ENGLISH - EN

Implantable Attachments

Reference: IFU-00002 Implantable Attachments

Version: 02 (05th May, 2025)

IMPORTANT INFORMATION.

READ THIS DOCUMENT CAREFULLY BEFORE USING THE PRODUCT.

CE 0123

Phibo Dental Solutions, S.A.
Pol. Ind. Mas d´en Cisa. C/Gato Pérez, 3-9. 08181-Sentmenat (Spain)
Tel.: +34 937151978 | Fax: +34937153997 |
email:info@phibo.com

Index

1. Product description

Phibo® implantable attachments are components or mechanisms, designed to be mounted on dental implants or transepithelial abutments, to support other abutments or dental prosthesis. Phibo® has the following types of implantable attachments:

- Healing attachments.
- Definitive attachments.
- Removable attachments.
- Temporary attachments.
- Screws.

Implantable attachments are manufactured with alloyed titanium, specifically Titanium-6 Aluminum-4 Vanadium (Ti-6Al-4V) as per the ASTM-F136-13 (2021) and ISO 5832-3:2022 standard (table 1).

Table 1 – Chemical composition of Ti-6Al-4V

MATERIAL	CHEMICAL COMPONENTS
Ti-6Al-4V	Nitrogen (N), Carbon (C), Hydrogen (H), Iron (Fe), Oxygen (O)
	Aluminium (Al)
	Vanadium (V)
	Titanium (Ti)

The ball abutments include an Ethylene propylene diene monomer (EPDM) O-Ring.
The Click and fix retentions and separator are manufactured with Nylon and silicone, respectively. For further information, please consult specific available information (**PRO-00008 Click & Fix Attachments)**.

2. Intended use

Phibo® implantable attachments are intended to serve as connectors between the dental implant and the dental prosthesis such as a crown, bridge, or denture. Implantable attachments are versatile to support different types of restorations.

3. Expected clinical benefit

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

4. Indications for use

Phibo® implantable attachments indications for use are described in table 2.

Table 2 – Indications for use of Phibo® implantable attachments.

GROUP	SUBGROUP	INDICATION
Healing Attachments	Healing Abutments	Provides mucosal protection after surgery, allowing tissue healing and the formation of a mucosal route or mucosal tunnel connection of the implant to the secondary structure or prosthesis.
	Healing Caps	Attached to the top of the abutment to prevent the gingival tissue from covering, during osseointegration of the implant, thus protecting the top of the abutment.
Definitive Attachments	Abutments	Serve as an intermediate structural element between the implant and the secondary structure or the prosthesis. Angled abutments allow to correct an extreme angular position of the implant in relation to natural parts or adjacent implants.
	Abutments Posts	Serve as intermediate structural elements modifiable by milling between the Phibo® Dental implant and the final prosthesis. Angled Abutment posts allow to correct extreme angular positions of the Phibo® dental implant, in relation to natural teeth or adjacent implants.
Removable Attachments	Ball Abutments	Mechanized attachments that, once fixed to the implant, serve as a retentive element of the constructed removable prosthesis, which incorporates the metallic cap that is fixed to the upper spherical portion of the ball abutment. Retention between the metallic cap and the spherical portion of the ball abutment is provided by an EPDM O-Ring.
	Click & Fix Abutments	Mechanized attachments that, once fixed to the implant, serve as a retentive element of the constructed removable prosthesis, which incorporates the metallic cap that is fixed to the upper portion of the Click & Fix abutment. Retention between the metallic cap and the abutment is provided by selectable retention caps.
Temporary Attachments	Temporary Abutments	Serve as a base for developing an immediate aesthetic reconstruction, using acrylic or relining machined polycarbonate sleeves.
	Temporary Caps	Serve as a base for the development of an immediate aesthetic reconstruction on top of abutments.
Screws	Implant Screws	Serve as the definitive retentive element between the abutment or the prosthesis and the implant.
	Abutment Screws	Serve as the definitive retentive element between the abutment or the prosthesis and the abutment.

5. Intended user and patient target group

Phibo® 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® implant systems. It is also necessary to consult the information gathered in this instruction for use and prosthodontic procedures associated with the implantable attachments. When required, Phibo® will support healthcare professionals with guidance on the use of medical devices. The medical device is not intended to be used by the patient in any case.

Implantable attachments are intended to be used during the oral rehabilitation of 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. Implantable attachments can be used in patients of all ages, in situations of loss, damage, defect, disease or deterioration of single tooth, multiple teeth, or full denture.

These products can be used in patients of several ages that have undergone surgery for the placement of one or more Phibo® dental implants, starting in adolescence once puberty has ended and the mandible-growth has stopped (usually at 16 years in girls and 18 years in boys).

6. Contraindications

There are general factors that could affect the performance of implantable attachments, 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.

Phibo® dental systems are not indicated in clinical cases with insufficient bone or poor bone quality.
The healthcare professional is responsible for making the final decision related to treatment in these cases.

7. Warnings

The person responsible for the rehabilitation, through correct planning, must guarantee an adequate safety margin, including teeth and vital structures. Otherwise, serious damage can be caused to vital anatomical structures with temporary and/or permanent injuries, as well as to the patient's health.

Each Phibo® implant system has its own design features that encompass implants, attachments, and instruments. 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 or an inadequate choice of attachments to support and transmit the expected loads, can result in mechanical failure of the system due to overload or fatigue, and substantial loss of surrounding bone.
In the event of a sterilization system failure, re-sterilization is not allowed, functional and biocompatibility specifications cannot be guaranteed.

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.

Magnetic Resonance Imaging (MRI) in patients with implanted abutments may cause heating, displacement, or image artifacts. Safe MRI is only permitted under the specified conditions outlined in the MR Safety Certificate available at our website.

8. Precautions

Do not use products with damaged or previously opened packaging.

Phibo® implantable attachments are supplied unsterilized, they must be cleaned, disinfected, and sterilized prior to use, according to the process described in the document **PRO-00007 Cleaning, disinfection and sterilization.**

Maintain aseptic technique while handling the device and throughout the entire surgical procedure.

Prosthodontic procedures describe in detail the precautions to be taken during treatment.

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

Phibo® implantable attachments are supplied unsterilized, they must be cleaned, disinfected, and sterilized prior to use, according to the process described in the document **PRO-00007 Cleaning, disinfection and sterilization.** No re-sterilization is allowed.
They are single-use products and therefore must not be reused.

11. Important before using Phibo attachments

The use and application of the Phibo® 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 product, 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.
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 label so that the attachment matches the planned. Open the blister carefully, following the instructions on the package and placing it in a clean field.

Cleaning, disinfection and sterilization

Phibo® implantable attachments are supplied unsterilized, for that reason it is mandatory to duly clean, disinfect and sterilize 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.

For cleaning purposes, use only an automatic method that has been validated.

Disinfection must be performed by immersing the attachments 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.

For sterilization of single items, the material must be placed individually in sterilization pouches and sealed.

Place the pouches to be sterilized in the steam autoclave and sterilize them using a cycle at 134ºC (273 °F) with fractional pre-vacuum, for 6 minutes, and 20 minutes for drying.

Detailed procedure for cleaning, disinfection, and sterilization of Phibo® implantable attachments is detailed in the Cleaning, disinfection and sterilization procedure (**PRO-00007**) available at Phibo's website (https://Phibo.com/formacion-y-servicios/ifus).

Use

The procedure to install an attachment follows a detailed and structured protocol. Each attachment has specific purpose and considerations to be taken:

Healing Attachments

Purpose: Healing attachments are used to shape the gingival tissue for future prosthetic steps, promoting optimal tissue health and contour around the implant site.

1. **Selection and Placement:**
    - **Select the Healing Attachment:** Choose the appropriate size and shape of the healing attachment based on the implant position and the anticipated final prosthetic restoration.
    - **Remove the Healing Cap:** If a healing cap is present, remove it using the appropriate driver tool.
    - **Position the Healing Attachment:** Place the healing attachment into the implant, ensuring proper fit. The attachment should engage the hexagon or other internal connections of the implant.
    - **Secure the Attachment:** Insert and hand-tighten the screw of the healing attachment, then use a torque wrench to apply the manufacturer's recommended torque, usually between 15-20 Ncm.

2. **Post-Placement Care:**
    - **Verify Placement:** Ensure the healing attachment is correctly fitted and stable.
    - **Monitor Healing:** Schedule follow-up visits to monitor tissue healing and make any necessary adjustments.
    - **Patient Instructions:** Provide the patient with instructions on maintaining oral hygiene around the healing attachment.

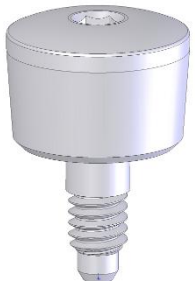

Figure 1. Healing abutment TSA.

Definitive Attachments

Purpose: Definitive attachments are designed to secure the final prosthetic restoration, providing long-term stability and function.

1. **Selection and Placement:**
    - **Select the Definitive Attachment:** Choose the attachment based on the final prosthetic design, considering factors like height, angulation, and connection type.
    - **Remove Temporary Components:** If temporary components or healing attachments are present, remove them using the appropriate tools.
    - **Position the Definitive Attachment:** Place the definitive attachment into the implant, ensuring proper alignment with the internal connection.
    - **Secure the Attachment:** Insert and hand-tighten the screw of the attachment, then use a torque wrench to apply the recommended torque, usually between 25-35 Ncm.
2. **Verification and Adjustment:**
    - **Check Fit and Function:** Ensure the attachment fits securely and aligns with the prosthetic design.
    - **Radiographic Verification:** Take radiographs to confirm the proper placement and fit of the attachment.

Figure 2. Abutment Post TSH.

Removable Attachments

Purpose: Removable attachments, such as ball abutments or Click & Fix attachments, provide retention for removable prostheses, allowing for easy patient maintenance. The self-positioning design allows the patient to easily place their overdenture without the need for exact alignment of anchoring components.

1. **Selection and Placement:**
   - **Choose the Removable Attachment:** Select the appropriate type and size of removable attachment based on the prosthetic requirements and patient preferences.
   - **Remove Existing Components:** If other components are present, remove them using the appropriate tools.
   - **Position the Removable Attachment:** Place the removable attachment into the implant, ensuring proper engagement with the implant connection.
   - **Secure the Attachment:** Insert and hand-tighten the screw, then use a torque wrench to apply the manufacturer's recommended torque, usually between 25-30 N·cm.
2. **Prosthesis Fitting:**
   - **Fit the Prosthesis:** Place the removable prosthesis over the attachments, ensuring it fits properly and provides adequate retention.
   - **Adjust for Comfort:** Make any necessary adjustments to the prosthesis for optimal comfort and function.
   - **Patient Instructions:** Instruct the patient on how to place and remove the prosthesis and provide care and maintenance guidelines.

Figure 3. CLICK & FIX Abutment for Bars.

Temporary Attachments

Purpose: Temporary attachments or abutments support provisional prostheses during the healing and osseointegration period, providing functional and aesthetic solutions.

1. **Selection and Placement:**
    - **Select the Temporary Attachment:** Choose the appropriate temporary attachment based on the provisional prosthetic design and expected duration of use.
    - **Remove Healing Components:** If healing caps or attachments are present, remove them using the appropriate tools.
    - **Position the Temporary Attachment:** Place the temporary attachment into the implant, ensuring proper placement and engagement.
    - **Secure the Attachment:** Insert and hand-tighten initially, then use a torque wrench to apply the recommended torque, usually between 15-20 N·cm.
2. **Prosthesis Fitting:**
    - **Fit the Provisional Prosthesis:** Place the provisional prosthesis over the temporary attachments, ensuring proper fit and occlusion.
    - **Adjust for Function and Aesthetics:** Make necessary adjustments to ensure the provisional prosthesis meets functional and aesthetic requirements.
    - **Patient Instructions:** Provide the patient with instructions on maintaining and cleaning the provisional prosthesis.

Figure 4. Temporary abutment Aurea EVO

Screws

Purpose: Serve as the definitive retentive element between the abutment or the prosthesis and the implant / abutment.

Figure 5. Aurea Evo Abutment Prosthetic Screw

Specific procedure for placement and handling of Phibo® TSA, TSH and Aurea EVO implantable attachments is detailed in the following documents:

- TSA prosthodontic procedure (PRO-00002).
- TSH prosthodontic procedure (PRO-00004).
- Aurea Evo prosthodontic procedure (PRO-00006).

13. Storage and disposal of information

Phibo® implantable attachments should be stored in a dry, clean place, protected from adverse conditions.
Implantable attachments 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® 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.
The summary of safety and clinical performance of Phibo® implantable attachments will be available on the European database for medical devices, Eudamed (https://ec.europa.eu/tools/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 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.
	For single use only.
	Unique Device Identifier.
	Medical Device.
 eIFU	Consult electronic instructions for use.
	Expiration date