English

INSTRUCTIONS FOR USE: Southern Implants® Scanning Abutments (CIA)

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Description

The CIA abutments are pre-manufactured titanium dental abutments that can be connected directly to an endosseous implant for use as an aid in prosthetic rehabilitation. They can be scanned directly using an intraoral or a model scanner. The extended PEEK screw is used during scanning to include a screw access hole in the milled crown. The cementing surface is roughened. They are available in engaging and non-engaging versions. Engaging versions are indicated for single implant cases. And non-engaging versions are indicated for multi-unit implant cases.

Note: Screws are sold separately for all abutments.

Intended use

Southern Implants® dental 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

Applicable for the Provata Implant System

The Provata Implant System is intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. The Provata Implant System is intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

Compatibility information

Southern Implants' implants should be restored with Southern Implants' components. The Scanning Abutments (CIA) are available in 5 implant connections. The abutment code and connection type can be identified by the specific abbreviations in the product codes. Range identifiers are summarised in Table A.

Table A - Compatible

Implant connection type	Compatible device
External Hex	Parts labelled CIA-EX-Ø (engaging components used with the corresponding connection interface being Ø4.0mm, Ø5.0mm and Ø6.0mm)
	Parts labelled CIA-NX-Ø (non-engaging components used with the corresponding connection interface being Ø4.0mm,Ø5.0mm and Ø6.0mm)
Internal Hex (M)	Parts labelled CIA-EM (engaging component used with Ø3.75mm, Ø4.2mm and Ø5.0mm platform)
	Parts labelled CIA-NM (non-engaging component used with Ø3.75mm, Ø4.2mm and Ø5.0mm platform)
Internal Hex PROVATA® (M / Z)	Parts labelled CIA-EM (engaging component used with Ø4.0mm, Ø5.0mm and Ø6.0mm platform)
	Parts labelled CIA-NM (non-engaging component used with Ø4.0mm, Ø5.0mm and Ø6.0mm platform)
	Parts labelled CIA-EZ (engaging component used with Ø7.0mm, Ø8.0mm and Ø9.0mm platforms)
	Parts labelled CIA-NZ (non-engaging component used with Ø7.0mm, Ø8.0mm and Ø9.0mm platforms)
TRI-NEX (EL) (Lobe)	Parts labelled CIA-EL-Ø (engaging component used with Ø3.5mm, Ø4.3mm, Ø5.0mm and Ø6.0mm platforms)
	Parts labelled CIA-NL-Ø (non-engaging component used with Ø3.5mm, Ø4.3mm, Ø5.0mm and Ø6.0mm platforms)
Internal Octagon (IT)	Parts labelled CIA-ITS and CIA-ITS6 (engaging component used with Ø4.8mm and Ø6.5mm platform IT implant respectively)
	Parts labelled CIA-ITS-NE and CIA-ITS6-NE (non-engaging component used with Ø4.8mm and Ø6.5mm platform IT implant respectively)

Scanning Abutments (CIA) are packed with their corresponding scanning pins. Prosthetic screws are sold separately. See Prosthetic Screw Instructions for use (CAT-8068) for recommended screw torques.

Storage, cleaning and sterilisation

This CIA abutments are delivered non-sterile and are intended for single use. Final restoration should be cleaned and disinfected, as per restorative material manufacturer's instructions, before intra oral use. Pre-vacuum sterilization method: Steam sterilize the abutments at 135°C (275°F) at 180-220kPa for 3 minutes. Dry for at least 20 minutes in the chamber. Only an appropriate Regulatory Authority approved wrap or pouch for steam sterilization must be used.

Note: Only an appropriate regulatory authority approved wrap or pouch for steam sterilization must be used. It is the responsibility of the user to establish whether or not their sterilizer is approved by an appropriate regulatory authority to meet recommended parameters.

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.

Contraindications

Do not use in patients:

- who are medically unfit for dental implant procedures (e.g. uncontrolled diabetes and intreated infection in nearby bone).
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6AL-4V)
- where adequate numbers 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 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 attempting 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 has orofacial 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. The post must not be reduced below a minimum height of 4mm in single implant cases. No additional angular correction is intended for the abutments. 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, thus rubber-dam application is recommended when appropriate.

Care must be taken to apply the correct tightening of abutments and abutment screws. Do not exceed recommended tightening torque for the abutment screw (refer to Prosthetic Screw Instructions for use CAT-8068 for recommended screw torques). Overtightening of the abutment may lead to screw fracture.

Post-surgery

Regular patient follow-up, and proper oral hygiene must be achieved and are essential for favourable long-term results.

Procedure for use

The limits of customization of CIA Abutments are shown in Table B.

Table B – Limits of Customization

Parameter	Limits of Customization
Wall thickness	No customization allowed
Diameter	No customization allowed
Angulation	No customization to provide additional angulation allowed
Post height	Not to be reduced below a minimum height of 4mm in single implant cases

Method 1: Digital workflow by using digital libraries

Scanning procedure

1. Download Southern Implants digital library for 3Shape and Exocad by registering on www.southernimplants.com.
   Note: Refer to website on a regular basis for library updates.
2. Load the libraries into the CADCAM system by following their instructions.
3. The implant position is obtained digitally by an intraoral scan of the patient with Scan flags attached to the endosseous implant, or a desktop scan of the dental model with the Scan flags attached to the laboratory analogue.
4. Remove the scan flag from the implants or from the model, replace with healing abutments.
5. The scan is then imported into the design software.

Designing procedures

6. The Scan flag in the digitalform is now matched and aligned with the corresponding Scan flag from the library.
7. The software recognises the relative position of the Scan flag to the implant or analogue, and place the abutment for the design steps.
8. The CIA abutment/s are chosen from the library, the user will determine the desired tooth or teeth positions needed for the abutment/s, and the path of insertion will be determined. This will govern the screw retained or cementable restoration if possible.
9. The software will guide the user through the steps to complete the restoration.
10. Selection of the restorative material. (The most common material to use is Zirconia).

Milling & sintering procedures

11. The restoration design is completed and the dsign file is sent to a milling unit or a production facility.
12. The milled custom abutment or screw retained restoration is to be sintered to the specifications of the manufacturer if Zirconia was used. Once sintered the abutment, custom abutment or restoration is cemented to the prefabricated titanium CIA abutment by closing the screw channel temporarily to keep the screw channel free of cement.
13. The milled substructure milled out of the material of choice is cemented onto the CIA abutments and the final restoration constructed and cemented onto this.

Method 2: Digital workflow by scanning directly without using digital libraries

Scanning procedure

1. Attach the CIA abutment to the lab analogue in the master model and screw down the appropriate laboratory screw and driver.
2. Abutment posts should be adjusted to the ideal occlusal height. Note: do not reduce the post height below a minimum height of 4mm in single implant cases.
3. Temporarily cover the screw hole with wax.
4. Scan using usual scan routines.
5. The CIA abutment may need scanning powder or a spray to scan properly. Note: With certain CADCAM systems, where the screw channel can't be created in the software, the PEEK scanning pin must be used.
   In single tooth applications, place the CIA abutment onto the implant or laboratory model with the anti-rotation lobe to the palatal/lingual aspect and secure it with the PEEK scanning pin.

6. Scan using routine scanning procedures.

Designing procedures

7. Follow steps 9 & 10.

Milling & sintering procedures

8. Follow steps 11 to 13.

Final Clinical procedures

1. Clean and disinfect the restoration as applicable per the restorative material manufacturer's instructions.
    a. For screw retained unites: Place and tighten the restoration screw. Verify the correct seating of the restoration using radiographic imaging. Tighten the restoration using a torque wrench, to the torque value specified for the applicable prosthetic screw (refer to Prosthetic Screw Instructions for Use in CAT-8068).
    b. For cement retained units: Place and tighten the restoration screw. Verify the correct seating of the substructure/custom post using radiographic imaging. Tighten the substructure/custom post using a torque wrench, to the torque value specified for the applicable prosthetic screw (refer to Prosthetic Screw Instructions for Use in CAT-8068). Close the screw access holes and cement the final prosthesis in place.

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.

Materials

CIA Abutment:	Commercially pure titanium (grade 4) or titanium alloy Ti-90%, Al-6%, V-4% (grade 5)
Scanning Pin:	Polyether ether ketone (PEEK)
Abutment screws:	Titanium alloy Ti-90%, Al-6%, V-4% Gold Alloy Au-61%, AG-16.5%, Pt-13.5%, Cu-9%

Note: The surface of the CIA abutment post is roughened.

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

Nonclinical testing has demonstrated that the Southern Implants® dental implants, metallic abutments and prosthetic screws are MR conditional.

A patient with these devices can be safely scanned in a MR system meeting the following conditions:

- static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- maximum spatial gradient magnetic field of 3000 Gauss/cm (30 T/m).
- maximum MR system reported SAR corresponding to Normal Operating mode for all landmarks (Head SAR of 3.2 W/kg for head landmark, 2 W/kg whole body, and appropriate partial body SAF for other landmarks). For imaging landmarks above the thorax, a continuous scan time of 15 minutes will require a cooling delay of at least 5 minutes.

- in the non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the Southern Implants' dental implants, abutments and prosthetic screws, when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Removable restorations should be taken out prior to scanning, as is done for watches, jewellery etc.

Should there be a no MR symbol on the product label, please note that this device has not been evaluated for safety and compatibility in the MR environment.

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.

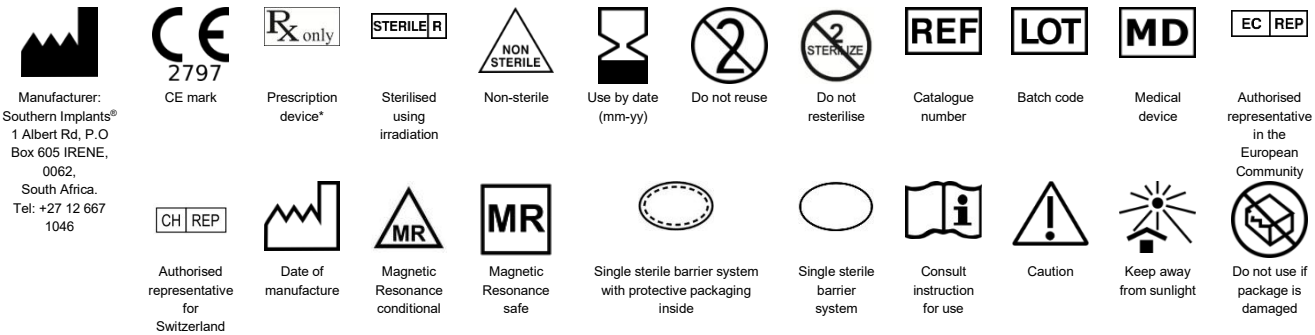
Basic UDI

Product	Basic-UDI Number
Basic-UDI for Metal Abutments	60095440387296
Basic-UDI for MA Direct Abut. Titanium	6009544050117Q

Related literature and catalogues

CAT-2004 – TRI-NEX Implants Product Catalogue
CAT-2005 – Internal Octagon (IT) Implants Product Catalogue
CAT-2020 – External Hex Implants Product Catalogue
CAT-2043 – Internal Hex Implants Product Catalogue
CAT-2060 – PROVATA® Implants Product Catalogue
CAT-8068 – Southern Implants® Prosthetic Screws Instructions for Use

Symbols and warnings



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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.