

INSTRUCTIONS FOR USE: Southern Implants® Prosthetic screws



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Description

The Southern Implants® Prosthetic Screws are pre-manufactured screws that can connect an abutment direct to an endosseous implant, or a restoration on compact conical level. The Southern Implants® Prosthetic Screws consist of gold, titanium, and brass screws. The gold and titanium prosthetic screws are supplied sterile and are intended for single patient use. The brass prosthetic screws are for Laboratory only, which are used to seat the prosthesis to the laboratory abutment analogue during prosthetic fabrication, and are not intended to come into contact with the patient. The screws are available in hexed, slotted, quad, unigrip and a torx connection. Ensure the correct screw and screwdriver is used with one of Southern Implants 6 implant connections.

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 Prosthetic screws are premanufactured prosthetic components directly connected to endosseous dental implants and intended for use in fully edentulous or partially edentulous maxilla and/or mandible to provide support for crowns, bridges or overdentures.

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' range there are 6 implant connections. The implant code and connection type can be identified by specific abbreviations in the product codes. Range identifiers are summarised in Table A.

Implant connection type	Compatible device				
External Hex (EX)	Parts labelled TSH2, TSHZ2, BSH2, GSQ2, GSQZ2, TSS2, TSSZ2, GSS2, GSSZ2, BSS2, TSU2, TSUZ2, GSU2				
	and GSUZ2 for 2 series threads.				
	Parts labelled TSH3, TSHZ3, BSH3, TSTZ2-ASC, GSQ3, GSQZ3, TSS3, TSSZ3, GSS3, GSSZ3, BSS3, TSU3,				
	TSUZ3, GSU3 and GSUZ3 for 3 series threads.				
	Parts labelled TSH16 and BSH16 for INPI implants.				
	Parts labelled TS-P-16, TS-P-16-ASC and BS-P-16 for Piccolo implants.				
	Parts labelled TS-EX-MC for Ø4.0 External Hex angled abutments, M2 threads.				
TRI-NEX® (EL) (Lobe)	Parts labelled TS-L-18, TS-L-18C, TS-L-18-ASC, GS-L-18, and BS-L-18 for M1.8 threads.				
	Parts labelled TS-L-20, TS-L-20C, TS-L-20-ASC, GS-L-20, and BS-L-20 for M2 threads.				
	Parts labelled PA-L-18, PA-L-18G and PA-L-18B for M1.8 thread passive abutments.				
	Parts labelled PA-L-20, PA-L-20G and PA-L-20B for M2 thread passive abutments.				
Deep Conical (DC)	Parts labelled TS-DC3-14, TS-DC3-ASC and BS-DC3-14 for M1.4 threads.				
	Parts labelled TS-DC4-16, TS-DC4-ASC and BS-DC4-16 for M1.6 threads.				
	Parts labelled TS-DC5-20, TS-DC5-ASC and BS-DC5-20 for M2 threads.				
	Parts labelled PA-DC3-14T and PA-DC3-14B for M1.4 thread passive abutments.				
	Parts labelled PA-DC4-16T and PA-DC4-16B for M1.6 thread passive abutments.				

Table A - Compatible

	Parts labelled PA-DC5-20T and PA-DC5-20B for M2 thread passive abutments.
Internal Hex (M-Series and	Parts labelled TS-Z-16, TS-Z-16-ASC and BS-Z-16 for M1.6 threads.
PROVATA®) (M)(Z)	Parts labelled TS-Z-18, TS-Z-18-ASC, BS-Z-18 and GS-Q-18 for 1-72 UNF-2A threads.
	Parts labelled PA-M-16T and PA-M-16B for M1.6 thread passive abutments.
	Parts labelled PA-M-18T, PA-Q-18G and PA-M-18B for 1-72 UNF-2A thread passive abutments.
IT (ITS) (ITS6) - Internal Octagon	Parts labelled TSIT2, GSIT2 and BSIT2.
	Parts labelled TS-IT-PA and BS-IT-PA for passive abutments.
Single Platform (SP1)	Parts labelled TS-SP-16, TS-SP-ASC and BS-SP-16.
	Parts labelled PA-SP-16T and PA-SP-16B for passive abutments.
Abutment level (MC)	Parts labelled TSH1, GSH1, BSH1, TSS1, GSS1, BSS1, TSU1, GSU1, TSH1-27, TSH1-NLT and TST1-ASC for
	straight compact conical abutments.
	Parts labelled GSS9, TSU9, GSU9, TSUZ9 and GSUZ9 for angled External Hex compact conical abutments.
	Parts labelled TS-Z-MC-16 and TS-Z-MC-18 for angled Internal Hex (M-Series and PROVATA®) compact
	conical abutments.
	Parts labelled TS-DC3-MC and TS-DC4-MC for angled Deep Conical compact conical abutments.
	Parts labelled TU-MCL-18C, GU-MCL-18, TU-MCL-20C and GU-MCL-20 for angled TRI-NEX® compact conical
	abutments.
	Parts labelled TS-SP-MC for angled Single Platform (SP1) compact conical abutments.
Procera System	Parts labelled TSP2 and TSP2C.

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) 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.

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- 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.

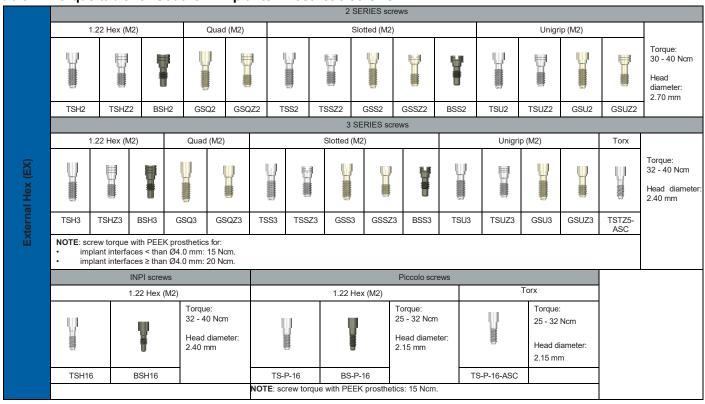
Less common but more persistent symptoms include, but are not limited to:

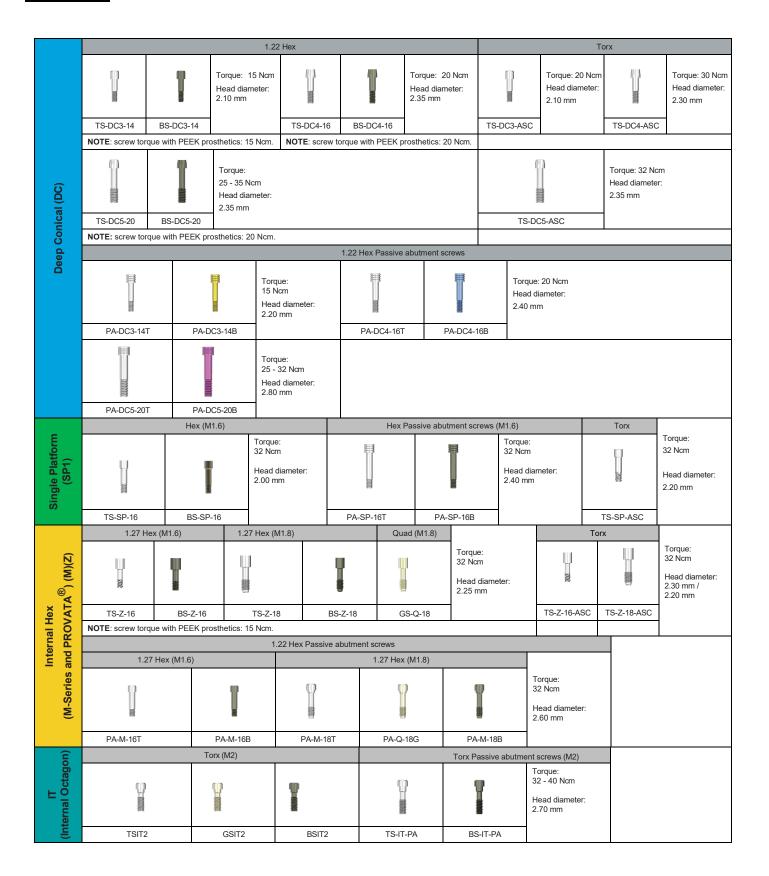
- allergic reaction(s) to implant and/or abutment material.
- breakage of the implant and/or abutment.
- loosening of the abutment screw and/or retaining screw.
- infection requiring revision of the dental implant.
- nerve damage that could cause permanent weakness, numbness or pain.
- histologic responses possibly involving macrophages and/or fibroblasts.
- formation of a fat emboli.
- 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.

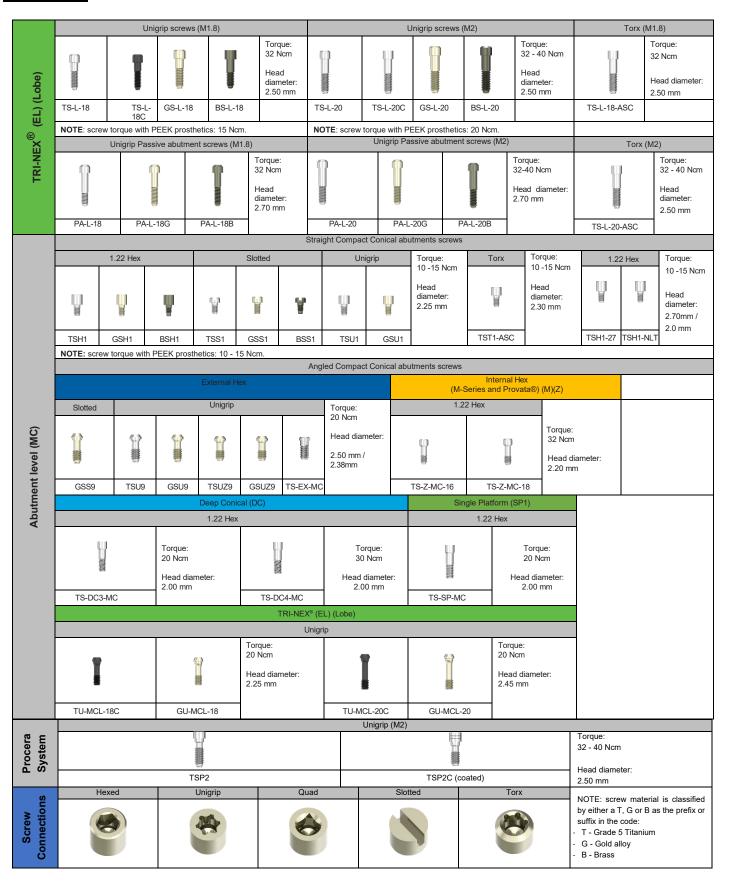
Handling procedures

Ensure the correct screw and screwdriver is used with the corresponding implant connection and abutment. Table B defines the recommended torque values for each correlating prosthetic screw.

Table B- Torque table for Southern Implants' Prosthetic screws







NOTE:

- always ensure that the correct screw is used for the relevant implant and component.
- due to design revisions and changes, screw tips may be flat or rounded.
- blackened brass screws are indicated for laboratory use only torque values do not apply.

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The 1.22/1.27 Universal Hex drivers are available in hand-held, hand-piece and wrench insert versions. The advantage is that the same driver can be used on both 1.22 and 1.27 Hex driving interfaces (this does not include 0.9 Hex interfaces). The Universal Hex driver will allow users to easily swap between External Hex / DC (Deep Conical) and PROVATA® (Internal Hex) ranges. All laser markings indicate "22U", which stands for 1.22 Hex and the tool being Universal.

These tools are also laser marked with the tool size (i.e. S/M/L) - on the idler of the hand-held drivers and on the shaft of the hand-piece and wrench insert drivers to indicate shaft length.

Below provides information on which driver is used with Southern Implants' variety of implant systems.

Table C – Southern Drivers

	Southern Dri						DEEP CONIC	AL & SINGLE
			EXTERNA	L HEX			PLATFORM (SP1)	
		Hexed		Unigrip	Quad	Slotted	Hexed	
	Cover screw drivers	Cover screw drivers Healing abutment and prosthetic screw drivers Prosthetic screw drivers		Prosthetic screw drivers			Cover screw, healing abutment and prosthetic	
Hand held	P2							
	I-CS-HD/L	I-HD-S/M/L	I-HD-22U-S/M/L	I-UGI-S/M/L	I-QDI-S/M/L	I-BD-S/M/L	I-HD-S/M/L	I-HD-22U-S/M/L
Handpiece		7	Surg		control of the second s	<u> </u>	7 X (Suts.
	I-HHD-09	I-HHD-22S/M/L	I-HHD-22U-S/M/L	I-HUG-S/M/L	I-HQD-S/M/L	I-HBDS/M/L	I-HHD-22S/M/L	I-HHD-22U- S/M/L
Wrench insert						and the second s		
	I-WI-09	I-WI-22S/M/L	I-WI-22U-S/M/L	I-WI-UG-S/M/L	I-WI-QS/M/L	I-WI-BS/M/L	I-WI-22S/M/L	I-WI-22U-S/M/L
	Internal Hex (PROVATA®/ M-Series) Hexed Quad Cover screw, healing abutment and prosthetic screw drivers Gold prosthetic screw drivers		TRI-NEX®	IT (Internal Octagon)	Abutment level (MC	Angulated Screw Channel		
			Gold prosthetic	Unigrip Cover screw, healing abutment and prosthetic screw drivers	Torx Cover screw, healing abutment and prosthetic screw drivers	Female hex Straight Compact Conicals	ASC Torx Angulated Screw Channel screws	
Hand held			JACI					
	I-HD-27S/M/L	I-HD-22U-S/M/L	I-QDI-S/M/L	I-UGI-S/M/L	I-SCS-S/M/L	I-AD	I-HD-ASC-S/M/L	
Handpiece		STREE	(com)	3	NO.	QVHI		
			I-HQD-S/M/L	I-HUG-S/M/L	I-HSCS-S/M/L	I-HAD	I-HASC-M-L	1
	I-HHD-27S/M/L	I-HHD-22U-S/M/L	I-FIQD-3/IVI/L				-	
Wrench insert	I-HHD-27S/M/L	I-HHD-22U-S/M/L			C Laon	No. No.	T	

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 retaining screws:Titanium alloy Ti-90%, Al-6%, V-4%Gold retaining screws:Gold Alloy Au-61%, Ag-16.5%, Pt-13.5%, Cu -9%Brass (laboratory) screws:Brass

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

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.

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
Basic-UDI for Prosthetic Screws (Titanium)	60095440501886
Basic-UDI for Prosthetic Screws (Gold)	60095440501784

Related literature and catalogues

- CAT-2004 TRI-NEX® Implants Product Catalogue
- CAT-2005 IT Implants Product Catalogue
- CAT-2010 Osseointegrated Fixtures 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 NVERTA® Implants Product Catalogue
- CAT-2070 Zygomatic Implants Product Catalogue
- CAT-2093 Single Platform (SP1) Implants Product Catalogue
- CAT-2095 External Hex INVERTA® 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.

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