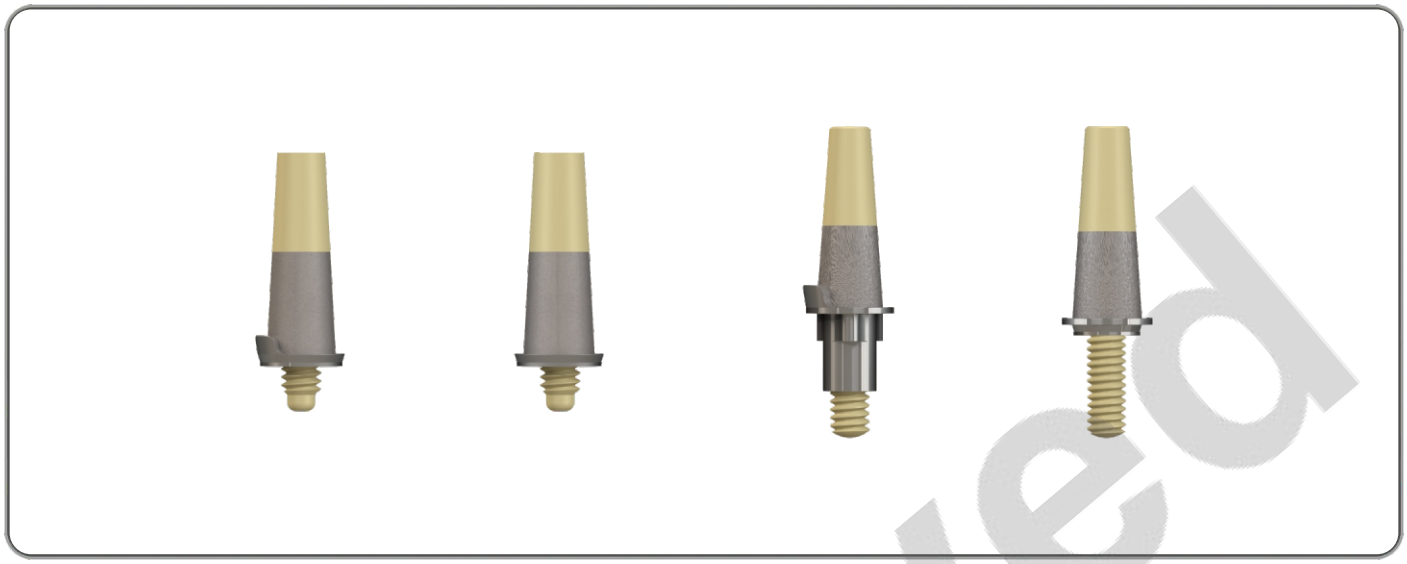
SOUTHERNIMPLANTS

INSTRUCTIONS FOR USE:
CIA 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.

Description:

CIA abutments are premanufactured components which are available in engaging and non-engaging versions for different connection systems. (Refer to Table1.) The CIA abutment is made from titanium or titanium alloy (Ti-6AL-4V) and includes a PEEK pin, to aid in manipulating certain CAD software during design procedures, to create a screw channel.These abutments are connected direct to an endosseous implant for use as an aid in prosthetic rehabilitation. Engaging versions have an anti-rotational "lobe" and are indicated for single unit cases.

The CIA abutments are available for the Tri-Nex, IT and External Hex product ranges.
Refer to individual product catalogues for product characteristics and compatible accessories:
Tri-Nex (CAT-2004), IT (CAT-2005), External Hex (CAT-2020).

Table 1

Code		Implant to be used with		Retaining screw torque	
Engaging	**Non engaging**		**Southern Scan flag**		
External hex range					**Prosthetic screw options**
CIA-EX-34		ø3.4mm external hex implants	SF-EX-34	32-40Ncm	3 series Titanium screw (Refer to Catalogue for codes & Instrument detail)
CIA-EX-40	CIA-NX-40	ø4mm external hex implant & MAX-6	SF-EX-40	32-40Ncm	
CIA-EX-50	CIA-NX-50	ø5mm external hex implant & MAX-7	SF-EX-50	32-40Ncm	
CIA-EX-60	CIA-NX-60	ø6mm external hex implant & MAX-8	SF-EX-60	32-40Ncm	
Tri-Nex range					
CIA-EL-35	CIA-NL-35	ø3.5mm Tri-Nex implant	SF-EL-35	32-40Ncm	TS-L-18 (Unigrip)
CIA-EL-43	CIA-NL-43	ø4.3mm Tri-Nex implant	SF-EL-43	32-40Ncm	TS-L-20
CIA-EL-50	CIA-NL-50	ø5mm Tri-Nex implant & TRI-MAX7	SF-EL-50	32-40Ncm	TS-L-20
CIA-EL-60	CIA-NL-60	ø6mm Tri-Nex implant & TRI-MAX8 & 9	SF-EL-60	32-40Ncm	TS-L-20
Internal Octagon range					
CIA-ITS	CIA-ITS-NE	ø4.8mm IT implants & MAXIT7	SF-IT	32-40Ncm	TSIT2 (torx)
CIA-ITS6	CIA-ITS6-NE	ø6.5mm IT implants & MAXIT 8 & 9	SF-IT6		

Note: refer to product catalogue for instruments and screw types available.

Images are for illustration purposes only and do not necessarily accurately represent the product.

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Indications:

CIA abutments engaging are indicated for single unit screw retained restorations,in CADCAM procedures.
Non-engaging CIA abutments are indicated for multiple fixed screw retained restorations, in CAD/CAM procedures. A screw retained restoration is indicated when the screw access hole is located through the cingulum of anterior teeth, and occlusal surface of posterior teeth.
If the position of the screw access holes are not favourable, custom abutments or a structure can be milled and cemented to the CIA abutments.

Contraindications:

Do not use in patients:
- who are medically unfit for dental implant procedures.
- who are allergic or have hypersensitivity to pure titanium or 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 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 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.
- Small diameter implants and are not recommended for use in the posterior region of the mouth.
- 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 Procedure:
- 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 torque of abutments and abutment screws.

Post Procedure
- Regular patient follow-up, and proper oral hygiene are essential for favourable long-term results.

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 healing abutments.
5. The scan is then imported into the design software.

Designing procedures:

6. The Scan flag in the digital form is now matched and aligned with the corresponding Scan flag in the library.
7. The software recognise the relative position of the Scan flag to the implant or analogue, and to 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 if a screw retained or cemented restoration is 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 design 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. Close the screw channel temporarily, prior to cementation, to keep the screw channel free of cement.

Digital workflow by scanning directly without using digital libraries:

Scanning procedures:

1. Attach the CIA abutment to the lab analogue in the master model and screw down with the appropriate laboratory screw and driver.
2. Abutments should be adjusted to the ideal occlusal height.
3. Temporarily cover the screw hole with wax.
4. Scan using usual scan routines.
5. The CIA abutments may need scanning powder or spray to properly scan.
   Note: With certain CAD/CAM systems where the screw channel can't be created in the software, the PEEK pin must be used.
   Place the CIA abutment onto the Implant or Laboratory model with the anti-rotation nip to the palatal / lingual aspect and secure it with the plastic scanning pin.
   Mark the occlusal height on the pin and unscrew it from the mouth/model if necessary to cut it down to the recorded marking.
   Now screw the pin back into position through the CIA abutment. The software will pick up the PEEK pin, allowing for a screw channel to be created.
6. Scan using usual scan routines & design procedures.

Designing Procedures

7. The software will guide the user to design the shape of the restoration.

Milling & sintering procedures:

8. Follow steps 10 to 12

Final Clinical procedures:

1. Clean and disinfect the restoration as applicable per the restorative material manufacturer's instructions.
   a. For a screw retained units: 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 Table 1.)
   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 Table 1), Close the screw access holes and cement the final prosthesis in place.

Materials:

CIA Abutment:	Titanium or Titanium alloy (Ti-6AL-4V)
PEEK Pin:	Polyetheretherketome (PEEK)
Abutment screws:	Titanium alloy Ti-90%, Al-6%, V-4%

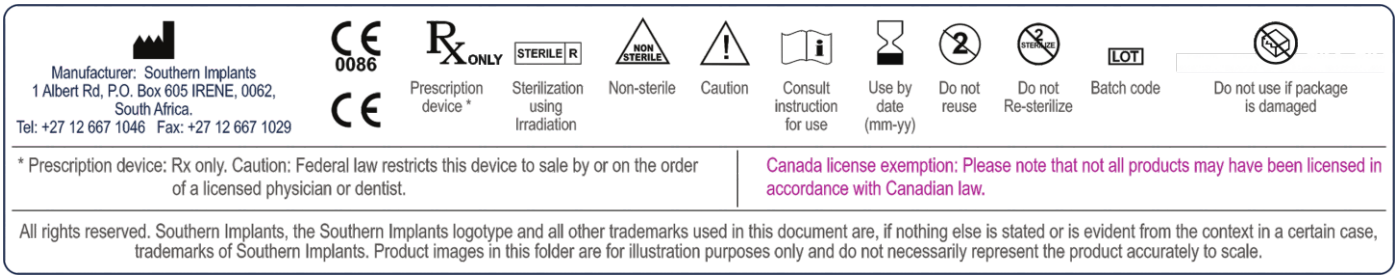
Storage, Cleaning & Sterilization

These abutments are supplied sterile 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. Do not re-sterilize or autoclave these components. 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.

Disposal:

Disposal of the device and its packaging shall follow local regulations and environmental requirements, taking different contamination levels into account.

Symbols & Warnings



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