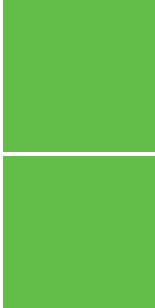
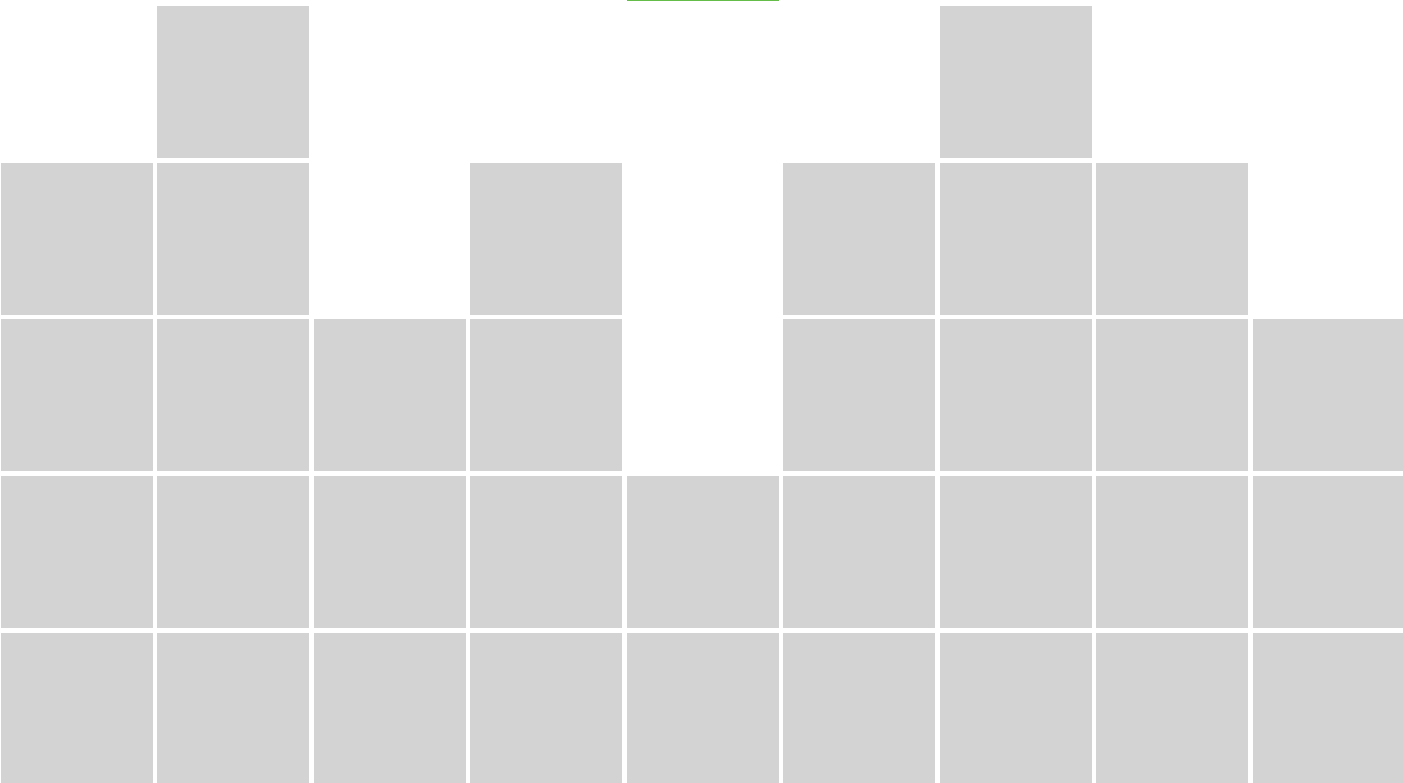
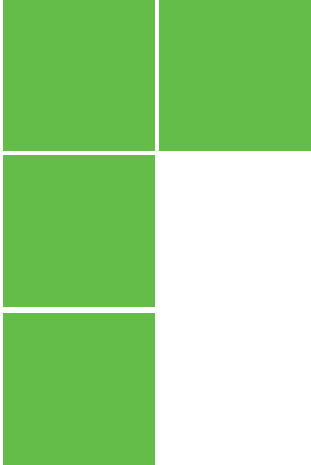


EASY GRIP[®] Implants



COMPANY
PROFILE

CONE
CONNECTION





THE COMPANY

T.F.I. System srl has been in the field of dentistry implants for over twenty years, providing customers with a range of reliable and technologically advanced products.

Over the years the company has specialised in the **design, development and production of dental implants and related surgical accessories.**

This has been possible thanks to a constant osmosis between the passion of implant dentists, who have to face and decide on the most appropriate implant-prosthetic solutions on a daily basis, and the company's team, which works by constantly focusing on improving the characteristics of the product.

The achievement of **ever higher quality standards, the simplification of surgical procedures** and the use of innovative techniques, represent the idea in which the company's values are enclosed:

QUALITY

SIMPLICITY

INNOVATION



CERTIFICATION

T.F.I. System srl, certified with the company quality system **ISO 9001** and **ISO 14801**, is on the market with the **Easy Grip®** brand, a range of products certified in Europe with the **CE mark** and with **FDA** authorisation for the USA.

RESEARCH

The company is constantly striving to seeking new functional and innovative solutions, in constant contact with the clinical and academic reality.

The product currently marketed stems from university research as well as from a constant passion aimed at overcoming the current limitations of implantology.



TREATMENT QUALITY

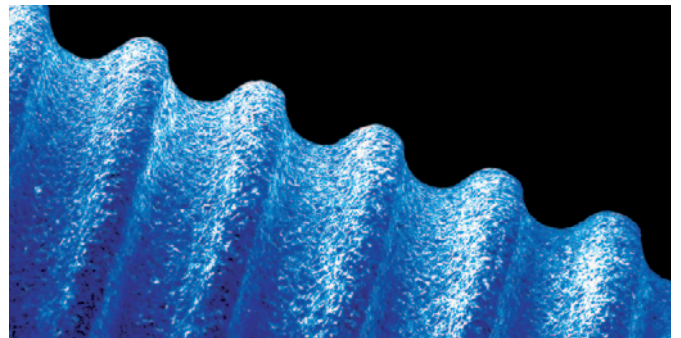
SURFACE TREATMENTS

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.

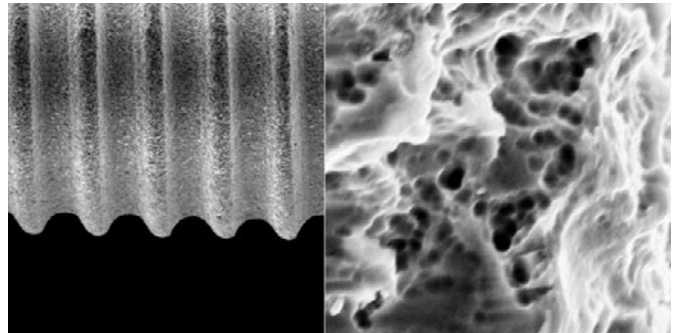
SLA (Sanding and Acid Etching)

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 implant dentistry.

**Etching**

Acid based with hydrofluoric acid 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 correct activation of osseointegration.

**Anodic colouring**

This technique is applied on both artificial teeth and implants in the neck zone and internal connection; 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.

SIMPLICITY IN THE SOLUTIONS

EASY GRIP® CONE CONNECTION

5° conometric connection

The intimate cone engagement generated by the 5° Easy Grip® CONE connection ensures an adequate sealing of the fixture, minimising the micro-gap with the prosthetic component, preserving good cortical bone health.

Double internal hexagon

The double internal hexagon allows 12 different positions for the insertion of indexed prosthetic components.

Through-bolt M1.8.

The Easy Grip® CONE connection system provides for the activation and maintenance of the fixture/abutment coupling by screwing with an M1.8 clamping screw.

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

TFI 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 production.

Unique anatomical connection

All Easy Grip® CONE prosthetic components adopt a single connection that can be used on any implant platform, SN, L and XL in platform switching.

The anatomical design of the prosthetic components provides a natural and aesthetic emergence profile for proper soft tissue management.



Simplicity

- Single connection
- Platform switching
- Anatomical emergence profile

Reliability

- Electrolytic treatment
- Double internal hexagon

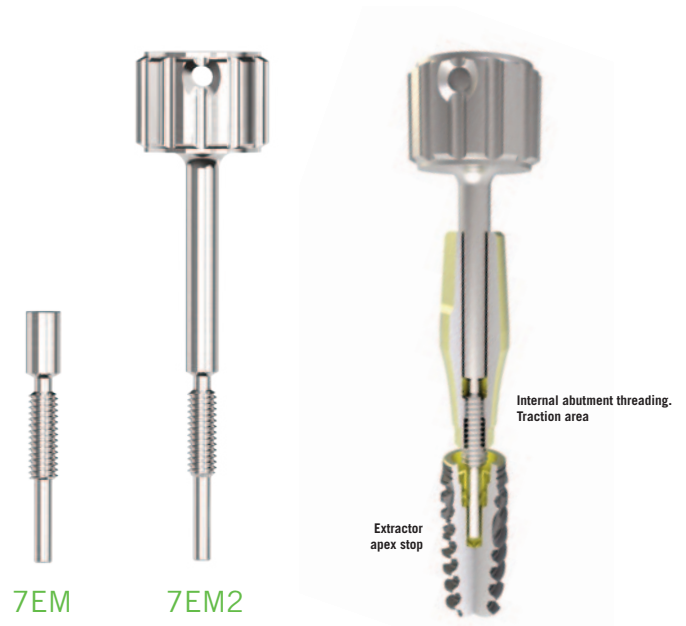
Precision

- 5° conical connection
- No bending and settling

EXTRACTOR KEY

The Easy Grip® CONE engagement at 5° generates a stable and tenacious fit that ensures proper implant sealing and stability of the prosthesis.

The final coupling can be removed with a manual extractor (7EM2) or, in the case of poor operating space, with the extractor screw (7EM).



TIGHTENING SCREW

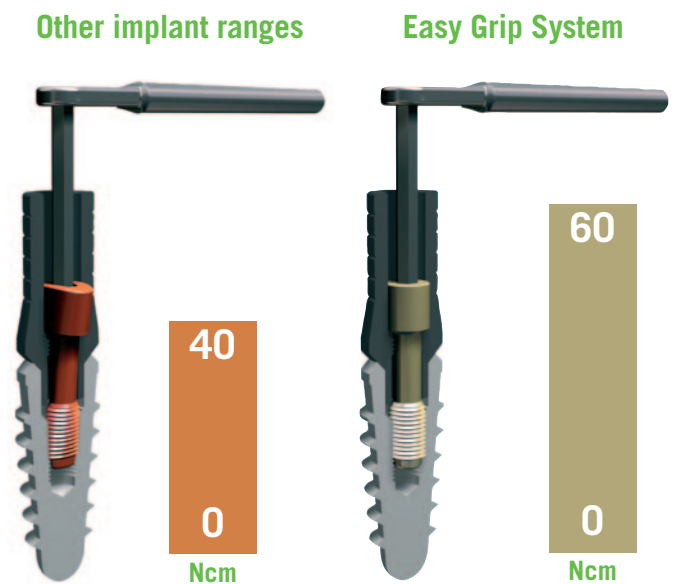
The optimal tightening of the conical fixture/abutment connection has always been a delicate element for all implant lines.

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 line, this torque force was identified as 30 Ncm;
- the physical-mechanical features of the material which the screw is made of;
- 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).

TFI 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.





INNOVATION

PACKAGING AND STERILISATION

Easy Grip® CONE implants are packaged:

- protected in a titanium tube;
- inserted in a plastic vial contained inside a sealed blister pack;
- conditioned for sterilisation in an ISO 8 class protected environment;
- gamma ray sterilised.

The packaging includes:

- a titanium grade 5 ELI implant;
- a grade 4 titanium closing screw;
- user instructions are available in electronic format on the website www.tfsystem.it, pursuant to EC regulation no. 207/2012;
- inside the package there are two convenient adhesive labels bearing the identification 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 package is equipped with a red anti-tampering seal which, if visible, demonstrates that it has been opened.

Short Neck
Large
Extra Large



Implant

Titanium tube

Closing screw

These and other simple and effective solutions lead an ever wider client base to choose the Easy Grip® implant line, maintaining a high degree of loyalty.

The focus on surgical protocol simplification, functionality and quality components and technological innovation are the common threads of every product of the line.

EASY GRIP® CONE IMPLANT SYSTEM

SERIES 70



Morphology:

- Self-tapping conical thread
- Connection: double internal hexagon
- Cortical microgrooves
- 5° Conical coupling
- Treated neck
- Lengths: 8 - 10 - 11.5 and 13
- Material: titanium grade 5 ELI
- Surface Osteogrip (SLA)
- Cap screw Ø 3.10 mm

SN SHORT NECK DN 3.75



L LARGE DN 4.50



XL EXTRA LARGE DN 5.00



EXTERNAL MORPHOLOGY

Conical implant with three full-body, 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 circular grooves

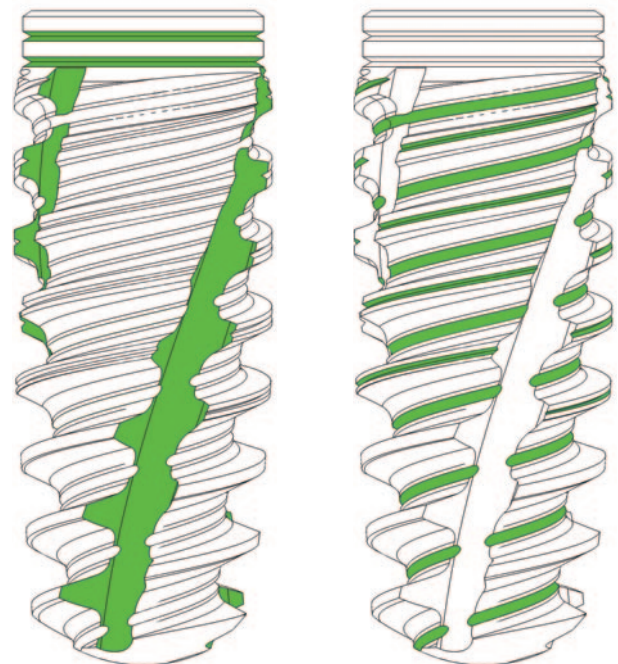
The presence of the cortical circular grooves on a rough surface, compared to implants with a smooth neck, offer better conditions for osseointegration and, under functional loading, are more effective in maintaining marginal bone (MBL), preventing natural post-operative bone resorption, resulting in:

- 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 loads as well as compressive; 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

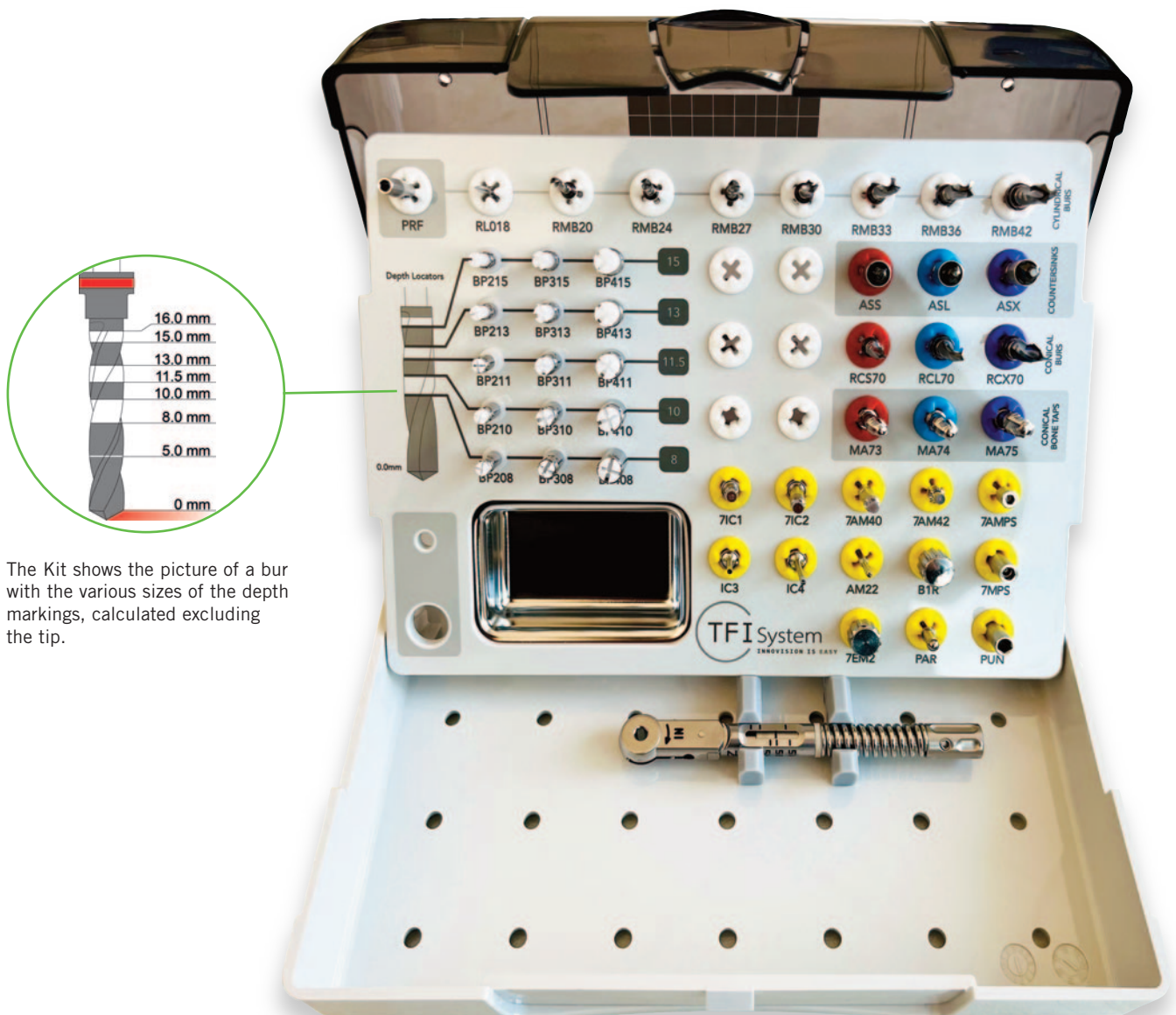
This is a square loop thread that is significantly load-bearing in the cervical part of the implant and more pronounced in the apical area, which generates targeted bone condensation in the case of insertion in D3/D4 type bone, increasing primary stability, which is particularly necessary in immediate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

The grooves on the core and in the ridge reduce friction during insertion into hard bone.



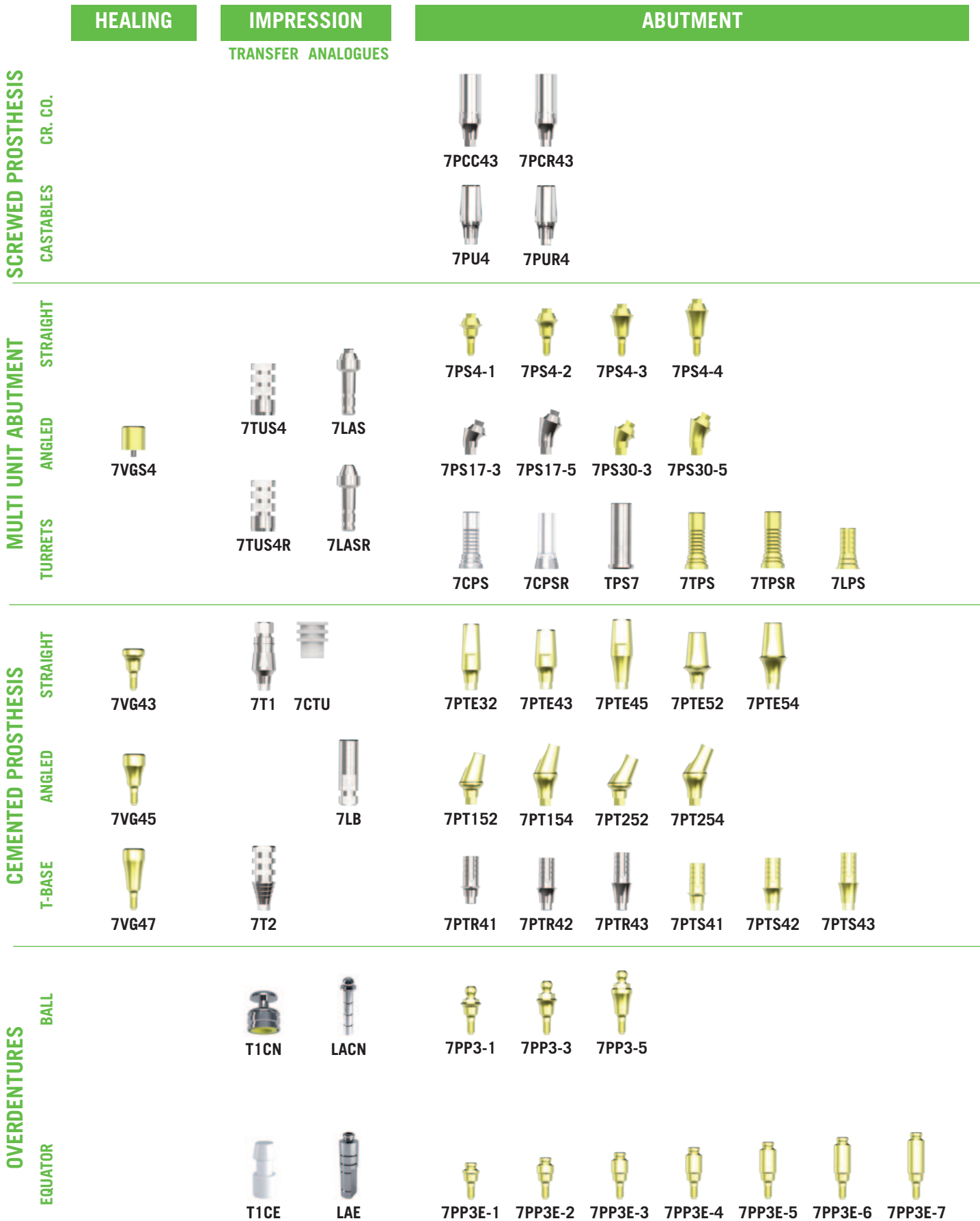
EASY GRIP® CONE SURGICAL KIT

Made of autoclavable Radei, it contains all surgical instruments, rotating and non-rotating, for implementing the surgical and prosthetic protocols of the Easy Grip® CONE Line (KIT70).



The Kit shows the picture of a bur with the various sizes of the depth markings, calculated excluding the tip.

GENERAL DIAGRAM





SCREWS

ACCESSORIES

DIGITAL SOLUTIONS

SCANBODY ANALOGUES ANGLED CHANNELS



The pictures are purely for illustrative purposes

Initial Burs



RA018 RL018

Pilot Burs



series BP2 RMB20 RMB24 RMB27

Depth Stops



BP208 BP210 BP211 BP213 BP215

Cylindrical burs



series BP3 RMB30 RMB33 RMB36

Conical burs



RCS70



BP308 BP310 BP311 BP313 BP315



series BP4 RMB42



RCL70 RCX70



BP408 BP410 BP411 BP413 BP415

Countersinks



ASS ASL ASX BRC3

Bone taps



MA73 MA74 MA75

Bone expanders



EC1 EC2 EC3 EC4

Burs Accessories



RL035

The pictures are purely for illustrative purposes



Keys

PROSTHETIC

IMPLANTS



B1R



B2R



IC3



IC4



AM22



AM25



7AM25S



7IC1



7IC2



7AM42



7AM40

Instruments and Accessories



7EM



7EM2



7MPS



7AMPS



MC3



MC4



CDM



DIS



MP



PAR



PUN



PRF



AMFO



CUD80



CU20



CL

SERVICES AND COURSES

SERVICES

Implant replacement service to enable the clinician to replace an implant that may have been mistakenly contaminated in any situation.

Implant passport, intended for the patient to store the identification data of inserted implants and as a reminder of follow-up appointments.



COURSES

Course in cadaveric surgical anatomy, consisting of a didactic part in the multimedia classroom and a practical part in the septic room.

Computer-guided implant surgery course for dentists who want to learn the correct techniques of computer-guided implantology.

Theoretical and practical implantology course on patients, which aims to enable participants to manage implant-prosthetic cases independently.

Workshop

Introductory course on the use of the Easy Grip® implant line.



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



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

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

Secondo l'articolo 8, escluso (4) della Direttiva Europea 93/42/CEE (ricepita 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

**Implanti 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/CEE

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

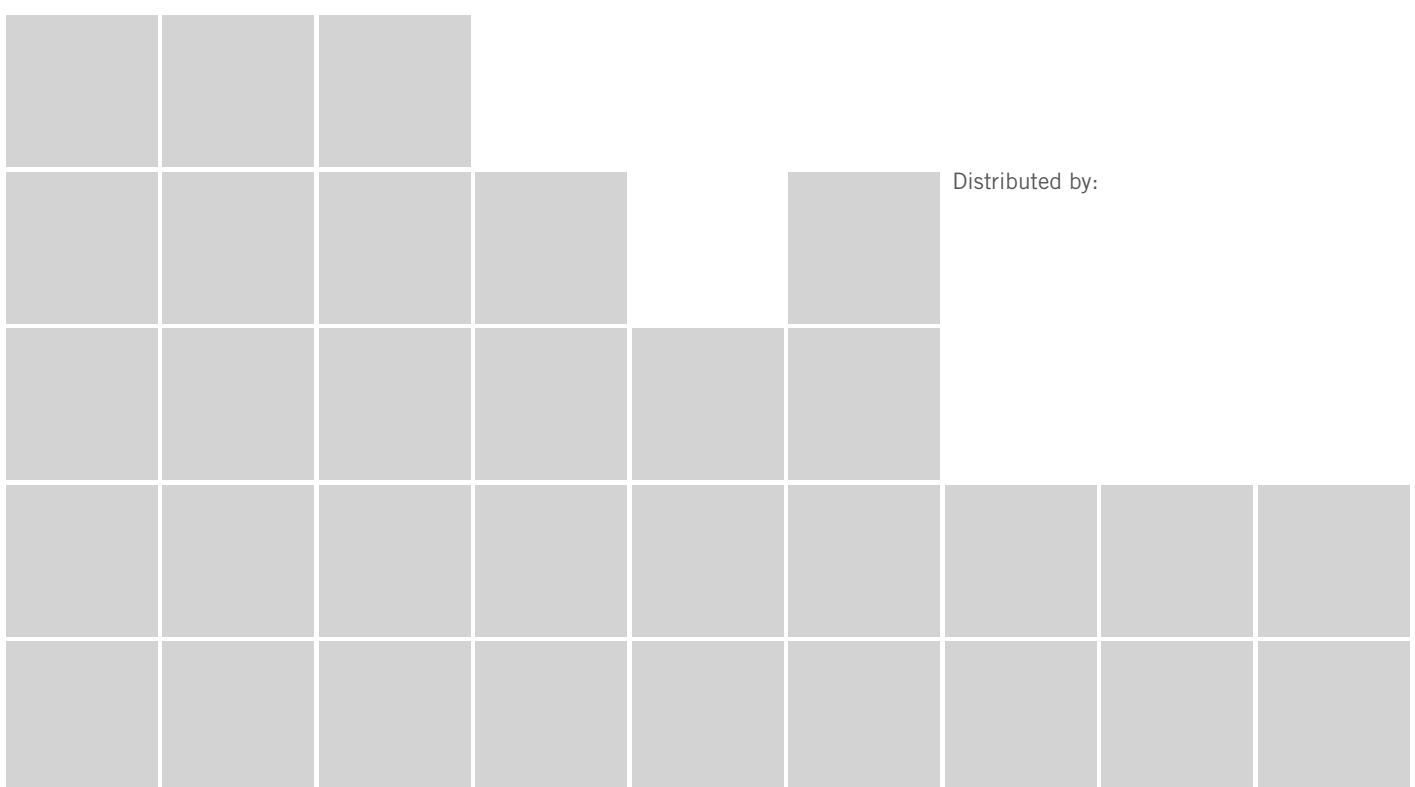
ICIM S.p.A.

PRIMA EMISSIONE FIRST ISSUE	EMMISSIONE 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)



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