ENGLISH - EN

TSA® Surgical Procedure

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

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

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

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

IMPORTANT BEFORE USING PHIBO®

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

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

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

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

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

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

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

Phibo®, TSA®, TSH®, Avantblast®, ProUnic®, ProUnic Plus, are registered and/or commercial trademarks of Phibo Dental Solutions, S.L. Phibo® implants are protected by an international patent. Other products and accessories are protected by patents or patents pending.

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

PRODUCT LIFESPAN

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

WARRANTY PLAN

The design of the product, its behavior and success of treatment are based on the indications mentioned above, and all those products that do not meet the indications described, and in clinical cases with insufficient bone, clinical cases with advanced surgeries, incorporation of biomaterials, sinus lift, bone filling, advanced surgical techniques, non-parallel implants, among others, are exempt from any warranty.

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

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

INCIDENT REPORTING

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

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

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

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

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

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

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

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01 INTRODUCTION

MICRODESIGN AND NANODIMENSION

Avantblast® is the surface of Phibo® implant systems. Continuing the line of research on implant surface treatment based on chemical attack.

The Avantblast® surface, made with double chemical attack, on pure Titanium grade 4, combines key factors to facilitate the biological response of the implant.

MACRODESIGN

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

02 PURPOSE OF IMPLANTS

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

IMPLANT DIAMETER

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

SERIES 3 IMPLANT

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

SERIES 4 IMPLANT

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

SERIES 5 IMPLANT

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

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

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

IMPLANT CONNECTION

The TSA® implant has four connections: 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.

03 INSERTION SPECIFICATIONS

The insertion specifications described in this procedure for each series of the TSA® implant are based on the type of root surface of the tooth to be replaced and on the average size, surface, and functional masticatory loads of the natural crown to be supported.

INSERTION HEIGHT

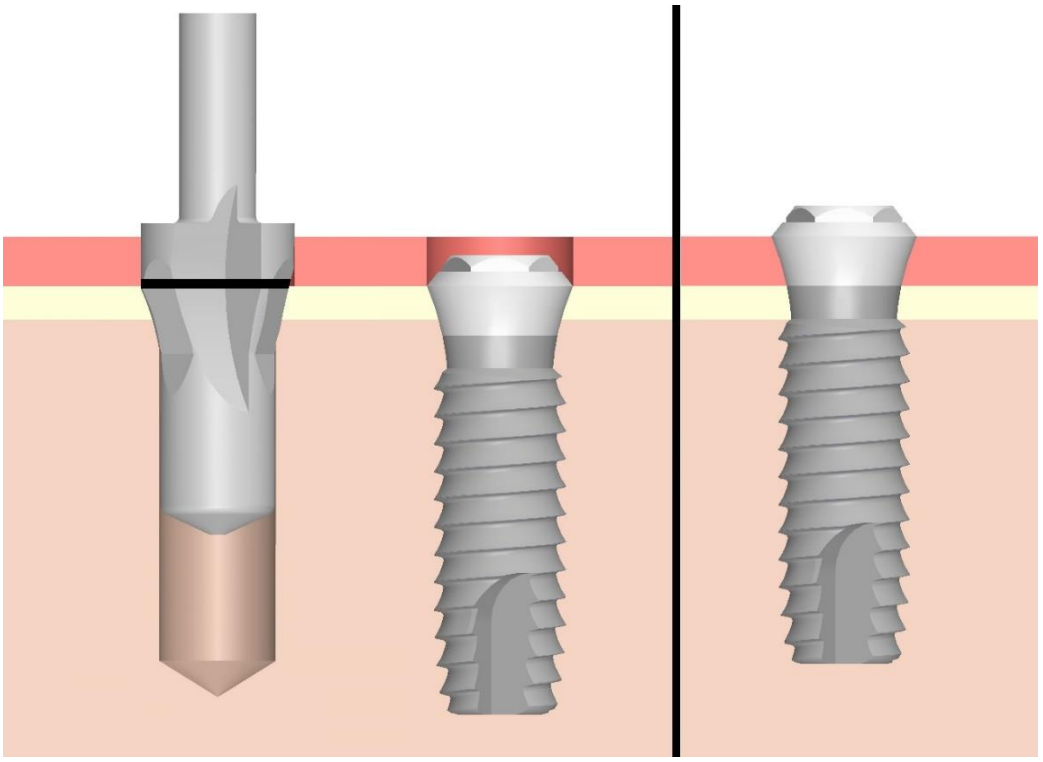
The TSA® implant is designed to position the implant shoulder 1.5mm above the bone crest, leaving this length of smooth neck as a biological space for the adhesion and sealing of the junctional epithelium. The milling length for inserting the implant will be the length of the implant, minus 1.5 mm.

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.

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

This surgical indication is less common and may lead to a lower success rate due to the potential retraction of bone tissue.

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.

SPECIFIC INDICATIONS AND INSERTION AREAS

SERIES 3 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 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 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.

IMPORTANT

Implants of 8.5 mm or shorter 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.

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. The surgical indication at crest level may lead to a lower success rate due to the potential retraction of bone tissue.
For crestal insertion, the cortical insertion bur must be used (ref. 178.0037 for S3, ref. 178.0047 for S4 and ref. 178.0060 for S5), since, if not used, the placement of the implant can lead to excessive pressure on the bone surrounding the implant, causing greater tissue retraction and in turn a potential decrease in the success rate. This configuration is not available for commercial references TSA 04.060, TSA 04.070, TSA 05.060 and TSA 05.070.
The design of the product, its behavior and success of treatment are based on the indications mentioned above, and all those products that do not meet the indications described, and in clinical cases with insufficient bone, clinical cases with advanced surgeries, incorporation of biomaterials, sinus lift, bone filling, advanced surgical techniques, non-parallel implants, among others, are exempt from any warranty.

MINIMUM DISTANCE BETWEEN TEETH AND IMPLANTS

As a general rule, a minimum distance of 3 mm between two adjacent implants and 1.5 mm between an implant and a tooth is recommended in order to preserve bone vascularization and the emergence profile.

04 TREATMENT PLANNING

The goal of dental implant treatment is to restore the functionality of lost natural teeth.
To achieve the objectives of treatment, treatment planning from prosthodontic rehabilitation is established as a fundamental basis. For this purpose, medical history, clinical and radiological diagnosis, examination, study models, among others, are used according to general rules and protocols applied in implantology.
Phibo® recommends carrying out a three-dimensional study (CT) and the use of surgical splints for the correct positioning of the implants, in all 3 dimensions (apical-coronal, mesiodistal or vestibular-lingual or palatine). The CT scan also allows us to recognize bone quality, an important factor for milling techniques.

The information required to carry out the treatment is:

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

CONTRAINDICATIONS

General Factors:

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

Systemic Diseases:

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

WARNINGS AND PRECAUTIONS

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

DIAGNOSIS AND TREATMENT PLAN

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

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

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

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

05 INSTRUMENTS

SURGICAL AND PROSTHETIC BOX

The surgical box comes unsterilized.

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

Commercial reference	Product description
171.0300	TSA® TSH® Surgical Box
171.0500	Start Surgical Box
171.0600	Prosthesis Box

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

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

The cleaning, disinfection and sterilization processes as well as the preparation of the surgical field are based on hygiene and patient safety procedures, included in general standards and protocols applied to dentistry.
Prosthodontic components and instruments for use in the mouth must be cleaned, disinfected and sterilized prior to use, according to the process described in the document “Cleaning, Disinfection and Sterilization of Prosthodontic Components and Instruments” PROSPLD.

SURGICAL DRILLS

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
175.0001	Precision drill
175.1018	Round Marking bur Ø1.8mm
175.1023	Round Marking bur Ø2.3mm
176.1123	Short pilot drill Ø2.3mm
176.1323	Long pilot drill Ø2.3mm
178.1128	Short surgical drill Ø2.8mm
178.1328	Long surgical drill Ø2.8mm
178.1130	Short surgical drill Ø3.0mm
178.1330	Long surgical drill Ø3.0mm
178.1136	Short surgical drill Ø3.6mm
178.1336	Long surgical drill Ø3.6mm
178.1243	Surgical drill Ø4.3mm
178.1249	Surgical drill Ø4.9mm
178.0037	Countersink drill S3
178.0047	Countersink drill S4
178.0060	Countersink drill S5
DS00	Screw drill stop
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

Drills with click stop :

Commercial reference	Product description
175.0001	Precision Drill
175.1018	Round Marking bur Ø1.8mm
175.1023	Round Marking bur Ø2.3mm
TS 23000	Pilot drill Ø2.3mm
TS 28000	Surgical drill Ø2.8mm
TS 30000	Surgical drill Ø3.0mm

TS 36000	Surgical drill Ø3.6mm
TS 43000	Surgical drill Ø4.3mm
TS 49000	Surgical drill Ø4.9mm
178.0037	Countersink drill S3
178.0047	Countersink drill S4
178.0060	Countersink drill S5
TOP S23 060	Drill stop S2 S3 6.0mm
TOP S23 070	Drill stopS2 S3 7.0mm
TOP S23 085	Drill stopS2 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

TOP SX XXX commercial reference stops can only be used with TS XXXXX commercial reference drills. For the placement of implants with lengths of 8.5mm or greater, both types of drills are fully functional and equivalent. For the placement of implants with commercial references TSA 04.060, TSA 04.070, TSA 05.060 and TSA 05.070, only click stop drills can be used.

DUAL-FUNCTION RATCHET

The TSA® 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.

06 SURGICAL FIELD PREPARATION

The preparation of the surgical field as well as the processes of cleaning, disinfection and sterilization of instruments, components, and equipment in implantology are based on hygiene and patient safety procedures, included in general standards and protocols applied in dental practices.
Below is a summary of a part of these standard protocols with the specific indications of the 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.

07 CLEANING, DISINFECTION AND STERILIZATION OF INSTRUMENTS

The cleaning, disinfection, and sterilization processes as well as the preparation of the surgical field are based on hygiene and patient safety procedures, included in general standards and protocols applied to dentistry.
Prosthodontic components and instruments for use in the mouth must be cleaned, disinfected and sterilized prior to use, according to the process described in the document “Cleaning, Disinfection and Sterilization of Prosthodontic Components and Instruments” PROSPLD.

IMPORTANT

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.

08 SURGICAL INSERTION SEQUENCES

IMPORTANT, BEFORE INSERTION

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

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

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

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

INCISION

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

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. In clinical cases where the diagnosis allows for surgery without raising the soft tissue flap, the circular scalpel is used to access the bone that will house the implant bed.

BONE BED PREPARATION

The TSA® implant is designed to position the implant shoulder 1.5mm above the bone crest for biological sealing and space. The milling length for inserting the implant will be 1.5mm shorter than the length of the implant. 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.

In specific cases with reduced availability of interocclusal height and with aesthetic compromise, it is recommended to position the implant shoulder at bone crest level where the milling length for inserting the implant will be equal to the length of the implant. This configuration is not available for commercial references TSA 04.060, TSA 04.070, TSA 05.060 and TSA 05.070.

The recommended rotational speeds for drills according to diameter are specified in the attached table.

Diameter	Description	R.P.M.
By series	Circular scalpel	350
Ø1.8	Round Marking bur	850
Ø 2.3	Round Marking bur	850
Ø 2.3	Precision Drill	850
Ø 2.3	Initial helical drill	850
Ø 2.8	Initial helical drill	750
Ø 3.0	Final helical drill Series 3	750
Ø 3.6	Final helical drill Series 4	650
Ø 4.3	Intermediate helical drill Series 5	550
Ø 4.9	Final helical drill Series 5	450
By series	Crestal Surgical drill	350
By series	Bone Tap	15

INITIAL SURGICAL SEQUENCE / MARKING BURS

The initial sequence begins with the Ø1.8mm marking bur, with a rotational speed of 850 rpm, inserting it through the guide of the surgical splint and marking the bone crest.

Once the marking is made with the Ø1.8mm marking bur, use the Ø2.3mm marking bur at a rotational speed of 850 rpm to mark and increase the diameter on the bone crest, centralizing the axis for the following osteotomies. Then use the Ø2.3mm marking bur to further deepen, until it crosses the cortical.

Commercial reference	Product description
175.1018	Round Marking bur Ø1.8mm
175.1023	Round Marking bur Ø2.3mm

INITIAL SURGICAL SEQUENCE / PRECISION DRILL

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

The initial sequence begins with the precision drill, with a rotational speed of 850 rpm, inserting it through the guide of the surgical splint, crossing the cortical bone and centralizing the axis for the following osteotomies.

Commercial reference	Product description
175.0001	Precision Drill

MILLING LENGTH

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

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
TS 23000	Pilot dril Ø2.3mm	37.0 mm

Then, the depth gauge/parallelizer is inserted to check the milling length and parallelism, allowing at this point to make corrections in the next osteotomy.

Commercial reference	Product description
177.0000	TSA® TSH® Depth gauge ø2.3mm
179.0028	TSA® TSH® Depth gauge ø2.8mm

The next osteotomy is performed with the Ø2.8mm helical drill at a rotational speed of 750 rpm, deepening to the planned length and then measuring the length of the bone bed using the depth gauge.

Commercial reference	Product description	Length
178.1128	Short surgical dril Ø2.8mm	33.0 mm
178.1328	Long surgical drill Ø2.8mm	41.0 mm
TS 28000	Surgical drill Ø2.8mm	37.0 mm

FINAL SURGICAL SEQUENCE SERIES 3 IMPLANT

Once the initial surgical sequence for all series has been completed, the final osteotomy sequence for the TSA® Series 3 implant is started. The diameters of the shoulder, body, and other specifications of TSA® implants are listed at the beginning of this procedure.

The final osteotomy for the TSA® Series 3 implant is performed with the Ø3.0mm helical drill, at a rotational speed of 750 rpm up to the planned length, applying gentle and intermittent pressure.

Commercial reference	Product description	Length
178.1130	Short surgical drill Ø3.0mm	33.0 mm
178.1330	Long surgical drill Ø3.0mm	41.0 mm
TS 30000	Surgical drill Ø3.0mm	37.0 mm

The Series 3 Ø3.0mm depth gauge is inserted to check if the total milled length is equal to the planned length. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product description
179.0030	TSA® TSH® Depth gauge ø3.0mm

In those cases where it is indicated to place the implant at crestal level and the bone quality is type I and II, the crestal surgical bur for shaping the implant shoulder should be used in all series by exerting gentle and intermittent pressure at a rotational speed of 350 rpm.

Commercial reference	Product description	Diameter and Length
178.0037	Countersink drill S3	Ø3.7 x 30mm

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

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

FINAL SURGICAL SEQUENCE SERIES 4 IMPLANT

Once the final surgical sequence for Series 3 has been completed, the final surgical sequence for the TSA® Series 4 implant is started. The diameters of the shoulder, body, and other specifications of TSA® implants are listed at the beginning of this procedure.

The final osteotomy for the TSA® Series 4 implant is performed with the Ø3.6mm helical drill, at a rotational speed of 650 rpm up to the planned length, applying gentle and intermittent pressure.

Commercial reference	Product description	Length
178.1136	Short surgical drill Ø3.6mm	33.0 mm
178.1336	Long surgical drill Ø3.6mm	41.0 mm
TS 36000	Surgical drill Ø3.6mm	37.0 mm

The Series 4 Ø3.6mm depth gauge is inserted to check if the total milled length is equal to the planned length. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product description
179.0036	TSA® TSH® Depth gauge ø3.6mm

In those cases where it is indicated to place the implant at crestal level and the bone quality is type I and II, the crestal surgical bur for shaping the implant shoulder should be used in all series by exerting gentle and intermittent pressure at a rotational speed of 350 rpm.

Commercial reference	Product description	Diameter and Length
178.0047	Countersink drill S4	Ø4.7 x 30mm

In the case of type I and II bone qualities, in thick cortical mandibular and maxillary areas, the threading of the implant thread must be shaped in the bone bed, using the Series 4 tap at a rotational speed of 15 rpm if using a contra-angle.

Commercial reference	Product description	Length
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

FINAL SURGICAL SEQUENCE SERIES 5 IMPLANT

Once the final surgical sequence for Series 4 has been completed, the final surgical sequence for the TSA® Series 5 implant is started. The diameters of the shoulder, body, and other specifications of TSA® implants are listed at the beginning of this procedure.

Prior to the final osteotomy, the sequence is performed with the Ø4.3mm helical drill at a rotational speed of 550 rpm up to the planned length, applying gentle and intermittent pressure.

Commercial reference	Product description	Length
178.1243	Surgical drill Ø4.3mm	33.0 mm
TS 43000	Surgical drill Ø4.3mm	37.0 mm

The Series 5 Ø4.3mm depth gauge is inserted to check if the total milled length is equal to the planned length. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product description
179.0043	TSA® Depth gauge ø4.3mm

The final osteotomy for the TSA® Series 5 implant is performed with the Ø4.9mm helical drill, at a rotational speed of 450 rpm up to the planned length, applying gentle and intermittent pressure.

Commercial reference	Product description	Length
178.1249	Surgical drill Ø4.9mm	33.0 mm
TS 49000	Surgical drill Ø4.9mm	37.0 mm

The Series 5 Ø4.9mm depth gauge is inserted to check if the total milled length is equal to the planned length. We recommend passing dental floss through the hole in the depth gauge to prevent the patient from swallowing it.

Commercial reference	Product description
179.0049	TSA® Depth gauge ø4.9mm

In those cases where it is indicated to place the implant at crestal level and the bone quality is type I and II, the crestal surgical bur for shaping the implant shoulder should be used in all series by exerting gentle and intermittent pressure at a rotational speed of 350 rpm.

Commercial reference	Product description	Diameter and Length
178.0060	Countersink drill S5	Ø6.0 x 30mm

In the case of type I and II bone qualities, in thick 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	Length
181.0255	TSA® Short Tap S5	Length 33.0 mm

IMPORTANT

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

09 IMPLANT LABELING

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, in the treatment log, the technical specifications of the laboratory associated with the clinic and the patient and, finally, place the label in any process that requires identification and relates to the patient's treatment.

10. PACK OPENING

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.

IMPORTANT

If for any reason the planned surgery is not performed, the inner 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 the sterile conditions 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 to securely transport it to the bone bed. If the implant falls out or loses its sterility, handling, cleaning, sterilizing or using the implant on the patient is completely prohibited.

11. REMOVING THE IMPLANT FROM THE BLISTER

IMPORTANT

Before removing the implant from the blister and inserting it into the bone bed, the torque of the contra-angle and the torque ratchet must be adjusted to a maximum torque of 35 Ncm. Manual or mechanical insertion of the implant should not exceed the maximum torque recommended; exceeding 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 holder, resulting in cold welding between the implant holder and the implant.
- Perceptible or imperceptible damage to the implant connection, resulting in fracture of the implant after short or medium term rehabilitation or misalignment of the prosthesis with the implant connection.
- Damage to the internal thread of the implant, resulting in misalignment of the permanent screws in the prosthesis, broken screws, or loss of the internal thread of the implant.

Possible causes:

- A final osteotomy sequence using a surgical bur with a diameter below the specification.
- Final sequence of milling and insertion of the implant in type I and II bone, without having adjusted the thread to the tap.
- Defective cut of surgical drills, etc.

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.

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.

12 IMPLANT INSERTION

IMPORTANT

If the insertion is in type I and II bone, brief intermittent pauses should be taken and even more so when placing implants of greater length and diameter. Irrigation must be continuous throughout the insertion procedure.
After completing the final milling sequence, verify that the bleeding and vascularization of the bone bed are correct and that there are no sharp bone protrusions that could interfere with the insertion of the implant or the subsequent manipulation of soft tissue.

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

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

PRIMARY STABILITY

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

MECHANICAL AND MANUAL INSERTION

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

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

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 IMPLANT HOLDER DISASSEMBLY

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

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 endwrench for implant holder

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 holder 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®

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

The different options for completing the surgery are as follows:

IMMEDIATE AESTHETICS

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

ONE-STAGE SURGERY

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

The implant shoulder above the 1.5mm bone crest remains in contact with the oral environment during the bone and soft tissue repair phases, through the healing abutment or healing cap of the ProUnic Plus® abutment, around which the suture is made.
For commercial references TSA 04.060, TSA 04.070, TSA 05.060 and TSA 05.070, the implant shoulder is 1 mm above the bone crest.

TWO-STAGE SURGERY. DELAYED FUNCTION

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

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

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

CONSIDERATIONS FOR PROCEDURES

The above procedures are recommended for optimal bone and clinical conditions. The average periods of time indicated for the osseointegration of implants in the procedures vary, depending on factors such as insufficient bone, clinical cases with 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.

POST-SURGICAL MAINTENANCE AND CONTROL

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.