EASY GRIP® Implants

TECHNICAL OPERATING MANUAL

CONE CONNECTION NARROW 3.0

ICIM

CERTIFICATO N. / CERTIFICATE No. 10110/1

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI / WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

T.F.I. SYSTEM S.R.L.

UNITÀ OPERATIVA / OPERATIVE UNIT

Via Giacomo Peroni, 400/402 - 00131 Roma (RM)
Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 19

Progettazione e realizzazione di impianti dentali, componentistica protesica, accessori e strumentazione

Design and manufacturing of dental implants, prosthetic components, accessories and instruments

DATA EMISSIONE / FIRST ISSUE	EMISSIONE CORRENTE / CURRENT ISSUE	DATA DI SCADENZA / EXPIRING DATE
15/09/1999	11/06/2021	10/06/2024

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.

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CERTIFICATO n. / CERTIFICATE No. 10111/1

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T.F.I. SYSTEM S.R.L.

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Via Giacomo Peroni, 400/402 - 00131 Roma (RM)
Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI CEI EN ISO 13485:2016

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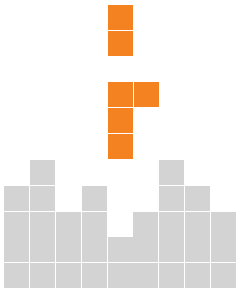
T.F.I. System srl (Tissue Friendly Implants System), a company with twenty-five years of experience in the field of implantology, certified with company quality system ISO 9001 and ISO 13485 proposes its **Easy Grip®** implant line, a certified product in Europe and with CE marking and **FDA** authorisation for the US.

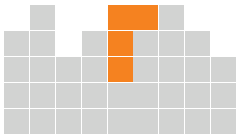
Since its introduction, the **Easy Grip®** line has focused on offering its customers a product that is simple to use, yet comprehensive in its range, maintaining a high quality level at decidedly competitive prices.

The focus on simplifying surgical protocols, component functionality and technological innovation are the common thread running through all **Easy Grip®** brand products.

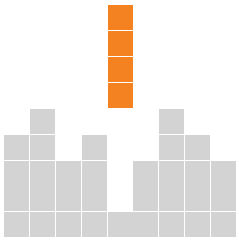
The simplicity and effectiveness of our solutions have led an ever-increasing number of customers to choose the **Easy Grip®** brand, maintaining a high level of customer loyalty.



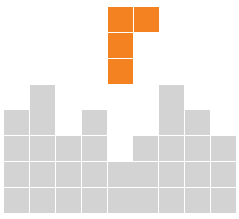
INTRODUCTION



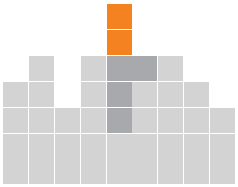
IMPLANTS



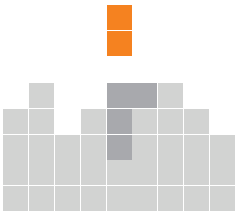
SURGICAL ACCESSORIES



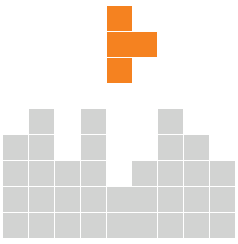
SURGICAL PROTOCOL



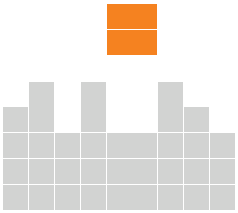
PROSTHETIC COMPONENTS



PROSTHETIC PROTOCOL



SERVICES AND RESEARCH



EASY GRIP® HEX, CONE AND NARROW LINE INSTRUCTIONS FOR USE

EASY GRIP® CONE NARROW IMPLANT SYSTEM

The Easy Grip® CONE NARROW implant system offers a simple and complete product in the range, consisting of 3.0 mm diameter tapered threaded implants manufactured from grade 5 ELI titanium.

Available in lengths ranging from 10 to 13 mm to meet the most common clinical needs.

Ideal in narrow interdental spaces, at the level of the upper lateral incisors or the lower central and lateral incisors.

Conical
Series 80

ND 3.00 - Narrow

(ND = nominal diameter)

EXTERNAL MORPHOLOGY

Conical implant with three, self-centring helical grooves:
- tapping;
- collection of bone frustules;
- increased osseointegration surface area (Dynamic Bone Management).

The rounded apex allows for completely safe use in risk areas and less trauma during insertion, resulting in improved vascularisation and osseointegration.

Anodised collar with micro-threads
The presence of the cortical micro-threads on a rough surface, compared to implants with a smooth neck, offer better conditions for osseointegration and, under functional loading, are more effective in maintaining marginal bone loss (MBL), preventing natural post-operative bone resorption, resulting in:
- optimisation of load distribution;
- reduction of stress levels;
- decreased bacterial proliferation.

Inverted sawtooth threading with double tapping start
It is a type of square threading which provides an optimised surface for transmission of intrusive and compressive loads; these loads are about 10 times lower than those occurring on standard (V-threaded) or spur threads. Dual-principle coils increase implant insertion performance during the surgical phase.

Progressive compression threading
This is a square threading that is significantly load-bearing in the cervical part of the implant and more pronounced in the apical area, which generates targeted bone condensation in the case of insertion in D3/D4 type bone, increasing primary stability, which is particularly necessary in immediate loads.

CE 0425

EASY GRIP® CONE NARROW CONNECTION

5° conometric connection
The Easy Grip® CONE NARROW 5° connection guarantees a perfect seal of the fixture, minimising the micro-gap with the prosthetic component, preserving the good health of the cortical bone.

Internal hexagon
The internal hexagon allows indexed insertion of prosthetic components.

Through-bolts M1.6
The Easy Grip® CONE NARROW connection system provides for the activation and maintenance of the fixture/abutment coupling by screwing with an M1.6 clamping screw

The activation of the conical coupling and the tightness of the clamping screw are therefore essential elements for the long-term reliability of the implant system.

T.F.I. System srl uses production techniques used in the aeronautical field that increase the breaking strength of clamping screws by around 50 per cent compared to conventional products.

Anatomical emergence profile
The anatomical design of the Easy Grip® CONE NARROW prosthetic components provides a natural and aesthetic emergence profile for proper soft tissue management.

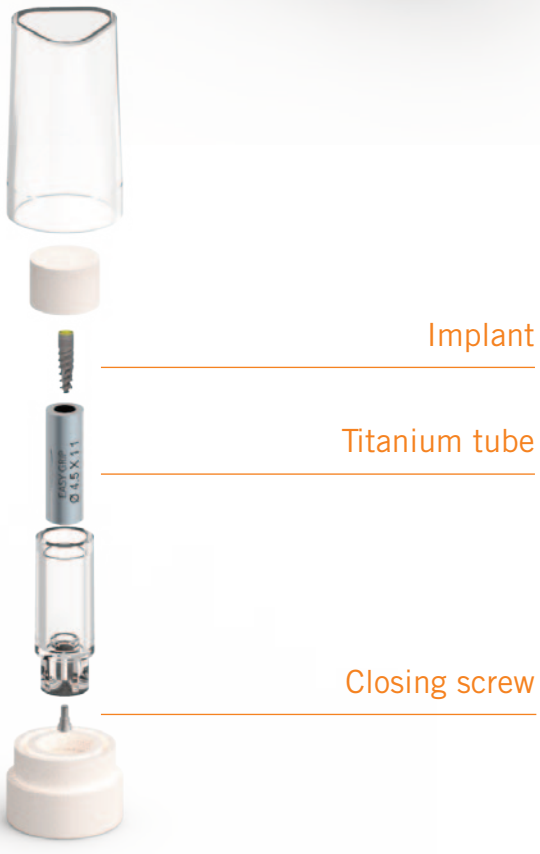
PACKAGING AND STERILISATION

Easy Grip® CONE NARROW implants are packaged as follows:

- suspended in a titanium tube;
- inserted in a double ampoule contained in a sealed blister;
- conditioned for sterilisation in an ISO 8 class protected environment;
- gamma ray sterilised.

The packaging includes:

- a grade 5 ELI titanium implant;
- a grade 5 ELI titanium closing screw;
- user instructions are available in electronic format on the website www.tfisystem.it, pursuant to EC regulation no. 207/2012;
- two adhesive plates with implant identification codes are placed inside the package, one to be affixed to the patient card in the doctor's office and the other to the implant card;
- the package is equipped with a red anti-tampering seal which, if visible, demonstrates that it has been opened;
- for the correct insertion of the implant, please refer to the dedicated section: "implant pick-up and positioning procedure" (see page 30).



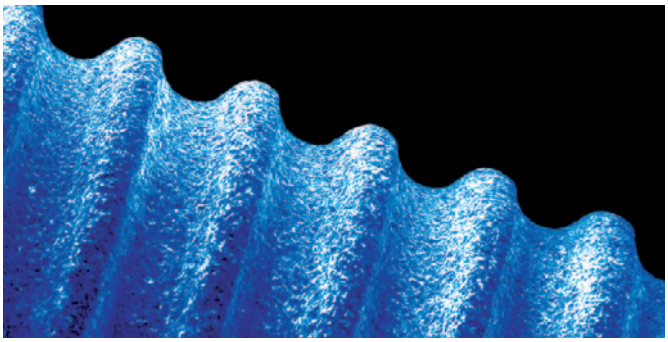
SURFACE TREATMENTS

The unique OsteoGrip® surface, which characterises the Easy Grip® implant line, is the result of specific surface treatments such as: Sandblasting, Etching, Anodic Colouring and Plasma Glow Discharge, specially designed to promote rapid bone regeneration.

SLA (Sanding and Acid Etching)

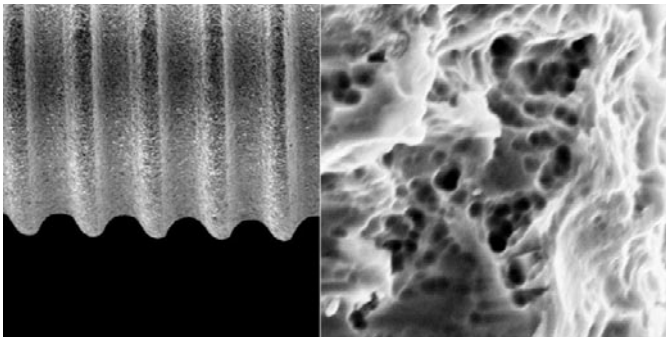
Following the excellent results, confirmed by the clinical literature, of the two subtractive sanding and acid etching techniques, it was decided to join the benefits in a single treatment, in order to achieve an SLA surface (Sandblasted with Long grit corundum followed by Acid etching with Sulfuric and Hydrochloric acid).

Introduced in 1998, it is one of the most documented rough surfaces in dental implantology.



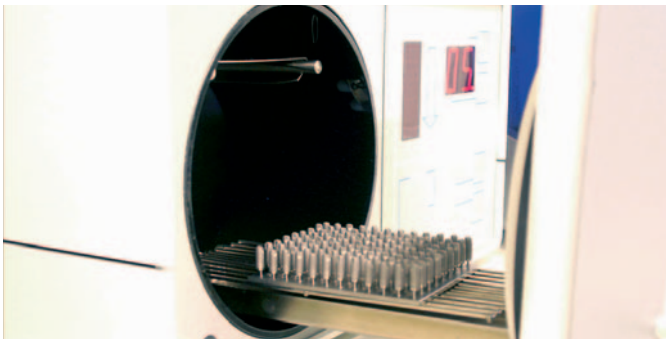
Etching

Acid based with a hydrofluoric acid mix for better osseointegration, to achieve optimal micro texture.



Plasma Glow Discharge

Surface decontamination through atomic bombardment with inert gas (Argon).
This treatment makes it possible to achieve surface decontamination results that cannot be achieved with other methods, at the same time as supporting the alkaline phosphatase (ALP) process, a critical stage in the correct activation of osseointegration.



Anodic colouring

This technique is applied on both artificial teeth and implants in the neck and internal connection area; it is used on scientific grounds to form a crystalline titanium oxide surface (Anatase) capable of reducing bacterial growth in the transmucosal portion of the implant; it has the added functional advantage of helping the user identify the prosthetic components.

TITANIUM GRADE 5 ELI (GRADE 23)

The best material for long lasting implant prosthetic results

Titanium grade 23, generally known as titanium grade 5 ELI (Extra Low Interstitial), is the titanium alloy (Ti6Al4V) currently used in the production of "Easy Grip®" implants and abutments.
For many years T.F.I. System srl has adopted this alloy in place of titanium grade 4 CP (Commercially Pure) for its characteristic properties that we briefly list below:

Hardness
The 6% aluminium presence increases hardness, reduces specific weight and improves the elasticity modulus "E". Furthermore, association with aluminium and vanadium reduces thermal conductivity by about 50%, but above all increases wear resistance by the same percentage.

Surface resistance
The Ti6Al4V ELI titanium alloy is an alpha-beta alloy, i.e. it contains both alpha stabilising (aluminium and oxygen) and beta stabilising elements (vanadium); this type of alloy may be surface treated in order to increase friction corrosion resistance.

Friction wear resistance
Here is an excerpt from the "titanium" page in Wikipedia: "it has the property of being biocompatible, with surface porosity similar to human tissue, so that it is physiologically inert.
For this reason, the Ti6Al4V ELI titanium alloy is used in hip and knee prosthetic components. However, due to the high ***friction coefficient*** it is never used as a component for articular joints."
Unfortunately, titanium surfaces obtained from turning commercially available bars have a relatively low friction wear resistance. In particular, titanium surfaces in mutual contact between them or with other metals are damaged quickly due to rubbing or friction (the so-called ***fretting corrosion***).
Surfaces may therefore completely seize up even with a light load and small relative movement.
This situation is due to adhesive wear, in which microscopic asperities on metal surfaces come into contact with each other as a result of relative sliding and tend to weld together, forming a bond that may have greater breaking strength than the strength of the underlying metal; the fracture, then, occurs at one of the asperities, causing a transfer of metal from one surface to another; the residue thus formed gives rise to the accelerated wear that occurs in titanium.
In view of this, it is essential to adopt appropriate solutions in order to use titanium in conditions in which wear might be a problem.

Fatigue resistance
The complex manner in which the microstructure and morphology contribute to changing the properties of the material, call for the fatigue behaviour to be generally assessed experimentally on a case by case basis, depending on requirements. In general it can be stated that all changes which result in an increase of the yield strength also lead to an improvement in fatigue resistance. Another key factor is the state of surfaces, whose poor finish is conducive to the onset of cracks, which may then propagate by fatigue even at very low loads. That is why we pay special attention to surface treatments.

Fracture toughness
The Ti6Al4V ELI alloy (titanium grade 5 ELI), is used for those applications requiring very high fracture toughness (for example hip prosthesis). This titanium alloy is treated with a particular process to reduce interstitial elements (ELI process), which significantly improves K values (effort which the material is able to withstand in the event of cracks), making it possible to reach values even twice as high as those of the simple Ti6Al4V alloy with normal levels of oxygen.

Breaking strength
Grade 5 ELI titanium has a value of 830 MPa, compared to 550 MPa for titanium grade 4.

Yield strength
Grade 5 ELI titanium has a value of 760 MPa, compared to 480 MPa for titanium grade 4.

Resistance to crack propagation
The natural formation of some surface defects is often originated by lathe methods, operation to be deemed necessary to achieve the desired processing result (thread start, grooves, etc.). Such surface defects are often the cause of cracks, generated following fatigue strain of the piece.
In the 'Surface Treatments' section, we take a closer look at the methods implemented by T.F.I. System srl to increase this type of resistance on products in the 'Easy Grip®' line. To reduce this phenomenon, T.F.I. System srl CNC (numerical control) lathes are equipped with additional items such as internal and external tourbillonage, indispensable to perform internal and external threads, with no surface defects.

For further details on titanium we recommend reading the second part of the ISTISAN 09/39 Report of the National Institute of Health.

EASY GRIP® CONE NARROW SURGICAL KIT

Surgical Tray Kit

Made of autoclavable Radel, it contains all surgical instruments, rotary and non, for implementing the surgical and prosthetic protocols of the Easy Grip® CONE Line **(KITCONE)**.

Users already in possession of an Easy Grip® Surgical Kit can use the Easy Grip® CONE NARROW 3.0 implant, equipping it with the corresponding screwing spanners.

The pictures are purely for illustrative purposes

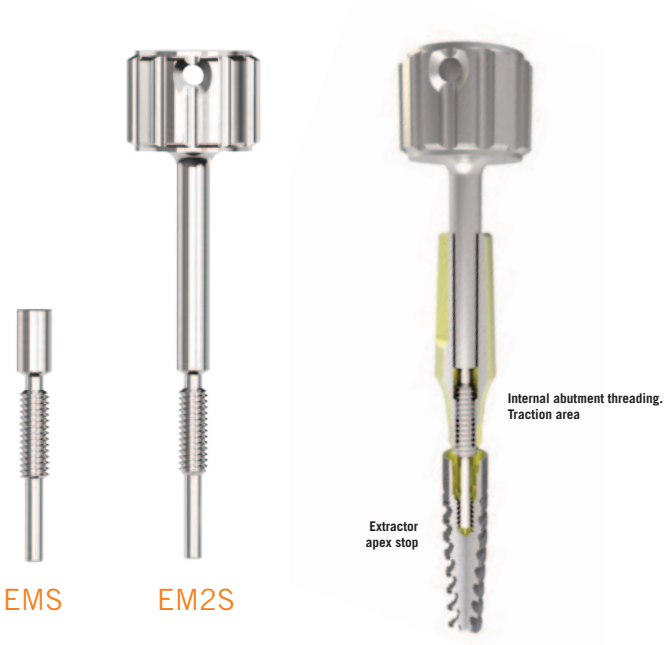
REVERSIBILITY OF THE EASY GRIP® CONE NARROW SYSTEM

The Easy Grip® CONE NARROW engagement at 5° generates a highly reliable coupling, guaranteeing:

- microbiological seal.
- high prosthetic stability.
- possibility of subcrestal placement.

If necessary, the final coupling can be easily removed through the use of a manual extractor (EM2S) or, in the case of limited operating space, with the extractor screw (EMS)(*).

(*) The use of extractors is not possible if an angulation correction of the screw access channel has been performed on a screw-retained prosthesis.



HIGH-PERFORMANCE SCREWS

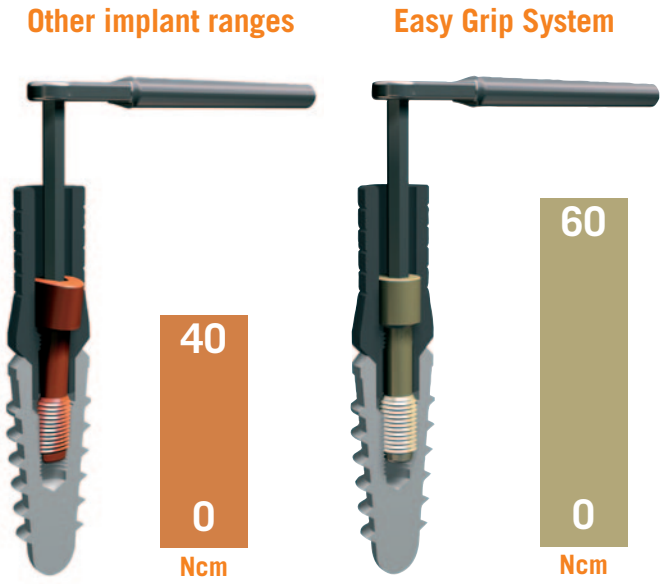
The optimal tightening of the conical fixture/abutment connection has always been a delicate element for all implant lines.

This value is affected by a range of variables, such as:

- the optimum torque force with which to tighten the screw; in the case of the Easy Grip® CONE NARROW line, this torque force was identified as 30 Ncm;
- the physical-mechanical features of the material from which the screw is made;
- the technique used to make the screw thread;
- the screw and connection morphology.

It must also be taken into account that the fixture/abutment coupling activates a frictional corrosion process of the titanium (fretting), which, in the long run, can promote screw loosening (settling).

T.F.I. System srl has tackled these critical issues with advanced techniques, producing a 5° conical coupling capable of generating a fixture/abutment seal and, making use of cutting-edge production techniques for the medical sector, drawn from the aeronautical sector, producing clamping screws capable of raising the deformation limit to 60 Ncm, increasing breaking strength by as much as 50% compared to standard production values of around 40 Ncm.



THE IMPLANT-PROSTHETIC TREATMENT

INDICATIONS:
The Easy Grip® CONE NARROW implant line may be used in fully edentulous maxillary or mandibular cases to anchor total prostheses or, in the fixed prosthesis, to make terminal or intermediate abutments of bridges and individual teeth.

CONTRAINDICATIONS:
Implant therapy is recommended against in the following cases:

1) general patient conditions: cachexia, diabetes, hyperthyroidism, anaemia, vitiligo, haemorrhagic diathesis, osteomalacia, osteitis deformans, osteogenesis imperfecta, immune system disorders, and any systemic disease or drug therapies that may impair the tissue repair ability, such as immunosuppressants and corticosteroids. Patients with neurotic or psychotic disorders or mental instability, and patients who smoke, abuse alcohol and/or drugs are to be excluded.

Heart disease and circulatory disease represent a general surgery contraindication and therefore also to implant therapy. Similarly, surgery should be avoided during pregnancy.

2) local conditions of the patient: inadequate bone quantity, presence of lesions in the soft tissues (such as leukoplakia, lichen, stomatitis, epulis, etc.), lesions in the hard tissues (such as cysts, granulomas, root residue, inflammatory changes, etc.). Inadequate oral hygiene. Past or current radiation therapy. Xerostomia. Bruxism and inadequate occlusal conditions.

3) the patient's age: in adolescents, implants should only be considered after bone growth is complete.

RECOMMENDATIONS:
Dental implants should only be reserved for patients who are sufficiently motivated and collaborative with a good level of oral hygiene. Each implant site must have undergone adequate diagnostic, clinical and radiological assessment. Incorrect procedures may result in the loss of the implant and biological damage. Adequate antibiotic coverage is recommended during and following surgery.

Easy Grip® CONE NARROW implants must be used as specifically designed instrumentation for oral implantology and only fitted with prosthetic components by T.F.I. System srl.

The patient should be adequately informed on the use and maintenance of the prosthesis, and the attending dentist must perform six-monthly checks and maintenance.

The life span of the entire implant prosthetic reconstruction is the longer the slower support bone resorption is.

It has been proven that a certain amount of bone resorption is physiological (Albrektsson, 1987), however, poor oral hygiene may lead to infectious complications that increase this loss. That is why it is important for the patient to be made aware of the need to maintain good oral hygiene and attend the routine checks.

Mobility of the implant, sensitivity to percussion, bone loss and infection are indicators of implant failure, which must then be removed.

WARNINGS:
Some complications may follow the surgical insertion of dental implants: bruising, bleeding, haematoma, soft tissue dehiscence, delayed healing, inflammation, infection, paraesthesia, hyperaesthesia, anaesthesia, chronic pain due to the implant, perforation of the maxillary sinus, anatomical structure lesions (nerve bundles and blood vessels), alveolar atrophy in the maxilla or mandible, oro-nasal or oro-antral fistulas, damage to adjacent teeth, bone fractures and rupture of the implant or instruments.

Delayed complications may occur in the event of prosthesis overload, such as fracture in the prosthetic superstructure, implant fracture, loosening of screws that connect the prosthesis and loss of integration. Imperfections and peri-implantitis are possible complications.

The surgical procedure to use the products of the Easy Grip® CONE NARROW Implant System is highly specialised: hence use of these products is solely limited to professionals and experts in the dental sector. Should the operator deem not to have the appropriate knowledge, they should follow appropriate training courses before using these products.

The surgical and prosthetic procedures described are to be considered a set of standard guidelines that may be applied to the particular requirements and circumstances that arise in practice, depending also on the manual skills, experience and diagnosis made by the legally qualified doctor.

The manufacturer cannot be held liable for the use of the product and the procedure followed.
The responsibility for the correct and proper use of the instruments and products is therefore borne by the user.

The Easy Grip® CONE NARROW range is continuously enhanced.
T.F.I. System srl therefore reserves the right to alter the design and production. Check for product updates on www.tfisystem.it

IMPLANT CHOICE:
The number, type and dimensions (diameter and length) of the implant to be inserted depend on a number of factors such as:

- quantity and quality of available bone
- the characteristics of the implant site
- masticatory force

these parameters should be properly assessed in order to select the implant correctly.

A Radiographic Template (RX9) is available where all the endosseous measurements of the Easy Grip® CONE NARROW implants are reproduced according to radiographic scales, allowing the correct implant length to be chosen during preoperative planning with a conventional approach.

The Easy Grip® CONE NARROW line is ideal in the case of:

- Limited ridges and interdental spaces.
- Upper lateral incisors.
- Lower central and lateral incisors.

M
NARROW

DN 3.00

Series 80 conical screws

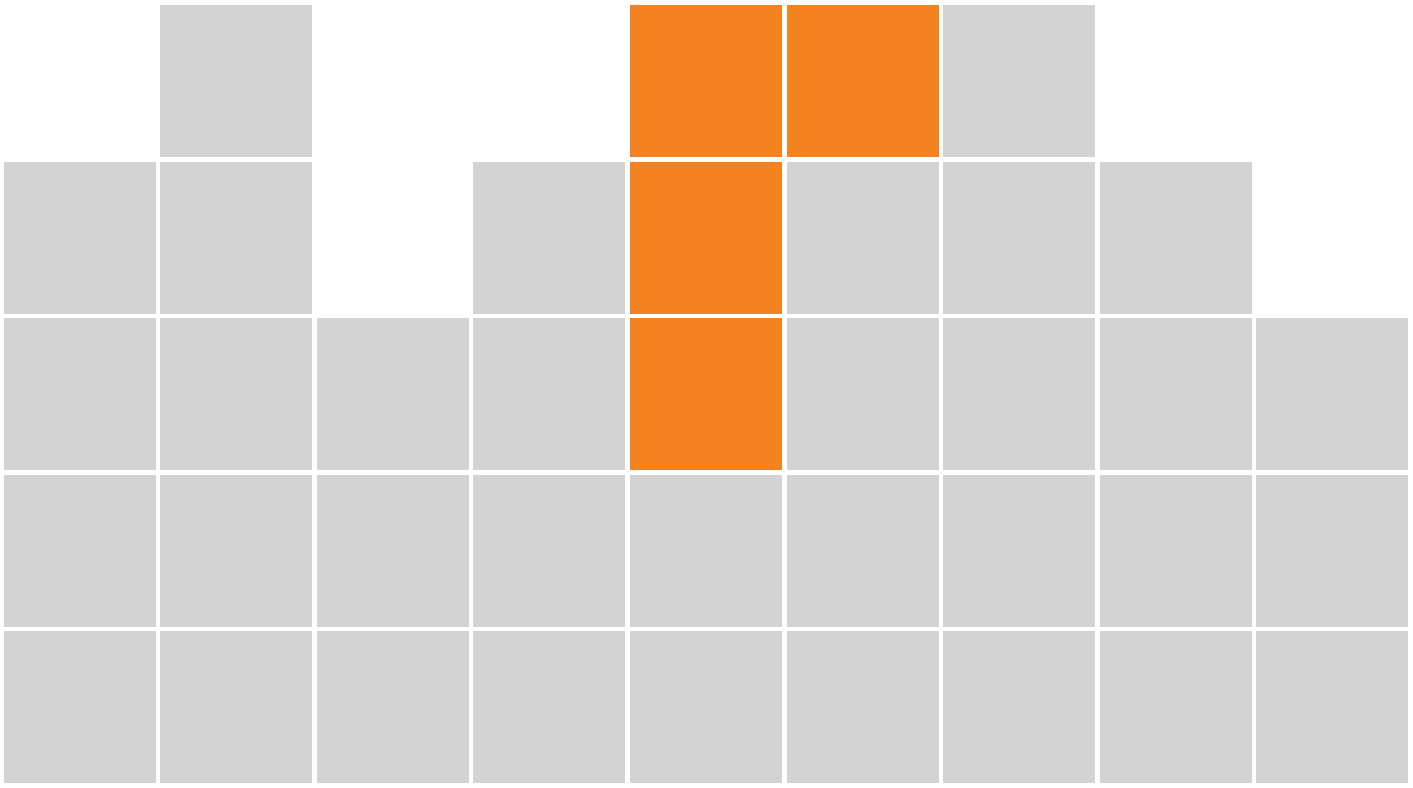
89M10

89M11

89M13

The pictures are purely for illustrative purposes

IMPLANTS



NARROW - 89M

Morphology

- Self-tapping conical thread
- 5° conical coupling
- Internal hexagon
- Cortical micro-threads
- Apex/body Ø 2.30/3.00 mm
- Lengths: 10 - 11.5 and 13 mm
- Material: grade 5 ELI titanium
- Surface Osteogrip (SLA)
- Cap screw Ø 3.00 mm

Ideal in the case of:

- Limited ridges and interdental spaces
- Upper lateral incisors
- Lower central and lateral incisors

Related products

Dedicated prosthetics
Easy Grip® CONE NARROW Connection

instrumentation
- Burs: RMB20 - RMB24 - RMB27
- Tap: MA82

Milling speed

- Hard bone (D1-D2): 500-800 rpm
- Soft bone (D3-D4): 200-300 rpm

VT2

CE 0425

M
89M10
DN 3.00
CONICO
CONE CONNECTION

Code	Ø Platform	Ø Apex/Body	Length
89M10	3.00	2.30/3.00	10
89M11	3.00	2.30/3.00	11.5
89M13	3.00	2.30/3.00	13

All measurements are in mm.

Standard surgical protocol for bone density **D1** **D1-D2** **D3-D4**

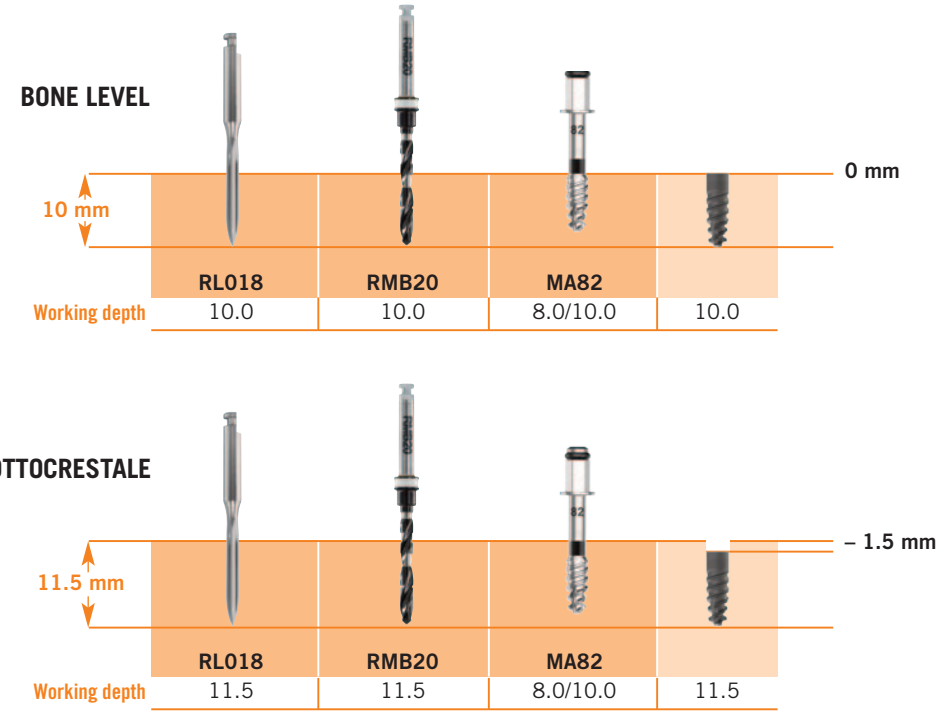
The biomechanical characteristics of the Easy Grip® CONE NARROW line allow flexible corono-apical implant placement, in the presence of sufficient bone and with respect for the "noble" structures, taking into account the osteotomy and not the length of the implant. Optimal implant placement is 1.5mm subcrestal, the depth of the surgical site preparation will then extend a maximum of a further two millimetres over the length of the implant, taking the next notch on the surgical drills as a reference: **working depth** 11.5 mm for implants with a length of 10 mm, 13 mm for implants with a length of 11.5 mm and 15 mm for implants with a length of 13 mm.

● recommended
○ optional

89M Narrow Ø 3.00		RLO18	RMB20	RMB24	RMB27	MA82	
Ø max		1.8	2.0	2.4	2.7	3.0	3.0
rpm max		850				15	
Bone quality	D1 very hard bone	●	●	●	○	(*)	D1
	D1 - D2 hard and very hard bone	●	●	○	○	(*)	D1 - D2
	D3 - D4 soft and very soft bone	●	○	○	○	(*)	D3 - D4

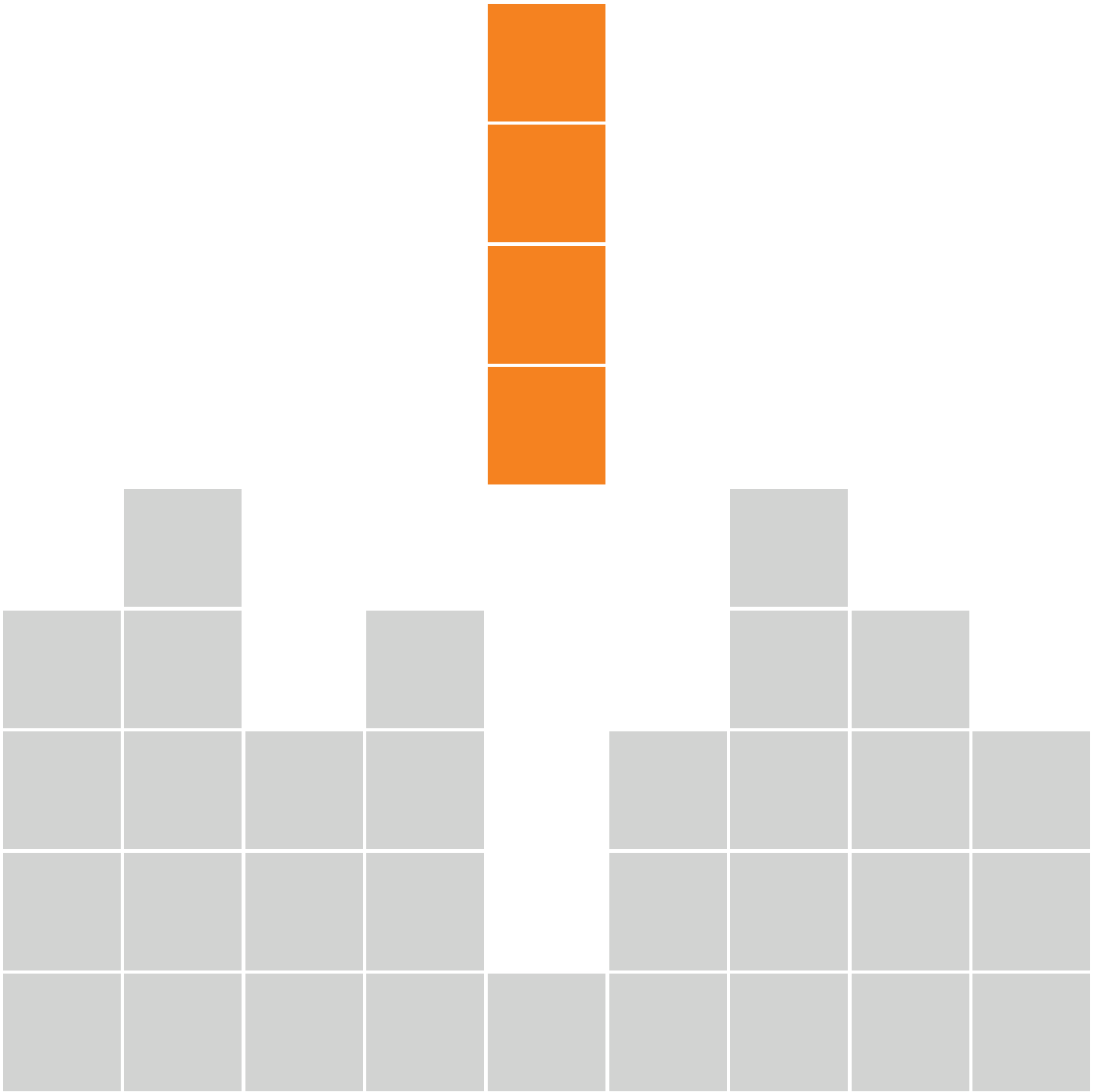
(*) Cortical preparation with the tap is always limited to 8 mm (beginning of notch) or 10 mm (end of notch) for all Easy Grip® CONE NARROW implant lengths. The working depth may vary depending on the final **Bone level** or **Subcrestal** position of the implant and the different bone conditions present.

Placement example of CONE NARROW implant with a length of 10 mm (89M10)



This surgical protocol simply indicates the methods and intended use of the various surgical accessories and instruments suited for the case, since the professional operator is responsible for the correct interpretation of the instrument application to the individual clinical case.

SURGICAL ACCESSORIES



Initial Burs

RA018 RL018

Surgical Burs

RMB20 RMB24 RMB27

Depth Stops

BP208 BP210 BP211 BP213 BP215 series BP2

Bone taps

MA82

Accessory Burs

RL035

The pictures are purely for illustrative purposes

Spanners

PROSTHETIC


B1R


B2R


IC3


IC4


AM22


AM25


7AM25S

IMPLANTS


IS1


IS2


AM32


AM30

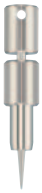
Instruments and Accessories


EMS


EM2S


7MPS

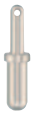

7AMPS


MC3


CDM


DIS


MP


PAR


PUN


PRF


AMFO

CUD80

CU20


CL

SURGICAL BURS

Cylindrical Easy Grip® surgical burs made from medical steel are helical and externally irrigated.

The DLC (Diamond Like Carbon) treatment that gives the bur its characteristic black colour not only improves the visibility of the depth markings during use but also enhances performance:
- Increased cutting hardness (precision).
- Increased abrasion resistance (number of uses).
- Increased resistance to chemical aggression (readability over time).

Used in sequence, in accordance with Easy Grip® surgical protocols, they make it possible to perform osteotomies according to the type and quality of bone available.

They are equipped with depth markings and can be used with fixed-height depth stops.

The colour code on the shank identifies the diameter of the implant for which the bur is used as the final step.

Caution: when milling in the vicinity of vital anatomical structures, the increased length of the drill, which varies from bur to bur, must be taken into account.

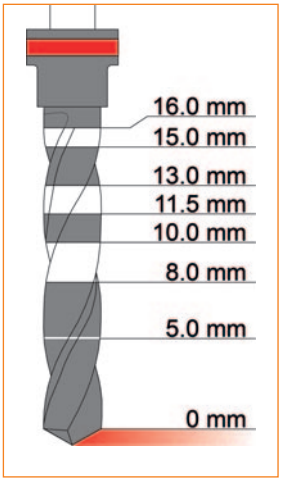

RMB20


RMB24


RMB27


serie BP2


PRF



Code	Colour ID	Diameter (mm)	Depth markings (mm)	Description
RMB20	☐	2.00	8-10-11.5-13-15	Surgical bur
RMB24	☐	2.40	8-10-11.5-13-15	Surgical bur
RMB27	■	2.70	8-10-11.5-13-15	Surgical bur

Related codes

Code	Length (mm)	Description
BP208	8	Stop for RMB2 burs
BP210	10	Stop for RMB2 burs
BP211	11.5	Stop for RMB2 burs
BP213	13	Stop for RMB2 burs
BP215	15	Stop for RMB2 burs
PRF		Bur extension

ACCESSORY BURS

Initial Burs

The **RA018** round initial bur and the **RL018** cutter create the site on the bone ridge for the initial burs.

Bone crest bur

RLO35: the bur specifically designed for evening the bone crest in one single pass.

RA018

RL018

RLO35

TAPS

Made of medical steel, they can be used either manually with the digital key (CDM), the ratchet (CUD80), the screwdriver handle for hexagonal inserts (CL) or with the contra-angle handpiece via the adapter (AMF0).

They are mainly used with compact bone to prevent forced introduction of the implant causing compressive bone stress and thus impairing healing.

MA82

Code	Colour ID	Diameter (mm)	Length (mm)	Description
RA018		1.80		Round initial bur
RL018		1.80		Initial lanceolate bur
RLO35		3.50		Bur for evening the bone crest
MA82		3.00	8/10	Tap for 89M

KEYS AND INSERTS

Wide range of surgical and prosthetic accessories common to all products in the Easy Grip® line.

Due to their small sizes, several accessories are fitted with a thread hole to prevent the risk of being ingested by the patient.

AM22

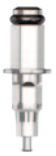
AM25

AM32

AM30

IC3

IC4



IS1

IS2

B2R

B1R

CDM

CL

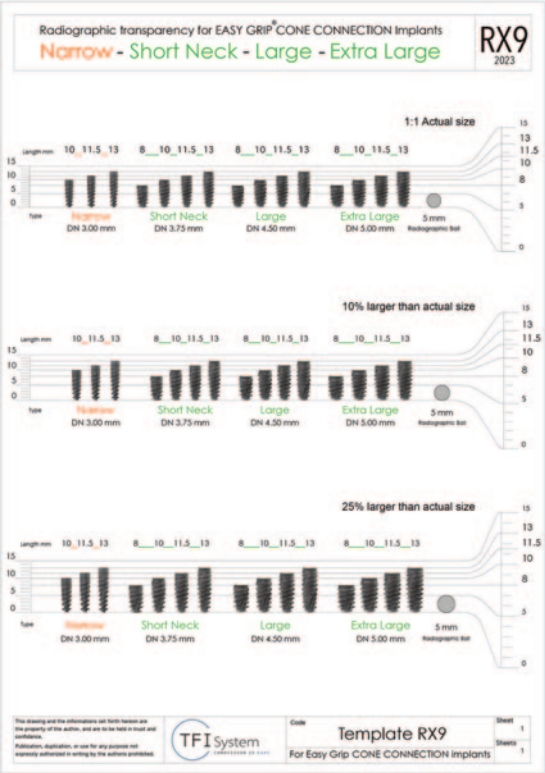
CUD80

CU20

Code	Material	Description
AM22	steel	Short contra-angle spanner e.g. 1.25 mm for screws
AM25	steel	Long contra-angle spanner e.g. 1.25 mm for screws
AM25S	steel	Contra-angle spanner for inclined screwing
AM30	steel	Long contra-angle implant installation spanner
AM32	steel	Short contra-angle implant installation spanner
AMF0	steel	Contra-angle adapter for e.g. 3.00 mm
B1R	steel	Hand screwdriver e.g. 1.25 mm for screws
B2R	steel	Shorthand screwdriver e.g. 1.25 mm for screws
CDM	titanium	Manual adapter for inserts and taps
CL	steel	Long manual spanner for inserts and taps
CU20	steel	Fixed ratchet
CUD80	steel	Torque ratchet
IS1	steel	Short implant installation spanner for ratchet
IS2	steel	long implant installation spanner for ratchet
IC3	steel	Short ratchet insert e.g. 1.25 mm for screws and stumps
IC4	steel	Long ratchet insert e.g. 1.25 mm for screws and stumps
7MPS	steel	Mounter for straight MUAs
7AMPS	steel	Mounter from contra-angle for straight MUAs

The morphology of handles and hexes may change with respect to what is shown here.

INSTRUMENTS AND ACCESSORIES

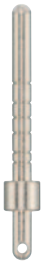


Easy Grip® CONE radiographic template

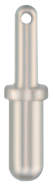
EMS

EM2S

MC3



MP



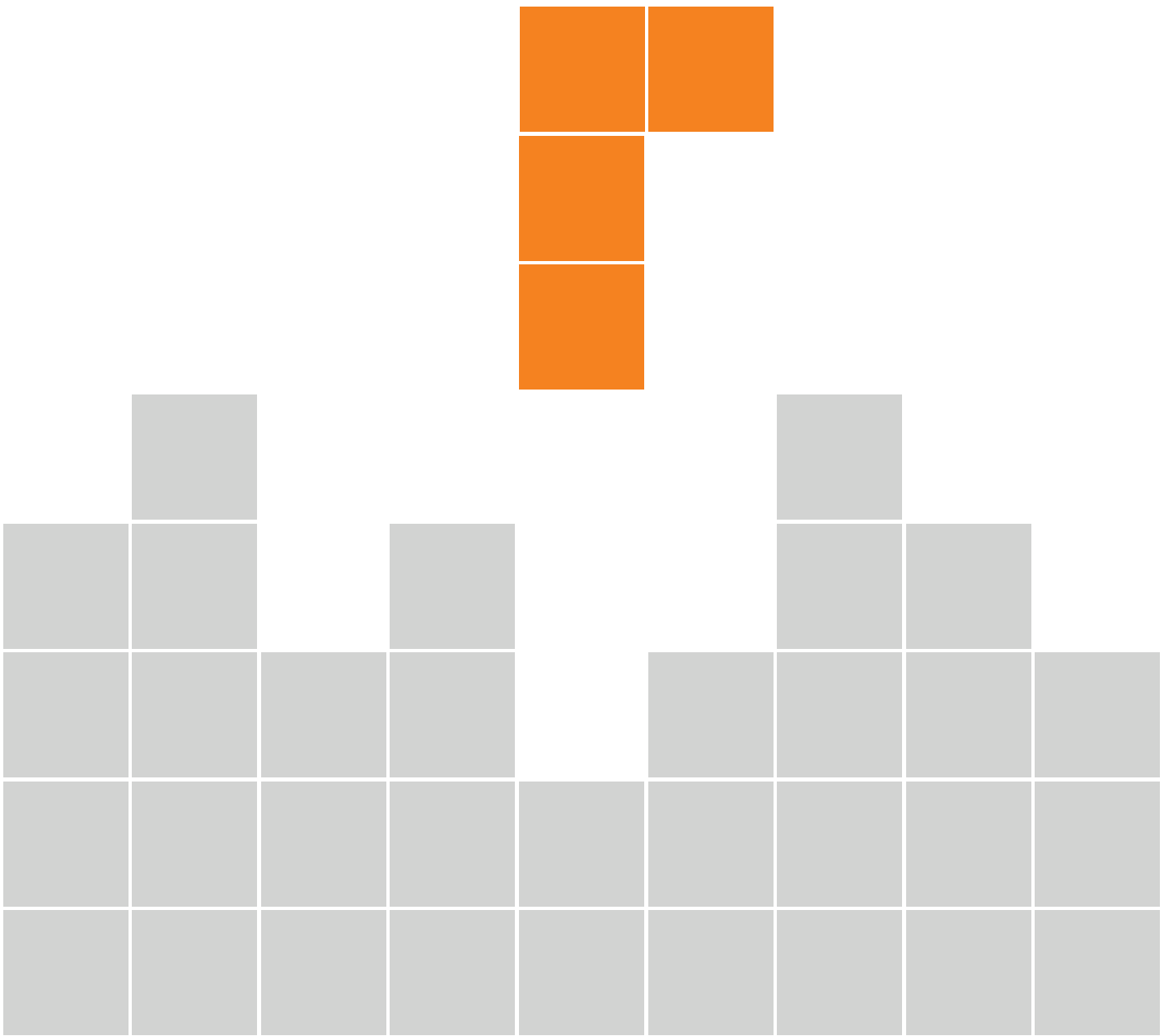
PAR

PUN

DIS

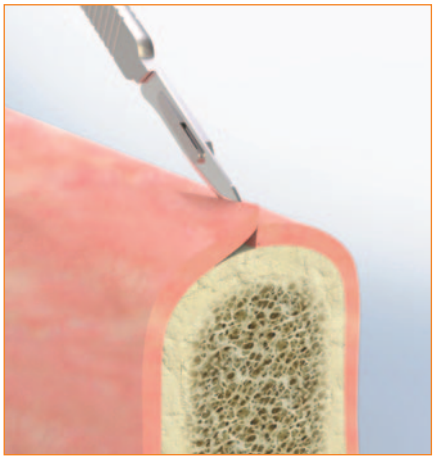
Code	Material	Description
EMS	titanium	Extractor screw M 1.6
EM2S	titanium	Extractor spanner M 1.6
MC3	titanium	Mucosal punch Ø 3.50 mm for SN implants
MP	titanium	Depth gauge
PAR	titanium	Paralleliser
PUN	titanium	Extension for mini-inserts and taps
DIS	titanium	Spacer
RX9		Radiographic template for Easy Grip® CONE series

SURGICAL PROTOCOL

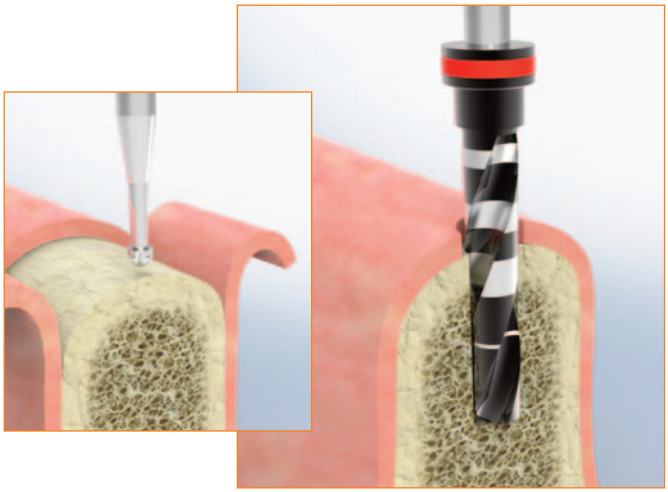


This surgical protocol simply indicates the methods and intended use of the various surgical accessories and instruments suited for the case, since the professional operator is responsible for correct interpretation of instrument application to the individual clinical case.

PREPARATION OF THE IMPLANT SITE



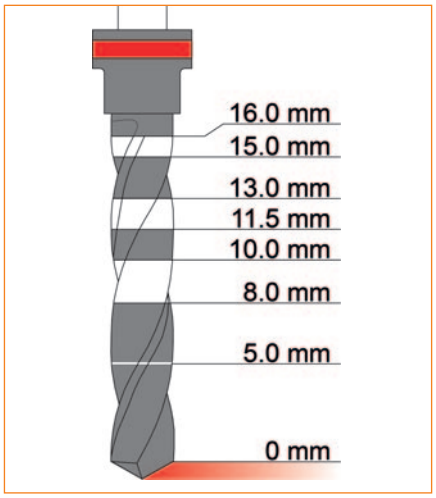
• Incision of the soft tissue and blunt dissection of the gingival flaps for access to the bone crest.



• Use in sequence of surgical burs starting from the RA018 round initial bur, to perforate the cortex and create the guide for subsequent use of the cylindrical burs. The RLO18 cutter may be used alternatively.

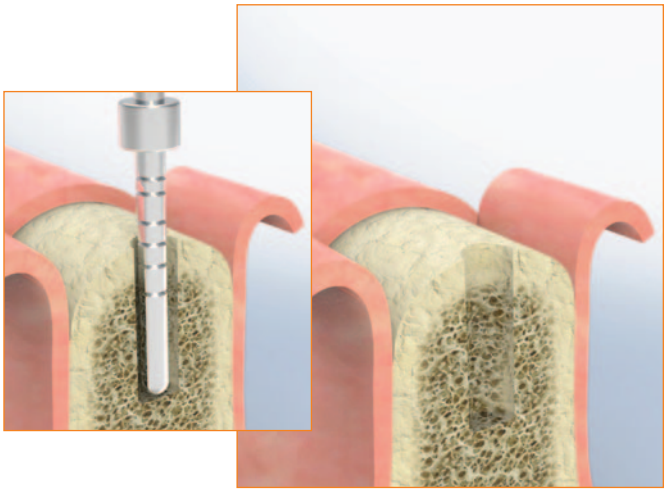
In the event of bony ridges with limit cross thickness or in the presence of poor bone density (type D4) it is recommended to replace the surgical burs with bone expanders, as appropriate, to achieve the proper depth of preparation without removing bone.

In the event of especially thin ridge bone it is recommended to use the bur kit for bone crest regularisation (RLO35), removing the crest-most section of the bone and creating an adequate bone platform.



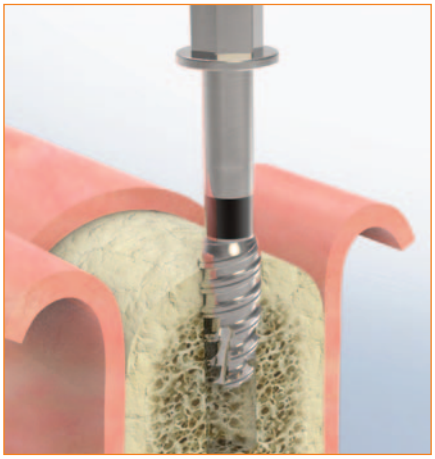
Bear in mind that cylindrical burs are slightly longer than implants, since it exceeds the tip length.

Therefore, while cutting near vital anatomical structures, one must take into account the greater length, variable according to the bur (see picture here and user instructions).



• **Final pass with externally irrigated cylindrical burs,** the exact sequence of burs is described in the pictures in individual implant sections.

Some bur steps may be omitted, at the dentist's discretion, depending on the bone density encountered.



• For high bone densities, after completing surgical site preparation with the burs, it is recommended to **tap** the hole with the suitable tap, to reduce compressive stress and make implant insertion easier.

Cortical preparation with the tap is always limited to 8 mm (beginning of notch) or 10 mm (end of notch) for all Easy Grip® CONE NARROW implant lengths.

The working depth may vary depending on the final BONE LEVEL or SUBCRESTAL position of the implant or the different bone conditions present.

Warnings:
It should be remembered that burs must have maximum cutting efficiency in order to avoid, while establishing the implant site, bone necrosis that would affect the subsequent osseointegration stage; for this reason, disposal is called for after creating 15-20 sites and in any case when bur cutting is impaired.

A further suggestion is to use the irrigation saline solution cooled at 4° C to achieve the maximum cooling capacity. Bone cutting must be carried out with an intermittent pumping action to allow for maximum cooling and remove bone detritus.

PROCEDURE FOR IMPLANT PICKING AND INSERTION

• Check the type of implant, its length and sterilisation expiry date on the label.

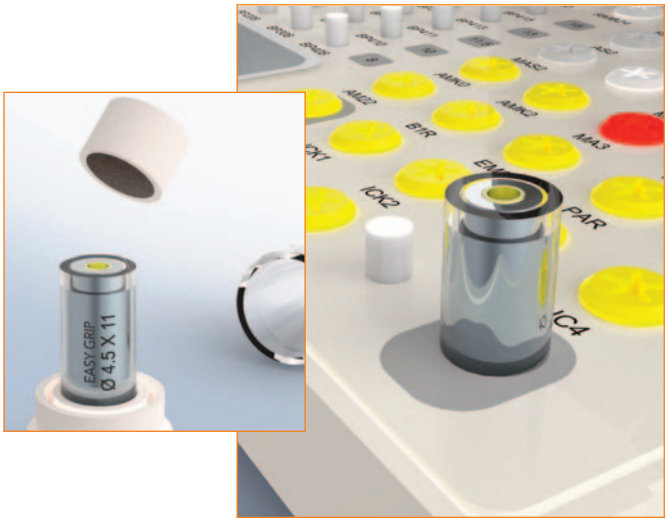
If the packaging is damaged, its contents may have lost sterility and therefore should not be used.
The package is equipped with a red anti-tampering seal which, if visible, demonstrates that it has been opened.

Open the package and take out the blister and adhesive labels bearing the implant identification batch and code, one of which can be placed in the doctor's medical file and the other on the patient's implant card.

• **Opening the blister:**
the nonsterile assistant removes the protective sheet by taking the tear corner between two fingers and pulling upwards.

This exposes the jar containing the tube with the implant, which must be set on a sterile cloth so that from then on it will solely be handled by the operator wearing sterile gloves.

• **Opening the jar:**
open the cap that the ampoule containing the implant is attached to, and pull it out.



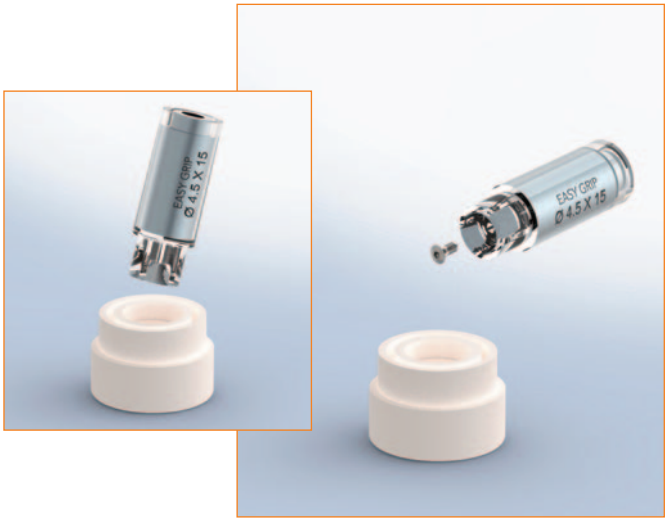
• **Opening the ampoule:**
remove the cap of the ampoule and expose the head of the implant housed inside the titanium tube.

• To safely withdraw the implant, the ampoule containing the implant can be inserted into the appropriate slot in the Tray kit.

• Take the implant with the most suitable driver for the case (mechanical aid or ratchet insert) and carry it to the implant site, screwing it all the way into position.

• Engagement of the driver takes place with a simple pressure on the system, during engagement the screwing of the driver itself keeps the engagement active.

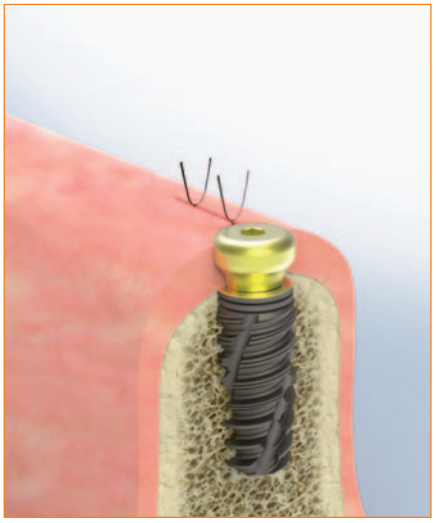
• Removal of the driver from the implant is achieved by gently rotating the driver anti-clockwise.



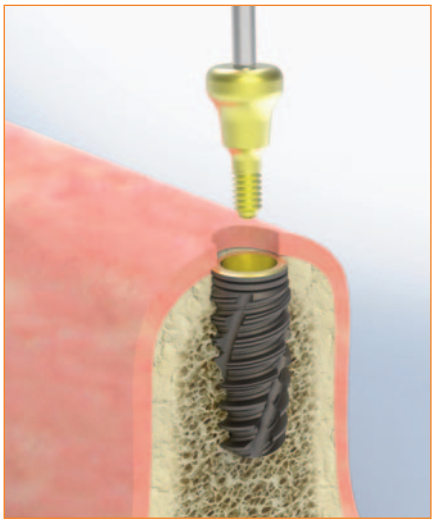
• The closing screw is housed at the bottom of the ampoule. To access it, remove the cap and unscrew it.

SINGLE SURGICAL STAGE TECHNIQUE

• Close the implant with the appropriate healing screw (VG24-x);
the choice of screw must be made:
- based on the location of the installation,
- according to the thickness of the soft tissue..

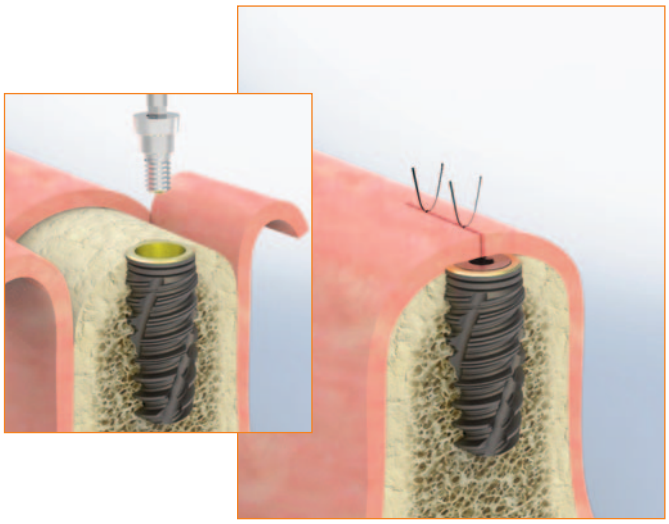


• Suture the gingival flaps around the screw.



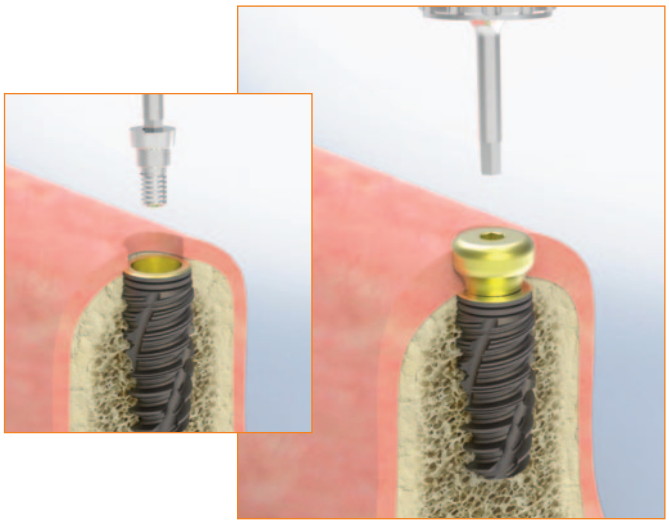
• At the end of the implant osseointegration stage, which may vary from 3 to 6 months depending on bone quality, type of procedure performed and the patient's clinical parameters, remove the cover screw from the implant and proceed with the prosthetic protocol.

DUAL SURGICAL STAGE TECHNIQUE



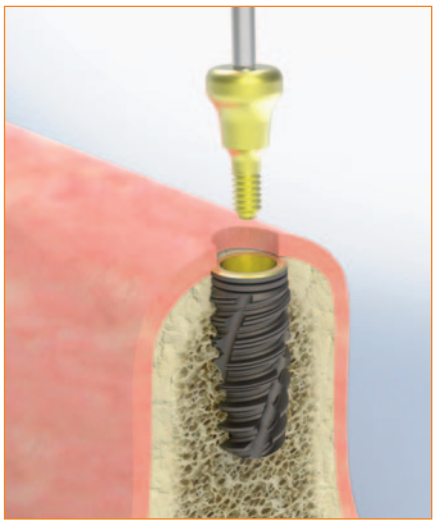
• Close the implant by means of the suitable plug screw picking it with the B1R or B2R hex from the base of the transport system.

• Suture the gingival flaps to totally cover the screw.



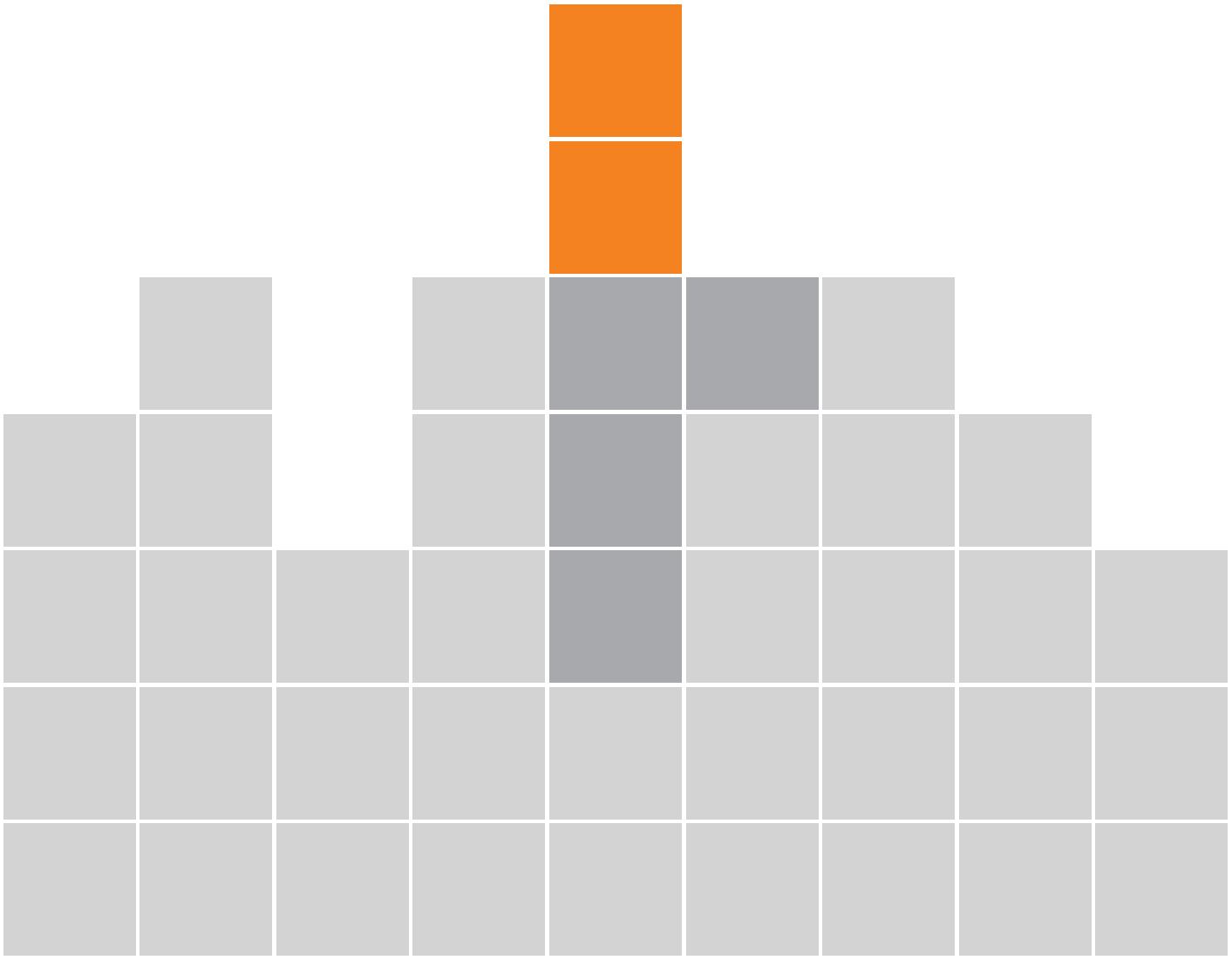
• At the end of the implant osseointegration stage, which may range between 3 and 6 months depending on bone quality, type of procedure performed and the patient's clinical parameters, remove the plug screw from the implant after incision of the overlying gingival tissue or by means of the circular tissue punch (MC).

• Position the appropriate healing screw on the implant.

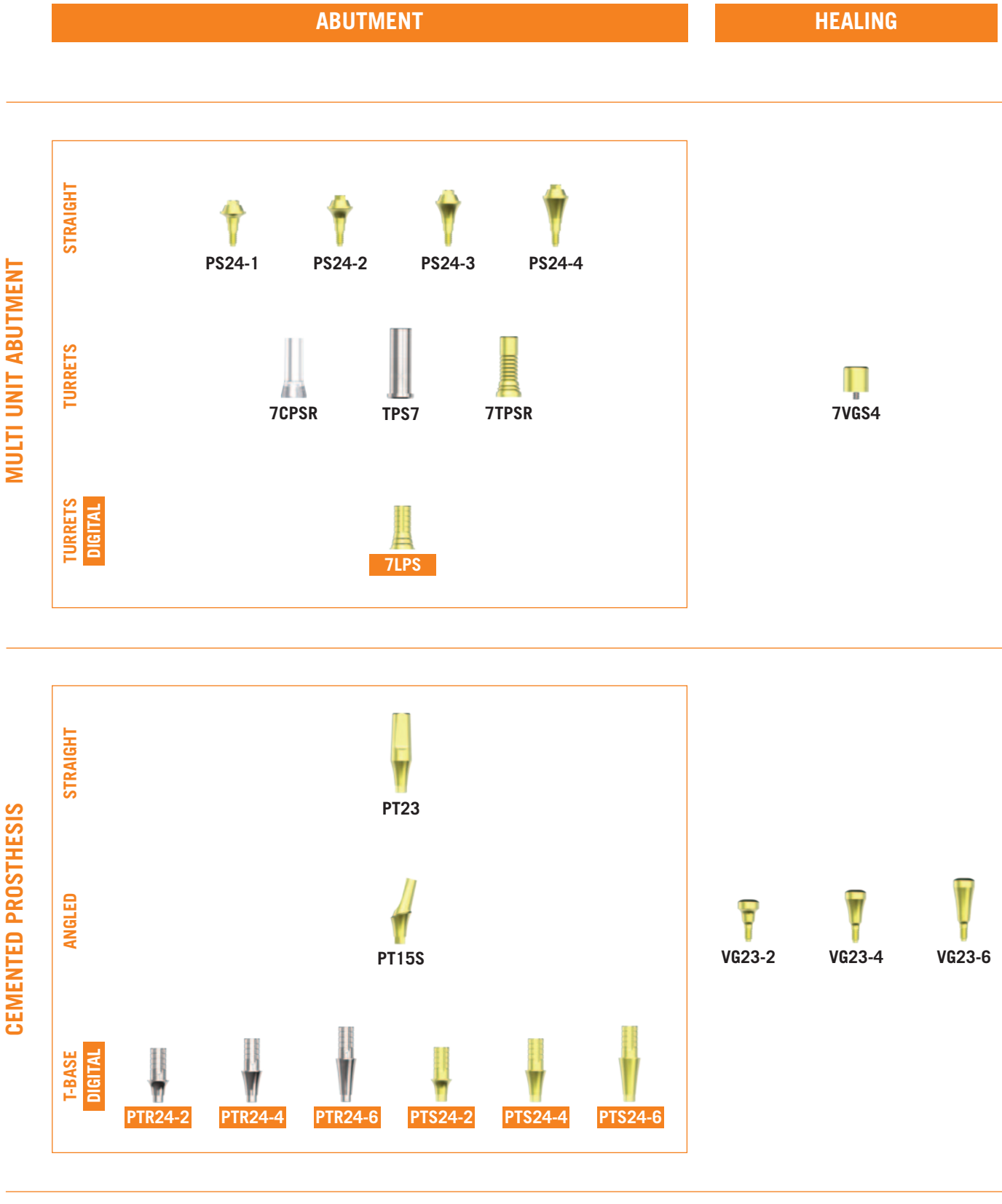


• Upon successful healing of the gingival tissues, remove the healing screw and proceed with the prosthetic stage.

PROSTHETIC COMPONENTS



GENERAL DIAGRAM



Code in the Easy Grip® digital libraries

IMPRESSION		SCREWS	DIGITAL SOLUTIONS		
TRANSFER	ANALOGUE		SCANBODY	ANALOGUE	ANGLED CHANNEL


7TUS4R


7LAS


7VOP


7SBPS


7LDS

7VAL


7VA


T3


T4


7CTU


LBM


VUS


SBSX


LDM

The pictures are purely for illustrative purposes

SCREWS

VUS

Universal connection screw for tightening the abutment to the implant.
The optimum torque for tightening is 30 Ncm

7VOP

Screw for tightening the MUA turrets of the Easy Grip® CONE series.
The optimum tightening torque is 15 Ncm

7VA - 7VAL

Occlusal screw for MUA for angled canals, short (7VA) and long (7VAL) version.
The maximum tightening torque is 15 Ncm

7VGS4

Healing screws for MUAs.
The maximum tightening torque is 15 Ncm

VT2

Cap screw included in the implant package.
Used to seal the implant during the bone healing phase.
The maximum tightening torque is 20 Ncm.

VG23-x

Healing screws for reconditioning the mucosal tissue.
Used to seal the implant during the bone healing phase.
The maximum tightening torque is 20 Ncm.

VLC1

Long screw pitch M1.6
for T3 transfer (direct impression).

7VLC5

Long screw pitch M1.4
for MUA transfer.

HEALING SCREWS

Made of grade 5 ELI titanium, they are used for mucosal reconditioning after the second surgical stage; available in three heights 2, 4 and 6 mm.

The screw head features a hexagonal socket to insert the 1.25 mm hex keys.

VG23-2

VG23-4

VG23-6

Code	Profile (mm)	Gingiva h. (mm)
VG23-2	4.00	2.00
VG23-4	4.00	4.00
VG23-6	4.00	6.00

TRANSFERS AND ANALOGUES

Transfers

Made of grade 5 ELI titanium, they are used for impression taking, available in the following versions:

- Indirect imprint with short screw and Teflon cap (7CTU sold separately).
- Direct impression with through-bolt.

Analogue

Made of grade 5 ELI titanium, they are used in the laboratory inside the plaster model to replicate the inside and prosthetic connection of implants.

7CTU

T3

T4

LBM

Code	Diameter (mm)	Profile	Description
T3	3.00	4.00	Transfer narrow imp. open
T4	3.00	4.50	Transfer narrow imp. closed
7CTU			Coping for transfer T4
VUS			Through-bolts M1.6
VLC1			Transfer screw M1.6
LBM	3.00		Analogue Narrow

MULTI UNIT CONCEPT

The Easy Grip® CONE NARROW Multi-Unit Abutment (MUA) range with **45° conical engagement** is designed for total and/or partial prostheses screwed onto multiple elements.

Available in different mucosal heights. Rotary and non "turret" abutments expand the prosthetic solutions available to the dentist, affording greater freedom of choice in the implant protocol.

Solution in the Easy Grip® libraries available for the following CAD/CAM systems:
- **3 Shape**
- **Dental Wings**
- **Exocad**

- **0° angles**
- **45° conical engagement** to correct further divergence and correctly position the prosthetic bar even with marked angles
- **High-performance screw** to assure mechanical resistance to masticatory strain and tightening torque (30 Ncm)

MULTI UNIT ABUTMENTS

In grade 5 ELI titanium, designed for total and/or partial prostheses screwed onto multiple elements, to transfer the working plane from the implant to the abutment.

The abutments and relevant accessories adopt the same frusto-conical 45° engagement as the Easy Grip® CONE line, which lets them be used even with marked angles, always ensuring correct passivation.

They are only available in a straight 0° version with a mucous membrane ranging from 1 to 4 mm.

The components and accessories: transfer, analogues, turrets, links, healing screws and scanbodies, allow the operator to make maximum use of the available bone while avoiding anatomical structures at risk of minimising the length of the prosthetic extremity in extension.

Digital solutions for Multi Unit Abutments can be found in the Easy Grip® CONE MUA library.

Within the library, the gluing turrets for MUAs associated with the 7LPS code can be selected under LINK.

The mathematics of this solution, available in rotary and non versions, create the perfect housing for the cementing of the turrets into the prosthesis, thus providing a "preformed" connection to customised digital rehabilitations, ensuring a perfect connection to the MUAs.

PS24-1 PS24-2 PS24-3 PS24-4

7LPS 7TPSR 7VOP

Code	Profile (mm)	Description
PS24-1	4.8	MUA Straight Narrow H 1
PS24-2	4.8	MUA Straight Narrow H 2
PS24-3	4.8	MUA Straight Narrow H 3
PS24-4	4.8	MUA Straight Narrow H 4
7TUS4R	5.0	MUA transfer with screw
7CPSR	4.8	Castable turret with screw
TPS7	4.8	Ti turret for screw welding
7TPSR	4.8	Ti turret with screw
7LPS	4.8	Bonding links with screw
7VOP		Universal occlusal screw M1.4

Related codes

Code	Description
7LAS	Anti-rotational MUA analogue
7LDS	MUA digital analogue
7MPS	Mounter for straight MUAs
7AMPS	Mounter from contra-angle for straight MUAs

CEMENTED PROSTHESIS

Easy Grip® CONE NARROW cemented technique abutments, manufactured from Grade 5 ELI Titanium, are equipped with the clamping screw (VUS).

PT23

VUS

PT15S

Code	Diameter (mm)	Gingiva	Description
PT23	4.0	6.0	Straight Narrow abutment
PT15S	5.0	4.0	Angled abutment 15° H 4 Narrow
VUS			Universal screw

CEMENTED PROSTHESIS

T-Base
These represent the ideal solution for creating bridges and/or bars with gluing technique through the use of the most common CAD/CAM systems.

They are available in non-rotary and rotary versions, with a clamping screw (VUS).

The trilobed profile of the cannula ensures an unambiguous position on the prosthetic part and an extremely accurate fit, leaving space for the anaerobic cement to distribute evenly.

Ideal for any need: for conventional approach, for traditional digital workflow (bench-top optical scanner) and for intraoral scanning applications.

The millimetric notches in the cementing cylinder allow the height to be customised according to the vertical spaces available.

Easy Grip® digital libraries CONE NARROW facilitate such customisation by offering pre-configured link housings in 4 and 6mm heights.

Available for the following CAD/CAM systems:
- **3 Shape**
- **Dental Wings**
- **Exocad**


PTS24-2


PTS24-4


PTS24-6


PTR24-2


PTR24-4


PTR24-6

Code	Diameter (mm)	Description
PTS24-2	4.00	T-base H 2 Narrow
PTS24-4	4.00	T-base H 4 Narrow
PTS24-6	4.00	T-base H 6 Narrow
PTR24-2	4.00	T-base H 2 rotating Narrow
PTR24-4	4.00	T-base H 4 rotating Narrow
PTR24-6	4.00	T-base H 6 rotating Narrow
VUS		Universal screw

Related codes

Code	Diameter (mm)	Description
LBM	3.00	Analogue Narrow
LDM	3.00	Digital analogue

DIGITAL SOLUTIONS

Scan Body
Made of matted Ti, it ensures excellent scanning results without the use of anti-reflection sprays.

They can be used for intra-oral and bench-top scans, guarantee the most accurate identification of angles, and are supplied with the corresponding occlusal screw.

Available in two types:
- **7SBPS**: MUA prosthesis, Library: Easy Grip® CONE MUA (pag. 41)
- **SBSX**: T-Base prosthesis, Library: Easy Grip® CONE NARROW (pag.43)

To facilitate identification by the dental technician, the MUA scanbody is laser-engraved with an "M" that is also visible on the STL file resulting from the intraoral scan.

All Easy Grip® digital libraries are available for the following CAD/CAM systems:
- **3 Shape**
- **Dental Wings**
- **Exocad**

CAUTION:
In the digital workflow, the implant line to be selected is Easy Grip® CONE NARROW.

7SBPS

7VOP

SBSX

VUS

Code	Library	Solution
7SBPS	EG CONE MUA	Multiple screwed CONE and CONE NARROW series prostheses
SBSX	EG CONE TBASE	NARROW series cemented single prostheses

Digital analogues

A line of digital laboratory analogues specifically for intra-oral scanning applications.

The cylindrical design with indexed base and counter-screw seal ensure high repositioning accuracy on the model while improving ease of insertion and attachment.

Available in two types:
- **LDM**: Replica implant 89Mxx (pag. 43)
- **7LDS**: Replica of MUA CONE (pag.41)

Can be used with Easy Grip® digital libraries available for the following CAD/CAM systems:
- **3 Shape**
- **Dental Wings**
- **Exocad**

LDM

7LDS

Screws and spanners for angled channels

The angled access channel solution offers the freedom to design optimised access channels for screws, tilt implants to achieve the ideal position and increase accessibility in areas where space is limited.

Suitable for use at angles up to 25° improves the handling and aesthetics of the restoration.

Prosthetic screws for angled canals are made of ELI Grade 5 Titanium, easily customisable thanks to blue anodising.

Equipped with a hexalobed engagement, they are used with the dedicated driver (7AM25S).

Available for MUA turrets in short (7VA) and long (7VAL) versions as a replacement for the corresponding 7VOP screw.

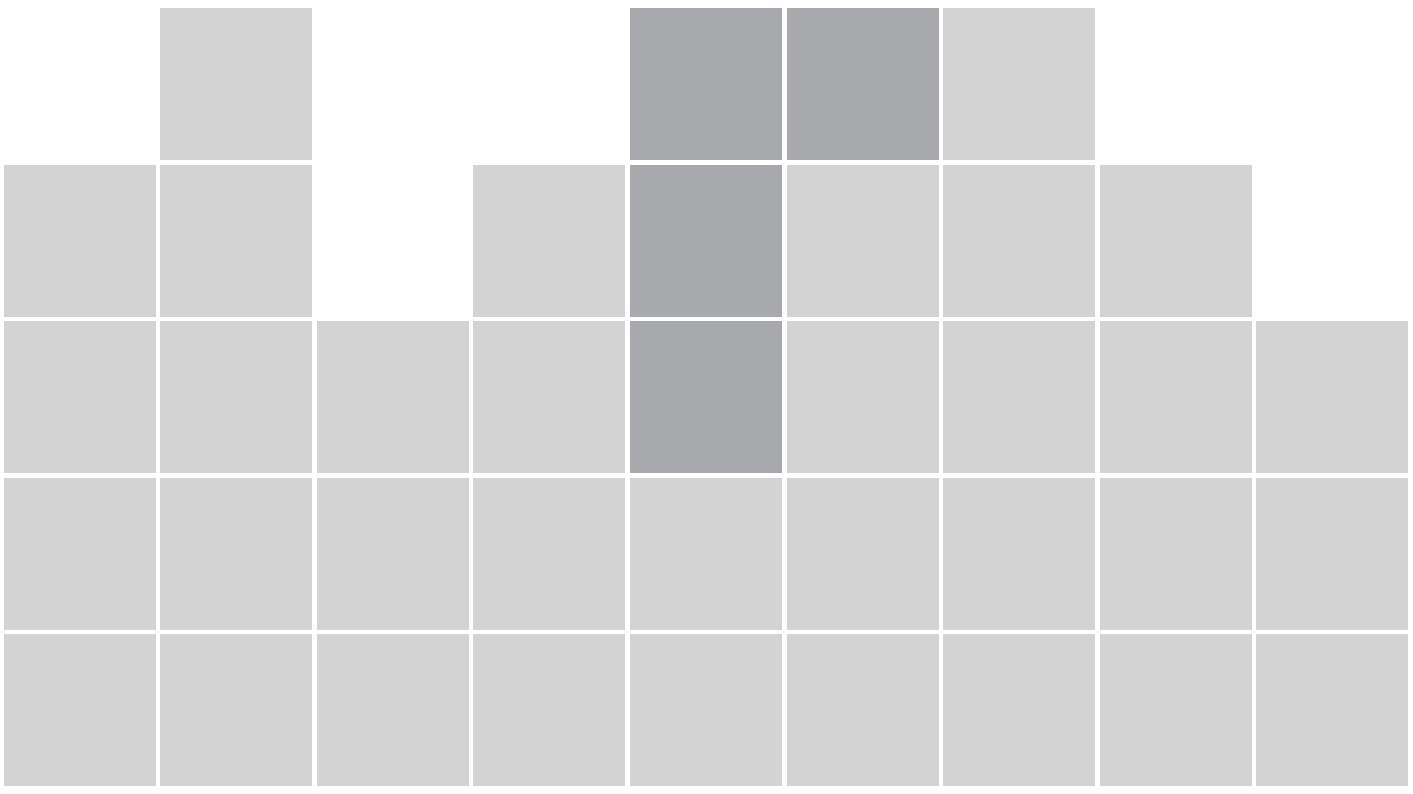
7VAL

7VA

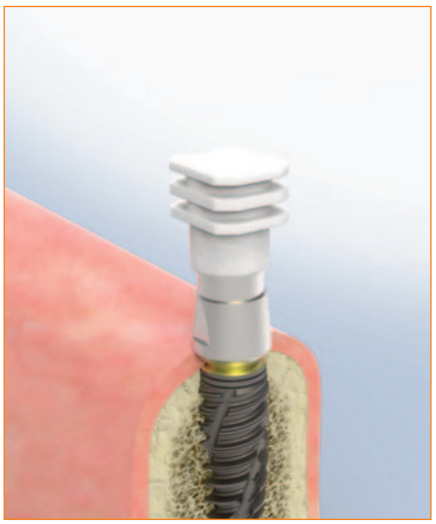
7AM25S

Code	Description
LDM	Narrow digital analogue (89Mxx plant replica)
7LDS	MUA CONE digital analogue
7VA	Short screw for MUA angled channels
7VAL	Long screw for MUA angled channels
7AM25S	Contra-angle spanner for high channels

PROSTHETIC PROTOCOL

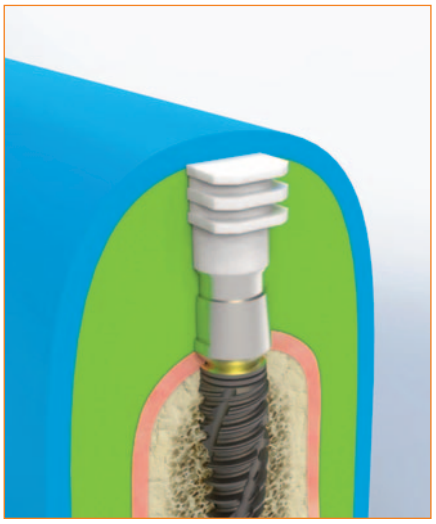


IMPRESSION TAKING: INDIRECT TECHNIQUE (SNAP-ON)

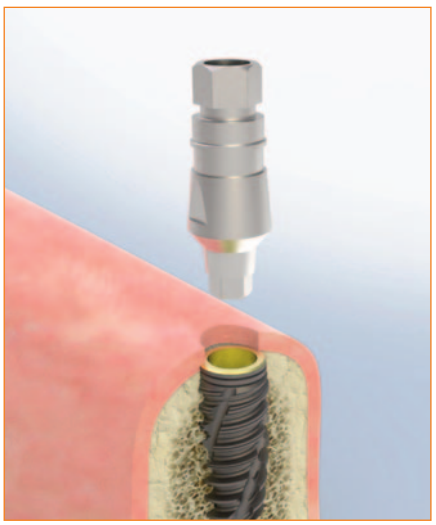


• Remove the surgical screw from the implant and introduce the transfer with short screw (T4) then tighten it to the implant with the B1R or B2R hex key.

To make impression taking easier, it is possible to use the transfer with the 7CTU coping.



• Place the tray with the impression material on the transfer and wait for the material to harden.



• Remove the tray from the oral cavity: the transfer will remain joined to the implant.

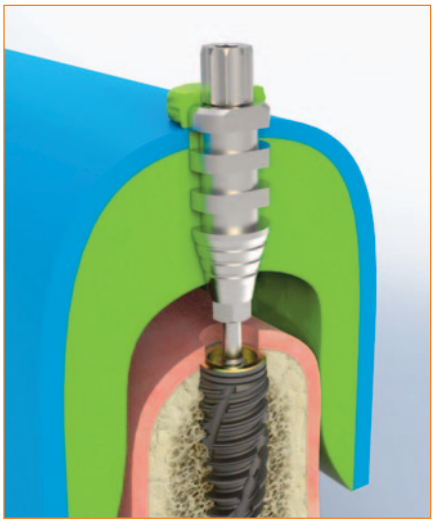
Remove the transfer from the oral cavity and reposition it on the impression checking correct positioning.

IMPRESSION TAKING: DIRECT TECHNIQUE (PICK-UP)

• Remove the surgical screw from the implant and introduce the transfer with long screw (T3) and tighten it to the implant with the B1R or B2R hex key

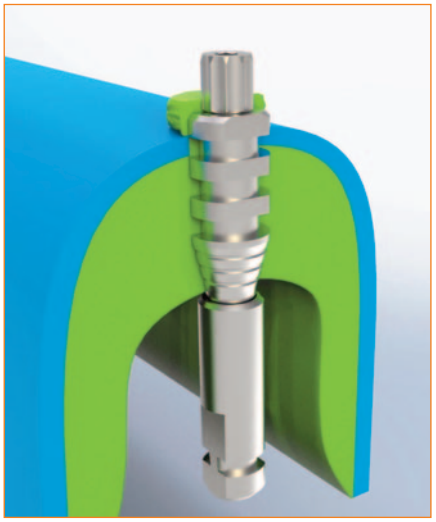
• Position the individual tray or standard perforated tray on the transfer so that the long screw of the transfer protrudes through the tray hole and is accessible for unscrewing.

Wait for the time required for the impression material to harden.



• Remove the transfer screw (VLC1) and remove the tray: the transfer will remain in the impression thanks to its retainers.

PREPARATION OF THE PLASTER MODEL

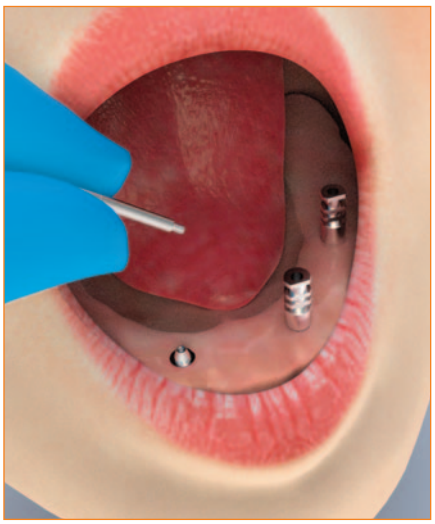


• Connect the LBM analogue to the transfer.

• Cast the plaster onto the impression, after positioning resinous material around the analogue for gingiva simulation.

• Remove the model from the impression: the analogue will be retained on the model bearing the exact position of the implant in the patient's mouth.

MUA - IMPRESSION TAKING WITH DIRECT TECHNIQUE (OPEN TRAY)



• **Transfer positioning**
Position the transfers, 7TUS4R (rotating) or 7TUS4 (non-rotating) on the head of the MUAs and tighten them with the long screw 7VLC5 supplied with the transfers.

• **Impression taking**
Place the individual tray or the standard perforated tray with the impression material on the transfers and wait the time required for it to harden.

Remove the excess material on the head of the transfers to aid in the subsequent removal of the tightening screw upon completing the impression taking stage.

• **Transfer procedure**
Unscrew and remove the 7VLC5 clamping screws from the transfers with the hand spanner (B1R or B2R) or ratchet bits (IC3 or IC4).

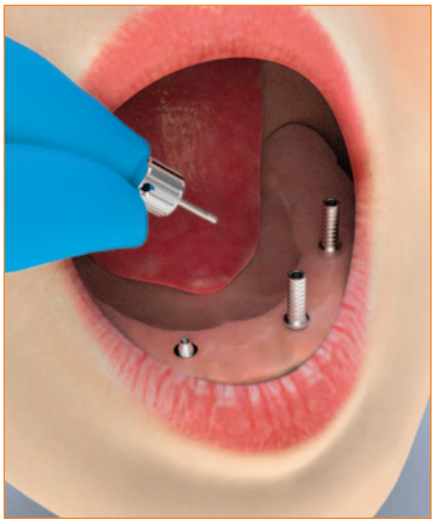
The transfers will remain in the impression thanks to the retainers.

• Insertion of the analogues
Insert the MUA 7LAS analogues into the base of the remaining transfers embedded in the impression material.

Then insert the 7VLC5 screws back onto the transfers and tighten them onto the analogues.

• Preparation of the plaster model
Cast the plaster onto the impression to create the model.

Remove the model from the impression after the plaster has set: the analogue will be retained in the plaster reproducing the exact position of the MUA in the patient's mouth.



• Making the prosthesis
Use titanium or castable sleeves (rotary and non) to make the prosthesis.

SERVICES AND RESEARCH

SERVICES

Implant replacement service
This service has been designed to enable the clinician to replace an implant that might have been mistakenly contaminated in any situation, e.g. an implant that fell on the floor or is no longer sterile due to accidentally opening the package.

Implant card
Intended for the patient to store the identification data of inserted implants and as a reminder of follow-up appointments, it is supplied with the implant.

*For further information refer to the website **www.tfisystem.it**, **Services** section*

COURSES

Course of surgical anatomy on cadavers
Structured in one didactic part in multimedia classroom and a practical one in the dissecting room, it has the following goals:
- recognise and identify the anatomical structures defined "*at risk*" in surgical and implantology practice in particular
- describe the main regenerative and reconstructive techniques achievable under outpatient local anaesthesia
- to perform on cadaver the various bone reconstruction techniques presented under the tutor's supervision.

Course on computer assisted implant surgery
Aimed at dental practitioners who wish to learn the correct computer assisted implantology techniques aimed at the treatment of simple and complex edentulous cases.

Theoretical and practical implantology course on patients
The aim of the Course is to allow participants to handle implant-prosthetic cases independently, from planning to surgery, according to the most current guidelines dictated by the literature.

Workshop
Introductory course on the use of the Easy Grip® implant range delving on the following issues:
- 20 years of clinical use worldwide and long-term follow up - Surgical advantages
- Prosthetic advantages
- Simplicity and ergonomics of the Easy Grip® system
- Maintenance and stability of bone and mucosal tissues through time.

*For further information refer to the website **www.tfisystem.it**, **Courses** section*

POLYTECHNIC UNIVERSITY OF MILAN

Dynamic fatigue strength test for endosseous dental implants
Breaking tests (with "almost statically" applied load and different tightening values of the implant/abutment coupling screw) as well as fatigue resistance tests (load applied cyclically) have been carried out in compliance with standard UNI EN ISO 14801 for validating the implant/abutment system.

UNIVERSITY OF L'AQUILA

Study into the mineralisation process of osteoblasts on differently treated titanium surfaces
This research highlights the peculiarities of the process called "OSTEOGRIP".
Specifically, aluminium oxide is identified as more suitable for sandblasting than zirconium oxide, and the validity of the Glow Discharge treatment for activating the osseo-integrative process is confirmed.

POLYTECHNIC UNIVERSITY OF THE MARCHE

Research and development of implant/abutment fixing systems in implant dental prosthesis
Pivotal research to establish the morphological features of the Easy Grip® range.

CERMET

Mechanical characterisation under dynamic fatigue of intraosseous implants
A series of mechanical tests were performed on the entire Easy Grip® CONE NARROW implant line in compliance with standard UNI EN ISO 14801 in order to validate the implant/abutment system and establish the maximum stress.

FDA 510K n. K073622

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: EASY GRIP

Indications for Use:

EASY GRIP implants are designed for use in partially or totally edentulous mandibles or maxillae for attachment of complete denture prostheses or as a terminal or intermediary abutment for fixed or removable bridgework or as a free-standing single tooth replacement. EASY GRIP implant system uses a two-stage implantation procedure or one-stage procedure.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073622

CE 0425

ICIM

Approvazione del Sistema Completo di Garanzia di Qualità
Full quality assurance system approval

Certificato N. / *Certificate No.* **0425-MED-004381-00**

Secondo l'allegato II, escluso (4) della Direttiva Europea 93/42/CEE (recepita con il Dlg n. 46 del 24.02.97)
According to Annex II, excluding (4) of EC Directive 93/42/CEE (as transposed into Dlg n. 46 issued on 24.02.97)

ORGANISMO NOTIFICATO / *NOTIFIED BODY*

ICIM S.p.A. - Identification number: 0425
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY

VISTO L'ESITO DELLE VERIFICHE CONDOTTE IN CONFORMITÀ ALL'ALLEGATO II ESCLUSO (4) DELLA DIRETTIVA EUROPEA 93/42/CEE DICHIARA CHE IL SISTEMA COMPLETO DI GARANZIA DELLA QUALITÀ ATTUATO DA:
ON THE BASIS OF THE ASSESSMENT PERFORMED ACCORDING TO ANNEX II EXCLUDING (4) OF EC DIRECTIVE 93/42/CEE DECLARES THAT THE FULL QUALITY ASSURANCE SYSTEM ENFORCED BY:

T.F.I. SYSTEM S.R.L.
Sede Legale e Operativa: Via Giacomo Peroni 400/402 - 00131 ROMA Italia

PER I SEGUENTI TIPI DI PRODOTTI, PROCESSI, SERVIZI
FOR THE FOLLOWING KINDS OF PRODUCTS, PROCESSES, SERVICES

Impianti dentali, protesica ed accessori
Dental implants, prosthetic system and accessories

Strumentario ed accessori
Instruments and accessories

È CONFORME AI REQUISITI / *IS IN COMPLIANCE WITH REQUIREMENTS*

Allegato II ESCLUSO (4) della Direttiva Europea 93/42/CEE
Annex II EXCLUDING (4) of EC Directive 93/42/EEC

Per l'identificazione dei modelli di prodotto vedere l'Allegato / *For identification of the model type see Annex*

Il presente Certificato è da ritenersi valido solo se accompagnato dal relativo Allegato / *This Certificate is valid only with the relative Annex*

Gaetano Trizio
Rappresentante Direzione / Management Representative
ICIM S.p.A.

PRIMA EMISSIONE / *FIRST ISSUE*	EMISSIONE CORRENTE / *CURRENT ISSUE*	DATA DI SCADENZA / *EXPIRING DATE*
27/04/2021	27/04/2021	26/05/2024

ICIM S.p.A. - Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)

KINGDOM OF SAUDI ARABIA
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

VISION 2030

SFDA

إذن تسويق جهاز / مستلزم طبي
Medical Device Marketing Authorization

Issuing Date: 02/10/2020	**Authorization Number:** MDMA-1-2020-1807	رقم الإذن:	تاريخ الإصدار: 15/2/1442
Expiry Date: 26/5/2024	**Version Number:** 4	رقم الإصدار:	تاريخ الانتهاء: 19/11/1445
Last Version Date: 18/2/2022			تاريخ آخر إصدار: 17/7/1443

The Authorization is issued in accordance with the Medical Devices Law issued by Royal Decree No. (M/54) dated 6/7/1442 HA,

أصدر هذا الإذن بموجب نظام الأجهزة والمستلزمات الطبية الصادر بالمرسوم الملكي رقم (م/54) وتاريخ 6/7/1442 هـ.

This authorization allows:

هذا الإذن يخول:

ME0000015495
T.F.I. System srl
Via Giacomo Peroni 400-402,Rome,00131 Italy

To market the medical devices listed in the attached annex* in the Kingdom of Saudi Arabia

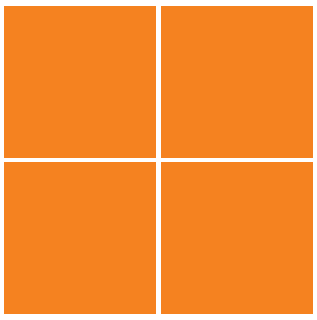
بتسويق الأجهزة / المستلزمات الطبية المحددة في القائمة المرفقة* في المملكة العربية السعودية

المدير التنفيذي لتقييم الأجهزة الطبية
Executive Director of Medical Devices Evaluation

د.عبد اللطيف بن سليمان الوطبان
Abdullatif S.Al Watban,Ph.D.

Page 1 of 46

EASY GRIP® HEX, CONE AND NARROW LINE USE INSTRUCTIONS



DENTAL IMPLANTS AND MINI-IMPLANTS FOR OVERDENTURES

Product

Dental implants and Mini-implants from the Easy Grip® line.
For full details of available components refer to the updated catalogue or www.tfisystem.it.

Features of the Easy Grip® CONE dental implant:
- material: titanium grade 5 ELI
- self-tapping screw
- connection: conometric and internal hexagon
- 10° conical coupling
- morphology: conical
- diameter: 3.00 - 3.75 - 4.50 - 5.00 mm.
- length 8.0 - 10.0 - 11.5 - 13.0 mm.
- surface: osteogrip.

Features of the Easy Grip® HEX dental implant:
- material: titanium grade 5 ELI
- self-tapping screw
- connection: internal hexagon and internal chamfer
- 45° conical coupling
- morphology: cylindrical, conical, anatomical
- diameter: 3.30 – 3.75 – 4.50 – 5.00 – 6.00 mm.
- length 5.0 - 8.0 - 10.0 - 11.5 - 13.0 - 15.0 mm.
- surface: osteogrip.

Features of the mini-implant for overdentures:
- material: titanium grade 5 ELI
- threaded cylindrical double-helix self-tapping screw
- connection: ball
- external hex for 2.20 mm screw.
- transmucosal route from 0 to 4 mm
- body Ø 2.70 mm, collar Ø 3.00 mm.
- length 7.0 - 9.0 - 11.0 - 13.0 mm.
- surface: osteogrip.

• The operator identifies the most suitable dental implant or mini-implant for overdentures depending on several factors, in particular:
a) the quantity and quality of available bone
b) the characteristics of the implant site
c) masticatory load
all these aspects should be properly assessed in order to select the implant correctly.

• Dental implants and mini-implants for overdentures are supplied sterile and are disposable.

• All the devices of the Easy Grip® CONE range in the package are identified by a product code and can be traced through a production lot number.

• Inside the implant package there are two adhesive labels bearing the identification batch codes of the implant, one of which may be inserted in the doctor's medical file and the other on the patient's implant card.

• The Easy Grip® CONE implant range is continuously enhanced. T.F.I. System srl reserves the right to alter the design and production.
Check for product updates on www.tfisystem.it.

Intended Use

• Intended only for qualified surgeons or dentists who have specialised knowledge and experience in dental implantology, and therefore are fully responsible for deciding on the actual use of the products in each individual case.
If the operator deems they do not have the appropriate knowledge, they should attend appropriate training courses before using these products.
Regular implantology refresher sessions are recommended.

• The Easy Grip® CONE implant system is designed to be surgically inserted in the maxillary and/or mandibular bone structure, thereby replacing missing teeth.

• The device is indicated as therapy in cases of:
a) complete maxillary or mandibular edentulism to anchor full prostheses
b) single and multiple distal and/or intercalated edentulism, in fixed prosthesis, to make terminal or intermediate abutments, final or temporary, of bridges and individual teeth.

• The Easy Grip® implant range makes use of the following procedures:
a) Two-stage (submerged implants)
b) Single-stage (non-submerged implants)
c) Immediate load
d) Deferred load.

• The device is disposable and its re-use, in addition to being unsuitable for the intended use, may cause serious infections with the possible loss of the implant and bone necrosis.

Contraindications

• All medical conditions that contraindicate oral surgery are to be considered valid contraindications also in the case of dental implants and mini-implants for overdentures.

• By way of example and without prejudice to the need for a specific clinical evaluation of each individual case, the Easy Grip® dental implants and mini-implants for overdentures cannot be used in the following cases:

1) general patient conditions: cachexia, diabetes, hyperthyroidism, anaemia, vitiligo, haemorrhagic diathesis, osteomalacia, osteitis deformans, imperfect osteogenesis, titanium allergy, immune system disorders, and any systemic disease or drug therapies that may impair the tissue repair ability, such as

immunosuppressants, corticosteroids and bisphosphonates. Patients with neurotic or psychotic disorders or mental instability, and patients with smoking, alcohol and/or drugs abuse are also to be excluded. Heart disease and circulatory disease represent a general surgery contraindication and therefore even to implant therapy. Similarly, surgery should be avoided during pregnancy.

2) **local conditions of the patient:** inadequate bone quantity, presence of lesions in the soft tissues (leukoplasia, lichen, stomatitis, epulis, etc.), lesions in the hard tissues (such as cysts, granulomas, root residue, inflammatory changes, etc.). Inadequate oral hygiene and/or poor periodontal status. Past or current radiation therapy. Xerostomia. Bruxism and inadequate occlusal conditions.

3) **the patient's age:** in adolescents, implants should only be considered after bone growth is complete.

Notwithstanding that the decision whether to proceed or not is solely taken by the qualified surgeon or dentist.

Side effects and precautions

• Inform the patient that the surgical placement of the implant may cause swelling, pain, bruising, inflammation, altered oral sensitivity and function and allergic reactions. These effects are usually temporary and the patient should immediately report them to the attending dentist.

• Instruct the patient about the precautions to be taken after the implant is inserted as well as during and after the treatment is completed, in order to prevent complications and changes in the performance of the prosthesis (example: avoid hard physical activity and mechanical loads in the implant area immediately after surgery, avoid occlusal trauma, maintain good oral hygiene, perform routine checks).

• The patient should be adequately informed on the use and maintenance of the prosthesis.
The attending dentist must perform six-monthly checks and maintenance.

It has been proven that a certain amount of bone resorption is physiological (Albrektsson 1987), however, poor oral hygiene may lead to infectious complications that increase this loss.
That is why it is important for the patient to be made aware of the need to maintain good oral hygiene and attend the routine checks.

Recommendations

• Dental implants and mini-implants for overdentures should only be reserved for patients who are sufficiently motivated and collaborative, with a good level of oral hygiene.

• Each implant site must have had an adequate diagnostic evaluation, clinical and radiological.

• Incorrect procedures may result in the loss of the implant and biological damage.

• Adequate antibiotic coverage is recommended during and following surgery.

• For positioning Easy Grip® dental implants and mini-implants for overdentures, use instruments that are specifically designed for oral implantology and in any case, surgical accessories and prosthetic components belonging to the Easy Grip® range.
The manufacturer will not be held liable in case of use of non-original components.

• Mobility of the implant, sensitivity to percussion, bone loss and infection are indicators of implant failure, which must then be removed.

• Dental implants and mini-implants for overdentures placed in the upper maxilla should not perforate the maxillary sinus; dental implants and mini-implants for overdentures placed in the lower maxilla must not touch, compress or sever the mandibular nerve.

• The life span of the entire implant prosthetic reconstruction is longer the slower bone support resorption is.

Warnings for use

• Some complications may follow the surgical insertion of dental implants and mini-implants for overdentures: bruising, bleeding, hematoma, soft tissue dehiscence, delayed healing, inflammation, infection, paraesthesia, hyperaesthesia, anaesthesia, chronic pain due to the implant, perforation of the maxillary sinus, anatomical structure lesions (bundles of nerves and blood vessels), atrophy of the alveolar bone in the maxilla or mandible, oroantral or oronasal fistulas, damage to adjacent teeth, bone fractures and rupture of the implant or instruments.

• Delayed complications may occur in the event of prosthesis overload, such as fracture in the prosthetic superstructure, implant fracture, loosening of screws that connect the prosthesis and loss of integration. Imperfections and peri-implantitis are possible complications.

• In the event of failure, the dental implant or mini-implant for overdentures must be disposed of considering it as biological waste to all intents and purposes, and handled according to local regulations.

Instructions for use

• The operating procedures of the device are found in the Technical Operating Manual of T.F.I. System srl - also available on www.tfisystem.it - and in the specific instructions provided in electronic format.

• The surgical and prosthetic procedures described are to be considered a standard set of guidelines that can be applied to the particular requirements and circumstances that arise in practice, depending also on the manual skills, the experience and diagnosis made by the legally qualified doctor.

• The manufacturer cannot be held liable for the use of the medical device and the procedure followed.
The responsibility for the correct and proper use of the instruments and products is therefore borne by the user.

• It is recommended not to use the sterile dental implant and mini-implant for overdentures beyond the indicated expiry date.

Pre-operative planning

The preparation for surgery includes:

- a consultation with the family doctor
- general medical and dental history
- clinical and radiological tests
- informed consent of the patient
- hygiene plan and any periodontal treatment
- adoption of the necessary drug prescriptions
- selection of the number, type, morphology and size of the implant or mini-implant that is most appropriate
- selection of the most suitable anaesthetic and sedative methods
- assessment of the risks of inadequate treatment of both soft and hard tissues
- identification and verification of the availability of both the prosthetic components and surgical instruments required for the implant surgery.

Surgical technique

The surgical techniques for dental implants and mini-implants for overdentures are taught at university or in specific training courses.
However, the following factors must always be considered:

- procedures should be carried out in suitable premises with appropriate aseptic conditions
- both hard and soft tissues should be treated with care using all necessary precautions
- the biological principles of osseointegration must be respected
- thermal trauma, which may cause bone necrosis, leading to possible impairment of the osseo-integrative process, should be avoided in all cases. For this purpose, adequate milling speed must be used with burs that have excellent sharpness and with specific diameters that increase progressively.
  Furthermore, drilling must be carried out with an intermittent pumping action to assure maximum cooling and removal of bone debris, to be achieved with adequate irrigation with sterile saline solution, preferably cooled to 4°C.
- appropriate clinical and radiological documentation should be created and filed
- it is essential to comply with the recommended healing times in implant surgery in order to use the masticatory load with fixed prosthesis (2-3 months for the mandible, 4-6 months for the maxilla), monitoring the progress of the osseo-integrative process by means of radiographic checks.

The surgical technique that allows immediate loading is only applicable in a few cases that are assessed and decided upon by the operator, who will also consider the following criteria:

a) the presence of adequate bone quantity
b) primary stability of the implants or mini-implants for overdentures, once inserted
c) good periodontal support
d) the absence of severe malocclusion or bruxism
e) the presence of adequate occlusal balance.

Packaging of the dental implant and mini-implant for overdentures

The packaging of the dental implant and mini-implant for overdentures of the Easy Grip® range consists of (from the outside inwards):

- packaging (cardboard box with product identification label)
- two adhesive labels bearing the implant production code and batch, one to place in the patient's medical file and the other on the patient's implant card
- external blister (rigid plastic container closed at the back by a product identification label)
- sterile jar containing the implant and the titanium closing screw.

• The packaging of the dental implant includes:

- a titanium grade 5 ELI implant;
- an ELI grade 5 titanium cap screw;

• The packaging of the mini-implant for overdentures includes:

- a titanium grade 5 ELI mini-implant.

Instructions for opening the Easy Grip® implant package

Fig. 1

• Check the type of implant, its length and sterilisation expiry date on the label. If the packaging is damaged, its contents may have lost sterility and therefore should not be used.
The package is equipped with a red anti-tampering seal which, if visible, demonstrates that it has been opened. Open the package and take out the blister and adhesive labels bearing the implant identification batch and code, one of which can be placed in the doctor's medical file and the other on the patient's implant card **(fig. 1)**.


Fig. 2

• Opening the blister: the nonsterile assistant removes the external protective sheet by taking the tear corner between two fingers and pulling upwards.
This exposes the jar containing the tube with the implant, which must be set on a sterile cloth so that from then on it will solely be handled by the operator wearing sterile gloves **(fig. 2)**.

Fig. 3

• Opening the jar: open the cap that the ampoule containing the implant is attached to, and pull it out **(fig. 3)**.

Fig. 4

• Opening the ampoule: remove the cap of the ampoule and expose the head of the implant housed inside the titanium tube **(fig. 4)**.

Instructions for HEX implant retrieval and insertion

• Take the implant with the most suitable driver for the case (mechanical aid or ratchet insert) and carry it to the implant site, screwing it all the way into position **(fig. 5 and 6)**.


Fig. 5

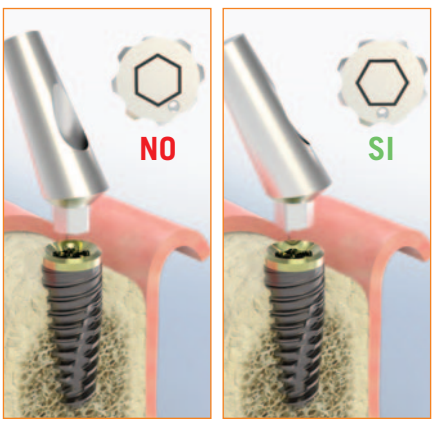

Fig. 6

Fig. 7

• The closing screw is housed at the bottom of the ampoule. To access it, remove the cap and unscrew it **(fig. 7)**.


Fig. 8

• If an Easy Grip® pre-angled abutment is used, it must be taken into account that these abutments have the angle of inclination on axis with the edge of the hexagon. Therefore, the hex of the implant must be rotated into the proper position while being tightened for appropriate implant/abutment alignment to be achieved **(fig. 8)**.

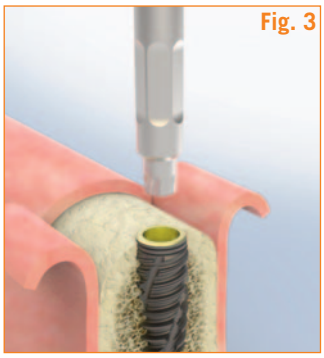


• In order to aid this operation, the head of the manual tightening hex key for the implants (B3R) bears the image of the corresponding position of the hex of the implants.

Instructions for picking up and inserting the CONE implant

• Take the implant with the most suitable driver for the case (mechanical aid or ratchet insert) and carry it to the implant site, screwing it all the way into position **(fig. 1)**.

• Engagement of the driver takes place with a simple pressure on the system, during engagement the screwing of the driver itself keeps the engagement active **(fig. 2)**.

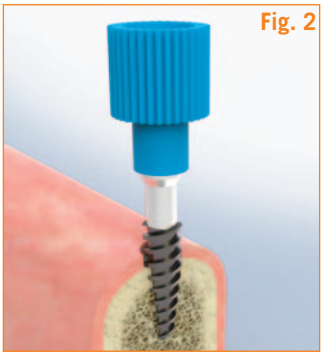


• Removal of the driver from the implant is achieved by gently rotating the driver anti-clockwise **(fig. 3)**.

• The closing screw is housed at the bottom of the ampoule. To access it, remove the cap and unscrew it **(fig. 4)**.

Instructions for removal and insertion of the mini-implant for overdenture

• Removal of the implant: by removing the cap (blue) from the tube, the implant, with the bone engaged, is removed from the packing **(fig. 1).**



• Transport it to the implant site by screwing it in until it is fully seated **(fig. 2).**

• Release the blue cap and finish screwing on the mini implant using the appropriate CMBO titanium insert, together with the manual CDM key or torque ratchet **(fig. 3 and 4)**.

If the effort is excessive (> 45 Ncm), do not to force the mini-implant. Remove it from the site and repeat the site drilling operation to increase depth.

• If the drilling depth matches the length of the mini-implant without being able to insert it (this might happen especially in cases of particularly hard bone D1), drilling may be repeated with the bur of the next diameter RMB24 (ø 0 2.4 mm).


Fig. 5

• For correct positioning, all the turns must be completely covered in the bone crest while the base of the ball of the mini-implant should protrude from the gingival profile to prevent subsequent compression of the soft tissues by the retention copings.


Fig. 6

If a resistance of at least 35 Ncm is not reached during insertion, immediate loading is not recommended **(fig. 5 and 6)**.

Warnings for USA

Caution: Federal law restricts these products to being sold only on prescription of an orthodontist.

Key to symbols

REF	**Product code**
LOT	**Production lot**
UDI	**Unique Device Identifier**
	Disposable
	Do not re-sterilise
	Sterilisation expiry date
IT	**Production data**
	Manufacturer
STERILE R	**Ray sterilised**
	Protect from moisture
	Do not use if packaging is damaged
NON STERILE	**Not sterile**
	Consult the instructions for use
	Warning
Rx ONLY	**On medical prescription only**

ROTARY DEVICES

Product

Handpiece/hex key adapter, Mechanical clamping aid, Depth stop, Corer, Bone expander, Bur, Surgical bur, Bone tap, Countersink, Bur extension. For full details of available components refer to the catalogue or website www.tfisystem.it.

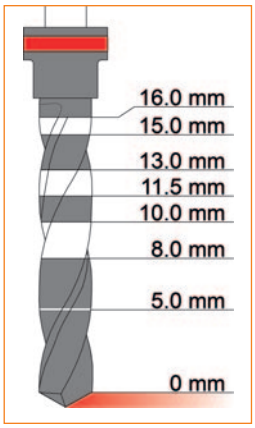
Material: medical steel, zirconium, tungsten or diamond.

Type of connection: for the contra-angle handpiece (bur, surgical bur, countersink, bur extension, adapter) or hex key fitted with O-ring to assure retention (bone tap, bone expander). All rotating devices are supplied nonsterile and are reusable.

• The **surgical bur** and the **countersink** are externally irrigated and designed for possible use with fixed height depth stops. Both can be used together with the PRF **bur extension**.

• The **depth stops**, should they be used for cylindrical surgical burs, must be selected based on bur diameter and depth required by the operator. The depth is indicated with laser coding on the outer diameter of the stop, expressed in millimetres.

• The **cylindrical surgical burs** in surgical steel have laser depth markings indicating the five heights of the Easy Grip® implants (see picture).



• The **bone tap** and the **bone expander** can be used both manually (with the digital key, the ratchet or the screwdriver handle for hexagonal inserts) and with the countersink handle by means of the AMFO **adapter**.
They are fitted with O-rings to ensure retention (replace O-rings after 15-20 sterilisation cycles).

• The mechanical aid is used by connecting it to the torque handpiece, using the suitable optimal values.

• All the devices of the Easy Grip® CONE implant range are identified in the package with a product code and can be traced through a production lot number.

• Rotary devices may be fitted with colour O-rings and/or laser coding, for better identification of the devices found in the surgical kit.

• The Easy Grip® CONE implant range is continuously enhanced. T.F.I. System srl reserves the right to alter the design and production. Check for product updates on www.tfisystem.it.

Intended Use

• Intended only for qualified surgeons or dentists who have specialised knowledge and experience in dental implantology, and therefore are fully responsible for deciding on the actual use of the products in each individual case.

• The device is intended for the preparation of the maxillary or mandibular implant site where the dental implants will be inserted.

• Bur kits are available for specific purposes (bone crest regularization kits, abutment milling kits).

Contraindications

• The device is contraindicated in cases where it is not possible to create an implant site (inadequate amount of bone, hard tissue lesions and lesions in anatomical structures).

• It is contraindicated to use rotating devices that do not belong to the Easy Grip® range to position implants.

Handling precautions

• Assure plenty of cooling by means of irrigation with sterile saline solution, preferably cooled to 4°C in order to prevent irreversible damage to the bone and/or adjacent tissue. The cooling liquid should be distributed over the entire active surface of the surgical bur. Stop drilling if there is no irrigation, for any reason.

• The bone is drilled with an intermittent pumping action and an appropriate number of revs (as indicated in the table below) to assure maximum cooling and removal of bone debris.

• Before using the burs, the operator should always ascertain their optimal cutting efficiency. Devices with deteriorated cutting efficiency due to the thread being worn, those that are bent or with an eccentric rotation should be immediately removed and not reused as they are unsuitable (they may cause overheating, which in turn will result in bone necrosis and/or the operator and the patient being injured).

• Since the instrument's cutting ability decreases with use, **it is recommended to dispose of it after creating 15-20 sites** and in any case, when the cut of the bur is inadequate and/or impaired.

• The working pressure must be between 0.3 and 2 N/mm2. Strictly avoid excessive pressure as it generates bone overheating and damages the working part.

• Insert the rotating device only in a suitable micromotor drill with a contra-angle fitting in perfect condition, carefully and

without force. Incorrect insertion may cause the instrument to vibrate and rotate eccentrically.

• Do not wrap or lean on the device during the processing as it risks breaking.

• With regards to **burs** and **countersinks** comply with the maximum rotation speed of 500-1000 RPM and the recommended speeds (indicated in **diagram 1**), while taking care to use the bur only after it has reached the speed of use before applying it to the part to be treated. The recommended speed for all **bone taps** and **bone expanders** is 15 RPM.
For the **crest bur** (RLO35) the recommended speed is 1000-1200 RPM.

• If use of the suitable **extension** is opted for, ensure the **surgical drill** is properly inserted and locked inside the extension. Proper housing of the drill on the extension is marked by a slight "click" when coupled.

• Due to the small size of the burs and instruments particular attention should be paid to make sure they are not swallowed by the patient.

• Take into account that measurement of the depth markings of the **surgical cylindrical burs** does not include the length of the tip, which varies depending on the bur (see **diagram 2**). Therefore, when drilling near vital anatomical structures, the extra length of the bur must be considered.

• If forced, depth stops may lose elasticity of the fins. In this case the position must be restored by tightening them slightly with a pair of tongs.

• Before tightening the prosthetic components, ensure the hex of the **mechanical aid** is inserted properly in the hex head of the screws or the implant, in order to prevent hex deformation. If the hex is worn, it is recommended to replace the surgical device.

• If the rotating device is used, it must be disposed of as biological waste to all intents and purposes and handled in accordance with local regulations.

Instructions for use

• For the product's operating procedures refer to the Technical Operating Manual of T.F.I. System srl - also available on www.tfisystem.it - and in the specific instructions provided in electronic format.

Diagram 1

Rotation speed

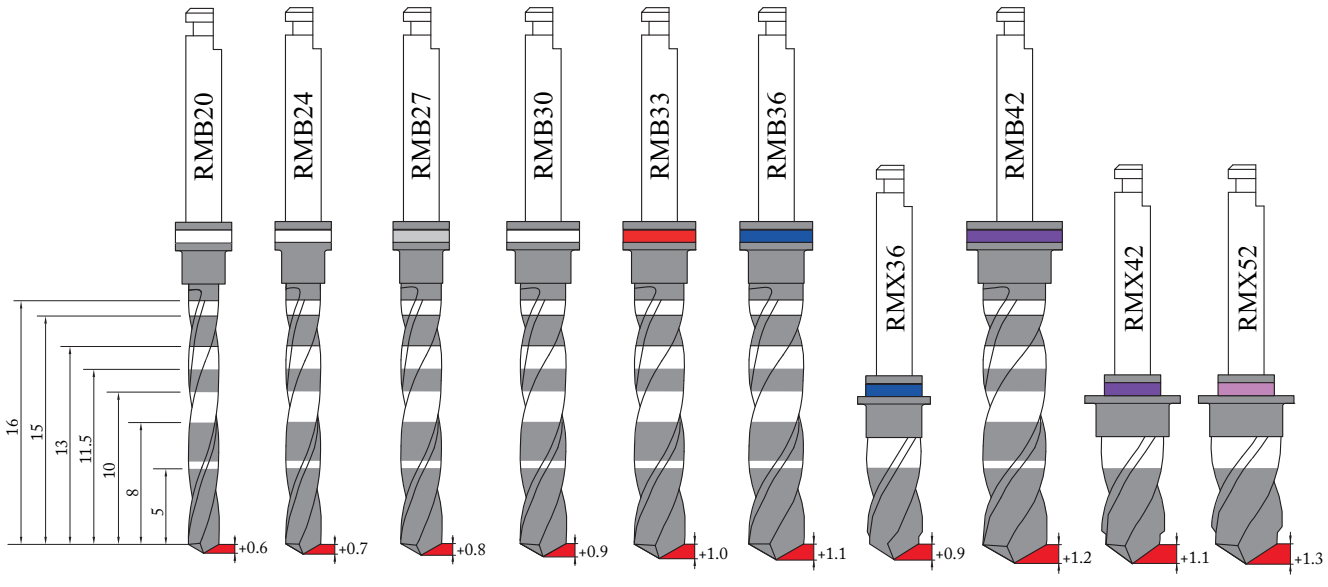
Code	Speed rpm
RLO18 RA018 RMB20 RMB24	850
RMB27 RMB30	750
RMB33 RMB36 RMX36	650
RMB42 RMX42 RMX52	550
AS2 AS3 - ASS AS4 - ASL AS5 - ASX	350

• The surgical and prosthetic procedures described are to be considered a standard set of guidelines that can be applied to the particular requirements and circumstances that arise in practice, depending also on the manual skills, the experience and diagnosis made by the legally qualified doctor.

• The manufacturer cannot be held liable for the use of the medical device and the procedure followed. The responsibility for the correct and proper use of the instruments and products is therefore borne by the user.

Diagram 2

Unit of measure: mm



• The surgical procedure decided by the implant dentist may range from being minimally invasive (using the mucotome) to lifting the total thickness of the sides and expose the bone.

• The positions of the implant sites are established using the **round bur** or the **cutter**.

• To create appropriate osteotomy for the position of the selected implant, a set of **burs** of increasing diameter are used.

• The implant dentist may also decide to use adequate **bone taps** or **bone expanders**, depending on the bone density found.

• The **countersink** is required to create the proper housing for the tapered neck of the Easy Grip® implants, thereby increasing the bone retention phenomenon at cortical level and preventing excessive compression of the microgrooves on the bone, which results in tissue necrosis.

Maintenance and storage

• Prior to being used on the patient the rotating device must always undergo validated processes of cleansing, disinfection and/or sterilisation, taking care to disconnect any depth stops from the burs.

• Before cleaning the instruments, manually remove the impurities using only specifically designed nylon brushes.

• **To clean:** place the used instruments in a cleaning solution, specific for reusable medical devices, with the relative dilution and contact time, making sure that they remain sufficiently immersed.
Pay particular attention that the cutting parts of the burs do not touch each other (use specific bur holder supports).
Clean the instruments in an ultrasonic bath, where applicable.
It is recommended to use enzymatic/neutral products (see "products that are incompatible with the instruments").
Immediately dry the instruments, otherwise there lies the risk of corrosion.

• **To disinfect**: place the used instruments in a special disinfectant solution, specific for reusable medical devices, with the relative dilution and contact time, making sure that they remain sufficiently immersed. Pay particular attention that the cutting parts of the burs do not touch each other (use specific bur holder supports). It is recommended to use products containing anti-corrosive additives (see "products that are incompatible with the instruments").
Immediately dry the instruments, otherwise there lies the risk of corrosion.

• **For sterilisation:** sterilise in steam autoclave for approx. 20 minutes at standard temperature of 121°C. Pay particular attention that the cutting parts of the burs do not touch each other (use specific bur holder supports). Once sterilisation is completed, store the sterile instruments in closed containers.

• Always keep the product clean and store in a dry place, avoiding impacts that might damage it.

• Do not use the device if the packaging is damaged.

Products that are incompatible with the instruments

When choosing the products for cleaning and disinfecting ensure they do not contain the following chemical components, as they may corrode and/or oxidise the instruments, in particular in the area with laser marking:

- organic, mineral and oxidising acids (pH 5.5 is the minimum value allowed)
- strong alkaline solutions (pH 8.5 is the maximum value allowed; it is recommended to use a neutral/enzymatic cleaning agent)
- organic solvents (for example alcohols, ethers, ketones, gasoline)
- oxidants (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- halogenated / aromatic hydrocarbons

Never use harsh chemicals or ammonium-salt based chemicals.

PROSTHETIC COMPONENTS

Product

Prosthetic components (Seal ring, Box for coping, Retention coping, Ball abutment, Abutment with shoulder, Aesthetic abutment, Abutment for CAD/CAM, Abutment for screwed prosthesis, Provisional abutment, Healing screw, Clamping screw, Occlusal screw, etc.). For full details of available components refer to the updated catalogue or www.tfisystem.it.

Material: titanium, surgical steel, cobalt chrome, PMMA, PEEK, POM, PS Crystal, PC.

• All prosthetic components are supplied nonsterile and are disposable, except for the healing screw which can be reused.

• All the devices of the Easy Grip® CONE implant range are identified in the package with a product code and can be traced through a production lot number.

• The Easy Grip® implant range is continuously enhanced. T.F.I. System srl reserves the right to alter the design and production. Check for product updates on www.tfisystem.it.

Intended Use

• Intended only for qualified surgeons or dentists who have specialised knowledge and experience in dental implantology, and therefore are fully responsible for deciding on the actual use of the products in each individual case. The prosthetic components can also be used by dental technicians who have attended relevant training courses.

• The device is intended to be used for the reconstruction of partial or full, permanent or temporary prostheses or as an anchor for removable prostheses (tooth replacement with cemented and/or screwed fixed prostheses or anchoring of removable prostheses by means of ball couplings) for Easy Grip® dental implants.

• Dental implants are designed to restore the aesthetic, phonetic, and masticatory functions in patients.

Contraindications

Making prosthetic devices with components that do not belong to the Easy Grip® range is contraindicated as it would affect reliability, especially the tightness of the fixture/abutment connection.

Side effects

Besides very rare cases of allergic reactions to titanium, there are no pharmacological side effects as the raw materials used for the devices are historically inert.

Handling precautions

• The lifetime of the prosthetic devices depends on their maintenance carried out by the patient, who must be thoroughly informed of the procedures to be followed. The doctor must perform check-ups and maintenance agreed with the patient.

• To assure reliable tightness of the fixture/abutment connection, it is recommended not to alter the friction generated by the hexagon of the pre-formed "friction-fit" abutment.

• Due to the small size of the surgical accessories particular attention should be paid to make sure they are not swallowed by the patient.

• Before tightening the prosthetic components, make sure the hex of the key, insert or mechanical aid is inserted properly in the hex head of the screws, in order to prevent hex deformation. If the hex is worn, it is recommended to replace the surgical device.

• If the prosthetic device is used, it must be disposed of as biological waste to all intents and purposes and handled in accordance with local regulations.

Instructions for use

• The operating procedures of the device are found in the Technical Operating Manual of T.F.I. System srl - also available on www.tfisystem.it - and in the specific instructions provided in electronic format.

• The surgical and prosthetic procedures described are to be considered a standard set of guidelines that can be applied to the particular requirements and circumstances that arise in practice, depending also on the manual skills, the experience and diagnosis made by the legally qualified doctor.

• The manufacturer cannot be held liable for the use of the medical device and the procedure followed. The responsibility for the correct and proper use of the instruments and products is therefore borne by the user.

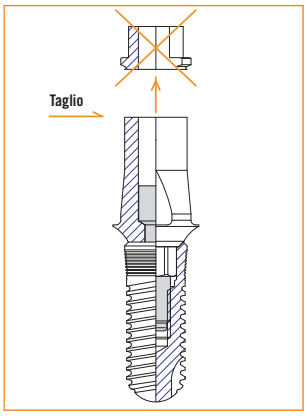
• **Ball abutments** are divided into three types:
- standard: with normo ball;
- sfero-flex: with mobile ball that assures tilting up to 7.5°;
- equator: with lowered ball.

• **The abutments** and **healing screws** are available in various sizes to best meet individual anatomical requirements.

• **The preformed abutments and healing screws** are in anodized coloured titanium; those intended for Short Neck implants (series 3) are yellow and those with an enhanced platform intended for Large, Extra-Large and Extra-Extra-Large

implants (series 4) are light blue. Always use pre-formed abutments with a series 3 connection for the Platform switching technique.

• In cases of **abutments for multiple connections** or **provisional abutments** the PTP series pre-formed abutment, fitted with a short and non-frictioning hex is to be used (PTP00 is with no hex).
The temporary abutments in PEEK have maximum six months' utilisation.
Castable abutments may be in PMMA material (plexiglass) or in PS Crystal (polystyrene crystal).



• **The PDT** (Easy Grip® HEX Line) can be used as a preformed abutment with a non-friction hexagon, in which case cut the part shown in the diagram opposite.

• Before connecting the prosthetic device verify that the implant has osseointegrated by carefully assessing:

a) no pain on percussion;
b) no device movement;
c) no radiological signs of peri-implant bone destruction.

Maintenance and storage

• Prior to being used on the patient the prosthetic components must always undergo validated processes of cleansing, disinfection and/or sterilisation.

• Before cleaning the instruments, manually remove the impurities using only specifically designed nylon brushes.

• **To clean:** place the prosthetic components used in a cleaning solution, specifically formulated for treating medical devices, with the prescribed dilution and contact time, ensuring they remain immersed for a sufficient amount of time.
Clean the instruments in an ultrasonic bath, where applicable.

• **To disinfect:** place the prosthetic components used in a special disinfectant solution, specifically formulated for treating medical devices, with the prescribed dilution and contact time, ensuring they remain immersed for a sufficient amount of time.

• **For sterilisation:** sterilise in steam autoclave for approx. 20 minutes at standard temperature of 121°C. Once sterilisation is completed, store the sterile prosthetic components in closed containers.

• Always keep the product clean and store in a dry place, avoiding impacts that might damage it.

• Do not use the device if the packaging is damaged.

SURGICAL ACCESSORIES

Product

Surgical accessories (Laboratory analogue, Positioning ring, Castable Box for coping, Allen key, Retentive coping for laboratory, Manual key, Ratchet, Abutment puller, Coping puller, PS Holder, PTS Holder, Insert, Handle with coping inserter, Laboratory tap, Depth Gauge, Tissue punch, Paralleling device, Pin-analogue, Transfer pin, Castable abutment, Test abutment, Extension for hex key, Surgical tray, Laboratory screw, Screw for waxing, Screw for manual key, etc.).

For full details of available components refer to the catalogue or website www.tfisystem.it.

Material: titanium, medical steel, radel, PMMA, POM, PEEK.

• The surgical accessories are supplied nonsterile and are reusable.

• The torque-adjustment ratchet is not a measuring device but a precision instrument with a range of ± 10% and a safety interval of 95% and can be dismantled.

• All the devices of the Easy Grip® CONE implant range are identified in the package with a product code and can be traced through a production lot number.

• The Easy Grip® implant range is continuously enhanced. T.F.I. System srl reserves the right to alter the design and production. Check for product updates on www.tfisystem.it.

Intended Use

• Intended only for qualified surgeons or dentists who have specialised knowledge and experience in dental implantology, and therefore are fully responsible for deciding on the actual use of the products in each individual case.
Some specific devices are also intended to be used by adequately trained dental technicians.

• The device is intended to be used for the preparation of the maxillary or mandibular implant site and insertion of Easy Grip® dental implants.

Contraindications

It is contraindicated to use surgical accessories that do not belong to the Easy Grip® CONE range to position Easy Grip® implants.

Warnings for use

• Before tightening the prosthetic components with screw, ensure the hex (or square) of the key or insert is inserted properly in the hex head of the screw, in order to prevent hex deformation. In the event of wear of the hexagonal (or square) section, it is recommended to replace the device.

• The Delrin gasket of the **CHE** hex loses functionality after 20-25 sterilisation cycles, it must therefore be replaced. This gasket must be inserted on the key until it snaps.

• To use the manual Sferoflex **ICMU** abutment key, press the piston ensuring the tongs are properly open, then insert the connection of the Sferoflex abutment in the tongs, release the piston ensuring the tongs close and completely enclose the hexagon; in this way the manual key is ready for the torsion action.

• Do not place the radel **surgical tray** to the walls of the autoclave during sterilisation cycles, as prolonged contact may cause permanent deformation.

•Before using the surgical accessory, the operator should always ascertain its mechanical integrity. If the device is not efficient, it must be immediately discarded and not reused as it is unsuitable.

• In order to assure correct operation, the torque wrench must be removed, disinfected, cleaned, lubricated and sterilised after each use.

• Due to the small size of the surgical accessories particular attention should be paid to make sure they are not swallowed by the patient. For this purpose, various accessories have a grommet hole for them to be secured to an adequate safety thread during surgery.

• The **analogues of the Easy Grip® HEX Line implants** are distinguished by two purposes:

a) those intended for the friction-fit pre-formed abutments are made of ochre-yellow titanium
b) those intended for castable or non-frictioning pre-formed prostheses are made of natural titanium.

• The **PDT mounter (Easy Grip® HEX line)** can be used as a transfer for indirect impressions with the help of the VU connection screw supplied; the **VLC3** long screw must be used when using it for direct impressions.

• The **VCDM screw** should always be used in conjunction with the CDM manual key (Easy Grip® HEX line).

• The fixture/abutment coupling (friction-fit for the Easy Grip® HEX line and conometric for the Easy Grip® CONE line) is very tenacious, so when it is necessary to detach this coupling, the use of the **EM2** abutment extractor spanner (**7EM2** for the Easy Grip® CONE line) or in the case of limited operating space, the **EM** extractor screw (**7EM** for the Easy Grip® CONE line) is recommended.

• If the surgical accessory is used, it must be disposed of as biological waste to all intents and purposes and handled in accordance with local regulations.

Instructions for use

• The operating procedures of the device are found in the Technical Operating Manual of T.F.I. System srl - also available on www.tfisystem.it - and in the specific instructions provided in electronic format.

• The surgical and prosthetic procedures described are to be considered a standard set of guidelines that can be applied to the particular requirements and circumstances that arise in practice, depending also on the manual skills, the experience and diagnosis made by the legally qualified doctor.

• The manufacturer cannot be held liable for the use of the medical device and the procedure followed. The responsibility for the correct and proper use of the instruments and products is therefore borne by the user. The test abutments allow the most appropriate abutment to be selected in the prosthetic planning stage.

• The optimal tightening torque for screwed Easy Grip® prosthetic components (codes PS, PP, 7PS and 7PP) and connection screws (codes VU, 7VU, VS and VUF) has been identified after appropriate study as 35 Ncm.

• The optimum torque force with which to tighten the occlusal screw is 15 Ncm for VOP, 7VOP, 7VA, 7VAL and 7VGS screws.

• The optimum torque force with which to tighten the angled channel screw 7VS is 20 Ncm.

• The optimum torque force with which to tighten the healing screw for MUA is 15 Ncm.

• The optimal torque with which to tighten the cap screws and the healing screws is 20 Ncm.

• Do not use the torque ratchet with torque values greater than 70 Ncm for the **CUD80**. Upon delivery the indicated torque values have a precision range of ± 10%.

Maintenance and storage

• Prior to being used on the patient the surgical accessory must always be subjected to validated processes of cleansing, disinfection and/or sterilisation, taking care to disconnect the two components of the mucotome. The torque ratchet must undergo cleaning processes fully disassembled without using hot water.

• Immediately after use (within two hours at most) and always before cleaning the instruments, manually remove the impurities using only nylon brushes intended for the purpose, rinsing the products under cold running water (<40° C.).

• **To clean:** place the used surgical accessories in a cleaning solution, specific for reusable medical devices, with the relative dilution and contact time, making sure that they remain sufficiently immersed. Clean the instruments in an ultrasonic bath, where applicable. It is recommended to use enzymatic/neutral products (see “products that are incompatible with the instruments”). Dry the instruments immediately. Never exceed the maximum temperature of 40° C.superare la temperatura massima di 40° C.

• **To disinfect:** place the used surgical accessories in a special disinfectant solution, specific for reusable medical devices, with the relative dilution and contact time, making sure that they remain sufficiently immersed. It is recommended to use products containing anti-corrosive additives (see ”products that are incompatible with the instruments”). Dry the instruments immediately.

• **For sterilisation:** sterilise in steam autoclave for approx. 20 minutes at standard temperature of 121°C. Once sterilisation is completed, store the sterile surgical accessories in closed containers.

• The surgical kit cannot exceed the following usage limitations: maximum time 20 minutes, maximum temperature 135° C., pressure 2.2 bar.

• Always keep the product clean and store in a dry place, avoiding impacts that might damage it.

• Do not use the device if the packaging is damaged.

Products that are incompatible with the instruments

When choosing the cleansing and disinfecting products, make sure they do not contain the following chemicals as they may damage the instruments:

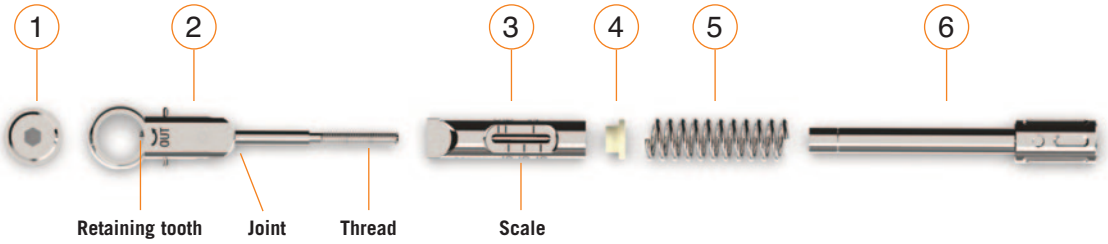
- organic, mineral and oxidising acids (pH 5.5 is the minimum value allowed)
- strong alkaline solutions (pH 8.5 is the maximum value allowed; it is recommended to use a neutral/enzymatic cleaning agent)
- organic solvents (for example alcohols, ethers, ketones, gasoline)
- oxidants (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- halogenated/aromatic hydrocarbons

Never use harsh chemicals or ammonium-salt based chemicals.

CUD80 TORQUE RATCHET KEY

The CUD80 torque ratchet is composed of the following elements:

1. Toothed wheel
2. Key head
3. Graduated bush
4. Washer
5. Spring
6. Adjustment nut



Possible preliminary adjustments

• Prosthetic adjustment - torque function: by actuating the relative nut it is possible to continuously adjust the torque range by the spring. The adjustment is visible on the scale of the graduated bush.

• Surgical adjustment - blocked function:
turn the adjustment nut to the ∞ (infinite) reference mark. Do not tighten too much.

Warning: do not loosen both screws (X) on the adjustment nut (see figure) to avoid losing the factory setting.

Use

By rotating the tightening torque adjustment screw (6), the torque ratchet may be adjusted according to the torque selected by the operator, ensure the reference value on the graduated bush (3) is aligned to the reading slot of the adjustment nut (6).

Correct use of the torque applicator

• To apply the torque precisely, it is necessary to press only on the grip of the adjustment nut (see arrow in the figure).

• Apply the torque, pressing with one finger only.

• Do not grasp the grip with thumb and index finger to apply the torque.

• When the set torque is achieved, the graduated bush bends in relation to the axis on the head of the key. The application of the torque is perceived by sound and touch.

When the torque has been applied, do not press any more, otherwise the ratchet key or the dentistry components could get damaged.

When you release the grip, the ratchet key goes back to its initial position.

Disassembly

• Before cleaning (regardless of the selected cleaning method), take apart the various components of the torque ratchet key. Disassembly does not require the use of tools, simply completely unscrew the adjustment nut (6) and take it out.

• Take care not to lose the plastic washer (4), as this would jeopardise the precision of the instrument. (The plastic washer only needs to be removed if visibly soiled. If necessary, the washer can be taken out. After cleaning, put it back in).

Maintenance

Slightly lubricate the marked points (see the initial Figure) with suitable lubricating oil.
Be sure to only use oils that are suitable for the instruments (white paraffin oil without corrosion inhibitors or other additives), approved for steam sterilisation (taking into consideration the maximum steam sterilisation temperature (taking into consideration the maximum applied sterilisation temperature) and with confirmed biocompatibility. Always use the minimum necessary amount.

Assemble the ratchet key and run a function test. After assembly and before sterilisation, the ratchet key must be in a loosened position of max 10 Ncm.

TFI System

INNOVISION IS EASY

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