English

INSTRUCTIONS FOR USE: Straumann® ZAGA™ Screw Retained Abutments

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Description

The screw-retained abutment for Zygomatic implants is a multi-unit 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.

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.

Indications for use for the implant system

Straumann® Zygomatic implants are intended to be implanted in the upper jaw arch to provide support for fixed 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.

Intended user

Dental technicians, Maxillofacial Surgeons, General Dentists, Orthodontists, Periodontists, 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 theatre or a dentist consultation room.

Intended patient population

Patients that have lost one tooth or multiple teeth.

Compatibility information

Use only original Southern Implants® components to restore Straumann® ZAGA™ Zygomatic ranges. Use components that correspond to the connection type, and prosthetic platform when restoring Zygomatic implants.

<table>
<tr><th colspan="4">Straumann® Zygomatic ZAGA™ Implants</th></tr>
<tr><th colspan="2">Straumann® Zygomatic Implant ZAGA™ Flat</th><th>Straumann® Zygomatic Implant ZAGA™ Round</th><th>Cover Screw and Driver</th><th>Abutment and Driver</th><th>Prosthetic Screw and Driver</th></tr>
<tr><td>CH-ZC-30.0</td><td>CH-ZF-30.0</td><td>CH-ZT-30.0</td><td rowspan="14">CH-CS
(cover screw)

I-CS-HD
(driver)</td><td rowspan="14">CH-SRA-xx*
(straight Screw-Retained Abutment)

046.401
046.411
(driver)</td><td rowspan="14">I-HD-M
(driver)</td></tr>
<tr><td>CH-ZC-32.5</td><td>CH-ZF-32.5</td><td>CH-ZT-32.5</td></tr>
<tr><td>CH-ZC-35.0</td><td>CH-ZF-35.0</td><td>CH-ZT-35.0</td></tr>
<tr><td>CH-ZC-37.5</td><td>CH-ZF-37.5</td><td>CH-ZT-37.5</td></tr>
<tr><td>CH-ZC-40.0</td><td>CH-ZF-40.0</td><td>CH-ZT-40.0</td></tr>
<tr><td>CH-ZC-42.5</td><td>CH-ZF-42.5</td><td>CH-ZT-42.5</td></tr>
<tr><td>CH-ZC-45.0</td><td>CH-ZF-45.0</td><td>CH-ZT-45.0</td></tr>
<tr><td>CH-ZC-47.5</td><td>CH-ZF-47.5</td><td>CH-ZT-47.5</td></tr>
<tr><td>CH-ZC-50.0</td><td>CH-ZF-50.0</td><td>CH-ZT-50.0</td></tr>
<tr><td>CH-ZC-52.5</td><td>CH-ZF-52.5</td><td>CH-ZT-52.5</td></tr>
<tr><td>CH-ZC-55.0</td><td>CH-ZF-55.0</td><td>CH-ZT-55.0</td></tr>
<tr><td>CH-ZC-57.5</td><td>CH-ZF-57.5</td><td>CH-ZT-57.5</td></tr>
<tr><td>CH-ZC-60.0</td><td>CH-ZF-60.0</td><td>CH-ZT-60.0</td></tr>
</table>

*xx denotes the abutment collar height

Clinical benefits

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

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, warp 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; Digital: 025.0001) 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 the screw access hole.
2. Screw-retain or cement final prosthesis, if applicable.

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 hygiene must be achieved to ensure favourable long-term results.

Storage, cleaning and 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 or abutments. Reusing these components may result in:

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

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 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.

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).

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.

Notice regarding serious incidents
Any serious incident that has occurred with the device must be reported to the manufacturer of the device and 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
Screw-retained abutment for Zygomatic implants:	Commercially pure Titanium (Grade 4) according to ASTM F67 and ISO 5832-3, UTS ≥ 900MPa

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.

Magnetic Resonance (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.

Compatible Components

The following components are compatible with the screw-retained abutment for Zygomatic Implants:

Product Number	Component Description
024.4323-04	Protective cap for Screw Retained Abutment, Ø4.6 mm, H 5.1mm, PEEK/TAN
024.4324-04	Protective cap for Screw Retained Abutment, Ø4.6 mm, H 6.6mm, PEEK/TAN
024.4325-04	Protective cap for Screw Retained Abutment, Ø4.6mm, H 8.1mm, PEEK/TAN
024.0020-04	Protective cap for Screw Retained Abutment, Ø4.6mm, H4.5mm, PEEK/TAN
024.0024	Temporary Coping for Screw Retained Abutments, Ø4.6mm, H 11.5mm, TAN
023.4751	Coping for Screw Retained Abutment, Bridge, Ø4.6mm, H 11mm, Ti
023.4754	Coping for Screw Retained Abutment, Bridge, Ø4.6mm, Ceramicor®/POM
023.4758	Burn-out Coping for Screw Retained Abutments, Ø4.6mm, H 11mm, POM
023.0028	Variobase® for Bridge/Bar Cylindrical Coping for Screw Retained Abutments, Ø4.6mm, H4mm, TAN
023.0032	Burn-out Coping for Variobase®, Ø4.6mm, H 11.1mm. POM
023.4752	Coping for Screw Retained Abutments, Ø4.6mm, H 5.5mm, Ti
023.4755	Coping for Screw Retained Abutments, Ø4.6mm, H5.5mm, Ceramicor®
023.4763	Occlusal screw for Titanium, Gold, Burn-out and Variobase® Copings, L 3.7mm, TAN

Additional information for these compatible components can be retrieved from http://ifu.straumann.com/ and searching for the product number.

Straumann® Titanium, gold, burn-out, Variobase® and temporary copings are premanufactured and are available in non-engaging versions. These copings are to be fitted indirectly onto the Straumann® Zygomatic Implants via the screw-retained abutments for Zygomatic implants.

The titanium, gold, burn-out, Variobase® and temporary copings (023.4751, 023.4752, 023.4754, 023.4755, 023.4758, 023.0032, 023.0028 and 024.0024) are used in the prosthetic restoration of dental implants. The intended use of these copings is to serve as a base for the construction of bridge and bar constructs. Depending upon the clinician's choice of prosthesis, the dental laboratory would design the final restoration according to the occlusal geometry of the abutment. The titanium, gold, burn-out, Variobase® and temporary copings are available in a straight (0°) configuration only. Final copings may be placed into occlusion for implants with sufficient primary stability or for implants that are fully osseointegrated. The final bar or bridge restoration is screw-retained to the abutment(s).

Consult the individual product instructions for use documentation for the restorative procedures (visit http://ifu.straumann.com/).

NOTE: some of the compatible components for the Screw Retained Abutments 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 ZAGA® Screw Retained Abutments for Zygomatic Implants	6009544050137U

Related literature and catalogues

CAT-8049-STR-HC - Straumann® ZAGA™ Zygomatic Implants
CAT-8048-STR - Straumann® ZAGA™ Drills & Handpiece Devices
CAT-8051-STR-HC - Straumann® ZAGA™ Cover Screws
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.