SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Southern Implants® Zygomatic Implants**
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Deutsch	**GEBRAUCHSANWEISUNG: Southern Implants® Zygomatic Implants**
Português	**INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® Zygomatic Implants**

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Intended use
The Zygomatic implants are intended to treat partially or fully edentulous patients with severely resorbed or absent maxillae for whom conventional implants are not an option as a means of fixing a permanent or removable dental or maxillofacial prosthesis.

Intended user
Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists and other appropriately trained and experienced implant users.

Intended environment
The Zygomatic implants are intended to be used in a clinical environment such as an operating theater or a dentist consultation room.

Intended patient population
This device is used in the dental restoration of partially or fully edentulous patients in the upper or lower jaw. Restorations may comprise single teeth, partial or full bridges, and may be fixed or removable.

Description
The Southern Implants Zygomatic range includes the standard Zygomatic-, the ZYGAN-, the Oncology and the ZYGEX Implants. The implants are up to 60mm long to enable anchorage in the zygoma and have a 55° head angle. They are made from biocompatible, commercially pure Titanium and are available in a range of lengths to be used with a range of prosthetic components (see the Zygomatic Implant product catalogue). All Zygomatic and Zygan implants in this range present the MSc feature, a 6mm coronal area of specific roughness.

Indications for use of our Zygomatic implants
The Southern Implants Zygomatic Standard Implant, the ZYGAN (narrow apex)-, the Oncology and the ZYGEX (narrow apex) implants are intended to be implanted in the maxilla to provide support for fixed or removable dental prostheses in patients with partially or edentulous maxilla. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. This implant system is not intended, nor should it be used, in conjunction with an angled abutment. These implants are not intended for single unit loading.

Contraindications
Do not use in patients:
- who are medically unfit for oral surgical procedures,
- with inadequate bone volume for zygomatic or conventional implants, or where adequate numbers of implants can't be placed to achieve full functional support of a prosthesis.
- who have undergone irradiation of maxillary bone.
- who are under the age of 18, have poor bone quality, blood disorders, infected implant site, vascular impairment, uncontrolled diabetes, drug or alcohol abuse, chronic high dose steroid therapy, anti-coagulant therapy, metabolic bone disease, radiotherapy treatment and sinus pathology.

Warnings
THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING.

- For the safe and effective use of dental implants it is suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements and radiographic evaluations.
- Responsibility for proper patient selection, adequate training, experience in the placement of implants, and providing appropriate information for informed consent rests with the practitioner. Improper technique can result in implant failure, damage to nerves / vessels and / or loss of supporting bone.
- The use of non-sterile items can lead to secondary infections of the tissue or transfer infectious diseases.
- Blunt drills may cause damage to the bone which could compromise osseointegration.
- Implant failure increases when implants are placed in irradiated bone as radiotherapy can result in progressive fibrosis of vessels and soft tissue, leading to diminished healing capacity. Additionally, use of Zygomatic Implants in bone tissue which has been irradiated as part of cancer therapy may result in the following:

• Delayed or failed osseointegration of implants due to reduced bone vascularity, clinically expressed as osteoradionecrosis
• Tissue dehiscence and osteoradionecrosis
• Implant failure and loss
• Implant treatment of irradiated patients is dependent upon issues like the timing of implant placement in relation to the radiation therapy, anatomic site chosen for implant placement and radiation dosage at that site and consequent risk of osteoradionecrosis.

Cautions
New and experienced Implant users should do training before using a new system or attempt to do a new treatment method. Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (i.e. poor oral hygiene, uncontrolled diabetes, are on steroid therapy, smokers, infection in the nearby bone and patients who had oro-facial radiotherapy.) Thorough screening of prospective implant candidates must be performed including:
- A comprehensive medical and dental history.
- Visual and radiological inspection to determine adequate bone dimensions, anatomical landmarks, occlusal conditions and periodontal health.
- Bruxism and unfavourable jaw relations must be taken into account.
- Proper pre-operative planning with a good team approach between well trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.
- Minimising the trauma to the host tissue increases the potential for successful osseointegration.
- Electro-surgery should not be attempted around metal implants, as they are conductive.

Pre-operative examination and planning
A full medical and dental history must be taken, with emphasis on the presence of soft and or hard tissue pathology. The patient must have clinically symptom-free sinuses and no pathology in surrounding bone or soft tissue.
It is recommended that a CT scan and or CBCT analysis be performed as part of the planning process in order to;

- Detect the presence of any pathology in the maxillary sinuses,
- Bone volume and condition,
- Jaw relationships.
- Zygomatic implants are recommended for the posterior (premolar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration.
- where there is insufficient bone for good stability of anterior implants, a quad Zygomatic protocol is indicated. This inviolves two Zygomatic implants per Zygoma with both of these implants angled to emerge in the anterior region.

Storage, cleaning & sterilisation
The implants, cover screws and healing abutments are supplied sterile (sterilised by gamma irradiation) and intended for single-use prior to the expiration date (see packaging label). Sterility is assured unless the container or seal is damaged or opened. If packaging is damaged do not use the product and contact your Southern representative/ or return to Southern Implants. Do not reuse implants, cover screws, temporary abutments and abutments. Re-using these components may result in:

• Damage on the surface or critical dimensions, which may result in

performance and compatibility degradation.
- Adds the risk of cross-patient infection and contamination if single-use items are reused.

Southern Implants does not accept any responsibility for complications associated with reused components.

Precaution: Maintain the sterility of the implant

1. Care must be taken to maintain the sterility of the implant by proper opening of the packaging and handling of the implant.
2. The outer rigid plastic box and the outside of the inner plastic blister tray-lid are not sterile; do not touch the outside with sterile gloves, and do not place the plastic box or blister tray-lid onto the sterile field.
3. Inside the plastic box, the sealed inner plastic blister and peel back TYVEK lid is sterile only on the inside. The sealed blister is to be opened by an assistant (with nonsterile gloves): remove the TYVEK lid and do not touch the sterile implant.
4. Follow the instructions illustrated in Figures 1 – 4 below to remove the sterile implant, maintaining sterility, and to attach the fixture mount and implant to the handpiece.
5. Maintain the sterility of the implant, after opening the tray and removing the implant, until placement in the surgical site.

Demonstrative images

***Note**: White gloves and background represent non-sterile items. Blue gloves and background represent sterile items.*

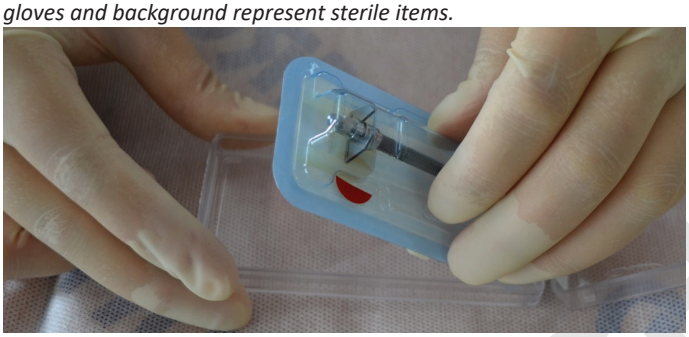


***Figure 1**: To open implant package in the nonsterile field, with non-sterile gloves, tear the address label to open the box. With non-sterile gloves remove the inner blister.*

***Figure 2**: The sealed blister must be opened by an assistant (non-sterile gloves). Peel back the TYVEK lid and present the open tray to the surgeon.*

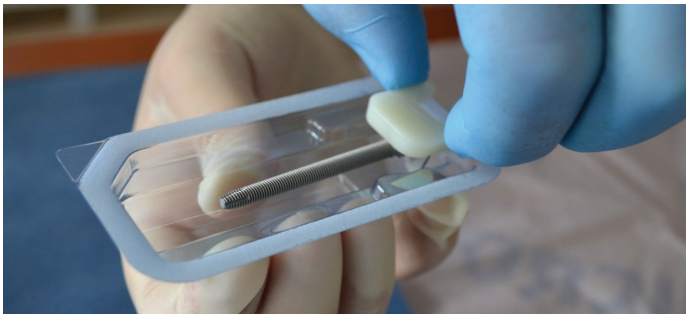


***Figure 3**: Without touching the outside of the blister, the surgeon removes the implant holder. Take care to not touch the implant.*

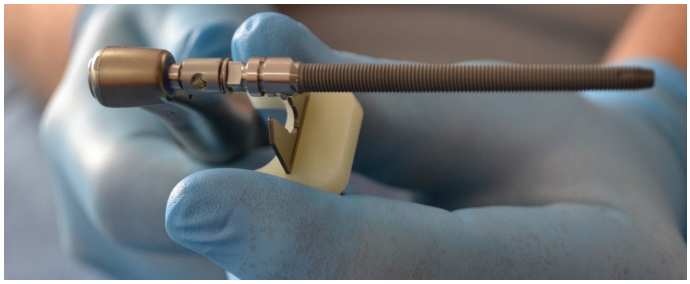
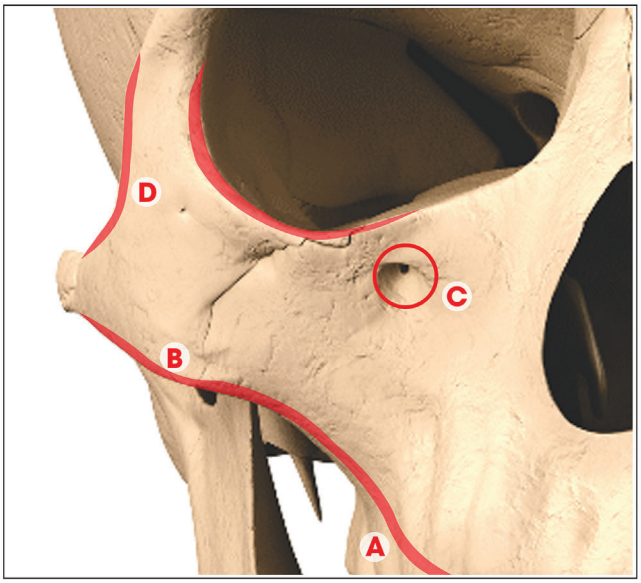


***Figure 4:** Engage the handpiece placement tool (I-CON-X) onto the fixture mount and with upwards movement, remove the implant from the titanium clip on the implant holder.*

During surgery

Take care that parts are not swallowed or aspirated during any of the procedures and apply the correct tightening torque to abutments and abutment screws.

Caution: Identify and protect vital structures like nerves, veins, arteries and especially the infraorbital nerve during surgical exposure of the lateral maxillary wall. Injury to any of these anatomical structures can lead to complications like nerve dysfunction or bleeding.



Anatomical landmarks
A. Posterior wall of the maxillary sinus
B. Zygomatic-maxillary buttress
C. Infra-orbital foramen
D. Fronto-zygomatic notch

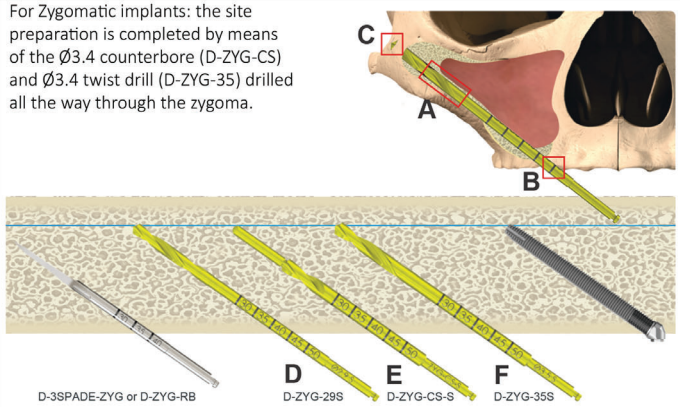
Surgical procedure standard Zygomatic and ZYGAN implants

A crestal incision is made from just anterior to the maxillary tuberosity on one side to the same point on the other side. Three vertical releasing incisions are made in the second molar regions and the midline. These 3 incisions facilitate flap mobilization beyond the infraorbital margin. In unilateral cases a hemi-maxillary approach is used. The buccal mucoperiosteal flaps are raised to expose the infraorbital nerve, the body of the zygoma and the zygomatic arch. A palatal flap is raised to expose the alveolar bone. The periosteum in the region of the upper molar teeth is incised to enhance flap mobility. A modified channel retractor (I-ZYG-RET) is placed on the upper border of the zygomatic arch.

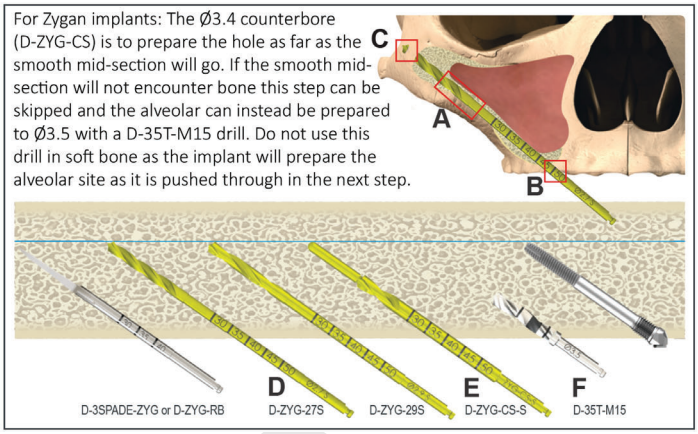
Raise a full thickness mucoperiosteal flap by making a crestal incision with bilateral releasing incisions in the tuberosity area and the midline if necessary.

Cut a small window on the lateral aspect of the maxillary sinus, and try to keep the Schheiderian membrane intact.
For Zygomatic and Zygan implants begin the entrance point of the implant (site preparation) with a round (D-ZYG-RB) or spade design (D-3SPADE-ZYG) pilot drill, at the first- second pre-molar area on the maxillary crest and follow the posterior maxillary wall. Aim to end just in front of the fronto-zygomatic notch to the cavity seen through the sinus window.

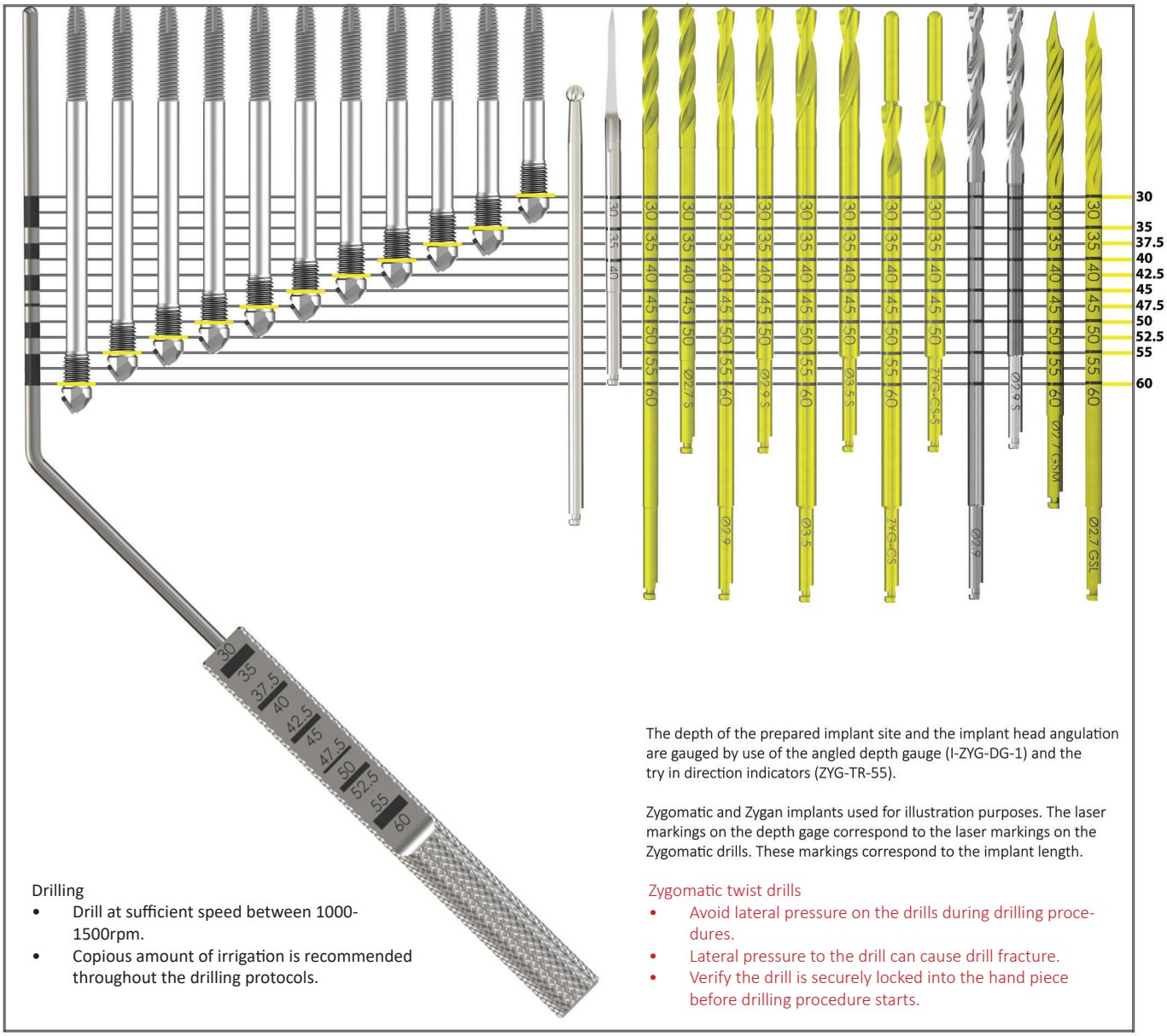
For Zygomatic implants: the site preparation is completed by means of the Ø3.4 counterbore (D-ZYG-CS) and Ø3.4 twist drill (D-ZYG-35) drilled all the way through the zygoma.



For Zygan implants: The Ø3.4 counterbore (D-ZYG-CS) is to prepare the hole as far as the smooth mid-section will go. If the smooth mid-section will not encounter bone this step can be skipped and the alveolar can instead be prepared to Ø3.5 with a D-35T-M15 drill. Do not use this drill in soft bone as the implant will prepare the alveolar site as it is pushed through in the next step.



IMPLANT LENGTH CODES (in mm)



The depth of the prepared implant site and the implant head angulation are gauged by use of the angled depth gauge (I-ZYG-DG-1) and the try in direction indicators (ZYG-TR-55).

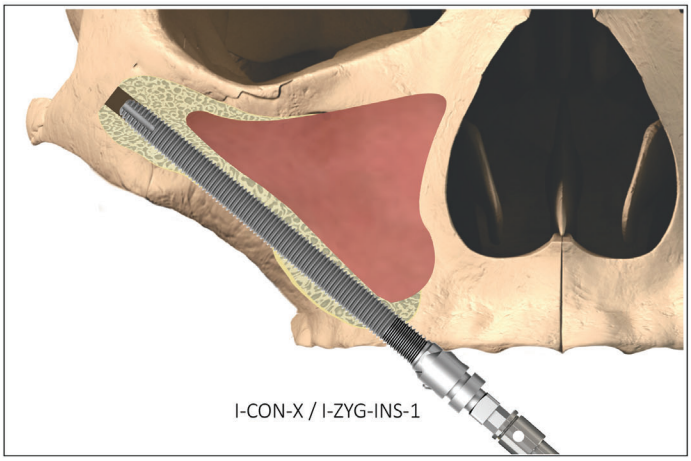
Zygomatic and Zygan implants used for illustration purposes. The laser markings on the depth gage correspond to the laser markings on the Zygomatic drills. These markings correspond to the implant length.

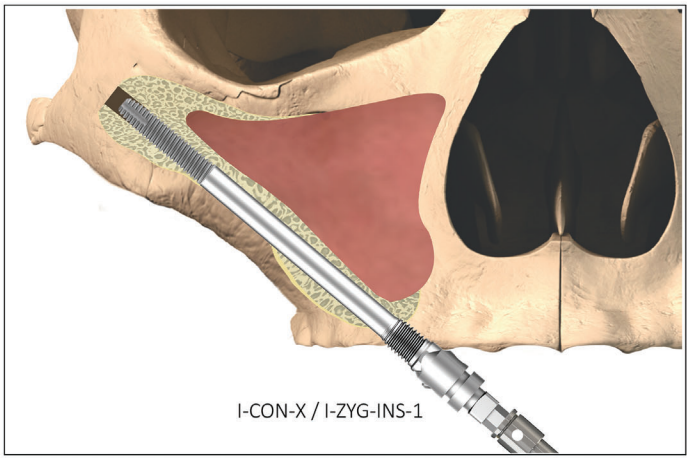
Drilling

- Drill at sufficient speed between 1000-1500rpm.
- Copious amount of irrigation is recommended throughout the drilling protocols.

Zygomatic twist drills

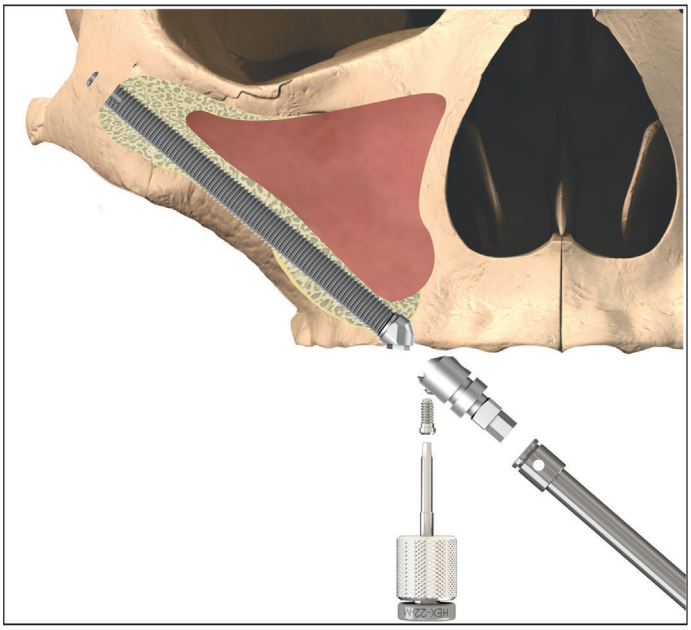
- Avoid lateral pressure on the drills during drilling procedures.
- Lateral pressure to the drill can cause drill fracture.
- Verify the drill is securely locked into the hand piece before drilling procedure starts.

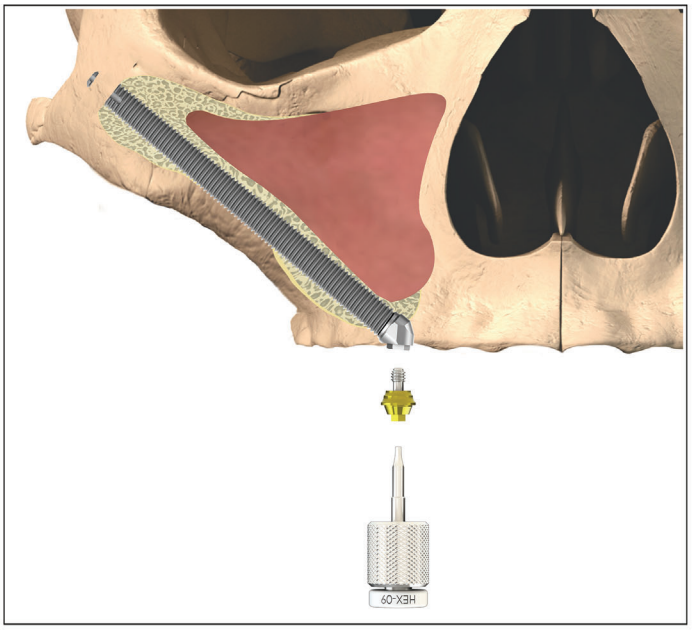




Before inserting the Zygomatic or Zygan implant, ensure that the implant site is free of soft tissue remnants. Any soft tissue that may have been picked up on the implant threads while moving through the alveolus and sinus must be cleared off before the implant enters the zygomatic placement site.

The handpiece with connector (I-CON-X) is used for the initial insertion of the Zygomatic & Zygan implants, with the torque control set at 50Ncm at 15rpm. When the handpiece torques out, switch to the surgical wrench (I- RATCHET-2) or the onion driver (I-ZYG-INS-1). Push the narrow-apex Zygan Zygomatic Implant straight through the alveolar preparation. You will only need to start rotation when the apex reaches the zygoma, thus reducing the insertion time. Avoid applying bending moments to the fixture mount while inserting the implant. Check the fixture mount screw for loosening periodically and re-tighten if necessary.





The implant must follow the prepared path of insertion. One revolution of the implant results in 0.6mm axial movement. Insertion is complete when the head is in the correct prosthodontic position and angle. Remove the fixture mount by loosening the screw with the I-HD (1.22mm). Either place a coverscrew or ø4mm External Hex prosthetic components.

Surgical procedure Oncology and Zygex implants

The same instruments and drilling procedure are used for the Oncology/Zygex Implants as above for the Zygomatic Implants, but since the anatomy is substantially different the procedure differs in the following way:

- No sinus window is required if the maxilla and the sinus have been removed. In this case, drilling begins directly in the zygoma.
- The implant placement position is determined by the available bone. However, in a standard maxillectomy case, the placement angle of the Oncology Implants in the zygoma is more horizontal than a standard Zygomatic Implant.
- Aim to position the head of the implant where the tip of the missing tooth root would have been. The prosthetic platform can be angled slightly forward to assist in the manufacture and fitting of the prosthesis.

Compatibility information

Use only original Southern Implants components to restore Southern Zygomatic ranges. Use components that correspond to the connection type, and prosthetic platform when restoring Zygomatic implants. For further information please see Zygomatic Product Catalogue CAT-2070.

NOTE: Angled Compact Conical abutments are not indicated to be used with Southern Implants Zygomatic implant ranges.

Zygomatic implants and compatible screws, abutments and screw drivers

ITEM CODE	IMPLANT LENGTH CODES (in mm)
ONC-55-	27.5N/ 32.5N/37.5N/42.5N/47.5N
ZYGEX-	30/35/37.5/40/42.5/45/47.5/50/52.5/55
ZYG-55-	30N/37.5N/40N/42.5N/45N/47.5N/50N/52.5N/55N/60N
ZYGAN-	35/37.5/40/42.5/45/47.5/50/52.5/55/60

COVER SCREW & DRIVER	ABUTMENT & DRIVER	PROSTHETIC SCREW DRIVER
SCU2 (Cover screw) I-CS-HD (driver)	AMCZ (Screw retained abutment), I-HAD (Driver)	1 Series screw (prosthetic screw), I-HD-M (driver)

Clinical benefits associated with Zygomatic implants

Patients can expect to have their missing teeth replaced and/ or crowns restored.

Healing

The healing time required for osseointegration depends on the individual and treatment protocol. It is the responsibility of the practitioner to decide when the implant can be restored. Good primary stability will govern if immediate loading can be done.

Implant care and maintenance

Potential implant patients should establish an adequate oral hygiene regime prior to Implant therapy. Proper post operative, oral hygiene and implant maintenance instructions must be discussed with the patient, as this will determine the longevity and health of the Implants. The patient should maintain regular prophylaxis and evaluation appointments.

Materials

Implant: Commercially pure titanium (grade 4)

Side effects

Potential Side Effects and Temporary symptoms: Pain, swelling, phonetic difficulties, gingival inflammation.

More persistent symptoms: The risks and complications with implants include, but are not limited to: (1) allergic reaction(s) to implant and/ or abutment material; (2) breakage of the implant and/or abutment; (3) loosening of the abutment screw and/or retaining screw; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/or fibroblasts; (7) formation of fat emboli; (8) loosening of the implant requiring revision surgery; (9) perforation of the maxillary sinus; (10) perforation of the labial and lingual plates; and (11) bone loss possibly resulting in revision or removal.

Breakage

Implant and abutment fractures can occur when applied loads exceed the tensile or compressive strength of the material. Potential overloading conditions may result from; deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing, clenching), loss or changes in dentition or functionality, inadequate prosthesis fit, and physical trauma. Additional treatment may be necessary when any of the above conditions are present to reduce the possibility of hardware complications or failure.

Changes in performance

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

MR Conditional

"Non-clinical testing and MRI simulations were performed to evaluate the dental implant system offered by Southern Implants. Non-clinical testing demonstrates that these products are MR Conditional. A patient with an implant from a Southern Implants System can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg and head average SAR of 3.2 W/kg, for 15 minutes of scanning (i.e., per pulse sequence) in the normal operating mode

The scanning conditions defined above will produce a maximum temperature increase of 4.9 °C in implants from Southern Implants systems after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by implants from Southern Implant System extends approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system."

Disposal

Disposal of the device and its packaging; Follow local regulations and environmental requirements, taking different contamination levels into account. When disposing of spent items, take care of sharp drills and instruments. Sufficient PPE must be used at all times.

Disclaimer of liability

This product is part of the Southern Implants product range and should only be used with the associated original products and according to the recommendations as in the individual product catalogues. The user of this product has to study the development of the Southern Implants product range and take full responsibility for the correct indications and use of this product. Southern Implants does not assume liability for damage due to incorrect use. Please note that some Southern Implants products may not be cleared or released for sale in all markets.

Notice regarding serious incidents

Any serious incident that has occurred in relation with the device must be reported to the manufacturer of the device and the competent authority in the member state in which the user and / or patient is established.

The contact information for the manufacturer of this device to report a serious incident is as follows: sicomplaints@southernimplants.com

Basic UDI

Product	Basic-UDI Number
Basic-UDI for Zygomatic Dental Implants	600954403871

Related literature & catalogues

Zygomatic: CAT-2070

Symbols and Warnings

Manufacturer: Southern Implant
1 Albert Rd, P.O Box 605 IRENE, 0062,
South Africa.
Tel: +27 12 667 1046

CE 2797

Rx ONLY — Prescription device*

STERILE R — Sterilization using Irradiation

NON STERILE — Non-sterile

Caution

Consult instruction for use

Use by date (mm-yy)

Do not reuse

Do not re-sterilize

LOT — Batch code

Do not use if package is damaged

MD — Medical Device

* Prescription device: Rx only. Caution: Federal Law restricts this device to sale by or on the order of a licenced physician or dentist.

Canada licence exemption: Please note that not all products may have been licensed in accordance with Canadian law.