English

INSTRUCTIONS FOR USE: Southern Implants® Titanium Cylinders

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Description

These are pre-manufactured dental implant 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. Refer to individual product catalogues for product characteristics and compatible accessories. The Titanium Cylinders are provided sterile; however, will no longer be sterile after modification.

Intended use

This device is intended to treat partially or fully edentulous patients eligible for placement of one or more dental implants as a means of fixing a permanent or removable single crown, partial or full-arch dental prosthesis in the upper or lower jaw. The devices allow for immediate or delayed prosthetic restoration based on the user's evaluation of the patient's eligibility.

This device constituents are classified as medical devices and are intended for single use on a single patient.

Indications for use

The Titanium Cylinders are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

Intended user

Dental Technicians, Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontists, Prosthodontists, and other appropriately trained and experienced implant users.

Intended environment

This device is intended to be used in a dental laboratory for making of the restoration and in a clinical environment such as an operating theatre or a dentist consultation room.

Intended patient population

Patients that have lost one tooth or multiple teeth.

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 ranges

Implant connection type	Compatible device
External Hex	Parts labelled TCP1h, TCBN1h/5h, TCB1h/5h, TCBA1h/5h, TCBBB1h/5h and TCMAX9-1h for engaging items
	Parts labelled TCP1nh, TCBN1nh/5nh, TCB1nh/5nh, TC9, TCBA1nh/5nh, TCBBB1nh/5nh and TCMAX9-1nh for non-engaging items
	Parts labelled TC-EX-(Ø)-(*) for engaging items
	Parts labelled TC-NX-(Ø)-(*) for non-engaging items
TRI-NEX® (Lobe)	Parts labelled TC-EL-(Ø) for engaging items
	Parts labelled TC-NL-(Ø) for non-engaging items
Deep Conical (DC)	Parts labelled TC-DC-(Ø) for engaging items
	Parts labelled TC-NDC-(Ø) for non-engaging items
Internal Hex (M)	Parts labelled TC-M (used with Ø3.75, 4.20 and 5.00 mm platforms) for engaging items
	Parts labelled TC-NM (used with Ø3.75, 4.20 and 5.00 mm platforms) for non-engaging items
Internal Hex PROVATA® (3M/ M/ Z)	Parts labelled TC-3M (used with Ø3.3 mm platform) for engaging items
	Parts labelled TC-3NM (used with Ø3.3 mm platform) for non-engaging items
	Parts labelled TC-M (used with Ø4.0, 5.0 and 6.0 mm platforms) for engaging items
	Parts labelled TC-NM (used with Ø4.0, 5.0 and 6.0 mm platforms) for non-engaging items
	Parts labelled TC-EZ-(*) (used with Ø7.0, 8.0 and 9.0 mm platforms) for engaging items
	Parts labelled TC-NZ-(*) (used with Ø7.0, 8.0 and 9.0 mm platforms) for non-engaging items
Internal Octagon IT (ITS/ ITS6)	Parts labelled ITS-TC1 (used with Ø4.8 mm platforms) for engaging items
	Parts labelled ITS-TC1ne (used with Ø4.8 mm platforms) for non-engaging items
	Parts labelled ITS6-TC1 (used with Ø6.5 mm platforms), for engaging items
	Parts labelled ITS6-TC1ne (used with Ø6.5 mm platforms) for non-engaging items

Single Platform (SP)	Parts labelled TC-SP for (used with Ø3.5, 4.0 and 5.0 mm platforms) engaging items
	Parts labelled TC-NSP for (used with Ø3.5, 4.0 and 5.0 mm platforms) non-engaging items
	Parts labelled TC-SP-PM (used with Ø5.0 mm platforms) for platform-matched engaging items
Compact Conical Abutments	Parts labelled TMC1/5 and TMCSL (used with Ø4.8 mm abutment platforms) for non-engaging items
	Parts labelled TMCW1/5 (used with Ø6.0 mm abutment platforms) for non-engaging items
Standard Abutments	Parts labelled TC9 for non-engaging items

(*) is indicative of various lengths or collar heights available.

Clinical benefits

Clinical benefits of dental implant therapy include improved chewing function, speech, aesthetics and patient psychological wellbeing. Through this procedure patients can expect to have their missing teeth replaced and/or crowns restored.

Before Surgery

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

During Surgery

Take care that parts are not swallowed or aspirated during any of the procedures and apply the correct tightening torque to abutments and abutment screws.

CAUTION: identify and protect vital structures like nerves, veins, arteries and especially the infraorbital nerve during surgical exposure of the lateral maxillary wall. Injury to any of these anatomical structures can lead to complications like nerve dysfunction or bleeding.

Post-surgery

Regular patient follow-up and proper oral hygiene must be achieved to ensure favourable long-term results.

Storage, cleaning and sterilisation

The component is supplied sterile (sterilised by gamma irradiation) 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. 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. Reusing these components may result in:

- damage to 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.

Contraindications

Contraindications to implant therapy include:

- patients who are medically unfit for oral surgical procedures.
- where adequate numbers of implants cannot be placed to achieve full functional support of a prosthesis.
- patients under the age of 18.
- poor bone quality.
- blood disorders.
- infected implant site.
- vascular impairment.
- uncontrolled diabetes.
- drug or alcohol abuse.
- chronic high dose steroid therapy.
- anti-coagulant therapy.

- metabolic bone disease.
- radiotherapy treatment.
- allergy or hypersensitivity to pure titanium, titanium alloy (Ti6Al4V), gold, palladium or iridium.

Other than the above, there are no side effects or contraindications unique to this system.

Warnings and precautions

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.
- Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.

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. Implant failure increases when implants are placed in irradiated bone as radiotherapy can result in progressive fibrosis of vessels and soft tissue, leading to diminished healing capacity.

It is important to be aware and avoid damage to vital structures such as nerves, veins and arteries. Injuries to vital anatomical structures may cause serious complications such as injury to the eye, nerve damage and excessive bleeding. It is essential to protect the infraorbital nerve. Failing to identify actual measurements relative to the radiographic data could lead to complications.

New and experienced implant users should do training before using a new system or attempting 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 orofacial 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 and periodontal health.
- bruxism and unfavourable jaw relations must be taken into account.
- proper preoperative planning with a good team approach between well trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.
- minimising the trauma to the host tissue increases the potential for successful osseointegration.
- electrosurgery should not be attempted around metal implants as they are conductive.

Should the device not operate as intended, it must be reported to the manufacturer of the device. The contact information for the manufacturer of this device to report a change in performance is: sicomplaints@southernimplants.com.

Side effects

Possible side effects to implant therapy include:

- pain
- swelling
- phonetic difficulties
- gingival inflammation

Less common but more persistent symptoms include, but are not limited to:

- allergic reaction(s) to implant and/or abutment material
- breakage of the implant and/or abutment

- loosening of the abutment screw and/or retaining screw
- infection requiring revision of the dental implant
- nerve damage resulting in permanent weakness, numbness, or pain
- histologic responses with possible macrophage and/or fibroblast involvement
- fat emboli formation
- loosening of the implant requiring revision surgery
- perforation of the maxillary sinus
- perforation of the labial and lingual plates
- bone loss possibly resulting in revision or removal of the implant.

Handling Procedures

Chairside procedure (making a temporary restoration)

NOTE: modification of Titanium Cylinders can be done with a carbide burr or disk. It is recommended to do this extra-orally and with copious irrigation during cutting.

1. Determine the cuff height that will be most suitable for the restoration. Titanium Cylinders are available in 1 mm and 5mm collar heights. DC (Deep Conical) and IT (octagon) are only available in 1 mm collar heights. PROVATA® (Internal Hex implant PROMAX® ranges) are available in 1 mm and 3 mm collar heights.
2. Connect the abutment to the implant and modify the abutment to the correct occlusal height, with no additional angular correction. Modification of the abutment must be done with copious amounts of irrigation intra-orally (extraoral trimming of the abutment is the preferred recommendation). For single-unit use, do not reduce the post below a minimum height of 4 mm.
3. With a 5 mm Titanium Cylinder 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.
7. Make final adjustments.
8. Clean and disinfect the restoration as applicable per the restorative material manufacturer's instructions.
9. Attach the Titanium Cylinder to the endosseous implant or compact conical abutment with the compatible prosthetic screw. Tighten the restoration using a manual torque wrench to the torque value specified in Table C.
10. Close screw access hole.
11. Cement final prosthesis if applicable.

Laboratory Procedures (making a temporary restoration)

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. The same steps as for clinical procedures will apply.

Clinical Procedures (placing the temporary restoration)

The clinician receives the restoration from the laboratory.

1. Remove the healing abutment.
2. Clean, disinfect and sterilise the restoration as described.
3. Insert the restoration into the patient's mouth.
4. Position the restoration on the implant/abutment making sure that the retentive elements of the implant/abutment connections are properly aligned.
5. Fix the abutment to the implant/abutment with the correct screw using applicable driver (Table B). Torque the screw down to the value indicated in Table C.

Table B

Driver Type	External Hex	DC	Tri-Nex®	Internal Hex / PROVATA®	IT	Single Platform	Compact Conical and Standard Abutments
1.22 mm/1.27 mm Universal driver	✓	✓		✓		✓	✓
1.22 mm hex driver	✓	✓				✓	✓
1.27 mm hex driver	✓			✓			✓
Unigrip driver	✓		✓				✓
Quad driver	✓			Gold screws only			✓
Blade driver	✓						✓
Torx driver	✓				✓		✓

Table C

Direct to Implant	Torque (Ncm)
External Hex	
Ø3.0 mm	25-32
Ø3.25, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	32-40
Tri-Nex®	
Ø3.5 mm	32
Ø4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	32-40
DC	
Ø3.0 mm	15
Ø3.5, 4.0 mm	20
Ø5.0 mm	25-32
Internal Hex (M-Series and PROVATA®)	
Ø3.75, 4.2, 5.0 mm M-Series implants	32
Ø3.3 mm PROVATA® implants	32
Ø4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm PROVATA® implants	32-40 32 Ncm max. for gold screws
IT Octagon	
Ø3.3, 4.1, 4.9, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	32-40
Single Platform (SP1)	
Ø3.5, 4.0 and 5.0 mm	32
Abutment Level	
On Compact Comical or Standard Abutments	10-15

6. Verify the correct seating of the restoration using radiographic image.
7. Do not exceed the recommended torque value as this may result in failure of the screw, abutment or implant. Do not torque less than the recommended value, this may result in loosening of the abutment that can lead to abutment or implant failure.
8. Close the screw access hole.
9. Cement the temporary prosthesis if applicable.

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

Titanium Cylinders: Titanium grade 2, 3, 4, or 5.
Abutment screws: Titanium alloy Ti-90%, Al-6%, V-4% or

Gold Alloy Au-61%, Ag-16.5%, Pt-13.5%, Cu -9%

NOTE: SP1, DC and Internal Hex (PROVATA®) Titanium abutments are anodized gold in colour.

Disposal

Disposal of the device and its packaging: follow local regulations and environmental requirements, taking different contamination levels into account. When disposing of spent items, take care of sharp drills and instruments. Sufficient PPE must be used at all times.

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 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.

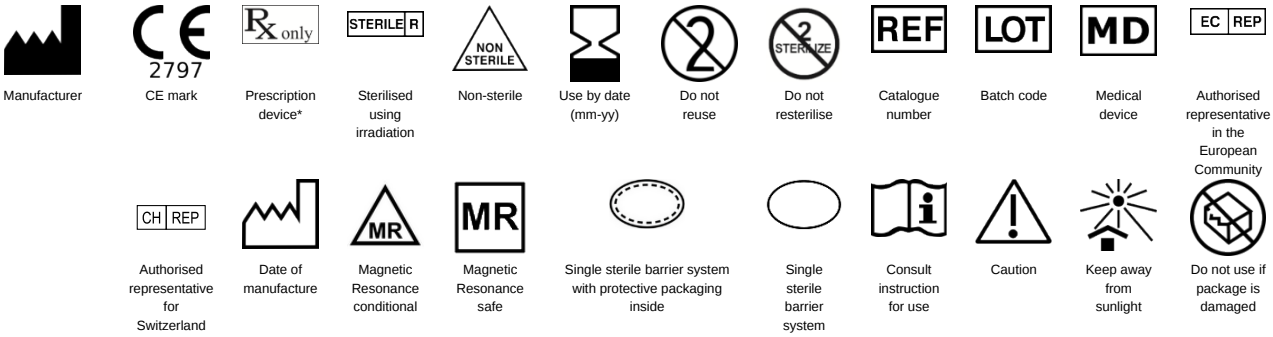
Basic UDI

Product	Basic-UDI Number
Basic-UDI for Metal Abutments	60095440387296
Basic-UDI for Direct Abutments	60095440500985 6009544050107N 6009544050117Q

Related literature and catalogues

CAT-2004 - TRI-NEX® Implants Product Catalogue
CAT-2005 - IT Implants Product Catalogue
CAT-2010 - Osseointegrated Fixtures Product Catalogue
CAT-2020 - External Hex Implants Product Catalogue
CAT-2042 - Deep Conical Implants Product Catalogue
CAT-2043 - Internal Hex Implants Product Catalogue
CAT-2060 - PROVATA® Implants Product Catalogue
CAT-2069 - Deep Conical INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic Implants Product Catalogue
CAT-2088M - Nazalus Product Catalogue and Surgical Manual
CAT-2092 - Deep Conical Pterygoid Implants Product Catalogue
CAT-2093 - Single Platform (SP1) Implants Product Catalogue
CAT-2095 - External Hex INVERTA® Implants Product Catalogue
CAT-2096 - External Hex Pterygoid Implants Product Catalogue

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.