English

INSTRUCTIONS FOR USE: Southern Implants® Titanium Blanks

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Description

Titanium Blanks are premanufactured prosthetic components intended to be connected to endosseous dental implants and act as a supporting base for permanent prosthetic restorations. The Titanium Blanks 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 non-sterile and are intended 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 Titanium Blanks are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The Titanium Blanks consist of two major parts. Specifically, the titanium base and mesostructured components make up a multi-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 Titanium Blanks used with the Ø3.0 mm External-Hex implants 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

The intended user for this system includes Dental Technicians, Maxillofacial Surgeons, General Dentists, Orthodontists, Periodontist, 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' Titanium Blank range there are 7 implant connection types. The compatible implant and connection type can be identified by specific abbreviations in the product codes. Range identifiers are summarised in Table A.

For further information see the SI Digital Product Catalogue (CAT-2063).

Table A - Compatibility

Implant connection type	Compatible devices
External Hex (EX)	Parts labelled BL-EX(Ø)-11 for engaging items
TRI-NEX (EL) (Lobe)	Parts labelled BL-EL(Ø)-11 for engaging items
Deep Conical (DC)	Parts labelled BL-DC(Ø)-11 for engaging items
Internal Hex (M)	Parts labelled BL-M-11 for engaging items (used with Ø3.75, 4.20 and 5.00mm platforms)
	Parts labelled BL-M-P45-11 for engaging items (used with Ø5.0mm platform)
Internal Hex PROVATA® (3M/M/Z)	Parts labelled BL-3M-11 for engaging items (used with Ø3.3 mm platform)
	Parts labelled BL-M-11 for engaging items (used with Ø4.0, 5.0 and 6.0mm platforms)
	Parts labelled BL-M-P45-11 for engaging items (used with Ø5.0 and 6.0mm platforms)
	Parts labelled BL-Z-11 for engaging items (used with Ø6.0, 7.0, 8.0 and 9.0mm platforms)

Internal Octagon IT (ITS/ITS6)	Parts labelled BL-ITS-11 for engaging items (used with Ø4.8mm platforms)
	Parts labelled BL-IT6-11 for engaging items (used with Ø6.5mm platforms)
Single Platform (SP1)	Parts labelled BL-SP-11 for engaging items (used with all SP1 platforms)
	Parts labelled BL-SP-PM-11 for engaging items (used with Ø4.5, Ø5.0mm and Ø6.0 platforms)

Additionally, the Titanium Blanks are suitable for use with the Ø11.5mm Medentika® blank holders. Refer to the Medentika® website for information on compatible blank holders and other related equipment.

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 the following procedure 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) 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

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

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 Catalogue (download from www.southernimplants.com).
2. Load the libraries into the CAD/CAM system by following their instructions.
   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.
3. Remove the scan flag from the implants or from the model. Replace healing abutments.
4. 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 relevant 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 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 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
1.22 mm/1.27mm Universal driver	✓	✓		✓		✓
1.22 mm hex driver	✓	✓				✓
1.27 mm hex driver	✓			✓		
Unigrip 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

Titanium Blank Abutment to Implant	Torque Value
External Hex	
Ø3.0 mm	32 Ncm
Ø3.25, Ø4.0, Ø5.0, Ø6.0, Ø7.0 and Ø8.0 mm	32-40 Ncm
Tri-Nex®	
Ø3.5mm	32 Ncm
Ø4.3, Ø5.0, Ø6.0, Ø7.0, Ø8.0 and Ø9.0 mm	32-40 Ncm
DC	
Ø3.0 mm	20 Ncm
Ø3.5 and Ø4.0 mm	30 Ncm
Ø5.0 mm	32 Ncm
Internal Hex (M-Series and PROVATA®)	
Ø3.75, Ø4.2 and Ø5.0 mm M-Series implants	32-40 Ncm
Ø3.3 mm PROVATA® implants	32 Ncm
Ø4.0, Ø5.0, Ø6.0, Ø7.0, Ø8.0 and Ø9.0 mm PROVATA® implants	32-40 Ncm
IT Octagon	
Ø3.3, Ø4.0, Ø4.1, Ø4.9, Ø5.0, Ø5.7, Ø7.0, Ø8.0 and Ø9.0 mm	32-40 Ncm
Single Platform (SP1)	
Ø3.5, 3.75, 4.0, 4.5, 5.0 and 6.0 mm	32 Ncm

Restoration design restrictions

The Titanium Blanks can be altered to the desired anatomical shape provided the pre-milled implant connection is not altered. Always ensure that any sharp edges are rounded.

For the Titanium Blanks CAD software designs, the following restoration design restrictions are applicable per connection interface type (See Figure 1 and Table D):

Figure 1 – Illustration of Design Restrictions

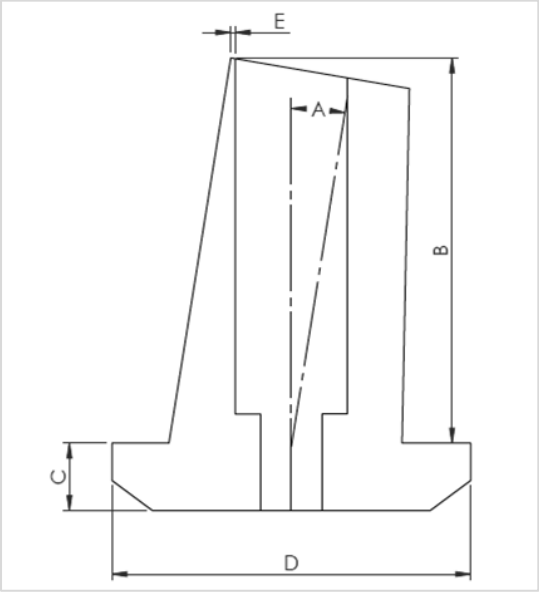


Table D – Design Restrictions

	Connection Interface	Indication	Maximum Abutment Angulation (A)	Chimney Height (B)		Collar Height (C)		Platform Diameter (D)		Minimum Chimney Wall Thickness (E) (i.e. screw hole to outer surface)
				Max.	Min.	Max.	Min.	Max.	Min.	
External Hex	IP	1 mandible, 2	20°	8	4,5	5	1,5	4,5	3,85	0,4
	IBN	All*	20°	8 for anterior use 4.5 for all regions			0,6	4,8	4,3	
	IB	All		8				5,5	4,8	
	BA	All						6,5	5,5	
	BBB	All						7,5	6,5	
Deep Conical	DC3	1 mandible, 2	20°			5	1,5	4,5	3,85	
	DC4	All	20°			5	0,7	4,8	3,85	
	DCR50	All				3	0,85	5,5	5,5	
	DC5	All				5	0,75	6,5	5	
Internal Hex (PROVATA/ M-Series)	3M	1, 2	20°			5	1,5	4,5	3,85	
	M	All					0,6	4,8	4,3	
	M-P45	All						5,5	4,8	
	Z	All						7,5	6	
Tri-Nex	EL35	All	20°			5	0,6	4,8	4,3	
	EL43	All				5		5,5	4,5	
	EL50	All				5		6,5	5,5	
	EL60	All				3		7,5	6,5	
Internal Octagon (IT)	ITS	All	20°			3	0,25	6	4,84	
	IT6	All				1,5		7,5	6,54	
Single Platform (SP1)	SP	All	20°			5	1,5	4,8	4,3	
	SP-PM	All						6,5	5,5	

*dependent on the selected maximum chimney height

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 Abutments:	Titanium alloy Ti-90%, Al-6%, V-4% (grade 5); Anodized yellow
Abutment screws:	Titanium alloy Ti-90%, Al-6%, V-4% (grade 5)

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.

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). In the interim, email clinical@southernimplants.com to request a Summary of Safety and Clinical Performance (SSCP) for these devices.

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.

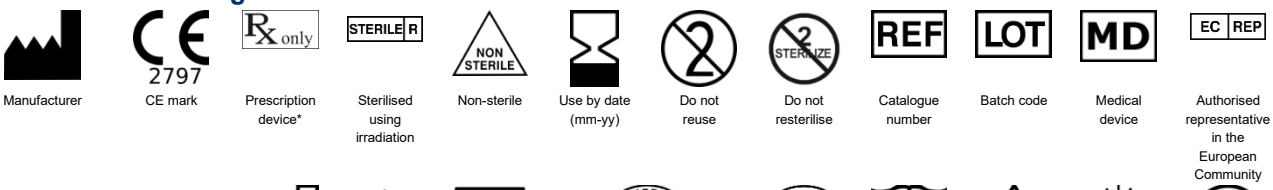
Basic UDI

Product	Basic-UDI Number
Basic-UDI for Metal Abutments	60095440387296
Basic-UDI for Direct Abut. Titanium	6009544050117Q

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 – Deep Conical INVERTA® Implants Product Catalogue
CAT-2095 – External Hex INVERTA® Implants Product Catalogue
CAT-2093 – Single Platform (SP1) Implants Product Catalogue
CAT-2063 – SI Digital Product Catalogue

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.