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 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.

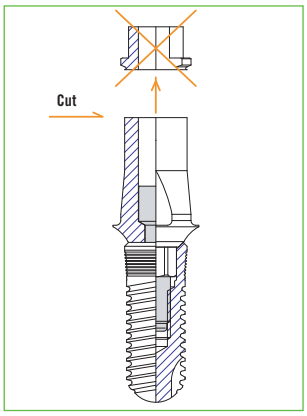
• **Ball abutments** are divided into three types:
- standard: with normo ball;
- sfero-flex: with mobile ball that assures tilting up to 7.5°;
- equator: with lowered ball.

• **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** may be used as a pre-formed abutment with non-frictioning hex, in which case, cut the part indicated in the diagram.

• 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.