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Prosthodontic components and instruments

Reference: PROSPDEFEXP0123
Revision: Rev.14 (11/2023)

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

SYMBOL	LEGEND
	Phibo Dental Solutions, S.L. P.I. Mas d' en Cisa | Gato Pérez 3-9 | 08181 | Sentmenat | Barcelona | Spain
	Lot number.
	Date of manufacture.
	Order number / reference number.
	CE 0123 represents certification by TÜV SÜD.
	Caution.
	Non sterile.
	Consult instructions.
	Unique Device Identifier.
	Medical Device.
	Contains hazardous substances.
CAS	Chemical Abstract Service The CAS number is an international identification standard for chemical substances. CAS: 7440-48-4
	Temperature limit.
	For single use only.

PHIBO® PROSTHODONTIC COMPONENTS AND INSTRUMENTS.

This document contains information for the use of prosthodontic components and instruments of Phibo®dental implant systems: TSA, TSH® and Aurea® Evo®.

Phibo® dental implant system products should only be used by properly trained professionals. For detailed information on product specifications, consult the corresponding surgical and prosthodontic procedure.

LIABILITY AND WARRANTY INFORMATION

The user must ensure that the product used is suitable for its intended purpose, in particular for procedures not explicitly recommended. Nor are these Instructions for use or procedures relieve the user of this obligation.

Phibo® dental implant system products should only be used with original components and instruments, in accordance with the relevant instructions and recommendations.

The use of non-original Phibo® products, components or instruments that come into contact with those referenced in the Phibo® catalog and procedures, will automatically void any warranty of the products manufactured by Phibo Dental Solutions, S.L.

The professional responsible for the clinical treatment must ensure the use of original components throughout the clinical and laboratory process. To claim any type of warranty, the clinician responsible for the treatment and patient, must provide the information required by Phibo® for this purpose.

1. DESCRIPTION

Phibo® instruments are made of stainless steel, tungsten carbide and titanium. Surgical drills are designed to withstand ten uses. Inadequate maintenance or lack of cleaning and disinfection can reduce the number of uses, in addition to causing treatment failure.

All instruments are color-coded or laser-marked for easy identification and proper use. Using instruments of other commercial brands, entails losing any type of warranty on the implants and other products.

Phibo® prosthodontic components are made of titanium and biocompatible plastic material. Some Phibo® abutments and screws are color-coded for easy identification and proper use depending on each implant series.

2. INDICATIONS

Phibo® instruments are designed to support the planning of treatment, preparation of the bone bed and insertion of Phibo® dental implants in the patient's maxilla or jaw. The instruments collect some screwdrivers / conveyors of prosthodontic components according to product catalog.

Phibo® abutments are attached to Phibo® dental implants to support the prosthesis. Prostheses can be unitary, partial or total, and be screwed or cemented to the abutment, or be removable.

Provisional plastic prosthodontic components are designed to support provisional restorations for a period of time not exceeding 60 days. These products should be used with the appropriate Phibo® dental implants and abutments, according to the corresponding surgical and prosthodontic procedure.

It is necessary to plan an implant treatment, once the clinical, radiological diagnosis and study models have been made, always starting from the type of prosthodontic rehabilitation that the patient needs and that ensures the success of the treatment and their expectations.

3. CONTRAINDICATIONS

It is necessary to perform a preoperative medical examination of the patient to determine any risk factors, in the intervention, implant insertion, or during treatment. Dental implants should not be used in patients who lack the necessary medical conditions for implant treatment and rehabilitation. The clinical manager should evaluate the potential benefits and risks of treatment for patients with localized or systemic factors that may affect the healing process of bone or soft tissue.

RELATIVE: age, stress, tobacco, pregnancy, bone deficiency, alcoholism, drug use, lack of oral hygiene, periodontal pathologies, addictions in general.

ABSOLUTE: Endocrine, (decompensated diabetes mellitus, hyperparathyroidism), blood dyscrasia that contraindicate execution of surgical treatments, cardiovascular and/or terminal pathologies, infectious diseases, treatments with radiotherapy, corticotherapy and anticoagulants, epilepsy, and psychological factors.

4. STORAGE AND HANDLING

Phibo products should be stored at a temperature between +10 and +40ºC in a dry, clean place protected from adverse conditions.

5. WARNING

Treatment planning and placement of dental implants require specific dental training. It is recommended that clinical users take courses with practical training to learn appropriate

techniques, including biomechanical requirements and radiographic requirements associated with treatment. Before placing Phibo® dental implants or their prosthodontic components it is necessary to be familiar with the corresponding surgical and prosthodontic procedures.
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. 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.
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. Microdesign & Macrodesign.

The procedure for using drills, bone taps and other instruments necessary for the placement of the implant are detailed in the corresponding surgical procedures. The implant placement and prosthodontic planning must be adapted to the individual conditions of the patient, especially the correct distribution of forces. Passive fit should be achieved in prosthodontic rehabilitation, as well as occlusal adjustment to the opposite jaw, 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, abutment, or screws of the abutment due to overload or fatigue and substantial loss of surrounding bone.
The lack of adequate quantity and quality of residual 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 lack of bone or soft tissue can produce an unfavorable insertion of the implant and a poor aesthetic result. Inadequate prosthodontic rehabilitation can lead to rehabilitation failure.

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.

6. DISINFECTION AND STERILIZATION

Phibo® prosthodontic components and instruments are supplied unsterilized. Do not use products with damaged or previously opened packaging.

Prosthodontic components and instruments for use in the mouth, must be cleaned, disinfected, and sterilized prior to use, according to the process described in the document "Cleaning, disinfection and sterilization of prosthodontic components and instruments" PROSPLD.

It is also necessary to clean, disinfect and sterilize reusable instruments and components after use.

7. PRECAUTIONS

SURGERY

Surgical procedures describe in detail the precautions to be taken during treatment.
Due to the size of the products, special attention must be paid, so that these are not ingested or swallowed by the patient. The design of Phibo® instruments for manual use, incorporates retention elements for use with dental floss or tape, to avoid accidental ingestion.
Every effort should be made to minimize damage to host tissue, paying particular attention to thermal and surgical trauma and the removal of contaminants and sources of infection.
The preparation of the bone bed requires the use of specific cutting instruments, with constant and intense irrigation, completing the surgical sequence detailed in corresponding surgical procedure at the speeds recommended there.
Otherwise, excessive torques may occur at implant insertion. An insertion torque equal to or greater than indicated can cause significant damage to the implant, in its connection, cold welding with the implant holder, and fracture / necrosis of the bone bed.
It is important to regulate both the contra-angle handpiece in the case of mechanical insertion, and the torque ratchet in manual insertion to the torque indicated in the corresponding surgical procedure of the Phibo implant systems. Inserting the implant and exceeding the indicated force will be sufficient indication to perform the complete surgical sequence defined in the surgical procedure again, and not partially.

PROSTHODONTIC REHABILITATION

Prosthodontic procedures describe in detail the precautions to be taken during treatment. The design of the type of rehabilitation and prosthesis must be done before the insertion of the implants.

8. ADVERSE EFFECTS

The adverse effects of dental implants, prostheses, and instruments include a range of complications that can arise from the implantation procedure, the properties of the implants themselves, and factors related to their handling and storage:

- Post-operative discomfort and inflammation: This is common and can include pain,

swelling, and bruising around the implant site.

- Local or systemic infections: Infections can occur due to non-sterile conditions during surgery, poor oral hygiene, or compromised immune systems. Additionally, infections may be linked to handling, cleaning processes, or non-aseptic techniques.
- Speech difficulties: This can occur if the implant affects the natural movement or positioning of the tongue and lips.
- Bone loss and fractures: Over-application of force during implant insertion or undue pressure from superstructures can cause bone fractures and loss. This can be exacerbated in cases of uncontrolled bone fractures or if the implants and their connections are subjected to disproportionate mechanical forces.
- Loss of implant: Causes include improper placement, bone loss, body rejection, or the use of implants with inappropriate dimensions, which could be due to errors in labeling or product specifications.
- Damage to adjacent teeth: Incorrect implant placement can harm neighboring teeth.
- Fracture of implants and prosthodontic components: Excessive force or manufacturing defects can lead to fractures in the implants or their components.
- Dental nerve damage: This can result in numbness, pain, or a tingling sensation in the teeth, gums, lips, or chin.

Errors in design, manufacturing, labeling, or generation of product specifications can lead to the use of inappropriate implants, potentially compromising patient health and leading to rehabilitation failure. Inadequate training or inexperience of the professional can lead to misuse of the product, possibly causing injuries, tissue damage, or complete failure of the surgical phase. Using implants that are in poor condition due to design errors, inadequate transport, or improper storage can result in serious mechanical breakage or deterioration, increasing the risk of implant failure and infection.

9. CONTAINS HAZARDOUS SUBSTANCES

Devices marked with a CAS number (CAS: 7440-48-4) contain more than 0.1% weight percent of cobalt. As a CMR substance of class IB, cobalt is classed as possibly carcinogenic, mutagenic and/or toxic to reproduction. Evidence has shown that the quantities of cobalt released by medical devices are so low that they do not pose a risk and no precautions have to be taken, provided that the medical device is used correctly and according to its intended purpose.