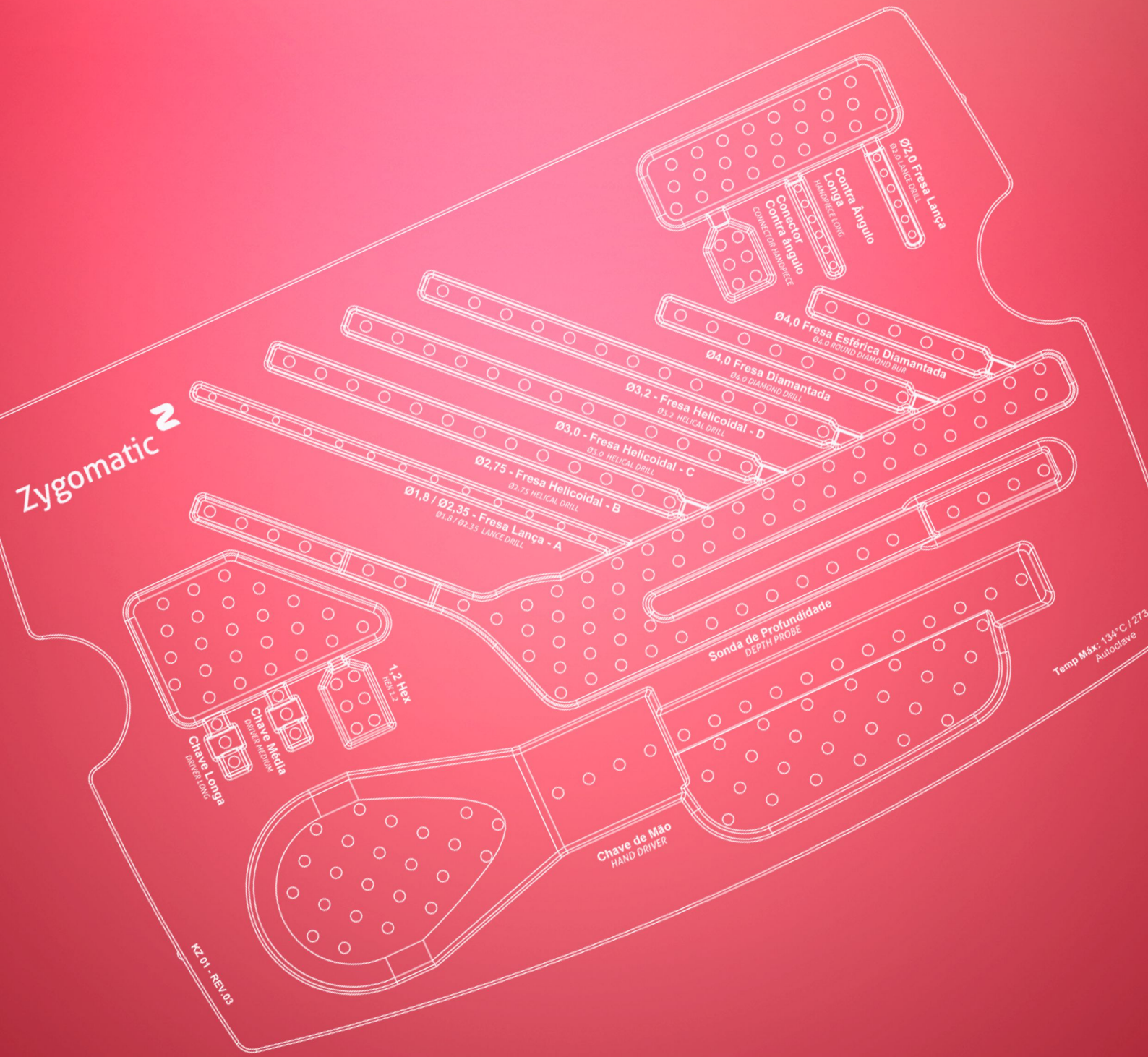
USER MANUAL
ZYGOMATIC



S.I.N.
Implant System

Zygomatic

ABOUT THIS MANUAL

Basic information about the S.I.N. advanced surgery system for Zygomatic implants offers the accredited dental surgeon the critical steps for planning surgical treatment with Zygomatic dental implants.

S.I.N. warns that the information in this manual alone is not enough to ensure that the worker is able to perform dental implant insertion surgery with anchorage in zygomatic bone.

For the correct use of the system, professional qualification in the specific dental area is required according to local regulations and advanced surgery training / accreditation for Zygomatic implants is recommended.

For specific product information provided by third parties, please contact the respective companies directly.

Note: Products featured in this manual may not be available in all markets, consult your local S.I.N. representative for more information.

S.I.N. Implant System

B

TECHNICAL SPECIFICATIONS

Zygomatic implants are manufactured from commercially pure biocompatible titanium with activated top with double acid etching (DAE) surface coating followed by nano-hydroxyapatite (HAnano) application in the thread area, whereas the cervical area is treated with HAnano only without prior DAE.

They are available in lengths from 30.0 mm to 60.0 mm (table 1) with 2.5 mm intervals between each length. The prosthetic connection used is 16° internal conical and its insertion is made with internal torque wrench supplied in the specific line installation kit where insertion is carried out with an insertion driver supplied and coupled to the implant.

The implant's platform angle with internal conical connection is given through abutments specific to each line.

Zygomatic Implants are to be implanted in the upper jaw arch to provide support for fixed dental prostheses in patients with fully edentulous maxillae. S.I.N. Zygomatic implant have both threaded and unthread part. The threaded portion of the implant is located in its apical part and is designed to provide anchorage in the zygomatic bone of the patient, surgeon must expect a high density bone at this area (D1/D2). The unthreaded smooth surface is intended to obtain passive stability upon the alveolar process with a press-fit insertion on surgical alveoli, or to rest against the bone, depending on the chosen technique. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. These implants are not intended for single unit loading.

LIST OF APPLICABLE PRODUCTS			
CODE	THREAD DIAMETER (MM)	PLATFORM DIAMETER (MM)	LENGTH (MM)
ILMZ 4030EN	Ø4.0	Ø4.0	30
ILMZ 4032EN	Ø4.0	Ø4.0	32,5
ILMZ 4035EN	Ø4.0	Ø4.0	35
ILMZ 4037EN	Ø4.0	Ø4.0	37,5
ILMZ 4040EN	Ø4.0	Ø4.0	40
ILMZ 4042EN	Ø4.0	Ø4.0	42,5
ILMZ 4045EN	Ø4.0	Ø4.0	45
ILMZ 4047EN	Ø4.0	Ø4.0	47,5
ILMZ 4050EN	Ø4.0	Ø4.0	50
ILMZ 4052EN	Ø4.0	Ø4.0	52,5
ILMZ 4055EN	Ø4.0	Ø4.0	55
ILMZ 4057EN	Ø4.0	Ø4.0	57,5
ILMZ 4060EN	Ø4.0	Ø4.0	60

Table 01: *List of applicable products*

SURGICAL INSTRUMENTS

The spade drill and helical drill are manufactured from stainless steel with DLC (Diamond Like Carbon) coating for greater cut effectiveness and wire durability. Other kit components, including drivers, diamond Drills, drivers and probes are made with surgical stainless steel. Trays and case base and cover are made from autoclave sterilization-resistant polymer.

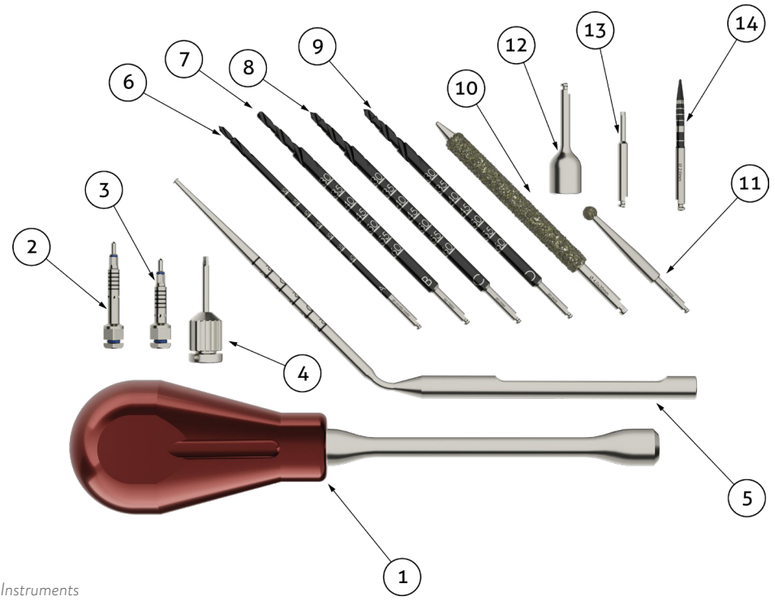


Figure 1: *Surgical Instruments*

ZYGOMATIC KIT			
ITEM	CODE	DESCRIPTION	QUANTITY
KZ 01		ZYGOMATIC KIT - BASE	1
		ZYGOMATIC KIT - COVER	
		ZYGOMATIC KIT - TRAY	
1	CMZ	HAND DRIVER	1
2	CCM 01L	DRIVER LONG	1
3	CCM 01M	DRIVER MEDIUM	1
4	CDH 1224	HEX 1.2	1
5	SOPZ	DEPTH PROBE	1
6	FRLZ 27	LANCE DRILL Ø1.8 / Ø2.35 mm	1
7	FHZ 2030	HELICAL DRILL Ø2.75 mm	1
8	FHZ 2932	HELICAL DRILL Ø3.0 mm	1
9	FHZ 3234	HELICAL DRILL Ø3.2 mm	1
10	FBD 40	DIAMOND DRILL	1
11	FBD 40E	ROUND DIAMOND BUR	1
12	CQCA 27	CONNECTOR HANDPIECE	1
13	CTHA 1224	HANDPIECE LONG	1
14	FL 20M	Ø2.0 LANCE DRILL	1

Table 02: *Zygomatic Kit*

C

PREPARATION

S.I.N. Implant System recommends that at least two units of each Zygomatic implant measurement be available for the surgical procedure. **Zygomatic** implants are indicated for total rehabilitation of atrophic upper jaw of which zygomatic bone anchoring is needed as a mean to prevent the use of additional graft procedures.

For the upper jaw anterior region S.I.N. Implant System recommends that 7 to 15 mm length implants or any implant model available from SIN Implant System be available to the worker (figures 2, 3 and 4). **Zygomatic** implants may receive immediate load when coupled with other implants and when inserted with adequate primary stability.

For drilling it is recommended to use a straight or angled handpiece or a contra-angle for coupling the Drills. For rehabilitation in single surgical stage, it is necessary to use prosthetic intermediates (multi-unit abutments and their respective protectors) which must also be available at the time of surgery.

Surgical site preparation must follow basic principles of implantology surgery, preceded by medical and X-ray examinations, computer tomography, digital photography and reverse rehabilitation planning.

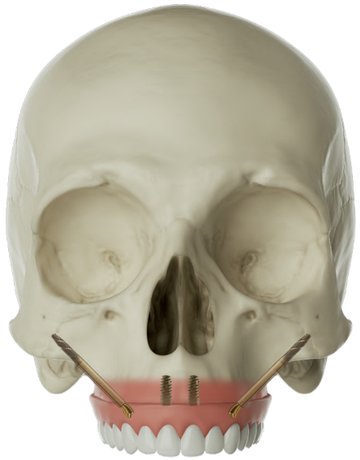


Figure 2. *Example of zygomatic implant insertion associated with anterior implants*

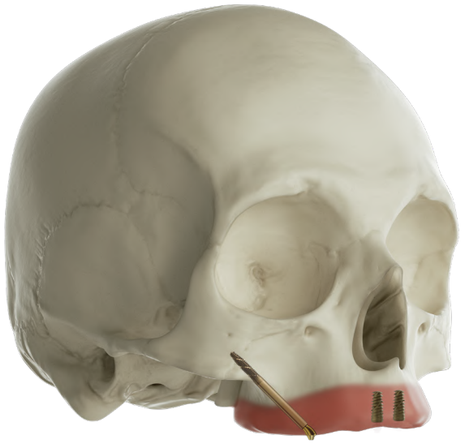


Figure 3. *Detail of zygomatic implant and its anatomical relation with the eye socket*

Figure 4. *Zygomatic implant with the threaded apical inserted into the Zygomatic bone*

D

SURGICAL TECHNIQUE

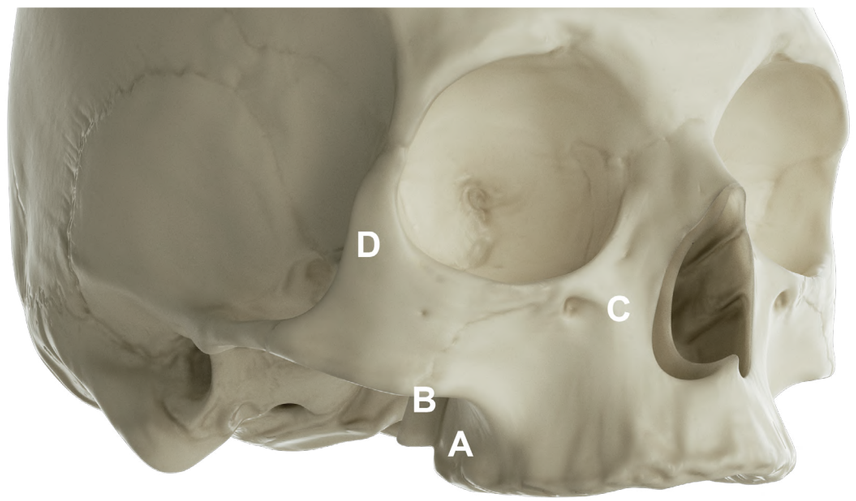
There are specific surgical techniques for the insertion of zygomatic implants, from traditional implants with zygomatic fossa exterior insertion to the trans-sinus technique described by Stella & Warner (2000). This type of procedures requires advanced knowledge and specific training.

1. INCISION

The incision is made in the maxilla ridge with two relaxing vertical incisions in the second molar region. After the incision, a mucoperiosteal flap is raised to expose the entire region where the implants will be installed. The entire extension of the upper jaw should be exposed to the piriform aperture, canine pillars, zygomatic and the entire alveolar process.

2. ANATOMY

Since this is an unconventional insertion for implant therapy, additional care must be taken to avoid damage to noble regions such as vascular structures and adjacent innervations to the surgical area to prevent injury that may result in trans- and post-surgical complications such as bleeding, neural damage and impairment, ocular globe damage and other complications.



A - Maxilla sinus posterior plate
B - Zygomatic suture
C - Infraorbital foramen
D - Zygomatic Frontal Notch

Figure 5. *Anatomy*

3. POSTERIOR ORIENTATION

Carefully expose the alveolar crest to the infraorbital foramen level for better anatomical orientation (Figure 6).

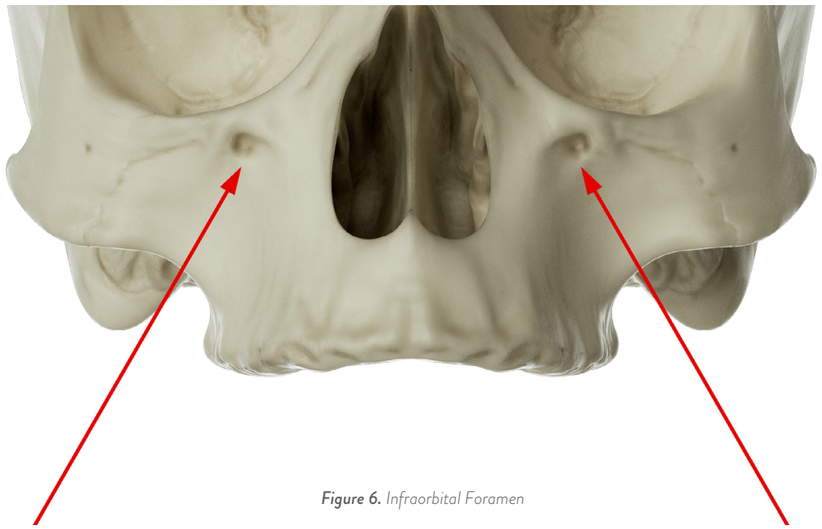


Figure 6. *Infraorbital Foramen*

4. POSTERIOR ORIENTATION

Expose the body of the zygomatic bone carefully to the level of the orbital nerve. Identifying and protecting the infraorbital nerve is essential to avoid injury and damage to the patient. Osteotomy must be performed as far posterior as possible, observing a 3 mm distance from the zygomatic bone posterior margin (Figure 7).

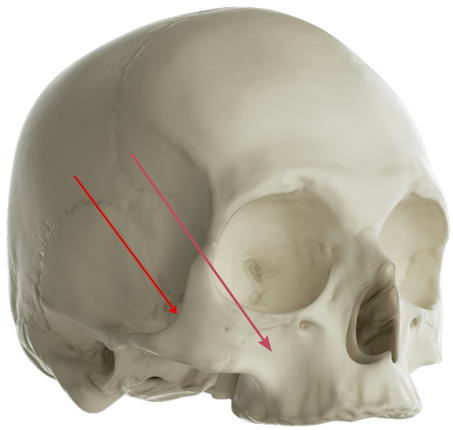
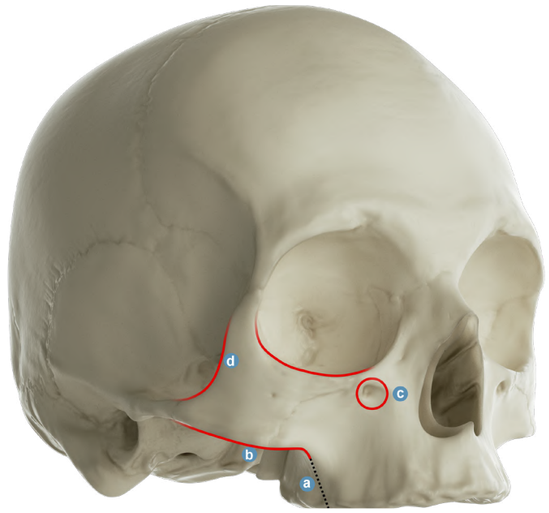


Figure 7. *Zygomatic bone posterior margin*



5. ORBITAL PROTECTOR

Position a retractor on the zygomatic frontal notch to facilitate view to the implant apical point and specially to prevent penetration of the orbital floor. When preparation is complete, reference points A through D will be visible (Figure 8).

Figure 8. *Anatomical references to protec orbital cavity from injury.*

6. VIEWING WINDOW

If necessary, according to the surgical technique used by the worker, carefully open a window of approximately 10 mm x 5 mm into the lateral plate of the maxilla sinus near the lower ridge of the maxilla bone. This window may vary in size and geometry according to each patient's anatomy and the surgical technique selected for each case. Maintain the maxillary sinus membrane intact, whenever possible. (Figure 9).

Figure 9. *Viewing Window*

E

SURGICAL PROCEDURES

After previous preparations of the maxilla ridge and buccal window, bone perforation procedures are initiated for subsequent insertion of the zygomatic implant. The sequence of standard Drills should be strictly followed, always with abundant water spray throughout the drill to avoid bone heating.

ROUND DIAMOND BUR

Made from surgical stainless steel with permeated diamond, this instrument is used for initial alveolar marking, severing the cortical bone ridge, marking the region to be drilled later; this Drill is driven by wear rather than cuts as other kit Drills.

- Maximum rotation: 1200 rpm;
- Position the Drill slightly leaned over the bone ridge and start drilling with light pressure;
- The cut depth should not exceed half the ball, otherwise it may cause heating.
- Do not make lateral movements during drilling, this could damage the alveolus and make it impossible to install the implants;
- Use abundant and uninterrupted irrigation.

Figure 10. ROUND DIAMOND BUR

2. LANCE DRILL

Made of surgical stainless steel with parallel helical profile, this instrument is used for the initial marking of the surgical alveoli, breaking the cortical bone crest for safe passage and no lateral deviations to the other Drills of the system.

- Maximum rotation: 1200 rpm;
- Position the Drill slightly leaned over the bone ridge and start drilling with.
- Do not make lateral movements during drilling, this could damage the alveolus and make it impossible to install the implants;
- Use abundant and uninterrupted irrigation.

Figure 11. LANCE DRILL

3. LANCE DRILL (A)

Made of surgical stainless steel with DLC (Diamond Like Carbon) coating, this instrument is used for zygomatic bone medial wall surgical alveoli perforation, breaking the cortical bone crest for safe passage and no lateral deviations to the other Drills of the system. This Drill has depth indication markings and must follow the longitudinal size of the implant to be inserted.

- Maximum rotation: 1200 rpm;
- Laser Marking: 30.0 to 60.0 mm;
- Position the Drill on the mark made with the spherical Drill and start drilling with slow and intermittent movements;
- Do not make lateral movements during drilling as this may damage the cavity and hinder implant insertion;
- Use abundant and uninterrupted irrigation.

Figure 12. LANCE DRILL (A)

Figure 13. DIAMOND DRILL

4. DIAMOND DRILL

Made from surgical stainless steel with coarse granulation diamond coating, 4 mm diameter pencil-shaped inactive tip.

- Maximum rotation: 1200 rpm;
- Position the Drill on the marking made with the helical lance and start drilling with slow and intermittent movements to enlarge the alveoli;
- Use abundant and uninterrupted irrigation.

5. HELICAL DRILL (B)

Made of surgical stainless steel with parallel helical profile and high cutting power, this tool is used for initial drilling of the cavity, creating a safe and bone-free passage for the other drills of the system.

- Maximum rotation: 800 rpm;
- Laser Marking: 30.0 to 60.0 mm;
- Position the Drill on the mark made with the anterior Drills and start drilling with slow and intermittent movements until reaching the predetermined depth;
- Do not make lateral movements during Drilling as this may damage the aveolous and hinder implant insertion;
- Use abundant and uninterrupted irrigation.

Figure 14. HELICAL DRILL (B)

6. HELICAL DRILL (C)

Made of surgical stainless steel with parallel helical profile and high cutting power, this instrument is used for the final perforation of the alveoli and has depth indications on the stem for drilling according to implant size.

- Maximum rotation: 800 rpm;
- Laser Marking: 30.0 to 60.0 mm;
- Position the Drill on the mark made with the spherical Drill and start Drilling with slow and intermittent movements to the predetermined;
- Do not make lateral movements during Drilling as this may damage the surgical alveoli and hinder implant insertion;
- Use abundant and uninterrupted irrigation.

Figure 15. *HELICAL DRILL (C)*

7. HELICAL DRILL (D)

Made of surgical stainless steel with parallel helical profile and high cutting power, this instrument is used for the final perforation of the alveoli and has depth indications on the stem for drilling according to implant size.

- Maximum rotation: 800 rpm;
- Laser Marking: 30.0 to 60.0 mm;
- Position the Drill on the mark made with the spherical Drill and start Drilling with slow and intermittent movements to the predetermined;
- Do not make lateral movements during Drilling as this may damage the surgical alveoli and hinder implant insertion;
- Use abundant and uninterrupted irrigation.

**The Spade and Helical Drills (A, B, C, and D) have alternative short options to facilitate milling in specific cases and are sold separately.*

Figure 16. *HELICAL DRILL (D)*

8. DEPTH PROBE

Made of titanium, the depth rods aim to assist the worker in the exploratory probing of the freshly drilled cavity and guide the professional in the perforated length. Perform the probing with each drilling performed.

Figure 17. *Depth Probe*

9. OPENING THE PACKAGE

The package contains the sterilized implant and must be handled with sterile surgical gloves in a sterile surgical drape.

- Easy to open package and handled with gloves;
- Tube made entirely of titanium prevents implant contact with other materials;
- Keeps implant and cover screw in separate compartments;
- Upper opening system with turning system that ensures implant sterilization;
- With its own connector, capture the implant with the contra-angle handpiece and move it until it perfectly fits the implant with internal conical connection;
- The Zygomatic system with MT type connection offers the implant cover in the same package (blister).

10. IMPLANT CAPTURE SYSTEM

Made from surgical stainless steel. This driver is used to capture the implant and to carry it to the insertion site.

Figure 18. Implant Capture System

- Remove the cap from the titanium tube leaving the implant internal connection exposed;
- If you choose to perform implant insertion with the contra-angle, connect the adapter driver to the contra-angle;
- If you choose manual installation, connect the capture driver directly to the manual driver or ratchet;
- Position the driver over the implant insertion driver and exert slight pressure;
- For best positioning, gently turn the package by hand so that the driver fits completely;
- Zygomatic Implant packaging features a locking system that facilitates driver placement inside the implant;
- Remove the implant from the titanium tube carefully and making sure that the driver is fully attached to the insertion driver;
- Take the implant

11. CONTRA-ANGLE CONNECTOR

Made from surgical stainless steel, the driver is used to adapt the capture driver to the contra-angle if the surgeon chooses the contra-angle insertion.

Figure 19. Contra-angle connector

12. IMPLANT INSERTION DRIVER

Made from surgical stainless steel, the driver is used to be adapted to the implant capture driver and is used if the surgeon chooses Zygomatic implant manual insertion.

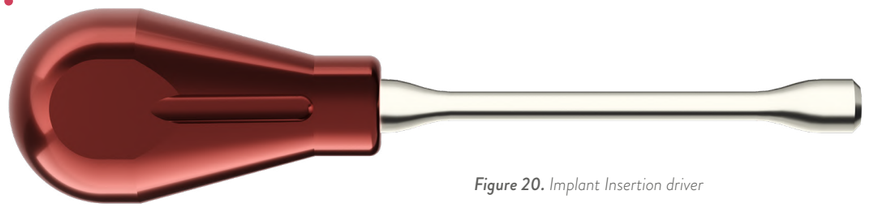


Figure 20. Implant Insertion driver

13. ORGANIZING TRAY BOX

Made from sterilization-resistant polymer, it organizes kit items facilitating sterilization, organization and transport.

Figure 21. Box

F

PROSTHETIC COMPONENTS

Mini conical abutment type abutments with angulations of 17/30 and 45 degrees with strap heights from 2.0 to 4.0 mm made of titanium alloy and anodized in gold color. Its locking torque is 20Ncm. Protectors are screwed over the standard multi-unit abutments with manual torque and should remain in position until the manufacture of the provisional or definitive prosthesis.

20 N.cm

ANGLED MULTI-UNIT ABUTMENT

CODE	ANG.	DIAM. (mm)	LENGTH (mm)
MAAM 4802I	17 °	4.8	2
MAAM 4803I	17 °	4.8	3
MAAM 4804I	17 °	4.8	4
MAAM 4832I	30 °	4.8	2
MAAM 4833I	30 °	4.8	3
MAAM 4834I	30 °	4.8	4
MAAM 4842I	45 °	4.8	2
MAAM 4843I	45 °	4.8	3

ABUTMENT PROTECTOR

CODE
PMA 4855
5,0 mm Profile

OPEN TRAY TRANSFER

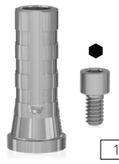
CODE
TMAM 4800

CLOSE TRAY TRANSFER

CODE
TMFM 4800

ANALOG

CODE
ANMA 4800



10 N.cm

TEMPORARY TITANIUM CYLINDER

CODE	
PTM 4800-3	For straight multi-unit
PTMS 4800-3	For straight multi-unit Suitable for laser welding
PTM 4800-2	For angled multi-unit

10 N.cm

CALCINABLE AND CO-CR CYLINDER

CODE	
CPM 4800-3	Plastic for straight multi-unit
CLEM 4800-3	Cobalt chrome for straight multi-unit
CPM 4800-2	Plastic for angled multi-unit
CLEM 4800-2	Cobalt chrome for angled multi-unit

POLISHING PROTECTOR

CODE
PPM 01

LABORATORY SCREW

CODE	DIAM. (mm)
PL 1405 Short	1.4
PTMA 13-1 Long	1.4

10 N.cm

RETAINING SCREW

CODE	LENGTH (mm)	
PRH 20	2	For angled multi-unit
PRH 30	3	For straight multi-unit

G

GENERAL INSTRUCTIONS

Special care and clarification on surgical instruments.

1. KIT CLEANING

- Remove manually all surgical instruments from the kit. Remove the kit box parts (lid, tray and bottom).
- Prepare the enzymatic detergent, according to manufacturer's recommendation.
- Immerse the trays into the prepared detergent solution and keep in contact for at least 5 minutes, then using a soft bristle brush, scrub the parts to remove organic matter from the products.
- Remove trays from detergent solution and rinse with tap water for 1 minute, repeat the rinse for two more times, a total of three rinses of 1 minute each.
- Visual inspection of each part for cleaning process residue or organic waste from product use.
- If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
- Dry with a soft, clean, dry cloth or disposable paper.

2. INSTRUMENT CLEANING

- Disassemble the product (if applicable). For the torque wrench, disassembly it completely, remove all the internal organic matter using tap water and follow to the next step only after performing such procedures.
- Prepare the enzymatic detergent according to the manufacturer's recommendation.
- Immerse all parts of the product into the prepared detergent solution and keep in contact for at least 5 minutes, then using soft bristle brush, scrub the parts to remove organic matter from the products.
- Remove parts from detergent solution and rinse with tap water for 1 minute, repeat the rinse for two more times, a total of three rinses of 1 minute each.
- Visual inspection of each part for cleaning process residue or organic waste from product use.
- If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
- Dry with a soft, clean, dry cloth or disposable paper.
- Follow to sterilization process.

3. STERILIZATION

- Reusable product is supplied non-sterile and must be sterilized before use;
- Dry all instruments before the steam sterilization cycle;
- The product must be enclosed in a steam sterilizable wrap;
- Steam sterilize at 121 °C cycles at 1 ATM pressure for 30 minutes or at a temperature of 134 °C at 2 ATM pressure for 20 minutes;
- Dry for at least 30 minutes;
- Always place the case in an autoclave on a flat surface and away from the sides of the device;
- Never overlap objects or even other cases.

4. CLEANING RECOMMENDATIONS

- Use the proper PPEs (gloves, masks, goggles, caps, etc.);
- Start cleaning immediately after surgical use;
- Never let the instrument dry containing organic waste after surgical use;
- Never let the instrument dry naturally after cleaning;
- Never use saline solutions, especially sodium hypochlorite and physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments and kit trays;
- Never use steel straws or sponges and abrasive products not to damage the instruments;
- Do not accumulate instruments in large quantities on top of one another to avoid deformation of minor and delicate parts.

5. STERILIZATION RECOMMENDATIONS

- Sterilize the products in the same day or one day earlier the procedure.
- The chemical sterilization is not recommended, once some products may cause the discoloration and damages to the case.
- Do not use temperature higher than 60°C to drying process.
- Do not use dry heat stoves for sterilization of the instruments and kits from S.I.N. - Implant System.

H

INFORMATION ON AMOUNT OF DRILLING, WEAR AND HEATING

I. Each drill in the Zygomatic Kit is suitable for up to 30 drillings provided that the rotation and cooling limitations indicated by the S.I.N. Implant System are observed. The worker should evaluate the cutting edge of the drill after each surgical procedure in order to identify possible premature wear due to use that may compromise the safety of other drilling.

J

ADDITIONAL INFORMATION

S.I.N. Implant System provides the dental surgeon with a portal with instructions for use of implants, prosthetic components, instrumental and kits. This portal can be accessed through the website: //www.sinimplantsystem.com.br/downloads/

Or through the QR code present on the external packaging of the products. Just install a free QR code reader application on your smartphone and direct it to the image on the packaging that will direct you to the instructions for use portal.

CONSULTAR INSTRUÇÕES DE USO
Consult Instructions for Use

www.sinimplantsystem.com.br/downloads/
para cópia física: sin@sinimplante.com.br ou 0800 770 8290
for printed version: sin@sinimplante.com.br or 0800 770 8290

K. INFORMATION ON ZYGOMATIC IMPLANT ACCREDITATION

Accreditation in advanced surgery with Zygomatic implants aims to enable the implant dentist to explore all treatment possibilities using this technique.
S.I.N. indicates a number of partners for the accreditation of Zygomatic advanced implant surgery.
Visit the website www.sinimplante.com.br and check the accreditation provider near your location.

L. LIFETIME WARRANTY

S.I.N.'s top priority is to ensure quality and safety for our customers. Offering the best in implants, components, surgical kits and instruments is a principle of S.I.N. and is the basis of our actions.

Our Quality Management System is certified by applicable regulatory agencies and also by international certifying bodies. Quality control is applied to all products manufactured by S.I.N., in order to ensure the success of our clients' surgeries, the compliance to quality standards, as well as adding value to all those who chose to give back the smile to various people.

S.I.N. has a strict process control, from the arrival of the raw material to the delivery of the final product.
Our suppliers are rigorously selected to obtain the best raw material in the market. In addition, we comply with the legislation and specifications of production standards in Brazil, Latin America and Europe, all strictly monitored by specialized professionals and proven through national and international certifications.

We rely on our very high-quality standard and therefore we offer warranty on all products sold as presented in this Policy, so our customers feel safe to use and purchase genuine S.I.N. products.

S.I.N.
Implant System

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