ENGLISH - EN

Surgical procedure TSA®

Reference: PRO-00001 Surgical procedure TSA®

Version: 01

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):

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

- φ 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

Since 1989, the research and development to improve the connection and behavior of forces during chewing has led to the concept of four TSA® connections of the internationally-patented Phibo® implant system.

Avantblast® is the surface of Phibo® implant systems. Continuing the line of research on implant surface treatment based on chemical attack. The Avantblast® surface, combines key factors to facilitate the biological response of the implant.

2. Characteristics of the TSA® Implants

Implant diameter & references

The TSA® implant system comprises three lines of self-tapping implants made of pure Titanium grade 4.

Series 3 TSA® Implants

- Body diameter of 3.6mm and shoulder diameter of 3.7mm available in different lengths.

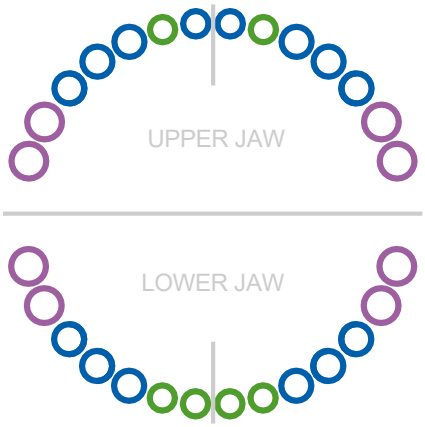
Series 4 TSA® Implants

- Body diameter of 4.2mm and shoulder diameter of 4.7mm available in different lengths.

Series 5 TSA® Implants

- Body diameter of 5.5mm and shoulder diameter of 6.0mm available in different lengths.

TSA® dental implants are designed for placement in one or two surgical stages, depending on biological spaces, prosthodontics and bone quality.



IMPLANT SYSTEM		TSA Implant		
PLATFORM		Series 3	Series 4	Series 5
INDICATIONS	Maxilla	Lateral Incisors	Central incisors, canines, and premolars	Molars
	Mandible	Lateral and central Incisors	Canines and premolars	

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

Commercial Reference	Platform Diameter	Length
TSA 03.085	ø 3.7mm	8.5mm
TSA 03.100	ø 3.7mm	10.0mm
TSA 03.115	ø 3.7mm	11.5mm
TSA 03.130	ø 3.7mm	13.0mm
TSA 03.145	ø 3.7mm	14.5mm
TSA 03.160	ø 3.7mm	16.0mm
TSA 04.060	ø 4.7mm	6.0mm
TSA 04.070	ø 4.7mm	7.0mm
TSA 04.085	ø 4.7mm	8.5mm
TSA 04.100	ø 4.7mm	10.0mm
TSA 04.115	ø 4.7mm	11.5mm
TSA 04.130	ø 4.7mm	13.0mm
TSA 04.145	ø 4.7mm	14.5mm
TSA 04.160	ø 4.7mm	16.0mm
TSA 05.060	ø 6.0 mm	6.0mm
TSA 05.070	ø 6.0 mm	7.0mm
TSA 05.085	ø 6.0 mm	8.5mm
TSA 05.100	ø 6.0 mm	10.0mm
TSA 05.115	ø 6.0 mm	11.5mm
TSA 05.130	ø 6.0 mm	13.0mm

Implant connection

The TSA® implant has four connections that can be used interchangeably: external hexagon, internal hexagon, external conical and internal conical.

The external hexagon and internal hexagon connections provide the anti-rotation feature of the prosthetic elements fixed to the implant in two equidistant spatial planes.

The internal and external conical connections provide the direction of axial, radial and bending forces, fixing the prosthesis to the implant.

The retention is provided by the retention screw, measuring 1.6 mm for Series 3 and 1.8 mm for the rest.

3. Insertion specifications

The insertion specifications described in this procedure are based on the average sizes of the positions where the implants are to be placed, as well as on the evaluation of the different bone qualities available.

The TSA® implant is designed to position the implant shoulder 1.5mm above the bone crest, leaving this length of smooth neck as a biological space for the adhesion and sealing of the junctional epithelium.

The milling length for inserting the implant will be the length of the implant, minus 1.5 mm.

For the commercial references TSA 04.060, TSA 04.070, TSA 05.060 and TSA 05.070, the implant is designed to be placed 1.0mm above the bone crest leaving this length of smooth neck as a biological space for the adhesion and sealing of the junctional epithelium.

The milling length for inserting the implant will be the length of the implant.

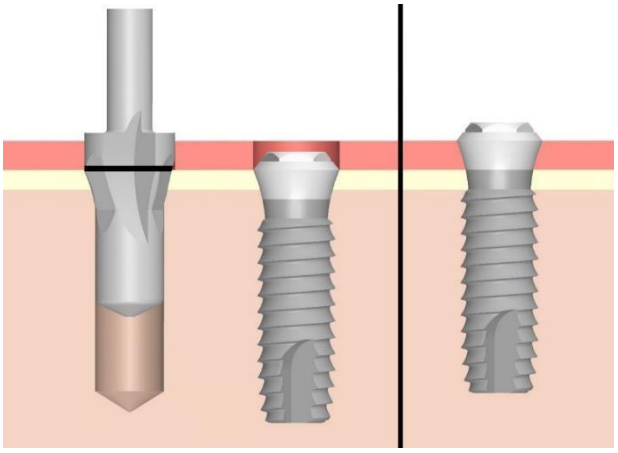
The creation of a 1 mm free space in the bone bed for a TSA implant, especially in the mandible with little space, is indicated to promote the formation of a blood neocoagulant in the apical bed that promotes vascularization in this type of dry bone.

In specific cases with reduced interocclusal space and aesthetic compromise, it is recommended to position the implant shoulder at the level of the bone crest. The milling length for inserting the implant will be equal to the length of the implant. This surgical indication is less common and may lead to a lower success rate due to the potential retraction of bone tissue.

In implants of 8.5 mm or shorter length, it is not recommended to position the implant shoulder at bone crest level, since they can suffer excessive pressure and cause greater tissue retraction and in turn a potential decrease in the success rate.

For these specific cases, the countersink drill must be used (ref. 178.0037 for S3, ref. 178.0047 for S4 and ref. 178.0060 for S5), 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.

This configuration is not available for commercial references TSA 04.060, TSA 04.070, TSA 05.060 and TSA 05.070.



Implants of 8.5 mm or shorter length are not suitable for supporting a single crown for type III or IV bone quality since they may suffer from a lack of primary stability.

Series 3 TSH® implant

- In single and multiple fixed restorations by replacing natural roots and supporting the crown of lateral incisors in the maxilla, and lateral and central incisors in the mandible.

- Rehabilitation of completely maxillary edentulous patients, by means of an overdenture supported by 4 or 6 implants in the middle and anterior areas, splinted using a rigid metal structure.

- Rehabilitation of completely mandibular edentulous patients, by means of an overdenture supported by 2 or 4 implants in the anteroinferior area, splinted using a rigid metal structure.

- In the case of Click & Fix abutments, the rehabilitation of completely edentulous patients is performed by means of an overdenture supported by 2 or more implants.

Series 4 TSH® implant

- In single and multiple fixed restorations by replacing natural roots and supporting the crown of central incisors, canines and premolars in the maxilla, and canines and premolars in the mandible.

- Rehabilitation of completely maxillary edentulous patients, by means of an overdenture supported by 4 or 6 implants in the middle and anterior areas, splinted using a rigid metal structure.

- Rehabilitation of completely mandibular edentulous patients, by means of an overdenture supported by 2 or 4 implants in the anteroinferior area, splinted using a rigid metal structure.

- In the case of Click & Fix abutments, the rehabilitation of completely edentulous patients is performed by means of an overdenture supported by 2 or more implants.

Series 5 TSH® implant

- In single and multiple fixed restorations by replacing natural roots and supporting the crown of molars in both the maxilla and mandible.

- In the case of Click & Fix abutments, the rehabilitation of completely edentulous patients is performed by means of an overdenture supported by 2 or more implants.

4. 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, , 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.

5. Instruments

Surgical box

Note: The surgical box comes unsterilized.

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

Commercial reference	Product Description
SBX 00001	Surgical Box TSA® TSH®

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 "**PRO-000007 Cleaning disinfection and sterilization**"

Surgical drills

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

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

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

There are two types of surgical drills for the Phibo® TSA Implant system. Some drills with screw height stops and another system of surgical drills with interchangeable “click” stops to guide the depth when making the bone bed.

The drill stops are optional and are sold separately.

They are mounted on the laser marks that indicate the insertion height of the implant.

Drills with screw stops:

Commercial reference	Product Description	Length
176.1123	Short pilot drill Ø2.3mm	33.0 mm
176.1323	Long pilot drill Ø2.3mm	41.0 mm
178.1128	Short surgical drill Ø2.8mm	33.0 mm
178.1328	Long surgical drill Ø2.8mm	41.0 mm
178.1130	Short surgical drill Ø3.0mm	33.0 mm
178.1330	Long surgical drill Ø3.0mm	41.0 mm
178.1136	Short surgical drill Ø3.6mm	33.0 mm
178.1336	Long surgical drill Ø3.6mm	41.0 mm
178.1243	Surgical drill Ø4.3mm	33.0 mm
178.1249	Surgical drill Ø4.9mm	33.0 mm
DS23	Dril stop Ø2.3mm	-
DS28	Dril stop Ø2.8mm	-
DS30	Dril stop Ø3.0mm	-
DS36	Dril stop Ø3.6mm	-
DS43	Dril stop Ø4.3mm	-
DS49	Drill stop Ø4.9mm	-
DS00	Screw drill stop	-

Drills with Click stops:

Commercial reference	Product Description	Length
TS 23000	Pilot drill Ø2.3mm	37.0 mm
TS 28000	Surgical drill Ø2.8mm	37.0 mm
TS 30000	Surgical drill Ø3.0mm	37.0 mm
TS 36000	Surgical drill Ø3.6mm	37.0 mm
TS 43000	Surgical drill Ø4.3mm	35.0 mm
TS 49000	Surgical drill Ø4.9mm	35.0 mm
TOP S23 060	Drill stop S2 S3 6.0mm	-
TOP S23 070	Drill stop S2 S3 7.0mm	-
TOP S23 085	Drill stop S2 S3 8.5mm	-
TOP S23 100	Drill stop S2 S3 10.0mm	-
TOP S23 115	Drill stop S2 S3 11.5mm	-
TOP S23 130	Drill stop S2 S3 13.0mm	-
TOP S23 145	Drill stop S2 S3 14.5mm	-
TOP S4 060	Drill stop S4 6.0mm	-
TOP S4 070	Drill stop S4 7.0mm	-
TOP S4 085	Drill stop S4 8.5mm	-
TOP S4 100	Drill stop S4 10.0mm	-
TOP S4 115	Drill stop S4 11.5mm	-
TOP S4 130	Drill stop S4 13.0mm	-
TOP S4 145	Drill stop S4 14.5mm	-
TOP S5 060	Drill stop S5 6.0mm	-
TOP S5 070	Drill stop S5 7.0mm	-
TOP S5 085	Drill stop S5 8.5mm	-
TOP S5 100	Drill stop S5 10.0mm	-
TOP S5 115	Drill stop S5 11.5mm	-
TOP S5 130	Drill stop S5 13.0mm	-

For the placement of implants with lengths of 8.5mm or greater, both types of drills are fully functional and equivalent.

- The Short Drill option allows for bone preparation for implants from 8.5 to 14.5 mm in length.
- The Long Drill option allows for bone preparation for implants from 8.5 mm to 16 mm.
- The Drills with Click Stops option allows for bone preparation for implants from 8.5 to 14.5 mm in length. The bone preparation for implants to 16 mm is not possible with these instruments.
- The Drills with Click Stops option they are the only possible ones for the bone preparation for the commercial references TSA 04.060, TSA 04.070, TSA 05.060 and TSA 05.070
- TOP SX XXX commercial reference stops can only be used with TS XXXXX commercial reference drills.

Specials Drills without stops:

Commercial reference	Product Description
175.0001	Precision drill
173.0001	Drill extender
178.0037	Countersink drill S3
178.0047	Countersink drill S4
178.0060	Countersink drill S5

Dual-function ratchet

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

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

The desired torque is set on the torque ratchet. When the torque ratchet exerts the force needed to reach the desired torque, its safety mechanism prevents the transmission of mechanical force.

Commercial reference	Product Description
172.0172	Dynamometric Ratched

Other Instruments

Below are the other Phibo® instruments mentioned in this procedure.

Commercial reference	Product Description
152.0001	Circular Scalpel Ø3.70
152.0002	Circular Scalpel Ø4.70
152.0003	Circular Scalpel Ø6.00

Commercial reference	Product Description
177.0000	TSA® TSH® Depth gauge ø2.3mm
179.0028	TSA® TSH® Depth gauge ø2.8mm
179.0030	TSA® TSH® Depth gauge ø3.0mm
179.0036	TSA® TSH® Depth gauge ø3.6mm
179.0043	TSA® Depth gauge ø4.3mm
179.0049	TSA® Depth gauge ø4.9mm

Commercial reference	Product Description	Length
181.0136	TSA® TSH® Short Contra-angle Bone Tap S3	33.0 mm
181.0336	TSA® TSH® Long Contra-angle Bone Tap S3	41.0 mm
181.0142	TSA® TSH® Short Contra-angle Bone Tap S4	33.0 mm
181.0342	TSA® TSH® Long Contra-angle Bone Tap S4	41.0 mm
181.0255	TSA® Short Tap S5	33.0 mm

Commercial reference	Product Description
172.0100	Short Adapter
172.0300	Long Adapter

Commercial reference	Product Description
173.0100	Mechanical Short Adapter
173.0300	Mechanical Long Adapter

Commercial reference	Product Description
172.1251	Hex Tool to Wrench Short
172.1252	Hex Tool to Wrench Medium

Commercial reference	Product Description
172.0001	Open end Wrench

Commercial reference	Product Description
174.1251	Manual Hex Driver Short
174.1252	Manual Hex Driver Medium
174.1253	Manual Hex Driver Long

Commercial reference	Product Description
173.1251	Contra-Angle Hex Driv. Short
173.1252	Contra-Angle Hex Driv. Medium

Commercial reference	Product Description
170.0001	Radiographic Template

6. 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 TSA® 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 TSA® 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 burs, scalpel blades, ratchets, adapters, among others, to avoid blows and deposits on the surface of instruments.

7. Cleaning, disinfection and sterilization of instruments

The processes of cleaning, disinfection and sterilization of instruments, and components, in implantology are based on hygiene and patient safety procedures, included in general standards and protocols applied in dental practices.

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

Failure to follow the instructions of the manufacturers of the products used in the processes described above can cause serious damage to the material such as oxidation of instruments, loss of cutting properties of surgical drills and durability, as well as complications in the next surgery, causing excessive bone heating/necrosis and non-osseointegration of the implants.

8. Surgical sequences

Before surgical sequences

The preparation of the bone bed is carried out through an initial surgical insertion sequence common to all series and an intermediate surgical sequence that allows reaching the final 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.

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 surgical sequences will be made according to the planned schedule, if necessary the radiographic template is available.

Commercial reference	Product Description
170.0001	Radiographic Template

For compromised cases the drill extender is available.

Commercial reference	Product Description
173.0001	Drill extender

Incision

Implants can be placed with mucoperiosteal incision, with the flap being raised for direct visualization of the bone, or without mucoperiosteal incision using a circular scalpel.

To use the circular scalpel, there must be keratinized gums, adequate bone width and a three-dimensional treatment plan must be carried out in advance to accurately determine bone volume.

Commercial reference	Product Description
152.0001	Circular Scalpel Ø3.70
152.0002	Circular Scalpel Ø4.70
152.0003	Circular Scalpel Ø6.00

The recommended rotational speed for Circular Scalpel is 350 rpm.

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.

In cases of narrow bone crests, it is recommended to increase their vestibular-lingual or palatine width, leaving sufficient bone margin after the implant has been placed.

Initial surgical sequence / Precision drill

The initial sequence begins with the precision drill for marking the bone crest, crossing the cortical bone and centralizing the axis for the following osteotomies.

The recommended rotational speed for Precision Drill is 850 rpm.

The use of the precision drill is also recommended in clinical cases where the diagnosis allows for surgery without raising the soft tissue flap.

It is recommended to use the laser mark on the precision drill at 8.5 mm to avoid going deeper after cutting the cortex, in order to allow the use of the first helical drill to define the depth and orientation of the bone bed.

After crossing the cortical, use the Ø2.3mm initial helical drill to further deepen (choose one of the three options), at a rotational speed of 850 rpm up to the planned length by exerting gentle and intermittent pressure, to avoid bone heating.

The depth gauge/parallelizer is then inserted to assess the drilling depth and parallelism, allowing corrections to be made at this point in the next osteotomy. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product Description	Length
175.0001	Precision Drill	32.0 mm
176.1123	Short pilot drill Ø2.3mm	33.0 mm
176.1323	Long pilot drill Ø2.3mm	41.0 mm
TS 23000	Pilot drill Ø2.3mm	37.0 mm
177.0000	TSA® TSH® Depth gauge ø2.3mm	-

Final Surgical Sequence Series 3 Implant

Before performing the final sequence of each series, it is necessary to perform intermediate osteotomies, which allow the diameter of the bone bed to be increased in a progressive sequence, avoiding bone heating and respecting the orientation and depth defined with the initial sequence.

For the TSA® Series 3 implant is performed with the Ø 2.8 mm helical drill will (choose one of the three options) be used at a speed of 750 rpm to the planned length, applying gentle, intermittent pressure.

The orientation and depth defined in the initial sequence can also be assess with the corresponding Ø 2.8 mm paralleling tool. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product Description
178.1128	Short surgical drill Ø2.8mm
178.1328	Long surgical drill Ø2.8mm
TS 28000	Surgical drill Ø2.8mm
179.0028	TSA® TSH® Depth gauge ø2.8mm

The final osteotomy for the TSA® Series 3 implant is performed with the Ø3.0 mm helical drill (choose one of the three options), at a rotational speed of 750 rpm up to the planned length, applying gentle and intermittent pressure. The orientation and depth defined in the final sequence can also be assess with the corresponding Ø 3.0 mm paralleling tool. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product Description
178.1130	Short surgical drill Ø3.0mm
178.1330	Long surgical drill Ø3.0mm
TS 30000	Surgical drill Ø3.0mm
179.0030	TSA® TSH® Depth gauge ø3.0mm

In those cases where implant emergence is compromised by the existence of residual bone, the crestal surgical drill should be used to shape the implant shoulder in all series, applying gentle, intermittent pressure at a rotational speed of 350 rpm.

Commercial reference	Product Description
178.0037	Countersink drill S3

In the case of type I and II bone qualities, in thick anterior and cortical mandibular and maxillary areas, the threading of the implant thread must be shaped in the bone bed, using the Series 3 (choose one of the two options) tap at a rotational speed of 15 rpm if using a contra-angle.

Commercial reference	Product Description
181.0136	TSA® TSH® Short Contra-angle Bone Tap S3
181.0336	TSA® TSH® Long Contra-angle Bone Tap S3

After the final milling sequence and before inserting the implant, it is important to check that the length matches the planned length.

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 or milling residue left on the bone bed that could interfere with the insertion of the implant or the subsequent manipulation of soft tissue.

Final Surgical Sequence Series 4 Implant

Before performing the final sequence of each series, it is necessary to perform intermediate osteotomies, which allow the diameter of the bone bed to be increased in a progressive sequence, avoiding bone heating and respecting the orientation and depth defined with the initial sequence.

For the TSA® Series 4 implant is performed with the Ø 2.8 mm helical drill will (choose one of the three options) be used at a speed of 750 rpm to the planned length, applying gentle, intermittent pressure.

Then continue with the Ø 3.0 mm helical drill (choose one of the three options) at a speed of 750 rpm to the planned length, applying gentle, intermittent pressure.

The orientation and depth defined in the initial sequence can also be assess with the corresponding Ø 2.8 mm or Ø 3.0 mm paralleling tool. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product Description
178.1128	Short surgical drill Ø2.8mm
178.1328	Long surgical drill Ø2.8mm
TS 28000	Surgical drill Ø2.8mm
179.0028	TSA® TSH® Depth gauge ø2.8mm
178.1130	Short surgical drill Ø3.0mm
178.1330	Long surgical drill Ø3.0mm
TS 30000	Surgical drill Ø3.0mm
179.0030	TSA® TSH® Depth gauge ø3.0mm

The final osteotomy for the TSA® Series 4 implant is performed with the Ø 3.6 mm helical drill (choose one of the three options), at a rotational speed of 650 rpm up to the planned length, applying gentle and intermittent pressure. The orientation and depth defined in the final sequence can also be assess with the corresponding Ø 3.6 mm paralleling tool. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product Description
178.1136	Short surgical drill Ø3.6mm
178.1336	Long surgical drill Ø3.6mm
TS 36000	Surgical drill Ø3.6mm
179.0036	TSA® TSH® Depth gauge ø3.6mm

In those cases where implant emergence is compromised by the existence of residual bone, the crestal surgical drill should be used to shape the implant shoulder in all series, applying gentle, intermittent pressure at a rotational speed of 350 rpm.

Commercial reference	Product Description
178.0047	Countersink drill S4

In the case of type I and II bone qualities, in thick anterior and cortical mandibular and maxillary areas, the threading of the implant thread must be shaped in the bone bed, using the Series 4 (choose one of the two

options) tap at a rotational speed of 15 rpm if using a contra-angle.

Commercial reference	Product Description
181.0142	TSA® TSH® Short Contra-angle Bone Tap S4
181.0342	TSA® TSH® Long Contra-angle Bone Tap S4

After the final milling sequence and before inserting the implant, it is important to check that the length matches the planned length.

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 or milling residue left on the bone bed that could interfere with the insertion of the implant or the subsequent manipulation of soft tissue.

Final Surgical Sequence Series 5 Implant

Before performing the final sequence of each series, it is necessary to perform intermediate osteotomies, which allow the diameter of the bone bed to be increased in a progressive sequence, avoiding bone heating and respecting the orientation and depth defined with the initial sequence.

For the TSA® Series 4 implant is performed with the Ø 2.8 mm helical drill will (choose one of the three options) be used at a speed of 750 rpm to the planned length, applying gentle, intermittent pressure.

Then continue with the Ø 3.0 mm helical drill (choose one of the three options) at a speed of 750 rpm to the planned length, applying gentle, intermittent pressure.

Then continue with the Ø 3.6 mm helical drill (choose one of the three options) at a speed of 650 rpm to the planned length, applying gentle, intermittent pressure.

Then continue with the Ø 4.3 mm helical drill (choose one of the two options) at a speed of 550 rpm to the planned length, applying gentle, intermittent pressure.

The orientation and depth defined in the initial sequence can also be assess with the corresponding Ø 2.8 mm or Ø 3.0 mm or Ø 3.6 mm or Ø 4.3 mm or paralleling tool. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product Description
178.1128	Short surgical drill Ø2.8mm
178.1328	Long surgical drill Ø2.8mm
TS 28000	Surgical drill Ø2.8mm
179.0028	TSA® TSH® Depth gauge ø2.8mm
178.1130	Short surgical drill Ø3.0mm
178.1330	Long surgical drill Ø3.0mm
TS 30000	Surgical drill Ø3.0mm
179.0030	TSA® TSH® Depth gauge ø3.0mm
178.1136	Short surgical drill Ø3.6mm
178.1336	Long surgical drill Ø3.6mm
TS 36000	Surgical drill Ø3.6mm

179.0036	TSA® TSH® Depth gauge ø3.6mm
178.1243	Surgical drill Ø4.3mm
TS 43000	Surgical drill Ø4.3mm
179.0043	TSA® Depth gauge ø4.3mm

The final osteotomy for the TSA® Series 5 implant is performed with the Ø 4.9 mm helical drill (choose one of the two options), at a rotational speed of 450 rpm up to the planned length, applying gentle and intermittent pressure.

The orientation and depth defined in the final sequence can also be assess with the corresponding Ø 4.9 mm paralleling tool. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product Description
178.1249	Surgical drill Ø4.9mm
TS 49000	Surgical drill Ø4.9mm
179.0049	TSA® Depth gauge ø4.9mm

In those cases where implant emergence is compromised by the existence of residual bone, the crestal surgical drill should be used to shape the implant shoulder in all series, applying gentle, intermittent pressure at a rotational speed of 350 rpm.

Commercial reference	Product Description
178.0060	Countersink drill S5

In the case of type I and II bone qualities, in thick anterior and cortical mandibular and maxillary areas, the threading of the implant thread must be shaped in the bone bed, using the Series 5 tap at a rotational speed of 15 rpm if using a contra-angle.

Commercial reference	Product Description
181.0255	TSA® Short Tap S5

After the final milling sequence and before inserting the implant, it is important to check that the length matches the planned length.

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 or milling residue left on the bone bed that could interfere with the insertion of the implant or the subsequent manipulation of soft tissue.

9. 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 (Implant Card) and relates to the patient's treatment.

10. Opening the blister

Before opening the pack, visually check that it is not damaged or opened or perforated, among others. In addition, before opening it, the data on the label should be checked so that the implant matches the planned diameter and length. The expiration date will also be checked before opening. Implants are supplied sterilized by radiation using Gamma Rays at 25KGy.

Phibo® system implants are provided individually.

The implant is delivered as follows:

- Outer color-coded cardboard box for each series of implants.
- Identification label, which includes a triple adhesive label for maintaining traceability and warranty.
- Product package insert inside the cardboard box.
- Double blister pack with Tyvek seal to ensure the sterility of the implant.
- Outer blister pack. It contains the inner pack. After opening, leave the inner pack in the surgical field to preserve sterile conditions.
- Inner blister pack. The pack 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 cardboard box by pressing on the section labeled “PRESS”, breaking the perforated line on the box to remove the double blister pack and the package insert inside.

Once the outer cardboard box is opened, it is important to read the instructions printed 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 pack, these two components must be manipulated by personnel who will not access the surgical field, so that aseptic and sterile conditions are preserved.

Open the inner blister carefully, after the final osteotomy, following the instructions on the Tyvek package and placing it in the surgical field. Opening the Tyvek package quickly or too forcefully may result in the uncontrolled fall of the locking screw out of the blister.

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

The sterility of the implant is guaranteed until the outer blister is opened. The inner blister does not maintain sterility over time.

Open the inner blister in the surgical field, remove the implant from its socket and then remove the locking screw. The implant is held in the inner blister by the friction between the implant holder and the area of the blister designed for this purpose. It is important to fit the adapters securely into the implant holder and check that they have been placed correctly before removing the implant. This will ensure that the implant is transported to the bone bed under appropriate conditions. If the implant falls out or loses its sterility, handling, cleaning, sterilizing or using the implant on the patient is completely prohibited.

11. Removing the implant from the blister

Prior to removing the implant from the blister pack and inserting it into the bone bed, it is necessary to adjust the torque of the contra-angle and of the dynamometric ratched to a maximum torque of **35N·cm**.

Manual extraction

Once the manual adapter is connected to the torque ratchet, insert it into the implant holder until you feel slight resistance and hear a “click” that indicates the adapter is connected.

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

Commercial reference	Product Description
172.0172	Dynamometric Ratched
172.0100	Short Adapter
172.0300	Long Adapter

Mechanical extraction

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

Hold the blister firmly and turn the contra-angle at a rotational speed of 15 rpm. Then remove it vertically, without moving it back and forth, separating the implant from the blister.

Commercial reference	Product Description
173.0100	Mechanical Short Adapter
173.0300	Mechanical Long Adapter

12. Implant insertion

Before inserting the implant and after the final milling sequence, it is important to check that the length matches the planned length and that there is no milling residue left on the bone bed.

Prior to removing the implant from the blister pack and inserting it into the bone bed, it is necessary to adjust the torque of the contra-angle and of the dynamometric ratched to a maximum torque of **35N·cm**.

Manual or mechanical insertion of the implant should not exceed the maximum torque recommended; exceeding these forces can cause serious or irreversible damage to the implant assembly 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 carrier, resulting in cold welding between the implant carrier 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 drill 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.

If the insertion is in type I and II bone, brief intermittent pauses should be taken even more so when placing implants of greater length and diameter.

Irrigation must be continuous throughout the insertion procedure.

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

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

It is important to start inserting the implant slowly, with a maximum insertion torque of 35 Ncm and a rotational speed of 15 rpm.

If the implant is inserted mechanically, do not insert it completely it is recommended, but finish the insertion manually with the torque ratchet, leaving it at the desired height and thus more directly ensuring the primary stability of the implant.

While inserting the implant, do not exceed the recommended forces, make sudden movements, or use the instruments in positions not aligned with the bone bed axis that could generate inadequate forces and tensions affecting the implant holder and implant assembly.

13. Removing the implant carrier

Once the implant is inserted, it is necessary to use the open-end wrench, to minimize the movements of the implant carrier and maintain maximum stability of the implant during the removal of the retention screw from the implant carrier.

Once the open-end wrench is in place, the manual or mechanical driver is inserted into the retention screw. The retention screw is removed in a counterclockwise direction. The retention screws of the implant holders are calibrated with a specific torque, to be removed manually or mechanically without any problem. Retention screws are held in the driver by friction.

Commercial reference	Product Description
172.0001	Open end Wrench
172.1251	Hex Tool to Wrench Short
172.1252	Hex Tool to Wrench Medium
174.1251	Manual Hex Driver Short
174.1252	Manual Hex Driver Medium
174.1253	Manual Hex Driver Long
173.1251	Contra-Angle Hex Driv. Short

Commercial reference	Product Description
173.1252	Contra-Angle Hex Driv. Medium

In those cases where the forces applied have been greater than those mentioned above, the retention screw may have been fixed to a greater degree to the implant holder and it may be slightly locked against the implant due to the friction and torsion of these elements.

When removing the retention screw and subsequently removing the implant holder, it is recommended to use the open-end wrench, exerting small movements counterclockwise to unlock the components.

The implant carrier is then removed with mosquito forceps.

Then, depending on the planned treatment, the surgery is completed according to the chosen procedure, first cleaning the area and the implant using saline solution, removing possible particles and elements from the osteotomy, which may hinder the placement and adjustment of the components and attachments to be used.

14. Procedures with Phibo®

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 compromised surgery and techniques, the use of biomaterials, sinus lift, bone filling, non-parallel implants, as well as the diameter and length of the implant, insertion area, scheduled prosthodontic rehabilitation, the height of the margin and tissue, the cortical space, the interdental distance and aesthetic compromise, etc.

There are several procedures in the TSA® implant system to complete the surgery, depending on the treatment that has been planned. Consult **PRO-00002 Prosthodontic procedure TSA** information on the processes to be applied in the planned treatment.

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.