

Implanting Trust, Smile Again!

# ISV+-



+ SIMPLE + STABLE + SMART

#### **IMPORTANT NOTE**

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

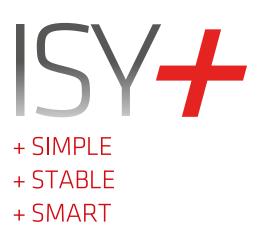
This manual provides dental practitioners and related specialists with general information regarding the use of ISY + dental implant systems.

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

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

© 2020 BTK - the smile system.





# INDEX

1.	CORPORATE BACKGROUND	4
2.	ISY + IMPLANT	6
3.	IMPLANT PORTFOLIO	10
4.	IMPLANT INSERTION PROCEDURE	11
5.	KIT, DRILLS AND TORQUE WRENCH	13
6.	SURGICAL PROTOCOL	20
7.	ADDITIONAL INSTRUMENTS	22
8.	PROSTHETIC	24
9.	OVERDENTURE	28
10.	TERMINI & CONDIZIONI DI CONSEGNA	30

# 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-6AI-4V, is widely used in orthopedics and shows excellent long-term physical and mechanical properties.



#### ENDOSSEOUS SURFACE DAE

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

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



#### IMPLANT-ABUTMENT CONNECTION

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

Apart from that, extremely tight tolerances as applied by BTK help to avoid micromovements.

Providing precision in every part produced is one of our key contributions ensuring longterm restorative success.



#### RESTORATIVE OPTIONS

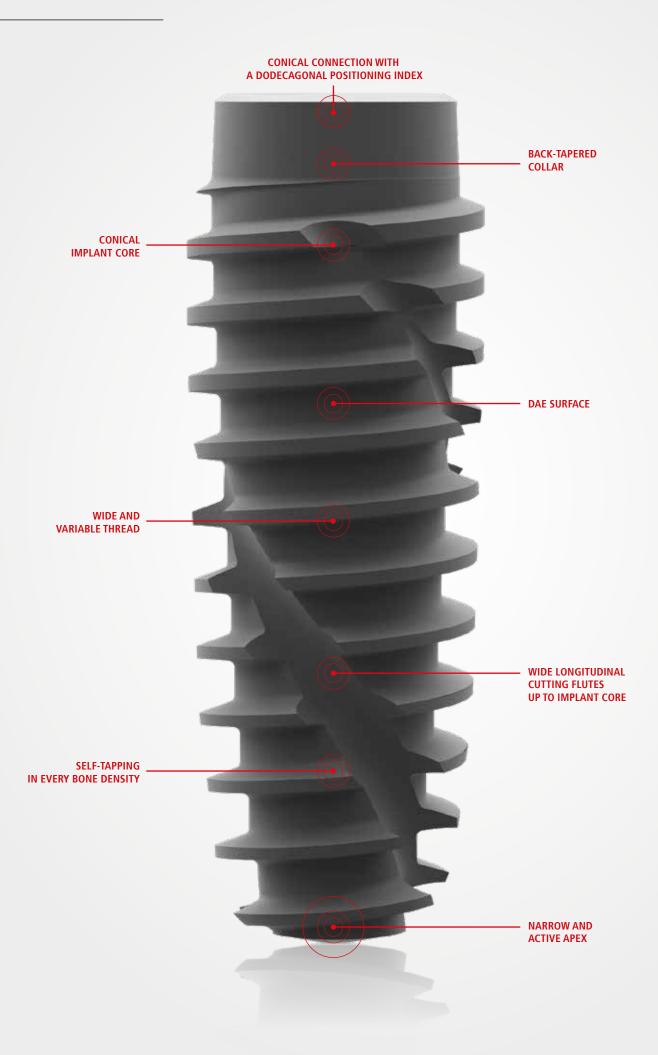
The purpose of dental implant therapy, now widely used in dentistry, is to replace lost dental elements with biocompatible titanium implants, in order to obtain a new and correct occlusion, using prostheses on implants.

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

# CE MADE IN ITALY, USED GLOBALLY

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

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



# CHARACTERISTICS OF ISY + IMPLANT

The ISY + implant is suitable for endosseous implant treatment in the upper and lower jaw and for functional and aesthetic rehabilitation of patients completely or partially edentulous.

ISY + dental Implant is made of commercially pure, cold-worked titanium Grade 4 and features a DAE (dual acid-etched) surface treatment.

ISY + is a bone-level implant, which replicates the natural tooth root and it has excellent self-tapping features.

The ISY + implant is highly versatile thanks to its particular morphology, and obtains excellent results in terms of ease of insertion and primary stability in any bone quality, ranging from cortical bone to the very soft one.

It is particularly suitable for early or immediate positioning after extraction or loss of natural teeth and for implant sites with newly formed bone.

The unique configuration of the threads profile offers, together with the morphology of the implant core and its surgical procedure, in addition to an excellent primary stability, a great BIC (Bone-to-Implant-Contact) value, thus making ISY + the ideal implant for immediate loading procedures in post-extraction implant sites or in area with newly formed bone.

Here are all the detailed features of the ISY + implant:

• **ISY + is a "full-treated" implant:** the DAE (dual acid-etched) surface treatment is made along the total length of the implant, except for the cortical bevel of connection between the implant platform and the junction with the prosthetic component, ranging from 0.1 mm to 0.72 mm in the 6 mm diameter implant.

This unique quality is typical of a sub-crestal positioning of the implant shoulder, which allows to maintain a considerable flexibility in the positioning protocol, submerging the implant in case of postextraction sites, or choosing a crestal positioning if the tissue biotype of the patient allows for it. In the cases of irregular bone crests, the sub-crestal positioning is definitely the best choice.

• The implant neck shows a back- tapering, with a fixed degree for all implant diameters, which is spread over a length of 1.25 mm, also stable for all the diameters.

This enables a reduction of load transfer in the cortical area during the insertion, avoiding the compression of the cortical bone itself and, as a primary consequence, the maintenance of bone and tissue levels over time, for a predictable and long lasting aesthetic result for the patient.

Considering a suggested subcrestal positioning protocol of about 1 mm, the area of cortical decompression increases to about 2.5mm, widely enough even in the case of very thick cortical bone. Micro-grooves are not present in the cortical area.

• The implant body has a controlled tapering, which gradually increases in the apical portion until converging to the dimensions of the coronal area: this feature, together with the validated surgical protocol, brings to excellent results in primary stability values, with a controlled insertion torque curve starting from the apical third.

• The implant apex has cutting edges and a narrow tip: the tight invitation site allows, especially in the case of high quality bone, to adapt the preparation to make it more fitting to the conical design of the implant core (step back preparation).

The cutting apex gives strong self-tapping properties on the implant itself, allowing effective progress also in the underprepared implant site in diameter, avoiding the phenomenon of spinning especially in poor quality bone.

#### • The thread, with variable depth and wide distance from the implant core:

It is characterized by the presence of deep longitudinal grooves (2 up to  $\emptyset$  4.1 implant, 3 in the larger diameters) which grants strong penetration features to the thread itself in the patient's bone, contributing positively to increase the primary stability and avoiding the risk of unfastening of the implant, especially in situations of low bone density.

• The single-lead thread with an optimized pitch according to the implant diameter: it allows a gradual insertion of the implant, with torque values that grow steadily, but which are already significant starting from the apical third.

• MORSE-TAPER implant-abutment connection, with a conical portion at 11°, with a dodecagon configuration, which performs the function of prosthetic index, especially for single restorations: compared to the connection with an hexagonal positioning index, it allows to achieve better performance of mechanical resistance, especially during implant insertion; moreover, it offers a greater flexibility for the prosthetic rehabilitation, useful in cases of single elements with tilted implants (typically in the frontal areas); it guarantees full compatibility with other implant systems already in the market and therefore a full accessibility with the most common cad-cam systems available.

• The prosthetic platform is unique and common to all ISY + implants, with diameter of : 3,3, 3,7, 4,1, 4,8 mm.

• Prosthetic components with KR connection (with the regular positioning hexagon). The doctor who already uses the BT SAFE system has the possibility to expand his surgical choice possibilities by using prosthetic components that he already knows and appreciates for the precision of mechanical coupling and for the wide choice of prosthetic techniques, as the DR connection with the positioning dodecagon is perfectly compatible for the entire range of prosthetic components with the KR connection.

• Same surgical kit of BT SAFE-ISY KONE-NANO implant system: to ensure greater cleanliness

and economy, while maintaining an extremely compact and versatile instrumentation.

BTK offers a focused portfolio of restorative solutions backed-up by comprehensive clinical experience, with a variety of medical devices that satisfy the clinical preferences and the needs of the patients. Moreover, thanks to the use of the most modern digital technologies, BTK designs and manufactures customized products, planned on the bone morphology of each individual patient. For the planning of the clinical case, BTK offers "3D Pilot" (the Btk guided surgery system), with a complete digital workflow and the realization of the correspondent surgical guide.

# MECHANICAL PERFORMANCE

The development of the product design has been accompanied by FEM (Finite Element Method) analysis, in-depth mechanical tests and fatigue strength tests conducted by accredited laboratories and in compliance to ISO 14801.

Mechanical risks play an important role in implantology, since they can increase the likelihood of cases failure, resulting in waste of time and waste of financial resources for both clinician and patient.

During the planning phase of the treatment, particular attention must be paid to avoid potential conditions of excessive load in both implants and prosthetic components, such as:

- Inadequate number of implants Parafunctions of the patient
- Inadequate implants length and /or implants diameter
- Excessive length of lever arms
- Incorrect positioning of the prosthesis

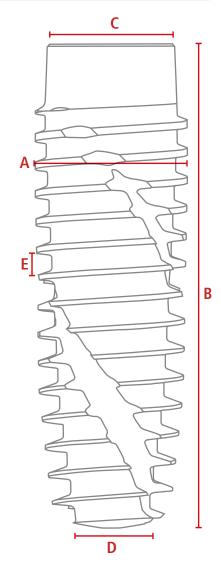
- Inadequate procedures during the prosthesis preparation
- Inadequate adaptation of the prosthesis
- Trauma resulting from accidents or from the patient's habits
- Occlusal interferences with excessive lateral forces

As a general rule, the implant with the largest possible diameter must be always used. Due to the reduced mechanical stability, implant with small diameter (<3.7 mm) should be used only in cases where low mechanical load is expected.

# IMPLANT PORTFOLIO ISY +

MORSE TAPER DODECAGON REGULAR (DR) C	implant length in mm B								
	⊘mm A	6	8	10	12	14	16	APEX Ø / mm D	THREAD PITCH mm E
	3,3		132DR33J	132DR33L	132DR33N	132DR33Q		1,4	0,9
(arte	3,7		132DR37J	132DR37L	132DR37N	132DR37Q	132DR37S	1,7	0,95
	4,1	132DR41G	132DR41J	132DR41L	132DR41N	132DR41Q	132DR41S	1,9	0,95
	4,8	132DR48G	132DR48J	132DR48L	132DR48N	132DR48Q		2,2	1
	6,0	132DR60G	132DR60J	132DR60L				2,3	1

Occlusal thread M1.6 Prosthetic platform Ø 2,8 mm FULL DAE Surface



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

PURPLE WHITE BLUE YELLOW GREEN IMPLANT DIAMETER 3,3 3,7 4,1 4,8 6,0

# HANDLING OF STERILE

#### CAUTION

The sealed package of the medical device (MD) must be opened in a surgically suitable environment.

The removal of the implant and of the cover screw, if provided, must be carried out using sterilized instruments, avoiding any contact with non-sterile surfaces.

The sterility of the medical device is only guaranteed if the following conditions are met:

the expiry date stated on the packaging is still valid; there is a red dot on the sterile vial that signals the successful operation of gamma ray irradiation; the sealed package has not been opened and does not show damage or perforations. If only one of the aforementioned conditions is not respected, the device must not be used.

The device is disposable; the reuse can compromise the safety features of the device making it inappropriate for its intended use. BIOTEC explicitly declares that the MD is for single use and assumes no responsibility for any re-use by users.



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.



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



3

6

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.



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.



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.

The BTK dental implants can be positioned manually with the Reversible Torque Wrench or they can be inserted using the contraangle handpiece. A range of 15 - 25 rpm is recommended for implant insertion and not to exceed the maximum torque indicated by BTK.

# IMPLANT INSERTION



The implant does not require tapping (neither partial nor complete), therefore you can proceed directly to the implant insertion after preparing, using the dedicated surgical drills for the ISY + implant line.

The narrow and active apex allows a simple entry in the implant site.

Check that the implant is placed at the desired depth; the self-tapping thread facilitates the operations of correct apical positioning

The insertion driver for ISY + with a morse taper dodecagon features a larger contact surface with the connection walls of the implant, therefore the engagement and removal operations are easier than the corresponding KR implant driver.

#### WARNING: The KR driver cannot be used on this implant system.

In case of high insertion torque values, a delicate off-axis movement may be necessary before extraction.

Insert the implant slowly into the previously prepared site.

A range of 15-25 rpm is recommended. During insertion, do not exceed the maximum torque values indicated below:

#### • implants $\leq Ø$ 3,7 mm:

insertion torque max. 35 - 45 Ncm

- implants > Ø 3,7 mm:
- insertion torque max. 45 65 Ncm

In the cap of the internal vial there is, for each implant family, the corresponding cover screw (locking screw), sterile and ready for use.

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

# SIMPLICITY REDEFINED ONE KIT

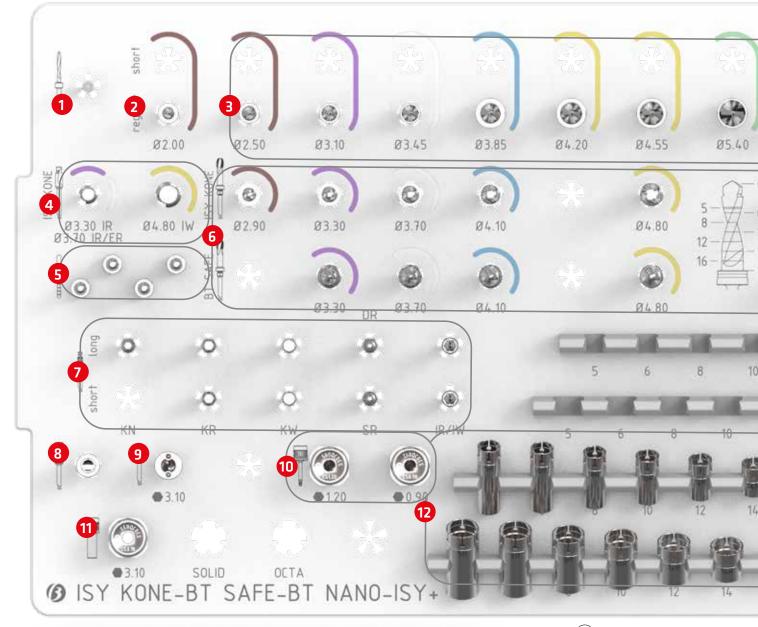
The surgical tray is used for the secure storage and sterilization of surgical and auxiliary instruments.

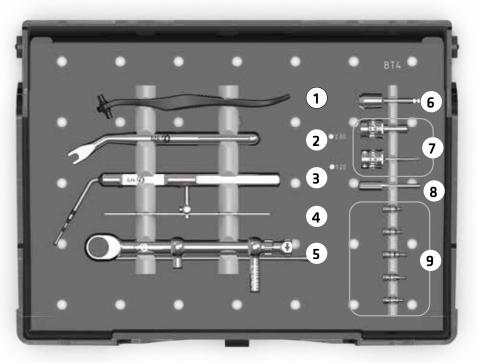
The surgical tray is made of a highly shock-proof thermoplastic, which is well established in medical applications and the material is suitable for frequent sterilization in the autoclave. General guidelines for the cleaning and sterilization are given in the corresponding GENERAL SURGICAL GUIDELINES (Ref. 06200117)

## SURGICAL KIT ISY KONE – BT SAFE – BT NANO – ISY+ REF. 624NA001



# INSTRUMENTS KIT REF. 624NA001





1 GUIDE SHAFT 502MA002 | Ø 2.5 mm

2 ANGLED WRENCH 30° 502MA003 | HEX 3.10

3 DEPTH GAUGE 540MA011 | Ø 1.8 mm L108 mm 30°

#### 4

SURGICAL GUIDE BT4 502MA006 (PIN Ø2.5mm)

5 TORQUE WRENCH JD, REVERSIBLE 501 JD003 90 Ncm



(6) **BONE PROFILER HS (BT4)** 435HS430 Ø 4.3 mm L25 mm

#### $(\mathbf{7})$

SCREWDRIVER JD (BT4)

530JD021 HEX 2.0 L10 mm 530JD014 HEX 1.20 L15 mm Ridotto

### (8)

**PARALLELISM PIN (BT4)** 540MA007 M1.4 L26mm

## (9)

#### **BONE PROFILER GUIDE**

435EN001 ΕN 435ER001 ER 435IR001 IR 435KR001 KR 435KW001 ΚW

	82.00
401HR202	Ø 2 mm L33 mm
2	
	LOT DRILL
	#2.00
426HR200	Ø 2 mm L36.5 mm
3 DRILLS	
-	#254
426HR250	Ø 2,5 mm L36.5 mm
	83.10
426HR310	Ø 2,75 - 3,10 mm L36.5 r
66048	8345
426HR345	Ø 3,45 - 3,05 mm L36.5 r
691	#3.85
426HR385	Ø 3,85 - 3,4 mm L36.5 m
	81.20
426HR420	Ø 4.2 - 3.7 mm L36.8 mm
	84.55
426HR455	Ø 4.55 - 4 mm L36.8 mm
	85.14
426HR540	Ø 5.4 - 4.7 mm L36.8 mm
	8570
426HR570	Ø 5.7 - 4.95 mm L36.8 m

SHARP LANCE DRILL

4 COUNTERSINK **ISY KONE INT-EXT** 

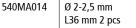




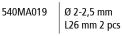
## 5

PARALLELISM PIN/ DEPTH GAUGE

820 --- 4 4 5 2 4 0 8 -- 528









TAPS ISY KONE
82.90
467HR290 Ø 2,9 mm L36 mm
83.38
467HR330 Ø 3,3 mm L36 mm
83.70
467HR370 Ø 3,7 mm L36 mm
84.10
467HR410 Ø 4,1 mm L36 mm
84.80
467HR480 Ø 4,8 mm L36 mm
B6.20
467HR600 Ø 6 mm L36 mm
I
TAPS BT SAFE
466HR330 Ø 3.3 mm L31 mm
STER ST
466HR370 Ø 3.7 mm L31 mm
84.10
466HR410 Ø 4.1 mm L31 mm
84.50
466HR480 Ø 4.8 mm L31 mm
CARL DO MERCINI
466HR600 Ø 6 mm L31 mm
7
IMPLANT DRIVER
530HL003 KN (REGULAR) L33 mm
530HS013 KR (SHORT) L23 mm
530HL001 KR (REGULAR) L33 mm
530HS014 KW (SHORT) L23 mm
530HL002 KW (REGULAR) L=33 mm
R-N
530HS022 IR-IW (SHORT) L25 mm
530HL005 IR-IW (REGULAR) L35 mm
530HS023 DR (SHORT) L25mm
530HL006 DR (REGULAR) L35 mm
8
DRILLS EXTENSION
520HS003 L28 mm
9 RETENTIVE WRENCH

E53.90

HEX 3.10

530HS017



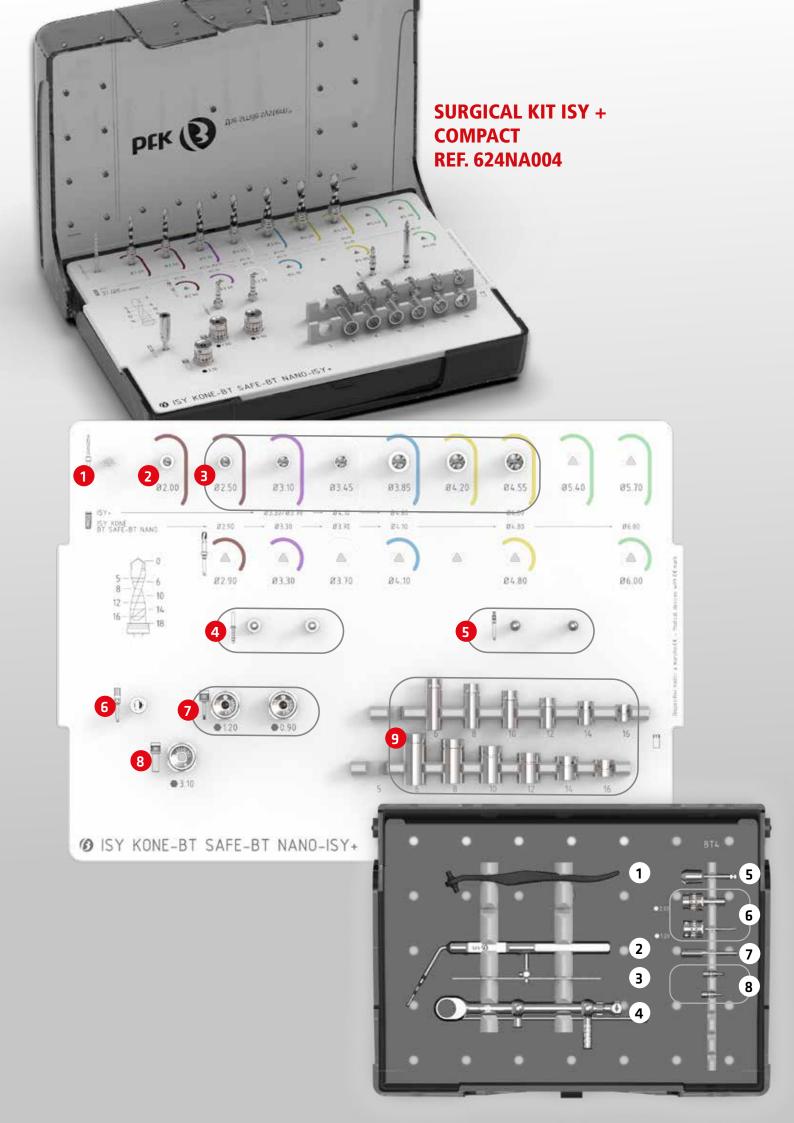


518NA714 H14 mm Snap Fit

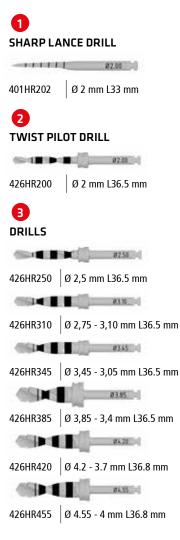


16R

518NA716 H16 mm Snap Fit



# INSTRUMENTS KIT REF. 624NA004



# 4

PARALLELISM PIN/ DEPTH GAUGE

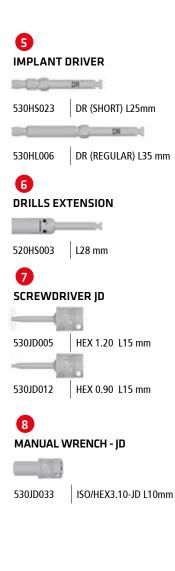
820 1-1-1= 22 -1-1 528 540MA019 Ø 2-2,5 mm

L26 mm 2 pcs

(1) **GUIDE SHAFT** 502MA002 Ø 2.5 mm

(2) DEPTH GAUGE 540MA011 | Ø 1.8 mm L108 mm 30°

(3) SURGICAL GUIDE BT4 502MA006 (PIN Ø2.5mm)



(4) TORQUE WRENCH JD, REVERSIBLE 501 JD003 90 Ncm

(5) BONE PROFILER HS (BT4) 435HS430 Ø 4.3 mm L25 mm

#### (6) SCREWDRIVER JD (BT4)

 530JD021
 HEX 2.0 L10 mm

 530JD014
 HEX 1.20 L15 mm Ridotto

9 DRILL STOP
518NA506 H6 mm Snap Fit
518NA508 H8 mm Snap Fit
15
518NA510 H10 mm Snap Fit
128
518NA512 H12 mm Snap Fit
14 R
518NA514 H14 mm Snap Fit
16R
518NA516 H16 mm Snap Fit
2
518NA706 H6 mm Snap Fit
518NA708 H8 mm Snap Fit
g —
518NA710 H10 mm Snap Fit
\$ −
518NA712 H12 mm Snap Fit
14.8
518NA714 H14 mm Snap Fit
16R
518NA716 H16 mm Snap Fit
7
PARALLELISM PIN (BT4)
540MA007 M1.4 L26mm
8

BONE PROFILER GUIDE 435KR001.02 2 pcs

# CHARACTERISTICS OF SURGICAL DRILLS

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

#### SURGICAL STANDARDS

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

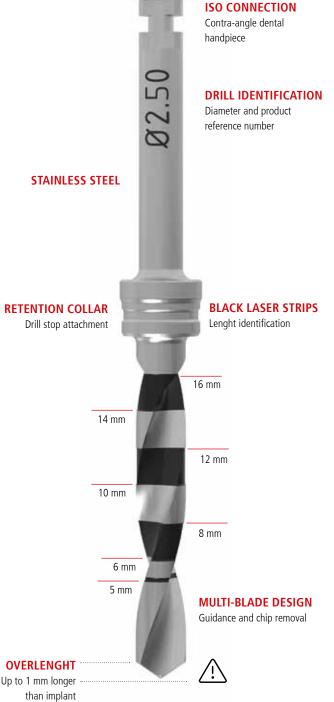
Before starting the surgical procedure and during the same procedure the following points must be taken into account:

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

#### NOTE

• For implants with a length of 18 mm, the corresponding depth markings on drills are not provided such as the suitable drill stops are not available. It is advisable to prepare the implant site taking into account that the length of the drill, from the tip and up to the retention collar, is equal to 18.8 mm. It is responsibility of the clinician to evaluate based on the clinical case, morphology and bone quality, as well as the inclination of the implant, how to prepare the implant site.

TOOL	SPEED (RPM)
LANCE DRILL	800
TWIST DRILL (PILOT) Ø 2mm	800
DRILL Ø<3.5mm	600
DRILL 3.5mm≤Ø≤4.5mm	500
DRILL Ø>4.5mm	400
COUNTERSINK	300/400
TAPS	<15

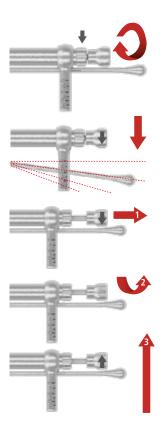


# **REVERSIBLE TORQUE WRENCH**

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

#### NOTE

Before the first and each following use, the Reversible Torque Wrench should be dismantled, cleaned, disinfected and sterilized in accordance with the instructions for use.



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

#### APPLYING THE CORRECT TORQUE VALUE

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

#### HOW TO CHANGE DIRECTIONS

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

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

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

DEVICE	MATERIAL	TIGHTENING TORQUE
Cover screw	Titanium GR5	from 5 to 8 Ncm ("hand tight")
Healing abutment	Titanium GR5	from 5 to 8 Ncm ("hand tight")
Impression Post screw, tightening to implant or implant replica	Titanium GR5	from 5 to 8 Ncm ("hand tight")
Retentive screw, tightening Scan Abutment to implant or implant replica	Titanium GR5	from 5 to 8 Ncm ("hand tight")
Retentive screw, temporary tightening abutment to implant	Titanium GR5	from 15 to 20 Ncm
Retentive screw, final tightening abutment to implant	Titanium GR5	from 25 to 30 Ncm
Straight Abutment BT4, final tightening to implant or implant replica	Titanium GR5	from 25 to 30 Ncm
Angled Abutment BT4, final tightening to implant or implant replica	Titanium GR5	from 20 to 25 Ncm
Retentive screw, prosthesis to abutment BT4 suprastructures	Titanium GR5	10 Ncm
Connector abutment to implant	Titanium GR5	from 20 to 25 Ncm

DEK

90705035 25 15

## SURGICAL PROTOCOL

The ISY + implant, thanks to its innovative morphology, has a surgical protocol which is characterized by the absence of tappers. The active threads, the longitudinal cutting grooves that go through the implant core and the cutting apex confer high self-tapping performances, so that the implant has high penetration features, even in high quality bone.

Following the suggested surgical procedure, the conical morphology of the core and the extremely tapered third apical, allow to obtain excellent primary stability values and high BIC values.

This feature is particularly important in very soft or regenerated bone, because it helps to increase secondary stability, to prevent the phenomenon of disosteointegration and to avoid the unfastening of the implant, especially in the early stages of the surgery (typically at the time of the removal of the cover screw or healing screw).

The tapering of the neck offers considerable flexibility in the depth of insertion of the implant.

The recommended positioning is subcrestal, with the bevel line positioned about 1 mm compared to the crestal margin of the bone. However, this positioning is flexible, in according to the specificity of the patient:

in the presence of thick biotypes, the implant can also remain crestal, taking care to expose only the implant shoulder.

On the other hand, if the biotype is thin (less than 1.5mm), or if there is new regenerated bone, or in post extractive alveolus, it is therefore advisable to sink more the implant, in order to contain the reabsorption, typical of the first year of functional load and to preserve the final aesthetic of the smile.

In all the cases, the deeply tapered neck facilitates the formation of an important blood clot at the time of insertion, which facilitates secondary stability and accelerates the osseointegration process. Considering all these characteristics, the surgical procedure is





characterized by a under-preparation for all implant diameters, compared to the standard preparation of the other BTK implant lines with the same surgical kit.

In particular, for the implant diameter 3.7 and 4.1, the procedure ALWAYS requires a preparation that ends with the drill with a smaller diameter than the preparation of other implant lines.

In softer bone quality, a "step back" preparation is recommended, with the larger diameter drills used partially in the longitudinal direction.

					DRI	LLS			
	ISY+ IMPLANT	Lance Drill 401HR202	Twist Drill Ø 2 426HR200	Drill Ø 2,5 426HR250	Drill Ø 3,1 426HR310	Drill Ø 3,45 426HR345	Drill Ø 3,85 426HR385	Drill Ø 4,2 426HR420	Drill Ø 4,55 426HR455
3,3	8mm 10mm 12mm 14mm	•	•	•	0				
3,7	8mm 10mm 12mm 14mm 16mm 18mm	•	•	•	0				
4,1	6mm 8mm 10mm 12mm 14mm 16mm 18mm	•	•	•	•	0			
4,8	6mm 8mm 10mm 12mm 14mm	•	•	•	٠	٠	0		
6,0	8mm 10mm		•	•		•	•	•	0

# ADDITIONAL INSTRUMENTS

Optional instrumentation dedicated to the correct management of the surgical procedure.

PICTURE	REF	PRODUCT NAME	SPECIFICATION
INITIAL PREPARATION			
87.00	401HS200	Round Drill HS	Ø2mm L30mm
87.00	401HS201	Lance Drill HS	Ø2mm L30mm
82.00	401HR200	Round Drill HR	Ø2mm L35mm
82.00	401HR201	Lance Drill HR	Ø2mm L35mm
DRILLS, LENGHT 32.5-32.8 mm (SHORT)			
82.60	426HS200	Twist Drill HS	Ø2mm L32.5mm
87.50 -	426HS250	Twist Drill HS	Ø2.5mm L32.5mm
	426HS310	Twist Step Drill HS	Ø3.1-2.75mm L32.5mm
B245	426HS345	Twist Step Drill HS	Ø3.45-3.05mm L32.5mm
and a second sec	426HS385	Twist Step Drill HS	Ø3.85-3.4mm L32.8mm
84.20	426HS420	Twist Step Drill HS	Ø4.2-3.7mm L32.8mm
24.55	426HS455	Twist Step Drill HS	Ø4.55-4mm L32.8mm
0540	426HS540	Twist Step Drill HS	Ø5.4-4.7mm L32.8mm
- 0728	426HS570	Twist Step Drill HS	Ø5.7-4.95mm L32.8mm
DRILL STOPS (SNAP-FIT) Ø5 FOR SHORT DR	LLS ≤ Ø3.45 mm		
	690NA258	Stop Kit	Ø5 S5-12mm BT Safe Isy Kone BT Nano
22	521NA505	Drill Stop	H5mm Snap Fit Short
8	521NA506	Drill Stop	H6mm Snap Fit Short
75	521NA507	Drill Stop	H7mm Snap Fit Short
(2) (2)	521NA508	Drill Stop	H8mm Snap Fit Short
105	521NA510	Drill Stop	H10mm Snap Fit Short
125	521NA512	Drill Stop	H12mm Snap Fit Short
DRILL STOPS (SNAP-FIT) Ø7 FOR SHORT DR	LLS ≥ Ø3.85 mm		
10 10 10 10 <u>10</u>	690NA259	Stop Kit	Ø7 S5-12mm BT Safe Isy Kone BT Nano
5	521NA705	Drill Stop	H5mm Snap Fit Short
85	521NA706	Drill Stop	H6mm Snap Fit Short
5	521NA707	Drill Stop	H7mm Snap Fit Short
00 1	521NA708	Drill Stop	H8mm Snap Fit Short
115	521NA710	Drill Stop	H10mm Snap Fit Short
R.	521NA712	Drill Stop	H12mm Snap Fit Short

PICTURE	REF	PRODUCT NAME	SPECIFICATION
DRILL STOPS (SNAP-FIT) Ø5 FOR REGULAR D	RILLS ≤ Ø3.45 mm		
	690NA256	Stop Kit	Ø5 R5-16mm BT Safe Isy Kone BT Nano
DRILL STOPS (SNAP-FIT) Ø7 FOR REGULAR D	RILLS ≥ Ø3.85 mm		
52 107 107 107 129 148 140	690NA257	Stop Kit	Ø7 R5-16mm BT Safe Isy Kone BT Nano
TAP DRIVERS, FOR MANUAL USE, COMPATIB	LE WITH REVERSIBLE TORQUE	WRENCH (JD)	
	530JD032	Adapter Connection	ISO/HEX3.10-JD L7.5mm
	530JD034	Adapter Connection	ISO/HEX3.10-JD L15mm
HEX DRIVERS, FOR MACHINE USE, COMPATI	BLE WITH CONTRA-ANGLE HA	NDPIECE (ISO)	
ES0.90	530HS002	Handpiece Driver	HEX0.90 L25mm
E50.90	530HS003	Handpiece Driver	HEX0.90 L30mm
E5120	530HS004	Handpiece Driver	HEX1.20 L25mm
E5120	530HS005	Handpiece Driver	HEX1.20 L30mm
HEX DRIVERS, FOR MANUAL USE, COMPATIB	LE WITH REVERSIBLE TORQU	E RATCHET (JD)	
	530JD003	Screwdriver JD	HEX1.20 L5mm
	530JD004	Screwdriver JD	HEX1.20 L10mm
	530JD006	Screwdriver JD	HEX1.20 L20mm
	530JD007	Screwdriver JD	HEX1.20 L30mm
	530JD011	Screwdriver JD	HEX0.90 L10mm
SCREWDRIVERS			
E5120 -	530HS012	Handpiece Driver	HEX1.20 L30mm Reduced
-	530JD015	Screwdriver JD	HEX2.0 L5mm
	530JD038	Screwdriver JD	HEX2.0 L20mm
	530JD036	Screwdriver JD	HEX1.50 L15mm
	530JD037	Screwdriver JD	HEX1.50 L30mm

# PROSTHETIC

#### HEALING & SOFT TISSUE CONDITIONING

PICTURE	REF	PRODUCT NAME	SPECIFICATION				
HEALING ABUTMENTS Ø 1.8 mm							
	201KR2A6	Healing Abutment KR	H2mm Ø1.8mm				
	201KR3A5	Healing Abutment KR	H3.5mm Ø1.8mm				
	201KR5A3	Healing Abutment KR	H5mm Ø1.8mm				
	201KR7A0	Healing Abutment KR	H7mm Ø1.8mm				
HEALING ABUTMENTSØ 2.	5 mm						
	201KR2A5	Healing Abutment KR	H2mm Ø2.5mm				
TIME .	201KR3A4	Healing Abutment KR	H3.5mm Ø2.5mm				
	201KR5A1	Healing Abutment KR	H5mm Ø2.5mm				
HEALING ABUTMENTS Ø 3	.5 mm						
	201KR1A0	Healing Abutment KR	H1mm Ø3.5mm				
	201KR2A1	Healing Abutment KR	H2mm Ø3.5mm				
INC.	201KR3A0	Healing Abutment KR	H3.5mm Ø3.5mm				
	201KR5A4	Healing Abutment KR	H5mm Ø3.5mm				
	201KR7A2	Healing Abutment KR	H7mm Ø3.5mm				
HEALING ABUTMENTS Ø 4	.5 mm						
	201KR1A1	Healing Abutment KR	H1mm Ø4.5mm				
	201KR2A2	Healing Abutment KR	H2mm Ø4.5mm				
III C	201KR3A1	Healing Abutment KR	H3.5mm Ø4.5mm				
	201KR5A2	Healing Abutment KR	H5mm Ø4.5mm				
	201KR7A1	Healing Abutment KR	H7mm Ø4.5mm				
<b>HEALING ABUTMENTS Ø 5</b>	.5 mm						
- 46	201KR2A3	Healing Abutment KR	H2mm Ø5.5mm				
metting and	201KR3A2	Healing Abutment KR	H3.5mm Ø5.5mm				
	201KR5A5	Healing Abutment KR	H5mm Ø5.5mm				
HEALING ABUTMENTS Ø 6	.5 mm						
	201KR2A4	Healing Abutment KR	H2mm Ø6.5mm				
m	201KR3A3	Healing Abutment KR	H3.5mm Ø6.5mm				
	201KR5A6	Healing Abutment KR	H5mm Ø6.5mm				

#### **IMPRESSION TAKING**

PICTURE	REF	PRODUCT NAME	SPECIFICATION
IMPRESSION POST			
	325KR0A0	Impression Post Pro KR	Plastic cap
	690NA073	Impression Post Screw	M1.6 HEX1.20 H7.9mm
	690NA091.10	Caps Kit Pro	Ø5.1mm Kit 10pcs
IMPRESSION POST PICK-UP			
#1	323KR0A0	Impression Post Pick-Up Screw	HUtile21.5mm Long Screw
	323KR0A2	Impression Post Pick-Up Screw	HUtile16.5mm Short Screw
24	323KR0R0	Impression Post Pick-Up Screw	HUtile21.5mm Rotating Long Screw
	323KR0R1	Impression Post Pick-Up Screw	HUtile16.5mm Rotating Short Screw
	690NA072	Impression Post Pick-Up Screw	M1.6 HEX1.20 H26.4mm
	690NA071	Impression Post Pick-Up Screw	M1.6 HEX1.20 H21.4mm
IMPLANT REPLICA			
CR 6	301DR0A0	Implant Replica DR	

INTERIM RESTORATIONS

PICTURE	REF	PRODUCT NAME	SPECIFICATION		
TEMPORARY ABUTMENTS					
	210KR1A0	Temporary Abutment KR			
	210KR1R0	Temporary Abutment KR	Rotating		
TALLER OF A	215KR0A0	Temporary Abutment KR	Peek		
	690NA070	Retentive Screw	M1.6 HEX1.20 H8.3mm		

#### **CEMENT-RETAINED PROSTHESIS**

PICTURE	REF	PRODUCT NAME	SPECIFICATION		
	214KR4A0	Transfer Abutment KR	H4mm Ø4.5mm		
	690NA091.10	Caps Kit Pro	Ø5.1mm Kit 10pz		
	690NA070	Retentive Screw	M1.6 HEX1.20 H8.3mm		
STRAIGHT AND ESTHETIC ABUT	MENTS Ø 3.5 mm				
	220KR1A2	Straight Abutment KR	H1mm Ø3.5mm		
	220KR2A0	Straight Abutment KR	H2mm Ø3.5mm		
	220KR3A0	Straight Abutment KR	H3.5mm Ø3.5mm		
STRAIGHT AND ESTHETIC ABUT	MENTS Ø 4.5 mm				
	220KR1A3	Straight Abutment KR	H1mm Ø4.5mm		
	220KR2A1	Straight Abutment KR	H2mm Ø4.5mm		
	220KR3A1	Straight Abutment KR	H3.5mm Ø4.5mm		
	219KR2A3	Esthetic Abutment KR	H2mm Ø4.5mm		
	219KR3A3	Esthetic Abutment KR	H3.5mm Ø4.5mm		
CTRAICHT AND ECTUETIC ADUT			H3.5mm Ø4.5mm		
STRAIGHT AND ESTHETIC ABUT		Churchelte Alexander (MD			
	220KR1A1	Straight Abutment KR	H1.5mm Ø5.5mm		
	220KR2A2	Straight Abutment KR	H2mm Ø5.5mm		
	220KR3A2	Straight Abutment KR	H3.5mm Ø5.5mm		
	219KR2A4	Esthetic Abutment KR	H2mm Ø5.5mm		
	219KR3A4	Esthetic Abutment KR	H3.5mm Ø5.5mm		
ESTHETIC ABUTMENTS Ø 6.5 m	m				
A	219KR2A5	Esthetic Abutment KR	H2mm Ø6.5mm		
	219KR3A5	Esthetic Abutment KR	H3.5mm Ø6.5mm		
ANGLED ABUTMENT 10°					
	220KR1C0	Angled Abutment KR	10° H1mm Ø3.5mm		
	220KR2C0	Angled Abutment KR	10° H2mm Ø3.5mm		
	220KR3C0	Angled Abutment KR	10° H3.5mm Ø3.5mm		
	220KR1C1	Angled Abutment KR	10° H1mm Ø4.5mm		
	220KR2C1 220KR3C1	Angled Abutment KR Angled Abutment KR	10° H2mm Ø4.5mm 10° H3.5mm Ø4.5mm		
	220KR2C2	Angled Abutment KR	10° H2mm Ø5.5mm		
	220KR3C2	Angled Abutment KR	10° H3.5mm Ø5.5mm		
ANGLED ABUTMENT 20°					
ANGLED ADOTWIENT 20	220KR1E0	Angled Abutment KR	20° H1mm Ø3.5mm		
	220KR1E0 220KR2E2	Angled Abutment KR	20° H2mm Ø3.5mm		
	220KR3E0	Angled Abutment KR	20° H3.5mm Ø3.5mm		
	220KR1E1	Angled Abutment KR	20° H1mm Ø4.5mm		
	220KR2E3	Angled Abutment KR	20° H2mm Ø4.5mm		
	220KR3E1	Angled Abutment KR	20° H3.5mm Ø4.5mm		
	220KR2E4	Angled Abutment KR	20° H2mm Ø5.5mm		
	220KR3E2	Angled Abutment KR	20° H3.5mm Ø5.5mm		
ANGLED ABUTMENT 30°					
	220KR1G0	Angled Abutment KR	30° H1mm Ø3.5mm		
	220KR2G0	Angled Abutment KR	30° H2mm Ø3.5mm		
	220KR3G0	Angled Abutment KR	30° H3.5mm Ø3.5mm		
	220KR1G1	Angled Abutment KR	30° H1mm Ø4.5mm		
	220KR2G1	Angled Abutment KR	30° H2mm Ø4.5mm		
	220KR3G1	Angled Abutment KR	30° H3.5mm Ø4.5mm		
	220KR2G2	Angled Abutment KR	30° H2mm Ø5.5mm		
333000	220KR3G2 690NA070	Angled Abutment KR Retentive Screw	30° H3.5mm Ø5.5mm M1.6 HEX1.20 H8.3mm		

#### SCREW-RETAINED / CEMENT-RETAINED PROSTHESIS

PICTURE	REF	PRODUCT NAME	SPECIFICATION
BT LINK			
	246KR1A0	BT LINK KR	H1mm Ø4.1mm
	246KR1A1	BT LINK KR	H1mm Ø4.1mm Rotating
	247KR1A0	Base BT LINK KR	H1mm Ø4.1mm no Cap.
že	247KR1A1	Base BT LINK KR	H1mm Ø4.1mm no Cap. Rot.
	205NA001.05	Castable Plastic Abut. BT Link	H1mm Ø4.7mm Kit 5pcs
	690NA083	Retentive Screw BTK	M1.6 HEX1.20 H8.3mm TP
	244KR0A0	SIR Link KR	H0.8mm Ø4.1mm
	248KR1A0	X3 Link KR	H1mm Ø4.1mm Multi Lenght
BT GRIP SCREWDRIVERS JD			
	530JD036	Screwdriver JD BT GRIP	HEX1.50 L15 mm (Short)
	530JD037	Screwdriver JD BT GRIP	HEX1.50 L30 mm (Long)
	690NA239	Retentive Screw BT GRIP	M1.6 HEX1.50
CAST-ON TECHNIQUE			
	245KR0A0	Gold Abutment KR	H1mm
	240KR1A0	CoCr Abutment KR	H1.5mm
	240KR1R0	CoCr Abutment KR	H1.5mm Rotating
	690NA070	Retentive Screw	M1.6 HEX1.20 H8.3mm
SCAN ABUTMENT			
	351KR1A0	Scan Abutment Extra-oral KR	
120	352KR1A0	Scan Abutment Intra-oral KR	
	690NA083	Retentive Screw BTK	M1.6 HEX1.20 H8.3mm TP

#### **SCREW-RETAINED PROSTHESIS**

PICTURE	REF	PRODUCT NAME	SPECIFICATION		
BT4 STRAIGHT ABUTMENT	S				
25	265KR1R0	BT4 Straight Abutment KR	Rotating Rot. H1mm		
$\nabla$	265KR2R0	BT4 Straight Abutment KR	Rotating Rot. H2mm		
10	265KR3R0	BT4 Straight Abutment KR	Rotating Rot. H3mm		
BT4 SLIM STRAIGHT ABUTMENTS					
	268KR1R0	BT4 Slim Straight Abutment KR	Rotating Rot. H1mm		
Y	268KR2R0	BT4 Slim Straight Abutment KR	Rotating Rot. H2mm		
BT4 ANGLED ABUTMENTS					
	266KR2L0	BT4 Angled Abutment KR	17° H2mm Ø4.8mm		
	266KR3L0	BT4 Angled Abutment KR	17° H3mm Ø4.8mm		
	266KR4L0	BT4 Angled Abutment KR	17° H4mm Ø4.8mm		
	266KR3G0	BT4 Angled Abutment KR	30° H3mm Ø4.8mm		

PICTURE	REF	PRODUCT NAME	SPECIFICATION
BT4 CAPS			
	330NA0A0.04	Covering Caps BT4	H5 Kit 4pcs
-	330BU0A0.04	Covering Caps BT4 Slim	H5 Kit 4pcs
	690NA024	Retentive Screw	M1.4 HEX1.20 10N
()	690NA075	Retentive Screw BT4	M1.6 Angled abutment KR
BT4 INTERIM RESTORATION			
	267NA0A0	BT4 Titanium Abutment	
	269BU0A0	BT4 Slim Titanium Abutment	
Dia	207NA0A0	Castable Plastic Abutment BT4	
	207BU1R0	Castable Plastic Abutment BT4 Slim	
	311NA0A0	Impression Post Pick-up BT4	with long Screw
-)-)-	311BU0A0	Impression Post Pick-up BT4 Slim	with long Screw
	690NA031	Vite Transfer Pick-Up	M1.4 HEX1.20 H17mm
	303NA0A0	Abutment Replica BT4	
	303BU0A0	Abutment Replica BT4 Slim	
	690NA024	Retentive Screw	M1.4 HEX1.20 10N
BT4 SCAN ABUTMENT			
21 <b>6</b>	351BT1A1	Scan Abutment Extra-oral BT	Rotating
in o	352BT1A1	Scan Abutment Intra-oral BT	Rotating
he	351BU1A1	Scan Abutment Extra-oral BU	Rotating (BT4 Slim)
En O	352BU1A1	Scan Abutment Intra-oral BU	Rotating (BT4 Slim)
BT4 BT LINK			
1	246BT1A1	BT LINK BT	H1mm Ø4.8mm Rotating
2,6	247BT1A1	Base BT LINK BT	H1mm Ø4.8mm no Cap. Rot.
	205NA003.05	Castable Plastic Abut. BT Link	H1mm Ø5.4mm Kit 5pcs
[III	246BU1A1	BT LINK BU	H1mm Ø4.1mm Rotating
26	247BU1A1	Base BT LINK BU	H1mm Ø4.1mm no Cap. Rot.
	205NA001.05	Castable Plastic Abut. BT Link	H1mm Ø4.7mm Kit 5pcs
CAST-ON TECHNIQUE			
	240BT1R0	CoCr Abutment BT	H1.5mm Rotating
	240BU1R0	CoCr Abutment BU	H1.5mm Rotating

# **OVERDENTURE**

#### **SPHERO**®



SPHERO® Block Normo Sphere Ø 2.5mm			SPHERO® Block Micro Sphere Ø 1.8mm		SPHERO® Flex Sphere Ø 2.5mm 0°-7.5° Flexibility	
REF	SPECIFICATION	REF	SPECIFICATION	REF	SPECIFICATION	
254KR1A0 254KR2A0 254KR3A0 254KR4A0 254KR5A0 254KR6A0 254KR7A0	H1mm H2mm H3mm H4mm H5mm H6mm H7mm	255KR1A0 255KR2A0 255KR3A0 255KR4A0 255KR5A0 255KR6A0 255KR7A0	H2mm H3mm H4mm H5mm H6mm	256KR1A0 256KR2A0 256KR3A0 256KR4A0 256KR5A0 256KR6A0 256KR7A0	H1mm H2mm H3mm H4mm H5mm H6mm H7mm	
Accessories Sphero®						
PICTURF	R	FF	PRODUCT NAME	SPECIFICAT	ION	

PICTURE	REF	PRODUCT NAME	SPECIFICATION
	530JD030	Wrench Driv. Sphero Block/Flex	Rhein83® 771CEF

NOTE Every SPHERO® as listed above includes the following products: 1pc. Titanium Abutment with self-aligning 2.5mm or 1.8 mm sphere, 2pcs. Soft Retention Pink Caps, 1pc. Stainless Steel Housing, 1pc. Protective Disk and 3 pcs. Directional Rings.

These Devices are manufactured by Rhein83.a Renew SS s.r.l. Via E. Zago, 10/ABC, 40128 Bologna Italy.

#### **BTK CONNECTOR**



Connector Abutment			
REF	SPECIFICATION		
261KR1A0	H1mm		
261KR2A0	H2mm		
261KR3A0	H3mm		
261KR4A0	H4mm		
261KR5A0	H5mm		
261KR6A0	H6mm		

CONNECTOR Accessories			
PICTURE	REF	PRODUCT NAME	SPECIFICATION
	530HS015	Locator <sup>®</sup> Handpiece Driver	L 23mm
() <del>]</del>	530HS016	Locator <sup>®</sup> Handpiece Driver	L 29mm
	530JD029	Locator <sup>®</sup> Screwdriver JD	L10mm (for reversible torque wrench JD)
•\\\\///•	540MA015	Angle Measur. Guide Locator®	
	540MA016.04	Parallel Pin for Locator®	Kit 4pcs
8	321NA0A0	Impression Post Locator®	
(3	301NA0A0	Implant Replica Locator® Abut.	
	690NA011	Replacement Males Locator®	
0	690NA022	Kit Locator®	Metal Cap + Blockout Spacer
	690NA054.04	Replacement Males Locator®	ON Black Kit 4pcs
	690NA006.04	Replacement Males Locator®	15N Blue Kit 4pcs (700gr. 0-20°)
	690NA008.04	Replacement Males Locator®	30N Pink Kit 4pcs (1400gr. 0-20°)
0	690NA010.04	Replacement Males Locator®	50N Neutral Kit 4pcs (2300gr. 0-20°)
	690NA005.04	Replacement Males Locator®	10N Red Kit 4pcs (700gr. 20-40°)
	690NA007.04	Replacement Males Locator®	20N Orange Kit 4pcs (900gr. 20-40°)
	690NA009.04	Replacement Males Locator®	40N Green Kit 4pcs (1400gr. 20-40°)
	690NA134.04	Replacement Males Locator®	0N Gray Kit 4pcs (0gr.)
	502MA004	Locator <sup>®</sup> Core Tool 3 in 1	
	502MA019	Locator <sup>®</sup> Male Removal Tip End	
	690NA020	Retaining Sleeve Locator®	Locator <sup>®</sup> core tool

**NOTA** Each "Connector Abutment" as listed above includes the following products: 1 pc. Connector Abutment; 1 pc. Denture Male Cap (Housing); 1 pc. Block-Out Spacer, 1 pc. each Locator® Replacement Males (blue / pink /clear). All these codes (except 530JD029, and Connector Abutments) are medical devices patented and produced by Zest Anchors Inc, 2061 Wineridge Place, Escondido CA 92029 USA. LOCATOR® is a registered trademark of Zest Anchors Inc.

# **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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#### **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.

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