SOUTHERNIMPLANTS®
Innovative Treatment Solutions

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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
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.

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

Intended environment
The cover screws 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 single teeth, partial or full bridges, and may be fixed or removable.

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 comercially pure titanium. All Southern Implants cover screws are provided sterile.

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 8mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.

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.

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 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.

Compatibility information
SI Implants should be restored with Southern components. In the SI range there are 5 implant connections, the implant code and connection type, can be identified by specific abbreviations in the product codes. Range identifiers are summarised in table A

Table A

Implant connection type	Compatible prosthetic device
External Hex (EX)	Parts labelled SCP-2, SCNU2, SCU2, SCAU5, SCU6, SC7
Tri-Nex (EL) (Lobe)	Parts labelled CS-L-(ø)
Deep Conical (DC)	Parts labelled CS-DC(ø)
Internal Hex (M)	Parts labelled CS-M, (used with ø3.75, 4.2 & 5.0 mm platforms)
Internal Hex Provata (M) (Z)	Parts labelled CS-M, (used with ø4.0, 5,0 &6,0 mm platforms)
	Parts labelled CS-Z, (used with ø7.0,8.0 &9.0 mm platforms)
IT (ITS) (ITS6)-Octagon	Parts labelled TT0 (used with ø4,8 mm platforms)
	Parts labelled TT6-0 (used with ø6,5 mm platforms), for engaging items

NOTE: Internal Hex (M-Series) implants are packaged with a cover screw (CS-M) except for IM-T4218 (18 mm length) implant.

Storage, cleaning & 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.

Materials

Cover screw: Commercially Pure Titanium (Grade 4)

Clinical 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).

Table B

Driver type	External Hex	DC	Tri-Nex	Internal Hex	IT
0.9mm Hex driver	✓				
1.22 mm / 1.27 mm Hex Universal driver		✓		✓	
1.22 mm hex driver		✓			
1.27 mm hex driver				✓	
Unigrip driver			✓		
Quad driver					
Torx driver					✓

3. Torque the cover screw down to the value indicated in Table C.
4. Reposition the flap margins together and suture closed.

Table C

Direct to Implant	Torque
External Hex	
ø3.0 mm	10-15 Ncm
ø3.25, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	10-15 Ncm
Tri-Nex	
ø3.5 mm	10-15 Ncm
ø4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm Tri-nex Implant	10-15 Ncm
DC	
ø3.0 mm	5-10 Ncm
ø3.5, 4.0 mm	5-10 Ncm
ø5.0 mm	5-10 Ncm
Internal Hex (M-Series & Provata)	
ø3.75, 4.2, 5.0 mm M-Series	10-15 Ncm
ø4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm Provata Implant	10-15 Ncm
IT Octagon	
ø3.3, 4.1, 4.9, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm IT Implant	10-15 Ncm

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 Conditional

Non-clinical testing and MRI simulations were performed to evaluate the dental implant system offered by Southern Implants. Non-clinical testing demonstrates that these products are MR Conditional. A patient with an implant from a Southern Implants System can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg and head average SAR of 3.2 W/kg, for 15 minutes of scanning (i.e., per pulse sequence) in the normal operating mode.

The scanning conditions defined above will produce a maximum temperature increase of 4.9 °C in implants from Southern Implants systems after 15 minutes of continuous scanning (i.e., per pulse sequence).
In non-clinical testing, the image artifact caused by implants from Southern Implant System extends approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

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

Related literature & catalogues

CAT-2004- Tri-Nex Implants Product Catalogue
CAT-2005- IT Implants Product Catalogue
CAT-2020- External Hex Implants Product Catalogue
CAT-2042- Deep Conical Implants Product Catalogue
CAT-2043- Internal Hex Implants Product Catalogue
CAT-2060- PROVATA® Implants Product Catalogue
CAT-2069- INVERTA® Implants Product Catalogue
CAT-2070- Zygomatic Implants Product Catalogue

Symbols and Warnings

Manufacturer: Southern Implant
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.