English

INSTRUCTIONS FOR USE: Southern Implants® Direct Abutments

South Africa - Headquarters: 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

CH REP
MedEnvoy Switzerland: Gotthardstrasse 28, 6302 Zug, Switzerland

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 8059 4490
E: info@southernimplants.co.uk

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

Description

These are pre-manufactured dental abutments connected direct to an endosseous implant for use as an aid in prosthetic rehabilitation.

Refer to individual product catalogues for product characteristics and compatible accessories

Cosmetic 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 or single restorations. 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.

Angled cosmetic abutments are not to be used with Co-Axis® implants.

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

For 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 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 teeth in the mandible and maxilla,
- immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
- 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.

For External Hex abutments:

Southern Implants' External Hex Implants are 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.
Southern Implants' External Hex Implants are 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 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

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.

The final restoration should be cleaned and disinfected, as per restorative material manufacturer's instructions, before intra oral use.

The restoration and abutment screw are to be sterilised with the following recommended cycle:

- Pre-vacuum sterilization method: wrapped, steam sterilize at 135°C (275°F) for 3 minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is FDA cleared for he indicated steam sterilization cycle.

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.

Do not use angled abutments on Co-Axis® implants.

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, 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 angled abutments are not recommended for use in the posterior region of the mouth.
- Angled abutments are not recommended for use with Co-Axis® implants.
- 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 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.

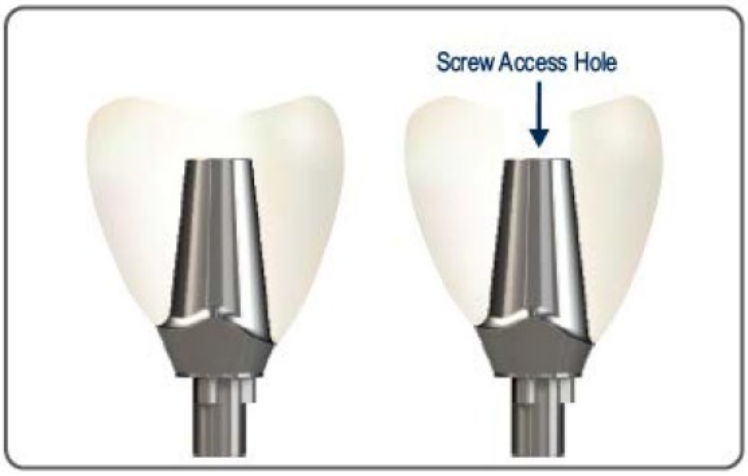
Table B

Implants Systems and Platforms		Recommended Torque (Ncm)
Deep Conical	Ø3.0	20
	Ø4.0	30
	Ø5.0	32
Internal Hex / PROVATA®	M / Z	32
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. For other abutments, an anti-rotational slot is required for single crowns.

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.



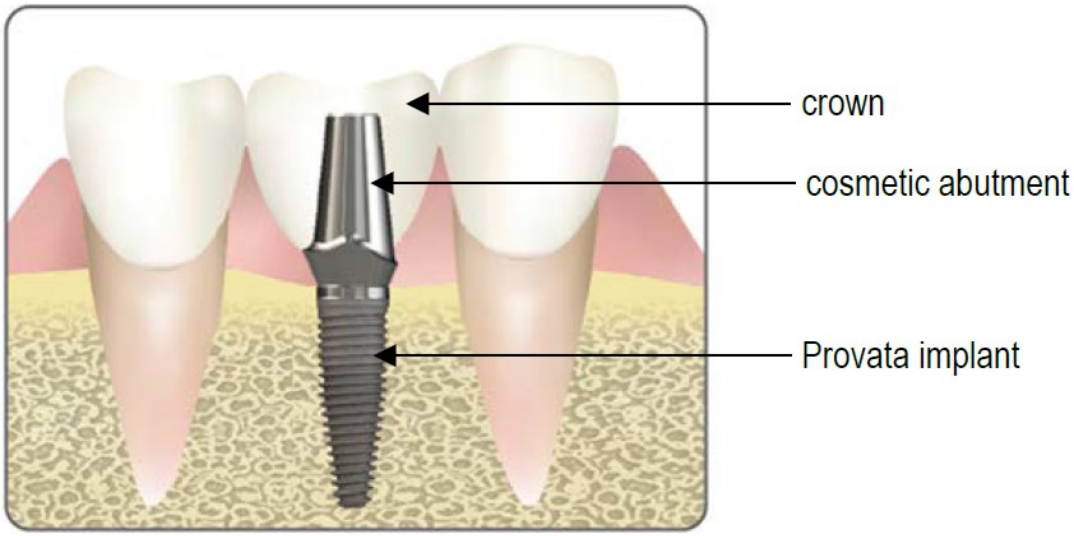
Laboratory procedure method 1:

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. For other abutments, an anti-rotational slot is required for single crowns.
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.

NOTE: External Hex angled Cosmetic Abutments are manufactured with a double hex providing more options for angulation.

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

Abutments:	Commercially pure titanium (grade 4 or grade 3) according to ASTM F67 and ISO 5832-2 Titanium alloy (Ti-6Al-4V) according to ASTM F136 and ISO 5832-3
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

Non clinical 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 SAR 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 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.

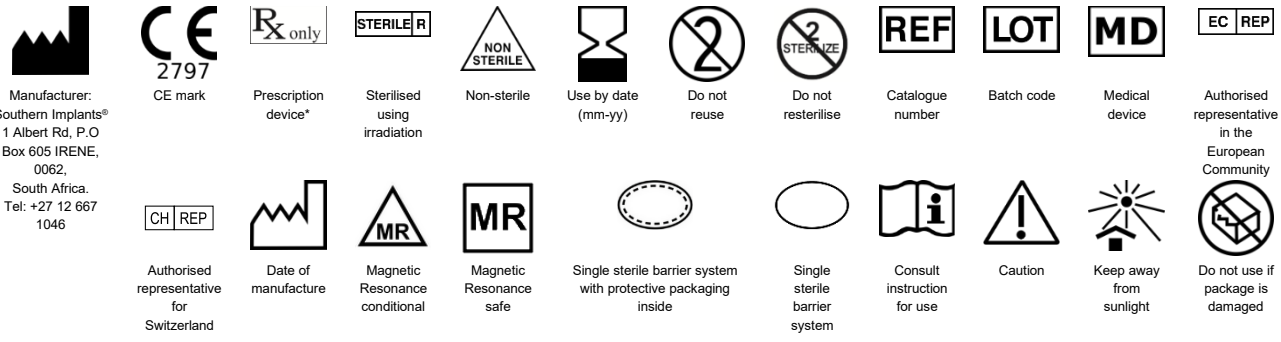
Basic UDI

Product	Basic-UDI Number
Basic-UDI for Metal Abutments	60095440387296
Basic-UDI for 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



* 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.