ENGLISH - EN

Non-implantable attachments

Reference: IFU-00004 Non-Implantable Attachments

Version: 00

Effective Date: 2024-11-08

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1. Product description

The non-implantable attachments are medical devices, made of Titanium or POM, that simulate the dental implant or the prothesis with the objective of aid in the design, manufacturing and placement of the implantable prothesis.

There are 5 group of non-implantable attachments:

φ **Dental Transfers:** are parts connected to the top of the abutment or implant within the oral cavity and secured by a screw, serve to transfer the position of the implant or abutment in the biological environment to a laboratory working model. This is achieved through the use of impression materials which, placed in a suitable tray, are hardened inside the oral cavity and fixed in the oral cavity. At the end of the process, a replica is obtained with the original position of the implant in the mouth.

Fig. 1 Transfer

φ **Analogs:** are parts connected to the transfer and secured by a screw, serve to replicate the position of the implant or abutment in the biological environment to a laboratory working model. This replication is essential for fabricating accurate and well-fitting dental prostheses, ultimately improving the efficacy and predictability of dental implant treatments.

Fig. 2 Analog

- **Casting cylinders:** are parts connected to the analog and secured by a screw. They act as moldable pattern for the creation of precise tooth structures ensuring high precision and adaptability in various dental applications.

Fig. 3. Casting cylinder

- **Laboratory screws:** are cylindrical bodies that have a hexagonal connection at the top to be able to tighten it using the screwdriver. In the upper part of its outer surface it has a knurling. This knurling provides greater support in the case of manual handling. In its lower area it has a metric thread to be able to make the connection between the abutment post and casting cylinder. This thread is designed to make the connection in the upper area of the corresponding abutment.

Fig. 4. Laboratory screw

- **Scanbodies:** are elements that connect with the implant or the analog and the abutment. They consist of two different areas: The lower area reproduces the connection of the implant or the abutment. The upper area is used as a reference during the scanning process.

Fig. 5. Scanbody

Materials

The Dental transfers, Analogs, laboratory Screws and Scanbodies are manufactured from Titanium, specifically Ti6Al4V alloy (commercially grade 5 titanium) that meets the international standard ISO 5832-3 and ASTM F136

Casting cylinders are manufactured in colored POM-C. POM-C is a copolymeric acetal resin with the chemical name Polyoxymethylene (Polyacetal copolymer) that complies with DIN EN ISO 527-2, and must not contain heavy metals (Cd, Hg, Pb, Cr (VI)).

2. Intended use

Phibo Dental non-implantable attachments are intended to assist in the design, manufacturing and placement of the implantable prothesis. They can be used outside or inside the oral cavity for a transitional period of time (less than 60min).

3. Expected clinical benefit

The final purpose is to restore the chewing, aesthetic and phonation functions by helping to replace lost dental pieces in the mandible or the maxilla by means of an appropriate prosthesis.

4. Indications for use

There is a specific intended use for each non-implantable attachment:

- Transfers: intended to be attached to the top of the abutment or implant within the oral cavity and fixed by means of a screw. The goal is to transfer the position of the implant or abutment in the biological environment to a laboratory working model. For this purpose, impression materials are used which, placed in a suitable tray, are hardened inside the oral cavity and fixed in the oral cavity. At the end of the process, a replica is obtained with the original position of the implant in the mouth.

- Analogs: are intended to complement and reproduce the position of the implant in the mouth of a working model after the transfer has been carried out by means of an impression. They serve as a connection model for the laboratory construction of the prosthesis intended to replace the lost crowns.

- Casting cylinders: serve as the basis for the lost wax model of the final aesthetic prosthesis. The Casting Cylinder attached to the wax model is soaked in plaster and after drying it is placed in an oven where it is melted, leaving the cavity in which the metal of the prosthesis will be cast.

- Screws: serve as an aid in the casting stage, allowing the housing channel of the final clinic screw to be kept intact.

- Scanbodies: is to provide a precise and reliable reference for capturing the position and orientation of dental implants during the digital scanning process. They serve as a crucial component in the workflow of creating custom dental prosthetics by ensuring accurate data transfer from the patient's mouth to computer-aided design (CAD) software.

5. Intended user and patient target group

Phibo non-implantable attachments are intended to be used only by healthcare professionals specialized in odontology and implantology. It is necessary to have training in dental implantological technology for the use of any of the Phibo non-implantable attachment. It is also necessary to consult the information gathered in this instruction for use and surgical and prosthodontic procedures associated to the device. When required, Phibo will support healthcare professional with guidance on the use of the medical device. The medical device is not intended to be used by the patient in any case.

Non-implantable attachments are intended to be used in patients who have lost single or multiple dental pieces in the mandible and / or maxilla.

There are multiple diseases or conditions that can lead to loss of any dental piece, such as age, periodontitis or break by accident. In these situations, restoration with dental implants is the most suitable treatment. Non-implantable attachments can be used in patients of all range of age, in situations of loss, damage, defect, disease or deterioration of single tooth, multiple teeth, or full denture. The use of implants in adolescence is indicated once puberty has ended, when the mandible-growth is stopped, usually at 16 years in girls and 18 years in boys.

6. Contraindications

There are general factors that could affect a surgical intervention 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 of dental instruments: Endocrine, Hematological, Acute or Chronic Infectious Diseases, Osteoporosis, Epilepsy, Maxillary Osteitis, Cardiovascular Radiotherapy Treatments, Corticosteroid Treatments, or Anticoagulant Treatments.

7. Warnings

The device is sold non-sterile. Do not use directly to the patient, clean and disinfect all parts and sterilize all parts in contact with the patient before use.

The reuse of single-use products may result in potential deterioration of their features, which involves the risk of tissue infection, surgical or prosthodontic failure and/or deterioration of the patient's health.

8. Precautions

Phibo® non implantable attachments are supplied unsterilized. They must be cleaned, disinfected, and sterilized prior to use, see section *12. Procedure.*

Do not use products with damaged or previously opened packaging.

Maintain aseptic technique while handling the instruments and throughout the entire procedure.

Due to the size of some products, special attention must be paid, so that they are not accidentally ingested / swallowed by the patient.

Each non-implantable attachment 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.

Ensure that the specified torque is adhered to when inserting attachments. Failure to do so may result in damage to the components or the screw. Additionally, avoid exceeding the recommended implant torque when tightening attachments, as this could cause the implant to rotate, potentially compromising successful osseointegration

It is important to regulate both the contra-angle handpiece in the case of mechanical insertion, and the torque wrench in manual insertion, to the torque indicated in the corresponding surgical procedure of the Phibo implant system.

Note: for additional information regarding the use and characteristics of the torque wrench, please refer to procedure **PROSPDIN.**

9. Side effects

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

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

10. Sterilization and reuse

Non-implantable attachments are sold non-sterile. Is responsibility of the final user to properly clean and sterilize the device before use.

All non-implantable attachments are single-use products and therefore should not be reused.

11. Important before using Phibo

The use and application of the Phibo® non-implantable attachments 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 Dental Solutions, S.L. from liability for damages or losses resulting from improper handling or misuse.

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

12. Procedure

First of all, ensure that non-implantable parts are used under clean and safety environment. Product is sold non sterile, assure asepsis after sterilization and during use.

12.1. Preparation and Initial Verification

Before using Phibo's non-implantable dental attachments, it is essential to carry out several initial checks:

Package Inspection: Visually inspect the package to ensure it is not damaged, opened, or punctured. Check the expiration date indicated on the package.

Product Label: Before opening the blister, make sure the reference number matches the desired one. Identification labels on each piece are intended to maintain traceability and guarantee the product used on the patient.

12.2. Package Opening

Blister Opening: Carefully open the blister following the instructions on the package and place it on a clean surface.

Handling the Pieces: Avoid direct contact with the pieces to maintain asepsis. Use gloves and tools to handle the attachments.

12.3. Cleaning, Disinfection and Sterilization

Before using Phibo's non-implantable dental attachments, it is essential to clean and disinfect the parts that will be in contact with the patient's oral cavity:

Initial Cleaning: Remove any residue from the attachments using sterile water and a soft brush. Avoid using abrasive tools that might damage the surface.

Disinfection: Immerse the parts in an approved disinfectant solution according to the manufacturer's instructions. Ensure complete immersion for the recommended duration.

Rinsing: After disinfection, thoroughly rinse the parts with sterile water to remove any disinfectant residue.

Drying: Allow the parts to air dry on a sterile surface or use sterile gauze to pat them dry. Ensure the parts are completely dry before proceeding to the next step.

Sterilization: For sterilization purposes, use a cycle at 134ºC (273 °F) with fractional pre-vacuum, for 6 minutes, and 20 minutes for drying.

Refer to **PRO-00007 Cleaning, disinfection and sterilization** for detailed instructions.

12.4. Clinical and Laboratory Procedure

Impression Taking and Preparation of the Working Model

Connect the Transfer: Place the transfer on top of the abutment or implant inside the oral cavity and secure it with the appropriate screw.

Impression: Use suitable impression materials, place them in an appropriate tray, and take the impression inside the oral cavity. Allow the material to harden, then remove the impression with the transfer attached.

Prosthesis Preparation in the Laboratory

Placing the Analog: Connect the analog to the transfer and secure it with the screw to replicate the position of the implant or abutment on the laboratory working model.

Casting Cylinder: Connect the casting cylinder to the analog and secure it with the screw. Shape the structure in wax or resin for casting.

Casting: Cast the shaped cylinder. Remove the cast structure and adjust the implant shoulder support. Test the metal structure.

13. Storage and disposal information

Phibo® non implantable attachments should be stored in a dry, clean place, protected from adverse conditions. Dental instruments must be discarded in an environmentally friendly manner in accordance with local regulations. Hazardous waste from contaminated devices or sharp objects must be disposed of in suitable containers that meet specific technical requirements.

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® non-implantable attachments.

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 in Phibo's website, at https://phibo.com/formacion-y-servicios/ifus/ifus-english/.
The summary of safety and clinical performance of Phibo dental instruments will be available on the European database for medical devices, Eudamed. It can also be requested from Phibo by 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.

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.
	CE 0123 represents certification by TÜV SÜD.
	Do not use if the packaging is damaged and consult the instructions for use.
	Unique Device Identifier.
	Medical Device.
	Consult electronic instructions for use.