SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Straumann® ZAGA™ Side Cut Burr**
Español	**INSTRUCCIONES DE USO: Straumann® ZAGA™ Side Cut Burr**
Italiano	**ISTRUZIONI PER L'USO: Straumann® ZAGA™ Side Cut Burr**
Français	**MODE D'EMPLOI : Straumann® ZAGA™ Side Cut Burr**
Deutsch	**GEBRAUCHSANWEISUNG: Straumann® ZAGA™ Side Cut Burr**
Português	**INSTRUÇÕES DE UTILIZAÇÃO: Straumann® ZAGA™ Side Cut Burr**

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

EC REP

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
The ZAGA™ Side Cut Burr are intended to be used to prepare the osteotomy for placement of the Straumann® Zygomatic Implant, ZAGA™ Flat Implant.

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

Intended environment
These devices are intended to be used in a clinical environment such as an operating theater or a dentist consultation room.

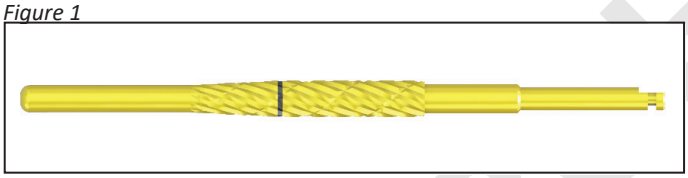
Intended patient population
This device is used in the dental restoration of partially or fully edentulous patients in the upper or lower jaw. Restorations may comprise single teeth, partial or full bridges, and may be fixed or removable.

Description
The ZAGA Side Cut Burr (Figure 1) is a drill dedicated to the Straumann® Zygomatic Implant System. This drill has a side-cutting action as opposed to a cutting tip to aid in this function. This drill is made from Grade 5 Titanium alloy and is anodised yellow. The ZAGA Side Cut Burr is a single-use drill. The drills are provided sterile and for single patient use only.

Table 1

ZAGA Implants				
Drill code	Material	Coating (if any)	Descripton of product	Number of uses
CH-D-CM	Titanium Alloy	800 rpm	Side Cut Burr Ø2.8-Ø3.9mm	1

Figure 1



Indications for use of our implant system
The 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.

Indications for use of the ZAGA Side Cut Burr
The ZAGA Side Cut Burr is indicated for use in drilling a canal-shaped osteotomy in the alveolar bone for placement of the Straumann Zygomatic Implant, ZAGA Flat Implants which has alveolar bone contact primarily along the back (palatal side) of the implant's coronal section.

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.
- Blunt drills may cause damage to the bone which could compromise osseointegration.

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. 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 or equipment.

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 Southern representative/ or return to Southern Implants. The device 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.

Sterilisation
Southern Implants recommends the following procedure to sterilise the instruments prior to use when packed in a tray.

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.

Clinical procedure
A proper clinical and radiological evaluation must be done to determine the bone dimensions and bone quality. Ensure that all instruments and drills are in a good condition.

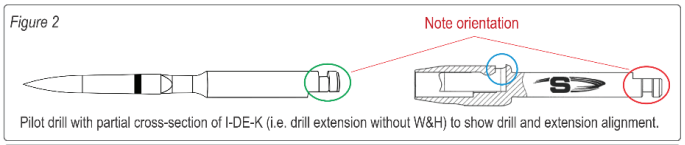
Surgical procedure
Case Planning:
A proper clinical and radiological evaluation must be done to determine the bone dimensions and bone quality.

Procedure:
1. Drill at sufficient speed (800rpm), with constant irrigation with sterile saline.
2. Use an up-and-down motion with the hand-piece, without stopping the motor. This will allow the irrigation to flush away bone debris on the drill.
3. Gradually enlarge the osteotomy in a stepwise approach to the desired diameter and depth.
4. During surgery the clinician will be able to assess the bone quality and should use dense bone protocols when necessary, to prepare the site. This is to avoid the implant getting stuck before it is properly seated in the osteotomy.
5. Avoid excessive lateral pressure (bending) on the drills during drilling procedures. Excessive lateral pressure to the drill can cause drill fracture.
6. Verify the drill is securely locked into the handpiece before drilling procedure starts.

Note: Connect the drill latch to the handpiece. If the latch is not inserted fully into the handpiece the torque is applied to the latch, resulting in possible twisting of the latch or damage to the handpiece. Consult the instructions for use of the handpiece to ensure proper engagement of the latch.

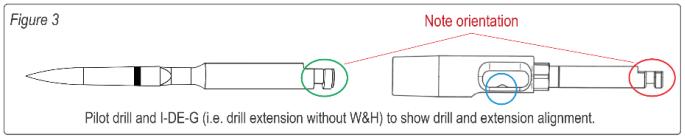
Drill extension
When a drill extension is used (I-DE-K / I-DE-G), care must be taken to ensure that the latch is fully engaged to prevent distortion. See Figure 2 and Figure 3 below.

Figure 2



Pilot drill with partial cross-section of I-DE-K (i.e. drill extension without W&H) to show drill and extension alignment.

Figure 3



Pilot drill and I-DE-G (i.e. drill extension without W&H) to show drill and extension alignment.

The orientations indicated in Figure 2 and Figure 3 ensure that the catch feature of the drill extension (circled in blue) slots into the latch groove of the drill (circled in green). This prevents the drill from sliding out of the drill extension.

Note:
- Do not apply more than 40-45Ncm to any latch type drill/ instrument, this could cause damage to the handpiece and latch of the instrument.
- Blunt drills cause excessive torque and result in damage to the handpiece or drill latch.

Materials
ZAGA Side Cut Burr: Titanium Alloy (Ti-6AL-4V), Anodised Yellow.

Clinical benefits
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).

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 Drills and Hand Piece Devices	600954403875
Basic-UDI for Reusable Instruments	600954403876

Symbols and Warnings

Manufacturer: Southern Implant
1 Albert Rd, P.O Box 605 IRENE, 0062,
South Africa.
Tel: +27 12 667 1046

Prescription device*

Sterilization using Irradiation

Non-sterile

Caution

Consult instruction for use

Use by date (mm-yy)

Do not reuse

Do not re-sterilize

Batch code

Do not use if package is damaged

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.