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Prosthodontic components and instruments

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SYMBOL	LEGEND
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	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 Phibo®'s prosthodontic components and instruments.

For detailed information on product specifications, consult the corresponding surgical and prosthodontic procedure: (PROCEPORSEVO, PROCEPROSTSA, PROCEPROSTSH, PROCEQUIREVO, PROCEQUIRTSA, PROCEQUIRTSH).

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. Some Phibo® abutments and screws are color-coded for easy identification and proper use depending on each implant series.

2. INTENDED TARGET POPULATION AND INTENDED USER

The recipient patients of the dental implants manufactured by Phibo® the company are people who present partial or total edentulism and require the replacement of teeth. The use of dental implants in children or in patients who have not completed the mandibular growth phase is not recommended. There is no known limitation of a maximum age in patients who require treatment with dental implants, if they have good health conditions.

Phibo® dental implant system products should only be used by properly trained professionals. The users are professionals in Odontostomatology, qualified according to the requirements and regulations in force of the sector and the professional associations in the dental implant sector and who have received the pertinent training, being able to be dentists, implantologists, and maxillofacial surgeons.

3. INTENDED USE AND INDICATIONS FOR USE

Phibo® instruments are designed to support the planning of treatment, preparation of the bone bed and insertion of Phibo® dental implants. Phibo® instrument products are intended to be used in patients undergoing restorative treatment using dental implants. In these situations, a restoration can be achieved through several treatment options that incorporate the Phibo® instrument products. The instruments collect some screwdrivers / conveyors of prosthodontic components according to product catalog.

Phibo® prosthetic components are attached to dental implants to support the prosthesis in order to restore the functions of chewing, aesthetics and phonation. Prostheses can be unitary, partial or total, and be screwed or cemented to the abutment, or be removable.

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.

Description and purpose of the different product families is described below.

Phibo® instruments:

Dental drills:

Phibo® Surgery Drills (Surgery Drill and Drill Stoppers) for use in combination with Phibo® dental implants. Precision drills, Pilot drill, surgery drills, countersink drill, round marking bur, and bone tap are made of stainless steel. The drill stoppers are made of stainless steel.

Phibo® Surgery Drills are indicated for the preparation and creation of an implant alveolus in the patient's bone support where the implant will be inserted. The realization of the implant alveolus will be carried out by means of the sequential passage of drills of different diameter.

Phibo® Surgery Drills are composed of:

- Precision Drills:
  They are instruments made of stainless steel with a pyramid-shaped tip. They are intended to serve as a surgical instrument for performing the initial drilling of the bone bed where the implant will be placed.
- Pilot Drills & Surgical Drills:
  They are instruments made of stainless steel formed by a cylindrical body with helical milled along the surface. They are intended to serve as a surgical instrument for the development of the bone bed where the implant will be placed.
- Pilot Drill and Intermediate Surgical Drills with Stoppers:
  They are instruments made of stainless steel formed by a cylindrical body with helical milled along the surface. They can be connected to a height stopper. Stopper allows to perform a bone bed with a precise height.
- Countersink Drill:
  They are instruments made of stainless steel, intended to reproduce the geometry of the implant head in the bone. Its geometry is different from the rest of drills described above, the design of its tip is tapered and has a milling to give a shearing effect.
- Round Marking Bur:
  They are instruments made of stainless steel and tungsten carbide. This drill is used for the preparation of the patient's bone support in those cases in which narrow ridges are present where the operation for the preparation of the implant alveolus is difficult due to lack of space.

Drill stop:

The purpose of Drill Stop is to serve as a mechanical element to facilitate adjustment of the drilling depth of the bone. Drill stops are made of stainless steel with laser marks that indicate either the diameter or the length of the corresponding drill.

Other instruments:

Bone Tap:

The Bone Taps are intended to serve as a surgical instrument for the creation of the thread profile in the bone bed before fixation of the implants. These can be manual, with ratchet connection, or mechanical, with contra-angle connection. They are made of stainless steel.

Contra-Angle Tap:

It is a bone tap which is hold and used with the contra-angle.(The contra-angle is the part of the hand piece of the implant motor, which is used to hold the drills and make them work in order to create the bone hole or bed for the implant placement.) It is made of stainless steel.

Contra-Angle Adapter:

They are intermediate connecting and transmitting torque elements between the counter-angle and the implant holder or any other element to be operated at twisting, with the requirement that the element provided a 3.5mm hexagonal connection in E/C. The hexagon is combined with a rubber seal to retain elements with friction.

The mechanical adapters with counter-angle connection, are made of stainless steel.

Contra-Angle Hex Driver:

It is a driver which is fastened and used with the contra-angle. The hex driver has the function of holding and allowing the implant holder from its container to the insertion point in the patient's oral cavity and its insertion into the implant alveolus that will have been created previously. The contra-angle holds and moves the different drivers to do its function. It is made of stainless steel.

Circular Scalpel:

The purpose of the Circular Scalpel is to create a circular clear cut without tearing the oral mucosa, and to preserve the gingival tissues. It is made of stainless steel.

Drill Extender:

The purpose of the Drill Extender is to allow an 18 mm increase in the initial length of the drills, through its connection to the counter-angle. This facilitates drilling in areas with limited space. It is made of stainless steel.

Phibo® prosthodontic components:

Abutments and freasable abutments:

This prosthetic component serves as an intermediate structural element between the implant and the final prosthesis. It is indicated for reconstructions with immediate aesthetics and immediate loading. It is used for screw-retained prosthetic reconstructions (crowns, bridges, and removable bars).

Conhex abutments, abutment posts, ProUnic abutments and transgingival abutments are designed for screw-retained restorations in cases with high disparallelisms between implants. They are made of Titanium grade 5.

Angled abutments and freasable angled abutments:

The purpose of the Angled Abutments is to serve as an intermediate structural element between the implant and the definitive prosthesis. The Aurea Evo Angled Abutment is indicated for screw-retained prosthetic reconstructions and allows correcting an extreme angular position of the implant in relation to natural pieces or adjacent implants. TSH and TSA freasable angled abutments allow an angulation of 15º or 25º (two variants). All the Aurea Evo angled abutments

allow an angulation of 17° or 30°. They are made of Titanium grade 5.

Click&Fix abutments and accessories:

The function of the CLICK & FIX® Abutments is to serve as an intermediate structural element between the implant or bar and the definitive prosthesis. CLICK & FIX® Abutments will be used for removable multiple prosthetic reconstructions for PHIBO® implant. They are made of Titanium grade 5. For more information, consult document IFUCLICK.

Temporary abutments:

The purpose of the Temporary Abutment is to serve as a base for the realization of an immediate esthetic reconstruction using acrylic or liner relining machined from polycarbonate. This reconstruction will have a definitive clinical screw as a retentive element. They are made of Titanium grade 5.

Healing abutments:

This prosthetic component provides mucosal protection after surgery to allow their healing and the formation of a mucosal route or mucosal tunnel connection to the secondary structure implant or prosthesis. Healing Abutments are compatible with TSA, TSH and Aurea Evo Implants. They are made of Titanium grade 5.

Ball abutments:

Ball abutments are mechanized attachment that, once are fixed to the implant, serve as a retaining element of the constructed removable prothesis, which incorporates the caps that are fixed in its portion higher. They are made of Titanium grade 5.

Healing caps:

These are products are connected to the top of the conical area of the abutment and resting on the shoulder of the implant inside the oral cavity. This prevents the gingival tissue covering prosthetic connection during implant osseous-integration and it protects the abutment during that period. They are made of Titanium grade 5.

Temporary caps:

The purpose of the Temporary Cap on is to serve as a base for the performance of an immediate esthetic reconstruction. They are made of Titanium grade 5.

Ti Bases:

The purpose of the Ti Bases is to serve as an intermediate structural element between the implant or the transepithelial abutment and the definitive prosthesis. Ti Bases are the basis of prosthetic reconstructions through manufacturing in CAD CAM technology. They are made of

Titanium grade 5.

Screws:

The main function of the screws is to be used as the retentive element between the crown and the abutment placed on a dental implant.

Screws are made of Titanium grade 5, some of them are anodized in the colour of the series. Tightening torque is indicated in the prosthodontic procedure.

4. 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.

5. STORAGE AND HANDLING

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

6. 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.

7. 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.

8. 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.

Phibo® Surgery Drills are reusable products. Before reuse they must be cleaned and sterilized. It is recommended to ensure that the Phibo® Surgery Drills used is suitable for the drilling sequence of the implant being placed. Phibo® Surgery Drills are subject to wear and tear due to their use, being the responsibility of the user the periodic renewal of these products. Phibo advises to check the cutting status of surgical drills before proceeding to use and recommends their replacement after 10 uses.

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.

9. 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.

10. 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.