ENGLISH - EN

Implants

Reference: IFU-00001 Implants

Version: 01

CE
0123

IMPORTANT INFORMATION.

READ THIS DOCUMENT CAREFULLY BEFORE USING THE PRODUCT.

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FORM4.2-00018 V.00

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1. Product description

Dental implants are prosthesis that interface with the bone of the mandible and maxilla to support a dental prosthesis such as a crown, bridge or a denture. Phibo has developed three lines of implants:

- The TSA® implant has four connections: external hexagon, internal hexagon, external cone and internal cone. The internal hexagon and external hexagon connections provide the anti-rotation characteristic of the prosthetic elements fixed to the implant. The internal and external cone connections provide axial, radial, and bending retention and secure the prosthesis to the implant.

Figure 1 – TSA® Dental Implants.

- The TSH® implant has various shoulder diameters with an external hexagon that provide the anti-rotation feature of the prosthetic elements attached to the implant by retaining the permanent screw of the prosthesis.

Figure 2 – TSH® Dental Implants.

- The Aurea® Evo implant connection has a hexalobular connection. This connection provides the anti-rotation feature of the prosthetic elements fixed to the implant in two equidistant spatial planes.

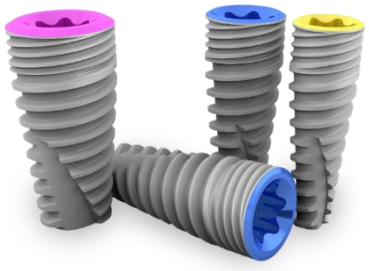

Figure 3 – Aurea® Evo Dental Implants.

All the dental implants are made of unalloyed titanium, specifically Titanium grade IV as per the ASTM F67-13 (2017) and ISO 5832-2:2018 standard, with the patented surface treatment Avantblast®, based on double chemical attack, that combines key factors to facilitate the biological response of the implant.

TSA®, TSH® and Aurea® Evo implants are packaged with the following components, manufactured with alloyed titanium, specifically Titanium grade V as per ASTM F136-13 (2021) and ISO 5832-3:2022 standard:

- Implant carrier,
- Implant carrier screw.
- Closure screw.

The composition of both raw materials is described in the following tables:

Table 1 – Chemical composition of grade IV Titanium.

MATERIAL	CHEMICAL COMPONENTS
Titanium grade 4	Nitrogen (N), Carbon (C), Hydrogen (H), Iron (Fe), Oxygen (O); Titanium (Ti)

Table 2 – Chemical composition of grade V titanium.

MATERIAL	CHEMICAL COMPONENTS
Titanium grade 5	Nitrogen (N), Carbon (C), Hydrogen (H), Iron (Fe), Oxygen (O); Aluminium (Al); Vanadium (V); Titanium (Ti)

2. Intended use

Phibo® dental implants are intended to be surgically introduced in the remaining bone tissue to replace the dental root. Dental implants are versatile implants designed for 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® dental implants are designed for placement in one or two surgical stages, depending on biological spaces, prosthodontics, and bone quality. Each reference has different indications according to the following table:

IMPLANT SYSTEM		TSA Implant			TSH Implant				Aurea Evo Implant		
PLATFORM		**Series 3**	**Series 4**	**Series 5**	**Series 2**	**Series 3**	**Series 4**	**Series 5**	**NP 3,5 mm**	**RP 4,3 and 4,8 mm**	**WP 5,5 mm**
INDICATIONS	Maxilla	Lateral Incisors	Central incisors, canines, and premolars	Molars	Not indicated	Lateral incisors, second premolars	Central incisors, canines, and premolars	Molars	Lateral incisors	Central incisors and premolars	Molars
	Mandible	Lateral and central Incisors	Canines and premolars		Lateral and central incisors	Premolars	Canines and premolars		Lateral and central incisors	Canines and premolars	
	Rehabilitation of completely **maxillary** edentulous patients	Overdenture supported by 4 or 6 implants in the middle and anterior areas, splinted using a rigid metal structure. For fixed restorations a minimum of 4 implants will be required, also using a metal structure.									
	Rehabilitation of completely **mandibular** edentulous patients	Overdenture supported by 2 or 4 implants in the anterior area, splinted using a rigid metal structure. For fixed restorations a minimum of 4 implants will be required, also using a metal structure.									

Table 3 – Indications for use of TSA®, TSH® and Aurea® Evo implants.

5. Intended user and patient target group

Phibo® dental implants 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 surgical and prosthodontic procedures associated to the implant system. When required, Phibo will support healthcare professionals with guidance on the use of the medical device. The medical device is not intended to be used by the patient in any case.

Dental implants 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. Dental implants can be used in patients of all range of ages, in situations of loss, damage, defect, disease or deterioration of single tooth, multiple teeth, or full denture. The use of this product 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 the implant performance, 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 implants are not indicated in clinical cases with insufficient bone or poor bone quality.

Implants of 8.5mm or shorter length are not suitable for bone quality type III or IV to support a single crown.

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

7. Warnings

The person responsible for the implant treatment, through correct planning of the rehabilitation, 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.

The patient must have an adequate volume of bone and bone quality for insertion of the necessary implants and to support the functional loads provided in service.

Each dental implant system has its own design features that encompass implants, prosthodontic components, 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, an inadequate choice of size, or an inappropriate position to support and transmit the expected loads, can result in mechanical failure of the

implant 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 osseointegration and treatment.
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

As a general rule, a minimum distance of 3 mm between two adjacent implants and 1.5 mm between an implant and a tooth is recommended in order to preserve bone vascularization and the emergence profile.
If, for whatever reason, the planned surgery is finally not performed, the blister pack containing the implant cannot be stored, maintained, or used for another surgery. The inner blister packaging does not maintain the sterility of the implant.
For crestal insertion, the cortical insertion drill should be used, since, if not used, the placement of the implant can lead to excessive pressure on the bone surrounding the implant, causing greater tissue retraction and in turn a potential decrease in the success rate (this configuration is not available for commercial references TSA 04.060, TSA 04.070, TSA 05.060 and TSA 05.070).

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

Implants are sterilized by gamma radiation. Phibo® dental implants come in individual units.
All implants are single-use products and therefore should not be reused.

11. Important before using Phibo

The use and application of the Phibo® dental implants are beyond the manufacturer's control. 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

Implant label

Before opening the blister, check the data on the label so that the implant matches the planned diameter and length.

The identification labels on each implant are intended to maintain the traceability and warranty of the product used on the patient. Place the labels in the patient's medical record and register, in the treatment log, the technical specifications of the laboratory associated with the clinic and the patient and, finally, place the label in any process that requires identification and relates to the patient's treatment.

Pack opening

Visually check that the packaging is not damaged, opened, or perforated. Check the expiration date (see section *Symbol description*).

The implant is delivered as follows:

- In an outer color-coded cardboard box for each series of implants.
- With three identification labels used for traceability and warranty.
- Double blister pack with double Tyvek seal to ensure the sterility of the implant.
- External blister: This houses the internal blister. After opening, leave the internal blister in the operating field.
- Internal blister: This blister houses the implant and its components (implant carrier, implant carrier screw, and closure screw).

Open the cardboard box by pressing on the section labeled “PRESS”, breaking the perforated line to remove the double blister pack. Once the double blister is extracted, peel off the external Tyvek sheet.

To preserve asepsis and sterility when handling the outer cardboard box and opening the outer blister, these two components must be manipulated by personnel who will not access the surgical field, so that the sterile field does not break.

Open the inner blister carefully, after the final osteotomy, following the instructions on the package and placing it in the surgical field. The screw on the lid may slip out of the blister if the package is opened too quickly and with too much force.

Remove the implant from its socket and then remove the closure screw. The implant is held in the internal blister by the friction between the implant carrier and the area of the blister designed for this purpose. It is important to fit the adapters securely into the implant carrier and check that they have been placed correctly before removing the implant. This will ensure that the implant is transported to the bone bed under appropriate conditions. If the implant falls out or loses its sterility, handling, cleaning, sterilizing or using the implant on the patient is completely prohibited.

Aseptic technique must be carried out throughout the entire surgical procedure.

Removing the implant from the blister

Before removing the implant from the blister and inserting it into the bone bed, the contra-angle and the torque wrench must be adjusted to a **maximum torque of 35 Ncm**. Manual or mechanical insertion of the implant should not exceed the maximum torque recommended; exceeding this torque can cause serious or irreversible damage to the implant and to the patient's health.

The indicators and consequences normally associated with exerting excessive force to insert the implant are as follows:

- Excessive torsion of the implant carrier, resulting in cold welding between the implant carrier and the implant.
- Perceptible or imperceptible damage to the implant connection, resulting in fracture of the implant after short- or medium-term restoration or misalignment of the prosthesis with the implant connection.
- Damage to the internal thread of the implant, resulting in a poor final fit of the screw in the prosthesis, broken screws, or loss of the internal thread of the implant.

Possible Causes:

- A final osteotomy sequence using a surgical drill with a diameter below the specification.
- Final sequence of milling and insertion of the implant in type I and II bone, without having adjusted the thread to the tap.
- Defective cut of the surgical drill, etc.

Figure 4 – Double blister packaging of a Phibo® dental implant.

Extraction of the Implant using a Contra-angle

Connect the mechanical adapter to the contra-angle and insert it into the implant carrier until you feel slight resistance and hear a click that indicates it is connected.

Hold the blister firmly and turn the contra-angle to **15 rpm**. Then remove it vertically without moving it back and forth, separating the implant from the blister.

Extraction of the implant using a torque wrench

Connect the mechanical adapter to the torque wrench and insert it into the implant carrier until you feel slight resistance and hear a click, indicating that it is connected.

Hold the blister firmly, and gently remove the implant vertically without moving it from side to side, separating it from the blister.

Implant insertion

After completing the final milling sequence, verify that the bleeding and vascularization of the bone bed are correct and that there are no sharp bone protrusions that could interfere with the insertion of the implant or the subsequent manipulation of soft tissue.

Before inserting the implant, ensure that it is the correct length. As an orientation during insertion, all implant holders have a mechanical mark 4 mm above the height of the theoretical crest area.

The implant can be inserted with or without irrigation so that the hydrophilic surface absorbs blood from the socket. The insertion of the implant should start slowly, with a maximum insertion torque of **35 Ncm** and a speed of **15 rpm**.

If the implant is inserted mechanically, do not insert it completely, but finish the insertion manually with the torque wrench, leaving it at the desired height and thus more directly ensuring the primary stability of the implant.

During insertion, do not exert excessive force, make sudden movements, or place instruments at inappropriate angles to the bone bed that could generate inadequate forces and tensions affecting the implant carrier and the implant. If the insertion is in type I and II bone, brief pauses should be taken and even more so when placing implants of greater length and diameter.

Removing the implant carrier

Once the implant is inserted, place the wrench in the implant carrier. The objective is to minimize the movement of the implant and maintain maximum stability while removing the retention screw from the implant carrier.

Once the wrench is in place, insert the tip of the manual or mechanical screwdriver into the retention screw. The retention screw is removed counterclockwise. The retention screw of the implant carrier is calibrated to a specific torque so that it can be removed manually or mechanically without difficulty. Retention screws are held in place on the tip of the screwdriver by friction.

If the forces applied are greater than those mentioned above, the retention screw can be screwed more tightly to the implant carrier and the implant carrier can be slightly locked against the implant, due to the friction and torsion of these elements. The open-end wrench must be used to remove the retention screw and then the implant carrier, making small movements in a counterclockwise direction to unlock the components. Then remove the implant carrier with mosquito forceps.

Subsequently, and depending on the treatment that has been planned, finish the surgery according to the chosen procedure. First, clean the area and apply saline solution to remove any particles or elements from the osteotomy that may interfere with the placement and adjustment of the necessary components and attachments.

A closure screw is included in each implant package.

13. Storage and disposal information

Phibo® dental implants should be stored at a temperature between +10 and +40°C in a dry, clean place, protected from adverse conditions.
Dental implants 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

Patients must be provided with an implant card along with the label or labels for the implant or implants for their personal record.
It is important that patients receive comprehensive details concerning contraindications, warnings, precautions and adverse effects associated with Phibo® dental implants.

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 Surgical and 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 implants will be available on the European database for medical devices, Eudamed at 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 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.
	For single use only.
	Do not resterilize.
	Expiration date.
	Unique Device Identifier.
	Medical Device.
	Consult electronic instructions for use.
	Double sterile barrier system. Sterilized using irradiation.
	Temperature limit (Upper limit of 40ºC, lower limit of 10ºC).