User manual by product category

Caution:
These instructions for use refer to products that are only to be used by qualified professionals (i.e. dentists and/or oral and maxillofacial surgeons) unless expressly indicated otherwise (i.e. for dental technicians). All personnel must be specially trained and the products must be properly handled to avoid any risk of infection. When necessary, the qualified personnel must explain the hygiene rules that the patient must adopt and plan a regular outpatient control program.

Product identification
Equival® compatible prosthetic components manufactured by Phentagon Lab S.r.l. are medical devices that are intended to be used in the oral cavity. The functions of the prosthetic components are: reconditioning of the gums, anchoring to dental implants to support dental prostheses and the taking of dental impressions.

Digital or conventional impression transfer
Impression transfers, complete with fixing screws, are designed to transfer the exact position of the implant connection, in terms of height, inclination and indexing, from the mouth to the dental model. They are available in various diameters and heights to ensure compatibility with the dental implant or the Multi-Unit abutment. Invasive surgical instruments for temporary use (a duration of less than 60 continuous minutes) not intended to be connected to an active medical device. Supplied with reusable, non-sterile fixing screws in individual or multi-packs.

Transfer screws
These are used to screw the transfers to the implants when the impression is being taken and are then screwed back into the plaster analogs. They are available in various diameters and heights to ensure compatibility with the dental implant or the Multi-Unit abutment. Supplied with the respective transfers or as spare parts. Invasive surgical instrument accessories for temporary use (a duration of less than 60 continuous minutes) not intended to be connected to an active medical device. Single-use, non-sterile supplied in individual or multi-packs.

Analogs
These devices are used by dental technicians to reconstruct the dental impression model made either of plaster or from a 3D printer. They are made of either grade 5 titanium or surgical steel. They are available in various diameters and heights, ensuring compatibility with the impression transfer. Single-use, non-sterile, non-invasive medical device supplied in individual or multi-packs.

Drivers , Instruments not connected to an external device
These components are used for screwing the retaining screws abutment / implant ,healing abutment and retaining screw for transfer. Product made of medical steel.. The product is reusable, and in normal conditions of use, it is advisable to avoid using it more than 30 times. Medical device supplied in individual or multi-packs.

Sterilisation
The devices do not have an expiry date and are supplied NON-STERILE. The user must autoclave sterilise the devices using a validated cycle in compliance with the requirements of standard ISO 17665-1:2007 (134°C, 10 min., 2 bar) before each use.

Storage
After sterilisation, the Equival® prosthetic components must be stored in the sterilisation pouches and only be opened immediately before use. Unless they become damaged, a sterile environment is normally maintained within the autoclave sterilisation pouches. Therefore, be sure not to use the components if the pouches containing the devices are damaged and to re-sterilise them in new pouches before use. The storage period for sterilised products inside the pouches must not exceed that recommended by the pouch manufacturer. The product must be stored in a cool and dry place, away from direct sunlight, water and sources of heat.

Warranty and limitations
The success of all implants requires that the surgical technique be meticulously performed. Careful patient selection and a final prosthetic restoration that meets the patient's individual needs are essential. The surgical planning of single or multiple implants and the selecting of the suitable shape and size of the prosthetic components for the patient's anatomy are also crucial for the success of the implant. Phentagon Lab s.r.l. therefore strongly recommends that all dentists take one or more endosseous dental implant courses to properly learn about the implant system. Since the factors relating to the services provided by the operator, the selection of the patient and the surgical and rehabilitative technique are out of its control, Phentagon Lab s.r.l. will not replace the product due to failures or other undesired reactions resulting from operator errors or the lack of operator information on the use of an implant, and cannot be held liable for any unsuitable conduct by the patient.
The prosthetic components are made of a medical grade titanium alloy. Numerous animal and human studies conducted over several years by researchers and reported in many scientific publications show that titanium is highly biocompatible. However, the prevention of fractures of an implant or injuries derived from trauma or other overloading such as, for example, a severe traumatic occlusion, cannot be guaranteed.
For these reasons Phentagon Lab s.r.l. can only provide guarantees relating to the correct use of its products.
This warranty replaces all other warranties, expressed or implied, including the marketability and adaptability to particular situations. Phentagon Lab s.r.l. only and exclusively replaces products that have been returned to Phentagon Lab s.r.l., have undergone the necessary inspections and are proven to be defective. Phentagon Lab s.r.l. is not liable for damages deriving from accidents or events caused by third parties and if the relative claim was unfounded or incorrect.
Unless expressly specified otherwise, the device is designed for single use only, and any attempt to recondition it for subsequent reuse compromises the quality of the materials and the effectiveness of the device. Phentagon Lab s.r.l. expressly prohibits the re-use of its single-use devices.

Package contents: 1 Product shown on the label, 1 User manual

Symbol	Description
	Caution, read the instructions for use
	Lot number
REF	Product identification code
	Non sterile. The user must autoclave sterilise the product using a validated cycle in compliance with standard UNI EN ISO 17665-1:2007
	Manufacturer
	Read the instructions for use
	Single-use device (where applied; see label)
CE	CE conformity marking

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