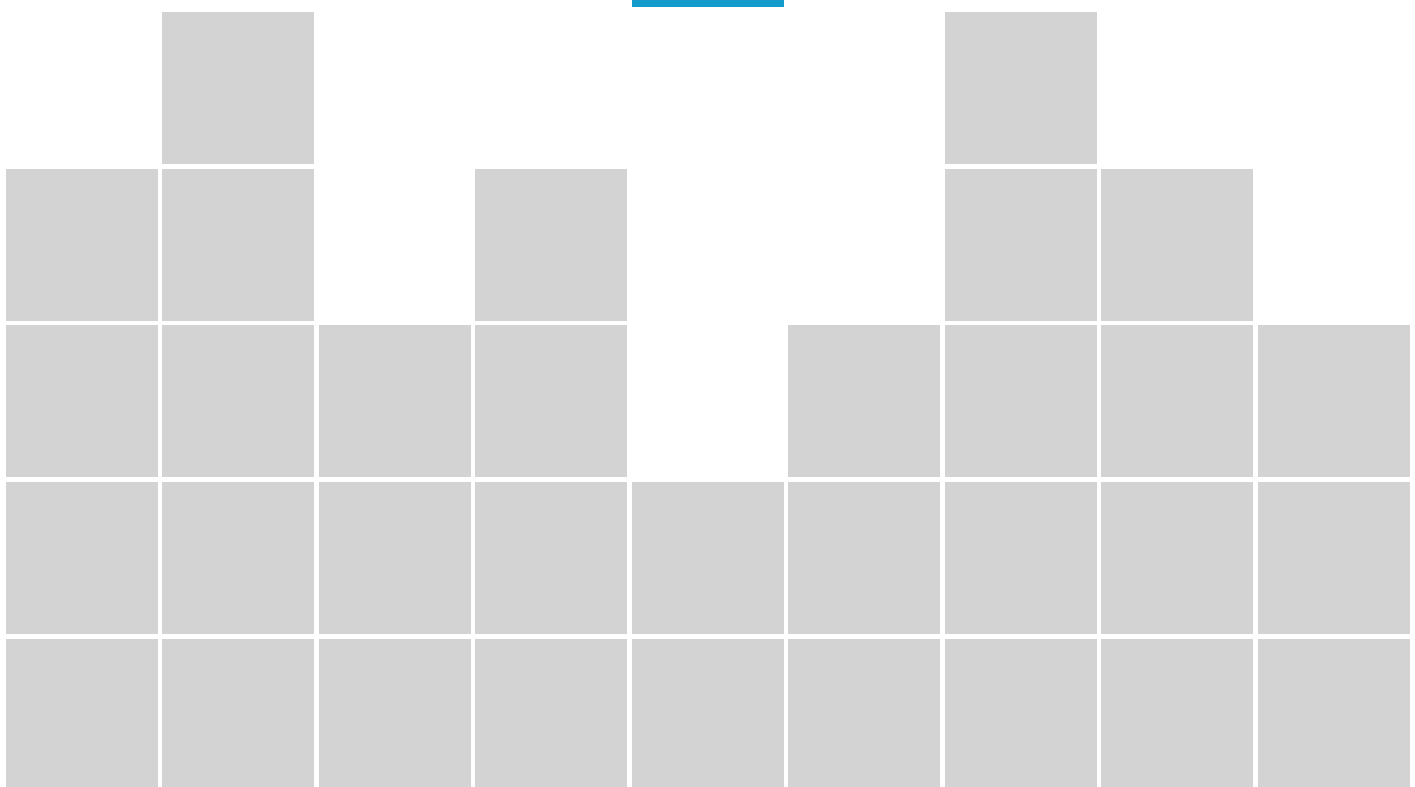


EASY
GRIP[®] Implants



COMPANY
PROFILE

HEX
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

SEMPPLICITY

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

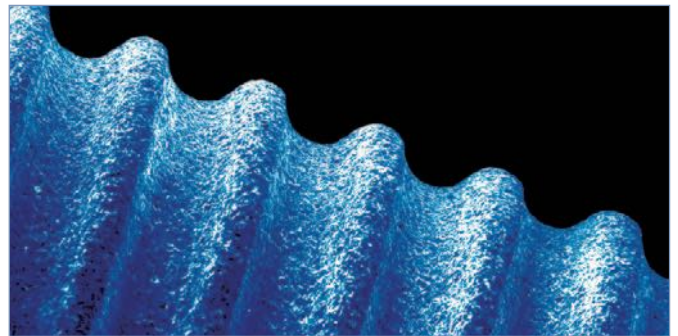
SURFACE TREATMENTS

The exclusive OsteoGrip® surface, featured by the Easy Grip® implant line, is the result of specific surface treatments such as Sandblasting, Etching, Anodic Colouring and Plasma Glow Discharge, specifically

designed to support rapid bone regeneration. Treatments such as anodic colouring are then performed on prosthetic components.

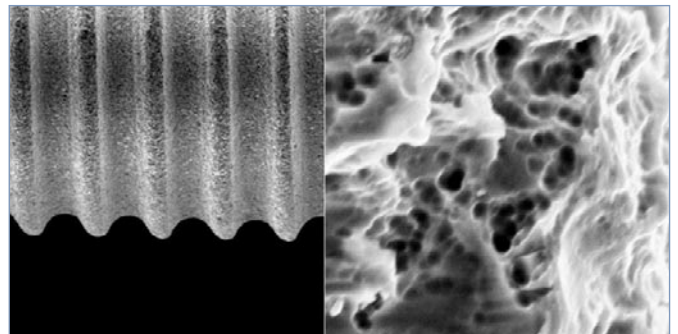
SLA (Sanding and Acid Etching)

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). This was introduced in 1998 and is one of the most documented rough surfaces in dental implantology.



Etching

Acid based with hydrofluoric acid for better osteointegration, to achieve optimal microtexture.



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 osteointegration.



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. The yellow anodic colouring of Easy Grip® necks has been implemented since September 2021 when the series 60 conical implant was placed on the market.

SIMPLICITY IN THE SOLUTIONS

SINGLE CONNECTION

Prosthetic connection of all the Easy Grip® implants features a hexagon socket with rounded angles and an internal 45° bevel, which increases stability and contributes to ensure the correct distribution of forces, by discharging the masticatory load evenly across the entire diameter of the implant.

The thread of double helix implants self tapping to provide an optimized surface for the transmission of both intrusive loads and compressive and divergent ones.

Simplicity

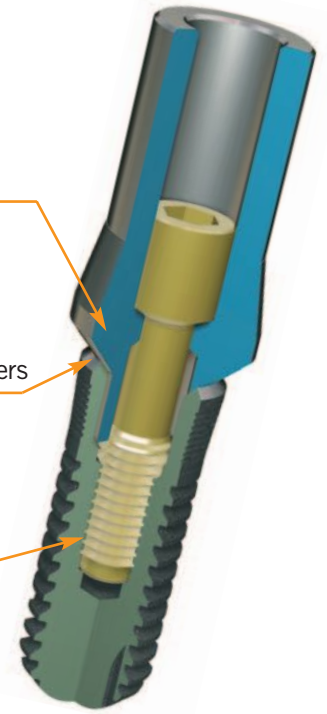
- Single connection for all implant diameters
- Platform switching method

Reliability

- Reinforced neck
- 45° conical internal support
- Internal hexagon with bevelled corners

Precision

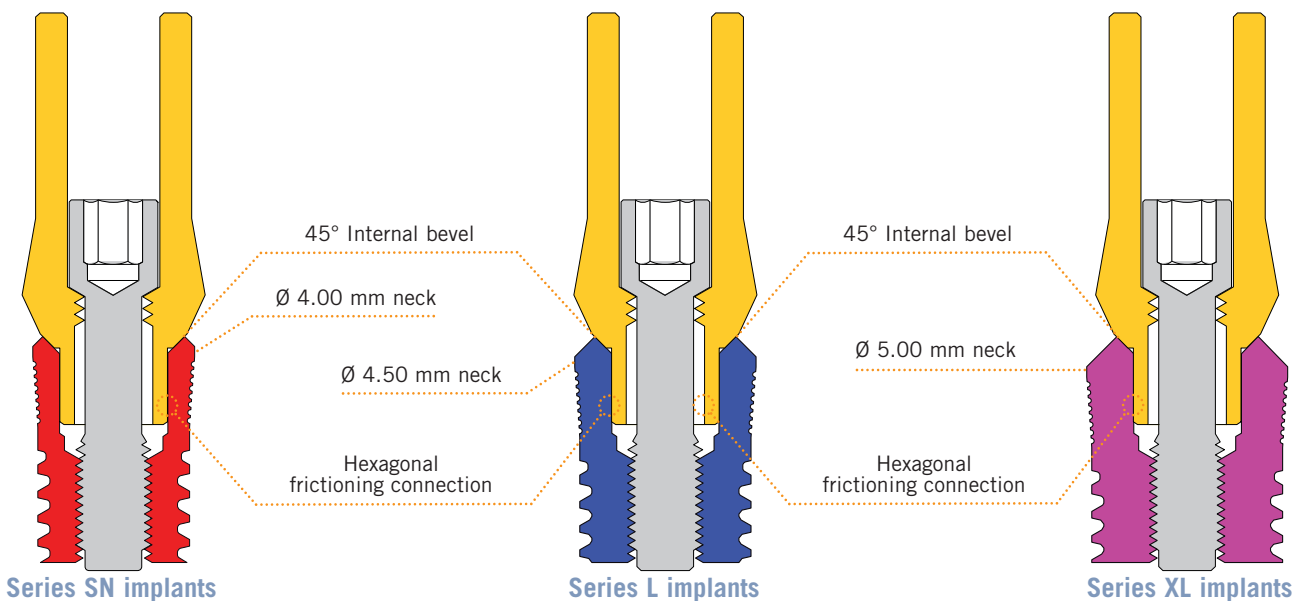
- Frictioning connection
- Tolerance within 5 µm
- No bending and settling



PLATFORM SWITCHING

This implant connection provides a range of prosthetic solutions, all made with a single standard connection, applicable to all implants in the Easy Grip® line, applying prostheses with the **platform switching method**.

SINGLE CONNECTION IN PLATFORM SWITCHING



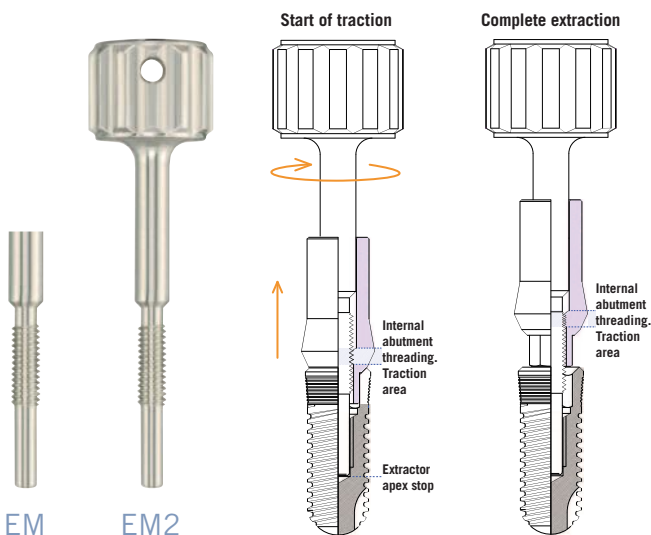
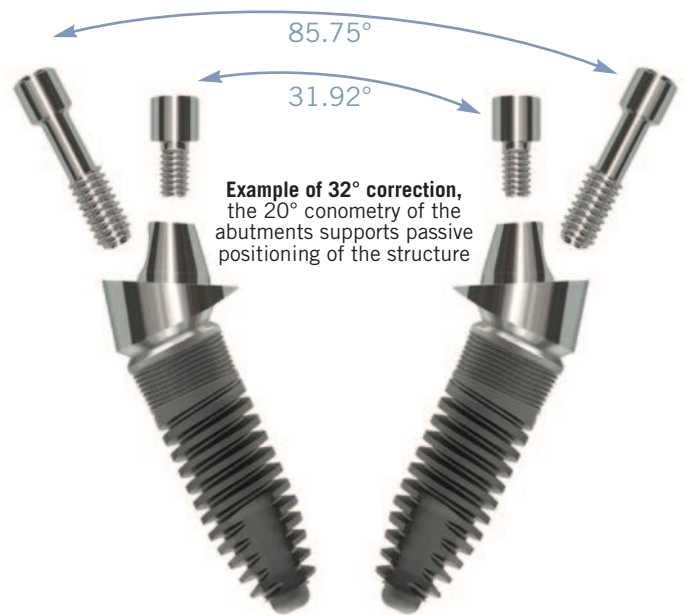
The Easy Grip® implants maintain **connection tolerances of 5 µm (friction fit)** the fixture abutment coupling achieved is very strong; such precision is guaranteed by Swiss numeric control machines and by quality checks carried out on every single piece produced. Such precision is a guarantee of reliability over time.

ALL-ON-SCREW SYSTEM

The range of Easy Grip® All-on-screw abutments, suitable for solving any disparallelism through **20° conical engagement**.

Dedicated to the total and/or partial prostheses, screwed onto multiple elements.

It makes it possible to widen prosthetic solutions available to the odontologist, affording greater freedom of choice in the implant protocol.



ABUTMENT EXTRACTING KEY

The friction-fit type fixture/abutment coupling in the Easy Grip® range is normally very steadfast, hence abutment detachment from the implant or from the laboratory analogue while making the prosthetic item might not be easy: that is why a suitable extracting key **EM2** has been developed for easy removal. In case of limited operating space, use the extracting screw **EM**.

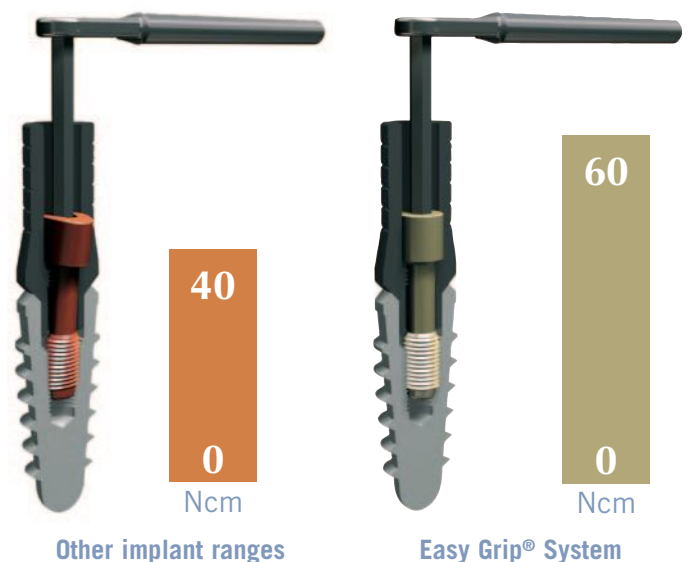
The extractor works by using the internal abutment threading which, working opposed to the groove end of the implant during the screwing action, lifts it and removes until it is completely detached.

TIGHTENING SCREW

the use of **rolled screws** to prevent the implants from coming unscrewed is essential for good, long term reliability of the implant.

T.F.I. System srl makes use of production techniques used in aeronautics.

As a matter of fact, the standard production process results in a breaking limit on the screw body at around 40 Ncm, while with the new method values around 60 Ncm can be reached, increasing the breaking strength of the screw by as much as 50%.





INNOVATION

PACKAGING AND STERILISATION

Easy Grip® 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.tfisystem.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.

Mini Short Neck
Short Neck
Large
Extra Large
Extra 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 that is part of the line.

EASY GRIP® IMPLANT SYSTEM

CYLINDRICAL HEX – SERIES 10



Morphology:

- Straight self-tapping double helix thread
- Connection: hexagon and internal bevel
- Cortical microgrooves
- 45° Conical coupling
- Smooth neck
- Lengths: 8 - 10 - 11.5 - 13 and 15 mm
- Material: titanium grade 5 ELI
- Osteogrip (SLA) surface

M MINI SHORT NECK
DN 3.30



SN SHORT NECK
DN 3.75



L LARGE
DN 4.50



XL EXTRA LARGE
DN 5.00



CONICAL HEX – SERIES 20



Morphology:

- Self-tapping conical thread
- Connection: hexagon and internal bevel
- Cortical microgrooves
- 45° Conical coupling
- Smooth neck
- Lengths: 10 - 11.5 - 13 and 15 mm
- Material: titanium grade 5 ELI
- Osteogrip (SLA) surface

SN SHORT NECK
DN 3.75



L LARGE
DN 4.50



XL EXTRA LARGE
DN 5.00



ANATOMICAL HEX – SERIES 30



Morphology:

- Cylindrical/conical self-tapping double helix thread
- Connection: hexagon and internal bevel
- Cortical microgrooves
- 45° Conical coupling
- Smooth neck
- Lengths: 8 - 10 - 11.5 - 13 and 15 mm
- Materiale: titanio grado 5 ELI
- Superficie Osteogrip (SLA)

SN SHORT NECK
DN 3.75



L LARGE
DN 4.50



XL EXTRA LARGE
DN 5.00



* Height 8 is without rounded apex



BONE LEVEL CONICAL HEX – SERIES 60



Morphology:

- Self-tapping conical thread
- Connection: hexagon and internal bevel
- 45° Conical coupling
- Smooth anodised neck
- Lengths: 8 - 10 - 11.5 - 13 and 15 mm
- Material: titanium grade 5 ELI
- Surface Osteogrip (SLA)

SN SHORT NECK DN 3.75



L LARGE DN 4.50



XL EXTRA LARGE DN 5.00



CYLINDRICA HEX SHORT – SERIES 50



Morphology:

- Straight self-tapping double helix thread
- Connection: hexagon and internal bevel
- 45° Conical coupling
- Smooth neck
- Length: 5 mm
- Material: titanium grade 5 ELI
- Osteogrip (SLA) surface

L LARGE DN 4.50



XL EXTRA LARGE DN 5.00



XX EXTRA EXTRA LARGE DN 6.00



MINI IMPLANTS FOR OVERDENTURES

The implant system also includes a mini implant for overdentures (**series MBO**), suitable for anchoring and

primary stabilisation of total mobile prostheses, especially in cases of narrow or atrophic ridges.

Morphology:

- Self-tapping double helix thread
- External hexagon 2.20 mm
- Ball connection Ø 1.80 mm.
- Transmucosal route 0-4 mm.
- Body Ø 2.70
- Neck Ø 3.00 mm.
- Lengths: 7 - 9 - 11 and 13 mm.
- Material: titanium grade 5 ELI
- Surface: Osteogrip (SLA)



MB0407



MB0409



MB0411

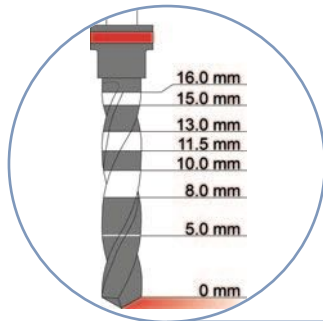


MB0413

KIT EASY GRIP®

SURGICAL KIT

Autoclavable and made of radel, it contains all the burs and surgical instruments required for positioning the implants, either with biphasic surgical protocol, or immediate loading surgical protocol (**KITTRAY**).



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



MINI SURGICAL KIT

A mini introductory kit to the Easy Grip® implant line is available.

The user will find the essential elements to implement standard surgical procedures referring to cylindrical and anatomical implants with screw connection.



INTERMEDIATE SURGICAL KIT

Reduced version of the Surgical Kit Tray made with Radel, autoclavable in three versions:

- the first containing the essential instruments for positioning cylindrical and anatomical implants;
- the second containing the essential instruments for conical implants;
- the third containing the essential instruments for Easy Grip® implants with hexagonal connection.

The kit may be sterilised in steam autoclave at 121°C for 20 minutes.

Fitted with a handy removable stainless steel pan, it is ready for inserting the depth stops.



EASYGRIP® 3D GUIDED SURGERY KIT

The kit, used in combination with the EasyGrip 3D software for implant planning, supports "guided" positioning of implants by means of custom surgical guides.



HEX CONNECTION PROSTHETIC COMPONENTS

Analogue	Transfer	Scan body	Healing screw			Abutments			
			Gingiva height			Ti	PMMA	Cr Co	
			2	4	6				
 LA2 LB2	 CTU T1	 SBPS				 PT30			
 LC3 LA3 LB3 LA4 LB4		 SBPTS				 PT33	 PU33	 CPCR	
		 SBFX				 PT34	 PU34	 PCR34	 PCR34R
 LLA3 LLA4	 T2	 SPS14				 PT35	 PU35		
						 PT36	 PU36		
						 PT38			

The colour code identifies the emergency profile

4
5
6
Emergency profiles

The images refer to products with connection 3 and are purely for illustrative purposes

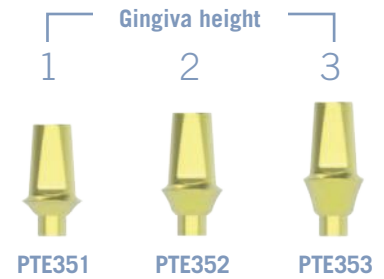


Abutments

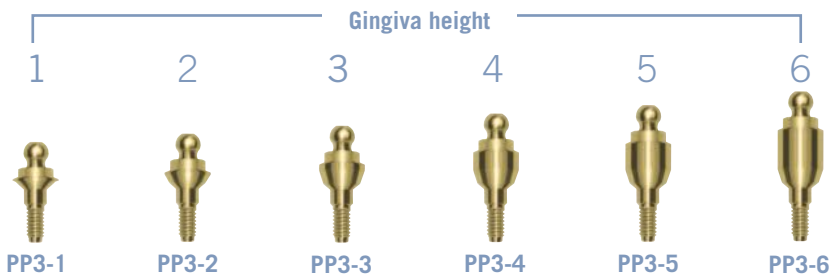
Pre-angled



Aesthetic



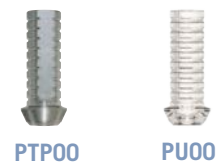
PP - Standard



Temporary



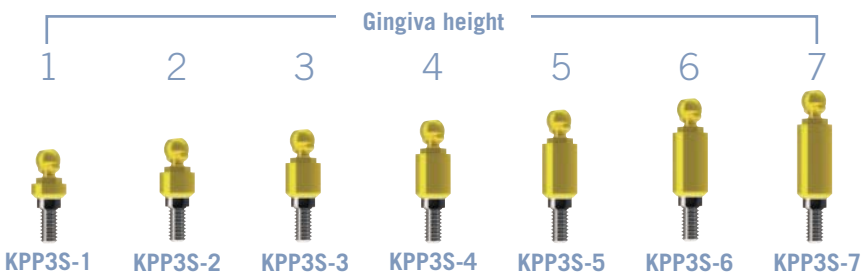
PP3E - Equator



Castable



PP3S - Sferoflex



PTS CAD/CAM



PS All on Screw



Codes included in the
CAD/CAM Easy Grip® library

Test abutments

PR15

Gingiva height

1 2 3



PR151 PR152 PR153

PR25

Gingiva height

1 2 3



PR251 PR252 PR253

PR35

Gingiva height

1 2 3



PR351 PR352 PR353

Castable abutments

PU15

Gingiva height

1 2 3



PU151 PU152 PU153

PU25

Gingiva height

1 2 3



PU251 PU252 PU253

PU35

Gingiva height

1 2 3



PU351 PU352 PU353

PUR35

Gingiva height

1 2 3



PUR351 PUR352 PUR353

Temporary abutments

PK15

Gingiva height

1 2 3



PK151 PK152 PK153

PK25

Gingiva height

1 2 3



PK251 PK252 PK253

PK35

Gingiva height

1 2 3

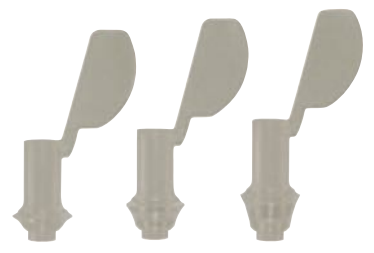


PK351 PK352 PK353

PKR35
































Gingiva height

1 2 3



PKR351 PKR352 PKR353



Angled abutments	 <p>PS322 22° Angled shoulder abutment 0 mm gingiva.</p>	 <p>PS330 30° Angled shoulder abutment 0 mm gingiva.</p>	
	 <p>PS324 22° Angled shoulder abutment 4 mm gingiva.</p>	 <p>PS334 30° Angled shoulder abutment 4 mm gingiva.</p>	
Straight abutments	 <p>PS34-0 Straight shoulder abutment 0 mm gingiva.</p>	 <p>PS34-1 Straight shoulder abutment 1 mm gingiva.</p>	 <p>PS34-2 Straight shoulder abutment 2 mm gingiva.</p>
	 <p>PS34-3 Straight shoulder abutment 3 mm gingiva.</p>	 <p>PS34-4 Straight shoulder abutment 4 mm gingiva.</p>	 <p>PS34-5 Straight shoulder abutment 5 mm gingiva.</p>
Sleeves	 <p>CPS4 Castable sleeve for straight shoulder abutments</p>	 <p>TPS4 Titanium sleeve for straight shoulder abutments</p>	 <p>CRPS4 Cobalt chrome sleeve for straight shoulder abutments</p>
	 <p>CPS5 Castable sleeve for angled shoulder abutments</p>	 <p>TPS5 Titanium sleeve for angled shoulder abutments</p>	 <p>CRPS5 Cobalt chrome sleeve for angled shoulder abutments</p>
Link	 <p>LPS4 Gluing link for straight shoulder abutments</p>	 <p>LPS5 Gluing link for angled shoulder abutments</p>	
Transfer	 <p>TUS4 Transfer for straight shoulder abutments</p>	 <p>TUS5 Transfer for angled shoulder abutments</p>	 <p>SBPS ScanBody for shoulder abutments</p>
Analogues	 <p>LAS4 Analogue for straight shoulder abutments</p>	 <p>LAS5 Analogue for angled shoulder abutments</p>	
Screws	 <p>VGS4-4 Healing screw for straight shoulder abutments gingiva 4.5 mm.</p>	 <p>VGS5-4 Healing screw for angled shoulder abutments gingiva 4.5 mm.</p>	
	 <p>VOP Occlusal screw for shoulder abutments</p>	 <p>VUF Universal rolled screw for angled shoulder abutments</p>	
Mounter	 <p>MPS Mounter for straight shoulder abutments</p>	 <p>HPS Mounter for angled shoulder abutments</p>	
Accessories	 <p>APS Finishing bur</p>	 <p>VLC5 Long screw for direct impression</p>	

ACCESSORIES FOR EQUATOR BALL ABUTMENTS

Castable	Accessories	Instruments
 <p>MCE</p>	 <p>CEV</p>  <p>CET</p>  <p>CEG</p>	 <p>CHE</p>
 <p>SEL</p>	 <p>CEN</p>  <p>CER</p>  <p>BACE</p>	 <p>HCHE</p>  <p>AME</p>
 <p>SEE</p>	 <p>T1CN</p>  <p>T1CE</p>  <p>LAE</p>	 <p>ICMU</p>
 <p>SET</p>		 <p>ISMU</p>  <p>MUI</p>

ACCESSORIES FOR STANDARD AND SFEROFLEX BALL ABUTMENTS

Accessories	Instruments
 <p>CNB</p>  <p>CNR</p>  <p>CNG</p>  <p>CNV</p>  <p>CNO</p>  <p>CNA</p>  <p>CNT</p>  <p>CNN</p>	 <p>ECT</p>  <p>ICT</p>
 <p>CRA</p>  <p>CRG</p>  <p>CRR</p>  <p>CRV</p>  <p>BTCN</p>  <p>BACN</p>  <p>BCCN</p>	
 <p>LACN</p>  <p>T1CN</p>  <p>PPCN</p>  <p>AD-0°</p>  <p>AD-7°</p>  <p>AD-14°</p>	

The pictures are purely for illustrative purposes

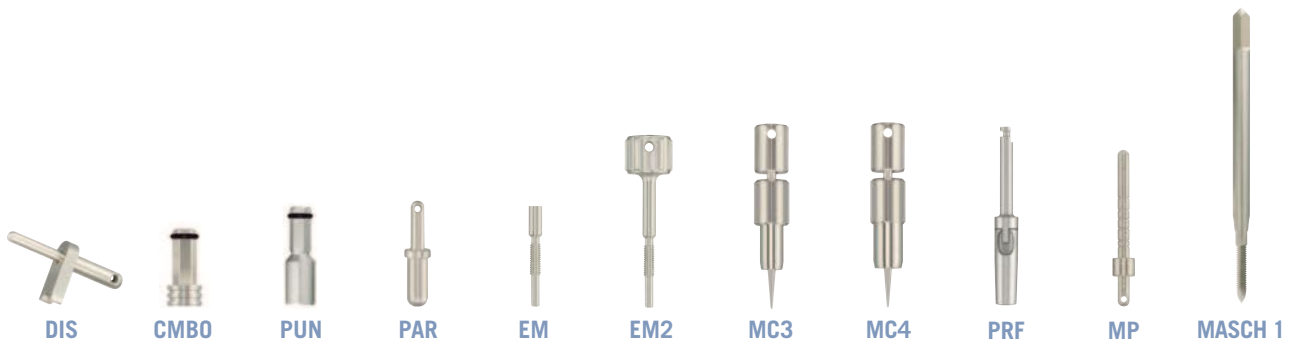


 series BP2	<p>Pilot Burs</p>  RMB20 RMB24 RMB27	<p>Initial Burs</p>  RA018 RLO18	<p>Accessory burs</p>  RLO35
 series BP3  series BP4	<p>Cylindrical burs</p>  RMB30 RMB33 RMB36 RMX36 RMB42 RMX42 RMX52	<p>Conical burs</p>  RCS00 RCS70 RCL00 RCX00 RCL70 RCX70	
<p>Depth Stops</p>  BP205 BP208 BP210 BP211 BP213 BP215 BP308 BP310 BP311 BP313 BP315 BP408 BP410 BP411 BP413 BP415		<p>Countersinks</p>  AS2 AS3 AS4 AS5 BRC3 ASS ASL ASX	
<p>Cylindrical Taps</p>  MAS2 MAS3 MAS4 MAS5	<p>Anatomical Taps</p>  MA3 MA4 MA5	<p>Conical Taps</p>  MS00 ML00 MX00 MA63 MA64 MA65	

Bone expanders



Instruments and Accessories



Hexes



Screw



Keys





SERVICES AND COURSES

SERVICES

Implant replacement service.

This service has been designed to allow 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 no longer sterile due to accidentally opening the package.

Implant card.

Intended for the patient to store the identification data of the inserted implants and as a reminder for check-ups. It is available free of charge on the doctor's request.



COURSES

Course on topographic anatomy on cadavers.

Structured in one didactic part in multimedia classroom and a practical one in the dissecting room

Course on computer assisted implant surgery,

aimed at dental practitioners who wish to learn the correct computer assisted implantology techniques.

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.



Workshop

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

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

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

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

Secondo l'allegato II, escluso (I) della Direttiva Europea 93/42/CEE (recapitata con il Dlg n. 46 del 24.02.97) e l'allegato II, escluso (II) della Direttiva Europea 93/42/CEE (in recepimento del Dlg n. 46 del 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 (I) DELLA DIRETTIVA EUROPEA 93/42/CEE DICHIARA CHE IL SISTEMA COMPLETO DI GARANZIA DELLA QUALITÀ ATTUATO DA ICIM S.p.A. È IN CONFORMITÀ CON LE ESIGENZE DI GARANZIA DELLA QUALITÀ PREVISTE NELL'ALLEGATO II ESCLUSO (II) DELLA DIRETTIVA EUROPEA 93/42/CEE.
ON THE BASIS OF THE ASSESSMENT PERFORMED ACCORDING TO ANNEX II EXCLUDING (I) OF EC DIRECTIVE 93/42/CEE, ICIM S.p.A. 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 (I) della Direttiva Europea 93/42/CEE
Annex II EXCLUDING (I) of EC Directive 93/42/CEE

Per l'identificazione dei modelli di prodotto vedere l'allegato I / For identification of the model type see Annex I
Il presente Certificato è da ritenersi valido solo se accompagnato dal relativo Allegato I / This Certificate is valid only with the relative Annex I

Gaetano Tibio
 Rappresentante Direzione / Management Representative

ICIM S.p.A.

<small>PRIMA EMISSIONE / FIRST ISSUE</small>	<small>EMMISSIONE CORRENTE / CURRENT ISSUE</small>	<small>DATA DI SCADENZA / EXPIRING DATE</small>
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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info@tfisystem.it

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