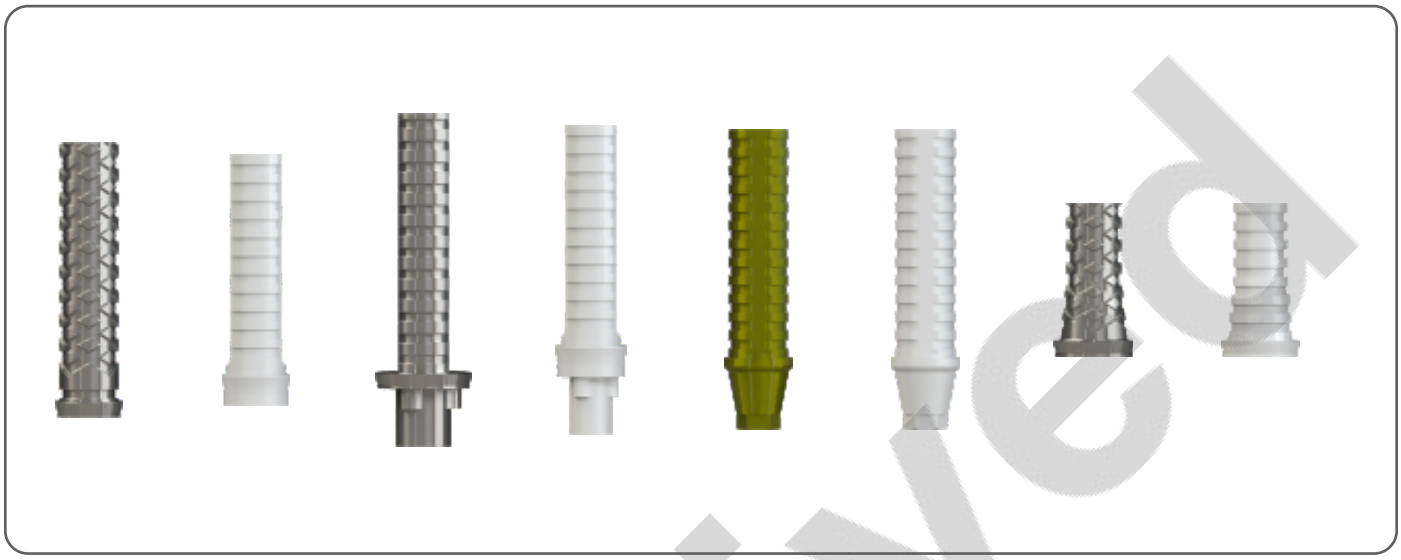
SOUTHERNIMPLANTS

INSTRUCTIONS FOR USE:
Temporary cylinders



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 that can either be connected direct to an endosseous implant, or connect the prosthesis to a compact conical abutment for use as an aid in temporary prosthetic rehabilitation.
The Titanium and PEEK temporary abutments are available in the Internal Hex, Deep Conical, Tri-Nex, IT, External Hex connection interfces and for the Compact Conical abutment for all these ranges. Refer to individual product catalogues for product characteristics:
M-Series (CAT-2043), DC (CAT-2042), Tri-Nex (CAT-2004), Provata (CAT-2060), IT (CAT-2005), External Hex (CAT-2020).

Indications:

Temporary Abutment engaging, is indicated for single unit screw retained custom abutment direct to an endosseous implant with a cement retained prosthesis.
Non-engaging Temporary Abutments are indicated for multiple fixed screw retained custom abutments direct to an endosseous implant with a cement retained prosthesis.
Temporary Abutments non-engaging (connected to the compact conical abutment) are indicated for multiple fixed screw retained custom abutments with a cement retained prosthesis.
Temporary Abutments engaging and non-engaging are indicated for screw retained restoration when the screw access hole is located through the cingulum of anterior teeth, and when the screw access hole is located through the occlusal surface of posterior teeth, both direct to an endosseous implant or on top of Compact Conical 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.

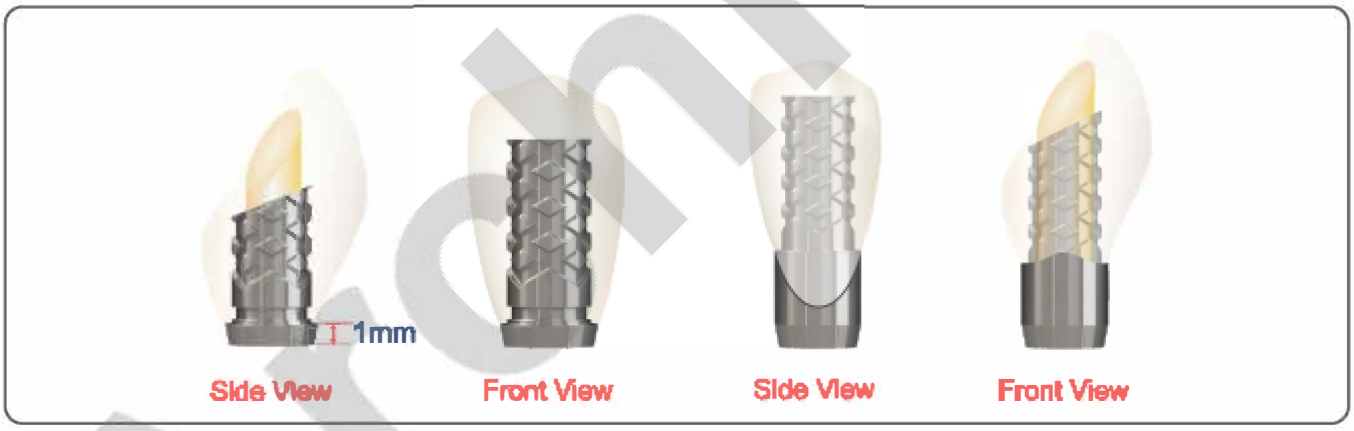
Cautions:

- 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
- 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:

Chair side: (making a Temporary crown)

1. Determine the cuff height, (based on the soft tissue profile)that will be most suitable for the restoration.
2. Connect the abutment to the implant and modify the abutment to the correct occlusal height, Modification of the abutment must be done with copious amounts of irrigation intra-orally. (Extra oral trimming of the abutment is the preferred recommendation).
3. With a 5mm Titanium abutment the collar can be trimmed to follow the contours of the soft tissue.



4. Close the screw channel hole in a way that will ensure the prosthetic screw can be retrieved.
5. Make a temporary restoration by using a pre-formed stent and suitable temporary material.
6. Unscrew the temporary prosthesis, make final adjustments, to finish off the temporary crown.
7. Clean and disinfect the restoration as applicable per the restorative material manufacturer's instructions.
8. Attach the Temporary abutment to the endosseos implant or on compact conical level:
   a. For a single unit: 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. (External Hex range, Tri-Nex range, IT range – 32-40Ncm. — Series range, Provata range – 32Ncm. DC range, ø3mm to 15Ncm, ø4mm to 20Ncm, ø5mm to 25-32Ncm)
   b. For multiple units: Place and tighten the restoration screw. Verify the correct seating of the restoration using radiographic imaging. Tighten the restoration using a manual torque wrench, to the torque value specified for the applicable prosthetic screw. (External Hex range, Tri-Nex range, IT range – 32-40Ncm. M-Series range, Provata range – 32Ncm. DC range, ø3mm to 15Ncm, ø4mm to 20Ncm, ø5mm to 25-32Ncm)
   c. For Compact conical abutment multiple units: Place and tighten the restoration screw. Verify the correct seating of the restoration using radiographic imaging. Tighten the restoration using a manual torque wrench to 10-15Ncm.
6. Close screw access hole.
7. Cement final prosthesis if applicable.

Laboratory procedures:

1. The laboratory receives the impression either implant level or abutment level.
2. The corresponding laboratory analogue is connected to the impression coping, fabricate a working model with removable gingival mask or soft tissue material.
3. Follow the same steps to manufacture a temporary crown. Deliver the crown for placement in the mouth.

Materials:

Titanium abutments: Titanium grade 2, 3, 4, or 5.

Peek abutments: Medical grade PEEK (DES 3000).

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

Note: DC Titanium abutments are anodized gold in colour.

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.

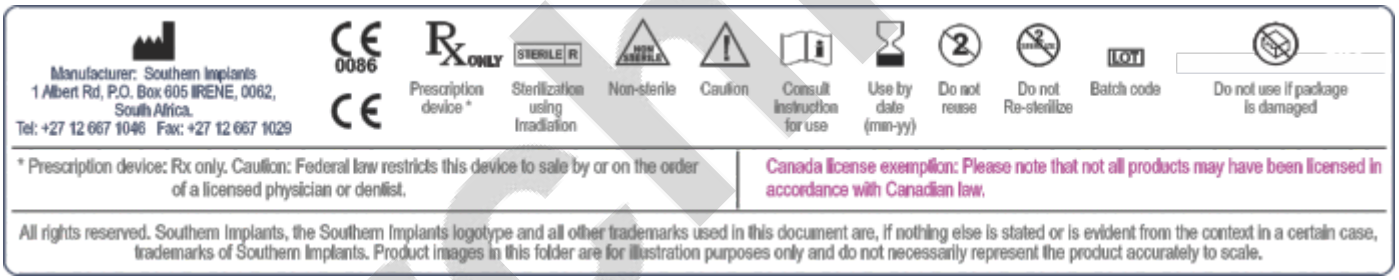
Storage, Cleaning & Sterilization

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.

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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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.