Surgical Procedure

TSA®

phibo

Surgical procedure TSA®

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SYMBOLS GUIDE

SYMBOL	LEGEND
	Phibo Dental Solutions, S.L. P.I. Mas d'en Cisa | Gato Pérez 3-9 | 08181 | Sentmenat | Barcelona | Spain
	Caution!
10 °C 40 °C	Temperature limitation
MD	This is a medical device intended for use on patients.
STERILE R	The implants are supplied sterilised. Gamma irradiation is the sterilisation method. The sterile barrier is the outer blister sealed with Tyvek.
NON STERILE *'Non sterile'*	Attachments and instruments are supplied unsterilised. See instructions for use for cleaning, disinfection and sterilisation
	Expiry date
	If the packaging is damaged or has been accidentally opened, the sterility of implants that are supplied sterilised may be jeopardised. Do not use the product and immediately inform the manufacturer at the email address garantiacalidad@phibo.com.
2	The reuse and/or reprocessing of disposable products may lead to a loss of product functionality and/or safety and potentially cause issues for the patient.
2 STERILIZE *'Do not resterilise'*	Resterilising disposable products may lead to a loss of product functionality and/or safety and potentially cause issues for the patient.
REF	Product reference no.
'Single-patient use'	Using disposable products for more than one patient may lead to a loss of product functionality and/or safety and potentially cause issues for the patient.

SYMBOLS GUIDE

SYMBOL	LEGEND
	Medical devices must be safely disposed of in sanitary containers approved for such purposes, and in accordance with the requirements of the current local regulations.
	The labelling of the products referred to in these instructions for use include traceability with UDI/unique device identification coding.
'eIFU' 	These instructions for use are electronic and are not enclosed in paper format. They are intended for healthcare practitioners. The instructions can be downloaded from the Downloads section of the manufacturer's website at www.phibo.com.
	Product batch number
	CE 0123 means that it is TUV SUD-certified.

TECHNICAL INFORMATION

The information given below is not sufficient to use Phibo® dental implants, because the person handling them also needs to have sufficient training and information in dental implant techniques to know how to use Phibo® dental implants.

In case you are not familiar with the clinical procedure described here, you can contact your Phibo® all solutions manager and he/she will provide you with the information and / or training required to carry out this procedure.

Please read the detailed information in the implant leaflet carefully before use. The instructions for using and maintaining Phibo® products are given in the documents and procedures manuals for the Phibo® implant system.

IMPORTANT BEFORE USING PHIBO®

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

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

The use of other components or products not manufactured by Phibo Dental Solutions, S.L., which come into contact with Phibo® implant system originals manufactured by Phibo Dental Solutions, S.L. in accordance with the original design specifications, may cause serious health problems for the patient as they are not intended for use with elements that are referenced in the documentation supplied by the manufacturer.

Any use of non-original components or instruments mentioned in this procedure, which come into contact with the referenced original components, will automatically cancel any type of guarantee on products manufactured by Phibo Dental Solutions, S.L. Because the use and application of the Phibo® dental implant system is beyond the control of the manufacturer, the user is responsible for any damage that may result from the use of the product. Phibo Dental Solutions, S.L. declines all responsibility for damage derived from incorrect manipulation or use.

Reusing single-use products may cause wear, with a risk of tissue infection, surgical or prosthodontic failure and/or deterioration of patient health.

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

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

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

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

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01 INTRODUCTION

MICRODESIGN AND NANODIMENSION

Avantblast® is the surface of Phibo® implant system. Continuing with the line of research on surface treatment in implants based on chemical attack. Generated with double chemical attack on pure grade 4 Titanium, the Avantblast® surface combines key factors that facilitate the implant biological response.

MACRODESIGN

Since 1989, as a result of research and development to improve the connection and the behaviour of forces during mastication, we discovered the concept of the four TSA® simultaneous connections in the Phibo® implant system, with an international patent.

02 PURPOSE OF THE IMPLANTS

The goal of TSA® implants is the recovery of chewing, aesthetic and phonation functions, replacing lost teeth in the mandible or maxilla by means of the surgical implantation of dental implants in the remaining bone tissue, and the rehabilitation of the various functions by means of suitable prostheses.

IMPLANT DIAMENTER

The TSA® implant system comprises three series of self-threading implants made from pure grade 4 titanium.

SERIES 3 IMPLANT

3.6mm body diameter, 3.7mm shoulder, available in various lengths.

SERIES 4 IMPLANT

4.2mm body diameter, 4.7mm shoulder, available in various lengths.

SERIES 5 IMPLANT

5.5mm body diameter, 6.0mm shoulder, available in various 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 6.0mm	6.0mm
TSA 05.070	ø 6.0mm	7.0mm
TSA 05.085	ø 6.0mm	8.5mm
TSA 05.100	ø 6.0mm	10.0mm
TSA 05.115	ø 6.0mm	11.5mm
TSA 05.130	ø 6.0mm	13.0mm

The TSA® dental implants are designed to be placed in one or two surgical stages depending on the biological and prosthodontic spaces and bone quality and quantity.

IMPLANT CONNECTION

The TSA® implant has four connections: external hexagon, internal hexagon, external cone and internal cone. The internal and external hexagon connections provide antirotation of the prosthetic elements fixed to the implant in the two equidistant spatial planes.

The internal and external cone connections provide the direction for the axial, radial and flex stresses, thereby securing the prosthesis on the implant. Retention is provided by the retainer screw, measuring 1.6mm for Series 3 and 1.8mm for the rest.

03 INSERTION SPECIFICATIONS

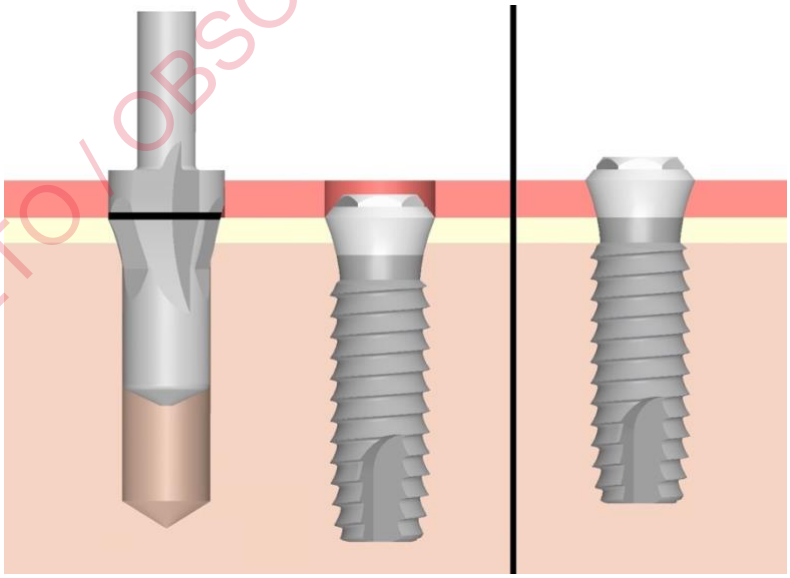
The insertion specifications described in this procedure for each TSA® implant series are based on the type of root surface of the tooth to be replaced and on the average size, surface area and the functional chewing force loads that the natural crown has to bear.

INSERTION HEIGHT

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

In specific cases characterised by a decreased interocclusal space with aesthetic demands, the implant shoulder should be positioned at bone crest level. The drilling length for implant insertion is the length of the implant. This configuration is not available for the 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 rate of success due to the potential retraction of hard tissue. For these specific cases, it is mandatory to use the countersink drill (ref 178.0037 for S3, ref. 178.0047 for S4 and ref.178.0060 for S5) if this drill is not used, the implant placement can produce excessive pressure in the surrounding bone causing a greater retraction of the tissues and therefore a potential decrease of the success rate.



The infracrestal configuration is not available for the references TSA 04.060, TSA 04.070, TSA 05.060 and TSA 05.070.

SPECIFIC INDICATIONS AND INSERTION SECTORS

SERIES 3 IMPLANT

- In fixed single and multiple restorations involving the replacement of natural roots and crown support for lateral and central lower incisors
- Indicated in the restoration of completely edentulous patients by means of an overdenture supported by four or six implants in the middle and anterior sectors, stented by a rigid metal structure.
- Indicated in the restoration of completely edentulous mandibles by means of an overdenture supported by two or four implants in the anteroinferior sector, stented by a rigid metal structure.
- For Click&Fix abutments, the restoration of total edentulous patients is performed by means of an overdenture supported by two or more implants.

SERIES 4 IMPLANT

- In fixed single and multiple restorations involving the replacement of natural roots and crown support for central incisors, canine teeth and premolars in the maxilla, and canine teeth and premolars in the mandible.
- Indicated in the restoration of completely edentulous patients by means of an overdenture supported by four or six implants in the middle and anterior sectors, stented by a rigid metal structure.
- Indicated in the restoration of completely edentulous mandibles by means of an overdenture supported by two or four implants in the anteroinferior sector, stented by a rigid metal structure.
- For Click&Fix abutments, the restoration of total edentulous patients is performed by means of an overdenture supported by two or more implants.

SERIES 5 IMPLANT

- In fixed single and multiple restorations involving the replacement of natural roots and crown support for molars in both the mandible and the maxilla.
- For Click&Fix abutments, the restoration of total edentulous patients is performed by means of an overdenture supported by two or more implants.

IMPORTANT NOTE

Implants measuring 8.5 mm in length or shorter are not indicated in bone of type III or IV osseous quality for supporting a single crown.
The design of the product, its behaviour and the success of the treatment are based on the indications given above. Therefore, all those products that do not conform to the indications described and the clinical cases involving insufficient bone, advanced surgery, application of biomaterials, sinus lifts, bone fillings, advanced surgical techniques, and disparallelisms between implants, among others, are not covered by any guarantee.

MINIMUM DISTANCE BETWEEN TEETH AND IMPLANTS

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

IMPLANT CARD

For those products that are implantable, the healthcare professional must provide an implant card to the patient. You can download an implant card from the Downloads section of Phibos website (www.phibo.com). The patient must receive an implant card with the traceability of the product (reference and lot number), as well as a description of the product, recommendations and precautions to be taken into consideration.

PRODUCT LIFETIME

The lifetime of the implant systems is estimated at 10 years for implantable products, 5 years for permanent abutments and 1 year for provisional abutments. The instruments have an indefinite lifetime depending on the use they are given, unless specifically indicated otherwise, as it is the case of surgical drills, with a stipulated maximum number of 10 uses.

GUARANTEE PLAN

The design of the product, its behavior and success of the treatment are based on the indications shown above, being exempt from any guarantee all those products that do not comply with the indications described and in clinical cases with insufficient bone, clinical cases with advanced surgeries, incorporations of biomaterials, maxillary sinus elevations, bone fillings, advanced surgical techniques, disparalelisms between implants, among others.

The use of the product outside of the indications for use specified here are excluded from the Product Guarantee Program. Any not indicated use (off-label), such as placement in a dental sector not indicated or the use of abutments and / or instruments not compatible with the product, entails additional foreseeable risks that can cause non-osseointegration or loss of the implant, as well as fractures or unplanned surgical interventions.

INCIDENT REPORT

In case of detecting an incident in a patient, immediately notify Phibo as a manufacturer by one of the following ways:

Via web, accessing the application with your user http://customercenter.phibo.com/
Or by downloading the quality guarantee form from the download 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 is implant or abutments, also include x-rays with loaded prostheses.

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

If you need it, you can request a pick-up from Customer Service by calling +34 937 152 688. You can also contact us by email: garantiacalidad@phibo.com

04 TREATMENT PLANNING

The objective of treatment with dental implants is to restore the functionality of the lost natural teeth.
To achieve the objectives of the treatment, treatment planning from the standpoint of prosthodontic restoration is established as the fundamental basis of treatment. To this end we use the patient's medical history, clinical radiological diagnosis, examination, use of study models, among others, in accordance with standards and general protocols applied in implantology.
Phibo® recommends performing a three-dimensional study (CT scan) and using surgical splints to position the implants correctly in the 3 dimensions (apexcrown, mesiodistal or vestibulolingual or palatal). The CT scan will reveal bone quality, an important factor for the drilling technique.

The general information to be gathered for treatment to be carried out is:

- Medical history.
- Personal and family medical history.
- General medical condition.
- State of dental health.
- Clinical and radiological exploration.
- Recording of anatomical condition through study models.
- Diagnosis and treatment plan.
- Patient's expectations.
- Possible contraindications.

CONTRAINDICATIONS

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

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

WARNINGS AND PRECAUTIONS

Implant with length of 8.5 mm or shorter are not indicated on bone type III or IV bone quality to support a unitary crown, as they may suffer from a lack of primary stability.
In 8.5 mm implants or shorter, it is not indicated to position the implant shoulder at bone crest level, as they may suffer excessive pressure and cause a greater retraction of the tissues and, a potential decrease of the success rate as well. Surgical indication at bone crestal level may lead to a lower success rate due to the potential retraction of bone tissue.
For crestal insertion, the cortical countersink drill must be used (ref 178.0037 for S3, ref 178.0047 for S4 and ref 178.0060 for S5), otherwise, implant placement may cause excessive pressure in the bone surrounding the implant causing a greater retraction of the tissues and a potential decrease of the success rate as well. This configuration is not available for commercial references TSA 04.060, TSA 04.070, TSA 05.060 and TSA 05.070.

For insertion into the bone bed, it is necessary to adjust the torque of the contra-angle and the ratchet torque to a maximum torque of 35 N·cm. If these forces are exceeded, it may lead to a lack of fitting between the implant and the abutment, as well as increasing the probability of fracture of the rehabilitation.

DIAGNOSIS AND TREATMENT PLAN

To confirm the initial diagnosis, impressions are made to obtain study models which are placed in a semi-adjustable articulator guided by the bite registration. This enables a diagnosis to be made of the edentulous zones and the dimensions of the available space, the patient's occlusion, the antagonist arch type of the sector to be restored.

A reconstruction wax-up is also made to establish the dimensions and design of the future prosthesis. The wax-up makes it possible to prepare the provisional restoration and build surgical guides for the placement of the implants and prosthodontic restorations needed for their insertion.

The clinical and radiological exploration and study of the models are basic tools for defining the type of restoration needed to ensure that the patient recovers his or her anatomical characteristics, chewing function and aesthetic appearance. A treatment plan is drawn up to include the planning of the restoration over time, type of prosthesis, and number of implants required as supports for the type of prosthesis, their position level regarding the osseous crest and the soft tissue, among other considerations.

The treatment plan and its scheduling constitute the fundamental basis for safeguarding the biological structures. The objectives are to plan the load along the implant axis, avoid extension elements, manage transversal loads, control stability, occlusion, hygiene and parafunctions, stimulating the osseous anchorage with the incorporation of a number of implants whose length and diameter are suited to their anatomical placement, making it possible to compensate for the various stresses that occur at different levels.

05 INTRUMENTS

SURGICAL AND PROSTHETIC KIT

The surgical kit is delivered unsterilised.

The design of the surgical kit provides enhanced ergonomics to the surgical field. It is composed of a base, a tray where the surgical instruments are placed, and a closable cover.

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

Before surgery, each component in the kit must be cleaned separately, paying special attention to the areas that are difficult to access.

Because the detergents used as chemical cleaning agents cannot, by themselves, eliminate all the dirt and/or residues, it is essential to clean the components manually and carefully with a sponge or soft cloth to dislodge material that has become adhered during surgery. For areas that are hard to reach, we recommend a clean brush with soft bristles. Do not use solvents, abrasive cleaning products, brushes with metal bristles or abrasive pads. We suggest using a mild, pH-neutral enzymatic detergent. The surgical kit can also be mechanically cleaned in an ultrasonic cleaning tank. Check that all the components in the surgical kit are clean and intact before use. Do not place any instruments in the tray that are not intended to be used with it; this is to avoid overloading the tray or an unsuitable entry of water vapour through the holes.

The processes of cleaning, disinfection and sterilization as well as the preparation of the surgical field are based on procedures of hygiene and safety of the patients, collected in standards and general protocols applied to the dental practice.

The cleaning, disinfection and sterilization protocol can be consulted in the generic instrument and prosthesis instructions for use PROSPDEFEX0123.

SURGICAL DRILLS

It is important to note that the surgical drills are designed for a maximum of 10 uses.
Proper care of the drills, including correct disinfection and cleaning, avoiding knocks, and eliminating any residues, favours their conservation and the maintenance of their cutting specifications. Also note that poor cleaning and maintenance shortens the life and cutting performance of the drills, possibly causing implant failure, and even serious damage to the patient's health.

For the Phibo® TSA Implant system there are two types of surgical drills. Some drills with screw-retained drill stops and another system of surgical drills with interchangeable stops by "click" to orient the depth to perform in the bone bed. Drill stops are optional and sold separately. They are mounted on the laser marks that indicate the height of insertion of the implant.

Drills with screw-retained 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	Surgical Drill Ø2.3mm short
176.1323	Surgical Drill Ø2.3mm long
178.1128	Surgical Drill Ø2.8mm short
178.1328	Surgical Drill Ø2.8mm long
178.1130	Surgical Drill Ø3.0mm short
178.1330	Surgical Drill Ø3.0mm long
178.1136	Surgical Drill Ø3.6mm short

Commercial reference	Product description
178.1336	Surgical Drill Ø3.6mm long
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	Drill Stop Ø2.3mm
DS28	Drill Stop Ø2.8mm
DS30	Drill Stop Ø3.0mm
DS36	Drill Stop Ø3.6mm
DS43	Drill Stop Ø4.3mm
DS49	Drill Stop Ø4.9mm

Drills with “click”-retained stops:

Commercial reference	Product description
175.0001	Precision Drill
175.1018	Round Marking Bur Ø1.8mm
175.1023	Round Marking Bur Ø2.3mm
TS 23000	Surgical 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 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

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

DUAL-PURPOSE WRENCH

The TSA® system wrench has the dual function of controlling torque and tightening the implant. The wrench is delivered unsterilised.

It is important to clean and disinfect it before use. The lower part of the wrench can be used to adjust the torque recommended for inserting or placing implants and for tightening the final prosthesis.

The torque to be used is fixed on the torque ratchet. When the torque ratchet comes to the indicated forces in relation to the set torque, its safety mechanism prevents the transmission of mechanical force.

06 PREPARING THE SURGICAL FIELD

As is the case with processes involving cleaning, disinfecting and sterilising surgical instruments, components and implantology equipment, the preparation of the surgical field is based on hygiene and patient safety procedures as laid down in standards and general protocols applied in dental practice.

Below is a summary of some of these standard protocols with the specific indications applicable to the TSA® implant system. The surgical field must be kept aseptic and sterile before and during the surgical operation.

The general aspects of preparing the surgical field include actions such as:

- The patient's medical history, technical information and treatment plan.
- Sterilised TSA® implant system surgical instruments.
- Instruments, components and general equipment, all sterilised for surgery.
- Surgery table protected by sterile drapes.
- Orderly placement of all instruments on the surgery table so that they are visible for use, taking into account the surgical procedures to be performed.
- Sterile drapes to protect operating room equipment and components.
- Surgical motor with new irrigation tubes.
- Preparing the patient for surgery. Mouthwash, cleaning and disinfection of the surgical site.
- Staff shall wear specific surgical clothing for this purpose, such as surgical gowns, masks, disposable sterile gloves, protective plastic glasses, suitable footwear, etc. In addition, arms and hands must be cleaned and disinfected according to standard protocol.

It is important to point out that, during the surgery, a sterile container with physiological saline solution must be used to deposit used instruments, such as surgical drills, scalpels, wrenches, adaptors, among others, in order to avoid the instruments from being knocked, or getting residue on their surfaces.

07 CLEANING, DISINFECTING AND STERILIZING THE INSTRUMENTS

The processes of cleaning, disinfection and sterilization as well as the preparation of the surgical field are based on procedures of hygiene and safety of the patients, collected in norms and general protocols applied to the practices in dentistry.

The cleaning, disinfection and sterilization protocol can be consulted in the generic instrument and prosthesis instructions for use PROSPDEFEX0123.

IMPORTANT NOTE

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

08 SURGICAL SEQUENCES OF THE INSERTION

IMPORTANT NOTE, PRIOR TO INSERTION

Special, sharp and constantly irrigated instruments should be used when preparing the osseous bed. The specific surgical sequence for the insertion of each implant should be carried out as set forth in this surgical procedure, and at the speeds recommended therein. Otherwise, there may be excessive forces in the insertion of the implant--greater than 35 Ncm-- exceeding the resistance of the bone and causing damage to the implant and its connection, cold soldering of the implant with the mounter, necrosis and bone fracture, etc.

The preparation of the osseous bed is accomplished through an initial surgical insertion sequence that is common to all the series, and a final surgical sequence which is specific to each implant series. During the surgical preparation of the osseous bed of the implant, the following must be borne in mind:

- φ Apply abundant external cooling using a water-based sterile solution or an NaCl solution, pre-cooled to 5º C.
- φ Apply gentle, intermittent pressure to the bone.

INCISION

Implants can be placed with mucoperiosteal incision and raising the flap to get a direct view of the bone or without mucoperiosteal incision using a circular scalpel. Using a circular scalpel requires keratinized gum tissue, proper bone width and a previous three dimensional treatment plan to find out exactly how much bone is available.

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

Once the incision is made, the flap is raised and the bone crest is uncovered, the initial surgical sequence can be started. If the bone crest is narrow, it has to be modified to increase the vestibulo -lingual or palatal width so there is enough bone margin after placing the implant. In clinical cases where the diagnosis reveals the possibility of surgery without raising the soft tissue flap, the circular scalpel is used to access the bone that will house the implant bed.

PREPARING THE BONE BED

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

In specific cases characterised by a decreased interocclusal space with aesthetic demands, the implant shoulder should be positioned at bone crest level. The drilling length for implant insertion is the length of the implant. This configuration is not available for the references TSA 04.060, TSA 04.070, TSA 05.060 and TSA 05.070.

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

Diameter	Product description	R.P.M.
According to 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 Surgical Drill	850
Ø 2.8	Initial Surgical Drill	750

Diameter	Product description	R.P.M.
Ø 3.0	Final Surgical Drill S3	750
Ø 3.6	Final Surgical Drill S4	650
Ø 4.3	Intermediate Surgical Drill S5	550
Ø 4.9	Final Surgical Drill S5	450
According to series	Countersink Drill	350
According to series	Bone Tap	15

INITIAL SURGICAL SEQUENCE / MARKING DRILLS

The initial sequence begins with the Ø1.8mm marking drill, at a rotation speed of 850 rpm. Insert the drill through the surgical stent guide and mark the bone crest. Once you have made the mark with the Ø1.8mm marking drill, continue with the Ø2.3mm marking drill at 850 rpm to mark and increase the diameter of the bone crest, centralising the axis for the osteotomies to follow. Deepen the osteotomy with the Ø2.3mm marking drill until the cortical interface is penetrated.

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

INITIAL SURGICAL SEQUENCE / PRECISION DRILL

We recommend using the precision drill in clinical cases where the diagnosis permits a flapless procedure. You will begin the initial sequence with the precision drill turning at 850 rpm, inserting it through the surgical stent guide, and drilling through the cortical interface of the bone while centralising the axis for the osteotomies to follow.

Commercial reference	Product description
175.0001	Precision drill

DRILLING LENGTH

Once you have drilled through the cortical interface, deepen the perforation with the initial Ø2.3mm twist drill at a speed of 850 rpm to the planned length, applying a gentle, intermittent pressure in order to avoid heating the bone.

Commercial reference	Product description	Length
176.1123	Surgical drill Ø2.3mm short	Length 33.0 mm
176.1323	Surgical drill Ø2.3mm long	Length 41.0 mm
TS 23000	Surgical drill Ø2.3mm intermediate	Length 37.0 mm

Then insert the depth indicator / parallelizer to verify the drilling length, which will allow you to make corrections in the next osteotomy.

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

Perform the next osteotomy with the Ø2.8mm twist drill at a rotation speed of 750 rpm. Deepen the osteotomy to the planned length and then measure the osseous bed length by using the depth indicator.

Commercial reference	Product description	Length
178.1128	Surgical drill Ø2.8mm short	Length 33.0 mm
178.1328	Surgical drill Ø2.8mm long	Length 41.0 mm
TS 28000	Surgical drill Ø2.8mm intermediate	Length 37.0 mm

FINAL TSA® SERIES 3 SURGICAL SEQUENCE

When you have completed the initial sequence for all the series, start the final osteotomy sequence for the Series 3 TSA® implant. The diameters of the shoulder and body, and the rest of the specifications of the TSA® implants, can be found at the beginning of this procedure.

For the final osteotomy to accommodate the Series 3 TSA® implant, use the Ø3.0mm twist drill at a speed of 750 rpm, drilling to the planned depth by applying gentle intermittent pressure.

Commercial reference	Product description	Length
178.1130	Surgical drill Ø3.0mm short	Length 33.0 mm
178.1330	Surgical drill Ø3.0mm long	Length 41.0 mm
TS 30000	Surgical drill Ø3.0mm intermediate	Length 37.0 mm

Insert the Ø3.0mm Series 3 depth indicator to confirm that the total drilled length conforms to the planned length. We recommend threading dental floss through the hole in the depth indicator to prevent it being swallowed by the patient.

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

Where implant positioning at crestal level is indicated, and bone quality is type I and II, use should be made in all series of the crestal surgical drill for conforming the implant shoulder, applying gently intermittent pressure, at a speed of 350 rpm.

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

When the bone quality in the mandibular and anterior maxillary zones and in the thick cortical interfaces are type I or II, you must shape the threading of the implant tap in the osseous bed by using the Series 3 screw tap at a rotation speed of 15 rpm if used with a contra-angle hand piece.

Commercial reference	Product description	Length
181.0136	Bone Tap Short TSA® TSH® S3	Length 33.0 mm
181.0336	Bone Tap Long TSA® TSH® S3	Length 41.0 mm

FINAL TSA® SERIES 4 SURGICAL SEQUENCE

When you have completed the final Series 3 surgical sequence, begin the final surgical sequence for the Series 4 TSA® implant. The diameters of the shoulder and body, and the rest of the specifications of the TSA® implants, can be found at the beginning of this procedure.

The final osteotomy for the Series 4 TSA® implant is performed with the Ø3.6 mm twist drill set to a drilling speed of 650 rpm to drill to the planned depth, applying gentle intermittent pressure.

Commercial reference	Product description	Length
178.1136	Surgical drill Ø3.6mm short	Length 33.0 mm
178.1336	Surgical drill Ø3.6mm long	Length 41.0 mm
TS 36000	Surgical drill Ø3.6mm intermediate	Length 37.0 mm

Insert the Ø3.6mm Series 4 depth indicator to confirm that the total drilled length conforms to the planned length. We recommend threading dental floss through the hole in the depth indicator to prevent it being swallowed by the patient.

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

Where implant positioning at crestal level is indicated, and bone quality is type I and II, use should be made in all series of the crestal surgical drill for conforming the implant shoulder, applying gently intermittent pressure, at a speed of 350 rpm.

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

When the bone quality in the mandibular and anterior maxillary zones and in the thick cortical interfaces are type I or II, you must shape the threading of the implant tap in the osseous bed by using the Series 4 screw tap at a rotation speed of 15 rpm if used with a contra-angle hand piece.

Commercial reference	Product description	Length
181.0142	Bone Tap Short TSA® TSH® S4	Length 33.0 mm
181.0342	Bone Tap Short TSA® TSH® S4	Length 41.0 mm

FINAL TSA® SERIES 5 SURGICAL SEQUENCE

When you have completed the final Series 4 surgical sequence, begin the final surgical sequence for the Series 5 TSA® implant. The diameters of the shoulder and body, and the rest of the specifications of the TSA® implants, can be found at the beginning of this procedure.

The final osteotomy is performed with the Ø4.3-mm twist drill at a drilling speed of 550 rpm up to the planned length, by applying gentle intermittent pressure.

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

Insert the Ø4.3mm Series 5 depth indicator to confirm that the total drilled length conforms to the planned length. We recommend threading dental floss through the hole in the depth indicator to prevent it being swallowed by the patient.

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

The final osteotomy for the Series 5 TSA® implant is performed with the Ø4.9 mm twist drill set to a drilling speed of 450 rpm to drill to the planned depth, applying gentle intermittent pressure.

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

Insert the Ø4.9mm Series 5 depth indicator to confirm that the total drilled length conforms to the planned length. We recommend threading dental floss through the hole in the depth indicator to prevent it being swallowed by the patient.

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

Where implant positioning at crestal level is indicated, and bone quality is type I and II, use should be made in all series of the crestal surgical drill for conforming the implant shoulder, applying gently intermittent pressure, at a speed of 350 rpm.

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

When the bone quality in the mandibular and anterior maxillary zones and in the thick cortical interfaces are type I or II, you must shape the threading of the implant tap in the osseous bed by using the Series 5 screw tap at a rotation speed of 15 rpm if used with a contra-angle hand piece.

Commercial reference	Product description	Length
181.0255	Bone Tap Short TSA® S5	Length 33.0 mm

IMPORTANT NOTE
Intense irrigation in all osteotomies and processes is required until implant insertion.

09 TSA® IMPLANT LABEL

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

10. OPENING OF THE PACKAGE

Before opening the package, examine it to be sure that it is not damaged, opened, perforated or has other defects. Then, check that the details printed on the label match the planned diameter and length. In addition, check the expiry date before opening. The implants are supplied sterilised by gamma irradiation at 25 kGy.
Phibo® system implants are packed individually.

The implant packaging consists of:

- Outer cardboard box with colour code for each implant series, including QR code for the eIFU (electronic instructions for use).
- Triple adhesive label to control traceability and guarantee (traceability removable label to be adhered to implant card.
- Double blister, sealed with Tyvek, guaranteeing implant sterility.
- Outer blister-type. This holds the inside Tyvek. The inner blister contains the implant with the implant holder and the cover screw. They are identified by a colour code indicating the series.

Open the outer cardboard box by pressing on the area showing the word “PRESS” to break the box open along the perforated line. This will free the double blister.

When the outer box has been opened, it is important to note the indications printed on the Tyvek for the correct opening of the outer blister. Be careful not to contaminate the sterile field when handling the outer cardboard box and opening the outer blister. To maintain sterility, these two packaging components must be handled by personnel who do not access the surgical field.

Open the inner blister with caution, after the final osteotomy, following the instructions printed on the Tyvek and placing it in the surgical field. If you open the Tyvek too quickly or with too much force, the cover screw may accidentally fall out of the blister.

IMPORTANT NOTE
If, for whatever reason, the planned surgery is finally not performed, the blister pack containing the implant cannot be stored, maintained or used for another surgery. The inner blister packaging does not maintain the sterility of the implant.
The sterility of the implant is guaranteed until the outer blister pack is opened. Over time, the inner blister does not maintain the conditions required to preserve sterility. Open the inner blister pack in the surgical field, remove the implant from its housing, and then remove the cover screw.

The implant is lodged in the internal blister pack by friction between the implant holder and the area designed for this purpose in the blister. It is important to secure the adaptors well to the implant holder and ensure that they are properly set in place, in order to be able to successfully remove the implant and transfer it to the osseous bed. If the implant falls and loses its sterility, it is absolutely prohibited to manipulate, clean, sterilise or use the implant in the patient.

11. REMOVING THE IMPLANT FROM THE BLISTER

IMPORTANT NOTE

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

Signs and consequences normally associated with excess stress when inserting the implant may include:

- Excessive torsion of the implant holder, causing a cold soldering joint between the implant holder and the implant.
- Perceptible or imperceptible damage to the implant connection, causing fractures of the implant after the restoration in the short or medium term, or lack of fit of the prosthesis with the implant connection.
- Damage to the thread inside the implant, causing subsequent misalignments of the final screws of the prosthesis, breakage of the screws or loss of the internal thread of the implant.

Possible causes:

- Final osteotomy sequence, through a surgical drill with a smaller diameter than established.
- Final drilling and implant insertion sequence in type I and II bone qualities, without matching the thread with the screw tap or matching the implant shoulder, in cases of crest level implant insertion.
- Defective surgical drill cut, etc.

MECHANICAL REMOVAL

With the mechanical adaptor connected to the contra-angle hand piece, insert into the implant holder until you feel a slight friction and hear a click, which means the adaptor has been connected.
Grasp the blister pack firmly and operate the contra-angle hand piece at a speed of 15 rpm.
Then remove the implant by gently separating it from the blister.

MANUAL REMOVAL

Connect the mechanical adapter to the dynamometric wrench and insert it in the implant holder until a slight resistance is felt and a click is heard, indicating that it is connected.
Hold the blister pack firmly and remove it gently vertically without moving it back and forth, separating the implant from the blister pack.

12 INSERTING THE IMPLANT

IMPORTANT NOTE

When the bone quality is type I or II, you should pause briefly and intermittently when performing the insertion, in particular when inserting implants of greater length and diameter.
Irrigate continuously during the entire insertion process. When the final drilling sequence has come to an end, check that the osseous bed is bleeding and vascularising satisfactorily, and ensure there are no sharp osseous projections that might interfere with the insertion of the implant or with subsequent manipulation of the soft tissue.

Before inserting the implant and after the final drilling sequence, it is important to verify, by using the depth indicator, that the length matches the planned value, and to ensure that the osseous bed is free of any drilling residue.

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

PRIMARY STABILITY

Various factors such as bone characteristics, bone quantity and quality, implant location and preparation technique, among others, will directly influence the degree of stability.

MECHANICAL AND MANUAL INSERTION

In the case of mechanical insertion, it is advisable not to insert the entire implant mechanically, and to complete the insertion manually with the dynamometric wrench, leaving it at the desired height and thus perceiving more directly the primary stability of the implant It is important to start the implant insertion slowly, maintaining continuous irrigation during the insertion, with a maximum insertion torque of 35Ncm and a rotation speed of 15 rpm.

During the implant insertion, you must not exceed the prescribed forces, make brusque movements or adopt positions with the surgical instruments during the insertion that would not align them with the axis of the osseous bed, thus giving rise to undue forces and tensions in the implant holder and implant.

13 REMOVING THE IMPLANT HOLDER

After inserting the implant, you must use the open-end wrench for the implant holder, with the objective of minimising the movements of the implant and maintaining the maximum stability during the removal of the retention screw of the implant holder.

With the open-end wrench is in place, insert the manual or mechanical screwdriver in the retention screw. To remove the retention screw, turn it anti-clockwise. The implant holder retention screws are calibrated with a specific torque so that they can be unscrewed manually or mechanically without any problems. The screwdriver retains the retention screws by friction.

Commercial reference	Product description
172.0001	Open end Wrench

If the forces applied were greater than those indicated previously, the retention screw may have been screwed down tighter than normal to the implant holder, which may be slightly locked onto the implant by the friction and torsion of these elements. In retention screw removal and subsequent implant holder removal operations, we recommend using the open-end wrench, making small anti-clockwise movements in order to unlock the components.

Now use a mosquito clamp to remove the implant holder.

Then, depending on the planned treatment, finish the surgery according to the chosen procedure, first cleaning the area and the implant with physiological saline solution, eliminating any possible particles and elements resulting from the osteotomy that may hinder the placement and fit of the components and accessories to be used.

14 PROCEDURES WITH PHIBO®

To finish the surgery, depending on the planned treatment, there are various procedures in the Phibo® implant system. Consult the TSA® system prosthodontic procedures to obtain complete, updated information on the processes to apply in the planned treatment.

The various options for finalising the surgery are:

IMMEDIATE AESTHETICS

The “Immediate Aesthetics” function is indicated for the placement of a prosthesis without occlusal contact, after completing the surgery, which has been made previously either in the laboratory or in the clinic.

For more information on immediate aesthetics, see prosthodontic procedure.

ONE-STAGE SURGERY

Procedure indicated in cases of medium-high bone density and quality. The minimum recommended waiting time before restoration is 6 to 8 weeks.

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

TWO-STAGE SURGERY. DELAYED FUNCTION

Procedure indicated for clinical cases where forces and stresses of any type to the implant must be avoided, and in cases of low cortical and trabecular bone density and quality that compromises the stability of the implant with respect to the type of restoration planned.

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

In the second phase, the soft tissue will be modelled around the healing abutment or the ProUnic Plus® abutment healing cap.

REMARKS REGARDING THE PROCEDURES

The procedures described above are recommended in optimal osseous and clinical situations. The average times for osseointegration of the implant indicated in the procedures vary according to factors such as insufficient bone, clinical cases with complex surgery or techniques, application of biomaterials, sinus lifts, bone fillings, disparallelisms between implants, in addition to the diameter and length of the implant, insertion sector, planned prosthodontic restoration, margin and tissue height, cortical space, interdental distance and aesthetic commitments, among others.

POST-SURGICAL MAINTENANCE AND CONTROL

After surgery, it is important to perform post-surgical follow-up and control, to include radiographic examinations and periodic checkups, according to general standards and protocols applied in implantology.

Surgical Procedure

TSA®

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