BT SCREW

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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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FOLLOW US ON

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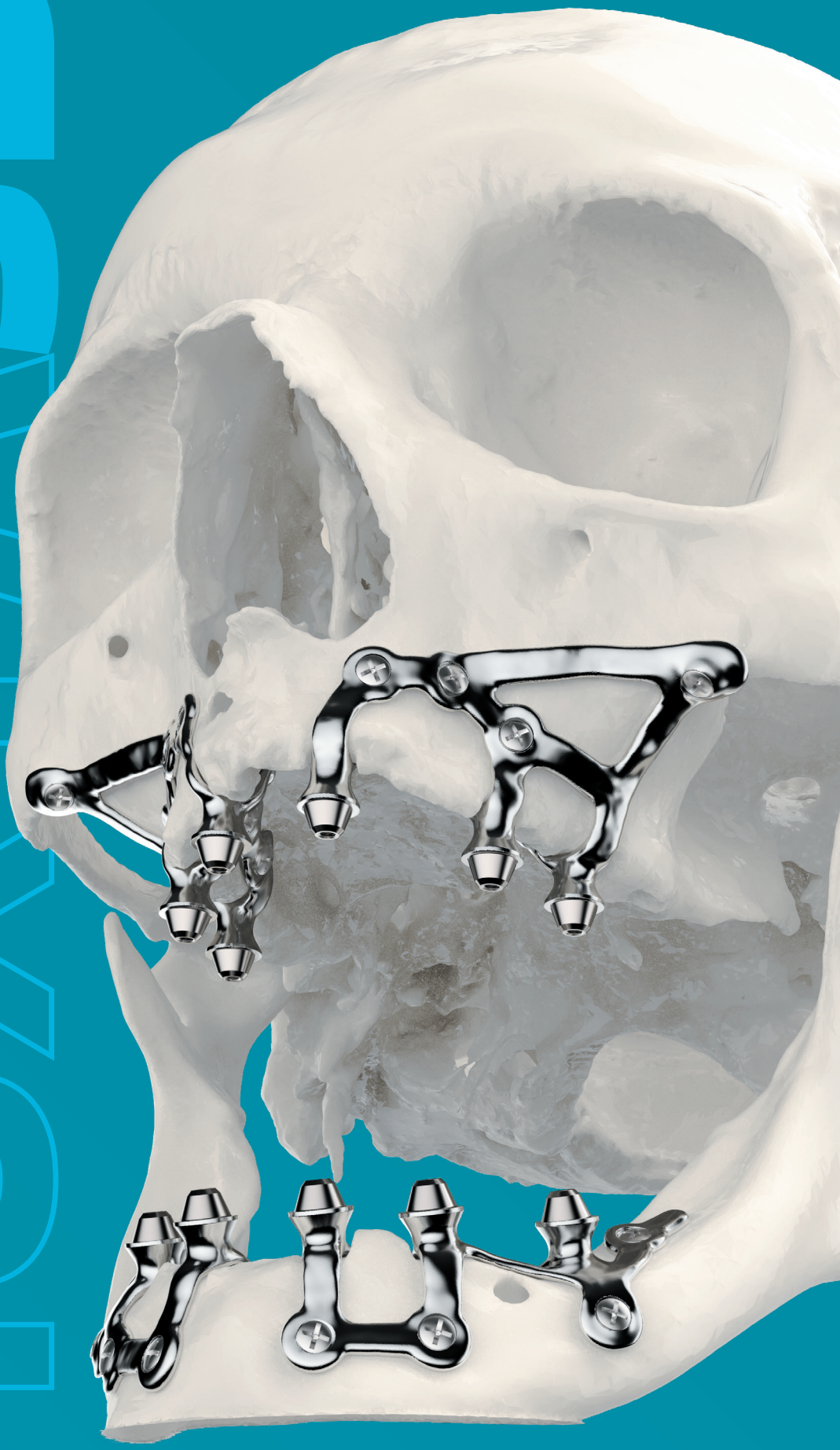
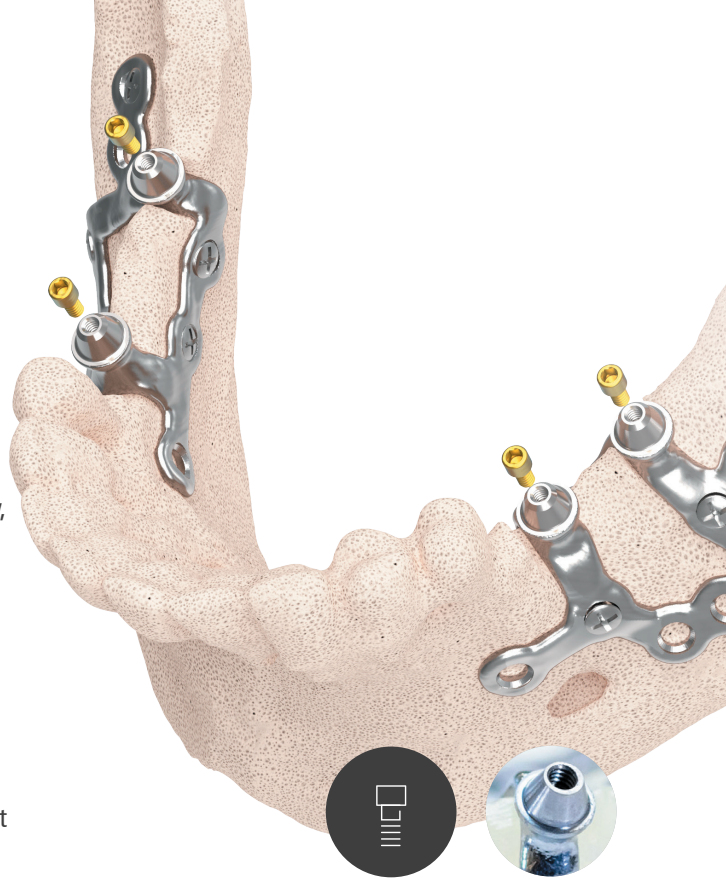
JUXTA 3D

3D PRINTED DENTAL IMPLANTS



DIGITAL DENTISTRY
CUSTOM-MADE MEDICAL DEVICES

IUXTA-3D



IUXTA-3D subperiosteal implant represents a real innovation in the solutions for maxilla and mandibolar severe atrophy. Through a totally digital workflow, starting with the patient's exams, specialist can perform an accurate project, custom made for the individual needs of the patient.

Thanks to over 20 years of experience in dental implants, and to many documented clinical cases, we update IUXTA-3D subperiosteal implants: **from now they are offered for screw-retained protocol, allowing to obtain appropriate and reliable prosthetic solutions.**

A revolution in iuxta-osseous medical devices, that takes full advantage on the quality and precision of digital methods, by supporting them with the best manufacturing technology.

It is possibile to perform any kind of rehabilitations: from small edentulism to full arches, for mandibular or maxilla.

Innovative features of IUXTA-3D:

- **DEDICATED TECHNICAL ASSISTANCE**
  Dedicated report for each case from the planning to the surgery.
- **100% DIGITAL WORKFLOW**
  Customized on each patient.
- **REPORT CUSTOMIZED FOR EVERY CASE**
  With 3D previews of the project and a detailed analysis of the implant and screws in relation to critical anatomical structures.
- **IN TITANIUM FOR MEDICAL USE**
  To guarantee the highest standards of biocompatibility and mechanical resistance.
- **HIGH CONTACT SURFACE**
  Optimized by FEM studies on strenghts analisys.
- **DESIGN-SHAPED SCREW HOLES**
  To ensure the best precision and facilitate surgery.
- **SCREW RETAINED PROSTHESYS**
  To ensure accuracy and oral hygiene.
- **WIDE RANGE OF PROSTHETIC COMPONENTS**
  To meet all restoration requirements.
- **IMMEDIATE LOADING PROSTHESYS**
  Manufactured and supplied before the surgery.

The IUXTA-3D implant is supplied with a 3D PRINTED RESIN REPLICA of the device and with the patient's BONE MODEL.

If clinician wants to perform bone modeling during surgery, BTK can provide a SURGICAL GUIDE, to drive the ostectomies.

The BTK Milling Center can also manufacture and deliver the temporary restoration for immediate loading for a fully-digital workflow. Otherwise BTK can provide the tecnician the matherials for the costruction of the temporary restoration.

PROSTHETIC COMPONENTS FOR IUXTA-3D

Iuxta-osseous implants, with **two or more abutments**, have one dedicated connection, called "BS". It is a M.U.A. with a larger dedicated screw than to standard M.U.A. components.
The following table lists all the BS prosthetics, dedicated to Iuxta implants with two or more abutments.
Only in the case of the Iuxta-osseous implant with **a single abutment**, the connection is with external hexagon ER: refer to the manual of implants with external connection for the choice of the ER prosthetic.

	**COVERING CAPS BS** H5.7 with screw Kit 4pcs	330BS0A0.04
	**BASE BT LINK BS** H1mm Ø4.8mm No Cap. Rot with screw	247BS1A1
	**TEMPORARY ABUTMENT BS** Rotating with screw	210BS1R0
	**TRANSFER PROPICK-UP BS** Hutile18.5mm Rot. Long Screw	323BS0R0
	**IMPRESSION POST PICK-UP SCREW** M2 Hex1.20 H18.2mm	690NA308
	**IMPLANT REPLICA BS** Rotating	301BS0R0
	**SCAN ABUTMENT INTRA-ORAL BS** Rotating	352BS1A1
	**SCAN ABUTMENT EXTRA-ORAL BS** Rotating	351BS1A1
	**BT LINK BS** H1mm Ø4.8mm Rotating	246BS1A1
	**CoCr ABUTMENT BS** H1.5mm Rotating	240BS1R0
	**CASTABLE PLASTIC ABUTMENT BS** Rotating	205BS0R0
	**RETENTIVE SCREW** M2 Hex1.20 for standard prosthetics	690NA307
	**RETENTIVE FLAT HEAD SCREW** M2 Hex1.20 H5.2mm Tp for BT LINK (CAD CAM prosthesis)	690NA306

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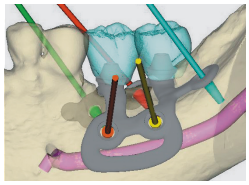
DIGITAL WORKFLOW
IUXTA-3D

CONE BEAM CT AND PRODUCTION OF A 3D VIRTUAL BONE MODEL

The process starts with the acquisition of the patient's tomographic imaging and of a DICOM file. During the examination, the patient must wear a **dedicated radiological guide. The DICOM file is sent by the clinician to the BTK TEAM**. The BTK TEAM checks the feasibility of the case and starts the design phase.

Immediate uploading of the DICOM file of the patient's tomography

http://upload.btk.dental/btk3d



DIGITAL PROCESSING OF THE IUXTA-3D STRUCTURE

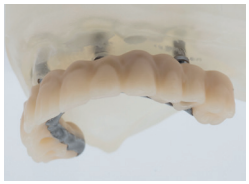
IUXTA-3D is virtually modelled on the anatomy of the patient by the BTK specialists, using a dedicated software.
The layout of the device is designed to bear the prosthetic load while guaranteeing the best passive fit. Abutment and screw positions are carefully evaluated on the bases of the prosthetic restoration and in compliance with soft and hard tissues management. The final project is then shared with the Prescribing Doctor, who can make changes and who confirms it before production takes place.

TITANIUM LASER MELTING - 3D PRINTING

After receiving the doctor's prescription, BTK produces the device by means of "Selective Laser Melting" technique. Homogeneous layers of highly pure titanium powder are melted using a laser in a selective way, based on the 3D virtual model. Then BTK milling centre finalizes the device screw-reatined abutments through a five-axis machine, ensuring the maximum mechanincal precision. The final object meets **high purity and microstructural homogeneity standards** that guarantee high mechanical performance.

CLEANING, DECONTAMINATION, PACKAGING AND SHIPPING

The IUXTA-3D implant is decontaminated in an automatic ultrasonic machine, it is packaged in a cleanroom under controlled atmosphere and delivered ready for sterilization in the clinician's office. All BTK production cycles are controlled and registered so as to guarantee the traceability of the product, in compliance with the most restrictive standards in the Doctor's practice.



TEMPORARY RESTORATION

If required BTK Milling Centre can produce temporary restoration for immediate loading.
Built according to the needs of patient and clinician, it can be used even immediately after surgery.

SURGERY AND SURGICAL APPLICATION

The surgery is performed under local anaesthesia or conscious sedation by qualified doctors.

BT SCREW SURGICAL KIT

Cortical screws kit for advanced surgery.

Ref. kit 667NA001

3D PRINTED
DENTAL IMPLANTS
IUXTA 3D

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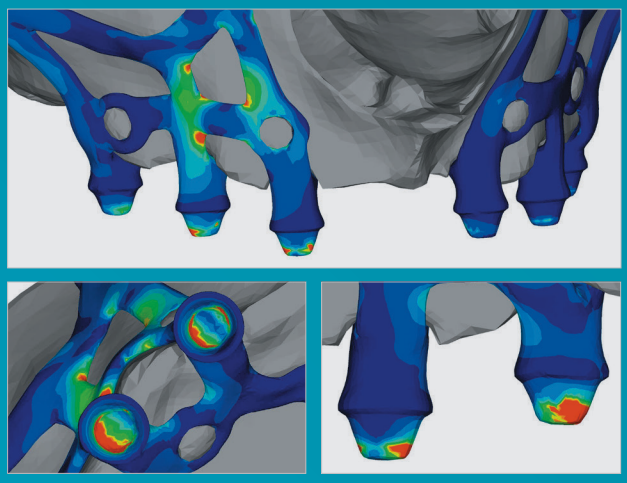
FEM ANALYSIS

FEM analysis is a tool that allows to analyze the three-dimensional model of the medical device by predicting its behavior once subjected to the chewing load. It is therefore possible to optimize the device by studying the best points of support, anchoring and the best morphology to ensure the success of the rehabilitation.



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BTK ACADEMY

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

Scan the QR CODE to find out the next BTK courses.

CERTIFIED QUALITY SYSTEM

Certified quality system
UNI EN ISO 9001 and UNI EN ISO 13485.

CE

CE marked product, in accordance with the directive 93/42/CEE and regulation (UE) 2017/745.

Biotec company is recorded on the Register of medical devices manufactures according to the Health Ministry regulation.

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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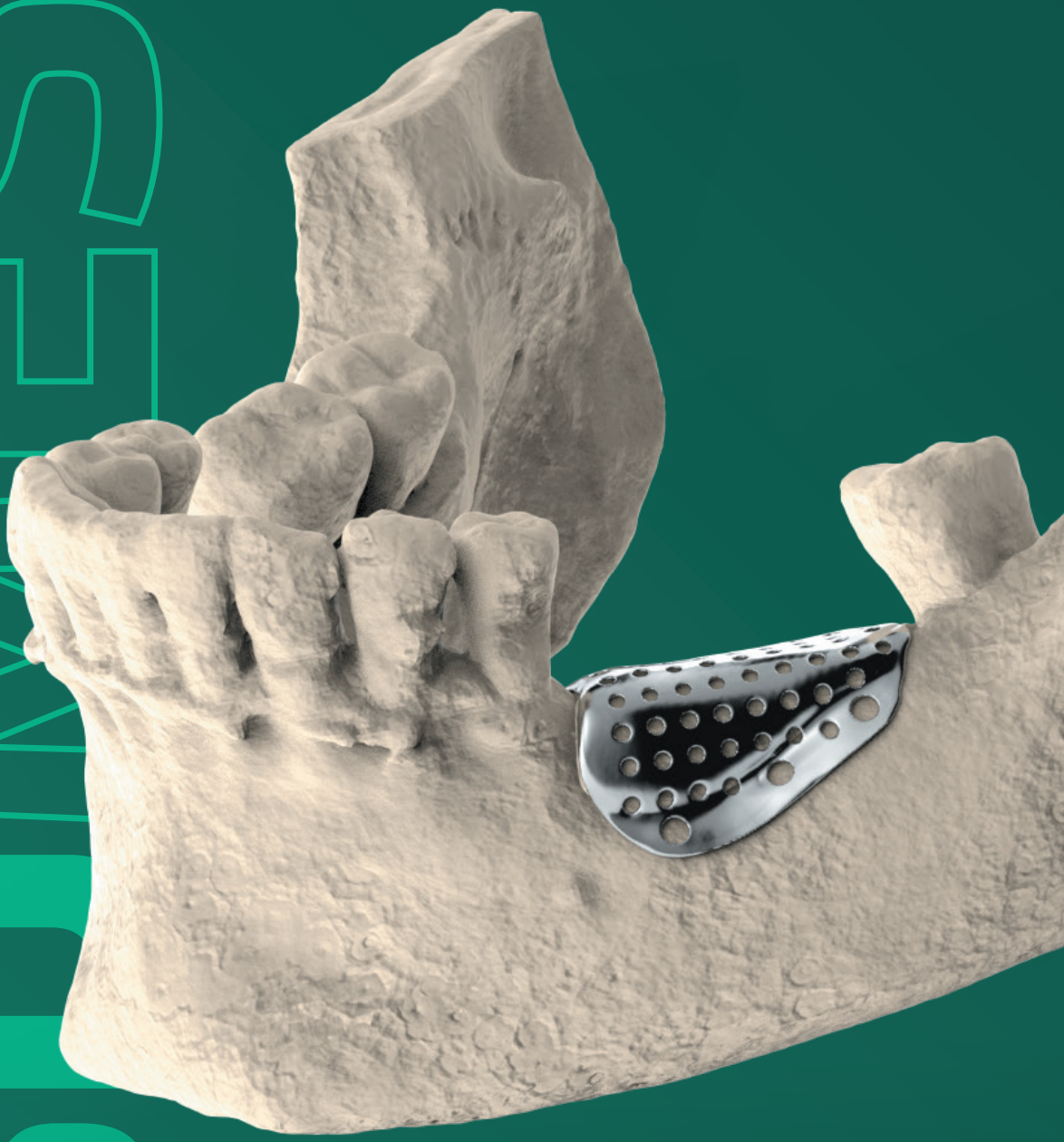
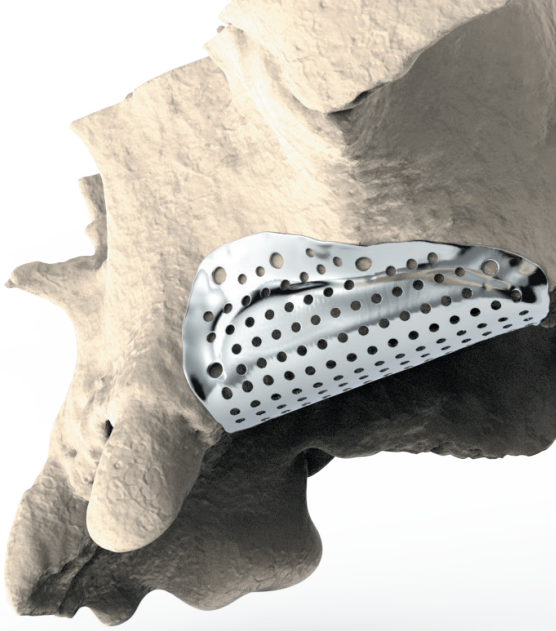
3D MESH

SOLUTIONS FOR GUIDED BONE REGENERATION



SOLUTIONS FOR GUIDED
BONE REGENERATION
3D MESH



GBR MESHES
3D MESH

It allows the biomaterial to adapt perfectly to the patient's bone anatomy and reduces the duration of surgery, thereby enhancing the success of bone regeneration.

The 3D MESH bone regeneration mesh is an implantable medical device made to measure for each single patient, in compliance with Directive 93/42/EEC and its subsequent amendments and integrations.

It is used by dentists in GBR procedures and it is applied where there is the need to make up for the lack of autologous bone of edentulous patients.

The specific purpose of the GBR mesh is to keep the regeneration material inside the bone defect cavity identified by the clinician and to guide the remodelling process according to specifically defined morphology and volume parameters. Furthermore, the device permits to keep the bone tissue separate from the soft tissue, thereby protecting the inserted biomaterial and favouring bone regeneration.

3D MESH is developed based on the clinician's plan and it is made in compliance with the specific treatment needs of each individual patient.

INNOVATIVE FEATURES OF 3D MESH

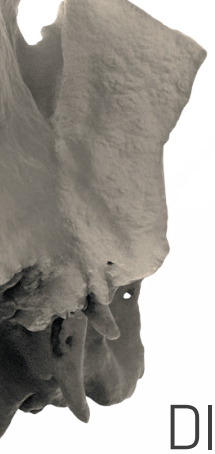
- DEDICATED TECHNICAL ASSISTANCE
  from planning to surgical intervention.
- 100% DIGITAL WORKFLOW
  customized for each patient.
- CUSTOMIZED REPORT FOR EACH CASE
  with three-dimensional project previews and a detailed analysis of the grid and screws in relation to critical anatomical structures.
- MEDICAL TITANIUM WITH 3D PRINTING
  to ensure maximum biocompatibility and strength.
- SHAPED SCREW HOLES
  to guarantee maximum precision and facilitate surgery.
- OPEN/CLOSED MESH
- THIN, RESISTANT, FLEXIBLE
- HIGH CAD-CAM PRECISION

PICTURE	TYPOLOGY	DIMENSION	CODE
	**SMALL**	**20x20x25 mm** (for small reconstructions)	C32TL10.00
	**MEDIUM**	**30x30x25 mm** (for medium reconstructions)	C32TL20.00
	**LARGE**	**60x30x25 mm** (for big reconstructions)	C32TL30.00

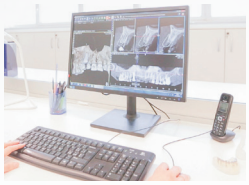
AVAILABLE WITH OPEN OR CLOSED WEAVE

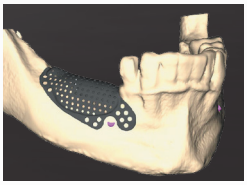
On request, the BONE MODEL and a COPY OF THE MESH in resin can also be product, by means of 3D printing.

visit **btk.dental**



DIGITAL WORKFLOW
3D MESH



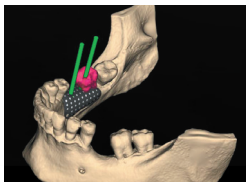


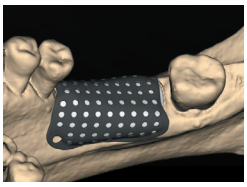
CONE BEAM CT AND PRODUCTION OF A 3D VIRTUAL BONE MODEL

The fundamental requirement is a Cone Beam CT of the jaw, with a special focus on the area with the defect. The process starts with the acquisition of the patient's tomographic examination. **The DICOM file is sent by the clinician to the BTK TEAM using the Web, for the beginning of the design phase.**

Immediately upload the DICOM file
of the patient's Tomographic examination.

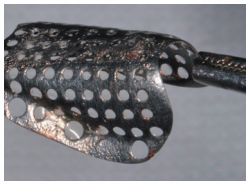
http://upload.btk.dental/btk3d

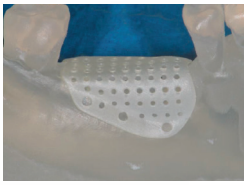




DIGITAL PROCESSING OF THE 3D-MESH STRUCTURE

Based on the patient's situation, the device is designed using the CAD modelling software within the framework of a fully digitalized work flow.
The morphological and dimensional features of the device and the position of the holes for the cortical screws **are specifically designed so as to fit the patient's anatomy, while preserving the noble structures.**
The outcome of the 3D MESH structure is shared with the prescribing dentist, who can make changes and who confirms it before production takes place.





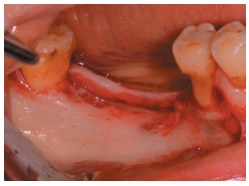
TITANIUM LASER MELTING - 3D PRINTING

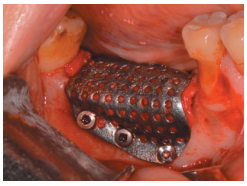
After receiving the dentist's prescription, BTK produces the component by means of the "Selective Laser Melting" technique. Homogeneous layers of highly pure titanium powder are molten using a laser in a selective way, based on the virtual 3D model. The final object meets **high purity and microstructural homogeneity standards** that guarantee high mechanical performance.

On request, it is also possible to deliver the bone model and a copy in resin of the regeneration mesh made by means of 3D printing.

CLEANING, DECONTAMINATION, PACKAGING AND SHIPPING

After the surface is electro-polished, the product is decontaminated and packaged, ready for sterilization in the clinician's office. All BTK production cycles are controlled and registered so as to **guarantee the traceability of the product, in compliance with the most restrictive standards of reference.**





SURGERY AND SURGICAL APPLICATION

The surgery is performed under local anaesthesia or conscious sedation. The device must remain in situ for the time established by the clinician, in function of the patient's clinical situation, to guarantee correct bone regeneration. After this time period, the device must be surgically removed and then the placement of dental implants is considered, provided that the right clinical conditions are met.

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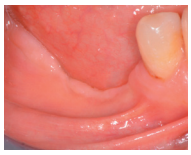
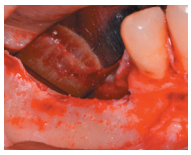
SURGICAL INDICATIONS

Titanium meshes are used in GBR procedures to favour the regeneration of bone volumes. They are usually associated with the usage of chips of autologous or heterologous bone or synthetic biomaterial. The assessment of the type of defect and suitable surgical skills in managing soft tissues are fundamental elements in achieving successful surgery.

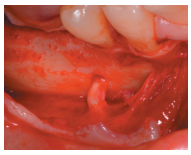
INSERTION SEQUENCE



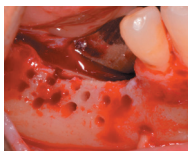
1 Anaesthesia and preparation of the surgical field.



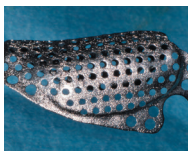
2 Incision of tissues.



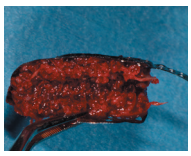
3 Raising of the flap and skeletisation.



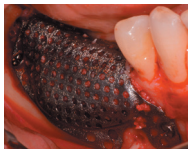
4 Preparation of the recipient bed and possible harvesting of autologous bone.



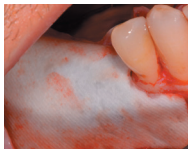
5 The sterilised mesh is taken out of the package.



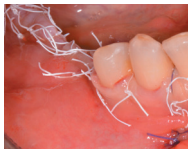
6 Use of biomaterial.



7 Placement of the mesh and insertion of the cortical screws.



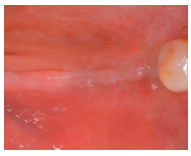
8 Covering of the mesh with resorbable membrane (recommended procedure).



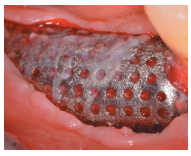
9 Suture of surgical flaps.

Photo: Courtesy by dr.Alessandro Cucchi

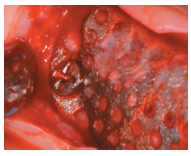
REMOVAL SEQUENCE



1 Anaesthesia and preparation of the surgical field.

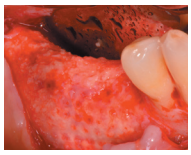


2 Incision of tissues and uncovering of the mesh.

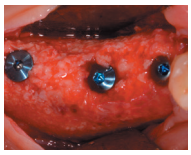


3 Removal of fixation screws using the dedicated drivers.

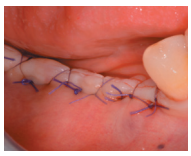
4 Removal of the bone regeneration mesh.



5 Checking of the state of regeneration.



6 Possibly, implant techniques chosen by the surgeon.



7 Suture of the surgical flaps.

Photo: Courtesy by dr.Alessandro Cucchi

SURGICAL KIT BT SCREW

Advanced surgery pin and cortical screw kit.

Kit Ref. 667NA001

SOLUTIONS FOR GUIDED
BONE REGENERATION
3D MESH

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TITANIUM MESHES FOR BONE REGENERATION

The future of guided bone regeneration in the digital era.

3D MESH is an innovative customized titanium mesh.

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3D MESH is printed in TITANIUM using SELECTIVE LASER MELTING technology, thereby guaranteeing top quality, performance and precision.

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