English

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

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Description

Scanning Abutments (CIA) are premanufactured 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.

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 External Hex Implants and Accessories

The abutment is used for both single tooth and multiple bridged units: Engaging abutments are indicated for single unit screw retained restorations. Non-engaging is indicated for multiple unit screw/cement retained restorations.

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 component is delivered non-sterile 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: wrapped, steam sterilize at 135°C (275°F) for 3 minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is FDA cleared for the indicated steam sterilization cycle.

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.
- who are allergic or have hypersensitivity to pure titanium, titanium alloy (Ti-6Al-4V) or polyetheretherketone (PEEK)
- 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.

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)

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.

Magnetic Resonance (MR) Safety

Scanning Abutments (CIA) have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artefact in the MR environment. The safety of the Scanning Abutments (CIA) Abutments in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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

Manufacturer:
Southern Implants®
1 Albert Rd, P.O Box 605 IRENE, 0062,
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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.