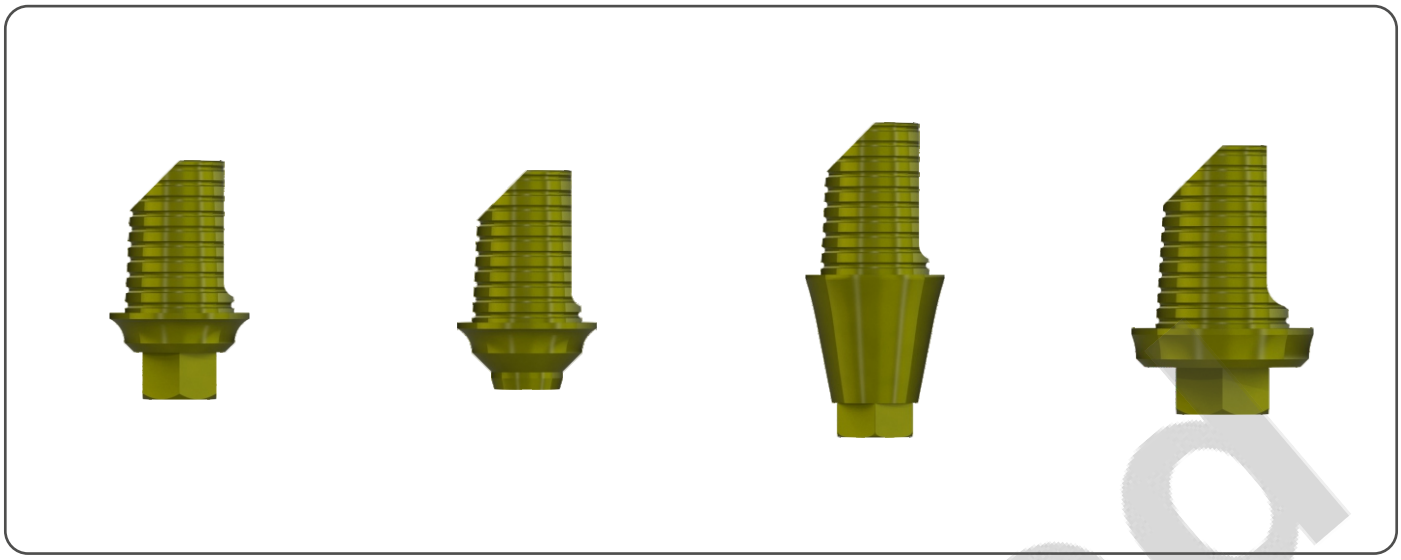


Intended use:

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:

CAB abutments are pre-manufactured components that are connected direct to an endosseous implant for use as an aid in prosthetic rehabilitation. The CAB abutment is made from titanium or titanium alloy (Ti-6AL-4V). CAB abutments are anodised yellow.

Note: Screws are sold separately for all abutments.

The CAB abutments are available in the DC, Internal Hex and Provata product ranges.

Refer to individual product catalogues for product characteristics and compatible accessories:

M-Series (CAT-2043), DC (CAT-2042), Provata (CAT-2060).

Table 1:

Product range	Product code	Platform ø of product intended to be used with	Southern Scan flag	Engaging	Non engaging	**Final screw torque**	**Abutment screw**
DC, Deep conical range	CAB-DC3	ø3mm deep conical implants	SF-DC3	√		15Ncm	TS-DC3-14
	CAB-DC4	ø4mm deep conical implants	SF-DC4	√		20Ncm	TS-DC4-16
	CAB-DC5	ø5mm deep conical implants	SF-DC5	√		25-32Ncm	TS-DC5-20
M-series & Provata internal hex range	CAB-M	ø3.75, ø4.20 & ø5mm internal hex implants	SF-M	√		32Ncm	TS-Z-18
	CAB-NM	ø3.75, ø4.20 & ø5mm internal hex implants	SF-M		√		
	CAB-Z		SF-Z	√			

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

Indications for use:
CAB abutments engaging are indicated for single unit screw retained restorations direct to an endosseous implant with the crown cemented onto the engaging CAB, during CADCAM 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.

Non-engaging CAB abutments are indicated for multiple fixed screw retained restorations direct to an endosseous implant with the bridge cemented onto the non-engaging CAB, during CAD/CAM procedures.

If the position of the screw access holes are not favourable, custom abutments or a structure can be milled and cemented to the CAB-NM abutment/s, which are screwed onto the endosseos implant.

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).
- 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.
- 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 must be achieved 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 from the library.
7. The software recognise 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 if a screw retained or cementable 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 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.

Digital workflow by scanning directly without using digital libraries:

Scanning procedures:

1. Attach the CAB 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 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 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.

CAB Abutment: Titanium or Titanium alloy (Ti-6AL-4V)
Abutment screws: Titanium alloy Ti-90%, Al-6%, V-4%
Gold alloy Au-61%, Ag-16.5%, Pt-13.5%, Cu -9%

Magnetic Resonance (MR) safety information:

This device has 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 this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage, Cleaning & Sterilization

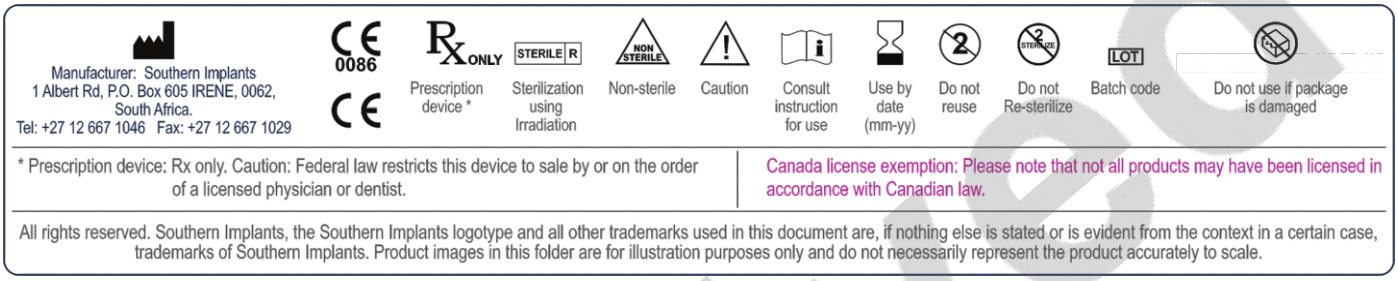
These abutments are delivered non-sterile and for single use. Final restoration should be cleaned and disinfected, as per restorative material manufacturer's instructions, before intra oral use.
Pre-vacuum sterilization method: Steam sterilise the abutments at 132°C (270°F) at 180-220kPa for 4-7 minutes. Dry for at least 20 minutes in the

chamber. Only a FDA approved wrap or pouch for steam sterilization must be used.
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



For Technical Assistance or additional product literature, please contact Southern Implants.

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