ENGLISH - EN

Dental Instruments Class IIa

Reference: IFU-00003 Dental Instruments Class IIa

Version: 02

CE 0123

IMPORTANT INFORMATION.

READ THIS DOCUMENT CAREFULLY BEFORE USING THE PRODUCT.

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1. Product description

Class IIa Dental instruments (hereafter; dental instruments) include oral cavity invasive instruments such as **drills**, **circular scalpels and bone taps**, specifically designed for tissue manipulation during surgical procedures. These tools are intended for precise cutting, drilling, and shaping of bone or tissue, ensuring accuracy and minimizing damage to surrounding areas. This group also comprises supporting instruments like **adapters, screwdrivers, implant taps** and **drill accessories** which are not directly involved in tissue manipulation but play a crucial role in dental restoration.

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

GROUP	SUBGROUP	MATERIAL
Adapters	Mechanical Adapter	Stainless Steel AISI 420 C
Screwdrivers	Mechanical Screwdriver	Stainless Steel AISI 440C
Bone Taps	Mechanical Bone Tap	Stainless Steel 1.4305
		Stainless Steel AISI 420C
Implant Taps	Mechanical Taps	Stainless Steel 1.4197
Circular Scalpels	Circular Scalpel	Stainless Steel 1.4197
Drills	Precision Drill	Stainless Steel 1.4034
	Pilot Drill	Stainless Steel 1.4197
	Surgical Drill	Stainless Steel 1.4197
	Countersink Drill	Stainless Steel 1.4197
Drill Accessories	Drill Stop	Stainless Steel 1.4305
		Drills Stops: Stainless Steel AISI 420C Drill stop screw: Titanium G5
	Drill Extender	Stainless Steel 1.4197

Table 1 - Materials of Phibo® dental instruments.

Some surgical 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, according to their design features, have specific indications for use. These are described in the table below:

GROUP	GROUP INDICATION
Adapters	They are intermediate connecting and transmitting torque elements between counter-angle and the implant holder or any other element to be operated at twisting.
Screwdrivers	The purpose of the screwdriver is, by means of the contra-angle motor, to tighten the screw in Phibo® attachments, with varying connections.
Bone Taps	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 an adapter, or mechanical with contra-angle connection.
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.
Circular Scalpels	Enables a precise and cylindrical cut without tearing the oral mucosae, and thus preserve the gingival tissues, for the subsequent insertion of the implant. It can be used in both mandible and maxilla. It is supplied in different diameters to adapt to the series of implants that will be placed.
Drills	Drills are intended to serve as a surgical instruments for performing the drilling of the bone bed where the implant will be placed.
Drill Accessories	Drill Accessories are tools designed to facilitate the drilling procedure of the bone bed, where the implant will be placed.

Table 2 - Indications for use of Phibo® surgical 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.

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 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 surgical interventions 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.

Cutting instruments are subject to wear and tear due to their use, being the responsibility of the end user to periodically replace these instruments. Phibo® advises to check the cutting status of these instruments before proceeding to use them **and recommends their replacement after a maximum of 10 uses**. If the instruments present signs of damage, wear or tear before reaching 10 uses, they must be replaced.

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.

Before initiating surgery, it is recommended to ensure that the selected Phibo® drills are suitable for the drilling sequence of the implant that is being placed. 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 the corresponding surgical procedure at the speeds and torque recommended.

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

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.

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. They 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 dental instruments

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 for surgery. 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**

Select the appropriate adapter that matches the size and connection type of the contra-angle and the component.
Attach one end of the adapter to the contra-angle and the other end to the implant or component. Ensure both ends are securely fitted to prevent slippage.
Use the contra-angle to apply the necessary force through the adapter to the connected component. Follow the specified torque values for the component in use.
After applying the torque, disengage the adapter from both the torque wrench and the connected component.

- **Screwdrivers**

Select the appropriate screwdriver bit that matches the screw or attachment to be used..
Insert the screwdriver bit into the manual handle or the mechanical handle (e.g., a contra-angle).
Place the screwdriver bit into the head of the screw, ensuring a firm and secure fit to avoid stripping or damaging the screw head.

Tighten the screw to the desired level. Avoid overtightening to prevent damage to the implant or prosthetic component.
Once the screw is tightened, carefully remove the screwdriver by pulling it away from the screw head.

- **Bone Taps**

Choose the correct bone tap size based on the diameter of the implant to be placed.
Attach the bone tap to a manual handle or powered surgical instrument (e.g., a contra-angle) ensuring a firm and secure fit.
Insert the bone tap into the pre-drilled osteotomy site. Slowly rotate the bone tap, either manually or with powered assistance, to cut the threads into the bone. Maintain steady pressure to ensure accurate threading.
After threading is complete, remove the bone tap from the osteotomy site.

- **Implant Taps**

Select the appropriate implant tap size based on the implant or screw fragment.
Connect the implant tap to a manual handle or a contra-angle for powered use, ensuring a firm and secure fit.
Insert the implant tap into the implant or around the screw fragment.
Rotate the tap to engage the screw fragment or implant and extract it.
Once the screw or implant has been removed, inspect the site for any remaining fragments.

- **Circular Scalpels**

Confirm the required size for the incision. Position the circular blade over the site of the intended incision.
Press gently and rotate the scalpel in a circular motion to create the desired incision.
After the incision, remove the circular scalpel and assess the incision for any adjustments.

- **Drills**

Prepare and select the correct drill(s) according to the surgical plan.
Attach the drill to the surgical motor (contra-angle) firmly.

- **Precision Drill**

Use the Precision Drill to make the initial perforation of the bone at the designated implant site.
Ensure the drill is aligned correctly with the implant's planned placement.
Begin drilling at a slow speed to create the initial hole, ensuring proper alignment.
Gradually increase speed as necessary, while irrigating the area with sterile saline to prevent overheating.
Drill to the recommended depth, ensuring stability before switching to the next drill in the sequence.

- **Pilot Drill**

Insert the Pilot Drill into the initial bone perforation created by the Precision Drill.
Carefully guide the drill, maintaining the correct trajectory and expand the hole to the necessary width, maintaining control and precision to avoid damaging surrounding bone tissue.

- **Surgical Drill**

Connect the Surgical Drill to the drill stop if necessary, setting it to the required depth.
Proceed to drill into the bone bed, ensuring alignment and depth consistency as per the implant protocol.

Monitor the drilling process to ensure the desired bone bed dimensions are achieved.

- **Countersink Drill**

Use the Countersink Drill after the bone bed has been fully prepared by the previous drills.

Align the drill with the prepared bone bed and proceed to contour the site, creating the necessary taper for the implant head.

Ensure that the drill's shearing effect creates a smooth, congruent surface for optimal implant seating.

Remove the drill and inspect the osteotomy for any bone debris.

φ **Drill Accessories**

Select the appropriate drill accessory (e.g., stopper, extender) based on the procedure's requirements.

Attach the accessory to the drill or drill bit as necessary.

Ensure a secure fit to avoid movement during drilling.

Use the accessory as an aid to control drilling depth or alignment.

Once the drilling is complete, remove the accessory from the drill.

For more detail regarding 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 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 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. Contains Hazardous Substances

Some drills and dill accessories could contain more than 0.1% weight percent of cobalt. As a CMR substance of class IB, cobalt is classified 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 must be taken, provided that the medical device is used correctly and according to its intended purpose.

20. 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.
	Expiration date
 CAS: 7440-48-4	Contains hazardous substances. The CAS (Chemical Abstract Service) number is an international identification standard for chemical substances.