English

INSTRUCTIONS FOR USE: Straumann® ZAGA™ Cover Screws

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Description

These are pre-manufactured temporary dental implant components used in the initial healing phase. Cover screws have built in screws for retention to the implant and are made of commercially pure titanium. All Southern Implants cover screws are provided sterile.

Intended use

Southern Implants® dental implant cover screws are intended to be used in the Maxilla or Mandible connected to the endosseous implant in order to protect the implants internal threads and implant during the healing phase and keep the soft tissue clear of the implant interface.

Indications for use

Southern Implants Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

- replacing single and multiple missing teeth in the mandible and maxilla,
- immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
- immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.

Intended user

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

Intended environment

The devices are intended to be used in a clinical environment such as an operating theatre 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 of single teeth, partial or full bridges, and may be fixed or removable.

Compatibility information

Southern Implants' implants should be restored with Southern components.

Table A

Implant connection type	Compatible device
Straumann® ZAGA™ Zygomatic (CH)	Parts labelled CH-CS

Surgical procedures

1. Select the appropriate cover screw.
2. Connect the cover screw to the implant and tighten the cover screws, with the applicable driver (Table B).
3. Torque the cover screw down to the value indicated in Table C.
4. Reposition the flap margins together and suture closed.

Table B

Driver Type	External Hex
0.9mm Hex driver	✓

Table C

Direct to Implant	Torque
Straumann® ZAGA™ Zygomatic Implant (CH)	Finger tighten

Clinical procedures

A proper clinical and radiological evaluation must be done to determine the bone dimensions and bone quality.

Clinical benefits

Through this procedure patients can expect to have their missing teeth replaced and/or crowns restored.

Before surgery

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

During surgery

Care must be taken that parts are not swallowed during any of the procedures, a 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 to ensure favourable long-term results.

Storage, cleaning and 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.

Contraindications

Do not use in patients:

- who are medically unfit for dental implant procedures.
- where adequate numbers of implants could not be placed to achieve full functional support of the prosthesis.
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6Al-4V), gold, palladium, platinum or iridium.
- 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 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.

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 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.
- 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.

Single use devices

Do not reuse devices indicated for single use. Use the device prior to the expiration date.

Side effects

Potential side effects and temporary symptoms: pain, swelling, phonetic difficulties and 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 and 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.

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.

Performance requirements

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).

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.

Materials

Material type	Commercially Pure Titanium (Grade 4)

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.

MR safety

Nonclinical testing has demonstrated that the Southern Implants® dental implants, metallic abutments and prosthetic screws are MR conditional.

A patient with these devices can be safely scanned in a MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 3000 Gauss/cm (30 T/m).
- Maximum MR system reported SAR corresponding to Normal Operating mode for all landmarks (Head SAR of 2 W/kg for head landmark, 1 W/kg whole body (for landmarks within 30 cm of the implant) or 2 W/kg whole body (for landmarks more than 30 cm from the implant), and appropriate partial body SAR for other landmarks). For imaging landmarks above the thorax, 15 min of scanning at normal operating mode for landmarks greater than 30 cm from the implant with a whole body SAR of 1W/kg for imaging landmarks within 30 cm of the implant.
- In the non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the Southern Implants dental implants, abutments and prosthetic screws, when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Removable restorations should be taken out prior to scanning, as is done for watches, jewellery etc. Should there be no MR symbol on the product label, please note that this device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

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 Metal Abutments	60095440387296.
Basic-UDI for Cover Screws	60095440500883

Related literature and catalogues

CAT-8047-STR-HC - Straumann® ZAGA™ Screw-Retained Abutments
CAT-8048-STR - Straumann® ZAGA™ Drills & Handpiece Devices
CAT-8049-STR-HC – Straumann® ZAGA™ Zygomatic Implants
CAT-8080-STR - Straumann® ZAGA™ Reusable Instruments
CAT-8082-STR - Straumann® ZAGA™ Instrument Trays
CAT-8083-STR - Straumann® ZAGA™ General Use Instruments

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.