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: 3.75 – 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 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.

Handling precautions

• 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

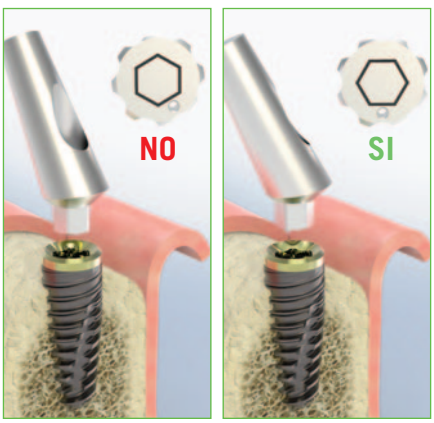

Fig. 6

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


Fig. 1

• 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)**.


Fig. 2

• 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)**.

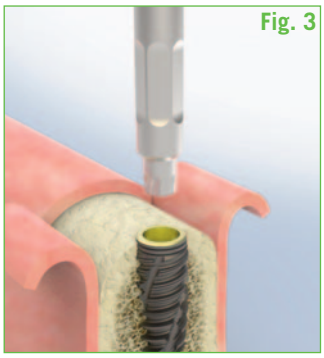


Fig. 3

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

Fig. 4

• 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


Fig. 1

• 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).**

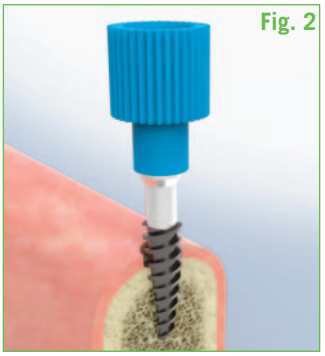


Fig. 2

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

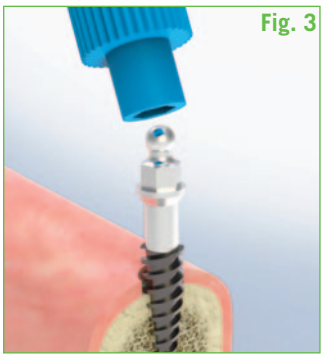


Fig. 3

• 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.

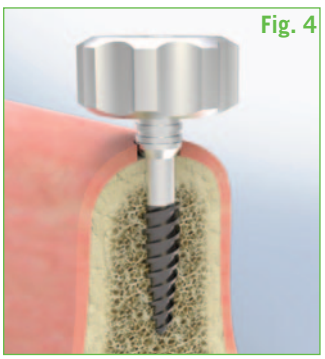


Fig. 4

• 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**