SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Southern Implants® Impression Copings**
Español	**INSTRUCCIONES DE USO: Southern Implants® Casquillos de impresión**
Italiano	**ISTRUZIONI PER L'USO: Southern Implants® Cappette da impronta**
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Deutsch	**GEBRAUCHSANWEISUNG: Southern Implants® Impression Copings**
Português	**INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® Copings de impressão**

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Intended use
Southern Implants® impression copings are intended to replicate the position of the implant. It helps create a replica of the position and orientation of the patient's implant. The impression coping is attached to the implant before an impression is taken using a screw. This facilitates the transfer of the dental implant position and orientation to a dental model that can be used by the laboratory to manufacture the prosthesis.
The impression copings are medical devices.
The impression copings are intended for single use on a single patient.

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

Intended environment
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
Impression copings are premanufactured components that is connected directly to an endosseous implant and is used single tooth and multiple unit reconstructions to take an impression of the patients. Impression copings come in a transfer (closed tray) and pickup (open tray) type configuration. These devices are supplied sterile, and for single patient use.

Indications for use
Impression copings are indicated for use when the position and orientation of the dental implant relative to other structures in the mouth need to be determined to transfer to a laboratory model for the construction of a dental prosthesis.

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 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 or aspired 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 summarized in table A.

Table A

Implant Connection type	Compatible prosthetic device
External hex (EX)	Parts labelled CP (used with ø3.0mm platform) Parts labelled CBNU, CBNU-W, CBN70 (used with ø3.43, 3.8, 3.89 & 4.07mm platform) Parts labelled CBV, CBU, CB70, CBU-W, CB75 (used with ø4.07, 4.3 & 4.5mm platform) Parts labelled CBAV, CBAU, CBA75, CBAU-W, CBAU-M (used with ø5.0 & 5.5mm platform) Parts labelled CBBBU, CBBB75, CBBBU-W (used with ø6.0 & 6.5mm platform) Parts labelled CMAX9, CMA9L (used with ø7.5mm platform)
TRI-NEX (EL) (Lobe)	Parts labelled IC-L-35, IC-L-35-W, ICT-L-35, ICT-L-35-W (used with ø3.5 & 3.7mm platform) Parts labelled IC-L-43, IC-L-43-W, ICT-L-43, ICT-L-43-W (used with ø4.3 & 4.5mm platform) Parts labelled IC-L-50, IC-L-50-W, ICT-L-50, ICT-L-50-W (used with ø5.0 & 5.5mm platform) Parts labelled IC-L-60, IC-L-60-W, ICT-L-60, ICT-L-60-W (used with ø6.0, 6.5 & 7.0mm platform)
Deep Conical (DC)	Parts labelled IC-DC3, IC-DC3-W, ICT-DC3, ICT-DC3-W (used with ø3.02 & 3.5mm platform) Parts labelled IC-DC4, IC-DC4-W, ICT-DC4, ICT-DC4-W (used with ø3.5 & 4.0mm platforms) Parts labelled IC-DC5, IC-DC5-W, ICT-DC5, ICT-DC5-W (used with ø5.0mm platform)
Internal Hex (M)	Parts labelled ICT-M, ICT-MW, IC-M (used with ø3.6mm platforms) Parts labelled ICT-MW-P45, IC-MW-P45 (used with ø3.6 & 4.5mm platforms)
Internal Hex Provata (M) (Z)	Parts labelled ICT-M, ICT-MW, IC-M (used with ø3.6, 4.5, 6.0mm platforms) Parts labelled ICT-MW-P45, IC-MW-P45 (used with ø3.6 & 4.5mm platforms) Parts labelled ICT-Z, ICT-ZW, IC-Z (used with ø5.6mm platforms)

IT (ITS) Octagon	Parts labelled ITS-CA5, ITS-TRC5, ITS-TRC-NE (used with ø4.8mm platforms) Parts labelled ITS6-CA5, ITS6-TRC5, ITS6-TRCNE (used with ø6.5mm platforms)
Compact Conicals	Parts labelled CMC1, CMC2, CMCW1, CMCW2 (used with compact conical abutments)

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:

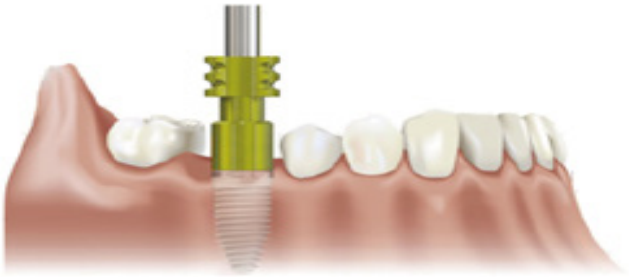
- damage on the surface or critical dimensions, which may result in performance and compatibility degradation.
- adds the risk of cross-patient infection and contamination if single use items are reused.

Southern Implants does not accept any responsibility for complications associated with reused components.

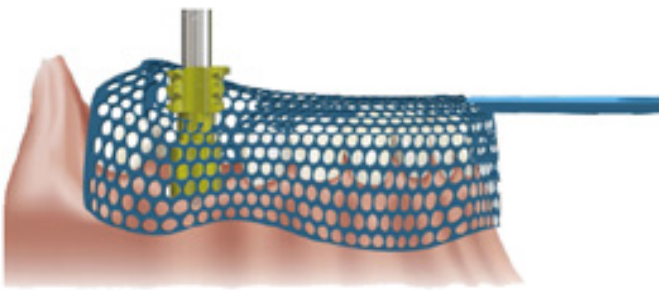
Surgical procedure

Pick up impression coping (open tray technique)

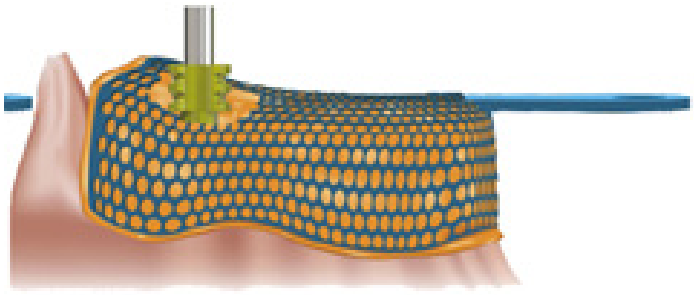
1. Select the impression comping. Screw the impression coping into the implant.



2. Use a custom impression tray with openings cut into the tray at correct location where the impression coping will stick out, this is needed to get access to the screw to loosen the impression coping from the implant. A stock tray can also be used, by modifying it to have the openings correspond to the implant position.



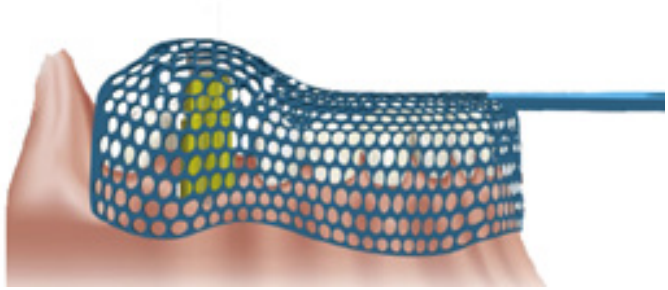
3. Fill the impression tray with impression material and take the impression, make sure that the openings in the tray corresponds to the implant position. Once the impression material has set use the appropriate driver and loosen the impression coping from the implant.



Transfer impression coping (closed tray technique)

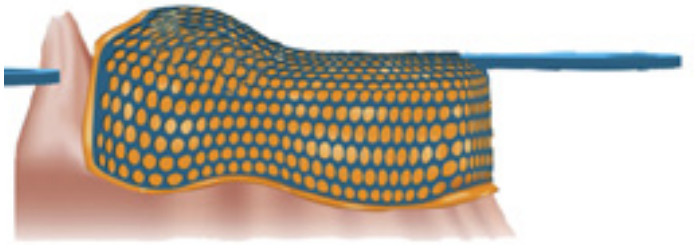
1. Select the impression comping. Screw the impression coping into the implant.

2. Use either a custom tray or stock tray, there is no need to cut opening into the tray as this is a closed tray technique.



3. Fill the impression tray with impression material and take the impression, Once the impression material has set remove the impression from the patient's mouth. If multiple implants are being restore, remove one impression coping from the patient and inset the impression into the impression, then continue to the rest. It is important to place the transfer coping into the same opening in the

material as what it was positioned in the mouth.



Clinical benefits
Patients can expect to have their missing teeth replaced and/ or crowns restored. Screwdrivers are used in dental procedures or in dental implant crowns & bridges.

Healing
The healing time required for osseointegration depends on the individual and treatment protocol.

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. 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.

Materials
Impression copings: Commercially Pure Titanium (Grade 4 or 5)

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.

MR Safey
These products have not been tested for MRI safety, however, an analysis and review of the literature has shown that the risks of scanning a Southern Implants implant system are not of concern under the following conditions:
- a static magnetic field of 1.5 Tesla and 3 Tesla.
- a magnetic field with a field gradient of 30T/M (3000G/cm).
- a whole body specific absorption rate (SAR) of 2W/kg, for 15 minutes of scanning.

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 Impression Coping	600954403878

Related literature & catalogues
CAT-2004 - Tri-Nex® Implants Product Catalogue
CAT-2005 - IT Implants Product Catalogue
CAT-2010 - Osseointegrated Fixtures 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

Basic UDI

Product	Basic-UDI Number
Basic-UDI For Reuasble Instruments	600954403876

Related literature & catalogues

CAT-8013 - Synthetic Implant Product Catalogue

Symbols and Warnings

Manufacturer: Southern Implants
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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.