English

INSTRUCTIONS FOR USE: Southern Implants® Zygomatic Implants

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Description

The Southern Implants Zygomatic range includes the standard Zygomatic (ZYG-55), the ZYGAN, the ZYGIN, the Wide ZYGIN (ZYGIN-W), the ZYGON, the Oncology (ONC-55) 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 grade 4 and are available in a range of lengths to be used with a range of prosthetic components (see the Zygomatic Implant product catalogue).

Indications for use

The Southern Implants Zygomatic System Standard implants, the ZYGAN (narrow apex), ZYGIN (narrow apex and coronal implant head), the Wide ZYGIN, the ZYGON, the Oncology and the ZYGEX (narrow apex) implants are intended to be implanted in the upper jaw to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxilla. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Compatibility information

Use only original Southern Implants components to restore Southern Implants 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.

Table A - Compatibility

Item code	Implant length codes (in mm)
ONC-55-	27.5N/ 32.5N/ 37.5N/ 42.5N/ 47.5N
ZYGEX-	30/ 32.5/ 35/ 37.5/ 40/ 42.5/ 45/ 47.5/ 50/ 52.2/ 55/ 57.5/ 60
ZYG-55-	35N/ 37.5N/ 40N/ 42.5N/ 45N/ 47.5N/ 50N/ 52.5N/ 55N/ 60N
ZYGAN-	30/ 32.5/ 35/ 37.5/ 40/ 42.5/ 45/ 47.5/ 50/ 52.2/ 55/ 57.5/ 60
ZYGIN-	30/ 32.5/ 35/ 37.5/ 40/ 42.5/ 45/ 47.5/ 50/ 52.2/ 55/ 57.5/ 60
ZYGIN-W-	30/ 32.5/ 35/ 37.5/ 40/ 42.5/ 45/ 47.5/ 50/ 52.2/ 55/ 57.5/ 60
ZYGON-	30/ 32.5/ 35/ 37.5/ 40/ 42.5/ 45/ 47.5/ 50/ 52.2/ 55/ 57.5/ 60

Applicable Implants	Cover Screw and Driver	Abutment and Driver	Prosthetic Screw Driver
ONC-55, ZYGEX, ZYG-55, ZYGAN	SCU2 (Cover screw) I-CS-HD (driver)	AMCZ (Screw retained abutment), I-HAD (Driver)	1 Series screw (prosthetic screw), I-HD-M (driver)
ZYGIN, ZYGIN-W, ZYGON	CS-ZYG (Cover screw) I-CS-HD (Driver)	MC-ZYG (Screw retained abutment), I-HAD (Driver)	1 Series screw (prosthetic screw), I-HD-M (driver)

Storage, cleaning and sterilisation

The implants are supplied sterile 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. Do not re-sterilize or autoclave these components.

Contraindications

Do not use in patients:

- who are medically unfit for oral surgical procedures.
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6AL-4V),
- with inadequate bone volume for zygomatic and conventional implants.
- where adequate numbers of implants could not be placed to achieve full functional support for a prosthesis.
- who have undergone irradiation of maxillary bone.

Warnings

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

- For the safe and effective use of dental implants it is strongly 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. 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.

It is important to be aware of and avoid damage to vital structures such as nerves, veins and arteries. Injuries to vital anatomical structures may cause serious complications such as injury to the eye, nerve damage and excessive bleeding. It is essential to protect the infraorbital nerve. Failing to identify actual measurements relative to the radiographic data could lead to complications.

Cautions

New and experienced implant users should do training before using a new system or attempting 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 orofacial 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 preoperative 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.
- electrosurgery should not be attempted around metal implants as they are conductive.

Precaution: maintaining sterility protocol

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. The packaging for the zygomatic implant differs from packaging used for the conventional dental implants in that there is no secondary rigid container inside the sterile tray. Instead, there is a stainless steel clip that supports the implant and fixture mount, keeping the implant from contact with the container.
4. Inside the plastic box, the sealed inner plastic tray-lid is sterile only on the inside. The sealed tray-lid is to be opened by an assistant (with non-sterile gloves). Remove the lid and do not touch the sterile implant. Follow the

instructions illustrated in (Figure 1 to Figure 8) 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.

The following images demonstrate the technique for removing the implant from the packaging while maintaining sterility. NOTE: white gloves and background represent non-sterile items. Blue gloves and background represent sterile items.

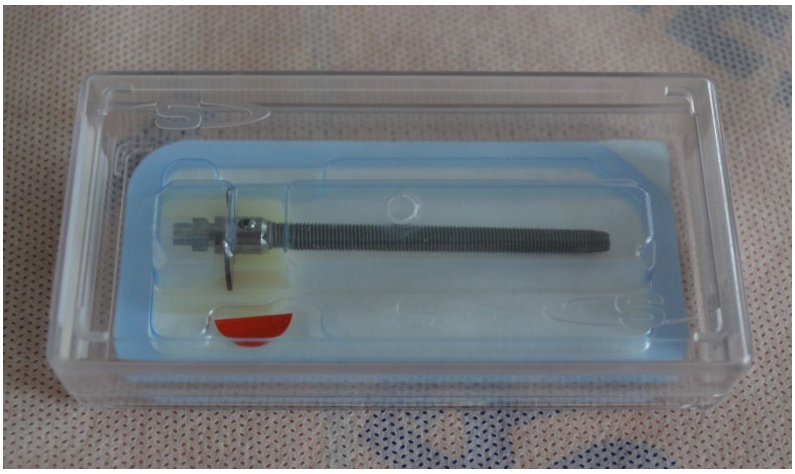


Figure 1: Implant package in the non-sterile field

Figure 2: With non-sterile gloves, open the outer box by tearing the tamper-proof address label.

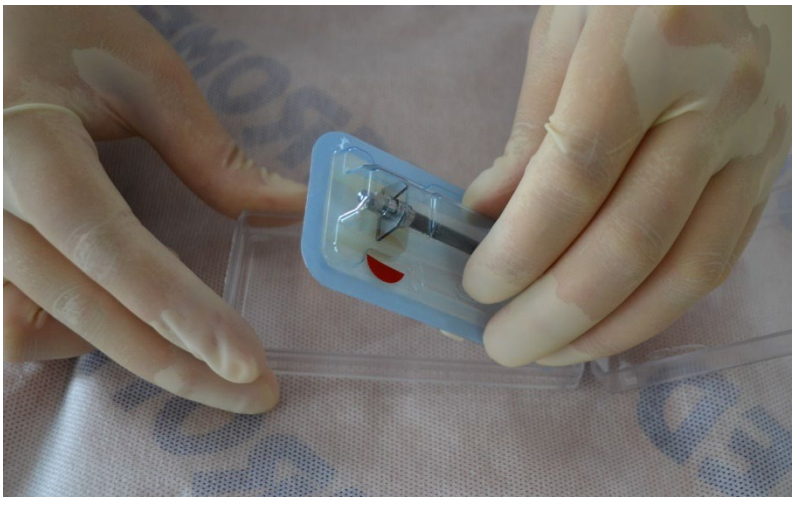


Figure 3: With non-sterile gloves remove the inner plastic tray-lid.

Figure 4: With non-sterile gloves, peel the TYVEK lid off of the plastic lid.

Figure 5: The assistant presents the open tray to the surgeon. Without touching the outside of the tray, the surgeon removes the implant holder with sterile gloves.

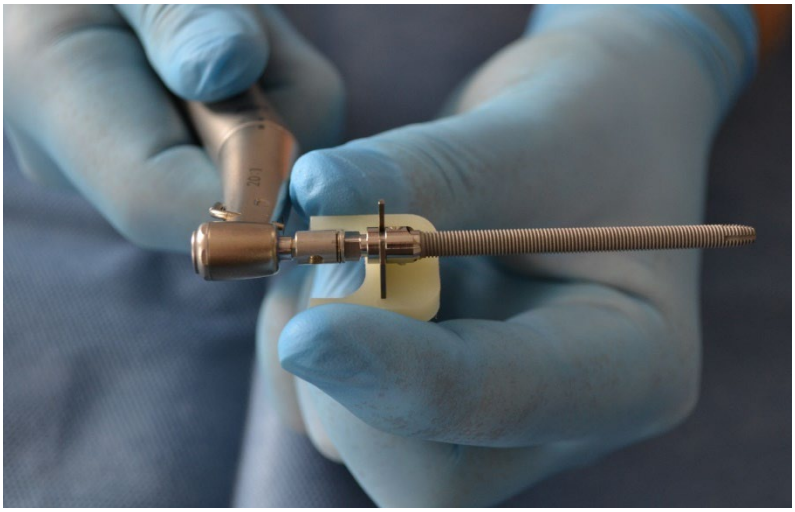


Figure 6: The surgeon engages the handpiece placement tool (I-CON-X) onto the fixture mount.

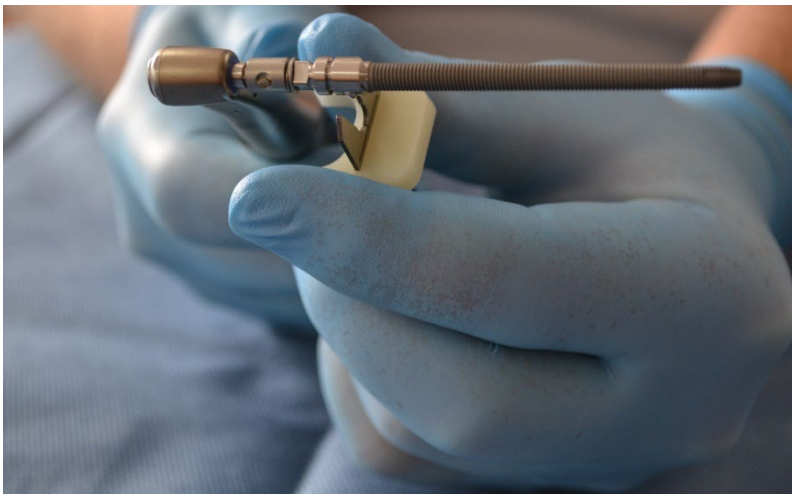


Figure 7: Using an upward force, the implant is removed from the carrier.

Figure 8: The implant is now ready for placement.

During surgery:

- Care must be taken that parts are not swallowed during any of the procedures, thus rubber-dam application is recommended when appropriate.
- Care must be taken to apply the correct tightening torque of abutments and abutment screws.

Post-surgery:

- Regular patient follow-up, and proper oral hygiene must be achieved are essential for favourable long-term results.

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:

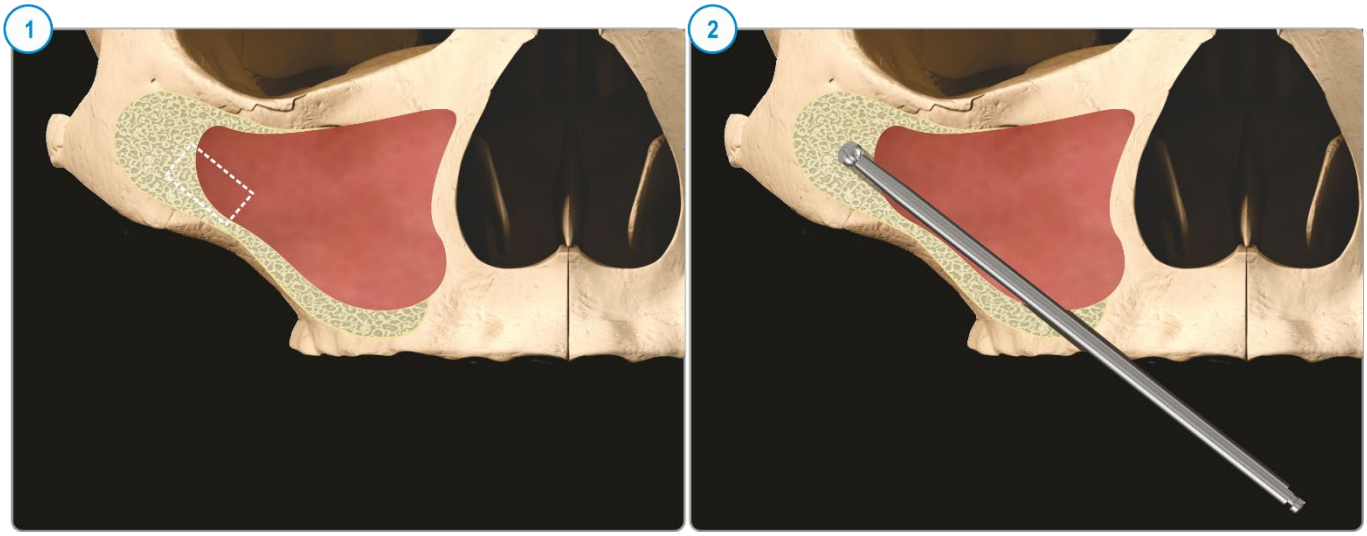
- Detect the presence of any pathology in the maxillary sinuses,
- Bone volume and condition,
- Jaw relationships.

Zygomatic implants are recommended for the posterior (pre- molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration.

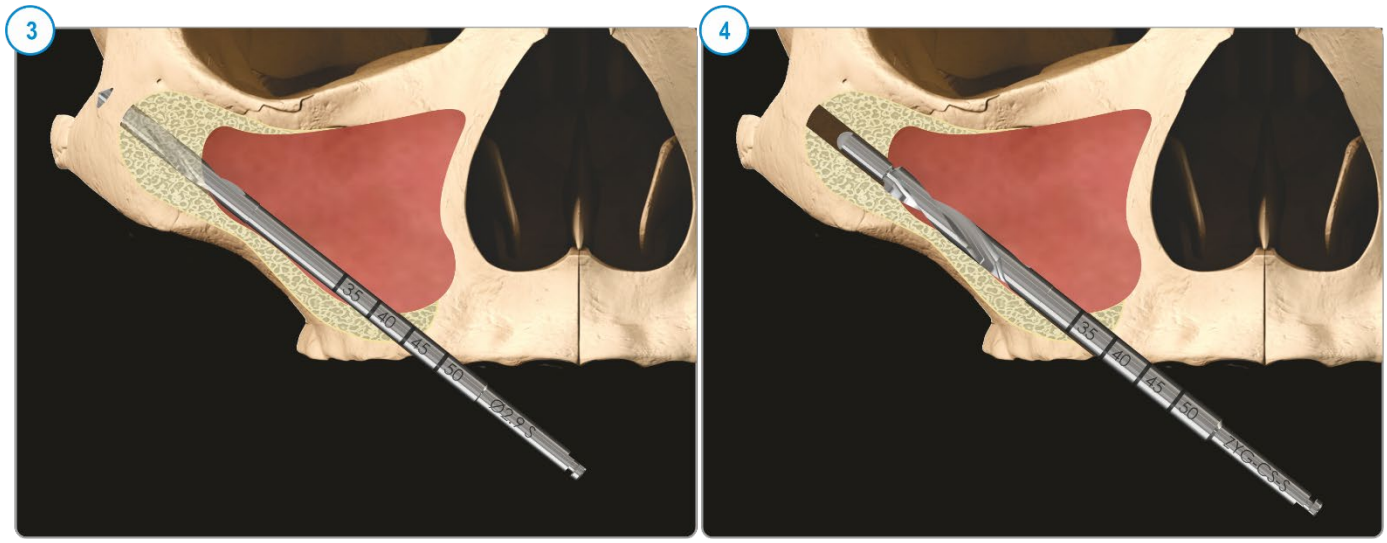
Surgical Procedure for the Standard Zygomatic (ZYG-55) Implants:

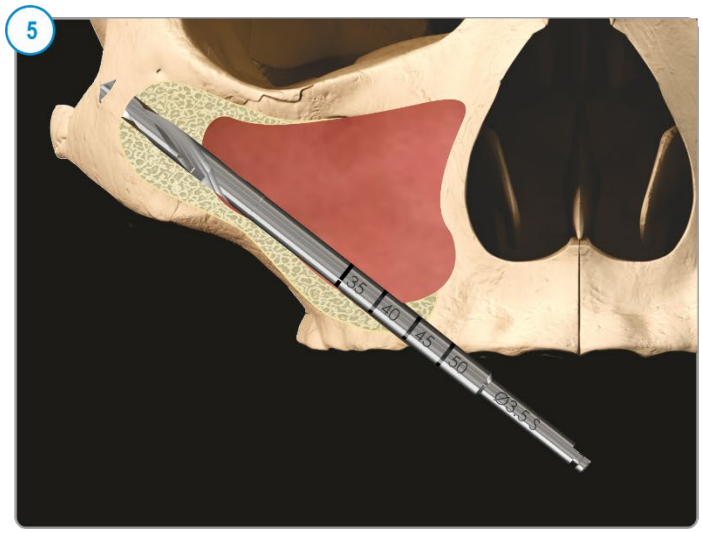
A crestal incision is made from just anterior to the maxillary tuberosity on one side to the same point on the other side. Three vertical releasing incisions are made in the second molar regions and the midline. These 3 incisions facilitate flap mobilization beyond the infraorbital margin. In unilateral 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.

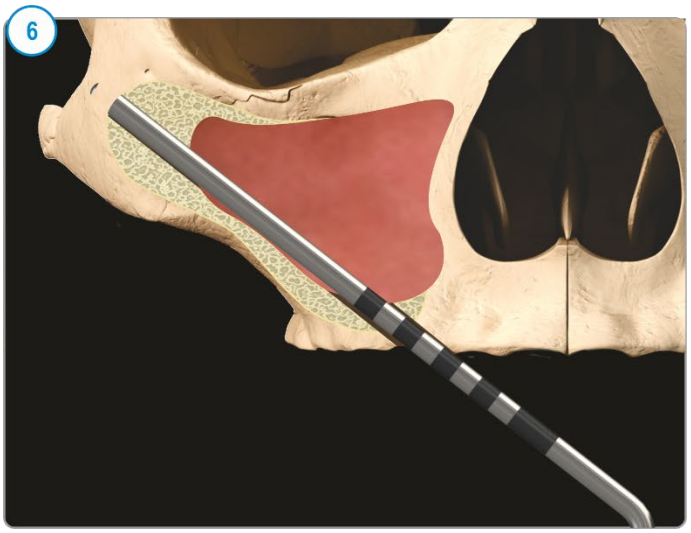
1) A small sinus window is cut on the lateral aspect of the maxillary sinus and the block of the bone is removed (Fig 1). The lining of the sinus is reflected, attempting to keep it intact if possible. Thorough reflection of the lining is essential.
2) Begin the entrance point of the implant (site preparation) for the zygomatic implant 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.
3) The entrance point on the alveolus is made using a round bur (D-ZYG-RB) and continued through the wall of the maxillary sinus to the cavity seen through the sinus window (Fig 2).



4) The implant site is established by means of the Ø2.9mm twist drill (D-ZYG-29), and continued into the zygoma (Fig 3). The sinus window gives a view to the correctly positioned penetration of the drills into the zygoma. Emergence of the drill out the zygoma is palpated on the cheek of the patient.
5) The site preparation is completed by means of the Ø3.4 counterbore (D-ZYG-CS) (Fig 4) and Ø3.4 twist drill (D-ZYG-35) (Fig 5) drilled all the way through the zygoma. Finally, an oval cut is made extending slightly buccal to the palatal alveolar emergence hole to allow for the prosthodontic restoration of the implant head.



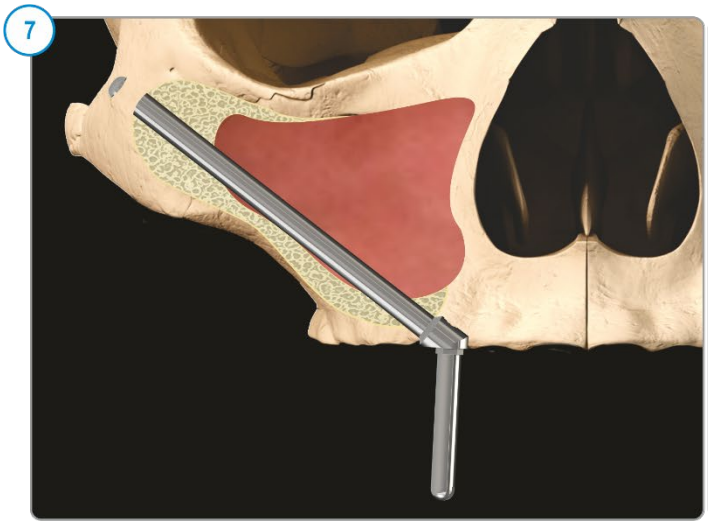


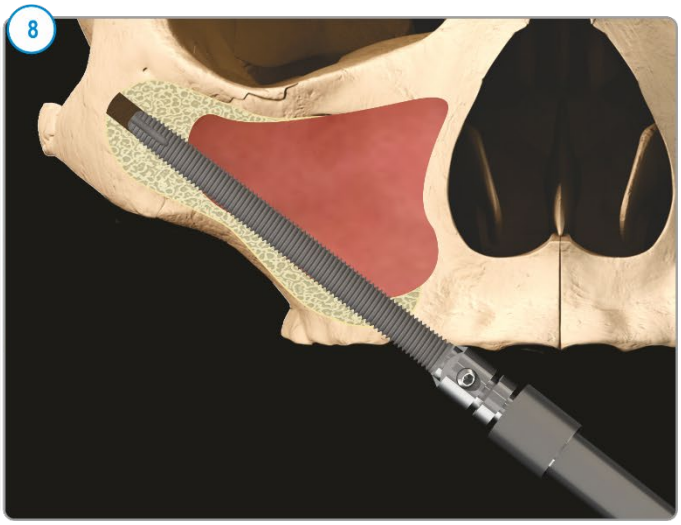


6) The depth of the prepared implant site and the implant head angulation are gauged by use of the angled depth gauge (I-ZYG-DG-1) (Fig 6) and the try in direction indicators (ZYG-TR-55) (Fig 7).

7) Before inserting the implant, ensure that the implant site is free of soft tissue remnants. The handpiece with connector (I-CON-X) is used for the initial insertion of the implant, 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) (Fig 8).

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.

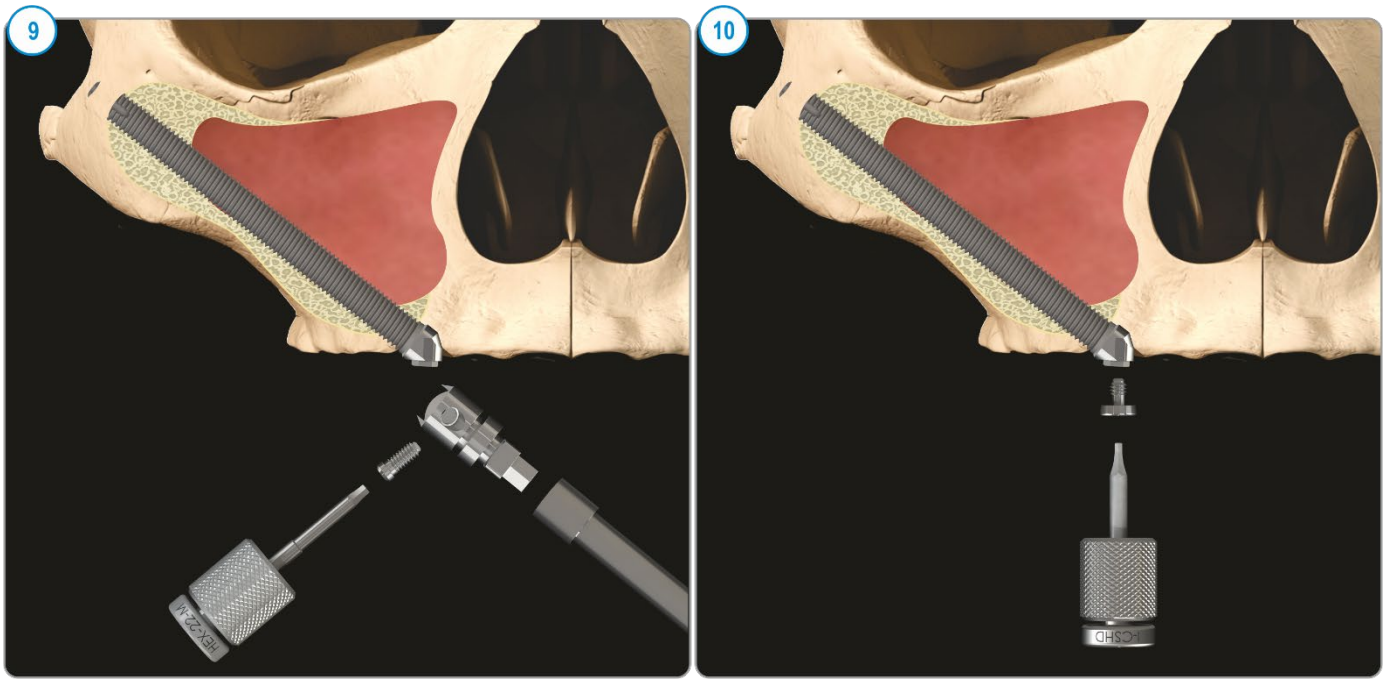




8) The implant must follow the prepared path of insertion. Any soft tissue that may have been picked up on the implant threads while moving through the alveolus and sinus must be cleared off before the implant enters the zygomatic placement site. One revolution of the implant results in 0.6mm axial movement. Insertion is complete when the head is in the correct prosthodontic position and angle.

9) The fixture mount screw is then loosened with the I-HD driver and the fixture mount is removed (Fig 9).

10) The cover screw (SCU2) is picked up and placed with the I-CSHD driver (Fig 10), or an immediate restorative protocol is carried out. Suturing is then carried out according to the surgeon's preference.



Surgical Procedure for the Oncology (ONC-55) Implants:

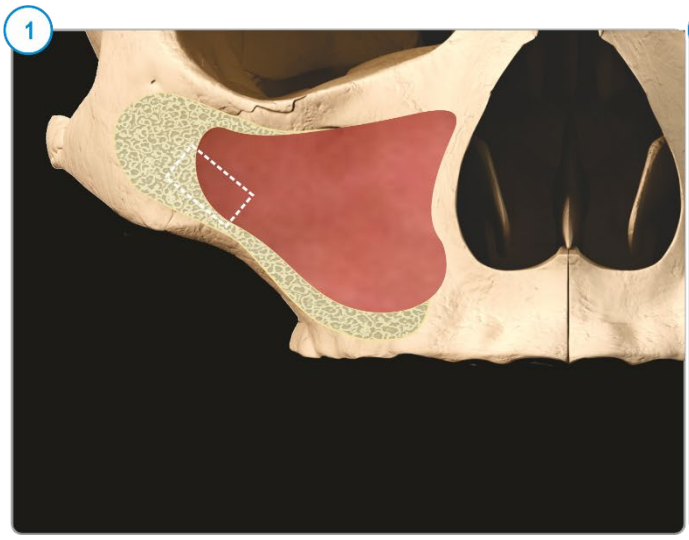
The same instruments and drilling procedure are used for the ONC-55 Oncology Implants as above for the Standard Zygomatic (ZYG-55) Implants, but since the anatomy is substantially different the procedure differs in the following way:

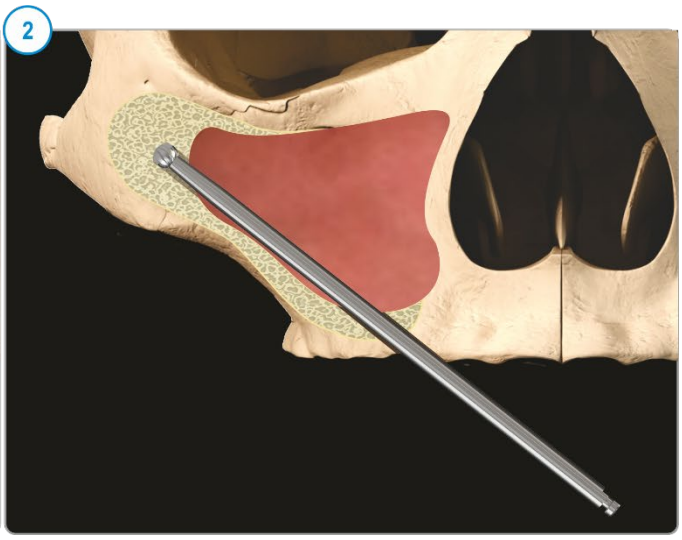
- No sinus window is required if the maxilla and the sinus have been removed. In this case drilling begins directly in the zygoma.
- The implant placement position is determined by the available bone. However, in a standard maxillectomy case, the placement angle of the Oncology Implants in the zygoma 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.

Surgical Procedure for the ZYGAN and ZYGIN 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.

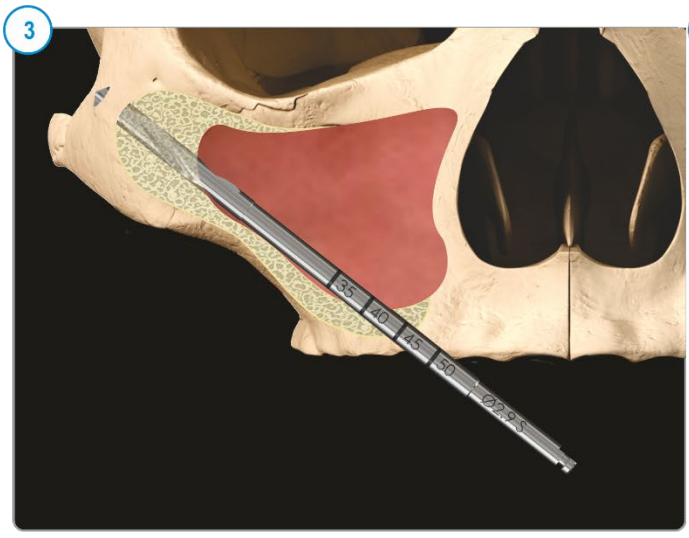
1) A small sinus window is cut on the lateral aspect of the maxillary sinus and the block of the bone is removed (Fig 1). The lining of the sinus is reflected, attempting to keep it intact. Thorough reflection of the lining is essential.
2) Begin the entrance point of the implant (site preparation) for the ZYGAN/ ZYGIN Implant 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.
3) The entrance point on the alveolus is made using a round bur (D-ZYG-RB) and continued through the wall of the maxillary sinus to the cavity seen through the sinus window (Fig 2).

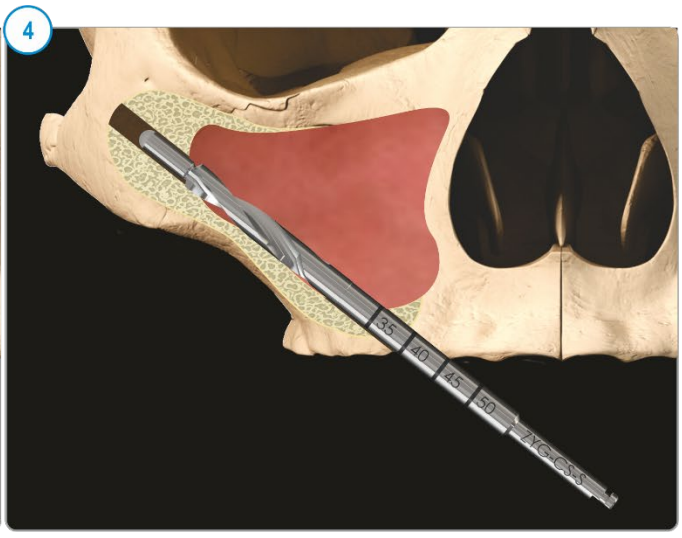


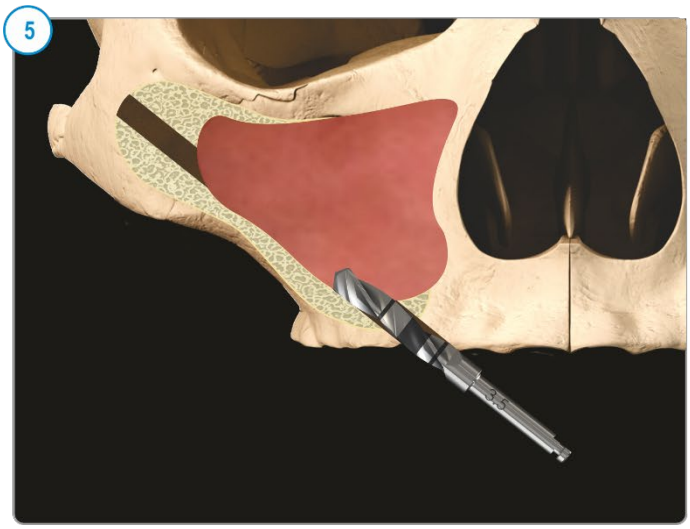


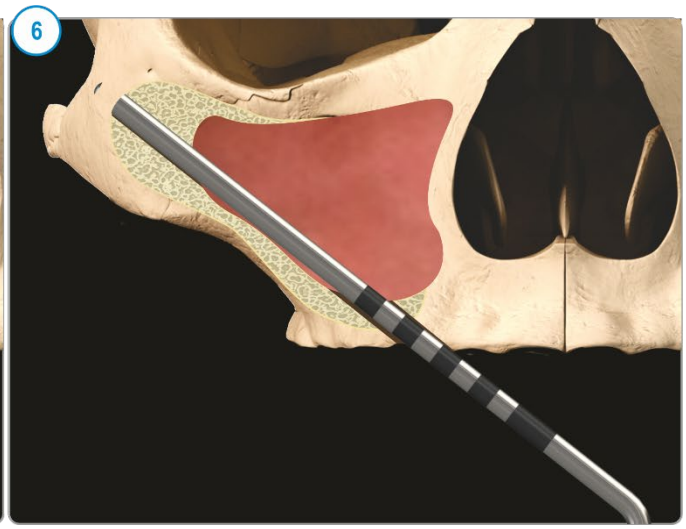
4) The implant site is established by means of the Ø2.9mm twist drill (D-ZYG-29), and continued into the zygoma (Fig 3). The sinus window gives a view to the correctly positioned penetration of the drills into the zygoma. Emergence of the drill out the zygoma is palpated on the cheek of the patient.

5) The Ø3.5 counterbore (D-ZYG-CS) (Fig 4) is then used 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 (Fig 5). 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. Finally, an oval cut is made extending slightly buccal to the palatal alveolar emergence hole to allow for the prosthodontic restoration of the implant head.





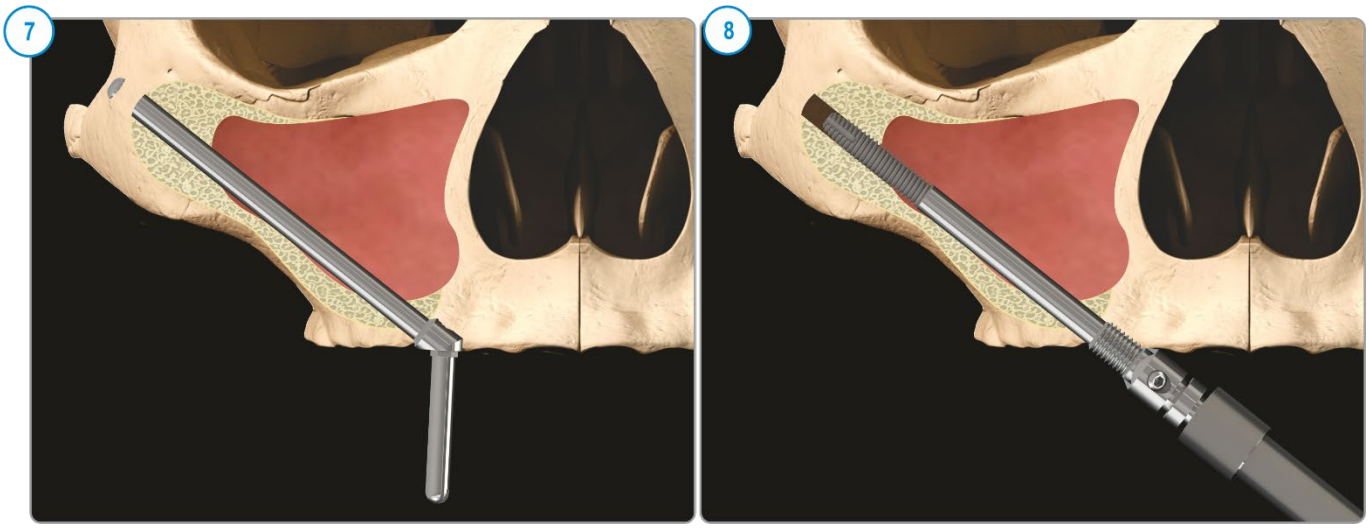




6) The depth of the prepared implant site and the implant head angulation are gauged by the use of the angled depth gauge (I-ZYG-DG-1) (Fig 6) and the try in direction indicators (ZYG-TR-55) (Fig 7).

7) Before inserting the implant, ensure that the implant site is free of soft tissue remnants. The handpiece with connector (I-CON-X) is used for the initial insertion of the implant, with the torque control set at 50Ncm at 15rpm. Push the narrow-apex Zygomatic Implant straight through the alveolar preparation. You will only need to start screwing when the apex reaches the zygoma, thus reducing the insertion time. When the handpiece torques out, switch to the surgical wrench (I-RATCHET-2) or the onion driver (I-ZYG-INS-1) (Fig 8).

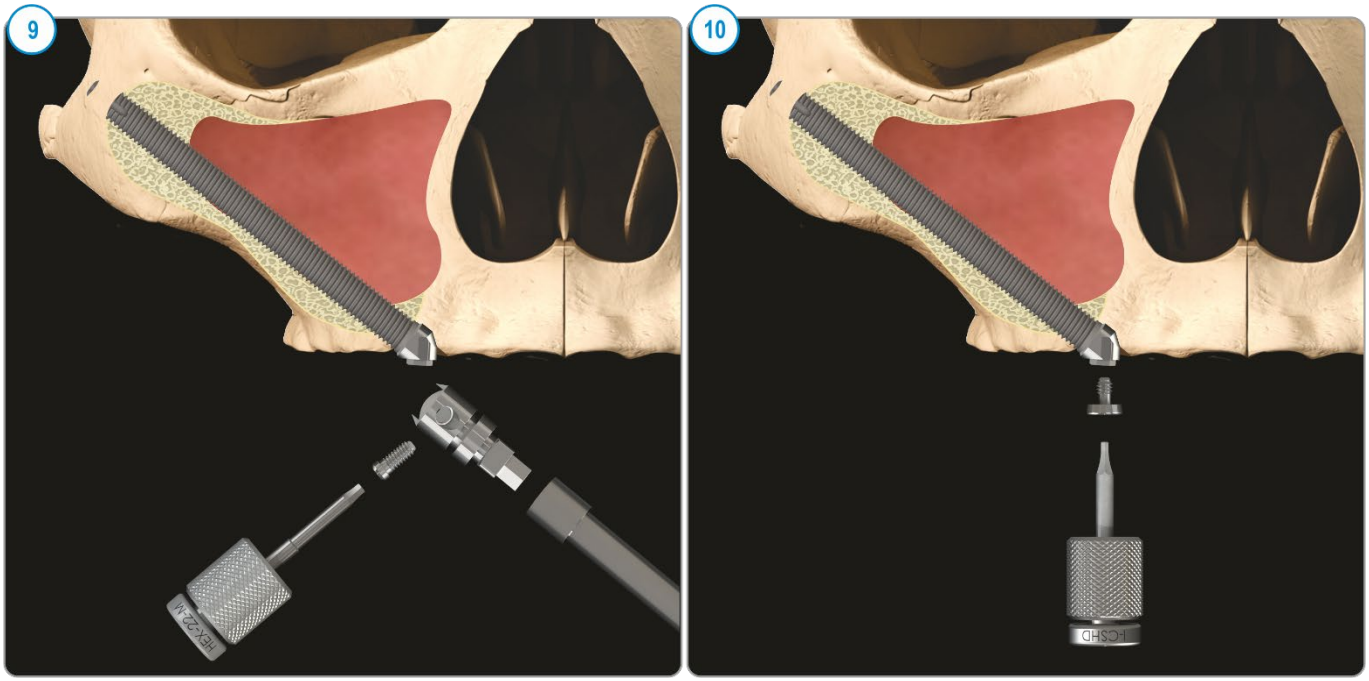
Avoid applying bending moments to the fixture mount while inserting the implant. Check the fixture mount screw for loosening periodically and re-tighten if necessary.



8) The implant must follow the prepared path of insertion. 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. One revolution of the implant results in 0.6mm axial movement.

9) Insertion is complete when the head is in the correct prosthodontic position and angle. The fixture mount screw is then loosened with the I-HD driver and the fixture mount is removed (Fig 9).

10) The cover screw (SCU2 for the ZYGAN or CS-ZYG for the ZYGIN) is picked up and placed with the I-CSHD driver (Fig 10), or an immediate restorative protocol is carried out. Suturing is then carried out according to the surgeon's preference.



Surgical Procedure for the Wide ZYGIN (ZYGIN-W) Implants:

The same instruments and drilling procedure are used for the Wide ZYGIN (ZYGIN-W) Implants as above for the ZYGAN and ZYGIN Implants, but since the anatomy is substantially different the procedure differs in the following way:

- Due to the larger implant apical diameter of the Wide ZYGIN, the side cutting burr (CH-D-CM) may be used create and/or enlarge the groove made in the alveolar ridge and/or the maxillary wall to aid in guiding the implant apex into site in the zygoma.
- One revolution of the Wide ZYGIN implant results in 0.75mm axial movement.

Surgical Procedure for the ZYGEX and ZYGON Implants:

The same instruments and drilling procedure are used for the ZYGEX and ZYGON Implants as above for the ZYGAN and ZYGIN 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 has been removed. In this case drilling begins directly in the zygoma.
- The use of the Ø3.5 counterbore (D-ZYG-CS) and Ø3.5 with a D-35T-M15 drill are not required due to the lack of alveolar bone in cases where the ZYGEX and ZYGON implants are indicated (i.e., maxillectomy cases).
- The implant placement position is determined by the available bone. However, in a standard maxillectomy case, the placement angle of the ZYGEX and ZYGON Implants in the zygoma is more horizontal than a ZYGAN 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.
- One revolution of the ZYGON implant results in 0.75mm axial movement.

Materials

Zygomatic Implant: Commercially pure titanium (grade 4)

Disposal

Disposal of the device and its packaging shall follow local regulations and environmental requirements, taking different contamination levels into account.

Magnetic Resonance (MR) Safety

MR Conditional

Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is locate outside of the RF coil.

A patient with this device can be scanned in an MR system under the following conditions:

Device Name	Southern Implants Zygomatic Implant Family
Static Magnetic Field Strength (B0)	≤ 3.0 T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

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.

Basic UDI

Product	Basic-UDI Number
Basic-UDI for Zygomatic Implants	60095440387194

Related literature and catalogues

CAT-2070- Zygomatic Implants Product Catalogue

Symbols and warnings


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

CE mark

Prescription device*

Sterilised using irradiation

Non-sterile


Use by date (mm-yy)


Do not reuse

Do not resterilise

Catalogue number

Batch code

Medical device

Authorised representative in the European Community

Authorised representative for Switzerland


Date of manufacture

Magnetic Resonance conditional

Magnetic Resonance safe


Single sterile barrier system with protective packaging inside


Single sterile barrier system


Consult instruction for use


Caution


Keep away from sunlight


Do not use if package is damaged

* 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.