English

INSTRUCTIONS FOR USE: Straumann® ZAGA™ Screw Retained Abutments

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Description

The ZAGA™ Screw-Retained Abutment is a multi-unit abutment that is connected directly to an endosseous implant and is used in multiple unit restorations 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 ZAGA™ Zygomatic Implant range for which it is designed. This abutment is only available in a straight configuration.

ZAGA™ Screw-Retained restorations are intended to be screwed directly onto the implant. Screw-retained restorations represent a secure and easy way to maintain a prosthetic restoration. The ZAGA™ Screw-Retained Abutments are only available in non-engaging versions, indicated for multi-unit cases.

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

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.

Compatibility information

Straumann® Zygomatic ZAGA™ Implants					
Straumann® Zygomatic Implant ZAGA™ Flat		Straumann® Zygomatic Implant ZAGA™ Round	Cover Screw and Driver	Abutment and Driver	Prosthetic Screw and Driver
CH-ZC-30.0	CH-ZF-30.0	CH-ZT-30.0	CH-CS (cover screw) I-CS-HD (driver)	CH-SRA-xx* (straight Screw-Retained Abutment) 046.401 046.411 (driver)	I-HD-M (driver)
CH-ZC-32.5	CH-ZF-32.5	CH-ZT-32.5			
CH-ZC-35.0	CH-ZF-35.0	CH-ZT-35.0			
CH-ZC-37.5	CH-ZF-37.5	CH-ZT-37.5			
CH-ZC-40.0	CH-ZF-40.0	CH-ZT-40.0			
CH-ZC-42.5	CH-ZF-42.5	CH-ZT-42.5			
CH-ZC-45.0	CH-ZF-45.0	CH-ZT-45.0			
CH-ZC-47.5	CH-ZF-47.5	CH-ZT-47.5			
CH-ZC-50.0	CH-ZF-50.0	CH-ZT-50.0			
CH-ZC-52.5	CH-ZF-52.5	CH-ZT-52.5			
CH-ZC-55.0	CH-ZF-55.0	CH-ZT-55.0			
CH-ZC-57.5	CH-ZF-57.5	CH-ZT-57.5			
CH-ZC-60.0	CH-ZF-60.0	CH-ZT-60.0			

*xx denotes the abutment collar height

Storage, cleaning and sterilisation

The ZAGA™ Screw-Retained Abutments 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.

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

Straumann® Protective caps, and Titanium and Gold Copings are non-sterile when delivered. Before intraoral use the final restoration needs to be cleaned and disinfected, as per restorative manufacturer's instructions. Southern Implants recommends the following procedure to sterilise the restoration prior to use:

Methods to sterilise the restoration and abutment screw:

1. Pre-vacuum sterilisation method: Steam sterilise the abutments 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 sterilise accessories are cleared by the FDA, for the intended sterilisation cycle.

Contraindications

Do not use in patients:

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

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 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, periodontal status, and adequacy of bone.
- 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.
- 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.
- regular patient follow-up, and proper oral hygiene must be achieved are essential favourable long-term results.

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. Connection impression copings (Traditional: 025.0012, 025.0014 or 025.0050; Digital 025.0001 or 025.0008) to the ZAGA™ Screw-Retained Abutment.
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 ZAGA™ Screw-Retained Abutment.

Second Clinical Procedure

Attach the prosthesis to the ZAGA™ Screw-Retained Abutment: 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

ZAGA™ Screw- Retained Abutment	Commercially pure Titanium (Grade 4) according to ASTM F67 and ISO 5832-3, UTS ≥ 900MPa

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

This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artefact in the MR environment. The safety of this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 ZAGA™ Screw-Retained Abutment range:

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
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
023.4763	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 and gold copings are premanufactured and are available in non-engaging versions. These copings are to be fitted indirectly onto the ZAGA™ Zygomatic implants via the ZAGA™ Screw-Retained Abutments.

The titanium and gold copings (023.4751 and 023.4754) 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 and gold copings are available in a straight (0°) configuration only and are not intended to be modified or fabricated to create any angulation or angle correction. 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).

Procedure for Gold Copings

A. Investment

Important: The internal configuration and the coping margin must be carefully cleaned inside and outside before investment. Do not cover the fragile margin of the copings with wax. The use of investment material for rapid heating methods (speed investment methods) is not recommended. Do not use wetting agents. Follow the manufacturers' recommendations of the investment compound. Ceramicor® is a non-oxidizing alloy and does not allow ceramic bonding.

B. Cast-on components of Ceramicor®

The melting range of the cast-on alloys must not exceed the liquidus of 1350°C/2462°F. Follow the recommendations of the alloy manufacturer. The modelling on the Ceramicor® component must be sufficiently thick (wax layer of at least 0.7mm). Note: Non-precious metal alloys must not be cast onto Ceramicor®. Ceramicor® is a non-oxidizing alloy and does not allow ceramic bonding. Dental casting alloys suitable for use with Ceramicor® include high noble alloys, precious metal alloys with a minimum gold and platinum group metals content of 25%, and palladium-based alloys with a minimum palladium content of 50% (refer to ISO standard 9693 and ISO standard 22674).

C. Solderable components of Ceramicor®

The solder must match the alloy combination. The liquidus of the solder must be 20-60°C/68-140°F below the solidus of the alloys that are to be bonded. Follow the recommendations of the manufacturer of the solder.

Important: The coping must be properly positioned in the abutment before the screw is tightened. Make sure to fix the coping to the abutment with the appropriate screw. Tighten the coping/occlusal screw with the respective screwdriver along with the ratchet (046.119) and torque control device (046.049) to the recommended torque of 15 Ncm.

Warning: Torques greater than 15 Ncm may result in failure of the coping and/or screw. Torque values less than the recommended values may result in loosening of the coping, which may lead to coping and/or restoration failure. Please note: Once the coping on the abutment has been screwed to the implant using the indicated amount of torque, it should not be removed anymore. Otherwise, a new screw is to be used.

Closure of the screw channel:

Important: Before fixing the restoration onto the coping, the screw openings are to be sealed off with cotton and a sealing compound (e.g. gutta-percha or composite restorative material). This allows for a later removal of the coping in a case a crown replacement is necessary.

Modification of devices:

In the conventional workflow, if required, copings may be modified in the dental lab or chair side according to the patient's anatomy. The height of the plastic modelling aid may be modified according to the occlusal plane of the individual situation. No reduction of the gold coping is permitted.

Procedure for Titanium Copings

Restoration design using a conventional workflow:

Caution: Always make sure to protect the abutment's prosthetic connection by fixing the abutment to either a polishing aid or an implant analogue during polishing and other lab procedures.

1. Place the abutment into the implant analogue on the working model. Make sure that the retentive elements of the analogue-abutment connection are properly aligned.
2. Fix the abutment to the implant analogue by tightening the basal screw hand-tight.
3. Place the coping onto the abutment. Make sure that the retentive elements of the coping-abutment connection are properly aligned.
4. Fix the coping to the abutment by tightening the occlusal screw hand-tight.

5. Fabricate a screw-retained restoration by using the coping and abutment. To make a crown follow the standard procedures according to the material manufacturer's instructions. Make a temporary restoration by using a pre-formed stent and suitable temporary material.
6. To ensure a correct transfer of the abutment position from the master cast to the patient, an individual index can be fabricated on the case. In the case of single crowns, the index is secured with support from adjacent teeth; and in the case of bridges, the abutments are splintered to one another.
7. Always use the corresponding screwdriver to remove the prosthetic devices from the implant analogue.

Important: The coping must be properly positioned in the abutment before the screw is tightened. Make sure to fix the coping to the abutment with the appropriate screw. Tighten the coping/occlusal screw with the respective screwdriver along with the ratchet (046.119) and torque control device (046.049) to the recommended torque of 15 Ncm.

Warning: Torques greater than 15 Ncm may result in failure of the coping and/or screw. Torque values less than the recommended values may result in loosening of the coping, which may lead to coping and/or restoration failure. Please note: Once the coping on the abutment has been screwed to the implant using the indicated amount of torque, it should not be removed anymore. Otherwise, a new screw is to be used.

Closure of the screw channel:
Important: Before fixing the restoration onto the coping, the screw openings are to be sealed off with cotton and a sealing compound (e.g. gutta-percha or composite restorative material). This allows for a later removal of the coping in a case a crown replacement is necessary.

Modification of devices:
In the conventional workflow, if required, copings may be modified in the dental lab or chair side according to the patient's anatomy. The coping height may be modified according to the occlusal plane of the individual situation. Reduction of the titanium coping post height to <4 mm is not permitted. Reduction of the titanium coping width is not permitted.

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-FDA - Straumann® ZAGA™ Zygomatic Implants
CAT-8048-STR - Straumann® ZAGA™ Drills & Handpiece Devices
CAT-8051-STR-FDA - Straumann® ZAGA™ Cover Screws
CAT-8080-STR - Straumann® ZAGA™ Reusable Instruments
CAT-8082-STR-FDA - 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.