SOUTHERNIMPLANTS®
Innovative Treatment Solutions

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Intended use
Southern Implants® dental implants abutment 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 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, partial or full bridges, multi-unit cases and may be fixed or removable.

Description
The Southern implants prosthetic range consist of abutments or cylinders for prosthetic rehabilitation on the Southern range of implants. These are pre-manufactured and can be attached direct or indirect to the implant as an aid in prosthetic rehabilitation. These instructions apply to gold abutments, gold cylinders and burn out sleeves. These components are supplied non-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 8 mm 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 SI 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 (*) is indicative of various lengths available.

Implant connection type	Compatible device
External Hex (EX)	Parts labelled GC-EX-(ø), for engaging items
	Parts labelled GC-NX-(ø), for non-engaging items
Tri-Nex (EL) (Lobe)	Parts labelled GC-EL-(ø), for engaging items
	Parts labelled GC-NL-(ø), for non-engaging items
Deep Conical (DC)	Parts labelled GC-DC-(ø), for engaging items
	Parts labelled GC-NDC-(ø), for non-engaging items
IT (ITS) (ITS6) - Octagon	Parts labelled ITS-GC1 (used with ø4.8 mm platforms) for engaging items
	Parts labelled ITS-GC1ne (used with ø4.8 mm platforms) for non-engaging items
	Parts labelled ITS6-GC1 (used with ø6.5 mm platforms) for engaging items
	Parts labelled ITS6-GC1ne (used with ø6.5 mm platforms) for non-engaging items

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Abutment level	Parts labelled GMC1 (used with ø4.8 mm abutment platforms) non-engaging
	Parts labelled GMCW1 (used with ø6.0 mm abutment platforms) non-engaging

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.

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 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 steriliser accessories are cleared by the FDA, for the intended sterilisation cycle.

Laboratory procedures

This abutment has a machined gold base which fits directly to the implant or compact conical abutment, together with a waxing sleeve, to facilitate the wax up process.

NOTE: The Gold Abutment is threaded and the plastic waxing sleeve screws onto the abutment, ensure the two components are screwed together at all times.

1. Place the abutment onto the implant analogue, make sure that the retentive elements of the analogue-abutment connection are properly aligned. Fix the abutment by hand tightening the lab-screw to the analogue.
2. Trim the plastic sleeve to the correct occlusal height, with no additional angular correction, and out of occlusion. (retaining a minimal height of 4 mm for single units), Fabricate a cement-retained or screw-retained restoration. Add wax to achieve the desired substructure.

Investment

1. Clean the abutment before investing, do not cover the abutment margins in wax, do not use wetting agents.
2. When investing, avoid the use of a tension reliever as it leaves a residue, which can result in metal creep.
3. Sprue the restoration, making sure the screw channel is vertical to the investment ring.
4. The use of investment material for rapid heating methods (speed investment methods) are not recommended.
5. A Phosphate bonded investment must be used.

WARNING: Cast onto cylinder using precious metal.

Casting Procedure

Gold abutment casting specifications:

1. The Gold (Ceramicor) abutment is not a porcelain-bonding alloy. The alloy is designed to have oxidation during casting-on procedures. Direct porcelain bonding could result in the porcelain turning green or chipping off due to a poor bond.
2. The Co-efficient of Expansion of SI Gold abutments are:
   25-500°C 11.9
   25-600°C 12.2
3. The melting temperature of the Gold abutment is approx. 1475°C.
4. Recommended cast on temperature is +/-920°C,
5. Casting at higher temperatures could result in distortion of the abutment.
6. Casting at lower temperature of 650°C will result in a miscast.
7. The furnace should run up straight to the casting temperature to reduce investment expansion. Too much expansion could result in overflow of metal onto the fitting surface of the abutments.

Recommended casting alloys:

Contact your restorative material supplier for a compatible material to Southern Implants Gold abutments.

Commonly used metals for custom posts (non-ceramic bonding) are: Stabilor, procast Y45-Argen, Argeno 1.

Commonly used metals for custom posts (Ceramic bonding) are: Argeno 1, Degudent U, Argident 3, Degunorm – Gold gate system, Bond- on 4, and Degudent G.

After casting procedure

1. After casting, the removal of the investment material is most critical. It must be removed ultrasonically. Do not sandblast, or blast the fitting surface with glass beads. If this surface is blasted in any way, the precision-machined gold part will not fit the implant as intended. If the abutments are to be sandblasted cover it with a thin layer of wax or use a polishing protector cap.
2. Work off the restoration as normal. Take care not to damage the fitting surface.
3. Before sending the restoration and model to the dentist, clean the model thoroughly with soap, water, and a toothbrush, or steam clean. Then clean the abutment crown and its screw, preferably in the ultrasonic bath. Assemble the crown to the model and send it to the dentist.
4. Occlusion: Implant borne crowns are usually kept out of occlusion by about one-tenth of a millimetre.

Clinical procedures

The clinician receives the restoration from the laboratory.

1. Remove the healing abutment or temporary restoration.
2. Clean, disinfect and sterilise the restoration as described above.
3. Insert the restoration into the patient's mouth.
4. Position the restoration on the implant making sure that the retentive elements of the implant / abutment connections are properly aligned.

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Table B

Driver type	External Hex	DC	Tri-Nex	Internal Hex	IT	Compact Conical screw
1.22 mm / 1.27 mm Universal driver	✓	✓		✓		✓
1.22 mm hex driver	✓	✓				✓
1.27 mm hex driver				✓		
Unigrip driver	✓		✓			✓
Quad driver	✓			Gold screws only		
Blade driver	✓					✓
Torx driver					✓	

5. Fix the abutment to the implant / abutment with the correct screw using applicable driver (Table B). Torque the screw down to the value indicated in Table C.

Table C

Direct to Implant	Torque
Ext-Hex	
ø3.0 mm	25-32 Ncm
ø3.25, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	32-40 Ncm
Tri-Nex	
ø3.5mm	32 Ncm
ø4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	32-40 Ncm
DC	
ø3.0 mm	15 Ncm
ø3.5, 4.0 mm	20 Ncm
ø5.0 mm	25-32 Ncm
Internal Hex (M-Series & Provata)	
ø3.75, 4.2, 5.0 mm M-Series	32 Ncm
ø4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm Provata Implant	32 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	32-40 Ncm

Abutment level	All Titanium cylinders on Compact Conical Abutments: 10-15 Ncm

6. Verify the correct seating of the restoration using radiographic image.
7. Do not exceed the recommended torque value as this may result in failure of the screw, abutment or implant. Do not torque less than the recommended value, this may result in loosening of the abutment that can lead to abutment or implant failure.
8. Close the screw access hole.
9. Cement the temporary prosthesis if applicable.

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.

Materials
Gold Abutment: Gold alloy Au-60%, Pd-20%, Pt-19%, Ir-1%
Plastic Sleeve: Polyoxymethylene (POM)
Abutment screws: Titanium alloy Ti-90%, Al-6%, V-4%,
Gold Alloy Au-61%, Ag-16.5%, Pt-13.5%, Cu-9%

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).

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

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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 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
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South Africa.
Tel: +27 12 667 1046

CE 2797 — 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.

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