**ENGLISH - EN**

# Aurea® Evo Surgical Procedure

Reference: PROCERQUIREVO
Revision: Rev.05 (05/2023)

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| SYMBOL | LEGEND |
|---|---|
|  | Phibo Dental Solutions, S.L.<br>P.I. Mas d'en Cisa \| Gato Perez 3-9 \| 08181 \| Sentmenat \| Barcelona \| Spain |
|  | Caution! |
|  | This is a medical device intended for use on patients. |
|  | Implants are supplied sterilized. Sterilized by gamma irradiation. The sterile barrier is the outer blister sealed with Tyvek. |
|  | If the packaging is damaged or has been opened accidentally, the sterility of the implants that are supplied sterilized may be compromised. Do not use the product and immediately inform the manufacturer at the email address garantiacalidad@phibo.com. |
|  | The reuse and/or reprocessing of disposable products can lead to loss of functionality and/or safety of the product and, potentially, cause problems for the patient. |
|  <br>'Do not re-sterilize' | Re-sterilization of disposable products can lead to loss of functionality and/or safety of the product and cause potential problems for the patient. |
| 'Single patient use' | The use of disposable products for more than one patient can result in loss of functionality and/or safety of the product and, potentially, cause problems for the patient. |
|  | Medical devices must be safely disposed of in approved medical containers for such purposes, and in accordance with the requirements of current local regulations. |
|  | The labeling of the products referred to in these instructions for use includes traceability with UDI encoding/unique identification of the device. |
| 'IFU'<br>  | These instructions for use are electronic and are not attached in paper format. They are intended for health professionals. The instructions can be downloaded from the Downloads section of the manufacturer's website at www.phibo.com. |
|  <br>**0123** | CE 0123 represents certification by TUV SUD. |

The information below is not sufficient for the use of Phibo® dental implants, but the person who manipulates it must have sufficient training and information on the dental implant technique for the use of Phibo® dental implants.

If you are not familiar with the clinical procedure described here, you can contact your advisor in the Phibo® business area and they will provide you with any information and/or training you may require to perform this procedure.

Consult the detailed information in the implant package insert before use. The instructions for use and maintenance of Phibo® products are listed in the documents and procedure manuals for the Phibo® implant system.

## IMPORTANT BEFORE USING PHIBO®

In its innovative and patented design, the Phibo® implant system incorporates advanced technological features, developed only for professionals who understand technology as an advantage and design as a benefit.

Phibo® complies with all the requirements established by European laws and guidelines relating to the manufacture and distribution of medical and health products. The Phibo® implant system is certified and authorized for sale by the corresponding European Notified Body. Phibo Dental Solutions, S.L. complies with the most rigorous international quality regulations for healthcare products, guaranteeing the perfect quality of its products, with the sole objective of constantly increasing customer satisfaction.

The use of other components or products not manufactured by Phibo Dental Solutions, S.L., that come into contact with the originals of the Phibo® implant system manufactured by Phibo Dental Solutions, S.L. according to the original design specifications, may cause serious damage to the patient's health as they are not contemplated for use with those referred to in the documentation provided by the manufacturer. Any use of non-original components or instruments indicated in this procedure, which come into contact with those referred to, will automatically void any type of warranty on the products manufactured by Phibo Dental Solutions, S.L.

The use and application of the Phibo® dental implant system is beyond the manufacturer's control.
The user is responsible for any damages that may be caused by the use of the product, releasing Phibo Dental Solutions, S.L. from liability for damages or losses resulting from improper handling or use.

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.

Phibo® implant system documentation is periodically renewed according to the state of science and technology. Phibo® product users should request product information on a regular basis, in addition to attending regularly established product and technical training courses. The use and placement of Phibo® implants in unsuitable areas and the use of surgical instruments or prosthetic components not listed in this procedure can cause serious damage to the patient's health and total loss of product warranty. The Phibo® implant system is designed for teeth rehabilitation in a single or multiple way, according to the traditional clinical processes listed in this documentation, and cases with insufficient bone for implant placement, clinical risk cases such as sinus lift, fillings, advanced surgical techniques, unsuitable or severe cases of non-parallel implants, among others, are excluded from any warranty.

The Phibo® implant system is distributed internationally in different countries with different technical and health regulations and legislations, and there may be differences in the procedure content from one country to another. Please contact the exclusive Phibo® distributor in your country and request documentation regarding the products and their availability.



Any illustrations that may appear in this document are not made to scale.

## PRODUCT LIFESPAN

The lifespan of implant systems is estimated at 10 years for implantable products, 5 years for permanent attachments and 1 year for temporary attachments. Instruments have an indefinite lifespan depending on their use, except where specifically indicated otherwise, as is the case of surgical drills, with a stipulated maximum number of 10 uses.

## 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 clinical cases with insufficient bone, clinical cases with advanced surgeries, incorporation of biomaterials, sinus lift, bone filling, advanced surgical techniques, non-parallel implants, among others, are exempt from any warranty.

Its use outside the indications for use specified here is excluded from the Product Quality Assurance Plan. Any off-label use, such as placement in a dental area not indicated or the use of attachments

and/or instruments that are not compatible with the product, entails additional foreseeable risks that may result in non-osseointegration or loss of the implant, as well as fractures or unplanned surgical and/or clinical interventions.

## INCIDENT REPORTING

If you detect an incident in a patient, immediately report it to Phibo as the manufacturer by one of the following ways:

Online, by accessing the application with your user ID http://customercenter.phibo.com/

Or by downloading the quality assurance form from the downloads section at www.phibo.com

Print the case form generated in Customer Center or downloaded from the web.

Include the affected product properly disinfected if it has already been used on a patient. If your case involves implants or attachments, also include x-rays with loaded prostheses.

Send the form and product to Phibo at the following address for the attention of the Quality Area: PHIBO DENTAL SOLUTIONS: P.I. Mas d'en Cisa, Gato Pérez 3-9, 08181, Sentmenat, Barcelona.

You can request a pickup from Customer Service by calling +34 937 152 688, if needed. You can also contact us by email: garantiacalidad@phibo.com

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## 01 INTRODUCTION

Avantblast® is the surface of Phibo® implant systems, which advances research into implant surface treatment based on chemical attack.
The Avantblast® surface is obtained through a double chemical attack on pure titanium grade 4, which combines key factors to facilitate the biological response of the implant.
Since 2016, research and development aimed at improving the connection and stress performance during chewing resulted in the hexalobular connection of the Aurea® Evo implant system.

## 02 PURPOSE OF IMPLANTS

The objective of Aurea® Evo implants is to recover function, aesthetics and health by replacing missing teeth in the jaw or maxilla by surgically implanting dental implants in the remaining bone tissue and restoring the different functions through appropriate prostheses.

### IMPLANT DIAMETER

The Aurea® Evo implant system consists of three lines of self-tapping implant platforms made of pure titanium grade 4.

- **AUREA EVO NP IMPLANT**

3.5 mm diameter platform and body, available in several lengths: From 8.5 mm to 14.5 mm, in increments of 1.5 mm.

- **AUREA EVO RP IMPLANTS**

Platforms and bodies of 4.3 mm and 4.8 mm in diameter, available in several lengths: From 8.5 mm to 14.5 mm, in increments of 1.5 mm.

- **AUREA EVO WP IMPLANT**

5.5 mm diameter platform and body, available in several lengths: From 8.5 mm to 13.0 mm, in increments of 1.5 mm.

| *COMMERCIAL REFERENCE* | *PLATFORM DIAMETER* | *LENGTH* |
|---|---|---|
| EVO NP 085 | Ø 3.5 mm | 8.5 mm |
| EVO NP 100 | Ø 3.5 mm | 10.0 mm |
| EVO NP 115 | Ø 3.5 mm | 11.5 mm |
| EVO NP 130 | Ø 3.5 mm | 13.0 mm |
| EVO NP 145 | Ø 3.5 mm | 14.5 mm |
| EVO RP 085 | Ø 4.3 mm | 8.5 mm |
| EVO RP 100 | Ø 4.3 mm | 10.0 mm |
| EVO RP 115 | Ø 4.3 mm | 11.5 mm |
| EVO RP 130 | Ø 4.3 mm | 13.0 mm |
| EVO RP 145 | Ø 4.3 mm | 14.5 mm |
| EVO RP 48085 | Ø 4.8 mm | 8.5 mm |

| | | |
|---|---|---|
| EVO RP 48100 | Ø 4.8 mm | 10.0 mm |
| EVO RP 48115 | Ø 4.8 mm | 11.5 mm |
| EVO RP 48130 | Ø 4.8 mm | 13.0 mm |
| EVO RP 48145 | Ø 4.8 mm | 14.5 mm |
| EVO WP 085 | Ø 5.5 mm | 8.5 mm |
| EVO WP 100 | Ø 5.5 mm | 10.0 mm |
| EVO WP 115 | Ø 5.5 mm | 11.5 mm |
| EVO WP 130 | Ø 5.5 mm | 13.0 mm |

**IMPLANT CONNECTION**

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.
The 1.6 mm retention screw is used for retaining narrow platforms and the 1.8 mm version is used for regular and wide platforms.

**MICRO-COILS**

The implant head includes 2 mm treated micro-coils that reach the crown, which is the point of contact with the bone crest. In implants with a length of 8.5 mm, the height of the micro-coil is 1.8 mm.

**MISMATCHED PLATFORM**

The Aurea ® Evo implant system has platform modification technology between the implant and the connection of the prosthetic abutment, moving the prosthetic space away from the marginal bone.

## 03 INSERTION SPECIFICATIONS

The insertion specifications described in this procedure for each series of Aurea® Evo implants are based on the type of root surface of the tooth that requires replacement and the average size, surface and masticatory loads of the upper crown to be supported.

**INSERTION HEIGHT**

The final insertion of the Aurea® Evo implant must be at the level of the crest, so that the entire surface of Avantblast® is protected by the bone.

**CLINICAL INDICATIONS AND INSERTION AREAS**

- General indications with appropriate width, height and bone qualities.
- Immediate load under optimal conditions where the implants achieve primary stability appropriate for immediate load (≥ 60 ISQ).

- **AUREA EVO NP IMPLANT Ø 3.5 mm**
  - In single and multiple fixed restorations, replacing natural roots and supporting the crown of

lateral incisors in the maxilla and lateral and central incisors in the mandible.

- **AUREA EVO RP IMPLANTS Ø 4.3 mm and Ø 4.8 mm**
  - In single and multiple fixed restorations, replacing natural roots and supporting the crown of central incisors and premolars in the maxilla and canines and premolars in the mandible.

- **AUREA EVO WP IMPLANT Ø 5.5 mm**
  - In single and multiple fixed restoration, replacing natural roots and supporting the crown of molars in both the maxilla and the mandible.

**WARNINGS**

Implant lengths of 8.5 mm or less are not suitable for supporting a single crown for type III or IV bone quality.

Product design and performance and the success of treatment are based on the indications described above. All products that do not meet these indications, clinical cases with insufficient bone, advanced surgery, inclusion of biomaterials, sinus lift, bone filling, advanced surgical techniques, lack of parallelism between implants, etc., will not be covered by any warranty.

**MINIMUM DISTANCE BETWEEN TEETH AND IMPLANTS**

To preserve bone vascularization and the emergence profile, the general recommendation is a minimum distance of 3 mm between two adjacent implants and 1.5 mm between an implant and a tooth.

## 04 TREATMENT PLANNING

The goal of dental implant treatment is to restore the functionality of lost natural teeth.

To achieve the objectives of treatment, treatment planning from prosthodontic rehabilitation is established as a fundamental basis. For this purpose, medical history, clinical and radiological diagnosis, examination, study models, among others, are used according to general rules and protocols applied in implantology.

Phibo® recommends carrying out a three-dimensional study (CT) and the use of surgical splints for the correct positioning of the implants, in all 3 dimensions (apical -coronal, mesiodistal or vestibular -lingual or palatine). The CT scan also allows us to recognize bone quality, an important factor for milling techniques.

The information required to carry out the treatment is:

- Clinical record.
- Personal and family medical history.

- General medical condition.
- Oral medical condition.
- Clinical and radiological examination.
- Anatomical condition record using study models.
- Diagnosis and treatment plan.
- Patient expectations.
- Possible contraindications.

**CONTRAINDICATIONS**

General Factors:
Age, Stress, Tobacco, Pregnancy, Blood Dyscrasia, Psychological Factors, Valve Prosthesis, Terminal pathologies, Lack of oral hygiene, Bone deficiency, Alcoholism, Drug Addiction, Poor medical condition.

Systemic Diseases:
Endocrine, Hematological, Acute or Chronic Infectious Diseases, Osteoporosis, Epilepsy, Maxillary Osteitis, Cardiovascular Radiotherapy Treatments, Corticosteroid Treatments, Anticoagulant Treatments.

**WARNINGS AND PRECAUTIONS**

For insertion into the bone bed, it is necessary to adjust the torque of the contra-angle and of the torque ratchet to a maximum torque of 35N·cm, since exceeding these forces can cause mismatches between implant and prosthesis, as well as increasing the probability of fracture during rehabilitation.

**DIAGNOSIS AND TREATMENT PLAN**

To confirm the initial diagnosis, impressions are made to obtain study models, mounting them on a semi-adjustable articulator using the bite record, which allows a diagnosis of the edentulous areas and the dimensions of available space, patient's occlusion, type of opposing arch of the area to be rehabilitated.

Reconstructive waxing is also performed, establishing the dimensions and design of the future prosthesis. Waxing allows for the preparation of temporary rehabilitation and surgical guides for the position of implants and the prosthodontic rehabilitation needed for their insertion.

Clinical and radiological examination and models are basic tools for defining the type of rehabilitation needed for the patient to recover anatomy, masticatory function and aesthetics. The treatment plan includes rehabilitation planning over time, the type of prosthesis, number of implants needed to support the type of prosthesis, level of position of the prosthesis in relation to the bone crest and soft tissue, among others.

The treatment plan and its planning constitute the fundamental basis for safeguarding biological structures, with the objective of foreseeing the load along the axial axis of the implant, avoiding extension elements, managing transverse loads, managing transverse loads, stability control, occlusion and control of hygiene and parafunctions, stimulating bone anchoring with the incorporation of a number of implants of length and diameter appropriate to the anatomical condition, allowing to counteract the different forces that act at different levels.

## 05 INSTRUMENTS

### SURGICAL BOX

The surgical box comes unsterilized.

The design of the surgical box offers great ergonomics in the surgical and prosthodontic fields. It consists of a base, a tray where the surgical and/or prosthetic instruments are located and a closing cover.

| Commercial reference | Product Description |
|---|---|
| EVO 00001 | Aurea Evo surgical kit |

Prior to prosthodontic surgery or procedure, it is necessary to clean each of the components of the box separately, paying special attention to those areas that are difficult to access.

Detergents used as chemical cleaners alone cannot remove all dirt and/or debris. Therefore, it is essential to manually and carefully clean with a sponge or soft cloth to remove as much of the adhered material as possible after surgery. For hard-to-reach areas, a clean, soft-bristled brush is recommended. Do not use solvents, abrasive cleaners, metal brushes or abrasive pads. The use of a mild neutral pH enzymatic detergent is recommended. In addition, the surgical box can be mechanically cleaned in an ultrasonic cleaner. Check that all components of the surgical box are clean and undamaged before use. Do not insert any instruments other than those indicated for this purpose, to avoid overloading or inadequate entry of water vapor through the holes.

The cleaning, disinfection and sterilization processes as well as the preparation of the surgical field are based on hygiene and patient safety procedures, included in general standards and protocols applied to dentistry.

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.

**SURGICAL DRILLS**

It is important to note that surgical burs are suitable for up to 10 uses.

Their maintenance, proper disinfection and cleaning, without blows, and without deposit of waste favors maintenance and their cutting specifications.

Note that inadequate cleaning and maintenance shortens the use and cutting performance of drills and may cause the failure of implant treatment, in addition to serious damage to the patient's health.

| Commercial Reference | Product Description |
|---|---|
| EVO 23000 | Precision drill |
| EVO 20000 | Pilot drill |
| EVO 31000 | Surgical drill Ø 3.1 mm |
| EVO 34000 | Surgical drillbur Ø 3.4 mm |
| EVO 38000 | Surgical drill Ø 3.8 mm |
| EVO 41000 | Surgical drill Ø 4.1 mm |
| EVO 44000 | Surgical drill Ø 4.4 mm |
| EVO 46000 | Surgical drill Ø 4.6 mm |
| EVO 52052 | Surgical drill Ø 5.2 mm |
| EVO 54000 | Surgical drill Ø 5.4 mm |
| TOP NP 085 | NP 8.5 mm drill stop |
| TOP NP 100 | NP 10.0 mm drill stop |
| TOP NP 115 | NP 11.5 mm drill stop |
| TOP NP 130 | NP 13.0 mm drill stop |
| TOP NP 145 | NP 14.5 mm drill stop |
| TOP RP 085 | RP 8.5 mm drill stop |
| TOP RP 100 | RP 10.0 mm drill stop |
| TOP RP 115 | RP 11.5 mm drill stop |
| TOP RP 130 | RP 13.0 mm drill stop |
| TOP RP 145 | RP 14.5 mm drill stop |
| TOP RPP 085 | RPP 8.5 mm drill stop |
| TOP RPP 100 | RPP 10.0 mm drill stop |
| TOP RPP 115 | RPP 11.5 mm drill stop |
| TOP RPP 130 | RPP 13.0 mm drill stop |
| TOP RPP 145 | RPP 14.5 mm drill stop |

| | |
|---|---|
| TOP WP 085 | WP 8.5 mm drill stop |
| TOP WP 100 | WP 10.0 mm drill stop |
| TOP WP 115 | WP 11.5 mm drill stop |
| TOP WP 130 | WP 13.0 mm drill stop |

Aurea® Evo implant system drills are designed with laser bands and interchangeable stoppers to guide the depth of the bone bed. However, this does not preclude the need for clinical controls using probes or other appropriate materials.

**TORQUE WRENCH**

The Aurea® Evo system wrench controls the torque and the ratchet wrench. The wrench is not sterilized.

| Commercial reference | Product Description |
|---|---|
| 172.0172 | Torque wrench |

The Aurea Evo system ratchet has the dual function of torque control and its own ratchet wrench. The ratchet is provided unsterilized.

It is important to disinfect and clean it before use. In the lower part of the ratchet, the recommended torque for inserting implants or placing and tightening the permanent prosthesis can be adjusted.

The torque is adjusted on the torque wrench. When the torque wrench reaches the required torque, the upper part or head folds down to indicate that the proper force has been achieved.

## 06 SURGICAL FIELD PREPARATION

The preparation of the surgical field as well as the processes of cleaning, disinfection and sterilization of instruments, components and equipment in implantology are based on hygiene and patient safety procedures, included in general standards and protocols applied in dental practices.

Below is a summary of a part of these standard protocols with the specific indications of the Aurea Evo® implant system.

The surgical field must maintain aseptic and sterile conditions prior to and during surgery.

General aspects in the preparation of the surgical field include actions such as:

- Patient clinical record, technical information and patient treatment plan.
- Sterilized Aurea Evo ® implant system instruments.
- Generic instruments, components and equipment sterilized for surgery.
- Surgical table protected by sterile towels.

- Placement of all instruments in an orderly and visible way for use on the surgical table, taking into account the surgical processes.
- Protection of operating room equipment and components with sterile towels.
- Surgical motor with new irrigation hoses.
- Preparing the patient for surgery. Mouthwashes and cleaning and disinfection of the surgical area.
- The staff will be equipped with surgical and specific clothing for this purpose such as surgical gowns, masks, sterile disposable gloves, protective plastic goggles, suitable footwear, among others. In addition, cleaning and disinfection of arms and hands according to standard protocol.

It is important to note that during the surgical procedure, a sterile container with non-saline solution should be used to deposit the instruments used such as surgical burs, scalpel blades, ratchets, adapters, among others, in order to avoid shocks and deposits on the surface of instruments.

## 07 CLEANING, DISINFECTION AND STERILIZATION OF INSTRUMENTS

Cleaning, disinfection and sterilization, as well as the preparation of the surgical field, are based on the hygiene and patient safety procedures included in the regulations and protocols applicable to dentistry. 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.

**IMPORTANT**

Failure to follow the instructions of the manufacturers of the products used in the processes described above can cause serious damage to materials, such as oxidation on instruments, loss of the cutting properties of surgical drills and a reduction in their lifespan. These, in turn, can cause complications in subsequent surgery, for example, excessive heating/necrosis of the bone, and prevent the osseointegration of the implant.

## 08 SURGICAL INSERTION SEQUENCES

**IMPORTANT NOTE, BEFORE INSERTION**

The preparation of the bone bed requires the use of special, sharp instruments, under constant irrigation, completing the specific surgical sequence for the insertion of each implant at the speeds indicated in this surgical procedure.

Failure to do so can cause excessive forces in the insertion of the implant - greater than 35N·cm- exceeding the strength of the bone, causing damage to the implant and its connection, cold welding of the implant with the implant holder, fracture of the implant, bone necrosis and fracture, among others.

The preparation of the bone bed is carried out by means of an initial surgical insertion sequence common to all series and a final surgical sequence specific to each series of implants. During the surgical preparation of the bone bed for the implant, the following must be taken into account:

- Use plenty of external cooling with sterile water solution or NaCl solution, pre-cooled to 5º C.
- Apply gentle, intermittent pressure on the bone.

**INCISION**

The implants can be placed with a mucoperiosteal incision and lifting the flap to obtain a direct view of the bone or without a mucoperiosteal incision using a circular scalpel. The use of a circular scalpel requires keratinized gum tissue, an adequate bone width, and a prior three-dimensional treatment plan to know exactly how much bone is available.

| Commercial reference | Product Description |
|---|---|
| 152.0001 | Circular scalpel Ø3.70 |
| 152.0002 | Circular scalpel Ø4.70 |
| 152.0003 | Circular scalpel Ø6.00 |

Once the incision has been made, the flap has been raised and the bone crest has been exposed, the initial surgical sequence can be started. If the bone crest is narrow, it must be modified to increase the vestibular-lingual or palatine width so that there is sufficient bone margin after the implant is placed. In clinical cases where the diagnosis shows the possibility of surgery without raising the soft tissue flap, the circular scalpel is used to access the bone that will house the implant bed.

**BONE BED PREPARATION**

The Aurea® Evo implant is designed so that the implant shoulder is placed at crest level. The length of the bone bed is prepared with an initial surgical insertion sequence common to all series and a final surgical sequence specific to each series of implants.

The length of the implant is the distance from the largest diameter of the implant shoulder to the implant apex.

After extraction, the position of the implant shoulder will be evaluated based on the surgical guide resulting from the previous diagnostic waxing; the shoulder should be 4 mm from the gingival margin of the future restoration.

To prepare the bone bed for maximum length in all implant diameters, apply minimum pressure at the end of the preparation, increasing the intervals and removing the bur from inside the duct to allow bleeding, reduce local pressure and cool to avoid overheating and possible bone necrosis.

The milling sequence will be conditioned by the type of bone according to the Lekholm classification, so the milling of type I bone will not be the same as that of type IV.

In type IV bone, milling along its entire length is recommended with all the burs except the last one in

the series, which will only be used in the coronal third of the new socket. Thus, the implant acts as a bone compactor, preserving and compressing the bone until it is finally inserted.

The recommended drill bit rotation speeds depending on the diameter are shown in the table below.

| Diameter | Description | rpm |
|---|---|---|
| 2.3 | Precision drill | 850 |
| 2.0 | Pilot drill | 850 |
| 3.1 | NP 3.5 drill | 750 |
| 3.4 | NP 3.5 dense bone drill | 750 |
| 3.8 | RP drill | 650 |
| 4.1 | NP 4.3 dense bone drill | 650 |
| 4.4 | RPP drill | 650 |
| 4.6 | RPP 4.8 dense bone drill | 650 |
| 5.2 | WP 5.5 drill | 650 |
| 5.4 | WP 5.5 dense bone drill | 650 |
| - | Bone Tap | 15 |

**INITIAL SURGICAL SEQUENCE/LANCEOLATE BUR**

The lance bur is recommended in clinical cases where the diagnosis allows for surgery without the need to raise the soft tissue flap.

The initial sequence begins with the lance bur at a speed of 850 rpm, marking and inserting through the bone crest and centering the axis to continue with the osteotomies.

There is no need to go as deep as expected with this Ø 2.3 mm tapered drill in its upper cylindrical area. This bur has two laser marks at 8.5 mm and 13 mm to guide you to the desired depth before measuring.

| Commercial reference | Product Description |
|---|---|
| EVO 23000 | Precision Drill |

**INITIAL SURGICAL SEQUENCE/BUR Ø2.0 mm**

After crossing the bone crest, the initial Ø 2.0 mm helicoidal drill is used at a speed of 850 rpm to penetrate deeper to the planned length, exerting gentle and intermittent pressure to avoid overheating the bone.

| Commercial reference | Product Description |
|---|---|
| EVO 20000 | Pilot drill |

Aurea® Evo system drills are designed with laser bands and click drill to guide the depth of the bone bed. However, this does not exclude the use of clinical controls using probes or other appropriate materials.

| Commercial reference | Product Description |
|---|---|
| TOP NP 085 | NP 8.5 mm drill stop |
| TOP NP 100 | NP 10.0 mm drill stop |
| TOP NP 115 | NP 11.5 mm drill stop |
| TOP NP 130 | NP 13.0 mm drill stop |
| TOP NP 145 | NP 14.5 mm drill stop |

Then, the depth gauge/parallelizer is inserted to check the length of the bur and its parallelizer and make minor corrections in the next osteotomy. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

| Commercial reference | Product Description |
|---|---|
| EVO 00200 | Parallelizer |

**AUREA ® EVO NP 3.5 FINAL SURGICAL SEQUENCE**

After completing the initial surgical sequence for the entire series, start the final osteotomy sequence for the Aurea® Evo NP 3.5 implant. The diameters of the shoulder, body and other specifications of the Aurea® Evo NP 3.5 implant are shown at the beginning of this procedure.

The final osteotomy for the Aurea® Evo NP 3.5 implant is performed with the Ø 3.1 mm tapered apex drill in the upper cylindrical area and at a speed of 750 rpm until the planned length is obtained, exerting gentle and intermittent pressure to avoid overheating the bones.

| Commercial reference | Product Description |
|---|---|
| EVO 31000 | Surgical drill Ø 3.1 mm |

If bone quality is type I or II in the mandible and anterior maxilla area, the bur that should be used for the Aurea® Evo NP 3.5 implant is the Ø 3.5 mm tapered apex drill for dense bone in the upper cylindrical

area and at a speed of 750 rpm.

| Commercial reference | Product Description |
|---|---|
| EVO 34000 | Surgical drill Ø 3.4 mm |

In the case of thick bone crests, the edges of the implant thread in the bone bed must be formed with the bone tap of the Aurea® Evo NP 3.5 implant.

| Commercial reference | Product Description |
|---|---|
| EVO 01035 | NP Bone tap |

The recommended depth of the bone bed to be reached with the tap is 8.5 mm from the bone crest level. The implant length and bone density evaluation will determine if more depth should be marked on the tap, but always remembering that too much depth can result in instability.

**IMPORTANT**

Use the tap to slowly form the edge by hand while connected to the wrench and/or at a speed of 15 rpm when using a mechanical tap with a contra-angle.

**AUREA ® EVO RP 4.3 FINAL SURGICAL SEQUENCE**

After completing the final surgical sequence for the Aurea® Evo NP 3.5 implant, begin with the final osteotomy sequence for the Aurea® Evo RP 4.3 implant. The diameters of the shoulder, body and other specifications of the Aurea® Evo RP 4.3 implant are shown at the beginning of this procedure.

The final osteotomy for the Aurea® Evo RP 4.3 implant is performed with the Ø 3.8 mm tapered apex drill in the upper cylindrical area and at a speed of 650 rpm until the planned length is obtained, exerting gentle and intermittent pressure to avoid overheating the bones.

| Commercial reference | Product Description |
|---|---|
| EVO 38000 | Surgical drill Ø 3.8 mm |

If bone quality is type I or II in the mandible and anterior maxilla area, the dril that should be used for the Aurea® Evo RP 4.3 implant is the Ø 4.0 mm tapered apex drill for dense bone in the upper cylindrical area and at a speed of 650 rpm.

| Commercial reference | Product Description |
|---|---|
| EVO 41000 | Surgical drill Ø 4.1 mm |

In the case of thick bone crests, the edges of the implant thread in the bone bed must be formed with the tap of the Aurea® Evo RP 4.3 implant.

| Commercial reference | Product Description |
|---|---|
| EVO 01043 | RP Bone tap |

The recommended depth of the bone bed to be reached with the tap is 8.5 mm from the bone crest level. The implant length and bone density evaluation will determine if more depth should be marked on the tap, but always remembering that too much depth can result in instability.

**IMPORTANT**

Use the tap to slowly form the edge by hand while connected to the wrench and/or at a speed of 15 rpm when using a mechanical tap with a contra-angle.

Abundant irrigation is necessary in all osteotomies and processes up to the insertion of the implant.

**AUREA® EVO RP 4.8 FINAL SURGICAL SEQUENCE**

After completing the final surgical sequence for the Aurea® Evo RP 4.3 implant, begin with the final osteotomy sequence for the Aurea® Evo RP 4.8 implant. The diameters of the shoulder, body and other specifications of the Aurea® Evo RP 4.8 implant are shown at the beginning of this procedure.

The final osteotomy for the Aurea® Evo RP 4.8 implant is performed with the Ø 4.4 mm tapered apex drill in the upper cylindrical area and at a speed of 650 rpm until the planned length is obtained, exerting gentle and intermittent pressure to avoid overheating the bones.

| Commercial reference | Product Description |
|---|---|
| EVO 44000 | Surgical drill Ø 4.4 mm |

If bone quality is type I or II in the mandible and anterior maxilla area, the drill that should be used for the Aurea® Evo RP 4.8 implant is the Ø 4.6 mm tapered apex drill for dense bone in the upper cylindrical area and at a speed of 650 rpm.

| Commercial reference | Product Description |
|---|---|
| EVO 46000 | Surgical drill Ø 4.6 mm |

In the case of thick bone crests, the edges of the implant thread in the bone bed must be formed with the tap of the Aurea® Evo RP 4.8 implant.

| Commercial reference | Product Description |
|---|---|
| EVO 01048 | RP48 Bone tap |

The recommended depth of the bone bed to be reached with the tap is 8.5 mm from the bone crest level. The implant length and bone density evaluation will determine if more depth should be marked on the tap, but always remembering that too much depth can result in instability.

**IMPORTANT**

Use the tap to slowly form the edge by hand while connected to the wrench and/or at a speed of 15 rpm when using a mechanical tap with a contra-angle.

Abundant irrigation is necessary in all osteotomies and processes up to the insertion of the implant.

**AUREA ® EVO WP 5.5 FINAL SURGICAL SEQUENCE**

After completing the final surgical sequence for the Aurea® Evo RP 4.8 implant, begin with the final osteotomy sequence for the Aurea® Evo WP 5.5 implant. The diameters of the shoulder, body and other specifications of the Aurea® Evo WP 5.5 implant are shown at the beginning of this procedure.

The final osteotomy for the Aurea® Evo WP 5.5 implant is performed with the Ø 5.0 mm tapered apex drill in the upper cylindrical area and at a speed of 650 rpm until the planned length is obtained, exerting gentle and intermittent pressure to avoid overheating the bones.

| Commercial reference | Product Description |
|---|---|
| EVO 52052 | Surgical drill Ø 5.2 mm |

If bone quality is type I or II in the mandible and anterior maxilla area, the bur that should be used for the Aurea® Evo WP 5.5 implant is the Ø 5.2 mm tapered apex drill for dense bone in the upper cylindrical area and at a speed of 650 rpm.

| Commercial reference | Product Description |
|---|---|
| EVO 54000 | Surgical drill Ø 5.4 mm |

In the case of thick bone crests, the edges of the implant thread must be adapted to the implant in the bone bed using the tap of the Aurea® Evo WP 5.5 implant.

| Commercial reference | Product Description |
|---|---|
| EVO 01055 | WP Bone tap |

The recommended depth of the bone bed to be reached with the tap is 8.5 mm from the bone crest level. The implant length and bone density evaluation will determine if more depth should be marked on the tap, but always remembering that too much depth can result in instability.

**IMPORTANT**

Use the tap to slowly form the edge by hand while connected to the wrench and/or at a speed of 15 rpm when using a mechanical tap with a contra-angle.

Abundant irrigation is necessary in all osteotomies and processes up to the insertion of the implant.

## 09. IMPLANT LABEL

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.

## 10. OPENING THE BLISTER

Before opening the package, visually inspect it to ensure that it is not damaged, opened or punctured, etc. Before opening, also check that the implant information on the label matches the required diameter and length. Check the expiration date before opening.

Implants are sterilized by radiation using gamma rays at 25 KGy. Phibo® system implants come in individual units.

The implant is delivered as follows:

- In an outer color-coded cardboard box for each series of implants.
- 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 Tyvek seal to ensure the sterility of the implant.
- Outer blister pack. This contains the inner packaging. After opening, leave the inner packaging in the operating field to preserve sterile conditions.
- Inner blister pack. This package contains the implant with the implant holder and the locking screw. The latter are identified by the color code of the corresponding series.

Open the outer box by pressing on the section labeled “PRESS”, breaking the perforated line on the box to remove the double blister pack. Once the outer cardboard box is opened, it is important to read the instructions on the Tyvek package to properly open the outer blister.

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 Tyvek package and placing it in the surgical field. The screw on the lid may slip out of the blister if the Tyvek package is opened too quickly and with too much force.

**IMPORTANT**

If for any reason the planned surgery is not performed, the blister containing the implant cannot be stored, saved, or used for another surgery. The inner blister does not preserve the sterility of the implant. The sterility of the implant is guaranteed until the outer blister is opened. The inner blister does not maintain sterility over time.

Open the inner blister in the surgical field, remove the implant from its socket and then remove the locking screw. The implant is held in the inner blister by the friction between the implant holder and the area of the blister designed for this purpose. It is important to fit the adapters securely into the implant holder 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.

## 11. REMOVING THE IMPLANT FROM THE BLISTER

**IMPORTANT**

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 holder, resulting in cold welding between the implant holder and the implant.
- Excessive torsion of the implant holder, resulting in cold welding between the implant holder 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 bur 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.

**MECHANICAL DISASSEMBLY**

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

| Commercial reference | Product Description |
|---|---|
| 173.0100 | Short mechanical adapter |
| 173.0300 | Long mechanical adapter |

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.

**MANUAL DISASSEMBLY**

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

| Commercial reference | Product Description |
|---|---|
| 172.0100 | Short wrench adapter |
| 172.0300 | Long wrench adapter |

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

## 12 IMPLANT INSERTION

**IMPORTANT**

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. Irrigation must be continuous throughout the insertion procedure. 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 and after the final milling sequence, ensure that the length of the implant is correct and that there is no milling residue left on the bone bed.
The implant can be inserted with or without irrigation so that the hydrophilic surface absorbs blood from the socket.
As an orientation during implant insertion, all implant holders have a mechanical mark 4 mm above the height of the theoretical crest area.

**PRIMARY STABILITY**

Several factors, such as bone characteristics, bone volume and quality, the implant location and preparation technique, among others, will have a direct effect on the degree of stability.

**MECHANICAL AND MANUAL INSERTION**

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.
The insertion of the implant should start slowly, with continuous irrigation throughout the procedure, a maximum insertion torque of 35 Ncm and a speed of 15 rpm.
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 holder and the implant.

## 13 REMOVING THE IMPLANT HOLDER

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

| Commercial reference | Product Description |
|---|---|
| 172.0001 | Open-ended wrench for securing implant holders |

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 holder 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.

| Commercial reference | Product Description |
|---|---|
| 174.1251 | Short manual screwdriver |
| 174.1252 | Medium manual screwdriver bit |

| | |
|---|---|
| 174.1253 | Long manual screwdriver bit |
| 172.1251 | Short Ratchet Screwdriver Bit |
| 172.1252 | Long Ratchet Screwdriver Bit |
| 173.1251 | Short mechanical screwdriver |
| 173.1252 | Long mechanical screwdriver |

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

Then remove the implant holder 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.

## 14 PROCEDURES WITH PHIBO®

There are several procedures in the Aurea® Evo implant system to complete the surgery, depending on the treatment that has been planned. Consult the prosthodontic procedures of the Phibo® system for complete and up-to-date information on the processes to be applied in the planned treatment.

The various options for completing the surgery are as follows:

### IMMEDIATE AESTHETICS

Immediate Aesthetics is indicated for the placement of a temporary prosthesis (previously made in the laboratory or clinic) without occlusal contact after surgery. For more information on immediate aesthetics, see the prosthodontic procedure.

### ONE-STAGE SURGERY

Procedure indicated in cases of medium-high bone density and quality. The minimum waiting times before restoration will be 6 to 8 weeks.

The implant shoulder remains in contact with the oral environment during the bone and soft tissue repair phases, through the healing abutment or healing cap of the Aurea® Evo abutment, around which the suture is made. Use the same prosthetic elements with the 4.8 mm diameter Aurea® Evo implants that are used for the 4.3 mm diameter Aurea® Evo implants.

| Commercial reference | Product Description |
|---|---|
| EVO NP 01.3 | Aurea Evo Narrow Platform 3 mm healing abutment |
| EVO NP 01.4 | Aurea Evo Narrow Platform 4mm healing abutment |
| EVO NP 01.5 | Aurea Evo Narrow Platform 5mm healing abutment |
| EVO NP 01.6 | Aurea Evo Narrow Platform 6mm healing abutment |
| EVO RP 01.3 | Aurea Evo Regular Platform 3 mm healing abutment |
| EVO RP 01.4 | Aurea Evo Regular Platform 4 mm healing abutment |
| EVO RP 01.5 | Aurea Evo Regular Platform 5 mm healing abutment |
| EVO RP 01.6 | Aurea Evo Regular Platform 6 mm healing abutment |
| EVO WP 01.3 | Aurea Evo Wide Platform 3 mm healing abutment |
| EVO WP 01.4 | Aurea Evo Wide Platform 4 mm healing abutment |
| EVO WP 01.5 | Aurea Evo Wide Platform 5 mm healing abutment |
| EVO WP 01.6 | Aurea Evo Wide Platform 6mm healing abutment |
| EVO NP 49.0 | Aurea Evo Narrow Platform temporary cap |
| EVO RP 49.0 | Aurea Evo Regular Platform temporary cap |
| EVO WP 49.0 | Aurea Evo Wide Platform temporary cap |

**TWO-STAGE SURGERY. DELAYED FUNCTION**

Procedure suitable for clinical cases in which the transmission of forces and loads of any kind to the implant must be avoided and in cases with low cortical and trabecular bone density and quality, compromising the stability of the implant regarding the type of restoration planned.

The minimum waiting times recommended before restoration will be 12 to 24 weeks. The implant shoulder and the locking screw are covered by soft tissue, without contact with the oral environment.

In a second stage, model the soft tissue around the healing abutment or the healing cap of the Aurea® Evo abutment.

**CONSIDERATIONS FOR PROCEDURES**

The above procedures are recommended for optimal bone and clinical conditions. The average periods of time indicated for the osseointegration of implants in the procedures vary, depending on factors such as insufficient bone, clinical cases with surgery and advanced techniques, the use of biomaterials, sinus lift, bone filling, lack of parallelism between implants, as well as the diameter and length of the implant, insertion area, scheduled prosthodontic restoration, the height of the margin and tissue, the bone crest area, the interdental distance and aesthetic compromise, etc.

**POST-SURGICAL MAINTENANCE AND FOLLOW-UP**

Once the surgery is finished, it is important to carry out a post-surgical follow-up and control, with radiographic scans and periodic checks according to the general rules and protocols applied in implantology.