

#### Intended use:

Dental implant abutments are intended to be used in the Maxilla or Mandible for supporting the prosthesis on endosseous implants in order to restore chewing function for the patient.

#### Description:

Titanium abutments are premanufactured and are available in different connections, collar heights, engaging and non-engaging versions. (Refer to Figure1.1). These abutments are to be fitted directly onto implants or indirectly, to the compact conical abutment), and intended for use as an aid in prosthetic rehabilitation.

Refer to individual product catalogues for product characteristics:

Internal Hex (M-Series CAT-2043 & PROVATA CAT-2060), Deep Conical (DC CAT-2042), Tri-Nex (CAT-2004), PROVATA (CAT-2060), Internal Octagon (IT CAT-2005) and External Hex (CAT-2020).

Figure 1

Code		Implant to be used with		Retaining screw torque	
Engaging	Non engaging		Cuff height		
External hex range					Prosthetic screw options
TCP1H	TCP1NH	ø3mm external hex implant	1mm	32-40Ncm	TS-P-16 (1.22mm hex)
TCBN1H /5H	TCBN1NH /5NH	ø3.25mm external hex implant	1mm/5mm	32-40Ncm	2 series Titanium screws. (Refer to Catalogues for codes & Instrument detail)
TCB1H /5H	TCB1NH /5NH	ø4mm external hex & MAX-6 implant	1mm/5mm	32-40Ncm	
TCBA1H /5H	TCBA1NH /5NH	ø5mm external hex & MAX-7 implant	1mm/5mm	32-40Ncm	
TCBBB1H /5H	TCBBB1NH /5NH	ø6mm external hex & MAX-8 implant	1mm/5mm	32-40Ncm	
TCMAX9-1H	TCMAX9-1NH	ø9mm MAX-9 external hex implant	1mm/5mm	32-40Ncm	
Tri-Nex range					
TC-EL-35-1 /5	TC-NL-35-1 /5	ø3.5mm Tri-Nex implant	1mm/5mm	32-40Ncm	TS-L-18 (Unigrip)
TC-EL-43-1 /5	TC-NL-43-1 /5	ø4.3mm Tri-Nex implant	1mm/5mm	32-40Ncm	TS-L-20
TC-EL-50-1 /5	TC-NL-50-1 /5	ø5mm Tri-Nex & TRIMAX7 implant	1mm/5mm	32-40Ncm	TS-L-20
TC-EL-60-1 /5	TC-NL-60-1 /5	ø6mm Tri-Nex & TRIMAX8 & 9 implant	1mm/5mm	32-40Ncm	TS-L-20

Images are for illustration purposes only and do not necessarily accurately represent the product.

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Code		Implant to be used with		Retaining screw torque	
Engaging	Non engaging		Cuff height		
DC- range					Prosthetic screw options
TC-DC3-1	TC-NDC3-1	ø3mm Deep conical implant	1mm	15Ncm	TS-DC3-14 (1.22mm hex)
TC-DC4-1	TC-NDC4-1	ø4mm Deep conical implant	1mm	20Ncm	TS-DC4-16
TC-DC5-1	TC-NDC5-1	ø5mm Deep conical implant	1mm	25-32Ncm	TS-DC5-20
Internal hex range					
TC-M	TC-NM	ø3.7 , 4.2, 5mm Internal hex & PROMAX6 implants	1mm	32Ncm	TS-Z-18 (1.27mm hex)
TC-Z	TC-NZ	PROMAX7 / 8 / 9 implants	1mm	32Ncm	TS-Z-18 (1.27mm hex)
Internal Octagon range					
ITS-TC1	ITS-TC1NE	ø4.8mm IT implants	1mm	32-40Ncm	TSIT2 (torx)
ITS6-TC1	ITS6-TC1NE	ø6.5mm IT & MAXIT implants	1mm	32-40Ncm	TSIT2 (torx)

Abutment level (Compact Conical abutment)					
	TMC1 /5	ø4.8mm platform Compact conical abutments	1mm/5mm	10-15Ncm	1 series Titanium screws. (Refer to Catalogues for codes & Instrument detail)
	TMCSL	ø4.8mm platform (Long)		10-15Ncm	
	TMCW1 /5	ø6mm platform Compact conical abutments	1mm/5mm	10-15Ncm	

**NOTE;** Refer to product catalogue for more information on Prosthetic screws and instruments.

### Indications:

These Titanium, cylinder type abutments are indicated for screw retained restorations when the screw access hole is located through the cingulum of anterior teeth, or through the occlusal surface of posterior teeth. There are versions for both direct fitting to an endosseous implant or on top of Compact Conical Abutments.

The engaging version of these Titanium abutments are indicated for single units and the non-engaging are indicated for multiple unit restorations.

### 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:

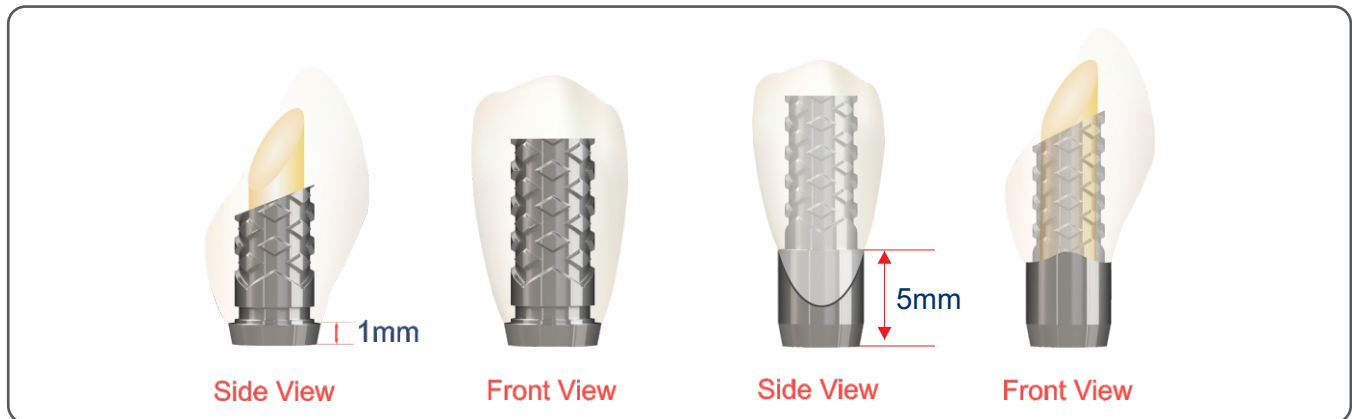
- New and experienced Implant users should do training before using a new system or attempt to do a new treatment method.
- Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (I.e. poor oral hygiene, uncontrolled diabetes, 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 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 are essential for favourable long-term results.

#### Procedure for use:

##### Chair side: (making a Temporary crown)

1. Determine the cuff height that will be most suitable for the restoration, (based on the soft tissue profile)
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. When using a Titanium abutment with 5mm cuff height, the cuff can be trimmed to follow the contours of the soft tissue.



4. Close the screw channel hole in a way that will ensure the retaining 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 endosseous implant or on compact conical level:  
For a single- & multiple units: Place abutment/s and tighten the retaining screw. Verify the seating with an x-ray and then tighten the screw with a torque wrench, to the torque value specified for the applicable prosthetic screw. (Refer to figure 1)
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, and a working model is fabricated 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. / Abutment screws: Titanium alloy Ti-90%, Al-6%, V-4%

*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 &amp; Warnings

 Manufacturer: Southern Implants 1 Albert Rd, P.O. Box 605 IRENE, 0062, South Africa. Tel: +27 12 667 1046 Fax: +27 12 667 1029	 CE 0086	 Prescription device *	 Sterilization using Irradiation	 Non-sterile	 Caution	 Consult instruction for use	 Use by date (mm-yy)	 Do not reuse	 Do not Re-sterilize	 Batch code	 Do not use if package is damaged
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\* Prescription device: Rx only. Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

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

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