English

INSTRUCTIONS FOR USE: Southern Implants® Custom Abutment Base (CAB) Abutments

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Description

The Custom Abutment Base (CAB) Abutments are pre-manufactured dental abutments that are connected direct to an endosseous implant for use as an aid in prosthetic rehabilitation. They can be scanned directly using an intraoral or a model scanner. They are anodised a yellow/gold colour and 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.

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.

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 Deep Conical (DC) Implants and Accessories

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 teeth in the mandible and maxilla,
- immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge
- especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective,
- immediate loading in all indications, except in single tooth situations on implants shorter than 8mm or in soft bone (type IV) where implant stability may be difficult to obtain, and immediate loading may not be appropriate

The intended use for 3.0 Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular incisors.

Applicable for 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 Custom Abutment Bases (CAB) Abutments are available in 3 implant / abutment 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
Deep Conical (DC)	Parts labelled CAB-DC(Ø)
Internal Hex (M)	Parts labelled CAB-M (engaging component used with Ø3.75mm, Ø4.2mm and Ø5.0mm platform)
	Parts labelled CAB-NM (non-engaging component used with Ø3.75mm, Ø4.2mm and Ø5.0mm platform)
	Parts labelled CAB-M-P45 (used with Ø5.0 platform during platform matching procedures)
Internal Hex PROVATA® (M / Z)	Parts labelled CAB-M (engaging component used with Ø4.0mm, Ø5.0mm and Ø6.0mm platform)
	Parts labelled CAB-NM (non-engaging component used with Ø4.0mm, Ø5.0mm and Ø6.0mm platform)
	Parts labelled CAB-M-P45 (used with Ø5.0 and Ø6.0mm platforms during platform matching procedures)
	Parts labelled CAB-Z (used with Ø7.0, 8.0 and 9.0mm platforms)

Custom Abutment Base (CAB) Abutments are not packed with their corresponding screws. See Prosthetic Screw Instructions for use (CAT-8068) for recommended screw torques.

Storage, cleaning and sterilisation

These abutments are supplied sterile and are intended for single use prior to expiration date (see packaging label). Sterility is assured unless the pouch 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.

Contraindications

Do not use in patients:

- who are medically unfit for dental implant procedures (e.g. uncontrolled diabetes and untreated 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 SUBSITUTE 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 to 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

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 angled abutments 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.

Custom Abutments are not to be shortened at any stage, as this would interfere with the Custom Abutments' scannability and digital function.

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 torque of abutments and abutment screws.

Post-surgery

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

Precaution: maintaining sterility protocol

The Custom Abutment Base (CAB) Abutments are packed in a peel pouch or blister base with a “peel-back” lid. Labelling information is located on the bottom half of the pouch, inside the packet or on the surface of the peel-back lid. Sterility is assured unless the pouch is damaged or opened.

Procedure for use

The limits of customization of CAB 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 customization allowed

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 CAB 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 CAB 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 CAB 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 CAB abutment to the lab analogue in the master model and screw down 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 CAB abutments are anodised yellow, so no need for powder or spray, in order to scan the abutment.
6. Scan using routine scanning 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 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 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

CAB Abutment:	Titanium grade 4
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 CAB abutment is anodized yellow/gold in colour.

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.

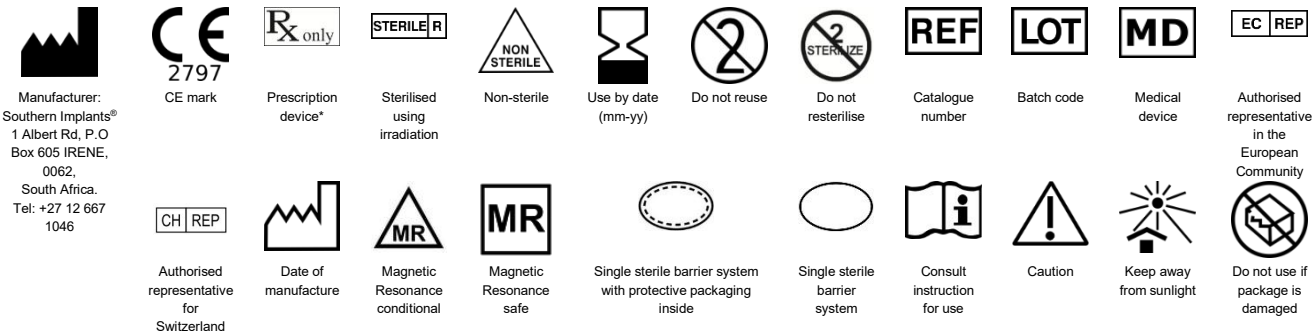
Basic UDI

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

Related literature and catalogues

CAT-2042 – Deep Conical 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



* 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.