ENGLISH - EN

Dental Instruments Class I

Reference: IFU-00005 Dental Instruments Class I

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IMPORTANT INFORMATION.

READ THIS DOCUMENT CAREFULLY BEFORE USING THE PRODUCT.

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Index

1. Product description

Class I Dental instruments (hereafter; dental instruments) include oral cavity invasive instruments, designed for assembling, adjusting, or removing dental implants, attachments, and prothesis. These instruments are critical in ensuring the secure placement of implants and other prosthetic devices.

These instruments are made from high-quality materials to ensure safety, reliability, and compatibility with sterilization processes.

GROUP	SUBGROUP	MATERIAL
Adapters	Manual Adapters	Titanium Grade 5
Screwdrivers	Manual Screwdriver	Stainless Steel AISI 440 C
		Stainless Steel AISI 420 C
		Titanium Grade 5
Implant Taps	Manual Tap	Stainless Steel 1.4104
Wrenches	Torque Wrench	Stainless Steel 1.4112
	Open end Wrench	Titanium Grade 5
Extraction Kit	Extraction Kit	Stainless Steel 1.4057
		Stainless Steel 1.4598
Depth Indicator	Depth Indicator	Titanium Grade 5
Surgical Boxes	Surgical Boxes	Polyphenylsulfone (PPSU)
		Stainless Steel AISI 316
		Silicone

Table 1 - Materials of Phibo® dental instruments.

Some instruments also come with an EPDM O-ring for tool fixation purposes.

2. Intended use

Dental instruments are intended to support surgical and prosthodontic procedures in implantology and restorative dentistry. They are designed to assist with various tasks, including bone preparation, tissue management, and the assembly of components.

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

Phibo® dental instruments' indications for use are described in the table below.

GROUP	GROUP INDICATION
Adapters	They are intermediate connecting and transmitting torque elements between the torque wrench and the implant holder or any other element to be operated at twisting.
Screwdrivers	The purpose of the manual screwdriver is to manually tighten the screw in Phibo attachments, with varying connections. The purpose of the Phibo Manual Handle is to serve as a connecting instrument with the adapter and the Phibo Screwdriver Bits.
Implant Taps	These references have been designed to assist in the removal of the screws or screw fragments from Phibo implants. They are used in connection with the contra-angle part or with a handle for manual use.
Wrenches	Wrenches are tools that allows the transmission of insertion and tightening forces, intended for screwing and unscrewing screws, prosthetic elements and implants.
Extraction Kit	Extraction Kit is intended to assist in the removal of distorted screws and implants without direct tissue contact. The success of the intended purpose is conditioned by the operating procedure followed by the professional, as well as the initial conditions of the screw to be removed.
Depth Indicator	The purpose of the gauges is to give the user an indication of the orientation and depth of the milling operation. For this purpose, the parallelisers or gauges are inserted into the milling operations already carried out and the orientation and depth achieved are checked. They can be left in the millings already made to serve as a guide for subsequent millings.
Surgical Boxes	The surgical boxes are intended to facilitate the location of the instruments necessary for the surgical procedure, to ensure perfect organization, accessibility and handling of these instruments, as well as protection during transfer to the surgical field after disinfection and sterilization of all instruments.

Table 2 - Indications for the use of Phibo® dental instruments.

5. Intended user and patient target group

Phibo® dental instruments 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 with the Phibo® implant systems. 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 instruments are intended to be used as tools for placement of dental implants and prosthesis, 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 and can be performed in patients of all ages, in situations of loss, damage, defect, disease or deterioration of single tooth, multiple teeth, or full denture.

Phibo® dental instruments can be used in patients of several ages that will undergo 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 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

Do not use products with damaged or previously opened packaging.

Phibo® dental instruments are supplied unsterilized. They must be cleaned, disinfected, and sterilized prior to use according to procedure PRO-00007 Cleaning, disinfection and sterilization.

The reuse of dental instruments that have not been correctly reprocessed 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.

Due to the size of some products, special attention must be paid, so that they are not accidentally ingested / swallowed by the patient. The design of Phibo® surgical instruments for manual use incorporates retention elements for use with dental floss or tape, to avoid accidental ingestion.

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.

It is important to regulate both the contra-angle handpiece, in the case of mechanical insertion, or the manual wrench, to the torque indicated in the corresponding surgical and prosthodontic procedure of the Phibo® implant system. A torque greater than indicated can cause significant damage to the tissue, implant, attachments or the final prosthesis.

8. Precautions

The person responsible for the dental 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.

Maintain aseptic technique while handling the instruments and throughout the entire surgical procedure. Surgical procedures describe in detail the precautions to be taken during treatment.

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:

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

10. Sterilization and reuse

Dental instruments are supplied unsterilized and must be cleaned, disinfected and sterilized prior to their first use. They are reusable devices and can undergo reprocessing, which means they must be cleaned, disinfected and sterilized after each surgical intervention. These indications are supplied in procedure **PRO-00007 Cleaning, disinfection and sterilization.**

11. Important before using Phibo

The correct use of the Phibo® dental instruments are beyond the manufacturer's control. The user is responsible for any damage that may be caused by the misuse of the dental instruments, releasing Phibo Dental Solutions, S.L. from liability for damages or losses resulting from improper handling or misuse.

Phibo® documentation is periodically renewed according to the state of science and technology, please 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 devices' label to confirm that it matches the instrument selected. Open the blister / pouch / package carefully, following the instructions on the package and placing it on a clean field.

Cleaning, disinfection and sterilization

Phibo® dental instruments 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.

Disinfection must be performed by immersing the instruments 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, 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. There is also the option to sterilize the instruments needed for surgery inside the surgical box used for storage. For this case, place the disinfected items in the surgical boxes' tray, and insert the filled surgical box in a sterilization pouch.

For further details regarding the procedure for cleaning, disinfection, and sterilization of Phibo® dental instruments, please consult the corresponding Cleaning, disinfection and sterilization procedure (**PRO-00007**).

Use

- **Adapters**

Ensure that all components (adapter, torque wrench, and implant holder or any other part to be operated at twisting) are cleaned and sterilized as per standard protocols. Attach the adapter securely to the torque wrench by aligning the connecting parts. Ensure a proper fit to prevent any movement during torque application.
Insert the opposite end of the adapter into the implant holder or any component that requires torque.
Apply the necessary torque using the torque wrench while holding the adapter securely in place.
Follow the recommended torque values specific to the implant or component being tightened.
Once the torque has been applied, remove the adapter by disengaging it from the torque wrench and implant holder.

- **Screwdrivers**

Select the appropriate screwdriver based on the type of screw or connection being used.
For screwdriver bits, attach the selected bit to the wrench or the manual handle of the Phibo® screwdriver.
Insert the screwdriver bit into the head of the screw. Ensure the bit fits securely to prevent slipping during manual tightening.
Hold the wrench or the manual handle firmly and rotate it to tighten the screw into the Phibo® attachment. Tighten the screw as required, but do not over-torque to avoid damaging the screw or the component.
Once the screw is tightened, remove the screwdriver by gently pulling it from the screw head.

- **Implant Taps**

Ensure the appropriate implant tap size is selected for the screw or fragment removal.
Attach the implant tap to a contra-angle or manual handle.
Insert the tap into the implant or over the screw fragment and rotate the implant tap to engage with the screw or fragment. Apply steady force to unscrew the fragment from the implant.
Once the screw or fragment is disengaged, carefully remove it from the site using forceps.

- **Wrench**

Select the correct wrench for the selected part (Torque wrench or Open-end wrench). For torque wrench, select the desired torque force to be applied for the screw or component to be tightened/unscrewed.
Fit the wrench securely onto the head of the screw or prosthetic element.
Apply the required force to either tighten or unscrew the component.
If using for insertion, apply steady pressure while rotating the wrench.
Remove the wrench once the desired torque is applied.

- **Extraction Kit**

Select the necessary tools from the extraction kit based on the screw or implant condition.
Position the extraction tool around the distorted screw or implant.
Use the designated tools in the kit to carefully loosen and remove the screw or implant.
Avoid contact with surrounding tissues.
Inspect the site for any remaining fragments and clean accordingly.

- **Depth Indicator**

Select the appropriate depth indicator or parallelizer.
Insert the depth indicator into the previously milled cavity.
Ensure the parallelizer is properly aligned with the milling operation to check the depth and orientation and assess the depth and orientation based on the indicator's position. Use the indicator as a guide for subsequent milling procedures.
Remove the depth indicator once the orientation and depth have been verified.

- **Surgical Boxes**

Organize the surgical instruments inside the box according to the procedural requirements.
Ensure that the instruments are cleaned and disinfected prior to placement in the box.
During the procedure, use the surgical box to easily locate and access the required instruments.
Maintain the sterile condition of the instruments while in the surgical field.
After the procedure, clean and disinfect the instruments accordingly, then return the instruments to the surgical box for sterilization. Ensure the box remains in good condition for instrument protection.
For instrumental use during the surgical procedures, consult the following documents:

- **PRO-00001 Surgical Procedure TSA.**
- **PRO-00003 Surgical Procedure TSH.**
- **PRO-00005 Surgical Procedure Aurea Evo.**

13. Storage and disposal information

Phibo® dental instruments 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® dental instruments.

15. Incident reporting information

Any incident related with Phibo® products should be immediately reported to Phibo®. For detailed instructions, please access your account on 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 competent local 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.