English **INSTRUCTIONS FOR USE: Southern Implants® TiB Abutments**

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Description

The TiB abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. TiB Abutments are indicated in Southern Implants digital workflow: scan files from desktop/intraoral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. These abutments are supplied nonsterile and for single use only.

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 TIB Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The TIB abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from desktop scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

The intended use for the TIB narrow abutments used with the Ø3.0 mm External hex and Ø3.0 mm Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular lateral and central incisors.

WARNING: small diameter implants and angled abutment are not recommended for the posterior region.

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. In the Southern Implants' range there are 8 implant and abutment connections. The implant code and connection type can be identified by specific abbreviations in the product codes. Range identifiers are summarised in Table A.

Table A - Compatible

Implant connection type	Compatible device	Compatible Third-party Scan Body Size
External Hex (EX)	Parts labelled TIBS-EX-(Ø)-(*) (used with Ø3.0 mm platform for engaging items)	Small
	Parts labelled TIB-EX-(Ø)-(*) (used with Ø3.25, 3.75, 4.0, 5.0, 6.0, 7.0 and 8.0 mm platforms for engaging items)	Large
	Parts labelled TIB-NX-(Ø)-(*) (used with Ø3.25, 3.75, 4.0, 5.0, 6.0, 7.0 and 8.0 mm platforms for non-engaging items)	Large
TRI-NEX® (EL) (Lobe)	Parts labelled TIB-EL-(Ø)-(*) (used with Ø3.5, 4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm platforms for engaging items)	Large
	Parts labelled TIB-NL-(Ø)-(*) (used with Ø3.5, 4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm platforms for non-engaging items)	Large

Deep Conical (DC)	Parts labelled TIBS-DC(Ø)-(*) (used with Ø3.0, 3.5 and 4.0 mm platforms for engaging items)	Small
	Parts labelled TIB-DC(Ø)-(*) (used with Ø3.5, 4.0 and 5.0 mm platforms for engaging items)	Large
	Parts labelled TIB-NDC(Ø)-(*) (used with Ø3.5, 4.0 and 5.0 mm platforms for non-engaging items)	Large
Internal Hex (M)	Parts labelled TIB-M-(*) (used with Ø3.75, 4.2 and 5.0 mm platforms for engaging items)	Large
	Parts labelled TIB-NM-(*) (used with Ø3.75, 4.2 and 5.0 mm platforms for non-engaging items)	Large
Internal Hex PROVATA® (3M/ M/ Z)	Parts labelled TIBS-3M-(*) (used with Ø3.3 mm platform for engaging items)	Small
	Parts labelled TIB-M-(*) (used with Ø4.0, 5.0 and 6.0 mm platforms for engaging items)	Large
	Parts labelled TIB-NM-(*) (used with Ø4.0, 5.0 and 6.0 mm platforms for non-engaging items)	Large
	Parts labelled TIB-M-P45 (used with Ø5.0 and 6.0 mm platforms for engaging items)	Large
	Parts labelled TIB-Z-(*) (used with Ø7.0, 8.0 and 9.0 mm platforms for engaging items)	Large
	Parts labelled TIB-NZ-(*) (used with Ø7.0, 8.0 and 9.0 mm platforms for non-engaging items)	Large
Internal Octagon IT (ITS/ ITS6)	Parts labelled TIB-ITS-(*) (used with Ø4.8 mm platforms for engaging items)	Large
	Parts labelled TIB-ITSNE-(*) (used with Ø4.8 mm platforms for non-engaging items)	Large
	Parts labelled TIB-IT6-(*) (used with Ø6.5 mm platforms for engaging items)	Large
	Parts labelled TIB-IT6NE-(*) (used with Ø6.5 mm platforms for non-engaging items)	Large
Single Platform (SP)	Parts labelled TIB-SP-(*) (used with Ø3.5, 4.0 and 5.0 mm platforms for engaging items)	Large
	Parts labelled TIB-NSP-(*) (used with Ø3.5, 4.0 and 5.0 mm platforms for non-engaging items)	Large
	Parts labelled TIB-SP-PM-(*) (used with Ø5.0 mm platform for engaging items)	Large
Compact Conical Abutments	Parts labelled TIB-MC-48 (used with Ø4.80 mm compact conical platform)	N/A
	Parts labelled TIB-MC-60 (used with Ø6.00 mm compact conical platform	N/A

*indicates the collar height

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

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: 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.
- where adequate numbers of implants could not be placed to achieve full functional support of the prosthesis.
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6Al-4V), gold, palladium, platinum or iridium.
- who are under the age of 18, have 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 and sinus pathology.

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

The side effects of the use of the system are not dissimilar to those of dental implant therapy. 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.

Precaution: maintaining sterility protocol

Implants are packaged as follows:

1. An outer package consisting of a rigid, clear box which acts as protection for the inner package.
2. The inner package consisting of a blister pack (clear plastic-formed blister base with a TYVEK “peel-back” lid).
3. Within the inner package, there is a hollow tube which contains one implant suspended from a titanium ring, this ensures the implant never touches the inside of the plastic tube.
4. Labelling information is located on the surface of the peel-back lid and on the outside of the rigid box.

Care must be taken to maintain the sterility of the implant by proper opening of the packaging and handling of the implant.

1. Open the implant package in the non-sterile field, with non-sterile gloves, tear the address label to open the box.
2. With non-sterile gloves, remove the inner blister pack. Do not place the plastic box or blister pack-lid onto the sterile field. The contents of this inner package are sterile.
3. The sealed blister is to be opened by an assistant (with nonsterile gloves): remove the TYVEK lid and drop or place the sterile tube onto the sterile field, open the tube cap and attach the implant placement tool onto the implant and carefully remove from the sterile tube. Do not touch the sterile implant.

Other sterile components are packed in a peel pouch or blister base with a “peel-back” lid. Labelling information is located on the bottom half of the pouch, inside the packet or on the surface of the peel-back lid. Sterility is assured unless the pouch is damaged or opened. Non-sterile components are supplied clean but not sterile in a peel pouch or blister base with peelback lid. Labelling information is located on the bottom half of the pouch or on the surface of the peel-back lid.

Handling procedures

Digital workflow by using SIDIGITAL libraries Scanning procedure (Intra-orally or using the 3Shape E3 desktop Scanner)

1. Download Southern Implants digital library for 3Shape by registering on www.southernimplants.com/cad-cam-home/ and following the instructions as provided in the SIDigital Catalog (download from www.southernimplants.com).
2. Load the libraries into the CAD/CAM system by following their instructions.
3. The implant position is obtained digitally by an intra-oral scan of the patient with scan flag attached to the endosseous implant, or a desktop scan of the dental model with the scan flag attached to the laboratory analogue.
4. Remove the scan flag from the implants or from the model. Replace healing abutments.
5. The scan is then imported into the design software.

Designing procedures

1. The scan flag in the digital form is now matched and aligned with the corresponding scan flag in the library.
2. The software recognises the position of the scan flag to the implant or analogue.
3. The TIB abutment is chosen from the library.
4. The software will guide the user through the steps to complete the restoration.
5. Selection of the restorative material: the most common material to use is Zirconia.

Milling and sintering procedures (using WorkNC CAM software, Roland DWX51D Milling Unit, SageMax NexxZR Zirconia, and Ivoclar Vivadent Multilink Hybrid abutment cement))

1. Follow the instructions for use of the CAD/CAM system and milling material being used.
2. The milled restoration is cemented to the prefabricated titanium TiB abutment. Close the screw channel prior to cementing to keep the screw channel free of cement.

Note, please refer to the applicable OEM labeling and instructions for use of the compatible systems and tools referenced above, for the relevant installation, validation, maintenance and and use-life guidelines.

Clinical procedures (Placing Restoration)

The clinician receives the restoration from the laboratory.

1. Remove the healing abutment or temporary restoration.
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 making sure that the retentive elements of the implant/abutment connections are properly aligned.

Table B

Driver type	External Hex	DC	TRI-NEX®	Internal Hex	IT	Single Platform	Compact Conical screw
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	✓				✓		✓

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".
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.

Table C

Direct to Implant	Torque
External Hex	
Ø3.0 mm	32 Ncm
Ø3.25, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	32 – 40 Ncm
TRI-NEX®	
Ø3.5 mm	32 Ncm
Ø4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	32 – 40 Ncm
DC	
Ø3.0 mm	15 Ncm
Ø3.5 and 4.0 mm	20 Ncm
Ø5.0 mm	25 – 32 Ncm
Internal Hex (M-Series & PROVATA®)	
Ø3.75, 4.2 and 5.0 mm M-Series	32 Ncm
Ø3.3, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm PROVATA® Implants	32 Ncm
IT Octagon	
Ø3.3, 4.1, 4.9, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	32 – 40 Ncm
Single Platform (SP1)	
Ø3.5, 4.0 and 5.0 mm	32 Ncm
Compact Conical Abutment	
All TIB abutments on Compact Conical abutments	10 – 15 Ncm

Warning for Narrow TIB Abutments

The use of materials (dental cement, ceramic or other top-half component and/or hybrid abutment-crown component), systems (scanners, milling units, CAD/CAM software) and tools other than those specifically identified in this Instructions for Use document is not recommended for the Narrow TIB Abutments (denoted by the TIBS product code).

Restoration design restrictions

For all TiB abutments, the following restoration design restrictions are applicable:

Design Parameter	Limits to customisation
Minimum gingival height (mm)	0
Minimum wall thickness (mm)	0.22
Maximum angulation (°)	20 (exception: 0° for TIBS-DC3-C1.5/3)

For narrow TiB abutments, the following restoration design restrictions are applicable:

Implant/abutment interface	Design Parameter		
	Minimum gingival diameter (mm)	Minimum diameter (mm)	Minimum post height (mm)
Deep Conical Ø3.0 mm	3.85	3.85	4.50
Deep Conical Ø3.5 & 4.0 mm			
External Hex Ø3.0 mm			

For the standard TiB abutments, the following restoration design restrictions are applicable:

Implant/abutment interface	Design Parameter		
	Minimum gingival diameter (mm)	Minimum diameter (mm)	Minimum post height (mm)
External Hex Ø3.43 mm / TRI-NEX® Ø3.50 mm	4.30	4.30	4.50
Deep Conical Ø3.5 & 4.0 mm / PROVATA® Ø4.0 & 5.0mm	4.50	4.50	
Deep Conical Ø5.0 mm / PROVATA® platform-matched / TRI-NEX® Ø4.30 mm / Single Platform regular platform	5.0	5.0	
External Hex Ø3.75 mm	5.10	5.10	

TRI-NEX® Ø5.0 mm / Single Platform platform-matched	5.50	5.50	
External Hex Ø5.0 mm	6.0	6.0	
External Hex Ø6.0 mm / TRI-NEX® Ø6.0 mm	6.50	6.50	

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

Material type Titanium Alloy (Ti-6Al-4V), Anodized yellow

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.

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.

Summary of Safety and Clinical Performance (SSCP)

As required by the European Medical Device Regulation (MDR; EU2017/745), a Summary of Safety and Clinical Performance (SSCP) is available for perusal with regard to Southern Implants® product ranges.

The relevant SSCP can be accessed at https://ec.europa.eu/tools/eudamed.

NOTE: the above website will be available upon the launch of the European Database on Medical Devices (EUDAMED).

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.

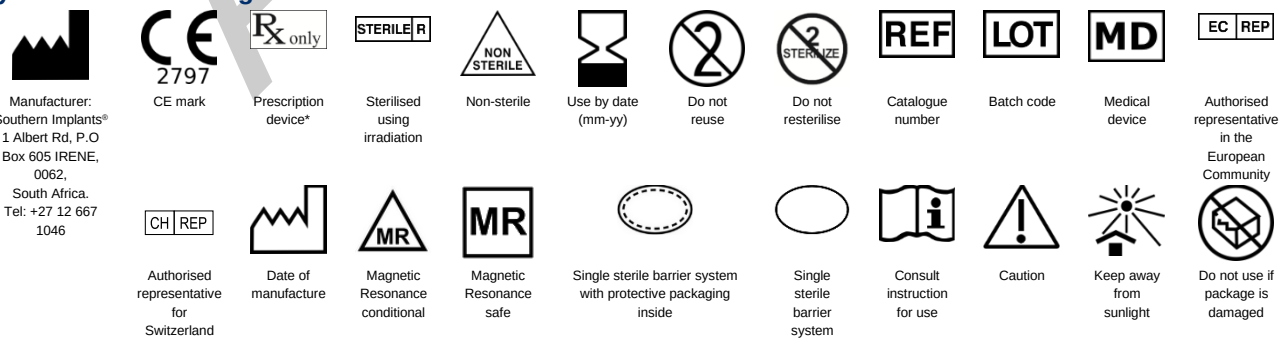
Basic UDI

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

Related literature and catalogues

CAT-2004 - TRI-NEX® Implants Product Catalogue
CAT-2005 - IT Implants 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 - INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic Implants Product Catalogue
CAT-2093 - Single Platform (SP1) Implants Product Catalogue

Symbols and warnings



Manufacturer: Southern Implants® 1 Albert Rd, P.O Box 605 IRENE, 0062, South Africa. Tel: +27 12 667 1046 | 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.