ENGLISH - EN

Surgical procedure Aurea® Evo

Reference: PRO-00005 Surgical procedure Aurea® Evo

Version: 00

IMPORTANT INFORMATION.

READ THIS DOCUMENT CAREFULLY BEFORE USING THE PRODUCT.

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I. General Considerations

Phibo® products 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 products.

It is also necessary to consult the information gathered in this procedure and related instructions for use (IFUs):

- **IFU-00001 Implants**
- **IFU-00002 Implantable attachments**
- **IFU-00003: Dental instruments Class IIa**
- **IFU-00004 Non - implantable attachments**
- **IFU-00005: Dental instruments Class I**

If you are not familiar with the surgical procedure described here, you can contact Phibo to provide you with any information and/or training you may require to perform this procedure:

- atencionPhibo@Phibo.com

Before opening the package of a Phibo product, please consult the information from the products' label and IFU. Any illustrations present on this document are not made to scale.

II. Sterilization and reuse

Phibo® dental implants are supplied **sterile**. Phibo® dental implants are not reusable devices and must not be reprocessed.

Phibo® attachments and dental instruments are supplied **unsterilized**. Prior to first being used, these devices must be properly cleaned, disinfect and sterilized according to the following procedure:

- **PRO-00007 Cleaning, disinfection and sterilization.**

Phibo® attachments are not reusable devices and must not be reprocessed.

Phibo® dental instruments are reusable devices and must be reprocessed according to procedure **PRO-00007** after each use.

III. Warnings

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.

The reuse of single-use products may result in potential deterioration of their features, which involves the risk of tissue infection, prosthodontic failure and/or deterioration of the patient's health.

IV. Important before using Phibo® products

The use and application of Phibo® products are beyond the manufacturer's control.
The design of the type of rehabilitation and prosthesis must be a planned procedure.
The user is responsible for any damage that may be caused by the misuse of the product, releasing Phibo Dental Solutions, S.L. from liability for damages or losses resulting from improper handling or misuse.
Phibo® implant system documentation is periodically renewed according to the state of science and technology. Do not hesitate to contact us for additional information.

V. Incident reporting

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 local competent authority.

VI. 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.

1. Introduction

Dental implants are prosthesis that interface with the bone of the mandible and maxilla to support a dental prosthesis such as a crown, bridge or a denture.

Aurea® Evo implants are manufactured with Titanium grade IV as per the ASTM F67-13 (2017) and ISO 5832-2:2018 standard, and are characterized by the patented surface treatment Avantblast®, based on double chemical attack, that combines key factors to facilitate the biological response of the implant.

2. Expected clinical benefit

The final purpose of the Aurea® Evo implant is to restore the chewing, aesthetic and phonation functions by replacing lost dental pieces in the mandible or the maxilla by means of an appropriate prosthesis.

3. Characteristic of the Aurea® Evo Implants

Implant diameter

The Aurea® Evo implant system consists of three lines of self-tapping implant platforms:

Aurea® Evo Narrow Platform (NP) Implants

- Implants with a 3.5 mm platform and body diameter, available in several lengths: from 8.5 mm to 14.5 mm, in increments of 1.5 mm.

Aurea® Evo Regular Platform (RP) Implants

- Implants with 4.3 mm or 4.8 mm platform and body diameter, available in several lengths: from 8.5 mm to 14.5 mm, in increments of 1.5 mm.

Aurea® Evo Wide Platform (WP) Implants

- Implants with 5.5 mm platform and body diameter, available in several lengths: from 8.5 mm to 13.0 mm, in increments of 1.5 mm.

Table 1 – Commercial references of the Aurea® Evo implants, and their corresponding platform diameter and length.

Commercial Reference	Platform Diameter	Length
EVO NP 085	Ø3.5 mm	8.5 mm
EVO NP 100	Ø3.5 mm	10.0 mm
EVO NP 115	Ø3.5 mm	11.5 mm
EVO NP 130	Ø3.5 mm	13.0 mm
EVO NP 145	Ø3.5 mm	14.5 mm
EVO RP 085	Ø4.3 mm	8.5 mm
EVO RP 100	Ø4.3 mm	10.0 mm

EVO RP 115	Ø4.3 mm	11.5 mm
EVO RP 130	Ø4.3 mm	13.0 mm
EVO RP 145	Ø4.3 mm	14.5 mm
EVO RP 48085	Ø4.8 mm	8.5 mm
EVO RP 48100	Ø4.8 mm	10.0 mm
EVO RP 48115	Ø4.8 mm	11.5 mm
EVO RP 48130	Ø4.8 mm	13.0 mm
EVO RP 48145	Ø4.8 mm	14.5 mm
EVO WP 085	Ø5.5 mm	8.5 mm
EVO WP 100	Ø5.5 mm	10.0 mm
EVO WP 115	Ø5.5 mm	11.5 mm
EVO WP 130	Ø5.5 mm	13.0 mm

Implant connection

Aurea® Evo implants have 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

Aurea® Evo implants have a platform modification technology between the implant and the connection of the prosthetic abutment, moving the prosthetic space away from the marginal bone.

4. 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 treated with 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 (Implant stability quotient)).

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.

5. Contraindications

There are general factors that could affect the implant performance, 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: Endocrine, Hematological, Acute or Chronic Infectious Diseases, Osteoporosis, Epilepsy, Maxillary Osteitis, Cardiovascular Radiotherapy Treatments, Corticosteroid Treatments, or Anticoagulant Treatments.

Phibo® dental implants are not indicated in clinical cases with insufficient bone or poor bone quality.
Implants of 8.5mm or shorter length are not suitable for bone quality type III or IV to support a single crown.
The healthcare professional is responsible for making the final decision related to treatment in these cases.

6. Warnings

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.
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.

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.
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.
Passive fit should be achieved in prosthodontic rehabilitation, as well as occlusal adjustment to the opposite dental arch, 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 due to overload or fatigue, and substantial loss of surrounding 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 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. Precautions

As a general rule, a minimum distance of 3 mm between two adjacent implants and 1.5 mm between an implant and a tooth is recommended in order to preserve bone vascularization and the emergence profile.
If, for whatever reason, the planned surgery is finally not performed, the blister pack containing the implant cannot be stored, maintained, or used for another surgery. The inner blister packaging does not maintain the sterility of the implant.
For crestal insertion, the cortical insertion drill should be used, since, if not used, the placement of the implant can lead to excessive pressure on the bone surrounding the implant, causing greater tissue retraction and in turn a potential decrease in the success rate.

8. Treatment planning and Diagnosis

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.

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.

9. Instruments

Surgical box

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 Box

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

Surgical drills can be used up to a maximum of 10 times, if proper maintenance, cleaning, disinfection and sterilization are performed. If the surgical drills present any sign of wear and tear before reaching 10 uses, they must be properly discarded and replaced.

Commercial reference	Product Description
EVO 23000	Precision Drill
EVO 20000	Pilot Drill ø2.0mm
EVO 31000	Surgical Drill ø3.1mm Aurea Evo
EVO 34000	Surgical Drill ø3.4mm Aurea Evo
EVO 38000	Surgical Drill ø3.8mm Aurea Evo
EVO 41000	Surgical Drill ø4.1mm Aurea Evo
EVO 44000	Surgical Drill ø4.4mm Aurea Evo
EVO 46000	Surgical Drill ø4.6mm Aurea Evo
EVO 52052	Surgical Drill ø5.2mm Aurea Evo
EVO 54000	Surgical Drill ø5.4mm Aurea Evo
TOP NP 085	Drill stop Aurea Evo NP 8.5mm
TOP NP 100	Drill stop Aurea Evo NP 10.0mm
TOP NP 115	Drill stop Aurea Evo NP 11.5mm
TOP NP 130	Drill stop Aurea Evo NP 13.0mm
TOP NP 145	Drill stop Aurea Evo NP 14.5mm
TOP RP 085	Drill stop Aurea Evo RP 8.5mm
TOP RP 100	Drill stop Aurea Evo RP 10.0mm
TOP RP 115	Drill stop Aurea Evo RP 11.5mm
TOP RP 130	Drill stop Aurea Evo RP 13.0mm
TOP RP 145	Drill stop Aurea Evo RP 14.5mm
TOP RP48 085	Drill stop Aurea Evo RP48 8.5mm
TOP RP48 100	Drill stop Aurea Evo RP48 10.0mm
TOP RP48 115	Drill stop Aurea Evo RP48 11.5mm
TOP RP48 130	Drill stop Aurea Evo RP48 13.0mm

TOP RP48 145	Drill stop Aurea Evo RP48 14.5mm
TOP WP 085	Drill stop Aurea Evo WP 8.5mm
TOP WP 100	Drill stop Aurea Evo WP 10.0mm
TOP WP 115	Drill stop Aurea Evo WP 11.5mm
TOP WP 130	Drill stop Aurea Evo WP 13.0mm

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 Torque Wrench has dual function: torque control and ratchet wrench.

Commercial reference	Product Description
172.0172	Torque Wrench

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.

10. 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, considering 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 drills, scalpel blades, ratchets, adapters, among others, in order to avoid shocks and deposits on the surface of instruments.

11. Cleaning, disinfection and sterilization of instruments

Cleaning, disinfection and sterilization of dental instruments must be performed following the indications of **PRO-00007 Cleaning, disinfection and sterilization**.

12. Surgical insertion sequences

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 considered:

- 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 drill 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 drills 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.

Recommended drill rotation speeds by diameter are shown in the table below.

Diameter	Description	RPM
2.3 mm	Precision Drill	850
2.0 mm	Pilot Drill ø2.0mm	850
31000	Surgical Drill ø3.1mm Aurea Evo	750
34000	Surgical Drill ø3.4mm Aurea Evo	750
38000	Surgical Drill ø3.8mm Aurea Evo	650
41000	Surgical Drill ø4.1mm Aurea Evo	650
44000	Surgical Drill ø4.4mm Aurea Evo	650

46000	Surgical Drill ø4.6mm Aurea Evo	650
52052	Surgical Drill ø5.2mm Aurea Evo	650
54000	Surgical Drill ø5.4mm Aurea Evo	650
-	Bone Tap	15

Initial surgical sequence / Precision drill

The precision drill 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 precision drill 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 drill 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 / ø2.0 mm Pilot Drill

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 ø2.0mm

Aurea® Evo system drills are designed with laser bands and “click-type” drill stops 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	Drill stop Aurea Evo NP 8.5mm
TOP NP 100	Drill stop Aurea Evo NP 10.0mm
TOP NP 115	Drill stop Aurea Evo NP 11.5mm
TOP NP 130	Drill stop Aurea Evo NP 13.0mm
TOP NP 145	Drill stop Aurea Evo NP 14.5mm

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

Commercial reference	Product Description
EVO 00200	Depth Indicator Drill Ø2.0 mm PHIBO

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 ø3.1mm Aurea Evo

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 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 ø3.4mm Aurea Evo

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	Bone Tap Aurea Evo NP

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 ø3.8mm Aurea Evo

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 4.3 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 ø4.1mm Aurea Evo

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	Bone Tap Aurea Evo RP

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 ø4.4mm Aurea Evo

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 ø4.6mm Aurea Evo

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	Bone Tap Aurea Evo RP48

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 ø5.2mm Aurea Evo

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 ø5.4mm Aurea Evo

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	Bone Tap Aurea Evo WP

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.

13. 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.

14. 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.

15. 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	Contra-Angle Adapter, Short
173.0300	Contra-Angle Adapter, Long

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	Ratchet Adapter, Short - to Mounter

172.0300	Ratchet Adapter, Long – to Mounter

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

16. 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.

17. Removing the implant carrier

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

Commercial reference	Product Description
172.0001	Open end Wrench

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	Manual Hex Driver 1.25mm, Short
174.1252	Manual Hex Driver 1.25mm, Medium
174.1253	Manual Hex Driver 1.25mm, Long
172.1251	Hex Tool 1.25mm, Short - to Wrench
172.1252	Hex Tool 1.25mm, Medium – to Wrench
173.1251	Contra-Angle Hex Driver 1.25mm, Short
173.1252	Contra-Angle Hex Driver 1.25mm, Medium

If the forces applied are greater than those mentioned above, the retention screw can be screwed more tightly to the implant carrier, and the implant carrier 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 carrier, 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.

18. 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 **PRO-00006 Prosthodontic procedure Aurea Evo** 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 **PRO-00006**.

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 3mm 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 3mm Healing Abutment
EVO RP 01.4	Aurea Evo Regular Platform 4mm Healing Abutment
EVO RP 01.5	Aurea Evo Regular Platform 5mm Healing Abutment
EVO RP 01.6	Aurea Evo Regular Platform 6mm Healing Abutment
EVO WP 01.3	Aurea Evo Wide Platform 3mm Healing Abutment
EVO WP 01.4	Aurea Evo Wide Platform 4mm Healing Abutment
EVO WP 01.5	Aurea Evo Wide Platform 5mm Healing Abutment
EVO WP 01.6	Aurea Evo Wide Platform 6mm Healing Abutment
EVO NP 49.0	Aurea Evo Narrow Platform Healing Cap
EVO RP 49.0	Aurea Evo Regular Platform Healing Cap
EVO WP 49.0	Aurea Evo Wide Platform Healing 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 closure 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.