SOUTHERNIMPLANTS®
Innovative Treatment Solutions

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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.

Description

The Straumann® Zygomatic Implant system includes the Straumann® Zygomatic Implant, ZAGA™ Round and the Straumann® Zygomatic Implant, ZAGA™ Flat. They are extra-long (up to 55mm) to enable bone anchorage in the zygoma, and have a 55° head angle. They are made from biocompatible, commercially pure, Grade 4 Titanium and are available in a range of lengths to be used with a range of prosthetic components. The apical threaded region of the implants are roughened for bone anchorage, while the coronal region has a smooth machined surface. This implant system is delivered pre-mounted with a fixture mount. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Indications for use

Straumann® Zygomatic Implants are intended to be implanted in the upper jaw arch to provide support for fixed dental prostheses in patients with partially or fully edentulous maxillae. 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.
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6AL-4V).
- with inadequate bone volume or quality 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.
- who are under the age of 18, 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, 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 strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements and radiographic evaluations.
- Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.

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 duced 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.

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, 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.
- minimizing 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.

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. 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 tray-lid are not sterile; do not touch the outside with sterile gloves, and do not place the plastic box or inner plastic tray-lid onto the sterile field.
3. The packaging for the implant is the same as that for previous Southern Implants zygomatic 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 nonsterile gloves): remove the lid and do not touch the sterile implant.
5. Maintain the sterility of the implant, after opening the tray and removing the implant, until placement in the surgical site.

During surgery

- Care must be taken that parts are not swallowed or aspirated 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, and are essential for favorable 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.
- determine bone volume and condition.
- determine jaw relationships.
- zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two

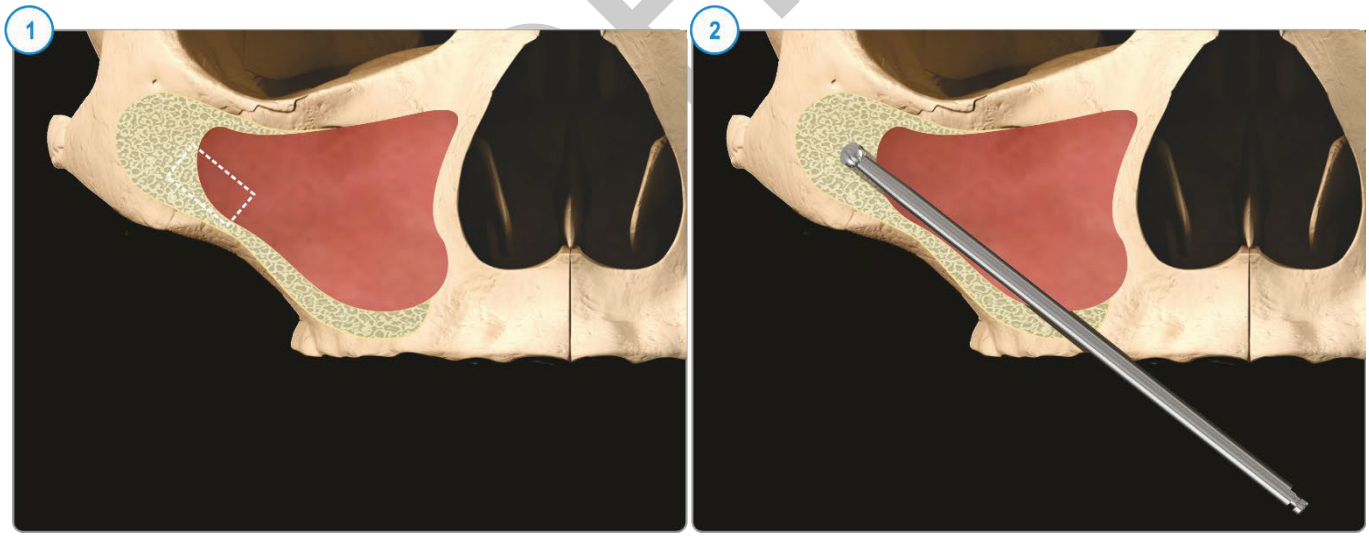
standard dental implants in the anterior region to support a fixed restoration.

- where there is insufficient bone for good stability of anterior implants, a quad Zygomatic protocol is indicated. This involves two Zygomatic implants per Zygoma with both of these implants angled to emerge in the anterior region.

Surgical Procedure for Straumann® Zygomatic Implants, ZAGA™ Round

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 channel retractor is placed on the upper border of the zygomatic arch.

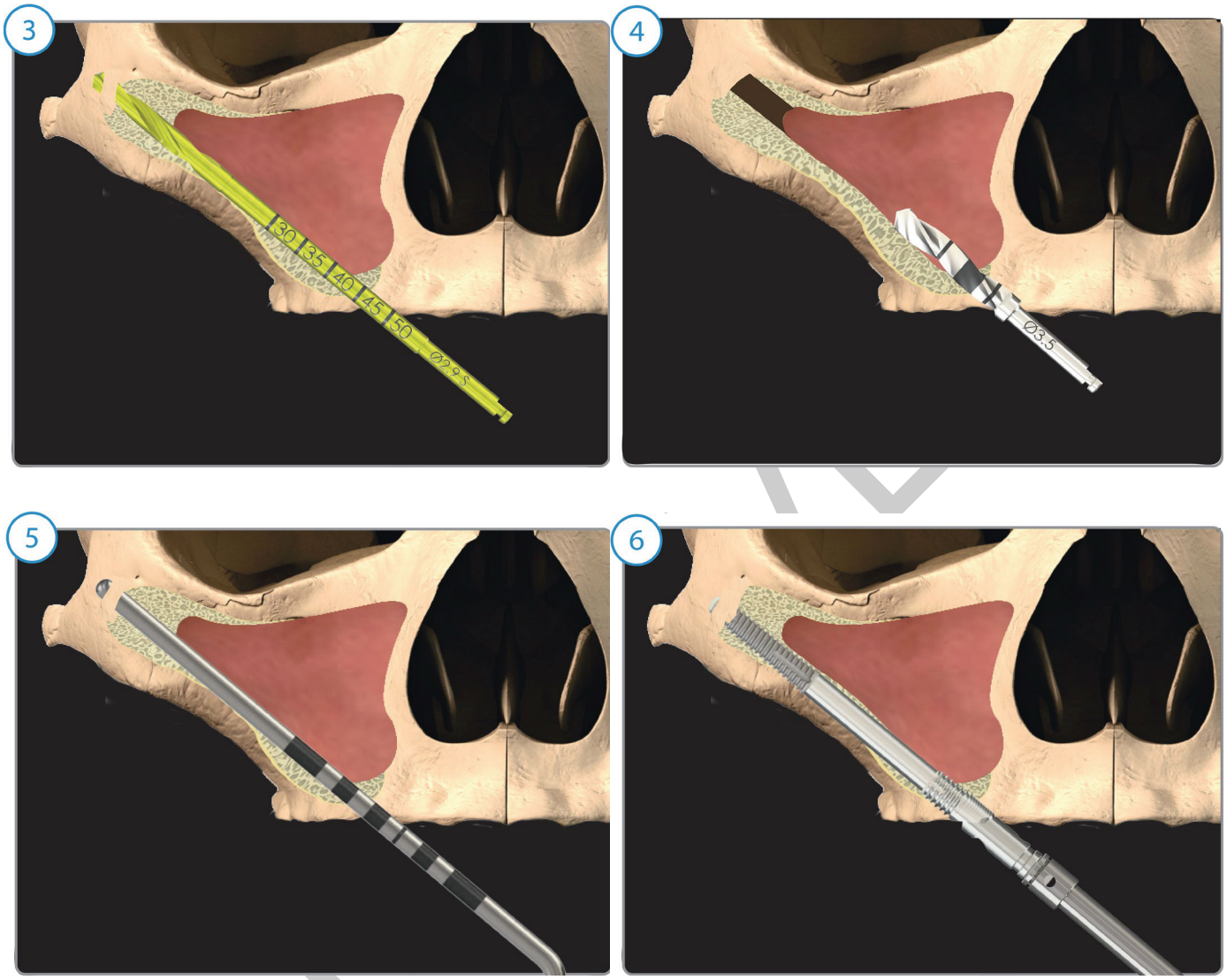
1. A small sinus window is cut on the lateral aspect of the maxillary sinus and the block of the bone is removed (Fig 1). The lining of the sinus is reflected, attempting to keep it intact if possible. Thorough reflection of the lining is essential.
2. Begin the entrance point of the implant (site preparation) for the Straumann® Zygomatic Implant, ZAGA™ Round 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) or a needle drill (026.0054) and continued through the wall of the maxillary sinus to the cavity seen through the sinus window (Fig 2) (D-ZYG-RB recommended drill speed: 1000-1500rpm; 026.0054 maximum drill speed: 800rpm).
4. The implant site is established by means of the Ø2.9mm twist drill (D-ZYG-29/ D-ZYG-29S/ D-ZYG-CH-29/ D-ZYG-CH-29S), and continued into the zygoma (Fig 3) (D-ZYG-29/ D-ZYG-29S/ D-ZYG-CH-29/ D-ZYG-CH-29S recommended drill speed: 1000-1500rpm). The sinus window gives view to the correctly positioned penetration of the drills into the zygoma. Emergence of the drill out the zygoma is palpated on



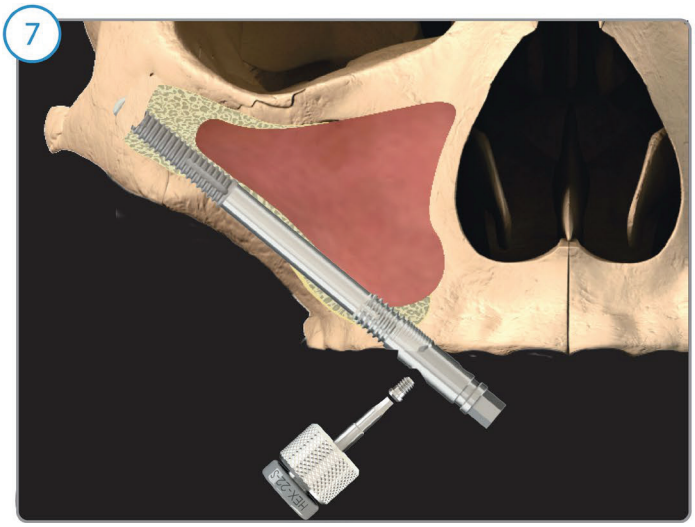
the cheek of the patient.

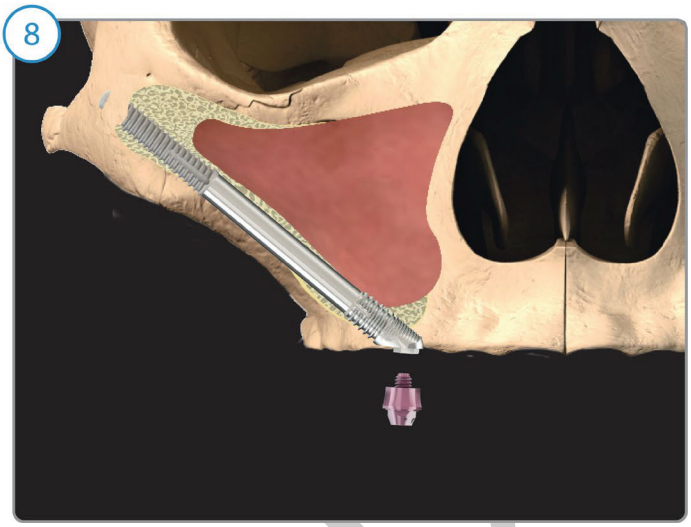
5. The Ø3.5 D-35T-M15 drill is then used to enlarge the hole in the alveolar ridge (Fig 4). (D-35T-M15 recommended drill speed: 1000-1500rpm) Do not use this drill in soft bone as the implant will prepare the alveolar site as it is pushed through in the next step. Finally, an oval cut is made extending 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 use of the angled depth gauge (CH-I-
7. DG/ I-ZYG-DG-1) (Fig 5).
8. 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 Straumann® Zygomatic Implant, ZAGA™ Round 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 (046.108, 046.119, 046.049) or the onion driver (I-ZYG-INS-2/ I-IMP-INS-2) (Fig 6). 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.

9. 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 0.8mm axial movement. Insertion is complete when the head is in the correct prosthodontic position and angle.



10. The fixture mount screw is then loosened with the dedicated screwdriver and the fixture mount is removed (Fig 7).
11. Should sufficient primary stability not be achieved for the implant, a cover screw (CH-CS) is placed with the dedicated driver (I-CSHD) for a two-stage protocol. For immediate loading, a screw-retained abutment (CH-SRA) with an appropriate gingival height is picked up and placed with the dedicated screwdriver (046.401/ 046.411) (Fig 8). Suturing is then carried out according to the surgeon's preference.
12. **Caution: Tighten the cover screw (CH-CS) only finger tight to avoid excessive loads. Tighten the screw-retained abutment (CH-SRA) to the recommended torque of 35Ncm.**

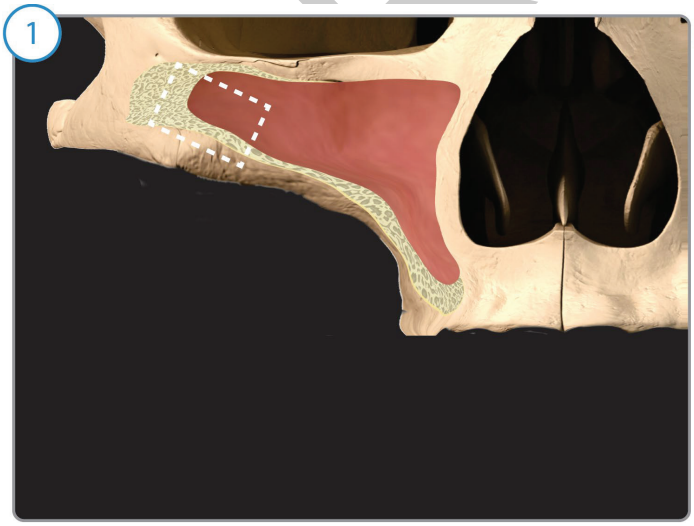


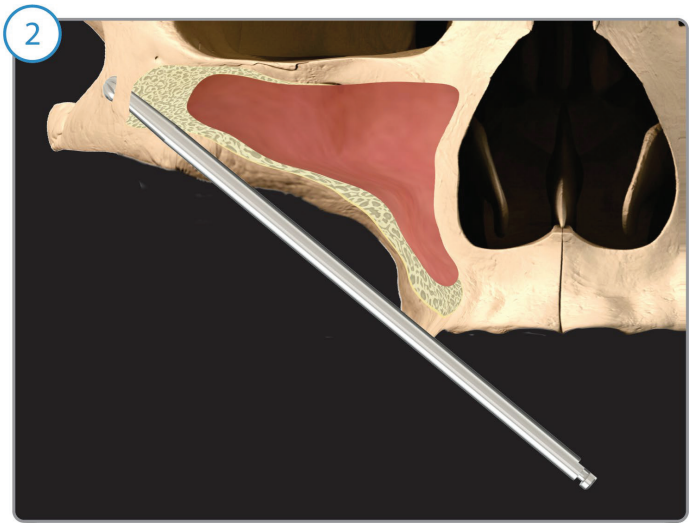


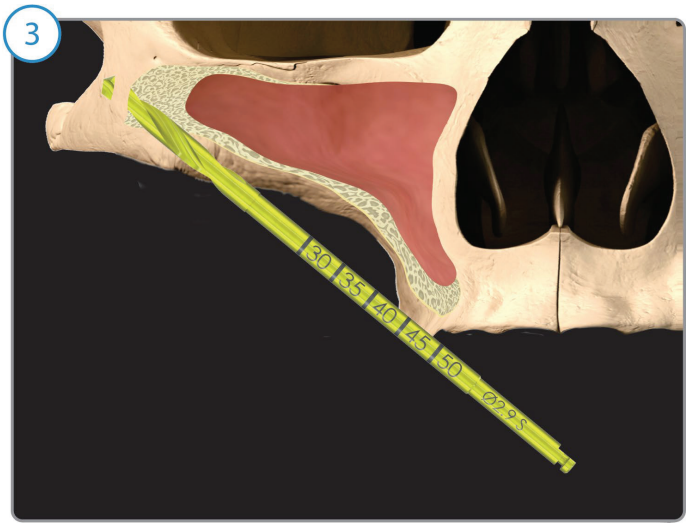
Surgical Procedure for Straumann Zygomatic Implants, ZAGA™ Flat

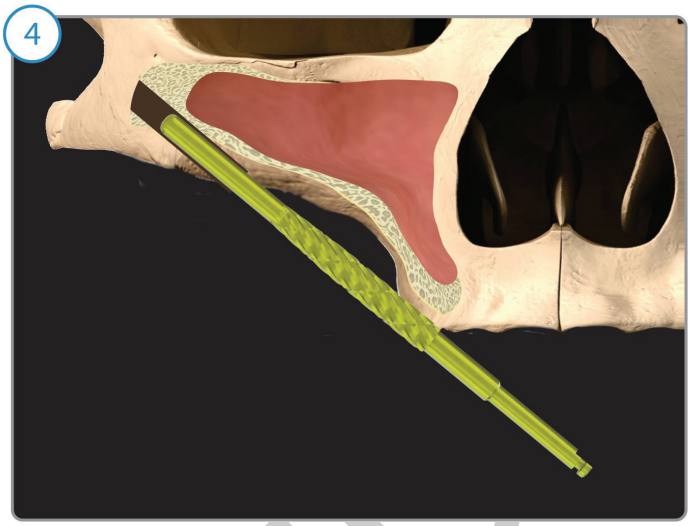
A crestal incision is made from just anterior to the maxillary tuberosity on one side to the same point on the other side. Three vertical releasing incisions are made in the second molar regions and the midline. These 3 incisions facilitate flap mobilization beyond the infraorbital margin. In unilateral 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 channel retractor 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 Straumann® Zygomatic Implant, ZAGA™ Flat 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) or a needle drill (026.0054) and continued through the wall of the maxillary sinus to the cavity seen through the sinus window (Fig 2). (D-ZYG-RB recommended drill speed: 1000-1500rpm; 026.0054 maximum drill speed: 800rpm)
4. The implant site is established by means of the Ø2.9mm twist drill (D-ZYG-29/ D-ZYG-29S/ D-ZYG-CH-29/ D-ZYG-CH-29S), and continued into the zygoma (Fig 3). (D-ZYG-29/ D-ZYG-29S/ D-ZYG-CH-29/ D-ZYG-CH-29S recommended drill speed: 1000-1500rpm) The sinus window gives 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. Use the ZAGA™ Side Cut Burr (CH-D-CM) to create and/or enlarge the groove made in the alveolar ridge in order to place the implant with the buccal face sitting flush with the alveolar bone outer surface (Fig 4) (CH-D-CM recommended drill speed: 1000-1500rpm).
6. The depth of the prepared implant site and the implant head angulation are gauged by the use of the angled depth gauge (CH- I-DG/ I-ZYG-DG-1) (Fig 5).









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 Straumann® Zygomatic Implant, ZAGA™ Flat 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 (046.108, 046.119, 046.049) or the onion driver (I-ZYG-INS-2/ I-IMP-INS-2) (Fig 6).
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.**
9. 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 0.8mm axial movement.
10. Insertion is complete when the head is in the correct prosthodontic position and angle. The fixture mount screw is then loosened with the dedicated screwdriver and the fixture mount is removed (Fig 7).
11. Should sufficient primary stability not be achieved for the implant, a cover screw (CH-CS) is placed with the dedicated driver (I-CSHD) for a two-stage protocol. For immediate loading, a screw-retained abutment (CH-SRA) with an appropriate gingival height is picked up and placed with the dedicated screw driver (046.401/ 046.411) (Fig 8). Suturing is then carried out according to the surgeon's preference.
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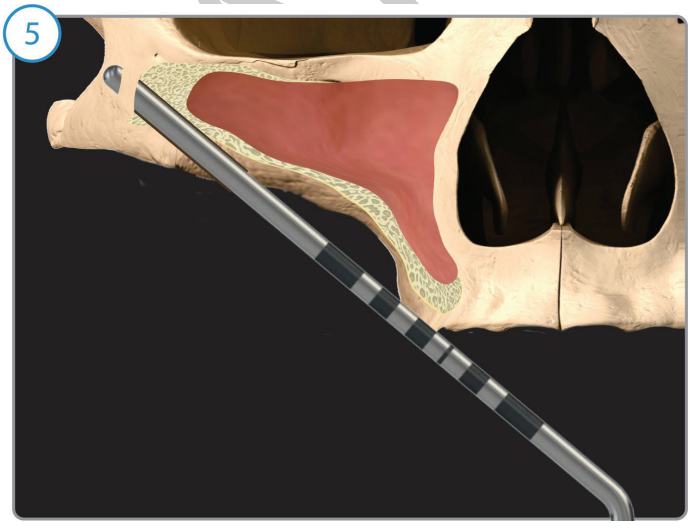

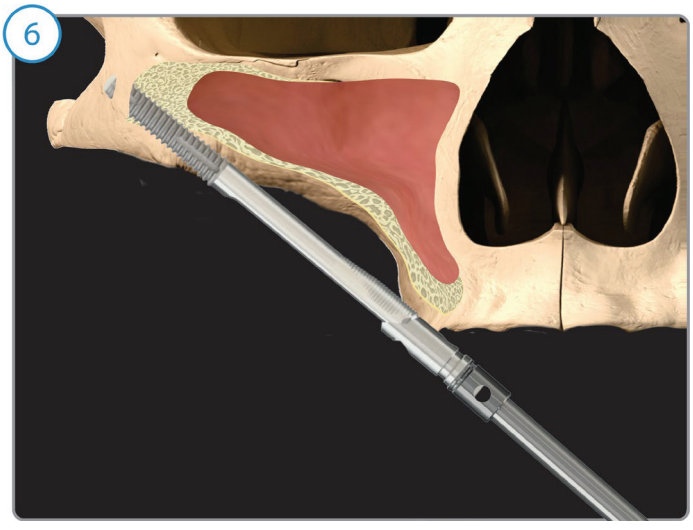

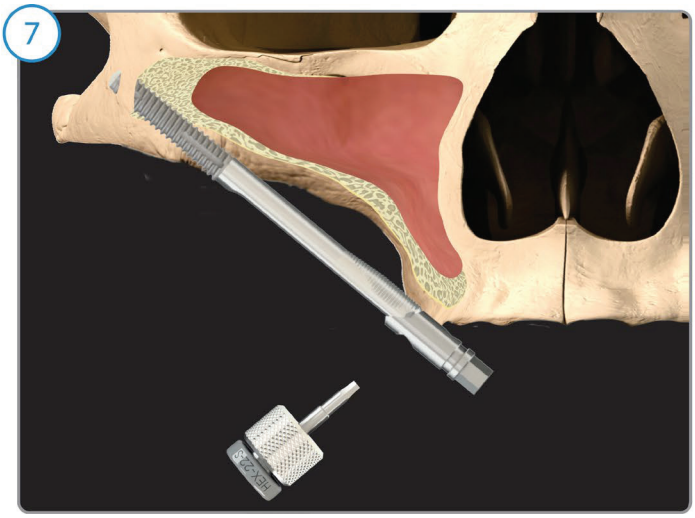

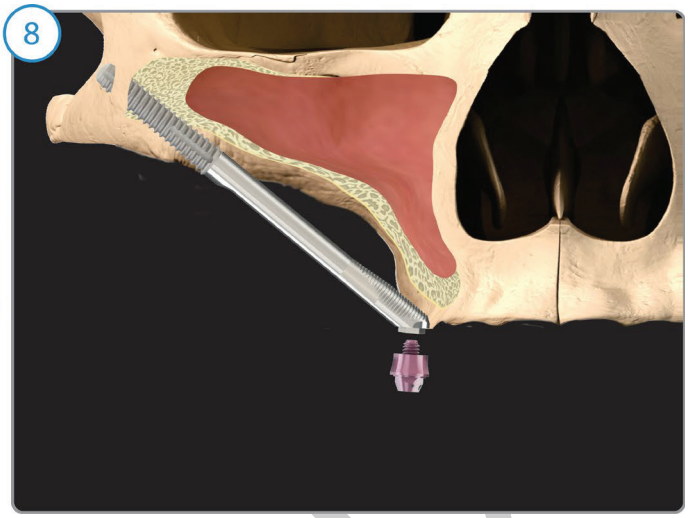

Warning
It is very important to be aware and avoid damage to vital structures such as nerves, veins and arteries. Injuries to vital anatomical structures may cause serious complications like injury to the eye, nerve damage and excessive bleeding.

It is essential to protect the infraorbital nerve. Failing to identify actual measurements relative to the radiographic data could lead to complications.

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
Straumann® Zygomatic Implant:	Commercially pure titanium (grade 4, ASTM F67 and ISO 5832-2, UTS ≥ 900MPa)

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 patent has not been told to expect).

MR Safety
These products have not been tested for MRI safety, however, an analysis and review of the literature has shown that the risks of scanning a Southern Implants implant system are not of concern under the following conditions:
- a static magnetic field of 1.5 Tesla and 3 Tesla.
- a magnetic field with a field gradient of 30T/M (3000G/cm).
- a whole body specific absorption rate (SAR) of 2W/kg, for 15 minutes of scanning.

Storage, Cleaning & Sterilization
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. This product should be stored, in its original packaging, in a clean and dry location, in a maximum temperature of 40°C and protected from direct sunlight.

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.

Symbols and Warnings

Manufacturer: Southern Implants
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.