English

INSTRUCTIONS FOR USE: Southern Implants® Direct Abutments

Southern Implants (Pty.) Ltd. 1 Albert Road, Irene, 0062, RSA
T: +27-12-667-1046 | **E:** info@southernimplants.com

EC REP
Southern Implants Europe AB: Holmgatan 30, S-791 71 Falun, Sweden
T: +46 23 13300 | **E:** ecrep@southernimplants.com

Subsidiaries

Australia
Southern Implants Australia
T: +61-(0)-8-9466-2627
E: info@southernimplants.com.au

Spain and Portugal
Southern Implants Iberica
T: +34 935 053 507
E: info@southernimplants.es

United Kingdom and Ireland
Southern Implants UK
T: +44-20-805-94490
E: info@southernimplants.co.uk

USA and Canada
Southern Implants North America Inc.
T: +1-561-472-0990
E: customercare@southernimplants.com

Description

The Southern Implants® Direct Abutments are pre-manufactured abutments connected directly to an endosseous implant for use as an aid in prosthetic rehabilitation.

Cosmetic, Anatomic and Scalloped Abutments

Cosmetic, Anatomic and Scalloped Abutments are single unit screw retained abutments, retained directly to an endosseous implant. The apical sections taper, which means they can be used for multiple unit restorations if parallelism is ideal. The scalloped collar is shaped to follow soft tissue contours providing better aesthetic results and acts as an anti-rotational function for single unit restorations. The Cosmetic, Anatomic and Scalloped Abutments are provided sterile, however, will no longer be sterile after modification. The angled abutments are not to be used with Co-Axis® implants.

Abutment Posts

The Abutment Posts are solid post abutments available in various collar heights. These abutments have tapered posts suitable for both single crowns and bridges, with anti-rotation flats. The Abutment Posts are provided sterile.

Angled Abutments

The Angled Abutments have a tapered post allowing it to be used in multiple-unit restorations in cases where parallelism is ideal. These abutments feature a smooth N6 surface finish and utilize a cement-retained prosthetic retention method. The Angled Abutments are provided non-sterile.

Octagon Abutments

The Octagon Abutments have tapered posts suitable for both single crowns and bridges, with anti-rotation flats. These abutments feature a smooth N6 surface finish and utilize a screw-retained prosthetic retention method. The Octagon Abutments are provided sterile, however, will no longer be sterile after modification.

Shouldered Abutments

The Shouldered Abutments have a tapered post allowing it to be used in multiple-unit restorations in cases where parallelism is ideal. These abutments feature a smooth N6 surface finish and utilize a cement-retained prosthetic retention method. The Shouldered Abutments are supplied sterile.

Intended use

Southern Implants® Direct 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

For the Internal Hex/ PROVATA® abutments:

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.

For the MAX abutments:

Southern Implants MAX implant is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

For Deep Conical abutments:

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 teetch 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 siutations 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

Compatibility information

Southern Implants' implants should be restored with Southern Implants' components. The product code and connection type can be identified by specific abbreviations in the product codes. Range identifiers are summarised in Table A.

Table A – Compatible abutment for implant range

Abutment Type	Implant connection type	Compatible device		Sterility Status
		Non-Angled	Angled	
Anatomic and Scalloped Abutments	External Hex (EX)	Parts labelled DN (*), DB (*), DBA (*) and DBBB (*)	Parts labelled DBNS12, DBS12, DBS24, DBAS12, DBAS24, DBBBS12 and DBBBS24	Provided Sterile
Cosmetic Abutments	TRI-NEX® (EL) (Lobe)	Parts labelled TCA-EL-(Ø)	Parts labelled TCA12-EL-(Ø) and TCA24-EL-(Ø)	Provided Sterile
	Deep Conical (DC)	TCA-DC(Ø)	TCA12-DC(Ø) and TCA24-DC(Ø)	
	Internal Hex (M)	Parts labelled TCA-M (used with Ø3.75, 4.20 and 5.00 mm platforms)	Parts labelled TCA12-M and TCA24-M (used with Ø3.75, 4.20 and 5.00 mm platforms)	
	Internal Hex PROVATA® (M / Z)	Parts labelled TCA-M (used with Ø4.0, 5.0 and 6.0 mm platforms)	Parts labelled TCA12-M and TCA24-M (used with Ø4.0, 5.0 and 6.0 mm platforms)	
		Parts labelled TCA-Z (used with Ø7.0, 8.0 and 9.0 mm platforms)	N/A	
Abutment Posts	External Hex (EX)	Parts labelled MB (*) and PBN (*)	N/A	Provided Sterile
	Internal Octagon (IT)	Part labelled TSAF (*) (used with Ø4.8 mm platforms) and TSA6-(*) (used with Ø6.5 mm platforms)	N/A	
Angled Abutments	External Hex (EX)	N/A	Parts labelled GB20, GB35, GBA20 and GBA35	Provided Non-sterile
Octagon Abutments	Internal Octagon (IT)	Parts labelled SYN-(*) (used with Ø4.8 mm platforms) and SYN6-(*) (used with Ø6.5 mm platforms)	Parts labelled SYN15D-(*), SYN20D-(*) (used with Ø4.8 mm platforms), SYN615D-(*) and SYN620D-(*) (used with Ø6.5 mm platforms)	Provided Sterile
Shouldered Abutments	External Hex (EX)	Parts labelled DBAN (*), DBN (*) and DBBBN (*)	N/A	Provided Sterile

(*) is indicative of various lengths available

(Ø) is indicative of the implant platform size

Storage, cleaning and sterilisation

Applicable for Sterile Components:

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.

Applicable for Non-Sterile Components:
This component is supplied non-sterile and is indicated for single use. If packaging is damaged do not use the product and contact your Southern representative or return to Southern Implants®. The devices must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

Do not reuse components indicated for single-use only. Re-using these components may:

- damage on the surface or critical dimensions, which may result in performance and compatibility degradation.
- adds the risk of cross-patient infection and contamination if single-use items are reused.

Southern Implants® does not accept any responsibility for complications associated with reused single-use components.

Southern Implants® recommends one of the following procedures to sterilise the restorations and non-sterile single-use components prior to use:

1. prevacuum sterilisation method: steam sterilise the device at 132°C (270°F) at 180 - 220 kPa for 4 minutes. Dry for at least 20 minutes in the chamber. Only an approved wrap or pouch for steam sterilisation must be used.
2. for users in the USA: prevacuum sterilisation method: wrapped, steam sterilise at 135°C (275°F) at 180 - 220 kPa for 3 minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is cleared for the indicated steam sterilisation cycle.

NOTE: users in the USA must ensure that the steriliser, wrap or pouch, and all steriliser accessories are cleared by the FDA, for the intended sterilisation cycle.

Contraindications

Do not use in patients:

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

IMPORTANT NOTICE: 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, patients on steroid therapy, smokers 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.
- Angled abutments are not recommended for use with Co-Axis® implants.
- Minimizing the trauma to the host tissue increases the potential for successful osseointegration.
- The abutments are intended for single use. Re-use may result in damage on the surface or critical dimensions. This may result in performance and compatibility degradation. The removal of proteins from the surface of the components is extremely difficult and these proteins, when implanted, can lead to secondary infections.
- The abutment post height must not be reduced below a minimum height of 4mm in single implant cases.
- No additional angular correction is intended for the abutments.
- Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.
- Electro-surgery should not be attempted around metal implants, as they are conductive.

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 are essential for favourable long-term results.

Procedure for use of the Anatomic, Scalloped and Cosmetic Abutments

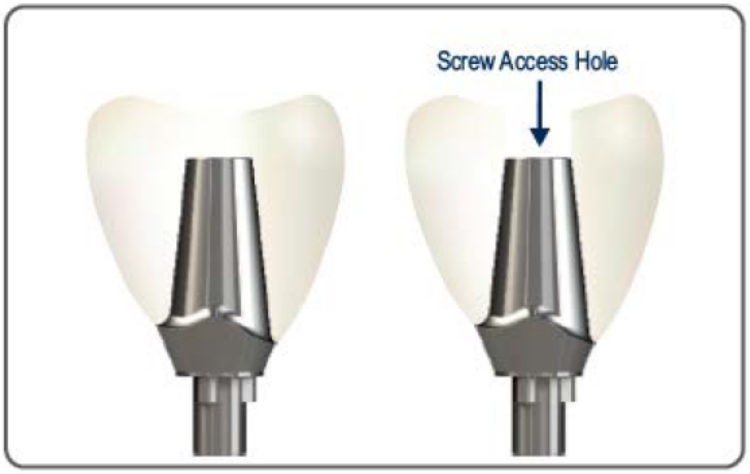
First clinical procedure Method 1:

1. Select appropriate abutment and check occlusal clearance.
2. The abutment may be shortened to the correct occlusal height. 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 patient mouth. For single-unit use, do not reduce the post below a minimum height of 4mm.
3. 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. Abutments to the dental implant, using a manual torque wrench to the torque value specified for the applicable prosthetic screw (see Table B). Do not exceed recommended tightening torque for the abutment screw. Overtightening of the abutment may lead to screw fracture.

Table B

Implants Systems and Platforms		Recommended Torque (Ncm)
Deep Conical	Ø3.0	20
	Ø4.0	30
	Ø5.0	32
Internal Hex / PROVATA®	M / Z	32-40 32 Ncm max. with gold screws
TRI-NEX®	Ø3.5	32
	Ø4.3 / Ø5.0 / Ø6.0	32-40
Internal Octagon IT	Ø4.8 / Ø6.5	32-40
External Hex	Ø3.0	25-32
	Ø3.25 / Ø4.0 / Ø5.0 / Ø6.0 / Ø7.0	32-40

4. The Cosmetic Abutments are manufactured with a scalloped edge providing an anti-rotational function.
5. To prevent impression material going down the access whole it must be closed with wax or silicone prior to impression taking.
6. A closed tray impression is taken and a temporary crown fitted. The abutment is not sent to the laboratory.

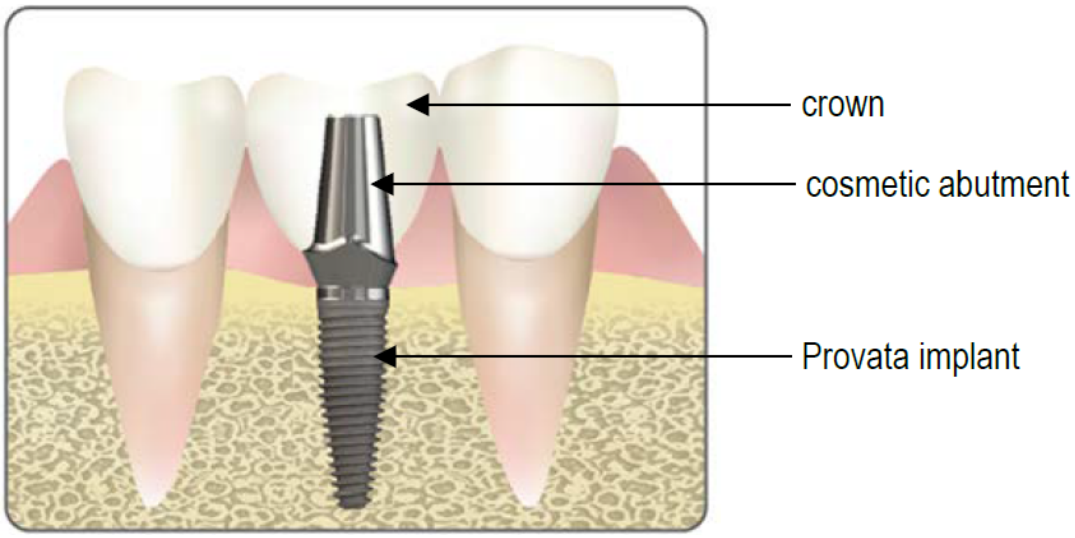


Laboratory procedure method 1:

1. Produce a working model with removable gingival mask.
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. 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. Abutments to the dental implant, using a manual torque wrench to the torque value specified for the applicable prosthetic screw (see Table B). 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.



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.

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 shorten the Abutment to the correct occlusal height. For single-unit use, do not reduce the post below a minimum height of 4mm. No additional angular correction is intended for the abutments.
3. The Cosmetic Abutments are manufactured with a scalloped edge providing an anti-rotational function.
4. Fabricate a crown or bridge using conventional casting techniques. Note: Do not pack porcelain directly onto the abutment. It serves as a post only.
5. For cement retained prosthesis the cementation of the restoration will take place in the mouth.
6. For screw retained restorations where the screw access hole is ideally located, the restoration can be cemented in the laboratory.

Second Clinical procedure method 2:

1. Remove the temporary restoration if applicable.
2. For cement retained restorations the abutment is attached to the implant, verify the tightening of the abutment (see Table B). 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.
4. 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. Abutments to the dental implant, using a manual torque wrench to the torque value specified for the applicable prosthetic screw (see Table B). Do not exceed recommended tightening torque for the abutment screw. Overtightening of the abutment may lead to screw fracture.
5. A radiographic image should be taken to verify the seating of the abutment.

Materials

Anatomic, Octagon, Scalloped and Shouldered Abutments:	Commercially Pure Titanium (Grade 4)
Cosmetic and Angled Abutments:	Commercially Pure Titanium (Grade 4 and Grade 3)
Abutment Posts:	Commercially Pure Titanium (Grade 4 and Grade 3) or Titanium alloy Ti-90%, Al-6%, V-4%
Abutment Screws:	Titanium alloy Ti-90%, Al-6%, V-4% Gold Alloy Au-61%, Ag-16.5%, Pt-13.5%, Cu -9%

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 2 W/kg for head landmark, 1 W/kg whole body (for landmarks within 30 cm of the implant) or 2 W/kg whole body (for landmarks more than 30 cm from the implant), and appropriate partial body SAR for other landmarks). For imaging landmarks above the thorax, 15 min of scanning at normal operating mode for landmarks greater than 30 cm from the implant with a whole body SAR of 1W/kg for imaging landmarks within 30 cm of the implant.
- 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 no MR symbol on the product label, please note that this device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

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.

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 Direct Abutments	6009544050117Q

Related literature and catalogues

CAT-2005 - IT Implants Product Catalogue
CAT-1138 - Cosmetic Anatomical Abutments Data Sheet
CAT-1127 - PBN Abutment Post Data Sheet
CAT-1107 - Straight Octagon Abutments for ITS Implants

Symbols and warnings


Manufacturer

CE mark

Prescription device*

Sterilised using irradiation

Non-sterile


Use by date (mm-yy)


Do not reuse

Do not resterilise

Catalogue number

Batch code

Medical device

Authorised representative in the European Community

Authorised representative for Switzerland


Date of manufacture

Magnetic Resonance conditional

Magnetic Resonance safe


Single sterile barrier system with protective packaging inside


Single sterile barrier system


Consult instruction for use


Caution


Keep away from sunlight


Do not use if package is damaged

* 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.