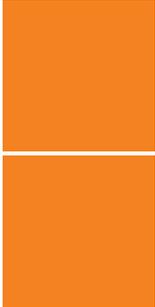
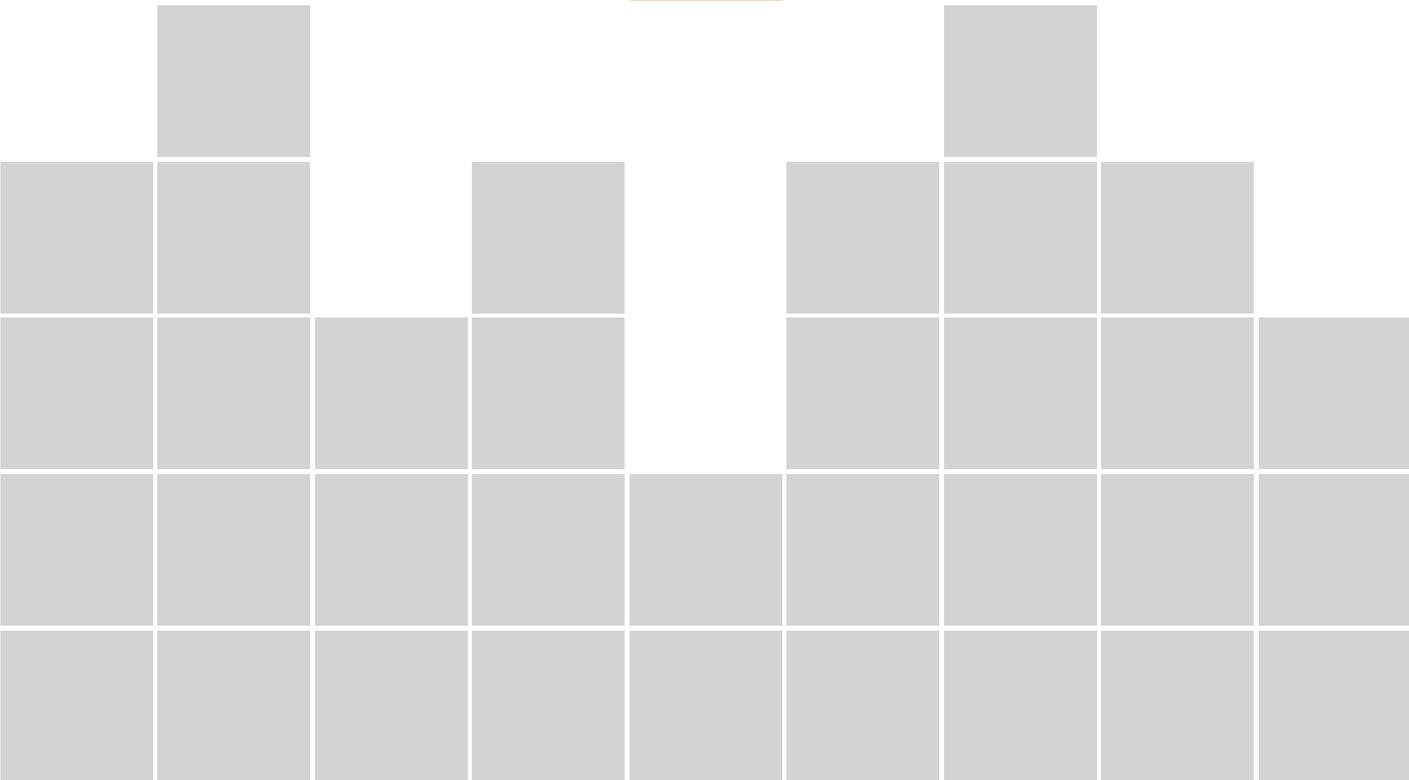
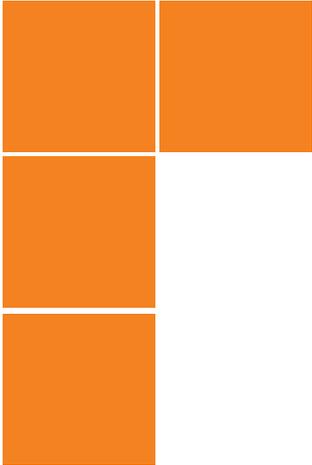


EASY GRIP[®] Implants



COMPANY
PROFILE

CONE
CONNECTION
NARROW
3.0



THE COMPANY

T.F.I. System srl has been in the field of dental implantology 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.



EASY GRIP® CONE NARROW IMPLANT SYSTEM

SERIES 80 Ø 3.0



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

M **NARROW**
DN 3.00



89M10



89M11



89M13

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.

SIMPLICITY IN SOLUTIONS

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.



Simplicity

- Electrolytic treatment
- Platform switching
- Anatomical emergence profile

Reliability

- Dedicated connection
- Conical coupling 5
- Internal hexagon

Precision

- No bending
- No settling

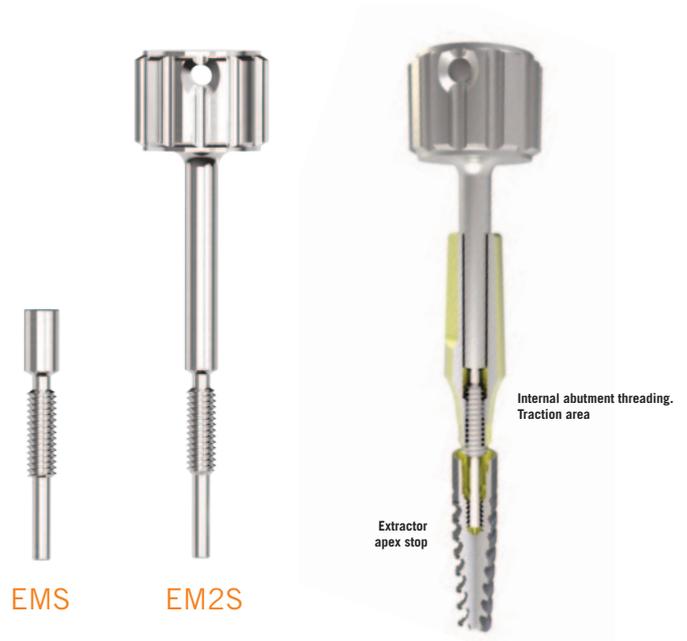
REVERSIBILITY OF THE EASY GRIP® CONE NARROW SYSTEM

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

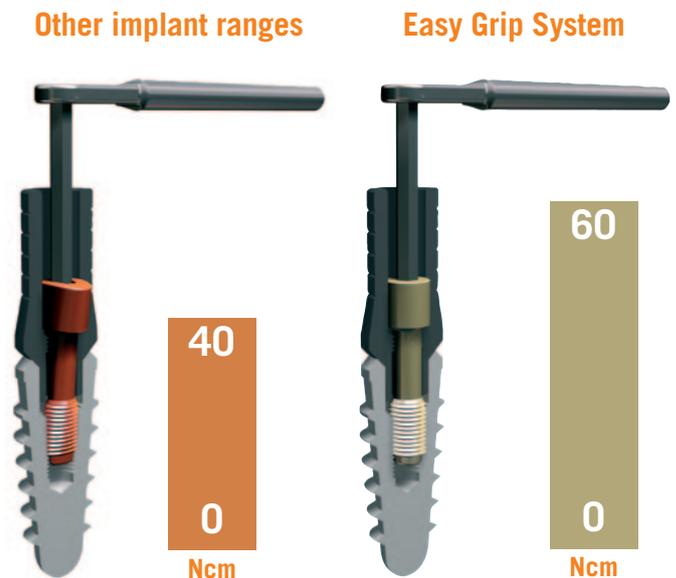
The optimal tightening of the conical fixture/abutment connection has always been a delicate element for all implant lines.

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.



INNOVATION

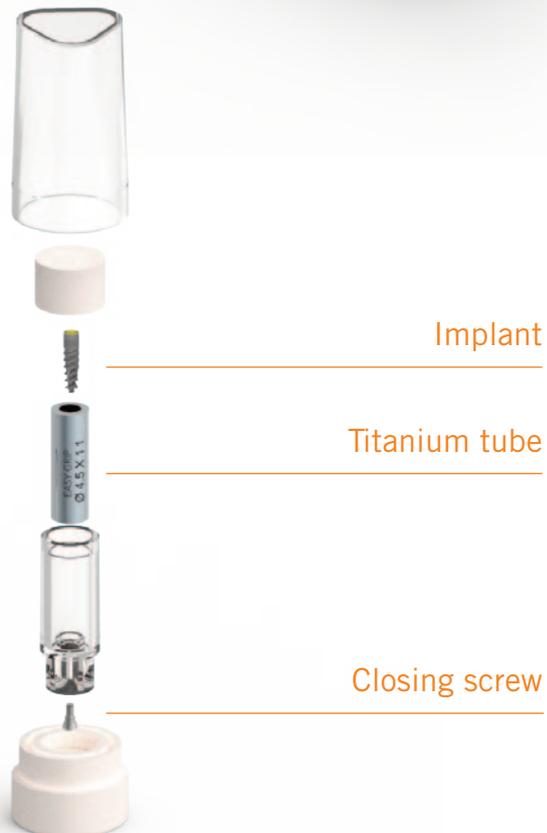
PACKAGING AND STERILISATION

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.tfsystem.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.



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.

TREATMENT QUALITY

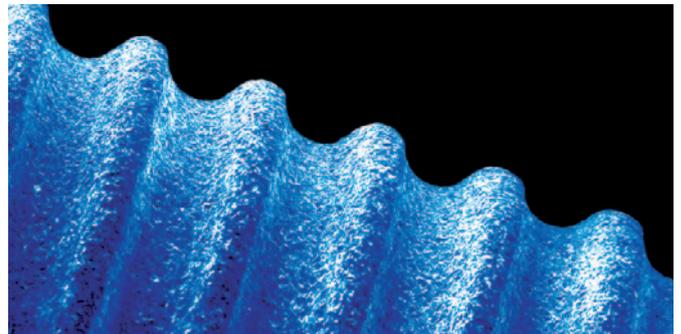
SURFACE TREATMENTS

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.

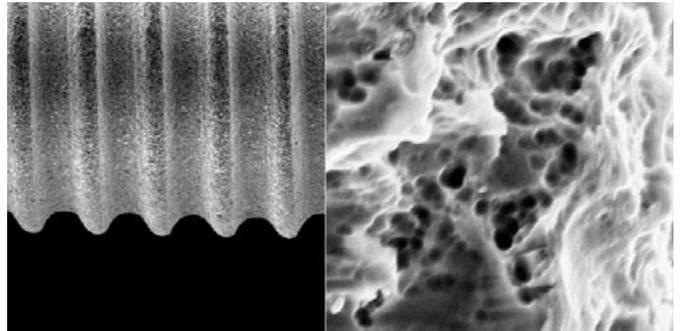
SLA (Sanding and Acid Etching)

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 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.



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.



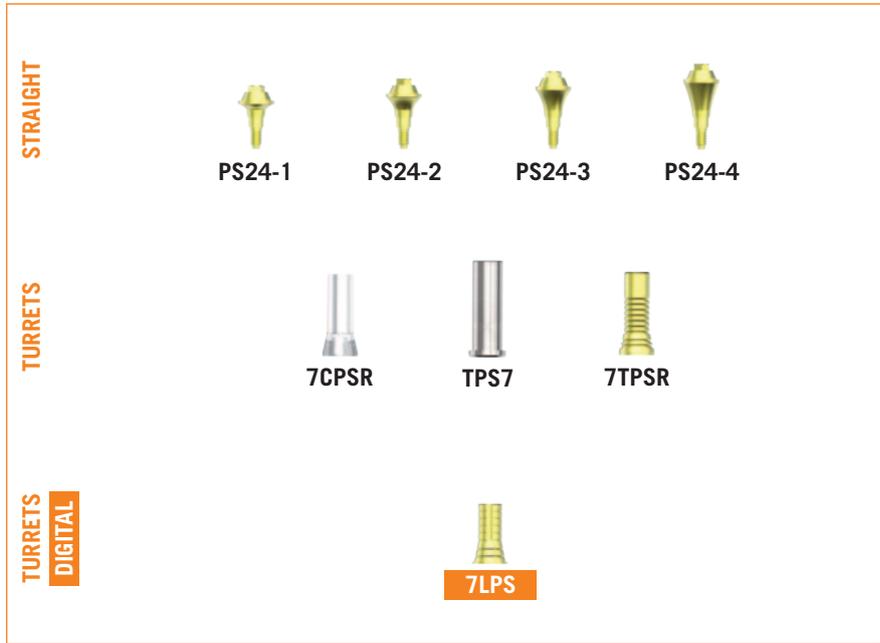
The pictures are purely for illustrative purposes

GENERAL DIAGRAM

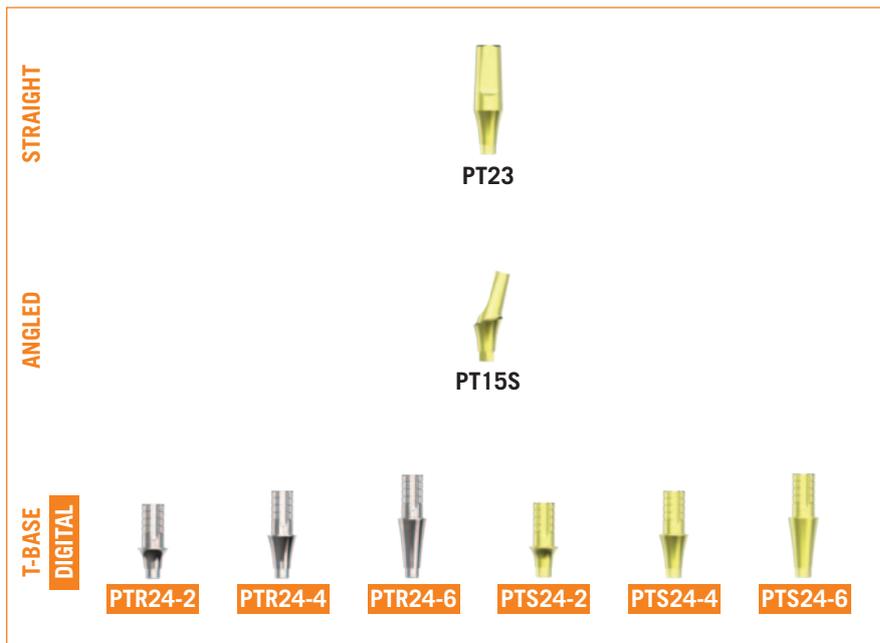
ABUTMENT

HEALING

MULTI UNIT ABUTMENT



CEMENTED PROSTHESIS



Code in the Easy Grip® digital libraries



IMPRESSION

TRANSFER

ANALOGUE

SCREWS

DIGITAL SOLUTIONS

SCANBODY

ANALOGUE

ANGLED CHANNEL



Initial Burs



RA018



RL018

Surgical Burs



RMB20



RMB24



RMB27

Depth Stops



BP208



BP210



BP211



BP213



BP215

series BP2

Bone taps



MA82

Accessory Burs



RL035



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

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



COURSES

Course in cadaveric surgical anatomy, consisting of a didactic part in the multimedia classroom and a practical part in the dissecting 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 IF 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, protesi 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.

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



T.F.I. System srl
Tissue Friendly Implants System
Via Giacomo Peroni 400-402
00131 Rome - Italy
www.tfisystem.it
info@tfisystem.it

