SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	INSTRUCTIONS FOR USE: Straumann® ZAGA™ Screw-Retained Abutments
Español	INSTRUCCIONES DE USO: Straumann® ZAGA™ Pilares atornillados
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Deutsch	GEBRAUCHSANWEISUNG: Straumann® ZAGA™ Schraubenhaltige Abutments
Português	INSTRUÇÕES DE UTILIZAÇÃO: Straumann® ZAGA™ Abutments aparafusados

South Africa - Headquarters: 1 Albert Road, Irene, 0062, RSA
T: +27-12-667-1046 | **E:** info@southernimplants.com

EC REP
Southern Implants Europe AB: Holmgatan 30, S-791 71 Falun, Sweden
T: +46 23 13300 | **E:** ecrep@southernimplants.com

Subsidiaries

Australia
Southern Implants Australia
T: +61-(0)-8-9466-2627
E: info@southernimplants.com.au

Spain and Portugal
Southern Implants Iberica
T: +34 935 053 507
E: info@southernimplants.es

United Kingdom and Ireland
Southern Implants UK
T: +44-20-8899-6845 / 6 / 7
E: info@southernimplants.co.uk

USA and Canada
Southern Implants North America Inc.
T: +1-561-472-0990
E: customercare@southernimplants.com

Intended use
Dental implant abutments are intended to be used in the Maxilla or Mandible for supporting a prosthesis on endosseous implants in order to restore chewing function for the patient.

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

Intended environment
The Screw-Retained abutments 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, partial or full bridges, multi-unit cases and may be fixed or removable.

Description
The Screw-Retained abutment for Zygomatic implants is a multiunit abutment that is connected directly to an endosseous implant and is used in multiple unit reconstructions when it is desirable to raise the prosthetic interface to a more apical position than that of an implant head for a screw retained restoration. This abutment is compatible with the Straumann® Zygomatic Implant system for which it is designed. This abutment is only available in a straight configuration.
The Screw-Retained Abutments for Zygomatic Implants are only available in non-engaging versions, indicated for multi-unit cases.
These abutments are provided sterile.

Table 1 - Compatibility

ZAGA Implants				
Straumann® Zygomatic Implant ZAGA™ Flat	Straumann® Zygomatic Implant ZAGA™ Flat	Cover Screw and driver	Abutment and driver	Prosthetic Screw and driver
Item Code	Item Code	CH-CS (Cover screw) I-CS-HD (Driver)	CH-SRA (Screw retained abutment) (046.401 / 046.411) (Driver)	I-HD-M (Driver)
CH-ZC-30.0	CH-ZT-35.0			
CH-ZC-32.5	CH-ZT-37.5			
CH-ZC-35.0	CH-ZT-40.0			
CH-ZC-37.5	CH-ZT-42.5			
CH-ZC-40.0	CH-ZT-45.0			
CH-ZC-42.5	CH-ZT-47.5			
CH-ZC-45.0	CH-ZT-50.0			
CH-ZC-47.5	CH-ZT-52.5			
CH-ZC-50.0	CH-ZT-55.0			
CH-ZC-52.2				

Indications for use
Straumann® Zygomatic Implants are intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. The Screw-Retained Abutments for Zygomatic Implants are intended to be screwed directly onto the implant. Screwretained restorations represent a secure and easy way to maintain a prosthetic restoration.

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.

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.

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.
- 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.

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 & sterilisation
These devices are supplied sterile (sterilised by gamma irradiation). Sterility is assured unless the, container or seal is damaged or opened. If packaging is damaged do not use the product and contact your Straumann® representative/ or return to Southern Implants. The devices must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

Single use devices
Do not reuse implants, single use drills, cover screws, temporary abutments and abutments. Reusing 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.

Cleaning and disinfection
An implant restoration is a single- or multiple-tooth implant crown, bridge or substructure, attached to a Southern Implants abutment or multiple abutments.
Before intraoral use the final restoration needs to be cleaned and disinfected, as per restorative material manufacturer's instructions.

Sterilisation
Southern Implants recommends the following procedure to sterilise the instruments prior to use/re-use:

Methods to sterilise these devices:
1. Pre-vacuum Sterilisation method: Steam sterilise the instruments at 132°C (270°F) at 180-220kPa for 4 minutes. Dry for at least 20 minutes in the chamber. Only an approved wrap or pouch for steam sterilisation must be used.
2. Pre-vacuum sterilisation method: Wrapped, steam sterilise at 135°C (275°F) for 3 minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is cleared for the indicated steam sterilisation cycle.

NOTE: Users in the USA must ensure that the steriliser, wrap or pouch, and all steriliser accessories are cleared by the FDA, for the intended sterilisation cycle.

First Clinical procedure
1. Select and connect appropriate abutment to the implant, using the dedicated abutment driver.
2. Place the abutment on the implant and tighten to 35Ncm with the appropriate driver and torque wrench. Caution: never exceed the recommended torque as overtightening may lead to screw fractures.
3. Verify the correct seating of the abutments using radiographic imaging.
4. Connect impression copings (Traditional: 025.0012, 025.0014 or 025.0050; Digital: 025.0001 or 025.0008) to the Screw-Retained Abutment for Zygomatic Implants.
5. Take an open or closed tray impression and remove/transfer the impression copings to the impression. Alternatively, perform a digital scan of the impression copings, thereafter removing the digital impression copings.
6. Connect the temporary restoration directly to the Screw-Retained Abutment for Zygomatic Implants.

Second Clinical procedure
Attach the prosthesis to the Screw-Retained Abutment for Zygomatic Implants: Place and tighten the restoration screw. Verify the correct seating of the restoration using radiographic imaging. Tighten the restoration using a manual torque wrench to 10-15Ncm.
1. Close screw access hole.
2. Screw-retain or cement final prosthesis, if applicable.

Materials
Screw-Retained Abutment for Zygomatic Implants: Commercially pure titanium (grade 4)

Clinical benefits
Through this procedure 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.

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 normal functional torque 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 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.

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 Metal Abutments	600954403872

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.