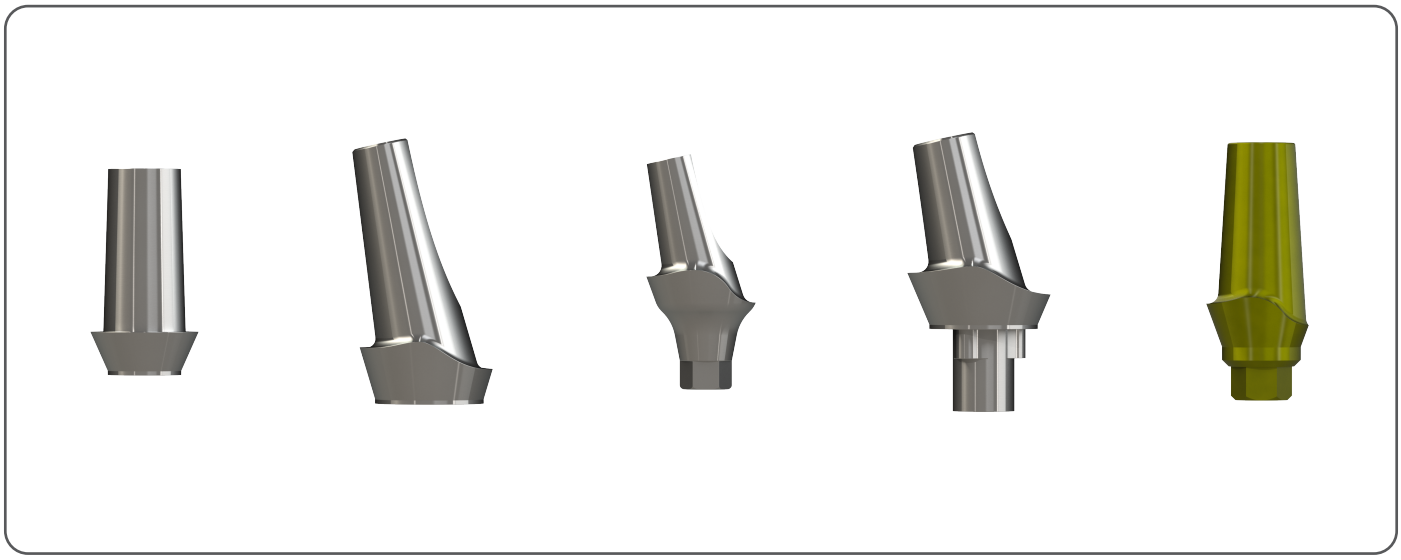
SOUTHERNIMPLANTS

INSTRUCTIONS FOR USE:
Cosmetic and Anatomical 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:

These are pre-manufactured dental abutments connected direct to an endosseous implant for use as an aid in prosthetic rehabilitation. The abutment is designed with a scalloped cuff that profiles natural soft tissue contours and is available in various collar heights based on the implant connection system. Made from titanium or titanium alloy (Ti-6AL-4V).
The Anatomic / Cosmetic Abutments are available in the Internal Hex, Deep Conical, Tri-Nex, IT, External Hex and Compact Conical connection interfaces. Refer to individual product catalogues for product characteristics and compatible accessories: M-Series (CAT-2043), DC (CAT-2042), Tri-Nex (CAT-2004), Provata (CAT-2042), IT (CAT-2005), External Hex (CAT-2020).

Indications for use:

Anatomic/Cosmetic Abutments are single unit abutments, retained direct to an endosseous implant, used with a cement retained crown..

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.

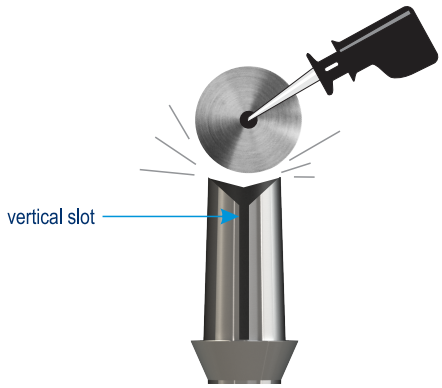
- Proper pre-operative planning with a good team approach between well trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.
- Small diameter implants are not recommended for use in the posterior region of the mouth.
- Minimizing the trauma to the host tissue increases the potential for successful osseointegration.
- Electro-surgery should not be attempted around metal implants, as they are conductive.
- 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.
- Regular patient follow-up, and proper oral hygiene must be achieved are essential for favourable long-term results.

Procedure for use:

First clinical procedure Method 1: (prep on Implant)

1. Select appropriate abutment and fit to the implant check occlusal clearance.
2. The abutment can be shortened to the correct occlusal height, or contoured to follow the gingival profile. Take care to leave at least 4-7mm conical height to provide sufficient surface for cement retention to the crown

   Use copious irrigation if the abutment is prepared in the mouth to avoid heating of the abutment and the implant/bone interface. It is recommenced to trim the abutment outside the patients' mouth.



An anti-rotational slot is required
for single crowns on External Hex Anatomical Abutments.

Cosmetic Abutments are manufactured with a scalloped edge
providing an anti-rotational function

3. Place and verify correct seating with radiographic image. Tighten the Abutment screw, 32-40Ncm for (External Hex range, Tri-Nex range, IT range, M-Series range and Provata range, for DC range, tighten the abutment for ø3mm implants to 15Ncm, ø3.5 and ø4mm implants to 20Ncm and ø5mm implants to 25-32Ncm. (Do not exceed recommended tightening torque for the abutment screw. Overtightening of the abutment may lead to screw fracture).
4. To prevent impression material going down the access whole it must be closed with wax or silicone prior to impression taking.
5. A closed tray impression is taken and a temporary crown cemented.

Laboratory procedure method 1:

1. Produce a working model with removable gingival mask. (Replica of the 'prepped' abutment).
2. Fabricate a crown or bridge using conventional casting techniques.
3. The final restoration is returned to the Dentist.

Second Clinical procedure method 1:

1. Remove the temporary restoration if applicable.

2. Verify and re-tighten the screw if applicable. Seal the screw access hole with silicone and cement the final 'closed' crown using conventional procedures. Caution: make sure that all excess cement is removed from the margin.

First clinical procedure Method 2:

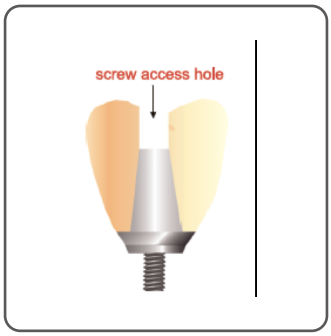
1. Take an impression of the implant interface using the appropriate impression coping: Refer to individual product catalogues for product compatible accessories: M-Series (CAT-2043), DC (CAT-2042), Tri-Nex (CAT-2004), Provata (CAT-2042), IT (CAT-2005), External Hex (CAT-2020).
2. Place healing abutment

Laboratory procedure Method 2:

1. Attach the laboratory analogue to the impression coping and produce a working model with removable gingival mask.
2. Attach the Abutment to the laboratory analogue and shortened to the correct occlusal height, if necessary the cuff can be contoured to follow the gingival profile. Take care to leave at least 4-7mm conical height to provide sufficient surface for cement retention to the crown
3. An anti-rotational slot is required for single crowns on external hex Anatomical Abutments.
4. Cosmetic Abutments are manufactured with a scalloped edge providing an anti-rotational function.
5. Fabricate a crown or bridge using conventional casting techniques. Note: Do not pack porcelain directly onto the Abutment. It serves as a post only.
6. If the screw access hole is favourably situated (occlusal surface of the posterior tooth) then the crown can be made with a corresponding access hole. Cementation of the crown to the abutment can be done on the model. This has the advantage that the cement line depth is not relevant and retrievability of the prosthesis is not compromised

Second Clinical procedure Method 2:

1. Remove the temporary restoration if applicable.
2. For cement retained restorations, closed crown; place the Abutment, verify the seating with radiographic imaging. Tighten the prosthetic screw with a torque wrench (32-40Ncm for External Hex range, Tri-Nex range, IT range, M-Series range and Provata range, for DC range, tighten the abutment for ø3mm implants to 15Ncm, ø3.5 and ø4mm implants to 20Ncm and ø5mm implants to 25-32Ncm. (Do not exceed recommended tightening torque for the abutment screw. Overtightening of the abutment may lead to screw fracture)



3. Cement the final crown or framework using conventional procedures after sealing the access hole, make sure there is no excess cement on the margin
4. For screw retained restorations the final restoration (crown and abutment) is attached to the implant, verify the seating and tighten the screw to required torque. (Do not exceed recommended tightening torque for the abutment screw. Overtightening of the abutment may lead to screw fracture)

Note:

1. External hex angled Cosmetic Abutments are manufactured with a double hex providing more options for angulation.
2. The Tri-Nex Cosmetic Angled Abutment can only be used when the implant is placed with one lobe facing to the buccal side of the mouth.

Materials:

Cosmetic Abutment: Titanium grade 3 or 4
Abutment screws: Titanium alloy Ti-90%, Al-6%, V-4% or Gold Alloy Au-61%, Ag-16.5%, Pt-13.5%, Cu -9%

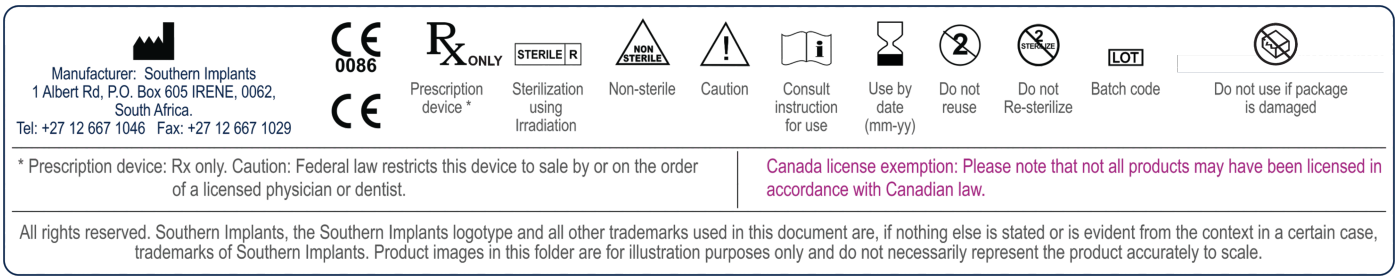
Magnetic Resonance (MR) safety information:

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 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.

Symbols & Warnings



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

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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.