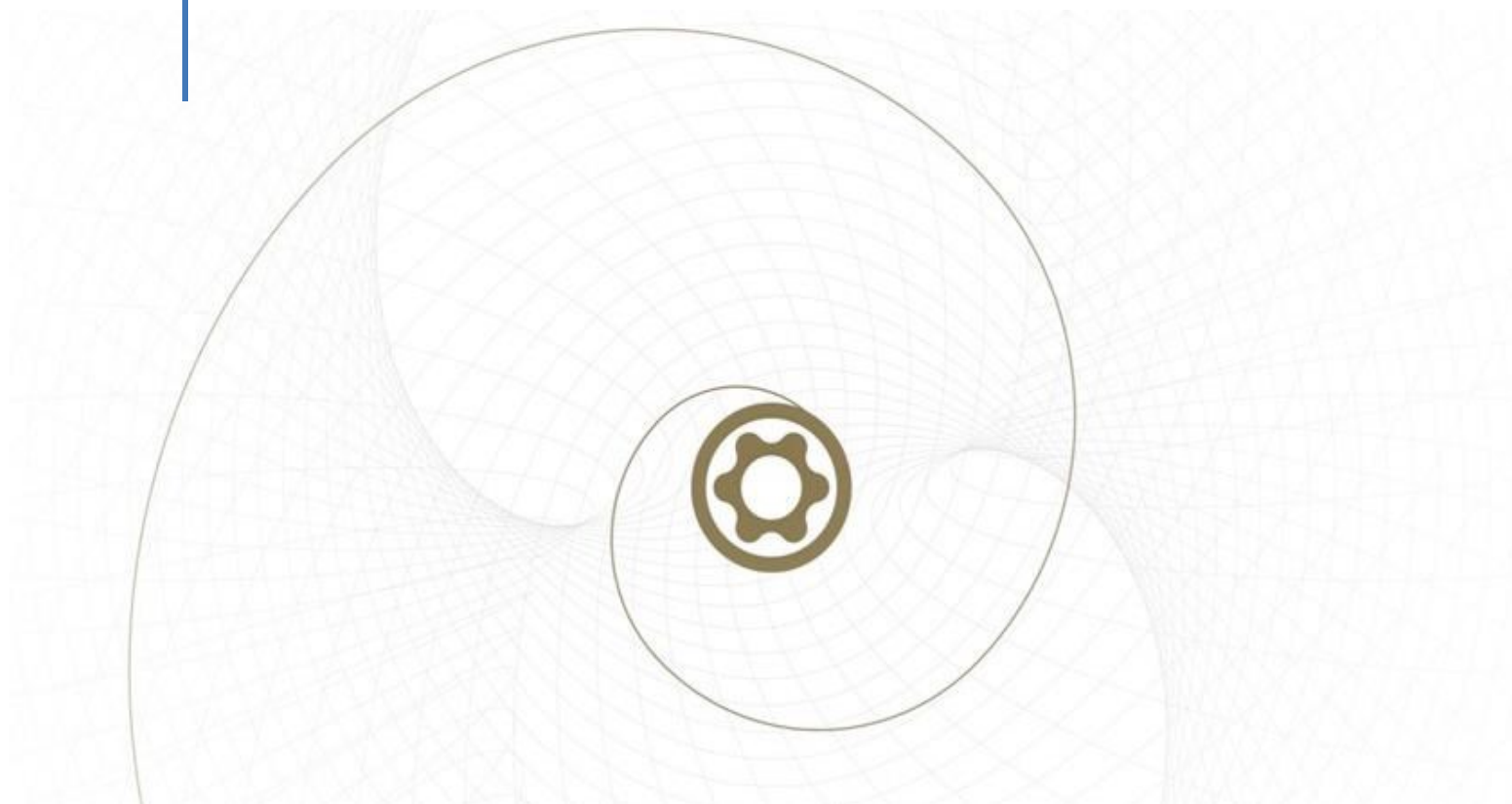














Aurea[®] Evo Surgical Procedure

Reference and Version:
Date approved:

PROCEQUIREVOSP_rev.004
2019.11.07



LABEL SYMBOLS

SYMBOL	LEGEND
	Phibo Dental Solutions, S.L. P.I. Mas d'en Cisa Gato Pérez 3-9 08181 Sentmenat Barcelona Spain
	Caution!
	This is a medical device intended for use on patients.
	The implants are supplied sterilised. Gamma irradiation is the sterilisation method. The sterile barrier is the outer blister sealed with Tyvek.
	Attachments and instruments are supplied unsterilised. See instructions for use for cleaning, disinfection and sterilisation
'Non sterile'	
	If the packaging is damaged or has been accidentally opened, the sterility of implants that are supplied sterilised may be jeopardised. 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 may lead to a loss of product functionality and/or safety and potentially cause issues for the patient.
	Resterilising disposable products may lead to a loss of product functionality and/or safety and potentially cause issues for the patient.
'Do not re-sterilise'	
'Single-patient use'	Using disposable products for more than one patient may lead to a loss of product functionality and/or safety and potentially cause issues for the patient.
	Medical devices must be safely disposed of in sanitary containers approved for such purposes, and in accordance with the requirements of the current local regulations.
	The labelling of the products referred to in these instructions for use include traceability with UDI/unique device identification coding.
'eIFU'	These instructions for use are electronic and are not enclosed in paper format. They are intended for healthcare practitioners. The instructions can be downloaded from the Downloads section of the manufacturer's website at www.phibo.com .
	
	CE 0123 means that it is TUV SUD-certified.
0123	

IMPLANT CARD

For implant products, the healthcare professional must supply the patient with an implant card. You can download the implant card model from the Downloads section of the Phibo website (www.phibo.com). The patient must receive an implant card with product traceability (reference and batch number), as well as a description of the product, recommendations and precautions to be taken into account.

PRODUCT LIFESPAN

The lifespan of implant systems is estimated at 10 years for implantable products, 5 years for permanent attachments and 1 year for provisional attachments. Instruments have an indefinite lifespan depending on their use.

WARRANTY PLAN

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

Any use outside of the instructions for use set out here is excluded from the Product quality warranty plan. Any off-label use, such as placement in a non-designated dental sector or the use of attachments and/or instruments that are not compatible with the product, entails additional foreseeable risks that may cause non-osseointegration or loss of the implant, as well as fractures or unscheduled surgical and/or clinical interventions.

INCIDENT REPORTING

In the case that an incident is detected in a patient, report it immediately to Phibo as the manufacturer in one of the following ways:



Online, accessing the application <http://customercenter.phibo.com/> with your username or by downloading the quality warranty form from the download section at www.phibo.com



Print the form of the case generated in the Customer Centre or downloaded from the website. Include the affected product duly disinfected if it has been used on a patient. If your case involves an implant 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 Department: PHIBO DENTAL SOLUTIONS: P.I. Mas d'en Cisa, Gato Pérez 3-9, 08181, Sentmenat, Barcelona.



If required, you can ask for it to be collected by the Customer Service Department by calling +34 937 152 688. Or you can contact them by email at: garantiacalidad@phibo.com

TECHNICAL INFORMATION

The information described below is not sufficient to use Phibo[®] dental implants; the person who handles the implant must have sufficient training and information on dental implant techniques to use Phibo[®] dental implants.

Read the information contained in the implant's information leaflet before using it. The instructions for using and maintaining Phibo[®] products are given in the documents and procedures manuals for the Phibo[®] implant system.

IMPORTANT BEFORE USING PHIBO[®]

The innovative and patented design of the Phibo[®] implant system includes advanced technological features developed only for professionals who understand technology as an advantage and design as a benefit.


Phibo[®] complies with all the European guidelines and legal requirements regarding the manufacture and distribution of medical and health products. The Phibo[®] implant system is certified and authorised for sale by the corresponding European Notified Body. Phibo Dental Solutions, S.L. complies with the strictest international standards on the quality of medical devices, guaranteeing perfect product quality, with the sole objective of constantly increasing client satisfaction.

The use of other components or products not manufactured by Phibo Dental solutions, S.L. that come into contact with the original components of the Phibo[®] implant system manufactured by Phibo Dental Solutions, S.L. in accordance with the original design specifications may seriously harm the patient's health, as these are not intended for use with the elements that are referenced in the documentation supplied by the manufacturer. Any use of components or instruments which are not the original components indicated in this document for the procedure and which come into contact with the components referenced shall automatically cancel any type of warranty covering products manufactured by Phibo Dental Solutions, S.L.

The use and application of the Phibo[®] dental implant system is outside of the control of the manufacturer and the user is liable for any loss or damage that may result from the use of the product, with Phibo Dental Solutions, S.L. held harmless for any loss or damage that may result from improper handling or use.

Reusing single-use products may lead to the deterioration of their properties, with a risk of tissue infection, surgical or prosthodontic failure and/or damage to patient health.

The documentation of the Phibo[®] implant system is periodically updated according to the state of scientific and technical knowledge. Users of the Phibo[®] system should request product information on a regular basis and attend the training courses on the product and technique that are held regularly. The use and placement of Phibo[®] implants in inappropriate sectors and the use of surgical instruments or prosthetic components not contemplated in this procedure may cause serious patient health problems as well as total loss of the product warranty. The Phibo[®] implant system has been designed for single and multiple dental restorations in accordance with the traditional clinical processes that are reflected in this documentation. Any guarantee excludes cases involving insufficient bone for implant placement, clinical risk cases such as sinus lifts, bone fillings, advanced surgical techniques, cases of severe or unsuitable lack of parallelism between implants and other cases.



The Phibo[®] implant system is internationally distributed in various countries with different technical and healthcare regulations and laws; accordingly, there may be differences from one country to another in terms of the contents of the procedure. Contact the exclusive Phibo[®] dealer in your country and request the documentation for the products and their availability.

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Any illustration that may appear in this document is not drawn to scale.

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01 INTRODUCTION

Avantblast[®] is the surface of Phibo[®] implant systems, progressing in the investigation of implant surface treatment based on chemical attack.

The Avantblast[®] surface is obtained using a dual chemical attack on pure grade 4 titanium, which combines key factors to facilitate the biological response of the implant.

Since 2016, research and development aimed at improving the connection and performance of stress during chewing gave rise to the hex-lobe connection of the Aurea[®] Evo implant system.

02 PURPOSE OF THE IMPLANTS

The purpose of the Aurea[®] Evo implants is to recover function, aesthetics and health by replacing lost teeth in the jaw or maxilla by surgical implantation of dental implants in the remaining bone tissue and to restore the various functions using appropriate prostheses.

IMPLANT DIAMETER

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

- **AUREA EVO NP IMPLANT**

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

- **AUREA EVO RP IMPLANT**

4.3 and 4.8 mm-diameter platform and body, available in several lengths: From 8.5 mm to 14.5 mm, in 1.5 mm increments.

- **AUREA EVO WP IMPLANT**

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

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 connection of the Aurea[®] Evo implant is hex-lobe. This connection prevents the prosthetic elements fixed to the implant from rotating on two equally distant spatial planes.

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

MICROTHREADS

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

MISMATCHED PLATFORM

The Aurea[®] Evo implant system features platform modification technology between the implant and the prosthetic abutment connection, moving the prosthetic gap away from the marginal bone.

03 INSERTION SPECIFICATIONS

The insertion specifications described in this procedure for each series of Aurea[®] Evo implant are based on the type of radicular surface of the tooth that requires replacement and the average size, surface and chewing loads of the upper crown to support.

INSERTION HEIGHT

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

CLINICAL INDICATIONS AND INSERTION SECTORS

- ☛ General indications with appropriate width, height and bone qualities.
- ☛ Immediate load in optimal conditions where the implants reach primary stability that is appropriate for immediate load (≥ 60 ISQ).
- **AUREA EVO NP Ø 3.5 IMPLANT**
 - ☛ In single and multiple fixed restoration by replacing natural roots and supporting the crown of lateral incisors on the maxilla and lateral and central incisors on the jaw.
- **AUREA EVO RP Ø 4.3 IMPLANT**
 - ☛ In single and multiple fixed restoration by replacing natural roots and supporting the crown of central incisor teeth and premolars on the maxilla and canine teeth and premolars on the jaw.
- **AUREA EVO RP Ø 4.8 and WP Ø 5.5 IMPLANT**
 - ☛ In single and multiple fixed restoration by replacing natural roots and supporting the crown of molars on both the maxilla and the jaw.

WARNINGS

Implant lengths of 8.5 mm or less are not indicated for bone quality type III or IV, to support a single crown.

The design and performance of the product and the success of the treatment are based on the indications described above. All products that do not comply with these indications, clinical cases with insufficient bone, advanced surgery, inclusion of biomaterials, sinus elevations, bone fillers, 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 vascularisation and the emergence profile, the general recommendation is a minimum distance of 3 mm between two adjacent implants and 1.5 mm between one implant and a tooth.

04 PLANNING THE TREATMENT

The purpose of dental implant treatment is to recover the functionality of the lost natural teeth.

To achieve these treatment goals it is essential for the treatment to be planned from the perspective of prosthodontic restoration. This is done by using the clinical history, the clinical-radiological diagnosis, examination and study models as per the general standards and protocols applied in implantology.

Phibo[®] recommends performing a three-dimensional study (CAT) and using surgical splints to position the implants correctly in the three dimensions (apex-crown, mesiodistal or vestibulolingual or palatal). The CAT will reveal bone quality, an important factor for the drilling technique.

The information to obtain to perform the treatment is as follows:

- ☐ Clinical history.
- ☐ Personal and family medical background.
- ☐ General medical condition.
- ☐ Bucco-dental medical condition.
- ☐ Clinical examination and x-rays.
- ☐ Record of the anatomical condition using study models.
- ☐ Diagnosis and treatment plan.
- ☐ Patient's expectations.
- ☐ Possible contraindications.

CONTRAINDICATIONS

General factors:

Age, Stress, Tobacco, Pregnancy, Blood dyscrasias, Psychic factors, Valve prosthesis, Terminal pathologies, Poor oral hygiene, Bone deficiency, Alcoholism, Drug addiction, Deficient medical condition, among others.

Systemic diseases:

Endocrine, Haematological, Acute or chronic infections, Osteoporosis, Epilepsy, Maxillary osteitis, Cardiovascular, Radiotherapy treatment, Treatment with corticoids, Treatment with anticoagulant agents, among others.

DIAGNOSIS AND TREATMENT PLAN

The initial diagnosis requires impressions to obtain study models, mounting them on a semi-adjustable articulator guided by the bite record. This allows a diagnosis of the toothless areas and the dimensions of the available space, patient occlusion and the type of antagonist arch of the sector to be restored.

A wax reconstruction is also made with the dimensions and design of the future prosthesis. The wax-up is used to make the provisional restoration and build the surgical guides to place the implants and prosthodontic restorations that are needed for insertion.

Clinical and x-ray examinations, as well as the models, are essential instruments to define the type of restoration that is necessary for the patient to recover oral anatomy, chewing function and aesthetic appearance. The treatment plan that is established includes planning restoration over time, the type of prosthesis to be used, the number of implants needed to support the prosthesis and their proper position with regard to the bone crest and soft tissue, among other items.

The treatment plan and implementation are essential to safeguard the biological structures. The goals are to foresee the load along the axis of the implant, avoid overextension, manage cross-section loads, control stability and occlusion as well as hygiene and parafunctions and to stimulate bone anchoring by including the necessary number of implants of the length and diameter for the available anatomical features and counteracting the forces at all levels.

05 INSTRUMENTS

SURGICAL KIT

The surgical kit is not sterilised.

The ergonomics of the surgical kit are highly adapted for surgery and prosthodontics. It consists of a tray that holds the surgical and/or prosthetic instruments and a cover.

Commercial reference	Product description
EVO 00001	Aurea Evo surgical kit

Each of the items in the kit have to be washed separately before surgery or the prosthodontic procedure, including the kit itself, paying special attention to areas that are difficult to reach.

Detergents used as chemical cleaners are not enough to clean all the dirt and/or residue. Therefore, it is essential to use a sponge or cloth to carefully remove all of the material that remains stuck after surgery. Using a brush with soft bristles is recommended for areas that are hard to reach. Do not use solvents, abrasive cleaners, metal brushes or abrasive pads. A soft enzyme detergent with neutral pH is recommended. Moreover, the surgical kit can be cleaned mechanically in an ultrasound tank. Make sure that all the items in the surgical kit are clean and not damaged before use. Do not place any inappropriate instruments in the kit to avoid excess loads and prevent steam from entering through the gaps.

SURGICAL DRILLS

They must be cleaned and disinfected properly, not banged and not accumulate residue to preserve their good condition and cutting properties.

Remember that inappropriate cleaning and maintenance will shorten the useful life and cutting properties of the drills, which may result in implant treatment failure and serious harm to the patient's health.

Commercial reference	Product description
EVO 23000	Lance bur
EVO 20000	Pilot bur
EVO 31000	Surgical bur Ø 3.1 mm
EVO 34000	Surgical bur Ø 3.4 mm
EVO 38000	Surgical bur Ø 3.8 mm
EVO 41000	Surgical bur Ø 4.1 mm
EVO 44000	Surgical bur Ø 4.4 mm
EVO 46000	Surgical bur Ø 4.6 mm
EVO 52052	Surgical bur Ø 5.2 mm

EVO 54000	Surgical bur Ø 5.4 mm
TOP NP 085	Drill stop NP 8.5 mm
TOP NP 100	Drill stop NP 10.0 mm
TOP NP 115	Drill stop NP 11.5 mm
TOP NP 130	Drill stop NP 13.0 mm
TOP NP 145	Drill stop NP 14.5 mm
TOP RP 085	Drill stop RP 8.5 mm
TOP RP 100	Drill stop RP 10.0 mm
TOP RP 115	Drill stop RP 11.5 mm
TOP RP 130	Drill stop RP 13.0 mm
TOP RP 145	Drill stop RP 14.5 mm
TOP RPP 085	Drill stop RPP 8.5 mm
TOP RPP 100	Drill stop RPP 10.0 mm
TOP RPP 115	Drill stop RPP 11.5 mm
TOP RPP 130	Drill stop RPP 13.0 mm
TOP RPP 145	Drill stop RPP 14.5 mm
TOP WP 085	Drill stop WP 8.5 mm
TOP WP 100	Drill stop WP 10.0 mm
TOP WP 115	Drill stop WP 11.5 mm
TOP WP 130	Drill stop WP 13.0 mm

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

DYNAMOMETRIC WRENCH

The wrench of the Aurea[®] Evo system controls the torque and the ratchet wrench. The wrench is not STERILISED.

Commercial reference	Product description
172.0172	Dynamometric Wrench

The wrench must be disinfected, cleaned and sterilised before use. The recommended torque for implant insertion or placement and tightening of the definitive prosthesis can be adjusted at the bottom of the wrench.

The torque is set in the dynamometric wrench. When the dynamometric wrench reaches the necessary torque, the top or head folds to indicate that the proper force has been achieved.

06 PREPARING THE SURGICAL FIELD

Surgical field preparation as well as cleaning, disinfecting and sterilising implantology instruments, components and equipment are based on patient hygiene and safety procedures found in the standards and protocols that are applicable to odontology.

Below is a summary of some of these standard protocols with the specific instructions for the Aurea[®] Evo implant system.

The surgical field must be aseptic and sterilised before and during surgery.

The general measures to take to prepare the surgical field include the following:

- ☛ Obtaining the clinical history of the patient, technical information and patient treatment plan.
- ☛ Sterilisation of the Aurea[®] Evo implant system instruments.
- ☛ Sterilisation of the instruments, components and generic equipment used during surgery.
- ☛ Protecting the operating table with sterile cloth.

- ☞ Placing all the instruments where they can be seen and in the appropriate order for use on the operating table, taking into account the surgical procedures.
- ☞ Protecting the surgical equipment and components with sterile cloth.
- ☞ Surgical motor with new irrigation hoses.
- ☞ Preparing the patient for surgery. Mouthwashes and cleaning and disinfecting the operating area.
- ☞ The staff must be provided with specific surgical clothing, such as surgical gowns, face masks, sterile disposable gloves, protective plastic goggles and appropriate footwear, among others. Arms and hands must also be cleaned and disinfected as per the standard protocol.

During the operation it is important to use a sterile recipient containing a physiological non-saline solution to deposit the used instruments, such as surgical drills, scalpels, ratchets, adapters, etc. to prevent them from damage and accumulating residue.

07 CLEANING, DISINFECTING AND STERILISING THE INSTRUMENTS

Cleaning, disinfecting and sterilising, as well as surgical field preparation, are based on patient hygiene and safety procedures found in the standards and protocols that are applicable to odontology.

The cleaning, disinfection and sterilisation protocol can be found in the document entitled **PROSPLDESP**.

WARNING

Not following the instructions of the manufacturers of the products used in the processes described above can cause serious damage to materials, such as rust on instruments, loss of surgical bur cutting properties and a reduction in their useful life. These, in turn, can cause complications in subsequent surgery, e.g. excess bone heating/necrosis, and prevent implant osseointegration.

08 SURGICAL SEQUENCES OF THE INSERTION

IMPORTANT NOTE, BEFORE INSERTION

Preparation of the bone bed requires the use of special, sharp instruments that are constantly irrigated to complete the specific surgical sequence for the insertion of each implant indicate in this surgical procedure and at the recommended speeds.

If this is not done as required, excess force may be applied for implant insertion over 35 N·cm - exceeding bone resistance and causing damage to the implant and its connection, cold welding of the implant with the implant holder, implant fracture, necrosis and bone fracture, etc.

The bone bed is prepared by an initial surgical sequence consisting in the insertion of all the series and a final surgical sequence that is specific for each series of implants. The following steps should be taken into account during the surgical preparation of the bone bed for the implant:

- ☞ Use a large amount of sterile water solution or NaCl solution previously cooled at 5°C to cool the area.
- ☞ Exert gentle and intermittent pressure on the bone.

INCISION

Implants can be placed with a mucoperiosteal incision and raising the flap to get a direct view of the bone or without a mucoperiosteal incision using a circular scalpel. Using a circular scalpel requires keratinized gum tissue, proper bone width and a previous three dimensional treatment plan to find out 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 is made, the flap is raised and the bone crest is uncovered, the initial surgical sequence can be started. If the bone crest is narrow, it has to be modified to increase the vestibulolingual or palatal width so there is enough bone margin after placing the implant. In clinical cases where the diagnosis reveals 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.

PREPARING THE BONE BED

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

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

After removal, the position of the implant shoulder will be evaluated on the basis of the surgical guide resulting from the previous diagnostic wax-up; the shoulder must be 4 mm from the gingival margin of the future restoration.

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

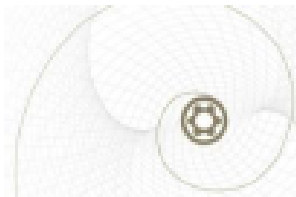
It is important to remove drilling residue with a syringe and a sterile solution at the end of the surgical procedure. Surgical drills must not be used more than 10 times. More frequent use can compromise the success of the implant treatment.

The drilling sequence will be conditioned by the type of bone as found in the Lekholm classification, so drilling for type I bone will not be the same as for type IV.

In bone type IV, drilling is recommended along the entire length with all drills except the last of the series, which will only be used on the coronal third of the new socket. Thus, the implant acts like a bone compactor, preserving and condensing the bone until it is finally inserted.

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

<i>Diameter</i>	<i>Description</i>	<i>rpm</i>
2.3	Lance bur	850
2.0	Pilot bur	850
3.1	NP drill 3.5	750
3.4	NP drill 3.5 dense bone	750
3.8	RP drill	650
4.1	RP drill 4.3 dense bone	650
4.4	RPP drill	650
4.6	RPP drill 4.8 dense bone	650



5.2	WP drill 5.5	650
5.4	WP drill 5.5 dense bone	650
-	Threading tap	15

INITIAL SURGICAL SEQUENCE / LANCE BUR

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

The initial sequence is started using the lance bur at a speed of 850 rpm, marking and inserting it through the bone crest and centring the axis for the osteotomies to follow.

It is not necessary to go as deep as planned with this conical bur that is Ø 2.3 mm in its upper cylindrical area. This bur has two laser marks at 8.5 mm and 13 mm to guide to the desired depth before measuring.

Commercial reference	Product description
EVO 23000	Lance bur

INITIAL SURGICAL SEQUENCE / DRILL Ø2.0 mm

After traversing the bone crest, the initial Ø 2.0 mm helical bur is used at a speed of 850 rpm to penetrate deeper to the planned length, with gentle and intermittent pressure being exerted to prevent bone overheating.

Commercial reference	Product description
EVO 20000	Pilot bur

The drills of the Aurea[®] Evo system are designed with laser bands and click-on bits to guide the depth of the bone bed. However, this does not exempt from the use of clinical controls using probes or other appropriate materials.

Commercial reference	Product description
TOP NP 085	Drill stop NP 8.5 mm
TOP NP 100	Drill stop NP 10.0 mm
TOP NP 115	Drill stop NP 11.5 mm
TOP NP 130	Drill stop NP 13.0 mm
TOP NP 145	Drill stop NP 14.5 mm

The depth gauge/paralleliser is then inserted to check the length of the bur and its parallel position and make small corrections in the following osteotomy. We recommend threading dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product description
EVO 20000	Paralleliser and Gauge

FINAL SURGICAL SEQUENCE AUREA[®] EVO NP 3.5

After completing the initial surgical sequence for the whole series, start the final osteotomy sequence for the Aurea[®] Evo NP 3.5 implant. The diameters of the shoulder, body and the rest of the specifications for 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 cone-shaped apex drill at the cylindrical upper area and at a speed of 750 rpm until the planned length is obtained, with gentle and intermittent pressure being exerted to prevent bone overheating.

Commercial reference	Product description
EVO 31000	Surgical bur Ø 3.1 mm

If the bone quality is type I or II in the jaw and anterior maxilla areas, the drill that should be used for the Aurea[®] Evo NP 3.5 implant is the Ø 3.4 mm cone-shaped apex drill for dense bone at the upper cylindrical area and at a speed of 750 rpm.

Commercial reference	Product description
EVO 34000	Surgical bur Ø 3.4 mm

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

Commercial reference	Product description
EVO 01035	Threading tap NP

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

IMPORTANT

Use the threading 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 threading tap with a contra-angle handpiece.

FINAL SURGICAL SEQUENCE AUREA[®]EVO RP 4.3

After completing the final surgical sequence for the Aurea[®] Evo NP 3.5 implant, start the final osteotomy sequence for the Aurea[®] Evo RP 4.3 implant. The diameters of the shoulder, body and the rest of the specifications for Aurea[®] Evo RP 4.3 implants 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 cone-shaped apex drill at the cylindrical upper area and at a speed of 650 rpm until the planned length is obtained, with gentle and intermittent pressure being exerted to prevent bone overheating.

Commercial reference	Product description
EVO 38000	Surgical bur Ø 3.8 mm

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

Commercial reference	Product description
EVO 401000	Surgical bur Ø 4.1 mm

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

Commercial reference	Product description
EVO 01043	Threading tap RP

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

IMPORTANT

Use the threading 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 threading tap with a contra-angle handpiece.

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

FINAL SURGICAL SEQUENCE AUREA[®] EVO RP 4.8

After completing the final surgical sequence for the Aurea[®] Evo RP 4.3 implant, start the final osteotomy sequence for the Aurea[®] Evo RP 4.8 implant. The diameters of the shoulder, body and the rest of the specifications for Aurea[®] Evo RP 4.8 implants 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 cone-shaped apex drill at the cylindrical upper area and at a speed of 650 rpm until the planned length is obtained, with gentle and intermittent pressure being exerted to prevent bone overheating.

Commercial reference	Product description
EVO 44000	Surgical bur Ø 4.4 mm

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

Commercial reference	Product description
EVO 46000	Surgical bur Ø 4.6 mm

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

Commercial reference	Product description
EVO 01048	Threading tap RPP

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

IMPORTANT

Use the threading 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 threading tap with a contra-angle handpiece.

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

FINAL SURGICAL SEQUENCE AUREA[®]EVO WP 5.5

After completing the final surgical sequence for the Aurea Evo RP 4.8 implant, start the final osteotomy sequence for the Aurea[®] Evo WP 5.5 implant. The diameters of the shoulder, body and the rest of the specifications for 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 cone-shaped apex drill at the cylindrical upper area and at a speed of 650 rpm until the planned length is obtained, with gentle and intermittent pressure being exerted to prevent bone overheating.

Commercial reference	Product description
EVO 52052	Surgical bur Ø 5.2 mm

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

Commercial reference	Product description
EVO 54000	Surgical bur Ø 5.4 mm

In the case of thick bone crests, the edges of the implant thread must adapt to the implant in the bone bed using the threading tap of the Aurea[®] Evo WP 5.5 implant.

Commercial reference	Product description
EVO 01055	Threading tap WP

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

IMPORTANT

Use the threading 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 threading tap with a contra-angle handpiece.

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

09. AUREA[®] EVO IMPLANT LABELLING

The purpose of the identification labels of each implant is to maintain the traceability and warranty of the product used in the patient. Place the labels in the patient's clinical record and form, in the treatment log book, the technical specifications of the laboratory associated with the clinic and the patient and, finally, place the label in any process that requires identification associated with patient treatment.

10. OPENING THE CONTAINER

Before opening the package, inspect it visually to make sure it is not damaged, open or perforated, etc. Before opening, also check that the implant information on the label matches the required diameter and length. Check the expiry date before opening.

The implants are sterilised by radiation using gamma rays at 25KGy.

Phibo[®] system implants come in single units.

The implant is supplied as follows:

- ☛ In an outer cardboard box with a colour code for each implant series.
- ☛ With three identification labels used for traceability and the warranty.
- ☛ Double blister packaging sealed with Tyvek wrap to guarantee implant sterility.
- ☛ Outer blister packaging. This contains the inner packaging. After opening, leave the inner packaging on the operating field to preserve the sterile conditions.
- ☛ Inner blister packaging. This packaging contains the implant with the implant holder and the cover screw. The latter are identified with the colour code of the corresponding series.

Open the outer box by pressing on the section labelled “PRESS”, breaking the perforated line on the box to remove the double blister package. Once the outer cardboard box has been opened, it is important to read the instructions on the Tyvek wrap to open the outer blister correctly.

To preserve asepsis and sterility when handling the outer cardboard box and opening the outer blister packaging, these two components should be handled by staff who will not access the surgical field, so the sterile field is not broken.

Open the inner blister carefully, after the final osteotomy, following the instructions on the Tyvek wrap and placing it in the surgical field. The cover screw may fall out of the blister if the Tyvek wrap is opened too quickly and with too much force.

IMPORTANT

If the planned surgery is not performed for whatever reason, the blister pack containing the implant cannot be stored, saved or used for other surgery. The inner blister pack does not preserve implant sterility.

Implant sterility is guaranteed until the outer blister pack is opened. The inner blister pack does not maintain sterile conditions over time.

Open the inner blister pack in the surgical field, remove the implant from its fitting and then remove the cover screw. The implant is held in the inner blister pack by the friction between the implant holder and the area of the blister pack designed for that purpose. It is important to fit the adapters firmly onto the implant holder and to check that they have been properly attached before removing the implant. This will ensure that the implant is transported to the bone bed in proper conditions. If the implant falls or loses its sterility, it is completely forbidden to manipulate, clean, sterilise or use the implant in the patient.

11. REMOVING THE IMPLANT FROM THE BLISTER PACK

IMPORTANT

Before removing the implant from the blister pack and inserting it into the bone bed, the contra-angle handpiece and dynamometric wrench must be set to a maximum torque of 35 N·cm. The manual or mechanical insertion of the implant must not exceed the maximum recommended torque; exceeding this torque can cause serious or irreversible damage to the implant and the patient's health.

The indicators and consequences normally associated with exerting excess 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.
- ☛ Perceptible or imperceptible damage to the implant connection, resulting in implant fracturing after restoration in the short or medium-term or misalignment of the prosthesis with the connection of the implant.
- ☛ Damage to the internal thread of the implant, resulting in poor final screw adjustment in the prosthesis, broken screws or loss of internal thread of the implant.

Possible causes:

- ☐ A final osteotomy sequence using a surgical drill with a diameter below the specification.
- ☐ A final drilling and implant insertion sequence in bone types I and II, without having adjusted the thread to the threading tap.
- ☐ Defective cutting by the surgical drill, etc.

MECHANICAL REMOVAL

Connect the mechanical adapter to the contrast and insert it in the implant holder until a slight resistance is felt and a click is heard, indicating that it is connected.

Commercial reference	Product description
173.0100	Short mechanical adapter
173.0300	Long mechanical adapter

Hold the blister pack firmly and rotate the contrast at 15 rpm. Then remove it vertically without moving it back and forth, separating the implant from the blister pack.

MANUAL REMOVAL

Connect the mechanical adapter to the dynamometric wrench and insert it in the implant holder until a slight resistance is felt and a click is heard, indicating that it is connected.

Commercial reference	Product description
172.0100	Short wrench adapter
172.0300	Long wrench adapter

Hold the blister pack firmly and remove it gently vertically without moving it back and forth, separating the implant from the blister pack.

12 INSERTING THE IMPLANT

IMPORTANT

If insertion is in bone types I and II, short pauses should be taken and even more so while inserting implants of greater length and diameter. Irrigation must be continuous during the entire insertion procedure. After completing the final drilling sequence, verify proper bleeding, bone bed vascularisation and that there are no sharp bone protrusions that may interfere with implant insertion or subsequent soft tissue manipulation.

Before inserting the implant and after the final drilling sequence, make sure that the length of the implant is correct and that there is no drilling residue left in the bone bed.

The implant can be inserted with or without irrigation so that the hydrophilic surface soaks up the blood from the socket.

As a guideline during implant insertion, all implant holders have a mechanical mark at 4 mm from the height of the theoretical crest area.

PRIMARY STABILITY

Several factors, such as bone characteristics, bone quantity and quality, 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 insertion manually with the dynamometric wrench, leaving it at the desired height and thereby ensuring the primary stability of the implant more directly.

Implant insertion should be started slowly, with continuous irrigation throughout the procedure, a maximum insertion torque of 35 N-cm and a speed of 15 rpm.

During insertion, do not exert excess force, make sudden movements or place instruments at improper angles with regard to the bone bed that can result in inappropriate forces and stress affecting the implant holder and the implant.

13 REMOVING THE IMPLANT HOLDER

Once the implant is inserted, place the open-end wrench on the implant holder. The purpose is to reduce implant movement to a minimum and maintain maximum stability while the implant holder retention screw is being removed.

Commercial reference	Product description
172.0001	Implant holder clamping open-end wrench

Once the open-end wrench is in place, insert the manual or mechanical driver tip into the retention screw. Retention screw extraction is counter-clockwise. The retention screw of the implant holder is calibrated to a specific torque so it can be removed manually or mechanically without difficulty. The retention screws are kept in place in the driver tip by friction.

Commercial reference	Product description
174.1251	Short manual driver tip
174.1252	Medium manual driver tip
174.1253	Long manual driver tip
172.1251	Short wrench driver tip
172.1252	Long wrench driver tip
173.1251	Short mechanical driver
173.1252	Long mechanical driver

If the forces applied are greater than those mentioned above, the retention screw may be screwed tighter to the implant holder and the holder may be slightly blocked against the implant, resulting from the friction and torsion of these elements. The open-end wrench should be used to extract the retention screw and then the implant holder, using small counter-clockwise movements to unblock the components.

Subsequently, remove the implant holder using a mosquito clamp.

Afterwards, and depending on the treatment that has been planned, finish the surgery according to the chosen procedure. First, clean the area and implant with physiological saline solution to eliminate any particles or elements resulting from the osteotomy and that can interfere with placing and adjusting the necessary components and attachments.

14 PROCEDURES WITH PHIBO[®]

There are several procedures in the Aurea[®] Evo implant system to finish surgery, depending on the treatment that has been planned. Refer to the prosthodontic procedures of the Phibo[®] system for complete and updated information on the processes to apply in the planned treatment.

The various options for surgery completion are as follows:

IMMEDIATE AESTHETIC.

Immediate Aesthetic is indicated for placement of a temporary prosthesis (made previously in the laboratory or clinic) without occlusal contact after surgery is completed. For further information about the immediate aesthetic, see the prosthodontic procedure.

ONE-STAGE SURGERY

Procedure indicated in cases of medium-high bone density and quality.

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 4.8 mm-diameter Aurea[®] Evo implants as are used for 4.3 mm-diameter Aurea[®] Evo implants.

Commercial reference	Product description
EVO NP 01.3	3 mm Aurea Evo Narrow Platform healing abutment
EVO NP 01.4	4 mm Aurea Evo Narrow Platform healing abutment
EVO NP 01.5	5 mm Aurea Evo Narrow Platform healing abutment
EVO NP 01.6	6 mm Aurea Evo Narrow Platform healing abutment
EVO RP 01.3	3 mm Aurea Evo Regular Platform healing abutment
EVO RP 01.4	4 mm Aurea Evo Regular Platform healing abutment
EVO RP 01.5	5 mm Aurea Evo Regular Platform healing abutment
EVO RP 01.6	6 mm Aurea Evo Regular Platform healing abutment
EVO WP 01.3	3 mm Aurea Evo Wide Platform healing abutment
EVO WP 01.4	4 mm Aurea Evo Wide Platform healing abutment
EVO WP 01.5	5 mm Aurea Evo Wide Platform healing abutment
EVO WP 01.6	6 mm Aurea Evo Wide Platform 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 indicated for clinical cases in which 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 with respect to the planned type of restoration.

Minimum recommended waiting times before restoration will be 12 to 24 weeks. The implant shoulder and cover screw are covered by the soft tissue, with no contact with the oral environment.

In a second phase, model the soft tissue around the healing abutment or Aurea[®] Evo abutment healing cap.



CONSIDERATIONS FOR THE PROCEDURES

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

POST-SURGICAL MAINTENANCE AND MONITORING

After surgery has been completed, it is important to perform post-surgical follow-ups and monitoring, with X-ray examinations and regular reviews being carried out in accordance with the general standards and protocols applied in implantology.

END OF DOCUMENT