ENGLISH - EN

Fixed Protheses

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IMPORTANT INFORMATION.

READ THIS DOCUMENT CAREFULLY BEFORE USING THE PRODUCT.

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1. Product description

Fixed prostheses are custom-made medical devices for dental use that are permanently attached to natural teeth or dental implants. These prostheses are designed under medical prescription for a single patient.

These products are based on an intermediate product, which serves as the framework of the dental prosthesis. Phibo® can manufacture these frameworks from the following materials;

- Cobalt Chromium (CrCo)
- Titanium (Ti)
- Zirconium (Zr)
- Polymethylmethacrylate (PMMA)
- Lithium Disilicate (E.MAX)

There are different types of protheses depending on the attachment system used:

ATTACHMENT SYSTEM	GROUP	DESCRIPTION
Screw-retained	Single structures	Individual restorations that are fixed directly to the implant or to the attachment by means of a screw, allowing subsequent retrieval for maintenance.
	Multiple structures	Multiple restorations that are screw-retained to two or more implants or attachments, designed to rehabilitate extensive edentulous spaces.
	Bars	Hybrid Structures: Structures that are screw-attached to multiple implants or attachments, designed to rehabilitate complete edentulous spaces.
		Overdenture bars: Fixed structures incorporating specific connection systems (attachments), designed to allow the anchorage and retention of a removable prosthesis that can be removed by the patient for hygiene and maintenance.
Cement-retained	Single structures	Restorations that are permanently cemented to previously prepared natural teeth or prosthetic attachments.
	Multiple structures	Multiple restorations that are permanently cemented to previously prepared natural teeth or prosthetic attachments.

2. Intended use

Fixed dental prostheses are intended to restore one or more missing teeth by permanently attaching them to natural teeth or dental implants. These prostheses are versatile, allowing for different configurations according to the anatomical and functional requirements of each case.

3. Expected clinical benefit

Fixed protheses are used to replace one or more missing teeth, thereby facilitating the recovery of masticatory, aesthetic, and phonetic function.

4. Indications for use

Fixed protheses are intended to be used in patients who have lost single or multiple dental pieces

in the mandible and / or maxilla.

5. Intended user and patient target group

Phibo fixed dental prostheses are designed exclusively for use by dental professionals. It is essential to consult the information provided in these instructions for use. If needed, Phibo will provide guidance to the healthcare professional on the proper use of the medical device. This device is not intended for direct patient use under any circumstances.

Various conditions, such as age, periodontitis, or accidental trauma, can lead to tooth loss. Fixed prostheses can be used in patients with missing, damaged, defective, diseased, or decayed teeth, whether for a single tooth, multiple teeth, or full dentition. In adolescents, fixed dental prostheses should only be used after jaw growth is complete, which typically occurs around age 16 in females and 18 in males, following the end of puberty.
It is important to conduct a prior clinical evaluation to determine if the patient is a suitable candidate for the placement of a fixed dental prosthesis, ensuring the treatment's appropriateness.

6. Contraindications

There are general factors that could affect the performance of fixed protheses, such as: Age, Stress, Tobacco, Pregnancy, Blood Dyscrasia, Psychological Factors, Terminal pathologies, Lack of oral hygiene, Bone deficiency, Alcoholism, Drug Addiction or Poor medical condition.

Systemic diseases could compromise the indications of use: Endocrine, Hematological, Acute or Chronic Infectious Diseases, Osteoporosis, Epilepsy, Maxillary Osteitis, Cardiovascular Radiotherapy Treatments, Corticosteroid Treatments, or Anticoagulant Treatments.

The healthcare professional is responsible for making the final decision related to treatment in these cases.

7. Warnings

Do not use products with damaged or previously opened packaging.

Each Phibo fixed protheses has its own design features. The use of inappropriate or third-party components may result in mechanical component failure, tissue damage, or deficient aesthetic results, due to incompatibility of specifications.

Passive fit should be achieved in prosthodontic rehabilitation, as well as occlusal adjustment to the opposite dental arch, avoiding excessive lateral forces. An insufficient number of implants, an inadequate choice of size, or an inappropriate position to support and transmit the expected loads, can result in mechanical failure of the rehabilitation due to overload or fatigue, and substantial loss of surrounding bone.

The onset of infections or diseases in general and changes in the patient's habits are some potential causes of failure of treatment.

8. Precautions

Phibo protheses are supplied unsterilized, they must be cleaned and disinfected prior to use.

9. Side effects

Implantology techniques may have adverse effects. The most commonly described adverse effects are:

- Transitory discomfort due to the surgery itself.
- Inflammation of the operation site.
- Local infections.

10. Sterilization and reuse

Fixed protheses are designed individually for each patient, therefore they could not be reused.

Product is sold non-sterile.

11. Important before using Phibo

The use and application of the Phibo® protheses are beyond the manufacturer's control. The design of the type of rehabilitation and prosthesis must be a planned procedure.

The user is responsible for any damage that may be caused by the misuse of the parts, releasing Phibo Cad CAM, S.L. from liability for damages or losses resulting from improper handling or misuse.

Phibo® documentation is periodically renewed according to the state of science and technology, please do not hesitate to contact us for additional information.

12. Procedure

Pack opening

Visually check that the packaging is not damaged, opened, or perforated. Check the data on the devices' label

to confirm that it matches the prothesis selected for the designated patient. Open the package carefully, following the instructions on the package and placing it on a clean field.

Cleaning and disinfection

Is mandatory to duly clean and disinfect all parts in contact with the patient. As general procedure, use only cleaning agents and disinfectants intended for the device's material, and follow their respective instructions for use, as provided by the manufacturers.

Disinfection must be performed by immersing the instruments in an adequate disinfectant bath, strictly following

the manufacturer's instructions regarding the recommended dose/concentration, immersion time, and temperature. The devices should not be in contact with one another.

The process of installing a screwed abutment versus a cement-retained one depends on the type of prosthesis and the desired clinical outcome. Here is a summary based on general principles and practices for these two options:

Screwed prothesis

- φ Preparation: For early and delayed loading, remove the implant or the healing cap and confirm that the implant has achieved adequate osseointegration and is free of infection. This step is not applicable for immediate loading.

  Ensure clean and decontaminated internal threads of the implant/abutment to guarantee proper seating.

- φ Abutment Placement: If required, select a compatible abutment with the correct height and angulation.

  Place the abutment into the implant body and secure it using a pre-torqued screw. Torque should follow the manufacturer's recommended settings to avoid over-tightening or loosening during use. For Phibo® abutments this torque must be 35 Ncm.

  Check the fit of the structure: implant abutment shoulder fastening, passivity, relation to the gum, contact points and occlusion.

- φ Final Prosthesis: Attach the final prosthesis, screw directly onto the abutment using a 1.25 mm driver tip and according to the recommended torque. This torque must be 15 Ncm For temporary protheses and 25 Ncm for definitive protheses.

  Fill in the screw hole using cotton wool and temporary filler material.

- Bars: Remove the healing cap from the implant, the transgingival abutment or the provisional prosthesis. Secure the bar to the implants using the 1.25 mm driver tip. Tighten the bar to a torque of 25 N·cm. Mount the overdenture onto the bar and perform the necessary adjustments.

Cement-Retained Protheses

These protheses could be installed on abutments or on natural teeth previously treated (dental stump). For abutment installation, please refer to the previous section *Preparation* and *Abutment Placement*. Once the prothesis is ready to be installed, please follow these instructions:

- Cementation:

  Mount the prosthesis structure in the mouth over the abutment.

  Check the fit of the structure: implant abutment shoulder fastening, passivity, relation to the gum, contact points and occlusion.

  Fill in the screw entry hole using temporary filler material.

  Cement the prosthesis. If the prosthesis will be removed for maintenance, use a

  temporary cement.

  Wait for the cement to set and remove any excess to avoid irritation or peri-implantitis.

For additional information Prosthodontic procedures are available at our website www.phibo.com.

13. Storage and disposal of information

Phibo® protheses should be stored in a dry, clean place, protected from adverse conditions until use.

If required, they must be discarded in an environmentally friendly manner in accordance with local

regulations.

14. Information to be supplied to the patient

It is important that patients receive comprehensive details concerning contraindications, warnings, precautions and adverse effects associated with Phibo® dental protheses.

15. Incident reporting information

Any incident related with Phibo® products should be immediately reported to Phibo®. For detailed instructions, please access with your account in the Customer Center Platform (www.customercenter.Phibo.com) and consult the document **EN-MCC-0424001 Manual Customer Center.**

Serious incidents must also be reported to the local competent authority.

16. Legal compliance

Phibo® complies with all the requirements established by European laws and guidelines relating to the manufacture and distribution of medical and health products.

17. Further information

For additional information or compatibility with other parts, please consult the Prosthodontic procedures available at Phibo's website, at https://Phibo.com/formacion-y-servicios/ifus/ifus-english/. The Instructions of Use and the Prosthodontic procedures can also be requested printed at Phibo® email atencionPhibo@Phibo.com.

18. Warranty Plan

The design of the product, its behavior and success of treatment are based on the indications mentioned above, and all those products that do not meet the indications described, and in, among others, are exempt from any warranty.

Fixed protheses have a warranty under the intended use of the product for 5 years, except for temporary protheses (PMMA) of 6 months.

19. Symbol description

SYMBOL	LEGEND
	Medical Device manufacturer. Phibo Dental Solutions, S.L. P.I. Mas d'en Cisa | Gato Pérez 3-9 | 08181 | Sentmenat | Barcelona | Spain
	Date of manufacture.
	Batch number.
	Catalogue number / reference number.
	Do not use if the packaging is damaged and consult the instructions for use.
	For single use only.
 CUSTOM MADE PRODUCT	Custom made medical device.
	Consult electronic instructions for use.
 CAS: 7440-48-4	Contains hazardous substances. The CAS (Chemical Abstract Service) number is an international identification standard for chemical substances.